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# A Workshop on Developing Risk Assessment Methods for Medical Use of Radioactive Material

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Supporting Documents

Edited by J. P. Tortorelli

**Idaho National Engineering Laboratory**
**Lockheed Idaho Technologies Company**

**Prepared for**
**U.S. Nuclear Regulatory Commission**




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# A Workshop on Developing Risk Assessment Methods for Medical Use of Radioactive Material

Supporting Documents

Manuscript Completed: May 1995
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Edited by J. P. Tortorelli

Idaho National Engineering Laboratory
Lockheed Idaho Technologies Company
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**Prepared for**
**Division of Industrial and Medical Nuclear Safety**
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**U.S. Nuclear Regulatory Commission**
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# ABSTRACT

A workshop was held at the Idaho National Engineering Laboratory, August 16–18, 1994 on the topic of risk assessment on medical devices that use radioactive isotopes. Its purpose was to review past efforts to develop a risk assessment methodology to evaluate these devices, and to develop a program plan and scoping document for future methodology development. This report contains a summary of that workshop, related technical papers, presentation material, and a transcript of the workshop.

Participants included experts in the fields of radiation oncology, medical physics, risk assessment, human-error analysis, and human factors. Staff from the U.S. Nuclear Regulatory Commission (NRC) associated with the regulation of medical uses of radioactive materials and with research into risk-assessment methods participated in the workshop. The workshop participants concurred in NRC's intended use of risk assessment as an important technology in the development of regulations for the medical use of radioactive material and encouraged the NRC to proceed rapidly with a pilot study. Specific recommendations are included in the executive summary and the body of this report.

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# APPENDIX B
# PRESENTATION SLIDES, DISCUSSION NOTES

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# OVERVIEW OF MEDICAL RISK ANALYSIS PROJECTS

Patricia A. Rathbun, Ph.D.

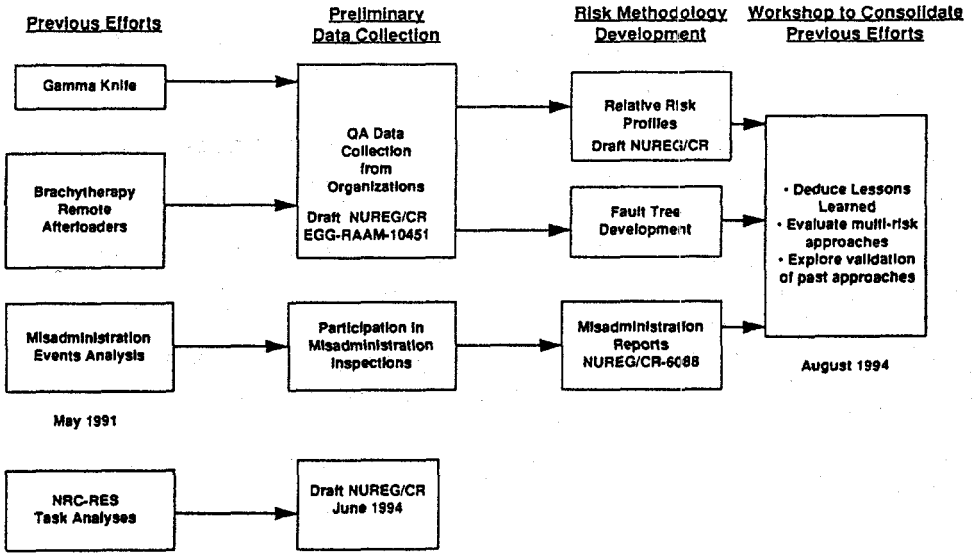
## WORKSHOP OBJECTIVE

- REVIEW PAST EFFORTS TO DEVELOP A RISK ANALYSIS METHODOLOGY
- DEVELOP A PROGRAM PLAN AND SCOPE FOR FUTURE EFFORTS

# PREVIOUS EFFORTS

- QUALITY ASSURANCE FOR GAMMA KNIVES (LLNL)
- QUALITY ASSURANCE FOR BRACHYTHERAPY REMOTE AFTERLOADERS (INEL)
- MISADMINISTRATION EVENTS ANALYSIS (INEL)
- HUMAN FACTORS IN BRACHYTHERAPY REMOTE AFTERLOADING (RES/PSE)

# MEDICAL RISK ANALYSIS PROJECTS PHASE I



## NRC: Gamma Knife Project

- The objectives of this project are:
  - to identify the device review or registration requirements
  - to identify quality control/calibration procedures for acceptance testing, routine calibration, and spot checks
  - to identify the equipment service requirements including identification of critical components
  - to identify the current standards and guidelines that are required or recommended by government and non-government organizations for the review of the associated computerized treatment planning system
  - to perform analyses to determine the risk implications of these devices

## QA for Brachytherapy Remote Afterloader Project Objectives

- Identify:
  1) Regulations, standards, and guidelines for safety review/registration of device
  2) Current practices/procedures for acceptance testing, routine calibration
  3) Current service/maintenance schedules, training requirements, and device critical components
- Develop recommended model program for acceptance testing, routine calibration, and safety checks
- Assess risk significance of potential faults in brachytherapy process

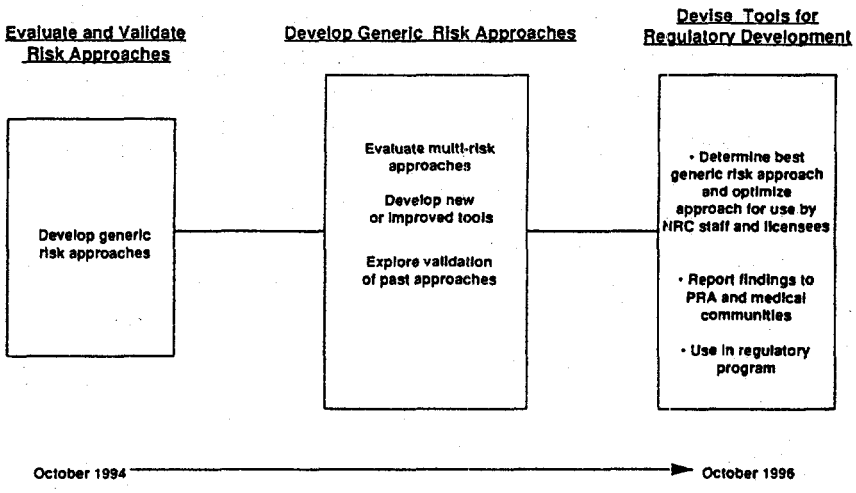
## Risk Analysis Task Is a Comprehensive Assessment of Brachytherapy Remote Afterloading Process

Objective

Provide qualitative/quantitative information on hardware and human action issues contributing to risk

- Identify dominant brachytherapy misadministration event sequences
- Identify critical process deficiencies
  - human errors, hardware faults
- Identify weaknesses in practices, procedures, and training
- Identify the effects on risk from major differences in device design, licensees' practices

## MEDICAL RISK ANALYSIS PROJECTS PHASE II



# NRC PRA IMPLEMENTATION PLAN*

| Regulatory Activity | Objectives | Methods | Target Schedule | Lead Office(s) |
|---|---|---|---|---|
| 4.1 Validate risk analysis methodology developed to asses most likely failure modes and human performance in the use of industrial and medical radiation devices | Validate risk analysis methodology developed to assess the relative profile of most likely contributors to misadministrations for the gamma stereotactic device (Gamma Knife) | Hold a workshop consisting of experts in PRA and HRA to examine existing work and to provide recommendations for further methodological development.<br><br>Examine the use of Monte Carlo simulation and its application to risk profiling.<br><br>Examine the use of expert judgment in developing error rates and consequence measures.<br><br>Conduct a series of HRA benchmarking and cross-validation exercises, including THERP and recent methodological developments in support of LP&S. | August 1994 | NMSS |
| | Continue the development of the relative risk methodology, with the addition of event tree modeling of the brachytherapy remote afterloader | Develop functionally based generic event trees | Ongoing | NMSS |
| | Extend the application of the methodology and its further development into additional devices, including teletherapy and the pulsed high dose rate afterloader | | October 1996 | NMSS/RES |
| | Develop user-friendly computerized guidance for materials licensees in risk analysis techniques for industrial and medical radiation devices | | October 1996 | NMSS/RES |

* Commission briefing September 8, 1994

# MISADMINISTRATION EVENTS ANALYSIS PROGRAM

T. J. LEAHY

IDAHO NATIONAL ENGINEERING LABORATORY

## PRESENTATION OUTLINE

- Program Objectives
- Program Methodology
- Event Investigation Findings
- AEOD Data Base Evaluation

# PROVISIONS OF "QM RULE"

- 10 CFR 35 amended in January of 1992 requiring all medical licensees to establish and implement a Quality Management Program (QMP)

- QMP must require:
  - written directive prepared prior to administration
  - positive verification of patient's identity
  - final plan of treatment must be in accordance with written directive
  - each administration must be carried out according to written directive
  - unintended deviations from written directive must be identified and evaluated, and corrective actions must be taken
  - prescribed reporting and record keeping

# MISADMINISTRATION EVENTS ANALYSIS PROGRAM OBJECTIVES

- Develop a more complete understanding of causes and contributing factors which result in misadministrations

- Use information to help determine whether scope and depth of QM rule is adequate

- Provide information to licensees

# PROGRAM CONSISTED OF TWO MAJOR ANALYSIS ACTIVITIES

- Seven on-site event investigations
  - Investigation teams led by INEL team leader
  - Three or more team members with relevant expertise in disciplines of radiation oncology, medical physics, nuclear medicine technology, risk analysis, and human factors
  - Investigations guided by defined protocols which evolved over course of program

- Analysis of AEOD data base and NUREG-0090 documents for years 1987-1992
  - Developed data base consisting of Abnormal Occurrences for period 1987-1991 and all 1992 misadministrations
  - Common causes of misadministrations
  - Correlations between direct causes and severities
  - Preventability through proper QMP implementation
  - Causes of "multiple misadministrations"

## EVENT INVESTIGATION FINDINGS

- Many misadministrations occurred due to a lack of procedures or procedures which were incomplete or ambiguous

- Although the QM rule has the potential to prevent many misadministrations, most licensees had not effectively implemented their QM programs

- A lack of substantial, direct involvement on the part of authorized users and radiation safety officers is often a direct cause

- Unique conditions or changes in routine are often factors

- Hardware failures are rare, but may have severe consequences

- Corrective actions were often narrow in focus

- Licensees often lacked systematic methods for detecting and mitigating misadministrations

# MISADMINISTRATION DATA BASE ANALYSIS FINDINGS

- A relatively small number of licensees have experienced multiple misadministrations due to common causes. These multiple misadministrations, however, involved 60% of patients in data base.
- Errors in computer programs or data entry were dominant cause of multiple misadministrations
- Major direct causes of single misadministrations were:
  - Procedure inadequacies (30%)
  - Professional errors (28%)
  - Communication problems (26%)
- Proper implementation of QM plans could prevent a large majority (up to 94%) of past misadministrations

# SUMMARY

- When properly implemented, QM programs can prevent many misadministrations
- Some authorized users and RSOs do not fully understand their role as defined in 10 CFR 35
- The concept of a "comprehensive safety culture" if communicated to, and embraced by all licensees, could reduce frequency of misadministrations
- Reference: Summary of 1991-1992 Misadministration Event Investigations (NUREG/CR-6088)



Idaho National Engineering Laboratory

# Past Work on HDR Brachytherapy

Author: Dana Kelly
Presenter: Tami Thatcher
Idaho National Engineering Laboratory

August 16, 1994

KELL-TAT-0894-001

## Outline of Presentation

- Knowledge base needed for risk evaluation
- Treatment spectrum and HDR process at institute studied
- Hardware reliability issues
- Human factors and human reliability issues
- Institute quality assurance practices at time of study
- Use of fault trees to model misadministration
- Conclusions

KELL-TAT-0894-002

## Establishment of knowledge base requires the following questions to be answered

- What is HDR treatment spectrum?
- What are steps in HDR process and how does process vary across treatment spectrum?
- How reliable is the hardware?
- What are important human factors and human reliability issues?
- What is the role of QA in preventing misadministrations?

KELL-TAT-0894-003

## Treatment spectrum at institute studied

- Institute studied is a large clinic for radiotherapeutic cancer treatment
- Small portion of clinic devoted to use of Nucletron Microselectron HDR for treatment of lung and esophageal cancers (HDR not used for gynecological tumors)
  - About 20 treatments performed each year, with about 3-7 dose fractions per treatment
  - All treatments are palliative

KELL-TAT-0894-003A

# Treatment spectrum at institute studied (cont.)

- Medical physics staff engaged in active research
- Institute runs residency program in radiation oncology
- Factors combine to place institute at extreme end of spectrum, so results are probably not generic

KELL-TAT-0894-004

# HDR process at institute studied

- Process is highly serial, with many steps; few steps done in parallel
- Numerous opportunities for medical physicist and radiation oncologist to recover from errors
- Approximately eight staff members play a role in the treatment process

# Hardware reliability issues

- Anecdotal evidence from vendor and users suggests Nucletron device is highly reliable
- No design data available from manufacturer to support this conclusion
- Area deemed to require further investigation

# Human factors and human reliability issues

- Significant human factors deficiencies associated with Nucletron computerized treatment planning system
  - Deficiencies place burden upon medical physics staff
- Skill and knowledge of physician are highly important
  - These parameters are difficult to model and quantify with present HRA methodologies
- Process conforms to rule-based taxonomy
- Success of treatment requires many human actions to be performed correctly

KELL-TAT-0894-007

# QA practices at time of study

- Institute had detailed, written QA protocol:
  - Acceptance testing, commissioning, and source calibration
  - Quarterly QA review
  - Daily device QA
  - Treatment procedures
  - Roles and responsibilities of various personnel
  - Review of treatment planning calculations, simulation films, and HDR programming
- Institute had Quality Management Program
  - Provides written policies and auditable records to demonstrate compliance with regulations

KELL-TAT-0894-008

# QA practices at time of study (cont.)

- Source strength calibration turned out to be important
  - Lack of accepted calibration standard for Ir-192
  - Vendor calibration data sometimes inaccurate

KELL-TAT-0894-009

# Fault tree models for misadministration

- Top event represents doses in error by >20%
- ASEP used to estimate screening HEPs for most human failure events
- SHARP skill-based screening values used for physician errors
- Screening value of 0.001 used for hardware failure probability (undeveloped event)
- Recovery by medical physicist and radiation oncologist modeled explicitly in fault tree

KELL-TAT-0894-010

# Fault tree models for misadministration (cont.)

- Analysis of fault tree found 44 failure paths, with overall screening probability of 0.05
  - All failure paths involved at least two errors
- Removing independent review of treatment plan increases misadministration probability to 0.30
  - 7 paths involve single error by dosimetrist and make up 96% of total probability
- QA activities associated with quarterly source change top risk increase importance list
  - Source strength calibration
  - Check of HDR positional accuracy
  - Check of timer accuracy and linearity

KELL-TAT-0894-011

# Conclusions

- Model felt to be reasonably complete, with exception of hardware information
- Screening HRA and fault tree illustrate human factors deficiencies in CTPS
  - Makes role of medical physics staff very important
- Much importance placed on skill and knowledge of physician
  - Difficult to model and quantify with present HRA techniques

KELL-TAT-0894-011A

# Conclusions (cont.)

- QA activities associated with quarterly source change are important
- Fault trees are effective and efficient means for modeling dose-in-error misadministrations at a particular institute or clinic
  - Fault trees may impede communication
  - Event trees with linked fault trees may be better generic approach

KELL-TAT-0894-012

# THE USE OF WORK PROCESS ANALYSIS MODEL IN RISK ASSESSMENTS FOR MEDICAL USE OF RADIOACTIVE MATERIAL

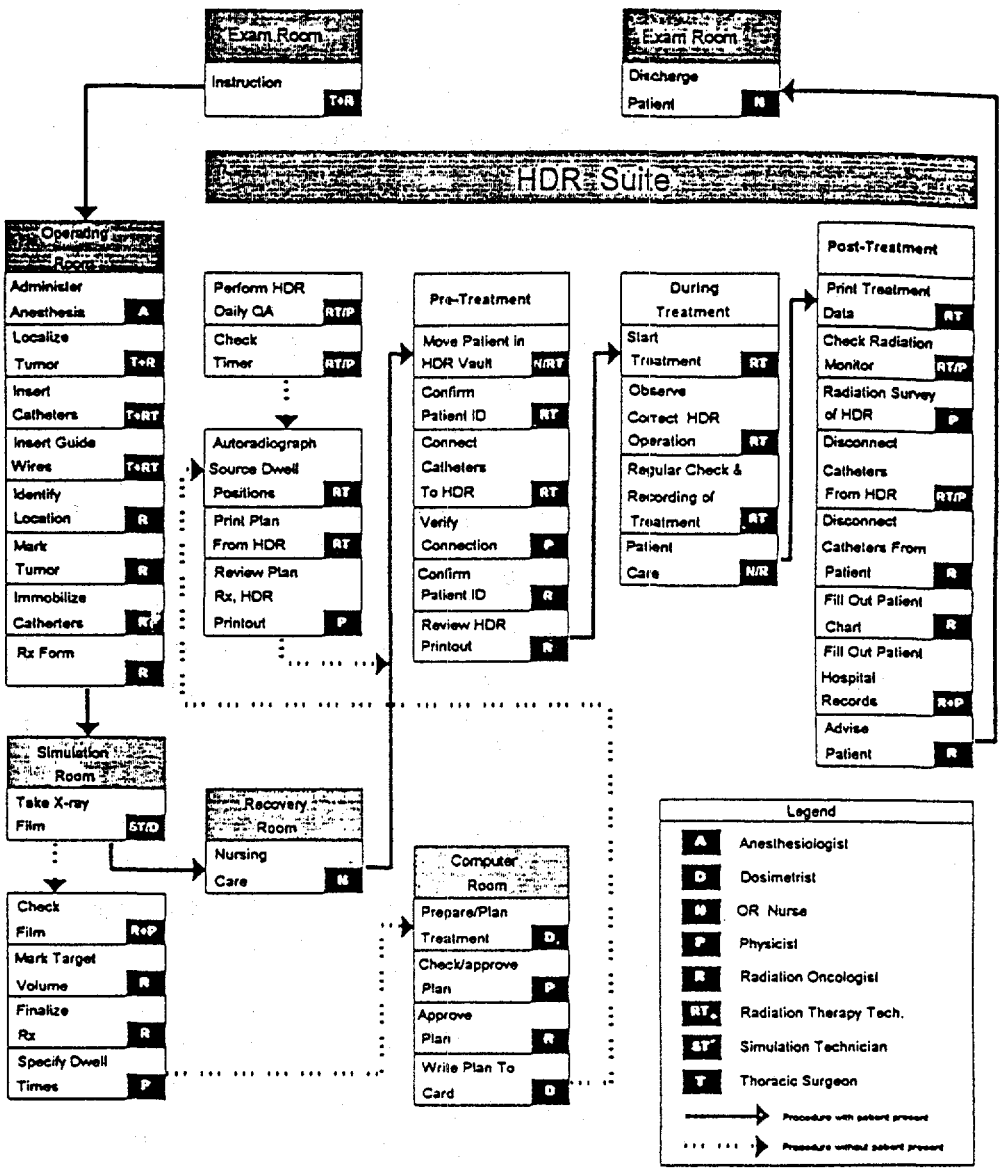
Jya-Syin Wu and George Apostolakis
UCLA

Presented at the Workshop on Development of Risk Assessment Methods
for Medical Use of Radioactive Material
August 16-18, 1994
Idaho National Engineering Laboratory
Idaho Falls, Idaho 83415

## *WORK PROCESS DEFINITION*

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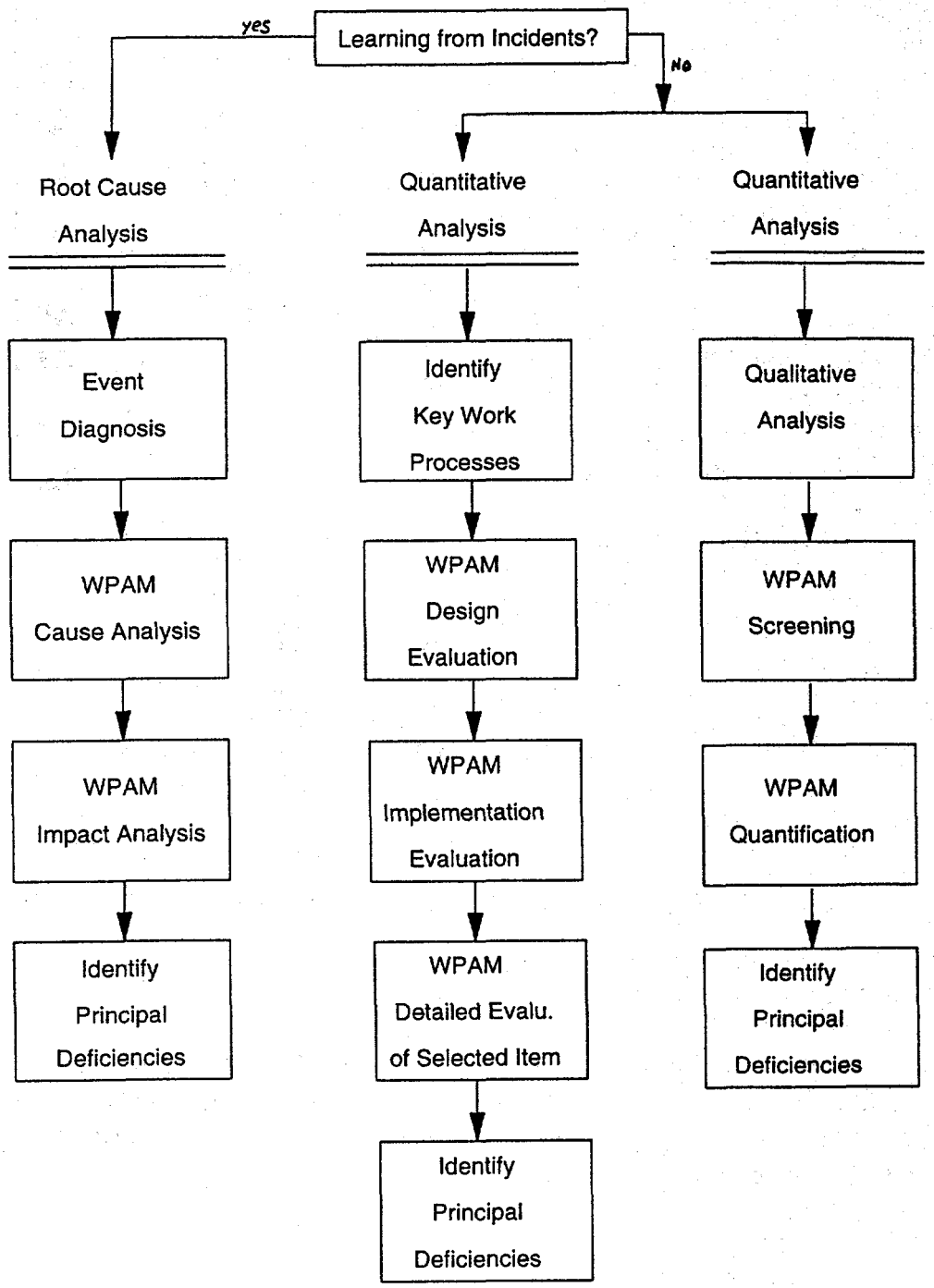
*A standardized sequence of tasks designed with the objective of achieving a specific goal within the operational environment of an organization*




*Process Flow Chart for Endobronchial High Dose Rate (HDR) Brachytherapy at Institute A*

*(D.L. Kelly, et al., "Risk Evaluation of High Dose Rate Remote Afterloading Brachytherapy at a Large Research/Teaching Institution," in Proceedings of the Probabilistic Safety Assessment International Topical Meeting, Clearwater Beach, Florida, January 26-29, 1993.)*

## HOW CAN WE MAKE THE WORK PROCESSES SAFER?



# *ROOT CAUSE ANALYSIS FOR WORK PROCESS RELATED INCIDENTS*

## *OBJECTIVES*

### *I. Event Diagnosis*

- *What went wrong?*
- *Which process(es) was involved?*
- *Which task(s) was involved?*
- *Which barrier(s) was breached?*
- *Whose function(s) was involved?*

### *II. Cause(s) of the Process Failure*

- *Procedure design of the process*
- *Field design of the process*
- *Implementation of the process*

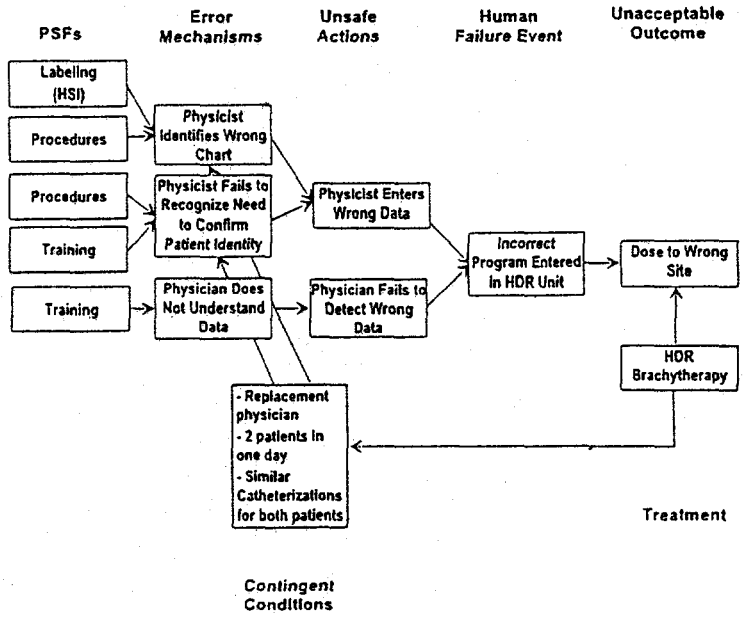
### *III. Potential Impact(s) of the Failure*

- *How significant the failure is?*
- *Which organizational factors are relevant to the incident?*
- *How significant are these factors ?*

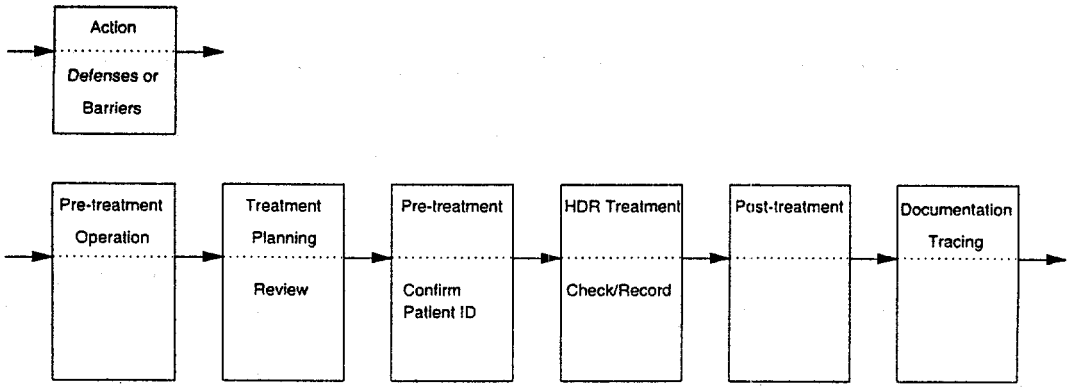
### *IV. How can an organization ~~can~~ be improved?*

## *Tools to Be Used in the Event Diagnosis*

| | |
|---|---|
| ■ *What went wrong?* | *HPES (INPO)*<br>*Human Error Modeling* |
| ■ *Which process(es) was involved?* | *HPES*<br>*Human Error Modeling* |
| ■ *Which task(s) was involved?* | *Flow Charts* |
| ■ *Which barrier(s) was breached?* | *Flow Charts* |
| ■ *Whose function(s) was involved?* | *Cross Reference Tables* |




*Source:* *John Wreathall, "Review of Medical Misadministration Event Summaries and Comparison of Human Error Modeling," presented at the Workshop on Development of Risk Assessment Methods for Medical Use of Radioactive Material, August 16-18, 1994, Idaho National Engineering Laboratory, Idaho Falls, Idaho*




The Flow Diagram for the Endobronchial HDR Brachytherapy

## *Tools to Be Used in Finding Causes of the Process Failures*

| | |
|---|---|
| ■ *Deficiencies in the procedure design of the process* | *Checklists* |
| ■ *Deficiencies in the field design of the process* | *Checklists* |
| ■ *Deficiencies in the implement of the process* | *Checklists*<br>*BARS* |

## The Cross-Reference Table for the Endobronchial HDR Brachytherapy Process

| TASK | ACTION/BARRIER | DEPARTMENT | PERSONNEL |
|---|---|---|---|
| Pre-Treatment Operation | Pre-Treatment Operation | | |
| | | | |
| | | | |
| Treatment Planning | Treatment Planning | | |
| | Review | | |
| | | | |
| Pre-Treatment | Pre-Treatment | | |
| | Confirm Patient ID | | |
| | | | |
| HDR Treatment | HDR Treatment | | |
| | Check/Record | | |
| | | | |
| Post-Treatment | Post-Treatment | | |
| | | | |
| | | | |
| Documentation Patient Tracing | Documentation/ Tracing | | |
| | | | |
| | | | |

# *CHECKLIST FOR INSPECTING WORK PROCESS*

*(A Sample Design/Impementation Checklist for Scheduling and Coordination of Corrective Maintenance)*

## *Procedure Design*

1) Is there a central organization (planning department and work control center) in charge of coordinating planned work?

2) What is the organizational relationship of the planning department and work control center to other departments in the working core; i.e., operating, maintenance, and instrumentation and control departments?

3) What are the barriers built into the system to correct errors made in the scheduling or coordination of maintenance work? What are their functions?

4) What is the standard process for the scheduling and coordination of a maintenance work?

## *Field Design*

1) Where is the work control center located?

2) What is the information transfer mechanism used in the work tracking system?

ASCA, Inc.

# *CHECKLIST FOR INSPECTING WORK PROCESS*
*(Cont.)*

*(A Sample Design/Impementation Checklist for Scheduling and Coordination of Corrective Maintenance)*

## *Implementation*

1) How many items are on maintenance backlog?

2) How many items on maintenance backlog are of PRIORITY 1?

3) How many equipment deficiency tags are on the main control panels?

4) Does the plan-of-day schedule reflect the ongoing work?

5) Does scheduling reflect prioritization of work with respect to safety impact?

6) What is the management philosophy in scheduling; i.e., which type of work usually gets higher priority?

7) Does the shift superintendent need to review most of the work package?

8) Are technicians often allowed to "negotiate" with the shift superintendent regarding assigned work?

9) Does the planning department communicate well with other departments?

10) Does the daily meeting on scheduling and coordination show conflicts

ASCA, Inc.

## *Behaviorally Anchored Rating Scales (BARS)*

- *An extension of the methodology used for assessing the performance of individuals to the process of assessing a nuclear power plant.*
- *Performance appraisals that*
  - *Represent important aspects of the work environment,*
  - *Offer common interpretation across raters, and*
  - *Assist raters in understanding various levels of performance on each of the dimensions being rated.*
- *BARS are constructed with the input of individuals who are likely to use the scales and couched in terminology familiar to the raters.*

## *Behaviorally Anchored Rating Scales (BARS) (Cont.)*

*Development of BARS for work process evaluation:*

*STEP 1* *Individuals familiar with the specific work process were brought together to suggest, from their collective experiences, factors they believe influence nuclear safety.*

*STEP 2* *With a given task or organizational dimensions, experienced panels then more completely defined the task / organizational dimension and provide behavioral anchors, indicative of various safety levels. The behaviorally anchored rating scales are single page scales with examples of poor, average and high behaviors for the dimension being assessed.*

*STEP 3* *The respondent (either an observer, interviewer or interviewee) is requested to read the definition of the task / dimension appearing at the top of the page, read up the scale - from ineffective to very effective behavior - and decide where she/he feels the plant ranks on the scale.*

## *Behaviorally Anchored Rating Scales (BARS) (Example)*

### PROBLEM IDENTIFICATION

***The way the organization encourages personnel to draw upon knowledge, experience and current information to identify any potential problems.***

| | | |
|---|---|---|
| **EXCELLENT** | 5 | Employees are encouraged to proactively identify potential problems (e.g., equipment, personnel, scheduling). Employees are asked to notify management of potential problems. Management investigates the situation and responds to employees' input with timely feedback. |
| | 4 | Employees are encouraged to notify management of problems they observe. Problems identified by employees are funneled into a system that evaluates the problem and makes a determination regarding future action. Employees receive feedback about problems that were acted upon. |
| **AVERAGE** | 3 | Employees have a system to report problems they identify. The decisions regarding which problems are attended to and which ones are ignored is made by a select group of individuals. Employees are seldom given feedback about problems they identified or problems that were fixed. |
| | 2 | Employees often feel that reporting a problem is simply an exercise in futility since the problems reported from the general employee group rarely receive consideration. In some situations, problem identification is met with extreme defensiveness. |
| **POOR** | 1 | Problems go undetected, or unreported, since most workers feel any effort to report problems is viewed as worker complaints. Employees fear being reprimanded for identifying problems. |

## *Tools to Be Used in Identifying the Potential Impacts of Failures*

- *How significant the failure is?* — *AHP*
- *Which organizational factors are relevant to the incident?* — *O/F Matrix*, *AHP*
- *How significant are these factors ?* — *BARS*

## *Tools to Be Used in Finding Ways to Improve an Organization* — *BARS*

The Organizational Factors Matrix for the Corrective Maintenance Work Process

| | Prioritization | | Planning | | | Execution | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Prioritization | Reviews | Planning | Reviews | Scheduling/ Coordination | Execution | QC | Post-Maint. Testing | Return to Normal Line-Up | Documentation |
| Centralization | X | X | X | X | X | X | X | X | X | X |
| Communication-External | | | X | | | | | | | |
| Communication-Interdepartmental | X | | X | | X | X | | | | |
| Communication-Intradepartmental | X | X | X | X | X | X | X | X | X | |
| Coordination of Work | | | X | | X | X | | | | |
| Formalization | X | | X | | X | X | X | X | X | X |
| Goal Prioritization | X | | | | X | | | | | |
| Organizational Culture | X | X | X | X | | X | X | X | | |
| Organizational Knowledge | X | X | X | X | X | X | X | | | |
| Organizational Learning | X | X | X | X | | | | X | | |
| Ownership | | | | X | | X | X | | | |
| Performance Evaluation | | | | | | X | X | | | |
| Personnel Selection | X | X | X | X | X | X | X | X | X | |
| Problem Identification | | X | X | X | | X | X | X | X | |
| Resource Allocation | X | | | | X | | | | | |
| Roles-Responsibilities | X | X | X | X | X | X | X | X | X | X |
| Safety Culture | X | X | | X | | X | X | | | X |
| Technical Knowledge | X | X | X | X | X | X | X | X | X | |
| Time Urgency | X | X | X | X | X | X | | X | | |
| Training | | | | | | X | X | X | X | X |

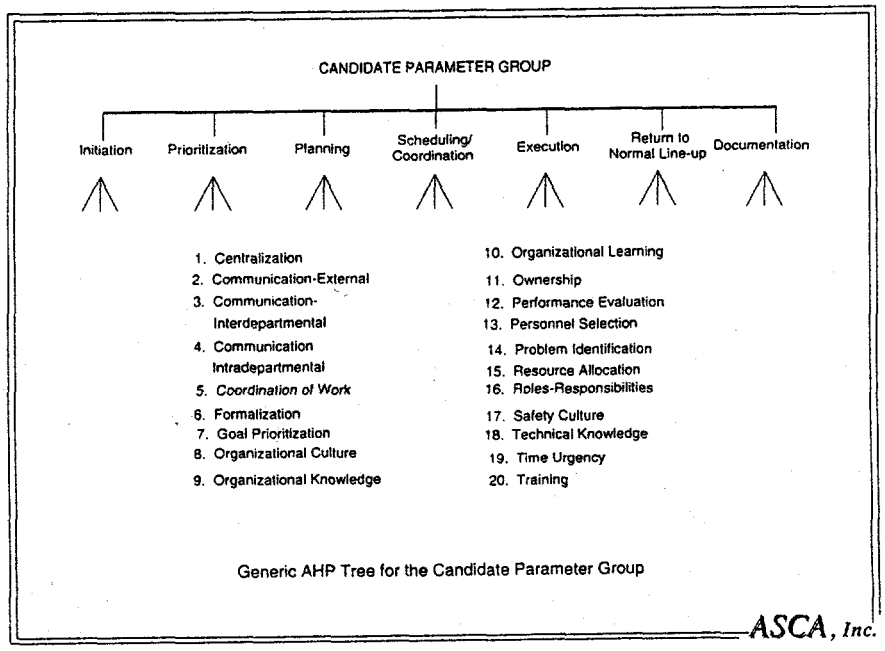
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# Definitions of Organizational Factors

| Organizational Factor | Definition |
|---|---|
| Centralization | Centralization refers to the extent to which decision-making and/or authority is localized in one area or among certain people or groups. |
| Communication-External | External communication refers to the exchange of information, both formal and informal, between the plant, its parent organization, and external organizations (e.g., NRC, state, and public). |
| Communication-Interdepartmental | Interdepartmental communication refers to the exchange of information, both formal and informal, between the different departments or units within the plant. It includes both the top-down and bottom-up communication networks. |
| Communication-Intradepartmental | Intradepartmental communication refers to the exchange of information, both formal and informal, within a given department or unit in the plant. It includes both the top-down and bottom-up communication networks. |
| Coordination of Work | Coordination of work refers to the planning, integration, and implementation of the work activities of individuals and groups. |
| Formalization | Formalization refers to the extent to which there are well-identified rules, procedures, and/or standardized methods for routine activities as well as unusual occurrences. |
| Goal Prioritization | Goal prioritization refers to the extent to which plant personnel understand, accept, and agree with the purpose and relevance of goals. |
| Organizational Culture | Organizational culture refers to plant personnel's shared perceptions of the organization. It includes the traditions, values, customs, practices, goals, and socialization processes that endure over time and that distinguish an organization from others. It defines the "personality" of the organization. |
| Organizational Learning | Organizational learning refers to the degree to which plant personnel and the organization use knowledge gained from past experiences to improve future performance. |
| Organizational Knowledge | Organizational knowledge refers to the understanding plant personnel have regarding the interactions of organizational subsystems and the way in which work is actually accomplished within the plant. |

## Definitions of Organizational Factors (Continued)

| Organizational Factor | Definition |
|---|---|
| Ownership | Ownership refers to the degree to which plant personnel take personal responsibility for their actions and the consequences of the actions. It also includes commitment to and pride in the organization. |
| Performance Evaluation | Performance evaluation refers to the degree to which plant personnel are provided with fair assessments of their work-related behaviors. It includes regular feedback with an emphasis on improvement of future performance. |
| Personnel Selection | Personnel selection refers to the degree to which plant personnel are identified with the requisite knowledges, experiences, skills, and abilities to perform a given job. |
| Problem Identification | Problem identification refers to the extent to which the organization encourages plant personnel to draw upon knowledge, experience,and current information to identify problems. |
| Resource Allocation | Resource allocation refers to the manner in which the plant distributes its financial resources. It includes both the actual distribution of resources as well as individual perceptions of this distribution. |
| Roles-Responsibilities | Roles and responsibilities refers to the degree to which plant personnel and departmental work activities are clearly defined and carried out. |
| Safety Culture | Safety culture refers to the characteristics of the work environment, such as the norms, rules, and common understandings, that influence plant personnel's perceptions of the importance that the organization places on safety. It includes the degree to which a critical, questioning attitude exists that is directed toward plant improvement. |
| Technical Knowledge | Technical knowledge refers to the depth and breadth of requisite understanding plant personnel have regarding plant design and systems, and of phenomena and events that bear on plant safety. |
| Time Urgency | Time urgency refers to the degree to which plant personnel perceive schedule pressures while completing various tasks. |
| Training | Training refers to the degree to which plant personnel are provided with the requisite knowledges and skills to perform tasks safely and effectively. It also refers to plant personnel perceptions regarding the general usefulness of the training programs. |




Generic AHP Tree for the Candidate Parameter Group

ASCA, Inc.

## *AHP Results for the Weights of MISCALIBRATION (MC) Candidate Parameter Group (Cont.)*

| *Weights* | *Organizational Factors* | *Scheduling/ Coordination* | *Execution* | *Return to Normal lineup* |
|---|---|---|---|---|
| *0.074* | *Interdepartmental Communication* | *0.074* | *0.0* | *0.0* |
| *0.178* | *Intradepartmenal Communication* | *0.037* | *0.031* | *0.111* |
| *0.222* | *Coordination of Work* | *0.222* | *0.0* | *0.0* |
| *0.263* | *Formalization* | *0.0* | *0.152* | *0.111* |
| *0.263* | *Training* | *0.0* | *0.152* | *0.111* |

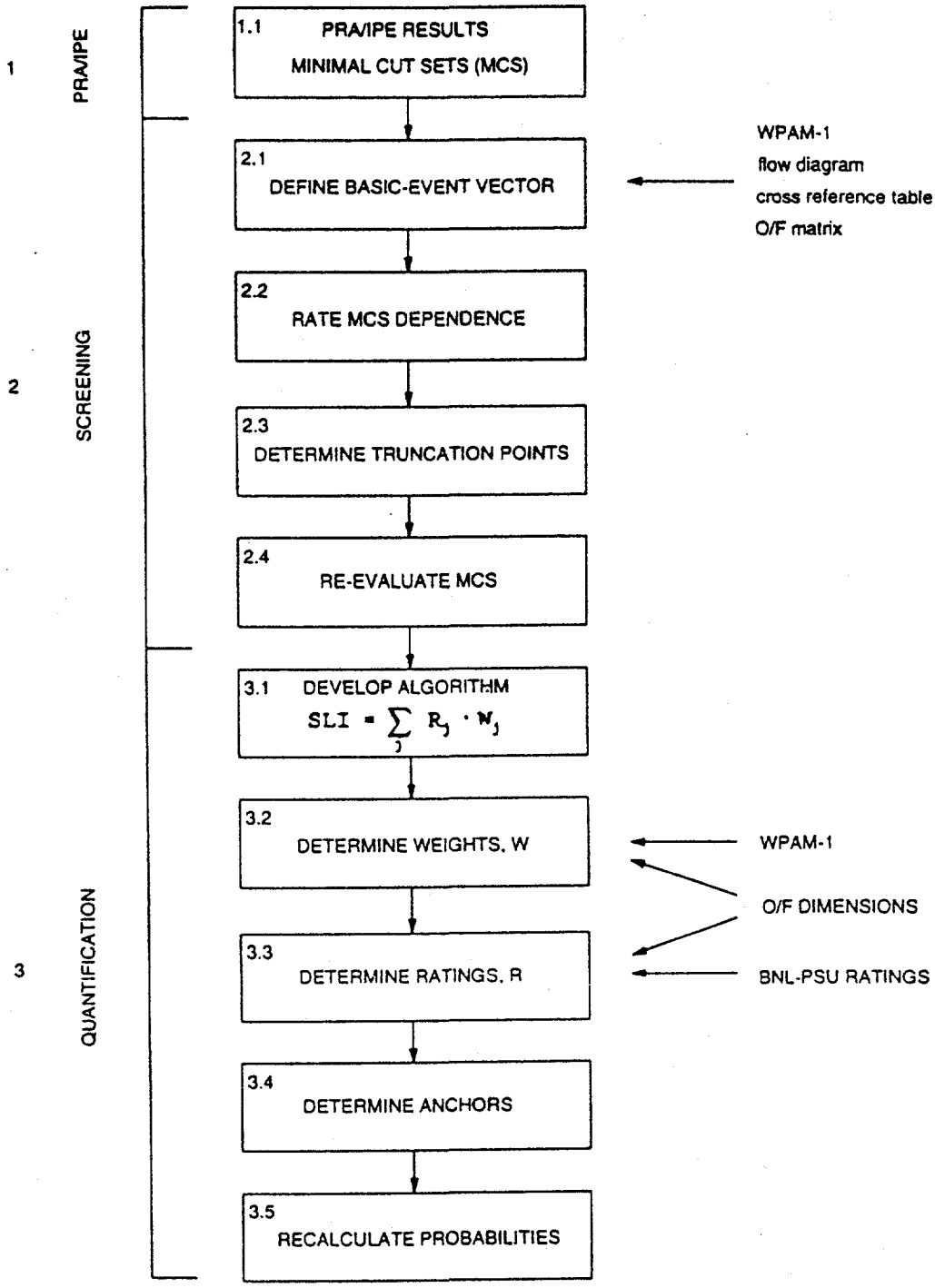
ASCA, Inc.

## *TOOLS USED IN QUALITATIVE ANALYSIS*

- *Identify Key Work Processes*
- *Evaluate Design of the Work Process* — *Flow Charts*, *Checklists*, *Cross Reference Table*
- *Evaluate Implement of the Work Process* — *Checklists*, *Interviews*, *BARS*
- *Evaluate Selected Items* — *AHP*, *BARS*
- *Identify Principal Deficiencies* — *BARS*

## *RISK MANAGEMENT*

| | MCS Frequency | Core Damage Frequency |
|---|---|---|
| IPE Results | $6.7 \times 10^{-9}$ | $1.9 \times 10^{-6}$ |
| Base Case--Original Rates | $5.5 \times 10^{-7}$ | $4.2 \times 10^{-4}$ |
| All Ratings Raised to "3" | $1.24 \times 10^{-7}$ | $1.9 \times 10^{-4}$ |
| Interdepartmental Communication (3) | $5.3 \times 10^{-7}$ | $4.1 \times 10^{-4}$ |
| Intradepartmental Communication (3) | $4.5 \times 10^{-7}$ | $3.5 \times 10^{-4}$ |
| Coordination of Work (3) | $3.8 \times 10^{-7}$ | $2.9 \times 10^{-4}$ |
| Formalization (3) | $3.5 \times 10^{-7}$ | $2.7 \times 10^{-4}$ |
| Training (3) | $3.6 \times 10^{-7}$ | $2.8 \times 10^{-4}$ |
| Inter- & Intradepartmental Communication (3) | $4.3 \times 10^{-7}$ | $3.3 \times 10^{-4}$ |
| Formalization and Training (3) | $2.3 \times 10^{-7}$ | $1.9 \times 10^{-4}$ |




Work Process Analysis Model II (WPAM-II)

# Human Factors Evaluation of Brachytherapy Using Remote Afterloaders

Workshop on Developing Risk Assessment Methods
for Medical Use of Radioactive Material

August 16, 1994
INEL, Idaho Falls, Idaho

Presented by
James R Callan, PhD
Pacific Science & Engineering Group Inc
6310 Greenwich Dr # 200
San Diego, California 92122

Project Officer
Isabelle Schoenfeld
NRC Contract # 04-90-074

## HFE Project Objectives

### NRC review of misadministration reports indicated cases of human error in RAB

- Identify factors which contribute to human error
- Evaluate impact of factors on function and task performance
- Prioritize performance problems
- Identify and evaluate alternatives for resolving problems of human error

2

# Methods

## A Human Factors Team Visited 23 RAB Sites

Spent 2-3 days at each site

Observed and recorded

- Treatment planning
- Treatment delivery
- Equipment usage
- Human-system interactions

Interviewed

- Staff involved in RAB

6

# Methods

Walked–through each staff member's job

Identified and analyzed

- RAB functions and tasks
- Human-system interfaces
- Procedures & practices
- Training
- Organizational support

7

## Function and Task Analysis

- Identified RAB functions and tasks
- Task performers / supervisors
- Workload factors
  - Time pressure, Mental Effort, Stress
- Distractors / distraction levels
- Skills required to perform
- Time requirements
- Step description
  - Feedback, Equipment needed

8

## Error Analysis Procedure

- Reviewed NRC and FDA reports
- Obtained subjective estimates of error from staff
  - High, Medium, Low
- Identified sources of distraction and possible effects
- Obtained workload data from users
- Validated / ranked error data using SMEs
  - Physicists and Oncologists

9

## Error Likelihood Estimates

- Panel of RAB experts evaluated
  - Each RAB task
  - Task linkages
- Tracked error consequences as they moved through RAB process
- Evaluated effect of errors on other tasks
- Identified current practices for detecting / correcting errors and their consequences

10

## Findings

- Five Major Functions
  - Patient Preparation
  - Treatment Planning
  - Treatment Delivery
  - Post-Treatment
  - QA and Calibration
- 23 Tasks
- Over 200 Task Steps
- 10 Critical Tasks

11

## Critical Task Identification

Human error was likely in one or more steps

The error might not be detected using current practices

The consequences of the error may include delivery of an unintended dose of radiation

- to a patient
- to a member of the staff

12

## Critical Task 1 Patient Scheduling and Tracking

<u>Errors</u>

Scheduling the patient for the wrong treatment

Bringing the patient or records to the wrong workstation

Delivery of treatment to the wrong patient due to mis-identification of the patient or records

13

## Critical Task 2
## Applicator Selection, Placement, and Stabilization

Errors

Failure to place the applicator near the targets

Failure to stabilize the applicator

Failure to transfer required information

14

## Critical Task 3
## Target Volume Localization

Errors

Failure to identify targets

Failure to specify the target volume adequately

15

## Critical Task 4
## Dwell Position Localization

Errors

Dwell specification error

Transfer of incorrect information on the chosen source positions

16

## Critical Task 5
## Dosimetry

Errors

Failure to measure source–target distances accurately

Failure to identify the activity of treatment sources

Failure to accurately calculate the dose that will be received by each target

Failure to communicate calculation results

17

## Critical Task 6
## Treatment Set-Up

Errors

Swapping two or more treatment channels

Connection of improper guide tubes

Modification of the spatial relationship between the applicator and the targets

18

## Critical Task 7
## Treatment Plan Entry

Errors

Entry of parameters from the wrong treatment plan

Entry of parameters different from those in the treatment plan

19

## Critical Task 8
## Routine QA and Maintenance

Errors

Failure to detect / correct problems

Failure to communicate results to staff

Creation of new problems during the QA or maintenance procedures

20

## Critical Task 9
## Source Replacement

Errors

Inadvertent exposure of staff to the source

Changes to afterloading equipment that compromise

- source positioning accuracy
- equipment integrity
- treatment delivery

21

## Alternative Approaches (Modifications)

### Modifications designed to

- Reduce likelihood of error
- Improve detection of error
- Facilitate correction of error
- Limit consequences of error

23

## Human–Systems Interface Modification Examples

Unambiguous data entry formats

Prominent labels on applicators

Improved feedback and visualization for treatment planners

Performance certification for software and hardware

24

## Job Performance Aid Modification Examples

- Highly visible identification tags on the patient and all RAB documents
- Applicator identification labels
- Applicator–channel map
- QA checklists that highlight failed or omitted checks

26

## Procedures and Practices Modification Examples

- Tagging procedures for patients and documents
- Use of an applicator–channel map for treatment planning and treatment setup
- Standardization of dosage units
- Minimization of patient movement between simulation and treatment
- Erasure of magnetic media used to transfer treatment plans

27

## Training Modification Examples

- Training in task performance and linkage procedures
- Training in error detection procedures
- Integration of QA with refresher training in emergency procedures

28

## Organizational Support Modification Examples

- Establish a QA program stressing early error detection
- Allocate error detection responsibilities
- Establish procedures that share information needed for error correction
- Certify RAB equipment and software after maintenance
- Make task linkages explicit
- Evaluate and monitor training effectiveness

29

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*MEDICAL RISK ANALYSIS WORKSHOP*



METHODS SELECTION

- IMNS GOALS
  - IDENTIFY SIGNIFICANT CONTRIBUTORS TO RISK FROM USE OF MEDICAL APPLICATIONS OF RADIOACTIVE MATERIALS
  - DETERMINE WHAT AREAS SHOULD BE CONSIDERED FOR REGULATION

*1* *8/12/94*

*NMSS*

*MEDICAL RISK ANALYSIS WORKSHOP*



METHODS SELECTION

| METHOD | CHARACTERISTICS |
|---|---|
| PRA | DEVELPED FOR COMPLEX, REDUNDENT SYSTEMS |
| | COMPUTES PROBABILITIES AND HEPs |
| | HRA BASED ON RESPONSE MODEL |
| HRA | ANALYZES COMPLEX PROCEDURES |
| | HEPs BASED ON COMPLEX SYSTEM DATA |

*2* *8/12/94*

*NMSS*

*MEDICAL RISK ANALYSIS WORKSHOP*

| METHOD | CHARACTERISTICS |
|---|---|
| EXPERT OPINION | CLOSURE DIFFICULT |
| | PREDICTION LIMITED TO PANEL EXPERIENCE |
| RELATIVE RISK RANKING | FRAMEWORK FOR "WHAT IF ..." |
| | QUALITATIVE IMPORTANCE |
| | SEMI-QUANTITATIVE RANKING |

*3* *8/12/94*

*NMSS*

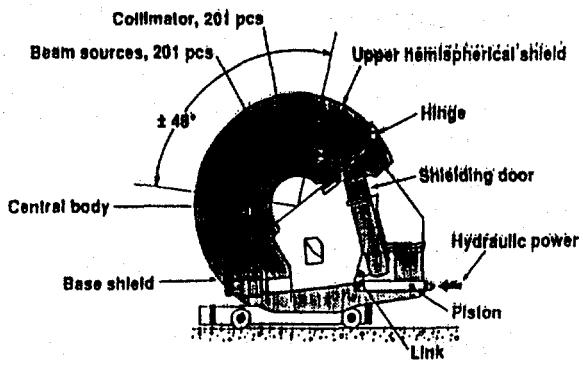
*MEDICAL RISK ANALYSIS WORKSHOP*

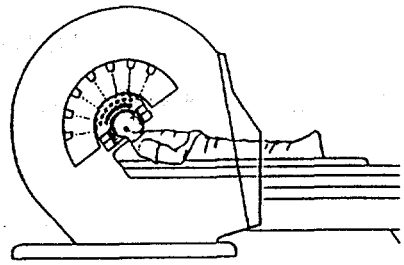
RELATIVE RISK RANKING METHOD

- IDENTIFY IMPORTANT MEASURES OF RISK
- DEFINE AND MODEL "SYSTEM" TO BE EVALUATED
- EVALUATE SYSTEM TO DETERMINE RISK CONTRIBUTORS
- DEFINE RANKING CRITERIA AND RANK CONTRIBUTORS
- ITERATE

*4* *8/12/94*

## The Radiation Unit



## Multi-disciplinary Project Team

- Scientists and engineers with expertise in QA/QC and regulatory compliance
- Radiation oncologists, medical physicists, and neurosurgeons with expertise in teletherapy
- Risk assessment experts
- Computer scientists
- Human factors specialists

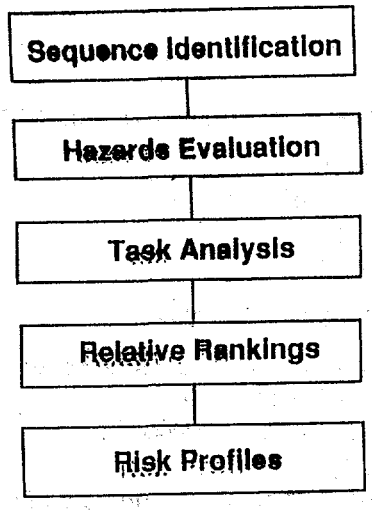
## Cooperation from Elekta and Facilities

- LLNL tracking of UCSF experience
- Elekta provides documentation and user manuals
- Elekta makes presentations to LLNL and NRC personnel
  - product overview
  - design of Gamma Knife
  - manufacturing
  - loading of Cobalt 60
- Two-day site visit in Los Angeles
  - familiarization with Gamma Knife facility
  - acceptance test procedure
  - routine calibration and checks
  - record keeping
  - observe patient treatment planning and procedure

## Cooperation from Elekta and Facilities cont'd

- Acceptance test for Rhode Island
- Cobalt 60 loading in Baltimore
- Visit manufacturing facility
- LLNL conducts multiple Gamma Knife site visits
- LLNL networking with Gamma Knife community

## Risk Methodology Overview (Gamma Knife)




## Gamma Knife Hazards Evaluation

- Ionizing radiation
  - patient (treatment cycle)
  - practitioner (normal and emergency conditions)
  - public (shielding)
- Hydraulic pressure
  - pressure containers/components
  - rapid pressure changes
- Electrical
  - inadvertent activation and de-activation
  - component and power source failures
- Mechanical operations
  - gamma unit
  - helmet hoist

# *Gamma Knife Sequences*

* ***Quality assurance programs***
  - ***gamma unit physics***
  - ***dosimetry***
  - ***safety measures***
* ***Treatment path***
  - ***imaging and localization***
  - ***treatment planning***
  - ***patient positioning and treatment***
* ***Abnormal events during gamma unit operation***

GAMMA KNIFE TASK DATA

*SAMPLE*

PROCESS: Treatment Planning

| | |
|---|---|
| 1. Task ID Number | 2.6 |
| 2. Task Description/Purpose | Take skull measurements (supine or prone position) |
| 3. Task Frequency (No. of times per patient; 0 if not performed) | 1-2 |
| 4. Performance Standards | ± (3-4) mm |
| 5. Support Equipment | Skull measuring bubble<br>Measuring stick<br>Data form |
| 6. Training/Knowledge Required (Academic, Equip., OJT, etc.) | OJT - apprentice training |
| 7. Ways to Reduce Errors/Risk (Procedures, Equip., Training, etc.) | Verification procedures<br>Refresher training |

## Gamma Knife Relative Rating Schemes



**Severity of Consequences**

For the most likely magnitude of error, rank (a,b,...) the most likely severities of consequence according to the following qualitative scheme based on generalizations of your experience:

1. ___No consequence

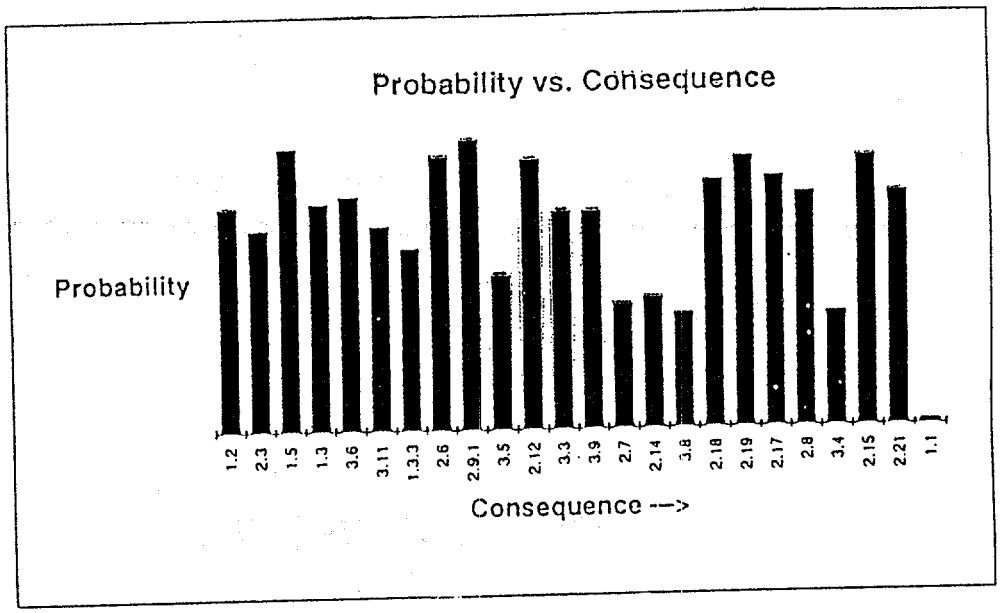
2. ___Very minor severity
   (some concern for complications, but no clinical significance)

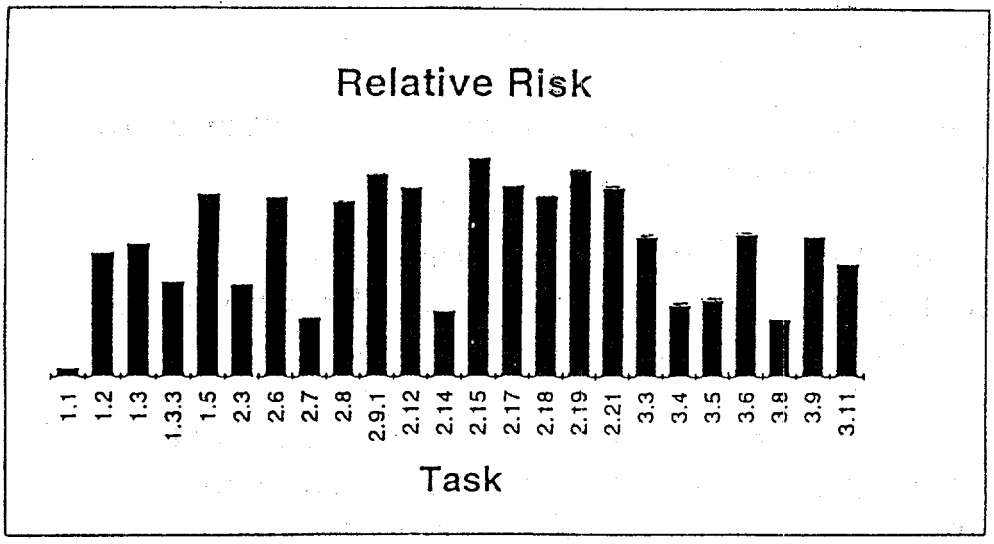
3. ___Minor severity
   (potential complications, may be clinical significance, but not a misadministration)

4. ___Severe
   (misadministration, complications, clinical significance)

5. ___Very severe
   (fatality; radiation contamination)

6. ___Specify other:


Probability vs. Consequence
Probability
1.2
2.3
1.5
1.3
3.6
3.11
1.3.3
2.6
2.9.1
3.5
2.12
3.3
3.9
2.7
2.14
3.8
2.18
2.19
2.17
2.8
3.4
2.15
2.21
1.1
Consequence -->


Relative Risk
1.1
1.2
1.3
1.3.3
1.5
2.3
2.6
2.7
2.8
2.9.1
2.12
2.14
2.15
2.17
2.18
2.19
2.21
3.3
3.4
3.5
3.6
3.8
3.9
3.11
Task

*NMSS*

*MEDICAL RISK ANALYSIS WORKSHOP*

# MEDICAL ISSUES

Patricia K. Holahan, Ph.D.

## RISK OF MISADMINISTRATIONS

## BACKGROUND

- No quantitative estimates of risks
- Historically, NRC concerned with frequency of misadministrations
- "Quality Management Program and Misadministrations" rule - limited quantitative estimate of consequences of errors
- Thresholds established considered medical consequences but focussed on significant deviations from prescribed treatment

## QUALITY MANAGEMENT PROGRAMS

- Teletherapy (including stereotactic)
- Brachytherapy (including remote afterloading)
- Strontium-90 eye applicators
- Radiopharmaceutical therapy
- NaI dosages greater than 30 $\mu$Ci

## RISK OF MISADMINISTRATIONS (continued)

- Probability of occurrence with medical consequences not equal to probability of occurrence of event
- Two ways of measuring consequences:
  - biological or medical consequences
  - occurrence of an error or deviation
- Must consider risk associated with prescribed treatment

# BRACHYTHERAPY EVENTS

- Computer errors
- Misplaced sources
- Dislodged sources
- Patient intervention
- Human error

# Therapy Misadministrations

| | 1990 | 1991 | 1992 | 1993 |
|---|---|---|---|---|
| Teletherapy | 12 | 2 | 14 | 5 |
| Brachytherapy | 8 | | | |
| Manual | | 14 | 10 | 17 |
| Afterloading | | 1 | 6 | 10 |
| Radiopharm. | 2 | 6 | 5 | 5 |

## Medical Policy Statement

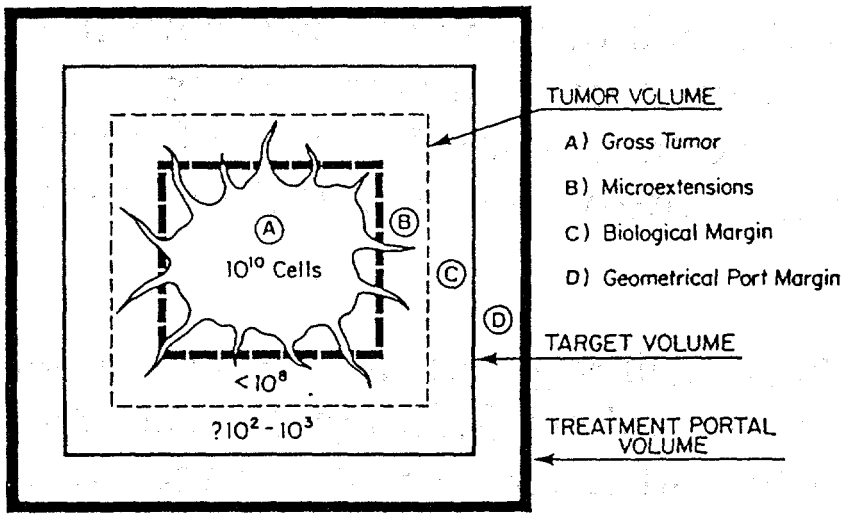
1. The NRC will continue to regulate the medical uses of radioisotopes as necessary to provide for the safety of radiation safety workers and the general public.

2. The NRC will regulate the radiation safety of patients where justified by the risk to patients and where voluntary standards, or compliance with these standards, are inadequate.

## Medical Policy Statement (Continued)

3. The NRC will minimize intrusion into medical judgements affecting patients and into other areas traditionally considered to be part of the practice of medicine.

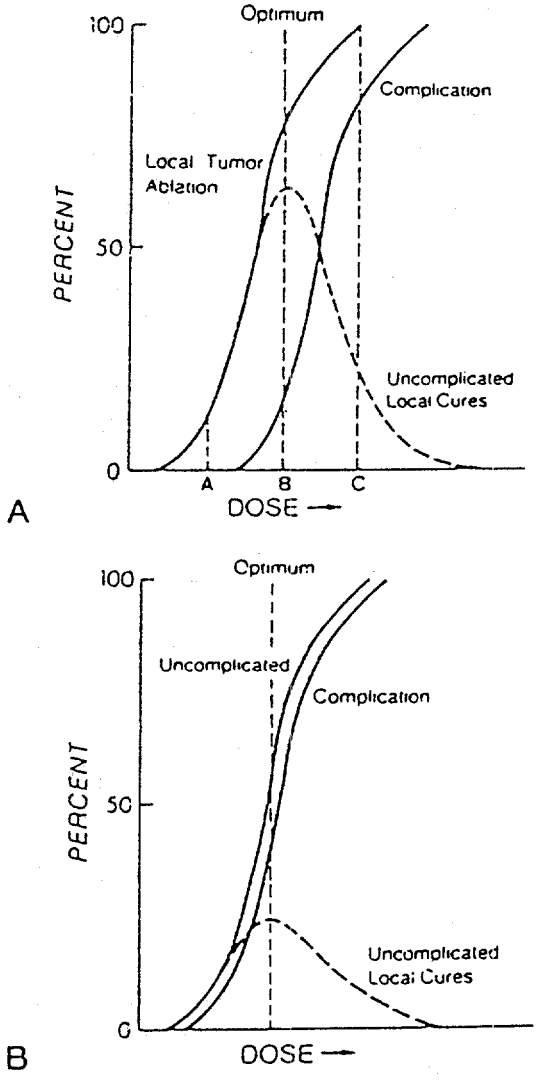
DEFINITION OF "VOLUMES" IN RADIATION THERAPY

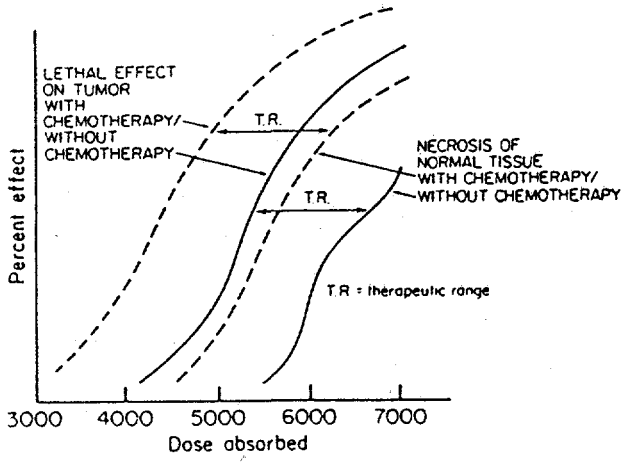


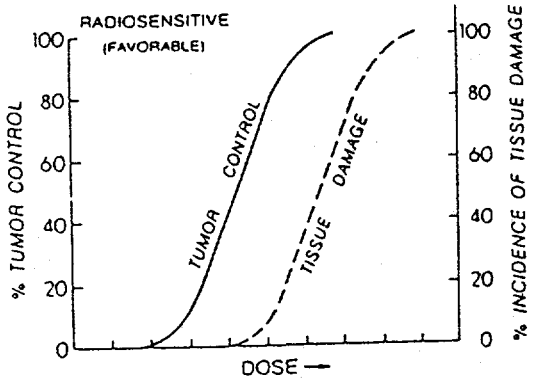

DOSE-FRACTIONATION IN RADIOTHERAPY

| TYPE | TIME→ | DOSE | SCHEDULE |
|---|---|---|---|
| Conventional | T | D | 200 cGy/day |
| Hyperfractionation | T | D+d | 115 cGy X 2/day |
| Accelerated MDF | $T/\frac{2}{3}$ | D-d | 150-200 cGy X 2/day |
| Modified Accelerated Fractionation | T | D+d | BOOST |
| Split Course | T+REST | D | REST → >250 cGy/day |
| Hypofractionation | T-t | D-d | 500 cGy/day |

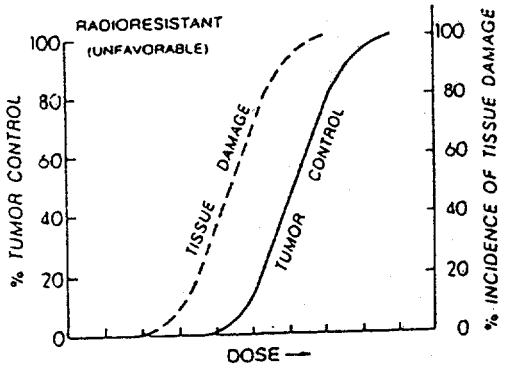
*FIGURE 1–12.* Various types of fractionation used in radiation therapy.


Optimum
100
Complication
Local Tumor
Ablation
PERCENT
50
Uncomplicated
Local Cures
0
A
B
C
DOSE
A
Optimum
100
Uncomplicated
Complication
PERCENT
50
Uncomplicated
Local Cures
0
DOSE
B


LETHAL EFFECT
ON TUMOR
WITH
CHEMOTHERAPY/
WITHOUT
CHEMOTHERAPY
T.R.
NECROSIS OF
NORMAL TISSUE
WITH CHEMOTHERAPY/
WITHOUT CHEMOTHERAPY
T.R.
T.R = therapeutic range
Percent effect
3000
4000
5000
6000
7000
Dose absorbed


RADIOSENSITIVE
(FAVORABLE)
% TUMOR CONTROL
% INCIDENCE OF TISSUE DAMAGE
TUMOR CONTROL
TISSUE DAMAGE
DOSE

A


RADIORESISTANT
(UNFAVORABLE)
% TUMOR CONTROL
% INCIDENCE OF TISSUE DAMAGE
TISSUE DAMAGE
TUMOR CONTROL
DOSE

B

*TABLE 1–1*
*Curative Doses of Radiation for Different Tumor Types*

**2000–3000 cGy**
- Seminoma
- Dysgerminoma
- Acute lymphocytic leukemia

**3000–4000 cGy**
- Seminoma (bulky)
- Wilms' tumor
- Neuroblastoma

**4000–4500 cGy**
- Hodgkin's disease
- Lymphosarcoma
- Histiocytic cell sarcoma
- Skin cancer (basal cell)

**5000–6000 cGy**
- Lymph nodes, metastatic ($N_0$, $N_1$)
- Squamous cell carcinoma, cervix cancer, and head and neck cancer
- Embryonal cancer
- Breast cancer, ovarian cancer
- Medulloblastoma
- Retinoblastoma
- Ewing's tumor
- Breast cancer (excised)

**6000–6500 cGy**
- Larynx (<1 cm)
- Breast cancer ($T_1$)

**7000–7500 cGy**
- Oral cavity (<2 cm, 2–4 cm)
- Oro-naso-laryngo-pharyngeal cancers
- Breast cancer ($T_2$)
- Bladder cancers
- Cervix cancer
- Uterine fundal cancer
- Ovarian cancer
- Lymph nodes, metastatic (1–3 cm)
- Lung cancer (<3 cm)

**8000 cGy OR ABOVE**
- Head and neck cancer (>4 cm)
- Breast cancer (>5 cm)
- Glioblastomas (gliomas)
- Osteogenic sarcomas (bone sarcomas)
- Melanomas
- Soft tissue sarcomas (>5 cm)
- Thyroid cancer
- Lymph nodes, metastatic (>6 cm)

*(Modified from Rubin P: Clinical Oncology: A Multidisciplinary Approach, 6th ed, p 64. New York, American Cancer Society, 1983)*

*TABLE 1–23*
*Possible Specific Sequelae of Therapy Discussed in Informed Consent*

| | SEQUELAE | |
|---|---|---|
| ANATOMIC SITE | ACUTE | LATE |
| Brain | Earache, headache, dizziness, hair loss, erythema | Hearing loss, damage to middle or inner ear; pituitary gland dysfunction; cataract formation; brain necrosis |
| Head and neck | Odynophagia, dysphagia, hoarseness, xerostomia, dysgeusia, weight loss | Subcutaneous fibrosis, skin ulceration, necrosis; thyroid dysfunction; persistent hoarseness, dysphonia, xerostomia, dysgeusia; cartilage necrosis; osteoradionecrosis of mandible; delayed wound healing, fistulae; dental decay; damage to middle ear and inner ear; apical pulmonary fibrosis<br>Rare: myelopathy |
| Lung and mediastinum or esophagus | Odynophagia, dysphagia, hoarseness, cough; pneumonitis, carditis | Progressive fibrosis of lung, dyspnea, chronic cough; esophageal stricture<br>Rare: chronic pericarditis, myelopathy |
| Breast or chest wall | Odynophagia, dysphagia, hoarseness, cough; pneumonitis (asymptomatic); carditis; cytopenia | Fibrosis, retraction of breast; lung fibrosis; arm edema; chronic endocarditis, myocardial infarction<br>Rare: osteonecrosis of ribs |
| Abdomen or pelvis | Nausea, vomiting, abdominal pain, diarrhea; urinary frequency, dysuria, nocturia; cytopenia | Proctitis, sigmoiditis; rectal or sigmoid stricture; colonic perforation or obstruction; contracted bladder, urinary incontinence, hematuria (chronic cystitis); vesicovaginal fistula; rectovaginal fistula; leg edema; scrotal edema, sexual impotency; vaginal retraction or scarring; sterilization; sexual impotence<br>Rare: damage to liver or kidneys |
| Extremities | Erythema, dry/moist desquamation | Subcutaneous fibrosis; ankylosis, edema; bone/soft tissue necrosis |

*TABLE 1–24*
*Acute Radiation Morbidity Scoring Criteria (RTOG)*

| | | SCORE | | | |
|---|---|---|---|---|---|
| ORGAN/TISSUE | 0 | GRADE 1 | GRADE 2 | GRADE 3 | GRADE 4 |
| Skin | No change over baseline | Follicular, faint or dull erythema, epilation, dry desquamation, decreased sweating | Tender or bright erythema, patchy moist desquamation, moderate edema | Confluent, moist desquamation other than skin folds, pitting edema | Ulceration, hemorrhage, necrosis |
| Mucous membrane | No change over baseline | Injection, may experience mild pain not requiring analgesic | Patchy mucositis that may produce an inflammatory serosanguinous discharge, may experience moderate pain requiring analgesic | Confluent fibrinous mucositis; may include severe pain requiring narcotic | Ulceration, hemorrhage, or necrosis |
| Eye | No change | Mild conjunctivitis with or without scleral injection, increased tearing | Moderate conjunctivitis with or without keratitis requiring steroids or antibiotics, dry eye requiring artificial tears, iritis with photophobia | Severe keratitis with corneal ulceration, objective decrease in visual acuity or in visual fields, acute glaucoma, panophthalmitis | Loss of vision (unilateral or bilateral) |
| Ear | No change over baseline | Mild external otitis with erythema, pruritis, secondary to dry desquamation not requiring medication. Audiogram unchanged from baseline | Moderate external otitis requiring topical medication, serous otitis medius, hypoacusis on testing only | Severe external otitis with discharge or moist desquamation, symptomatic hypoacusis, tinnitus, not drug-related | Deafness |
| Salivary gland | No change over baseline | Mild mouth dryness; slightly thickened saliva; may have slightly altered taste such as metallic; these changes not reflected in alteration in baseline feeding behavior, such as increased use of liquids with meals | Moderate to complete dryness; thick, sticky saliva, markedly altered taste | | Acute salivary gland necrosis |
| Pharynx and esophagus | No change over baseline | Mild dysphagia or odynophagia; may require topical anesthetic or nonnarcotic analgesics; may require soft diet | Moderate dysphagia or odynophagia; may require narcotic analgesics; may require purée or liquid diet | Severe dysphagia or odynophagia with dehydration or weight loss (>15% from pretreatment baseline) requiring NG feeding tube, IV fluids, or hyperalimentation | Complete obstruction, ulceration, perforation, fistula |

*(continued)*

*TABLE 1–24*
*(Continued)*

| | | SCORE | | | |
|---|---|---|---|---|---|
| ORGAN/TISSUE | 0 | GRADE 1 | GRADE 2 | GRADE 3 | GRADE 4 |
| Larynx | No change over baseline | Mild or intermittent hoarseness; cough not requiring antitussive; erythema of mucosa | Persistent hoarseness but able to vocalize; referred ear pain, sore throat, patchy fibrinous exudate or mild arythenoid edema not requiring narcotic; cough requiring antitussive | Whispered speech, throat pain or referred ear pain requiring narcotic; confluent fibrinous exudate, marked arytenoid edema | Marked dyspnea; stridor or hemoptysis with tracheostomy or intubation necessary |
| Upper GI | No change | Anorexia with ≤5% weight loss from pretreatment baseline; nausea not requiring antiemetics; abdominal discomfort not requiring parasympatholytic drugs or analgesics | Anorexia with ≤15% weight loss from pretreatment baseline; nausea or vomiting requiring antiemetics; abdominal pain requiring analgesics | Anorexia with >15% weight loss from pretreatment baseline or requiring NG tube or parenteral support; nausea or vomiting requiring NG tube or parenteral support; abdominal pain, severe despite medication; hematemesis or melena; abdominal distention (flat plate radiograph demonstrated distended bowel loops) | Ileus, subacute or acute obstruction, perforation, GI bleeding requiring transfusion; abdominal pain requiring tube decompression or bowel diversion |
| Lower GI including pelvis | No change | Increased frequency or change in quality of bowel habits not requiring medication; rectal discomfort not requiring analgesics | Diarrhea requiring parasympatholytic drugs (*e.g.*, diphenoxylate); mucous discharge not necessitating sanitary pads; rectal or abdominal pain requiring analgesics | Diarrhea requiring parenteral support; severe mucous or blood discharge necessitating sanitary pads; abdominal distention (flat plate radiogrpah demonstrates distended bowel loops) | Acute or subacute obstruction, fistula or perforation, GI bleeding requiring transfusion, abdominal pain or tenesmus requiring tube decompression or bowel diversion |
| Lung | No change | Mild symptoms of dry cough or dyspnea on exertion | Persistent cough requiring narcotic, antitussive agents; dyspnea with minimal effort but not at rest | Severe cough unresponsive to narcotic antitussive agent or dyspnea at rest; clinical or radiologic evidence of acute pneumonitis; intermittent $O_2$ or steroids may be required | Severe respiratory insufficiency; continuous oxygen or assisted ventilation |
| Genitourinary | No change | Frequency of urination or nocturia twice pretreatment habit; dysuria, urgency not requiring medication | Frequency of urination or nocturia less frequent than every hour; dysuria, urgency, bladder spasm requiring local anesthetic (*e.g.*, phenazopyridine) | Frequency with urgency and nocturia hourly or more frequently; dysuria, pelvic pain, or bladder spasm requiring regular, frequent narcotic; gross hematuria with or without clot passage | Hematuria requiring transfusion; acute bladder obstruction not secondary to clot passage, ulceration, or necrosis |
| Heart | No change over baseline | Asymptomatic but objective evidence of EKG changes or pericardial abnormalities without evidence of other heart disease | Symptomatic with EKG changes and radiologic findings of congestive heart failure or pericardial disease; no specific treatment required | Congestive heart failure, angina pectoris, pericardial disease responding to therapy | Congestive heart failure, angina pectoris, pericardial disease, arrhythmias not responsive to nonsurgical measures |

(*continued*)

*TABLE 1–24*
*(Continued)*

| ORGAN/TISSUE | 0 | SCORE GRADE 1 | GRADE 2 | GRADE 3 | GRADE 4 |
|---|---|---|---|---|---|
| CNS | No change | Fully functional status (able to work) wih minor neurologic findings; no medication needed | Neurologic findings sufficient to require home care; nursing assistance may be required; medication including steroids; antiseizure agents may be required | Neurologic findings requiring hospitalization for initial management | Serious neurologic impairment that includes paralysis, coma, or seizures >3 per wk despite medication; hospitalization required |
| Hematologic WBC (× 1000) | ≥4.0 | 3.0–<4.0 | 2.0–<3.0 | 1.0–<2.0 | <1.0 |
| Platelets (× 1000) | >100 | 75–<100 | 50–<75 | 25–<50 | <25 or spontaneous bleeding |
| Neutrophils (× 1000) | ≥1.9 | 1.5–<1.9 | 1.0–<1.5 | 0.5–<1.0 | <0.5 or sepsis |
| Hemoglobin (GM %) | >11 | 11–9.5 | <9.5–7.5 | <7.5–5.0 | — |
| Hematocrit (%) | ≥32 | 20–<32 | 20 | Packed cell transfusion required | — |

*Guidelines*
*The acute morbidity criteria are used to score/grade toxicity from radiation therapy. The criteria are relevant from day 1, the commencement of therapy, through day 90. Thereafter, the EORTC/RTOG Criteria for Late Effects are to be utilized.*
*The evaluator must attempt to discriminate between disease and treatment-related signs and symptoms.*
*An accurate baseline evaluation prior to commencement of therapy is necessary.*
*All toxicities of Grade 3, 4, or 5* must be verified by the principal investigator.*
** Any toxicity that caused death is graded 5.*

*TABLE 1–25*
*Late Radiation Morbidity Scoring Scheme (RTOG, EORTC)*

| ORGAN/TISSUE | 0 | GRADE 1 | GRADE 2 | GRADE 3 | GRADE 4 | GRADE 5 |
|---|---|---|---|---|---|---|
| Skin | None | Slight atrophy, pigmentation change, some hair loss | Patchy atrophy, moderate telangiectasia, total hair loss | Marked atrophy, gross telangiectasia | Ulceration | Death directly related to radiation late effect |
| Subcutaneous tissue | None | Slight induration (fibrosis) and loss of subcutaneous fat | Moderate fibrosis but asymptomatic, slight field contracture; <10% linear reduction | Severe induration and loss of subcutaneous tissue; field contracture >10% linear measurement | Necrosis | |
| Mucous membrane | None | Slight atrophy and dryness | Moderate atrophy and telangiectasia, little mucus | Marked atrophy with complete dryness, severe telangiectasia | Ulceration | |
| Salivary glands | None | Slight dryness of mouth, good response on stimulation | Moderate dryness of mouth, poor response on stimulation | Complete dryness of mouth, no response on stimulation | Fibrosis | |
| Spinal cord | None | Mild L'hermitte's sign | Severe L'hermitte's sign | Objective neurologic findings at or below cord level treated | Mono-, paraquadriplegia | |
| Brain | None | Mild headache, slight lethargy | Moderate headache, great lethargy | Severe headache, severe CNS dysfunction (partial loss of power or dyskinesia) | Seizures or paralysis, coma | |

*(continued)*

*TABLE 1–25*
*(Continued)*

| ORGAN/TISSUE | 0 | GRADE 1 | GRADE 2 | GRADE 3 | GRADE 4 | GRADE 5 |
|---|---|---|---|---|---|---|
| Eye | None | Asymptomatic cataract, minor corneal ulceration or keratitis | Symptomatic cataract, moderate corneal ulceration, minor retinopathy or glaucoma | Severe keratitis, severe retinopathy or detachment, severe glaucoma | Panophthalmitis, blindness | |
| Larynx | None | Hoarseness, slight arytenoid edema | Moderate arytenoid edema, chondritis | Severe edema, severe chondritis | Necrosis | |
| Lung | None | Asymptomatic or mild symptoms (dry cough), slight radiographic appearances | Moderate symptomatic fibrosis or pneumonitis (severe cough); low-grade fever, patchy radiographic appearances | Severe symptomatic fibrosis or pneumonitis, dense radiographic changes | Severe respiratory insufficiency, continuous $O_2$, assisted ventilation | |
| Heart | None | Asymptomatic or mild symptoms, transient T-wave inversion and ST changes, sinus tachycardia >110 (at rest) | Moderate angina on effort, mild pericarditis, normal heart size, persistent abnormality T wave and ST changes, low QRS | Severe angina, pericardial effusion, constrictive pericarditis, moderate heart failure, cardiac enlargement, EKG abnormalities | Tamponade, severe heart failure, severe constrictive pericarditis | |
| Esophagus | None | Mild fibrosis, slight difficulty in swallowing solids, no pain on swallowing | Unable to take solid food normally, swallowing semisolid food, dilatation may be indicated | Severe fibrosis, able to swallow only liquids, may have pain on swallowing; dilatation required | Necrosis, perforation, fistula | |
| Small/large intestine | None | Mild diarrhea, mild cramping, bowel movement 5 times daily, slight rectal discharge or bleeding | Moderate diarrhea and colic, bowel movement >5 times daily, excessive rectal mucus or intermittent bleeding | Obstruction or bleeding requiring surgery | Necrosis, perforation, fistula | |
| Liver | None | Mild lassitude, nausea, dyspepsia, slightly abnormal liver function | Moderate symptoms, some abnormal liver function tests, serum albumin normal | Disabling hepatitic insufficiency, liver function tests grossly abnormal, low albumin, edema or ascites | Necrosis, hepatic coma or encephalopathy | |
| Kidney | None | Transient albuminuria, no hypertension, mild impairment renal function, urea 25–35 mg%, creatinine 1.5–2.0 mg%, creatinine clearance >75% | Persistent moderate albuminuria (2+); mild hypertension, no related anemia, moderate impairment renal function; urea >36–60 mg%, creatinine clearance (50–74%) | Severe albuminuria, severe hypertension, persistent anemia (<100%), severe renal failure, urea >60 mg%, creatinine >4.0 mg%, creatinine clearance <50% | Malignant hypertension, uremic coma; urea >100% | |
| Bladder | None | Slight epithelial atrophy, mild telangiectasia (microscopic hematuria) | Moderate frequency, generalized telangiectasia, intermittent macroscopic hematuria | Severe frequency and dysuria, severe generalized telangiectasia (often with petechiae), frequent hematuria, reduction in bladder capacity (<150 cc) | Necrosis, contracted bladder (capacity <100 cc), severe hemorrhagic cystitis | |

*(continued)*

*TABLE 5–14*
*Tolerance Doses (Single Dose—Whole Organ)*

| TARGET CELL | COMPLICATION END POINT | DOSE RANGE (cGy) $TD_5$–$TD_{50}$ |
|---|---|---|
| **RANGE: 100 TO 1000 cGy** | | |
| Lymphoid and lymphocytes | Lymphopenia | 200–500 |
| Bone marrow hematopoietic stem cells | Aplasia | 200–1000 |
| Lens epithelium | Cataract | 200–800 |
| Ovarian oocytes | Sterility | 200–600 |
| Testes spermatogonia | Sterility | 200–600 |
| Lung type II cells | Pneumonitis | 700–1000 |
| Gastrointestinal epithelial cells | Enteritis | 500–1000 |
| **RANGE: 1000 TO 2000 cGy** | | |
| Range: 1000 to 2000 cGy | | |
| Colorectal epithelial cells | Colitis | 1000–2000 |
| Upper aerodigestive mucosa | Mucositis | 1500–2000 |
| Kidney | Nephritis | 1100–1900 |
| Heart | Carditis | 1800–2000 |
| Liver | Hepatitis | 1500–2000 |
| Peripheral nerve | Neuropathy | 1500–2000 |
| Spinal cord | Myelopathy | 1500–2000 |
| Brain | Encephalopathy | 1500–2000 |
| Microcirculation | Vasculitis | 1500–2000 |
| Connective tissue stroma | Inflammation | 1500–2000 |
| **RANGE: >2000 cGy** | | |
| Bone and cartilage | Osteitis/fracture | >2000 |
| Muscle | Myositis/myopathy | >2000 |
| Endocrines: pituitary/adrenals | Hypopituitarism | >2000 |
| Pancreas | Addisonian | >2000 |
| | Pancreatitis/diabetes | >2000 |

*(Rubin P: The law and order of radiation sensitivity, absolute vs relative. In Vaeth JM, Meyer JL [eds]: Radiation Tolerance of Normal Tissues, vol 23. Basel, Karger, 1989)*

*TABLE 5–15*
*Tolerance Doses $TD_5$–$TD_{50}$ (Fractionated Dose—Whole or Partial Organ)*

| TARGET CELL | COMPLICATION END POINT | DOSE RANGE (cGy) $TD_5$–$TD_{50}$ |
|---|---|---|
| **RANGE: 200 TO 1000 cGy** | | |
| Lymphocytes and lymphoid | Lymphopenia | 200–1000 |
| Testes spermatogonia | Sterility | 100–200 |
| Ovarian oocytes | Sterility | 600–1000 |
| Diseased bone marrow (CLL or multiple myeloma) | Severe leukopenia and thrombocytopenia | 300–500 |
| **RANGE: 1000 TO 2000 cGy** | | |
| Lens | Cataract | 600–1200 |
| Bone marrow stem cell | Acute aplasia | 1500–2000 |
| **RANGE: 2000 TO 3000 cGy** | | |
| Kidney: renal glomeruli | Arterionephrosclerosis | 2300–2800 |
| Lung: type II: VCTS | Pneumonitis/fibrosis | 2000–3000 |
| **RANGE: 3000 TO 4000 cGy** | | |
| Liver central veins | Hepatopathy | 3500–4000 |
| Bone marrow | Hypoplasia | 2500–3500 |
| **RANGE: 4000 TO 5000 cGy** | | |
| Heart/whole organ | Pericarditis and pancarditis | 4300–5000 |
| Bone marrow microenvironments, sinusitis | Permanent aplasia | 4500–5000 |
| **RANGE: 5000 TO 6000 cGy** | | |
| Gastrointestinal | Infarction necrosis | 5000–5500 |
| Heart/partial organ | Cardiomyopathy | 5500–6500 |
| Spinal cord | Myelopathy | 5000–6000 |
| Brain | Encephalopathy | 5400–7000 |
| **RANGE: >6000 TO 7000 cGy** | | |
| Mucosa (UAD) | Ulcer | 6500–7500 |
| Rectum | Ulcer | 6500–7500 |
| Bladder | Ulcer | 6500–7500 |
| Mature bones | Fracture | 6500–7000 |
| Pancreas | Pancreatitis | |

*VCTS: vascularconnective tissue systems; UAD: upper aerodigestive tract*
*(Rubin P: The law and order of radiation sensitivity, absolute vs relative. In Vaeth JM, Meyer JL [eds]: Radiation Tolerance of Normal Tissues, vol 23. Basel, Karger, 1989)*

# INTRODUCTION TO HUMAN RELIABILITY ANALYSIS



Idaho
National
Engineering
Laboratory

Workshop on Developing Risk Assessment Methods for Medical Use of Radioactive Material

Lee T. Ostrom, Ph.D., CSP, CPE
August 16, 1994

## Overview

- Discuss:
  - Human Error Analysis
  - Task Analysis
  - Qualitative Analysis
  - Quantitative Analysis
- Example Problems:
  - Commercial Airline Example
  - Medical Misadministrations

# Human Error Analysis (HEA)

- The systematic identification and modeling of potential human errors in the design, construction, operation, or maintenance of a system.
- Human factors research is the basis for HEA.
- Much of the work has focused on the development of human reliability analysis (HRA) methods.
  - HRA is a body of methods and data explicitly intended to model and quantify the probability of human errors, and to incorporate the probability for human error into the overall quantitative risk of a system.

# Human Error Analysis (HEA) (con't)

- We have performed work using HEA for numerous government agencies including:
  - The Nuclear Regulatory Commission (NRC),
  - The Department of Energy, and
  - National Aeronautic and Space Administration (NASA).
- The following is a brief example of how we have applied the concepts to a problem for NASA.

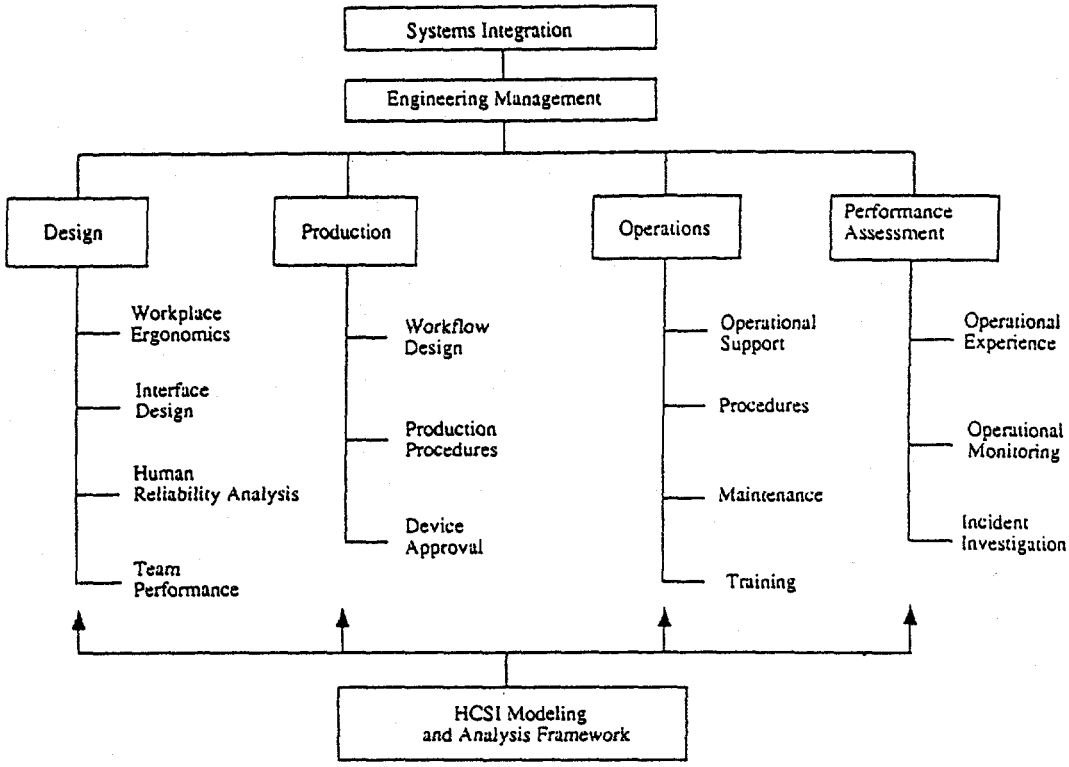



Figure 1: The Idaho National Engineering Laboratories Approach to Human Centered Systems Integration[4].

# Task Analysis

- The results from a task analysis forms the basis for the human reliability analysis

# Task Analysis (continued)

A task analysis is performed by:

- Reviewing information concerning the design of the system
- Reviewing pertinent procedures, training materials, and other supporting documentation
- Interviewing performers, trainers, and technical personnel
- Walking the performers through various scenarios
- Watching the actual process

# Task Analysis (continued)

- How is the task performed (who, what, when, and how)?
- What are the critical steps in the process (these are the sub-tasks that need to be performed correctly or task failure occurs)
- How much time does it take to perform the critical steps and is there enough time?
- Are there means for the operator to recover from an error in a critical step?
- What types of controls and instrumentation do the performers use?

# Task Analysis (continued)

- Are the controls and instrumentation designed according to human factors principles?
- Determining the level of stress to which the performers are exposed
- Determining whether the environment is rapidly changing (dynamic) or there is a very logical progression of the situation (step-by-step)
- Determining the impact of other performance shaping factors
  - organizational factors
  - distractions
  - lighting

# Qualitative Analysis

During this phase:

- A model of the process is developed using tools like event trees and HRA event trees
- This model is used to determine the potential failure paths and provide a framework for quantification
- This model is also used for ensuring completeness with the performers

# Quantitative Analysis

The failure probability is calculated after completing the model of the process.

This is done by:

- Selecting the most appropriate human error probability (HEP) for the task or subtask from a database
- Using expert judgement
- Using a time reliability technique
- Others

# Quantitative Analysis (continued)

Why quantify?

- To provide management justification for providing means to correct the situation
- To be able to help prioritize tasks for improvement

# Example Problems

- Commercial Airline Example

# Background

- The commercial aviation industry has many years of experience with automated systems
- Some unexpected effects have been observed following the introduction of automated systems
  - Workload may increase at times
  - Pilots don't always understand system behavior
  - New types of error have been introduced

BILLA-CAW-0493-002

# Background (cont)

- The nuclear industry has utilized many techniques for modeling human and system errors
- NASA sponsored a study at INEL to apply these techniques to the study of pilot error
- Lessons learned are applicable to the introduction of advanced technology in the nuclear power industry

BILLA-CAW-0493-003

# Approach

- Obtain aviation safety reporting system (ASRS) reports of altitude deviation events in glass cockpit aircraft
- Develop models of altitude maintenance tasks using two perspectives
  - Sequential model
  - Functional model
- Map altitude deviation events onto sequential and functional models

BILLA-CAW-0493-004

# Approach (cont)

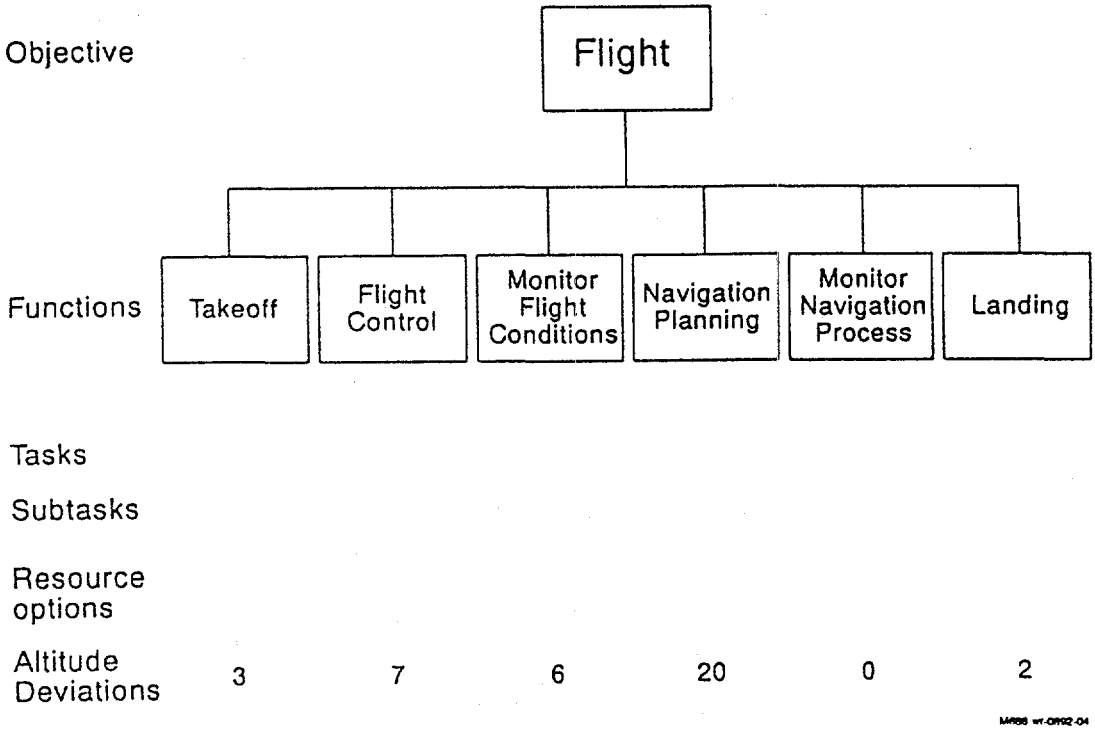
- Identify error categories
- Perform callbacks of specific altitude deviation events
- Develop recommendations for intervention

BILLA-CAW-0493-005

# Functional Model

- Illustrates success paths for providing critical safety functions
- Shows functional relationships of systems and tasks
- Shows context of individual tasks within overall flight functions
- Can be used to show sequence of attention to critical functions
- Can be used to show the effects of distractions
- Can be dynamically exercised to show the effects of human errors or hardware failures

BILLA-CAW-0493-006




# Sequential Model

- Illustrates the sequence of tasks and potential error paths
- Event tree shows sequence of human and hardware actions
- Human Reliability Analysis (HRA) event tree shows more detailed breakdown of human tasks
- Used qualitatively to classify errors for specific events
- Can be used to quantify probabilities for errors or sequences

BILLA-CAW-0493-007

## Human Actions on Altitude Deviation Event Tree

| | |
|---|---|
| ALTMTR-CALIB | Flight crew checks and notes altimeter discrepancies before takeoff |
| BARO-SET | Proper reference barometric pressure obtained and set by flight crew |
| NEWALT-CLEARNACE | Flight crew receives new altitude clearance (includes XING Restrictions) |
| SETUP-AP-ALTCHNG | Flight crew properly programs and engages Auto Pilot (AP) for altitude change and capture |
| P-ALTAWARE-1 | Flight crew monitors altitude change in terms of clearance and any crossing restrictions |
| P-ADJST-ALTCHNG | Flight crew reprograms AP, or disengages AP and flies climb/descent to meet clearance and crossing restrictions |
| P-MONITOR-ALTCAP | Flight crew monitors approaching capture altitude and altitude capture by the AP |
| P-CAPTURES-ALT | Flight crew disengages AP and flies altitude capture |
| P-ALTAWARE-2 | Flight crew monitors hold altitude and maintains vigilance for deviation warnings |
| PILOT-HOLDS-ALT | Flight crew reprograms AP, or disengages AP and flies, to hold altitude |

## Hardware Events on Altitude Deviation Event Tree

| | |
|---|---|
| AP-CLIMB/DESCEND | AP climbs/descends as programmed to meet clearance and any crossing restrictions |
| AP-CAPTURES-ALT | AP captures altitude as programmed to meet clearance |
| AP-HOLDS-ALT | AP holds altitude as programmed |

# Review of ASRS Reports

- 200 reports were obtained for glass cockpit altitude deviations between 4/91 and 1/92
- Reports were screened to identify those where automated systems played a role in the incident
- Reports with insufficient detail were eliminated
- 34 reports were selected for coding
- Events were mapped onto the sequential and functional models

BILLA-CAW-0493-008

# Coding of ASRS Reports

- Each ASRS report was examined to identify the characteristics of the incident from the sequential and functional perspectives
- Mapping the ASRS report on the sequential model highlights:
  - Where in the task sequence the errors occurred
  - Whether available recovery paths were used
  - What interventions could prevent the errors
- Mapping the ASRS report on the functional model highlights:
  - The functional context of the error
  - Whether distractions contributed to the incident
  - What success paths were available for mitigating the error

BILLA-CAW-0493-009

# Callbacks

- ASRS reports typically don't provide enough detail to fully code the sequential and functional models
- Callbacks by ASRS personnel were used to solicit additional information from the pilots involved
- Fifteen additional ASRS reports were obtained for callbacks
- A questionnaire of generic and incident specific questions was developed for each report
- Sequential and functional models were updated based on callback results

BILLA-CAW-0493-010

# Results: Altitude Deviations in Advanced Technology Aircraft

- Errors were distributed throughout the sequential and functional models
- Most common categories were:
  - Setting up autopilot for altitude change (sequential)
  - Programming the flight management system (functional)

BILLA-CAW-0493-011

# Results: Altitude Deviations in Advanced Technology Aircraft (cont)

- Predominant types of errors included:
  - Inadequate understanding of automatic functions
  - Incorrect manipulation or monitoring of automated systems
  - Errors introduced from external sources
- Some pilots seem to delegate monitoring as well as control to automated systems

BILLA-CAW-0493-012

# Conclusions: Value of the Methodology

- Model-based analysis of errors enhances consistency of event classification
- Models provide a guided inquiry into the details of human errors
- Sequential and functional models provide complimentary perspectives
- Event-specific callback questions evoked useful information

BILLA-CAW-0493-013

# Example Problems

- Medical Misadministration

# Methodology

The methodology entailed utilizing a probabilistic risk assessment approach, augmented with human reliability analysis.

The data used for the analysis was obtained from two sources:

- The investigation of the actual event, and
- A visit to another facility, not involved in the event.

# Methodology (Cont)

The risk assessment methodology only dealt with the top event, which was one of three possible. They are:

- Wrong treatment site,
- Wrong dose, or
- Wrong patient.

This analysis deals with the wrong treatment site.

# Methodology (Cont)

The event analyzed involved the manual brachytherapy modality.

Event Description

A patient undergoing treatment for cervical cancer received an unintended dose of radiation to her labial skin and the inner aspects of her thighs. This occurred because the technologist selected the wrong sources which were of a smaller diameter than the correct sources. The sources slipped through the opening in the end of a helical spring designed to keep the sources at the end of the source carriers of the Henschke manual brachytherapy applicator used in this treatment. A complete description of this event is contained in NUREG/CR-6088.

# Methodology (Cont)

The analysis methodology entailed:

1) developing the process model;

2) developing the fault trees;

3) developing the HRA event trees for specific human action sequences;

4) quantifying the model;

5) generating the cut sets; and

6) conducting a sensitivity analysis.

# Results and Discussion

The risk assessment was interesting because it highlighted:

(1) the failure path that lead to the event,

(2) the estimated effects of licensee's corrective actions on the failure path, and

(3) another failure path that is not only reasonably probable, but could go undetected.

# Results and Discussion (Cont)

The analysis process was also beneficial because it clearly showed the sequence of events and how the performance shaping factors at the facility affected the outcome. Also, it give a reasonable estimate of risk reduction after postulating changes to the facilities process.

# Results and Discussion (Cont)

Lack of a specific human reliability database that addresses human errors for medical procedures and specific hardware failure rates for medical equipment lead to the methodology producing less than ideal results.



Idaho
National
Engineering
Laboratory

# An Introduction to Traditional Risk Assessment Tools and Their Application to Nuclear Medical Misadministrations

Steven D. Novack

August 16, 1994

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## Overview

- Event Tree Analysis
- Fault Tree Analysis
- Application to Nuclear Medical Misadministrations
- Strengths and Limitations of These Techniques

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# Event Trees

- Features
  - Relates a sequential procedure to individual functions
  - Visualizes event sequence progression
  - Provides end-to-end tracability of a chain of events (accident sequence)
- Primary Utilization
  - Identifies accident sequences which result in some outcome of interest
  - Provides a basis for quantification of accident sequences

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# Event Tree Terminology

- Initiating Event
  - The starting point
- Top Events
  - Events or actions which affect the outcome

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# Event Tree Terminology cont'

- Branching
  - Indicates that there is some effect on the outcome
    - Up Branch - success (something works)
    - Down Branch - failure (something does not work)
- End States
  - Groups of accident sequences which share certain characteristics

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# Event Tree Terminology cont'

- Sequence
  - A combination of procedure/system successes and failures, in response to an initiating event, which results in some outcome of interest

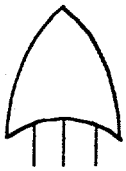
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# Fault Tree

- **Purpose**
  - **Identify ways in which a process/system can fail**
  - **Identify causal relationships of failure events**
  - **Quantify process/system failure probabilities**
  - **Characterize process/system weaknesses**

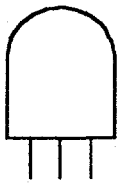
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# Fault Tree Building Blocks



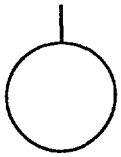
"OR" Gate

Logic gate representing the Boolean union of input events, The output will occur if at least one of the inputs exist,



"AND" Gate

Logic gate representing the Boolean intersection of the input events. The output will occur if all of the inputs co exist.



Basic Event

A basic component fault which requires no further development.

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# Fault Tree Terminology

- Minimal Cutset
  - A minimum combination of sufficient faults to result in the occurrence of the event of interest
- Dominant Contributors
  - Failures which are quantitatively the largest contributors to the likelihood of defined events

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# Similarities between Event trees and Fault Trees

- Both tools can model the same process/system
- Output of both are boolean logic models

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# Differences between Event trees and Fault Trees

- Event Trees apply inductive reasoning and map a specific event to a general outcome and answers the question if this event occurs what happens next
- Fault Trees are deductive in nature and map a general outcome to a specific event answers the question how can this outcome occur

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# Importance Analysis

- Definition : A measure of an event's contribution to the derived risk
- Results: Identify events that contribute significantly to the derived risk
- Types of Importance calculations
  - Fussell-Vesely method (fractional risk)
  - Risk Reduction Ratio
  - Risk Increase Ratio

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# Application Objectives

- Develop estimates of relative and absolute risks to the patient associated with potential misadministrations during treatment
- Identify importance of specific medical procedures, device interlocks and alarms
- Determine the risk significance of past events
- Identify key tasks, functions and safety barriers

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# Strengths of this approach

- Provides a visual representation of the treatment process
- Estimates quantitative results in terms of risk
- Incorporates human errors, hardware, software and common mode failures in the models
- Current software tools exist to aid analyses

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# Limitation of this approach

- Data for model quantification and development will be difficult to obtain and will not be based on extensive operating experience
- Although the tools have been used to model similar processes such as Hazop studies, experience in modeling nuclear medical treatments is limited

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# Generic Error Modeling

## A Framework for Analyzing & Modeling Human Failure Events

John Wreathall
John Wreathall & Co., Inc.
Dublin, Ohio

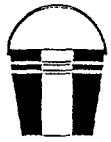
## Need for Taxonomy

- Events involving multiple human failures in technological settings can seem complex & inscrutable:
  - no single discipline owns the whole story
  - no common language across disciplines
    - common terms have conflicting meanings
- Can generic causes be found beneath the details of events?

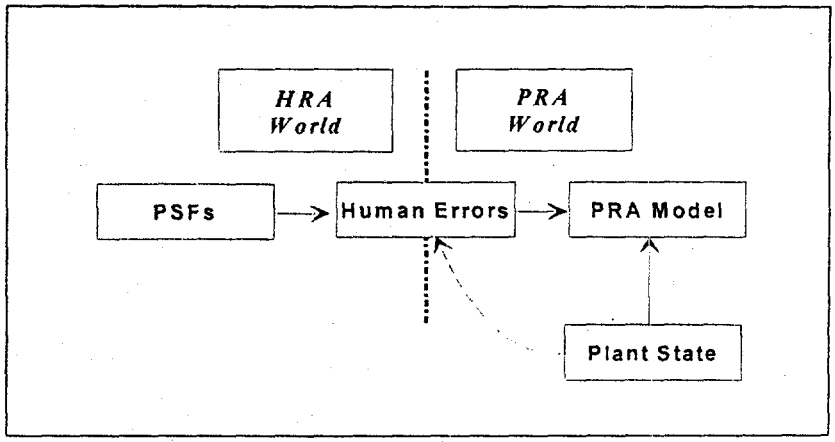
# Data without a framework...

...is like a body without a skeleton

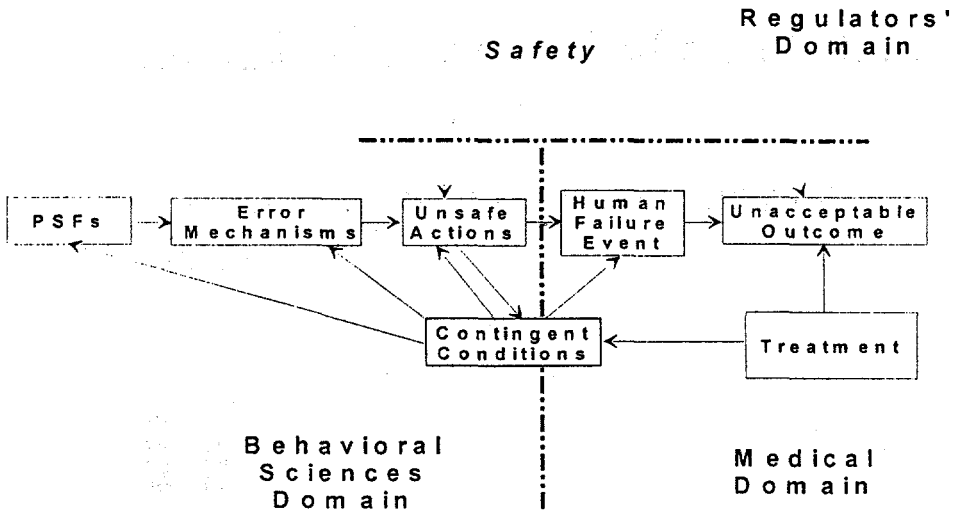
All you can do is carry it around in a bucket.



# Existing HRA/PRA Framework



# Framework




# Uses of Framework

- Provides multidisciplinary terms of reference for event analyses
  - allows different "explanations" for different communities
- Focuses on most common "cause" of problems
  - human behavior in unplanned conditions
- Allows collection of data & structuring of analyses

# Potential Applications

- Provide "root-cause" explanations for events
  - ensure consistent data gathering
- Provide qualitative assessments of mis-administration defenses embedded in regulations, QA programs, and practices
- Provide common terms of reference for quantitative risk studies

# Unsafe Actions versus Human Errors

- "Human error" means different things to different disciplines
  - PRA: human-caused failure of a system or function
  - psychology: (e.g.) a deficient outcome in a cognitive process
- Human error - a common term that prevents communication
  - no amount of effort has resolved conflicts about meaning
- Unsafe actions are those actions done (or left undone) that cause a less safe state

# Human Failure Events

- Term used in PRAs for "human" basic event
  - usually expressed as a human-caused failure mode of equipment or treatment mode
- Used to avoid any inference of fault or "where the error lay"

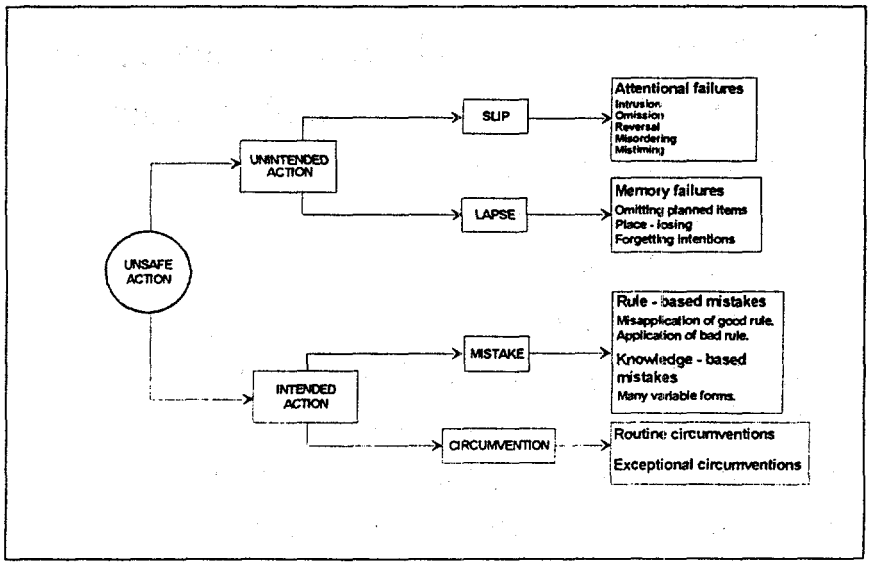
# Unsafe Actions (1)

- Slips & Lapses
  - actions performed not as intended
    - Slips: of memory
    - Lapses: in attention
- Mistakes
  - actions performed as intended, but erroneous intention
    - Rule-based: following an incorrect or flawed "rule"
    - Knowledge-based: intentions formed on incomplete or incorrect knowledge

# Unsafe Actions (2)

- Circumventions
  - actions taken intentionally that break "rules"
    - only way to perform task in practice
    - more efficient way to perform task
    - easy way out & usually no penalty, except ...
    - "rules" conflict
  - consequences can be hidden for long periods & subtle in effect
  - not sabotage -- no intention to cause harm

# Classification of Unsafe Actions



# Unsafe Actions

- Can be "active" or "latent"
- Can have consequences of omission or commission
- No implication of fault

# Error Mechanisms

- "Spark" that starts the chain of consequences
- Failures "between the ears"; unobservable
- Examples include failures in:
  - attention (slips)
  - memory (lapses)
  - recognition (lapses)
  - situational appraisal (RB, KB mistakes)
  - verification (RB, KB mistakes)
  - incomplete knowledge (RB, KB mistakes)
  - inaccurate knowledge (RB, KB mistakes)

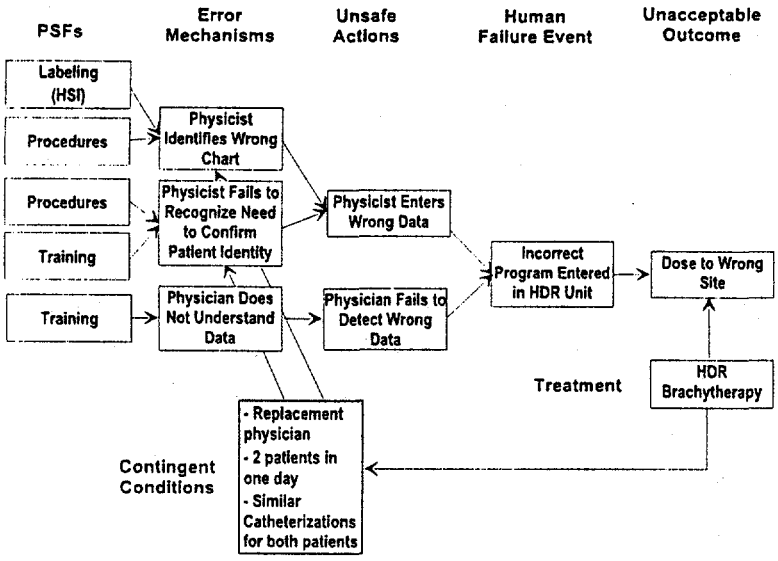
# Influences on Error Mechanisms

- Represent combinations of PSFs & contingent conditions
- Error-mechanism dependent
  - *attentional failure:* distraction, workload, stress, etc.
  - *recognition failure:* poor S/N ratio, distraction, stress, etc.
  - *situational appraisal failure:* counter-indications to appropriate rule, data buried in mass of signals that indicate "strong-but-wrong" rule, poor training or procedures, etc.
  - *knowledge failures:* inadequate training, procedures, supervision

# Contingent Conditions

- Create opportunities for unsafe actions
  - error mechanism becomes particular unsafe action depending on actual task
  - sensitivity of task activities to errors mechanisms
    - dynamic tasks
    - small margins of safety
    - multiple failure paths

# Example Analysis -
## Event A, Remote Brachytherapy




# Use of Framework In Analysis of Events

- Framework assists in analyzing human performance in significant events
  - brings structure to complexity
  - relates viewpoints of different disciplines
- Analysis can be:
  - qualitative
  - quantitative

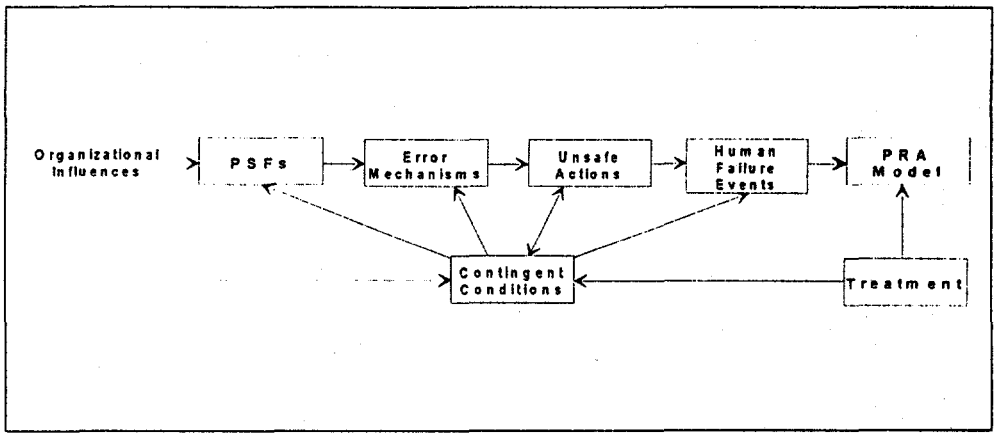
# Existing HRA/PRA vs. Serious Accidents & Near Misses

- Circumventions, lack of knowledge, & refusal to believe evidence are not modeled - major elements of accidents
- Dependencies between human errors not modeled
- PRAs are causal models of equipment failures, but current HRA models do not provide causal explanations of human errors - how to fix things?

# Limitations

- Will not accommodate "everything" that affects human performance & safety
  - "life events" (source of uncertainty?)
- Continuous state of refinement
  - development focuses on what's needed to solve problems (never "complete", only "sufficient")
  - based on evolving knowledge in "input" disciplines
    - psychology
    - human factors
    - PRA

# Including Organizational Influences




# Organizational Issues & Risk Assessment

- Regulated community is not homogeneous:
  - Westrum's classification:
    - Generative: Proactive safety management
    - Calculative: Compliant safety management
    - Pathogenic: Shunning safety management
- PRAs model calculative behavior
  - What fraction of facilities are "pathogenic"?
    - 5%? 1%?
- How do regulators reduce/eliminate pathogenic behavior & encourage generative behavior?

# Conclusions

- Provides assistance in understanding causes & effects of human contributions to safety and risk
  - qualitative and quantitative uses
- Indicates changes needed in HRA to make PRA more complete
  - integral assessment of PSFs & contingent conditions

# Implications of Framework for QM & Regulation

- Are "real causes" of "real events" controlled by current QM requirements?
- Do other regulatory requirements address "real causes" of "real events"?
- What changes are needed in current regulatory programs to address safety management processes?

# Why Should One Collect Data?

- Possible reasons:
  - Verifying that nuclear materials licensees are complying
  - Determine if any trends exist warranting further actions
  - Prioritizing regulatory activities and inspections
  - Characterize risk of radiation treatment
  - Move towards risk based regulations

**Existing NRC reporting requirements support some, but not all of theses needs.**

NMSS-JHB-0894-001

# Probabilistic Risk Assessment Tries to Answer Three Basic Questions:

What can go wrong?

If something goes wrong, what are the consequences?

How likely is it?

**To support Probabilistic Risk Assessment, the data collection process must also try to provide answers to these questions.**

Existing reporting requirements address:

- Some (but not all) of the types of things that can go wrong - based on actual experience
- The magnitude of the difference between prescribed vs. actually delivered dose (but not the medical consequences)

NMSS-JHB-0894-002

## The problems of collecting the right data, and interpreting it to support better regulatory decisions, is not unique to radiation therapy.

Typical problems in assessing risks using experience data include:

- Radiation treatment personnel are competent, hence the frequency of procedures where something goes wrong is small.
- NRC reporting requirements provide the ability to track details of specific procedures where something goes wrong, but not the total number of procedures performed without incident.
- Pooling of high consequence and low consequence events into a common category in order to get non-zero statistics.
- Quality Assurance of experience data bases.

NRC has had to deal with these same problems in assessing risks of operating nuclear reactors.

NMSS-JHB-0894-003

## Significant differences exist in the data collection of power reactors vs. radiation treatments.

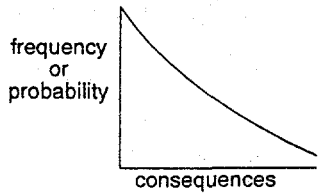
- Power reactors are assumed to operate continuously, detailed operating histories exist to estimate the frequency of certain types of events. (Events/yr)

- Radiation treatment frequencies differ from facility to facility and are intermittant. No attempt is made to maintain frequency of usage statistics. (Events/treatment)

- Hundreds of risk assessments have been performed for different types of power reactors - missing data on one facility can be estimated using data from other facilities.

NMSS-JHB-0894-004

## As a tendency, risk analysts would expect higher consequence events to have lower frequencies.




The majority of our experience is thus from frequent, low consequence events.

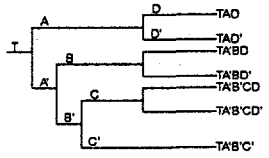
Numerous approaches have been used to extrapolate from the region where we have experience - to low frequency region.

All essentially involve a decomposition process into a hypothesized chain of events (typically modelled by an event tree).
Prob[event]=Prob[a] * Prob[b] *** Prob [x]

Carrying out this analysis can be done via Moments methods, Monte Carlo method, Latin Hypercube sampling.

All approaches depend on models and assumed probabilities.

## An event tree model, based on event experience, and typical treatment procedures can show pathways leading to various possible outcomes (high/low consequences)




Simplified example:
Prob[A']-0.001 Prob[B']-0.01 Prob[C']-0.5 Prob[D']-0.05

Most likely outcome: Path TAD, everything O.K. Prob[TAD]-0.95

Something goes wrong, but recovered without misadministration:
Path TA'BD Prob[TA'BD]-0.001

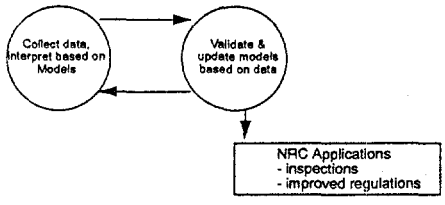
Misadministration:
Paths TAD', TA'BD', TA'B'CD', TA'B'C' Prob[---]-0.05 (sum of all paths)

## Studying Misadministration Data can allow us to retrospectively validate model assumptions.

Some limitations have to be dealt with:

- Different types of facilities can have significantly different numbers of overall individual treatments being performed.
- Quality Management processes are significantly different between facilities.

## Data Collection and Risk Assessment must be recognized as ongoing iterative processes.




Models should not exceed the availability of data to support the models.

Data bases should have sufficient taxonomies and quality assurance to allow more sophisticated models in the future.

# CURRENT REGULATORY SCHEME

Larry W. Camper, M.S., M.B.A.

## BRACHYTHERAPY

- 10 CFR 35.400 - Use of sources for brachytherapy
- 10 CFR 35.404 - Release of patients treated with temporary implants
- 10 CFR 35.75 - Release of patients containing permanent implants
- 10 CFR 35.406 - Brachytherapy sources inventory
- 10 CFR 35.410 - Safety instructions
- 10 CFR 35.415 - Safety precautions
- 10 CFR 35.420 - Possession of survey instrument

## TELETHERAPY

- 10 CFR 35.600 - Use of a sealed source in a teletherapy unit
- 10 CFR 35.605 - Maintenance and repair
- 10 CFR 35.606 - License amendments
- 10 CFR 35.610 - Safety instruction
- 10 CFR 35.615 - Safety precautions
- 10 CFR 35.620 - Possession of survey instrument
- 10 CFR 35.630 - Dosimetry equipment

## TELETHERAPY (continued)

- 10 CFR 35.632 - Full calibration measurements
- 10 CFR 35.634 - Periodic spot checks
- 10 CFR 35.636 - Safety checks
- 10 CFR 35.641 - Radiation surveys
- 10 CFR 35.643 - Modification of teletherapy unit
- 10 CFR 35.645 - Reports of surveys, checks, tests, and measurements
- 10 CFR 35.647 - Five-year inspection

## TRAINING AND EXPERIENCE

- 10 CFR 35.940 - Training for use of brachytherapy sources
- 10 CFR 35.960 - Training for teletherapy
- 10 CFR 35.961 - Training for teletherapy physicist

## NRC ACTIONS RESULTING FROM BRACHYTHERAPY MISADMINISTRATION - INDIANA, PENNSYLVANIA

- Updated P&GD FC 86-4: Information required for licensing remote afterloading devices - Includes Standard License Conditions
- NRCB 92-03: Release of Patients after Brachytherapy
- IN 92-84: Release of Patients Treated with Temporary Implants
- NRCB 93-01: Release of Patients after Brachytherapy Treatment with Remote Afterloading Devices

## BULLETIN 93-01

- Physicist/RSO and AU present
- Emergency procedures
- Physical survey with detection instrument

## EMERGENCY PROCEDURES

- Capability to handle surgical intervention in emergencies involving source breakage
- Resolution of accident situations

## AREAS OF CONCERN

Discussed with NRC's Advisory Committee on the Medical Uses of Isotopes

- Availability of industry standards
- Treatment planning
- Training and Experience
- Fractionated brachytherapy

## DOSE FRACTIONATION

- Defined for teletherapy
- Not defined for brachytherapy or radiopharmaceutical therapy

## ADEQUACY CONCERNS

- Adequacy of existing brachytherapy regulations
- Adequacy of existing standards and procedures
- Quality assurance checks and calibrations for brachytherapy similar to teletherapy

## FUTURE DIRECTION

- Major revision of 10 CFR Part 35
- Conduct public meetings to discuss regulatory criteria to address changing technologies
- Input from NAS study
- Investigate use of industry standards

## GOALS AND QUESTIONS

- What is a measurable endpoint for risk of medical devices?
- How do we obtain this measure?
- What is the cost?
- How do we quantify risk for regulatory purposes?

Discussion notes from room marker board

## Knowledge Base

- How to consider unreported events?
- Develop, tune numerator, denominators using data from NRC, non-agreement and agreement states (soon to be available), hospitals, manufacturers (confidentiality issue).
- Other efforts at NRC - task analysis, Pacific Science and Engineering, LLNL, INEL; professional organization (RTOG, AMA organization, etc.); misadministration database in AEOD; staff efforts; FDA (problem reporting system).
- Concern that data from manufacturer service reports may be skewed (e.g. inadvertent ejection of source).
- Use data to get at operational issues - especially on the evident "easy" items to be modeled.

1

Discussion notes from room marker board

## Knowledge Base (cont.)

- Recordable events from investigations, inspections.
- Human performance data to identify classes of contingency factors (event outside medicine).
- State Departments of Health
- When considering data in NRC - must consider input sources.
- Anecdotal data? Talk to the people who do the work.
- What of this list is really needed, that is not overburden on medical community.
- Use context from NAS - risk compared to other medical procedures, risk done right vs. risk done wrong.

2

Discussion notes from room marker board

## Special Considerations

### Medical Community

- Comparison of isotope risk to non-treatment by radiation
- Endpoints - deaths, medical consequences (consequences are multi dimensional)
- Concerned about learning to do better
- Regulator must not prevent/limit treatment, make cost prohibitive
- Patient (plant) is already at risk
- Number of gamma knife treatments known - similarly other data is present, logs.

3

Discussion notes from room marker board

## Human Error

- Training because of resources, turnover
- Institutional factors (cost benefit)
- Written procedures - present, clarity, etc.
- Oral procedures
- Ergonomics of equipment, computers, output from computer instrumentation, units, simulations, sources, planning software, etc.

4

Discussion notes from room marker board

## Human Error (cont.)

- Treatment by untrained, temporary personnel
- Workload/stress
- All PSFs
- Ways to prevent tunnelization of cognition
- Contingent conditions
- Simple stuff like color coding.

5

Discussion notes from room marker board

## Modeling

- Models must lead to identification of alternate paths
- Decision analysis tools: probability, use, cost (applicable to broad level problems)
- Event/Fault tree structures: including sensitivity, importance, screening, including a greater sensitivity to context (GEM), identifying underlying causality of human performance.
- Relative risk

6

Discussion notes from room marker board

## Modeling (cont.)

- Quantitative: to represent the study of past events, plus sensitivity, understand sequence, understand faults, modify sequence, then quantify.
- Qualitative
- Group similar devices, treatments, process, institutions (counter-intuitive perhaps)
- Conduct some PRAs in detail, some at higher level to identify common features. Consideration of process first.
- Inductive vs. deductive aspects.

7

Discussion notes from room marker board

## Risk Analysis Uses

- Characterize (understand) frequency and consequences of misadministrations.
- To inform medical community, public, & regulators of risk.
- Where inadequate to improve performance (causality of wrong behavior).
- What measures are necessary to keep performance adequate (causality of "proper behavior").
- Risk significance of events.
- Support, risk based evaluation of PDR.
- By comparison to levels of risk in similar phenomena, no additional regulations necessary (what is the standard).

8

Discussion notes from room marker board

## Risk Analysis Uses (cont.)

- Provide a context for comparison, that is pedigreed.
- What is the difference when done correctly vs. incorrectly.
- Risk management.
- Enhanced credibility of community.
- Tool to gain, understand, communicate, & train.
- Identification of outliers (few critical equipment, procedures, etc.).

9

Discussion notes from room marker board

## Conclusions

- Start with available data
- Augment with easily available data
- Model - a sample, using a combination of event/fault/GEM
- Choose method to model.
  - Teletherapy is oldest and has best data.
  - HDR is perhaps most dangerous and has most growth.
  - Generic study could be done given 5-10 years.
  - Limited study can be done in short term
  - Procedures and technology were evolutionary from manual to LDR *remote afterloading* to HDR RAL.
  - Conclusion: manual, LDR, HDR model development in parallel.

10

Discussion notes from room marker board

## Conclusions (cont.)

- Lay out rational to IMNS Division Director on why we should do this. Explain magnitude of scope of manual analysis addition.
- Could start with single device and examine in detail, but would not provide background for regulatory issues. Six is too many. Choosing manual, LDR, HDR in parallel is doable and provides broad basis for regulations.
- Review and see what additional data/analysis is needed.
- Get Dr. Pollycove's data into a risk assessment article.
- Let NAS study run its course.
- Denominator. Must give IMNS Division Director estimate of resources to generate denominators and numerators as well as why it is needed and what accuracy is needed. How would it be useful to refine beyond what is now known (outliers, variant error modes, normalized characteristics of events).

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# APPENDIX C

# TRANSCRIPT

Reported by: Karen Konvalinka, C S R

EASTERN IDAHO COURT REPORTERS

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# C.1. OPENING SESSION

## C.1.1. Welcome—Mr. Tortorelli

MR. TORTORELLI: Good morning. I'm Jim Tortorelli, and I've had the fun of organizing this workshop, my first workshop.

We've been working on this for quite awhile, and I'm really happy today. It's great to finally get this thing going and see you all here, and I just want to say I do appreciate everybody coming. It takes a week out of your schedule. You're all highly qualified and busy people. That's the kind we want to get here, but I know some of you made big sacrifices to come here.

I'd like to go over a couple admin. things first, before we get started.

(A discussion was held off the record.)

MR. TORTORELLI: Anything else? Okay, John.

## C.1.2. Introduction—Dr. Bickel

DR. BICKEL: Thank you. First of all, I'd like to welcome all of our guests and program sponsors and other members of the NRC-INEL lab staff. The genesis, I guess, of this workshop that we're holding over the next couple of days was some discussions we had with our program sponsor, Dr. Pat Rathbun, I guess it was about a year ago, who said it was probably about time we convened a small workshop bringing together some medical experts and some safety analysts for the purpose of evaluating the safety and risks associated with radiation therapy treatments.

What we'd like to accomplish over the next couple of days is, first of all, to discuss work that has been funded by the office of NMSS dealing with several different types of radiation therapy devices, both brachytherapy, remote afterloaders and the Gamma Ray Knife and, additionally, work that has been done to investigate past medical misadministrations.

Additionally, we'd like to lay the groundwork for understanding the actual safety and risk implications of misadministration events, that is an incident where the patient does not get what the doctor ordered. He gets more or less, a significantly different amount.

In discussing the safety and risk implications of this type of therapy, what we first of all want to accomplish over the coming two to three days is to identify where is the state of the art in studying the safety and risk of this type of therapy? What can we likely achieve in the coming years, applying standard methods and possibly improved methods. We would hopefully like to leave the workshop at its conclusion with an understanding where we are going in studying this type of process, using conventional and maybe nonconventional safety and risk assessment techniques.

Clearly, we must also recognize the importance of what we're trying to accomplish in doing this. Radiation therapy and diagnostics approaches are a very important tool in the detection and treatment of certain types of cancers and some other types of medical problems. The U. S. Nuclear Regulatory Commission is chartered by our Congress to regulate the use of nuclear materials in such a way as it maximizes public benefit and minimizes the risks associated with the use of that material. That obviously, you know, recognizes, when you think about it, our Congress at some point a long time ago recognized the fact that you've got risks and benefits that are being weighed there. And the NRC, by law, is chartered to try and strike the balance of how that is done. Clearly, we're trying to achieve an efficient regulation of radiation therapy devices in terms of how they're distributed, used, and that the public is basically getting maximum benefit.

With that in mind, I've discussed now what we're trying to—what we're going to do, what we're going to try to accomplish. I'd like to turn it over now to our first major speaker, which will be Larry Camper, who will be discussing, basically, an overview of the work going on. Larry?

## C.1.3. Overview—Mr. Camper

MR. CAMPER: Okay, thank you. Good morning again. I'm—on the schedule you'll see Dr. Carl Paperiello is to be the speaker. I'm pinch-hit-

ting for Carl. I'm—my name is Larry Camper. I'm the Section Leader of the Medical and Academic Section of the NRC headquarters. Carl is my Division Director, and the Medical Use Program falls under Carl's responsibility.

My primary role, and that of my staff, is to develop policy, technical guidance, regulatory guidance and various issues associated with the medical and academic uses of radioactive material that we regulate.

Now today, as you know, we're here—as I look at the program, the description is very interesting in the program. We want to review past efforts to develop a risk analysis methodology to evaluate the risk of use of radiation emitting medical devices and to form a program plan and scoping document for future methodology development.

Now two thoughts come to mind in talking with Carl about what he wanted me to convey to you in his behalf. First of all, the meeting is very timely. I think it's fair to say that the Medical Use Program and the attention being devoted to it by the Commission and by members of the public, by the Congress has grown dramatically in the last two to three years. There's hardly a week goes by that there's not something going on that deals with medical radiation therapy use. As recently as our last ACMUI meeting we went to that group which is an Advisory Committee to our organization, our division, to the Commission to explore questions associated with brachytherapy, and in particular, high dose rate remote afterloading brachytherapy.

So this meeting comes at a very timely point, because over the next year, we intend to go out and hold a series of workshops and put in place an advanced notice of proposed rule making in which we would invite the medical community and those interested to participate in a major revision of Part 35.

Now in the next few months, we will commence these workshops that deal with brachytherapy. And I know in a few minutes, that Dr. Rathbun is going to introduce the NRC staff when she makes her comments. But while up here, I do want to make a comment or two about two of the individuals here from the NRC. One is Dr. Judith Stitt. Dr. Stitt is a member of our Advisory Committee on the Medical Uses of Isotopes. She's a practicing radiation therapist, and will be actively involved in helping us to conduct a number of workshops and public meetings in the months to come. We have a meeting coming up in Florida in December with the American Brachytherapy Society. Next spring we're putting together a mega-meeting, if you will, that will involve The American College of Radiology, The American Association of Physicists and Medicine, The American College of Medical Physics, The Health Physics Society, The Society of Nuclear Medicine. It will be a very large meeting over two days conducted in Washington to take a look at all of the regulatory issues associated with the use of brachytherapy and, in particular, high dose rate remote afterloading.

I'd also like to point out Dr. Myron Pollycove. Dr. Pollycove is our Medical Visiting Fellow. He's been with us now for, I guess, two years or so, Myron? Dr. Pollycove was one of two of our first Medical Visiting Fellows, and the idea was that we wanted to augment our staff with directly available medical expertise. Dr. Mark Rotman was also a Medical Visiting Fellow. He is a radiopharmacist and he has now returned to NRH. And Dr. Pollycove, the approach that we had used for our Medical Visiting Fellow is to have them involved from the beginning. We have withheld no policy issue from Dr. Pollycove. He has talked with us about our good practices and our bad practices, and he's been a readily available source of information of a medical nature.

Now the reason I point these two physicians out to you is because over the months to come, they're both going to be actively involved in the regulatory process we'll be undertaking as it relates to medical radiation therapy use.

Now in talking with Carl, and for those of you who know Carl, Carl is sort of a quintessential scholar. And I couldn't begin to capture things as well as Carl would probably do if he were here to articulate them himself. Carl has that natural tendency to take something of global proportions in a wide scientific merit and kind of put it right down to the succinct, that kind of jabs you right in the chest and says, yeah, that is the issue.

But at least I will attempt to convey to you his thoughts, and please excuse my voice. I picked up a cold last night in the air conditioning in the hotel.

Okay, first slide. All right, Carl's first point was that radiation medicine accidents result from

human errors similar to observations and other human endeavors. Pilot error, if you will. We hear the comment often from the medical community that we regulate, and we especially did this when we were developing quality management role. Look, we've got a frequency of occurrence of misadministrations of on the order of ten to the minus four. Why are you putting in place this rule if we don't need it? We're down to the level of human error. Exactly. Of course you're at the level of human error. Unfortunately, some of those human errors end up in grave consequences up to and including patient deaths. Not unlike the pilot who doesn't go through the checklist before the airplane takes off.

So Carl's first point is, yes, this is the practice of medicine, but this is not truly unique. This is going on in other endeavors that we, as humans, undertake. And there are symptoms and signs and indicators that can be captured and corrected.

Of course there are human machine interface errors. In some cases, the computer screens or the programs are not designed particularly well. We recently had a misadministration, several misadministrations, eight of them in Billings, Montana, and if one looks through the manual that is associated with the software question, if one looks at the printout to that computer system, you see great problems and discrepancies. Now that led to problems with the operator interfacing with the machine correctly. In some cases, the operator doesn't pay attention to the scope or to the commands or to the indications. So classical human machine interface errors which will be seen in other endeavors, as well.

His third point was that command control and communication have not kept up with the growth of the delivery system. His intention, if he were here, was to quote a few lines from the Charge of The Light Brigade, as a classic example of a failure to exercise adequate command, control and communication. Now if you stop and think about it, it's true. We often see situations where authorized users are not involved the way they should be in the actual delivery of the radiation therapy.

We see poor communication between the authorized user, between the authorized user and the physicist, between the physicist and the therapy technologist and amongst therapy technologists, very poor communication. All those, of course, fall under the umbrella of command. It's not being properly supervised.

In reading some of the background information coming out on the plane, I was struck by some of the findings when INEL looked at seven misadministrations for us. You pointed out, however, there was a problem in supervision and inadequate authorized user involvement in many cases. Poor control, command and communications. Next slide.

Well, what are some of our objectives, or what do we think are proper objectives for licensees to employ in trying to prevent these problems? We think that prevention of errors requires defense in depth, both in redundancy and diversity. It's not enough to just put more redundant steps in place. They must be redundant, and they must be diverse. They must be unique. They must cause you to approach a possible error pathway from a different angle, a different series of evaluations, so redundancy and diversity.

However, redundancy and diversity must be coupled with cost benefit. You can't put in place for licensees to carry out a series of redundant or diverse operations that give no consideration to the amount of time it takes; that gives no consideration to the cost involved. So we have to bear in mind cost.

We can learn from other areas of technology. Medicine is not truly unique. Now there are medical practitioners who bristle at that phrase, right, Dr. Pollycove? Not Dr. Pollycove himself, but some others, two of his colleagues in particular.

DR. BICKEL: I think I heard bristling.

MR. CAMPER: Yes, that bristle at the thought that medicine is not unique. Well, from Carl's perspective, what he's really saying is that, yes, we recognize that medicine carries with it certain unique characteristics and patient/physician interface has some uniqueness to it, but if you look at it in terms of human endeavor and how errors occur, it's really not that unique, particularly when it comes to machine interface, communication errors, things not being written down properly, procedures not being in place. It really is not unique in that content.

So the take-home points that Carl wanted me to share with you as we meet over the next two

and a half days is that, as I started out by saying—and I'll talk more tomorrow when I talk to you about the current regulatory scheme—there's a lot going on today in the radiation therapy arena.

Our Commission has testified on Capitol Hill before Senator Glenn, after the Indiana, Pennsylvania incident in which a patient was unfortunately killed. There has been a series of articles in The Cleveland Plain Dealer. There has been human experimentation phenomenon that we've seen recently over the Clinton Administration and the Department of Energy, Secretary O'Leary. There is a great deal of interest in medical radiation use.

We foresee dramatic changes to our regulation, particularly as it relates to brachytherapy and to high dose rate load afterloading.

Now what we're going to discuss over the next two and a half days is obviously—it's very academic. You bring to this meeting a lot of scholarly observations based upon experience, based upon your academic credentials, and that's quite worthwhile. We want to learn from what you have observed thus far. We want to learn where you think we ought to go from now and how we ought to use it. But the take-home point is we need to be able to use it. We need usable recommendations, things that can go from purely academic observations, studies and analyses, to suggestions or recommendations that can undergo the public comment process, the interaction process with the regulated community, and can ultimately end up in regulatory language and/or regulatory guidance.

It needs to be reasonable criteria for all the obvious reasons. We cannot impose upon our licensees unreasonable criteria.

And finally, cost benefit. Cost benefit is always a component of any regulatory development, always has been, always will be. But in today's marketplace with the medical community, cost benefit is extremely important. I don't need to tell you what's going on today with talks of health care reform, concerns about spiraling health care costs, projections as we turn to the next century. We need to make sure we bear in mind cost benefit.

So what's reasonable; what's implementable; cost benefit is a consideration; and, try to structure it in ways we can put it through the regulatory process and ultimately implement guidance or findings that you may have.

Again, on behalf of Carl, I want to express his apology for not being able to be here. Due to some personal health reasons, he could not be here. He would like to have been here. I think we'll miss his comments over the next two and a half days. I'm sure he would have interjected a lot of useful thoughts, but be that as it may, I think we'll have a worthwhile session. We're looking forward to your feedback, and I thank you for the opportunity to make comments on Carl's behalf, and I'll talk to you again tomorrow morning about the current regulatory scheme and some concerns we have about how we might implement some of the things we're going to discuss with us. Thank you.

DR. BICKEL: Thank you, Larry. I'd now like to turn the discussion over to Dr. Rathbun.

MR. TORTORELLI: We're going to pass around a list of names and addresses of attendees in what probably looks like a random order. If you're not on here, please add your name and full address and phone numbers, but if you're on here, please check to make sure we've got it right or give me a little check or initial at the end.

DR. BICKEL: As we're getting Pat wired, the next item on the discussion will be a review of some of the past work sponsored in the office of NMSS.

# C.2. REVIEW OF PAST WORK

## C.2.1. Overview—Dr. Rathbun

DR. RATHBUN: Well, I would also like to join the previous speakers in welcoming you all here today, the members of the INEL, the members of the NRC staff, and sort of everybody else. I'm just really astonished at the level of expertise that we have assembled in this room. And after I finish my talk, I think I would like to ask you all to go around the room and maybe briefly introduce yourself, because I may be the only person in the room who knows everyone, but even as I look around, there are a couple people I don't know either. So we have an interesting situation here where we're clearly moving on to new effort, because no one person knows everyone.

I would also like to take this opportunity to convey to you Carl Paperiello's personal sadness at really not being able to come. He places a very, very high value on this project. I think we have five members of his staff here today, including Dr. Pollycove and myself, who report directly to Carl. He had looked forward to this for some time, but he has offered the INEL a free trip to Washington in about three weeks to bring him up to speed on what has happened here. So we have another opportunity, all expense paid trip to White Flint Two.

To restate the objective of this workshop as it's in your brochure, and as Larry gave it to you, we really do want to spend time on the first day and a half of going through the work that we have supported to date. I think it's all been very valuable. It's certainly been interesting. It's been challenging, and I think if we all come together with a kind of common understanding of how we got to this day, I think we can then, using the expertise of the combined people in this room, move forward into some really exciting work.

All right, since I love to put up the big pictures, I put up my view, and everyone said, no, Pat, you can't do this. But it won't show on the tape, but this is my view of how we got to this day. It's also—I have some handouts I could give you to augment what you can't see up here. They're coming around now.

Over three, three years ago in May of 1991, we placed three—

DR. BICKEL: I just ripped off an antenna off an old Ford. Would you like this?

DR. RATHBUN: Thank you, that was very tactful, John.

We placed these three projects. This one at the Livermore Laboratory and these two here at the INEL. At the same time, the Office of Research was funding a Human Factors Task Analysis Project of the brachytherapy remote afterloader, which will be reported on separately.

We kind of went off down the road, and we really didn't exactly know where we were going. It was an opportunity for me, who is really a risk analysis individual, not that familiar with medical, to try to marry up these two fields and move forward. Could you go to the next slide?

This just shows—the next slide is just where we were. Okay, I want you to go to the next slide. I want to show you how we first envisioned this project, and how we moved from where we were to where we are.

We had multiple objectives, which had very little to do with risk analysis. We wanted to look into very much hardware issues, quality control, calibration, service requirements, standards and guidelines. And we had a little bit of attention paid to risk analysis. Well, you see what has happened is over time, this field has become more and more important to the NRC, and we're devoting all of the time to risk analysis and very little to the remainder of this. This is a slide made by Livermore maybe three years ago. Now I want to go to one made by the INEL three years ago.

DR. BICKEL: Uh-oh, truth and consequences.

DR. RATHBUN: This was made up probably by John or a member of his staff, and you see we had the same type of parallel project going on here. Review the standards and guidelines, look into current practices, maintenance schedules, and we were considering developing a model program.

Well, what happened is we came to realize that without the risk part of these projects being developed, we really never could come up with a model program. So we moved on, and we began to spend time here.

What I found so interesting, and I was just going through my old documents. We really—this is exactly what we set out to do, and this is kind of where we ended up today. Let's go one more document. This is from the INEL. They didn't know I was going to do this.

And this is how they first envisioned the risk analysis, how they really first envisioned this project.

Okay, provide both qualitative and quantitative information on the hardware and on human actions. Identify dominant event sequences. Look at the process deficiencies, the human errors and the hardware faults, and identify weaknesses in practices, procedures and training. And then finally, look to see if there are differences in the different devices or licensing practices.

I don't think that that's—I mean, I thought that was very good, and I think that that's pretty much still a very laudable objective. So I think we have everything going here. We have the background.

Okay, let's go to the next slide. So where does that leave us here, or where does that really take us to? What is it that we want to do? Well, we've had some different players now enter and, yeah—oh, no, keep going onto this one. We didn't exactly coordinate this.

Okay, one big change that we have here is the introduction of this person here, Dr. Trish Holahan, who will be co-managing the project with me. I guess that's how we'll call it that, and who has now taken over as Project Manager of the Misadministration Project. She will be attempting to integrate more into this project the medical aspect.

I think to date we, who are pretty much represent the NRC risk community, have brought that perspective. With Trish's introduction into this project, we hope to bring much more looking at consequence analysis and medical issues.

We have another individual here with us today, and that's Mr. Jim Shepherd, who is also an NRC risk person. He has worked with me from day one on these projects providing technical guidance and technical assistance and will be presenting to us today the material developed at the Livermore National Laboratory.

We also have Dr. Jim Johnson, who's sitting in the center there to the right of the spotlight, who is representing the Office of Research. Currently our plans for this project are at a suitable time in the near future, which in NRC space is some time in the next year probably, we intend to transition this project to the Office of Research, where we would hope that their expertise could dramatically move this work forward. We have not totally selected the date for that, but this has been told to the EDO that this would be happening.

There's one more person, Bob Prato is here from AEOD. They are responsible for maintaining the agency's data bases, and I don't know if he knows he's going to be speaking to that issue in a few minutes. We might have not told you that yet.

I think I've got everybody, so now I get to the part I just got so excited about this morning when I started looking around this room. After we go through the different briefings, Harold Blackman, who will be leading us in different group discussions, and at that point in time that's where we look from the formal presentations to those of you in this room to help us to develop the rest of this approach.

So I would like now, if you think this is appropriate, to go around the room and, perhaps, have everybody else just take a minute and introduce yourself, so we all know who we are before the break.

Would you like to start, even though you would have been introduced anyway?

MR. WREATHALL: I'd be happy to.

DR. RATHBUN: Thank you.

MR. WREATHALL: I'm John Wreathall, consultant of INEL on the Medical Misadministrations Project looking at the question of human errors and how they can be related to the PRA or risk analysis perspective, and, also, introducing a new framework that has come out of other industries and other technologies as to what are the circumstances under which people err or make mistakes and the factors surrounding them.

DR. GRIGSBY: My name is Perry Grigsby. I'm a physician at the Mallinckrodt Institute, consultant to the INEL. I suppose I'm in this role because we have several different types of remote afterloaders, I think one of each, and perform about 300 brachytherapy procedures per year.

DR. BLEY: I'm Dennis Bley. I'm a consultant in risk analysis. I've been doing risk analysis work since the early '70s. I come out of an engineering background, and for the last couple of years I've been working with John Wreathall in another NRC program, looking at human errors and working at this approach to building a framework for bringing multi-disciplines together to look at the causes and ways to deal with human error.

DR. BUDNITZ: I'm Bob Budnitz. I have a consulting practice in Berkeley, and I've been doing risk assessment for about the last 15 years.

DR. RATHBUN: Well, I just want to add one thing. He used to be the Director of the Office of Research when I first went to work for the NRC in maybe 1980.

DR. BUDNITZ: I left 14 years ago.

DR. RATHBUN: That's right. It was a long time ago, Bob. Judith?

DR. STITT: Yes, I'm Judith Stitt. I'm a clinician. I'm one of the people who are perpetrating all of this mischief. We are doing misadministrations with the University of Wisconsin, and I'm a recent member of the ACMUI, and fairly vocal about high dose rate brachytherapy. For those of you who have been at the meetings.

DR. RATHBUN: We've introduced you, but go ahead.

MR. SHEPHERD: I'm Jim Shepherd. I'm a Risk Analyst at the Nuclear Regulatory Commission. Everything I didn't learn when I worked here with John and Harold, I learned from our good friend John Wreathall.

DR. POLLYCOVE: As introduced previously, I'm the Visiting Medical Fellow at the headquarters in Rockville. My background is initially I trained as a physicist and worked as a physicist and then went into medicine and was Director of the Nuclear Medicine Department at the University of California in San Francisco, San Francisco General Hospital for about 30 years before I retired.

DR. RATHBUN: Jim, did you want to just expand on what I said about you?

DR. JOHNSON: My name is Jim Johnson. I'm with the Office of Research working the Probabilistic Risk Analysis Branch.

DR. LARSON: I'm Dave Larson from San Francisco, California, radiation oncologist and use the Gamma Knife, treat hundreds of patients. I guess that's why I'm here. Also use linear accelerator competing technology, and I might mention parenthetically I've been involved with Ed Jones a little bit over the years from Lawrence Livermore Laboratory in introducing him to various uses of the Gamma Knife.

DR. CALLAN: My name is Jim Callan. I'm at Pacific Science & Engineering in San Diego. I'm a biological psychologist, and our company is on contract with NRC research to do human factors engineering with brachytherapy equipment and processes.

DR. WU: I'm Jya Syin Wu. I'm half-time with UCLA. Our group has worked on risk assessments for many years, especially nuclear field. In recent years we've started working on issues related to organization and management, and I'm here to share some of the things we learned.

DR. RATHBUN: Tim, why don't you go ahead.

MR. LEAHY: I'm Tim Leahy. I'm a Unit Manager here at the INEL. The majority of my background is in safety and risk analysis, and I've had the opportunity to serve as the Program Manager for the Misadministration Events Analysis Program sponsored by Dr. Rathbun over probably at least half the life of the program.

DR. RATHBUN: Right.

DR. SIU: I'm Nathan Siu. I'm with the INEL. The last several years I've been working in risk assessment method development and some research.

MS. THATCHER: I'm Tami Thatcher. I'm a risk analyst at the INEL.

MR. LIPP: I'm David Lipp. I'm a radiological engineer here at the INEL. I've been working on

the material events data baser for Sam Pettijohn in AEOD.

MR. HANEY: Lon Haney, psychologist in the Human Factors Unit here at the INEL. I'm a human reliability analyst and I've been involved in this project for some time.

DR. GLASGOW: I'm Glenn Glasgow from Loyola University, Chicago. I'm a medical physicist. I'm also a health physicist with long-standing interest in applications of radiation safety as they apply in medical radiation therapy. I'm a consultant to INEL on one of their prior reports of quality management, and I've chaired the AAPM Task Group Report 41 on remote afterloading technology.

DR. OSTROM: I'm Lee Ostrom, ergonomist at the INEL.

MR. NOVACK: My name is Steve Novack. I'm a risk analyst for INEL.

DR. RATHBUN: And we have already introduced Bob.

MR. PRATO: I'm Bob Prato. I work for the Office of Analysis and Evaluation of Operational Data.

DR. RATHBUN: I mean, you can see that it's just amazing the body of expertise that is here today, and I am confident that this will result in a wonderful product.

I would like you to take one more look at the very last slide, or whatever it is that I have in my package. You won't be able to read this at all, but if you just look at the one in your handout. This is the NRC PRA Implementation Plan. And what is going on right now within the NRC, basically led by the Office of Nuclear Reactor Regulation, NRR, supported by the Office of Research and AEOD and my office, NMSS, we are trying to steer PRA in some kind of consistent coherent path.

These projects, both the Gamma Knife and the brachytherapy project, have been discussed over the past three years in all agency PRA meetings of this group. This section that I have reproduced for you here is, basically, what I have told the NRC is what we're going to do. And I'm saying here that this workshop is to validate and expand the methodologies that we worked on so far.

You know, I talked about what are some of my objectives. What I believe will change is where I talk about the method sections. When you get this you will see it. The first thing is to hold the workshop, and what I wanted to do then was draw a big box around it and say to the EDO and the Chairman, well, I'll tell you when I get back from this workshop exactly what I'm going to do. But they wouldn't let me do that. So I went ahead, and I put down the things that I had believed all along were the way we should start.

I believe where we will really go is where this group guides us over the next couple of days. Okay? Thank you very much. I guess the next person is John.

## C.2.2. Misadministration Events —Mr. Leahy

DR. BICKEL: I'd now like to introduce Mr. Tim Leahy, who will give a discussion of the work in the Misadministration Events Analysis Program.

I pointed out that we started this program about May of 1991, and we have, basically, finished seven major investigations of misadministrations. Tim?

DR. RATHBUN: You did nine. Trish just said you did two more under the new management, Jim Tortorelli.

MR. LEAHY: I've been asked to give you a short briefing on what we accomplished in looking at seven event investigations, as well as a brief analysis of the AEOD data base that has been compiled over a number of years to help characterize what we've learned about the nature and causes of misadministration events.

What I'd like to talk to you about over the next 15 to 20 minutes, first of all I'd like to tell you a little bit about the objectives of our program; I'd like to tell you how we actually went about conducting the work; I'd like to focus primarily on what we found as a result of our investigations; and, I'd like to wrap up by telling you about what we learned by looking at the records associated with past misadministration events.

The starting point for all this is really the QM Rule, Quality Management Rule, 10 CFR 35.32, which was adopted or implemented in January of 1992 and essentially required that all medical use

licensees establish and implement a Quality Management Program.

Although there are a number of provisions to this rule, the most important ones are really outlined here.

First of all, licensees are to make sure that they have in place a written directive prepared by an authorized user prior to any administration of regulated isotopes. There are, of course, some exceptions allowed to this for emergency situations and so forth, but as a general rule, this requirement applies.

The rule also requires that positive verification of a patient's identity be established by at least two independent means. Normally that would mean checking a wrist badge, looking at a driver's license, asking them verbally for their name, verifying it with a family member, possibly some other means of verifying their identity. In any case, positive identification by at least two independent means.

The rule also requires that the final plan of treatment be carried out in accordance with the written directive.

Each administration must be carried out according to written directives.

That any unintended deviations from the written directive have to be identified, evaluated, and corrective actions put into place.

Finally, there are a number of prescribed requirements for reporting and record keeping.

We had several objectives as a part of this Misadministration Events Analysis Program. The most basic one, I guess, in a general sense was we were trying to generally learn more about the causes and contributing factors that result in misadministrations. From a qualitative perspective, we were trying to figure out what kinds of factors seemed to be associated with errors that result in patient misadministration.

More specifically, we were trying to gather that information to help evaluate whether or not the scope and depth of the QM Rule would really be adequate to have a significant impact in reducing the frequency and/or severity of misadministration events. That is to evaluate the adequacy of the QM Rule.

Finally, we hoped to provide that information by publishing this document, which eventually came out and which, of course, is available to licensees, and I'll talk more about this in a moment. We hoped to provide that information to licensees in the hope that they will use that information to learn more about how some of their colleagues at other facilities around the country have fallen off track from time to time and take from that some suggestions on how they may be able to improve their programs to avoid similar kinds of potential problems.

Our program really consisted of two major analysis activities. The first was a series of on-site investigations of misadministrations as often as we could and as close as we could to the actual time that those misadministrations took place.

Each of the events was selected on the basis of, for lack of a better term, I'll just call it interesting characteristics. We were trying to obtain a representative sample of different treatment modalities, various kinds of circumstances. We were trying to look at large facilities as well as small facilities, generally tried to get a sample that was representative of the kinds of treatments that are taking place across the spectrum.

The events that we looked at included teletherapy, manual brachytherapy, high dose rate brachytherapy, and we also examined a diagnostic iodine 131 procedure.

Each of the investigation teams was led by an INEL team leader who was either a risk analyst or human factors analyst. And, of course, those two disciplines are closely aligned with one another in many respects.

The teams generally included three or more members, and depending on the nature of the event, the team members other than the INEL team member were always bringing expertise from the fields of radiation oncology, medical physics, nuclear medicine technology and other risk analysis or human factors kind of a background.

Each of the investigations was guided by a protocol, really a series of checklists. We had some flow diagrams and so forth, and those protocols really evolved over the life of the program. As we learned more from the earlier investigations, we incorporated those lessons learned into the later investigations.

The second major analysis activity was looking at AEOD's Data Base dealing with past misadministration events and at the NUREG 0090 documents, together covering the years 1987 through 1992. Essentially what we did was look at all the abnormal occurrences that occurred during the period of 1987 through 1991, as well as all of the misadministrations which were reported during 1992.

There were some things that took place in the way the AEOD was—the office of AEOD was recording their data and so forth that made it easier for us to deal with the 1992 data from AEOD and the earlier years from the NUREG 0090 documents dealing with abnormal occurrences.

The focus of our look at this enlarged data base was really focused on four issues.

First of all we were looking at common causes of misadministrations.

We were to look at correlations between the causes of misadministrations and the severities of those misadministrations.

We were to look at the preventability or potential preventability of past misadministrations had the licensee properly implemented the QM Rule requirements prior to the time the misadministration took place.

And finally, we were to look at causes of multiple misadministrations, that is misadministrations that involved more than one patient at the same facility due to the same underlying causes.

What did we find? First of all, I was really struck by the remarks Larry Camper was delivering on behalf of Carl Paperiello about how predominant human error is, how common the kinds of errors that we see in nuclear medicine procedures are, that is common to the same kinds of errors we see in airline mishaps, nuclear power plant operations, chemical operations. Anytime you have people interacting with equipment, we tend to get certain errors that have a lot of commonalities.

Also, I was struck by his emphasis on the issue of command, control and communication. I think when we go through our findings on the seven events that we took a look at, you'll see that that theme emerges pretty strongly.

The first thing we found is that many misadministrations occurred due to a lack of adequate procedures. That is, either there are no procedures in place or the procedures are incomplete or they're ambiguous in some way. This underlying cause was common to all seven of the investigations that we went out on. All seven of the events involved some inadequacy in procedures.

We point out in the findings of this program, in the document that we published from this program, that other technologies, recognizing that even highly educated, well intentioned professionals can make errors, have put into place a number of very formal measures that are designed to reduce the frequency or severity of those errors. We found that level of formalism to generally be lacking in the facilities that we visited as part of this program.

We pointed out, also, that good procedures are clear; they're concise; they lead people through things in a step-by-step fashion; they anticipate potential problems before they occur, and they prescribe responses to those problems should they occur. Again, we often found this to be lacking in some of the facilities we visited.

The second finding, we found that although the QM Rule has the potential to prevent many misadministrations, the licensees that we visited as part of this program really had not effectively implemented their QM program. Some licensees tended to view the QM Rule as just another paper requirement that they had to comply with. In fact, if I could just read very briefly an excerpt from this document, I can probably more effectively give you the flavor of that.

"We found that some licensees"—and I'm quoting now from the document—"... some of the licensees involved in misadministrations investigated in this project viewed the QMP requirement as merely a paper requirement that's largely irrelevant to them. And consequently, they approached compliance with the requirement as a pro forma exercise", that is, they were going through the motions. "Although they may have developed a QMP, they did not achieve true implementation of the intent of 10 CFR 35.32, in that the plans were not known to or used by licensee staff. It was observed that in several instances, the licensee staff were unaware of the existence of the poor applicability of the QMP. In one case, the licensee's RSO had signed the QMP, but could not remember what it

contained. In another case, the QMP did not meet the requirements of 10 CFR 35.32. At least one of the team investigations revealed that the licensee's QMP had been prepared by a consultant, and that the licensee had little or no direct involvement in preparing or implementing the plan. All of this suggests that licensees may not understand the requirements and intent of 10 CFR 35.32."

So a very strong finding there, again, that they tended to view it, if they were aware of it at all, as a paper requirement that had to be dealt with, that didn't really become a part of their overall safety culture or safety awareness.

We found often that there was a lack of substantial direct involvement on the part of authorized users and radiation safety officers. Again, the RSO sometimes would regard his or her duties as peripheral to their real job, in quotes, beyond the RSO in the same sense that I'm on the committee to lead the United Way drive at the INEL this year. It's something I do, but it's peripheral to my real job.

We often found that authorized users had no direct role. In some cases, they had literally no direct role in either prescribing or delivering the treatment for their patients.

In some cases the authorized users did not understand the role of the radiation safety officer or the QMP. In fact, in one case the authorized user involved in the event didn't even know who the RSO was at that facility.

We found in some cases there were unique conditions or changes in routine that were factors in these events. The kinds of changes that occur when new people are involved in a procedure, perhaps they changed equipment or materials providers. In one case there was a holiday weekend involved, and they were trying to get a crew together on short notice and went ahead. In one case there was a patient who was unable to assume the regular position for the treatment that was prescribed, so they had to improvise and put the patient in a different position than normally would have been required, resulting in misadministration.

So anytime we see a deviation from the usual, we may predispose misadministration events.

We found generally that hardware error—excuse me, hardware failures are rare, but when they occur, they potentially have some very significant consequences.

We found that very often the corrective actions that licensees put into place were rather narrow in focus. They were specifically designed to prevent the same kind of misadministration from occurring again, but often weren't directed more generally as we referred to it a more comprehensive safety culture that really needs to be implemented.

And finally, we found that licensees often lacked any kind of systematic way to detect and mitigate misadministrations once they were occurring. Although the majority of the events that we looked at were, in fact, detected, very often it was—I think we used the words in the document, we said it was fortuitous. What we mean is, it was dumb luck in some cases that those events were detected in the way they were. And for those of you who are interested, you can refer to the document and see some examples of that.

By looking at this data base that we assembled, we also learned some things. What we were attempting to do with this data base is, first of all, we recognize that the seven event investigations that we had gone out on really constituted a very small sample. And any conclusions that we went away with on the basis of that very small sample might be subject to question on that basis. So we were trying to obtain some kind of validation to what we learned in the seven event investigations.

Also, we were trying to generally see if there were things in the larger data base that we could learn that we hadn't observed in our seven on-site investigations.

So what did we learn from the analysis of the data base? We learned first of all that although a relatively small number of licensees had experienced multiple misadministrations, again, multiple misadministrations we defined as events that affect multiple patients at the same facility due to some kind of a common cause.

Although there were a small number of licensees that had experienced multiple misadministrations, these multiple misadministrations did account for 60 percent of patients in our data base.

To be more specific, there were 11 licensees who had experienced multiple misadministrations. There were a total of 216 patients in our data base.

128 out of those 216 patients were involved in multiple misadministrations.

The most common cause of these multiple misadministrations was error in computer programs or error in entering data into computer programs. Twenty-one of those 128 patients were affected by computer program errors. All of the others were affected by data entry kinds of errors, including one group of 13 patients that were all misadministered as a result of using an erroneous time dose curve calculation.

We found that the major direct causes of the single misadministrations, that is the misadministrations that involved only one patient, were first of all procedure errors or procedure inadequacies that accounted for 30 percent of that population. Professional errors, which we defined as basically situations where the professional involved knew what to do, understood the procedure, intended to carry out the procedure, but due to mental lapse, physical slip of the hand, whatever it might be, made an error in any event. The kind of thing that happens when you try to dial a particular telephone number. You know what number you're trying to dial, but you come up with the wrong one anyway for whatever reason.

And finally, communication problems. Some related to the lack of a written directive; some related to oral communications between staff members that didn't work; things of that sort.

We also looked at this issue of hypothetically if the QM plan had been properly implemented prior to the time of the misadministration, what would be the potential that that misadministration would have been prevented? Now this is a pretty subjective business. There's no question about that. Indeed, one could argue that given that in its simplest form the QM Rule really requires that a licensee prepare a written directive and then carry out the treatment so that it meets the written directive, by that logic all misadministrations would be preventable. And by definition, anything that deviates from the written directive is outside of the provisions of the QM Plan.

That's not an interpretation we thought made much sense, so what we did was, we looked at all the events. And we determined that in our judgment at a minimum any well-implemented QM Program ought to require a written directive be prepared, other than in emergency circumstances as allowed by the rule, and that the identity of the patient should be positively verified. That's an absolute minimum, and we felt that in those cases where a written directive was in place and the identity of the patient was positively verified, those events would very likely have been prevented by the QM Rule.

We felt that events that were caused by inadequate training, poor procedures, supervision, errors of judgment would be somewhat likely to be prevented by an adequate implementation of the QM Rule or QM Plan on the basis that many of these things go to that issue of command and control and communication.

On that basis then we found that 36 percent of the events would very likely have been preventable. Forty-two percent would somewhat likely have been preventable. This is for the single misadministrations now, those involving a single patient. And all of the multiple misadministrations would have been preventable, giving us an overall result then that as much as 90 percent, or as many as 94 percent of the patient misadministrations involved in the data base would have been at least somewhat likely to have been prevented through a proper implementation of the QM Plan.

Again, we recognize that this is a pretty subjective business, but we tried to take a reasonable approach to making this determination.

The last issue, which is not reflected on this slide, the last issue that NRC asked us to look at for the data base was trying to draw some correlations between the causes of misadministrations and the relative severities of those misadministrations.

We really struggled with that. We had difficulty at first trying to figure out how one goes about defining severity. You know, what does that mean, given that there are a number of organ sites, underdoses count as misadministrations just as do overdoses, the whole issue of defining severity was just very difficult.

Eventually we came up with some kind of a proxy for severity, just a percent deviation from prescribed dose. We recognized the imperfections of that proxy, but used it nonetheless. And we found that at best there was some very weak correlations between causes and severity. So that's why we left that off the slide.

In summary then, overall through the event investigations, as well as the data base analysis, we found that when properly implemented, we think there's a substantial improvement in the safety culture, that is through proper implementation of the QM Plan. They have the QM Plans, when they're properly done, have the potential to prevent many misadministrations.

We found that there's a lot of room for improvement through increased direct personal involvement on the part of RSOs and authorized users.

We found that the general concept of a comprehensive safety culture, that is a safety culture that really guides all of the activities in these facilities, if we could communicate that to the licensees, and if it was embraced by the licensees, we could see a substantial reduction in the frequency of misadministrations.

This comprehensive safety culture would be translated into better procedures, better delineation of roles of staff members, clearer lines of communication, things of that nature.

Finally, for those of you who are interested in knowing more about the program, I would direct you to this document entitled Summary of 1991-92 Misadministration Event Investigations, published as NUREG/CR–6088.

I'd be happy to take any questions if you have any. Thank you. Yeah, Dennis?

DR. BLEY: One quick one. One of the conclusions you got to, in general, people are not implementing the QM Rule in an effective way. You went to six sites?

MR. LEAHY: Seven sites.

DR. BLEY: Seven sites. Were they ones that have had more than their share of incidents, first question?

And the second one is, do you have any—is it reasonable to really infer that for the whole population, or might there be a lot of them out there you aren't seeing much about because they have done a better job in this area.

MR. LEAHY: Well, I think that's an excellent question/point. The fact, the mere fact that we came in contact with these seven licensees implied that they had some kind of a problem to begin with. So there's a certain amount of selection going on there.

And we would be—I wouldn't care to try to extrapolate from those seven to the general population. As a matter of fact, I would guess that many licensees are doing very well in that regard.

What we did find is that there are some—even some large visible highly respected institutions that don't seem to have really gotten the point of what the NRC is after with this rule.

DR. BUDNITZ: What is the estimate of the cost of the rule for a reasonable size hospital, compared to if they didn't do it?

MR. LEAHY: I don't know the answer to that. Larry?

MR. CAMPER: Well, let me try to take a cut at both of these, the last one first.

I don't recall the exact numbers of what it cost per facility, and I apologize, but it's been awhile since we put this rule together. I can tell you that the cost our staff estimated was dramatically lower than that estimated by some members of the regulating community. The difference in the numbers was pretty striking.

A given that I can't give the exact numbers, I can tell you an observation that the net result of what it takes to put in place the Quality Management Program is not that dramatic in terms of cost consideration. The reason it's not is because of two things: Number one, many of the systems that were already in place in the institutions with fine tuning and attention to the program can, in fact, result in an adequate Quality Management Program.

And secondly, most facilities were already using something like a written directive to begin with. It may have existed in two or three places, and it may have needed some fine tuning, but it wasn't a situation where you had to put in place an entirely new record-keeping system or an entirely new approach to dealing with this concept of Quality Management. So I don't think the actual incremental cost increased was that great, although I can't give you exact numbers.

I did want to comment on the other comment, and that is does this relate to what we've seen

elsewhere? I can give you two observations, and I do this with some concern and trepidation, because it's always difficult to draw conclusions from a limited data base.

The two observations I will share with you just the same:

One is that in the case that was being discussed, seven events were evaluated by the INEL as an independent evaluation under contract with NRC. We wanted the perspective of an outside organization evaluating certain events. We have contract dollars earmarked in the future for subsequent evaluation of events. We think it's worthwhile to have that outside look and to ultimately compile it into something that the community can look at, the regulating community can look at, and say ah-ha, I see what happened here or I see why this event occurred.

But two observations, one is I think it's fair to say in almost every reactive inspection that we have done, and we've run about 25 to 30 therapy misadministrations per year in NRC controlled states, that there had been deficiencies and/or violations associated with the licensee's Quality Management Program. So that's a leap of faith I recognize, but there is certainly something going on here in terms of Quality Management Program weaknesses and related findings in misadministration events.

The second observation is how bad are the programs overall. Dr. Larson's group, in concert with us, has reviewed about 1,700 Quality Management Programs. About 70 percent of those, if I remember correctly, ended up in what we call Category 2 or Category 3 letters. Category 2 letters to licensees where there were weaknesses or omissions observed in your program. We suggest you take a look at your program and see if you want to modify your program. Or, and the mainstay was Category 3, which said that based on what you submitted, you appear to fail to meet the objectives of 10 CFR 35.32. And I emphasize "based on what you submitted", because as you can all appreciate, there's a phenomenon that goes on between what is presented in the written program and what actually occurs on the site.

We expect that what we find on site will not be quite as bad as what we found in the review of the written programs. In other words, we think they're doing a little bit better job than what they actually were able to compile into a written format.

The other observation is that with regard to the Quality Management Rule, it addresses limited diagnostic, it addresses greater than 30 microcuries of sodium iodine, it addresses all therapy. What we did find is that with regards to greater than 30 microcuries of sodium iodine, up to therapy levels, the regulated community seemed to miss that point entirely. It will, I believe, if you call for a paradigm shift in how they do business in the sense of that, historically in nuclear medicine, diagnostic procedures involving sodium iodine greater than 30 microcuries below the therapy threshold, let's say one to two millicuries, have not required a written directive like we require in this program. And if one looks at the programs that Dr. Larson's group reviewed for us, following the standard review plan and questions that we put in place, most licensees just miss that entirely. And we see it in reactor inspections, and we see it in routine inspections.

So I don't know if that's any kind of indicator. It's a leap in faith at best, but it gives you some idea of what we've been observing.

DR. BUDNITZ: I've got a question about the total number. You just mentioned 25 or 30, and then you qualified that by saying in some states. Are those in the states you regulate rather than the agreement states?

MR. CAMPER: Yeah, that's correct.

DR. BUDNITZ: So are the agreement states many many more? By the way, California is an agreement state.

MR. CAMPER: I anticipated your question. We run about—in NRC-controlled states, we run about 25 to 30 therapy administrations per year. Now understand that of the 6,000 or so medical licensees in the United States, the agreement states regulate two-thirds of those. So we do not—we do not have good data today about the number of misadministrations occurring in agreement states, and there are several reasons for that.

Number one, it wasn't until 1990 that they had to start trying to collect it. They provide it to us voluntarily today, although there's a program in place now that the agreement states provide to us their findings, and the Quality Management Rule

doesn't become effective in the agreement states until January of next year.

DR. BUDNITZ: I've got another question. You must have two different staff functions then. One is you have the function of what I call a rule-making function, and then a second is you must have to have another function called tending after these licensees who aren't in agreement states. Obviously, they're mixed up, but those are two functions, and your rule-making function obviously applies to the agreement states. When you pass a new rule, the agreement states have to live with it. How many staff do you have in NRC in this area? And can you give me a rough breakdown? I literally have no idea.

MR. CAMPER: Well, the medical—when you say two functions, I would say that there's a whole lot of functions.

DR. BUDNITZ: Well, sure, but I was thinking about your generic functions separate from looking after the licensees in the agreement states, look after what they do.

MR. CAMPER: Well, we have—we do provide a great deal of assistance, but at this time we have, there are nine of us in our section and Dr. Pollycove is ten.

DR. BUDNITZ: So that's one more.

MR. CAMPER: One more, and there's a couple of others.

DR. BUDNITZ: So that's another, everybody in agreement?

MR. CAMPER: Not really, no.

DR. BUDNITZ: So there's sort of ten or a dozen who together look after this?

MR. CAMPER: Well, that's the entire medical program.

DR. BUDNITZ: I understand that. Now in the agreement states, they must have one or more in each of these large states, and maybe a fraction of a person. So nationwide there may be 20 or 30 such people looking after this?

MR. CAMPER: Yeah, those are good rough numbers, right.

DR. BUDNITZ: And how much do you spend every year on contracts? How big is this?

MR. CAMPER: Well, it varies. Our program runs anywhere from one to four million or so per year, roughly that size. Not a lot, actually. We could certainly use more resources and do more, but we work with what we have to.

DR. BUDNITZ: Thanks.

DR. LARSON: I have a question, actually for Larry, I guess. Has an estimate been made, or at least an estimate made on the ratio of reported misadministrations to unreported?

MR. CAMPER: No, we have not done that. The problem is, how do you know when they're unreported? Now we've always suspected there are unreported misadministrations. With the QM Rule, two things have happened. The numbers have gone up slightly, which is not the desired result, of course, in reporting. But be that as it may, actually what happened was we think it's gone up because of heightened awareness. Now we have fractionated teletherapy.

But, no, we suspected for some time that all misadministrations were not reported. We don't know exactly what the number is, and, no, we've never undertaken an analysis to try to get to the ratio relationship.

### C.2.3. HDR Risk Evaluation —Ms. Thatcher

DR. BICKEL: I think we're getting into maybe a little of what we're going to do in our discussion sessions, and I've got to crack the whip as the emcee.

What I would like to do, moving on, is introduce Tami Thatcher, who will be discussing the recently carried out work on the high dose rate of brachytherapy. Tami?

MS. THATCHER: I'm going to be discussing some of the risk evaluations that the INEL has conducted for high dose rate brachytherapy. The author of this presentation and the lead analyst for the work is Dana Kelly. Unfortunately, he's not here to describe this work today.

This presentation is going to focus on one particular study, give you some overviews of one particular study that was performed, and hopefully

provide a starting point for some of the issues that need to be addressed, some of the questions that arise as you start to move on this kind of task.

As we start to do risk assessment work, the purpose is in trying to figure out how a misadministration can occur. Now it's very important to look at the misadministrations that are occurring, that have occurred, and to study them. And I think that there are more—there are many benefits to come from that. This is the side of the analysis where you don't—instead of waiting for an accident or mishap to occur, you try to predict where are the vulnerabilities. So I think the two—I think it's timely that Tim's talk was before this one. I think that we have to use the experience of past misadministrations, but the work with risk assessment has to use that, but its job is to try to predict where the vulnerabilities are without waiting for the next misadministration. So that's sort of the objective.

And as you identify the vulnerabilities, the ways that a misadministration could occur, you try to rank the significance of them in terms of which are the most likely, how can we make corrections?

The presentation, my next slide talks about the knowledge base that's needed to perform a risk evaluation and most of the following slides provide an overview of the specific study that was performed. And I'd like to say that the study that was performed was a fairly brief effort. It was a one-week visit to a facility and a fairly short time period in writing up a report. It was not a long drawn-out project. This was a fairly brief project.

I think that Dana wanted to make this point with the presentation, the point of you can go and analyze one particular facility, but what does that tell you about other facilities? The question comes about because we have a broad treatment spectrum. There are a lot of different facilities performing treatment, and at any one facility, there are a lot of variety in the treatment modalities, different organs are being treated, different treatment settings. There's a lot of variety in what's performed at one single facility, and there's a lot of variety at all the different facilities. So when you go and take a close look at one facility and one treatment type, as we did in this project, you know, how generic are those conclusions?

And the question is, could there be a strategy that we could use in selecting which types of treatment or which facilities that we analyze closer?

I think I'll kind of leave that issue for now, but I hope that it gets some thought in the workshop. Some of the issues that we run into as we start to try to perform a risk assessment, is trying to understand the role that hardware plays and trying to grapple with how do we get information that tells us what the failure rate of the equipment is? This is one of the first issues we'd like to prioritize, the likelihood of different equipment failures. This is really hard when you don't have a data base of how reliable the hardware is.

As from Tim Leahy's talk, we know already that human error plays a tremendous role in misadministrations that have occurred.

Obviously human factors and human-related issues are at the center of a risk analysis of misadministration events. And I think as we've been discussing, there are—the role of QA in preventing misadministrations is one that requires thought. If we're making rules, but they're simply not being followed, maybe, you know, there are a lot of issues to grapple with there.

The treatment spectrum at a particular institute that was studied can be characterized as a large clinic, and a small portion of this clinic is devoted to the use of Nucletron HDR brachytherapy treatment for lung and esophageal cancers. This is a fairly narrow range of treatments and relatively few treatments performed each year, 20 treatments each year with three to seven dose fractions per treatment.

DR. BUDNITZ: What was the HDR?

MS. THATCHER: High dose rate. At this facility, the medical physics staff is engaged in active research and is a teaching institution. They were on a residency program. These factors combined to place this institute probably at one end of the spectrum, so that the conclusions drawn from a risk assessment of this facility may not be broadly applicable.

To characterize the high dose rate in brachytherapy processes at this institute, the process is highly serial. Many steps take place, and very few steps are done in parallel. There are numerous opportunities for the medical physicist and the radiation oncologist to recover from errors, but

certainly the process is completely dependent, almost dependent completely on human actions being performed correctly every step of the process. About eight staff members play a role in the treatment process.

During the study, significant human factors deficiencies were found associated with the computerized treatment planning systems relating to the human interface being confusing and difficult to use. The feedback from the interface being relatively poor, which limits the ability to quickly detect and correct human errors. This was one interface that was found to be quite poor during that analysis.

And obviously, the skill and knowledge of the physician are highly important, but this is difficult for us to model with present HRA methodologies. The success of the treatment requires that many human actions be performed correctly.

The current model, the fault tree model, which is basically a collection of what are the ways that we could cause a misadministration; what are the failure modes that could cause a misadministration, combined with what are the potential places for recovery. When might one of the staff detect a problem and correct it before it becomes a misadministration? You simply have the recovery ended with these failure modes. I think there's a lot of room for further modeling, further HRA analysis to really justify credit for a particular failure mode, because as you study events that have occurred, it's apparent that sometimes a review is conducted, but it's much too narrow in scope. It doesn't find the problem. Someone is asked to review the numbers that were input into the treatment, but were they input properly from the planning device to the device that actually gives the treatments? The numbers were correct. That person wasn't asked were the actual numbers correct, they were just asked did I copy these numbers correctly from here to here. Well, the answer is yes. Were the numbers correct? No, they weren't.

Sometimes reviews are conducted, and they're too narrow in scope to uncover the problem.

Other times when you read about a misadministration, it's not apparent that there should have been a review step there. In hindsight, you can look at it and say, well, there should have been a review by someone there, but many of the misadministrations occur as practically a single error causing the problem, and no one detects it. There isn't an adequate independent review that would uncover the problem.

So I guess for this study, because of the rigor in the written procedures, a lot of credit was given to recovery actions, but I would challenge future studies to really take a more in-depth look at this issue of justifying human recoveries.

Just briefly, in this study the hardware reliability data was not available. We—there is a suggestion that the device is highly reliable. That's probably true, but we don't have data supporting this conclusion, and clearly more work needs to be done in this area. It wasn't done for this particular study with its fairly limited scope.

This institute had very detailed written quality assurance protocol requiring acceptance testing, commissioning and source calibration, quarterly QA review, daily device QA, treatment procedures, roles and responsibilities of various personnel were written down. And the reviews, various reviews at different phases during the treatments, were required in writing to be performed of the planning calculations of the simulation films and the HDR programming.

The institute also had quality management programming.

For this particular study, source strength calibration turned out to be a fairly significant finding, because of the lack of accepted calibration standards for Ir-192, and because vendor calibration data is sometimes inaccurate. It's a fairly important function that they calibrate, that they calibrate the source before it's put in the afterloader.

The fault tree models that were developed from this study representing a dose in error of greater than 20 percent, as I say, lists the failure mode, that they identify the failure modes, the ways that misadministration could occur. And some of those ways are—many of those ways are from human errors and the accident sequence evaluation program. Allen Swain's ASEP methodology was used to estimate the human error probabilities. This was—this is the most simplistic approach that could be taken. It's generally a conservative approach. It doesn't require a detailed task breakdown. That's not what we're proposing everyone do. This was a practical solution at the time, and the results of the estimates could be

traceable, and have some relative merit, but this isn't what we're suggesting that everyone do in their analysis. The physician errors were modeled with sharp skill-based screening values, and the hardware was simply—well, the hardware failures were not developed and screening value of one to the minus three was used.

Recoveries by the physicist oncologist were modeled explicitly in the fault trees. My feeling is that a lot more human reliability analysis is needed in this area to specifically analyze the likelihood that you'll recover from a specific error, because as I say, certain errors are harder to detect than other errors, and I think you have to look very closely at the written plans and at what they're actually doing in practice to justify whether or not a review will really be likely to detect the problem at all.

In this analysis, 44 failure paths were found, with an overall screening probability of 0.05, which I think most would agree this is a very conservative estimate.

The importance of the independent review, the recoveries by staff, can be analyzed. If you remove independent review of the treatment plan, you greatly increase the risk to .3.

DR. GLASGOW: Before you go on, could you comment briefly on the—I'm sure all risk people in the room know the screening probability well, but what do you mean that there are five chances in a hundred that an error will occur undetected? What do you mean exactly by screening process?

MS. THATCHER: Well, they were coarse estimates assigned to the error probabilities. That's—

DR. RATHBUN: Did they come from a data base? I mean, when you just assigned those errors, are they coming from somewhere, some body of literature?

MR. SHEPHERD: What does that number mean? What is it telling you? That's what he's asking.

DR. BICKEL: He's saying they're trying to find all pathways that involved two errors and that had an overall probability greater than that. In other words, they were looking for high probabilities.

MR. SHEPHERD: It means that two percent of the time you get it wrong.

MS. THATCHER: That's correct. As I said, this was using ASEP values, very conservative estimates of human error probabilities.

On the other hand, it's possible to use ASEP and assign credit to a recovery that's really very unlikely to be successful, because a review simply isn't going to be performed or a review is not going to be of sufficient depth to find the problem. But certainly there are—there's a lot of room for improvement on these estimates. This work was done back in early 1992. As I say, it was a fairly small short project, but it did show some—it could identify failure modes, and you could find relative importances between the different failures that could lead to a misadministration. Again, the quarterly source change was found to be very risk significant if it was not performed correctly.

The project demonstrated that a model could be created, but it really does open a lot of questions to some difficult issues about quantifying the hardware reliability and issues about appropriate HRA methodologies and methodologies for quantifying the human errors. I think that the findings, and the findings that illustrated the difficulties deficiencies in the computerized treatment planning system, can be uncovered from a human factors-type of approach, but in the modeling we do have a difficult time trying to model and quantify the skill and knowledge of the physician.

So in conclusion, it was found that using fault trees did provide a useful framework for identifying failure modes at this facility. There are some shortcomings to fault trees that probably just need to be overcome by better documentation. It's not our intent to have people having to sort through fault trees.

One of the issues to address when you decide on a methodology might be to decide on some requirements for the documentation. Who is the audience going to be? At what level do you want to present the information? You can do a detailed analysis, and perhaps there needs to be more thought given to the presentation of the analysis. What are the requirements? How much data do you want in the report? How clearly described do you want all of the failure modes, which I think can enhance the analysis.

DR. BICKEL: Thank you. Are there any questions? Yeah, Larry?

MR. CAMPER: You may or may not have this at your fingertips, but looking at Page 1.7 or 1-7 of the report, you say that the important roles played by the institute, A, medical physicists and illustrated by moving the independent review of the computerized treatment plan from the logic model in re-analyzing the model, there are, again, 44 failure pathways and so on your 5.3, the seven paths there involve a single error. These seven failure paths all involve errors by the dosimeters that generate the treatment plan. They contribute approximately 96 percent of the misadministration probability. Now, again, we're looking at a single event here, but do you recall what these errors were that the dosimeter could make?

MS. THATCHER: I believe they were computer data entry errors. I don't—

DR. CALLAN: We published a large list that—there are many possible.

MR. CAMPER: Well, I'll take a look at the list then. It's striking. Again, you have to be cautious about single events and, likewise, we do see a lot of problems with treatment planning, and I just find the conclusions very striking, but I'll take a look at—

DR. BICKEL: With that, I'd like to suggest that we take our break. One question?

DR. GLASGOW: I'm not a happy camper yet. I need a little more understanding of the term screening probability as it's used here from someone. There are 44 pathways that involve two steps?

DR. BICKEL: Right.

DR. GLASGOW: Now are you saying that the probabilities in 100 procedures of one of those pathways occurring is five percent? I don't know what you mean by a screening probability.

DR. BICKEL: Okay, let me try and real quickly answer that. When a logic model was put together, you know, that involves combinations of events, we use like a fault tree or an event tree-type approach to try and lay out chains of events, because you're looking at a combinatorial process. You're going to have a large number of possible combinations. To get the problem usually down to a more workable level, you want to try and screen out or separate certain pathways that are a little bit more likely than others.

So what is done is an estimate is made of the likelihood of individual elements of a chain. They get combined. You can multiply or add or do some probabilistic calculations which tends to separate out lower likelihood pathways from higher likelihood pathways.

Now what they're saying they did is they set a—you lined up all the possible probabilities of different combinations or pathways. What they're saying they did was to set some screening probability level, in other words, above that number we would consider it, and all kinds of very very low probability event things they would discount. So they're trying to focus on the ones that were most likely. That's with the—

DR. GLASGOW: These 44 pathways each—

DR. BICKEL: Were above that screening threshold, yes.

DR. GLASGOW: —five percent screening test. But it doesn't relate to the probability of a misadministration occurring in, say, a certain number of procedures. It means if there was a misadministration—

DR. BICKEL: It was more likely to be caused by some of these.

DR. GLASGOW: At least a five percent possibility it was one of these 44—

DR. BICKEL: I think that's correct, yes.

DR. SIU: John, so you're saying this is a conditional misadministration occurring, or absolute, in terms of—given that the misadministration occurs, there's a five percent or greater probability?

DR. BICKEL: It's the screen number. Tami could give you the exact number of how things separated.

What I'd like to do is, I'd like to call the break now and have us resume here at about a quarter after. It will get us a little bit better on track. Then we'll jump in with our next scheduled speaker.

(A recess was taken.)

## C.2.4. Organizational Factors—Dr. Wu

DR. BICKEL: I would like to take the opportunity to introduce Jya Syin Wu from UCLA. I think I pronounced it close. She works with George Apostolakis, and we hope to have George here. He's in Greece, and I understand his father is very ill, so he's visiting there.

But she'll be talking about the issue of organizational factors and the work that they've been doing there and how it might be applicable to the area of looking at risk associated with radiation therapy. You have the floor.

DR. WU: I'm grateful for the previous speakers who mentioned that a lot of problems and issues in the nuclear medical field is because of lack of formalization and some problems raised from poor command control and implementation. And with that, I have some views to talk here.

First of all I want to say a few words about my presentation. We haven't done any work in the nuclear medical field. However, we have done a lot of work with the work process using a work process analysis model in risk assessment in nuclear power plants. And throughout—my hope is throughout my presentation you can see the similarity between the two high risk industry and use some of our experience. We've spent a lot of resources and effort in this field, so if you can find anything useful here, just welcome to use it.

Another comment, first of all what do we mean by work process? A work process here is a standardized sequence of tasks designed with the objective of achieving a specific goal within the operational environment of an organization. Some people like to use the word procedure, and in our case we like to leave it as a little bit broader, because procedure, a lot often you stick with something written down on one booklet. And work process is a lot broader, but you can look at it that way.

One note I want to make here, the difference between nuclear power plant and medical facilities. With nuclear power plant, we know that it's highly standardized, heavily regulated. And on the other hand, a nuclear medical field, although I'm not very much familiar with, I would suspect it's not as much standardized as nuclear power plant. And from the presentation I heard previously, they may not be as heavily regulated as the current nuclear industry is facing.

Therefore, because of the situation, the work process, when we get into the nuclear power plant and look at their work process, more than often we have—they would bring us thick document, procedures being reviewed, revised, revision up to 30 or something. And it's easier for us, as analysts, to look into their procedures and talk to them.

In the nuclear medical field, the situation may be a little bit different. However, just because of that, I think there's more room to work with, and it may be more—should be more cost effective, because as you improve the procedures, and the point about the procedures being is it's being designed. You think in your head and, also, it's something that you work routinely and, therefore, if there's any flaw, deficiency, once you improve it there's a hope that the same type of errors will not be committed or not be made afterwards.

And here I present just to show one example—by the way, I use a lot of examples we made when we did the nuclear power plant. I want to apologize for that, because we don't have resources for looking into the field. However, this is a standard or one work process flow chart for a high HDR therapy. And you can see that there's prior to the operation, prior to the treatment you have some operation. You have planning, and you have pretreatment and you have HDR treatment, et cetera. It looks to us, it's very similar to a process that we're looking into in nuclear power plant.

And what we did is first of all is to simplify the very complicated process into a diagram like this. And on this diagram, the concept is important here. We put that there's actions here, pretreatment operation, treatment planning, pretreatment, treatment, post-treatment, and so on. And then we try very hard to look into if there are barriers. So the bottom of the dash are the barriers, and those are tasks designed in the process to prevent or to catch up, to catch any mistakes committed in the action.

And that way, even physicians or technicians made mistakes in their actions, somebody will be able to catch it up.

To use the work process analysis model, we consider work WPAM you will see that on and on, and it's a package of tools that was designed to improve the process safety. That's the basic. And

we've developed a checklist, flow chart, analytical tools and so on. And, basically, we use these tools in three areas: We use it for root cause analysis, for qualitative analysis and quantitative analysis.

And the purpose of all these tools is to make the work process safer. And if you have an incident that you can learn from past experience, you usually would like to go to the root cause analysis and here you would try to look into the event.

You want to find the cause. First of all, you want to find if it's related to a work process. You want to find out the cause in that work process, what went wrong. Another thing you want to make it cost effective is to you want to see how that incident would impact the work process. Is it worth the whole organization to spend resources to improve it? If it's just a random cause or things happen once and would never occur in the future, you may not want to spend resources into it.

And then you identify the principal deficiencies.

This is one way of using it, and the other way of using it, using the tools that we have developed, is quantitative and qualitative. By doing quantitative, you don't depend on your incidents. Instead you go and talk to the field workers and ask, look for the process that are key work processes. Those are significant, or they use it routinely. At nuclear power plants, it's usually easy to identify several, such as maintenance work process, instrumentation. They would identify equipment calibration and so on.

And after that, you will look—use the checklist evolving in the model to see how the process has been designed. Is there any room for improvement there?

Then you want to see how—if the process had been designed with fairly satisfaction, you want to see how they are implemented. It doesn't mean that a good process will always get good enough attention and the worker there will follow it.

And then after you identify several, you may want to go into detail evaluation. We have some tools to work on that.

And another last branch, which I'm not going to spend too much time, because in this presentation it's qualitative. We presented several papers at the other conferences. This is to do the quantitative analysis. You start with qualitative analysis, and if you have the PRA or probabilistic risk assessment already done, and you can go this route, which will give you—our hope is to get impact on the risk at nuclear power plants, its risk core melt frequencies. Here you may want to read what the impact on the risk probability.

Now I'll go through in detail on the first group here, which is root cause analysis introducing some of the tools we've developed and the rest, I'll just briefly go through. Hopefully, I will stay in the time frame that I'm allowed.

To do the root cause analysis, we want to do event diagnosis. We want to identify the causes, impact, and then where we can make improvements. And in the event diagnosis, we want to know what went wrong, which process was involved. Because that's important. If it's not process related, then you can't do this. Which task was involved and which barrier was breached and whose function, whose responsibility. With a cost analysis you want to see is there any room for the procedure design improvement, if there's room for field design improvement, and is there any room for implementation improvement.

Then you would—we would like to do a potential impact analysis, because not all—you want to prioritize your recommendations. Here I'm going to introduce some of the tools we developed here. Not always we developed, are developed in the field.

What went wrong, first of all you do the standardized or root cause analysis. A lot of nuclear power plants they are doing this right now, and one method developed by INPO is called human performance enhancement system. They have the time sequence of the event, and they identify how the human related to that incident.

I'm not going to spend my time here. And another method you can use is human error modeling. I believe John will present it in a later session.

After that, I use his view graph. I'm very grateful for that.

MR. WREATHALL: You're welcome.

DR. WU: Well, the whole point is here, is we are not trying to just come up with our method. We'd like to hope all the method is already developed in the field. For example, in John's presenta-

tion, I'm sure he will go into great detail. He will identify what went wrong with this specific event, such as there is dose misadministration, and he would identify the cause of that. Probably it will be a procedure cause. And he will probably further identify which procedure and which work process is involved. We will be able to pick up from there, and we will see here—we will see which process was involved, and then we would go to the flow chart, which I've shown you before. We will see which tasks went—the cause is within which tasks. Is it because of somebody made some mistakes, and what are the barriers to catch that mistake? Why the barrier didn't function as it should be.

Our experience is when we presented to the Site with a few workers, they usually take it comfortably, because this is a very clear presentation. We would ask them how do you do the process? What are the tasks? And we would give them a recommendation, and they would identify where it went wrong. And they would tell us what are the barriers. Then we would ask why the barriers didn't work.

One interesting finding was in one of the miscalibration situations ended with the reactor tripped, and the poor worker was the one who got punished. But by looking at the chart, the shift supervisor which was their manager, not the instrumentation, it's from the operation department manager. He ought to sign the thing, and they never come up with a signature sheet. And this shift supervisor never asked for it. He never saw it. And this poor guy got punished. We were asking them, where is the barrier? How come the barrier didn't function? And the answer was interesting, because they never thought of it. This shift supervisor never thought his job was to—would be a secondary barrier to this whole process. And they come up with, "Why didn't we punish the shift supervisor?"

So that's the kind of thing—the whole concept is not new. Everybody would thought of this. The point is, we wanted to find out communication, too, with the field worker. You have to present it clearly. Let them have a say in it. Let them tell you what are the barriers, where the thing went wrong. And we talked to quality assurance, and they sit there and say, "Ah, this is a nice picture to show our people there. We ought to put this in our training program."

And those are the things we want to get through with. And so that's clear, and I won't spend too much time on the flow chart and where the barriers went wrong and whose function was involved. Again, every time we would do this, but here we developed some tools here just to help it, to make it clear. We would ask them, you tell me, what task, whose action and what barriers, which department involved, who is the one who should be responsible for that action. And they would identify the responsible, if there's an incident, whose responsibility and so on.

And then we want to find out causes. With the process we used, we rely on checklists. We rely on—there are three parts: One is procedure design, one's field design, and one's implementation. They're all important, and most of the time we spend not only on procedure design, but field design and implementation. Checklist is also important thing here.

I don't have any checklists for medical field, however, I do have one for from our previous study where their procedure design, this one we worked closely with what we called substantive expert, who's experienced in doing the specific work process. Like here is with maintenance we work with people with great experience in maintenance. If you're in medical, you should work with somebody from that field. This is to go through the design, and we have the advantage of—we have INPO, which is an organization of utility work together, and we have other utilities work process to share experience with. So we look at one. They come up with—INPO come up with so-called good practice, and for a process such as maintenance, these are the process we envision as a good one. So we compare one specific process with that so-called good one, and you look at procedures and then see if there's any significant flaws or any kind of character should be reflecting the cause in the procedure which didn't, and et cetera.

And the field design is important. We also look into the location, sometimes paperwork gets circulated several times, you get to the end place and it takes a person to run into the next building, et cetera.

Those may not be as significant as procedure, but sometimes it comes as a handicap to the success of certain processes.

And implementation I don't need to go into. The point is it's not us. We act here as nominative expert. We provide the tool, the theme of the tool, the way to present it. And it's the field workers, it's the field expert who has to get involved. And we guide them, and they come up with checklists on each specific tasks that they think is important.

And we use a tool called a BAR to find the deficiency in the implementation of the process. You'll find it's very helpful. And this is the behavioral—well, I lost it. But we call it the Behavioral Anchor Rating Scales. And this is the tool that involves three steps: First of all, it's useful because it's—first of all, we asked an expert in the field what do they envision a successful task should be or successful—if we are looking at an organizational dimension, such as communication or coordination, we would ask questions as what do they envision a very successful task. And so this involves three steps:

The first step individuals familiar with the specific work process were brought together to suggest, from their collective experiences, factors they believe influence nuclear safety. This should be the specific work process.

And then Step 2, with the given task or organizational dimensions, experienced panels then more completely define the task and provide behavioral anchors indicative of various safety levels. And then the behaviorally anchored rating scales—they would come up with a single-page scale with examples of poor, average and high behaviors.

And then somebody would get into the—and then you go to Step 3, the respondent is requested to read the definition or to explain the definition to the field worker, and then they would decide which or where she or he feels the plan ranks on the scale.

And I brought one example of the behavioral anchored scales with me today. This is not, again, directly related to your case, but this is a suggestion of problem identification.

Our problem there was the plant people, are they capable of identifying the plant problem on site and immediately. And so we've come up with a set, and the reasons one, two, three, four, five. And you can come up with three or nine if you want, and it's poorly performed, average performed and excellent.

By excellent, the plant people should behave as the following. These are the poorly performed. They should behave as follows.

If they are excellent, the employees are encouraged to pro-active identify potential problems, and then employees are asked to notify management of potential problems, and management investigates the situation and responds to employees' input with timely effect.

On the other hand, if it's poorly, you go to the site, and you find out the problems went by undetected or unreported, or employees fear being reprimanded for identifying problems. If you found this, you are ranking poor. And on the other hand, you are considered high.

And by doing that, if you have—we call it BARS. If you have the BARS for each different task or the task you have in mind, specifically the task that you selected, and you can go to a facility, you get experts to come up with rank. You go to a specific facility and see if they're well performed or not, and then you can give recommendations.

And the last thing we did was to develop a set of tools to identify potential impacts of failures. And as I pointed out before, the reason we do this is we want to prioritize our recommendations. The tool we used for that, we used a scheme called AHP, which is an analytical priority process. We would, by doing here comparisons, these are the tasks we identified. And under each task we pointed out all the important dimensions or you can select several of them under each task, and by doing—well, the basic idea for AHP is to do a comparison so that you can focus your attention to a localized situation. By doing that, we would hope—what we would hope is to find the weights, which for example in this specific case, we have a special event in mind. We had different tasks, and we had different organizational factors. And by doing the AHP I mentioned before, we can come up with weights, if you sum up here you can see which tasks place more important role in this specific event and, also, by adding up this way, you can see which dimension placed more importance.

And by doing that, you may want to emphasize your resources in one of the specific conditions, such as in this one you may put your efforts

in training your employees, doing a better job in scheduling and coordination. And they should get more training or emphasis on their coordination skills of work.

By doing that, I come up—basically I've presented the tools we had for root cause analysis. I pointed out that we would do the flow chart and BARS, event diagnosis. And you would have different tasks for your cause analysis and impact analysis. And similar tools can be used in qualitative analysis. And here the only thing is you don't have an incident. Instead, you have to identify from the basic—from field experts which key process you have to spend your time.

And if you do have a PRA, we come up with a fancy—not fancy, a sophisticated way of doing the quantitative analysis.

DR. BICKEL: Would you be able to summarize?

DR. WU: I'm done.

DR. BICKEL: Oh. We'll have more time to discuss it in the—

DR. WU: What I was going to say is if you would like to hear more, I'll be happy to spend another hour on the quantitative analysis.

### C.2.5. AEOD Database—Mr. Prato

DR. BICKEL: We'll have time in the discussion time for discussions.

I would now like to talk a little bit about the database effort. And we have Mr. Bob Prato from NRC's Office of Analysis and Evaluation of Operating Data.

He has, I guess, a brief, more informal presentation where he's going to discuss what their activities are in that area. Bob?

MR. PRATO: Good morning. My name is Bob Prato. I work for the Office For the Analysis and Evaluation of Operational Data.

I'm sorry I'm not prepared with a more detailed presentation this morning, but I would like to thank Pat for the opportunity to inform this audience of what we're doing and where we presently are in the development of materials events database.

To begin, I'm going to state the obvious, and the obvious is that operational experience is a fundamental element of the regulatory process, and more importantly, the education and cost effective improvement of our industry.

To convert operational data into useful information, over the past decade the industry has developed a number of tools, including probable risk assessment, root cause analysis, human reliability assessment and others. All of these contribute to risk base regulation and operational feedback to the industry for improvement in the use of byproduct materials.

To this end, the Office of AEOD has been working on a database for the past year, a new database. We have been gathering operational data on the materials in the medical area since 1981. This database was basically a flat database with only very key pieces of information, and not sufficient information to adequately contribute to some of these tools mentioned before.

Therefore, about a year ago we joined a partnership with INEL to develop a material event database. This database is a three-dimensional database that's intended to gather enough information to be able to reproduce and evaluate different events with multiple paths for errors and mistakes and deficiencies in the performance of the different efforts involved in material applications.

Right now we have developed a database. The shell is in place, and it's still in its infancy, but we have begun to input information. Right now we have the 1984 information in there, 1983, and I'm sorry, 1994 information, '93, '92 and '91.

We are in the process of converting previous databases, which include the NRER, which is the Non-Reactor Event Recording Database and the Medical Misadministration Database dating back to 1981, and we're going to convert all this information into a single database known as the Materials Events Database.

We are in the process of quality controlling the information that is in the database right now. We have three year's worth of information. We're trying to make sure we can fill in all the pertinent blanks. A lot of this requires going back to some of the licensees in the agreement states and gathering additional information. We're also in the process of making sure that the input is standardized,

so that we avoid some of the problems we've experienced in the past with multiple identification of same type of cause or effect.

We plan in December of 1994, to make this database available to other organizations, which include the regions, agreement states, research and academic organizations in the industry and other organizations like the ACMUI.

Some time in the far future, we are still considering electronic reporting. One of the lessons we've learned with the reactor side, which has the sequence coding database, that it requires a cooperative effort between the licensee and the regulators to develop an effective database that can be used in the regulatory process, as well as in the training and education process. That's it. That's the status right now. Anybody else have any questions?

DR. BUDNITZ: Do you have enough money to do this right?

MR. PRATO: I beg your pardon?

DR. BUDNITZ: Do you have enough money to do this right?

MR. PRATO: We have allocated sufficient resources right now for the first phase that we're working on right now, which is, basically, the input for the medical and materials information, based on the input from the licensees. We would—we have a request from the industry to make the database flexible enough to include events that are not byproduct material oriented, for instance X-ray, I–123 misadministration, that type of event.

We have that capability. We can expand the database to include that. The resources on that part of the database, which will make it very diverse, very flexible to be used by the entire industry. You've got to understand there are two halves, the NRC licensees and the agreement state licensees. The agreement states really need that other half where we can gather the information at a level where it can be analyzed for the non-byproduct materials. Those resources are still pending and still being discussed. But the database has been developed with the flexibility to be expanded very easily. Yes?

DR. BLEY: I'm not sure if it's for you, Bob, or for others.

Based on what we heard earlier this morning about risk analysis being more a feature of looking at these kind of events, were the needs of risk assessment specifically factored into thinking about the structuring of this new database to make sure it's going to be particularly useful for that activity?

MR. PRATO: We've tried to model it after the SCSS Database, which is the reactor side, which has been very useful. But even with the reactor side, there are certain key elements that are not available. For instance, how many attempts were there to operate a piece of machinery versus the number of times it failed. There are key pieces of information that are really not very cost effectively data.

The other problem we're facing on the material side and the medical side is the lack of resources on the licensee level to provide the detailed information, and to get the database to the point where we have this level of information to do a sufficient analysis, not only from NRC licensees, but from the agreement state licensees, which can be particularly useful in the area of agreement states, because we can help find where the agreement states have been more successful and why, and where they are not as successful and help them to correct their program and improve.

DR. BLEY: You just hit on something that was sort of a trigger for me. The licensee's involvement, a major problem with essentially all of the databases in the nuclear power business has been lack of a real incentive on the licensee's part or lack of understanding why it would be especially useful to them to participate strongly, maybe even to influence how this database is built.

MR. PRATO: I'm not sure that's true. I wrote the first two LERs for Susquehanna, and they went through a great deal of effort to be very specific and put in a lot of great detailed information.

DR. BUDNITZ: It's a mixed bag.

MR. PRATO: I beg your pardon?

DR. BUDNITZ: It's a mixed bag, though. Some are and some aren't.

MR. PRATO: That's so. I think as a whole, though, the reactor side try to avoid blame, but try to get sufficient information into the database, because they have a great need for it, as well. That information they use extensively.

I am not sure, although I worked in the medical end, I am not sure how the medical licensees look at it.

DR. RATHBUN: They would prefer to give no information. Would that be fair? Most of them, by and large.

DR. BUDNITZ: Do the vendors of this equipment maintain their own databases at all?

DR. RATHBUN: Yes, some of them do. Some of them have—it depends. Some of them have failure rate databases.

DR. BUDNITZ: To what extent are they licensees?

DR. BICKEL: Most of them are foreign countries.

DR. RATHBUN: The Gamma Knife Project has been the one in which we had the most access to the failure rate databases.

DR. BUDNITZ: Do you have any legal muscle to have access to that?

MR. CAMPER: There are certain FDA reporting requirements or device failure. We do have a Memorandum of Understanding in place now with the FDA, which we put in place this year, in fact, that allows us to exchange information, and I'm virtually sure we could get access to that information from the FDA if we requested it.

DR. RATHBUN: But Nucletron was brought up earlier has an extensive failure rate database. Early on, three years ago they had agreed to make available to us, but understandably they became nervous about the whole thing, you know, where was this all going, and so they kind of walked away from that. That is an area, the whole area of data and failure rate data for the device is certainly something we have to look into as a key point.

MR. CAMPER: In many cases the manufacturer, Nucletron, for example, won't make information on failures available to their customers, particularly their generic implications. They're reasonably good about that.

MR. PRATO: We may not get to the point where we'd like to be, but we're making great strides in improving that information. We're making great strides in improving the level of cooperation between the agreement states, the regulators, the science industry, and I think we're moving in the direction of trying to improve the relationship we have with the licensees, so that we get better information.

## C.2.6. NRC/RES Supported Work —Dr. Callan

DR. BICKEL: We're going to discuss the issue of the databases, I think, in greater detail in some of the breakout sections, because obviously we've got an interplay between the data that's available, how it can be utilized in a risk assessment and how a risk assessment you might want to collect the data a little bit different in the future, and I think we're going to have some discussion on that probably tomorrow. Thank you very much, Bob.

Our next speaker is Mr. Jim Callan from Pacific Science and Engineering. Jim is going to talk about the human factors assessment performed on brachytherapy. And this work was done for the Office of Research at NRC under Isabelle Schoenfeld.

DR. RATHBUN: John, because of the importance of this talk and the one that comes after, if we could go back to my talk this morning, there were like four major projects: The one here at INEL, the two here at INEL, the one at Pacific Science and Engineering and later on the Gamma Knife.

I would like you, Jim, to take your time and go ahead and go to the lunch break if you want to, and then we'll—I would like that. If it doesn't work, we'll have to get Mr. Shepherd up here. I would prefer to take the time to truly understand this work and to look at it. To some of us it would be the first time we would have to walk through it, and that would move Jim Shepherd to after lunch to begin to talk about the Gamma Knife, if that's acceptable to Mr. Shepherd. Thank you.

DR. CALLAN: Now this project differs somewhat in that our goal was to go to as many places as we could afford to go to and to collect information about the general use of remote afterloading devices in brachytherapy. And this includes both high dose rate and low dose rate remote afterloaders, and to document the use in generally normal circumstances, although we couldn't avoid but run across occasions and sites where there had been misadministrations or errors

occurred. But it's generally a broader look than just going to someplace that is having misadministration and ferreting out the causes of misadministration.

So we went to 23 sites across the country, spent two or three days at each site with a team of between two and four people at each site.

Now I'm not going to talk a lot about the methodology or the questionnaires and the instruments that we used. I'd rather jump to findings. If you have questions about how we found out what I'm going to tell you about, I would be glad to talk to you about that later on.

So we went through each job of each remote afterloading brachytherapy responsible person, including radiation oncologists, therapists, dosimetrists and physicists. And we occasionally interviewed and discussed the job of management people in radiation therapy departments or in radiation diagnosis departments, and sometimes we went even to hospital heads and discussed it with them.

These are the five areas we concentrated on:

The functions and tasks, that is the breakdown of remote afterloading brachytherapy;

The human system interfaces with the equipment;

The procedures and practice, or you could call it a work process;

The training involved for each of the different types of people, and the training procedures set up by the site or the institution;

And, then the organizational support given to the department and brachytherapy by the larger clinic or hospital.

The first step was to try and break down the process as much as possible, and the immediate difficulty we discovered was that at each of the 23 sites, remote afterloading brachytherapy was conducted differently. It's conducted differently because different sites concentrate on different kinds of treatments. Some sites are mostly lung treatment sites. Other sites are mostly gynecological treatment sites, and so the procedures obviously for two different organ systems are quite different.

And some sites are more low dose rate sites and some sites are more high dose rate sites. And that's significantly different, as well.

Incidentally, the sites were guaranteed anonymity, and everybody we interviewed was guaranteed anonymity, and that's anonymity from NRC, as well.

We looked at who performed the tasks and supervised the tasks, what the workload factors were on the tasks as viewed by the operator, whether it was high time pressure mental effort stress or low, and there's an instrument and a scale we use to determine that. The distracters and distraction levels in the vicinity of the operation of that task, what skills were required to perform the task, how long it took to do it, and then we broke down the task into steps.

So we wound up with about 20 some odd tasks, each was between five and 20 steps. And those aggregated into about five general functions like treatment planning, treatment, et cetera, the five major functions, as I just mentioned.

Now I'd like to step to one aspect of our analysis and concentrate on that for the rest of the talk. This has to do with what we call critical task identification. From the task and the breakdown of the work of remote afterloading brachytherapy, we established that some were more critical than others. This is a common feature in human factors analysis is to concentrate on critical tasks. Those are tasks in which human error was likely in one or more parts of the task, and that the error might not be detected using current practices, and that the consequences of the error may include delivery of an unintended dose.

We've been talking about patient misadministrations for the most part today, but we have to keep in mind that there are misadministrations on record to staff members as well.

The first critical task was patient scheduling and tracking through the process. The errors that we documented within that are scheduling a patient for the wrong treatment; taking a patient to the wrong place; and, delivering treatment to the wrong patient due to misidentification of the patient or the patient's records.

The best anecdote in this is the story of the patient brought down under sedation for a high

dose rate treatment and had no identification on him, so they asked him his name, and he said his name was Jones. This is a pseudonym, of course, and they started to treat him as Jones when somebody recognized that he wasn't Mr. Jones, he was

Mr. Smith. And it turns out that he had been in a hospital room with Mr. Smith, and both of them thought it would be a clever idea to exchange names and tell the staff that they had the other fellow's name.

There was no misadministration, but this is the kind of thing—these are the kind of strange things that can happen in these settings.

Critical task two is the applicator. The applicator, for those of you who don't know the process, is the device, and I include catheters under this general term of applicators for this purpose. Catheters and applicators are the guides that guide the high or low dose rates device to the correct position in the patient's tissue. If the applicator is not placed where it's supposed to go, obviously the treatment will not be to the right place. If the applicator is placed in the right place, but then there's failure to stabilize it so it moves subsequently, obviously there will be treatment to the wrong place. And if the information about where the applicator is is not transferred from the person who placed the applicator to the person who is carrying on the treatment at the next stage, then there can be a mistake at that point, too.

This highlights one of the important things we discovered, and that is a communication between the task and the functions. It's easy to analyze in our analytical way that there's a step and a step and a step and a step, but remember, each step is performed by an expert in that step, and the next step might be performed by someone who is not so familiar with the first step. So the information about Step A has to be transmitted accurately to the person conducting Step B.

Frequently the guy doing Step A's expertise does not completely overlap with that of the person conducting the next step. There may be some overlap, but not 100 percent.

So if I tell Pat that I have done these things, and she understands what I do, but not completely, she may be off in her understanding of what I did just a little bit.

Target volume localization has to do with correctly identifying the mass, the tumor, the organ, the tissue that you want to treat and specifying that volume, generally a radiation oncology responsibility here.

In high dose rate treatment particularly, the position of localization is critical, and the specification of the point at which the instrument stops, the points along the path to be treated at which it stops can frequently cause an error, and I mean frequently, more frequently—we're still talking about very small frequencies—because, for example, the starting point was misidentified. If the starting point is misidentified, everything can look correct in the treatment and the treatment timing, and yet everything is offset by a certain amount. This is the kind of error we're talking about here.

And then transferring incorrect information on chosen source positions has to do with the fact that the information is collected initially in a diagnostic X-ray situation and then transferred to a treatment program, and that transfer between the measurement of the location of where things should be and the measurement of the location where the treatment will be can cause an error, and it's kind of a communication error, as well.

These are the dosimetry kinds of errors we identified. I think they're kind of obvious. We talked about some of them already. These are rather detailed, but one that's kind of interesting is we have a communication error identified again, and that is the calculation results are not communicated adequately to the next person in the serial chain of events, which would be the treatment itself.

Treatment set-up errors include these kinds. There can be up to probably 24 channels, although we've never seen anybody use that many channels in a high dose rate treatment. If the channel guides are switched, then the treatment design for Channel A might be applied to Channel B, and that for Channel B applied to Channel A, obviously. So it's such simple recommendations that we include are things like labeling the channels, checking the labels to make sure that the device does not get installed backwards.

Connection of improper guide tubes has to do with the diameter and size of the guide tubes, and I can't remember what the last one involves.

DR. STITT: The applicator moves in the patient before you give the treatment.

DR. CALLAN: Probably that's what it is, thanks.

A frequent problem, particularly in lung cases in which you have a partially sedated patient with a very nauseating tube down his throat and lung, and he could be, for example, an emphysema patient or lung cancer patient with a lot of coughing. There's no guarantee that that little device down there is exactly in the same place that you placed it originally. Although most institutions take great care with such things.

You have to remember that this is a human process, and that the people we're dealing with here are people trained to care for patients. Their first number one priority is the safety and health of the patient. And so these are not—there's not a motivational question particularly. These are highly trained professionals. A lot of this work is done by Ph.D.'s, medical physics and by M.D.'s and by people with Master's Degrees, and their goal is to do it correctly. And most of the time they do.

The treatment plan entry involves entering in the plan that you've determined and the dosimetry figures into the treatment planning computer and the treatment computer, and these are things that can happen: The wrong treatment plan is used and somehow the parameters entered, if they're entered manually, for example, from some kind of access, those treatment numbers get transposed or entered in error, so everything is done correctly up to that point.

And in this case a routine QA we're referring to the quality assurance performed on the equipment on a regular basis by the staff, not the QA of the operational procedure itself, but QA like QA when changing out sources, QA when testing out the machine for various purposes.

And source replacement, which is approximately a high dose—you can forget about it for low dose systems. In high dose systems it's approximately a quarterly process, and there can be inadvertent exposure of staff to the source, because the staff may be participating with the manufacturer, or may be installing the source themselves, and during these times the source is exchanged, there's a possibility for exposure to staff. These, again, are radium sources, high dose radium sources.

And there might be changes to afterloading equipment that could compromise these things later, like source position, equipment integrity and treatment delivery. These are the kinds of errors that could then result in multiple misadministrations to multiple patients if they aren't caught.

Incidentally, out of 23 sites visited, I found one site that did not make an independent measurement of activity on the occasion of a source exchange. So it was not in my view, and I'm not sure that was their practice, it's just they didn't—we didn't have a good report on that site. So my one of 23 would suggest that everybody, at least nowadays, is doing independent source activity tests at the time of change over.

I asked everybody whether they trusted the numbers on the delivered source to the box provided by the manufacturer, and they said no. These are almost always physicists, and they generally know what they're doing.

DR. GLASGOW: Well, I'm not sure I would agree with that all the time, make some comments along those lines, if I might?

DR. CALLAN: But these things can still happen on source calibration, that is, there's an error made in the measurement of the activity and be, I think a more common possibility being an error in recording that number and in passing that number on to everybody else.

Typically, the activity decay can be tested by just posting a table on the wall and saying, okay, so many days later so many percent decrement in activity, and anybody who just bothers to look at the table can check that against what's going on in the treatment planning system and have themselves a nice, easy way to determine whether he's in the right ballpark anyway.

DR. BUDNITZ: Do you know any sources that they delivered for whom the report is you can't trust what the manufacturer sends you? How frequent are those actually wrong?

DR. CALLAN: Well, they're always a little—well, not—I don't know, I can't give you a good number. I do know that they're delivered with a date, which may not be the exact date that you receive it, and as of, and they're measured as of a

date, so you have to make a little adjustment or calibration there. Would you answer that, Glenn?

DR. GLASGOW: Well, yes, I will try to answer that. There's unfortunately developing a major, in my judgment, a major misunderstanding here regarding the manufacturer's calibrations. Manufacturer's calibrations are correct to within the precision they state. The problem is people want that precision to be higher. They are stating their calibrations to within, generally, ten percent.

Now that ten percent is a much larger precision range than we commonly use in external beam radiotherapy. So it's not the "manufacturer's number is wrong". When the physicists compare it, the physicists are failing to put into their own comparison their own potential uncertainties in measuring. If the source is stated to be ten curies with a ten percent range of error, it could be nine; it could be 11. If I measure it to be 9.5 by some technique, do I agree or do I disagree with the certificate? Technically, I agree. The problem is that many in the physics community are attempting to provide a greater level of precision to the process than the manufacturers have assigned to the source. And so the theory arises that "the sources are wrong". They have never been wrong in that sense. They just have not been as precise as we would like for them to have been relative to some other work we do.

DR. BUDNITZ: How do I know that the 9.5 isn't plus or minus four?

DR. BICKEL: You have a standard calibration—

DR. GLASGOW: That's one of the points that has to be addressed. Unfortunately, some of the measurement work done by physicists, there's a tremendous tendency to carry everything out to the third decimal place, when the reality is that the uncertainties are, you know, ranging three to five percent in various steps. And so it's an area of some—it's an area of some confusion, simply because it's not as precise as our external beam radiotherapy work. If we have a cobalt unit, we really do know the "dose rate" from the cobalt unit to within two or three percent absolutely, or very close to that. But we have never in brachytherapy, even with the manual conventional sources purchased from the manufacturer they have always arrived with a certificate that clearly stated that the absolute number as a group had large uncertainties. Over time we have learned that those precisions, we improved the process, but brachytherapy as a discipline has always involved less precision. It has been more an art, in many cases, than it has been a science.

DR. CALLAN: Here's where I am at this point. Those are the ten critical steps. Incidentally, to aid us —and I have to give credit here to the University of California San Diego radio-oncology staff of physicists, dosimetrists, therapists and oncologists who helped us to do this.

And the next thing was we developed a series of alternatives which you might call recommendations. We don't use the term recommendations, and I can either include those or I can stop at this point. The alternatives are things we derived based on these problems, where we think, you know, great improvement can be made.

For example, one of the biggest problems is the human system interface of the treatment planning system, and that was the most significant problem as determined by all of the people we interviewed. The treatment planning system itself is the highest stressed activity, et cetera, the most difficult. And here are some kinds of things that came out of this data, format disambiguity, labels on applicators—this is for various kinds of human system interface, not just treatment planning here—better feedback and visualization for the planners and performance certification for software and hardware, which doesn't exist, particularly for the hardware.

Software systems and treatment planning provide a wide variety of options and paths for different kinds of treatments. We found that most of the sites become good at one or two and don't deviate, because the complexity of the treatment planning system is such that if somebody gets off on a path that takes them somewhere else, they don't know how to find their way back. And they don't know—they're not sure of the outcome of the system and its recommendation. So they don't like to use it.

That's one of the reasons I think why you see at one place just lung treatments, just single channel lung treatments, because a single channel lung treatment planning system is simple, easy to understand. That's not the only reason you only see that one kind of treatment. It may be that the radiation oncologist at that place does not like to use

remote afterloading brachytherapy for anything but single channel lung treatment, and one of the reasons is the difficulty of following the computer software built for treatment planning.

Would you like to see some more like that, or do you feel that gives you the idea of what we did?

DR. RATHBUN: I guess one question we have is when will we be able to see all of them together?

DR. CALLAN: You've asked me that before, haven't you?

DR. RATHBUN: Well, if not now, it's a great time. If it's going to be another year, I'd like to hear it now.

DR. CALLAN: Well, this is all written up—it started out in several large volumes rather roughly drafted, and in order to make it readable and distributable nationally, it's been revised extensively, and it's now down to two small volumes. And it's being—going through final review at NRC now.

DR. RATHBUN: I guess what we will do is to ask the program manager in research if we could make drafts available for this group, so that they could have it included.

DR. CALLAN: I believe we already made available the basic test analyses to somebody, INEL, somebody at INEL. The idea was if our task analysis breakdown of the process is helpful to those doing the risk and probability-type work, well then we're happy for them to have it.

DR. RATHBUN: They're shaking their head over there, somebody in the back row has had it.

DR. BICKEL: There was an early draft. Not officially, so none of it was utilized in any of—

DR. CALLAN: Well, it was official—

DR. RATHBUN: I'm sure it was official, and I think Harold has just forgotten.

DR. BLACKMAN: Not likely, Pat.

DR. RATHBUN: So because, you know, if we're going to have a final proceeding here where we've taken kind of all the data, we'll have to work that out, I guess, with—

DR. CALLAN: Well, I don't know if you want to put that in this—the risk analysis we did involved finding out from people what their perception of risk was at each of the different stages. So it was more like perception versus analysis.

Some things that were different were the perception of stress at different points in the task. I found that very interesting, and there was a lot of consistency among the people responding.

A few little side things we did like that, but they don't exactly fit in the theme of this session particularly, but they're probably of interest to several people.

DR. BICKEL: If you don't mind, I'd like to at least include the rest of the slides from the proceedings.

MR. TORTORELLI: From all the presenters, I do need a paper copy of your slides sometime by noon tomorrow.

MR. SHEPHERD: On the theory that if I can ask you three more questions, you guarantee that I don't have to talk until after lunch—do you have a feel for the relative percentage or magnitude of those errors that occurred in interface kinds of problems versus those that were within a single step, wouldn't really seem to dominate in terms of—I mean the magnitude of the number of times—

DR. CALLAN: Well, the two kinds of things I'm thinking about, there's the interface of the operator with the equipment and the process, and there's the interface between steps in the process.

MR. SHEPHERD: I was thinking more of between the steps.

DR. CALLAN: Yeah, we were not prepared to find—what we did find was there was a lot of problems sometimes in communicating. When somebody's completed a process, and he's an expert in some kind of calibration, and then he leaves that information for somebody else, he or she, then that second person's understanding of the calibration process is not quite in sync with the first person's, it either could be left with the mistake in it or the second person could read it and adopt an error in interpretation of what he's reading. I think that's an interesting outcome of what we do.

MR. SHEPHERD: There were a number of errors related to scheduling, you know, wrong patient, wrong treatment, whatever. Did that—or did you look and see whether those kinds of errors were related in any way to total workload at the facility during the time they occurred?

DR. CALLAN: Patient scheduling errors were probably the rarest of the kind of errors we found. We included them because everybody knows that a patient scheduling error is potentially so catastrophic, the wrong guy gets the wrong treatment, and maybe never gets caught.

MR. SHEPHERD: When the error occurs, was it a function of what the total workload at the facility was? Was it more likely to occur if you've got 14 people sitting out in the hall waiting to be treated?

DR. CALLAN: Didn't have the data for that.

Here's a question I meant to ask earlier. Some sites treat several hundred patients in let's say high dose rate brachytherapy per year. Other sites treat less than one a week, okay? Are the misadministrations at the high frequency treatment sites per treatment greater than the other? It would suggest those places who do lots of treatments, who are very skilled in doing particular kinds of treatments, might not have as many misadministrations because their skill level is so high.

On the other hand in the low frequency treatment place, they might have more relatively because their skill and proficiency is not so high. It's something you can—I think you can get out of the AEOD.

DR. GRIGSBY: What's the—do you know from your data what the relative number of procedures performed at the various institutions on an annual basis is?

DR. CALLAN: Yes, I do. I know exactly.

DR. GRIGSBY: Okay, what is that rate?

DR. CALLAN: I don't have it right here. It's an approximation. For places like yours, it's very high, as I recall. Some certain specialty institutions do lots of treatments. Well, what's a lot of treatments?

DR. GRIGSBY: That's what I'm asking.

DR. CALLAN: How about one a day or how about two a day?

DR. GRIGSBY: I would submit that no one does that on a regular basis.

DR. CALLAN: Okay, on an average?

DR. GRIGSBY: If you look at—

DR. CALLAN: Two or three a week, would you buy that?

DR. GRIGSBY: —the number of procedures administered at various institutions, about 300, 350 is sort of upper limit.

DR. CALLAN: Per?

DR. GRIGSBY: Per year for any dose rate.

DR. CALLAN: Are you talking about manual?

DR. GRIGSBY: Manual, remote, PDR, HDR, LDR, MLDR.

DR. CALLAN: We've reported, and I don't remember what the numbers were, the places where we visited we did collect that information.

DR. GRIGSBY: But I'm just saying the order of magnitude is 300, 350, Glenn?

DR. GLASGOW: Yes, certainly.

DR. GRIGSBY: And goes down to one.

DR. BICKEL: You wonder how they justify the cost of keeping the license and all the equipment if they're only doing one a year.

DR. GRIGSBY: I visited an institution that has to remain anonymous, with a part-time contracted physicist, two technologists to do the external beam and a part-time physician who do about five or six manual brachytherapy procedures per year. And I don't think any of them had a clue as to what they were doing.

The physicist didn't want to take responsibility, because he was just contracted to do the isodose. The techs didn't want to do it, because they gave the external treatments, and they didn't really know about brachytherapy.

DR. CALLAN: We went to all kinds. We went to large, small, university affiliated, private clinics

and from East Coast to West Coast to north to south. We tried to cover—

DR. GLASGOW: It's just a comment, the question of frequency of medical procedures actually is pretty well understood, particularly in complex areas such as cardiac transplant work. For example, those facilities that do greater than 200 cases per year, their actual success rates are far superior than to facilities that do fewer than 200 per year. So that type of information is of great interest now to the Federal Government in terms of reimbursement of the various Medicare schedules and to HMOs in deciding to enter in contracts with treatment facilities as to whether or not the facility really has the technology in place and really knows how to use that technology.

So frequency of use relates not only to misadministration. It really relates ultimately to the patient care.

DR. BICKEL: Larry?

MR. CAMPER: Just a quick note of interest. When you talk about the number of medical procedures, what is the frequency of occurrence of misadministration, there is something that hasn't been mentioned that comes to mind. That is it's not just the number of procedures. It's the number of times that radiation is administered and, therefore, an opportunity for an error to occur exists.

Now that is an elusive number. We've tried getting a handle on it, and we've come to the conclusion that getting the denominator would require us to put into place a regulatory reporting department, where all licensees were to be on the same level playing ground with a clear understanding of what the expectation was, to compile that data and provide it to us.

Now we could do that, but then the question surfaces, well, to what end? What is the utility of putting that additional record keeping burden on the medical community? Would it change, for example, the frequency of occurrence of misadministration by an order of magnitude. Unlikely. I'm talking about the actual number of times that radiation is administered. For example, you do a procedure in your facility as compared to a procedure in another facility. Your procedure may not involve the exact same number of applications of radiation of the HDR device.

DR. GRIGSBY: I'm talking about total number of applications into numbers for brachytherapy.

DR. CALLAN: A single event.

MR. CAMPER: Well what is a single event? Is a fractionation a single event?

DR. CALLAN: Yes.

MR. CAMPER: Okay. Well, that's what we're getting at, too.

DR. GRIGSBY: If you do four of those, that's four procedures.

MR. CAMPER: That's what we'd like to try to understand, too, but the number is an elusive number.

DR. CALLAN: Here's another problem. I don't know that you need to know exactly to the plus or minus one around the country how many are performed. I think you need to know in general how many are performed. The denominator does not have to be within, you know, tens. We're talking about thousands of things here occurring, and the number is going to be, then nominator is going to be very small anyway. The numerator is going to be small anyway.

So if we have a good, rough idea, that should help.

DR. GRIGSBY: I think most institutions record the number of procedures. Don't you know how many procedures—Glenn, don't you know how many procedures? I have an annual report, monthly report of how many events.

MR. CAMPER: A couple things. I think the degree to which they do that is varied and, secondly—

DR. GRIGSBY: No, huh-uh.

MR. CAMPER: Our observations, as far as the degree to which they know the exact number of times radiation is administered is varied. When we evaluate, and we do inspections to events, the degree to which records are kept is variable. That's certainly true. Some do it with great sophistication; some do it—the one that comes to mind is the therapist who kept it all in his mind. He kept it all in his mind. He kept it all in his head. That's ex-

actly what he told us. Well, I don't write that down, I keep it all in my head.

DR. LARSON: But he certainly has billings that's computerized. The information is available in some format.

MR. CAMPER: Well, the problem is the information is available in different degrees and different formats. There's no uniform way.

But one comment about, you know, generally knowing what the number is. We think we have a pretty good idea what the number is right now. The problem is that that approach doesn't hold a lot of water when a Congressman on the hill is asking the chairman of your agency what is the frequency of occurrence, or more specifically, what is the frequency of occurrence by institution type or by state or by region. Those kinds of answers require good, detailed database. And right now we don't have that. And the question is, should we do it? Is it worthwhile?

It might be worthwhile if you're trying to answer that kind of question in that kind of form. On the other hand, the regulated community might argue that it's a burden that's not going to change the order of magnitude of numbers and therefore carries with it the cost of the burden that's not warranted. It's a tough—

DR. STITT: A comment, there's a group called The Patterns of Care we're familiar with, and there's to be patterns of care in brachytherapy awarded, and it's a cross-section. It's not all studies done in this country or in a period of time, but it does look at large teaching institutions, medium-sized, whatever that is, community institutions. So it gives you a spectrum, and it's been used for many years looking at how external radium therapy relates to the outcome in early stage Hodgkin's Disease. And you can look at it by how many patients are treated at these institutions, number of patients, equipment, education of staff, et cetera, et cetera.

That can be something, I mean it's just being awarded. It hasn't even been started, but it would give at least the Congressman some sort of answers to that.

MR. CAMPER: Well, just a couple quick comments. What we are doing is we're doing a National Academy of Science study that's going on, and it's looking at the risk of the use of radiation in medicine as compared to some other modalities that go on, for example, anesthesiology, surgery and what have you.

From their study, we made, ascertained tools that will better help us get a handle on what is the frequency of occurrence, what is the risk.

We are, as a result of the spectrum of quality management, we are asking our inspectors to collect information concerning the number of times the licensee prepares a written directive for the various modalities. Now, once again, that doesn't get at how many times did you administer it. It just means how many times did you prepare a written directive. Some of the written directives may have details and some may not, in terms of numbers of fractionations. But we're also looking at other sources of information that is published in the literature from various professional organizations.

But thus far, to try to find one source where it all readily exists and one you can turn to and put your hands on is elusive. Maybe in due course that will get better.

DR. CALLAN: Is a written directive a grease pencil on a—

MR. CAMPER: No, it is not.

DR. CALLAN: It isn't?

DR. GRIGSBY: That was going to be my question this afternoon.

MR. CAMPER: There has to be a written record maintained.

DR. CALLAN: You could later make it in more permanent form, let's say, for the treatment it's a grease pencil on an X-ray film.

MR. CAMPER: I understand it's a written record provided, it's available for subsequent review and inspection to determine—

DR. GRIGSBY: Maintained in the hospital record permanently.

MR. CAMPER: I mean some people put written directives on some pretty strange, you know, vehicles. As long as it contains information that's required, by definition in the regulations, if it's maintained for review for a required period of time, certainly it could be on X-ray film.

MR. TORTORELLI: Well, Jim, I think you succeeded. You didn't have to talk before lunch. Why don't we take a break for lunch. We'll resume at 1:00.

(The noon recess was taken.)

## C.2.7. Gamma Knife Risk Analysis —Mr. Shepherd

DR. BICKEL: Let me introduce Jim Shepherd. He's going to talk about some studies that have been done in the last couple of years regarding the use of the Gamma Knife.

MR. SHEPHERD: Before we talk about risk analysis, based on some of the questions that came out this morning, let's back up a step.

What is risk? And more importantly, how are we going to measure it? We go to a classic PRA. A risk analyst will tell you that the risk is the probability of occurrence times the consequences of the magnitude comes out with some number. So we have two components to risk. We have some occurrence, whether it's a frequency or a magnitude or a probability, whatever we use to measure that. And we also have some consequences of interest. And there can be a number of measures of consequence.

In the case of isotopes, we're concerned with is the total dose accurate? Is the location of the dose accurate? Or in the rare case, is it even indeed the patient the one to whom we intended to administer the dose?

So when we're doing risk analysis, there are a couple of questions we have to start with. The first one is why are we doing this? And what that really means is what specifically do I, as the manager directing the study, want to learn from it? What do I want to do with the results of this study so that when I pick my method, it will give me an output in a form that I can use. If I want to know should I go in Direction A, or should I go in Direction B, it's not necessarily useful if I pick a method that only calculates the probabilities of those two directions. Likewise, if I'm interested in selecting between two options which one will be most effective, then I need more numerical evaluations.

When we come to combining probabilities or likelihoods and magnitudes, the question that sometimes gets confused is are they dependent or are they independent? And what does that mean in terms of us?

In fact, they are totally independent. If they weren't, we couldn't do a probability times the magnitude to come up with the answer, because we'd be violating some mathematical rules of statistics.

What it means to us is that I can change either one of those without having any effect on the other. So if I come up and I say I want to have some kind of guidance that says this is an acceptable level of risk, be it for medical, be it for power plants, be it for automobiles or whatever, I can do things that will change the frequency of accidents. It might be training; it might be redundant hardware; it might be redundant instrumentation; it might be different computer program. But once the event occurs, I haven't done anything yet that would change the magnitude of the consequences.

Likewise, without touching the magnitude of—or the frequency, I can go in in the case of a car I put an air bag in. The air bag doesn't have any effect at all on how often there are car accidents, but it has a dramatic effect on what the results of those accidents are.

So as we start doing risk analysis, we need to know what are the goals of our analysis, and what kinds of things particularly we, as regulators, actually change in the practical sense.

So let's begin with a brief statement of what I see as the NMSS goals in the risk analysis project.

What we're trying to do is identify those aspects of the application of isotopes to people that contribute to risk and then determine what of those, indeed, if any, are the proper subject of regulatory influence.

There are a wide variety of methods that can be used to determine what the risk is or how it's measured. In the case of the Gamma Knife, which is actually a unique device, and I'll get to that briefly in a minute, it's not immediately clear how we are going to measure these risks. So we looked at a number of options.

If we take a classic probabilistic risk analysis based on event trees, fault trees, a lot of probability calculations, we came up with things, for example, discussions on data this morning that indicated that while this method is generally directed toward

probabilistic-type calculations, at this point in time, we don't have the data to support that level of detail.

Further, things like fault trees are really designed to tell us about multiple simultaneous failures of redundant and diverse hardware, and some human error, also. But by and large, we don't tend to have diversity and redundancy in the medical instruments. So the method doesn't directly fit.

HRA, the classic HRA using things such as THERP, was designed primarily to augment and to fit into the probabilistic risk assessment. Again, there is analysis of complex systems with complex procedures, not that things like the Gamma Knife aren't complex, but compared to a nuclear power plant, for example, where there are multiple systems that perform the same function, again, there's a little bit of a mismatch.

At the other end of the spectrum, basically, is the generically, we'll call it the expert opinion, which, using a Delphi technique, for example, we simply select a panel of experts and say what do you think the biggest problems are. And they tell us, and we get a good feel for those things that those experts have experienced in their use of the equipment. But this does not necessarily give us a basis for predicting what kind of things might go wrong, nor is it strongly oriented to telling us what kind of things we might use to regulate.

Practically it can be sometimes difficult to gain closure when you have a diverse group that's not sitting together. Something of a balance between those is known as relative risk ranking, which is really a framework in which we can take expert opinion, we can take what data we have, and we can do some amount of "what if" modeling. We can come up with semi-quantitative ranking scales.

We'll pick a number that will represent a range of things that can happen and then compare that to other things that can happen. This appeared to us to have promise to begin looking at devices such as the Gamma Knife, so that we could then focus our attention on issues that appeared important, and then do a more detailed analysis on those, rather than trying to do a huge analysis from the very beginning. As we have heard, the data collection effort can be horrendous. It's not clear what the benefits of collecting all the available data would be, so the idea of this method is to focus our efforts at the beginning.

To give you a brief overview of it, we identify some measure of risk, develop some type of logic model for the system that we're studying. In this case, it's the entire patient treatment system with the Gamma Knife, which begins all the way from the diagnosis.

Then we can evaluate what kinds of things, what steps within that contribute to the risk as we defined it.

Then we will, taking expert opinion and whatever data is available, put a relative scale on those items to determine which ones appear to be the major contributors.

And then more importantly is to iterate through this process until we get some kind of a stable model that says consistently these are the areas which contribute to the risk as we define it.

So that's a brief overview of the methodology and the approach we're taking.

For those of you who are not acquainted at all with the Gamma Knife, it's a unique device in that the radiation sources are stationary, and we move the patient around in order to get him in the right treatment position. It's simply a large cell with 200 Cobalt 60 sources and collimators fixed in place. The patient is then laid on a table with an alignment device, a helmet, slid up into a treatment position, time is measured, and then he's slid back out of the treatment position.

The actual focus of the radiation is determined by a set of plugs that are put in the helmet. Now plug in blocks the radiation; plug out allows the radiation through; and, that then gives a very small focal point generally inside the brain.

So we asked Livermore to look at this device to determine what they thought were the major contributors to risk. They started out with a multi-project, or a multi-disciplinary project team, in which we had a wide variety of expertise. Some risk assessment, but there was a fair amount of emphasis on input from the medical community, so that we would get an adequate representation of their feeling and their experience.

In the United States, Electa Corporation is the manufacturer and distributor of these devices.

Electa and Livermore worked quite closely through all phases of the project, in order to determine how the system operated, where the weaknesses were, what kinds of things could be done to fix it. This is just a brief listing of some of the major interfaces they had with Electa.

To take the relative risk ranking methodology and apply it, they have these following steps:

The sequences that were identified as basically the process of handling the patient from the time the treatment is defined through the imaging, placement of the stereotactic frame on into the placement in the machine, the timing and the treatment back out. And generally there will be multiple treatments for a single event.

Hazards, there is a difference between a hazard and a risk. And we get a little bit into semantics, but every technology has their own. A hazard is a potential for something to happen. For example, if you're driving down the road in your vehicle at 65 miles an hour with a full tank of gas, there are at least two hazards there: One is the fact that you're in a two or three or four thousand pound vehicle going 65 miles an hour, and if that doesn't seem a hazard when you're inside, think about something outside seeing that coming towards them. There is certainly potential there. And when we have seen, in cases of severe accidents, where the gasoline will explode and create a much worse situation than if it hadn't.

Those are hazards. That's not the same as the risk, which is the consequence rate, some combination of the consequence and the frequency.

The hazards that we looked at for the Gamma Knife are identified. Of course, the radiation, the hydraulic pressure. The hydraulic pressure that moves the gate, the front door to the machine and, also, moves the patient in and out. Electrical systems, control systems which can inadvertently actuate the system, and then there's simply the mechanical pieces of the equipment that could possibly fail.

Looking at the sequences that Livermore identified, they are related to three major areas: One is the quality assurance of the system to begin with, has the dose been measured properly, and we talked earlier about the radiation treatment plans. Is the source really what the manufacturer says it is or what we compute it to be, and so on.

There is the treatment path. One of the bigger areas, it turns out, is actually taking the location of the aneurysm or whatever is being treated and translating that into a three dimensional coordinate system that gets fed into the treatment plan.

One obvious error is reversal of the film. I know in one pretreatment room, the camera is on one side, the other one is on the other side. The plan calls for them to be treated in Room 1. Well it was busy for something else, so the patient is imaged in Room 2, and a question inspector asks, well how does the treatment planner who's entering the data in the computer know this? The answer is, well, I tell him. What if he isn't here? I put a yellow sticky on his computer terminal. Yellow stickies are wonderful, but they're not infallible.

Another problem that comes up is in the third dimension, the Z dimension, because there's a scaling factor between the film and the coordinates that go into the system. And that seems to be a problem that comes up again is does the technician actually get that scaling factor correct.

There are abnormal events during the unit operation, for example, the patient being stuck in a nontreatment position. Interestingly enough, in the nontreatment position, the patient is going to get considerably less radiation than they would if they were in the treatment position, because they've got this huge steel helmet up there that protects them.

So the kinds of things we would look at for abnormal operation is the patient stuck in the treatment position where they are continuing to get the full dose and we can't get them back out.

One other thing that was found was generally when the door is open, because of the shape and placement of the sources, they consider anything coming out to be purely scattered. It turns out there was one spot just below the carriage into each side which, in fact, focused that, and there was basically a fairly significant stream of radiation coming out. This has since been corrected in all of the units in the U.S.

But these are the kinds of things that were identified in the sequences.

On the relative ranking, what they came up with was a relative scale of consequences ranging from, I'm going to call it, a one if there's no conse-

quences. I'm going to call it a five if there is severe damage or potential of fatality.

There's then a similar ranking scheme for frequency. You know, zero to five patients, five to a hundred, a hundred to two hundred and so on.

DR. BLEY: Jim, can I back you up to that last viewgraph you had? You don't need the viewgraph, but did you say that this analysis of scenarios identified this area where there was focused streaming? And my question was don't they measure around that thing?

MR. SHEPHERD: That would be stretching it a little bit. Because of the study going on, these measurements were made.

DR. RATHBUN: They were taking photographs of a phantom. They were just doing different dose calculations during the acceptance testing at the University of Rhode Island. And they actually brought that to the attention of the physicist, who then took it on, and that's been published in the Gamma Knife literature widely. But that was a pretty significant issue to be uncovered in the course of a risk analysis study.

DR. BUDNITZ: How many devices are there like this normally?

MR. SHEPHERD: Twenty-four.

DR. LARSON: About 55 now, and there's 60 been ordered, not all installed yet.

MR. CAMPER: In the case in discussion, two of the—two of the Cobalt 60 sources, the collimator—it does not meet the design specifications. The beams were off track on two of the 201 sources.

MR. SHEPHERD: This is an example of a piece of a sequence that's used for a task where there's some task number which is a discreet step in the process of treating the patient. In this case, take the skull measurements. These two, whether they're supine or they're prone, not only in Gamma, but in others, have been important in contributors to misadministration, which side of the image are you really looking at.

How often this happens? Performance standards, how much tolerance can we really allow before we start to get to something that would approach misadministration. Now the current rule says plus or minus 20 percent. In the case of the Gamma Knife, where we have very high doses, on the order of, what, 2500 R per hour at the treatment position? If the location is off by 20 percent, in some parts of the brain you could very rapidly be approaching lethality. So this performance standard is something that needs to be looked at. Should it or should it not be subject to regulatory guidance?

The physical equipment and, also, the software where the pieces of paper, as Jim said just before lunch, one of the problems they identified is translating the information, not to be confused with the data, but the real information from one step to the next, so that each person in the sequence understands what's going on, not that they just necessarily have all of the data.

How the people who are doing the job learn to do that job. And we get into questions like what should the training requirements be? Should there be certification? Is it not necessary to do certification? How much on-the-job training is required? How much oversight by a licensed person is required, and so on.

And, also, when we identify errors, what would resolve that kind of an error? Is it more training? More practice? Change the form? Change the basic requirements for the individual doing that kind of function to be different, so they would better understand the thing, and so on.

So what they did is, they took this kind of a sequence for each step going through the Gamma Knife, and I don't have time to go through all 40 or so of them. And they assigned, using these relative ranking scales of probability into consequence, relative consequence, to each of them.

And what we come up with is a profile that looks like this. And you'll find this, if you can't read this one, you'll find it in, I believe, Section 3.4 of the paper which is in the back of the manual.

So this gives us a feel where we use the word probability, take that loosely. This is not probabilistic in the statistical sense. Increasing consequence along this line. If we then say we're now going to combine probability and consequence to determine what the risk is, we get a profile that looks about the same. But now what we have is those things that are higher are, in fact, the things

that are calculated using this model to be the more significant contributors to risk. We can then pick one of those. We can then step back and see is it a contributor because it's a higher probability, or is it a contributor because it's a higher consequence?

In Section 3.5 of the report, Livermore reports on an interesting study they did using a Monte Carlo technique, which is a fairly standard technique of sampling for different error rates and putting them together, and looked at what are the major contributors to a particular sequence and what happens if we adjust that.

And, in fact, what they looked at was the imaging question again, and they said if we devise a system where we no longer have an error in the Z coordinate, it would significantly drive the total risk down.

Given the time limitations, that's all I was going to say at this time. We can talk about it more in the workshops. If anyone has any questions, I'll try to address them.

DR. WU: When you talked about consequence, what do you mean by severe consequence?

MR. SHEPHERD: In this case, the consequence is in the opinion of the person being asked. It's generally looking at what are the effects on the patient of this error.

Now the thing we have to be careful of is what do we, as regulators, try to measure? Do we get into the area of biological effect? At this point we have not. We have simply said the physician has prescribed a dose, and we're going to measure the actual compared to that prescription. And if it's outside of the 20 percent bound, we say it's wrong. And if it's inside that bound, it's okay.

It's an interesting question in the case of this device, where you have extremely high doses in sensitive parts of the body, where 20 percent may or may not provide adequate protection for the patient. So it's still a question.

DR. BLEY: The one bar chart you put up there is kind of a disturbing one, the one that had increasing consequences on the X axis and probability.

In most kinds of activities, just by the seat of the pants I'm worried about this more than that, we put either more reliability or more checks in place, so this kind of a curve, as consequences go up, they're less likely. Even when we haven't done a PRA ahead of time. This one doesn't work like that at all. Have you thought about that? Can you give any thoughts on it? Is it that these are all real bad? From that other scale you had, the ones on the right are a whole lot worse than the ones on the left. Is it that they're just—

MR. SHEPHERD: On this one what we've said is this is lower consequence.

DR. BLEY: Well, the one was lower—

MR. SHEPHERD: This is a higher consequence.

DR. BLEY: And kind of severe at those numbers, I think, from your other chart. Maybe not? So maybe we don't care much about any of these?

MR. SHEPHERD: I wouldn't say we don't care much about any of them. The one that is more interesting is actually the other one that looks at the risk, the relative risk, where we combine those two. And now those that are bigger are the ones that are of more interest.

DR. BLEY: Not ordered them by consequence now. You've ordered them by risk.

MR. SHEPHERD: No, these are simply ordered by task number. I could reorder the task number—

DR. BLEY: Let me disagree. That other one I find real interesting. I find it curious that there aren't things—if I had generated a result like that, I think what I would have really worried about is why it turned out that way. Is it real? Are people not thinking about safety? This is a procedure we only use for the desperate, so it really doesn't matter? I'd just be real curious about it, and I'm wondering if anybody has pursued that. I know the authors aren't here.

DR. RATHBUN: Is there a concern that you see highly risky sequences, and your question is how did it happen that those things are so risky?

DR. BLEY: My concern is that the things that have higher consequences aren't less likely than the things that have low consequences. Usually when we—

DR. RATHBUN: That's right.

DR. BLEY: When we design a process, a treatment, a machine, we pay more attention to the things that can do more harm. And it doesn't look like that happened. Maybe the analysis isn't right.

DR. RATHBUN: Yeah..

MR. SHEPHERD: Exactly the reason I brought up at the beginning the idea of probability and consequence are, indeed independent.

DR. BLEY: But when we build things, we worry about them.

MR. SHEPHERD: When we build things we have to build in redundancy so that we drive down one or the other.

DR. RATHBUN: At the time that this work was being done, we had a very loose grasp of this whole consequence thing. I mean, in fact, the Idaho laboratory was forbidden to deal with it, you know, they're really nice guys. We said, "You just deal with departures from what the physician prescribed. Don't be worried about how dead, how hurt, you know, nothing biological."

Now Livermore went a little bit further and, basically, started to move into that area with their kind of combined indices thing. Hopefully, and I wouldn't put a lot of value in the results per se of what you see up here. It's more that we tried the method. It's more that we tried to begin to take another step toward it.

We're hoping now with the new—with new players being introduced who are more familiar with medical, we can actually get into that.

So, you know, I thought it was a great methodological exercise. We got the profiles. I don't know that I would really buy off on any of them, if that's what you're asking me.

DR. BICKEL: The other thing, it's also conceivable that in some kind of a complicated engineered system that you haven't systematically gone through and studied, that you could, in fact, find a high consequence, high probability outlier that maybe wasn't really thought out.

DR. BLEY: This isn't outliers. This is kind of completely random—

DR. BICKEL: It's random. I think it may be more characteristic to say that that was a screening. That was an attempt to try a method.

MR. SHEPHERD: Now remember, we're talking about relative risk. Nowhere have we anchored this thing, so all we can say looking at that particular chart, for example, is procedure 1.5 or maybe 2.9.1 is higher than the rest of them. But we haven't said how high that is.

DR. BLEY: I'm still looking at probability versus consequence.

DR. WU: I think it's a matter of scale. That's why I asked what we mean by consequence. In the inverse curve we're talking of long scale. Now here we don't know the scale. If it's linear, then it doesn't matter too much, because they are the same range.

DR. RATHBUN: Time out here, time out.

MR. SHEPHERD: I don't want to get into the specific results—

DR. RATHBUN: Right.

MR. SHEPHERD:—because the results of this study were not to analyze the Gamma Knife and come up with guidance for the regulatory agency and say here's how we have to go in and start regulating Gamma Knives.

DR. RATHBUN: And the goal of the workshop is to take these types of things as they appear from the work that we have in front of us and say, well, that's probably not a very good way of presenting that, because it doesn't demonstrate sufficiently the magnitude of this issue. Or relative risk profiling is probably a nice way to present things, but without much more data, et cetera, et cetera, you know, this is what we're really here to do.

But we've had—this has actually come up every time I've ever seen anybody try to present this particular slide. And I expect that one of the things we're looking for is ways to move on now past where we have been sort of stuck.

DR. BLEY: I won't pursue it anymore.

DR. RATHBUN: That's all right.

DR. BLEY: The reason I brought it up, though, was it's the kind of a piece that if I were doing the study, or if it were my machine, or I was

using it, I'd look at that, and I'd say either this isn't telling me the right thing, or something is really wrong about the way we're operating. And it would have been a focus to think about what else to do.

MR. SHEPHERD: Yeah, or it could be that there's a problem with the system. It could be there's a weakness with the methodology.

DR. BLEY: Yeah, and that's what I'm saying. Did anybody think about that?

DR. RATHBUN: This is risky to even present this here, particularly when we have members of the medical community who deal—a member of the medical community who deals with this every day, because we did promise that there is really no numbers attached to this. It's just a method. You know, this could be something totally different.

MR. SHEPHERD: I'd say one more thing. If we get into probability space, and we're talking about things down to ten to the minus five or ten to the minus six range, a factor of two isn't really a real significant difference. You know, given the level of data that we have, you can't measure it. So when you look at this chart even on a relative scale, if you don't see a factor of two, it doesn't necessarily mean that there's any real difference.

MR. PRATO: I can just mention one example to you afterwards. I think I've thought of an example of a case where probability and consequence with the Gamma Knifes. I'll tell you afterward.

# C.3. MEDICAL SESSION

## C.3.1. Introduction and History —Dr. Holahan

DR. BICKEL: Moving on, I would like to introduce our next speaker, Trish Holahan from NRC.

DR. HOLAHAN: I'm Trish Holahan. I'm with the Medical and Academic Section, and what I'm trying to do is we've heard a number of talks on the risk analysis, and now we're going to hear a couple of talks in terms of the medical implications and the medical consequences and current QA and QC procedures for a lot of these medical devices. And what I'd like to do is give you a little bit of history of where we've looked in terms of risk of misadministrations and sort of what we've been looking at as far as regulations that we've got today.

In the past, there really hasn't been any quantitative analysis, in terms of the estimates of risk of a given misadministration or misadministrations, and the first misadministration reporting rule was in 1980, and we were more concerned with just a collection of data to look at the frequency of misadministrations and look at it in terms of what the root causes were, whether or not there were generic implications, and what actions needed to be taken, if any.

With the development of the QM Rule, which was effective in 1992, there was starting to be a limited quantitative analysis of the consequences of the errors, but again, in terms of looking at the consequences, there were a number of public meetings, looking at both medical consequences and also just the fact that an error had occurred. And the thresholds that were established considered harm, but they were set at levels—the levels that were established in the QM Rule for misadministration reporting were below that at which harm was detected.

For example, for the brachytherapy misadministration it was a threshold dose of 20 percent deviation from what was prescribed. And these were based on comments from the public meetings, levels at which no adverse effects were expected. But it was significant enough to indicate that there was an error.

There was also an internal mechanism for licensees to keep recordable events, which was an even lower threshold, ten percent in the case of brachytherapy, which was sort of a trigger to indicate that there was a problem, they needed to look at the system, but it wasn't necessary to report it to NRC.

So, again, the QM Rule focused on those administrations of byproduct material that had more of a consequence in terms of risk. The QM Rule didn't impact on diagnostic nuclear medicine, with the exception of diagnostic sodium iodide, primarily because there was very little risk if there was an error, unless it reached a certain threshold. And there is a definition of diagnostic misadministration which has a whole body threshold of five rem or an organ dose of 50 rads.

The QM Rule applied to teletherapy, which includes the Gamma Knife; brachytherapy, both manual involving Cesium 137, I-125 permanent implants, Gold 198, permanent and temporary implants; and, also, the remote afterloading, both low dose and high dose rate remote afterloaders. It also covers eye plaque, I-125 eye plaque therapy, Strontium-90 eye applicators; and then in the nuclear medicine and in radiopharmaceutical therapy environment, radiopharmaceutical therapy and sodium iodide both I-125 and I-131 involving greater than 30 microcuries.

Again, this dose was picked because an error in excess of this could result in a dose to the thyroid of 50 rads or greater. Again, it was based on an organ dose.

As Jim just mentioned, risk is sort of a combination of probability and consequence. And it's important, and I believe Dr. Grigsby is going to get into this a little bit more, in terms of not to equate the consequences of a medical consequence with the consequence that an error has occurred. ICRP has traditionally looked at the probability of an event occurring with a potential loss and consequence primarily dealing with the risk of cancer induction, while again, in terms of radiation ther-

apy, the majority of patients already have cancer. There is a probability associated with them developing secondary cancers from the actual treatment and, therefore, again, the focus of the QM Rule was looking at deterministic effects or effects other than cancer or genetic effects.

Again, as we have just heard, there are two ways of measuring these consequences, the biological or the medical consequences and this—these are going to depend on a variety of factors, the dose, the organ, the dose rate, the medical condition of the patient, other treatment that the patient is undergoing. I'm sort of going to touch on those very briefly, and I believe you'll hear more about those later.

Then the other way of measuring the consequences, which is a primary way our risk analysis has been going so far, is the occurrence of an error or a deviation, anything, for example, greater than 20 percent. The focus of the QM Rule was to provide high confidence that the dose delivered was in accordance with what was prescribed by the authorized user.

Now there are two types of errors associated with that. If it is somebody other than the authorized user delivering it, you could have that error and, therefore, it's not being delivered in accordance with the authorized user. We have also seen errors where the error is made by the authorized user. But it was not what was originally intended.

Also, in considering risk of an error, you must also take into account the risk that's associated with the prescribed treatment. Again, in the medical field, the patients are being deliberately exposed to radiation. There's a certain risk associated with that. There's a certain risk associated with not having any treatment at all. So these are all factors that impact on the overall risk.

Now I'd like to sort of briefly go through some of the types of events that we have seen to date. We talked earlier about the misadministrations that we have seen, and over the last two years of misadministrations that we've investigated or gone out on inspections have almost all been related in one way or another with a failure either to implement or to follow the licensee's quality management program.

The brachytherapy events that we've seen, there have been computer errors, there have been misplaced sources, both with manual brachytherapy and, also, dislodged sources with manual and with high dose rate brachytherapy, patient intervention. For example, endobronchial HDR treatments, sometimes the patient will pull at the tube, dislodge it, coughing. It's not a direct deliberate action, but you can have an inadvertent patient intervention by the coughing. Some of the gynecological applicators, they have been dislodged or pulled out by the patients, and then there's the human error factors in terms of dosimetry, the actual administration, treatment planning. There's a number of other factors involved in that.

As far as the Gamma Knife, the types of errors that we've seen are observing problems with the timers, and then, also, with the X-ray film being inverted and being forced in in the wrong fashion and the wrong side of the brain being treated. Those are the primary types of errors that we've seen with the Gamma Knifes.

The numbers, we've talked about these a little bit earlier. These are the therapy misadministrations over the last four years, and this is only in NRC's data, so this is about one-third of all the licensees. As we discussed earlier, we are starting to get some information on the agreement states, but we don't have a lot as yet, and it doesn't come in necessarily as quickly as the events occur. So the information on the agreement states is not always quite as up to date. About six of the agreement states, as of a month ago, have adopted the Quality Management Rule, so they now have these same reporting requirements as the NRC states. But that still leaves 23 states that have not yet adopted the QM Rule and, therefore, are under the older definition for misadministrations.

But there have been—it's hard to say if this is a real change in teletherapy. I think in '92 we saw an increase here with the number of fractionated teletherapy misadministrations, based on the weekly dose.

Brachytherapy, both in manual and remote afterloading, we've seen an increase in brachytherapy misadministrations.

Now what's not included in this chart for the afterloading is the errors in the fractional HDR doses, as currently these are only based on the total dose, so if there's an error of greater than 20 percent in a single fraction of HDR, but the total dose is not exceeded, it's not by definition a misadmin-

istration. But this is obviously still an error that there's a risk associated with, and at the recent meeting of the ACMUI it was discussed and probably has as great a consequence in terms of medical implications as an error in the total dose.

And then this is radiopharmaceutical therapy, I-131, and other radiopharmaceutical therapies increased.

Now what NRC also has to—or keeps in mind in the development of all regulations is in 1979 the Commission issued a general policy statement on the medical use of radio isotopes. And the first—it contains three items. The first is that NRC will continue to regulate the medical uses as necessary to provide for the safety of occupational workers and the general public.

The second item is one that I'd like to focus on is that the NRC will regulate the radiation safety where justified by the risk to the patients and where voluntary standards are not acceptable, or are inadequate.

And finally the third statement is that NRC will minimize intrusion into medical judgments affecting patients and into other areas traditionally considered to be part of the practice of medicine.

So with all the rule makings that we are either currently underway or have recently developed, we need to keep in mind the medical policy statement and look at if we are in agreement with these three statements.

So that's all that I really wanted to say. If anybody has any questions?

DR. GLASGOW: You didn't comment on the important second part of the second directive.

DR. HOLAHAN: Voluntary standards?

DR. GLASGOW: Which is voluntary standards. There are, of course, voluntary standards being developed contiguously by various agencies—not agencies, but various organizations. What is the mechanism by which the NRC determines whether voluntary standards are adequate or whether or not they're being widely adopted.

DR. HOLAHAN: Well, actually we are currently in—Larry Camper addressed this earlier—looking into a major revision of Part 35, which is the medical use of byproduct material. And one of the—during the development of that revision, we are going to hold public meetings and talk to the various professional organizations and societies and look to see what professional standards are out there or what voluntary standards have been developed. And where possible, refer to those standards in terms of regulations.

So we are trying to, first of all, glean a feeling for what standards actually are in existence, for example, for remote afterloading. And I know AAPM has just recently come out with the Task Force Report. I understand ACR is currently developing some standards for QA\QC, and I am aware—so we are looking to the professional organizations for input with regard to that and to what extent those are being adopted.

DR. GLASGOW: In risk analysis, I'm sure many of those in the room can comment better than I can, but there are always levels in any technology at which we deem the technology to be either generally acceptable or non-acceptable, based upon the risk of the number of unplanned events out of a certain number. This is risk analysis well understood, ten to the minus one in a million, one in a hundred thousand, so on and so forth. At what particular point from the NRC's viewpoint, do you have a sense that the risk—your number of misadministrations up there is only one part of the equation.

DR. HOLAHAN: Correct.

DR. GLASGOW: If you were to analyze this from that particular viewpoint, how many misadministrations have occurred per hundred thousand procedures? Do you have a sense for what risk threshold you think requires standards by the NRC?

DR. HOLAHAN: Okay, well first of all what I'd like to say is we do have some, we discussed the denominators a little bit earlier. The frequency of occurrence in terms of the relative rate of misadministrations is on the order of about ten to the minus four, between one and three times ten to the minus four.

Obviously, that's primarily based in terms of teletherapy, that's number of patients, not number of administrations.

DR. GLASGOW: And if I'm not mistaken, that is sort of the general level of acceptability of the technologies, is it not; or is that too high?

DR. HOLAHAN: I don't have the direct answer to that question, I mean somebody here may be—

DR. GLASGOW: As a member of the public, we generally don't accept that.

DR. HOLAHAN: What I was going to say, and we have been asked this question as to the rate, and we've indicated that it is not just the rate that indicates the risk, but also the consequences. And we're looking at the generic implications. I mean, it could be that something happened to the very very low rate of frequency, but if that incident does result in a patient death, then the consequence is particularly significant.

So it's more than just the rate of occurrence of that event to look at the risk. I mean, we have to take into account what the probability of something happening and also what that consequence is.

DR. GLASGOW: Obviously patient death, either in the short term or in the long term is the real pinpoint in almost all the risk analysis that's done, in looking at risk in other technologies for the most part.

DR. HOLAHAN: That's right. However, a lot of them are done, as I mentioned earlier, in terms of mortality with cancer. We can't necessarily use that in this case, because a number of the patients already have cancer, and there is a certain risk associated with the treatment in and of itself.

But we're talking about the risk due to the errors. The other thing I didn't mention is that there is also a risk associated with an underdose, which isn't due to the radiation, but can have just as devastating consequences to the patient as an overdose.

## C.3.2. Treatment Variations—Dr. Grigsby

DR. BICKEL: I think we could suffice to say that there is not an equivalent safety goal that the Commission is going to take—I was going to say on the reactor side of the NRC, took the Commission possibly, oh, eight, maybe about eight years to put together a safety goal on what they were trying to achieve with the regulation and have available with regard to comparing any proposed changes to regulations again. Maybe in, you know, five, five to ten years from now, there may be an equivalent one, but you obviously need a greater basis of research data and, you know, people looking at, you know, relative risks of treatment versus nontreatment, you know, to have that kind of a framework where they can really do that.

I think activities like some of the research that has been started in the last couple of years may lead to the ability of the NRC to have a safety goal for medical use of, you know, radio isotopes. It's a complicated thing, because, yeah, you've got source material that's being used to treat cancer, and then you've got linear accelerators maybe right across the hall, and they've got a different set of standards and goals, although it's still doing the same thing, which is trying to dose a tumor.

I'd like to move onto our next speaker, who will be discussing just kind of that subject. Perry Grigsby from the Mallinckrodt Institute of Radiology will be talking about what we do know about the effects of doses on tissues—

DR. GRIGSBY: What we don't know.

DR. BICKEL: What we don't know.

DR. GRIGSBY: I hope I didn't make too naive of an assumption and tell you guys a lot of stuff you already know. I've got a couple of questions. One is, there are different ways that one can—that a physician can become an authorized user. But one way is to be certified by the American Board of Radiology. And to be certified by the American Board of Radiology, we've discussed today the—if we exclude the external beam and the stereotactic, we've discussed several different types of brachytherapy, including radiopharmaceuticals. And the question is, of all these different kinds of procedures, how many procedures do I have to be experienced as a resident in training before I can be certified by the American Board of Radiology? What number of procedures? I mean, there's a minimum number of procedures to date that the accreditation guidelines say there's a minimum number of procedures. That can be any combination of the different things that we've talked about. We've talked about many different things. What is the minimum number of procedures?

DR. CALLAN: You're asking us?

DR. GRIGSBY: Yeah.

DR. CALLAN: A guess, four.

DR. GRIGSBY: Pretty close. I think it used to be two or three, but now it's ten. So in four years of training or three years of training, I can watch somebody do ten procedures and go out and do these on my own. That's right.

DR. CALLAN: At that point you are certifiable.

DR. GRIGSBY: You've been talking to my wife, haven't you? Dad gummit! Well, you know, you do ten procedures and you spend your three years and take the exams and become authorized.

The other question is, let's say I have high blood pressure, and I go to my internist—or I go to my internist, and he says, "Gee, you got high blood pressure and you need some treatment." And he says, "I'd like you to try this medicine." And he says, "Here are the risks and the benefits of this medicine", and I just accept those. I listen to him. I don't ask a lot of questions. And he tries it for a couple of months and it doesn't work, so I go back in a couple of months, and he says it doesn't work, we're going to try Medicine B. Here are the risks and benefits of this medicine, and we'll try it for a couple of months and come back in two more months. And I go back, and it didn't work, and he says we'll try Medicine C.

What's the difference in that and what we do with radiotherapy? Radiotherapy, once it's delivered, we can't take it back. You can't change it; you can't take it back. There's nothing you can do about it. Once it's delivered, it's always there. It's like a surgeon performing an amputation of a limb. Once it's gone, it's gone, and you can't put it back on.

This is a slide demonstrating the concept of how we look at solitary tumors, with the largest concentration of the tumor cells in the center. And we have a lot of names, both for external beam therapy and for brachytherapy on what these different volumes are that cover the different known or presumed densities of tumor cells.

So if I go to do a brachytherapy procedure, and I put an applicator either inside the lumen or a body cavity or some interstitial needles into a solid body part with these tumor cells present, then the placement of that, setting aside the issue of high dose rate and the catheters moving and whatever, just the mere placement of that is based solely on my judgment. And none of this assessment assesses my judgment in that placement, I think. Right?

DR. RATHBUN: Right.

MR. TORTORELLI: Right.

DR. GRIGSBY: That's one real part of all this, and I don't know the answer. Maybe the answer to the judgment issue has to do with training that one receives. I really don't know. But none of this addresses that particular issue.

DR. RATHBUN: Right.

DR. GRIGSBY: Pardon me? MKS—Medical Knowledge Systems in Detroit?

Well, just, you know, like you have to change the rules and the regulations, we have to change the names of the units every couple of years, so now it's centigray instead of rad.

This table, the purpose of this, and this is for external beam therapy, but the purpose of this is curative doses of radiation for different tumor types, and there's a wide variation. Men that do have pure seminomas perhaps receive 2,000 or 2,500 centigray, and they're cured. But other patients receive much larger doses, and with the intent of being cured.

So, again, within the spectrum of the sensitivities of different cancers to different doses, and then, you know, what's a 20 percent error here compared to a 20 percent error here? There are marked differences. But, again, these numbers are for external beam therapy and not brachytherapy.

Our goal and objective with radiotherapy is to have a percent tumor control, and our information over the years is that this is a sigmoid-shaped curve, that as we have increasing dose, there's a portion of the curve in which the slope is fairly steep, and then it plateaus. And we'd like to have a tissue damage curve that parallels it, but it's far to the right. But that's not always the case. There could be the possibility that this curve could be to the left.

For example, we have patients with carcinomas of the cervix in which brachytherapy is routinely used. They're cured of their tumor and have

a relatively low overall complication rate. Patients with melanomas or osteo sarcomas, which are relatively radio resistant, few of them are cured, be it with external beam, but few are cured just simply because not enough dose of radiation can be given to avoid damage to normal tissues.

The other point is that on this curve of tumor control, the deviation of 20 percent, one possibility is the most common one or the one we assume is tissue damage from an overdose. But you can slide right back down the tumor control curve, if there's a 20 percent underdose. And the consequence of that is—long-term consequence of that could be worse than 20 percent greater, depending on the situation.

Again, an example would be a lady with carcinoma of the cervix. A 20 percent greater brachytherapy dose might result in not death and not a second cancer, but a bowel or bladder problem that might result in a permanent colostomy or permanent artificial bladder, whereas a 20 percent decrease in dose might result in an inability to cure the cancer. And once that occurs, then that's not curable and death results.

Now these two curves are sort of the simplest to model or the simplest two models to go on. Another confusion factor then is to throw in chemotherapy, and that's what these dash lines appear to represent. And I don't think any of us know exactly where these curves fall.

So today we've been talking, or we've been assuming we're talking purely about patients that receive radiotherapy, but if patients receive chemotherapy at the same time, which a lot of patients do these days, then these tumor control curves and normal tissue curves will change to some degree, usually resulting in more normal tissue complications than without the chemotherapy.

Another point I was asked to address was dose rate, and this slide is dose rate as it relates to external beam therapy. And if you'll bear with me just a minute, I'll try to explain this.

This is the fractionation schedule of conventional external beam therapy. Five treatments Monday through Friday for one, two, three, four, five, six weeks. Now a different way of doing that would be what we call hyperfractionation. Instead of getting a 200 centigray a day five days a week for six weeks, we give 115 twice a day. Or another way might be accelerated fractionation or modified accelerated fractionation or split course. There are many different ways of giving a dose of radiation to cure the tumor, and if you multiply all of these out, these numbers don't add up to the same total number. Presumably the effect does, but the rad number doesn't add up to the same number.

For brachytherapy, we have continuous low dose rate brachytherapy. Again, the example of cervical cancer. A lady may have two—she may have a low dose rate implant continuously for 48 hours and have a second one two weeks later. And that would be the brachytherapy portion of her treatment. Or she might have a high dose rate treatment, one a week for five weeks is a possibility. Or one scenario would be the pulse dose rate machine in which presumably they get the low dose rate treatment, maybe given twice at two-week intervals, but then the radiation is given in doses of pulses.

The example this morning, looking at severity and you came up with a delta dose, when I read these materials over, I thought well, gee, that's not a bad way of looking at it. You couldn't look at percent dose, and I kept thinking this delta dose would be okay. The problem with that with brachytherapy is you can't mix high dose rate and low dose rate together, because delta dose is just the difference in what was given and what was intended. So if you stayed with that model, you'd have to separate the two. You would have to separate the two.

I have to ask Dr. Stitt, the Point M that you all used for high dose rate, just the brachytherapy portion, that number would total how much?

DR. STITT: It depends on the stage. In our fashion of doing things, it would be 45 gray to two gray.

DR. GRIGSBY: So two to 45?

DR. STITT: Yeah, for a total course.

DR. GRIGSBY: For traditional low dose rate, then it would be maybe four to 65, so the schema in which dose is given, either high dose rate or low dose rate, is going to result in an entirely different total number.

So if you look further at the delta dose, the two things will have to be separated out.

Again, with regard to consequences and patient tolerance to radiation, the worst consequence, or presumably the worst consequence that we've talked about, would be death. Another measure was the chance of a second malignancy, which I would put low on my list as being relevant issues. The relevant issues are the tolerances of individual tissues. If a brain implant was done, then the patient could suffer—and a misadministration occurred, then the patient could suffer necrosis of the brain. And if they're lucky, perhaps they would expire. If not lucky, they could suffer the consequence that's worse than death.

This table is not—these numbers aren't meant to be taken as absolute, but they are whole organ external beam radiation numbers for tolerances to tissues. This is the end point of the complication, the TD55 and TD550 are the five and 50 percent incidents range for these things to occur. And you'll see that these complications or end points, colitis, mucositis, nephritis, these are all sort of acutely occurring problems and are not, what we call, long-term sequelae.

See, if at our institution, if we have a misadministration, I think I have to submit a written report within like 15 days, 30 days—15 days.

DR. RATHBUN: Yes.

DR. GRIGSBY: And when I do that, I have to report what the consequence of this misadministration was to the patient. But in all honesty, if a patient has received a large enough dose, you know, I may not know what that consequence is until weeks, months or perhaps even years later.

And this is an example of when we, at our institution, when we obtain an informed consent from the patient, we divide it into two areas, an area of acute side effects of the treatment, and then an area of late side effects or possible late complications that patients could suffer.

So the acute effects are something we might see with a brachytherapy misadministration, but some of these severe long-term consequences could result, and that's in explaining or trying to explain the informed consent to the patient, the radiation therapy oncology group and other cooperative research groups have developed sets of criteria by organ site for side effects and complications. And by no means am I going to go through all of these, but just to show you, there are organ sites, and then the severity levels are graded similar to what we are looking at for the stereotactic, zero for none, all the way up through four or five, which would be death. And these can be acute, or as in this table, it can be late effects, just depending on what the time course of the events occur.

So from a point of view of medical-biological consequences to the patient, I would suggest that you continue to look at the dose variances that you did. That might show something, you know, really interesting, especially if you separate high dose rate and low dose rate.

But the punishment that an institution receives or the fine from the NRC is based on this kind of system, right?

DR. RATHBUN: Right.

DR. GRIGSBY: It's the grading of the severity of it based on an entirely different set of criteria. But the biologic and medical consequences of a misadministration, I think, would have to be rated in this manner, as well, zero to four, zero to five.

MR. CAMPER: Does that translate into a different percentage error threshold for brachytherapy? For example, as compared to HDR, for low dose brachytherapy? I mean, today we have it 20 percent. It's an error threshold other than was intended. Do I believe in that? Do you think brachytherapy percentage tolerance is not the right number, should be broader as compared to HDR because there's greater consequence?

DR. GRIGSBY: Are we talking about the 20 percent number?

MR. CAMPER: Yes.

DR. GRIGSBY: My opinion of the 20 percent number is that it's a very reasonable level, and should 20 percent be different for low dose rate versus high dose rate, I don't know, probably not. But then it depends on whether we're talking about total dose or dose per fraction.

MR. CAMPER: Right. It's currently written, except for teletherapy, we do have fractionated, which is the lower level. But for brachytherapy and HDR we currently only deal in terms of total does.

DR. GRIGSBY: See, my medical judgment would be, let's say, again, we have a lady with

cervical cancer, and my intent is to do two low dose rate brachytherapy procedures, and to just make the numbers easy, let's say it would be 4,000 plus 4,000. And if I exceeded the first one by, say, 25 percent, that would be 5,000. And so I'd make the second one 3,000.

DR. BUDNITZ: If you knew it, you wouldn't care how much, huh? But you'd have to know it.

DR. GRIGSBY: And my judgment would be that the medical consequence of this one versus this one is pretty much the same. But now Dr. Stitt can tell us, would—

DR. STITT: Let's try some numbers. Boy, I just—

DR. GRIGSBY: How many implants do you do for cervical cancer?

DR. STITT: Five. Let's say we do ten gray per fraction, ten gray times—make it centigray, so 1,000 times five, five fractions is going to be 5,000. Now make—

DR. GRIGSBY: Would you do it 1,200 times four?

DR. STITT: No.

DR. GRIGSBY: See—

DR. BUDNITZ: But if the first one was 1,300 and you knew it, you wouldn't care very much.

DR. STITT: Thirteen hundred makes a lot of difference if your rectum is sitting right behind it.

DR. BUDNITZ: Well, let's say you're doing 200 every day. There must be some difference.

MR. CAMPER: Just for the gratification of the audience, when we went through and developed the current reporting threshold, and we assigned the 20 percent value and the ten percent for Gamma Knife and ten percent for fractionated teletherapy and what have you, the kind of discussion we're having here right now is the very kind of discussion we got into. Now we were meeting with the AC, the American College of Medical Physicist and the AAPM, the American College of Radiology and a lot of very experienced learned folks in the room. We were trying to come up with what's the right number.

And when you get into brachytherapy, because of the body part being treated, its size, the tumor volume, a litany of things, you get into some real problems as to what's the right number to settle on. So we settled then on these percentage error thresholds, which were essentially a doubling of what had previously been misadministrations, which are now reportable incidents, and these were because in the final analysis, the general feeling was amongst these groups that were meeting was that what we can put our hands around is a standard or an area, if you will, that most of us would say it's unacceptable in our practice, because we get into all kinds of problems.

The one exception to that threshold that Trish Holahan mentioned earlier for whole body, which is five TEDE of 50 r organ, because that was fairly easy. Because now you're talking about whole body equivalence and organ equivalence and you're at or below deterministic effects. When we start getting into tumor volumes very small, different body part, different consequences, that's why we settled, if you will, on percentage error bands outside of which they would become reportable, just for what that's worth.

DR. GLASGOW: I'd like to add my two cents, if I may quickly, and that is the basis of fractionating high dose rate therapy and continuous low dose rate therapy—and someone correct me if I misstate this—is generally an accepted equivalency. It's felt that there are equivalent schedules with equivalent effects that can be achieved. There may be superior effects. That's still under investigation. So in the sense that the two methodologies are assumed equivalent, it would probably be inappropriate to try to set different error rates, based on different total doses.

I think the one 20 percent works well for both areas, because not enough hard science is really known about the equivalency. So you have to assume that the equivalency exists and that the 20 percent total dose, by whatever mechanism one specifies, would be appropriate.

DR. GRIGSBY: When we were going over some of these whole organ doses and tolerances for significant effects, somebody pointed out that, gee, I thought I read somewhere that prostate cancer gets on the order of 16,000 centigray from a brachytherapy procedure. And that's exactly right. See, again, back to your stuff, I-131 rad and HDR rad and an I-125 seed implant into a prostate rad

and an LDR rad aren't all the same. Now whether the 20 percent should be different or not, I don't know. But for the folks evaluating it, all of those rads can't be lumped together, nor can they really be lumped in with external beam rad either.

Then the final couple of things I take the opportunity to say that at our institution, the PDR is dead. It died a long time ago. The resource book, it gets addressed two or three different times, but I suspect the machine will never be resurrected.

DR. STITT: Is it dying at other places, too, Perry, because of regulation?

DR. GRIGSBY: Yeah, and probably rightfully so. It's like having a high dose rate machine running 24 hours a day, and it's very dangerous.

And the other thing is, this is just kind of a social comment, the schema for the high dose rate, I think that maybe came from our institution, I'm not sure. But if you remember, they were showing us an overhead this morning, and it had 30 or 40 boxes on it. A simple example is when ladies have carcinoma of the endometrium, they may have a hysterectomy, and then they may have a vaginal cup implant afterward. And that vaginal cup implant can be given with low dose rate brachytherapy, one implant, one procedure for about 48 hours, or be given with high dose rate therapy, and they might have three high dose rate treatments over a period of three or four or five weeks, whatever.

If you look at the—that flow diagram for the high dose rate with all 30 or 40 boxes, if I get—and I'm almost to the point where I'm being regulated out of existence or QA'd out of existence. If I have to go through all 40 of those steps three different times for a single patient, and within the next couple of years get paid a single fee for doing that, compared to going to the operating room, putting the applicator in, taking a film of it, deciding which sources and how long, going up to the cesium room with the technologist and getting them out of the safe and putting them in the patient and I'm done with it, and I don't have to deal with the human machine interface except the safe has hinges on the door. There is no computerized treatment planning performed. I mean we do it, but that's not—we're not dependent upon it. In fact, if the computer treatment plan differs from the hand calculations, we make the computer guys get it right.

So there's going to be a, you know, the number of remote afterloaders in the United States is increasing significantly, but they won't—not every institution, I don't think, will have them, and for many different reasons. It's easier not to do it. It's easier just to do manual afterloading with the same results and not have all of the tremendous QA procedures and doubling my time and effort to get it done.

That's it. Thank you very much.

DR. BICKEL: Thank you very much.

DR. BLEY: Could I ask a quick question? It is not for you as much as all the people I saw nodding their heads yes as you threw out that challenge at the beginning that the risk, at least as I understood it, as far as you know, the risk assessments are not evaluating the possibility that the physician's judgment and where to do the placement is wrong. And I guess I'd say why isn't that part of the risk assessment, to everybody who agreed?

DR. BICKEL: Probably it's Item 3 of the—

DR. BLEY: Because they didn't think of it—

DR. BICKEL: It's Item 3 of the NCR's Policy Statement saying they're not going to engage in the practice of medicine.

DR. BLEY: Yeah, but that's different from doing an assessment. If you're doing a risk assessment, that's part of the risk.

MR. TORTORELLI: But we're assessing the risk of not carrying out the prescription. We're not assessing the risk of the doctor practicing medicine for them.

DR. BICKEL: We're making the assumption—

DR. BLEY: So it's a scope definition in the beginning, based on the NRC policy?

DR. BICKEL: They're basically focusing on the fact that when they decide, you know, when the attending physician decides what he wants to do and he does this thing and they write up the order, we're basically looking at what goes wrong in the process, so the patient doesn't get what the doctor ordered. We're not making the assumption what's the risk of the physician—maybe that's

something for the—for President Clinton or even Bill to worry about with national health care, but it's not the scope of this thing right now.

With that, I would like to introduce our next—is there one last question?

DR. HOLAHAN: The one slide that you showed right near the beginning, the dose ranges for the curative doses? The curative doses, the high doses, the 6,000 centigray or above, is that based on curative dose of the tumor or the normal tissue tolerance?

DR. GRIGSBY: The table as presented was based on the tumor and not necessarily normal tissue tolerance. But, again, that table is based on external beam radiotherapy numbers, and low dose rate. At our institution ladies with cervical cancer are treated with low dose rate brachytherapy and the doses to the cervix can be on the order of 20,000 to 22,000 centigray to the surface of the cervix, and they can be tremendously high.

So we've got to keep that in perspective.

### C.3.3. QA/QM Programs and Concerns —Dr. Glasgow

DR. BICKEL: Thank you. Our next speaker is Dr. Glasgow from Loyola University.

DR. GLASGOW: My first most important question is how much time do I have?

DR. BICKEL: You can take 45 minutes. Well, the information is of such interest, we want to hear it all.

DR. GLASGOW: No, no, I just need to make sure I pace myself properly.

Well, I suppose I want to thank Jim for the invitation. I'm not quite sure. My career may be at risk for consorting with the NRC, and that's always the risk we run whenever we lend our expertise to the regulatory agencies.

You're going to need your book, so while I'm talking you can get your book out, and I will first admit that I have had a great deal of difficulty with this particular preparation. Jim charged me to identify the common elements of the quality assurance programs that are under regulatory control, particularly brachytherapy, and that would, of course, be conventional low dose rate remote afterloading and high dose rate remote afterloading, and to determine the relative value of the elements that existed in various QA programs, to try to sort out those that he called really effective versus those that only added paperwork to a process and did not enhance patient safety.

I read substantial components in the proceedings, noticed that one of the speakers had developed a system of trying to quantitate a system of high, moderate and low risk, tried to apply that to some of the QA elements that existed and got very frustrated and simply gave up, and decided to take a totally different approach after working with it for a period of time.

What I've chosen to do is, I'm not going to use any visuals at all, which is always a challenge. I'm going to go through starting on page—it's the material that will begin on Page 8-1, which is the quality management and remote afterloading brachytherapy. This is the document that was put together by Jim and the group here at INEL, and I discovered when I looked at this carefully that it included new information that I had not previously seen, specifically, it includes not only the NRC statements that exist in the regulatory guise in the regulations that are required, but it also includes information in their more recent policy directives, which are used internally, I believe, by the NRC to instruct their inspectors regarding how to review license and what questions to ask. So I was quite pleased to see that, because the actual regulatory basis of quality assurance for the NRC is really rather common between high dose rate and the conventional brachytherapy work that we do. There are obviously differences, but the things on which we do QA are really the same.

As I reviewed the material that was in Jim's very excellent document, I noted that there are certain aspects of the NRC rules and quality management which are rather highly effective, or another set which are difficult to implement, impractical or whose intent is not clear to the user. So I've gone through this document about three times, and I've highlighted for comment those portions of it which, in my judgment, are deserving of some comment. I came up with about 50 some items and feared that I might not have an opportunity to finish them all in the time allocated, so I went through it again and tried to get the number down and identify among those 50 those that I felt were very important. So I'm going to take you through

this particular draft, and I'm going to make some comments about the components of the NRC regulatory framework as it exists at this particular time. And the purpose of doing this, particularly for the people from the NRC who are in the room, is to share with you my experience over the last 20 years as a U.S. NRC licensee. At this particular time I work under U.S. NRC licensee at Hines V.A. Hospital. I also work directly under an agreement state license at Loyola University in the State of Illinois. And I've had a lot of experience in these 20 years in dealing with U.S. NRC inspectors. I've also been involved in some specific incidents that involved patients in various hospitals, so I do have some degree of experience to bring to the table that I'd like to share with you.

I want to make it clear that I'm not speaking officially today in any aspect for any organization. The comments that I make are totally on my own, and I will accept the consequences thereof. I do not speak today for the AAPM, any medical organization. These are purely my own comments regarding the state of the art.

Also, this is not a critique of Jim's report, which I think is a very fine report, but rather it is a critique or comments regarding the actual material that is in the report. It's not a critique of his review of the report, but it's rather comments that I would like to make about certain aspects of the regulatory guides as they exist, and as new regulations are considered for high dose rate, and as you try to prepare new documents, you may be able to draw on my comments in the consideration of new materials.

Now we had—a moment ago I made some comments about voluntary guidelines. There is, for high dose rate remote afterloading, a task group report by the American Association of Physicists in Medicine. Of the various organizations of which I am a member, the AAPM certainly does one of the better jobs of publishing material for their members, which are particularly physicists, regarding what is good practice or what should be considered as good practice. I chaired this task group and this particular report, and Dr. Grigsby is a member of this group, and this particular report has been in existence for about a year. And comments regarding this particular report are included in the material that we're going to review, but I'm not going to say a lot about it. If there are those in the room who really—I don't think that's the case—but if there are those in the room who really don't understand what this remote afterloading is all about, I did bring along a copy of a short article that I presented a couple of weeks ago at the National Summer School of the American Association of Physicists in Medicine. I'd be glad to make some copies. It's a short synopsis describing three different units, how they work and how these systems generally work. And anyone who would like to have a copy of that, just see me, and we'll make arrangements. If you felt it was beneficial for each participant to have, we certainly can do that.

Now make sure, I'm going to be checking off some things as I go through here to make sure I say all the things that I want to say.

MR. TORTORELLI: Let me interject—

DR. GLASGOW: Yes.

MR. TORTORELLI: —your excellent report there is available to anybody who wants one. The address is actually at the end of the document. There's a phone number you can call in that box, so you can have your own.

DR. GLASGOW: Now the approach I'm going to take, if I don't comment on it, I generally found it to be useful as a regulatory document. In other words, I'm only going to comment on the things which I think may be—deserve review. The problem that I had when I tried to answer the question what is the relative value, from my perspective, most of the regulations that have come forward from the NRC over the years have been of value. I have not found too many things that exist in the regulations that are not of value, that do not have a sound basis and which are not contributory in a positive sense in some way. This was one of the difficulties in my putting together the talk. There hasn't been a large number of things that are in the regulatory process that are not really positive and contribute in some way. They are all well intended, that I know. And I'm very sure that there's a good reason for the current language that's been used. However, I'm going to take the prerogative of advising a few of the things which trouble me or on which I'd like to make a comment.

I should also start out by saying that generally while the tone of this meeting is an emphasis on the need for increased quality assurance and good practice, the economic forces of the medical envi-

ronment at this time are working directly against that. And I think that has to be understood.

I cannot go to administration and say I'd like to have another physicist, another individual to help improve our quality assurance practice. The question that is being posed to me is how can you get by with one less person? How can you provide greater productivity, which means more work output from your people, with fewer people and less time? How can you cut the number of patient days in the hospital? How can you cut the patient stay days? What can you do to reduce costs? That is a predominant emphasis in most hospitals at this time. And while there is lip service to maintaining quality while that process is underway, my own judgment tells me that it is indeed to some extent lip service, and it's going to be difficult to maintain high standards of quality, particularly at academic medical centers where our costs are higher and where we have been involved actually in developing some of these programs. These programs of good practice do not come from community hospitals for the most part. They generally come from the academic centers, and the academic centers are going to be under increasing pressures to keep people to do that type of work. It's going to become, I'm afraid, a real luxury to have people around who do that.

DR. GRIGSBY: Let me interrupt. There is—there are data to address that issue. There is a published list, and, of course, I don't have it with me, that's a survey of managed care plans at HMOs of the top ten factors that they consider to be important in choosing various providers. And the first one is cost. Quality is about number seven or number eight, very clearly.

DR. GLASGOW: Right. Okay, let's go to Page 8-7 and start with the NRC regulations. And one of the first ones, 35.11, License Required B, and the question is supervision. This was discussed at the AAPM summer school recently, and it is an area of some concern to me, and I will throw out some quick comments regarding it. I might say that while I will try to keep the time, if you want to interject short questions as we go along, I'll try to answer them at the time. I think it's better to do that on this particular basis.

The statement made is that an individual may receive, possess, use or transfer byproduct material under the supervision of an authorized user. The authorized user, of course, is the physician authorized user, authorized to use the radioactive material in the care of patients. The interest here is the question of who manipulates sources and places them in patients and who operates the high dose rate equipment. Historically on GYN services, the question of who inserts the source has not particularly been an issue. In the large service there may be a source curator, an individual who, under the supervision of the authorized user, may actually insert the sources into the patient.

In interstitial work, that's far less common. I've rarely seen a physicist given the responsibility to insert the radium seeds in catheters that are in a patient, because the hazard of that could be somewhat higher. I don't think that's a very common practice.

In remote afterloading, there's been a tendency for physicists to assume the responsibility of actually programming, setting up, and in some cases, pushing the button and treating the patient. The reason this becomes somewhat of an issue is that in terms of licensure, physicists are not licensed to treat. We're only licensed to do a variety of other. We're not licensed at all, for the most part, except in the State of Texas. Physicians are authorized to treat patients, and radiation therapy, radiation therapists or radiation therapy technicians are licensed by their states, in many cases, to treat patients, but not the physicists. So in my own facility, when it comes to the high dose rate, we have trained our radiation therapy operators to do the actual treatments. We are there; we do the redundant secondary checks; but, when it comes time to push the buttons, we're very careful that we do not treat. I'm also very careful that we do not insert the sources in the patients. When we take the sources, radium seeds, to the patient's room, we transfer the sources to the physician, explain the activity and the number, the physician implants.

The question of who is doing what is an area that's—could potentially lead to misadministrations, because of miscommunications. And I would throw out to those with responsibility in this area that the question of supervision and responsibility may need some review. The question, the terminology is being raised, which I'll mention later, about adjectives on physicists. You already have the teletherapy physicists, and the American College of Radiology has a new standard, which I have read, which uses the term brachytherapy physicists. And statements have been made that

with high dose rate, we may have to develop a brachytherapy physicist analogous to the teletherapy physicists, with that individual having specific responsibilities.

The difficulty with that is that it creates some subspecialists for physicists that are not recognized for the physicians. We do not have a brachytherapy physician; we do not have a teletherapy physician. The physician's medical responsibilities are broad, and I'll comment on that later. But with the physics community, there is being a tendency to try to specialize, making sure the person has the right experience. I think we have to be a bit careful about that. I much prefer the term physicist in medicine as the describer of the individual, as opposed to adjectives that seem to be limiting the person's responsibility.

DR. GRIGSBY: Let me interrupt one more time.

DR. GLASGOW: Yes, okay.

DR. GRIGSBY: I think forever physicians have always delegated things to others. So we can do whatever it is we end up doing. But as these procedures become far more complex, there's going to be a greater tendency to do that, to delegate all of these responsibilities to someone else with the potential for the communication blocks to add up.

DR. GLASGOW: Right.

DR. GRIGSBY: I put sources in patients until we got the damn machine, and I don't know how to run the thing. So I've got to depend on somebody else.

DR. GLASGOW: Well, that's a good example.

DR. GRIGSBY: And then the Ph.D. doesn't want to do it, because he's not an authorized user to treat patients, and it gets delegated.

DR. STITT: Well, our therapists may be authorized to push a button, but they refuse. Our GTs will not get involved in our high dose brachytherapy treatment, because they don't want the responsibility.

DR. GLASGOW: Right, it's a question that relates—we'll comment later—it's a question that relates to training. There are certain presumptions of who is going to be responsible and who is going to be trained. And it can get very—each place is doing it differently. That's what I know. Okay, I'm taking too much time. I must move a little bit faster.

On Page 8-7, the written directive, I'd like just a few comments, not so much about the written directive as about the footnote to the written directive. I'd like to point this out as a place where an NRC recommendation causes confusion. The written directive, there should be one, and it should be reasonably clear. But what's to be done in a case judgment is required that the patient's condition is such that a delay is required. In one paragraph we have that the physician can wait 48 hours before documenting an oral revision. And then in another paragraph down below, that if because of the patient's condition, a written directive must be prepared within 24 hours. So we have a 48-hour rule and a 24-hour rule.

Now when I wrote my own quality management program, I declined to do this. I adopted two 48-hour standards and simply said if this is an example of where asking the physician to keep track of two different time frames, two working days, one working day, is too difficult to implement, just practically speaking. And these are the type of things that I would encourage you, as you write regulations, to think about a little bit.

Physicians have a great deal of difficulty complying with understanding and implementing all of these regulations. And they come then with too many footnotes regarding 48 hours, 24 hours. It just gets confusing for all involved, and it should be an application of the KISS Principle: Keep it simple. And I would suggest that keeping time frames as standard as possible has great merit.

Next Page 8-8, No. 5. Any unintended radiation is to be identified and evaluated. Well, here in the quality management program we see that there is an emphasis in identifying any unintended deviation, but yet we are going to be adopting a sampling technique. Now those two are in conflict. You're not going to be able to identify any unintended deviation by sampling technique. Those are two directly contradictory statements. It just doesn't work. It's not possible. So I just throw it out for whatever it's worth.

The question of a representative sample of patient administration, here's an area where statistical principles applicable to a large number of proce-

dures simply don't work in a hospital, because the number of procedures are far too small. Most services are doing probably fewer than 100 high dose rate administrations in a year, and you cannot do statistical sampling of any type. In our own high dose rate program, we have to QA every patient record. The reason I have to QA every patient record is to meet the definition of finding any unintended deviation, and statistical sampling techniques of any kind, simply cannot work on case numbers that are in the tens or even, quite frankly, in the hundreds. It just is not a good approach. It doesn't work very well.

Okay, what other things do I need to comment on? Let's go over to Page 8-11, and let me discuss the radiation safety committee very quickly. This is a reasonably long-standing NRC directive regarding the membership in the radiation safety committee as being a three-person program consisting of the authorized user, the management and a nurse. The reason the nurse is included is because nurses are frequently exposed to radiation during brachytherapy, and they are also a population of individuals with whom it is difficult to accurately communicate and express the hazard, or lack thereof, of what's being done in the procedure. Unfortunately it is my considered opinion that most of the nursing representatives on the safety committees are, unfortunately, some of the last-informed people about radiation safety. They certainly should be there, but I'm not sure that they should be considered to be one of the three core members. The number needs to be increased from three to four. You get into a situation here where the nurse, who is often dramatically uninformed about radiation effects, can play too large of a role on a small committee on questions sometimes of which they have little understanding. And this is just an area that has troubled me for a long time, so given the opportunity to comment, there you have it.

Okay, on Page 8-13, Section 35.13C, a license must apply for and receive a license amendment. Here we have the term teletherapy physicists, and I've already discussed the ACR and brachytherapy physicist. Again, I just want to stress that I think it would be better to try to use more generic terminologies, that is perhaps recognized terminology. The physics community is in some turmoil, because we don't know who we are, and we keep calling ourselves by different names. We have different organizations who allegedly represent us. If we are Board Certified by the American College of Radiology, which many of us are, we are therapeutic radiological physicists. If we are members of the American Association of Physicists in Medicine, the proper name of that group is one that I like, Physicists in Medicine. Physicists first, performing our role in medicine. It's a proper—it's what we really are, but we come to other groups who are using other definitions. I see radiation oncologist physicists being bandied about, all sorts of descriptive terms. It is a problem area of describing who we are and what we do, and I just would advise some caution in putting on describers. I'm not sure I can give you—I'm not sure that any of the so-called professional groups can give you an adequate definition. There are just too many of them floating around these days, and I would encourage perhaps broader terms there.

DR. POLLYCOVE: Does medical physicists, although it's just slightly shorter, but does it to you have a different connotation than physicist in medicine?

DR. GLASGOW: Yes, it does. A physicist in medicine I would judge to be a more creative person, perhaps more intellectual.

DR. GRIGSBY: I have a Master's Degree in medical physics, but they dare not consider me a physicist in medicine, because, see, I'm not a physicist. No, I do have a Master's in medical physics besides. So I'm not really a physicist. I'm a medical physicist. He's a physicist in medicine, but I'm not equivalent.

DR. POLLYCOVE: When you say medical physicist, it doesn't mean that you're a physicist?

DR. GRIGSBY: I don't think so.

DR. GLASGOW: It's a particular definition. There are graduate programs in medical physics. There's also a rather large number of physicists who have come into the field and there are many physicists who might be working on research projects who are not caring for patients, who are clearly physicists who are working in medicine. But my point is that the definitions of who we are is rather confusing at this point in time, and you have to be careful even about the adoption of any one term, because different groups are promoting different agendas.

DR. STITT: But when you say teletherapy physicists, it almost implies that there's some—that if you look somewhere, there is certification for you as a teletherapy physicist. I can see lawyers asking for credentials, and that's a concern I have.

DR. GLASGOW: The NRC's teletherapy physicist is exceptionally well defined.

DR. STITT: But in the correctness of units, we don't have teletherapy. I mean, maybe we do in practice, but not by definition.

DR. GLASGOW: No, we never refer, outside of the NRC, to a teletherapy physicist. It's a term that's not recognized outside the regulatory group.

DR. BUDNITZ: I'm a physicist. My Doctorate's in philosophy.

DR. GLASGOW: Well, that's right. I mean there's a tremendous number of creative—

DR. BUDNITZ: No, naturals.

DR. GLASGOW: Naturals, yes, that's true. Okay, now on Page 8-14, Section 3.2.5 on personal monitoring, I'd just like to make a couple of quick comments regarding the philosophy of personnel monitoring.

Number one, adults likely to receive in one year a dose in excess of ten percent of the limits. Well, if one were using this standard, ten percent of the current five rem per year limit would be 500. And hardly anyone would really be monitored. But we come down to number three, individuals entering a high or very high radiation area. Now the intent here, obviously, is to have a badge on someone who is in an area where they are at risk. And I guess I don't have any real problem with that, but that particular requirement basically forces the badging of exclusively everyone, whereas the statement above implies that the real interest is only in monitoring those who would be likely to get exposures greater than about 500 millirem per year. And there's two different intents that are working there, and I understand the role of each, particularly in number three. If someone is in an area where there is hazardous equipment, you'd like for them to have on a badge. On the other hand, that is particularly forcing the monitoring of a large number of individuals without, for the most part, a real benefit. And clearly, the intent above would be to monitor far fewer individuals, based upon the consequences of they're getting 500 mr per year. I just offer that to you as a point.

Now the other area of confusion, 8-16, there's been a lot of confusion about this, and I guess I may as well raise it. Of course, everyone knows now that the new limit is 100 mr per year for a member of the individual public. This is the new limit that has been adopted. Yet the regulatory situation allows an out, and the out is Section 20.105A wherein a specific license application, as I understand it, you can still ask for the 500 mr per year dose to a member of a specific unrestricted area if you will provide justification. This is being widely ignored in the physics community, and everyone is really focusing quite hard on the 100 mr, which I think is probably the NRC's intent. But I think people do need to understand that it appears to us that the NRC will accept the 500 mr per year limit for an unrestricted area, based upon the stated regulation. And I have advised people that they should consider adopting this if they have good justification to do so.

DR. HOLAHAN: Just to very quickly verify that's only for temporary nature and that's sort of indicated in the new regulations, it's for a stated situation. It's not for a permanent situation.

DR. GLASGOW: It's not meant to be for a permanent situation. It has been an area of some confusion in licensing and looking at new facilities, so I appreciate your comments on that.

Now on Page 8-18, I'd like to address the question of date and doing some of these QA checks on "day of use". A lot of this equipment is of the nature that it can be left on. And the nature of the patient's scheduling doesn't always allow you to do everything "once each day of use". I would like to throw out the use of a term within 24 hours of use prior to the actual procedure.

For example, there may be situations where if we want to do a case early in the morning, we would like to do our quality assurance on the—we could do the quality assurance on the evening before. As it is, we have to do everything on that day, and in a busy service, this becomes quite difficult. There needs to be a little more flexibility and understanding the nature of this equipment that one can argue that, well, if you turn off the circuit breaker at night, and you know, you didn't check it all out the next morning, you haven't checked it just before you use it. But practically speaking in

the way that hospitals are working at full schedule, the physicists have to do a lot of night work to get ready for the next day. And giving some consideration to doing something within a certain time frame might give us more flexibility than absolutely requiring something to be done on the "day of use". I throw that out to you for your consideration.

MR. TORTORELLI: Then you're saying leave it energized?

DR. GLASGOW: You can consider leaving it energized. I'm not sure that you can make a case that simply—well, someone in failure analysis can comment on this better than I, but if you've turned something off, and you turn it back on, in terms of doing the type of checks that we do, I'm not sure that we really, practically speaking, are violating any good principle there. I don't know.

DR. BICKEL: It would depend.

DR. GLASGOW: It would depend.

DR. BICKEL: That's for sure. I have an old beat-up PC in my office, and if I leave it on it works better than when I turn it on and off every night. It depends.

DR. GLASGOW: Yes, it may depend, but much of this equipment is designed to be left on. There are some mechanisms we could leave it on and have it ready. Day of use is a bit restrictive in the real world of human services.

One of the more frequent areas of validations that is hard to comply with on 8-18 is No. G. Make sure that the machines are not left unattended and that console keys will be inaccessible to authorized users. People frequently are in violation of this particular QA Rule, simply because it's difficult to implement in a practical matter throughout the course of the day, particularly if you have, as we do, a high dose rate unit in a cobalt vault. There are times when technologists will have to step away from the equipment, and you cannot go through total shutdown, door lockage and certain other good practice things which are clearly intended here. It just is not good practice. It just becomes onerous, even though the intent is very clear that you don't want to have someone come in and operate the equipment. But in the real world of practice, people aren't running around, you know, turning on machines in the hospital. So that's an area where maybe rewording that or rephrasing it might help as we read these regulations.

On Page 8-21, Section 35.420 on survey meters. On the high dose rate unit, a decision has been made that the highest level on the survey meter is probably one, 1,000 millirem per hour, which is one r per hour. I guess that's all right, but I'm a little uncomfortable with it, because the dose rates that one could potentially be working in are quite a bit higher than this. At a meter, the dose is about 4.6 or almost five roentgen per hour. If you're really close to the patient and the source is out, the rates are quite high. If someone were using a meter in that situation, the meter is pegged. People get very confused by meters which are pegged. They don't quite know what that really means, and I would suggest that maybe calling for a higher limit on the survey meters for high dose rate might be of some advantage. I just toss it out as a consideration.

On Page 8-23, this regards Provision 20.203 at the top of the page, regarding the posting of patient rooms in brachytherapy. There's been a relaxing of the posting requirement, and you would generally think this is a good idea. It basically says that in conventional brachytherapy, we don't have to post areas any longer with signs that say caution, radioactive material, high dose rates, that if the area is under control by a nurse or someone else, we can get by without posting.

In the real world of nursing education, this leads to great confusion. You have to now try to explain to the nurses why certain rooms are posted and certain other rooms are not posted. And while it's a relaxation of the older standard, I'm not sure whether it actually has served us well as we try to educate people about the use of signs and the presence of radioactive material. It's just become a bit confusing to try to explain why this room is posted and this room is not. To the nurse, for all intents and purposes, the rooms and the patients look like they're about the same. And so it's more of an educational problem.

On Page 8-26, I'm going to make a comment that I had to write in this report regarding the frequency with which we do quality assurance. How frequently do we have to do quality assurance? Very very difficult question. The best that I could say about it is—I should get an award for this sentence. Quality assurance checks should be performed at sufficient frequency to guarantee the

equipment works properly during the therapy session. I felt that was one of my better sentences as a writer over the years.

How frequently is that? Well, I don't know. I couldn't figure it out. What I do know is that a lot of our equipment doesn't know about the lunar cycle, okay? We are locked into doing certain things monthly and at certain other times, and the reality of how often you need to do something on equipment really derives from surveillance of failure rates and some other things, and we are falling into traps of doing things on certain frequencies, and it's leading to work that, in my judgment, is not really contributing to patient care.

Now it's not easily dismissed. I'm not going to say that we shouldn't be doing quality assurance checks. It's just very very difficult to say how often. And monthly is the easy answer, but it certainly is generating a lot of work, a lot of measurement on some equipment that is highly reliable. I would say that there might be checks that could be made at 45-day intervals that would reduce the number of checks and the number of reports substantially during the year, or maybe 60-day intervals that would not compromise the actual QA process. It's not easily answered, but I just want to comment on it.

Now other things very quickly. Let's go to Page 8-30, and let me comment on the question of source calibration. Page 8-30, Section C on the calibration of sources in high dose rate units.

There's been a substantial amount of confusion, in my judgment, on this. Certainly the physicist needs to have made a decision regarding how to calibrate the source. The problem that we have is that this has been an evolving question. There hasn't been clear answers on the best way this should be done. And we are asked in this policy directive that we should submit to the NRC what our procedure is. That implies one would be held to that procedure, however, and there may well be good reasons that one might want to change the procedure as new information and new techniques are developed.

And then under the licensing process, we have to refile a procedure with the NRC. I think we may be going too far there. It may be sufficient to have inspectors to review those procedures at the time of inspection, rather than have them submit it as a part of a license, wherein my understanding of licensure, it locks you into following that procedure under a license. Someone might want to comment on that a little bit later, but I throw it out to you.

Down in the next to the last paragraph, the expected and measured output rate should be within plus or minus five percent. Well, that sounds good, but keep in mind that these certificates that we're receiving are really only ten percent certificates. And we don't like to say we're off by five percent, but the reality of it is that the certificate has a ten percent uncertainty. And that is probably, practically speaking, too tight of a standard. We cannot, in good faith, say that—there is a tendency for the physicists not to apply any uncertainty to the numbers that he's deriving. And to take his numbers absolute and the vendor's number as being incorrect. It's an example where I think that a statement of accuracy has gotten ahead of the actual science of source measurement as it's currently being performed.

In the last paragraph we have a requirement for calibrating or electrometers every two years. This comes from the NRC, the AAPM's policy, but I would ask if you went to the Wisconsin ADCL and asked for a review of how often the calibration factor is changing on the chambers, I think you would discover that these instruments are quite stable, and that a three-year interval is probably as accurate or as good as a two-year interval. I've been getting these things calibrated every two years for the last 20 years, and our instruments have been remarkably stable. I would suggest that they might be able to look at that.

DR. STITT: Just a comment, Glenn, to bring up something that was brought up—you brought up earlier, and that has to do with cost of things.

DR. GLASGOW: Yes.

DR. STITT: That comment, as far as frequency of a variety sorts of things, back in the badging, the high dose, very high dose versus the dose in excess of ten percent of the limit, a lot of those things are expensive programs, some more so than others. And certainly in our JCAHO requirements, which all hospitals are visited for, if you have been found to do certain procedures within certain frameworks and have certain outcomes, and you're very stable over the years, you no longer have to be evaluating those things at all. And if you've looked at that, say, with respect to badging, that would be something NRC would

want to hear about, but there would be whole types of badgings, just as a small example, that you could eliminate. And that comes back to costs. We're in a process at my place to see how many people we can do without. And it starts with physicians, and it's the physicists and the dosimetrists and the clerical and the nursing, and we are losing staff. We don't have the money to pay people nor the patient pool.

So just a couple of examples we have to pay attention to what these things cost.

DR. GLASGOW: Right, on Page 8-33, for example, the question of six-month leak tests. We've been doing six-month leak tests of a lot of sources for a long time. There is a requirement at the bottom of the page that sources which are leaking should have reports filed with the NRC, and it would be interesting for me to know how many such reports have been filed with NRC regarding leaky sources over the last 20 years. Have there been any?

MR. CAMPER: There have been some, but it's infrequently.

DR. GLASGOW: It's a highly infrequent procedure, and I would suggest that this could go to annually instead of every six months. These are some areas where we are doing things, perhaps, at a frequency level that's not justified by the type of results that we're getting back.

I'm going to—I'm about out of time. I'm going to go through this quickly, and on Page 8-37, comments on just the real important ones.

In the suggestions regarding quality assurance on applicators, this is in a section on—this is 8-30, Section F, Section F on the mechanical integrity of applicators.

In this particular section, this is for high dose rate, regarding the QA that one would do. And in this particular section, there's an implication that the presence and correct placement of any internal shields and other elements should be determined, and it's in this particular section where there's an implication that it should be done far more frequently than it actually is done.

We actually do these type of checks more on an annual basis than we would a monthly basis, and there's no indication in most of these applicators—this is an example where, yes, it would be good practice to X-ray all applicators before each use, but it's just impractical. We have to have programs that might do that type of work annually, but certainly not on a monthly basis.

DR. GRIGSBY: You know, to add to that, Glenn, some of the remote afterloading equipment, especially the either Manchester or Fletcher ovoids, the heads of the darn things are removable.

DR. GLASGOW: Yes.

DR. GRIGSBY: And, you know, this doesn't address that issue at all. Those things can be mixed up, turned backwards, and you never see it on an X-ray.

DR. GLASGOW: On Page 8-38, Section 4.41, the quarterly inventory. I'd like to discuss that just quickly.

There's been a long-standing NRC requirement that we do a quarterly inventory of all radioactive sources. The intent is two-fold: number one, to make sure we haven't exceeded our possession limit and, number two, to guarantee all the sources are there.

There's a general impression from our perspective that this is not a highly effective mechanism and probably could be done on a less frequent basis, possibly at a six-month basis rather than quarterly. First of all, the inventory procedures that we have in place for looking after sources addresses the question of are all the sources there? We have in place other procedures that are required on source accountability that determine that the sources are there. We have to do that much more frequently. We can't wait quarterly to find they're missing.

So the intent is possibly then to make sure you haven't exceeded your limit, and I'm not sure that the hospital exceeding the limit inadvertently by a small fraction is really of great consequence. It's more a violation, perhaps, of a license statement. And I don't have a sense that the quarterly inventory requirement, long existing though it is, whether it at this particular time could not be relaxed to a lesser time frame, or how many situations has it picked up that a source was missing, or that a licensee was markedly over their particular possession limit.

Okay, with that let's go to Page 8-44, and there is one very important statement on this page, H,

regarding high dose rate procedures. And that is a licensee shouldn't do any procedures for which they cannot, basically, extract a jammed source out of the patient and get it back into its shielded container. This requires a great deal of judgment and work up front controlling the procedures. There may be procedures that are well being carried out where in a given facility people haven't thought through all of their various procedures well enough to know that they really can't retrieve the sources in all circumstances. I think it's an excellent rule and probably very important, but I think it's going to have to be given some degree of emphasis in educating users of high dose rates that there are limitations to the type of procedures that they can do, and they are limited to those which they can recover the sources.

With that, on Page 8-49, I would also like to comment, 8-49, 5193 very quickly on measured dose rates, how you do surveys in areas.

It is not absolutely necessary, and it's often impractical to always do a meter survey around unrestricted areas in hospitals. There are situations where this requires you to go into the adjacent patient's room, or if you do it as literally stated, you've got to go upstairs and crawl under the bed of the patient who's in there to prove. This has always been an area of some difficulty. There are ways that physicists can guarantee that there's no excess exposure in adjacent unrestricted areas by doing baseline surveys in advance with sources in the room to prove that there are certain levels they should not exceed. And this particular requirement asking for there being measured dose rate in unrestricted areas really can get to be a problem practically in certain areas. And there needs to be an option there for the allowance of other alternate procedures that could be on file that would confirm that you haven't exceeded those particular dose rates.

I think I've taken up all my time. I appreciate your patience. There are one or two—one final comment perhaps on Page 8-60 to finish, the question of physician responsibility or training.

The question comes up regarding responsibility and how one becomes an authorized user. The most common way and easiest way to become an authorized user is to pass the Board exam. But most residents coming out of the residency program haven't passed the Board exam yet, and they can't become an authorized user, so they have to file their NRC Forms A and B and get their preceptor signatures. And in so doing, they have to verify that they've met the training requirements. And the ones that are particularly difficult are those that are listed under No. 2, where we have 500 hours of supervised work experience which includes ordering, receiving and unpacking radiation materials and performing the surveys, checking meters, preparing implanting seal sources, maintaining running inventories.

In the real world, physicians don't do most of this work. They know about it, and the physicists are doing it for them. They will certainly help prepare and work on the implant medical aspects of the case, and in many instances they are, indeed, preparing sources. But as for receiving, checking meters, doing running inventories, almost—in many cases I'm going to tell you that there's someone else around who's really doing that. And this is just an example of where the understanding of the NRC regarding what the physicians are doing, I don't think matches up with the reality of the real world in which it's being done.

I will quit with that. There were a few other things I wanted to comment on, but I've taken far too much time. I appreciate your attention. I don't know that I've done what I was supposed to do, but I appreciate having the opportunity to make these comments.

DR. BUDNITZ: I don't know anything about what you've been talking about in detail, but I have a couple of observations.

You can classify your comments here into maybe three classes, some of which are totally unrelated to risk, and for which the risk perspective is of no use. The last one, you know, I don't care whether the guy certified maintains administrative control. It has nothing to do with this. Others of which are directly risk relevant and where a risk perspective or a risk analysis could provide the basis for a decision about, you know, what tests maintenance interval ought to be or whatever.

Then there's some in between which have some risk angle, but not direct or not complete or other considerations. Now for the ones where there's a direct risk relevance—excuse me, where a risk analysis could have a direct bearing on a decision that you might recommend, the only way to make a rational decision is go and do that risk

analysis. And if, in fact, it's something that needs to be maintained quarterly is now being maintained monthly, the analysis might show the risk significance of whatever is being proposed directly, perhaps not. It might be directly. And it strikes me that in the brave new world of risk-based regulation, which I assume the Nuclear Regulatory Commission is moving towards, that's what the Chairman says, that they would be receptive to such analysis.

DR. GLASGOW: I think they would be receptive. I think the difficulty is the data bases do not exist.

DR. BUDNITZ: If the data base does not exist, then how can you say that quarterly is better than monthly? How do you know?

DR. GLASGOW: I only have my perception and my experience.

DR. BUDNITZ: Ah, but you see, that's no better than theirs without an analysis. Only analysis should, in my view, be admissible as evidence for a change. What the heck.

DR. GLASGOW: Well, there are very few cases, for example, the six-month leak test might be a situation where in NRC files they may have enough reports to say is this effective to continue this?

DR. BUDNITZ: No, I'm not talking—if you're going to talk about monthly and annual, it may be you don't need an analysis. If you're talking about a factor of two, gee, everybody's jumping in—short of an analysis. So I would put it back to you. You're a physicist, right? You ought to be able to do that analysis or find some college to do it and then go back to them and put the analysis on the table. And then they'll say, yeah, otherwise I don't blame them—

DR. GLASGOW: Well, I'll throw it out to you. Here is an example.

DR. BUDNITZ: You should do an analysis.

DR. GLASGOW: We've been doing cobalt monthly calibrations on spot checks for cobalt monthly for the last 20 years, and I would judge that the number of cobalt units that are found to be not decaying properly outside five percent within that time frame is probably—have there been any such reports or findings?

DR. BUDNITZ: So there's your data.

DR. GLASGOW: No. So on the other hand, what's really being checked there is not the activity of the cobalt unit, it's really the functioning of the machine. The check really is of another function that the source may not be positioning properly, and, therefore, gives the appearance of an inappropriate activity.

But once the regulation is in place, there isn't a lot of analysis retrospectively to determine if it could now be moved to quarterly. I would judge that we could probably do—I'm not aware that this particular regulation is really being effective at this time on cobalt units, based upon data collected. I don't know. The data has to be within the NRC, but that's a good example where you could look at the information and, perhaps, find it.

DR. BICKEL: What I think you're really saying is it's history repeating itself, because what you have is regulations that were based on people's good judgment, and then as people got a little bit further along, they went back and studied how good was that good judgment? And in some cases they found that, you know, it needed some refinements.

DR. HOLAHAN: It's not necessarily though based on good judgment, but it's as a result of either something that has come up where addressed before with the misadministration where you're looking at the root causes and the generic implications, and often those regulations have resulted out of generic implications of a misadministration, series of misadministrations or something like that.

MR. CAMPER: Well, one more comment. How a regulation gets created or how an allied certain body of regulations comes into existence in a prolonged period of time results from many factors, some of which are good signs, some of which are good technology, some of which are public perception, some of which are agendas or pressures applied by various indices that change over time. We look, for example, at the teletherapy units; we look at the teletherapy physicists; those who have had serious incidents that occurred years ago in the 1970s. Now in some cases, regulatory criteria evolved from only one incident. Now is that the right way to go or the wrong way to go? Well, you can debate that.

But the problem is that you should always bear in mind that a regulation comes about as a result of many causal factors and conditions. One of the things they want to do, there are certain things in the regulations today that you've touched on a lot of points here today, and I would love to have the time to discuss them with you, some of which I agree and some of which—

But one of the things we do want to do in this next revision, Part 35, is, we do want to challenge the professional organizations by saying the following: If not this criteria or this standard, then what? And invite you, and if you have data, and you have conclusions and findings, and as he points out, and if your organization wants to do an analysis that shows that quarterly inventories are over-bearing and redundant at certain intervals, then bring forth that standard, and we will certainly entertain it.

DR. BUDNITZ: Nothing speaks like data or analysis.

DR. GLASGOW: Thank you, again.

DR. BICKEL: Thank you. With that I'd like to declare a ten-minute break, and I'd like to hold it to ten minutes, because we are running late, and I want to try to make some attempt to get us back on schedule. So could we resume here at five minutes of 4:00?

(A recess was taken.)

# C.4. RISK AND RELIABILITY SESSION

## C.4.1. Introduction—Dr. Blackman

DR. BICKEL: I'd like to introduce Dr. Harold Blackman from the Idaho National Engineering Lab. Harold will be giving, basically, an introduction to the risk aspects of this project. You got it.

DR. BLACKMAN: Okay, we got sort of a short introduction here, but normally I take off a lot of money to set me up so that I'm going to look good with whatever I'm doing, but I must admit that I didn't pay him this time. But he did an excellent job of setting up—yes, Bob—this next section, because what—

DR. BICKEL: I never thought of it that way.

DR. BLACKMAN: But this next section really is dealing with risk and reliability and dealing with how we currently are utilizing some of the modeling techniques in order to accomplish that. And to kind of reiterate what Bob said, when we're talking about risk and reliability analysis here, we're talking about doing an analysis that will give us a relative measure of risk at a point in time with a given system. And that's all we're talking about doing. We're not talking about telling a doctor how to do his work. We're not talking about telling the NRC how to regulate. We're not talking about how to tell a physicist what rules to write down in a book. We're not doing that.

We're talking about a methodology, okay, a model, a technique that can be used to help someone who will tell all those people what to do. And that's what it is. And that's what we're really talking about. And we're talking about trying to understand how those techniques might be utilized by a regulator, might be used by a given professional society to help them to make decisions that are going to allow them to provide the service, or whatever it may be that they're doing. So that's the point of emphasis here.

Now what's kind of neat about what we've heard today is we heard Larry start out talking about, well, human error seems to be a driver here. And then we heard Tim Leahy talk about some errors which seem to need to be kind of human-related procedures and HMI errors in dealing with software and that sort of thing. Then we had Tami show us one brief example of how a fault tree was used to analyze one particular situation. And it appears to show there was some promise there it might work. And then we've heard more detail about other methodologies like—I never say it right, WPAM. You know, how that kind of a system of systematically investigating things works, which really WPAM, with all respect to George, is a really sophisticated task analytic procedure, and we heard about the classic task analysis, and tomorrow morning—we moved John until tomorrow, because we really want to finish on—start off tomorrow morning on a really high note, and we know John will do that for us. So we pushed him to the morning. And we're going to hear about another technique which helps to visualize that kind of data as well. But again, those are all techniques of investigating and collecting data that then are going to be supplied to a PRA approach, which will become part and parcel to the models and the quantification strategy that's used.

So we built a real nice case here for Dr. Lee Ostrom, who's from Human Reliability Unit in my organization, to come up here and talk a little bit about Human Reliability Analysis. And for those of you here who aren't risk people, you'll hear us say PRA and PSA and HRA, and really we're talking about the same thing. Human Reliability Analysis is, in fact, probabilistic risk assessment, and it is probabilistic safety assessment. It's just a little subset. And so as he talks about it, he's using analytic techniques which are PRA. And so with that little brief introduction, Lee, if you want to come up and talk to us about human reliability.

## C.4.2. Human Reliability Assessment —Dr. Ostrom

DR. OSTROM: Okay, I'm going to talk a little bit about Human Reliability Analysis, so when I talk about those aspects, the risk analyst people can turn their ears off, because I'm going to take a very basic approach to it. And when I talk more about some of the medical things we looked at and some of the misadministrations, if the medical people want to pipe in with some supplementary information so I get the terminology correct, that

would be appreciated. Feel free to ask questions any time during the presentation.

What I'm going to talk about is I'm going to begin the presentation, discuss a little bit about human error analysis and our approach to it with my particular bent on things, a little bit about task analysis, what to do to support a human reliability analysis in the way of task analysis, talk a little bit about the benefits of qualitative analysis and quantitative analysis, and then I'm going to have two example problems.

One is from the commercial airline industry and concerns some work we did for NASA, where we looked at the aviation safety reporting system, and then I'm going to talk a little bit about one of the medical misadministrations that we analyzed, using classic HRA and PRA techniques.

Human error analysis is the systematic approach to identifying and modeling potential human errors in any sort of system. What we're concerned about here, obviously, is the medical systems, but you can use these techniques to look at any system, chemical plants, nuclear power plants, airline industry, ship building, maritime accidents and so forth.

When we do HRA modeling, HEA, we use human factors research as a base for it. We're hopefully not just pulling things out of the air and making them up as we go along. There's a lot of human factors research out there, and we utilize that in our approach to HRA.

Much of the work that we do is focused on the development of human reliability methods, and there's many methods out there. And, basically, what we use HRA methods for are to model the human in the system and, hopefully, help to quantify the rate at which humans err, which is a very difficult task. And that provides us some potential benefits.

This slide may be a little difficult to see, but we're developing a model here of what we call human centered system integration, and in that model we look at all phases of the life cycle of any sort of device, whether it be a medical device or reactor or airplane or so forth. And we look at it from the design through the end of its life and perform an assessment. And we view human reliability analysis as impacting all phases of this, but we especially view it on the potential impact on the design of the device. We do an HRA at the beginning of the life cycle. We can improve the design and, hopefully, eliminate many of the human errors, so we don't have to go back and do these assessments and so forth, because there would be less of it.

Okay, as we heard earlier today about task analysis and how it's performed, we use the results from the task analysis as the basis for our human reliability analysis.

Task analysis is performed by reviewing information concerning the design of any system that we're looking at; reviewing pertinent procedures; training materials, other supporting documentation; interviewing any performers that are involved, any technical staff that are involved; walking the performers through various scenarios, accident scenarios, normal operations and so forth; and, watching the actual process.

As we do the task analysis, we want to know how the task is performed, who, what, where, when and so forth. We want to know what are the critical steps in the process, as we heard Jim Callan talk about this morning, because those are the steps we know that if the operator doesn't perform them correctly, there could be failure. And whether we're looking at major consequences or minor consequences depends on the type of analysis we're performing.

We want to know how much time it takes to perform the critical steps and whether or not there is enough time. If it takes an hour to do a certain critical step and there's only 30 minutes or we remote the reactor, then there's obviously going to be certain disaster.

We want to know if there's a means for the operator to overcome a failure of a critical step, the recovery paths. And we want to know what types—what are the types of controls and instrumentation the performer needs to do his job. Are they available? Are they easy to use? Do they conform to human factors principles?

We also want to know what type of stresses the performers are under. In a medical situation, when we've gone out and looked at misadministration events, some of the things that we were curious about is whether the time pressure to get patients in and out of a facility puts stress on the individuals. In a power plant, it could be the amount

of time it takes to perform a task or alarms going off that stresses the individual. In other situations, it could be the safety culture or the management supervision of the employees that puts stress on people, or it could be standing up in front of a room talking to people about what you do.

We also want to know whether or not the environment where people work is dynamic, that means is it rapidly changing or does it progress very logically in a step-by-step fashion.

Then we want to know about all the other performance-shaping factors, organizational factors, distractions, lighting. It's quite a long list.

After we have done a task analysis and collected this data, we begin to form a qualitative analysis. And at this point we start developing a model of the system. Okay, we hope to develop a very generic model, but in some cases it's not always possible, because we don't have generic information. We have specific information about one process at one facility. And we can't always extrapolate that to all types of facilities.

When we developed the model, we used things like event trees and HRA trees to help us visualize where people—how people can succeed and how people can fail within that process.

The model is then used to help us provide a framework for developing a quantification or quantifying the model, and it also helps us determine whether or not we need to find other ways that operators can recover from potential errors.

We also use the model to help us ensure that we have done a complete analysis. We can take our preliminary models back to the performers and say is this actually what you do, or do you do other things or other steps or are we overlooking anything we need to be concerned about.

Okay, this basically is an event tree, and I'll explain a little bit more about this when we talk about one of the examples. But at each of these junctions, we have a task or something happens where we can either succeed at the task and then have success, or if we do something wrong, we can have failure within the system. This particular model has to do with altitude change in an aircraft. We're flying an aircraft, and we want to maintain a certain altitude. And these are all the different ways, different potential pathways we can fail in maintaining an altitude in an aircraft. And I'll explain some of that a little bit later. But this, basically, is an event tree.

This is an HRA event tree, and all the paths headed this direction are successful, where the operator performs a task successfully, and these are our failure paths coming off in this direction. In this particular case, again I'll talk about it in more detail later, but it concerns one of the events we investigated concerning a manual brachytherapy procedure.

In this particular case, the physician correctly sounds the uterus for positioning the colpostat, and the failure point is that the physician incorrectly sounds the uterus. Another possible failure is that the physician incorrectly adjusts the uterine stop on the colpostat, or another failure is if the physician improperly packs the vagina with material when they're implanting the colpostat.

After we've done our qualitative model, we then attempt to do the impossible, and that's quantitative analysis. In this case, we're trying to put a probability of failure on our human errors. And what we're hoping to do, this is done by looking at the types of tasks the operator does in selecting human error probabilities from some sort of data bases like data tables that are in the technique for human error rate prediction, or using something like expert judgment, where we get an expert panel together and ask them, well, what do you think the potential for failure is on this type of task? And then we do some sort of statistical analysis to find out whether or not we're in the ballpark or more data needs to be collected.

We can also use some sort of time reliability correlation if we're looking at a real time critical task, and there's many many more different ways. These methods are being developed all the time.

Why quantify? Sometimes it's used to provide management justification for finding means for correction. I guess the initial reason we quantify is to be able to feed the data into a probabilistic risk assessment to get an overall risk number. But if I were to use the numbers, I would use it to help justify whether or not I need to do corrective actions, and to help me prioritize tasks if we're doing some sort of correction. If I have one priority that says I'm going to fail one out of five times, I'm going to try to take corrective actions on that be-

fore I do have a task that has ten to the minus four potential for failure.

Okay, so that's in a nutshell a brief overview of HRA. What I'm going to talk about now are some specific examples of what we've done recently. The first is a commercial airline example. And some of the background behind this, this work was sponsored by the National Aeronautics and Space Administration, and we did this work to look at advanced cockpit aircraft to find out why people made errors in these types of cockpits, and what was the driver behind that.

The commercial aviation industry has used automation for many years. Their cockpits are highly automated. The latest generation aircraft on the 767, the air bus, the 777. The new generation 737s are highly automated, much more automated than nuclear power plants, for instance, even the ones going into Europe and Asia that are much more automated than U.S. plants.

Medical devices approach the complexity of some of these aircraft, whereas because they're computer driven, some of the modes are automatic, as compared to power plants where most of the modes are still manual, and the operator has complete control of the process.

Some of the unexpected effects of this automation are that workload may increase at times. The pilots that we had information on don't always understand how the automation works, why modes change in the flight management computer at various times, and new types of error have been introduced because of this automation.

The approach to this work was that we first obtained aviation safety reporting system reports of altitude deviation events in glass cockpit aircraft. And glass cockpit aircraft are the advanced type of aircraft, again, like the 767, 737s and so forth.

Each year there's about 2,000 altitude deviations each year.

DR. BLACKMAN: I have a question. Would you point out what kind of data base the ACRS is?

DR. OSTROM: Okay, what the ACRS is—

DR. BLACKMAN: ASRS, I'm sorry.

DR. OSTROM: If I, as a pilot, commit some sort of error that could be noticed by the FAA and the flight controllers and so forth, I can have immunity if I call into the ASRS and say I screwed up. I busted my altitude; I broke my clearance; I didn't stay on the right course coming into the airport. And I give them a complete report over the telephone. They send me a little ticket in the mail that says I'm free and clear, and then if the FAA comes back to me and says you screwed up, what were you doing there, I can pull my little get-out-of-jail-free card out of my pocket and say I called the ASRS, and I'm free and clear.

Approximately 2,000 reports are reported to the ASRS each year, and it's quite a vast data base. It's not as good a data base as we'd like to see. All of us analysts would like to see more data in the data base, but it's a good amount of information on aircraft events.

DR. BLEY: Because we were talking earlier about getting good data, licensees and that sort of thing, the things that we always worry about in getting good data is that people who report events don't want to tell you the whole story, because they'll get in trouble for it. So it seems the opposite is here. They may well be concocting a bit of a story to cover themselves.

Has there been anything you've heard about that out of this data base?

DR. OSTROM: Not concocting. They come out with some pretty poignant comments about what has happened and about management of the airline they're working for, the computers that are in their aircraft. They're quite—I think they're pretty honest. We don't know that there may be the guy out there who's falling asleep at the wheel and woke up and said, all right, all I have to do is call up and get this get out of jail free card and I'm fine.

MR. WREATHALL: A comment to Dennis, the factor that gives you immunity is that you made a report, not what the report is about. So you don't have to provide blame to anybody other than yourself, but you can. The fact you made the report gives you immunity, so there's no motivation—yes, you can abuse your employer, but, you know, that's part of business as usual in a reported data base. There's nothing gained from it in this case.

DR. OSTROM: The difference between this and the medical system is that, you know, as long as nobody was hurt, as long as they just busted their altitude and didn't crash, nobody was injured. Whereas in a medical situation and you try to do a data base like this and somebody got too much radiation, not enough radiation, the wrong site and so forth. So there's always those liability issues that come in.

MR. SHEPHERD: But that doesn't necessarily mean someone gets hurt.

DR. OSTROM: Right, but there's more potential liability that I can envision.

MR. WREATHALL: In almost all cases, the event is self-recovered by the person who's making the report. So it's not only they failed, but they also recovered.

DR. OSTROM: Or the pilot not informing that everything was fine. Or in some cases actually the flight controller says—they were supposed to be at 28,000 feet and they went to 31,500, and the flight controller actually said, you know, what's your current altitude, or your current altitude is 31,500, so it was kind of a prompt. So I mean there's kind of a more of a communal attitude.

MR. TORTORELLI: It's also easier to evaluate. There's no late effects there. You either crash or you don't.

DR. OSTROM: So the odds are in the room here somebody has been through an altitude bust some time during the year.

Okay, what we did is, we developed two models. We developed a sequential model process and a functional model, and we mapped the altitude deviations onto those particular models.

We first searched the ASRS data base for advanced cockpit altitude deviations. We found 200 that occurred between four of '91 and one of '92. We familiarized ourselves with the format, and then we did a second screen to identify those dealing with human system interface errors.

The coded reports were labeled and grouped. We did a cluster analysis to see how they fell out, of the difference points in the models. And this suggested the tasks, where the errors could have occurred within the system or where they were more likely.

This is one of the examples of how they were coded. And this, basically, is the words out of the report. There's some more information within the reports, but this is just part of the text:

We were rapidly climbing, 2500 feet per minute back down to flight level at 28,000 to take advantage of lighter head winds. The Captain was flying, and I said clear altitude of 28,000 in the altitude window.

Now these devices are very compact, and the functions of the flight management computer are multiple. I mean one control, if you pull it a certain way it does one thing. If you turn it a certain way it does another thing, if you push it in and so forth. So they are multi-functioned instruments.

The Captain assumed the plane had now descended in altitude. Instead it continued to climb because we had not reprogrammed the flight management computer. With the auto-pilot still engaged, the aircraft continued to climb and eventually leveled at 31,500, when air traffic control started asking us what our altitude was.

So they prompted them to say, you know, something—there's a problem.

We coded this, sequential coding was for set-up altitude change, and the functional coding was navigational planning for the flight management system.

The functional model illustrates success paths for providing critical safety functions. In this case we looked—we had identified six critical safety functions which we will talk about in a few minutes.

It shows the functional relationships of the systems; shows context of individual tasks within the overall flight functions; can be used to show sequence of attention to critical functions. If the pilot was attentive to one set of critical functions, but should have been attentive someplace else, it helps us identify those problems. It can be used to show the effects of distractions and can be dynamically exercised to show the effects of human errors of hardware failures.

Okay, our critical functions we identified for this were take-off, flight control, monitor flight conditions, navigation planning, monitoring navigation process and landing. Of the reports that we analyzed, 20 of them fell out in the navigation

planning block, so if I, as an analyst, were looking at someplace to attack first, I would begin to look at that part of the process, saying this is where we should begin a further analysis. And it is a very complex system, and as I'm approaching an airport, the conditions change dramatically quickly, and I may have to change my navigation planning very quickly, and the device did not lend itself well for that.

The sequential model illustrates a sequence of tasks and any of my potential error paths that I have associated with that.

The event tree shows sequences of human and hardware actions involved in any sort of process, and the HRA event trees show more detail because of the breakdown of human tasks.

These are used qualitatively to classify the types of errors and can be used to help quantify using the appropriate human error probability.

And this is one—we showed one a minute ago. This is one of the trees we felt—Lon developed, actually, for this particular operation. In this particular case, the flight crew received a new altitude clearance, and so it's information being communicated to the pilots. And the pilot not flying fails to hear the new altitude, one of the failures. The recovery to that is that the pilot flying fails to hear the NAC from the controller. So both of those—both of the pilots did not get that information, and then we consider it a failure of the system in this potential altitude loss. But if one of those things succeed, then we come down here to this junction, and at this point the pilot not flying can hear right or wrong instructions, and then recovery from that is that the pilot not flying omits the NAC read back to the controller, the wrong information is being communicated.

So these are the different failure paths associated with these tasks.

So when one develops models of various processes, this helps us identify where the potential error paths are and the potential recoveries to those errors.

Okay, the particular example we talked about a minute ago where we said it was a set-up problem, the wrong altitude, the wrong altitude. In this particular case, the example we showed mapped onto the sequential model that was developed. In this case, the pilot fails to enter the new altitude in the altitude reminder window and the recovery from that, the second pilot fails to remind or set new altitude in the ARW, Altitude Reminder Window. So that particular case mapped real well on this particular sequential model.

So hopefully we've developed these generic models to begin with, and mapped what our particular instances are that we find out in the real world onto them and see how they work. They may not always fit real well.

The second problem I want to talk about concerns a medical misadministration, and this particular effort was very short in duration, about two week's worth of effort, just to look and see how HRA methods apply to medical misadministrations.

The data for this analysis came from the investigation of an actual event and a visit to a second facility to fill in the holes in the information we didn't get from the investigation.

When we did the analysis, we only dealt with the top gate, which was one of three possible, and these three possible are wrong treatment site, wrong dose or wrong patient. And this particular example concerned wrong treatment site.

This particular misadministration concerned a patient who was undergoing treatment for cervical cancer using a manual brachytherapy approach. I just happen to have a mock-up of a colpostat here. What happened was that the patient had received 13 fractions from external beam radiation, and initial treatment with—an initial manual brachytherapy boost, 13 more treatments with external beam, and then follow up with the second manual brachytherapy boost.

The particular device that the physician used was a Henschke Applicator, which is not typical now in the industry. Most of them use a Fletcher Suit. But this particular applicator, now this is just a mock-up, requires that the source be inserted into a source carrier, which this represents, they're put in with a pair of tongs, and then a spring with a little—a spring that's got a helical shape and narrower on one end than the other end is inserted behind it, and then a cap is placed over the top, and the spring is to keep the source at the distal end of the colpostat. Then the colpostat with the source carrier is inserted into the Henschke

Applicator after the applicator has been inserted into the patient.

In this particular instance, the technician opened the wrong source drawer, because the source drawers were not labeled very well. In fact, they were confusingly labeled, pulled out the wrong sources, put them in the colpostat. Because they were smaller in diameter than the correct sources, they slipped through the end of the spring. And as a conservative measure, we said that they were fixed in location for the approximately 24 hours of treatment. And instead of a irradiating the cervical area where the cancer was, they radiated the trace to the vagina and caused some blistering of the skin. They also irradiated the inner aspects of the thighs.

When they discovered the problem, which was discovered by an X-ray which looked to see if the sources were appropriately located to do the dosimetry halfway through the treatment, they couldn't see the sources on the X-ray film, and went in and used the radiation detector and found out the patient was still hot, removed the sources, inserted the right correct sources and the patient went through the treatment for another 48 hours to complete the treatment.

The patient wasn't informed, I believe, of the problem for about three months, but actually had received radiation to the wrong site. The discovery of the situation, as Tim talked about today, this is one of the situations that was fortuitous. This particular dosimetrist or medical physicist wanted to do—to ensure the sources were correctly positioned and did the second X-ray. And it wasn't required. He could have just drawn the sources in the X-ray and done his dosimetry from that. But because he was training somebody else, he thought he would do it the correct way and X-ray the patient when the source was in place.

So when we developed the models for this, we first developed a process model to show all the steps that were involved, which is kind of analogous to what we do with the functional model. We then develop the fault tree. We've developed specific HRA event trees with specific human sequences. We quantified the model as best we could and generated cut sets and conducted a sensitivity analysis.

Obviously since we had done an investigation, we knew about the sequence. We knew about the sequence. And the sequence was specific to the site, because hopefully out there in the general medical community, the sources are better labeled than what we saw at this particular site, and we're not mixing smaller diameter sources in drawers that are incorrectly marked. But in this case, the failure that we saw was that the radiation technologist opened the incorrect drawer. The radiologist technologist supervisor failed to detect the error, and they were incorrectly using the source log book to log the sources in and out of storage. So the failure path we saw was the first one here. There were two chances to recover from this right away, and both of them failed.

Some other potential failures is that the radiation technologist could have selected the wrong sources from the same drawer from other sources stored there, but they would have probably caused—possibly caused other problems. And the radiation supervisor, radiation technology supervisor could, again, have not detected the error, and, again, they were not using the log book appropriately.

Another sequence that was interesting, and this is one slide I had up a few minutes ago. Other ways we found that they could have failed was if the physician incorrectly sited the uterus or adjusted the sail incorrectly. When they insert the colpostat, there's a little sail uterine stop device that is if it's not adjusted appropriately, the source is too far inside the uterus or not inside the uterus far enough, so the dose is not shaped correctly.

The physician could incorrectly place the whole device and improperly pack it so that the device could become loose and move when the patient is rolling over, and so forth. So there are other failure paths that we saw.

This particular sequence was interesting, because a lot of these failures could go undetected. You could have a misadministration and nobody would really know it, because there's no really good means of checking to make sure the device is placed correctly, other than with skill, the physician's skill.

Just a brief discussion. This risk assessment was interesting because it highlighted the failure path that led to the misadministration, and the reason it did is because we knew about it real well. We also knew the performance shaping factors, and in that particular institution, the performance

shaping factors were not very good, poor labeling, poor communications, radiation technology supervisor had not performed the task for 14 years, but when she did, when the two were in the room together, the radiation technologist selected the drawer of those sources the radiation technology supervisor had used so many years before. So we knew this information beforehand.

We also could look at the effects of licensee's corrective actions to determine whether or not they had a beneficial impact and how they impacted the overall modeling, or did they just impact the failure paths we looked at. We also saw other failure paths that could go undetected from the analysis.

So in summary, the analysis was beneficial because it showed the sequences of events and the performance-shaping factors, how the performance-shaping factors at the facility impacted—could have impacted this event. It also showed us a reasonable estimate of risk reduction if certain corrective actions were implemented at that particular facility.

Now some of the problems, obviously the classic one, is that there's no specific human error data base for the medical community, and there are no specific hardware failure rates, except this morning we heard like the Gamma Knife device has good data failure rates and Nucletron is keeping a good data base.

However, with manual brachytherapy devices that don't have any moving parts, per se, the failure rate information is expert estimation at best.

Now the reason we kind of generalize this model to other types of cervical cancer treatments is because this particular hospital is using a device that isn't used very much anymore. The Fletcher Suit device, rather than having a spring holding the source at the end—I lost my source—the source is held differently in the end of the ovoid and is locked in place. The ovoids could be placed incorrectly, but you would not get a similar-type problem.

DR. STITT: Oh, yes you can. I just did a consultation for one which happened in the same fashion with a Fletcher Suit, and there's still a stopper that goes in, and if you use the wrong length stopper from ignorance, then you get all the sources sitting completely out of—

DR. OSTROM: Okay, but in the center rather than—

DR. STITT: Yeah, the colpostats or the—

DR. OSTROM: Right. And one of the things we saw was with the tandem that they cut the plastic incorrectly and that could create a similar problem.

So, questions?

DR. GLASGOW: But your problem here really related to the individuals.

DR. OSTROM: It related to human error.

DR. GLASGOW: Not to equipment per se?

DR. OSTROM: Right.

DR. GLASGOW: So actually when you speak of the human data base, you really are there referring to individuals who normally carry out functions successfully thousands and thousands of times, and for some reason failed. In this particular case you're dealing with an individual who has 100 percent failure rate.

DR. OSTROM: Yeah, it was 100 percent. Human factor training was another performance-shaping factor. She was new to the organization.

DR. BLACKMAN: I guess I would add to that, though, the way that you stated that would make, I think, the lay person believe that you could not predict reliably performance of the human. And I take strong issue with that. In fact, we knew, because of the factors that were present in that particular hospital, that in fact care had not been taken and there was a very high probability that, in fact, the human would fail.

So I take issue a little bit with the direction that your statement made, because if you go to a facility, and you mentioned the labeling, you mentioned the training, and there were many other factors.

DR. GLASGOW: So you're saying had you gotten the facility's training records, you might have been able to assign a probability that something like this could have—

DR. BLACKMAN: Most assuredly.

DR. GLASGOW: To within what factors, factors of ten, a hundred, a thousand? I mean, could you—how accurately could you have predicted that there would be a situation where a person would do something once in 14 years? I mean, that would be almost impossible.

DR. BLACKMAN: I'll have to think about that. I'll tell you tomorrow.

DR. BUDNITZ: It's really hard, but you can see situations. All of us here over the years, you can see situations where it's a set up to fail. It doesn't mean they don't do it a hundred times right, but when it happens, they're just setting it up wrong.

DR. GLASGOW: I've often noticed that usually these situations that occur are normally the sequential occurrence of two events that go wrong or more. That's been one of the themes today, is that not the case?

DR. BICKEL: We looked at one that there must have been about four or five things. It was like a chain. It was in a hospital that they were trying to complete a patient's treatment before Thanksgiving or something like that, and it was an unusual treatment that they had not done, repeated many many times before. So it was an unusual treatment.

You had, I think, one of the physicians who was most knowledgeable about it took off early and did a switch-off to another one of his colleagues. Right at the time that they were getting ready to program the device, the physicist in medicine—I'm trying to use the terms correctly—got a phone call from a foreign country regarding a committee activity or a conference that was upcoming. The patient was sitting there, you know, all set, and so they paged another guy. And what they got, as I understand, they got a graduate student who was certified as a user. The graduate student came in, and guess what, he had been studying all night the night before for an examination. He came in, walks in, and, you know, you look at this chain, and you say, God, if they got through that thing without something going wrong, that would have been a miracle. There were so many contributing things, it was a set-up. There was no way, with all the things that contributed, that they were going to get through that without something going wrong. I think what was unusual is when we talked to the people involved, one of the technologists made the comment, yeah, there was so much going wrong that day that it was—we were thinking we were going to have a misadministration on that event.

And, you know, the real issue was it was a set-up. There was no doubt about it.

DR. GLASGOW: But it doesn't matter what the—you don't look at a bad event and find that somebody who normally does things right all the time in a common situation just for the hell of it did it wrong this time. You really don't see that happening when you look at the bad events. Whenever you look at the bad events, there are other conditions that made it quite likely for them to do that.

DR. BUDNITZ: So the intervention, either regulatory intervention or measured intervention, is to reduce the frequency and severity of the set-up events. That's where it's at. I think that's one of the lessons we've learned.

DR. BLACKMAN: For the training to recognize when you're in—

MR. WREATHALL: Or bad management actually creates the combination or that coupling of combinations which creates the circumstance. That's what we'll be talking about tomorrow.

DR. BUDNITZ: That's one of the lessons, I guess, we've heard the hard way.

MR. WREATHALL: And we continue to learn it. We never stop learning it.

DR. BICKEL: Hopefully if we really get into how to assess the risk of these lengthy processes, maybe one of the insights that comes from this work is the recognition of exactly where somebody says, wait a minute, stop. We're heading down a bad pathway. Let's regroup here and do this thing right.

A lot of these, when you read the misadministration reports, you come to the conclusion one or two people asking the right question at the right time would have stopped it. You know, but it's recognizing what are those most critical steps, the most important steps in there that control the safety of the process. And I think maybe that's a good lead into maybe our next speaker.

MR. SHEPHERD: One more comment on the probabilities, when we do predictive probability analysis, I can say there will be one such error in a thousand. I can't say that's the one that's going to be wrong.

So when you say can I predict it, well somebody who only does it once in 14 years, no.

And also, just because I predict one in a thousand doesn't mean that after 999 haven't occurred, the next one is going to be wrong.

## C.4.3. Fault Trees and Event Trees —Mr. Novack

DR. BICKEL: Our final speaker for the day is Steven Novack. And Steven going to do a little bit of greater detail and discussion of fault tree modeling versus event tree modeling, the pros and cons of how they can be applied and studied.

MR. NOVACK: Thank you. My name is Steven Novack. I'm a Risk Analyst at the INEL. I guess you could call me a physicist in risk analysis.

I've been involved with risk assessment for about 11 years now, including nuclear powers assessments and hazard assessments, environment ecological risk assessments. I'm also co-author of the NUREG that Tim Leahy mentioned, and I did some work with Bill Galyean.

I'm going to—I was asked—I should say I was targeted by Jim Tortorelli to introduce two traditional risk assessment tools extensively used in the aerospace industry, commercial nuclear power plant risk assessments and hazard comments for DOE sites.

We'll see tools everybody's really mentioned so far. I'm going to give a basic view of event tree and fault tree analysis. I'm going to try to apply that a little bit to nuclear medical misadministrations and go through some of the limitations of the techniques.

Event trees. Well, we saw a nice one—you could barely see it back there—from Lee. Event trees are inductive in nature. They answer the question, if this particular event occurs, what happens next? They relate a sequential procedure to an individual function. For example, they relate in misadministrations a treatment that could be a procedure. An individual function would be something like choosing the incorrect patient.

It visualizes event sequence progression and provides some sort of traceability of accident sequences. And you can think of accident sequences as a chain of events.

It's primarily utilized to identify a particular chain of events which result in some sort of outcome of interest, such as a misadministration. It provides a basis for probabilistic quantification of accident sequences.

I'm going to go a little bit through the terminology, knowing that there is a very diverse group of people here, and that perhaps if we're working in the same set of terminology and ideas, we can communicate a little bit better.

An initiating event. Well, that's basically the starting point. For example, in a hazard assessment, an initiating event would be something like an electrical panel fire, an internal. An external event would be an earthquake or flood or tornado. In commercial nuclear power plant, a loss of cooling accident would be an initiating event. In nuclear medical misadministrations, we chose treatment. There was a little discussion before about going back to diagnosis as opposed to treatment, but we're not really analyzing the doctor, we're analyzing the treatment.

The top event. The event occurs after the initiating event. For example, in hazard assessment, it would be like the success or failure of the fire department arriving in time to put out the electrical panel fire.

In nuclear power plant, it would be the reactor protection system activating the control rods.

In medical misadministration, it would be the success or failure that a particular patient was given the wrong treatment.

Sequence. Sequences is basically a combination of procedure, successes and failures, in response to some sort of initiating event which result in some outcome of interest. That's a chain of events, basically.

Lee explained this fairly well. Branching. Branching indicates some sort of effect on the outcome, generally up with success, it works. Down means failure, something does not work.

End states are groups of accident sequences which share some certain characteristics. End states are fairly important in evaluation of your event tree. How you determine your end states makes a big difference in what the results are. For example, hazard assessments. Well, a particular end state might be a large release of contamination. In commercial nuclear power plants, it's in terms of damage. In nuclear medical misadministrations, we particularly use a consequence as an end state as of high, low, medium doses to the patient.

You can group sequences in a lot of other manners. We can look at specific medical devices; you can look at specific treatments; you can look at specific facilities. So it really depends on what you're interested in looking at, as far as what the event tree is going to get to.

There's a nice complicated event tree. Actually, I made some copies here.

MR. WREATHALL: Same one as in the book?

MR. NOVACK: The same one that's in the book.

MR. WREATHALL: I still can't read it.

MR. NOVACK: You probably still can't read it. Well, let me just briefly explain it a little bit.

If you go all the way to the left, you can see that this is the initiating event here, and that the other categories up there are top events, the finer sequences.

Categorize them into initiating a process, planning a treatment, program treatment and executing a treatment.

At this end you'll see the results of each accident sequence which is represented by each one of these lines.

I think that's about all I'm going to say about the event tree for now. You can take a look at that. It's an example event tree that the INEL developed specifically for the HDR brachytherapy afterloading device, and it's an example of how we might use event trees to quantify medical misadministrations.

DR. GLASGOW: Do you assign a probability of occurrence in each of the steps along the top? Is that how you ...

MR. NOVACK: That's correct. And I'm going to try to make this a little bit brief, because I know you're all getting hungry.

I'm going to introduce fault trees now. You saw some of the fault trees that Tami introduced. Lee mentioned them, as well.

The purpose of the fault tree is to identify ways in which a process system can fail; identify causal relationships of failure events; quantify the failure probabilities; and, characterize some of the system weaknesses by evaluating the fault tree.

Fault trees, as opposed to event trees which are binary trees, these are multi-nodal trees. They can have more than—two or more events. They are deductive in nature, tend to answer the question how did this event occur.

The infamous basic building blocks of a fault tree. There are other types of gates and events used in fault trees. However, these are the basic ones, and the idea generally used with risk analysis is you can basically model anything you want with these three components.

The "or" gate, the representation of the Boolean union of input events, and the output will occur if at least one of the inputs exist.

The "end" gate is a Boolean intersection and the output will occur if all the events coexist.

And the basic event is a basic component fault which isn't developed further.

So what does all that mean? Well, here's an example: If, for example, I was interested in different ways I could fail to get to my morning meeting in the morning. An example of an "or" gate might be my car battery is depleted or I lost the key or my tire is flat or my alarm wasn't set.

An example of an "and" gate might be that everything worked fine, but I fell back asleep, good human error, and my back-up system, which is my wife, failed to wake me up. Those are connected by "and" gates.

DR. STITT: We always take the heat.

MR. NOVACK: Models are developed by actually linking events and then Boolean equations, which are mathematical expressions based on Boolean algebra that represent the model are then developed by evaluating that particular fault tree.

A couple other terminology, minimal cut sets, which is a combination of sufficient fault to result in some sort of occurrence, in this case a medical misadministration.

And then dominant contributors. A lot of people mentioned dominant accident sequences that the idea pertains to dominant faults, as well. They are failures which are quantitatively the largest contributors to the likelihood of some defined events.

And this is what you should have in front of you now, an example of a fault tree with the top page that is the source that dwells beyond prescribed time. This is also for an HDR brachytherapy device. I'm just going to point out a couple things in here. If you look closely, you'll see over on the left-hand corner here some software faults, going through an "or" gate. You'll see two different timers here, a primary timer and a secondary timer anded together mean that they both must fail in order to fail this top gate.

You'll see hardware failure, such as microprocessors, common cause failures of the timers.

My point being that there's lots of different types of things in these fault trees mentioned in lots of different talks that I heard this afternoon. And they can be appropriately accommodated in this type of logic model.

Just an example of a minimum cut set, you'll see that any one of these faults will fail the top gate because they're connected by an "or" gate here and, therefore, each one of these faults are minimum cut sets.

I'm just going to go through similarities between event trees and fault trees. Both tools can model the same process, and actually the output of both are Boolean logic models. Generally speaking, event trees are the easiest for lay people to understand. Fault trees get a little complicated, you can get lost in them, and it's best to, if you can, put information for understanding and visualization.

Some differences between event trees and fault trees. Again, event trees apply some sort of inductive reasoning and map a specific event to a general outcome and answer the question if this event occurs, what happens next?

Fault trees are deductive in nature and map a general outcome to a specific event and answer the question how can this outcome occur?

Event trees tend to have combinations of success and failures, and fault trees focus mostly on faults.

There are several additional analyses that an analyst can perform to aid in characterization of their data or their model when they're developing fault trees and event trees. One of them is an importance analysis. An importance analysis is basically a measure of the event's contribution to some derived risks, the risk being probability times consequence.

The results identify events that contribute significantly to the derived risk, and I just want to mention briefly a couple types of importance analyses. We don't need to go into detail on them, but just for information, there's something called a Fussell-Vesely Method which is a fractional risk; there's a risk reduction ratio method; and, a risk increase ratio.

In general, what it does is allow the analyst to rank events, or in this case of medical procedures, perhaps to rank tasks, based on some sort of risk contribution.

In the application objectives, interested in developing estimates of relative and absolute risks to the patient associated with potential misadministrations during treatment process; identify importance of specific procedures, alarms, device interlocks; determine the risk significance of past events; and, identify key tasks, functions and safety barriers.

And to do this, I generally, after looking at some of the analyses, I generally tend to like large event trees with small supporting fault trees. That's my personal opinion, and I think that it allows hardware failures to come into play. It gives a good visualization of the procedure.

Some of the strengths of this approach. Obviously it gives you a visual representation of what's going on, of the treatment process. It also estimates quantitative results in terms of risk, which is what we're trying to get to here, and we're

able to then make some sort of decisions based on contributions to risk. It incorporates human errors, software, hardware and common mode failures as shown in the fault trees, and nicely enough, there's lots of tools available to do this type of analysis.

Some of the limitations. Well, we kind of hit these a couple of times. Three words: Data, data, data. They're going to be difficult to obtain. We don't have extensive operating experience in a lot of these things. Something known as GIGO in the software industry, garbage in, garbage out. Any sort of modeling analysis of data is important. Obviously what you put in is going to represent what you get out.

Although there are lots of tools available, and this has been used in different industries, really limited use in medical misadministrations. I think really it is left up to maybe some of the discussions later on about whether how appropriate these techniques are in the use of medical misadministrations. That's it.

Any short questions?

DR. WU: I have a comment here. We worked on fault trees and event trees for many many years. Our experience—I want to share experience. I don't want to discourage you in any way.

We found that it's fairly—we feel fairly comfortable with if we use fault tree analysis or event tree analysis doing hardware system analysis. In the last project we did for NRC on nuclear power plant, we tried to use event tree and fault tree analysis. We spent a lot of resources in trying to develop a fault tree and event tree for a project similar to yours, which is heavily organizational related, and it's work process instead of systems.

And we found the most difficulty we faced was these events are heavily dependent to each other. For example, if you identify the wrong patient and use the wrong applicator placement, and usually it's the same staff under the same organization under the same supervisor. And it's very very hard to identify tendency.

MR. NOVACK: Under the same type stuff, is that what you're saying?

DR. WU: Right, under the whole big common cause factor there is the organization. Not only is it very hard to find the specific data, because you use data from the industry which is more—it's quite heavily—even the human reliability data or more generic than in plant specific.

And we found it's very very difficult to use the comfortable old methodologies that we relied on for a long time.

And another notion is on the software. When you try to develop fault tree for software, it's a whole different ballgame, and we tried very hard to develop fault trees for software. First of all, the size of the fault tree is quite unmanageable.

Secondly, there's no data. How are you going to identify the data associated one single line or a sub-role?

Those are the difficulties we face, and we try very hard to struggle with. And I just want to share my experience.

MR. NOVACK: I think those are good points and good comments, and I think it still remains to be seen whether these approaches can be used appropriately in misadministrations.

DR. BICKEL: We would like to have these types of points, I think, brought up again in the discussion sections that we plan for tomorrow.

So without further questions, Pat, would you like to—

DR. RATHBUN: No.

DR. BICKEL: You don't want to have the last word?

DR. RATHBUN: No. I have the last word.

DR. BICKEL: With that, it's a wrap, folks. See you here tomorrow morning then.

(The hearing was adjourned for the day)

## C.4.4. Generic Error Modeling —Mr. Wreathall

DR. BICKEL: I guess our first speaker today is John Wreathall, who will be discussing—who will be, basically, kind of take up what we did yesterday, which was generic error modeling.

MR. WREATHALL: What I'm going to talk about is, it impinges on several of the things we talked about yesterday. In fact, there's some variations in from what I had originally planned be-

cause of some of the discussion yesterday. The slides will not necessarily follow in the traditional coherent fashion.

The subject of what I'm talking about is the question of human error and how human error is analyzed in events, how human error should be represented in risk assessments and safety studies. And it relates to human reliability, which we talked about yesterday, to event analysis and data bases, data gathering, all those areas, so we can get information from what we experience and try and make use of it in some way in the future. So what I'm talking about is essentially that human performance part of the system we're dealing with, the hardware, the medical processes and purposes behind it.

The perspective that I'm bringing into this is much associated with some of the discussions at the beginning yesterday. Larry mentioned that in many ways human error is a common factor across technological systems, be it aviation, be it nuclear power plants, chemical processes, and as we now found in the medical administrations area. So what I'm trying to do is to bring a common view of human error.

DR. GLASGOW: I get to go to conferences like this and ask incredibly dumb questions at various times, and usually when I come across terms I don't know I can go to the dictionary and ask. I know taxidermy. I trust that this particular term is not an IRS term, but tell me a little bit more about exactly the meaning of this term, okay, because I don't know it.

MR. WREATHALL: It has nothing to do with stuffing of dead chickens. I'd like to make that clear.

DR. GLASGOW: I thought perhaps it was stuffing scientists.

MR. WREATHALL: It could well be. Bob mentioned stuffing the IRS.

What I'm meaning by taxonomy is simply a set of classifications. And by that, the classifications are aimed to try and provide levels of relationships between different factors that you can see in events. And I'll go on to explain specifically what I'm talking about. But the term taxonomy is really just a way of classifying things.

So what here I'm going to be doing is taking the view on human error and bringing in classifications that relate to the causes, the types and the consequences of human errors. And that's what I'll be talking about.

Why do we need such a classification? Well, particularly in the question of the medical misadministrations and other technical disciplines, what we see is from the outside, there seems to be a lot of complexity in events, in the specifics of the events. Some person did this; another person did that; this was happening; something else was happening; and, it's quite a rich picture in terms of all the different factors that seem to be going on. And if you just look at a single event, it seems very complex, and it seems very specific to that incident.

What we need to do is try and back away from that and pull some broader principles, if we can, from the events that we see. Now when we're dealing with human actions in technical settings, it's a multi-disciplinary question. There's no one group that deals with all those aspects of it. Engineers might be dealing with the nuclear power plant part and plant corporation people; human factors people may be dealing with a specific human part of that, procedures, the man interface and so on; but, no one discipline deals with the whole big picture. So what we need to do is to have a way for bringing in the perspectives that each of those disciplines bring to that problem to try and pass out the different contributions.

The second thing that tends to cause confusion is the fact that there is often no common language between these disciplines. And the most notorious term in this area, the term human error, it's a common term used in behavioral sciences and engineering and risk assessment. It has entirely contrary meanings between those communities.

What a PRA analyst means by human error is usually a human cause of a failure of a piece of equipment. In a power plant an operator fails to start a piece of equipment. In the case of the medical misadministrations, a wrong piece of data is entered into the computer, the set-up program. Whereas to a behavioral scientist, particularly a cognitive psychologist, the human error is a much different set of issues to deal with the mental processes of what was going on and associated to that.

So if we talk about what are we going to do about human error, people start coming to thinking very different thoughts about it. There was a NATO conference, I think in '84 or '85, on the question of human error. It took about a week with about 20 people there, engineers, psychologists, lawyers, and they came up with a final definition to work on a common definition of human error. It was a human error occurs in those circumstances where an outside expert deemed it was the wrong thing to do. Not an exactly useful definition to work in the community. So when we use these terms, we need to be careful about their meaning.

And last at the bottom here, as we try to pass out these contributions and the different disciplines and clarify the language, what are the generic lessons we can learn from the particular events that have taken place?

Let me cast that statement in a slightly different way, and that's my view. When we talk about gathering data, we have to know what it is we want to gather and why we're gathering it, because without that, we're just gathering pockets of data. You're going to store them; you're going to hold them; but, what can you do with them? It's very difficult to work that out. So I'm trying to avoid just generating buckets of data.

Let me talk a little bit about the world of PRA and how human errors typically have been found fitted in here. Can people read that? It seems to be very dark.

And this is addressing some of the discussion yesterday on what PRA and Human Reliability Analysis are, how they work and how they fit together, to give you a sense of where I'm starting from in the risk analysis perspective and what I'm going to talk about.

The PRA models, the logic model, the fault tree, the event tree which we talked about in the last presentation by Steve yesterday, these are the models that say here is the sequence by which someone can be given an unacceptable dose. Those identify in them the so-called human errors as potential causes of some of the pathways in there. The typical process by which the PRA is done is the logic models are identified first, and then handed to the human reliability analyst is a list of human errors. Data entry and set-up program, for example, is a kind of human error that would be identified to the human reliability analyst.

It's somewhat a fuzzy boundary between the two, but these are identified to the analyst who then goes off and looks at the kind of things we heard about from Lee, the shaping factors, the quality of the interface, procedures and all that. And based on what he's found in those, how good they are, and some other factors, a number or a profile is identified for the particular human errors, and then the human reliability quantification process generates probabilities that are then put in the fault trees and event trees to quantify risk.

I'm going to argue that this is a dangerously simplistic way of viewing the human interactions, and when we talk about data of events in the real world, they really don't map into this framework here.

Now at the risk of leaping from one extreme to the other, what I'm proposing is this view, and I'd like to maybe close off this top part initially, the role of regulators, since we'd like to keep them at arm's distance as much as we can. But I will come back to that, because it has an important role, maybe in the discussions, particularly in the next day or so.

So let me deal with this part. Maybe if I just move this up. Well, I'm not sure how well—

DR. BICKEL: You know that you can't get regulators out of the picture?

MR. WREATHALL: Nicely put. Okay, let me talk about this part first, which is the modeling question of the analysis question.

In the issues we're dealing with specific in the risk assessment sense or even in the safety assessment sense, there are specifically unacceptable outcomes that are identified with those exceeding 20 percent dose to the wrong body part and so on. But in the risk assessment is the top event, if you like, or the consequence event in the logic models.

In the same way that the PRA had human errors that can contribute to those, we have human failure events. And I'm changing the terminology specifically because of that issue to deal with what is a human error or what are the issues we're dealing with? I'm breaking it into two parts, and I'll go on to discuss that in a moment.

The point is that the human failure event is seen in the context of the cause of the unacceptable outcome. It is, if you like, the entry of the wrong data in the set-up program, the selection of the wrong patient. So this, the human failure event, is the human-related cause that has an unacceptable outcome. But that has a whole bunch of causes, if you like, associated with it. Why did that happen?

A human error is not just the answer to why something happened. It's something that needs an explanation itself. And what we're seeking to do is to use this part of the information to explain why that happened, because there may be factors in here that require different ways of gathering data, analyzing the data and interpreting it, and then in a risk assessment, going to different models. So let me come back this way.

The unsafe actions then is the first step back here, and it's the specific things the person did at the time that led to this human failure event. Why was it they selected the wrong patient? Did somebody misread a risk label? Did someone confuse two numbers when they entered the data in the computer set-up program? What specific human-related factors led to that system-related consequence? And we have ways of classifying this. When we talk about taxonomies, we're talking about ways of classifying these factors in here. And I'll go on to talk about these in a moment.

So this is the thing the person did, the action taken by a person or the action not taken by a person that puts, in this case, a patient in a less safe state. Safety as defined in this unacceptable outcome.

In terms, that's the action taken, but that action resulted from some cognitive processes, some thinking activities or some reading activities, reading data and then transcribing it into a program.

There are things that are not observable. These are the between-the-ears part of the problem, this part. But these, in turn, the reasons why we have errors in what we do is very much shaped by the things we're provided with in the setting that we're in. So the performance-shaping factors of the influences that we talked about like procedures, like man and machine interface, like the training, but it's in the context of what was going on at the time.

There's a great variety of conditions under which people are taking the actions. We heard about the difference with the frequencies with which different institutions perform certain activities, some are five a year, some are 200 a year. Those provide very different conditions, particularly if the five per year suddenly has to do three in one day. That creates very abnormal conditions and can create opportunities for people to make errors that would not occur if it was simply once a month or once every two months.

What we call the contingent conditions is something that PRA and HRA has not really focused any attention on in the past, and that is what are those conditions the task is putting on people, the activity is putting on people—in this case the treatment—that creates the conditions by which errors are almost forced. And underlying this is a sort of belief I have and others have, and that is, on the whole, professional people are very reliable except when conditions force them to fail, rather than people being a randomly varying thing, some days they succeed, some days they fail. There is that element we are somewhat stochastic in our behavior, but usually systems have defenses built in to catch those, particularly in a high hazard system: Power plants, chemical plants, medical processes have checks in place. So most of the things that might cause—that are minor errors very rarely result in unacceptable outcomes. It's when the sort of barriers in place break down that those become significant failures.

So I'll go on to talk about various elements in here. Maybe just to come back to that top line. I quickly stepped over the comment here that when I talk about unsafe actions, it's an action taken that puts the patient in a less safe state. And that presumes that we can define what we mean specifically by safety. And we had in the presentation yesterday a good example of the difficulties in picking specifically what we mean by less safe, especially when it comes to a kind of risk assessment or regulatory domain as to what should be the unacceptable outcome. Is it the 20 percent deviation? Should it be ten percent? Should it be an absolute delta dose? All those kinds of issues are embedded in is it really unsafe. Compared with the nuclear power plant, there's a very different dimension in the medical misadministration where not treating the thing is as dangerous, in some cases, as overtreating, maybe more so. So the criteria of safety to judgment of the action made the

patient less safe is a little more complex. And that's something that can be debated, but in the end it comes down to a regulatory issue. What do you decide is safety in this context? And similarly, how is safety defined at the end here?

If we're dealing with risk assessment, risk assessment has, in practice, to have very specific outcomes that we will define as the unacceptable conditions, largely black and white criteria. Whereas here, it's much more shades of gray. So it's not always possible to relate in the risk assessment sense the same definition of safety here as it is here. Life is a little more complex than that.

Just to go over the various paths of that framework and maybe bring out some of the points on it. Just to reiterate why we broke down the unsafe actions versus the term human errors.

First of all, as we mentioned, the term adds confusion rather than clarity in most questions. It really has in the past delayed communications, and just to reiterate that bottom line, the definition: Those actions done or left undone that cause a less safe state. So when I talk about unsafe actions, I'm talking specifically about those human actions that are causing a safety problem.

Now this is more relating specifically to the PRA environment. The human failure events, if you like, the basic events in the risk assessment that talk about the human caused failures. They may or may not involve errors on the part of people, or they simply may be people performing an action that is exactly the right thing to do as, for example, defined in the procedural or some other written protocol but, in fact, in the circumstance was the wrong thing. But the person may have no blame attached. It seemed it was judged even after the event to be exactly the right thing to have done. So there's no question of blame attached to a human failure.

Now the dead chicken stuff, the taxonomy part. I want to bring in a classification of the different kinds of unsafe actions. And the reason I'm doing this is because when we start talking about the consequences of particular types of human errors and the causes of those different kinds of human errors, we're dealing with different factors across the spectrum.

So to move on, there are a variety of definitions, classifications of what here we're calling unsafe acts. And the distinction I'm making here, at least on the first slide, are those actions taken where the outcome that the person took was not really what they intended. A simple every-day example is you're dialing a phone number you know, and you transpose two digits. It's not what you intended. It was simply just a slip in attention while you're dialing. Some other number comes into your mind and, you know, they have a common prefix, and you finish up dialing the wrong number.

The point about the actions performed were not as intended that's very important is that in most cases, it's very easy to recognize that you've done that and correct it yourself. It's human nature that these occur very frequently, and it's also human nature that you correct it yourself before any consequence of any significance happens.

Just to give you a scary indicator on how frequent these are, there was a program of where a person sat in the third seat in the cockpit, and they observed the pilots were observed to make typically eight errors an hour, principally in this classification. And all of them were nonconsequential, all of them were self-corrective. It would be such things as setting up the wrong frequency on a radio communication and call a particular tower, and, of course, they don't call back. You recognize it's an error and reset the numbers.

There's a distinction in here that is mine, and I really want to dwell on it, that if you're carrying phone numbers around in your head and then some time you just can't recall a number, or you have a number that's almost right is more of a memory problem. And those are being labeled slips, where you're just holding something in your memory, and you just can't recall it correctly. The other is where you're distracted by something. You're performing some task, the phone rings, and you go back to performing the task, you know, continue it and you skip a step. Your attention has been distracted by something.

Slips and lapses. For the purposes of what we'll be doing here, essentially, really the same thing. The same thing in terms of the kinds of consequences they lead to. Cognitive psychologists would get into great slugging matches as to whether they are the same thing or not. It's not important for our distinction here.

The big distinction in terms of the impact on safety is compared with those actions that were taken as were intended, but the intention was wrong. And in this case, you have people performing a whole set of actions that are programmed. They're purposeful. They go ahead and carry out those actions and be very diligent and very persevering in the face of problems, but it's the wrong intention. Now the problem with this is that these are almost impossible, not always, but almost impossible to self-correct at the time, because the intention that you have is the intention you're following. And what happens after that is just the outcome of that intention. So here, applying a treatment to the wrong patient, you have a patient there, you believe it's the right patient. The treatment starts, you're very diligent in pursuing that treatment.

There are a minor, somewhat minor, subset of these, but it can result either from you simply have the wrong knowledge or you're applying the knowledge, but the knowledge is wrong, or where you're following some kind of written procedure commonly in nuclear power plant, less common in the medical area, I think, where the procedure itself contains the flaws and errors. So you're purposely applying that, but it's the wrong or faulty procedure. That's found to be a big problem in certain modes of operation in power plants. The procedures themselves contain the errors.

The third classification, which is an interesting one and a little controversial. Again, actions taken intentionally that break rules, what we've called circumventions. An example was described yesterday, classic example in Glenn's discussion of QA programs, and that requirement that people shall remove keys from equipment when it's unattended. In practice, really can't do that. It's not that they don't want to, it's just an impossible thing. In one sense is an example of a set of circumventions where the rules just cannot be performed in the way that in practice the world operates. The danger then comes that other people now assume that rule is in place, people will follow it, and build assumptions and other safety rules assume that to be performed. That's when the danger really arises. That's one of the kinds of circumventions that we do deal with where it can, in practice, be the only way that a task is performed. Or it may be the most efficient way. Certainly one of the ways in which organized labor can pretty much slow down any organizational function is to apply the regulations to the letter of the regulations, a work to rule plan. That, in itself, is a measure of how much the world really cannot live by the simple written rule. There's an awful lot of things that have to be done either that are inconsistent with it or are not covered by that.

Coming down the spectrum of sort of removing blame from the person towards being a more blame-worthy situation is that it can be an easy way of performing the task. It's not the way you were instructed to do it, not the way you intended to do it, but in practice it happens to be easier. If you have to perform tasks in different locations, it's quite common to perform all those tasks associated with one location and go to the next location and do the tasks there. And if the job is not really well designed, it may require you to go to A, B, back to A, back to B and so on. And if people don't run into problems with that, they will learn very quickly the quickest way of doing something. And if there are no penalties—I don't particularly mean organizational penalties, though those are one case—I really mean that there's no unacceptable outcome—in most cases, that becomes the normal way of doing business.

Then, of course, when I talk about those contingent conditions one day that sequence becomes important, the person follows the old way of doing things and an unacceptable consequence arises.

The last category which has been found a big problem in transportation is that there are thick rule books to be followed, particularly in things like railroads, some degree in the aviation industry, where the rules themselves are just inconsistent. You can't meet all the requirements. You can meet one and not the other, or they conflict each other. The person left to resolve that conflict is just the poor guy at the sharp end on the day.

So one important point about this circumvention. It's not sabotage. There's no intent to cause harm. It's just that the only way to do the job or the most efficient way to do the job is not really to follow the written rules.

Now the distinction—okay, just one more slide before I get to that. In terms of the outcomes the risk assessment community deals with, the unsafe actions can be active or latent. That is, the unsafe consequence of that can be immediately revealed. You immediately know it by what is happening, or it can cause latent problems. That is, it's

defeating barriers that are in place that may be important in some future event, perhaps disables alarms or interlocks that in some future event would have been the barrier that could have prevented some problem.

And depending on the setting, that same unsafe action can have a consequence that leads to something being missed out, so-called error of omission in a risk assessment. The kind of remark an operator fails to take some action as a human failure event in a PRA is the failure of omission or operator inadvertently actuates, operator creates a new situation is the act of commission. But none of these imply, in most cases, fault with the individual involved. Usually they have been set up by some circumstances.

On involving a data base that has absolutely zero credibility in terms of the statistics, but reflects the biases and prejudices of the analyst, I just want to mention this result about events in nuclear power plants during low power and shutdown, that is the conditions when the reactor is not generating power, but maintenance work is going on, refueling and so on.

We looked at some events and identified what kinds of human errors, human failure events, unsafe actions, were involved in that. Now on the original, this is a clearly light gray and this is dark gray. I don't know whether you can see the distinction here.

Mistakes, the actions performed that were the purposeful pursuit of a faulty intention, were a moderately larger contributor to events that had a major potential consequence in terms of safety. In terms of events that had a minor or relatively minor implication for safety, the slips and lapses, they're more frequent, but not the purposeful intention were the contributors.

And this matches the bias in the sentence that it's those actions taken that are what you intended, you keep doing it, you don't self-correct, you don't detect there's a problem with that. Perhaps less frequent than slips and lapses, but when it comes to significant safety problems are the much bigger, or at least a bigger contributor. So when we talked about what are the causes of human error, what is really important to know is what are the causes of mistakes.

Let me move along to talk about that in a little bit. I'll just touch on the question of error mechanisms. It's the part where cognitive psychology really plays its role.

The big problem with it, at least in terms of engineers and analysts, it's the unobservable part of the event. You don't really know what was going on in the person's mind. You can see the action that was taken. You can find out and go back and do interviews and assessments and INEL has been doing that in these event investigations where people are going out and doing interviews very soon after the event, are probably the only way of gaining information on this, certainly reading event reports of any kind are. You can draw inferences, but you don't know the specifics.

The point is that there are different error mechanisms associated with the different kinds of slips and lapses here, problems in attention, memory and recognition, versus these in the mistake category here. The situation of appraisal, verification, knowledge problems here.

So if we're going to concentrate some effort on looking at the mistake part of the human contribution, it's what are the factors that lead to these particular error mechanisms and others like it that lead to the consequence of mistakes, trying to reduce down the things and the dimensions we need to look at, so we can look at those that are important in more detail.

The slips and lapses involving the intentional failures, things like distraction, workload and stress, are contributors in that area. They're the principal factors that affect the slips and lapses. We're not so much interested in that as we were in the various causes of the mistakes, the recognition failures, the situation appraisal failures.

So what these are aiming us towards, as I had in that earlier slide—as we backtrack in terms of trying to decipher information in real events, as we try and uncover theories in cognition in behavioral sciences in this area to lead us back to what kinds of shaping factors do we need information on, on what factors or what conditions appear to be contributors, the biggest payoff comes if we limit this to a particular area of mistakes. So what I'm trying to do is to get back to what are the principal lists of precepts and the contingent conditions that we need information.

Going down here, we have, at least in this language, information on information sources, distractions in the activities, the role of stress again. And the situation appraisal area, what we're really dealing with is information which is not always necessarily as clear as it should be and, in fact, when we're trying to make an assessment, we the operator, we the person performing the task, what information is coming to us that allows us to understand exactly what it is we should be doing. This is in the area, for example, where the poor training in procedures tends to play an important role. The knowledge failures, clearly the information base that the person is working to, the training and procedures, the supervision play an important role.

So when you want to gather information on the PSFs, the PSFs specifically associated with these errors, if we're to focus on the mistakes part. Again, using an entirely invalid statistical sample, too small claim to its proof, we do indeed see different PSFs down here, performance shaping factors associated with communications, design—these are nuclear power plant examples. The specifics here relate to the nuclear plant setting. The common conditions across the communications, the displays and labeling, man/machine interface, the content and the layout of the procedures, supervision, training, and the work setting. There are discriminations across here. Communications play a big role in mistakes, particularly the rule-based mistakes, the instruction passed from one person to another, negligible contribution mistakes. No distinction in design, but in terms of the man/machine displays, human machine interface plays a big role in the set-up of the mistakes, moderate for slips. When we deal with labeling, this is again power plant issue where the equipment is distributed through large areas, so you have to go to a specific piece of equipment to actuate it. It tends to play a somewhat bigger role here than slips. And so on.

The point is that there are some distinctions you can observe in the data that support our theories on why particular errors mechanisms are associated with particular PSFs. And, therefore, related to the data gathering, if we're going to come up with better working theories, at least in the risk assessment part, where I will argue at the end of this that the human contribution right now is not a well-modeled part of the problem, that we really need a gathering that will allow us to fill out the questions in here.

Coming now to contingent conditions, those are the parts of the work setting that create the opportunities for the unsafe actions, how particular error mechanisms become particular unsafe actions. A slip may or may not, or should I say the memory being fallible, as it always is, doesn't cause problems in all cases, because we either have notes that we follow; we have records that we keep. The problems only become important when we're doing a particular task where the records are not available and notes are not available or whatever.

So there's something in the workplace, as well as the error mechanisms, that are important to actually create opportunities for human error part.

Also, there are certain kinds of activities that we perform that make us a greater risk from those error mechanisms that do exist. Performing dynamic tasks where we're following step after step after step that may be paced at a fairly active rate has opportunities for errors that just a static task that I perform this action and then I can walk away.

Humans are not very precise creatures when they're performing tasks, you know, drawing samples, performing tracking tasks with controls. There tends to be a margin associated with that. We've most of the time, by the way jobs and tasks are designed, they're not important. But where we're dealing with a very narrow boundary line, it's very easy to fall over that. And there's an opportunity for an action with just normal human behavior and very tight tracking to become an unsafe action. If there are many ways that you can go wrong performing an action or an activity, then clearly the opportunities are so much greater. So even if we have a common error mechanism rate, if you will, the opportunities for just getting it wrong increase.

MR. SHEPHERD: May I ask a question? On your first item error mechanism there, does feedback in the system play any role in this?

MR. WREATHALL: Yes, feedback from a system is a very good way to recover from slips and lapses, because then you know that what you were intending to have happen isn't happening, and you can go out and find, yes, indeed, I started

the wrong piece of equipment. You know, I did, indeed, enter the wrong data. I read it on the screen, and I can correct it.

The best example is an every-day use of the phones that you have that have a digital readout of the number I dialed. I find I rely on that a lot to correct errors that I commit in numbers. If that now goes away, you will find that your adaptation to that feedback is lost, and the potential for that now to become an unsafe action is that much greater.

DR. BLEY: Related side of that that you've hinted at, but I don't think you've said it quite explicitly, and that is does feedback from the system do us much good with respect to mistakes? And yesterday somebody had said, gee, all we need is somebody to say, oh, you're doing something wrong and everything comes clear. And I think for mistakes, that's not true. We're remarkably adept at rationalizing inconsistent information coming back to us and explaining it away.

DR. BLACKMAN: I think you have to be careful on that one, very careful. The body of research on feedback that largely comes from, which there's years and years of research on this, would not agree with that statement at all. And in fact, the feedback, the only function feedback really performs is, in fact, correcting errors. That's what it does, okay? It works two ways, all right?

One way that it works is for the slips and lapses that John just mentioned, and what that is, that's immediate recognition that you've done something wrong. And then the second case, the second way the feedback functions, there's a whole series of studies that talks about it where you've actually made a mistake where you've formed an intention and said I'm going to do this because I know it's right, and I'm going to fix it. And then you get feedback that says you're not doing—you're not right. And generally what that does, and the best analog I can think of is when you're taking an exam. How many of you have taken exams? No one? Incredible.

Anyway, when you take an exam and you answer a question and you know you've answered it right, and you get the test back and the professor says you're wrong. What's your first reaction?

MR. CAMPER: He's mistaken.

DR. BLACKMAN: He's mistaken. He's wrong. I'm right. And what do you do? You scurry about trying to prove that you are, in fact, correct.

So actually, when you've formed an intention and you believe that you're right and you get feedback that suggests that you are, in fact, wrong, generally what it does is it even heightens awareness even more, and what you generally do is pursue additional feedback that either confirms or disconfirms your hypothesis. So the actual function—it's actually stronger in terms of its functionality.

MR. WREATHALL: But in the last case you're talking about, I think in most cases the tendency is to seek out information that confirms you are right, compared to looking for oh, yes, I'm wrong, and I'm going to prove myself wrong.

DR. BLACKMAN: You do seek information, right, but as a matter of course, when you—

MR. WREATHALL: You may uncover—

DR. BLACKMAN: —when you seek that you continue to disconfirm—

MR. WREATHALL: You can be very good in persuading yourself you are right and now the book's wrong. And you can continue the logic back to explain why you're still right.

DR. BLEY: If you look at operational events, you see many of them where people have just bypassed that. Eventually—

DR. BUDNITZ: May or may not.

DR. BLEY: I don't think we're disagreeing all that much. Eventually it sinks in, or you find more information. But during critical periods of time in real accidents, you see times when people just rationalize away these things or say I know I'm right and this book's wrong.

DR. BLACKMAN: Well, the work that's been done by Gary Klein, I don't know if you're familiar with it, which is basically—go ahead. We can talk about this later, because I don't agree, obviously.

MR. WREATHALL: We will straighten Harold out later, even though he will persist in the face of all these corrections.

DR. BLACKMAN: I know I'm right.

MR. WREATHALL: Just to illustrate all these abstractions that I've been talking about on contingent conditions and unsafe actions, trying to bring it to a specific example that may make something a little more common to the group that's here.

In the handout is a study which we did of just two or three events to see if this framework had any relevance to this. The framework grew out of some work originally started that Jim Reisen was doing with Royal Dutch Shell on human errors on oil rigs and in the oil exploration business. That started us down the pathway of the relationship between humans and human errors and how systems and organizations or systems, engineered systems come into problems. So the ideas on relaying this came from a quite different discipline.

It then became a little bit refined with some work on British Airways, British Airways Engineering, not pilot problems, but engineering problems in aircraft maintenance. And it kind of has grown elements as time has gone on. The latest work that we were doing, and still continue to do in this area, is work being done for the NRC on human performance during low power and shutdown events, the Office of Research and Jim Johnson and his group is doing this work under it.

We then tried to bring that framework to see what it did and if it had use in any medical misadministration activity. So let me at least try and illustrate the concepts and what it is we're doing and what some of the distinctions are here. This was an Event A in the NUREG that's also in the handout, the remote HDR brachytherapy, where we had, in fact it was discussed yesterday briefly, the event where we had a cycling of different people, replacement positions, two patients in one day, each of whom had similar catheterizations being done at a facility that was used to no more than one a day, in fact, very rarely that number. So it was a case where when I talk about contingent conditions at the bottom here, things that in the way this activity came about were unusual conditions for the way business was done at this facility. The number of patients having similar catheterizations led an opportunity for the wrong patient to be given or the patient to be given the dose intended for the other patient.

Backtracking from here, this was classified in the event system as a dose to the wrong site, because the treatment plan for the one patient was for a different location compared to the patient who was dosed. The way that came about in terms of the human failure event was that the wrong data were entered into the programming set-up part of the HDR unit.

So here we have the consequence and what will be described as a human error cause if one were simply to take pilot error information as to why this came about, somebody entered the wrong data. That level of explanation doesn't really help us correct what the problems are, so as we go back down the tree seeking what were the causes of this, the physicist himself was—picked up the wrong folder, the wrong chart. There were two charts just lying there. There seemed to be, at least in the event descriptions and the discussions I had, no way that indicated which chart was particularly in sequence with the way the patients were going to come in. There were just two charts laying around, so there was a problem associated with labeling.

DR. BICKEL: There was one other contributing factor. There were more people in the treatment control area.

MR. WREATHALL: Right.

DR. BICKEL: And one of them happened to sit down on the table, sitting on one. So when the guy came in, all he saw was one chart.

MR. WREATHALL: That's a level that I didn't have any information. Particularly what I call the procedure part, the chart management procedures here, just lying around and people sitting on them, was a factor in here in selecting the wrong chart. Whether there could have been a system in place to locate charts and to have better management of them would seem an open question here.

The data, also, as well as picking up the wrong chart, had performed no task to confirm the patient's identity, because the physician who was normally there would have identified what patient it was, yes, this is the right patient. I recognize the individual. So he, himself, did not go and check that the patient identity corresponded with the chart. So the physicist was associated with this—I have the wrong chart for the right patient kind of situation. So he goes ahead and enters the data.

Now the procedure in place at this facility required the physician to review the data that was

entered into the set-up program, the printout that came from that before the treatment went ahead. Now this particular physician, it turned out, had absolutely no way of understanding the information that came on the printout. The printout itself was a very obtuse source of information at best, as I recall. I think I've seen the sample. It was just a sequence of numbers looking like a computer dump. Really has no basis. He's been given no basis to understand what it means, so he has no way himself of detecting that wrong data.

So the physicist has entered the data for another patient. The physician who knows this is the right patient he was expecting has no way of recognizing that the data in the set-up program does not match his prescription.

So these two lead to the failure that led to that HDR unit going ahead and starting treatment for the wrong site.

Now in the way business was normally done here, things that would not allow that to happen first of all would be a low turn-out of patients. There would normally only be one chart in the room and one patient being done that day. Or even if there are two patients, the particular treatment that was going on was unusual in that facility, and as I remember, it was a nasocatheterization, relatively few patients anyway would have that kind of catheterization. Here we happened to have two patients, both of whom can be treated through the nasocatheterization.

So this creates the opportunities, and the way business was done at this facility really allowed these deficiencies here to lead to this unacceptable outcome.

Obviously, training issues in here, and the way the charts were managed were important factors.

DR. GRIGSBY: Can I make a point from the physician's point of view? One of the things I tried to point out yesterday, in going from, at least in my opinion, in going from manual afterloading brachytherapy to HDR, you have two boxes there. The physician does not understand the data and fails to detect wrong data. I would submit that the majority of physicians who participate in HDR, don't understand it and won't detect wrong data.

MR. WREATHALL: Right.

DR. GRIGSBY: When the physicist gives me a printout on an HDR patient, I don't have a clue as to what the heck all of that stuff means.

DR. BUDNITZ: Foreign language.

DR. GRIGSBY: We've built into our system a couple of checks that I do understand, but as far as I'm concerned, they can program the thing incorrectly, and I'll never know the difference. And I'm supposed to be responsible for signing off on that, makes no sense to me. I'm supposed to verify something that I don't have the skill, ability or knowledge to do.

MR. WREATHALL: And it would be unreasonable, at least in the printouts I've seen. I can't see how anyone other than the person who programs the machine routinely—

DR. GRIGSBY: Right. If I learned how to do the treatment planning on the software program, input all of the data, then I would understand it. But otherwise, there's no way.

MR. WREATHALL: I think that's a good example of where you would reasonably expect to find patterns where this line appears in more than one event, for the very reason the system is not designed to be understood by the physician in practice. And that that check is missing in not only this event, but other events. And it highlights as one particular defense barrier that people might assume in the written regulation that in practice is just worthless.

Now this one was perhaps even more worthless than I would imagine in others, in that the program in the computer didn't even have the patient's name in it. That was a handwritten note after the event. So even if you had the patient's name entered in the set-up and that part printed up the data, that would have corrected at least the wrong patient's set-up.

DR. GLASGOW: The name on the printout is very small print as compared to—

DR. BICKEL: What's funny is the name is real tiny, and then the dwell times and the numbers tend to be larger.

MR. WREATHALL: Yes, Glenn.

DR. GLASGOW: I think from my perspective, however, the technology preparing for cancer pa-

tients is becoming increasingly sophisticated, and rightly or wrongly relative to the physician's role. The physicians will have less of a direct role even in the future. I'm afraid we're going to see physicians even more dependent upon other technical staff who will be executing treatments.

Another area right now is the area of external beam radio-surgery, where the physician's role at the planning computer can be very labor intensive, and they can do a lot of work, or after doing a minimal amount of work, that would be delegated to another person, and it's another sophisticated system giving high doses and single fractions where the patients, without proper check, could be damaged very quickly. And to me, and three-dimensional treatment planning, which Dr. Grigsby alluded to yesterday, is another area which because of the time constraints on the physician, there simply isn't enough time to allow the physician to be the person who does the entire procedure at the computer. So other individuals assume responsibilities and the mechanisms of checks regarding intent and what is being done becomes increasingly difficult.

There's also a tendency to be training fewer radio-therapists, radiation oncologists in the future, and we may see the day in which the actual number of patients cared for by our medical colleagues may actually double, and the number of technical people around to implement procedures will increase, and more patients may well be cared for by fewer physicians using more expensive and sophisticated technology.

DR. LARSON: Except those two examples you give aren't really examples in the same league, the two occasions that the physician has the data which he understands and signs off on. That's apparently not the case in the—although there's a strong technical component, but at least the physician signs off on something he understands.

DR. GRIGSBY: The only thing I can check off on on the HDR is, you know, I can look at a set of isotope curves and see that they're, you know, the relative shape that I want. But that means very little.

About the only thing I can do is look at the total number of seconds for dwell time. And if it's within reason, and it's a treatment that we do more than one time, then ...

DR. GLASGOW: That's a piece of data—

DR. OSTROM: If the physicians are failing to detect wrong data, that's a piece of information that wasn't communicated, and—

DR. BICKEL: What is interesting, and on this scenario was that it was the total dwell time is what stopped—is what stopped the event in this particular case. That was the only piece that the physician and the medical physicist recognized was at variance.

DR. GRIGSBY: That's the only thing—

MR. WREATHALL: That was fortunate because that wasn't part of the review. That was a discussion that happened to take place while the treatment was going on. I think there was a student present who said something like how long is this going to go on for, and one guy said two minutes, and the other guy said ten minutes. And they said oh, oh. And that was how they found the problem. But it was while the treatment was in place.

Just a second before I come to you. If this were to be a common problem across other events, you really can't review what goes into this computer. Other technologies and other industries have found different ways to provide feedback in here, and that's things like the read back system.

Instead of you looking at the printout, for example, get the physicist to read back his data entry. That at least provides one level. It doesn't defend against all human failure modes, but it defends against one major class of mistakes, and that's the wrong patient versus the prescription.

So what I'm trying to say in here is once you identify the class of the problem, you may find in other industries technology. Aviation, for instance, deals with this because people are remote. Therefore, you have air traffic control read back on instructions sent over the wire. You may find that's an alternative way to build this defense back in—so that simply reviewing computer printouts never will.

But what I'm trying to say is, once we've got a perspective on the human error causes in here in a kind of generic sense rather than just a medical industry oncology treatment specific setting, you may find solutions to these problems that other people have found for different reasons. And that

feedback question, read back question is an example.

DR. GRIGSBY: My first suggestion then, you know, would be just to take that physician line out of the model, but the second one is that maybe the more correct thing is what you just said, is leave that in the model, but provide a different mechanism for a check other than just checking something that I don't understand, that I have no clue.

MR. WREATHALL: It comes back to Larry's comment earlier, and that is human errors are human errors. They happen to manifest themselves in different ways in different places. The point is that defenses against human errors are as diverse as the settings in which they occur. And defenses can be borrowed from one area or learned from one area to replace—

DR. BUDNITZ: Well, I had two comments in that they went at cross-currents with each other, so I'll make them and see what you think.

The first, if in a given protocol you observe that this sort of thing seems likely, or the check is inadequate, you can imagine putting in the appropriate remedy of the type you just mentioned. You borrow techniques elsewhere. And that will work every time in decreasing error rates if you've done the analysis and if it makes sense. But there's a problem. The problem is that doing that throughout can burden the system unduly with various operations that the poor physician is stuck with that will get in the way of doing what the physician is uniquely supposed to be doing. You know, the physician, after all, is uniquely supposed to be doing—some of the things, that's his—the physician's job is the doses and stuff. But yet you've got the physician in the checking role of something that isn't a physician's job. It might be the physicists or maybe the technician, so you want to tailor those, because there is the danger of institutionalizing checking actions, barriers or the like, because the person is there even though it's not the person's skill level that is required to do that. And that then permanently institutionalizes inefficiency, which leads intelligent physicians or physicists to take the shortcuts, because they quickly realize, I shouldn't be doing this job. So they stop, or at least not diligently pursue those things.

So that's another side. Now the cost currents there tell me that before these things are put in place, there has to be some very careful thinking about not just whether it's needed, but who amongst the various actors is the appropriate one to do the job.

MR. WREATHALL: I don't disagree with that, and I think we took this as a simple case as to how you can start searching for solutions, not to suggest that is a solution. It may be the worst solution, but at least it's just to illustrate that solutions have been covered in other areas for what is essentially the same problems in this work. They manifest themselves uniquely here, because this is medicine and not aviation, not oil rig exploration. But these are common to most disciplines.

DR. BUDNITZ: Okay.

DR. BLEY: The thing I'm enjoying about this conversation is suddenly everybody is looking at this event and talking about possible solutions and trying to understand it. It's structured in this framework, and the fact of getting it up this way puts a tool in front of people to actually look at it, think about it, regulators to look at it, physicians, physicists, administrators to get these things understood and out on the table.

MR. WREATHALL: We haven't even talked about the PRA yet.

DR. BLEY: Just understanding what happens.

DR. BUDNITZ: But, John, that's the other piece of it. It is most common in my experience, using PRA, that much of the benefit comes before you have to do the quantification. You know, it jumps off the page once you've written it down. Not the numbers.

DR. WU: In nuclear industries, we face the problem quite often, for example, maintenance. The whole process to start with, each utility has their own maintenance process. Therefore, there's lots of loss, inefficiency and places that are easy to make mistakes.

And then INPO is an organization that all industry comes together, and they publish good practice, and they gather experienced maintenance people together and publish different guidelines. And they provide them to the utilities, and they would refer to that and look at their own maintenance process, for example.

And since they have a good example, and they have people that they can ask questions and borrow their experience, and that makes a lot of work process work better.

I don't know about this industry.

DR. GRIGSBY: This is just a quick point again, although in that sequence, I, as a physician, may not understand these things that I'm being asked to approve, et cetera, and that's highly inefficient and doesn't make a lot of sense. On the other hand, from a regulatory point of view, there is something to be said for requiring my presence there, even though I don't understand it, you know, requiring my presence has a lot of implication.

DR. RATHBUN: If you sign it, sooner or later you're going to figure out—

MR. WREATHALL: Even in the simple sense, in this particular case, this is only one case. It was only because the physician and the physicist were having a conversation during treatment that it ever became discovered. So there's a lot of things that aren't necessarily rigorously included in formal analyses, yet become very important. And that is an example.

Let me just move on a little bit, because there are a couple more things I want to dwell on. I'm kind of reiterating, perhaps, what was said about the uses of the framework. It provides, in fact, ways for the different communities to relate their different parts to this by breaking them out explicitly. The medical community, the human factors community, the systems design people all can see their own explanations and what can be done to address those.

So many times the human behavior and unplanned conditions, unplanned in the sense of the way things are done at this facility turns out to be the dominant cause of problems, at least in the events we looked at in the reports. And perhaps importantly for people involved in trying to gather lessons in the future, it provides a basis to describe what data you really need to get to the level of information to get to these causes.

DR. RATHBUN: It also separates whether that was a regulatory problem and whether it's a medical problem.

MR. WREATHALL: Yes, and maybe the medical community can solve more generic problems by creating solutions rather than—

DR. RATHBUN: Rather than a regulatory solution.

MR. WREATHALL: Excuse me, I keep moving. I realized yesterday how difficult it was to read much below this common level here.

Root cause is always an ambiguous term, because everyone has their own definitions and interpretations. I'm using root cause in the sense of here for the most of the people involved in the regulatory practice, regulatory side and the practical side. It seems to address the kinds of root causes they would be concerned with, and it provides data gathering at least on a consistent basis, which certainly in the industries, even like the nuclear power industry, that has not really gone on. Different reports have been written at so many different levels using the data other than stored in the bracket have proved so difficult, and it does provide qualitative assessments or an opportunity for qualitative assessments and things like how effective is QA? What role would QA have played in preventing this event? How to look at different practices. Are they a practical defense, regardless of what regulations we have. And it gives you the common terms of reference providing things like human error terminology.

I just want to touch on a couple of things that have come up in conversation or other people's presentations. One of them was discussion on organization factors and how that relates into this or how I would describe it relating.

If I take this framework here and say, well, what role does the organization play in causing safety problems? What the organization does, and I won't worry too much about what I mean by organization, is it provides the facilities and tools that people work with, the procedures, the quality assurance programs, the training. An organization may be distributed in that sense. And it also creates the work and task combinations.

So in terms of risk assessment, it's a coupling effect. Performance shaping factors, the quality of the training, the quality of the procedures, the quality of the man/machine interface are no longer independent. They become strongly dependent. The organization provides poor training proce-

dures, so the quality here tends to become a coupling that what would assume to be independent failures in the risk assessment become, in fact, strongly coupled.

They can also create conditions by which failure is almost guaranteed. The example that was discussed yesterday, and the one that is in the handout in my paper concerning the selection of sources at the clinic, the radiation technologist selecting the wrong sources and then not fitting the applicator, the one that Lee talked about, can be illustrated with a unit, was a case that the organization really set up for failure. It wasn't the individuals involved. It was the organization that created that.

Now having put that in, how does that relate to analysis, keeping with the risk assessment? It plays a very big role. This is something I created yesterday, and it's not as ergonomically designed as I would like. But it's got an important point in here. When we talk about organization issues and their assessment in risk and, also, qualitatively in the NRC's business, the regulated community is not homogenous. Not all facilities are equal one to another. And one person who's done work on that, I really want to bring to the attention here is Ron Weston. He is an organizational psychologist who has looked at how organizations respond to crises in the sense of the reaction to the Tylenol, you know, damages and so on. But the work he did there was to look at how different an organization can prepare themselves, but seemed to carry it over to safety management.

Very crudely you can see three levels of safety management. Of course, organization's line is continual here, but in practice you can see three basic angle points. Those organizations that have proactive safety management, they learn the lessons from small incidents. They don't wait for things to happen and then try and close the door afterwards. They go out and say what things are going wrong? What can I learn from these little things? How can I fix them?

People at the lower levels of the organization can take actions themselves when they believe and see that there are safety problems.

Most organizations, at least intuitively seem to fit into the middle category, what we call compliance safety management. They meet the regulations; they're happy to meet the regulations. They discuss these things, and they negotiate solutions to problems raised. They have a bureaucratic solution to safety problems. You identify a problem; come and tell your manager; he will take it to the Safety Review Board; and, they'll come out with a policy and change things. It's a kind of a good—things are well under control. The organization is doing what it needs to do.

One distinction here is that they don't believe that something can be safe enough. They're always looking to implement safety. Here the safety is judged by a cost benefit analysis. If we did this, how much would it cost? Does that justify our investment? Those types of questions.

The third category, one of my favorites except when I have to deal with them directly, what Weston called pathogenic here. His terminology is referring to the fact that they will do anything to avoid safety management if they can. They believe it's a bad thing. It's a conflict with productivity goals of the organization. They love to fire whistle blowers. They will suppress problems. They will give misleading safety reports, a whole bunch of chemical process industry in the past has fallen into that category. The regulators are now pursuing them with the OSHA process safety management regulations and so on.

The point is that risk assessment, in fact, is modeling this kind of safety management. People are following the written rules. People are following procedures. They're doing the things that they should do by the letter of the law, and that's fine, and you may come out with probabilities of fatalities of ten to the minus two or whatever, ten to the minus four. The question is, what fraction of the organizations you're actually regulating fall into this category where the risk assessment really has no validity? Is it five percent? Is it one percent? I don't know. But the point is that when you make a judgment about what risk assessment is saying, it's talking about one of the categories of organization, not all categories, and not all can really be treated equally.

Then the question that faces the regulators, who get all the fun in this, is what are you going to do to eliminate pathogenic behavior? How are you going to get rid of those? What are you going to threaten them with to make them at least meet the intent of the regulations? And in fact, what can you also do to encourage stepping up to the proactive safety behavior, the good organizations? And,

of course, the challenge, the good challenge here is that the things that might do this, reducing the pathogenic facilities, tend to discourage, increase reporting, increase inspection, increasing the regulatory burden, does some of this, but also it comes as this. So there's kind of the problem.

The observation I would make that may be helpful is not yet a ready solution, and that is at least there are some crude tools that allow you to look at information about behavior in here such as safety indicators, performance indicators. There are some open questions as to how you interpret information, such as at least in the power industry, the numbers of unnecessary scrams, outages of safety equipment and so on, that involve reporting to people honestly in their reports. These people, for instance, may report many more of these, because they're always willing to talk about their problems, and these people never admit to them. So simple caps of events may be quite misleading. But on the other hand, I think there are ways to address that, and that's involving focused regulations, now not all organizations, but some.

DR. BLACKMAN: The HRA model we put up yesterday of the medical facility that had the mislabeled drawers—

MR. WREATHALL: Uh-huh.

DR. BLACKMAN: Would you call that—which of those categories of safety compliance would you put that?

MR. WREATHALL: I didn't have enough information about organization. When we discussed this when I was doing an analysis earlier, there were questions that really weren't answered, weren't available as to what the pattern of behavior in this organization had been in the past.

DR. RATHBUN: But they're a little unusual.

DR. BLACKMAN: Let me interrupt you a little further there. The point that I'm trying to get at there is that your risk assessment models the facility, the system as it is, okay, and just take the systems with the evidence that's there, compiles it and puts it together and presents a picture. It does not make judgments as to whether they are proactive, compliant or shunned, at all. And that is up to how the tool itself is used by management, ergo Risk Management, which is really a different question than the question of whether or not the tools can be used to model what the facility or system or whatever it is you're looking at.

MR. WREATHALL: Let me disagree a little bit and say first of all risk assessments when performed proactively without a particular event to use as an anchor, involve many assumptions. One of the assumptions that is nearly always used is that people follow the steps required in written procedures, regulations, guidelines and so on. In pathogenic organizations, you can't make that assumption with any confidence. They do not. They will lie, cheat and steal their way to get the fastest turn-around, the cheapest product. OSHA has found that with the process chemical industry, that you cannot rely on regulations being followed.

So that removes one of the mainstays of probabilistic risk assessment when you are assessing proactively how that organization will perform in the future. You can't rely on independent checks. You can't rely on administrative checks being in place, for instance.

So that's really what I'm meaning when they model the compliance part of the safety management in relation to that. Now it's true that nominative organizations will do that. They will do that and more. And part of the problem in modeling that is that performance will continue to improve with time, so what you assess at any one time is a snapshot, and perhaps the best indicator here is an organization that learns and improves constantly.

Therefore, as it performs its procedures or performs its actions, uses its man/machine interface, for example, the case that we talked about in that event, I would expect proactive organizations to say, yes, I recognize I have a problem here, and I'm going to improve it. And so my assessment today is not how that would work in say six months or two years, if they are operation problems. That's much less of a problem about using risk assessment then the assumption that people do follow rules and instructions and procedures.

DR. BLACKMAN: I guess I would disagree. We don't assume, and that's why you go to the facility; that's why you talk with operators; that's why you do all the in-depth task analysis, because what you find out when you talk to them, its operators tell you, no, we don't follow that procedure at all. Why don't you follow that procedure? Well, because it takes too much time. It wastes my time. It's inaccurate. It's not what my

management wants me to do. If I were to do that, I would be fired.

And you get that information through, if you're really doing a good analysis, you get that data.

MR. WREATHALL: If you're doing a really good analysis many of the problems inherent in most facilities go away. The problem is one of defining exactly the issues you're going to have built into the risk assessment, for example, the contingent conditions. Most analyses look at, I would argue, and here we're talking generic PRA versus the INEL's specific players PRA, search for nominal conditions. What is the normal way operators do things? How is the task performed under normal conditions?

DR. BLACKMAN: You're so kind.

MR. WREATHALL: Of course. I recognize the hat.

The problem comes in that accidents occur during off-normal unplanned conditions, for the most part. And that is hard to find by the risk analyst. It's hard to see the things which people haven't thought of in the future.

What I'm arguing in the analysis is perhaps there are generic patterns we can find if we search the event data base properly. But it's all part of that generic PRA focuses on nominal conditions and takes certain assumptions.

DR. RATHBUN: See, in this particular situation, if you kept looking, you found that their attitude toward sources permuted the way they did business. They had some sitting around in the storage room. They didn't even know where they were. We thought we had a lost source issue. This was part of their whole—they weren't pathogenic, but they were certainly disorganized.

MR. WREATHALL: They were disorganized.

DR. RATHBUN: Yeah.

MR. WREATHALL: In my mind, and this is an area I would not hasten to say is a well-established body of science that anyone can use a protocol—

DR. RATHBUN: But it is cool to think about it.

MR. WREATHALL: —is it A, B or C. The biggest distinction in my mind is the one I would give to Harold, and that is the extent to which the organization learns from its own experience. Does it just fix the problem that occurred last, changes the line in the procedure, changes a step in the set-up program that was particularly error prone. But it doesn't ask the question what other similar situations could that be a problem in, and let's go and search if there was one.

Before I go any further, Glenn has a question.

DR. GLASGOW: I just want to make the observation to everyone from my own experience and perspective within the field of radiation therapy, radiation oncology and cancer therapy, there are few written procedures relating to the process of caring for the patient. For a variety of reasons, physicians, staff members are not interested in having a lot of written procedures. There are a lot of standardized processes, certain steps that occur sequentially that everyone understands, but there's generally a tendency not to want to write these down into a procedure manual.

I don't know how commonly procedure manuals, for example, if I ask my physician colleagues if they have a written procedure manual in the simulator for the simulation procedure of a prostate patient that you could hand the book to a new tech and say come back three days later and can you do a prostate based on this manual? Most of the information passed along is verbal. It's about a standard process, but written procedures, per se, are really minimal in the medical environment, relevant to, perhaps, these other larger industries.

MR. WREATHALL: That's a good point. When I talk about procedures, I'm in some cases lapsing back into power plants and chemical process industries and aviation to a large degree. But also I mean by procedure such things as that invaded patent of doing things that is either common across the community and, therefore, comes from shared knowledge, or is the way a particular facility does things and it's passed down by the on-the-job training that relates one to another.

Coming back to that other event, the lost source issue, and a key factor in there, and I'm getting to it here, circumventions and their role in this and that's the deliberate, but not malevolent breaking of rules. That started out when the non-trained technician is going to select the sources.

She was undergoing training when this went on. The person training her disappeared, and for some reasons that we don't specifically know in the reports, it could be word, she thought it looked good for her or she wanted something to do, went out to select the sources without having the training, knowing she didn't have the training. That was the start of this chain of events, and a case where circumvention played a major role.

I have two slides left, and I'm well over what Jim originally assigned me as 20 minutes to talk about this.

DR. BUDNITZ: John?

MR. WREATHALL: Yes?

DR. BUDNITZ: I just had a comment. If you put back that slide for just a moment, you identified three different, or Weston identified three different classes of behavior. These are institutional behaviors.

MR. WREATHALL: Correct.

DR. BUDNITZ: And I just want to argue that there's another dimension which isn't captured here, and that—and it can be best characterized in two words, careful versus careless. The fact is that the organizations can be compliant and be careful, or they can be compliant and be careless. And one of the situations of one of these events that was analyzed, one of those seven, at least it's in my mind, was the result of carelessness, not purposeful, but careless. And that can also be true of the third category.

When you talk about pathogenic, it sounds to me like there's—and we see this occasionally—purposeful bypassing of safety regulation and the like.

More to the point is, I think that's less common than the following: what you're talking about there is purposeful, because people are irresponsible. More likely, I think, is an organization that is firmly convinced that they are plenty safe, and these regulations are overkill. So bypassing them doesn't compromise safety, so they bypass them feeling in their mind a responsible safety goal has already been attained, and all this regulatory junk can be bypassed because.

And that's why they cooperate to the minimum, and it's costly and expensive. And that turns out to be, I think, more common than the irresponsible one.

MR. WREATHALL: This is just to illustrate one of the organizational variables that when you do a risk assessment you tend to think of all organizations as homogenous.

You're right, there is different work than this in organizations about what's termed the three C's. In that case it's commitment, competence and cognizance. That is to do with commitment to the safety requirements, which is this dimension; competence in how you go about achieving these, and that's your carelessness and carefree and, you know, caring—commitment, competence and cognizance is just the information leap, the feedback by which management knows it's accomplishing its requirements. I mean, there's nothing much more than quality management built into that.

But those are the dimensions you're talking about that go beyond that level of setting goals and requirements in the organization.

MR. CAMPER: One additional observation, and by the way, this is a very good way of expressing the problems that we face, and you're right on the mark.

One of the things—one of the ways it manifests itself is if we look at our inspection, for instance. The point I would make is that it is a dynamic process. We see organizations that are nominative, that will slip to calculative, and in some cases even to pathogenic. And this is after several successful inspections.

And one of the things we look at is as a way of easing the regulatory burden and expense, can we spread out our inspection frequencies? And that seems like a reasonable thing to do. But the problem is that history and performance in a nominative range or even the calculative range is no guarantee that performance will continue. And what do you do about it?

MR. WREATHALL: That's right. Changes in management, changes in individuals in management cycle you through. What could be the best organization in the world can very quickly slip to the bottom with a change in organizational structure. Bob and I were discussing some instances of that.

So, you're right, it's not a static view, and there are implications to the regulatory process.

DR. BICKEL: You need to summarize.

MR. WREATHALL: Yeah, I have summary slides here. The summary slide here is just to talk about the relationship of HRA and PRA, and their ability to represent severe accidents.

We talked just a little bit towards the circumventions. They are not in the PRA. They are not in the PRA data. This relates to nuclear power plants, but there's an equivalent, I think, in the medical community. The question of lack of knowledge, lack of technical knowledge, is not a question in the PRA. It's are people following the rules or not, and refusal to follow evidence, the question of pursuing mistakes, is not an issue in the PRA. Those tend to cause all matter of dependencies that, again, are not in the risk assessment.

The HRA models that describe operator fails to do in the power plant or physicist enters incorrect data does not discriminate about the different causes and the PSFs surrounding those different causes.

One of the problems that I mentioned early on is this question of communication between the different disciplines. PRAs are only just starting to emerge. Again, I mean this—intrusive therapy, Harold. The work at INEL is the best I've seen that really reflects this ability to go beyond the simple PRA simplistic process. But having said that, INEL is not the only group doing work in risk assessment, and I'm really castigating the whole community here.

Some other particular comments on there, I will speak on. The closing slide, which was the title that Jim gave me, what are the implications of this QA and regulation? And they come back to what extent are you really analyzing and trying to control, for want of a better word, the real causes of the real events, at least the way we've passed them out here. I haven't had, since the package came, time to compare what your current QA program requirements are versus what we've seen in the generic descriptions.

What other programs do you have beyond QA reporting requirements that may address that, and then I guess the closing slide is an opening for discussion later today is what needs to be done to get the closure on that?

So that's what I have.

## C.4.5. Data Needs and Collection —Dr. Bickel

DR. BICKEL: Thank you, John. I can tell we're going to have a very—I think we're going to have a very fruitful discussion session when we break out, because I think we're starting to lay the groundwork.

Well, I am John Bickel, and I am the Manager of the Safety and Risk Evaluation Unit here at the INEL. And I'm going to talk to you a little bit now about the data collection needs and the data collection process targeted at supporting risk assessment work in the area of medical radiation therapy equipment.

It's very interesting, when I first started looking at the types of data needs one would need to perform a risk assessment in medical-type processes, I immediately jumped back to a former life I used to live when I was working in a nuclear utility about, oh, ten or 15 years ago. And—now I've really jumped back to my old days, but the immediate problems that were faced were that the utility collected a tremendous amount of data, and we were starting a risk assessment process, and I'm starting to gather all the people and the resources needed to carry out a study on, I think it was Millstone Unit One. I think, Wreathall, you were poking your nose around one of those years.

MR. WREATHALL: '81 maybe, huh?

DR. BICKEL: It was many moons ago, and I was confronted by the organization at the utility that collected and filled out NPRDS reports, that's the Nuclear Plant Reliability Data System. And they were convinced that they were going to be a major player in the ongoing risk assessment, and they come forward, and they tell me we've got all this data, we've got this and that. And I'm going, well, that's very interesting. However, you really don't have the data that I need.

They're going, what do you mean? We've been collecting failure experience on pumps and valves and instruments and this and that, and events and incidents. I'm going, well, that's helpful and it's a piece of it, but you really don't have what we need.

They go, my God, we've been collecting all this data for years, and you're going to do a risk assessment, and you're telling us that we've been collecting the wrong data?

And I'm going, yeah, that's right. What you've collected is a tremendous amount of data on events, but you've given us no information on how to put the context of those events into what's been going on over the passage of time. You haven't told me how many hours did you run that pump before it failed. You also can't seem to tell me of the number of failures that occurred when you tested things, how many demands did you put them through?

So they're going, why are we collecting this data, and I said, you're collecting it but you're collecting it for different purposes. The NPRDS reporting was being done for purposes other than doing risk assessment.

So it brings us to a question why are we collecting data right now in the medical area? What are the purposes of the data? Well, the data that's being collected right now, I think if we go back and look at where it originates from, there's a couple of reasons why it's there, some of which are what's actually being done and things like we'd like to use the data for in the future.

One of the first reasons you observe is that one of the things you're doing with the collection of data is that you're verifying that the nuclear materials licensees are complying with the requirements of their license. They have source material. If something goes wrong, they have reporting requirements. The issuance of their reports and, you know, one facet is being done to show that they are carrying out the requirements of the license.

Other reasons you might want to collect the data that are maybe not as well written down is that the data, as gathered and assembled, can be used to determine if any trends exist that warrant further actions by the regulator. In other words, if you collect enough information over time, you can study it and try and understand what the data is telling you. You may figure out you want to modify regulations.

Other activities along there, prioritizing, regulatory activities and inspections. It isn't probably a stated reason why such data is collected, but one would recognize that if you have an organization like the NMSS, and they find out that more radiation exposures are going on with source material licensed to well loggers than use of materials in hospitals, well they're going to say, maybe we ought to shift some of our inspectors looking at more at what they're doing in Texas with, you know, oil well logging versus what's going on in the hospitals, but you have to have a context of these events that you see reported, you know, what's the frequency of them or their likelihood?

Another activity that we're hopefully going to try and use the data for at some point is to use the data to help characterize in some way, shape or form, the risk of radiation treatment. This is the question that I think Larry alluded to the other day, the Chairman of the NRC keeps getting asked by people like Senator Glenn and other Congressmen, well, how risky is this? Tell me that you, the Federal Regulator, are doing a good job in controlling those risks.

So if you want to try and use the data to characterize the risks, there are, of course, certain burdens, what kind of data you want, what it must look like and how it's collected.

Eventually some time in the future, this is not something that's official where the NRC is directed, but they may be moving toward risk-based regulations, at least from speeches made by the Chairman of the Commission.

The existing reporting requirements, particularly for the medical misadministrations and, in fact, an awful lot of the other data that the NRC collects, supports some of these reasons why you're collecting the data, but clearly it doesn't support all of them. We can clearly look at it and say, well, the data that's collected is some kind of an indication that the licensees are complying, but it probably needs an awful lot more to carry out activities of this level on—you want to view that as a hierarchy. If we are trying to utilize the data for performing probabilistic risk assessment, which is hopefully what we're going to end up with as a game plan and how to do that at the end of this workshop, I think we need to focus on what are the questions a risk assessment tries to answer. Basically, there are three:

A risk assessment should focus on what can go wrong;

If something does go wrong, what are the consequences of that;

And, third, the probabilistic side, how likely is it?

Those three questions are the essential items that are being asked when one wants to do risk assessment.

To support a risk assessment, the data collection process of what you're trying to go out and gather must try and provide questions—or answers to those three questions. Clearly the existing reporting requirements, as they're structured right now, and as they stand on the books, they do address some pieces of it.

First of all, they do identify some, but not all, of the possible types of things that can go wrong, based on actual experience. In other words, if you look at the data, the nature of the events that have occurred out there, you probably capture a, hopefully a sizable portion of the types of scenarios of what can go wrong.

However, we have to recognize that not all of the things occur at the same, you know, anticipated frequency. So some of the types of failure modes, frankly, have not been observed in the experiences reported in the data base. We have to keep that in mind.

So we cannot just take the data that's collected on misadministrations and say we understand the full spectrum of all the things that could go wrong.

Another thing that the requirements do address is that they identify the magnitude of the difference between what was prescribed and what was actually delivered, in terms of the dose. That's one of the items that has to be spelled out. However, when you look at what were the medical consequences, in other words, what was the significance of the overage or under amount in the delivered dose, not all of the reports give a clear picture as to what were the actual medical consequences. You may find a line item in the report that says, you know, we discussed it with the patient. We don't anticipate any long-term effects. But that's, you know, exactly what does all that mean? It does not allow a sorting in some cases of the significance of particular misadministrations. You can't bend them into categories very easily.

MR. CAMPER: Let me make one comment just for clarification.

DR. BICKEL: Yeah, Larry?

MR. CAMPER: The reporting requirement for misadministrations in [10 CFR] 35.33 does require the licensee to report to us the assumed or projected medical consequences. And in addition to that, our medical consultants, and we tend to use medical consultants in probably 90 percent or greater of misadministrations.

DR. BICKEL: Right.

MR. CAMPER: One of the things the medical consultant does is take a look at what the licensee's perception is of the consequences and what the licensee plans to do about it, and provides us with feedback on the adequacy of the management plan.

DR. BICKEL: What I'm actually trying to say, yes, I agree with what you're saying. What somebody would probably really like to see for doing a risk assessment is seeing some kind of a binning process, where you had some capability of saying, yeah, we've had, you know, we've had about 20 in this area, and so many here, and, you know, we haven't really seen much here—whoops, we've had one over here on that.

We don't really have information that would right now allow us to bin all those hundreds of events if you go back over the totality.

MR. CAMPER: In terms of—that's certainly true.

DR. BICKEL: This is the kind of thing that at some point somebody tried to look at the data and do risk studies just purely based on the data, they'd like to see some kind of a binning. That would facilitate that. Yeah, Jim?

MR. SHEPHERD: Are you saying, John, that's an analytic shortcoming, not a data shortcoming?

DR. BICKEL: It's basically because we're coming at it as a risk assessment person, and we're trying to look at a data base and use it. But the data base was, in actuality, set up for other purposes. We're trying to use that data for something that is maybe a little bit beyond what the data base was set up for.

MR. CAMPER: Let me add one more comment just to help clarify that question.

DR. BICKEL: Yeah.

MR. CAMPER: Something to consider is that we have—your point about the medical consequences of being able to bin them is a worthwhile comment. One of the problems you get into about whether it's been analyzed or not is because as an agency, we've never asked for it to be analyzed.

DR. BICKEL: Right.

MR. CAMPER: And the reason we haven't asked for it to be analyzed is two-fold: Number one is, we assume that the licensees are in the best position of characterizing possible consequences and developing follow-up plans. And at least thus far, we have been somewhat eager to truncate our involvement in the misadministration consequences to a patient, because we believe that falls into the practice of medicine. And we want to extract ourselves from that.

Now it does raise a question amongst ourselves, though, to what degree can we totally extract ourselves or when can we do that? But I tell you that, because I think that's part of the reason why an analysis is not taking place.

DR. GRIGSBY: I have a comment.

DR. BICKEL: Yeah.

DR. GRIGSBY: We were cited for a couple of events which were considered to be misadministrations about a year ago. And to put it in perspective, my judgment as a physician as to the medical consequence of both of those events was zero.

But now wait a minute. But the ultimate consequence was that I thought that the cause, the root cause of the problem was a machine failure, and we took those machines out of use and will never use them again.

See, so the medical consequence is zero.

DR. BUDNITZ: For the event that happened.

DR. GRIGSBY: For the two events, the two patients involved. Just effectively zero. There was no medical consequence whatsoever.

But my perception was that the unreliability of the machines was so great that future patients could suffer.

DR. BICKEL: By the absence of—

DR. GRIGSBY: —significant consequences, and we took those two pieces of very expensive equipment out of use. I refused to use them any longer.

See, so how do you balance that on your consequence equation?

DR. BUDNITZ: I think I understand it, and let me try to describe my understanding of it.

You see, one of those patients might have had a very adverse effect, but because certain things didn't fail that might have failed, they didn't suffer the consequence. But your judgment was that the risk that this might happen a third time, and it really would be bad was too great, right? So what did you do? You can structure an analysis of the event you saw and ask how many barriers were left to make sure that the terrible thing didn't happen, and you decided, you as the responsible party decided there weren't enough barriers.

And that structured analysis can be part of how you set up this thing. In the reactor arena, we do that all the time. A couple of valves fail, and you say, gee—

DR. BICKEL: Accident sequence precursors.

DR. BUDNITZ: Right, how many more things might come about before you actually get in a disaster and you say, gee, that was fine, or the next one wasn't?

Now that analysis can not only be structured using the methods, but it can provide important insights into what steps you can take—instead of taking it out of service—you add another barrier or you bolster something else or you provide some procedure, so that you don't have to take the drastic action. You can do something in between that allows you to continue to use it and with the additional protection you need.

And I think that's another important value of the structured analysis.

DR. BICKEL: The point you raise is very interesting, because in the reporting that's required

for the medical use licensees of the source material, they're reporting the actual outcome, you know, they had an event, there was an outcome.

DR. BUDNITZ: They told you what happened.

DR. BICKEL: What I think is very different from like say the reactor world, which is horrendously more regulated, is that they are reporting information on intermediary things where something broke, but there was no outcome. And that was because there were many, many more barriers. But the NRC monitors the barriers individually and, you know, remedial actions, I don't want to scare anybody that's involved in medical physics or oncology or radiology that people would be suggesting that maybe it would be a neat idea to report all the individual barriers. I mean, first of all, my God, there goes health care costs out the roof.

DR. BUDNITZ: On the other hand, the nice thing about these structured analyses is that once you have it done for a particular gadget or protocol, then when you have one of these oddball events that doesn't go all the way—

DR. BICKEL: You have a framework for starting to sort out what happened and—

DR. GRIGSBY: But, see, some of that is reported to the FDA.

DR. BUDNITZ: Yeah, well some of it doesn't get reported to anybody.

DR. BICKEL: Is this the pharmacopoeia thing?

DR. BUDNITZ: Well, some of it probably doesn't get reported to anybody, right?

DR. GRIGSBY: For a machine or device failure, but—

DR. BUDNITZ: You see, but I'm worried about something, John, and I just want to be sure that I say it, and I said it before: Part of the problem with trying to structure a reporting system that can catch the things he's talking about is that there are undoubtedly a whole lot of them that would be very costly to report and kind of interesting, but not that interesting, and you can imagine there go health care costs again. And these procedures now become uncompetitive and patients are going to die because of that.

DR. BICKEL: Well, or probably go to Canada or Mexico to be treated.

DR. BUDNITZ: No, no, or the procedures will become too costly, and they'll be used less often than they should be.

DR. BICKEL: Yeah, Bob?

MR. PRATO: The gentleman who mentioned he took those two pieces of equipment out, I assume you did some sort of formal risk analysis on that, failure analysis. For you to take out two pieces of equipment, very costly and that has the potential to save lives, you did some sort of analysis, whether or not you did formally and documented it, is not the question. But that information that you had to make your determination, did you provide that information in your event report?

DR. GRIGSBY: We provided the information—

MR. PRATO: That's a key piece of information. That type of information we routinely get from the reactor side.

DR. BUDNITZ: Perry, to be blunt, is there another hospital somewhere that has that same piece of equipment that didn't learn the lesson that you learned?

MR. PRATO: Two pieces of very expensive equipment that may be used nationwide, based on an analysis you did, whether or not you formally documented it, you have that knowledge, and that knowledge hasn't been transferred.

DR. BUDNITZ: It may or may not have.

DR. GRIGSBY: Let me answer your question. There are a couple of things. The specific piece of equipment, I don't know how many of them are in the United States, ten or less.

DR. BUDNITZ: Ten or less.

DR. GRIGSBY: Between five and ten. The rumblings in the physics community was that, gee, we don't think these things work real well.

DR. BUDNITZ: That was sort of the scuttlebutt or something.

DR. GRIGSBY: And some of my physicist friends told me that, gee, they're hard to use. We don't think they work well. We're still playing with them, and we've not actually treated patients with these machines.

Before we clinically implemented, or before we implemented the clinical use of the machines, we set up a—I set up a form analysis to document the use of the machine, what things can go wrong, ease of use or difficulty of use. And we've collected that data on every case that was done.

So over a period of two, two and a half, three years—two and a half years, the physics community still said, gee, we're having problems with our machines. They're difficult to use. We don't think we can do that. We had demonstrated specific problems, occurrences that couldn't be explained or that the manufacturer couldn't fix.

And I guess the ultimate occurrence was two misadministrations—

DR. BUDNITZ: Near misses or something.

DR. GRIGSBY: Near misses, the manufacturer, again, couldn't explain why these malfunctions occurred, so we said we're taking them out of circulation.

There was an analysis trying to repeat the failure by our physicist, as well as the manufacturer, and the formal analysis. But it couldn't be demonstrated.

And I don't know that anyone is using these machines in the United States today.

Secondly, I took the data that I had collected on the cases over the years and wrote that up and submitted it to our trade publication to say here are the problems. And I've yet to get it published.

The first reviewer said simply anecdotal, no thought went into this, threw it in the trash. I collected data since 1988, so it's still out there somewhere. People don't want to hear bad news, and somebody squashed my article.

MR. PRATO: Just to elaborate—

DR. GRIGSBY: It wasn't you, was it, Glenn?

DR. GLASGOW: Which equipment was that? No, it wasn't me, but you are referring to the PDR or what do you—

DR. GRIGSBY: The interstitial device.

DR. GLASGOW: The microSelectron local tree. I thought it was, but ...

DR. BICKEL: I'd like to move things on, because we have to get onto the working group sessions, and I want to finish just the discussion of the data. And I'm elated that it's provoking such interesting thought. But maybe what we ought to do, I would like to ask the people, keep these thoughts. We're going to have like a round table discussion on this and other related issues.

(A brief recess was taken.)

MR. PRATO: Can I make one other comment? We do have mechanisms internal to the agency that can deal with situations like this if we know. We can do special case studies work with other licensees that have experienced the same problem and put out generic information.

This is the point that I was trying to make yesterday that the reactor side understands that reporting is a tool to their benefit. We have, from my perspective, from what I've seen, I don't think we've gotten that message out to the materials and medical arena.

DR. GRIGSBY: I think in the medical field, you know, the physicians or whoever, have some degree of fear of reporting, because of the consequences that will result.

DR. BUDNITZ: Are you talking about insurance liability questions and the like?

DR. GRIGSBY: No, just the regulatory consequences.

DR. BUDNITZ: Just the hassle?

DR. GRIGSBY: Yes, you know, I don't have a problem with a medical misadministration like the example I'm giving, except I have two major concerns: One is if the information gets into our local newspaper, it's inconsequential and, boy, I don't want it to hit the newspaper and cause some adverse publicity.

And the other is that NRC will just beat me into the ground with paperwork. I mean, I spent hours and hours of needless paperwork on that, on an event where I already said I gave up. I'm not going to use the machines anymore. I think I'm

still going to have to answer problems on our PDR when it's got cobwebs on it, and we'll never use that again.

But I think somebody is going to make us answer some more questions.

DR. BICKEL: Back to the problem at hand. I want to talk about, very briefly, the problems of collecting the data, you know, basically what's the right data, the interpretation.

And I guess one of the points I'd like to make is that from what I've looked at, the data that exists, the problems in collecting the right data and interpreting it to support better uses is not unique to radiation therapy activities. I would suggest that the same types of problems exist almost in every other type of system where we've tried to go out and collect reliability data on an engineered system.

The typical problems in assessing risks, using the experience data that I see in radiation therapy, are typical of the ones I've seen. I'll just list a couple of them:

One is that, basically, the people that are carrying out the process are highly motivated; they're highly trained. They don't make a whole lot of errors. When you try and look at that, what it means if you're trying to collect reliability data is you've got a very thin pool of experience.

The overall frequency of procedures for something going wrong is small. You're looking for the typical needle in a haystack, and then trying to split the needle into what caused, you know, this part of the needle or the other.

The NRC's reporting requirements provide the ability to track the detail of specific procedures where something went wrong. You got a misadministration. However, what the reporting requirements right now do not elicit very well is what's the total number of procedures performed without an incident, you know, what reliability people call what's the denominator? How big is the population?

Another area that's, I'd say, related to this is that we recognize from the different types of field investigations is that the types of treatments performed in different facilities are different across the board. You've got some hospitals that will have the same machine, but will only use them for one type of treatment. In other words, they may have a Nucletron HDR unit, and they only use it for GYN treatments. You've got a same identical unit used in another facility. They're using it only for palliative treatments of lung cancer conditions, or things like that.

So the use of the equipment, how often it's used, the differences in the facilities are very significant, and they tend to skew the problem a little bit.

One of the problems that also occurs, and, again, this somewhat relates to the inability right now of breaking out events into particular consequence categories, is that there is a pooling of high consequence and low consequence events into one common category, namely, there was a misadministration. And a lot of it being done just because you're facing the situation of you don't have any statistics.

As an example, I drew this little chart here that, basically, when you have some bin where you don't have any events, you're going to say, well, let's kind of collapse it together, because we don't have enough experience to chop it up finer.

Another area is the issue of quality assurance of the experience data bases. What I'm talking about there is the data gets submitted. It gets certain reviews done right now, but the degree that the people on the receiving end go back and challenge or ask people to correct or update the information is, it's kind of a catch as catch can. Something looks wrong, maybe somebody goes back and challenges and says can you clarify what you meant by this?

So the experience that's, basically, in these data bases, there is some potential that there could be a misunderstanding of what actually occurred.

Now we, as part of our work on the retrospectively going back and looking at the data base, we did find discrepancies where you could find in there, if you try to just quickly sort and search on maybe some key areas, we found areas where the same event somehow got in there multiple times. And in other cases, something that we knew existed, we had some difficulty finding. So it's an indication that maybe there's a need to improve the quality assurance of the data base that would be used for this.

I characterized again that the problems I'm talking about here, it's the same thing that they've had when we've looked at reactors. And if you went to somebody that was studying the chemical industry or some other high technology area you're trying to assess reliability, it's basically, you could list the same problems exist in other high technology areas where you're trying to study reliability.

There are, however, some significant differences that I do think also need to be kind of laid out.

NRC spends a lot of its time looking at reactors. One of the things that's kind of a simplifying assumption in that area is that power reactors are assumed to operate continuously, and that they also have very detailed operating histories that they have to report. It makes it relatively easy to estimate the frequency of the events of certain types per year and get a very quick simple frequency of something breaking down.

That's a very significant thing. This has allowed the NRC, over the last ten years, to look at the trend of operational events and, in fact, be able to go to Congress on a regular basis and say, hey, you know, 15 years ago the average U.S. nuclear power plant may have experienced between five and ten unplanned shutdowns a year. We have gone out and we have done this and that, and we've really beat on the industry and cracked the whip, and now we're down to a range where a lot of plants have no unplanned shutdowns a year and you'll have a few with one or two. So you can very clearly see cause and effect relationships, very simple statistics that the number of unplanned shutdowns is something as a trend that has improved.

Radiation treatment frequencies differ from facility to facility. And, hence, when you're looking at a misadministration being reported at one particular hospital or clinic, it's very difficult to understand is this thing caused by a large throughput or very infrequent procedure or anything like that? It makes it very difficult to, right now on a particular facility, to understand the trend. In other words, the hospitals and clinics are different.

I think we heard mention from some of the discussions yesterday we have some that do a couple treatments a year. You have others that are doing them in the order of hundreds.

No attempt right now in the reporting mechanisms is really made to maintain frequency of usage statistics on an individual licensee basis. That data does not exist within the NRC. Maybe it can be obtained from the participating hospitals, but it's not easy for the NRC to get the denominator number. In other words, to try and estimate events per treatment, because different facilities, different frequencies.

Another key difference between the power plant world and the radiation therapy is that in the power plant world, there have been literally hundreds of individual risk assessments performed for different types of power reactors. Where one encounters the situation of missing data on one facility, because of the fact that they are operated continuously, similar regulations, similar operating modes, procedures, you can tend to migrate one set of data from one place to another, and it gives you an ability to fill in some missing data.

I don't think I would want to do the same type of thing where I had a clinic with very, very few treatments being performed and not having a number, and then trying to say, well, I'll go to a place like Mallinckrodt Institute of Radiology where they have lots, and I'll take their experience and try and apply it to another clinic that is completely different. I don't think I can do that.

Those are what I see as differences in the data collection needs.

I think we've heard people discuss the other day the fact the reliability and risk analysts, as they go into the process of trying to understand risk, they're going into it with a particular assumption in mind. And that is that if you drew a plot of increasing consequences versus frequency or some measure of likelihood probability, you would tend to see a decreasing-type curve. We would expect that you're going to have an awful lot of frequent, low consequence events and very, very infrequent high consequence events.

The experience that the NRC currently captures right now with the reporting requirements basically comes from the very frequent low consequence events. And maybe that's—well, I mean maybe that's what we would expect. We do not have high frequency of people dying, you know, the event in Indiana, Pennsylvania is fortunately a rarity, and we expect maybe they will occur at some kind of an infrequent interval.

Numerous approaches are utilized by risk analysts in the process of trying to extrapolate down into this region where there's not a whole lot of good experience. And the typical approach is obviously to try and model some chain of events that you cannot observe from actual experience, and then use the laws of probability theory to say that some rare event is, basically, the product of a chain of individual events that occurred and kind of multiply them.

One possible way that can be utilized to construct this chain of events is the use of an event tree. It's not perfect.

The other approach that was discussed yesterday utilized by Lawrence Livermore, which was more of an approach to an expert elicitation to identify what are the likely chains and their consequences, it's basically the same type of thing.

In either case, what a risk analyst is trying to do is make some projection of the high consequence events that involve malfunctions, some of which there may not be any data for, you know, from past experience.

When you decompose the problem into some type of a chain of events, you know, the particular approach that a risk analyst would use, there are a lot of different options. One could utilize Monte Carlo methods. You could do a method of Moments, Latin Hypercube sampling. Any one of these approaches will give you some way of getting the probability of some low frequency event.

All of these approaches, whether you use an event tree; whether you use a fault tree; whether you use the relative risk profiling method developed; every one of them requires some degree of conjecture on the part of the analyst and the construction of a model. The purpose of the model is the identification of that chain of events.

The approach is also sensitive to what are the assumed probabilities? Some of those probabilities we can probably extrapolate from experience, but not all of them. And I think that's, again, we're into the data question.

If I try to look at the question of how I would use an event tree model and collect data, this would support any type of an event tree model based on some type of an event experience. And the procedures used in the processes that are used in a particular facility, we can use an event tree to lay out pathways.

Yesterday I think Steve Novack gave a description of what an event tree could do to break the process down. I've shown a very simple one with simple example numbers. If we start off here saying the objective of the day is to provide a treatment, and you've got a number of controls and possible things that could go wrong in here, we could characterize different outcomes as to being either nothing happened, everything worked okay. That would be this end stage here, successes all along.

We could additionally identify where maybe one thing went wrong, but it was recovered by maybe a checking procedure or something like that where you have one failure, but it is caught.

You can additionally have a misadministration where something went wrong either procedurally or mechanical equipment broke down, and, you know, it is going to result in a deviation.

In this sample problem, let's say that these deciding events here had probabilities one in a thousand, one in a hundred. Maybe this is a 50-50 thing of somebody checking something like maybe this is the probability of the doctor catching the physicist in medicine has programmed the HDR unit incorrectly and say that it's only 50-50 that he's going to catch that.

If you put through numbers into an event tree model, you're going to end up with estimates of the probability of those end pathways.

One of the things that comes out of here is that one of the pieces, you know, if we want to try and relate this event tree model back to actual experience, what is it that our actual experience is capturing? The actual experience reported right now in the reporting data mechanisms amount to the situation where a misadministration occurs. They do not report all of the successes. I mentioned that before.

Additionally, there are low probability pathways here, in other words, where there's a large chain and very, very low numbers. They will not be seen in operating experience. They're there, but, again, they are low probability pathways. Maybe they are of high consequence.

What I'm trying to illustrate here is that you see certain pieces of these chains of events and operating experience. You do not see all of them, and this is analogous to the—I think Bob Budnitz asked the question about the accident sequence precursor applications. Clearly there's a need to try and construct the pieces on these sequences that you do not observe in data.

Studying the actual misadministration data in the context of having some type of a structured model, either an event tree or relative ranking approach or something like that, gives you the capability of retrospectively validating the model assumptions. In other words, if we construct a simple model, we collect data, kind of, you know, throw the data against the model and say is the model reconciling itself with the data we're experiencing? It gives you some ability to validate that you understand what are the important controls and the safety significance of particular procedures.

Some limitations, though, will have to be dealt with. And, again, when you collect data, you've got to recognize that there are different types of facilities, they've got different numbers of treatments being performed, and, hence, just because you get one event being reported at a facility, that does not imply good or bad quality management activities.

It also has to be recognized, and I think John Wreathall's discussion maybe started the ball rolling, is that a lot of risk assessment is done on an assumption that people are trying to do a good job. I think the experience from the field, on the other hand, is that there is a spectrum of different levels of quality management processes that are out there. You know, hopefully we are moving them in a higher direction, but there is an assumption there that we have average quality management in place, where in reality, a lot of misadministrations are seeming to occur at places where it is not so good.

What I'd like to summarize with is that the data collection process and the ongoing risk assessment—can anybody read any of this? Gee, and I thought it was just wine from last night.

MR. CAMPER: That's better.

DR. BICKEL: I just thought it was fuzzy logic here or something. But the ongoing activities of collecting data, constructing models, comparing the data against the models, I'd like to point out should be an iterative process. One collects data, maybe based on some crude interpretation based on a model. You use the data. Maybe you fix the model, and the models become updated based on more data. You throw it back and say, well, what does that tell me about the data? Maybe I want to collect the data slightly differently.

This is an iterative process that with more data you can come up with a more sophisticated model. With a more sophisticated model, you need more sophisticated data.

In the interim, though, if you have good data that you can explain and have some kind of a taxonomy—I'll use that word again—you're now in a mode where the NRC can utilize the data for risk based inspections and improving regulations, based on risk insights.

As you get into the process, though, we have to recognize we're still in kind of a starting point. The risk assessment models we would be setting up now, we have to recognize we cannot exceed the availability of the data to support those models. There is a limit. But we don't want to do the thing so crudely that we're going to be handicapped in the future.

The data bases should have a sufficient taxonomy. In other words, it's broken down and may be characterized by consequence level, provides some additional information on the nature of frequency of treatments as to a particular place. In other words, you want to have the data digested multiple different ways so it can be used in the future.

You want to have, basically, quality assurance in there, also, to assure that you can utilize the stuff, and it does have validity in the future.

What I've touched on in here then in this brief presentation are the facts that there are some similarities in the data collection problems that we face with trying to understand medical radiation therapy and reliability analysis problems in many other disciplines. There are common problems. I would suggest that we're going to probably get down to some common solutions. I believe that we will probably need to make estimates on the number of treatments being planned. This is not different from what is done right now in the reactor world in making assumptions about the amount of

testing that's being done in the absence of absolute numbers.

MR. CAMPER: John, question?

DR. BICKEL: Yes.

MR. CAMPER: How would you do adjustments, number of treatments being planned, number of procedures being planned?

DR. BICKEL: What I think you'd have to do is you would have to possibly take four, five, maybe some sample facilities, okay? You'd probably want to get one that is maybe a large central city, you know, big city hospital that has a, maybe a university program and is doing several hundred a year. I think you would want to get an understanding of exactly how many treatments they do there.

I would then look at their misadministration experience. I'd like to try and collect different types of facilities.

So that's one example of a facility that's going to have a certain challenge frequency to try and understand what's going on there.

I think you could possibly identify different types of facilities. Maybe there's, you know, I think we need to talk with some of our medical consultants here, but I think you've got places that are teaching hospitals that may be trying new and different things. You may have hospitals that are more—they're not doing as much experimental stuff, but they have a large—

MR. CAMPER: Figure out some way to weight that, the preference of the physician, treatment modalities being used there versus what's going on in the mainstream—

DR. BICKEL: Yeah, but the idea is you attack that kind of a problem with—you've got to have some kind of a taxonomy. In other words, you've got to understand when you see, you know, one facility that only has one type of treatment modality, why it is you're only getting misadministrations of a particular type. You're going to have to, you know, there's going to have to be some need to separate them.

I think in some other places we're going to have to make estimates about what is the frequency of treatments, and I believe that from the discussions we've had mainly in coffee breaks so far, the people in the hospitals know pretty accurately how many treatments a year that they do. They don't report it, but they have a good handle on it.

MR. CAMPER: Do you have any idea, properly selected, carefully selected defined approach, you think nine data points, up to nine data points would be an adequate number?

DR. BICKEL: You mean like nine specific facilities?

MR. CAMPER: Yeah, carefully selected, considering criteria, similar to what you were suggesting.

DR. BICKEL: What you're talking about now is doing an experimental design. I think that's what you're asking—

MR. CAMPER: Well, that's what I'm trying to do is figure out a way to collect the data. If such a model could be developed, and I could go to as many as nine different facilities, which put me below the OMB threshold for seeking data on licensing.

DR. BICKEL: We've got the regulation side speaking, yeah.

MR. CAMPER: Because if I go beyond that, then I get into—

DR. BICKEL: I think that's an outstanding topic for discussion in workshop. I think that is literally where we have to head. We have got to get to the point that we understand specifically what is it we ought to do to develop a proper estimate.

DR. GRIGSBY: What is it that you right now, given the limitations, what is it that you would like to know preliminarily, just an approximate total number of procedures performed?

MR. CAMPER: I would like to know the number of times that an administration of radiation takes place and, therefore, the opportunity for an error to occur exists. That means how many fractionations do you do? How many radiopharmaceutical therapies you do. In other words, every time the possibility exists. That is, as I see it, the ultimate denominator.

DR. GLASGOW: Let me just comment quickly that some of those data bases do exist

within the various physician organizations. We fill out forms numerous times a year reporting to either ASTRO or RTOG what equipment we have, how many square feet we have, to keep our program accredited for training residents. We have to report the number of cases, and it's quite detailed reports for the training facilities.

DR. BICKEL: It's the number of patients treated, though, that you fill out, and that's not of interest.

MR. CAMPER: There's a number—there are a number of data bases available that get at this issue. We explored this. There's no single data base that compiles—

DR. GRIGSBY: Well, then just require it. Just say you've got to do it.

MR. CAMPER: First of all, we got to require you to do it. We've got to put in place the regulatory requirement—

DR. GRIGSBY: No problem.

DR. CAMPER: —collection requirement and so forth. There's going to be a whole segment of the medical community that say wait a minute. There you go, one more thing to report, one more data to collect. But the real question, I mean that's a burden. That's bad enough itself. You should not tread in that area unless you've really thought it through. But more importantly, once you get it, what do you do with it?

DR. BICKEL: My comment right there is they have the same problem in the reactor world. Let's take the situation of a, you know, somebody in Bob Prato's organization that looks on the reactor site. They get maybe a number of reports from a particular licensee saying a critical valve has failed. How do they know how many valves they have of a similar population at that plant?

One of the things that, you know, is a nuisance in the power reactor business is that all the damn plants are different. They maybe built two or three in the whole country that are identical. They've got some with 100 valves like that. You may have another one that has only 20. So what have they done in that case?

Well, what they have done is they have acknowledged that there is a uncertainty in the total population size, and they have made estimates that they have reviewed with panels of people that have recognized, you know, they've anchored how big the variability is. They, basically, said there's uncertainty. Let's just deal with it. Let's acknowledge the uncertainty and propagate those uncertainties through the estimates of failure rates.

And the number of pumps and valves in a particular facility is an area that is a source of uncertainty.

DR. SIU: One thing I'd like to mention, although this is a good source for discussion later, is figure out how many denominators you want. You talk about a global population which may be nine facilities with appropriate weighing factors will give you a very good estimate. But you want to break down these estimates into nine different categories, because now you want to come up with failure rates that are relevant for each of these different facilities, then you have to have maybe nine within that sub-population. So, again, it depends on what you're driving at. And you really do need a taxonomy or model to tell you.

DR. GLASGOW: I'm interested in sort of the basic question if the NRC were to consider risk based regulations, at what levels of risk would you consider regulations necessary?

MR. CAMPER: Well, that's a good question. You asked it yesterday, and you asked it in the context of—the point I want to make is when we did the Quality Management Rule, the Commission was well aware that the frequency of misadministrations dropped to the order of ten to the minus four, to minus five, perhaps—ten to the minus four. Now that number obviously wasn't an acceptable number, okay? The medical community argues, and they argued with me in many places, many times that this is an acceptable number. It's human error. We can't get it any better and what have you.

Now I understand their argument, but the number wasn't acceptable because the Commission chose not to remain in the reactive mode. Chose to put in place the Quality Management Rule.

The problem that you have when you asked your question, and it's a very valid and reasonable question is, in whose opinion is the number acceptable? Furthermore, it's one thing to say can we get the risk down, this frequency of events down to minus five. That's an acceptable number.

There are those who would say that's not acceptable at all, because even in a low frequency occurrence, some of them can carry grave consequences. So the idea that it only happens one in 100,000 times or one in a million times has only a certain amount of validity, because that one time can carry with it consequences.

So the question is what's the score? And I don't know what the score card is.

DR. BICKEL: To amplify what you're saying, Larry, to amplify it, what that's like saying is that the frequency of misadministrations is the sum of all of these is ten to the minus four, but the problem is, is that what is that ten to the minus four number? I mean, basically, you've taken this whole realm of consequences and collapsed them into one bin in saying that a misadministration is, you know, more or less than 20 percent of, you know, what was the prescribed dose. Therein is the problem. If one wanted to get the risk-based regulation, what one would be trying to understand is, well these things over here are some indication of the reliability of the process control. And there's a lot of data. But the risk that people are worried about is what's going on down in this realm. And that number, maybe that number isn't ten to the minus four.

DR. GLASGOW: Well, the related problem that I see in all the discussion about risk analysis parallels the risk analysis work that was done in health physics regarding cancer risk to patients. That is the uncertainties on the risk estimates. When you come to trying to assign a probability on the event tree, realistically when you get to the end point, there's a substantial difference. If it's ten to the minus four, I'm going to guess it's plus or minus ten, five or whatever. It's large. It's quite large.

DR. BICKEL: And that is exactly the types of problems, like I'm trying to say we have to deal with in the reliability analysis of equipment and processes that are highly reliable. You end up with a small number and a humongous uncertainty on that number. And the real issues are getting data and trying to understand what are the sources of that uncertainty? Can you control the uncertainty? You know, will processes make it better or make the uncertainty go away?

DR. BLEY: There's one thing that seems to be missing, and your comment, Larry, ten to the minus four not being acceptable. And we're looking at a little piece of something here. We're looking at the misadministrations in a certain procedure in the treatment of a patient. If we look at a power plant, and we look at how a certain safety system functions, we've come to the point we'd say it's really silly to say that if that system fails at ten to the minus four for trial, that's unacceptable.

What we're interested in is how does the whole system perform? What contributes to its riskiness?

Here, and Myron brought this up at lunch yesterday, so I'm coming back to it. Here we don't have you walking down the street facing a ten to the minus four chance of being injured by this. We've got a patient in a treatment program who's already sick, and this is showing up in the sequence of that patient. I guess I haven't heard anybody here talk about what's the risk to that patient from going through this treatment process, and how much does the risk of this misadministration we're talking about contribute to that risk? Are we affecting it at all, and I'd like to hear some of you who know about that talk about that a little bit.

DR. HOLAHAN: It's not just the risk of going through that process, but also the risk of not going through that treatment process.

MR. CAMPER: When I say it wasn't acceptable, just to clarify that, what I mean was it wasn't acceptable in the context the Commission did not want to remain in the reactive mode and have misadministrations reported only. We had ten years of data. We ran about 400 diagnostic misadministrations per year at a fairly constant rate. We ran anywhere between 15 to 25 therapeutic misadministrations per year during that ten years, very constant rate.

What they chose to do was amongst the alternative available to us, which was disseminate further information via information notices, a policy statement, have some additional reporting or what have you in bulletins. They chose to go the rulemaking route. And the reason was primarily was because they didn't want to remain in a reactive mode given what they had. So therefore I say that number we knew, which was a fairly reasonable estimate. It's got its problems, but it's reasonably accurate. They just said we need to do more. And what we did, in fact, was put in place—

DR. BLEY: I understand that, but I think at this point it makes sense to try to put this in some perspective for the discussions that are coming up later.

DR. LARSON: Let me just respond. I can't respond for the brachy, but for the Gamma Knife, I can give you numbers there for certain. The Gamma Knife is used for patients with malignant brain tumors or benign brain tumors or congenital malformations, and all of those have serious consequences if they're not taken care of. And there are certain risks associated with the procedure, and the patients are well aware of that. Assuming everything works correctly, and it's not a misadministration, the risks they assume are, depending on how you define them, I could tell you in more detail. But it would be up to 25 percent for certain kinds of toxicities in certain kinds of patients and may be as low as five percent for other sorts of patients, but somewhere in that range, five to 25 percent. And the patients are willing to assume that risk. The misadministration risk for the Gamma Knife is completely buried in the noise.

DR. STITT: One of the frustrations in the medical community is, let's say that a particular patient is going through the system. What is their risk of having a problem in the end with the machine not functioning during the biopsy, having a blood product contamination with the HIV virus, and then throw in the potential for a misadministration or some sort of abnormality occurring during brachytherapy? We are in an area that is highly regulated, because it's radioactive isotopes. But if you put it in the broad spectrum of the medical care, why are we here?

DR. GRIGSBY: We give patients presumably informed consent, and we say provided that we deliver the treatment as intended, this is the chance you have of having a given side effect.

I don't sit down and say provided that we screw it up.

DR. BICKEL: You know, the relative ratio of numbers to me is kind of interesting, because I've had, you know, I think everybody in their own experiences have had family members that have gotten very serious diseases, and the doc comes in and talks to the family and says, well, you know, if we operate, I think I can give you an 80 percent chance that he'll live another five years. If we choose not to operate or do something, you know, I think he'll be gone within six months. The choice is yours.

Now you're talking numbers that are like 50 percent or 80 percent, and now we're dealing with ten to the minus four, ten to the minus six.

DR. POLLYCOVE: For death, but ten to the minus four for misadministration.

DR. BLEY: We're asking the hospitals to devote some of their resources to addressing this problem. And is that a reasonable thing to do, given the resources they have?

Now if it's cheap and easy, and it sounds like some of this stuff is almost good practice.

MR. CAMPER: Two observations, and I think that Dr. Stitt was right on the mark. Part of what goes on here, and rightly or wrongly, is the simple truth of the matter is the nuclear industry is asked to hold to a different standard. That's rightly, wrongly, that's a fact.

The other problem is that when you look at some of the frequency of occurrences of other errors in medicine, and I've heard some pretty outlandish numbers during discussions. I mean I've heard drug administration errors that were 20 percent in some cases.

Then the question that begs is is that okay? Why isn't something done about that part of the health care industry. Because if in fact, those error rates are real, that's a pretty monumental problem.

So I'm flipping it around saying, yeah, we were extreme over here, and I think some would argue we are, but I'm not so sure that what's going on elsewhere is the way it should be done either.

MR. TORTORELLI: And that's a question that somebody else can work on after we generate a model and give you data and numbers. This comes back to the point that we brought out yesterday. Those are good thoughts, but that's pretty far down the road.

What we want to do here is try and figure out how we're going to analyze this particular method. If we get done, then somebody else, not us, not the people in this room, is going to decide whether ten to the minus four is acceptable or not, and whether or not they want to study some other things that are going on.

DR. BICKEL: I'd like to propose as we take the break, we'll have Larry Camper's presentation right after that. And that will probably take us to lunch. And then we'll start the fun stuff.

(A recess was taken.)

# C.5. REGULATORY ISSUES

## C.5.1. Regulatory Background —Mr. Camper

MR. TORTORELLI: Larry Camper is going to come up and talk for a bit and give us some of his perspectives on the regulatory issues that are going to affect our workshop this afternoon.

After that, we'll probably break, go to lunch, rearrange the tables and get them in a big circle. When we come back, Harold Blackman will say a few words, and we'll get started on the fun part. Larry?

MR. CAMPER: Thank you. All set? Good morning again, and I've got to tell you, from my perspective of the regulator, I've really enjoyed yesterday and today, and I think this morning I'm getting the impression that you're really getting very close to the mark, the progress mark. I also sense that you are aware of some of the problems that we have as regulators trying to find the balance between some of the extremes you've talked about here the last day or two.

And what I want to try to do in this session before we go into the workshop is sort of get us back to the big picture, kind of share with you the current regulatory framework, how we got to where we are, some of the factors that go into creating regulations, and then try to talk to you about it in a program or performance standpoint.

Myself, Dr. Glenn, my boss, Dr. Paperiello, the Division Director, we're interested in risk analysis and risk assessment as a tool, as a tool that we can use as regulators to hope, in the final analysis, to create reasonable regulations that are properly balanced.

Now when I say put it into regulatory space, I shouldn't say regulations, I should say regulatory space. It's not just a matter of creating regulations. Some part of our task is regulation; some part of it is guidance; some part of it is making available to the regulated community the findings of symposiums and discussions such as this; the findings of some of the work that's already been done; and, ultimately the document that will be created. And for that matter, some of it deals with helping the industry find other solutions to some of these problems that we've talked about. So it's not just regulation. It's a spectrum of possibilities in the regulatory space.

What I want to do for you now is kind of go through the regulations we have today, we call the current regulatory scheme. Most of you here are scientists of one type or another. You're risk analysts; you're physicists. I'm a health physicist, but the technical part of my training is in health physics, medical physics. Most of us are scientists, and, therefore, we tend to look at these things, regulations that is, from a scientific perspective. We think that if we go through the right kinds of exercises and bring to bear good science and good technical considerations, we will in turn develop reasonable regulations based only on scientific and technical merit. That's a reasonable way to look at it if you're a scientist.

Unfortunately, or fortunately, depending on how you look at it, regulations get made by a host of factors. For example, public health and safety in its truest sense is a consideration. Events that occur are a consideration. Sometimes even a single event will cause us to put in place certain regulatory adjustments. They can be rules; they can be guidance; they can be dissemination of information; but, even a single event.

Observations by staff, the NRC staff, is a consideration that takes place in the rule making process. Inspection results, enforcement actions, science and technology, hopefully, as I mentioned. Politics, various viewpoints on how to properly regulate the nuclear industry and specifically the medical use of radiation. And let me tell you that those viewpoints are diverse. And in many cases, they are absolutely opposed to one another.

Risk. Risk is also a consideration. Now I think it's fair to say that if I look at the regulations today in Part 35, I draw the conclusion that gross risk has been considered. Gross risk in the context that brachytherapy or teletherapy has some inherent risks associated with it, by virtue of the fact that we are administering radiation to patients.

On the other hand, though, I don't think there's an awful lot of classical risk analysis in Part 35 as it exists today. And perhaps there should be more of that. And one of the things we want to take a strong look at when we next revise part 35 is more consideration for classical risk analysis, which most of you are far more familiar with than I am.

But what I want to do now is kind of step you through the regulations, just to give you the overview. And I am encouraged by the comments that I'm hearing this morning, particularly in the last few sessions, because it tells me that you really are cognizant of some of this stuff. And what I thought we'd do as we head into the workshop is just sort of remind you of some of these things, and you'll have the overall picture.

Now I'm not going to go through all of these in great detail. I put this slide up because I want you to see that our regulations are primarily contained in the 35-400 series, with the exception of 35-75, which deals with patient release. The main thing is I want you to see that there are many aspects to brachytherapy regulations. I mean, they range from things as straightforward and obvious as the use of the sources to patient release criteria into the public domain, to safety instructions for people that are working with these sources, such as nurses, for example, to possession of survey instruments. They cover a wide spectrum of issues.

Similarly, for teletherapy. Some of the same kinds of considerations as for brachytherapy. Use of the sources, maintenance and repair of the devices, safety precautions, dosimetry equipment to be used for doing all output evaluations. But teletherapy, unlike brachytherapy, also has some criteria that was alluded to yesterday by Glenn in his presentation with regard to calibration measurements, periodic spot checks, safety checks and the like.

Now most of this criteria that you see right there grew out of a single event involving multiple patients that occurred at Riverside Hospital in the 1970s, approximately 30 patients, as I recall, 31 patients were over-exposed. And a result came about because of two reasons: A physicist did not evaluate the output of the therapy beam for more than two years. In other words, he did not put an ionization chamber to the beam and actually take a measurement for over two years, and he was using the wrong graph for determining the output of the device.

Now one of the questions that we have explored recently with the ACMUI, and I'll talk about this a little bit later, is should we have similar or parallel requirements of a quality assurance nature in our regulations under the category of brachytherapy, like what you see here for teletherapy. And generally the feedback we receive from the ACMUI was that such an approach seemed to be reasonable and warranted.

Another issue in our regulations is training experience. Now if this doesn't have a whole lot to do with risk analysis, it has a lot to do with several things and it has to do with competency of the physicians and their training experience. It has something to do with turf battle, but the real question is, what is the proper level of training experience for those physicians who want to use brachytherapy and teletherapy and for physicists that we identify in our regulations as teletherapy physicists. And the reason we identify a teletherapy physicist, to get back at the question Glenn had on his mind yesterday, is because we want to make sure in the realm of teletherapy that a physicist has, in fact, demonstrated to us specific types of training and experience regarding teletherapy. Now many of those are physicists in medicine, medical physicists. Some of them are health physicists. But the point is, they have specific training in the realm of teletherapy.

But training and experience is an issue in our regulations for the use of these forces.

Several times over the last couple of days, we have touched upon an event that occurred in Indiana, Pennsylvania in 1992. And as a result of that, a number of things happened. There was a substantial amount of regulatory activity on our behalf. There was a great deal of public interest in this via newspaper articles, and, of course, there was even congressional interest in this event. But we did certain things that now fall into the realm of regulatory reactions. We upgraded something known as Policy Guidance Directive FC86-4. And, in fact, the article, the paper that Glenn was quoting from yesterday from some of his NRC concerns also has information contained within this P&GD.

Now what this did was to upgrade the criteria that our region used in licensing for the HDR device. We also put out two bulletins. Now bulletins have the capacity to require licensees to report

certain things. It has the affect, if you will, of a rule in that regard.

We also put in place an information notice which talks about releasing patients that have undergone brachytherapy procedures, be they low dose rate brachytherapy or whether they be high dose rate. So a great deal of regulatory activity came about as a result of that particular event.

The theory is that those requirements that were called for in the bulletin would now be embodied within Part 35 when we next revise it.

Both 93-01 require a couple of significant things. They require that a physicist or RSO and the authorized user be present, be physically present during an HDR procedure. It required the licensee to have emergency procedures, and it required a physical survey with the detection instrument.

A comment was made yesterday we were talking briefly about PDR and some concern in the realm of PDR, which is pulsed dose rate; that the idea that we would require the physical presence of a physicist or authorized user will shut down that modality, because if you will, it goes on for several hours, several days. We are receptive to alternatives to the physical presence of a physicist and authorized user. We came very close to getting one submitted by me of the few institutions in this country that uses PDR. They chose to withdraw their option at the last minute, because they believed that they could not meet the commitments that they had proposed to us. But we remain receptive to alternatives. In the case at hand, they were willing to use a cadre of specially trained nurses and house physicians to monitor the device while this proceeding was going on. That, under certain conditions and circumstances, would have been acceptable to us. But the licensee chose to withdraw that process. So PDR, we're still open to discussions on PDR.

The emergency procedures that were required in the bulletin. It required the licensee to have the capability to handle surgical intervention in emergencies involving source breakage, to be able literally to surgically intervene and remove the HDR source if need be. That is something obviously one of the speakers mentioned, I forget which one it was, but what this really says to licensees is if you're going to do HDR, you need to determine ahead of time which procedure it is that you're willing to do or not do, because you have this possible consequence. You need to be prepared for it.

DR. STITT: Larry?

MR. CAMPER: Yes.

DR. STITT: Question about that. In talking about the limits of doing this thing up there, is it true then let's say at a HDR unit at a free scanning rate at a therapist center, which is common, and they're doing an endobronchial case, which is also a very common application. Those people wouldn't have a thoracic surgeon in the operating room or any of these sources in that facility. So are those people then not allowed to do that sort of thing?

MR. CAMPER: We want to take another course. What we require them to do in the bulletin is to tell us what their emergency procedures are going to be. How are you prepared to address a contingency associated with those types of procedures that you plan to do in your institution? We have not gone back, and we don't have any plan to go back and evaluate or critique their emergency response conditions and then make some determinations as to whether they could or could not do it. What we've asked them to do thus far is to comply with those emergency intervention responses.

DR. BUDNITZ: So that's an information request.

MR. CAMPER: It's a bulletin.

DR. BUDNITZ: Yeah, but it has the character of an information brochure. You're telling them to tell you—

MR. CAMPER: That's correct.

DR. BUDNITZ: There's no real legal requirement to do anything. You just want them to tell you what their emergency procedures are. Of course, you're hoping they'll think about it and so on. So it's a requirement to tell them.

But just to pursue this, when you set up this, you must have had some knowledge or judgment about the frequency or probability or likelihood that source breakage would occur, huh?

MR. CAMPER: No, none. What we had was, what we had was two events that occurred. We had a patient that had died as a result of accumulation syndrome, right? We had another event a few days

after that event involving the same device in which another source broke off in the patient—

DR. BUDNITZ: And got it out.

MR. CAMPER: What we did was, based upon—we would have done it based upon a single event. But based upon the two events, we put in place the requirements in the bulletin, which included an emergency response. See, this is the point I was making earlier. We don't always have the need to know how many—what's the probability of this occurring, because we're going to take very prompt and effective action, sometimes based upon a single event.

DR. BUDNITZ: But what if there were 20 million every year, and you had one? Maybe that's an over-reaction. I don't know there are 20 million, of course. If there was one in 20 million, you'd say that's an inappropriate response, boy, did your knee jerk, huh?

MR. CAMPER: Well, certainly. And there are those who criticize—

DR. BUDNITZ: I wasn't criticizing you at all. I was trying to understand whether you had any statistical basis. By the way, a judgment is a perfectly good statistical basis if your judgment is based on experience, and you talk with other people, and everybody says, gee, this is not something that's acceptable.

MR. CAMPER: We do not have a statistical basis for making the requirement. Rather, we had what we thought was an appropriate response to the event, an understanding that some of these procedures could result in situations a source could break off in someone's chest.

DR. BUDNITZ: And they would die?

MR. CAMPER: Right.

DR. HOLAHAN: That's what I was just going to say. It's not so much how often it would happen, but if it did happen, it's because of the dose rate you can't take a few hours or days to figure out—

MR. CAMPER: You can't leave the source in there, right.

DR. LARSON: The same thing happened several years ago and it was already in the NRC data base. We reviewed a report that is the source broke. Just happened to break after it was being withdrawn, so instead of remaining in the patient, it went on the floor. In fact, that happened twice.

DR. BUDNITZ: Yeah, but I'm making a general point, and this is intended to help NRC understand the consequences of their bulletins. And this occurred in your area.

I read every bulletin that comes out in the reactor area and only some of yours. And most of them seem like they're sensible. Occasionally one comes out and obviously somebody hit their knee and they jerk and in retrospect there was no proper basis for that bulletin, and yet the licensees are running around spending money.

MR. CAMPER: I'm not sure I would agree with you.

DR. BUDNITZ: Excuse me, and thereby not doing other things, they put the sources over here instead of over here.

But I don't know whether that's true here, but it seems to me that the nice thing about risk assessment, it provides a context.

MR. CAMPER: I understand that.

DR. LARSON: But if Senator Glenn says—

DR. BUDNITZ: The hell with Senator Glenn. He doesn't run the agency. Only the Congress, by vote of the law and the President's signature runs the agency. Now I was in that agency. I was a senior officer in that agency. All too many times, a single little Congressman in some little district somewhere made the whole agency do stupid things. That's nuts.

MR. CAMPER: Well, in the case at hand, we had a patient death. We had other events—

DR. BUDNITZ: It's also real, but it's nuts.

MR. CAMPER: —we had a patient death. We had another event involving the same device two days later, and clearly understood that there was a possibility of an emergency situation resulting. We thought it was appropriate to—we want to know what our licensees—

DR. BUDNITZ: I wasn't attacking your judgment. Of course you did the right thing, because you had something—but wouldn't it be better if there was some risk information available so that

you could account for that, as well as these other factors in making suggestions. Of course it would be better.

MR. CAMPER: Of course.

DR. BUDNITZ: Sometimes you can look at the risk information and say, well, it isn't really a risk thing, or maybe I've got this other thing going on. That's okay, you did it. But at least you had the information.

MR. CAMPER: I think we would rather be criticized for over-reacting than under-reacting.

DR. BUDNITZ: Not if money spent on useful things is now spent on useless things. That costs lives, too.

MR. CAMPER: Certainly, but in the case at hand, when you're talking about the possibility of doing HDR procedures where the source can become dislodged in the lung, I'm not sure that's a waste of time or money.

DR. BUDNITZ: Well, I'm not arguing with you, you know, you have to be real careful sometimes.

DR. GRIGSBY: Removing that source is probably the reason that the PDR is not going to be successful, because you're going to have to have somebody there who can remove the source for the same reason.

MR. CAMPER: All right, so we put this in place to have these emergency procedures, and my point is, I want you to be aware of some of the regulatory actions that we've taken, they're bearing upon the regulations as we move ahead in the future to revise Part 35.

All right, now we have a number of concerns about brachytherapy and teletherapy, and we discussed these with our Advisory Committee—

DR. BLEY: Larry, may I back you up a little bit on this, because something just—

MR. CAMPER: I think you just did.

DR. BLEY: Back to what you were talking about, just a little aside thing came up. But after this, PDR is not being used now, and part of it is because it's too hard to meet that requirement and getting in fast. But the idea of comparative look at risk, by not doing the PDR anymore, are we increasing risks to patients more, and you say we didn't tell them not to do it anymore. We just told them they had a procedure. But the result of that means they don't do it anymore.

So a risk assessment to consider, is it more risky to the patient by driving this kind of therapy out of the treatment regime, compared to the alternative you put on them?

It seems a reasonable—it seems an important thing.

DR. BICKEL: That's something we'll discuss this afternoon. Let's not try and answer that right now. That's one of the types of questions this whole thing is designed to develop the methodology to answer, okay?

MR. CAMPER: We'll come back to that.

DR. BICKEL: Onward.

MR. CAMPER: Okay, the things that we are concerned about are what is the availability of industry standards when it comes to practices associated with brachytherapy and teletherapy, and particularly brachytherapy? If one looks at misadministrations that occur involving brachytherapy, one comes to the conclusion that the industry standards are not particularly sound. Either they're not clearly understood by many practitioners. In some cases they may not exist for certain parts of the use of the modality. But what we want to know is what industry standards are available? And the reason for that is two-fold: one we'd like to understand then, because it might have a bearing and influence upon what kinds of regulatory criteria or guidance we do or do not create.

Number two, and more importantly, to the maximum extent possible, we would like to embody industry standards into our regulations or our guidance documents.

We have a very great concern about treatment planning. Many errors occur in treatment planning processes that lead to misadministrations. We see this time and time again. We'd like to know a lot more about what is state of the art practice in treatment planning, and what do we need to do in terms of either regulations or guidance to further enhance this area of practice?

Training and experience, of course, for physician authorized users or for other individuals in-

volved with the delivery of the radiation in the brachytherapy or teletherapy process.

In fractionated brachytherapy, for those of you who have taken the time to look at the Quality Management Rule closely, you'll note that in that rule we don't have a definition for fractionated HDR misadministrations. And the reason for that is, teletherapy we do; fractionated HDR we do not. And the reason for that is, and I can tell you candidly I was a member of the team that wrote the QM Rule, is that at the time we wrote the QM Rule, HDR technology was emerging. This was back three or four years ago. It was emerging. It was becoming mainstream. We were not aware, frankly, of the practice involving HDR well enough to understand that many HDR procedures involve a fractionated approach. So there's no definition today for fraction HDR. We are going to go out shortly with a generic letter to licensees. We will ask them to report fractionated HDR events, and we plan a criteria threshold for doing that.

So fractionated brachytherapy, even fractionated radiopharmaceutical therapy is something we have an interest in and want to know more about and, in turn, determine what we need to do in terms of our regulations.

Now these are areas of concern that we discussed with the ACMUI. We generally got back feedback from the ACMUI. They understood it was there, in fact, made a number of comments at the time that these are reasonable areas of concern, that more information was warranted, and that in some cases additional regulatory development is indicated.

DR. GRIGSBY: For each fraction of brachytherapy, there is to be a written directive for each separate fraction?

MR. CAMPER: That's right. You can create one written directive, but that applies to all of your fractionations, and that's done in many cases, or you can create one for each one.

DR. GRIGSBY: One for each one, that's right.

MR. CAMPER: Dose fractionation in the QM Rule is defined for teletherapy. It is not for brachytherapy or radiopharmaceutical therapy, which I mentioned. And this is something that we most likely will address when we next revise Part 35.

We have some concerns about adequacy, adequacy of our existing brachytherapy regulations. And probably the easiest way to demonstrate this is the one I've already shown you. And that is that we have no requirements for brachytherapy that parallel those for teletherapy when it gets at things like doing quality assurance or quality control checks on brachytherapy devices. Our regulations are simply silent on that issue.

DR. BUDNITZ: Larry, you considered that lack of parallels is a problem, but you could go one of two ways. You could add it to one or reduce it to the other and find some other way of accomplishing the check, I suppose.

MR. CAMPER: That's a possibility. It's not likely we would reduce the dose of teletherapy, but again, the reason for that is we've had an event—and we've had other events, too.

DR. BUDNITZ: And you've had experience with it.

MR. CAMPER: I think the general feeling is we probably need to do something in brachytherapy along the lines of what we've done in teletherapy, unless there's compelling and convincing evidence to the contrary. And when we go out in the advancement of proposed rule making and we are in the public comment period, we intend to explore these kinds of questions. And we may get feedback that would cause us to re-decide what we currently do.

We have some concern about the adequacy of existing standards and procedures. And by that I mean the adequacy of those procedures and standards that exist amongst the professional organizations who have a vested interest in brachytherapy and teletherapy. We're trying now to review those standards, and interestingly enough by the way, since the Quality Management Rule came into place, there's been a lot of activity by professional organizations along the lines of the kinds of things we call for in the Quality Management Rule. Now whether you do it under the guise of quality assurance, or whether you do it under the guise of practice standards, the net result is that many professional organizations have put in place within their standards, within their inspection processes, certification processes, things that are

called for in the Quality Management Rule. So even to the critics of the Quality Management Rule, I say you've got something very positive going on.

Now what we need to do, the next step is to find out what is the adequacy of those existing standards in professional organization, and once again, to the maximum extent possible, talk to them, work with them about their standards, hold meetings, find out what's on their mind, how can they improve their standards and how can we embrace them in retrospect. We would prefer not to create new regulatory requirements if, in fact, professional standards exist. We would prefer to embody them within the regulation, either by direct reference or equivalency.

DR. CALLAN: Excuse me, Larry. Are you talking about teletherapy, are you talking about all external beams or just cobalt?

MR. CAMPER: I'm talking only about cobalt. Obviously, we don't—we have no authority over regular facility.

DR. CALLAN: And you're aware of the reduction in treatments of cobalt therapy?

MR. CAMPER: That's correct, I am.

Talking about linear accelerators, I get asked questions about linear accelerators. Some of the questions I get asked, for example, is the NRC, do we intend—are we trying to take over linear accelerators? The answer is absolutely not.

There are some people, I believe, on the hill who think we should, but we have no intention of that. It's not up to us to do that. That's up to the Congress of the United States. So anytime I refer to teletherapy, it's strictly with cobalt units.

Quality assurance checks in calibration for brachytherapy is similar to teletherapy. I think I've probably already said what I need to say about that.

So these are some concerns that we have. That leads me then to future direction, which is kind of the theme of some of the things we're talking about this afternoon. What are we going to do about some of these things?

Well, we do plan a major revision of Part 35. That is currently scheduled to be completed in 1997. We have a management plan, a so-called medical management plan that contains about 90 action items, some of which grew out of the incident investigation team at the incident in Pennsylvania. Others are items that the staff identified, the ACMUI identified, or the agreement states identified. And we hope to—a major part of the medical management plan is the revision of Part 35.

Now let me tell you that in this revision of Part 35, I'll quote Carl Paperiello on this. We intend to go to the world with this revision of Part 35 and do an advanced notice of proposed rule making, and I suspect most of you are familiar with what that means. We will lay out the concept or the revision. We will solicit comment. We intend to hold a lot of workshops. I alluded in my opening remarks yesterday to several workshops coming up. I think I called it mega workshop, which we will hold in the spring, involving the American College of Physics, American Association of Physicists in Medicine, ASTRO, AGRO, Dr. Stitt is going to be there representing directly the ACMUI. And we hope to get a lot of information about these questions, as far as brachytherapy standards and practices and appropriate regulatory approaches and guidelines. So we're going to go out and get a lot of input and react to that input.

In addition to these public meetings which will take place over the next two years, we are looking for input from our National Academy of Science Study. Currently the National Academy of Science under contract is conducting an independent review of our medical use program. This grew out of, primarily out of some concern expressed to the Commission by members of the medical community, even by our own ACMUI in a briefing before the Commission, that basically said that the regulatory burden of our regulations on the practice of radiation medicine was out of proportion to the risk involved. Certainly the nuclear medicine community, in particular. I think we always have to be careful about defining the nuclear medicine community as compared to the radiation medicine community. The term often is used nuclear medicine. As Dr. Pollycove, I'm sure, would be quick to tell you, they mean two different things, two practitioners. So I think the nuclear medicine community of which Myron is a part of that does diagnostic and therapy nuclear medicine, feels that, at least some of them feel that the regulations

are over-bearing or are disproportionate to the risk involved.

The other part of the radiation medicine community has not been as vocal or as strident about it. I think they have—my perception is that they have mixed feelings about it.

But what we want to try to get from the National Academy, we asked the National Academy to do some very big picture kind of analyses. We've asked them to take a look at standards and regulations across the 50 states. We've asked them to take a look at risk. We've asked them to take a look at our regulations when compared to other things that go on in medicine, such as anesthesiology, surgery and the like. So we hope to get some information from this study that we can incorporate and use in modifications of our regulations. That's due to be completed in 1996.

I've already talked quite a bit about investigating the use of industry standards. To give you an example of what I mean, for those of you, again, who are familiar with Part 35, if you look at Part 35 with regard to dose calibrators, we have very prescriptive requirements in

Part 35 of dose calibrators. We tell you what kinds of checks to do, the frequency with which to do them and so on. What we would probably rather do is have regulatory language that would say that you, the licensee, will have a program for evaluating your dose calibrator consistent with ANSI standard whatever or it's equivalent. And then we would define the equivalent in guidance phase. Because what happens today is that because we have very prescriptive requirements for those, in some cases our inspector will go in and someone hasn't done a dose calibrator constancy, for example, three or four times out of 365 times in a year that results in a violation. Well, that's really not what we're after. What we're after, though, is whether or not the licensee has in place an acceptable program for evaluating the performance of the dose calibrator. It makes much more sense to have it that way. If we can embrace ACMUI standards or AAPM guidelines or other professional society guidelines that make it clear that, you know, those kind of guidelines or the equivalent, and we would define the equivalent, based upon the use of those industry standards. So I think that kind of approach, when we revise Part 35, will go a long way as compared to what we currently have.

So that's generally the regulatory scheme that we exist with today. It has—there are many reasons why it is the way that it is. I'd like to be able to say to those of you in the room who are risk practitioners that there's a lot more classical risk considerations. I think there's some, but not a lot. There's room for improvement in that regard.

I think by and large the regulations exist today because of observations, events, publishing. We now have several revisions to Part 35, public comments, and those kinds of things with some consideration for growth risk concerns. Probably we need more consideration, classical risk assessment.

As we go into the workshop then this afternoon, I'd like for you to be thinking about these questions. I asked my boss, Dr. Glenn. I said, well, John, what do you want to see? What do you think is valuable as we try to bring risk considerations to bear? What do you need, as a regulator, to help us do our job better?

These were his comments. He'd like to know what is a measurable input for risk of medical devices. Glenn has gotten at this question a couple of times. And it is a worthwhile question. How do we obtain this measurement?

DR. BLEY: What does that first one mean?

MR. CAMPER: It means—

DR. BICKEL: How far do they want to go?

MR. CAMPER: How far do you want to go? What is the acceptable number and how do you measure to get to that point?

DR. BUDNITZ: It's a safety goal sort of question.

MR. CAMPER: A safety goal sort of question. How do we obtain this measure? Now some of these things you've alluded to in other processes. There are processes on the power side of the house, for example. Will that work on the medical side of the house? It might. And if so, how can we do that? What is the cost? We cannot talk about analyses and regulatory processes in the medical environment today if we don't talk about cost. As all of you know, cost has always been a consideration in the regulatory scheme. And on the medical side of the house today, it's even more paramount than what's the case historically? Because it's been

stated very well by several of you. You get to the point where the health care industry will simply say the cost is too great to meet the standard. The cost is too great to meet this regulatory scenario. It can't be done. And when you get into that kind of debate, you really come to the heart of the matter. It's a hard question. What about cost in getting some of this information?

And how do we quantify risk for regulatory purposes? What is the appropriate level of risk? What's the number? What's the standard that you use to determine that number is acceptable?

DR. SIU: Larry? A clarification on the first one again. To me that means you're looking at the dimension, the measure, rather than you're not talking about what is the level at which the risk is acceptable. You're saying what is the variable I'm interested in.

MR. CAMPER: I think it's both. It's how you get to the end point, and you have to define those parameters, because obviously if you're going to come to some conclusion, everyone has to, A, understand how you got there; and, B, hopefully buy into it. So it's really both, but yes, the parameters, how you got there is an important part, not just the end point. Bob?

DR. BUDNITZ: Let me propose a formulation, and see whether it makes sense to you. I've been listening now for a day and a half, and I haven't heard you or anybody else say that you were going to regulate the risk end point. I haven't heard that, and I don't suppose that's what you're saying that you're going to write a regulation that says that only if the risk of a patient suffering death is less than ten to the minus five for the procedure or whatever you come up with would you have things to go on. You're not going to regulate that way.

I assume that remains so, and that's one of the matters. And part of it is I don't know how you regulate.

On the other hand, and we faced that in the reactor business long ago. We don't know how to do that.

On the other hand, you can use the risk information to evaluate how good your regulations are. In other words, you can have that in mind and develop regulations that accomplish that broadly without regulating a device that way. Is that what I'm hearing?

MR. CAMPER: It is what you're hearing, and the latter is doable. I'm not sure the former is.

DR. BUDNITZ: Yeah, I would agree.

MR. CAMPER: Because as I pointed out in the beginning, there's so many parameters that go into creating regulatory criteria.

DR. BUDNITZ: But you see, one way you could say is suppose we had this criteria in mind and you said you would be happy with NRC's regulations if ten minus something per procedure were achieved nationwide on the average, and you also found the outliers, remember, because you don't want three hospitals killing all the people, and the others are doing just great. We've got to find them in order to fix them.

If you had such a notion in mind, then what you would do is establish a regulatory framework that didn't have risk in the regulations, but which you then kept staring at to see whether it was accomplishing that goal, in which case you have the question about what is the input? The input doesn't have to be directly measurable in that sense, except over a broad long-term aggregate, you know? You certainly wouldn't measure it for any given device, because any given device is only going to do 100 of these a year. Okay?

On the other hand, if there's 1,000 of them or 100 of them, you might get ten to the point per year, and you might get something.

And then how to obtain the measure then has to be in that regard a broad aggregate, because there could never be any device, unless you had a horrible practitioner, that would ever show any real trends directly.

Then you're back up to analysis. You use analysis, right. And it seems to me that that might be the logic that you are pointing towards here without having said it quite the way I said it.

MR. CAMPER: Well, I think we're open to suggestions. I mean, we come to you really in a sponge. It's very difficult—

DR. BUDNITZ: It's a real hard problem.

MR. CAMPER: We're certainly—we will never be able to create regulations that are risk-driven only, because there's just too many parameters and too many influences, too many different viewpoints and on and on and on.

The question then becomes to what degree can risk analysis be a consideration that you can gauge the performance of your program, and it may well be if you don't have—if you can put it into—in other words, if you create reasonable regulations where you're saying to the regulated community, we've considered some risks. There are certain things that we have to do, even to deal with these risk considerations. And we're developing reasonable regulations that they provide input on.

What we might be able to do, though, is tool more effectively and go back to look at our inspection program, for example, frequency of inspections, can we lessen them because the performance criteria seems to be met at a level of acceptability?

DR. BUDNITZ: Or whether the training area or calibration or whatever.

MR. CAMPER: I was going to say our training or calibration, for that matter. That's a tool we could probably use.

DR. BUDNITZ: Absolutely, absolutely.

MR. CAMPER: So that's really all I had to say about the existing regulatory scheme. I really wanted to get you thinking about the big picture as you enter into this afternoon. I think you've already been doing that this morning some.

Any other questions?

DR. GLASGOW: I'd like to add just a couple of quick comments, if I may, on the bullet today relative to cost and, perhaps, to Dr. Grigsby's comments about actually the impact of regulations.

It's not always simply the cost, particularly if there's an alternate methodology of treatment. I'm just back from our national meeting where at numerous points I heard teletherapy, cobalt teletherapy being referred to as "the dead technology". And the reason that it's being referred to as the dead technology relates to a licensing renewal fee that's being assessed to licensees.

The NRC has mandated to recover their approximately $500 million a year cost from fees and various others and to prove that they break even. And the net effect of this particular impact is that cobalt is dead, for the most part, in terms of a new market. There are some reasonably nice units out there, hundred centimeter units with high activity sources, and we actually purchased two of them at Loyola.

But the perception has grown, that because of the regulatory cost, which actually in the medical field is not a large cost, a license of $15,000 to $20,000 relative to income produced—

DR. BUDNITZ: Is that per year?

DR. GLASGOW: Yes, per year. But relatively speaking, it's not really a big cost. But the perception is that it's suddenly a new NRC requirement fee, and so the cobalt teletherapy market is down the tubes, and five years from now there will be few of these units, for the most part, being marketed, because of regulatory requirements.

On the other hand, they are a cost-effective modality, and they can be used for the treatment, head and neck patients of certain types, and they might be a way to keep hospital costs down in some sense in the medical care industry.

So you do have to be careful sometimes about how regulation has an impact.

On the pulse dose rate, I need to add a comment, a clarification comment. Whereas in St. Louis they've certainly made decisions not to pursue that technology, that's not the case in California. The rule that you've implemented on quality management, if I'm not mistaken, California's an agreement state—

MR. CAMPER: That's correct.

DR. GLASGOW: And, therefore, that rule is not in effect at this point in California, and PDR flourishes in California at the University of California at San Francisco where they have a very active program. And it also flourishes worldwide.

So in the worldwide community, this particular technology is still of some interest, because there's no regulation that is hampering it from going forward. California will have to deal with this regulation in a particular period of time, but until

then, they are using the unit and are using it successfully.

MR. CAMPER: Can I make one comment just to clarify?

DR. GLASGOW: Yes.

MR. CAMPER: The requirements to have an authorized user and a physicist or RSO present during high dose rate afterloading therapy, including PDR, resulted from a requirement in the bulletin. It wasn't a Quality Management Rule at all, okay? And you are correct, California is an agreement state, but come January of 1995, all agreement states are affected by the Quality Management Rule. It's Division 2 compatibility item for definition means it has to be verbatim.

DR. BLEY: Will they be affected by the bulletin?

MR. CAMPER: No.

DR. BLEY: So they'll never see it?

DR. BUDNITZ: Do the agreement states usually adopt the bulletin or never or what?

MR. CAMPER: Most often they do, but not always.

So anyway, Glenn, you're saying that it's still flourishing—

DR. GLASGOW: Well, it's still flourishing, yes. But it does show how a particular regulation can call a halt to the industry.

Now you might say, which is more hazardous to the patient? Is it truly—which of the two technologies, high dose rate or pulse low dose rate might really ultimately be more hazardous to the patient? True, with the PDR, there are obviously hazards. But there is a factor of ten difference in the activity of the sources that are being used. In one case it's a one curie source, and in the other case it's a ten curie source. Relatively speaking, if there is an incident on the PDR unit, it is with a lower activity source. And in any retrievable situation, there is less hazard across the board from radiation exposure from working with that technology than there is with working with a high dose rate source.

So sometimes the effect of the regulation may have a totally different impact.

It was really the intent, if I'm not mistaken, of the marketers of the PDR to get away from high dose rate treatments by offering this new modality. They had a reason to produce it. It's a competitor to their own equipment, and I think their rationale in making this available was that they felt that this particular methodology of caring for patients might ultimately be more advantageous than high dose rate. But with this particular regulation in place, it will effectively—it's a challenge for, if I were at Mallinckrodt and trying to write regulation, it, indeed, would be a challenge to write something that you would find acceptable. It would be a challenge. There's no question about that.

MR. CAMPER: I guess from our perspective, it came down to, first of all, you're right. The dose rate is lower, but it's still high enough that we felt there was a concern.

The question is really do you want a situation where a device, such as the PDR, on the program conditions is periodically moving the source in and out of several dwell positions over several hours of time, is it worthwhile having that physically closely monitored as opposed to having it monitored remotely by either a nurse, via a monitor, or most commonly by occasional visits in? That was the dilemma that we faced, and believe me, we did think long and hard about the PDR issue. In the final analysis, we felt that if it warranted close physical monitoring, although the dose is lower than the HDR, it was still high enough that we felt it warranted close observation.

But it was never our intent or our desire to shut down the industry.

DR. GLASGOW: No, I'm sure that it wasn't, but—

MR. CAMPER: But we felt there was an issue that required monitoring, as I described.

Other thoughts or questions? Okay, thank you, as, again, I've enjoyed what we've talked about thus far, and we look forward to the rest of the workshop.

MR. TORTORELLI: Okay, let's go eat. At 1:15 we'll start up.

(The noon recess was taken.)

# C.6. WORKING SESSIONS

## C.6.1. Introduction—Dr. Blackman

DR. BICKEL: Now let's move on to kind of the group discussion phase of the workshop. I'd like to try and make people rethink about what may be, you know, what our opening, I guess our opening objectives were. And I think we're here to try and lay out how one should go about developing risk assessment models, data bases, to be utilized in the future by the NRC. We recognize there are some gaps in information, some technologies and things that need to get done, and that's the objective. We're also supposed to try and use this to refocus on some of the questions that started to arise in the formal presentations. Glenn?

DR. GLASGOW: Is the premise open to discussion?

DR. BICKEL: Sure, I guess. No one from NRC is—

(A discussion was held off the record.)

DR. BICKEL: With that fact, I'm going to turn over the rest of this to Dr. Blackman, who is going to try and help add some structure and form to this rather amorphous effort we have going on.

DR. BLACKMAN: What I've done to try and at least get us started in a conversation, obviously we want to hear all points of view and consider those in terms of the output of the workshop.

But, also, we want a product. So we do not want to spend, to be quite frank, the next day and a half philosophizing about, you know, issues which are tangential to this particular—to the task at hand. The task at hand is really considering the question of risk and risk assessment. That's what we want to focus on, and that's what we want to concentrate on.

Now to try and help get us started here, what I've done is, I've put the three words on a cloud up on the white board up there that we've heard to kind of kick us off, in fact I thought were very nice words, which were the words usable, reasonable and then cost benefit. And I guess I would ask us to focus on the usable and reasonable aspects of that, because cost benefit, obviously, is a product of doing risk and reliability assessment. That is a product of what actually comes out the end of it.

DR. BUDNITZ: Does usable include understandable?

DR. BLACKMAN: I think so, Bob.

DR. BUDNITZ: That's a crucial element. With physicians and physicists not in this business, to understand this thing, that's very important.

DR. BLACKMAN: You bet. Yeah, I think that's—

DR. BUDNITZ: We found that out in the other arena.

DR. BICKEL: I think it would also be real neat if Senator John Glenn could understand it.

DR. BUDNITZ: That's not a joke.

DR. BICKEL: No, to me that's an important issue, because if, in fact, a lot of things that are going on are being driven by some of our Congressmen and Senators and whatnot, being under the klieg lights of ABC news, and they're not in a position to say, hey, compared to, you know, when I flew in the space capsule in the '60's, this is a piece of cake. If they aren't aware of that perspective and are unable to communicate it, the outcome is going to be pressure on NRC or the dumb regulations.

DR. POLLYCOVE: I think the problem is more severe. I think that Senator Glenn may understand it, but I think the public doesn't understand it. And I think that much of what our Congressional Senators and Congressmen do is not a product of their misunderstanding. It's a product of their understanding exactly what gets points with their constituents.

So I think the root, when we're talking about root causes—

DR. BICKEL: The Cleveland Plain Dealer doesn't understand it.

DR. POLLYCOVE: I think the root cause is the public, and unless they can understand it, and they don't think quantitatively, they only think qualitatively. So unless they can understand it in qualitative terms, we're up against a stone wall.

DR. GRIGSBY: Well, the average reading level in the United States is sixth grade, so the public is not going to understand, and that's a fact.

DR. POLLYCOVE: And the newspapers and the TV play to the public. Give them what they want.

DR. BLACKMAN: Well, let's turn—the way I've broken this up, being the simple-minded individual that I am, I've broken it up into three categories.

I've broken it up into a question of the knowledge base that's required to do this kind of analysis, because we kept hearing issues related to the knowledge base. I think I've heard that over and over again, data, data, data.

There's two kinds of data, of course, the data to actually develop the models themselves, which is one kind of data. And then the second kind of data, which is used to quantify those models. So I think we want to talk about that.

And then the aspects of that data is the quality of the data and the quantity of the data. And we heard the quantity of the data, how much do you have to have in order to do a credible analysis and, of course, the quality aspect of that.

What I would propose doing is spending the next two hours talking about that, if we need it, and then moving to the question of modeling itself. You know, we heard about different kinds of modeling techniques. We heard about event trees, fault trees; we heard about WPAM, which, I think, we can consider a technique of modeling and, also, generic error modeling. There are others which are out there, but I think that we should at least look at those and say are those usable and reasonable, two hours on that to close the day. Tomorrow morning, two hours on special considerations, which are, you know, really a part of what other special considerations that are part of the medical community that will either make this work or not allow it to work. And then probably the other special consideration is since human error seems to be dominating these kinds of affairs, what is it about human error that we need to think about in terms of making this kind of an effort work?

DR. GLASGOW: The other thing that's sort of implied here, and I want to make sure. There's also the issue of the risk of instrumentation specific equipment versus the risk of the process of use by users. And my sense of it is it's the latter on which you predominantly want to focus.

Am I mistaken?

DR. BLACKMAN: Well, let me put it this way. What I heard, okay, and I'm trying to interpret what I've heard over the last two days. This is my take and my interpretation on what I've heard and how to guide us, okay?

Now if, in fact, we don't agree that it's the human risk, if that isn't where we should be spending some time considering that, then we need to correct that now.

And what I guess I would ask you now before we get started is do we want to make—what kind of modifications might we want to make to this approach this afternoon and tomorrow before we get started?

DR. LARSON: Just for what it's worth, I'm not going to be here tomorrow morning. I'm not sure that it matters that much. It's a relatively small item, but I won't be here tomorrow.

DR. BLACKMAN: Maybe we could move modeling until tomorrow morning and consider the special considerations next. Why don't we do that? We'll reorder that.

What other things? Anything else? Gosh, you're an easy group.

DR. GLASGOW: We feel uneasy contradicting.

MR. WREATHALL: What do you mean by the word reasonable? That's such a latent term that has no real specific meaning to me.

DR. BLACKMAN: Well, that's a good question. That's a good question.

MR. WREATHALL: Reasonable approach for reasonable people.

MR. SHEPHERD: Be reasonable. Do it our way.

MR. CAMPER: Well, I was going to say, a couple thoughts on the term usable and reasonable.

Usable, to me as a regulator, means the following: You come up with models, guidelines, findings or what have you, that I can then use in one of several ways. Either we can translate it into regulatory language or regulatory considerations either in reg. language itself or in stated consideration, discussions of regulatory. It can be used as a basis for developing a guidance document that explains some facet of this problem to the regulated community. So usable means something like that, a tool that I can use in the context of the regulatory arena.

Reasonable means that it would withstand scrutiny by our scientific peers, by the regulated community. In other words, you take to them findings or suggestions that, based upon a discussion of those suggestions, that in the final analysis while they might not all agree that a particular regulatory approach is necessary or required, they would agree that in the final analysis the result was reasonable. It would stand the reasonable man approach or woman approach to the respective ladies here?

MR. WREATHALL: If I could just test what I'm thinking, that would really comprise acceptable. And it's acceptable to the regulated community, would it include acceptable to the legislative community?

MR. CAMPER: I'm not sure acceptable will work, because I think it's fair to say that most of what we impose upon the medical regulated community is not acceptable.

MR. WREATHALL: In one sense.

DR. BUDNITZ: What do you mean is not acceptable? It must be acceptable to somebody. The Congress and the American public want it.

MR. CAMPER: I said the regulated community.

DR. BUDNITZ: Oh, it's not acceptable to the regulated community.

MR. CAMPER: To the medical regulated community. Most generally—you have to be careful when you say that, because there's a small aspect of the medical community that's a strident vocal and, in some cases, vehemently opposed to it. But the majority of the regulated community is quiet. You really don't hear much from them.

But the bottom line is, you don't want to put in place extreme requirements that most people would look at and say that's simply unreasonable and overbearing.

On the other hand, you don't want to put in place requirements that have absolutely no regulatory teeth to them whatsoever. They're unenforceable. They can't be monitored as to what the results were in a particular regulation.

So it's reasonable in that context.

MR. HANEY: One term we use in HRA is PRA defensible. That means in terms of the methodology and the data and the approach is defensible. That may be another way of saying suitable.

DR. BUDNITZ: I've raised understandable in that regard. It's much the same. The people that didn't do the analysis have to be able to understand it.

DR. BLACKMAN: Is that helpful?

DR. WU: I have a question here. I just want to understand we're talking about regulatory framework, or we're just making recommendation to the industry, because to us, that sometimes is different.

Like a lot of models we provided meant to help the industry to become a good practice, but we may be more reluctant to suggest it become a regulatory device.

I'm not so sure in this workshop, which ...

DR. BLACKMAN: It's in support of the regulatory community specifically. I mean, that's what we're here for. We're looking at risk assessment and reliability in support of the regulatory community, and whether or not it is usable, reasonable and will be cost beneficial for their use. So it is specifically in support of the regulatory community.

MR. CAMPER: I wouldn't view it as a device. I wouldn't view it that way at all. I think that rather I would view it as this is an opportunity to convey to the regulators our findings, our suggestions for tools that I might use in the regulatory process, because, you know, this is your opportunity to do

that. And you should capitalize on that opportunity.

The degree to which we end up using this advice or any advice that we're given is obviously a function of many things. But this is your opportunity to share with us what your thoughts and findings are.

DR. BICKEL: One thing that I think might help us focus on the word usable, is what are the uses that one can envision will spring forth once we have a risk assessment in place. Because if we can define what things we want to use it for, I think it will be a little bit easier to start filling it out.

Obviously, one of the things that I would guess is on the list is to properly characterize the frequency and consequences of misadministrations. Is that a more properly, rather than a kind of lumped approach that exists now?

### C.6.2. Knowledge Base—Dr. Blackman

DR. BLACKMAN: Okay, what do you say we attack the knowledge base? What do you say we consider whether or not we believe that the present knowledge base, the data bases that are out there, the data bases that may exist at hospitals that currently, you know, aren't looked at, you know, all of that information that is necessary in order to do modeling and quantification.

Let's start with modeling, and let's talk about that a little bit. Any impressions?

DR. CALLAN: I have an impression that all the data available in the government is not being utilized or analyzed sufficiently.

DR. GRIGSBY: See, the—again, I'll go back to the orange book and the summary of the seven events, plus the review of the 200 and something misadministrations. I found that quite interesting. It was a unique document in the sense that it's the first time I've seen any documentation of a large number of events trying to characterize where the problems lie. And so granted that the data that are currently available may be somewhat limited, just the fact that somebody took the time and effort to pull all that stuff together and lump some of the problems into some broad categories, to me is very useful.

I think the oncology community, the responsible ones in that community, which most of them are, will look at a document like that if it's presented to them and be able to use that information to help decrease the risk of a misadministration.

DR. GLASGOW: It seems to me that practically speaking, in order to—there is knowledge existing within the hospitals and medical centers. There are internal reports filed with Radiation Safety Committees on recordable events that don't reach the NRC. They are hidden in the files. They're not hidden in the files, they're just part of the filing processes with the committees.

But I think practically speaking, to really—to get at what I think you need to know would require a survey of all users at high dose rate remote afterloaders asking basic questions regarding how are you using the unit; how many treatments; how many times has the source gone in and out over this last year; how many failures did you have that were machine failures? You really, in order to get at risk that's associated with the equipment and, also, the question of how successfully the technology is being used, it seems to me that you almost have to start with a collection of that type of information.

I don't see really any way around it in order to do the sophisticated analysis I've heard presented here. You have to have a much better data base than you have.

MR. SHEPHERD: Well, it seemed to me in conversations that I've been in and overheard, that a great deal of data exists at the treatment facilities, some of it in the form of medical records, some of it in the form of billing records. And I'm not sure that we, as a regulatory agency, are aware of all of the data that currently exists and what form it's in.

So I think before we run off and start specifying what other data should be collected, we first need to determine what data is already there, and then what access we might have to that existing data.

Clearly, we would not be able to walk in and take everything, because I think the Privacy Act considerations and other things ...

DR. BUDNITZ: Harold, I think you got the cart before the horse. I think a discussion of data

should logically follow a discussion of what the applications are of any information we might derive. And then, also, follow a discussion of what modeling methods are available that we need, whatever data it is. And then back up and say what data are there, and what new data could we get?

Because it's obvious that there are data not yet compiled, not yet collected, in fact some not yet contemplated that could be of some benefit, but costs a lot to get. And I think—or the data, you know, NRC has gotten, hasn't looked at in a certain way. And all of that ought to follow from, not lead the rest of the discussion.

MR. WREATHALL: I think the danger is if you get into a bucket mode. You gather buckets of data, and afterwards, as you try and make sense of it, you find you have three-quarters of what you need and a great deal more than you wanted in other areas, and you've invested large sums of money, and you don't go back and start a new data exercise all over again. It's a needs driven response.

DR. BLEY: When you don't follow that approach, one thing we've found everywhere else in gathering data is not only you've got extra that you don't need, but you find out you didn't collect a few of the key things you did need.

I've heard some discussions around the room today that make me think that once we talk about maybe modeling what these things are, a small task force of a few physicians, a few others, physicists, could identify where and how you could get the key pieces of information you need to do the modeling at a minimum cost. If you need some elaborate system later, that's one thing. But nothing I've heard tells me that the risk benefit payoff here would call for putting in place a large data base.

DR. BUDNITZ: And furthermore, the NRC, I know full well, has procedures whereby the anonymity of data collected for certain purposes can be assured, so that, sure, if somebody has gone out and killed a patient, that may not be available to us. But—although maybe, but it may not be anonymous. If you're just collecting data on certain failure on human errors or large data events for other purposes, that can be collected anonymously, and that uses some of these other problems.

Nevertheless, we need to—let me just argue the case. We need to work back to the data from the—

DR. BLEY: Perhaps even voluntarily.

MR. WREATHALL: The most successful one has really been the aviation safety reporting system, because of the particular benefit it has to the person reporting. It's not perfect, but at least it gathers most of it.

DR. BUDNITZ: That system is anonymous, but that's also true in the reactor operator system. When reactor operators report events, that can be done anonymous ways.

MR. WREATHALL: There isn't the problematic incentive as there is in—

DR. BUDNITZ: Not afraid of incriminations.

DR. STITT: You did what I was going to suggest, so I guess we're both brilliant. I think we need to start at the bottom and work backwards. You can get millions of numbers, but why do we want these? What are they for? What do we want to come up with? Let's start—

MR. HANEY: It appears to me there's one class of data that's obviously missing, regardless of what model you use, because it's the type of data that Jim Shepherd mentioned like number of treatments, outcome. That stuff is probably there, but to do a good, especially human reliability model, you need to have data and on the influences, the context of the task and need to know the process. You need to know the organizational climate. You need to know training, experience, level of stress.

So that data is obviously probably nowhere other than you'll have to go get it.

DR. BICKEL: Yeah.

DR. BLACKMAN: Well, let's go back to—let's go to uses then, as it was suggested.

So we're now at uses.

DR. BICKEL: We had only one, which is to properly characterize frequency and consequences of misadministrations. That's one.

I think some of the things that Larry said earlier, we would want the data available to better

characterize the significance of certain issues that NRC is trying to regulate. In other words, if we want to try and study the benefits of having independent checks by the physician on what the medical physicist is doing, you know, we're going to want to collect data that supports future activities.

So what we need to figure out is, you know, what types of regulatory initiatives would one be wanting to try and understand over the next few years. We mentioned future rule making and things like that.

MR. CAMPER: Future rule making related to regulatory guidance implementing any rule changes?

DR. GRIGSBY: See, in collecting data from our own institution regarding—now this is a separate topic now. If I have a population of patients, and I'd like to evaluate that population and learn something from it, I sort of have a gut feeling of, yes, I have this population, and I sort of know they were treated in a given manner, and there's some things that influenced the outcome of these patients. I don't know really what they are, but there's some things that influenced the outcome. And if I look at those factors and appropriately evaluate those factors, then ultimately what I'm going to say is these are the factors that influenced the outcome of these patients. Therefore, my conclusion is such.

So if I don't know what data I need to collect, then the wisest thing I can do is sit down and write my paper first. I write my introduction, my materials and methods, my result section and my discussion and conclusion, leaving certain key holes. And when I go back and when I do that, and when I review that, I'll say these are the data that I need to collect.

So maybe the NRC should write the regulations first, and then we could determine what data needs to be collected to validate the regulations.

MR. CAMPER: I don't think you understand. You make my life so easy. I would argue that that's no problem.

DR. BUDNITZ: I'm going to argue that that's backwards. Let me describe.

Harold wrote uses, number one, characterize the frequency and consequences of misadministrations.

Okay, why do you want to do that? Well, there are obviously two things to me here, obvious to me, but maybe they won't be obvious to anybody else, and maybe they're not even right.

First, both the regulator and the medical community and the patients and the public want to know what the risk is. They want to know—we know that. People are saying that. Why do they want to know? Because they want to know whether it's adequate or requires further work to make it adequate.

Now if—and by the way, nobody's defined adequacy yet, but somebody has got to. So you want to know this. You want to know if it's adequate.

Now if it's adequate, you want to ask is there some measure that needs to be taken by somebody or other to keep it adequate, maintain its adequacy. If it isn't, you want to find out what sources cause it not to be and fix those. It might be a few hospitals that are just not doing it right, and you got to go after them. And maybe it's a broader thing that everybody has to do.

DR. BICKEL: Bad equipment.

DR. BUDNITZ: Or whatever it is. So obviously, to me it's completely obvious that having characterized the frequency, what you do is, you want to know whether it's adequate, if so—

DR. BICKEL: Measure of frequency—

DR. BUDNITZ: That's for somebody else to decide. And if it is, what measures we should continue to do to keep it that way.

DR. GLASGOW: Well, the first question though, procedurally it's already in place a mechanism for collecting this information to the QM programs, as I understand it. They will be in effect January first, you said for your agreement states. And, therefore, there will be reports to NRC of the misadministrations. You will get the number of those. What's missing is the denominator that's required to find the frequency.

DR. BUDNITZ: There's something more that's missing, though. What's missing is a systematic analytical framework in which the gathered data,

which might be, you know, all different kinds of data are brought together for a systematic analytic arrangement to satisfy these questions, to characterize the frequency and the consequences.

DR. GLASGOW: I can answer that first question for our facility relatively easy.

DR. BUDNITZ: Okay, but you can't answer for the nation.

DR. GLASGOW: All I have to do is determine how many times we actually—

DR. BUDNITZ: But, Glenn, you can't answer that for the nation.

DR. GLASGOW: No, but I'm saying if they were to ask me retrospectively even, we have records on how we've treated. We know exactly how many fractions.

MR. WREATHALL: So you're saying that's a practical step that can be—

DR. GRIGSBY: Someone can do that.

MR. WREATHALL: The information exists. We've learned that, if nothing else.

DR. BUDNITZ: What we all know, we all know that to gather such information could be costly. It has to be structured in a way that produces the systematic framework at the minimum cost.

DR. BLACKMAN: Let's take—I heard a bunch of things. I've been writing away. We'll get you right next.

DR. POLLYCOVE: Time to characterize frequency. Don't leave that.

DR. BLACKMAN: I promise. What we've got up here right now is one of the uses could be to characterize frequency and consequences.

The second one what I heard was, and actually it was before we went the other direction and came back, was to inform the medical community.

And then what Bob said, I added—

DR. BUDNITZ: I said you do one in order to do two.

DR. BLACKMAN: That's fine. That's okay. I'm just trying to get them written down here to inform these people, too, and I took what you said and called it risk.

DR. BUDNITZ: Whatever it's called.

DR. BLACKMAN: Then three and four fell out, where inadequate and to improve performance, what measures are necessary to keep performance adequate?

All right, now that's all I've heard to date, and it's your nickel.

DR. POLLYCOVE: Now, I've just been at the NRC for a little more than two years, and I think I can characterize the frequency and consequences of misadministrations.

Now on the basis of the review of the misadministrations, it would appear that just grossly they occur, as we stated before, with the frequency of about ten to the minus four.

Of those misadministrations that occur, no more than ten percent, and probably considerably less, but somewhere in that ballpark have some permanent sequelae that are negative.

And as far as deaths are concerned, they're less than one percent of the misadministrations that occur.

So what we can now characterize on the basis of that ten to the minus four, that's based on patients that are treated per annum, not procedures.

DR. LARSON: Is that brachytherapy only or—

DR. POLLYCOVE: No, all—

DR. LARSON: In other words, teletherapy—

DR. POLLYCOVE: Right, right. This is radiation therapy. So that brachytherapy is roughly, as best estimated by the people who are in radiation oncology, of a total of let's say 550,000 patients treated per annum, about, perhaps, 150,000 at the most are brachys or less.

So it's still a small percentage. Most of them are accelerator treated, and I think the brachytherapy is now beginning to be about the same as the cobalt.

But at any rate, so what we're talking about is patients treated per annum. You know, nationally it's about ten to the minus four.

Now in the patients that are treated per annum, some are treated twice. I'm showing all the error in poor—how poor the data is. Some are treated twice and, of course, many of the patients have fractionations, so that 20 to 30 fractions.

So we're talking about a minimum denominator of 550,000. And the number of misadministrations occur ten to the minus four.

So I think ten to the minus fifth or less for any consequential injury, ten to the minus six as a minimum. In other words, if the actual incidence is considerably less, less, less, too little errors, then ten to the minus six for deaths and ten to the minus fifth for any consequences that are permanent in the patients.

Now the question is, you want to know—they say, well, that's pretty rough data. Pretty rough data for risk analysis. Well, the question is why do you want it better characterized? If you know it's less than ten to the minus six for deaths, and it's less than ten to the minus fifth, that's a pretty good characterization of the risk. You say, well, we don't know the denominator, how big the denominator is or how much less it is. Well, the question is, why would we want to know how much less it is than ten to the minus sixth or ten to the minus fifth? What impact would that have on our regulations? What impact would that have on the medical community if we knew the denominator better and could say how much less?

DR. CALLAN: Well couldn't we better inform the public, as they suggested a minute ago, by knowing that number?

DR. POLLYCOVE: I don't think they know the difference between ten to the minus fourth and ten to the minus sixth or ten to the minus eighth.

DR. BUDNITZ: How much precision is necessary? I can't answer that question, but I can tell you that when it says characterize the frequency and consequences of misadministrations, I interpret that differently than you, in a slightly important way, but I want to just say, it isn't just the number, Myron, it's characterizing them.

DR. POLLYCOVE: What?

DR. BUDNITZ: It's characterizing them. If you—let me describe. If, in fact, most of them occur in a very few facilities, that characterization is useful to everybody, public decision makers, medical community, rather than uniformly spread around, because—now let me tell you why—because if intervention is called for to improve performance, it tells you something.

DR. POLLYCOVE: Well, that, within the NRC states, we can characterize, because we have reports that are missing in the other—we know where they're occurring.

DR. BUDNITZ: So I had in mind that the characterization involved not only the frequency and the consequences—

DR. POLLYCOVE: Right, right.

DR. BUDNITZ: —which you have already given us a rough feeling for. But, also, some sort of—there are a few other figures, this question about whether they're mostly in a few facilities, the question about whether it's mostly a certain type of brachytherapy that's dominating or whether it's mostly—or not. Maybe it's all spread around.

DR. SIU: Generally you want to characterize to support the decisions that are going to be made.

DR. BUDNITZ: Well, except, Nathan, that he's right, that if in fact the total is smaller, let's walk away from it.

DR. SIU: Well that's the first condition. You decide whether or not something has to be done, and then if you do decide something has to be done, now you have to have enough detail so you can see—

DR. BUDNITZ: But you can't even decide if something needs to be done even if the total is small enough. You may not want to—if you found out it was three hospitals keep doing it, even if the total is smaller, you want to land on them.

So there's a little more to it than just the total number—we all understand that.

DR. POLLYCOVE: Oh, yeah. I'm not saying that characterizing is the whole story. I'm saying that to what extent do you want to determine the frequency? To what accuracy do you want the denominator? We know it's much greater than the

550,000 we're using now. We know it's much greater. So, you know, you can just ...

DR. SHEPHERD: We would like to add it to the proper order of magnitude.

DR. GLASGOW: I just wanted to make a quick comment that we don't want to overlook that there is a federal program in place recently, the Medical Safety Devices Act sponsored through FDA, by which any patient killed on a piece of equipment or which there is a serious incident must already be reported. So there is a reporting mechanism for the most serious consequences already in place. But, again, it doesn't address the denominator of frequency. It's just a reporting system.

MR. WREATHALL: There's an interesting parallel between the discussion here, I think, and one that the FAA is going through on aviation safety. That is to do with, yes, the likelihood of dying in an aircraft accident seems to be acceptably low—

DR. BUDNITZ: And it's going down.

MR. WREATHALL: But, in fact if you look at the characterizations, you look at commuter flights, differentiating from the large body aircraft—

DR. BUDNITZ: They're going up.

MR. WREATHALL: They're going up. Right now the ratio is about four to one, four times more likely to die on a commuter flight than you are on a wide body plane, but it's not stable. And if you didn't have base line data, you wouldn't know it was going up, and you wouldn't know whether to intervene. Now the FAA, because it gathers the data, now has programs that are going through rule making for what has to be done for the commuter flights.

And it seems to me that it's not just the numbers, what is the trend, and maybe the trend within subsets. And if you can identify that, then you know when you need to intervene.

But without those data, you would never know what was happening.

DR. BLACKMAN: Well, John, doesn't the FAA fall into proactive category of organizations? Just a comment, but it's true.

DR. BUDNITZ: Let me tell you about another activity that to me struck as very weird in that area.

Within the last two years, the Aeroflot slot system has broken down into something like 20 different little airlines, as big as the big international one. And although their total crash rate over the previous ten years was only 20 percent higher than the west, it's now about a factor of four to five higher than the west. The U.S. Government has forbidden U.S. employees and contractors from flying in Aeroflot, unless there's no other way to get to Kazakhstan. And even there, you're supposed to try and take the train.

I'm involved in that, and I just got a directive about it.

But the commuter flight I rode here is four times greater than the jet I rode from San Francisco, and they didn't intervene in that.

Now think about it.

DR. POLLYCOVE: Well, there's a difference between four times and what is it now in Aeroflot?

DR. BUDNITZ: It's four to five times higher than the commercial practice, but so is the commuter flight I just took from—

DR. POLLYCOVE: Aeroflot has only gone up four or five percent?

DR. BUDNITZ: Yeah, and that's real data.

DR. BLACKMAN: All right, so uses. What other uses do we have? What other uses do we have?

MR. WREATHALL: Three and four, a wide set of things under the heading of causality.

DR. BLACKMAN: And what might those be?

MR. WREATHALL: They could be many things, many dimensions to many people. There's an interesting part in what you have in three and four. Causality of bad behavior and the fourth one is causality of good behavior. And we often focus on failures and bad things. There's also, what is keeping us so well? We succeed because of and we fail despite.

DR. BICKEL: In theory, what you're asking there is do a risk assessment and then do an importance analysis.

MR. WREATHALL: Only if the risk assessment contains the ingredients—

DR. BUDNITZ: Now let me ask the medical people in the room how much accuracy would be adequate? That was the question Myron, you know, a factor of three.

DR. BLACKMAN: May I ask a question? I think you're dropping down—

DR. BUDNITZ: No, no, that's a use question.

DR. BLACKMAN: What, accuracy of the data?

DR. BUDNITZ: The medical people and the regulators to say, gee, that's good enough. If they need only a factor of three plus or minus to make the decisions they have to make about intervention and informed consent and all that junk, then a lot of data doesn't have to be gathered in quite the same way as if they really needed the 30 percent.

DR. POLLYCOVE: There are two aspects to how much is missing. On the one hand, how much is necessary to tighten the restrictions or make the regulations more strict.

And then there's another component, a certain component of it needs only one or two cases. Now there's a great deal of—

DR. BUDNITZ: Of course, of course, of course.

DR. POLLYCOVE: That shows a double—

DR. BUDNITZ: Yeah, absolutely, sure.

MR. HANEY: There's one thing that seems to be coming out of this discussion that I don't see up here in the uses we're talking about, frequency, consequences, we're talking about how to measure performance. But isn't something we've been talking about identifying where to intervene, you know, which part of the small risk that is represented by this process is the place where we can intervene? Which type of treatment, which facility, which type of organization?

MR. WREATHALL: Almost a definition of causality, as I have it, is related to when you can intervene. Those are your definitions for what's controllable.

DR. BUDNITZ: In fact, you quickly learn here this is an iterate process. I think that's right.

The first thing you do is you do a rough characterization, and you kind of see where you are, where it may be inadequate. There you might gather more data to characterize it better, if you feel you need to. Then you go—

DR. BICKEL: Yeah, I agree. No argument out of us.

DR. SIU: I think you mentioned the risk significance of particular events as opposed to a generic—

DR. BICKEL: Oh, yeah.

DR. BUDNITZ: There's events versus data. That's what Myron was saying, right?

DR. POLLYCOVE: Yeah.

DR. BUDNITZ: One event—

DR. POLLYCOVE: Very illuminating, and you know you have to plug that hole. And you don't need a lot of data to do that. And irrespective of whether the risk is ten to the minus six or ten to the minus three, you're going to plug that hole, because it's an obvious source of severe consequences, and you're going to plug it, if it can be done with reasonable—

DR. BLACKMAN: What questions is it that the ACRS asks in an assessment that you can't answer, that these tools might be able to answer? What questions is the National Academy of Science asking that you can't answer that these tools might be able to help answer? What is that these tools might provide you in your job that would make your decision making—I mean, how are you going to apply these tools in your job?

I think those kind—and I see some of them here. I mean, obviously some of them are up here. But are there other things that come to mind where you see these tools, perhaps, helping?

DR. RATHBUN: Well, I don't know whether this is captured by what you have on the board, but one of the reasons we wanted this risk analysis work to go on was to support a risk analysis of the—

DR. BICKEL: Model program.

DR. RATHBUN: The PHDR, the PDR, because we understood there are issues that might be essentially destroyed by over-regulation and et cetera. And we were looking for a risk basis to analyze the device. We were actually trying to help the medical community that time.

There was a specific goal.

MR. CAMPER: One of the things that—Nathan touched on this earlier and Pat's example of PDR, and that is I mean, let's go to two things.

First of all, why—and if you take a look at Myron's comments about what we know about the frequencies of errors and misadministration. It begs the question, and this is really the same thing I said during my comments. What would we do differently? Probably not much, because of how we tend to react even to singular events. It's kind of like why climb the mountain? Because it's there. There's a compelling desire, I think, in some circles to simply better characterize frequencies of misadministrations, to have a more precise and, therefore, defendable number to be able to speak with greater validity and accuracy. And that, in and of itself, is a worthwhile goal, for no other reason than just that. It's worthwhile.

Now let's assume for sake of discussion, that we know what the number is. Let's assume that we find that it's, you know, 2.3 times to the minus four versus one times to the minus four, or numbers in that order of magnitude. The big question then becomes for us, as a tool as regulators, is what's the number in which you would look at the frequency of occurrence of misadministrations and say by comparison to other phenomenon and establish risk criteria is something that as a regulatory agency, we don't have to worry about, or we have to adjust our program accordingly, because we're in a particular range, and by comparison to other scientific literature and established risk coefficients, we need to do more, less, the same or let it go.

So what's the standard, if you will, if I'm saying this well?

DR. RATHBUN: I also wanted to bring in on what Larry is saying exactly what it is that the National Academy of Science has been asked to do.

Now they have been asked to take this risk and place it in the context of other risks associated with medicine, surgery, anesthesia. So we're looking to them to take this regulated area and give us a context for it. So that is specifically one of their charges.

Their other charge is to look at how risky is this when it's performed correctly versus when it's performed incorrectly?

So that is exactly what the three things are that we've specifically asked them to do.

DR. GLASGOW: But in answering the question of risk in that context, you clearly have to assess the question of how frequently are these procedures being performed, and you have to get that information. If you don't have any risk coefficient, you don't have any risk to compare to their studies, because they'll come back and tell you out of so many surgeries how many went bad, out of so many how many anesthetizations are bad. So you have to have the denominator data collected here.

DR. RATHBUN: We have it.

DR. POLLYCOVE: We have, as I say, a minimum. Ignoring repeated patient treatments, ignoring fractionations, so we know that the denominator is much greater than. We've characterized it that far.

DR. BUDNITZ: Myron, it can't be very hard to extend the number of patients to whatever fractionations or repeated things you needed by doing some survey.

DR. POLLYCOVE: Yes, but the question is, what's the point? If we know that deaths are ten to the minus six now, do we gain a great deal by going into all the fractionations and repeatedly showing us now it's really ten to the minus seven?

DR. BUDNITZ: But if you could turn Myron Pollycove loose on the telephone and in one week find that information and hone it up, it would be worth it, right?

DR. POLLYCOVE: If I could get a ballpark estimate. If we ignore all the fractionations in this and this and this, it's ten to the minus six. A few samplings showed that—

MR. CAMPER: But there's a problem with that, and that is Myron is pretty close. We think it's

pretty close, but, of course, the question then becomes what's the pedigree for the estimate? How well is the estimate documented?

DR. POLLYCOVE: Well, the number of patients, this minimum figure is well pedigreed. It was determined by the American College of Radiology going around to all the hospitals and finding out the equipment and how frequently it's used, how many patients were treated on the equipment, and so the only thing that was omitted was the additional brachytherapy treatments, which were estimated by radiation oncologists to comprise a small fraction that built it up another 55,000 or 75,000.

So that the pedigree, as far as the minimum figure, is well established. And we're just talking about there's no good pedigree on how much greater it is. And what we're saying is, well, you could get a very rough estimate by doing a sample survey and documenting exactly what you did, what the responses are, and that on the average it seems that about for every patient treated per annum, there were so many procedures done.

DR. BUDNITZ: Two and a half.

DR. POLLYCOVE: It would be a very soft figure. We might go from ten to the minus six, ten to the minus seven. Maybe even higher. What good would it do?

MR. SHEPHERD: At one point it would make a difference, and that is the point at which you make a decision, I'm now going to impose an additional regulation at this point on this procedure for this type of device. At the point where you're going to make that decision, it's possible we need a higher pedigree for the data than what we have.

DR. BUDNITZ: Possibly.

DR. BLEY: That goes to Items 3 and 4 up there.

DR. HOLAHAN: The other thing I was going to say in terms of getting that actual number, if we're fine tuning the denominator, we're also going to start fine tuning the numerator, because we're going to start getting the information in from the agreement states. So that is going to increase the numerator. Right now the numbers—

DR. POLLYCOVE: You see, again, this has all been based on misadministrations, saying that it's the same as in the agreement states. But, again—right, right. And we just don't know.

DR. HOLAHAN: Could be better; could be worse. We don't know.

DR. GLASGOW: I don't think you want to lose sight of the fact that this is not a large data base. Actually, the number of machines out there may be only 200, 250. This is not 3,000 instruments. It's a large—350, okay. It's in the hundreds.

MR. CAMPER: You're going to include brachytherapy?

DR. POLLYCOVE: Pardon?

MR. CAMPER: Including brachytherapy, not just HDR?

DR. BLACKMAN: What about other uses? What if we change focus up to the top of this list? I've heard kind of two general uses, and the two I have heard, one, managed risk, which is what most of this is about. And the other one is enhance the credibility of the NRC and, perhaps, the medical community.

It seems the top level is things we're talking about here. Are there others up at that level that this would help?

MR. WREATHALL: Political solutions.

DR. POLLYCOVE: Actually political is the main thing.

DR. BLEY: That's a credibility issue. Maybe it's different than the—

(A discussion was held off the record.)

DR. BLACKMAN: Other uses.

DR. LARSON: It seems to me that even if you had these numbers, wave a magic wand to get the numbers absolutely precisely, what you'll have is reported misadministration rate, and the only way to get the true rate is to do a survey of, say, 1,000 charts, 10,000 charts, some number of charts. There's that caveat, and you have to understand that going to all this effort, you'll always have that caveat, which is going to dilute the effect of that somewhat.

DR. RATHBUN: And Carl discussed that with the Chairman, actually, the exact process you just

described. And pretty much they concluded that it really wouldn't change the way we regulate. So it's not really—

DR. LARSON: No, but I'm addressing the credibility issue. If there's more credibility by having these numbers very precisely, you won't be as credible as you think, only because people will be always saying well, there's a caveat. We don't really know after all.

DR. POLLYCOVE: Well, the thing is, if you can establish the risk is much less than—

DR. BUDNITZ: Some acceptable item.

DR. POLLYCOVE: See, and you can defend that number with great validity.

DR. LARSON: Well, see, I would buy what you already said already satisfies that requirement.

MR. SHEPHERD: Well, is it possible that if we did this survey we would find that the actual number of administrations was an order of magnitude greater than what we have measured?

DR. LARSON: I have no idea.

MR. SHEPHERD: And if it's not going to be an order of magnitude, then we have roughly the same certainty with the numerator that we do with the denominator. If the numerator can change significantly, also, then we need to look more carefully.

DR. POLLYCOVE: Well, there's always the question of unreported misadministrations. How many of them do we not detect?

The feeling that I have gotten since I've been at the NRC is that within the NRC states, it's a small fraction of the ones that are reported, because it's only occasionally that very careful inspections turn up things that were not reported. And, of course, that's not all of them, but the fact that they occur with such low frequency, despite the fact that the inspections are done very carefully and in a very aggressive manner, would indicate to me that within the NRC states, at least, that we're not going to double it by half reported and half unreported. We're not in that ballpark. We might be 95 percent reported or 90 percent, ten percent.

DR. BUDNITZ: Nothing's that good anyway. We're not talking about ten percent here.

DR. SIU: My guess is that the credibility comes not so much from having a real precise estimate of frequency and consequence, but demonstrating that there's a very clear understanding of what the risk level is. And so if you can have a reasonable estimate of what the rate of misadministration would be, plus or minus something we know what the errors are caused by, we think there's reason to believe the errors are small, to me that would demonstrate understanding of the risk level. And that's good enough, I think.

MR. SHEPHERD: One thing on credibility, you know with nuclear power a few years ago, we used to compare the risk of nuclear power with other risks like cancers from smoking and, in fact, lost some credibility, because there is a perception by the public of the difference in their control over the situation. So we need to be very careful even with the NAS study what we are comparing the risk of a procedure with an isotope too.

And I think whatever we compare it to will have some influence on our credibility, also.

DR. LARSON: In that regard, let me just mention it seems to me one natural measure would be the risk that the patient is assuming by undergoing the procedure. And if the risk associated with misuse of the device is one or two orders of magnitude less, probably everybody would say that's pretty reasonable.

DR. BLEY: The voluntary risk.

DR. LARSON: The voluntary risk you're already taking, yeah.

DR. POLLYCOVE: Let me address that, because that's another area we went into. And I used figures out of standard textbooks. The one has three authors and is cancer. You probably know the three authors.

DR. STITT: DeVita?

DR. POLLYCOVE: Yes, that's the one. I went to that textbook, a new edition just came out, and looked up the complications in terms of death and serious impacts with various procedures, chemotherapy, radiation therapy and surgery in about half a dozen different types of malignancy. And it turns—for radiation therapy, per se, DeVita said that about one percent of all patients treated—it depends upon the type of therapy. But sometimes it's a half a percent, sometimes more. As a

result of the radiation therapy in the subsequent few months resulted in death, and this could be ascribed to the therapy properly delivered.

So that was the incidence. But one percent.

DR. BUDNITZ: And the people know that going in, and it's worth the risk for the benefit.

DR. LARSON: Well wait a second. I'll just argue with your number a little bit here. I understand the source of it and so forth, but I think it would be unfair to use that number for something where a patient is undergoing Gamma Knife treatment, where we know that the risks that they are undergoing are much larger than one percent. And they understand that, also, and it's voluntary. So that would be the correct measure for them, but for brachytherapy it might be a different number yet.

DR. POLLYCOVE: That's right, but I'm saying just to get a broad overall, they're saying sometimes less; sometimes more. It's around one percent.

Now we're just saying that we know just from using the—a very conservative denominator and using the NRC data and assuming that it's the same in terms of misadministrations, whether it's ten to the minus fourth or two times ten to the minus fourth, that the deaths due to misadministrations are ten to the minus six or—no, no, less than ten to the minus six. That was the one that doesn't take into account repeated treatment of patients and fractionation of doses. So we know that it's considerably less than ten to the minus six.

And so we have, the patient goes in knowing he has a one percent chance, ten to the minus two. Anesthesia alone is ten to the minus three. So buried as an insignificant grain of sand in the ten to the minus two is the ten to the minus six or seven or eight. That's the minimum figure.

DR. BLACKMAN: Let's talk back here to the uses. We have on the board is the question is it worth it? We'll consider that as we continue here. Yeah, Nathan?

DR. SIU: Three possible uses that have been touted, at least in the power industry applications, one would be as a tool to gain understanding, and I've argued that's something that is included in credibility—as a tool to gain understanding the process you're dealing with, and some people found that's actually one of the biggest benefits in doing this kind of an analyses, as a tool to communicate, and, three, as a tool for training.

DR. BLEY: Training who?

DR. SIU: Well, again, you can think it's part of the understanding, but not if you've got people who have to learn about the process they're supposed to regulate.

MR. TORTORELLI: So it could be the users; it could be the regulators; it could be the patient; it could be the general public; Congress, any number of things?

MR. WREATHALL: In your numbers one and three, and it may be buried, but the impression I have of the outliers. We're talking a lot about averages, average risks, and we hear, you know, for some treatments the actual risk from the procedure is much higher than what we're talking about as the average.

And really what you're concerned with, and maybe it's part of risk management, and maybe it's part of the tools of communicating and training and so on. And that's to find what are those few critical seizures, activities, equipments where it's much higher than in the seemingly low level. Bob talks about these, you know, three hospitals killing all the patients. He'd kind of like to know that.

DR. BUDNITZ: If it was true.

MR. WREATHALL: Three types of pieces of equipment as some of Wood's work in anesthesiology has shown, particular pieces of equipment doing a lot of damage. If you could identify those, it's not what are the average risks. It's what are the things that are really causing—

DR. STITT: That's the second statement that Trish showed yesterday. There's the three different parts of the NRC's—

DR. HOLAHAN: Medical policy statement?

DR. STITT: Right, and the second one had to do with—I don't remember the words, but it referred to those that are not performing up to adequacy and having the ability to make them perform in some fashion.

DR. HOLAHAN: Yeah, where the voluntary standards are inadequate.

DR. BLACKMAN: Is there an item on inadequacy in the reg. now?

DR. HOLAHAN: No. 3.

DR. BLACKMAN: Read No. 3 and see if that captures your point.

DR. STITT: Yeah, the mission statement, No. 2.

DR. BLACKMAN: Does that capture your thoughts?

DR. STITT: Let's see the facts.

MR. TORTORELLI: Causality of wrong behavior.

DR. HOLAHAN: Not really.

DR. GLASGOW: I'll make just one more comment, and that is the causality of much of the wrong behavior, to those who use equipment is abundantly clear to most of us in the field. And that is the inadequate training that we provide our staff. We are training, and I want to ask this question of the group, although it's a little off the topic.

I'd like to sort of know, those who are in the power reactor or in other areas, what fraction of time, of employee's time, would generally be taken for the process of retraining?

DR. BICKEL: One-sixth.

DR. GLASGOW: One-sixth, okay. In the hospital, I'll tell you that that rate would be one percent would be a high number. There's nothing approaching one-sixth in our hospital associated with the training and use of the equipment, once they know how to do it. I'm talking about ongoing continuing training, and that is really to me the great difficulty that we have in the control of the use of our equipment. The staff changes; we have new physicians come in and out; new technologists. Keeping the staff competency level at the right level is clearly the biggest problem.

It doesn't take a huge risk analysis to know that as a user.

DR. BUDNITZ: Myron, I want to ask you a layman's question. You said that without argument about the details, that the risk that a patient runs of a fatal or very adverse outcome might be one percent or so going in, even when the procedure is followed properly.

DR. POLLYCOVE: That's correct. When everything—where the written directive is followed exactly and delivered as—

DR. BUDNITZ: Right, now suppose you did a thousand. That means roughly that would be ten of them that would—

DR. POLLYCOVE: Yes.

DR. BUDNITZ: Now is that because unbeknownst to the physician, that particular patient is more sensitive, or there's some other variation?

DR. POLLYCOVE: That's right. There is a—

DR. BUDNITZ: Is the variation in the sensitivity of different tissue that's seemingly identical?

DR. POLLYCOVE: That's right—no, no. There's a variation in patients in radiation sensitivity. That's right, not just organ to organ, but as genetically that patient is constituted—

DR. BUDNITZ: Unbeknownst to the physician.

DR. POLLYCOVE: Sure, how would he know?

DR. BUDNITZ: No, no, but presumably you can imagine that over the years you might be able to develop indicators that would say that that class of patient—I mean, you could imagine this—and then you could reduce that.

DR. POLLYCOVE: In addition, there are minute variations. Well, we know that that's true in every other situation where patients are subjected to procedures that are not part of their standard environment, in other words when you have drugs; when you subject people to radiation at high levels. Now you disagree. You think everybody reacts to radiation in identical fashion?

DR. GLASGOW: No, no, he's agreeing with you.

DR. POLLYCOVE: I don't know if he's agreeing or not.

DR. BUDNITZ: The reason I'm asking this is here I am the layman. I'm trying to figure out if somebody is going to try to intervene on this mis-

administration side and spend X dollars on it, is there money worth spending on that other much larger thing that could be fruitfully spent?

DR. POLLYCOVE: You mean how to identify—well, you see—

DR. BUDNITZ: If I could cut that one percent in half, I've got a lot more leverage.

DR. POLLYCOVE: Wait a minute. The thing is not driven by the sensitivity of the patient. The thing is driven by the sensitivity of the tumor, and as was pointed out earlier, there are curves where you expect to get 100 or you hope to wipe it out, and if you don't reach that level, the best you can do is palliate it, and it's going to come back. Certain tumors are very resistant and require high amounts of radiation that the patient can't tolerate at all.

So what you're trying to do is—I'm not a radiation oncologist, so please correct me if any of these—

DR. GRIGSBY: That's right.

DR. POLLYCOVE: What you're trying to do is achieve the maximum dose to benefit and get rid of the tumor to try to achieve a cure, and at the same time have the least amount of permanent damage or death to the patient.

So you titrate at this level, and so you'll find out that overall you do more good if you irradiate at this level, even though a certain percentage are going to have serious or fatal consequences.

DR. GLASGOW: The classic example is protection of the spinal cord, that there are certain patients in whom you can treat the spinal cord to the safe level of, let's say, 45 rad or centigray, and in 100 patients that will work just fine. But there may be two or three patients out of that group who have a low sensitivity, and you may get a radiation mellitus at what is allegedly the safe dose. So it's that type of tissue response thing that he's referring to for radiation therapy.

DR. GRIGSBY: But there's more to it than that. The outliers of the consequences that presumably occur at low frequencies—I've been thinking about this all day. You see, with radiation, the one percent takes into account not only the sensitivity of the tumor, the radiation sensitivity of the tumor, the radiation sensitivity of the patient, but a whole host of other factors, the patient's nutritional status, the patient's income, other diseases, co-morbidities.

DR. POLLYCOVE: That's part of sensitivity, I mean that determines the response of the patient. You're absolutely right. It's not just genetic.

DR. GRIGSBY: Radiosensitivity, but there's more to it than that. Maybe one or two percent of all the patients we treat to some degree expire as a result of their treatment.

DR. POLLYCOVE: That's right.

DR. GRIGSBY: Because of patient variation.

DR. POLLYCOVE: Even though the dose given was in accordance with the written directive.

DR. BUDNITZ: Now you would agree that over the years you would hope that you could get your arms around more and more of these factors and tailor the treatment better and better, right? That ought to be a goal of the practice.

DR. POLLYCOVE: Well, you can't control the nutritional status and the poverty.

DR. GRIGSBY: Wait a minute. Yes, you can. The American College of Radiology has a certain set of standards, and we, as a part of the QA process monitor weekly the weight of all patients, and if there's a problem with it, then there's an intervention.

We monitor, according to ACR standards, which patients have side effects and have to be admitted to the hospital. I mean, yeah, we are looking at these different factors.

DR. POLLYCOVE: Sure.

MR. SHEPHERD: I think in theory if you collected enough genetic data on every patient, you could get to the point where variation of the tumor size aside, you could tailor the treatment to the nearest few centigray, but I'm not sure that that kind of data collection effort would ever be worthwhile or even feasible.

DR. STITT: I think we're barking up the wrong tree here.

DR. HOLAHAN: Dr. Grigsby and I—let him address that, because I think that's what you're getting at is can you predict how a patient—

DR. BUDNITZ: Well, I wasn't arguing that you could ever do it perfectly, but obviously the profession ought to be, and presumably is, attentive to as much of this as they can, and they're trying to do the best they can.

DR. GLASGOW: But there are limited resources—

DR. HOLAHAN: But they have been.

DR. GRIGSBY: But they have been. Predictive assays have been evaluated. I was telling her some of the early studies that I read about have evaluated go back all the way to the 1940s for predictive assays.

I'm not saying—and I don't know of any predictive assay today that influences me as to the prescription that I make. Are there any?

DR. STITT: I'm frustrated, because I think what we need to be talking about—I can tell you that if you need to have pelvic irradiation for some sort of cancer that's there, and you have hypertension and you're a smoker, and list several other factors, the chance of you having a small bowel injury because of a variety of vascular factors, is going to make that higher than the fellow who does not have hypertension, does not smoke, et cetera, et cetera, et cetera.

But you know that going into it. We already talked about that business up there, what's the risk of the treatment in general that you accept going into it versus something that I can't control.

DR. GLASGOW: It's sort of independent to the patient risk. In the Indiana, Pennsylvania situation, for example, the patient who was injured was a very elderly patient in very sad shape. And her actual physical—if you read that report, many physicians might have said this was not a candidate for therapy. The entire process of treating this patient was not particularly a very smart thing to be doing.

But the regulatory rule was independent of this patient status, so it doesn't really get into it very much.

DR. LARSON: Let me just make one comment about Myron's one percent and the death rate. If you want to define death by radiation as what the coroner's report says, radiation enteritis, radiation pneumonitis, radiation myelitis and so forth, in our department we treat perhaps a couple thousand patients a year. In ten years we might have one such patient. So it's really at a much lower level. Radiation may contribute. A person may have all these other factors, and that may be a higher level.

So I think one has to be careful with this percent, I think it's too high a number—for survival.

DR. POLLYCOVE: This is what the textbook says, that within a short period of a few months, if a patient dies, they ascribe that as being influenced and as a result of the treatment. And I'm just saying that if patients are informed of that when they go in, and they know, as was mentioned before, they have 100 percent chance of dying within a year if nothing is done, and with this they have a one percent chance, and a chance that they may have several years of reasonable—and a very small chance of a cure.

So this is what they know. And now we tell them that by all this regulation, we can alter some minute indiscernible incomparable portion of that one percent.

### C.6.3. Medical Considerations —Dr. Blackman

DR. BLACKMAN: Okay, sounds like we've beaten these to death. We have a good list. What we're going to do is, we're going to get that copied. We're going to circulate that, and we appreciate some time over the next course of the next few hours and tomorrow you can comment on that, mark it up and get it back to us, because we'd like feedback on the use list.

Now what I'd like to do is, I'd like to move to the special consideration kinds of aspects, and see whether there are any other ideas.

Basically, the only thing that I caught and wrote down, although I think there's probably more that's been mentioned that I didn't quite get in the last hour, was the comparison of what I'm calling the isotope risk to the nontreatment. You know, if you don't get treated versus—

DR. HOLAHAN: On nontreatment by radiation or nontreatment?

DR. BLACKMAN: Nontreatment by radiation.

DR. BICKEL: Chemotherapy versus—

DR. POLLYCOVE: The patient in whom it was—they come to radiation treatment because it was deemed the best of the alternatives.

DR. BLACKMAN: Right, the best alternative available. You're right, okay.

Other medical considerations that are special that we need to factor in when we're thinking about risk and reliability.

DR. BUDNITZ: Other medical considerations?

DR. LARSON: Well let me just point out that end points for risk would be death, as we've talked about. But another misadministration could lead to a neurologic damage or some other kind of an injury. And there's much more data regarding that end point, the risk of complications than there is for the risk of death.

DR. POLLYCOVE: That's the one where it's an order of magnitude greater.

DR. LARSON: Right, exactly, yeah.

DR. POLLYCOVE: So instead of ten to the minus six on that we come to complications we talk about ten to the minus fifth or less, depending on how much larger the denominators.

DR. BUDNITZ: Those are important complications, but it's not death.

DR. POLLYCOVE: That's right. Ten to the minus four misadministrations, ten to the minus fifth, a tenth of those roughly or less of the misadministrations result in some kind of permanent injury, whether it's severe or moderate or less. And ten to the minus fifth might be too large, but it's up to—but, again, browsing through DeVita, I got the impression that it was, the complications were about ten times greater than the deaths.

DR. BLACKMAN: Okay, so we see another aspect that's unique is the fact that the consequences are, in fact, multi-dimensional, so they include not just death, but also medical complications, okay?

What else? What else is special?

DR. SIU: Is there anything about the effect on the industry that should be considered?

DR. BLACKMAN: What about the question of—

DR. POLLYCOVE: Well, of course, as far as the medical community is concerned, I mean any, as you would say, fault in the event is of importance to us. In other words, if we see there's a breakdown, but it didn't occur, it didn't result in a death or medical complication, that's still an end point that we're very concerned about. In other words, we're concerned about any breakdown in the procedure that we set up.

And so that we do have the same end points that you would have in the nuclear reactor, where something goes wrong, but nothing really happened, or there was a mistake of moderate or mild degree in the dose, but nothing happened. Those things are also end points that we're very concerned about.

DR. GLASGOW: I think the special end point that we have to keep in mind is that the regulation that comes forward must not be so onerous, it comes down to the question of reasonability, that it has sufficient impact.

For example, on the Gamma Knife with its 201 cobalt sources, if someone sat down and said, you know, I think that you should have the daily dose profile across each collimator and make sure it hasn't changed during the night. One might write out procedures that would be so onerous it would have a tremendous impact. It would cut, you know, cut you down.

DR. BLACKMAN: Let me see if I captured it. Are you saying regulation must not prevent or limit treatment?

DR. GLASGOW: You have to be very careful to make sure that the regulation—yes.

DR. STITT: And to enhance upon that, and this is beyond what we're trying to do here, but in my practice, I'm hearing this relates to cost and cost benefit. I'm hearing, for example, chemotherapists saying there are a lot more chemotherapists than radiation oncologists out there. They use drugs that are not regulated; that they can give, you know, slip under the table late at night. And brachytherapy, basically, is not very widely available, in spite of the fact that we're all gathered here to talk about it. A few places do brachytherapy. You can get a lot of chemotherapy most anywhere

in the country, and it's much cheaper to give. Even if it's an expensive drug, it doesn't require the technical staff, the fancy gizmo you paid $300,000 for, and the price of regulation.

So I think that across this country, I would be curious to see how it is in California, but radiation oncologists, patient numbers, undertreatment, as far as factoring both teletherapy and brachytherapy, are being reduced. Where are those patients going? Why are they not coming into centers? It's open to a lot of question, but many patients are no longer being referred, so if it's another obstacle, they're either going to get palliative care or chemotherapy, some other fashion that's just plainly easier to do and may well be cheaper. And that benefit may be greater, because the cost benefit ratio has changed.

DR. POLLYCOVE: And, again, according to DeVita, the risks of death are greater in chemotherapy than in radiation therapy with correctly administered dose.

DR. BICKEL: That is a true—

DR. STITT: That is true.

DR. LARSON: I'm not sure this is really a non-sequitur, but we keep having the example that the nuclear power industry, which I know nothing about other than there may be a community someplace, and if something goes wrong with the reactor, that community, which was previously healthy, may now have some threat to it. And that's different from—I mean, that's where the analog breaks down, that's one place where it breaks down. Because the patient has something that's wrong with them from the start. And that maybe has to be factored in in some way. I'm not exactly sure how.

DR. BICKEL: What you're saying is that the—you're basically starting off with people that are not whole.

DR. LARSON: Yeah, exactly. They've got a problem. They've got a threat to their life already.

DR. GLASGOW: But legally—let me come back to the point. I don't think, though, whether equipment is safe or efficacious in the regulatory sense or in the sense of being approved by FDA, that really comes into question. It's true. It's true, but a patient will not choose to be treated on a riskier piece of equipment. And I don't think that the nature of the regulatory process would generally allow riskier equipment to be used for patients who are at higher risk. That's—

DR. LARSON: It does come in the following way. If you were to say I have a patient who has a 50 percent chance of death if they don't undergo treatment; they have a 25 percent chance of undergoing death if they do; and, it's not misadministered, it has a one chance in 10,000 of having death, or some number like that, if there's a misadministration. I mean that just helps put this in context.

DR. GLASGOW: It puts it in terms of context, but in terms of trying to do risk analysis on the equipment or methodology, though, I don't think it really—I don't think it really helps, to answer the question.

DR. POLLYCOVE: I think that's the point is that we would clean up obvious areas that can be remedied without risk analysis. That's your point, and that's my point. You don't need risk analysis to try to clean up a piece of equipment that you know has a wire in it that is liable to break after it is inserted and removed 30 times. You've got to clean that up. You don't need risk analysis for that.

DR. CALLAN: What if a patient asks you which is the safest, less risky for me, the brachytherapy machine or the cobalt teletherapy machine?

DR. BUDNITZ: Or an accelerator?

DR. GRIGSBY: I've never had anybody ask me that.

DR. POLLYCOVE: First of all, they'll never ask you that. The point is if your chances of survival are much better with the brachytherapy, and you have a one chance out of 1,000 that it will go wrong, you're obviously going to take your improvement of 20, 30, 40 percent and forget about the tenth of a percent. But patients don't think quantitatively. It's the physician that has to make that judgment. He can explain what the risk is.

DR. SIU: I think the discussion's a little bit off track. I think that the point is the special considerations with regard to risk assessment, and the question was does this affect the way we do risk assessment? I think in some ways it does. It's a breakdown in the analogy between the power plant and the—thanks, Jim. It breaks the analogy be-

tween the power plant and the medical application. The break makes the difference in the modeling, because in this case for every path you have on your event tree there are obvious outcomes for certain probabilities. So those have to be put in. That's one minor way in which the analysis might be affected. And there may be others that have to be considered.

But, again, the discussion I think should be addressing that point rather than acceptability of one technology over another.

DR. BLACKMAN: Now the other thing that I'm trying to gather on, and what I think I hear you saying is we don't need it, and it's too detailed.

DR. POLLYCOVE: No, no, no. What I'm saying is we don't need it to correct the instrument. That's what I was saying.

DR. BUDNITZ: Oh, that may be. But that's a different point.

DR. POLLYCOVE: That's the only point I made is that we don't need the risk analysis to decide whether or not to clean up that instrument. He brought up an instrument, and I—

DR. BUDNITZ: That's a narrow point.

DR. BLACKMAN: Okay, all right. I'll take that one off.

DR. POLLYCOVE: I'm not that adversarial.

DR. BLACKMAN: Just checking. We want to get everything up here.

The other thing that I've heard mentioned from the medical community is this question of data and data bases. Is there anything that is important about the data that's routinely collected for risk and reliability? Are there any insights there that might be important to be considered here?

DR. LARSON: I just mentioned about the Gamma Knife only. I mentioned to Larry earlier that I think some of this can be solved easily, the number of patients treated with the Gamma Knife in the United States is known within probably a percent or so.

DR. BUDNITZ: Roughly, what is it?

DR. LARSON: Well, as of—well, worldwide as of 1993 it was 16,700 and something. And about half of those were in the U.S. I mean the number is known. And in the U.S. in 1993 there were about 3,000 patients treated and probably about 4,000 in 1994.

So the denominator, I think we can get a pretty good accuracy.

DR. HOLAHAN: Can I ask a question on that? That's the number of patients with the Gamma Knife—

DR. LARSON: Virtually everybody gets treated with the Gamma Knife, one treatment.

DR. HOLAHAN: You don't give multiple—one treatment, but within those treatments aren't you doing multiple sites, perhaps?

DR. LARSON: Well, the person goes in and out of the machine several times within the space of an hour or two. That's still called one treatment. We're not calling that—maybe you want to, but nobody's calling that separate administrations.

DR. HOLAHAN: Yeah, but if you're looking at every time an error can occur, that it's every time the patient goes in and out of the machine. So actually the number of administrations is higher than the number of patients.

DR. BUDNITZ: The number of opportunities for an error.

DR. HOLAHAN: That's correct. That's what—

DR. LARSON: There is a way to get a handle on that number, in a sense we know the average number of times—we wouldn't have it for all the patients, but we would be able to say what the average number is if they want to know. So that's a rough characterization.

And in terms of the number of misadministrations, then somebody must have that information. I don't have it, but it must be a small number, and it must exist.

DR. GLASGOW: Has one occurred?

DR. HOLAHAN: Yes. There's been one that we're aware of with the Gamma Knife.

DR. LARSON: What was the consequence, just out of curiosity?

DR. HOLAHAN: I don't know the medical consequences. The wrong side of the brain was treated.

MR. CAMPER: The X-ray film was labeled incorrectly.

DR. HOLAHAN: And it was forced in inverse, so that's the only one that we're aware of.

DR. CALLAN: In every site we visited for brachytherapy, I believe every one of 23 sites kept a log for every administration. So they knew every time that a patient went in there.

So if you were looking for that data, I'm almost certain you could get it by asking them. It's no big secret.

DR. BLACKMAN: Other medical related things. Okay, it's a wrap.

DR. BICKEL: Can I just ask before you—

DR. BLACKMAN: No, you can't. But you can go ahead and ask.

(A discussion was held off the record.)

DR. GRIGSBY: Didn't AES do a survey of the number of procedures?

DR. STITT: Yeah, they did. They didn't publish that, did they?

MR. SHEPHERD: Number of procedures, number of cervix patients, number of endometrial patients?

DR. STITT: I don't know if it was published.

DR. GLASGOW: There's a substantial data base that exists on the use of radioactive material in the published literature. There are a variety of ways one could get reasonable estimates of the denominators.

But coming back to the discussion, I think the magnitudes that have been quoted are pretty good ballpark numbers. As has been pointed out, it doesn't really relate always to the regulation. If there's a gross misuse of the technology, there's going to be a response.

If someone kills someone on a Gamma Knife, acutely, let's suppose something terrible happened and they give a brain 5,000, cause acute short-term death within a few hours, it will cause a quick review of all Gamma Knife procedures. That's the way the system works.

DR. CALLAN: There's one other possibility if you wanted to sample nine or less, you could go to the manufacturer, and I believe they will give you the counter number that tells you how many times in brachytherapy high dose machine that the source was extended and retracted, and then you subtract the number of calibrations from that and would give you a pretty good approximation of treatment.

DR. BICKEL: That would give you the total. You know, as I sat there thinking about what would I want in terms of characterizing it, I'd also want to break it down into what types of modalities would you use.

DR. CALLAN: Yeah, but I was just looking at the total numbers.

DR. BUDNITZ: I don't think—is there anybody in the room that thinks it would be difficult to get those totals, approximately? I don't hear anybody that thinks it would be hard to get.

DR. HOLAHAN: For teletherapy, as well, do you think?

DR. GRIGSBY: For teletherapy as well and, yeah, you can get it for total number of fractions for teletherapy. But with regard to that, and his speaking of characterization of teletherapy, my gut sort of tells me that for teletherapy, the misadministrations occur on the first or second treatment. I mean, the ones we've experienced, they don't occur on the 30th treatment. See, it's the set-up—

DR. HOLAHAN: That's not all—I would say most of them that's probably true, but not all of them.

DR. GRIGSBY: Okay, but most of them. See, so when you characterize it, then you need to—

DR. BUDNITZ: You have to pull that in.

DR. BICKEL: The one they irradiated the old tattoo?

DR. BLACKMAN: That's the human error.

DR. BICKEL: They had the patient that had the two tattoos?

## C.6.4. Human Error—Dr. Blackman

DR. BLACKMAN: We're now to human error. I know it's tough to talk to you guys. You want to talk data.

Okay, let's talk human error here. What are special considerations in human error? Now I just heard one. I don't know quite how to characterize that and write that on the board, but we certainly know from experience that human errors tend to occur in certain places with certain procedures.

DR. GRIGSBY: Training.

DR. BLACKMAN: Training?

DR. WU: I think human error, well at least we should try to think in terms of institution, because if it's related to training or procedure, and then it's a more systematic way of finding those causes. And once you find a cure for it, it tends to be more cost effective than if you strike each incident individually.

DR. GLASGOW: It's clearly training, because of the turnover rate. The turnover rate of the technical people in the hospital is high. We've had 14 different physicians in our department in the last nine years. We've had any number of radiation therapists who operate the equipment, and because of that turnover rate, the process of keeping everyone trained in all procedures at a particular competence level is quite challenging. I think it's probably our biggest deficiency and our biggest challenge, because there's no incentive. The hospital is not excited these days at all if I ask to keep a technologist after hours for an hour and pay them time and a half to give training. Uh-oh, I'm in trouble already. That's not productive.

DR. STITT: Well, training is related to procedures and how well they are written, if they are written, if they're ambiguous, how they're used for training.

DR. HOLAHAN: Sometimes seeing where they brought in—where somebody called in sick, so they bring in somebody who's not routine and who hasn't been trained, nurses and things like that.

DR. GLASGOW: For example, on our GammaMed, on our high dose rate unit, I have an absolute rule that there can be no treatment by an agency technologist, that is anyone who's hired from the outside. And that automatically limits my pool of the people who use the device to a core group, but I cannot have an agency temporary person operating that equipment. I just won't allow it.

DR. BUDNITZ: Everywhere where human error is discussed, sooner or later you come around to the ergonomic questions about the design of consoles and the like. And I don't know how much of that contributes here, but there's no place else where it's other than important, you know, airplane consoles, refinery consoles.

The human factors design of those things to make them user friendly is often important. I don't know whether your incidents show much of that or not much or what, but I would be surprised if it wasn't—

MR. SHEPHERD: I would extend that one more. As pointed out this morning, if you get an output that a physician is supposed to read, he can't understand it just because of the format it's in. So it's more than just the hardware. It's the whole interface.

DR. BUDNITZ: You know, the classic idea there are four levers, all look alike, and if you made them look a little different, they know that the red one is the one that—you know, that sort of thing.

DR. GLASGOW: Well, no, there are classic problems. For example, much of this equipment, first of all, is not American manufactured. It's European manufactured. For example—and the European specifications are different. Our classic example was one that arrived with a red, yellow and green light.

DR. BUDNITZ: Oh, and the red and green didn't mean—

DR. GLASGOW: Red is go and green is stop. And we had to deal with that.

DR. GRIGSBY: Absolutely, how ass-backwards can it get?

DR. CALLAN: The systems were full of those things, and we documented hundreds of them in the report.

DR. BLACKMAN: Okay, so we clarify procedures by adding the term written in here, okay? We got ergonomics and tried the kind of—we'll

cover the waterfront in terms of all those ergonomic issues related to that.

Now did I miss something else that was said?

DR. BUDNITZ: Yes, yes, besides the ergonomics of the panel, and so on, he talked about the readability or obscurity of output printouts to the other users.

DR. GLASGOW: For example, our printout for activity is AKT, the German abbreviation for activity. The notation is classic German notation.

DR. CALLAN: How about workload and stress?

DR. POLLYCOVE: Yes, yes. That is—and the reason—well, first of all it's important. The reason why it's extremely important now is because with managed care, you're reducing the personnel. You're trying to progressively increase the output. And so there's more and more workload stress on the individual.

We just recently had an incident where the technologist supervisor, very well experienced, was harassed. She was pulled away from what she was doing. She had to tend to something else. She came back and picked up the wrong syringe. So this is very important, and will become increasingly important.

MR. HANEY: Well, are we trying to come up with examples that we think are particularly important to this task? Because in terms of human error, there's a whole set of influences that we've identified called performance shaping factors.

For example, here's a list, like a whole bunch of them. These are all on the list, but there's many more. So we could make a list.

DR. CALLAN: When you put that up, I thought you were asking for information.

Actually I put it up.

DR. BLACKMAN: Yeah, I was interested, primarily interested in those which we felt had a greater than normal impact.

DR. LARSON: Would you read examples of those? Just read some examples.

MR. HANEY: Staffing, shift, morale, administration, feedback, is it dynamic versus step by step, experience, practice, communications, cognitive complexity. Some of these may be embedded in some of the ones that are listed, but motivation, supervision, fatigue, tagging, labeling, is it pre or post-accident, responding to an emergency.

DR. POLLYCOVE: Do they have written procedures on that list?

MR. HANEY: Oh, yes, the second one.

DR. POLLYCOVE: Good.

DR. SIU: You remember that exercise where they have you draw a fault tree for a car?

DR. BLACKMAN: I remember that.

DR. SIU: Unless you lay out part of that fault tree for the people already, they're liable to miss parts of it. They're focusing on supervising. And the exercise we just went through, they are sort of like that. Maybe you want to pass that list around, and maybe people want to mark it up for issues specific to this.

DR. BUDNITZ: You'll see something that they didn't get.

MR. SHEPHERD: Well, No. 3, Harold, you've added written, but this morning someone was saying that written procedures are not all that common.

DR. STITT: We were saying that medical aspects of care commonly are not written down, yet a technical aspect would be. I think Glenn brought that discussion up, didn't you?

DR. GLASGOW: Yes.

DR. STITT: How a group of radiation oncologists might make decisions about and brachytherapy recommendations for prostate cancer commonly is not written down within the department. However, how they set up a four-field pelvis, in many departments is written down as part of the procedure manual.

So procedure-type of manuals are. The medical indications cannot be, because primarily you're very liable for medical malpractice. If in your department you say I always treat conservative breast cancer in this fashion, and then Dr. Grigsby treats it slightly different, you've got written documents that attorneys can use against you. So we tend to

leave it with the textbooks and our own in-house education.

DR. GLASGOW: But my impression is that even the technical components are not, for many of the things that we do, are not well written out. In most hospitals, they may not even exist.

DR. GRIGSBY: In most hospitals they're not, they're not.

DR. GLASGOW: I would say they meet the test. It's done by rote memory, this is the way we do it.

DR. GRIGSBY: We have at the simulator, we have a policy that a simulator person can read that says this is how you simulate prostate, and we even have it by stages and such.

At the treatment machine there's a policy on here's how you treat it. These are the set-up things.

In our staff room, there's a physician's treatment policy that says for these different stages, they're acceptable dose ranges, and we've made it not so specific so that you don't get trapped into certain things, because to some degree, there isn't an art in medicine and patient variation.

And those documents are extremely important. But in most places, they don't exist.

DR. POLLYCOVE: Well, that's why there should be an emphasis on them. Because in my experience, unless you have that written procedure of these technical and they're not followed by someone, you have no recourse.

DR. BUDNITZ: Did you have them always at UC Medical Center?

DR. POLLYCOVE: Yeah, in our nuclear medicine section we have every procedure written down. And when there are deviations, we say, well why didn't you follow—

DR. BUDNITZ: But Myron, what I'm hearing is that your experience isn't typical of the—

DR. POLLYCOVE: No, but I'm saying in my experience unless you have that in place, you're going to run into more human errors. That's all I'm saying.

MR. WREATHALL: Is it fair to say that in many cases the written procedures and the way the nuclear community think about it are the user manuals for the equipment? And that's as far as it goes, a step by step guide, here's what you do, then you do this, then you do this, then you do this. It's only from the discussions I've had with people, it's really only user manual for equipment like the set-up program, the software, that user manual provides that. There's nothing you write specific for your facility that's analogous to that.

DR. GLASGOW: He has excellent procedures in his facility. And most places will do it at the instruction of a particular physician of long-standing who has a particular methodology and wants to do it in the following manner. And if that physician is replaced by another physician, suddenly there will be a change and confusions can arise.

MR. WREATHALL: That's following the same mode of operation as the non-radiation treatments. I mean, that's just the nature of the medicine that you don't work with written procedures. You work by oral practice and so on.

DR. GRIGSBY: But it's our mental philosophy, that familiarity and written procedures will avoid errors, and we've stood by that for a number of years.

DR. BLACKMAN: Okay, well we will consider this list to be at least a first cut at emphasizing those kinds of factors. And if you would also look at that and then amend and mark that up. And, yes?

MR. TORTORELLI: I'd like to expand No. 5 to be sure we remember that ergonomics is more than just equipment at hand, but there's a whole array behind it, the planning computers, the simulation devices and methods of flipping X-rays, that sort of thing. And then some of the sources themselves, such as we recently had the iodine seeds. One looks like another, even if it's ten times as strong.

DR. BLACKMAN: Okay, and one final comment, and then I think what we're going to do is we'll close on human error, take a 15-minute break, and then I'll come back and attack the next area.

DR. HOLAHAN: I was just going to—I'm not sure. It may come under the training, but the other type of thing we've seen is when patients go from a LINAC to a cobalt, and the treatment parameters

are adjusted slightly, but if it's the same therapist who set them up for the accelerator, may be setting them up the same way for the cobalt.

So you're in a routine.

DR. RATHBUN: Cross training.

DR. HOLAHAN: Well, it's not only cross training that they do both. It's just that they're so used to seeing a patient on a daily basis on one machine.

MR. HANEY: Also, Harold, there's influences specifically on our SS. There's important influences we got at it a little bit earlier.

DR. BLACKMAN: That's the only way I can—since I'm standing up here and I'm thinking.

I said one comment, didn't I. We're done, 15-minute break.

(A recess was taken.)

### C.6.5. Modeling—Dr. Blackman

DR. BLACKMAN: What I'd like to do before we actually start to talk about the modeling is make sure we kind of refresh our memories about uses, so that when we look at the kinds of models that are available, we can be discussing them in light of how they will be applied.

So uses, characterize frequency of consequence of administrations. And inherently, as part of that we're inferring some kind of quantification to inform, to improve, risk significance, risk-based evaluations by comparing risk and similar phenomenon, et cetera, risk management, tools to gain and understand communication, frame, identification of outlier. So just to kind of keep that in mind as we're talking about it.

Now we've heard a few different kinds of modeling. We did spend quite a bit of time on what I would term as the standard accepted techniques that are predominantly used today in PRA and PSA. And those were the event and fault tree structures which we've talked about, and then we've also talked about—I guess what I've categorized—well, I don't know what to call it. The newer approaches, which are trying to investigate how to do these kinds of analyses like WPAM and GEM.

Those are more the newer ways of thinking about it. So I'm not sure where to start.

DR. GRIGSBY: Let me start. Let me call it something different then. I don't know anything about it—

DR. BUDNITZ: That's a good way to start it.

DR. GRIGSBY: I understand, okay, this is, in a sense, work in progress and all of that. But as I was going through the event and fault tree analysis, I kept thinking that at the end of the reading, I was going to be led back to the tree, and it would be pointed out that a given arm or a given process was at fault in a given incidence or a large number of procedures. And, therefore, we should institute certain regulations or suggestions or whatever to change that particular arm or branch of the tree.

That was sort of the so what. But I never got to that in any of the publications.

Then in addition to that, in business and in medicine, there's the field of decision analysis, which takes these trees, and you can take an event tree or take a fault tree, and you can give several values to the different branches. You can assign a probability value to a given branch. You can assign a utility, which is an outcome to a branch, and you can assign a cost in dollars to a branch. With probability and either utility or cost, you can then analyze the various branches. You can do cost effectiveness analysis, based—I mean these computer programs are already written. They're commercial programs, so you can—pardon me?

DR. BICKEL: It's a contingency analysis.

DR. GRIGSBY: You can do a cost effective analysis; you can do a sensitivity analysis; and, the model is based on Boolean statistics with Markov processes that you can add into it. So, you know, I know how to do that stuff, but I don't know how the validity, you know, is that valid to add into faults or errors.

DR. SIU: I think you're looking at the very broad decision problem. I have a number of alternatives. I'm going to look at the probabilities of certain outcomes and what is the, as you say, utility or the consequence which can be converted into a utility. So you can think of the fault tree and event tree as being one tool to develop the probability of a particular outcome. So it's an embedded part of what you're talking about. Certainly event

trees or risk assessment came from the decision analysis arena early on. That's what led to them.

So I guess I'm not sure, when we're talking about just risk assessment, what might be different other than if you want to use Markov models.

DR. GRIGSBY: If you go down a given path, and you find out from probabilities that this path is the one that has the greatest chance of error, then you should go back and change that.

DR. SIU: Oh, of course.

DR. GRIGSBY: I mean, there are change nodes and there are decision nodes.

DR. SIU: That's right. You're embedding the risk assessment part or the tool into the larger decision analysis package.

DR. GRIGSBY: Or cost effectiveness. If you have a given regulation on a given arm of this thing, you may find out just by modeling it's simply too expensive to do. Or you may find that another is not sensitive to changes in probability. Maybe another arm is more—so my suggestion then would be to kind of take these further into that kind of a model.

DR. BLACKMAN: Okay, so that's a consideration of adding in some of the tools that may generically be used in decision analysis and see how they might be applicable.

I'm putting up event fault tree structures as a tool that is one which was presented that may have applicability and be used.

DR. RATHBUN: Relative risks.

MR. TORTORELLI: I guess my view of that in this context is that whatever model we develop needs to be able to support that, and particularly the sensitivity analysis, where if you have some concern, and you want to make something more safe, where can you get the best improvement for the least costs, the least work the least time?

DR. BLACKMAN: Okay, let me add on sensitivity importance. What else do we want to tack on there that needs to be a part of this level analysis to support further looks that are broader issues in decision analysis?

Can I add anything to that? Are you jumping down?

MR. WREATHALL: No. In addition to that, you had over on the other board the question of generic error modeling, somewhat separate from the event tree-fault tree. It seems to me that all the generic error modeling is doing is that the event tree, particularly modeling and PRAs, needs to be more sensitive to the context. We have to add in some elements. What I'm talking about is contingent conditions somehow included in the consideration in the event trees. Not that you need a different form of modeling.

So all I'm trying to do is to specify some additional elements that need to go into the PRA models, rather than you need a different class of modeling. Just right now, the event tree-fault trees are not sensitive to those functions.

DR. BLACKMAN: Right, may I use the word context?

MR. WREATHALL: Yes. It was the word we used two years ago, so it's fine to use it now.

DR. BLACKMAN: Sometimes there is another new word, so I hate to be behind the times in my words.

MR. HANEY: We shouldn't lose the point that it can be qualitative as well as quantitative. That will also provide valuable insight.

MR. WREATHALL: Absolutely.

DR. BLACKMAN: That's screening. I put screening up there just to kind of categorize it with the event tree structures.

MS. THATCHER: One of the points that John Wreathall made that maybe I'd like to emphasize, maybe he hasn't made it here today as much as in some other discussions, is the need for a way to model things that you can systematically incorporate what you've learned about past events. With the modeling—with the framework that he laid out, you could use that to represent past events. You could study past events in a taxonomy that made a lot of sense that you could look at in a lot of dimensions. So you could study past events systematically, but you could also study events that haven't happened.

You could look at past events and ask yourself if a few more barriers were breached what would have happened? What could have happened? So you can put together a modeling technique that

you can incorporate the knowledge from past events, plus you can hypothesize what could be happening, what could go wrong.

DR. SIU: So you're putting a constraint on one of the modeling forms that we selected?

MS. THATCHER: I think it would be a very desirable attribute, and given the information that's there, there's a data base of events, but they really require analysis to pull meaningful insights from them. I think a lot more insights could be pulled from the data base with the systematic analysis, using a framework like John Wreathall's. And it provides information and richness for your additional models that are more hypothetical.

DR. BLACKMAN: Okay.

DR. BLEY: I'd like to take off from that and kind of describe an organization to this analysis before we get to the risk management step.

The way I've been thinking of it lately is in three pieces. The first piece is understanding the process in a modeling sense. And the things that help us there are maybe the Gamma Knife kinds of ideas that had the hazards identification and the sequencing.

And the section in our book that we didn't really go through, it has types of entries for sequences.

So we understand the process in a modeling sense with some kind of a sequence modeling understanding the hazard. The second step is understanding the events, exactly what Tami was talking about. And there the framework John talked about, the work process kind of thing, lets us understand what happened and what are the causes for it, which then lets us go back to that sequence model and see where the human really fits, what the human failure events are.

And the third piece then is to quantify the process model with the key being identified to human failure events, and then the quantification, and maybe it's not a simple kind that we're used to in a fault tree and event tree phase, but you come back to the framework of human error events and some kind of elicitation process to quantify those. We aren't ever going to have actuarial data on those that we're going to live with and be happy with.

Maybe some of the Gamma Knife relative risk kind of judgmental ideas on some of these, and maybe part of it is this fault tree-event tree stuff. But from the events we've seen, that's not what's going to be important. It's coming up with this other quantification so the process modeling, the events themselves—

DR. BUDNITZ: Why don't you—why do you downgrade the standard?

DR. BLEY: Well, from the events we've seen—

DR. BUDNITZ: I'm not arguing. I'm just trying to understand the rationale.

DR. BLEY: Two parts. One is from the events we've seen, the hardware by itself doesn't seem to be the key factor in the events that are occurring.

Number two is when we built—say we use an event tree for this process. When we build that event tree, it's going to be a much simpler one than you see when you do a large nuclear power plant, and maybe it's one that you don't want to quantify with fault trees, because the conditional probability calculation—because then we can track the dependencies among the human events.

And it's probably of an order, you know, if you can't do it by hand, you can write your own little code and do it pretty easily.

DR. SIU: I don't understand. To me that's an event tree.

DR. BLEY: To me, too, Nathan. But to much of the world it's not.

DR. BUDNITZ: Just to give an example, yesterday we saw an event tree was put up, and then actually was in the book, and we discussed it a couple times.

Let me say it had about a dozen top events, you remember, and then you went along, there were a bunch of decision points, and some of them didn't break and some of them did.

Well, it's probably not very hard to quantify that by hand.

DR. WU: If you find all the conditions.

DR. BLEY: It's going to be real hard to find all the conditions.

DR. BUDNITZ: That's what I'm saying. Having done it the usual way, then you've got to stare and see if there are any linkages that you kind of—your judgment tells you are important, you're going to go iterate on them.

MR. WREATHALL: Let me jump in.

DR. BUDNITZ: It doesn't have to be sophisticated to get most of what you want.

MR. WREATHALL: It doesn't, but I would start, perhaps, from a different perspective and say what the framework that I presented was a description of causality. And what PRA represents are consequences principally, I mean little local consequences, something happened that didn't work. Something happened and the person made an error.

What we have is the framework causality that's a different level from an event tree representation. And if you start—and what I think I'm coming to, the realization is to do the event specifications, the PRA-type specifications, you've got to start from the causality level. What are the conditions under which it was caused to break down, and then how could they fit into the scenario, rather than saying, okay, now, I've got sequences. What could conceivably be the linkage? I think that's why PRA has failed in the past, because you can't deduce from the perspective of I have a sequence, what could be the dependencies in there, rather than letting me hypothesize the causal mechanism of human failure and how could that occur in this context.

DR. BLEY: Which means you need a search team for how those conditions—

DR. BICKEL: Right, you used the magic word, which is search. I think one of the things that is important about a risk assessment process is that you're setting up a process to sort through possible outcomes and, you know, this happened and then this changed and that changed. And I guess I'll reveal a personal bias. I think a structured approach like some kind of an operator action, an event tree or a regular event tree creates—it's a mind frame that you're saying, okay, I'm here. Now what could possibly happen from here that could, you know, affect things later on? And you go through that process.

That is different, I think, than a purely judgmental approach, where you say, well, what could go wrong. Let's just make a list of them.

To me, that was the one area that I felt was, you know, the relative risk part did not set up a structured process that leads you down an investigational path.

DR. BLEY: If you don't structure an elicitation process, modeling—

DR. BICKEL: You end up whoever comes to the table is the thing. You don't have a process whereby you sit down and go through all possible outcomes.

I view that, you know, something like an operator reaction event tree lays out the possible chains of things that people and equipment and procedures and miscommunications can do. And you're going to get a bigger thing, and—

DR. BUDNITZ: Let me throw a monkey wrench in here, and you tell me if I'm wrong about it.

My impression is if you go to his hospital and go to his device and spend some time, an experienced analyst like you or you or me or him or there are half a dozen of us, I'm sure, could lay out something like that, and in short order get it mostly pretty right. I'm talking structure.

DR. BICKEL: His hospital.

DR. BUDNITZ: His hospital, his device. But then you might go to the manufacturer and say who else—and he said, oh, he sold me the exact same model to that guy in Houston at M.D. Anderson. You go to that hospital, and you talk to whoever's running that. You sit down with them.

DR. BICKEL: Different process.

DR. BUDNITZ: Right. And I'm not sure how much you could transfer. Even an experienced analyst—now if that's true, and there's 350 of these devices, and they're all different, you are possibly saying that the only way to do this right is to do 350 of them. And that's a bear. And I'm wondering about whether that is a necessary burden to get at what we're after, or whether there's some way to get at it without that there.

DR. BICKEL: We debated this thing two years ago. It's kind of interesting, but we had to try to scope out how to do risk assessment like this.

DR. BUDNITZ: Remember, identical gadget, but, of course, it's all in the procedures.

DR. BICKEL: We were sitting there at one point saying, well, let's see. Are the treatment modalities different?

DR. BUDNITZ: Never mind the treatment. I was just saying imagine exactly the same treatment modalities, you know—

DR. BICKEL: Let's take one case. You go to one hospital, and it's got an HDR machine. And they use it for how many different approaches, four or five or something like that.

And then you say, well, now let's see, that's Nucletron. You know, I think at the time there were like four vendors. We had Omnitron, Nucletron and GammaMed. I think there was a fourth, but he went out of business or something.

DR. RATHBUN: We had one in Texas that went out of business.

DR. BICKEL: And then we say now let's say we've got five by four, and then the next question was, gee, what about the differences between, the significant differences in processes or culture, because one is a teaching hospital and is willing to try experimental treatments that are nonstandard, and they may be one of a kind-ish type things.

DR. BUDNITZ: Another one is just routine and does self-standards.

DR. BICKEL: Yeah, and you end up with a lot of possible permutations. Some of them should be able to group and—

MR. SHEPHERD; We did this with reactors. It was called ASEP, and look where we ended up.

DR. BUDNITZ: But those of you in the room that aren't aware, ought to know about the history. The fact is that when Rasmussen did the first two in 1974 and '75, everybody said great, but it's a bear to do all 110. You ought to know that in the last two or three years all the 110 reactors have been done, but it cost a half a million dollars each, and by the way, which adds up to $50 million, and it's maybe even more.

Now every reactor is worth a billion or two, and there are 100 of them. And the risk is huge. So everybody understood the benefit.

Now that's a little different.

DR. BLEY: And the goals are a little different, Bob.

DR. BUDNITZ: I'm not arguing the case, but it really is different.

DR. BLEY: At one point you said am I wrong, and you're half right.

DR. BUDNITZ: And I'm half wrong.

DR. BLEY: You're half wrong.

DR. BUDNITZ: I agree. A little overstated, but—

DR. BLEY: The two parts that I want to talk, one is the business that any six of us could walk in McFerry and look at the model. I want to talk about that in a second—

MR. BUDNITZ: You don't agree with that?

DR. BLEY: Not quite, for a reason I really think is important—okay, I'll tell you now. We could lay out the event tree with the key kinds of things that could go wrong.

DR. BUDNITZ: I'm not sure you have the data to support it, but go on.

DR. BLEY: You just told me you could go in and do it.

DR. BUDNITZ: No, no, I said I could structure the model. But getting the data to support it is a different—

DR. BLEY: You can't get the data. You aren't even going to understand exactly why these things occur or how to search for those relevant conditions when it's most likely to go wrong, unless you take a framework for something else to really understand these events and what was going on, why these errors occur and come up with the classes of important errors. And nobody's done that yet.

DR. BUDNITZ: That's very profound.

MR. WREATHALL: That's right. You don't go in and you do 350—

DR. BUDNITZ: I wasn't saying you did.

MR. WREATHALL: No, no, because that's not where the discrimination and risk lie. It lies in very gross factors.

DR. BUDNITZ: So I was asking the question about whether there was some way, short of doing 350 times however many modalities there are to get at the important, you know, discriminant.

DR. CALLAN: That's why we took 28, and we put it into two collective process descriptions, one for high dose rate and one for low dose—actually three, and a partial one for intermediate for a machine that's not around much anymore. But we know that's been done, if you want to use that.

DR. GRIGSBY: Five boxes of—

DR. CALLAN: Two hundred steps and 20 tests and five functions.

DR. GLASGOW: But at some particular point, I think the test is going to have to be subdivided. Because the scope of your workshop is reasonably broad across radioactive material. The reality is if you have high dose rate units, their use has caused the use of conventional manual radioisotopes to be less. There are fewer of those procedures.

The Gamma Knife is an industry in and of itself with a whole different process of use than applies to high dose rate. And then you have the cobalt teletherapy units which, I presume, I'm not sure are still we're still within the scope of this discussion, but I believe maybe they are, plus you have the other administration of other radioactive materials, which we've discussed very little. So you are really going to have to talk about dividing the process according to the technology, I believe.

DR. LARSON: It seems rational to divide the university versus private practice and so forth. I'll just give a counter-example with the Gamma Knife. You know, I'm a teaching institution, and I visit other teaching institutions. It would appear to be identical in terms of what they do, and yet the process to me appears entirely different.

What they're doing, if you wanted to structure that, would be different at the different institutions. So it may be there's some other way you have to subdivide it.

MR. TORTORELLI: Until we actually go out and do several analyses, we're not going to know how different they are. And what we may find is after we do four or five, if there's a great deal of similarity and you can add other, do a small partial to find the differences.

DR. BLEY: I don't think you need to do 300. If you really needed to know the risk of each machine, like I got a reactor and it's got a lot of risk that affects a lot of people, I need to know about that machine. These I think are all different, too, but if we do some, what is it that Larry and Pat and others at the NRC need? I think what you need is to be able to look at these results and say is our quality management program addressing the things that appear to be important from a reasonable sample of some different—

DR. SIU: Let me throw in an idea here. It seems that there are two general classes of models that we've sort of been talking about. One is like the event tree-fault tree sort of sequenced based model. Another one might be something along the lines of, although John didn't say explicitly, work with basically a correlation model, says that the rate of misadministrations, for example, is a function of a number of different parameters, and depending on the level of the parameters, I can compute what that rate might be or I can predict what that might be. So that's sort of you've got a correlation on the one hand; you've got a sequence model on the other hand; and, the difference between the two largely is the sequence information that the event tree is providing.

A question is, do I need that to make the decisions that I'm concerned about?

DR. RATHBUN: You reminded me of the event tree that we did draw, which are really pitiful, and a bunch of us got together, and I was very scared to put them out in front of this learned group. We're not here to pick one method anyway. I think the framework that you laid out which is that we're going to start here. We're going to add to that, and maybe we're just going to describe the system. Maybe we're going to do something like what Jim said.

I just want you to look at those event trees for a minute, because they are just basic simple stuff. They're in the book, written by—they're in Section 9, and they were drawn by a group of people in Europe just sitting around trying to—they're peo-

ple from Sweden, Germany, a couple people from the United States.

And this is just a basic, simple model. Now the one on Page 92 is drawn for me by the INEL. So, of course, it's going to be complicated and fancy.

If you go to the one on 93, but if you go down and you look at it, each time—and this is just totally basic. You said, well, is the source safe or unsafe, and every time either they use their survey meter or they don't, the meter either works or it doesn't, they either regard it or they don't regard it. Well, it does not take a rocket scientist to understand that the NRC had better be paying a lot of attention to where we put our time and effort requiring they do the survey.

I mean, that's why we have the INEL here draw event—this is the event tree from Indiana, Pennsylvania on 92. It's the same old thing. Then look at the next one on 94. I've even forgotten what it is we were modeling here, but it's the same old thing. This is from Europe. They didn't mind saying that. I said gee, I don't think I can say the worker's death. The source is safe or it's unsafe. The interlock worked or it didn't work. They blocked over it and bypassed it, which they do all the time. And they do in hospitals. I've seen them do that. It's either, you know, the alarm works or it doesn't work or they disable the alarm.

And if you keep down this path, you die. Well, if we had had them required and enforced that they had surveyed that patient when she went out of that room, we'd have had a whole different situation.

And my point here is that sometimes the simple stuff can show you a lot in regulatory space. So I would see this as a stage.

Now then when you move on into the more, you know, the quantification of the models, et cetera, well then it depends upon what we're looking at.

But I would like to stay with some simple principles.

DR. BUDNITZ: You were agreeing with where I was headed, and not surprising. Several people, after I said that, came around to it. That is surely it would be dumb to run out and do 350 devices times a bunch of modalities.

On the other hand, surely you got to do some of them—

DR. RATHBUN: Yes.

DR. BUDNITZ: And some in gory detail in order to find out where you are.

DR. RATHBUN: Exactly, exactly. It's a step by stage methodology.

MR. BUDNITZ: And then regroup and see what you learned.

DR. GRIGSBY: I'd just like to point out and bring back into focus now. He's talking about 300 something high dose rate units. I'm telling you we're one of the largest institutions that does procedures, and high dose rate constitutes less than ten percent of what we do.

So are we going to ignore all of the other stuff that we're doing? I mean we're spending an awful lot of time on high dose rate, which, I mean, Dr. Stitt, she—high dose rate constitutes a major percentage of what you do.

DR. STITT: Right.

DR. GRIGSBY: But, I mean, there's still other procedures out there. There are radiopharmaceuticals that we administer.

DR. RATHBUN; Well, we spent two years working on the Gamma Knife, and decided that's one of the things we want to look at very very hard here. If we keep on going with those types of methodologies, will they ever apply to anything but the Gamma Knife? I don't know that answer. That's one of the question we're trying to grapple with.

DR. GLASGOW: I sort of wanted to ask the question in reverse. Had you had this event tree that's laid out here on the death of the patient and actually a death had not occurred. Suppose you had this information as a part of this analytical process, and you had some probabilities that had been assigned, and over here on the right-hand side you had some risk estimates that you would have used for these consequences, would those likely have resulted in the same type of regulatory response that you actually put forward having had the death of the patient?

MR. CAMPER: Yeah, because we, in fact, had the survey requirement in 35-400. Some may argue that it's not as clear as it could be for HDR devices. I mean, we could certainly pull them out and—

DR. GLASGOW: But I mean as a regulatory process. I think what I'm trying to understand here is the system that you're trying to put in place is that you would like to have event trees that would show probabilities of outcomes of some consequence.

If you were able to assign numbers of probabilities to these, which we've discussed in great detail, and they were of some particular level, suppose they were ten to the minus four or ten to the minus three, knowing what you know, but the patient not having died, would you possibly have responded? Because if you would not have, then this entire process of risk analysis may not be leading you into the right direction.

MR. CAMPER: No, I understand. I think we would have responded, and I think we did respond.

DR. GLASGOW: You responded—you're misunderstanding my question. You responded because the patient was killed.

MR. CAMPER: No, no, no, no. I'm saying we had already responded by putting in place a regulation that should have prevented it from happening in the first place. The licensee did not conduct the survey as required by existing regulations.

MR. TORTORELLI: If there was no regulation, and if an analysis was done and found a hole not covered by regulation—

MR. CAMPER: Would you then, in turn, create a regulation?

MR. TORTORELLI: Yes.

MR. CAMPER: Probably, yes.

DR. RATHBUN: Well, it would be one more factor that would go into the normal way we go about proposing regulatory change, staff insight, petitions for rule-making, you know, the customary regulatory process.

MR. CAMPER: Right.

DR. RATHBUN: The risk analysis would augment that, and would presumably give us a more rational basis for finally, you know, taking those actions. It's certainly not instead of the others. It is to augment. That is what they do in, you know, yeah.

MR. SHEPHERD: Let me throw out an idea on the use of modeling that a logic model of this process should give us three things.

One is, what can go wrong?

Another one is, how is the operator licensee, whoever, going to know that that thing went wrong?

And then, what are they going to do about it?

And if the model can't tell you those things, it hasn't answered all of the questions that we need answered.

DR. RATHBUN: One of the reasons—

DR. BLACKMAN: Those uses, by the way, are on the uses list.

DR. RATHBUN: It's sometimes reported that we didn't like the fault tree approach. That's not really true. What happened is, some of the fault trees that were drawn early on were just so complicated that we could never really relate to them in terms of—

DR. BUDNITZ: They were inscrutable.

DR. RATHBUN: Yeah, they were totally inscrutable as fault trees are want to be. And so what we said is—well, to some of us they are.

DR. BUDNITZ: It's an acquired skill.

DR. RATHBUN: Now I guess I haven't got it yet.

DR. BUDNITZ: Excuse me, an acquired taste.

DR. RATHBUN: An acquired taste, yeah. And so what we've said is wait a minute here. We've got to take this big huge thing here, and we've got to, you know, look at some use to come out of it. And, basically, we thought maybe a more illustrative technique, not necessarily better, just more illustrative.

DR. BUDNITZ: But more scrutable.

DR. RATHBUN: Scrutable, yes.

DR. BLACKMAN: So drawing back to discussing the modeling thing in general, you know, I think much of this has fit in very nicely. I was writing while you people were talking, so let me see if I captured some of the great thoughts that were lying around out there.

For the exchange between Dennis and John, I tried to capture that by adding information here, where I started to—what I first heard was GEM would be a great front and based on this process of investigating, understanding faults and modifying the sequence and then quantifying, and that is a tool that might allow one to do that to better build fault and event trees.

I also heard that it was a way that you could understand those things which were not, perhaps unknown kind of events that might have occurred that actually would be the larger causative agents at a higher level that actually causes those things to occur, which would be important to identify. Okay, so I tried to capture that here, here and here.

This is the qualitative stuff that you've been talking about, and I just wrote down the word quantitative, didn't add anything to it, because, again, to accomplish some of the uses, you do have to—

I heard grouping. Now this is obviously not an exhaustive list here. I just heard grouping based on similar devices, grouping based on similar treatments, grouping based on—I heard institutions mentioned, but I wasn't sure whether that was—you were suggesting that as a possible idea or not. But there's a whole bunch of ways one might go to group this in order to do these kinds of analyses.

And I think that kind of brings us up, I think, to where we are right now. Did I miss anything?

DR. WU: I want to say one thing. I know that event tree, we used it quite a lot, but event tree has the benefit of analyzing existing system or process.

From what I've heard here is for quite many institutions, there's not even a standard process, because it left much to the physician. They would prescribe the process.

So what we would suggest is to study the process first.

DR. BICKEL: We agree.

DR. WU: And, also, in—I don't even know that that will be the event tree you want to analyze, because there's—well, in nuclear industry, because they are more or less standardized, that we would assume they are the ones we're going to analyze.

Now you're in a situation you don't know—even know what to analyze.

DR. BUDNITZ: That was where the suggestion came that you go do a few of them and see whether you can extract from those some common important features, so that you can focus. And if you can, it helps. And if, God forbid, you can't, they're all different, you say, oh, boy, am I stuck, unless you've learned that.

MR. TORTORELLI: We've learned that, and we've learned something. We're still farther along.

DR. WU: Not only that they're different, they're different from time to time. That's what I'm saying. From what we are hearing here is they're not only different from organization to organization, they're different from time to time. Am I right? If that's the case, what are you going to study?

DR. BUDNITZ: There's a consensus around the table, and I'm going to see whether I can capture it, see whether you disagree, that there's going to be a lot of commonality, despite all of the diversity. I don't think you know that until you do it, but that's what people seem to be saying.

DR. BLEY: At least commonality and the kinds of human errors that are most important.

MR. TORTORELLI: We've been asked to do several studies. We can look and see what the level of commonality is, and then evaluate whether that can be put to our use or not.

DR. LARSON: It was more of the same, but—

DR. BLACKMAN: Why add more of the same?

DR. BUDNITZ: Dave, you made a comment earlier that I want to pursue just one question.

You have a suspicion that different kinds of institutions, teaching hospital versus self-standing therapy unit—

DR. LARSON: Well, that's what I would have thought.

DR. BUDNITZ: Your suspicion is that there'll be groupings of that kind, institutional-type of groupings that will be more similar one to the next—

DR. GRIGSBY: We know that. We know that from patterns of care studies about the rest of what we do in radiation oncology, and there's absolutely no reason to believe brachytherapy is going to be any different.

DR. LARSON: No, I was speaking about the Gamma. I wasn't addressing brachytherapy. All I was saying was this seemed to be counter—no, no, this seems to be a counter-example. The point I was making was a counter-example that amongst three good teaching institutions who treat a lot of patients with the Gamma Knife, their process appears entirely different.

DR. BUDNITZ: It could be that what determines, whatever remaining risk there is of this kind of thing is still governed by the same sort of two things.

DR. LARSON: It could be. It could be.

DR. GLASGOW: Correct me if I'm wrong, you have the advantage with the Gamma Knife that you have one manufacturer to start with.

DR. BUDNITZ: Are they all identical?

DR. LARSON: Yes, in the U.S. they're all identical.

DR. GLASGOW: So you only have one product, one manufacturer. That is a little easier to deal with.

DR. LARSON: I assume you're talking about human factors in addition to mechanical questions, right?

DR. GLASGOW: Right.

DR. LARSON: The human factors are totally different, totally different.

DR. BUDNITZ: The fact that all the Gamma Knifes are identical helps.

DR. GLASGOW: Yes, it certainly will help in that case.

MR. WREATHALL: The fundamental steps have to be the same.

Harold, in your role as board-keeper there, on that question of role of sensitivity to contact in the fault tree, fault tree, what the generic error modeling fault tree is trying to give is a framework to causality of human errors. And a better way of saying that greater sensitivity to context is really to say including a reflection of what we identify as the causality of important human errors in those events we've seen. And that really more relates to what Tami was saying about what it is that's in PRA now, to my mind, does not cover what the real underlying causes of the human errors are and what needs to be added to the fault tree-event tree structure. So it's a little bit more in the context. I didn't really express that at first.

DR. RATHBUN: John, let me ask you this question: If you were to take generic error modeling, how would you use that with regard to the Gamma Knife? Would you be able to use any of the existing information that has been captured? Or would you have to start all over again?

MR. WREATHALL: If you say what is captured is what is represented in the report, I think there's a limited amount of information I could take there. What well may be in the minds of the analyst and perhaps in their files could provide more information. But I don't know enough about the Gamma Knife procedure and its setting to understand where I would be looking for those what here we call contingent conditions. That's what missing.

DR. RATHBUN: But there would be no reason intrinsic in the methodology that you could not then try it on another device, assuming you had the other information. Similarly, maybe you could use it on an accelerator.

MR. WREATHALL: It implies certain—the framework implies certain questions that you could then go out and try and answer, either from the data base of events or from the knowledge of the analyst.

DR. RATHBUN: So it's generalizable.

MR. WREATHALL: It gives you a set of structured questions you could apply.

DR. SIU: But you're embedding it in the event tree-fault tree frame work, and not necessarily the separate entity—

MR. WREATHALL: The knowledge you gain from going through that can be applied in event tree-fault tree-like setting. The quantification of those fault trees and event trees, I think, would be quite different from the traditional HRA process, because you have to ask different questions.

DR. SIU: Sure, sure, but if we're dealing—

MR. WREATHALL: Inherently, it doesn't require a new framework of analysis, other than fault tree-event trees.

DR. SIU: Getting back to the point that Harold has on the board, I guess when you talk about modeling, one issue is whether the modeling structures that are going to be employed, although I raise the issue of correlational versus event sequence based, it seems to be pretty much the consensus that there is a preference for an event sequence base, and I have no problem with that. I mean, I'll learn how to do it.

There are also issues of practicality, and I guess some of these discussions covered that.

And then the user requirements have already been discussed, so maybe that would be a way to organize some of the bullets that you've got there.

MR. HANEY: When you talk about event trees, most of us talk about PRA-type event trees, but there's also an HRA event tree. And typically what we do is we use this PRA-type event tree, like we've been talking about, to make hardware and human failure a top event to identify sequence. Then to identify the influences for a human error, it appears on one of these top events, we've built an HRA event tree. And this event tree is specially designed to identify all those PSFs that I passed around. It's especially structured to identify dependence between tasks or dependence between people, it can account for recovery factors.

And it's intended to be used for sensitivity, because you can restructure the tree to add a recovery here or reduce dependence there or decrease or increase the influence of a performance-shaping factor in this branch.

And using that structure, you can identify dominant failure sequences or chains or paths through the tree. And if you go to the step of quantifying it, even it if it's in a relative sense rather than absolute, relative error rates, one configuration rate versus another, then you can use it to quantitatively identify those dominant error chains, and you can identify what steps you should take to reduce that probability or get rid of those dominant ones or avert them totally.

So I just wanted to make the point that there is a standard accepted technique that accounts for all these kinds of influences that we can use.

MR. SHEPHERD: What drives the recovery model?

MR. HANEY: Pardon?

MR. SHEPHERD: What drives the recovery model?

MR. HANEY: Well—

MR. SHEPHERD: What starts recovery?

MR. HANEY: Well, it doesn't matter. You identify—

MR. SHEPHERD: Something has to start recovery of the probabilities—

MR. HANEY: Right, no, you identify an error and then you identify ways to recover from the error. And they can exist, or they can not be there. Or you can add them if there's one needed.

MR. SHEPHERD: It's the feedback that you're going to get from the system. In the case of a nuclear power plant, which is what THERP was designed for, you got 4,000 alarms in there.

THERP was designed for the assembly of nuclear weapons, which is flipping a handful of switches and are they in the right position.

DR. RATHBUN: You guys are speaking in tongues again. THERP is a technique for—

MR. SHEPHERD: So far I don't see the feedback mechanism in the medical side that would drive the recovery model.

MR. HANEY: No, the recovery could be a second person checker. That wouldn't really require feedback. It would require communications.

There are certainly, though, feedbacks like alarms, the rad alarm goes off in the room, you hit the stop button. The printouts during the dose is a feedback. So I think there are analogies. There may not be as many. You know, we may not have

2,000 enunciators, you know, we might have six. That makes the model even simpler.

MR. SHEPHERD: Well, in some cases I think it may be not be one until a very long time frame is passed.

DR. GLASGOW: Well, the 2,000 alarm approach might work well. The physician wouldn't have time to unplug them all. It might be purely a cheap approach.

MR. HANEY: No, I think we need a simple approach to get to the high level things.

DR. BLACKMAN: I sat down, so I'm not on the board anymore, so I figured I could ask a question.

When you go in to collect the data for such an analysis for that model, would you—the way I'm viewing it is when one went in to collect data for that model, and one went in to collect data for this model, one would go in exactly the same way, armed with a similar set of questions, perhaps a little more in-depth questions in certain areas and investigations. And then one would collect that data, and then what we're really discussing is how one takes that data—

DR. BICKEL: And uses it.

DR. BLACKMAN: And uses it.

MR. WREATHALL: I'm not sure that is true. Were you putting that as a hypothesis or a statement of absolute truth?

DR. BLACKMAN: Actually it was kind of a loaded question, because yeah, I do in fact believe that is the case, since we do normally, in task analytic approaches to data collection, we normally ask questions about and investigate causes, error mechanisms, error modes, intention formation and all those kinds of things that allow you to draw that model.

So all I'm saying is that when you go in and you do this data collection effort, it's important that you consider those factors, because you're absolutely right. They're critical in terms of getting to the general level kind of model that we're going to want to see.

MR. WREATHALL: I guess in my own experience is that when one goes in and starts to do the kind of interviews or the kind of investigations and data gathering we're talking about, in practice the HRA analysts, or most of them, underplay the questions of context. And they really don't go into and investigate those deviant abnormal conditions which, in practice, underlie what seem to be the dominant failure conditions.

DR. BLACKMAN: But you and I do.

MR. WREATHALL: This end of the table seems to be doing it. Nobody else in the universe does it.

So there is a danger that the message goes out and, therefore, all HRA analysts do it, which is certainly not the case.

DR. RATHBUN: Well, there's another danger, a worse danger.

MR. WREATHALL: Can I just follow up on Lon's comment on the human error trees, event trees. These tend to—they tend to finish up producing sequences of human errors that become important for failure. And then you stare at them, and you say, yes, okay, they seem broadly to be independent. Perhaps there are some common factors between them. But then you look at the events that have occurred and, in fact, there are just sweeping causes that cause whole chains of things to occur that don't seem to fall out. If you started out just identifying the list of human errors that could have caused that. And I think there tends to be a danger that if you start out with a human error event tree, in fact, you're driven into the alley of not being able to ascribe causes. You kind of backed yourself into a corner, and now how do I explain that. Whereas if you start from a causality viewpoint, and then what could be the consequences of that cause, now you start seeing masses of errors propagating themselves everywhere with reasonable explanation that would never normally be a non-INEL PRA.

MR. HANEY: We all start from the HRA event tree. You start from a system.

MR. SHEPHERD: Which is even more narrow.

MR. WREATHALL: That's the problem. That's the narrowest part of the human perspective.

MR. HANEY: No, no, no. This system analysis identifies broad human actions and hardware

events that can influence the system. Then you can start using high level techniques to screen out those human events that aren't going to matter. Even if it does fail, the probability of the sequence that's involved in doesn't matter. So you start focusing down to those events that are unimportant, and you start investigating those in terms of cause and other things.

DR. BUDNITZ: Let me ask a question which you can help clarify: Is it true that one or more of these techniques is more inductive than others, and some of them more deductive? I mean, they all have inductive parts, and some have deductive.

Yes, so you know the answer, of course, that's true. Now that's a loaded question, because what I'm going to come to ask is whether it is really very important in this cockeyed situation we're dealing with here, that we concentrate on the ones that are more deductive and less inductive, because the situations are as they are. And maybe that isn't so. Let me think about that.

Because I have been in some analysis situations where, because of the large number of possible entries, they can only be arrived at inductively, the likelihood of getting them all completely done is reduced. I'd much rather have just a few and be able to deduce from them, you know, as things follow. And they kind of follow more logically then just by—induction is kind of, in this business, it's called staring at it. I hate to say it that way, but there's a lot of that. All of us have been there. You know, you kind of talk to it and stare at it and stare at it some more, and you add a couple more things.

MR. HANEY: You can use either approach.

DR. BUDNITZ: Of course you can, but I'm wondering about whether there's a trap here in this complicated situation where relying on induction, where completeness can't be—assure much confidence.

DR. RATHBUN: Right. We have to sell this to the medical profession.

DR. BUDNITZ: Well, hell, we have to sell it to ourselves first.

DR. RATHBUN: So I always get really nervous when you bring out your list. And I'm going to go back and tell Carl well, they're going to look at cognitive complexity, and we're going to go to the ACMUI and say we've got the answer now. We've got analysts looking at cognitive complexities. And I always get really nervous whenever we shift down into these very, you know, tried and true and good techniques, but they don't play well out in Peoria.

DR. BICKEL: Well, the answer is we can do something or we can do nothing.

DR. BUDNITZ: I wasn't saying we should do nothing. I was saying one of the figures of merit for deciding which way to approach this ought to be staring at it and saying that if something is more inductive and something else is more deductive, you ought to kind of want to lean one way rather than the other way.

MR. WREATHALL: You see, what the generic error modeling concept is saying is that there are a few limited important causes and consequences of human errors for which you can then deduce what are potential system of consequences.

DR. BUDNITZ: That's less inductive, actually. That's more deductive.

MR. WREATHALL: The induction is limited to human error. Human errors in a general sense is what I'm going to deal with. If I take the alternative method, which is to specify a large number of individual failure examples and try and deduce common causes for that—

DR. BUDNITZ: That's a mess.

MR. WREATHALL: It's an infinite open space.

MR. CAMPER: Let me ask a question, if I may, just so I understand this from a utility standpoint. Is the approach that's being discussed purely preventative in nature?

DR. BLEY: No, I hope not.

MR. CAMPER: Is it both preventive in nature, in terms of you would go in, for example, to X number of HDR facilities; you would analyze their process using the model typical to what you're discussing; and, then identify certain events that could occur and communicate that information to the regulated community, and, hopefully, that would prevent them from happening? Or is it only first event and root cause analysis?

DR. BUDNITZ: It's certainly not only—

DR. BICKEL: Let me suggest what I think we're trying to do is to develop some kind of a model, put it together, quantify it, throw it against the data, reconcile it. Don't do anything as a regulatory agency with it for two or three iterations.

MR. CAMPER: Right.

DR. BICKEL: Remember the—I guess on the reactor side, they started playing with fault trees and even trees in 1972 or '73. They did not start making major applications until—

DR. RATHBUN: Three Mile Island.

DR. BICKEL: What the hell, 1980 something or other. But what's going on—but the point is, it would be useful to start modeling, start iterating with the data and try and make reality and the modeling converge. What we've been doing, I think, at least my perception, and everybody knows that I have a bias toward getting on with it.

But for a couple years, we've been saying, well, we don't know what the approach is, so let's not do anything. Let's debate it some more.

I would very much say do some modeling, compare it against actual data, start, you know, torture the data until it confesses, and, basically, start to get an understanding of the thing where you got a consultant consistent picture between models and data and experience.

DR. BUDNITZ: I can supplement your urgency with the following observation: Sure it took 15 years on the reactor side, but all of that experience has allowed us to start from a much higher plane. We're not inventing something, you know.

DR. BLACKMAN: May I suggest what we've got here, we've got—which I took down, because I wanted to have inductive, and I didn't have any room to write it, a good list of the concerns of modeling now.

I guess what we want to do now is break for the day. Come back in the morning. Get the knowledge base aspects. You have the material that we produced today, at least the rough list. If you have some thoughts about it tonight, by all means reflect on it, bring it back tomorrow. We'll start at 8:00, and we'll hit the knowledge base questions and then we'll summarize.

DR. GLASGOW: Let me make one comment to follow up—

DR. BLACKMAN: You know, anybody wants to make anymore comments to anyone, it's open and everyone—if you want to take off you can take off. We'll close it down.

(The hearing was adjourned for the day.)

### C.6.6. Knowledge Base Revisited —Dr. Blackman

DR. BLACKMAN: Okay, we're going to get going here. The next topic that was on our list was knowledge base to be considered, and what I did is just kind of transfer the information I had over here over here. And these are some of the things people have mentioned while we were talking about the other topics so I may have got them accurate or inaccurate, so we can revisit them. But someone had mentioned yesterday how to consider unrecorded events in risk knowledge base as a topic we should think about. Then this whole question of developing and tuning numerator-denominators using data. And yesterday we heard there were perhaps a variety of sources that might be used to do those kinds of things, including the data bases at the NRC that come from the—we have the nonagreement states, which are going to be providing data, as well as agreement states, which is soon to be available. And then also, perhaps, data bases at hospitals, looking at how those might amend. And then also manufacturers. I heard that we might be able to get a good deal from manufacturers. Those are the only two things I kind of picked up in the general area of knowledge base for doing risk assessment.

DR. RATHBUN: We have their data.

DR. CALLAN: You have professional organizations.

DR. BLACKMAN: Okay, so we've got—we have the other efforts.

DR. RATHBUN: Livermore.

DR. BLACKMAN: At the NRC.

DR. RATHBUN: And other NRC data collections. Yeah, not only contractor, but staff efforts and data.

DR. BLACKMAN: What's that other lab?

DR. RATHBUN: The other lab.

DR. BLACKMAN: I don't remember the name.

DR. BUDNITZ: Lawrence.

DR. BLACKMAN: It's hard for me to write that.

DR. RATHBUN: Now, now.

DR. BLACKMAN: All right.

DR. RATHBUN: There's the misadministration, the AEOD thing.

DR. BICKEL: Is that Harriet's?

DR. RATHBUN: Harriet's and Dennis' combo, whatever it is. And there's something called Miss Ad.

MR. PRATO: Miss Ad is the old version—Miss Ad and NRE were combined to—into the MED, Materials Events Data Base.

DR. RATHBUN: But that's available, because I just gave it to the National Academy of Science.

MR. PRATO: All the information in the Miss Ad is going into the MED. They're in the process of converting it now. So eventually the Miss Ad will disappear.

DR. RATHBUN: We could give them a disk containing the data, because we gave it to the NAS. So we could give you that.

There's also the Pacific Science and Engineering Data, and we'll be speaking to research about that.

MR. PRATO: They have the Miss Ad. INEL has that.

DR. RATHBUN: They have the current version?

DR. BICKEL: I think that was the basis of the misadministration data review, or at least an earlier revision.

MR. PRATO: They're converting it into a format that can be transferred directly to the MED.

DR. CALLAN: Food and Drug Administration.

MR. PRATO: That should be done within the next six months.

DR. BICKEL: Does Pat or somebody, can somebody explain, as a result of the MOU that you have with FDA, are they fully swapping back and forth this type of information?

MR. CAMPER: Yes, they are.

DR. CALLAN: It's publicly available. But you just have to learn how to get it.

DR. BUDNITZ: We mentioned the manufacturers undoubtedly have data. Whether you can get it is a question. I mean, you know, you ought to be able to get as you can in the reactor arena under the confidentiality promise.

DR. RATHBUN: We have never, you know, sort of aggressively pursued it. When the laboratory was talking to them and initially they said fine, we never sent follow-up letters.

DR. BUDNITZ: I mean what are there, a half a dozen manufacturers that—

DR. RATHBUN: And if they understood the context, I think they would give it to us.

DR. BUDNITZ: You would have to make them the promise about, you know—

DR. RATHBUN: Right, no fines.

DR. BICKEL: See, 'cause I think one of the areas that the manufacturers of the data would fill in is the following: Your misadministrations, obviously, report where something malfunctioned and it caused a problem. And what I think the manufacturers have is that the authorized user is doing some kind of a periodic test. The term of the thing is malfunction in some way, and he calls and puts in a service call, and they come out to service it. I assume that that's rare, but they must have records that we got a service call from such and such hospital.

DR. RATHBUN: The Gamma Knife certainly was.

DR. GRIGSBY: But the caution is that of the multitude of problems that we've had with our equipment, I know that almost all, not all, but almost all of the responses and the subsequent report that's generated says our machine didn't malfunc-

tion. You guys did something wrong. Right, Glenn?

DR. GLASGOW: That's correct, yes.

DR. CALLAN: But it's very useful information, and some of that you can look at and determine—here's an example.

DR. GRIGSBY: It may not be correct—

DR. CALLAN: Twice it was reported to Nucletron that the seeds at the end of the stainless steel cable fell out, okay? It didn't happen in the patient. They fell on the floor. If that had been known by NRC, and somebody had thought, well, if the seeds can come out on the floor, why can't they come out in the patient?

And you had regulated it somehow, I don't think you've done that necessarily, but there might have been some preventive action taken before the event in Pennsylvania.

It was a different machine, and it was a different type of an accident, a different break, but the concept was there, and it was available in the FDA data base.

DR. GRIGSBY: See, we reported sources being ejected in some of our low dose rate machines inadvertently multiple times, and it ultimately resulted in what was called a misadministration on two occasions. But this was over two or three years we reported we were having problems, and they just kept saying you're using it wrong.

DR. CALLAN: They get out there, and I think the information is useful, even though it may be somewhat disguised in the narrative. You can learn a lot by looking at it. These things are not always going to pop out in field searches and computers. You're going to have to dig through them manually and look at them. There aren't that many.

MR. PRATO: Why aren't these reported per Part 21?

MR. CAMPER: It depends on whether they categorically can fit the requirements part. Some do, and some do not. Those that do are reported. But some do not.

The other point I would make, too, I don't think that you're going to find manufacturers giving us any information in the absence of a regulatory requirement. I really don't.

DR. CALLAN: But it's a regulatory requirement that they give it to the FDA.

MR. CAMPER: That's right. Some categories of events, that's correct.

DR. BUDNITZ: Let's try to remember the objective. What we're trying to do is find the easy things that dominate this risk, you know, a few things. And if they claim that the hardware worked fine, but it was some operator problem, more often than not that's my experience from a lot of other engineering arenas. It's because it's difficult to operate properly, rather than simple, or in the jargon of the PCs, it's not user friendly.

And it could be that making it user friendly—remember, it operated perfectly, right? But making it user friendly could be one of the most important ways to head off these events.

MR. SHEPHERD: But that costs money for little feedback.

DR. BUDNITZ: It may or may not. It depends on which laws you identify.

DR. CALLAN: We have a volume full of recommendations on approved user system ideas, alternatives we call them. So there are dozens of possibilities out there.

DR. BUDNITZ: You just have to see if there are a few that can identify that fits most of it.

MR. WREATHALL: But even in terms of risk analysis, to know there are operational problems and what that rate is is a big step down toward the human reliability thing. That's the operational experience that we very rarely get.

DR. BUDNITZ: Fair comment, right.

DR. CALLAN: The area that mushy is manual brachy. I mean if you think high dose rate radiation is hard with a computer driven machine, wait until you look at the variety of experience of treatment that goes on in the manual world.

DR. GRIGSBY: The manual world is simple. You just open the safe, get what you want, and put it in the patent. That's the easy thing you can do.

DR. BUDNITZ: And then read your watch, 20 seconds.

MR. CAMPER: We have to start sending Perry copies of all the misadministrations from brachytherapy. It will be very enlightening.

DR. GRIGSBY: With my luck, I'll be sending you something next week. Open my mouth.

DR. CALLAN: If that's the case, why is the misadministration ratio manual to remote afterloading like ten to one?

DR. GRIGSBY: Is it?

DR. HOLAHAN: No, we had this slide yesterday of misadministrations. They're getting close.

DR. GLASGOW: It's getting close, but what you've got to remember is one of the denominators may be declining. There are some of the manual work being displaced by the afterloaders work. So to some extent you have to keep that in mind as you try to look at the two.

DR. BICKEL: When you do it manually, how do you control the dwell time?

DR. BUDNITZ: With a watch.

DR. GRIGSBY: The dwell time? The dwell time is 48 hours, 72 hours.

DR. BICKEL: It's not a problem.

DR. HOLAHAN: Now with manual you tend to see things like slippage of applicators and minor shifts and that sort of problem and patient intervention.

DR. STITT: There's a lot of stuff that's unreported. We all know that, and with manual sources, if they're slipped, who's to know it?

But in any of the remote devices that are all—there's a million pieces of paper, and every little doo-dad is documented there. So it's real hard to hide that sort of thing. And I'm sure the stuff that we weren't aware of in the past—

DR. GRIGSBY: Inadvertently high.

DR. STITT: Inadvertent, right. There's just a lot more documentation, so that we're probably going to see more remote devices or remote misadministrations simply because there's this large volume of things that the computer spits out at you. And the manual form is very artistic. They sort of put it there, you think it's there and hope it's kind of close to where you started out with, and you take it out 48 hours later. And you have no idea some of the parameters changed.

DR. BLACKMAN: Okay, a lot of stuff here on getting data from formal sources that collected.

Any other, perhaps, sources that may not be ones that have been structured or formally collected, just as an idea?

DR. GLASGOW: Well, through the NRC mechanism, there will be in the safety reports of various facilities recordable events, which are those which are—

MR. CAMPER: We can examine those during inspection.

DR. GLASGOW: So if you want to focus on—but it depends upon magnitude. You may not think that it's worth your effort to focus on things which are less than the 20, but there would be a measurable number in that range of things that were not misadministrations and should be in the data base of the institution.

DR. BLACKMAN: We spent a lot of time talking about your—so I was thinking maybe we might need other sources of information to get other kinds of things we were talking about.

MR. WREATHALL: I was going to say, these are all dealing really with the operational experience and how misadministrations occur. In terms of framework and the elements dealing in causes of human error, we're dealing—we're trying to use a diverse set of technologies to look for common experience, so in terms of that part of it, we have the data bases that NRC has developed for the human factors experience of which INEL is the major contributor to that.

We're going to be talking to the National Transportation Safety Board to find out what kinds of information we can get from them.

Most of these are experience reports that we then have to analyze in terms of the factors we have in the framework. No one is collecting data specifically around those. Rather, we are taking reports and interpreting them.

DR. RATHBUN: You mean power plant data?

MR. WREATHALL: THE AEOD human factors incident investigations analogous to the medical misadministration data gathering.

The National Atomic Energy Agency is looking to start a program, perhaps built around the framework that's one of the candidates later this year, but that would be a slow time scheduled project. We're talking three to five years for international reporting around the elements of that A-frame, whether it's this one or another one is still to be decided. But it's that body of knowledge outside medicine, in addition to these events we will be working on.

DR. CALLAN: How about State Department of Health, Radiological Health Departments?

DR. BUDNITZ: Those are not agreement states, though.

DR. CALLAN: Right.

DR. BICKEL: Has there been an attempt to exchange data back and forth with the agreement states? Do they exchange data?

MR. CAMPER: I would say that the degree to which they exchange data, I'm not sure. I don't think there's a lot of it, frankly.

We now have the agreement states reporting misadministrations voluntarily, though. But it's getting better, but I'm not confident there's a viable conduit that exists right now. We have to put something in place to make a more meaningful exchange of information. I don't think it really exists right now.

MR. PRATO: There is talk of having the MED replace state data bases, where they start putting their information directly into the MED. They're going to be on line within about six to eight months, and that's the intent so we all have a uniform source of information to do our studies and our analysis with.

The states are looking for the ability to go beyond their borders and look at national trends to help them do their job, as well. And the Material Events Data Base are supposed to be the answer for that.

The problems with that, they want us to expand the data base to include accelerator incidents, and there is a question on who's going to fund that and how is that going to be built into the system. But they are very anxious to get the MED, very anxious.

DR. BICKEL: One of the immediate questions that arises in my mind is the agreement states, in general, when you look at some of the people on the list, tend to be some of your bigger major states. And some of the states that NRC regulates are—well, they're places like Idaho, okay? And, you know, I just wonder what your thoughts are. Is there any potential that your data base is skewed by the nature of the people that NRC is still regulating?

In other words, that it might be—

MR. CAMPER: Well, I think, sure I think it has to be skewed. There are some large states, of course, that we regulate, larger licensees, Ohio, Pennsylvania. But clearly, if you're only looking at 22 states, 23 states out of 50, and the population distribution, sure, it's skewed. There's no question about it. It's inherently skewed.

DR. CALLAN: You need Texas, New York, California and Florida.

DR. BICKEL: To get a real picture.

MR. CAMPER: Yeah, that's right.

DR. CALLAN: And those states have rather large programs, and can give—probably will give the data if you ask for it.

MR. CAMPER: There's an emerging desire between us and the agreement states, and the agreement states amongst themselves, to compile better information, exchange information. I think the MED is part of that process. But there may be other steps we can take to better formalize the process. But, historically, that exchange of information has not been ideal, but it's getting better.

DR. CALLAN: The largest body of information, according to my source, is Europe. And there's some in Japan. But in Europe for high dose rate brachytherapy, it's been going on there since the late '60's, I believe. And there's a lot more treatments.

MR. PRATO: About eight or nine months ago we were in contact with the European community to try and set up some free exchange of information. And we're still looking at that. There is no organized effort that I know of in Europe that we can go to one source and get information and exchange information. What we're thinking about doing is trying it on a trial basis. To implement that within our agency is very easy. All we need to do is get the EDO's permission. To do it internationally, we have to deal with the State Department. We have to deal with the Commission. We've got to get permission from the Commission.

So what we, I think, intend to do within the next year or so, is to set up some sort of agreement with maybe Mexico, maybe one of the European countries, see how this process works, see what kind of information we get in and put out, and from there expand it into a full-blown effort.

DR. BUDNITZ: For most of the countries, it may be possible to do it quite easily. You know, we have agreements between NRC and all the various regulatory agencies around the world to exchange reactor data.

MR. PRATO: That covers materials, as well.

DR. BUDNITZ: And what I'm saying is all you have to do is say, and if the British has some event on their reactor, we get all these reports. And we could say and this, and add a clause. You don't have to renegotiate anything, and you don't have to go all through the crazy channels of the State Department renegotiation.

And some of those are rather easy to amend. I was involved in the small amendment to one of those agreements recently in which everybody kind of nodded, and somebody noodled something, and it went through, because it was so obvious.

DR. GLASGOW: I just wanted to make a quick observation, which maybe was obvious to everyone as well. But I'm not sure who presented the statistics on misadministrations, but if you go through and subtract out those that have been reported for remote afterloaders, the number over the four-year period that reported is reasonably constant. And the recent increase—

DR. BUDNITZ: But there's been a decrease in the others.

DR. GLASGOW: No, there has not.

DR. BUDNITZ: No, I don't mean events, the administrations are going down, because the others are replacing it.

DR. GLASGOW: Well I'm just saying if you could just numerically subtract out the afterloader numbers, you sort of have a flat background of all the misadministrations for all the other technologies that have been reported, and the growth in misadministrations parallels—I'm sure if you had the sales chart from Nucletron on the number of sales, the number of misadministrations will parallel the sales chart. They go up together.

Again, I don't think it's so much a question of the reliability of the product as it is the competency of those who are learning to use the product.

DR. GRIGSBY: I think it's a false assumption to presume that the number of manual applications is going down. It has at our institution, it has at her institution, but there are other institutions that continue to do it, and there are some institutions that do HDR that did not do manual before.

DR. GLASGOW: Well, in fact, I would judge that the majority of the cases is still in the lung at other sites, rather than GYN.

DR. CALLAN: At least one installation got rid of their HDR machine and reverted completely to manual.

DR. SIU: One important part of the information may be, we've been talking about data bases, but how about anecdotal information? Typically on the power side you talk to licensing examiners among other folks because they have experience with people performing the operations, even if they don't have formalized, in terms of a data base in numbers. Is that going to be explored?

MR. CAMPER: Uh-huh.

DR. BICKEL: You mean like inspection reports, the follow-ups?

DR. SIU: Or talking to the people, I don't know if there's a relicensing sort of exam situation here or, again, in talking to the inspectors after an event, trying to get more sequence-type or structural information.

DR. BUDNITZ: I have a reaction to this long list, which is it's all nice to have, I guess, but I don't really know how much of it is worth having, if it costs quite a bit of money to get. And some of this stuff could be costly.

And more to the point, it would be destructive of medical operations.

DR. RATHBUN: What's it going to go into?

MR. SHEPHERD: Well how is it going to be evaluated and who's going to decide whether it's something that can actually be used in the regulatory framework, or whether it's just—invariably, you're going to have the disgruntled individuals, who are going to take a very negative approach to everything that happens. And how are we going to have the knowledge to be able to sort out what is true and what are people just complaining about things that they don't want?

DR. BUDNITZ: If you have a lot of money, you could say, what the hell.

DR. BLACKMAN: Do we want—yeah.

DR. BLEY: Back to the question you asked John before about applying the framework, what we found in the reactor business in applying the framework, looking at several different kinds of reports for the licensee event reports that get done on every major event have a summary. And when you go through that and try to apply the framework, you don't get much.

When you go to the full LER, you get more. But when you go to an event that had what we call an augmented inspection team report, where NRC sent out four or five people to interview the people involved, you got a whole lot more information that fit.

Is there anything for any of these misadministrations akin to that augmented inspection team report?

MR. WREATHALL: There's the INEL investigation teams have gone out.

DR. BLEY: Oh no, the seven events were gleaned from other reports, it says.

DR. BUDNITZ: No, Dennis, they went to the sites.

DR. HOLAHAN: And there have been two more since that seven that the INEL went out on, and that's an ongoing—

MR. CAMPER: There's a contractual mechanism in place for that to continue.

DR. BUDNITZ: Trouble is, it's wonderful to get a glimpse, but it—and it couldn't be systematic. It's too expensive.

DR. BLEY: Well, yeah, and you get more out of a few of those than a ton of the others, to understand what's really going on.

DR. HOLAHAN: And there's also a reactive inspection done for the majority of misadministration, and there's an inspection report filed following that, and there have been at least one this year that was an AIT following a misadministration, which INEL is also involved in.

DR. RATHBUN: One of the things Carl Paperiello wants is a standardized way of looking at these misadministrations from the NRC. So we're trying to work on preparing some kind of consistent approach to that. But inspectors, as in the power plant world, think deterministically. And they don't think that sequence-wise, this is not their skill. This is not what they've been trained to do. So this is a whole area that we have to take a look at.

DR. BLEY: The thing we've talked about some is using the framework as a guide for the people who are investigating, to make sure they pick up the key points of information.

DR. WU: Tools such as we presented over there, sort of tried to put things systematic so that you can provide them a sure training period, and they have the tools that they can go out and do a more systematic way of investigation.

DR. RATHBUN: In the ideal world, the inspector would go out with his or her methodology to collect this information. And it would feed right off their PC right into the AEOD data base. That would be the big picture in the sky, if we could do that. But that's a long way down the road.

DR. HOLAHAN: The inspectors do take a checklist with them that's been developed for misadministration, that they sort of go through.

DR. RATHBUN: But it's—yeah, and that's good. But it's not a root cause analysis like the teams can do.

DR. BLACKMAN: Why don't we take a look at our list here and see which of these are readily available and which aren't, and so that we can at least come to agreement that some of these are readily available, so maybe that's the place to start.

And then if additional data is needed in order to support the kind of model we're talking about, then one can systematically go through and see where to add.

So let's see, obviously—okay, this is kind of a question.

Developed new numerator and denominator data from. Obviously that's available. This will be available.

DR. HOLAHAN: That's the same thing.

DR. BLACKMAN: All the same thing, one big line. These two—

DR. BUDNITZ: Hospitals?

DR. BLACKMAN: Possibles. Hospitals and then manufacturers. You know I guess we could find out whether or not—we could ask the question how much work would it take in order to get that kind of data. So these are kind of question marks.

DR. GRIGSBY: I don't think our hospital has a clue as to when we have an event.

DR. GLASGOW: Well, they may in the quality management program that's active these days. The quality management process outside the NRC within a hospital, as it's working in most places, is meant to capture these events.

But whether you could get it out of the data base or not—

MR. CAMPER: The problem is, the definition for an event needs to be established. You're right, Glenn, that in the QM Rule there are certain thresholds that capture reporting requirements, but what we're talking about here, I think, is every time something goes wrong using an HDR, whether it's the computer malfunctions, a catheter doesn't work properly, these things don't lead to misadministrations, but they're an event you would like to be aware of, because it helps you to compile an overall understanding of the performance of the devices and, hopefully, prevent future mishaps.

So clearly identifying what the event is is something I think you need to do.

DR. BLACKMAN: So we kind of have these as possibles, but we're not clear on that.

DR. BUDNITZ: Wait, wait. You left out the agreement states. You see the non-agreement states are the NRC. But then there's the agreement states.

Now it's not obvious that that's as easily obtainable as you think.

DR. HOLAHAN: Because it's voluntary.

DR. BUDNITZ: But more to the point, there's a couple dozen of them, and they're going to be variable. Some of them may not even be doing it properly. Some of them probably are. I would guess that.

DR. HOLAHAN: Well, also, only six of them have adopted the QM Rule, which have consistent definitions or compatible definitions with ours. So the others are still reporting a variety of misadministrations, but under the old definitions.

DR. BLACKMAN: But there is data available from them as to—I mean, that data is available.

MR. CAMPER: That's misadministrations you're talking about. There's this host of events that are precursors in some cases.

DR. BLACKMAN: So there is some amount of data.

MR. PRATO: Again, based on all indications right now, it looks like we're going to have them being doing direct inputting into the MED, from their offices directly to the MED.

So I think that information is going to be available. They are very enthusiastic about this, and they're pushing for it.

DR. CALLAN: Remember, you have two, basically two high dose manufacturers. And they should have records on almost every malfunction of the equipment. And so you don't have to worry about OMB, you know, if you can get it from them. You have two places to start where you can

get a large volume of data, and they see across all the installations all over the country.

DR. HOLAHAN: If they'll provide it.

DR. CALLAN: If they'll provide it. I'm not judging how good the data is or whether or not they provide them. I'm just telling you it's there.

DR. BICKEL: But with foreign manufacturers, we've got very little leverage.

DR. CALLAN: They all have local representatives in the United States to keep this stuff for them.

MR. TORTORELLI: Certainly.

DR. CALLAN: I don't know what your leverage is.

DR. BLACKMAN: Okay, obviously we've got the task analysis stuff that was done, which should, you know, that's—the NRC—And we have the MED.

DR. RATHBUN: Livermore.

DR. BUDNITZ: Well, the FDA is there, obviously.

DR. BLACKMAN: And the FDA?

DR. BUDNITZ: Sure.

DR. BLACKMAN: Now someone had said staff efforts. Pat? It was you who said staff efforts.

DR. HOLAHAN: Basically what we're saying is the internal data base.

DR. BLACKMAN: Okay, so there are internal data bases.

MR. CAMPER: We have compiled a long list now of events in a broad context of that term, that we have been compiling now probably over the last couple of years. And it ranges from every time the computer burps to bent needles. It's a host of kinds of events.

And we've compiled all that information, and we're providing it to the FDA. So that information is available. There's no question about that. And that effort will continue.

So these are things that we learn from inspections that licensees report to us that don't meet the misadministration threshold, but they feel like—we have certain licensees, and we're glad they do, but anything anytime happens with the HDR, they have a compelling urge to call the NRC and say, hey, we want you to know that this happened.

And that's fine, because it helps us learn more about what's going on operationally. It's not a regulatory requirement, but we do have staff member data available.

DR. HOLAHAN: We also have information on hospital misadministrations that we determine not to be misadministrations, but they're a problem.

DR. BLACKMAN: Any other—professional organizations was mentioned, and I assume that would be pretty much it. Is that a question as to whether—

DR. GLASGOW: Well, I think that's in terms of what you will find there may be suggestions regarding procedures. I don't believe—you may find something regarding the number of procedures somewhere in some of the medical organizations, if you search properly.

DR. STITT: There was a summary, I alluded to it yesterday, by the American Brachytherapy Study, and they sent a questionnaire to—I'm not sure where we got our list, but hospitals everywhere. It was voluntary, and asked you to say how many of this, that and the other thing you do.

DR. GLASGOW: Right. One data base I would specifically mention might be RTOG. RTOG collects radiation therapy oncology, collects substantial information on facilities and equipment, and at least the number of cases or treatments of particular types.

DR. GRIGSBY: Not in brachytherapy.

DR. GLASGOW: Not in brachytherapy?

DR. GRIGSBY: I mean it may have the number of accelerators and Cobalt 60 units and may have the number of remote afterloading devices, but as far as number of cases, not—

DR. GLASGOW: Not in RTD? The other data base is the data base on the training programs.

DR. GRIGSBY: Correct.

DR. GLASGOW: The residency training programs must file the number of case numbers by cases.

DR. GRIGSBY: To the AMA.

DR. GLASGOW: And what group would that be?

DR. GRIGSBY: Ultimately the American Medical Association has that through the ACGMB.

DR. STITT: That's only folks that do residency training.

DR. GLASGOW: But the residency accreditation group that accredits the training programs—

DR. GRIGSBY: There are a hundred of those.

DR. GLASGOW: Approximately, and they would represent some of the larger facilities than a substantial data base, and there has to be case filings regarding the type of cancer and the type of treatment. And I think—

DR. GRIGSBY: And the number of procedures.

DR. GLASGOW: Yes, and the number of procedures.

DR. GRIGSBY: And type.

DR. GLASGOW: Right, and it might be useful.

DR. STITT: And it tells you what the academic community is doing. It does not say anything about the very large group of folks that are practicing medicine that don't have residency training programs.

DR. BLACKMAN: It looks like we have some questions here, and kind of jump down to recordable events, which obviously that would be available, since those are done and are available.

This data is available, but the problem with this is that it will require quite a bit of analysis, which means that it's expensive as opposed to some of the other data for example that might be—that's available. But you're going to have to spend money. So I'm going to put some dollar signs there.

MR. WREATHALL: The only caveat there, Harold, is that those programs—excuse me—those data are also being gathered for other projects. So it wouldn't necessarily be only medical misadministration programs. It may be a contributor, but it wouldn't necessarily have to be done specifically for this, because we're dealing with a generic model.

DR. BLACKMAN: A generic model, right. Any feel for availability of information here?

DR. CALLAN: I talked to a couple of the State Health people, and they say they have records. I don't, you know, they're probably variable.

DR. BLACKMAN: Okay, so we at least have a list of where to start, which would be less, less costly anyway and less burdensome, perhaps, with that.

There was also another item on our list of uses here, which was—now I've forgotten—oh, providing a context for comparison. That is pedigree was one of the uses. I think most of the data that we talked about so far is data specific to the, you know, the radiation question.

DR. BICKEL: Yeah.

DR. BLACKMAN: What about that item? Is that something that we should be concerned about right away or not?

DR. BICKEL: That was Dr. Pollycove. I got the impression from him that he felt that his book with the three authors called Cancer, that's being reissued for 1994, has a lot of that in it, but other sources it sounded like we wanted to get were something associated with the comparative risks of other ongoing medical activities of which radiation therapy has to be put in that context.

DR. BUDNITZ: That's what the NAS Committee is supposed to be doing.

DR. RATHBUN: Well, that's right. The thing is—

DR. GLASGOW: I don't think you want to open that Pandora's box. Your charge is to deal with the question of the safety of a process within radiation therapy. And I think you're only going to open yourself up to too broad of a question that

can't be answered even by physician colleagues in a quantitative sense.

I just don't think that's going to—

DR. BICKEL: But, Glenn, what that can lead to, because I think people have been down this road on other high tech issues like aircraft and nuclear power plants, is that you establish a goal, basically in a vacuum, that people are trying to assess a level of safety, and all of a sudden you end up with, as an example in the reactor world, you know, official beliefs that the policy to be pursued is that we should—the utility industry should spend ten million dollars per averted death as a criteria for making cost benefit decisions.

If somebody applied that kind of goal to any other human endeavor, you know, the country would be bankrupt.

DR. GLASGOW: And we know that. And we know that.

DR. BICKEL: And we ought to put—okay, I don't want—it's my opinion that we ought to try and put the risks associated with radiation therapy into some kind of a context of, you know, where does it fit in with the overall medical activities.

DR. BLEY: At least for the patients we're talking about.

DR. BICKEL: All we could end up with, the fact—eventually we're leading towards some kind of a safety goal. It isn't written down. It will probably take ten years to get there. I would hate to see a safety goal emerge for radiation therapy that, basically, results in the regulation of certain types of therapy out of existence, because one set of criteria were applied, and something completely doesn't exist or is, you know, for let's say chemotherapy or surgery.

DR. GLASGOW: It's already taking place.

DR. BICKEL: It ain't a good thing.

DR. RATHBUN: From the standpoint really of the scope, I think the idea is that the National Academy—

DR. BICKEL: Is going to do that?

DR. RATHBUN: Will provide the context. I mean they have a specific—I wish I had actually put their charge up here. They have been asked to look at that. Now that's not for establishing a safety goal. It's to give the Chairman a sense—

DR. BICKEL: A perspective.

DR. RATHBUN: —a perspective on overall risk. And I would see their work as complimentary. We would be looking at the labs to provide us a more methodological, you know, detailed—

DR. BICKEL: If we could get their final report, I think that would be an outstanding—

DR. RATHBUN: Well, you can. My fear is more that they are kind of looking around themselves for how to approach the topic. And my more fear is that they will be out here asking you all how to do it, and no one will know how.

MR. CAMPER: Do you have the slide—

DR. RATHBUN: No, no, no. No one is—I don't have. I did not prepare a slide. But, again, they are to look at—I didn't say that. Never in public. But within the risk area, the National Academy of Science has to look at three big things: One is the overall legislative organizational context. I mean should the NRC even be regulating nuclear medicine? Who should be regulating it?

DR. BUDNITZ: Well, they can't answer that question.

DR. BICKEL: That's a Congressional decision.

DR. RATHBUN: But in other words, what is the actual framework for regulating this technology?

Then they have this—they also have to look at the policy statement. Trish had earlier put up that slide. The NAS has been asked to look at our policy and look at how contemporary regulation relates back to the earlier statements.

And then there's this whole thing of the risk, and it has two sections. One is what is the risk of this effort in comparison to other types of medical procedures, and then what is the risk of this done right versus what is the risk of this done wrong?

Now that should provide an adequate context to take the information that we develop in a more technical sense and put it together and then move down the road to a safety-type goal.

DR. BLEY: Have they set up a schedule?

MR. CAMPER: Yes, it's due in 1996.

DR. RATHBUN: But they have now commissioned a technical paper on this risk work and, frankly, Lester Lave, who many of you know, is working on that, and I had hoped he could join us here, and that would have helped a lot.

But, you know, they're not risk experts. They're going out into the community for this.

DR. BUDNITZ: It's not only '96, but the Academy isn't known for meeting their schedules.

DR. RATHBUN: Well, and they've come to realize that because of their extensive peer process, they really have to be finished next July with the report. Well, I don't think so.

But then, again, we've got $1.2 million downtown Washington to do this. We want to spend our money here, you know, in more of a technical, you know, analytical approach.

DR. BLACKMAN: So we'll rely on context coming from that.

DR. RATHBUN: Well, for now, for now.

DR. BICKEL: I would characterize if you go back and think about, because there's an awful lot of people involved in Wash 1400, obviously when the work was done, there was the question of what does this all mean? Can we compare this to something else we can put our foot around?

DR. BUDNITZ: The Rasmussen report got into hot water, not because the work was good, but because they did those comparisons that people jumped up and down.

MR. SHEPHERD: Again, it was the lightning strikes and the cancer from cigarettes. That's not a valid comparison.

DR. BUDNITZ: There was little dispute that Dr. Rasmussen's work wasn't just wonderful. It was just those comparisons that got him into trouble.

DR. GRIGSBY: I think I understand what it is that you're going to do, and maybe it's a bit presumptuous, but give me three or four days, and I could develop credible, a single credible slide that says something to the effect that 40 or 50 percent of patients taking medications don't take it on schedule. You know, as directed.

DR. BUDNITZ: That's just typical.

DR. GRIGSBY: Twenty percent of all hospitalized patients receive inappropriate medications, or medications that weren't prescribed, medication accidents.

Five percent of all—four percent of all patients undergoing surgery experience some type of anesthetic or surgical death, you know, to put it into orders of magnitude. Ultimately, that's what they're going to do, but it will take a lot of analysis to do it.

But if you want to compare what it is that we're doing to something, that's what it's going to be on the order of.

DR. BICKEL: Well, that's the kind of thing I think you need to—I think there is a need—

DR. RATHBUN: Well, Dr. Pollycove did it, and frankly, I thought—

DR. POLLYCOVE: Just like you said, two or three days.

DR. RATHBUN: I thought that we had given you that, but maybe what we could do is—too bad you didn't bring it with you.

DR. POLLYCOVE: I didn't bring it with me, but we'll be glad to—

DR. RATHBUN: Yeah, we'll be glad to send that, and you can include that in the material that goes out—

DR. BICKEL: You'll work up and get the—

DR. POLLYCOVE: Parts of it are published. It just hasn't been pulled together.

DR. BICKEL: That's what I say, pull it together and get it into a journal or something.

MR. SHEPHERD: But I think we've got the same problem here that we had with nuclear power. As soon as you put the word nuclear on there, the perception in the public shifts dramatically. It's got nothing to do with the technology—

DR. GRIGSBY: See, that's why magnetic resonance imaging devices are not nuclear magnetic

resonancy imaging devices. We're not going to be that stupid to put nuclear on everything, right?

DR. GLASGOW: That's right, and that's why my department is still called radiotherapy, because I hope people will sort of feel like it tunes into a station.

MR. SHEPHERD: Get a set of headphones—

DR. GRIGSBY: We never place radioactive needles into patients. We have these little plastic catheters like they put in your veins.

DR. STITT: We do brachytherapy. It sounds very—

DR. HOLAHAN: That totally confuses them.

DR. RATHBUN: The only way you know you haven't received radiation. The tube in your arm is plastic.

DR. BLACKMAN: All right, additional things regarding knowledge base? All right, I guess I would propose we take a ten-minute break then.

MR. CAMPER: May I suggest one—may I raise one issue when we come back, given our time constraints? Let me just kind of give you a thought that I had last night when I was talking to Trish Holahan about it. And, you know, I am not a PRA or HRA viewer. I'll defer to the pros in the room on that topic. What I'm concerned about is, I'm coming from a programmatic standpoint, implementation standpoint.

Yesterday afternoon we spent a fair amount of time talking about a model, and the utility of the model, as I understood it, and this is what I want some feedback on when we come back is the following: Possibly we could go into certain HDR facilities before an event occurs. They could be picked in a fashion that made some sense. For example, we could take a large institution. We could pick a community hospital. We could pick a private practice scenario, go in and evaluate their program through a fault tree-type of approach, analyzing what they do, uncover potential problems, compile this information, share it with the community, so they could then take that information and review it and learn from it and, hopefully, prevent a mishap in their facility.

Similarly, the model might be used, at least in part, for doing a root cause analysis, where we go in after an event and determine what caused the event. And, again, share that information with the community.

So that's my perception of utility of it thus far. What I'm looking for is some feedback as to, A, is that a correct perception; B, are there other uses for it; and, C, how do we refine that so that it's clear that we have that utility available to us?

So give that some thought, and from a programmatic standpoint, if I'm all wet let me know. If there are other ideas, that's fine, too. Just give us your thoughts.

DR. GRIGSBY: I think you're exactly right.

MR. CAMPER: Okay.

MR. SHEPHERD: Yeah, if you can't predict with anything, you haven't learned from doing the model.

DR. BICKEL: We were talking about the same thing.

DR. GRIGSBY: You're going to get some generic treatments that micro-procedures might be different, but generically there's some global status—

MR. TORTORELLI: And the barriers can be presented, and if they want to employ them, that's fine.

MR. CAMPER: Good, that's much more attractive.

DR. BLACKMAN: From that perspective you're going to have the so-called contingency factors identified from a human error point at a level that can also be learned from a delta.

DR. HOLAHAN: From a user friendly point, though.

MR. TORTORELLI: Yes, and that certainly can be used as a training tool.

DR. RATHBUN: Right, that training tool and something to support the inspector, ultimately. That's one of Carl's goals is that this could all result in some kind of, you know, assist for the inspector.

DR. BLEY: And, of course, you play it up against your QM to see if you're picking up your key pieces.

DR. BUDNITZ: I have a suggestion about an iterative process for gathering data and doing analysis, which when I say it, should be pretty obvious. We spoke of it yesterday afternoon, which is I'm hearing consensus that some analysis is going to be recommended, maybe we haven't fully clarified how much or what kind. And it's also obvious that some of this data gathering activity should begin soon, especially the stuff that's real easy, where it's there but you have to get access and feed it in. Obviously easy, the FDA has got it, and these agreement states and non-agreement states that are starting to feed in. So that will go in.

Probably what needs to be done is to do all that easy stuff, because it's inexpensive and it's there, and then do some analysis, and then only after that is accomplished, perhaps a year hence, go back and find out whether all the rest of this more complicated data would be beneficial, considering its cost, or whether you already have enough.

And, also, what kinds of data you need to improve the analysis, where the analysis is ambiguous because of the data. There are some areas where the analysis will be robust. The data isn't that good, but the analysis will be robust anyway, because it isn't the data that are driving the insights. You kind of know where you are, and you don't have to refine it too much.

There may be some other areas where, without some better data, the analysis is of little use.

So there's some sort of iterative process between the data gathering and the analysis phases, and it will probably be a year or two before you know, maybe a year, maybe more, before you know how much more is worthwhile.

DR. CALLAN: You're suggesting starting inside the house and sort of working out?

DR. BUDNITZ: I was suggesting, you know, Bob here—where has he gone? Obviously the focus, obviously the focus for the NRC's data, you know, bringing the rest of this data into the unified system, all the easy stuff. So you're going to go do that, I guess, as budget and effort allows.

DR. STITT: This afternoon.

DR. BUDNITZ: Well, not this afternoon, but in fact you already—some of it's going on, and some of it is just starting, and some of it is easy and you just kind of, you know, want to get everybody goosed up to do it. In a year hence, the analysis activities will tell us how much more you need.

And by the way, it's two different things. There's data, and there are events. We cannot forget that they are different. Data are all the little things which are only interesting in the statistical sense. And then there are events.

In any event, the events are always important. You can never forget the events, which, by the way, aren't necessarily on this list, except in a few lists.

Mostly what was over here, Harold, was the data.

MS. THATCHER: Well, the data base, his data base is events. There's very little statistical data you can actually glean from it. It's really events and, basically, you know, I've looked at the data base. I've looked at the updated 1991 to 1994 data base, and you can't sort anything in a meaningful way. A lot of fields are not filled out. You know, you basically have a listing of events, go fish to get more documentation on those events so you can understand what happened.

MR. WREATHALL: But that's part of the iteration of the model specifying what you want to pull out of the event history to put in the data base. It's that cycle.

DR. BUDNITZ: But you see, there are events which contain some data, but then there's just data that aren't in events. You know, events meaning, I'll define an event as something that's major enough so that it exceeded some threshold, so you really write up the whole event. Then there's what we call data, which are different.

DR. RATHBUN: But what does the methodology look like that all this data is going to fit into? When do we find that out?

DR. BUDNITZ: That's, presumably, what the analysis part develops and then iterates on.

DR. RATHBUN: Sort of emergent you mean, based on what's available?

DR. BUDNITZ: You got to try—

MR. SHEPHERD: That's always been a question, do you let the data drive the model or do you let the model drive the data? The answer is yes.

DR. BUDNITZ: Both ought to be driven by what you want or need.

DR. BLACKMAN: I'd like to try to answer that question. I'd say what I think I have heard is that we would see a combination of event fault trees with a more processed looking kind of a model, like John was talking about, to display the results and make it understandable and clear. That's what I see.

DR. RATHBUN: Now, but wouldn't we want to, as a first step, take that approach and put it with existing information, specifically the Livermore work or his work, and see what we already have?

DR. BUDNITZ: That's probably right.

DR. BLACKMAN: And I think the only thing I would add is that you may want to take their work and Livermore work, and you may want to supplement with some of the—

DR. BUDNITZ: Easier data.

DR. BLACKMAN: Easier data that's available.

DR. RATHBUN: Okay.

DR. BUDNITZ: And by the way, there are some areas where the data—I won't say whether they're easy or difficult—but without gathering extensive data, you kind of know where you are, data-wise, because there's enough—it's either anecdotal or there's been some compilation in a narrow area that can't be that—it's not that wrong. So without doing extensive data work, you'll have enough to start.

DR. RATHBUN: To start, and see if it works, see how the medical community accepts it, see whether—take those regulations that we were walked through, and see if we would gain any insights into ways of revising them, based upon risk insights.

MR. SHEPHERD: One of the comments yesterday was that, gee, we can't analyze the fault trees, because we don't have enough quantitative data to be able to cut down the number of minimal cut sets to a reasonable number. My reaction to that is if the model is that complicated, it's not going to be useful for what we need at this point anyway.

DR. BLEY: It's not focusing on what's important in the real events.

MR. SHEPHERD: The model has got to be simple enough that we can get ideas out of it and not numbers.

DR. BUDNITZ: If what you said, if that turned out to be the fact that the only way to get, you know, the appropriate insights was very complicated, model-wise and data-wise, probably we just ought to say well, heck.

MR. SHEPHERD: I don't remember who said it, but somebody yesterday was talking about having to have a certain amount of quantitative data to be able to run the model, which is certainly true when we get into the power plant.

DR. BUDNITZ: I think we all hope and expect it won't be that way.

DR. BLEY: It's never the case when you go to do it. It's simplified.

DR. RATHBUN: There is a lot of data that has already been collected, I mean I see it everywhere. You have it in power plants; you have it in airplanes; you have it in the Gamma Knife; you have it in the brachy remote afterloader; and, before I feel comfortable about additional data collection efforts, I'd like to see us use what we have.

Now it might be because we didn't collect it for this reason, it's limited and it's, you know, inadequate. But I think we sort of have a responsibility to try that.

DR. BICKEL: I agree.

DR. BUDNITZ: I was arguing for a little more. Let me try to make my case.

There are some data elements, like the FDA data and the agreement state stuff, that, damn it, you got to go do that.

DR. RATHBUN: Okay, I agree with you.

DR. BUDNITZ: Whether it fits the model, you just got to do that, because you'll be attacked for not pulling together some kind of obvious stuff.

DR. RATHBUN: What I've heard is let's all get on the plane and fly back to Mallinckrodt, you know. We've been there many times. Every time the NRC gets an idea, we fly off to Mallinckrodt.

DR. GRIGSBY: We've got work to do to—patients.

DR. RATHBUN: We've been to practically every—not you, and I understand that's a problem, but we've visited a gazillion of these places, and that's where I become resistant.

So, okay, well what about that break? Let's try that break.

(A recess was taken.)

## C.6.7. Future Plans—Dr. Blackman

DR. BLACKMAN: What we've got up on the board here in the center is a start at—kind of a start at what I heard at the end of the second prior to break. And what I heard was is that as far as where we should go from here is to really—is to start with the available data, look at that data, perhaps augment it with the other data that is easily attainable, data which is presently in the data bases or that we can get our hands on. I also heard that we have expanded the definition of data to, of course, include events. I didn't write that up there, but that is the case.

And then to model a sample using a combination of event fault gem-like structures to model it to, basically, see what it looks like, see how it works, see whether the data is adequate. At the point that we were to finish that effort, we would then review to see what additional data is necessary to support and what additional analyses may be required to support the effort.

With that kind of—with that kind of little summary, what I'm going to do is, I'm putting down my pen as far as leading the discussion, and I'm going to turn it back over to Pat and to John to see whether or not we want to discuss those list of steps or to kind of wrap up and review where we've been.

DR. RATHBUN: Well, thank you.

DR. BUDNITZ: The unresolved one is No. 3, what the detail is.

DR. BLACKMAN: Yeah.

DR. RATHBUN: Larry?

MR. CAMPER: Two questions or thoughts to ponder: One, in my mind I still would like to get a little more clarification as to the risk context that may result from the effort that we've described. It may be, for example, that trying to put it in perspective to other risks from other modalities in medicine is the way to go, and the NRS study may result in something of a time mismatch there. But it would be interesting to know what the risk context would be.

And the second question or thought is, I think I have the impression now that the idea of getting the denominator—

DR. BICKEL: Yes.

MR. CAMPER: —which we talked about early on, that's not quite clear to me where that stands now, if it stands at all.

So just as you go through your thoughts ...

DR. RATHBUN: One thing I would like to start with to think about is what device? I mean are we going to stay now and work on the high dose rate afterloader trying to incorporate or, you know, is it the time to—are we going to go back to the Gamma Knife and move on? And I think we have to try now and take our best shot at what is the next step.

It does seem like it is the high dose rate afterloader. I do understand the Gamma Knife is more like teletherapy.

DR. GLASGOW: The question—I've been concerned about this all along. You have at least four distinct areas in different technologies that you focused on, and actually more, that's correct.

If, however, the question is do you need to test the modeling aspect against one of the technologies, then there's some merit in—there's a couple approaches. You could say go to the oldest most reliable technology, which is the cobalt teletherapy, where you have the longest collection of information about misadministration and use of the equipment. And test your modeling aspect against the older technology. That would be one approach.

The other approach, if you want the equipment to be most similar, go to the Gamma Knife, because there's only one model of those. The patient

data base is limited, and it's a more defined problem set for you to deal with.

DR. BUDNITZ: And you've done a lot of analysis already.

DR. RATHBUN: And a lot has been done.

DR. GLASGOW: A lot has been done, apparently.

DR. RATHBUN: Theoretically.

DR. GLASGOW: But it's not clear to me which approach you're trying to take. If the question is do you want to focus on the technology that affects the greatest number of patients most acutely, or which of the technologies is the most dangerous at this particular time, then from the misadministration reports, it would be high dose rate that we would single out.

DR. RATHBUN: Yeah.

DR. CALLAN: That's also the technology that seems to have the greatest growth. Looking to the future where the application would be most widely appreciated, it may be in high dose, I don't know.

DR. HOLAHAN: I guess another question is are we going to focus on devices or are we looking at medical use of radioactive material which is how the workshop was entitled, because that does apply to manual, and it's a broader—it applies to radiopharmaceutical therapy. It's a bigger picture.

DR. BUDNITZ: I could ask a question about whether your objective is more short-term or more long-term, your NRC objective. Because if you don't have a pressing short-term objective, but want to think about a five or a ten-year agency need, you might want to concentrate on working in the modeling area about something that would be more generic or could be applied more broadly.

On the other hand, if your agency really needs to have some results in the next year or so for some other reason, maybe you don't want to concentrate on something generic.

DR. RATHBUN: I don't think we have ten years, but I think we have two years.

DR. HOLAHAN: I think we're going to try and use it in terms of the new revision of Part 35, and that's—

MR. CAMPER: Couple years. You know, in listening to some of Glenn's comments, and you really laid it out nicely in terms of options, but I think in terms of the biggest bang for the buck in public health space, it's the HDR. It has the highest potential for danger; it's clearly an emerging, evolving technology. We've found, for example, that a mobile HDR has been licensed in the State of California. That raises a host of questions from a public health and safety standpoint, and if you were to focus on HDR, I think in the final analysis we would probably get the most meaningful product in terms of public health and safety consequences.

DR. HOLAHAN: That would be applied to others.

MR. CAMPER: Sure.

MR. SHEPHERD: Well let me just ask a question. Would it be reasonable to attempt to model, using any of these techniques, something along the manual applications?

DR. GRIGSBY: Well, you know, I think—I know it's not going to happen this way, but if you model the manual stuff, I mean if I look back at the evolution of what we've done, we've modeled our HDR after the manual procedure. So we had a very strict manual procedure in place. Then we got a low dose rate remote afterloader, and we just modified our procedure to some degree to deal with the machine interface, and then when the HDR came along, we modified the procedure a bit more.

So the procedure has evolved over time.

DR. RATHBUN: That's really interesting. We're looking at evolution—

DR. GRIGSBY: And then this PDR—

DR. RATHBUN: —idea.

DR. GRIGSBY: —half-breed is another word I was going to use, but I wasn't sure if it was male or female—you know, came along and we had to modify our procedure again.

MR. SHEPHERD: What I was thinking in terms of a risk model, when we talk about identifying places where errors occur, it would, it seems to me, by necessity, get much more down into the ac-

tual physician's hands. And I'm not sure that that's a proper place to try and put—

DR. GRIGSBY: What gets into the physician's hands?

MR. SHEPHERD: No, that the model would—okay, you're manually placing the seed, and the error ultimately is you've got these things in the wrong place, or you've got the wrong ones. And it seems to me that I no longer know where to draw the line between a model of a system, and now I'm trying to apply an engineering model to a truly medical practice, which even if it could be done, probably isn't a proper thing for the regulatory agency to be getting into.

DR. GRIGSBY: You'll never convince me that I've put the implant in the wrong place. I'll tell you that that's outside—you're not a physician, and that's outside of your judgment, unless it's right versus left, clearly the wrong site.

But to quantitate or evaluate the localization of what I've done is something you'll never be able to do.

But taking, you know, the placement—

DR. RATHBUN: That's what he's saying.

DR. GRIGSBY: —placement is a step, and then, you know, you had five categories—

DR. CALLAN: Five basic functions.

DR. GRIGSBY: You know, the procedure, the pre-planning—

DR. CALLAN: Right, pre-treatment, post-treatment.

DR. GRIGSBY: Those are common features to manual remote LDR, remote HDR—

DR. RATHBUN: Gamma Knife.

DR. GRIGSBY: —Gamma Knife.

MR. SHEPHERD: So that the difference between the two is an area that we shouldn't be fooling with anyway. So the manual is probably not one that we would want to look at for further study.

DR. RATHBUN: No, I think he's saying the opposite.

MR. SHEPHERD: Up to the point. If I heard you, the major distinction in the process comes to the actual placement. You do it or you have somebody put in a catheter, and then a machine puts the actual isotope in.

DR. GRIGSBY: The placement is outside the scope of this crew.

MR. SHEPHERD: That's what I'm saying.

DR. RATHBUN: Even if it's put in the wrong place—whatever that means—

MR. SHEPHERD: Where we don't need to distinguish the manual from the other—

DR. RATHBUN: I mean if you put it in his foot instead of in his hand, that's not our problem, right?

MR. CAMPER: Not if he does it by design it's not our problem.

DR. RATHBUN: If at the last minute he said foot would be better, what is it to us?

MR. TORTORELLI: But that's exactly the same whether it's the machine driven or the manually driven. Those numbers of misadministrations that we've investigated, most of them have been manually placed. And then the problem is either a source of a strength other than intended was used, or it was clearly put in a place other than where the physician intended. And the machines, the analogy with the machine is that they have to load these applicators and place them in the patient. And we're not going to say we don't like the way you place it, but if at the end he says, whoops, wrong lung, then that's a misadministration, whether it's manual or machine.

DR. GLASGOW: I think the distinction is that on manual afterloading, as it's done conventionally, there's little question that the equipment, which in this case is simply the radioactive source and its applicator, its carrier, for the most part is a proven technology. We're not questioning that the cesium tubes that have been in existence for the last 20 years are not reliable or they carry risk in the same way you're questioning on the high dose rate that the actual machine may have a failure. In the manual conventional afterloading, the issues are almost all human error related. Someone made a mistake in ordering an activity in the process. It's almost an entirely human error process.

DR. WU: I think it would be very interesting to compare the human and the machine, because here you have similar process, but you have different barriers. The cause of the error is different, and there you may have a decision problem. And when you have the machine, introduce the machine, you introduce error mechanism such as man-machine interface, and you introduce communication error between the physician and the technician who operates the machine.

And the whole picture will be still the same, but then you may look at each task, because there are different barriers may be introduced, and I think John would agree with me, because you introduce new magnetisms, et cetera.

MR. WREATHALL: I was going to say from the events that we looked at, even the ones in the NUREG, that the interesting aspects from the human error points in both the manual and the HDR that were quite different.

The manual ones had to do with going to safes and pulling out the wrong sources, what I would consider in some ways a much lower kind of human error, but common across many disciplines.

Whereas in the HDR, the problem seemed to more relate to the program set-up, software kinds of problems, which are a more modern and slightly higher tech set of problems, but they're not as set of problems—

DR. GRIGSBY: The HDR technology, one, it's a transfer device, and with manual that's someone's hands. But the other part of it is for a manual implant, a lot of institutions will put the sources in the patient before a computer output is generated, sometimes several hours before a computer output is generated. And but for HDR, you wait for that computer output before the treatment is given. And that provides for a whole new problem of human error and interface with the machine.

MR. WREATHALL: That's right. The HDR removes some human modes and creates some that are quite different.

DR. RATHBUN: Let's talk about human error. Let's talk about human errors that we care about. And the human errors that we care about are the ones that we can take some kind of regulatory position on. And then there's all the other neat human errors that you guys like to study.

Okay, now I always get really nervous whenever we start talking about—and now we'll look at something else new. We'll go look at the manual, and then I'm told that there are a whole different set of errors that go with that technology.

That may be true, but unless they are errors that, you know, I can sit down and say, well, shoot, if I told them they must have a survey, you know, they must have a physician that can be, you know, read something. Those are the kind that I care about. I don't care much about, you know, whether it's cognitive here or it's blah, blah, blah, frankly, you know, unless—now you're going to tell me I need this for the model, right? But go ahead.

MR. WREATHALL: No, I guess what I'm trying to say is first of all I'm only really talking about those that have potential significant unsafe outcomes. Therefore, in all of those cases you should care, given the charter that was talked about.

And the other point is, I'm trying to say probably simpler than people are saying, because there are going to be some kinds of errors that have significant potential consequences that are common to both. Treatment review and those things, whether that's part of the study or not, I don't know yet. All those are going to be common.

And then there seems to me two clusters that distinguish manual from HDR. One is in things like source selection and manual checking that the sources are in the right place versus program set-up. And that's just two clusters, and you can deal with those in a relatively simple way.

So I don't think it's going to be, well, we should invest all our money in just one, and there's no opportunity to look at the others, because I don't think—

DR. GRIGSBY: They're parallel.

MR. WREATHALL: They're parallel, and there aren't big differences. There are clusters of differences, and you can treat them, I think, fairly directly.

DR. RATHBUN: Well, I'm very taken with the idea that we could have an evolutionary-type situation—

DR. GRIGSBY: That's what really happened at our institution.

DR. RATHBUN: Right, and that's what really happened, and I observed that in the Gamma Knife situation, too, which was very clear to me that they were building on existing teletherapy procedures and modifying them.

DR. GRIGSBY: Right.

DR. RATHBUN: And I had never seen a teletherapy process, but I figured it out that that must be what was going on.

So in order to really analyze the situation, I had to look at where the errors were in the process before.

DR. GRIGSBY: Dave Larson talked about academic institutions having different procedures, but I think he was talking about a very micro level.

DR. RATHBUN: Me, too.

DR. GRIGSBY: And if you look at a macro level, all those institutions are going to have certain groups of events or procedures.

DR. STITT: To enhance upon that, some of the places where I've been looking at misadministrations in the high dose level were places that had not used manual afterloading before. Because many small institutions don't do manual, because it's expensive. They don't have enough patients. But you can, for $150,000, go buy yourself a gizmo and put it in your room, and you can do anything to anybody with it, and there's a tremendous learning curve where you've not moved from one step to the next. And some of the really God-awful things that happen, I think Indiana were Pennsylvania's problems, pretty much.

DR. RATHBUN: And that's because they don't have that body of information that you worked your way through.

MR. SHEPHERD: What we saw with the reactors, every reactor that started up made the same basic set of errors. Everybody put their own little spin on it, but—

DR. BUDNITZ: They learned from each other.

MR. SHEPHERD: Nobody learned from everyone else's errors.

DR. BUDNITZ: I think—you'll agree that's an exaggeration, but there's all too much—

MR. SHEPHERD: Right.

MR. CAMPER: Let me pick up on this evolutionary idea. The evolutionary idea is an important concept, and I guess I would ask the question, where is HDR going? Because a transition has already occurred. The horse has left the barn, so to speak.

Now the question is ACR going to continue to evolve—for example, we know it's going mobile. That's a given. Where is it going, and what could be picked up?

DR. STITT: I think where it's going has to do with what the regulations are, and as much as I don't like to regulate out things, I do in a sense of, for example, the NRC could make a statement, unless you have a full-time physicist at this particular site, plus whatever these criteria are, you cannot do high dose rate brachytherapy. And part of several experiments with patient problems were with part-time docs that moved from one institution to the next, who simply were monitoring this patient on their cellular phone as they moved from doc in the box A to doc in the box B, physicists who operate under contract. Seriously.

And that's a real high risk for getting yourself into trouble.

DR. BUDNITZ: But are you convinced that regulating those who would have a substantial risk—

DR. STITT: I think we have to look at it.

DR. GLASGOW: While there's focus on the academic facilities, I can't quote it, but I'm going to guess it's the 80-20 rule. I'm going to guess that 80 percent of the patients treated are in smaller facilities. I don't know that, but I'm going to guess that it's something—

DR. STITT: A little on the high side, I think.

DR. POLLYCOVE: I think there's great merit to running in parallel from the manual on, because the regulations that are in place have historically been developed and are dealing with the manual. And by identifying the clusters that are different, it focuses on what regulatory changes may need to be made because of the new technology.

So to clearly pry those apart, I think would be very helpful—

DR. GRIGSBY: I think HDR evolved to PDR. It got its butt bit, and it backed off. And other than being either stationery or mobile, HDR, you know, other than it's going to go to other body sites, it's going to go to intra-operative. But is there going to be another machine or a next step for HDR, I don't know. I don't think so.

DR. CALLAN: I think there'll be new treatment planning equipments.

DR. GRIGSBY: Oh, three dimensional. There will be three dimensional treatments.

DR. CALLAN: Three D are virtual reality treatment.

DR. GRIGSBY: Sure, sure, there will be.

DR. CALLAN: But in the actual treatment equipment itself—

DR. GRIGSBY: Yeah, that piece of equipment is probably going to be fairly stable for a number of years, but the treatment planning will evolve to 3-D, no doubt about it, and the virtual treatment planning.

DR. CALLAN: See, the technology is a very precise stepping motor that has the ability to know exactly where it is and how far to move very precisely.

DR. GLASGOW: On the Gamma Knife side, one would expect that because of the cost of these machines, that we would not see a large number of them being installed in the future. My perception had been that this could be done with a linear accelerator at one-tenth of the cost. And that's where the growth is going to be. But I was surprised to see an article recently that corrected me on that, that said the companies, because the fee schedule is so tremendous on this device, that they are now being installed free. And the companies will put in the four million dollar unit free of charge to hospitals that will enter into an agreement, so that they capture a certain component, a $30,000 charge that's being made per patient.

So they may continue to be—

DR. RATHBUN: We'd certainly like to see that amount—

DR. GLASGOW: There may continue to be a growth of that product, which I probably would have thought that because of regulatory concerns, and the fact that it has 201 cobalt—

DR. GRIGSBY: That was in The Wall Street Journal about four weeks ago.

DR. GLASGOW: —might cause people to walk away from it.

DR. BLACKMAN: Okay, well let's come back to—I think what I heard is what we ought to do is we ought to concentrate on high dose. We ought to start with manual and evolve to the more automated systems.

DR. BUDNITZ: I thought I heard that they ought to be done in parallel.

DR. WU: In parallel.

DR. BUDNITZ: That's what I was hearing.

DR. POLLYCOVE: So we can see clearly what the differences are.

DR. BUDNITZ: And now you're talking about model development.

DR. BICKEL: Well, you know, I keep thinking that the data and modeling are iterated—

DR. BUDNITZ: I agree, but we're talking about starting—

DR. BICKEL: As the data is being done, two parallel paths.

DR. BUDNITZ: Which really means—I mean if you're going to go back over here to AEOD and the data tasks and gathering all that stuff, they ought to concentrate on gathering the data for those modalities like if they got all those agreement states entering data to enter in, start entering that stuff, not something else.

DR. RATHBUN: I always hate to be the wet blanket, but what the heck. What I would really like to see you do is to—when you come to Washington to brief Carl, I would like you to lay out the rationale for why we should do this. In other words, the assembled body of people here suggested that we look at these modalities in parallel, or possibly as an evolutionary process, because we believe that that way we can find a risk growth path or something like that, and I'd like an assess-

ment of, you know, the underlying rationale for that.

And more importantly, because manual sounds to me like the new thing to do, what is the magnitude of that? So I can make some kind of a decision about, you know, what this does to the scope here and what other things I'd have to give up.

DR. POLLYCOVE: It seems to me that the manual is, basically, a portion of subset of—

DR. BICKEL: A subset of the process.

DR. RATHBUN: Now that's how Carl sees it. Let me just be very blunt here. When the proposal to do manual came across, our position is why should we refund another topic. That should have been captured in what you did for the high dose rate.

So I need to understand what it is that is the magnitude of this. If it's small and simple, and doesn't require, you know, two more years of going out and doing investigation, I'm sure that would be acceptable.

If it does, then we always have to decide is there a better way to spend our money.

DR. BUDNITZ: I had an angle for the argument.

DR. RATHBUN: Okay.

DR. BUDNITZ: You see, there's an alternative approach, in fact two or three alternative approaches which we're not preferring. And it would help to describe to each other here why we're not preferring them, and then that validates the approach being taken.

You could start with a single device, you know, a single device, like one of these afterloaders or the Gamma Knife and so on, and just beat it to death. I mean, spend a lot of money on it.

DR. RATHBUN: We did that.

DR. BUDNITZ: And develop a model.

DR. RATHBUN: We did that, and I learned from that experience.

DR. BUDNITZ: And the notion is spending a year and a half on that wouldn't provide you with a diverse enough input to help make a decision about what you're really going to try to do.

Alternatively, you could decide you're going to do four or five or six of these things, and that's just too much.

So you're stuck with a couple of them. Well, which two? You want to try to find two that are similar enough, but yet have some comparative differences and some similarities. And that's when you go to the manual and the remote, but otherwise similar. Because there are similarities that help understand the differences and the similarities.

DR. GLASGOW: Another important reason I think to do the manual and the remote in parallel is, one is replacing the other. And you may find information that would allow a physician to make some judgment, to some extent, regarding the relative risk. Or someone might say, well you know, this study says that the high dose rate is really riskier than I realized, and that manual is safer than I realized.

Or you may find the reverse. Someone may say, I was not aware of so many misadministrations with manual, and the high dose rate, while it may appear riskier, in reality, some way, form or fashion has produced fewer misadministrations.

DR. BUDNITZ: More to the point, if you have identified a few key things where you intervene and kill the risk by observing procedural changes.

MR. WREATHALL: Related to what you're saying is the important point about the level at which you're doing the analysis. You can describe all the forms of radiation treatment at one very simple level that is all the same. You know, you identify the problem; you put in the radiation in the patient; comes out. It makes no difference whether it's manual, HDR or whatever.

As you start to refine the details of the analysis, they start to depart. And if you go to finer and finer analysis, HDR in every facility becomes different. So the question is where am I wanting to draw the boundaries to make the distinction in the analysis?

And the point that you mentioned is that it's at the level at which interventions become different under the regulations, so when I talk about doing these in parallel, I'm only limiting it to what is the

necessary level of analysis to make that distinction. And it may be when we talk about parallel, you can think, you know, the beginning of the whole process is here and there's some pathway through here that comes to the end, those first steps—and I don't remember the task analysis—the first steps are common whatever level you're working at, and it's only part of this. The source selection can be manual, the program setting, if you're dealing with HDR become different, and then they converge back into follow-up and check-up.

DR. BUDNITZ: Right, that's an accurate description.

MR. WREATHALL: So it's only the levels here that become parallel. It's not a major program that you do this, you do this, and you do all the micro-step tasks—

DR. BUDNITZ: But there's a second piece of the rationale, and let me try to see if I can capture it. The fact is that there's a data development needed to parallel, right? But for this particular set, there's already some data that can help the modeler as the other data being developed, and that may not have been true for some of the other things you might have had.

DR. RATHBUN: Looking at your own—your diagram, take any one of them, actually. 320, this one. This is on Page 320. You have the performance shaping factors, labeling procedures, training. Well, you know, we can influence regulation in a lot of those areas.

You start talking about treating the contingent conditions, that's where you're really getting out of the area that the NRC can do much about, or it gets hellacious. You know, we can't hardly tell you in their model they specify what they call the performance shaping factors, and then they found in the investigations, we found a set of contingent conditions. For example, we always found if the attending physician was not present, then you're on a road that is going to take you to a problem.

DR. GRIGSBY: See, radiopharmaceuticals follow this same path. The beginning and the end is the same, it's just a little bit different in the middle.

MR. WREATHALL: But the place where NRC can think of interventions on contingent conditions, those seem to vary very much by the size of the facility.

For example, if you're only dealing with one part-time physicist, it creates certain opportunities for a whole class of failure modes that come about that wouldn't happen if you have ten on call all the time.

So those are more to do with the kinds of facilities than how you might differentiate rules.

DR. RATHBUN: But let's say I know, because I went to every one of those, that if you don't have the attending physician you are on a potential failure path. There isn't—I mean, so what? I can't say to you—I could maybe put a note out to you saying be careful when the attending physician is not there, but in regulatory space, we can't say only the attending physician will ever treat the patient with radioactivity.

DR. GLASGOW: I just wanted to interject—

DR. RATHBUN: That wouldn't work very well if we said that.

DR. GLASGOW: The only way to think about what we want to do, however, is also in terms of the risk to the patient. Certain of these technologies are legal risks; others are not. We're generally not going to kill a patient, I don't believe, with a GYN low dose rate treatment. There may be a misadministration by definition—

DR. GRIGSBY: But you see, they don't die acutely, and that's the difference. They may die in a year, but they may not die acutely.

DR. BUDNITZ: If you give them half the dose you thought they were going to get—

DR. GLASGOW: Well, yes. The focus here, though, is there are certain technologies here. You could have two deaths next week—

DR. RATHBUN: From a Gamma Knife.

DR. GLASGOW: —from a Gamma Knife, or you could have two deaths next week from a high dose rate. It could happen. It's not outside the realm of probability, in terms of occurrence. Some of these other things that you're looking at with the radiopharmaceuticals and the manual conventional afterloading aren't threatening the patient's life in

an acute sense. And you may want to keep that in your equation.

MR. TORTORELLI: I think there are other ways to influence the safety of the public besides regulations, too. If this study comes up with certain background that can help make better regulations, wonderful. But maybe we'll find certain performance shaping factors or contingencies or whatever. And if we get an article published in the appropriate medical journals, people may alter their behavior when they're prescribing and carrying out these treatments.

MR. CAMPER: Well that's a good point, because you have guidance documents. You can also meet with professional societies, discuss your findings, encourage them to develop standards. You're right, there's a host of possibilities.

MR. WREATHALL: In effect, your example about bulletin asked if we're planning on the same things seemed to be a similar thing. Don't say you cannot do this, but tell us what your plans would be if it happens.

MS. THATCHER: These insights to give you a feel for whether regulation would be effective. What would the effect of this be? When you understand these subtle insights, and you look at this and say this isn't going to be effective, or it's going to be effective at compliant facilities, it would give you some information that way.

DR. GLASGOW: But you have to keep in mind that on the unit on which the death has occurred, that unit is not in the market anymore. And were there to be, unfortunately, a death of another patient next week on a Nucletron device, you can rest assured that the likely reaction would be that someone would be going to their site and shutting them down.

MR. CAMPER: Two comments. There are still devices in the field, same devices still in the field.

Number two, it's in the process of becoming re-marketed by a different organization.

DR. GLASGOW: But not in America, is it?

MR. CAMPER: I think they want to market it in the United States. They're seeking to do that.

DR. GLASGOW: I see.

DR. BUDNITZ: Let me ask a question about international influence. In the nuclear reactor arena, what the U.S. NRC does has enormous muscle overseas. Not everywhere. The French never listen to anything. But generally. Is that true in this arena, too? That is what you do with Part 35, is it influential in other countries or not so or what?

MR. CAMPER: I don't think what we do in the medical regulatory space is influential around the country.

DR. HOLAHAN: Except Canada is looking into doing some regulation.

MR. CAMPER: I would then, in turn, qualify that by saying that we do seem to have more inquiries from foreign entities as to our medical regulation program.

DR. STITT: When I talk to colleagues, particularly in Europe, there's a lot of high dose radiotherapy going on there, much longer than we've been doing it, and they can't believe how regulated the medical industry is here. They say we'd never put up with it. And those aren't even the French. Those are the Germans and the Dutch.

DR. BLACKMAN: Well, let's—maybe we should turn our perspective to the question that Larry brought up about risk contacts.

I think we kind of have a handle on the model of what you've asked us to do, where you would be able to present and make a case why we would be dealing with both the manual and the auto and the evolutionary concept.

What about the risk context issue? You know, we have a study which has been done by the NRC already. That's a place to start. We have the National Academy work going on. We have—in one of the comments that was raised earlier in that session was maybe we don't really want to do anything with that right now. Maybe we want to wait and see what NAS comes up with, perhaps referencing the work done already by the NRC. But that's about as far as we got, I think.

MR. CAMPER: My inclination is with regard to the NAS study, I would let the NAS study run its course. See what you can do separate, independent of that as an additional informational source. I think that—I think that for several reasons.

Number one is, we do have a time line here. We're going to revise—we plan to revise Part 35 by the end of 1997 as a final rule, which means if you back that off, you get into '96, even late '95 we're aggressively into the process.

The NAS study will finish, at least in theory, in 1996. There's been some recognition there might be some delays. I would just let it run its course. I think any other additional information that can be gathered would be very useful to us.

And then as the NAS study is completed, we can compare the two sets of findings and, perhaps, from that will come information that would send us one way or the other.

DR. RATHBUN: Yeah, I think they probably will have to extend—

MR. CAMPER: What do you think, Pat? Is that reasonable?

DR. RATHBUN: I think that's right. I think the best thing to do with the NAS is just let them do their thing. That's why we got them. Let them be independent, and let's see what they have and what they recommend.

DR. STITT: We're going to get Dr. Pollycove's material?

DR. RATHBUN: Uh-huh.

DR. BLACKMAN: So you're suggesting, perhaps, Dr. Pollycove's material, perhaps, formalizing it? I don't know—

DR. POLLYCOVE: Right, right. I'll clean up and get a couple of greater-thans and less-thans in there and send it to you.

DR. BLACKMAN: And then we may want to do some additional, as was suggested, putting it in like a research article, risk perspectives.

DR. BICKEL: I was thinking that would be a very good step.

DR. RATHBUN: In terms of a product from this particular effort, make it clear that we made a conscious decision to step out of this area.

In other words, let the record show that we didn't just forget about it. We decided to defer the NAS to the NAS. And for the purposes of this situation use what

Dr. Pollycove has already prepared.

DR. BUDNITZ: Myron, you were gathering and analyzing information from other sources?

DR. POLLYCOVE: Yes.

DR. BUDNITZ: I'm just curious about whether the primary literature is extensive in this area, or not. Are there other people who spend their whole life playing in that sandbox—

DR. POLLYCOVE: In certain areas there's a good deal of work. For instance, the extent to which prescribed medication in hospitals, there have been a few studies there.

DR. BUDNITZ: In the New England Journal and JAMA and so on?

DR. POLLYCOVE: No, not published there, but it's been published, yes, it's been published.

And there are little pieces of if you do this operation by this procedure, for this indication, you'll have a certain morbidity and mortality.

DR. GRIGSBY: There's incidents—

DR. POLLYCOVE: And it differs from one study to another, depending on the circumstances, the severity of the patients treated, the experience of the surgeon and so forth. And these little bits and pieces that—

DR. BUDNITZ: But as far as you know, there isn't any scholar out there someplace that's been spending the last little while trying to pull this stuff together?

DR. POLLYCOVE: No.

DR. BUDNITZ: I don't mean just radiation stuff, but—

DR. POLLYCOVE: No, no.

DR. BUDNITZ: There isn't.

DR. GRIGSBY: Not in a risk context.

DR. POLLYCOVE: What DeVita and et al have done in their, essentially, reference text on cancer is they've pulled together these different articles and applied them in various portions and come to their best considered opinion of an average value for these little pieces.

And I've used their data and other data to put this thing together.

DR. BUDNITZ: So, basically, their compilation from lots of other sources is an original piece of scholarship?

DR. POLLYCOVE: Yes, but you see, their compilation deals with this particular surgery of this cancer, or treatment with chemotherapy of this cancer and different stages. So that although they've compiled it, they've done it in—you have to, you know, go all over and look at these different things.

Nowhere have they put it all together, which isn't a big deal, but nobody has done it, as far as I can tell.

DR. GRIGSBY: Right.

DR. POLLYCOVE: And it isn't a big deal, because I did it in a week. But there it is.

DR. BICKEL: But you knew where to look.

DR. POLLYCOVE: It's referenced.

DR. BICKEL: You knew where to look.

DR. BUDNITZ: He's got a random person doing it with him.

DR. BLACKMAN: Okay, well then the next issue that was brought up was a question of a denominator.

DR. BICKEL: The denominator, I think, needs to be filled in. I think we used the word that we need to make the numerators separated out into, you know, modalities, and maybe types of facilities and get corresponding denominators to go with them. There needs to be a little bit of massaging both numerator and denominators.

DR. RATHBUN: Only Carl can make this decision. What you need to do is to arrange for Carl your best estimate of what it's going to take to do his. Whether or not he will want that done, I can't say. But what he needs to have presented to him is really if you believe you know how to do it, and you do, then tell him. And tell him how you would do it and what is the level of effort.

DR. HOLAHAN: I would also suggest, too, that we, in presenting it to him, is that it's why you believe that it's needed.

DR. RATHBUN: Yeah.

DR. BUDNITZ: I wish I could see it.

DR. POLLYCOVE: You see, again, I just want to say it once more that in terms of the denominator, we know that it's much greater than X. And we can defend that.

DR. BICKEL: Yeah.

DR. POLLYCOVE: And then the question is, if you want to refine it and find out how much greater than X the denominator is, how it would be useful. That's the whole—especially when we have this other piece of data that I'm giving you that gives the risks for these various types of procedures when done correctly.

DR. SIU: I thought I heard that refinement of the denominator in a different sense. It wasn't how accurate it was going to be, but how many categories are you going to define for which you need numerators and denominators, distinguishing between larger research facilities and mobile facilities, for example. How many different categories do you need, and then to develop appropriate statistics for each one.

DR. POLLYCOVE: Well, you see if you know that throwing in many—the majority of the facilities are not university research facilities, that using a denominator overall, which include these facilities, you have a risk that's for mortality, morbidity that is far less than ten to the minus six and ten to the minus fifth. Then you can certainly, by prying it apart, and find out, well, it's even less for the well controlled large institutes, and it's even—it's greater, you see.

But unless all of them are coming from these small places, which we know isn't the case from our events, there's not much to be gained by saying, well, it's ten to the minus fifth for this facility, and it's ten to the minus sixth for that facility. The point is that if these differences, now that you're beginning to split between, are still minute and inconsequential relative to the risk of the patient having the procedure done correctly. Why split?

DR. SIU: Again, it depends if you know the answer beforehand. I guess I've heard there was factor of four difference, that seemed to be something that we were saying, gee, that's worth looking into.

DR. POLLYCOVE: Well, there might be a factor of four difference, but when you already have a factor of 100,000 difference—

DR. BICKEL: I think if I had to characterize why it would be useful to split it, it's obviously two reasons. One is if you aggregate the whole thing from the beginning and don't lay the groundwork for future data collection efforts by AEOD in the next five years, if it's all aggravated you'll never split it out, no one will see the need for it. That's one reason why it ought to be—there ought to be some attempt to define logical groups.

The other reason we did here was that the number of treatments performed in some facilities is one or two a year, and we also heard that there were some facilities that had 300. And any, you know, I would have a problem trying to lump the two, you know, my gut feeling, and we've got more human factor specialists around here are going to tell you that there are obviously going to be differences in the way those facilities run. In some it's done four times a year and in some it's 300. They're different populations.

DR. POLLYCOVE: Right, and I think that those recommendations, on the basis of experience and practice and so forth, can be made without extensive data gathering.

DR. BICKEL: Yes, that's what I'm saying. I don't think you need this much data gathering. It's interpretation of the data gathered.

DR. RATHBUN: Your view of the denominator is different from Senator Glenn, and I think that's what's causing the issue here is that we don't want this big study of the denominator.

But you're proposing another use for that in the risk context.

MR. WREATHALL: The point is to come back to the point of searching for outliers. You're only going to cut the data if you suspect there's a possibility that one of those is an outlier compared to the rest.

Now the fact that they all may have a low risk, that's more the question about why you're doing the whole thing in the first place. But given you're doing the study, one of the reasons for regulations is to search for outliers, so you have to be able to divide the data to look for, what would the outliers be? That's a rationale—

DR. RATHBUN: Put in that context, Carl may be willing to go on—

DR. BUDNITZ: Which means you want to go into the exercise with some best judgment of experts as to where the outliers are likely to be, based on the experience and the data we already know, and then find out whether that's so as you get into it.

DR. POLLYCOVE: Well, of course, the events themselves point to outliers, not just the number of events that occur in a facility, but the number that occur per annual number of treatments.

DR. BUDNITZ: And also the kind of events?

DR. POLLYCOVE: Yes, right. So that the events themselves are pointed to outliers. I mean, you know, we know that a stand alone facility that has been recently beefed up and crashed to cash in on a modality is going to have a very high risk. And it was demonstrated very well at Indiana.

So the events themselves point to the outliers.

MR. WREATHALL: Yeah, I agree.

DR. WU: Not necessarily, because for example, we're talking about manual and remote. Now I heard that you are evolving from one into the other. I would assume the other one is not indeed mature. So you may see similar situations later on when you're moving to a new area. You do want to know, have sort of sense how riskier or safer.

Now if you don't have a way to distinguish the data, and because you have more procedures on the earlier ones, you will see more events.

Now the new ones you will see less event. That doesn't—

DR. POLLYCOVE: Well, that's why we're relating it to the number of procedures.

DR. SIU: Right, and if you don't have a way to distinguish these two kind of procedures, which quote, unquote denominator, and then you will still not—won't be able to find an index for your risk.

DR. POLLYCOVE: Well, when the events occur at any given facility, at that facility we do know the number of procedures. So we have that data for the facilities in which it occurred. And although we may have one event per year in a

Cleveland clinic, and perhaps one event per year in some small place, when we relate it to the number of procedures, the difference is enormous.

MR. WREATHALL: It seems to me what you're saying is categories for outliers, there's really only been two broad groups identified in discussion. One is modality, and the other is class of facility, in some way, large, small, teaching, whatever. Those seem to be the only ways in which I've heard people suggest you need to have the data, so far.

DR. CALLAN: Well, there's some staffing considerations have been brought up about the type of contracts the staff is on and whether they're full-time or part-time.

MR. HANEY: Well, in terms of risk modeling, it would be useful to categorize them in terms of the type of event, or more specifically, where was the error? What was the error? Was it in treatment planning, or was it in the execution, or—well, we're not doing that. But for a data base, you start helping quantify a model, you want to know what the error is. How many of these errors were of this type, how many that type? It doesn't matter what the facility was or even what type of equipment or modality it was. If the error was similar and the context was similar, it would be really valuable to know that.

So that's another way to look at it, although that kind of data, I know, would be really hard to get. But that would be the most valuable, in terms of risk modeling, as I see it.

DR. BICKEL: I think from the data that exists right now, you will be able to identify from a process—from the process in what phase of the process it broke down. And in some cases, I think Tami can tell you what all—some of the root causes are pretty clear. Some of them are a little semi-cryptic, and some of them, the fields are empty. But I do believe we have the ability to identify what phase of the process failed. And I think that that would be, again, that would be a useful thing.

And that effort was started in that, you know, in the NUREG on misadministrations, where we did look at that data.

I think what we're talking about here is an extension, going a little bit beyond working up the denominators and trying to get denominators for different types of categories. Try to see, basically see—take a second look at that data that exists. And I'd like to see if we could fill in estimates of the denominators, based on, you know, possibly some type of telephone conversation with the people involved at the hospitals to try and get an estimate of their treatments per year of different types.

That, I think, is the critical denominator you want to get.

DR. BUDNITZ: But, John, you know, there's this problem which you and I and a bunch in this room are intimately familiar with. When you read these event reports, and I'm not talking about medical reports only, but it's got to be true there. And then, you know, there's somebody writing it up, and they're trying to figure out who's to blame over here. So they write something up. And then, as often as not when you go do a full investigation, it's really not—the cause is elsewhere. There is a deeper cause, or it's somebody else. That's just the common experience, as often as not. And that tells you that there's more to it than just compiling data that come in.

DR. HOLAHAN: But if they—

DR. BUDNITZ: And I don't know what to do about that, but—

DR. HOLAHAN: But as the data that comes in, and I think Bob indicated yesterday, also includes inspection reports and consult reports, it's got that data in there.

DR. BUDNITZ: Some of it, yeah. so maybe do some corrections to it.

DR. BICKEL: I certainly would not be able to go in and tell Carl what I think needs to be done every time there's a misadministration anywhere in America and send out the "Swat Team" where we—

DR. RATHBUN: Within 24 hours.

DR. BICKEL: Forty-eight.

DR. BLACKMAN: Unless there's a holiday, then it's 72.

DR. RATHBUN: How quickly we—

MR. WREATHALL: Those events that have been analyzed that have a serious and significant outcome, the information gathered by that process is significantly better and more useful for your future use than is contained in the report.

DR. BUDNITZ: And by the way, we all understand that the human nature that led to the observation I just made, you know, a lot of these are trying to assign blame. And that's different than cause.

DR. RATHBUN: It's how the inspector thinks. Inspectors think what piece of paper didn't get filled out, you know. That's how they are.

MR. SHEPHERD: Their little inspection mode.

DR. RATHBUN: They're not process people, and when we augmented the inspections with the risk analyst, it's amazing what happens.

DR. BUDNITZ: Part of that, the whole concept of blame gets into the way of some analysis, and it's usually what these people are thinking about.

DR. HOLAHAN: It's also different than getting the licensee's root cause analysis. And I think that's what—the inspector comes in and does a little bit more, and then the INEL can come in—

DR. RATHBUN: And the real root cause might have been truly a different doctor. And that's life. There's nothing we can do about that.

MR. CAMPER: Let me take you back to basics here for a minute.

DR. RATHBUN: Back to reality?

MR. CAMPER: As I see it, there are two denominator questions. There's the fundamental question, what is it, which I will characterize as the denominator. By that I mean how many times do misadministrations occur, given the opportunity for them to occur, okay? And we've had some discussions over the last couple days about existing data bases, various organizations, et cetera. And there may be a way in contractual contexts that you could get a handle on some reasonable estimate of that number.

Secondly, there appeared to be, and I agree, other subset denominators, if you will, perhaps by treatment modality, that would be useful to know. There are other ways that one could look at the denominator. I mean, there's all kinds of possibilities.

For example, you could consider population demographics, states, you know, there's a whole bunch of things. But by modalities seems to be the most fruitful.

But I think that Pat, with having said all that, I think Pat summarized it so very well a few minutes ago. And that is what I think would be useful when you come to talk to Carl would be to think about those two kinds of major denominators. If you believe there's a way to get a reasonable estimate of them in a fairly timely manner, tell him how you would do it, why you would do it, what the cost would be and what the time line would be. Because Pat's absolutely on the mark. The only way Carl can make this decision, because there's some complicated issues associated with this denominator question that might not be so clear to all of you here. It's a very complicated issue for a host of reasons that we won't bore you with.

But I think if you could lay that kind of information at his doorstep, that would really facilitate his decision making.

(A discussion was held off the record.)

MR. HANEY: Okay, the point I was making, the types of numbers you were suggesting gathering will give you a clue as to where to start looking, where to model, which modality, which type of facility. It's useful for that, but it's not really useful in terms of developing a model of the process and the risk. For that kind of modeling, you want data on what was the event, what type of error occurred. So I just wanted to make a point that those aren't the only two types of important data.

MR. CAMPER: I agree, and please, again, understand. The reason we got into this denominator question was because it's a basic question that we've been confronted with in different forums. There are some who believe that the pursuit of the number for the sake of pursuing it in and of itself is a worthwhile goal. It may well be. I won't debate it one way or the other.

But it is a big question mark. It's a fairly fundamental question that I don't think we're quite comfortable with our position today on it, what we can or cannot say about it. And at the same time,

we look at various ways to obtain this information like, for example, requiring our licensees to submit it. And we say, wait a minute. That carries with it a substantial cost and burden which we're just not sure that the efficacy is there, given some of Myron's comments, you know, the order of the magnitude is probably not going to change the final analysis anyway. So is the cost worth it?

So we're stuck with this dilemma. I mean, on one hand we're comfortable with where we are today. We think we have a fairly reasonable depiction of the denominator, but could it be better? Yes. Is it a pretty fundamental basic? Yes. How do we get there?

DR. RATHBUN: And how much does it cost?

DR. BICKEL: I think what you're going to find is there will be some surveys, there will be some expert estimations that will be reviewed, and I want to say again, this is the same problem they have in the reactor side. They don't have the exact denominators at the reactor site. They never have.

DR. BLEY: The only place you see them there is when you do a plant specific study.

DR. BUDNITZ: And by the way, it's also true in the aircraft industry.

DR. BLEY: And root through 30,000 pieces of paper.

MR. SHEPHERD: And then you argue over what kind of prior you used.

DR. BICKEL: Wait a second—

DR. RATHBUN: Let him speak for himself in Washington, John.

DR. BICKEL: But what I'm trying to say is, I believe that you will find it will give you more insights. I don't think you have to go out and collect it at every single solitary hospital and clinic in America to get a reasonable estimate. But I do think there should be some effort made to make a reasonably good estimate and understand what the uncertainties are in that estimate, and propagate through the event so you see what you've got and how precise the answer is.

DR. BUDNITZ: Just one example. Myron was pointing out you have a pretty good count of the number of patients treated. Now you know, it doesn't take too much work to try to figure out fractionations, what the average is in representative situations, and then you'll have your arm around that pretty well.

DR. BLEY: You know, the one thing we really haven't talked about on the data, we talked about on analysis you might do several site specific studies, go to specific locations. And when you do that, you might well do a good job on the data for that particular facility, and then when you have several of those, you can compare those with your general overall averages and see if they're consistent. Because as you said, in the nuclear energy business, the only place we've got good denominators are at the sites where we've done site specific data collection.

And you can infer from that through the others. You see some pretty common—

DR. BUDNITZ: I think you could probably plan a protocol for the data, again, go a long way without—

MR. SHEPHERD: Well, I think one question we need to ask as an agency is what are we really going to learn? If we're dealing with an area that's ten to the minus five, ten to the minus six, two to three orders of magnitude greater than other medical procedures, how much of an answer do we owe Senator Glenn, and how much regulation should we really be in?

And maybe the NAS will help us answer that question. But I think we need to get a feel for where we're going on that before we decide whether we need to refine it at all.

DR. GLASGOW: I think the answer to that is well understood. If one of our surgeons kills a patient tomorrow, Senator Glenn will not be upset. But if I kill the patient, it will be national news. And that's the reality in which we're working, and that's what we keep coming back to. The risk in this area with radiation is not in the public perception compared to other risks. It's just not. It's just not acceptable. Death by radiation in the United States is not acceptable. It isn't. Death by other means is acceptable and expected, part of the process. But not with radiation.

DR. RATHBUN: Now the NAS has been asked to come up with a denominator, if you really think about it. The only way they're going to be

able to compare those done right and those done wrong is to have some number. Now we'll just have to see what they do, and they're doing more than the denominator in capital letters.

I think Carl will find that very interesting, the perspective developed here.

DR. BLACKMAN: I guess I would suggest at this point that we're probably ready to summarize, and would we like to take a short break and then wrap?

DR. RATHBUN: Uh-huh.

DR. BLACKMAN: So why don't we break until, say about five after 11:00 and come back and we'll have a summary.

(A recess was taken.)

# C.7. CLOSING

## C.7.1. Summary—Dr. Bickel

DR. BICKEL: I guess we are at a point of summarizing, and I think I'd like to just offer my perspectives.

We started the meeting a few days ago. I stated there were a few things I was hoping we were going to get out of this. One was to review some of the work that had been done to date that was of a preliminary nature, seek out some new information on how that could be improved and applied to the process of understanding the risks of radiation therapy.

And then additionally, solicit some inputs, ideas of things that maybe we hadn't thought about by bringing in some specialists from the medical profession.

And then, hopefully by the concluding point, which is where we're at now, have a thumbnail sketch of an outline as to where we go from here technically to understand the problems of assessing the risk of radiation therapy.

And I think we've, you know, I'm very pleased. I think we've accomplished these objectives. We've had an interesting interchange, and if Dr. Rathbun lets me, we ought to get this group together maybe when we get a little more or something similar, because I've found it very profitable to have inputs from Dr. Pollycove—

DR. BUDNITZ: Myron and I will host such a meeting in Berkeley at any moment.

DR. BICKEL: I've heard this California thing before.

DR. BUDNITZ: This isn't California. This is Berkeley.

## C.7.2. Closing Comments—Dr. Rathbun

DR. BICKEL: Pat, would you like to offer a few words for the assembled masses?

DR. RATHBUN: Is this the wrap?

DR. BICKEL: This is the wrap.

DR. RATHBUN: Okay, well I want to join John in thanking you all and telling you how I think this has been tremendously valuable. You know, I've heard things that I've been struggling with for several years, and I think that we've managed to get together just exactly the right group of people to air these issues.

What we still have left to do is to kind of go forward here and think maybe about a time line, try to get some sense of what activities would come first and second, and what kind of dissemination, you know, do we need to go to the ACMUI. What do we really need to do next? I don't know whether you want to do that now or take the time to work on that before you come to Washington. I don't know if you want to bring any of your contractors with you. I think there's still a number of things to be decided.

Am I to sort of wrap up and dismiss everyone? I'm not quite sure what your expectation is.

Maybe we should go around the room now and get some thoughts from the group, final closing ideas.

DR. BICKEL: I'll start off. I really wish to thank all the people that took time out of their obviously very busy schedules. I realize, you know, it is difficult to get professionals all together in one room, and things like that, and I just can't say thanks enough for your inputs, your thoughts. Your discussions have been very very helpful. Jim?

MR. TORTORELLI: Some of you still owe me slides.

DR. BICKEL: That's right, we'll hold your plane tickets and your passports until we get your slides.

MR. TORTORELLI: Do people need me to read their names out loud?

DR. BUDNITZ: Yeah, sure. It's not me.

MR. TORTORELLI: I'll come around and see people.

MR. WREATHALL: Overall perspective at the end is being a scary amount of what seems to be cohesion at this stage. That really bothers me. We're all going down a blind alley somewhere. I don't know where it is.

I'm just astonished by the amount of synergy that happened here. Many of us came in from different backgrounds. We've never really interfaced with the medical community on the things we've been doing in the past, and to find that, indeed, some of the ideas do fit, not just mine, but others around here seem to fit into a way of thinking that makes sense to you and has some benefit is a great surprise and accomplishment of this week.

And I think I can see how it goes forward into what we want to do. So I think it's been very successful, plus sitting next to Perry here and hearing all the asides that nobody else has.

DR. RATHBUN: You wrote them down like we asked you to do, didn't you?

DR. GRIGSBY: It's my turn? From my perspective, I hope that ultimately we're not overburdened, the physicians aren't overburdened with paperwork, and that our flexibility to treat our patients isn't hindered. Those would be my two biggest concerns. We talked about that earlier.

Otherwise, our patient safety is extremely important. We make great efforts at Mallinckrodt to treat our patients in a safe manner. We welcome our visitors, both official visitors and unofficial ones, because they ask so darn many questions and how do you do this, and we find we can improve our processes because of all the question.

But I perceive that patient safety is of ultimate importance, and it's my perception that patient safety is—or that the risk from brachytherapy is greater at some institutions than it is at others, and I would like to see it improved everywhere.

DR. STITT: I feel, as Perry said, we're going to hold hands and sing a song? Have a reading?

DR. RATHBUN: We could do that.

MR. CAMPER: We could do that.

DR. HOLAHAN: We made a circle after Girl Scouts.

DR. STITT: As a physician member of the ACMUI, there's definitely going to be something going on regarding high dose rate brachytherapy, and the fascinating things I've gotten out of this meeting are that I had no idea that we, from so many different backgrounds, actually, had so much in common. There are things I'm going to go back to my institution with, and those are very personal to the institution, yet what's really on the horizon for me has to do with working as a member of the ACMUI, because something will be coming down pretty quickly.

How is that going to relate to the information to the modeling and some of the theory being translated into brachytherapy came up here? I think that the NRC is going to be making some statements soon relating to safety issues. And I don't like to be whatever overregulated is. It's hard to define. But patient safety is really what I'm concerned about. And there seems to be quite a variation in what we're seeing in practice around the country. The practicalities of that will come up in ACMUI and the NRC, and some statements will be made. That is a true statement.

DR. BUDNITZ: I guess I'm concerned that what we have here is a thumbtack, and we're trying to hit it in with a sledgehammer or maybe even a pile driver. And what I mean by that is that it may not be necessary to bring in the full-blown apparatus of a risk assessment on these problems. I spent the last ten or 15 years, and there are a bunch of us in the room that have, practicing these ways of thinking, and trying to find ways to get the most insight for the simplest and most transparent effort.

Transparency is as important as simplicity, you know, to communicate to others. And I'm worried about the possibility that complex methods won't be very understandable even as they're necessary to get certain insights. I want to warn everybody about the danger there, without arguing that the way of thinking, problemistic way of thinking about the risks is extremely important and needs to be communicated broadly.

MR. SHEPHERD: I think the thing I came away with is that we need to develop a model of the process that on the one hand does not become a burden to the medical community for us to collect data in the broadest sense, and I mean even the

pieces that go into the model, not just the number of events. But that ultimately will provide results back to the medical community that they perceive as a benefit, as well as providing to us, the regulators, something that is of benefit.

If we don't do that, then I think we will by and large fail by bringing this group together. And John was talking about the synergism, and I think there's a great deal of it here. But if we can't ultimately come up with something that's useful to both sides, we will not have really fulfilled our abilities.

MR. CAMPER: I, too, have learned a lot and have enjoyed this. Probably, as you can tell, throughout most of my comments as a program manager, I was responsible for a very busy program of which this is a component.

My concern is really about usability, implementation. We have to license; we have to inspect; we have to monitor; we have to regulate; we have to adjust.

So myself and Carl and John Glenn, we're very programmatically oriented. And how can we use what we do here?

I'm very encouraged by the group. I mean, we have a great deal of experience and knowledge here, and I think what I'm most impressed by is that you've all been very cognizant of usability and being reasonable and cost considerations. And that has permeated the theme of our discussions, and I'm very impressed by that because that's, in the final analysis, what we have to work with.

I think that the model and the plan that's been discussed yesterday afternoon and this morning appear to be on the mark. I think we've got the right kinds of considerations. I look forward to the briefing with Carl Paperiello and John Glenn and, perhaps, other senior managers as well. I think there's some things to be done between now and then as you sort of congeal all we've done here to make it a presentation to Carl, but I'm confident that will happen.

As we move ahead, I think it's important that the proceeds of meetings such as this and the findings of meetings such as this be communicated with the regulated community. I would compliment INEL in that regard on the events report NUREG that was created. I think it's an extremely useful document. There's valuable information there to be disseminated to the community, and I think there will be information from this and other meetings that will be valuable.

And then finally, I think the real important thing is that we're headed toward a major revision to Part 35. I pointed out that Carl has characterized it as wanting to interface with the world. The regulation of the medical community with regards to using radiation is not an easy task. It's a highly sophisticated industry. It is an industry that is accustomed to functioning somewhat autonomously. They feel strongly about regulation, the regulatory presence. They feel strongly about being actively involved in the process, and in all of these types of meetings, and all the ones we will hold in the public arena in the future, I hope will resolve in a significant reasonable cost effective revision of Part 35.

We'll never end up with a situation where everyone will walk away and say I'm happy with Part 35, because generally people don't like to be regulated. But it will be a public process. It will be a reasonable process, and I think this kind of collective scientific unit will make us a more meaningful product in the end.

I've really enjoyed it. I commend all of you, and thank you all for your help.

DR. WU: I'm here to represent Professor Apostolakis' group at the UCLA to share some of our experience with nuclear industry and nuclear organization in the previous project we were working on. And I hope I have bring some useful thoughts into the group. Although I think—well, with George, if he were here with his jumping up and down, it would be much more fun.

There's one point I want to bring. In the past we learned a lot that nuclear institutes and organizations, the organizations has learned a lot from communication among institute and organizations. They even brought up a new term for that. They call it organizational learning. And this issue has been addressed by more and more organization scholars.

So I think—and also, the professional society and institute has put out a lot of so-called standards, good practice so that all the institutions can learn from it and use it as an example. And some of them just adopt it, save them a lot of effort. And

I think that would be a very useful experience to learn here.

DR. BLEY: I've enjoyed these three days immensely and learned a lot about an area quite new to me and, as John, quite surprised by the unanimity of where it seems we're headed. I guess what I'd hoped for or kind of the opposite side to what Bob was saying, what I had hoped for is what's produced from the analysis is something that is very clear and very obviously highlights what's important, so that the medical community might adopt some of this in the areas where it really sees a high risk, and it could be especially useful in helping people.

The last thing I'd like to do is kind of a presumptuous challenge to the medical folks here. Having watched—and I don't want to say this as a criticism of regulation, but having been involved for about 26 years in a parallel industry of power, watching people accept additional regulation as one more thing and they'll get off my back, let's move ahead. Finally now after almost burying themselves, they're starting to cooperate rather than work in an antagonistic way. If you can work with the folks at the Commission and support the things that make sense and not accept the things that don't make sense, but show why they don't make sense and work together, with a new rule coming up it's a perfect opportunity for real cooperation to lead to sensible regulation for the good of the patients and the whole industry. I think that would be fantastic. But don't just wait for it to come, because it might not be what you want.

MR. PRATO: I'm glad to have the opportunity to be here. I've learned quite a bit, and I only returned back to the medical area after being away for about ten years for about a year, I've been very pigeon-holed in a very specialized task. And getting this perspective has really helped, and I just hope I can continue to be a part of this process. I'm sure Mr. Jordan is going to want to make every contribution he possibly can to this effort, and I just hope I'm the one that he chooses to continue on.

DR. JOHNSON: I'm here representing an organization in the Office of Research, an organization that has traditionally done most of the PRA work in the agency, and I guess I'm here because it's likely that some time in the future we will become even more involved in this particular area.

I think it's also interesting to note that there is something called a PRA Implementation Plan that hopefully has been signed off by the EDO and maybe even, as we speak here, be on its way to the Commission. I think it's important for us not to lose sight of what's going on in the—on the reactor side of the house, because they are facing the same problem that we've been discussing here for the last two and a half days. And that's how can the agency more effectively use PRA information.

It is the case that they are probably a lot further along than we are here. First of all, they have PRAs that have been completed on all of the plants that are operating in the country. And the question then remains is how do you use this stuff? And I think this gets to Larry's point that he's made over and over again, and there are a number of initiatives that are fairly far along, and I think it would be interesting to just take a look at what they are doing.

This PRA information, as far as I'm concerned, it doesn't matter how much data you gather and how much you study this. When you produce these numbers, there's always going to be large uncertainties in it. And the question is, how do you use it? And if I could characterize what's going on right now in the agency, they tend to try and identify what the important contributors are and then associate some kind of risk significance with it. And because of all the large uncertainties, these things get kind of lumped into broad categories, you know, things that are most risk significant, medium risk significance and then low risk significance. And then the challenge then is to come up with some kind of regulatory response that kind of matches this risk significance. And to some extent, that kind of accounts for some of the uncertainty that's in the process. So I think we can learn a great deal. There are at least two initiatives at the NRC that's ongoing, and they're cooperative kinds of initiatives. The industry is highly involved in these activities, so I think it would be of interest for us to just keep our eyes focused on what they're doing on that side, because it should provide some valuable information for us.

I've learned a great deal. This is my first introduction to this side of the aisle. It's been informative for me.

DR. SIU: Well, as an analyst, I guess I'll echo some of Bob's concerns, which may surprise some of you who know I like complex models. I like

putting all the details in and figuring out how everything reacts.

DR. BUDNITZ: Me too, because that's where the fun is.

DR. SIU: That's where the fun is. But clearly because of the usability issues, you do have to be careful here. And that's not to say that an event tree-fault tree methodology or whatever else is selected need be implemented in a complex way. I mean clearly, come up with trivial trees will come up with some purpose. But we do have to be a bit careful.

Like many of the other folks before, I've learned an awful lot. This is my first real exposure to this area. I think it's really neat that people are starting to look at risk in a structured way, and I'll just plug some conferences that are going to come up on risk assessment. There's one in Crete in particular in 1996, where we would like to see contributions for people involved in this area, because this is a new application of risk assessment. I'll let it go at that.

DR. GLASGOW: Well, I want to commend INEL on the quality of their popcorn. It's really some of the best that I've had.

DR. BUDNITZ: And it's only 50 cents, too.

DR. GLASGOW: No, I have enjoyed the experience. I appreciate the invitation, and I hope I've managed to contribute significantly.

I am concerned. I'll share with you a variety of those concerns rather quickly. In response to the comment about can professional organizations put forward standards, yes, we do. In fact, we haven't commented on it, but there is a new AAPM document called Task Group Report 40, which has just been published and has extensive quality assurance procedures for physicists to perform on high dose remote afterloader units. Plus, a variety of other medical instruments that are in the field. Unfortunately, the general response to this document at our national meeting was from the membership was you can't really expect us to do all of that, because there isn't time. There are constraints; there are cost constraints; there are time constraints. So on the one hand, the organizations make a good effort to identify good practice and good standards, but clearly the application of those in the medical community on a voluntary basis is not widespread.

Generally the medical community knows what they should be doing in order to carry out the safety of radiation. The problem is that it is not done. It's simply not followed for a variety of reasons. And for that reason and that reason alone, while we will see continued regulation, I believe, of the industry, because it does have the potential for lethal incidents. And I must add that there are evolving technologies not under regulatory control which use radiation, particularly the linear accelerators and external beam radiotherapy treatments where the potential for lethal events exist. So I don't believe that regulatory concerns over the next ten years will be less. I think that they, unfortunately, will likely be required in order to bring the medical community into compliance. Because like it or not, regulations do their job. They are burdensome in some sense, but they do bring to a group or to a hospital a level of performance which otherwise might not be performed.

I must say, though, that I'm not sure that the mechanism of risk analysis that you're following here, as I understand it based upon applications to other large-scale systems, is really going to work on what is essentially a small-scale project. I have some of the same concerns that others have expressed here. It really is a strong tool. There may be other methodologies or mechanisms that could put in place the regulations in a more straightforward fashion.

DR. CALLAN: I thank you all for inviting me to join this group. After having spent four years at the very detailed level of man machine interface in the individual stages in the process in the small clinics and hospitals, I appreciate the opportunity to gain this public health regulatory perspective that we've had for the last several days. It's been very valuable to me, and I want to thank the INEL for including me and the NRC.

DR. HOLAHAN: I'd like to again reiterate that I appreciate this workshop. I've learned a lot. I now understand a lot of new acronyms I've learned.

But I'd like to reiterate some of what Bob and Larry had said. I think with all this modeling is not to get burdened and weighted down with the numbers, but come up with something that's user friendly, both for the regulatory agency and also

for the medical community, that we could perhaps go out with something and help them, as well as the NRC.

DR. POLLYCOVE: I've noted a concern about outliers and where, perhaps, a large number of problems come from. And the balance to me that seems to be struck is regulations that will affect this area, and at the same time not compromise or inhibit or, in fact, eliminate the good work that's being done in a majority of large institutions, and that's the problem.

Obviously the large institutions feel that they know what they're doing, and it's correct, and they're doing a good job. They're exemplary in many respects, and to have this needless burden, which is putting them at a disadvantage with regard to the amount of personnel, cost, competition with other modalities and so forth, to them is irrational and needless.

But they don't see what we see in the headquarters, the outliers and the sort of things that can happen in other situations. So how to, with a minimum amount of regulation, deftly crafted to clean up that area without inhibiting the majority of good people that are doing this safely. And that's where the problem is.

And, again, as far as the PRA and the nomenclature and this orientation, I appreciate it very much, and I enjoyed it.

DR. RATHBUN: I've probably said plenty throughout this day, but I do want to again thank all of you. It's just been tremendous. And I would also especially like to thank the INEL, because you've done a wonderful job.

John and Harold have taken their personal time from a very busy management schedule to help us, and I think that that has been the key to success. And I would like to thank Jim, who has done a yeoman's job in pulling everything together. We've had a long and very successful relationship with the INEL and these projects have not always gone easily, but we've gotten out, I think, a very good product and timely and really look forward to moving into this next phase of the work.

DR. BICKEL: Thank you. With that, it's a wrap.

(The hearing was adjourned.)

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10. SUPPLEMENTARY NOTES

11. ABSTRACT *(200 words or less)*

A workshop was held at the Idaho National Engineering Laboratory, August 16-18, 1994, on the topic of risk assessment on medical devices that use radioactive isotopes. Its purpose was to review past efforts to develop a risk assessment methodology to evaluate these devices and to develop a program plan and scoping document for future development. This report presents a summary of that workshop, related technical papers, presentation material, and a transcript of the workshop. Participants included experts in the fields of radiation oncology, medical physics, risk assessment, human-error analysis, and human factors. Staff from the U.S. Nuclear Regulatory Commission (NRC) associated with the regulation of medical uses of radioactive materials and with research into risk-assessment methods participated in the workshop. The workshop participants concurred in NRC's intended use of risk assessment as an important technology in the development of regulations for the medical use of radioactive material and encouraged the NRC to proceed rapidly with a pilot study. Specific recommendations are included in the executive summary and the body of this report.

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