NUREG/CP–0144
INEL–94/0111
Vol. 1
CONF-9408251--Vol.1

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

Summary

Edited by J. P. Tortorelli

Idaho National Engineering Laboratory
Lockheed Idaho Technologies Company

Prepared for
U.S. Nuclear Regulatory Commission

Reprinted October 1995

AVAILABILITY NOTICE

Availability of Reference Materials Cited in NRC Publications

Most documents cited in NRC publications will be available from one of the following sources:

1. The NRC Public Document Room, 2120 L Street, NW., Lower Level, Washington, DC 20555-0001
2. The Superintendent of Documents, U.S. Government Printing Office, P. O. Box 37082, Washington, DC 20402-9328
3. The National Technical Information Service, Springfield, VA 22161-0002

Although the listing that follows represents the majority of documents cited in NRC publications, it is not intended to be exhaustive.

Referenced documents available for inspection and copying for a fee from the NRC Public Document Room include NRC correspondence and internal NRC memoranda; NRC bulletins, circulars, information notices, inspection and investigation notices; licensee event reports; vendor reports and correspondence; Commission papers; and applicant and licensee documents and correspondence.

The following documents in the NUREG series are available for purchase from the Government Printing Office: formal NRC staff and contractor reports, NRC-sponsored conference proceedings, international agreement reports, grantee reports, and NRC booklets and brochures. Also available are regulatory guides, NRC regulations in the *Code of Federal Regulations*, and *Nuclear Regulatory Commission Issuances*.

Documents available from the National Technical Information Service include NUREG-series reports and technical reports prepared by other Federal agencies and reports prepared by the Atomic Energy Commission, forerunner agency to the Nuclear Regulatory Commission.

Documents available from public and special technical libraries include all open literature items, such as books, journal articles, and transactions. *Federal Register* notices, Federal and State legislation, and congressional reports can usually be obtained from these libraries.

Documents such as theses, dissertations, foreign reports and translations, and non-NRC conference proceedings are available for purchase from the organization sponsoring the publication cited.

Single copies of NRC draft reports are available free, to the extent of supply, upon written request to the Office of Administration, Distribution and Mail Services Section, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

Copies of industry codes and standards used in a substantive manner in the NRC regulatory process are maintained at the NRC Library, Two White Flint North, 11545 Rockville Pike, Rockville, MD 20852-2738, for use by the public. Codes and standards are usually copyrighted and may be purchased from the originating organization or, if they are American National Standards, from the American National Standards Institute, 1430 Broadway, New York, NY 10018-3308.

NUREG/CP–0144
INEL–94/0111
Vol. 1

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

Summary

Manuscript Completed: May 1995
Date Published: August 1995

Edited by J. P. Tortorelli

Idaho National Engineering Laboratory
Lockheed Idaho Technologies Company
Idaho Falls, ID 83415

Prepared for
Division of Industrial and Medical Nuclear Safety
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555–0001
NRC Job Code L1939

HH

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.

CONTENTS

VOLUME 1: SUMMARY

A WORKSHOP ON DEVELOPING RISK ASSESSMENT METHODS FOR MEDICAL USE OF RADIOACTIVE MATERIAL

APPENDIX A
WORKSHOP PAPERS AND REFERENCE MATERIAL

VOLUME 2: SUPPORTING DOCUMENTS

APPENDIX B–PART 1
PRESENTATION SLIDES

APPENDIX B–PART 2
DISCUSSION NOTES

APPENDIX C–TRANSCRIPT

EXECUTIVE SUMMARY

Overview

A workshop was held at the Idaho National Engineering Laboratory (INEL), 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.

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 attended the workshop. Other experts were invited to provide the perspective of the wider technical communities. Some of these experts had participated in preliminary risk assessments to evaluate various methodologies in this area.

The workshop began with presentations in several areas: NRC regulatory programs; medical uses of radioactive material; probabilistic risk assessment (PRA) methods; and analysis and modeling of human errors and human performance.

Following these presentations, discussion sessions allowed the participants to explore areas of interface between the technical disciplines, the extent of medical device performance knowledge and data, the applicability of existing, new and developmental PRA and HRA methods, and strategy of applying these methods to the medical use of isotopes.

The workshop ended with several specific recommendations for the NRC:

- A demonstration quantitative risk assessment of a specific medical device and modality should be performed now
- PRA event and fault trees supplemented by generic error modeling should be used
- An estimated denominator should be established
- The demonstration risk assessment should be used as a baseline and foundation for future studies.

Overall, it was the opinion of the attendees that performance of a risk assessment would be consistent with developing NRC policy on risk-based regulation.

Benefits

Several benefits to both the users and the NRC from risk assessment and human reliability analysis were identified.

The licensees, by performing an analysis on a device or process, could identify the different human errors or equipment failures that could result in unwanted outcomes before these errors or failures actually occurred. The licensee could then take physical or procedural steps to reduce the potential hazard.

The results of a formal risk assessment could serve as a framework for discussions between licensees and the NRC (and others in the regulatory community, e.g., the U.S. Food and Drug Administration). These discussions could lead to alternatives to proposed regulatory actions that would achieve the same results but be more efficient in terms of facility operations. This has been found within the nuclear power plant community to be an important benefit, and has, in part, led to all such facilities having risk assessments performed.

The workshop participants generally agreed that it would be appropriate and reasonable for NRC to base regulations on the results of risk assessments. The use of risk assessment methods would be in accordance with NRC's plans to rely further on risk-assessment methods as described in the recent NRC policy statements—*Proposed Policy Statement on the Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities, SECY-94-218,* Washington, D.C.,

August 18, 1994; and U.S. Nuclear Regulatory Commission, *Proposed Agency Wide Implementation Plan for Probabilistic Risk Assessment (PRA), SECY-94-219*, Washington, D.C., August 19, 1994.

(cf. Appendices A-1, A-2)

Discussions

Potential sources of data were identified, some of which will become more standardized among the Agreement States* in 1995. Trial applications will determine the extent of the data needed.

Human errors were found to be a very large contributor to misadministration events; about 86% of events studied to date involved a primary contribution from human errors. However, human errors are themselves influenced by the design or operability of equipment and from particular organizational factors in the facilities. Risk-assessments conducted today typically only provide partial modeling of these causes of human error. Discussions at the workshop and elsewhere indicated that improvements in the risk assessments and risk assessment methods are needed. It was noted that other research programs exist at NRC and elsewhere that can provide important insights in this area.

Finally, risk assessment methods use some criterion to define an outcome as unacceptable. In the case of nuclear power plants, for example, a common criterion is damage to the radioactive fuel in the core—this is also an example of an outcome-based requirement. In the case of medical misadministrations, the criteria include a dose variance of a certain percentage, a dose to the wrong site, or a dose to the wrong patient (compared with the prescribed treatment). These are performance based criteria and do not necessarily correlate with equivalent effects to the patient's health. The workshop participants recognized that performance-based requirements are necessary since the NRC policy is to avoid the practice of medicine and outcome-based requirements would require medical judgment. Several performance-based comments for consideration in the next rule review were offered.

Conclusions & Recommendations

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. It was recommended that NRC follow a program of incremental developments to improve the accuracy and veracity of the risk assessments. The participants outlined a plan for the NRC. This program would seek to improve the availability of relevant event data associated with misadministrations and the accuracy of modeling human errors and their causes.

The first study should be of a well-understood process—possibly low dose rate brachytherapy. Improvements in human-error modeling should be integrated into the risk-assessment logic modeling process, together with bounding data.

This development process was recommended to be started now and performed incrementally so that the methods can be developed, employed and evaluated in a controlled fashion.

* "Agreement State" means any State with which the U.S. Nuclear Regulatory Commission or the Atomic Energy Commission has entered into an effective agreement under subsection 274b of the Atomic Energy Act of 1954, as amended.

FOREWORD
by NRC Staff

This report, prepared by the INEL, summarizes the views and opinions of participants in a workshop designed to review past efforts to develop a risk assessment methodology to evaluate radiation-emitting medical devices containing byproduct material. Based on this workshop, the INEL recommends: 1) performance of a demonstration quantitative risk assessment of a specific medical device and modality; 2) use of PRA event and fault trees supplemented by Generic Error Modeling; 3) establishment of an estimated denominator; and 4) use of the demonstration risk assessment as a baseline and foundation for future studies.

The NRC staff recognizes that this workshop presented a unique forum in which many diverging opinions were presented, including those of the medical and risk analysis communities. The staff is considering implementing recommendations 1, 3, and 4. However, because of the preponderance of human error and minimal redundancy of hardware safety systems, as well as the paucity of data on system failures in the medical arena, the staff has serious reservations about the choice of classic PRA using fault trees as the most cost-effective approach. The staff plans to continue development of a risk analysis methodology for radiation-emitting medical devices.

ACRONYMS

AEOD	Office for Analysis and Evaluation of Operational Data, US Nuclear Regulatory Commission
AHP	analytical hierarchical process
CFR	Code of Federal Regulations
HDR	high dose rate
HRA	human reliability assessment
INEL	Idaho National Engineering Laboratory
LDR	low dose rate
NMSS	Office of Nuclear Material Safety and Safeguards, US Nuclear Regulatory Commission
NRC	US Nuclear Regulatory Commission
PRA	probabilistic risk assessment
QA	quality assurance
QM	quality management
RES	Office of Nuclear Regulatory Research, US Nuclear Regulatory Commission
WPAM	work process analysis method

VOLUME 1: SUMMARY

A WORKSHOP ON DEVELOPING RISK ASSESSMENT METHODS FOR MEDICAL USE OF RADIOACTIVE MATERIAL

1. INTRODUCTION

1.1 Purpose

A workshop was held at the Idaho National Engineering Laboratory, August 16–18, 1994 on the topic of 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.

1.2 Overview

Attendees included experts in radiation oncology, medical physics, risk assessment, human-error analysis, and human factors; and U.S. Nuclear Regulatory Commission (NRC) staff associated with the regulation of medical uses of radioactive materials and with research into risk-assessment methods. Other experts were invited to provide the perspective of the wider technical communities. Some of these experts had participated in preliminary risk assessments to evaluate various methodologies in this area.

The workshop consisted of three parts. The first part was a series of presentations concerning the primary topics: NRC regulatory programs, the medical uses of radioactive material, the technology of risk assessment, and the issues associated with the analysis and modeling of human errors. Several presentations were based on, or related to, prepared papers; copies of these papers are included as Appendix A. Copies of the presentation materials are included as Appendix B. The presentations were followed by the discussion sessions in which all attendees provided input in response to posed questions or topics. The transcript of the workshop is included as Appendix C. The workshop ended with a summary session in which the majority of the participants agreed upon several specific recommendations for the NRC:

- A baseline, quantitative risk assessment of a specific medical device and modality should be performed now
- PRA Event Trees/Fault Trees and HRA GEMS should be used
- An estimated treatment denominator should be established
- This risk assessment should be used as a foundation for future studies and development.

Overall, it was agreed that performance of a risk assessment would be consistent with developing NRC policy on risk-based regulation.

2. PRESENTATIONS

2.1. Disclaimer

The views and conclusions contained in this document are those of the authors and should not be interpreted as necessarily representing the official policies, either expressed or implied, of the United States Government, the Idaho National Engineering Laboratory, or Lockheed Idaho Technologies Company. Any use of trade names or trademarks in this publication is for descriptive purposes only and does not constitute endorsement by the U. S. Nuclear Regulatory Commission.

2.2. Regulatory Background

NRC staff present at this workshop provided a series of summary presentations.

2.2.1 NRC's Role in the Medical Use of Radioactive Material

NRC is required by the Atomic Energy Act of 1954, as amended, to regulate the medical use of radioactive material to protect the health and safety of the public. The scope of these regulations includes the storage and uses of the radioactive material, the training and qualifications of the personnel, the performance of radiation surveys, and the use of quality management (QM) programs. These regulations are set out in Title 10 of the Code of Federal Regulations (10 CFR), with most of the medical uses covered by Part 35 of that title (10 CFR 35). (Occupational worker dose limits are prescribed in 10 CFR 20.)

NRC does not regulate the clinical judgments of physicians.

In a policy statement published on February 9, 1979 (44 FR 8242), entitled "Regulation of the Medical Uses of Radioisotopes: Statement of General Policy," the NRC stated:

> (1) The NRC will continue to regulate the medical uses of radioisotopes as necessary to provide for the radiation safety of 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.
>
> (3) The NRC will minimize intrusion into medical judgments affecting patients and into other areas traditionally considered to be a part of the practice of medicine.
>
> The NRC has the authority to regulate the medical use of byproduct material or radiation from byproduct material to protect the health and safety of patients, but also recognizes that physicians have the primary responsibility for the protection of their patients. NRC regulations are predicated on the assumption that properly trained and adequately informed physicians will make decisions that are in the best interest of their patients.
>
> NRC's Responsibilities
>
> The NRC distinguishes between the unavoidable risks attendant in purposefully prescribed and properly performed clinical procedures and the unacceptable risks of improper or careless use. The NRC is responsible, as part of its public health and safety charge, to establish and enforce regulations that protect the public from risks of improper procedures or careless use.

The point of reference, then, for determining whether administration of radiation is a misadministration is the physician's prescription.

(cf. Appendices B-13, C-1.3)

2.2.2 Risk Assessment in NRC Regulatory Programs

NRC is presently evaluating a proposed agency-wide policy on the use of risk assessment in regulatory programs. This policy is described in *Proposed Policy Statement on the Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities, SECY-94-218,* Washington, D.C., August 18, 1994; and U.S. Nuclear Regulatory Commission, *Proposed Agency Wide Implementation Plan for Probabilistic Risk Assessment (PRA), SECY-94-219,* Washington,

D.C., August 19, 1994. Both of these are included in Appendix A. If adopted, this policy would support and endorse the use of risk assessments, which would provide a basis for improved regulatory decision-making; more efficient use of agency resources in focusing efforts on the most safety-significant issues; and a reduced industry burden in responding to less safety-significant issues.

(cf. Appendices A-1, A-2, B-1, C-2.1)

2.2.3 Development of Risk Assessment Technology

Section 4.1 in the proposed implementation plan associated with the policy statement, includes the need for development of risk-assessment methods "to assess most likely failure modes and human performance in the use of industrial and medical radiation devices." Specific objectives associated with this need extend over a period of years. They include:

- Validation of the risk assessment methodology, including holding this workshop, with experts in risk assessment and human reliability assessment (HRA) to examine existing work and recommend further methodological developments; examine the application of Monte-Carlo simulation methods to risk profiling; examine the use of expert judgment in developing error rates and consequence measures; and conduct a series of HRA benchmarking and cross-validation exercises;
- Development of the relative risk methodology; and
- Development of user-friendly computerized guidance of risk-assessment methods for licensees.

(cf. Appendices B-13, C-5.1)

2.3. Medical Uses of Radioactive Material

These presentations addressed issues and concerns associated with the medical uses of radioactive material as they may relate to the use of risk assessment in regulation.

2.3.1 Introduction to Medical Issues

This presentation summarized the perspective of NRC and its regulation of medical misadministrations.

A primary focus of NRC's regulatory activities has been on controlling the occurrence rates of misadministration events. Misadministration events are defined in 10 CFR 35 for radiopharmaceuticals, brachytherapy, teletherapy, and gamma stereotactic surgery. In addition to prescriptive regulations concerning such factors as training of physicians and teletherapy physicists, surveys and checks of radiation levels, uses and storage of sources, and so on, NRC has developed a quality management (QM) rule that has been in place since January 27, 1992(Code of Federal Regulations, Title 10, Section 35.32), to ensure administration is in accordance with the written directive. A collection of the QM requirements of the NRC and other professional organizations relating to remote afterloading brachytherapy is summarized in NUREG/CR–6276.

(cf. Appendices B-7, C-3.1)

2.3.2 Treatment Variations & Consequences

This presentation identified some of the complexities involved in attempting to set criteria for unacceptable-outcomes related to medical misadministrations beyond the simple wrong-site and 20%-variance criteria established by NRC.

As shown in the presentation materials in Appendix B, there are numerous intervening variables that can determine whether a dose of some variance is likely to cause a significant adverse health effect. These include:

- The margin between the dose needed to ablate the tumor cells and the sensitivity of the normal tissue along the radiation-dose path. If there is a wide margin, increases in the tumor-killing dose may have a small impact on healthy tissue. If there is a narrow margin, then even a small excessive dose could cause extensive necrosis of the healthy tissue. One effect of chemotherapy or other concurrent treatment can be to change these sensitivities, both absolutely and relatively.
- The sensitivity of particular organs or regions to radiation doses. Certain organs or regions of the body are subject to the development of a range of sequelae (complications) because of

radiation treatments even at commonly prescribed doses. These can range from minor acute symptoms (such as hoarseness and coughing for treatment to the lungs) to major complications (such as progressive fibrosis of the lungs). Such sequelae (even death) following treatment would not necessarily be indicative of any misadministration.

- Sensitivity variations between patients. Each patient, besides having a unique geometry and stage of disease, will respond differently to radiation treatment to some degree. While usually small, these variations between individuals contribute to the variations in treatment success and complication severity.
- The potential for harm from under-treatment. Unlike many other situations faced in risk assessments, *safer* does not always equate to *lower dose*. In radiation oncology, patients are already sick, often terminally. Therefore, any risk assessment must consider that doses lower than prescribed may have the consequence of failing to cure a disease which could then become fatal.

In addition to the uncertainties between dose-variance and health effects, there are uncertainties associated with treatment site. Radiation prescriptions allow for some uncertainty in the location of the target tumor, which itself will probably not have a distinct boundary with healthy tissue. Therefore significant doses of radiation may be delivered to healthy tissue during a normal course of treatment.

Finally, it is not unusual for there to be some adverse reaction by healthy tissue to a properly administered dose, and no detectable adverse reaction to a misadministration.

(cf. Appendices B-8, C-3.2)

2.3.3 Misadministration Events

This presentation described the activities undertaken by the INEL in performing investigations of misadministration events on behalf on NRC; this work has been published in NUREG/CR-6088. Two phases of work have been undertaken.

First was the evaluation of NRC reports collected by AEOD and those reported in NUREG-0090 relating to misadministration events in the years 1987 to 1992. This evaluation found that although only a small number of facilities reported multiple misadministration events, multiple misadministrations made up 60% of the patients in the database. The major causes of multiple misadministrations were associated with the use of computer programs or data entry activities. For single-misadministration events, the dominant causes were procedural inadequacies, professional errors (such as slips and lapses in performing arithmetic computations or in dose administration), and communication problems. It was concluded that proper implementation of the QM plan was at least somewhat likely to have prevented the vast majority (~94%) of previous medical misadministrations.

The second phase of work is the on-going, on-site investigation of misadministration events soon after they are discovered. These investigations are performed by multi-disciplinary teams involving at least three team members and cover the disciplines of radiation oncology, medical physics, nuclear medicine, risk assessment, and human factors. NUREG/CR-6088 presents the results of investigations of seven events; other investigations are continuing. The factors identified as important include: unique conditions or changes in routine; lack of, or use of ambiguous, procedures; and lack of substantial participation by authorized users and radiation safety officers. So far, hardware failures have rarely been involved, but were associated with severe consequences.

It was observed that many of the facilities had not implemented their QM programs effectively. Further, once an event had occurred, corrective actions were narrow in focus and lacked any systematic approach to identifying and correcting the causes or consequences of misadministration events.

While these investigations are labor-intensive, they seem to be the only source of data that yields the level of detail of the human contribution for improved HRA methods to be developed in this area.

(cf. Appendices B-2, C-2.2)

2.4. Risk Assessment Methods and Issues

These presentations used past work to illustrate traditional risk assessment methods and highlight concerns with respect to their use in medical analyses.

2.4.1 Risk Assessment Tools

Risk assessment is an analysis process that examines the likelihood and consequences of postulated events (NUREG-1050). Risk assessment methods were first developed in the late 1960's in the aerospace industry for application in the development of weapon systems for the Department of Defense, and for the Apollo lunar-landing program. Subsequently, the technology was adopted and developed by the Atomic Energy Commission for application to the U.S. nuclear power industry. The first widely published risk assessment, the Reactor Safety Study (WASH-1400/NUREG-75/014), established the basic elements that, while refined and extended, still comprise the major elements of risk assessment.

The risk-assessment process starts with identifying a series of postulated events—usually called initiating events—that has the potential to lead to some unacceptable outcome, such as harm to a patient. Logic models called event trees are developed by the risk analysts to identify what additional events (called top events) must occur and in what combination or sequence for the initiating event to result in an unacceptable outcome. The event tree identifies these particular combinations of top events in a graphical form, usually called accident sequences. In some studies, the likelihood of each accident sequence is quantified through calculations with the probabilities and the frequencies of the particular top and initiating events.

In some cases data may already exist to provide the probabilities of each top event in the sequence, in which case the arithmetic process is simple and direct. In other cases where data may exist, not for the event itself but for the causes of the event, fault tree models are created. Fault trees are a separate logic model from event trees, but are related in the following way. A fault tree will represent graphically the range of causes (such as human errors or equipment failures) for a top event. The fault tree is created by using a series of gates that portray whether the top event comes about from single causes or whether combinations of failures are needed to cause the top event. Boolean logic is then used to calculate the probability of the top event based on the various causes.

Once the event sequences have been identified and quantified, straight-forward techniques exist to determine which events in the event tree and their corresponding causes in the fault trees are the most important factors.

Specialized techniques have been developed for evaluating human errors (as discussed below), and the influence of common-cause failures in risk assessment models. These errors and failures can overwhelm the implicit assumption that the probabilities of the top events in the event trees are independent of each other.

The strengths of this approach include:

- It provides a graphical representation of the process and the failures necessary to obtain an unacceptable outcome;
- It provides estimates of the likelihood of unacceptable outcomes that can enable a comparison between outcomes; and
- It is a well-established methodology used extensively in other fields (though not in medicine) and its use by NRC is supported in the NRC's impending policy statement on the use of risk assessment in regulatory activities (See Appendix A-1).

There are potential limitations in this approach, however. These are:

- Data associated with specific top events or their causes may not be readily available, and could require the gathering of additional reliability data (this limitation is not unique to this method);
- The technique has not been applied directly to this or any other medical application (as presently known); however, no fundamental limitation in its potential use here is foreseen.

(cf. Appendices A-7, B-10, C-4.3)

2.4.2 High-Dose-Rate Brachytherapy Risk Evaluation

In order to evaluate the feasibility of using risk assessment methods for medical misadministrations, a limited application was performed for misadministrations during the use of an HDR brachytherapy remote afterloader. The study was intended to identify:

- what knowledge base is required to perform such a risk assessment;
- how effectively event-tree, fault-tree, and human-reliability techniques might represent the causes of misadministration events;
- relative importance of failures of hardware verses human errors in misadministration events; and
- how effective might QA/QM practices be in minimizing misadministrations.

Sufficient information concerning the operation of an HDR remote afterloader was available from several sources to create the logic models. Data associated with hardware failures were sparse and, in some cases, non-existent, so expert estimates were required. Human errors were modeled using standard techniques and could be represented appropriately in the models.

The analysis indicated that human factors deficiencies in the machine controls were a major concern and, consequently, the role of the medical physics staff in preventing misadministrations was vital. Similarly, the knowledge and skills of the physicians with respect to the performance of the treatment were of critical importance.

The role of the medical physics staff in the quarterly QA activities associated with a source change were also important.

The conclusion of this study was that fault trees could effectively and reasonably represent the risks associated with using HDR brachytherapy remote afterloaders. The next steps recommended were additional site visits, construction of site specific process models and logic models, and comparison of the models.

(cf. Appendices A-3, B-3, C-2.3)

2.4.3 Gamma Knife Risk Evaluation

In order to evaluate alternative approaches to the traditional risk assessment methodology, a risk assessment of the Gamma Knife device was performed. Rather than using event and fault trees, and human reliability modeling, this study used relative-risk-ranking.

In this study, the entire process was divided into a sequence of component processes, and hazards in the processes were selected for examination. Then, using expert opinion and available data, the identified hazards are given a rank relative to each other in their consequence and again for their frequency.

After iterating, a consensus is reached for the ranking that best represents what the experts believe to be the sources of greatest relative risk.

This study did not anchor the risk scale, it does not provide an estimate of the absolute frequencies or consequences of misadministration events. It does indicate where and why the more frequent misadministrations will occur regardless of the overall frequency.

(cf. Appendices B-6, C-2.7)

2.4.4 Data Needs and Collection

Traditional risk assessment techniques rely heavily on the use of data, such as equipment failure probabilities, human error probabilities, and the frequencies of initiating events. However, these are not the only data needs. In order for NRC to assess the effectiveness of its regulatory programs, it must also be known how often misadministrations are occurring, how significant the misadministrations are, and whether there are any trends.

NRC has established requirements for licensees to report certain kinds of data, especially event data such as the occurrence, causes, and circumstances surrounding a misadministration event, but these data are not sufficient for the purposes of risk assessments. For risk assessments, the data must include the number of failures and the number of successes in order to get a ratio. However, success data are not reported to NRC. The self-analyses of causes of misadministrations vary from one facility to another both in detail and accuracy. This makes data combination nontrivial. Reports of misadministration events are relatively rare because of the overall high quality of the system;

therefore, the data are statistically very limited with respect to use in risk assessments.

These limitations are not unique to the analysis of misadministrations; similar limitations apply in nuclear power-plant applications and aerospace studies where real-world failures are few. Therefore, the risk-assessment community has developed ways of compensating for such limitations. These include the use of generic data (such as electrical equipment data gathered from different industries), the use of bounding data and sensitivity analyses, and the application of modeling techniques (particularly for human errors and common-cause failures). Those misadministration events that do occur can be used to calibrate these alternative methods. However, actual event data would provide more scrutable results.

It is recognized that additional sources of data exist. For example, the total number of administrations at a facility will be recorded in the facility records and the patient-billing data. Summaries of these data are often provided to outside organizations for other purposes. NRC should consider these possible sources for use in risk assessments. Trial applications with some limited additional data would indicate whether further data gathering is necessary and its costs. This would help determine which data should be collected.

(cf. Appendices B-12, C-4.5)

2.5. Human Errors and Human Performance

These presentations addressed the methods available to perform human reliability assessments in medical procedures, and described some of the work already conducted

2.5.1 Human Reliability Assessment

As mentioned above, the analysis of human errors and the representation of their role as causes of unacceptable outcomes are a part of risk assessment. For the types of events described in the event investigation, human performance made a significant contribution to the misadministrations. Therefore it is important that the reliability of humans be included in the risk assessment process.

The approach presently taken in identifying human errors is through the use of a systematic identification of all the actions that must be performed correctly to prevent an unacceptable outcome from occurring. The process for performing this structured identification is called a task analysis. A task analysis involves extensive analysis of procedures and training materials, discussions with practitioners, and walk-throughs of activities, to identify every important human-system interaction. The task analysis can identify time-critical steps and opportunities for the detection and recovery from failures. Once the task analysis has identified the necessary steps, ergonomic evaluations of the controls and indications, the procedures, and the levels of stress can be performed, along with assessments of other influences like organizational factors and distractions.

Once these evaluations of the necessary actions have been made, the HRA process creates logic models that portray the individual and sequential human errors that must occur to cause failures of equipment or processes. Failure probabilities are then assigned to the individual errors using standards HRA techniques, and then combined using Boolean algebra to produce an overall probability of human error for inclusion in the PRA.

The use of this approach allows the analyst to evaluate the impact of changes in the ergonomic factors, training, and so on. This can be used to identify specific improvements that would reduce the probabilities of those errors modeled in the analyses.

(cf. Appendices A-4, B-9, C-4.2)

2.5.2 Human-Factors Evaluation of Remote Afterloading Brachytherapy

As part of a separate NRC/RES program, a detailed description and analysis of the human factors associated with brachytherapy using high-dose-rate remote afterloading systems were made. (Results not yet published.) Its goals were to identify the factors that contribute to human errors, evaluate the impact of these factors on function and task performance, prioritize the performance problems, and identify and evaluate alternative modifications for improving performance.

The evaluation began with a description of the overall processes involved in performing HDR brachytherapy, followed by a detailed function and task analysis involving walk-throughs of each staff

member's job and its human-machine interfaces, procedures and practices. Training and organizational support were also taken into account. For each step in the task analysis, potential errors were identified from NRC and FDA reports, staff interviews, and evaluations of the work setting. Errors and their likelihoods were estimated, and the impacts of errors on other steps in the task analysis were assessed.

The result of this analysis was the identification of ten critical tasks in which human errors were likely in one or more steps, and the consequences of which could be a misadministration to the patient or staff member. The ten are:

- Patient scheduling and tracking
- Applicator selection, placement, and stabilization
- Target volume localization
- Dwell position localization
- Dosimetry
- Treatment set-up
- Treatment plan entry
- Routine QA and Maintenance
- Source replacement
- Source Calibration.

For these critical tasks, modifications to improve the performances were identified; these included improvements in the human-machine interface, job-performance aids, procedures, and so on.

(cf. Appendices B-5, C-2.6)

2.5.3 Organizational Factors

This presentation described work performed to develop methods to include the systematic influences of organizational factors in risk assessments. It used as its point of reference the concept of a work process: a standardized sequence of tasks designed with the objective of achieving a specific goal within the operational environment of an organization. This work process analysis method (WPAM) involves several stages of evaluation.

The first stage is the development of a work-process model that describes the principal steps in the tasks being performed. This uses an analysis similar to the function and task analyses described earlier, though not in the same detail as required for the human reliability and human factors analyses. The analysis then examines each step identified in the work process to find where "barriers" (built-in administrative defenses such as reviews or supervisory activities) should prevent misadministrations. Checklists are then used to identify possible deficiencies in the design and field application of procedures, and their implementation of the steps in the work process.

Next, assessments are made of the behavioral deficiencies. The deficiencies are rated against behaviorally anchored rating scales (BARS). BARS allow the subjective assessment of the identified deficiencies by providing specific examples of representative good, average, and poor performance for the particular factors. (For example, how effective is the problem-identification process within the organization?).

By the use of appropriate calculational processes such as the analytical hierarchical process (AHP), these deficiency assessments can be converted to probabilities for use in the risk-assessment process. Perhaps what is more important, the significance of organizational issues causing weaknesses in operations can be highlighted, together with their associated behavioral factors.

(cf. Appendices B-4, C-2.4)

2.5.4 Generic Error Modeling

In the development of risk assessment methods for the Reactor Safety Study, human-system interactions were viewed largely as just another cause of equipment failures; an operator failing to start a pump was no different (as far as the pump operation was concerned) from a mechanical or electrical fault. Human errors were principally portrayed in the fault trees as another cause of equipment failures. However, following the accident at Three Mile Island, where operator errors were much more extensive and *systematic*, it became clear that the human participation in major incidents went beyond the level of disabling individual items of equipment. As a result, method developments in the area of HRA have continued.

The work presented here has been performed largely as part of another NRC project. The thesis of this work is that, at least for professional set-

tings, people are very reliable except when circumstances cause them to fail. It is the frequency of these circumstances that is most influential for predicting human errors. The goal of this project has been to develop a way of describing what these circumstances are so that their frequencies can be assessed.

While this work is not yet complete, preliminary results indicate that by far the greatest feature of failure-prone circumstances is that the activity is being performed in a significantly off-normal mode. In medical misadministrations this could include a significant increase in workload or the use of temporary substitute workers. The effect of these off-normal conditions (called contingent conditions) is to nullify several of the barriers that are effective for normal operations. As a result, errors that would either not normally be possible, or would be detected and corrected, instead lead to a misadministration.

One of the goals of this project is to develop an improved HRA method that corresponds more closely to the roles of human errors found in major accidents. Event analyses using the perspective of human errors in major accidents are being used in nuclear power plant settings, and have been applied to misadministration event reports. In these cases, it effectively identifies the causes of those errors important in the events.

(cf. Appendices A-5, A-6, B-11, C-4.4)

3. DISCUSSIONS

Following the presentations, there was a period of group discussions. These discussions focused on clarifying:

- The relevance of how risk assessment relates to the medical uses of radioactive material
- What aspects of risk assessment technology in this application may be different from other applications
- What data are required to be successful in applying risk assessment technology in this area
- How medical applications can be modeled using risk-assessment methods
- What special considerations need to be addressed in these applications.

3.1 Risk Assessment for Medical Uses of Radioactive Material

Risk assessment could provide a framework for combining the different causes of misadministration events involving medical sources, together into a single analytical picture so that the impact of the different causes could be compared, and an overall measure of safety could be assessed for a particular modality. Data from near-miss events and partial failures can be combined through the use of logic models to estimate the likelihood of misadministrations before they occur. Because a risk assessment represents causes of failure, the effectiveness of regulatory programs that address these causes can be assessed before they are put into practice. Thus, NRC can compare the likely effectiveness of changes in regulations against the costs of implementing the regulations. As discussed in the NRC's Policy Statement concerning the use of risk assessment in regulations, this will increasingly become the process for regulation by the commission.

Risk assessment, as a technology, has been applied to nuclear power plant operations since the mid-1970's. Its application to the medical uses of radioactive material is still developmental, and some components of the methodology require improvement. Discussions identified several areas for potential improvement or modification for this particular application, as discussed below.

(cf. Appendix C-6.1)

3.2 Data Requirements

To use risk assessment methods effectively, it is important that all relevant information be included. This includes experienced failure data for particular pieces of equipment and a structure to relate these data to scenarios for which no data yet exist.

Risk assessment activities in the nuclear power industry have identified the importance of obtaining relevant failure data to be used in the risk assessment models. Initial information on the occurrence of failure events (equipment failures and misadministrations) can be obtained through existing NRC reporting requirements.

Equipment failure events for medical radiation equipment might be obtainable from equipment manufacturers or from the quality assurance (QA) records at individual facilities. However, for risk-assessment purposes, the number of times a piece of equipment operated successfully or a patient was treated correctly must also be known to obtain the rate of failure per administration.

Discussions concluded such treatment data do exist in the medical community, but are not collected centrally or as part of any formal reporting system. Some summaries of these data are provided in surveys by professional societies, and are also reported to the Joint Committee on the Accreditation of Hospitals. It was suggested that the performance of a risk assessment trial application would identify what data are necessary. The most cost-efficient methods to obtain them could then be determined. The trial use would also allow an evaluation of the various failure and misadministration data sources.

The NRC has other activities that relate to this area. These include the task analyses of HDR

brachytherapy and the development of improved human reliability assessment (HRA) methods (discussed in other presentations), the creation of performance-related databases by AEOD, and the detailed investigations of misadministrations by the INEL for NMSS.

(cf. Appendices C-6.2, C-6.6)

3.3 Modeling Requirements

It was generally agreed that the use of risk assessment fault trees and event trees supplemented by Generic Error Modeling (GEMS) would provide the most effective means for assessing the risks of misadministrations.

This approach includes the identification of hazardous results, the identification of the different sequences of events that lead to these hazardous results (using event trees), the decomposition of these different sequences of events to the extent that data or modeling can quantify the probability of the event (using fault trees), and the application of data for quantification. This type of approach was demonstrated as viable in the limited application risk assessments presented in section 2.4.2 above. The addition of the GEMS methodology will further codify the root causes and human errors that underlie the basic events of the fault trees and indicate what sort of corrective action, including possible regulation, would best reduce the frequency of the unintentional acts.

This approach has several important advantages. It can assign importance indices to individual errors or equipment failures for the different contributing causes; these allow priorities to be set when planning system improvements. It allows the sensitivity to changes in the context of human actions to be explored explicitly in the models. And, with GEMS, it can identify specific actions that can be employed to reduce the number of human errors.

The disadvantage of a study of this type is the difficulty in acquiring sufficient, reliable data. Methods that rely to a great extent on expert judgment do not face this problem.

The alternative approach, of estimating the relative likelihood and consequence of particular failures of the steps in a task analysis, was considered to have two potential limitations. First, simply using the task analysis directly may lead to the omission of possibly significant scenarios that, while having a relatively low likelihood, may have a potentially high consequence in terms of the impact on patient health. Second, by using the judgment of clinical physicians as the basis for estimating the likelihoods, these judgments could be biased by their every-day experience that would not include the low-probability, high-consequence scenarios not experienced in routine clinical practice.

(cf. Appendix C-6.5)

3.4 Special Considerations for Medical Risk Assessments

The special considerations needed when applying existing risk assessment methodology to medical misadministrations were divided into two categories for discussion: general medical community and treatment environment; and the patterns of human errors.

3.4.1 Medical Setting Issues

The medical setting imposes certain variables and requirements on risk assessment not normally encountered in other settings.

The definition of unacceptable outcomes will often have *both* lower and upper limits, instead of just one or the other. In radiation-treatment, an undiscovered under-exposure can sometimes have a more serious result on the patient than overexposure; since underirradiation may fail to stop the progress of a fatal disease that might have been cured with the correct treatment.

The definition of unacceptable outcomes can not be based on the actual outcome—the effect on the patient. The treatment, when performed correctly, can still have significant health hazards as demonstrated by examples described in the presentations of the closeness and frequent overlapping between treatment doses and dose levels that result in complications.

Over-regulating has the potential to raise the risk to the public. Some regulations may increase the time and cost required to perform a process. Other things being equal, if a process becomes more costly in time and money, then it will be

used less *even though the need remains constant.* In response to higher costs; alternate, less-costly, and possibly less-appropriate treatments will be used or treatment may be completely dismissed. In this case, the effect of over-regulating a relatively safe modality is a net decline in patient safety.

(cf. Appendix C-6.3)

3.4.2 Human Error Issues

In the event investigations performed by the INEL for NRC, certain patterns of behavior were observed to recur. Perhaps the most important were circumventions—the deliberate, non-malicious breaking of safety rules. The incident at Indiana, Pennsylvania (NUREG-1480) involved such failures. Other cases of deliberate rule-breaking were observed in at least two of the events evaluated by the INEL (NUREG/CR-6088). This rule-breaking behavior contributes to the erosion of safety. The behavior is often brought on because of such factors as prior false alarms (which had to be ignored to get the job done), time or work pressure, or rules that did not match the job.

Another common factor was that the important errors occurred in off-normal contexts, such as an unusual number of patients or participation by inexperienced staff. When combined with some deficiency in the human–machine interface (labeling, training, etc.), the result was a misadministration.

(cf. Appendix C-6.4)

3.4.3 Other Issues

Several other factors must be considered in a medical risk assessment.

- Many of the machines have very poorly designed human-machine interfaces.
- Written procedures (other than user manuals) rarely exist for specific treatments; oral instructions are the most common procedures.
- Workload can be very intense.
- Training (particularly in-service training) is limited.
- Temporary personnel are often involved.

(cf. Appendix C-6.4)

4. CONCLUSIONS & RECOMMENDATIONS

At the end of each discussion session, the participants summarized the session and developed pertinent conclusions or recommendations. Overall, it was found that performance of a risk assessment would be consistent with the developing NRC policy on risk-based regulation. The participants agreed that a risk assessment would provide benefits for both the NRC and the medical community, and formulated several specific recommendations for the NRC for the future of this project.

(cf. Appendix C-6.7)

4.1 Benefits to NRC

The attendees at this workshop supported the NRC's use of risk assessment as an important tool in the development of its regulatory products in the area of the medical uses of isotopes.

Risk assessment methods that provide understanding and insights into the level of safety to the public, and the causes of harm to the public will support the NRC in its mission to ensure appropriate standards of safety. Risk assessment can identify which causes are most important and what regulatory actions may be most influential in increasing the level of public safety.

Risk assessment, by its hierarchical nature, can be performed at many levels of detail. By a careful choice of the level of detail in the modeling, risk assessments can provide support to the regulatory programs, as NRC itself has identified in its Proposed Policy Statement on the Use of PRA Methods in Nuclear Regulatory Activities.

4.2 Benefits to Users and Licensees

Risk assessment, by its integrated modeling of the different facets of the medical uses of isotopes, can allow the facilities to identify the features in their own facilities that may give rise to operational problems, and how such potential problems may be removed or reduced. For example, by performing a risk assessment on a machine, the different kinds of human errors or equipment failures that can result in unsafe or inefficient outcomes will be identified before these errors or failures will have occurred in practice. The facility may then plan what steps it would take in the event that such an error or failure occurred, and search for a change in design or operating practice that could remove the potential hazard before a patient was unintentionally harmed.

With risk assessment models a facility is able to explore whether changes in operation (such as staffing changes) will have an effect on safety. This would allow proactive assessments of changes proposed to reduce costs or improve operational efficiencies.

Facility risk assessments provide a basis for discussions with NRC and others in the regulatory community (e.g., the U.S. FDA), to suggest alternatives to proposed regulatory actions, where it can be shown that alternative regulations may achieve the same overall effect but have less impact on facility operations.

4.3 Recommended Approach for Development

To provide the most effective fulfillment of these uses of risk assessment, several modifications in current risk assessment methodology were recommended. NRC is urged to view these recommendations as candidates for incremental changes in the methods used to date, rather than as a condemnation of these methods.

Most important was the conclusion that these developments should take place in an applied risk assessment.

4.3.1 Incremental Development

In order to provide NRC with a risk assessment methodology that will enhance the regulation of medical uses of radioactive materials, the workshop identified improvements in the technology to accommodate specific issues. These developments are associated with extending the sources of data, improving the representation of human errors and

their causes, and refining the interpretation of unacceptable outcomes.

It is important that the improvements are cost-effective; that is, the improvement in risk analysis is expected to result in an improvement in regulatory practices. Developments that are unlikely to relate to existing or proposed regulations should not be undertaken for their own sake.

These developments should be performed incrementally, with each increasing degree bringing a level of improvement in the technology.

4.3.2 Extending Data Sources

Data already exist in a variety of forms that are relevant to the levels of risk from medical misadministrations. These include the data concerning the rates of events meeting the NRC reporting requirements contained in 10 CFR 35. In addition, there are data from events analyzed by the INEL that contain more detailed information, particularly associated with human errors.

Data are reported by existing mechanisms to NRC for the non-agreement states. These reports identify misadministrations meeting NRC reporting criteria provided in 10 CFR 35. However, similar data have not been gathered in accordance with a common standard from the agreement states, which involve the majority of U.S. residents. Starting in 1995, consistent event data will become available from these states. This will increase the number of events available for use in risk assessments.

While these event reports will provide additional unacceptable outcome data, there are no data reported formally concerning the number of treatments performed. Such data are needed to allow calculations of relative probabilities of unacceptable outcomes. In principle such data do exist in diverse locations, some of which are not in a reportable form (such as patient billing records). Individual facilities maintain these records for their own purposes, and summaries may be reported to other organizations such as professional bodies and accreditation agencies.

An examination of the data available at several facilities will be useful in estimating treatments at similar facilities and determining the cost-benefit of additional data collection.

The NRC should obtain the readily available data from the organizations already involved.

Where additional data are required, these can be provided in many cases by expert judgment. These judgments in many cases are needed only to provide bounding estimates of particular items by postulating, for example, "If event 'x' occurred at least as frequently as 'f' [some frequency estimate], then I would expect to have at least several events in the reported event data. I have seen no such events reported, so the frequency of these events is probably no more than 'f'."

4.3.3 Representing Human Error

Human errors were identified in discussions as an overwhelming source of misadministration events (up to 84%), yet this area represents one of the weakest parts of risk assessment methods.

NRC is currently funding the development of improved models of human error (for example, the GEMS framework) and the impact of organizational performance (for example, the WPAM method) for nuclear power plant applications that seemed directly relevant to the area of medical misadministrations.

These techniques should be considered during the development and application of the risk assessment methods.

4.3.4 Defining Unacceptable Outcomes

Because of the unlimited variations possible in brachytherapy and other radiation treatments, it is not currently practical to establish specific radiation level standards for every case. Given this, the NRC set a few general standards for gamma stereotactic radiosurgery, teletherapy, brachytherapy, and several radiopharmaceutical uses.

The current brachytherapy misadministration threshold for incorrect dose is ±20% of the prescribed dosage. In establishing this value the NRC worked with representatives from major medical professional associations.

Misadministrations are not limited to incorrect dose magnitude. They also include administration to the incorrect patient, to the incorrect location, via incorrect modality, etc. (See 10 CFR 35.2 for a full definition.)

4.3.5 Baseline Risk Assessment

A sample analysis should be undertaken using the conventional tools of risk assessment (fault trees and event trees), but supplemented with methods to improve the understanding of the causes of human errors. This sample analysis could be of one procedure, such as LDR brachytherapy (which is well understood and for which many data exist, though for which the actual health hazards are low), or be a comparative analysis between, for example LDR and HDR brachytherapy (for which fewer data exist, but which has a greater potential for harm). This sample analysis should be at a sufficient level of detail to enable evaluation of its usefulness to both NRC and licensees.

The sample analysis should then be subjected to a review by NRC, physicians and physicists qualified in the field, and risk-assessment and human-error experts (such as those attending this workshop), to identify the strengths and weaknesses with respect to meeting the purposes stated earlier. That review should identify the next set of incremental modifications required to satisfy NRC's needs. Such modifications should also be evaluated for their benefit to the licensees.

The NRC should perform a limited scope risk assessment as soon as possible to establish a baseline for incremental developments.

4.4 Summary

The workshop ended with several specific recommendations for the NRC:

- A demonstration quantitative risk assessment of a specific medical device and modality should be performed now
- PRA Event and Fault Trees supplemented by Generic Error Modeling should be used
- An estimated denominator should be established
- The demonstration risk assessment should be used as a baseline and foundation for future studies.

Performance of a risk assessment would be consistent with developing NRC policy on risk-based regulation.

(cf. Appendix B-14)

5. CITED NRC DOCUMENTS

NUREG-1050	U.S. Nuclear Regulatory Commission, Probabilistic Risk Assessment (PRA) Reference Document
NUREG-1480	U.S. Nuclear Regulatory Commission, Loss of an Iridium-192 Source and Therapy Misadministration at Indiana Regional Cancer Center, Indiana, Pennsylvania, on November 16, 1992
NUREG-75/014	U.S. Nuclear Regulatory Commission, Reactor Safety Study - An Assessment of Accident Risks in U.S. Commercial Nuclear Power Plants (WASH-1400)
NUREG/CR-6088	Summary of 1991-1992 Misadministration Event Investigations
NUREG/CR–6276	A Compilation of Current Regulations, Standards, and Guidelines in Remote Afterloading Brachytherapy

APPENDIX A

WORKSHOP PAPERS AND REFERENCE MATERIAL

CONTENTS

APPENDIX A
WORKSHOP PAPERS AND REFERENCE MATERIAL

A.1. NRC PROPOSED POLICY STATEMENT ON THE USE OF PROBABILISTIC RISK ASSESSMENT METHODS IN NUCLEAR REGULATORY ACTIVITIES

SECY-94-218

August 18, 1994

FOR: The Commissioners

FROM: James M. Taylor /s/
Executive Director for Operations

SUBJECT: PROPOSED POLICY STATEMENT ON THE USE OF PROBABILISTIC RISK ASSESSMENT METHODS IN NUCLEAR REGULATORY ACTIVITIES

PURPOSE:

To propose a policy statement concerning the use of probabilistic risk assessment (PRA) methods in nuclear regulatory activities.

To inform the Commission that the staff intends to publish the proposed policy statement in the Federal Register for public comment.

DISCUSSION:

PRA techniques are valuable in the analysis of design, operation, and maintenance aspects that affect nuclear safety. PRA techniques are useful for separating out the important safety aspects from the unimportant; for determining priorities and resource allocations; and for estimating the sources and magnitude of risk, particularly relative risk.

NRC requirements associated with the defense-in-depth philosophy and with the deterministic evaluation of design basis accidents have been effective in ensuring public health and safety. PRA has been used to complement these traditional, nonprobabilistic methods of analyzing nuclear plant safety and to facilitate the assessment of a broad range of beyond design-basis conditions involving multiple component failures or complex system interactions and interdependencies.

PRA methods have been applied successfully in numerous regulatory activities, proving to be a valuable complement to deterministic engineering approaches. Several recent Commission policies or regulations have been based, in part, on a recognition of the value of PRA methods and insights. Some of these policies and regulations include the Backfit Rule (§50.109, "Backfitting"), the Policy Statement on "Safety Goals for the Operation of Nuclear Power Plants" (51 FR 30038), the Commission's "Policy Statement on Severe Reactor Accidents Regarding Future Designs and Existing Plants," (50 FR 32138), and the Commission's "Final Policy Statement on Technical Specifications Improvement for Nuclear Power Reactors" (58 FR 39132). The NRC has also used risk-based methods to refine the regulatory program for facilities and operations other than reactors. For example, the EPA proposed regulatory standard for high level waste is probabilistic in nature and requires a risk-based analysis, referred to as a performance assessment.

The NRC has completed several important studies that focus on PRA applications. Recently, the NRC's PRA Working Group, established by the Executive Director for Operations (EDO), assessed the status and initiated development of guidance for consistent and appropriate uses of PRA. The NRC Regulatory Review Group, also established by the EDO, reviewed Office of Nuclear Reactor Regulation programs and practices with an emphasis focusing on replacing prescriptive requirements and guidance with requirements based on performance and risk insights. The NRC Regulatory Analysis Steering Group has been overseeing the development of guidance for supporting and justifying proposed regulatory actions. Significant recommendations and guidance on the use of PRA methods have resulted from these studies.

Implementation of a policy statement regarding the use of PRA methods in nuclear regulatory activities would improve the regulatory process in three areas: through improved risk-effective safety decision-making; through more efficient use of staff resources; and through a reduction of unnecessary burdens on licensees. To realize these improvements, the staff proposes to increase the use of PRA in reactor regulatory matters to the extent supported by the state-of-the-art in PRA methods and data and in a manner supportive of the NRC's traditional defense-in-depth philosophy. However, expanded use of PRA in regulation may raise additional technical, policy, and legal issues that must be addressed to accomplish this goal. The staff has identified several technical issues associated with uncertainties in calculated probabilities, limitations in data and modeling, difficulties in addressing design or construction errors, and limitations in modeling human performance, especially errors of commission and organizational or safety culture issues. These technical issues are being addressed in the staff's PRA Implementation Plan.

There are several important regulatory or resource implications that follow from the goal of increased use of PRA techniques in reactor regulatory activities. First, the staff, licensees, and Commission must be prepared to consider changes to regulations, to guidance documents, to the licensing process, and to the inspection program. Second, the staff and Commission must be committed to a shift in the application of resources over a period of time based on risk findings. Third, the staff must undertake a training and development program, which may include recruiting personnel with PRA experience, to provide the PRA expertise necessary to implement these goals. Additionally, the staff must continue to develop PRA methods and regulatory decision-making tools and must significantly enhance the collection of equipment and human reliability data for all of the agency's risk assessment applications, including those associated with the use, transportation, and storage of nuclear materials.

CONCLUSIONS:

Based on the discussions above, the staff concludes that an overall policy on the use of PRA in nuclear regulatory activities should be established so that the many potential applications of PRA can be implemented in a consistent and predictable manner that promotes regulatory stability and efficiency. This policy statement would be valuable in articulating the Commission's current position on the role of PRA in various regulatory programs and in communicating that position to the staff, the public, licensees and applicants for licenses. In addition, the staff concludes that lessons-learned from operating experience and utilizing PRA methods should be more aggressively applied to achieve greater coherence in our overall regulatory program. Therefore, the staff proposes a policy statement (Enclosure 1) containing the following elements regarding the expanded NRC use of PRA:

(1) The use of PRA technology should be increased in all reactor regulatory matters to the extent supported by the state-of-the-art in PRA methods and data and in a manner consistent with, and complementary to, the NRC's traditional defense-in-depth philosophy (which is based, in part, on qualitative risk considerations).

(2) PRA and associated analyses (e.g., sensitivity studies, uncertainty analyses, and importance measures) should be used in reactor regulatory matters, where practical within the bounds of the state-of-the-art, to reduce unnecessary conservatism associated with current regulatory requirements, regulatory guides, license commitments, and staff practices. Appropriate procedures for implementing changes to regulatory requirements should be developed and followed. The intent of this policy is that existing rules and regulations shall be complied with unless revisions to these rules and regulations are made on the basis of the PRA insights.

(3) PRA evaluations in support of regulatory decisions should be as realistic as possible and all necessary supporting data should be publicly available for review.

(4) The Commission's safety goals for nuclear power plants and subsidiary numerical objectives are to be used with appropriate consideration of uncertainties in making regulatory judgments both in the context of backfitting new requirements on facility licensees and in granting relief from unnecessary regulatory requirements.

COORDINATION:

The Office of the General Counsel has reviewed the proposed policy statement and has no legal objection to it. The Advisory Committee on Reactor Safeguards (ACRS) reviewed the proposed policy statement and discussed the policy statement with the staff at its May meeting. The ACRS letter discussing the Proposed PRA Policy Statement is enclosed.

RECOMMENDATION:

The staff recommends that the Commission:

NOTE that unless directed otherwise, the staff will publish the proposed PRA policy statement (Enclosure 1) in the Federal Register for a 60-day comment period. The staff will publish the proposed PRA policy statement no earlier than 10 working days from the date of this Commission paper.

NOTE that the staff will continue to develop and implement a detailed interoffice plan for the expanded use of PRA in regulatory activities and that this plan will be provided to the Commission in August 1994. The Staff Requirements Memorandum dated May 18, 1994, requesting additional information regarding resources necessary to implement this proposed policy will also be addressed in the PRA Implementation Plan.

James M. Taylor

Executive Director

for Operations

Enclosures: (1) Federal Register Notice Regarding the Proposed PRA Policy Statement
(2) ACRS Letter dated May 11, 1994

ENCLOSURE 1

(NRC Draft for FR, not final version)[7590-01]

NUCLEAR REGULATORY COMMISSION

Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities; Proposed Policy Statement

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed policy statement.

SUMMARY: The Nuclear Regulatory Commission (NRC) is proposing a policy statement regarding the use of probabilistic risk assessment (PRA) in nuclear regulatory matters. The Commission believes that an overall policy on the use of PRA in nuclear regulatory activities should be established so that the many potential applications of PRA methodology can be implemented in a consistent and predictable manner that promotes regulatory stability and efficiency and enhances safety. The proposed policy statement would improve the regulatory process through improved risk-effective safety decision-making, through more efficient use of agency resources, and through a reduction in unnecessary burdens on licensees. The NRC will modify existing regulations and/or develop new ones as a result of new information from accident behavior studies and risk data when a sound scientific basis is found to exist.

DATES: Submit comments by (60 days after publication in the Federal Register). Comments received after this date will be considered if it is practical to do so, but the Commission is able only to ensure consideration for comments received on or before this date.

ADDRESSES: Send comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch.

Deliver comments to: One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852, between 7:45 am and 4:15 pm Federal workdays.

Copies of comments received may be examined at: NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC.

FOR FURTHER INFORMATION CONTACT: Thomas G. Hiltz, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555. Telephone (301) 504-1105.

SUPPLEMENTARY INFORMATION:

I. Background

This policy statement sets forth the Commission's intention to encourage the use of PRA and to expand the scope of PRA applications in reactor regulatory matters to the extent supported by the state-of-the-art in terms of methods and data. The NRC is also using risk-based methods to refine the regulatory program for facilities and operations other than power reactors. Since the early 1970s, the NRC has expended significant resources in the development and application of PRA technology. This included the ground-breaking work of the Reactor Safety Study (documented in WASH-1400) in 1975. On January 18, 1979, the NRC issued a policy statement, entitled "NRC Statement of Risk Assessment and the Reactor Safety Study Report (WASH-1400) in Light of the Risk Assessment Review Group Report" [Risk Assessment Review Group Report, NUREG/CR-0400]. In addition to addressing specific criticisms of WASH-1400, the 1979 policy statement articulated limitations in the

use of PRA in the regulatory arena. Many of these limitations have been addressed, however, some still remain pertinent today. Primary among these limitations is the characterization of uncertainties associated with calculated probabilities of reactor accidents. PRA methodologies have, however, provided a better means for identifying and narrowing the range of uncertainty.

Until the accident at Three Mile Island (TMI) in 1979, the Atomic Energy Commission (now the NRC), used probabilistic criteria in certain specialized areas of licensing reviews. For example, site hazards, both man-made (e.g., nearby hazardous materials and aircraft) and natural (e.g., tornadoes, floods, and earthquakes), typically involved the use of probabilistic arguments and initiating frequencies to assess risks. The Standard Review Plan for licensing reactors (NUREG-0800) and some of the Regulatory Guides supporting NUREG-0800, provided review and evaluation guidance with respect to probabilistic considerations.

The TMI accident substantially changed the character of the analysis of severe accidents worldwide. It led to a substantial research program on severe accident phenomenology. Both major investigations of the accident (the Kemeny and Rogovin studies) recommended that PRA techniques be used more widely to augment the traditional nonprobabilistic methods of analyzing nuclear plant safety. In 1984, the NRC completed a study (NUREG-1050) that addressed the state-of-the-art in risk analysis techniques.

PRA methods have been applied successfully in numerous regulatory activities and have proved to be a valuable complement to deterministic engineering approaches. This application of PRA represents an extension and enhancement of traditional regulation rather than a separate and different technology. Several recent Commission policies or regulations have been based, in part, on a recognition of the value of PRA methods and insights. Some of these policies and regulations include the Backfit Rule (§50.109, "Backfitting"), the Policy Statement on "Safety Goals for the Operation of Nuclear Power Plants" (51 FR 30038), the Commission's "Policy Statement on Severe Reactor Accidents Regarding Future Designs and Existing Plants" (50 FR 32138), and the Commission's "Final Policy Statement on Technical Specifications Improvement for Nuclear Power Reactors" (58 FR 39132). An example of a major past PRA application is the Systematic Evaluation Program (SEP), in which risk importance was used to assess the significance of deviations from current licensing criteria for some of the oldest operating reactors. PRA methods also were used effectively during the anticipated transient without scram (ATWS) (§50.62) and station blackout (§50.63) rulemakings, and supported the generic issue prioritization and resolution process. Additional benefits have been found in the use of risk-based inspection guides to focus NRC inspector efforts and make more efficient use of NRC inspection resources.

In NUREG-1150, "Severe Accident Risks: An Assessment for Five U.S. Nuclear Power Plants," the NRC used technological developments of the 1980s to assess the risk associated with five nuclear plants. This study was a significant turning point in the use of risk-based concepts in the regulatory process and enabled the Commission to greatly improve its methods for assessing containment performance after core damage and accident progression. The methods developed for and results from these studies provided a valuable foundation in quantitative risk techniques.

Currently, the NRC is relying extensively on PRA techniques to assess the safety importance of operating reactor events and is using these techniques as an integral part of the design certification review process for advanced reactor designs. In addition, the Individual Plant Examination (IPE) program and the Individual Plant Examination - External Events (IPEEE) program (an effort resulting from the implementation of the Commission's "Policy Statement on Severe Reactor Accidents Regarding Future Designs and Existing Plants") have resulted in commercial reactor licensees using risk-assessment methods to identify any vulnerabilities needing attention.

II. Purpose and Scope

The NRC established its regulatory requirements to ensure that a licensed facility is designed, constructed, and operated without

undue risk to the health and safety of the public. These requirements are largely based on deterministic engineering criteria, involving the use of multiple barriers and application of a defense-in-depth philosophy. Beyond its deterministic criteria, the NRC has additionally formulated guidance, as in the safety goal policy statement, that utilizes quantitative, probabilistic risk measures. The safety goal policy statement establishes top-level objectives to help assure safe operation of nuclear power plants. For the purpose of implementation of the safety goals, subsidiary numerical objectives on core damage frequency and containment performance have been established. The safety goals provide guidance on where plant risk is sufficiently low such that further regulatory action is not necessary. Also, as noted above, the Commission has been using PRA in performing regulatory analysis for backfit of cost-beneficial safety improvements at operating reactors (as required by 10 CFR 50.109) for a number of years.

The application of PRA to nuclear regulatory activities has evolved with improvements in PRA techniques and data bases. PRA techniques can be used to derive valuable insights, perspectives, and general conclusions as a result of the integrated and comprehensive examination of the plant design and a structured examination of plant and operator response to events. For a nuclear power plant, a plant-specific PRA can be used to derive plant-specific insights and conclusions where appropriate plant-specific modeling and data are available and used appropriately. PRA sensitivity studies are particularly useful in focusing designers, operators, and regulators on important aspects of design, operation, and maintenance.

The Commission has considered recent improvements in nuclear technology and accumulated experience with risk assessment methods, and concludes that increased use of these techniques as an integral part of the regulatory decision-making process is now justified. Consequently, the Commission has adopted the policy that the use of PRA should be encouraged and the scope of PRA applications in nuclear regulatory matters should be expanded to the extent supported by the state-of-the-art methods and data.

An important aspect of the expanded use of PRA technology would be a strengthening of NRC's defense-in-depth philosophy by allowing quantification of the levels of protection and by helping to identify and address weaknesses or overly conservative regulatory requirements in the physical and functional barriers.

However, the application of traditional risk methodology used in assessing risk for power reactors is limited for those applications where failures are primarily the result of human action, especially errors of commission and organizational or safety culture issues. In addition to limitations in modeling human performance, the Commission may need to address several other technical issues. These issues are related to the uncertainties in calculated probabilities, limitations in data and modeling, and difficulties in addressing design or construction errors. These issues have been recognized and are being addressed in the staff's PRA Implementation Plan.

In addition, the Commission expects policy and legal issues to emerge as increased reliance is placed on probabilistic- and performance-based approaches to support regulatory requirements and licensing decisions. Some of these issues, such as using PRA to assess the severity level of an enforcement action, are being addressed in the staff's PRA Implementation Plan. Those emerging issues not addressed in the plan will be addressed as needed.

III. The Commission Policy

Although PRA methods and information have thus far been used successfully in nuclear regulatory activities, there are concerns that PRA methods are not consistently applied throughout the agency, that sufficient agency PRA/statistics expertise is not available, and that the Commission is not deriving full benefit from the large agency and industry investment in the developed risk assessment methods. Therefore, the Commission believes that an overall policy on the use of PRA in nuclear regulatory activities should be established so that the many potential applications of PRA can be implemented in a consistent and predictable manner that promotes regulatory stability and efficiency. Implementation of the policy statement would

improve the regulatory process in three areas: through improved risk-effective safety decision-making; through more efficient use of agency resources; and through a reduction in unnecessary burdens on licensees.

Therefore, the Commission proposes the following policy statement regarding the expanded NRC use of PRA:

(1) The use of PRA technology should be increased in all reactor regulatory matters to the extent supported by the state-of-the-art in PRA methods and data and in a manner consistent with, and complementary to, the NRC's traditional defense-in-depth philosophy (which is based, in part, on qualitative risk considerations).

(2) PRA and associated analyses (e.g., sensitivity studies, uncertainty analyses, and importance measures) should be used in reactor regulatory matters, where practical within the bounds of the state-of-the-art, to reduce unnecessary conservatism associated with current regulatory requirements, regulatory guides, license commitments, and staff practices. Appropriate procedures for implementing changes to regulatory requirements should be developed and followed. The intent of this policy is that existing rules and regulations shall be complied with unless revisions to these rules and regulations are made on the basis of the PRA insights.

(3) PRA evaluations in support of regulatory decisions should be as realistic as possible and all necessary supporting data should be publicly available for review.

(4) The Commission's safety goals for nuclear power plants and subsidiary numerical objectives are to be used with appropriate consideration of uncertainties in making regulatory judgments both in the context of backfitting new requirements on facility licensees and in granting relief from unnecessary regulatory requirements.

There are several important regulatory or resource implications that follow from the goal of increased use of PRA techniques in reactor regulatory activities. First, the NRC staff, licensees, and Commission must be prepared to consider changes to regulations, to guidance documents, to the licensing process, and to the inspection program. Second, the NRC staff and Commission must be committed to a shift in the application of resources over a period of time based on risk findings. Third, the NRC staff must undertake a training and development program, which may include recruiting personnel with PRA experience, to provide the PRA expertise necessary to implement these goals. Additionally, the NRC staff must continue to develop PRA methods and regulatory decision-making tools and must significantly enhance the collection of equipment and human reliability data for all of the agency's risk assessment applications, including those associated with the use, transportation, and storage of nuclear materials.

This policy statement affirms the Commission's belief that PRA methods can be used to derive valuable insights, perspective and general conclusions as a result of the integrated and comprehensive examination of the design of the nuclear facilities, its response to initiating events, the expected interaction between its elements and between the facility and operating staff, and the structured examination of its operating characteristics.

Dated at Rockville, Maryland, this day of _____, 1994.

For the Nuclear Regulatory Commission

Samuel J. Chilk,

Secretary of the Commission

A.2. NRC PROPOSED AGENCY-WIDE IMPLEMENTATION PLAN FOR PROBABILISTIC RISK ASSESSMENT (PRA)

SECY-94-219

August 19, 1994

FOR: The Commissioners

FROM: James M. Taylor /s/
Executive Director for Operations

SUBJECT: PROPOSED AGENCY-WIDE IMPLEMENTATION PLAN FOR PROBABILISTIC RISK ASSESSMENT (PRA)

PURPOSE:

To inform the Commission of the proposed agency-wide PRA Implementation Plan that provides the necessary interoffice framework for strengthening and increasing the use of PRA technology in agency regulatory activities.

DISCUSSION:

In a November 2, 1993, memorandum to the Executive Director for Operations, the directors from the Office of Nuclear Reactor Regulation (NRR), the Office of Nuclear Material Safety and Safeguards (NMSS), the Office for Analysis and Evaluation of Operational Data (AEOD), and the Office of Nuclear Regulatory Research (RES) collectively focused on the findings of and recommendations made by the PRA Working Group, the Regulatory Review Group, and the Regulatory Analysis Steering Group regarding the status of PRA use and its role in the regulatory process. In the memorandum, the Office Directors concurred in the need to systematically expand the use of PRA within the agency. In order to ensure that the many potential applications of PRA can be implemented in a consistent and predictable manner that promotes regulatory stability and efficiency, the staff commenced work on an interoffice PRA Implementation Plan.

In order to establish top-level guidance on the use of PRA in nuclear regulatory activities and aid in development of a detailed PRA Implementation Plan, the staff proposed a policy statement regarding the use of PRA in regulatory activities. On August 18, 1994, the staff forwarded SECY-94-218, "Proposed Policy Statement on the Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities," to the Commission. In that Commission paper, the staff stated that an overall policy on the use of PRA in nuclear regulatory activities should be established so that the many potential applications of PRA can be implemented in a consistent and predictable manner that promotes regulatory stability and efficiency. In addition, the staff stated that the use of PRA technology in NRC regulatory activities should be increased. The increased use of PRA methods and technology is not intended to supplant the defense-in-depth based regulations, but to complement those deterministic methods by using PRA technology in activities where methods and data are well understood. Even where data may be sparse, the technology may also represent a valuable supplement to the deterministic methods. The staff believed the increased use of PRA technology would lead to improved risk-effective safety decisions, more focused and efficient utilization of NRC staff resources, and reduced industry burdens.

The Office of Nuclear Reactor Regulation (NRR) coordinated the efforts of the Office of Nuclear Regulatory Research (RES), the Office of Nuclear Materials Safety and Safeguards (NMSS), and the Office for Analysis and Evaluation of Operational Data (AEOD) in the joint development of the draft PRA Implementation Plan. The PRA Implementation Plan was developed to ensure that the increased use of PRA methods and technology in nuclear regulatory activities would be implemented in a consistent and predictable manner that promotes regulatory stability and efficiency. This PRA

Implementation Plan provides the framework for management oversight of the increased and appropriate use of PRA methods and technology in regulatory activities.

The proposed PRA implementation plan (enclosed) is considered a "living" document and is provided for the Commission's information. The staff considers the PRA Implementation Plan to be a management tool that will help ensure the timely and integrated agency-wide use of PRA methods and technology. PRA methods have been applied successfully in numerous nuclear regulatory activities and have proven to be a valuable complement to deterministic engineering approaches. However, the increased use of PRA in nuclear regulatory activities has broad implications and could result in changes in many areas associated with our current regulatory framework. These areas, considered by the staff in developing the draft PRA Implementation Plan, may include: changes to regulations and guidance documents and inspection programs; a substantial shift in staff resources including recruiting and training programs to provide the necessary PRA expertise, an increased emphasis on continued development of PRA methods and decision-making tools, and enhanced reliability data collection. As discussed in SECY-94-218, expanded use of PRA in nuclear regulatory activities may raise additional policy, technical, and legal issues that will be considered in subsequent modifications to the PRA Implementation Plan.

The Advisory Committee on Reactor Safeguards (ACRS) discussed the draft PRA Implementation Plan during its May 5-7, 1994, meeting. The ACRS recommended that the PRA Implementation Plan 1) emphasize improving and adding consistency to cost/benefit analyses, 2) address the need for continuing PRA research, and 3) be made available for public comment. Although not part of the PRA Implementation Plan, the staff is addressing improving and adding consistency to cost/benefit analysis. The staff's Regulatory Analysis Guidelines (NUREG/BR-0058, Rev. 1) are being revised. Further, a draft Regulatory Analysis Technical Evaluation Handbook (NUREG/BR-0184) has been prepared. The need to conduct PRA research has been incorporated into the proposed PRA Implementation Plan. The staff plans to solicit public comment on the PRA Implementation Plan through a public workshop to be held this fall.

In its Staff Requirements Memorandum of May 18, 1994, the Commission requested additional information regarding resources necessary to implement the proposed PRA Policy Statement and the PRA Implementation Plan. In Section V.A of the enclosed PRA Implementation Plan, the staff discusses its strategy for ensuring that adequate resources are made available to fully implement the plan.

The staff plans to provide the Commission with semi-annual updates on the status of actions discussed in the PRA Implementation Plan.

James M. Taylor
Executive Director
for Operations

Enclosure: PRA Implementation Plan

PRA IMPLEMENTATION PLAN

August 12, 1994

prepared by
Office of Nuclear Reactor Regulation
Office of Nuclear Regulatory Research
Office of Nuclear Materials Safety and Safeguards
Office for the Analysis and Evaluation of Operational Data

I. BACKGROUND

I.A Introduction

The 1979 nuclear accident at the Three Mile Island (TMI) nuclear power plant substantially changed the character of the analysis of severe accidents worldwide. Both major investigations of this accident (the Kemeny and Rogovin studies) recommended that the staff increase its use of probabilistic risk assessments (PRAs) to augment its traditional, nonprobabilistic methods of analyzing nuclear plant safety. It also led to a substantial research program on severe accident phenomenology.

The issuance of NUREG-1150, "Severe Accident Risks: An Assessment for Five U.S. Nuclear Power Plants," for which the Nuclear Regulatory Commission (NRC) staff took advantage of the technological developments of the 1980s to assess the risk, including containment performance and consequence analyses, associated with five selected plants, represented a significant turning point in the use of risk-based concepts in the regulatory process. Similarly, since the mid-1970s the NRC has conducted a number of studies on risk associated with the fuel cycle including, for example, transportation and high- and low-level waste management.

PRA methods have been applied successfully in numerous regulatory activities, proving to be a valuable adjunct to deterministic engineering approaches. Several recent Commission policies or regulations have been based, in part, on a recognition of the value of PRA methods and insights. Among these policies and regulations include the Backfit Rule (§50.109, "Backfitting"), the Policy Statement on "Safety Goals for the Operation of Nuclear Power Plants," (51 FR 30038), the Commission's "Policy Statement on Severe Reactor Accidents Regarding Future Designs and Existing Plants," (50 FR 32138), and the Commission's "Final Policy Statement on Technical Specifications Improvement for Nuclear Power Reactors," (58 FR 39132). In addition to the past application of risk assessment techniques in the Systematic Evaluation Program and rulemaking on anticipated transients without scram, PRA methods were utilized effectively during the station blackout rulemaking and in support of the generic issue prioritization and resolution process. Currently, PRA techniques are being used to assess the safety importance of operating reactor events and as an integral part of the design certification review process for advanced reactor designs. The NRC has also used risk-based methods to refine the regulatory program for facilities and operations other than reactors. For example, the Environmental Protection Agency (EPA) proposed regulatory standard for high level waste is probabilistic in nature and is referred to as a "performance assessment."

I.B Review Groups

There have been some recent criticisms of the staff's use of PRA. Primarily, these criticisms are that PRA methods are not applied consistently throughout the agency, that sufficient staff PRA and statistical expertise is not available, and that the staff is not deriving full benefit from the large agency and nuclear reactor industry investment in developing and applying risk assessment methods. To address these concerns, the agency established three high-level review groups. Specifically, (1) the PRA Working Group has assessed the status of and initiated development of guidance for consistent and appropriate current uses of PRA; (2) the Regulatory Review Group has reviewed NRC processes, programs, and practices with a focus on seeking replacement of prescriptive requirements and guidance with requirements based on performance and the use of risk insights; and (3) the Regulatory Analysis Steering Group has updated guidance for conducting regulatory analyses, including use of risk insights, for proposed regulatory actions. During this same period, the nuclear power industry established the Nuclear Energy Institute (NEI), formerly the Nuclear Management and Resources Council (NUMARC), Regulatory Threshold Working Group to promote the use of probabilistic safety assessment technology and other new approaches to regulation as an aid to focus industry and regulatory attention and resources more effectively on safety concerns. The staff has prepared a proposed Commission policy statement to declare the agency's commitment to increase the use of PRA methods and insights in its regulatory activities. This policy statement would articulate the Commission's position on the role of PRA in various regulatory programs and communicates that position to the staff, the public, licensees, and applicants for licenses.

II. PRA IMPLEMENTATION PLAN GOAL

In a November 2, 1993, memorandum to the Executive Director for Operations, the NRC Office of Nuclear Reactor Regulation (NRR), Office of Nuclear Material Safety and Safeguards (NMSS), Office for Analysis and Evaluation of Operational Data (AEOD), and Office of Nuclear Regulatory Research (RES) collectively focused on the findings of, and recommendations made by, the above three NRC study groups regarding the status of PRA use and its role in the regulatory process. In the memorandum, the offices concurred in the need to systematize and expand the use of PRA within the agency. A proposal was made to formulate a comprehensive plan for the application of PRA technology and insights throughout the agency. It is expected that this plan will provide the framework for continued and future applications of PRA at the NRC.

Development of a plan of this type is especially timely in recognition of Presidential Executive Order 12866. Among other guidance, this order calls for regulatory agencies to consider the degree and nature of risks posed in setting their regulatory priorities, as well as costs and benefits of intended regulation. NRC's large investment and substantial experience in the development of PRA methodology and in selected applications puts it in a strong position to implement the executive order.

This integrated PRA plan will provide substantial benefits, including

- improved regulatory decision-making,
- more efficient use of agency resources in focusing efforts on the most safety-significant issues, and
- reduced industry burden in responding to less safety-significant issues.

Therefore, the goal of the PRA Implementation Plan is to achieve these benefits by increasing the use of PRA in regulatory matters to the extent practical given the state-of-the-art in PRA methods and data available. This goal implies risk-based regulation in its broadest sense and raises technical, policy, and legal issues that must be addressed. An important aspect of the expanded use of PRA technology in reactor regulation will be a strengthening of NRC's defense-in-depth philosophy by allowing quantification of the levels of protection and by helping to identify and address weaknesses in the physical and functional barriers, should they exist.[1]

The staff recognizes that there are limitations in the current applications of PRA technology. However, these limitations are not necessarily unique to the PRA technology and can also apply to deterministic methods. In general these involve practical limitations in methods, models, and data used in PRA's which can introduce substantial uncertainty, both quantified and unquantified. This is especially true in the analysis of certain human performance issues, common cause failure analysis, and evaluation of seismic hazards. Human performance issues associated with errors of commission and organizational and management issues are examples of areas where current PRA's are limited. While these limitations may affect the precision in estimated risks, the PRA frame work offers a powerful tool for logically and systematically evaluating the sensitivity and importance to risk of these issues and their associated uncertainties. Reliance on PRA technology in decision-making continues to increase.

It is important to note that not all of the agency's risk management activities lend themselves to a risk analysis approach that utilizes a probabilistic, fault tree methodology. As mentioned earlier, current PRAs are of limited usefulness for modeling certain human performance considerations, especially errors of commission and organizational or management issues. In the areas of industrial and medical uses of nuclear materials, for instance, the primary contributor to overexposures is

---

[1]Note: The defense-in-depth philosophy for reactors is essentially equivalent to the multi-barrier concept used for a geologic repository for disposal of high-level waste.

human error. Also of note is the difference in the availability of failure data for nuclear reactor and industrial or medical events. Materials events are generally frequent enough to allow statistical study, whereas reactor events are infrequent and require the use of probabilistic techniques.

Given the dissimilarities in the nature and consequences of the use of nuclear materials in reactors, industrial situations, and medical applications, the PRA Implementation Plan recognizes that a single approach to risk management is not appropriate. The staff will, however, share methods and insights to ensure that the best use is made of available techniques to foster consistency in NRC decision-making. The updated NRC guidelines for conducting Regulatory Analysis are expected to be an important step forward fostering this agency-wide consistency.

There are several important implications that follow from the goal of increased use of PRA techniques in reactor regulatory activities. First, the staff, licensees, and Commission must be prepared to embrace changes to regulations, to guidance documents, to the licensing process, and to the inspection program. Second, the staff and Commission must be committed to a shift in resources based on risk findings. Third, the staff must undertake a recruiting and training program to provide the necessary PRA expertise. Additionally, the staff must continue to develop PRA methods and regulatory decision-making tools and must significantly enhance the collection of equipment and human reliability data for all of the agency's risk assessment applications, including those associated with the use, transportation, and storage of nuclear materials.

III. DISCUSSION OF ISSUES RELATED TO RISK ASSESSMENTS OF REACTORS

III.A Decision Criteria

NRC's regulatory requirements were developed to ensure that a licensed facility "can be operated without undue risk to the health and safety of the public" (Appendix A, 10 CFR Part 50). They are largely based on deterministic engineering criteria involving the use of multiple barriers and defense-in-depth. Implementation of this plan will increase the systematic use of risk assessment techniques. To ensure consistent and appropriate decision-making that incorporates PRA methods and results, it is crucial that coherent and clear criteria are applied. As part of this plan, such decision criteria will be established (incorporating safety goals and backfit rule considerations) that address the interdependence of probabilistic risk and deterministic engineering principles. The process of developing these criteria will involve communications among the NRC, the nuclear industry, and the public to ensure an understanding by all parties of the role of PRA methods and results in NRC's risk management efforts.

III.B Data

The NRC staff uses equipment performance data in the conduct of PRAs, reliability analyses, component failure studies, and plant aging studies; identification and resolution of generic issues; preparation for inspections; and reviews of technical specifications change requests. For these purposes, the staff uses generic data supplemented with a limited amount of plant-specific data. The use of the generic data is problematic because the data have not been verified or updated and do not differentiate between plant-to-plant variations in performance or changes in performance as reactor plants age. The ad hoc collection of plant-specific data is costly and inefficient.

The availability of human performance data is even more problematic. One reason is the lack of established and accepted human performance analysis methods and models upon which to base the collection of human performance data. This is particularly important in the analysis of operator performance in response to events during which both acts of omission and commission may occur. Human reliability methods and data are currently the focus of research and limited evaluations of human performance issues raised by analysis of operating reactor events.

As the NRC and the nuclear reactor industry move toward greater use of PRA, the need for better data on human performance, plant-specific safety system availability data (at the train level), and equipment reliability data will increase with the increased role of PRA in the regulatory decision-making process. Increased availability of data on equipment and human performance is very

important to implementing many risk-based regulation initiatives. For example, this information is essential for implementing the maintenance rule and in supporting the development of risk-based technical specifications.

This plan recognizes the need to collect equipment and human performance data and includes an approach for collecting this data, derived from operating experience, to continue to provide a source of credible performance data for NRC use in the regulatory process.

III.C Consistent Methods

The PRA Working Group identified the need for the development and use of consistent PRA models and methods. Some steps toward this goal have already been taken, such as the use of RES-developed codes by agency staff. Other tasks that are now being undertaken include the development of more user-friendly computer interfaces; the development of low-power and shutdown models, external events models, and Level 2/3 PRA models compatible with the needs of events assessment staff; and the development of methods for consistently identifying the appropriate detailed PRA model for use in the analysis of individual events or issues.

It is important to note that not all of the agency's risk management activities lend themselves to a risk analysis approach that utilizes a probabilistic, fault tree methodology. This plan recognizes that a single approach to risk management is not appropriate. RES has the lead responsibility for developing and validating risk assessment models and methods.

III.D Training

Implementation of the plan will require users and developers of the new methods to have significant experience in PRA methods and statistics. It will take time for these staff members to gain the necessary experience. Some of the knowledge and skills needed to do this work can be obtained though traditional training. However, on-the-job training, classroom instruction, and industrial experience will be needed in order to acquire some of the required knowledge and experience. Recruiting of outside experts and intensified development of current staff members will likely be necessary to gain this staff experience. This process will take several years to accomplish and will be a major factor in the success of the PRA plan and in establishing the pace of its implementation.

Another issue is the training of the staff who will not be directly working with PRA methods. As the agency shifts to greater use of, and reliance on, PRA methods and risk-based regulation, all technical staff members, including inspectors, will need to develop an understanding of the strengths and weaknesses of PRA methods and their use. Training of such staff will be a critical part of the change in the regulatory culture of the agency. This training will require a large resource commitment over the next several years, since the number of staff members who will need the training is large.

To support the goal of improved regulatory activities through increased use of PRA technology, this plan includes an extensive training program. This training program is based on the systems approach to training, which includes completing job task analyses, developing learning objectives, developing and delivering courses, soliciting student and management feedback, and modifying the PRA training program as necessary.

IV. RISK-BASED CONSIDERATIONS IN OTHER THAN REACTOR PROGRAMS

IV.A Decision Criteria

There will be significant benefit from the cross-fertilization of the experiences gained from risk assessments as applied to NMSS facilities and operations with the experiences from PRA for power reactors. However, traditional methods used to assess risk in power reactors are not always appropriate for those NMSS applications where failures are primarily the result of human action and are only secondarily due to equipment-modes of failure. For NMSS-associated applications, risk-based methodologies will be used to the extent that the complexity of the system and the risks posed

by the system require a particular complexity of analysis, and to the extent it can be supported by the state-of-the-art in terms of methods and data.

The NRC staff has used these criteria to assess the appropriate applications of probabilistic safety assessment techniques (which include PRA and other systematic safety assessment methods) to low-level and high-level radioactive waste disposal in the form of performance assessments. Furthermore, the 1985 version of 40 CFR Part 191 (EPA's high-level waste standard) prescribed the use of probabilistic safety assessment techniques (i.e., performance assessments) to assess the safety of the disposal of high-level nuclear waste. To provide additional assurance that the EPA regulations are satisfied, the Commission has formulated additional regulatory requirements in 10 CFR Part 60 (including deterministic requirements for some subsystems of the repository). Future techniques to be used for the assessment of risk for a high-level waste facility will depend on the requirements and standards that are expected to be developed by the EPA in 1995 as required by the Energy Policy Act of 1992. The Energy Policy Act of 1992 also requires that within 1 year the NRC is to modify its technical requirements in 10 CFR Part 60 to be consistent with the requirements to be developed by the EPA.

IV.B. Consistent Methods

The NRC has been developing performance assessment methods for low-level and high-level waste since the mid-1970s and intensified using performance assessments techniques in the late 1980s and early 1990s. This has involved the development of conceptual models and computer codes to model the disposal of waste. Because waste-disposal systems are passive, the fault-and-event-tree methods used for active systems in PRA studies for power reactors had to be adapted to provide scenario analysis for the performance assessment of the geologic repository at Yucca Mountain, Nevada. In regard to high-level waste, the NRC staff participates in a variety of international activities (e.g., the Performance Assessment Advisory Group of the Organization for Economic Cooperation and Development, Nuclear Energy Agency) to ensure that consistent performance assessment methods are used to the degree appropriate. In regard to nuclear medicine applications, NRC contractors have recently completed the preliminary development of a relative risk-ranking approach for analyzing nuclear medical devices.

V. AGENCY RESOURCE IMPLICATIONS

V.A Reactor Applications

Each Office associated with this PRA Implementation Plan has considered the resources required to implement this plan and has made or is making organizational changes or commitments supporting the enhanced use of PRA in reactor regulatory activities. NRR, for example, has initiated plans to add five senior positions to its Probabilistic Safety Assessment Branch and one Senior Level Service (SLS) position. The recent AEOD reorganization highlights the important role of PRA with the renaming of the Trends and Patterns Analysis Branch to Reliability and Risk Assessment Branch. AEOD's Technical Training Division has initially re-programmed approximately 2 full time positions, from the Reactor Technology Training Program, to work on the identification of PRA training needs and the subsequent curriculum development. The recently-proposed RES reorganization consolidates its PRA staff and methods development, staff support, and IPE/IPEEE review functions from three branches into one branch, improving the efficiency of the use of these staff resources.

The staff has started implementing portions of the PRA Implementation Plan. Initially this plan requires significant resources because of the developmental nature of the activities (e.g., development of decision criteria, guidance documents, training curricula, etc.). Current staffing level and level of expertise in the PRA area is not sufficient to fully implement this plan. Therefore, the staff plans to 1) augment its current staffing in the PRA area with personnel who have expertise in PRA methods and techniques and 2) develop additional in-house PRA expertise.

The resources needed to implement the PRA Implementation Plan will result from strategic hiring, re-direction of existing staff technical resources, including both technical reviewers and inspectors (from reduction in lower priority reviews and inspections), and conversion of management positions

as part of the agency's streamlining initiative. The staff plans to add personnel in the PRA area to 1) analyze and apply PRA techniques to safety decision-making, 2) continue agency training in PRA methods and applications, and 3) develop guidance and implement risk-based (risk-focused) inspections and reviews. As staffing levels allow, priority consideration will be given to filling future vacancies with PRA skilled recruits. In the long term, existing staff resources will be re-directed to support the enhanced usage of PRA methods as outlined in this plan. This shift in resources will take place over several years after 1) considering the progress of our recruiting and training programs and 2) identifying less risk-significant areas where fewer staff resources are needed.

PRA expertise will be developed through modifications to the current PRA curriculum and additional curriculum development. Training will be used to increase the PRA skills of the current staff over the next several years. Where staffing and expertise levels are not keeping pace with emergent requirements associated with enhanced use of risk-based methodologies, the staff will procure technical assistance/contractor support. Contractor support will be used to supplement the staff's knowledge level as the staff continues to develop its own in-house expertise.

V. B. Non-Reactor Applications

An agency goal is to develop staff capability to review and provide timely feedback on major performance assessments and to make adequate independent licensing decisions. Training needs to meet this goal are currently being evaluated, and it is anticipated that training will be developed to address these needs.

The NRC anticipates that the staffing for activities associated with performance assessment is at the appropriate level through fiscal year 1997. Additional staff to address the anticipated level of complexity of the Department of Energy's performance assessment are provided for in outyear budgets. Risk assessment capability (including specific training) to deal with emerging issues in using risk analysis to analyze the use of nuclear medical devices will be augmented as required by the demands of the developing methodology.

VI. PRA IMPLEMENTATION PLAN DEVELOPMENT

VI.A Process

As a result of significant contributions to this plan by the Regions and headquarters program offices, regulatory activities for which PRA and other risk-based methodologies can have a role were identified. As part of the development of this plan, each office established an approach for accomplishing the goals and objectives for PRA use in its regulatory activities. The issues considered include objectives, methods, guidance development, training, regulatory changes, PRA methods and data, and resource implications.

The appendix contains tables detailing the results of this planning effort to date. Specifically, these tables give an overview of the objectives and methods associated with increasing the use of PRA technology in specific areas of reactor regulation and identify additional non-reactor programs areas where risk-based methodologies are being considered. More detailed internal planning documents are being developed by each program office to specify responsibilities, approaches, interface requirements, and interim milestones.

VI.B Policy Statement

As discussed earlier, the staff has prepared a proposed policy statement to declare the agency's commitment to increased use of PRA methods and insights in its reactor regulatory activities. This proposed policy statement would articulate the Commission's current position on the role of PRA in various regulatory programs and it would communicate that position to the staff, the public, licensees, and applicants for licenses. This is particularly important because significant improvements have been made in PRA methods, the NRC staff and industry have acquired additional experience in applying PRA, and because substantial operating experience has been accumulated since the Commission last published a policy statement on the use of PRA in 1979.

The staff plans to issue the proposed policy statement for public comment in September 1994. The staff plans to continue discussions with the Advisory Committee on Reactor Safeguards (ACRS) on the proposed PRA policy statement in January 1995 and present the final PRA policy statement to the Commission in March 1995. The staff anticipates publishing the final policy statement by April 1995 and intends to periodically brief the ACRS on the status and progress of the PRA Implementation Plan.

VI.C Ongoing Activities

During finalization of the PRA policy statement, the NRC will continue its current activities as outlined in the PRA Implementation Plan including the development of consistent PRA models and methods and will expand the data base on human performance reliability, plant-specific safety system availability, and equipment reliability. The NRC staff has been using PRA in design certification reviews, operating event assessments, licensing action reviews, and performance assessments of low-level and high-level radioactive waste disposal. In addition, the NRC will continue its current activities associated with industry initiatives, including the following

- Appendix B, Quality Assurance - Initiate pilot graded quality assurance program in September 1994.
- Appendix J, Containment Leakage - Publish proposed rule in late fall of 1994.
- Generic Letter 89-10, Motor Operated Valves - Follow up on industry implementation of the NUMARC and owners' group guidance concerning operability of motor-operated valves.
- Development of a means to establish an equipment reliability and availability database to support the maintenance rule and performance-based regulation.

The staff will continue to work with NEI to identify areas of mutual interest for the use of PRA methods and insights and plans to continue its interactions with the Institute of Nuclear Power Operations (INPO) concerning strengthening availability of plant-specific failure data.

Regulatory Activity	Objectives	Methods	Target Schedule	Lead Office(s)
1.1 DEVELOP DECISION CRITERIA FOR REGULATORY APPLICATIONS OF PRA	* Develop decision criteria for determining when it is practical to enhance the regulatory decision-making process through the use of PRA; thereby, achieving the benefits of improved regulatory decision-making, as well as, more efficient use of agency and industry resources.	* Determine methods for dealing with uncertainties. * Evaluate available industry guidance. * Develop a draft position document that defines proposed decision criteria. * Incorporate experience from initial pilot applications, such as those under Item 1.2 below. * Solicit public comment on proposed decision criteria.	09/95	NRR & RES
	* Develop risk-based criteria for plant-specific and generic regulatory decisions in those areas determined practical using the criteria developed above.	* Identify PRA data and information needed to support staff evaluation of generic and/or plant-specific PRA results within the context of various regulatory activities. * Consider extension of safety goal concepts to specific applications. * Evaluate available industry guidance. * Develop draft guidance and decision criteria for the use of PRA results in regulatory activities. * Solicit public comment on proposed guidance and decision criteria. * Finalize guidance document.	03/96	NRR & RES
	* Revise decision criteria based on 1 to 2 years experience, reassess the appropriateness of the decision criteria and staff use of risk-based methods and insights.	* Compare decision criteria to staff positions associated with selected "PRA application" areas. * Provide recommendations to ensure consistency in staff positions across "PRA application" areas, as needed.	12/97	NRR

1.0 REACTOR REGULATION (CONT.)

Regulatory Activity	Objectives	Methods	Target Schedule	Lead Office(s)
1.2 PILOT APPLICATION OF RISK-BASED CONCEPTS TO SPECIFIC REGULATORY INITIATIVES	* Develop staff positions on emerging, risk-based initiatives, including those associated with: 1. Motor operated valves. 2. Regulatory credit for on-line systems to monitor risk (e.g., as related to compliance with the maintenance rule, system configuration control and on-line maintenance). 3. ISI/IST requirements. 4. Graded quality assurance. 5. Containment leakage requirements. 6. Fire protection. 7. Maintenance Rule. 8. Risk-based alternatives to current system of deterministic technical specifications.	* Interface with industry groups. * Evaluation of appropriate documentation (e.g., 10CFR, SRP, Reg Guides, inspection procedures, and industry codes) to identify elements critical to achieving the intent of existing requirements. * Evaluation of industry proposals. * Evaluation of industry pilot program implementation. * As appropriate, identify proposed regulatory document revisions and develop associated regulatory analysis to support recommended revisions.	1. 12/94 2. 10/95 3. 12/96 4. 7/95 5. 9/95 6. 11/96 7. 7/95 8. 9/96	NRR
1.3 INSPECTIONS	* Include a pilot application of the use of risk-based results and insights in a trial assessment as part of the Customized Inspection Planning Process (CIPP).	* Develop risk-based input and guidance to the pilot inspection effort. * Assist in the evaluation of findings & development of recommendations for upcoming inspection activities to evaluate the effectiveness of licensees in identifying and resolving potential safety issues prior to them revealing themselves as plant problems.	6/94 Complete Ongoing	NRR
	* Continue to provide headquarters expertise in risk assessment to support regional inspection activities.	* Encourage interactions between regional and headquarters personnel in the assessment of the risk associated with plant configurations and events. * Provide opportunities for rotational assignments for regional personnel to headquarters for OTJ training on the use of PRA.	Ongoing	NRR

Regulatory Activity	Objectives	Methods	Target Schedule	Lead Office(s)
	* Provide guidance on the use of plant-specific and generic information from IPEs and other plant-specific PRAs.	* Develop guidance for the planning and conduct of inspection activities including those associated with implementation of the maintenance rule and evaluation of reliability assurance programs, 10CFR21 activities, emergency operating procedures, SAMGs and 10CFR50.59 evaluations. * Develop guidance on the disposition of inspection findings; i.e., when findings should be simply discussed with licensee management, or included in inspection reports (and in what manner), or recommended for enforcement action, enforcement discretion, or for determination of the appropriate severity level. (This activity will require interface between NRR, OGC and OE.) * Monitor IPE and IPEEE results and insights to identify needed revisions or additions to inspection guidance.	6/96 2/97	NRR NRR
1.4 OPERATOR LICENSING	* Revise knowledge and ability (K&A) catalogs (NUREGs 1122 and 1123) to incorporate operating experience and risk insights.	* Monitor contract in place with SEA through NRR/HOLB. * Coordinate with NEI. * Monitor insights from HRAs and PRAs (including IPEs and IPEEEs) and operating experience to identify additional revisions required to initial, requalification and examination inspection guidance for operator licensing activities. Monitoring activities will include cognizance of guidance developed under Item 1.1 above.	11/94 12/96	NRR NRR & Regions
	* Revise the Examiner's Handbook to reflect revised K&A's.	* Assess changes to K&A catalogs and their impact on guidance provided in the Examiner's Handbook. * Modify Examiner's Handbook as needed.	9/95	NRR
1.5 EVENT ASSESSMENT	* Continue to conduct quantitative event assessments of reactor events while at-power and during low power and shutdown conditions.	* Continue to improve models.	Ongoing	NRR
	* Develop guidance for improving risk assessments of reactor events while at power.	* Use the information gathered during a job task analysis (being conducted through AEOD TTC).	10/95	NRR

1.0 REACTOR REGULATION (CONT.)

Regulatory Activity	Objectives	Methods	Target Schedule	Lead Office(s)
	* Develop guidance and models for conducting risk assessments of reactor events during low power and shutdown conditions.	* Develop model options * Develop prototype model * Test model * Refine model for staff use * Develop guidance and procedures	9/96	NRR & RES
	* Develop guidance and models for conducting risk assessments of reactor events initiated by external events.	* Develop model options * Develop prototype model * Test model * Refine model for staff use * Develop guidance and procedures	9/96	NRR & RES
	* Assess the desirability and feasibility of conducting quantitative risk assessments on non-power reactor events.	* Define the current use of risk analysis methods and insights in current event assessments. * Assess the feasibility of developing appropriate risk assessment models. * Develop recommendations on the feasibility and desirability of conducting quantitative risk assessments.	6/95	NRR
1.6 EVALUATE USE OF PRA IN RESOLUTION OF GENERIC ISSUES	* Audit the adequacy of licensee analyses in IPEs and IPEEEs to identify plant-specific applicability of generic issues closed out based on IPE and IPEEE programs.	* Identify generic safety issues to be audited. * Develop audit plan; i.e., what constitutes an adequate licensee analyses. * Select plants to be audited for each issue. * Evaluate results to determine regulatory response; i.e., no action, additional audits, or regulatory action.	1/96	NRR

Regulatory Activity	Objectives	Methods	Target Schedule	Lead Office(s)
1.7 REGULATORY EFFECTIVENESS EVALUATION	* Develop guidance for evaluating changes in risk as a result of cumulative changes to plant design, Tech Specs and features of the licensing bases, and other changes to plant operation and operating experience.	* Develop model options. * Develop prototype model. * Test model. * Refine model for staff use. * Develop guidance and procedures.	9/96	NRR & RES
	* Apply the developed guidance to assess the effectiveness of major safety issue resolution efforts (e.g., SBO and ATWS rules) for reducing risk to public health and safety.	* Select issue(s) for assessment. * Apply model to assess reduction in risk. * Evaluate results. * Propose modifications to resolution approaches, as needed.	9/97	NRR
1.8 ADVANCED REACTOR REVIEWS	* Continue staff reviews of PRAs for design certification applications.	* Continue to apply current staff review process.	Ongoing	NRR
	* Develop SRP to support review of PRAs for design certification reviews of advanced reactors.	* Develop draft SRP. * Solicit peer and industry review. * Finalize SRP.	9/95	NRR
	* Develop staff guidance for use of risk analysis methods and insights as part of the construction and startup test inspection program.	* Develop draft guidance. * Solicit peer and industry review. * Finalize staff guidance.	9/96	NRR

1.0 REACTOR REGULATION (CONT.)

Regulatory Activity	Objectives	Methods	Target Schedule	Lead Office(s)
	* Develop guidance on the use of updated PRAs beyond design certification (as described in SECY 93-087).	* Develop draft guidance. * Solicit peer and industry review. * Finalize staff guidance.	9/97	NRR
	* Develop staff guidance on the use of risk assessment methods and insights to evaluate proposals for simplification of emergency planning requirements for plants with greater safety margin.	* Develop draft guidance. * Solicit peer and industry review. * Finalize staff guidance.	12/95	NRR
1.9 ACCIDENT MANAGEMENT	* Develop risk insights to support staff review and inspection of industry accident management programs (e.g., SAMG and containment performance improvement).	* Periodically search the IPE and IPEEE data bases (BNL/RES) to develop risk insights germane to accident management strategies.	9/97	NRR & RES

Regulatory Activity	Objectives	Methods	Target Schedule	Lead Office(s)
2.1 PASSIVE SYSTEMS RELIABILITY ASSESSMENT	* Develop information needed to permit an assessment of the reliability of components in passive safety systems proposed for use in advanced reactor designs.	* Participate in NRR/RES workshop on licensing needs, identifying short and long term needs for AP600 and SBWR.	9/94	RES
		* Initiate project to respond to NRR short term needs.	9/94	RES
		* Initiate projects to respond to NRR long term needs.	9/94	RES
		* Provide support to NRR RAI and SER development.	Continuing	RES
		* Provide support for NRR RAI and SER development for CANDU.	Continuing	RES
		* Continue confirmatory research on AP600 and SBWR.	Continuing	RES
2.2 METHODS DEVELOPMENT AND DEMONSTRATION	* Develop, demonstrate, maintain, and ensure the quality of methods for performing, reviewing, and using PRAs and related techniques for existing reactor designs.	* Develop and demonstrate methods for including human errors of commission in PRAs.	6/96	RES
		* Develop and demonstrate methods for better using operational events data in PRAs.	3/97	RES
		* Develop and demonstrate methods for including aging effects in PRAs.	6/96	RES
		* Develop and demonstrate methods for including design and construction errors in PRAs.	6/96	RES
		* Develop and demonstrate methods for performing simplified PRA Level 2/3 analyses.	3/96	RES
		* Develop and demonstrate methods to incorporate organizational performance into PRAs.	9/97	RES
		* Develop improved methods for performing sensitivity and uncertainty analyses.	12/94	RES
		* Develop and demonstrate risk assessment methods appropriate for application to medical and industrial licensee activities.	TBD	RES
		* Perform a limited reevaluation of one or two of the NUREG-1150 plant risk assessments, integrating the effects of the methods improvements noted above.	Start -2/97	RES

2.0 REACTOR SAFETY RESEARCH(CONT.)

Regulatory Activity	Objectives	Methods	Target Schedule	Lead Office(s)
2.3 TECHNICAL SUPPORT AND GUIDANCE DEVELOPMENT	* Provide technical support to agency users of risk assessment in the form of support for risk-based regulation activities, technical reviews, issue risk assessments, statistical analyses and such, and develop guidance for agency uses of risk assessment.	* Support refinement of existing guidance for using PRA for particular staff functions and develop new guidance as requested.	Continuing	RES
		* Continue to provide ad hoc technical support to agency PRA users.	Continuing	RES
		* Expand the database of PRA models available for staff use, expand the scope of available models to include external event and low power and shutdown accidents, and refine the tools needed to use these models.	Continuing	RES
		* Continue maintenance and user support for SAPHIRE and MACCS computer codes.	Continuing	RES
		* Support development of risk-based regulatory improvements.	Continuing	RES
		* Support agency efforts in reactor safety improvements in former Soviet Union countries.	Continuing	RES
2.4 IPE AND IPEEE REVIEWS	* Provide technical support to agency users of risk assessment in the form of support for risk-based regulation activities, technical reviews, issue risk assessments, statistical analyses and such, and develop guidance for agency uses of risk assessment.	* Interim IPE insight report (60 plants).	11/94	RES
		* Conduct reviews of IPE and IPEEE submittals and develop insights.	12/95(IPE) 12/97 (IPEEE)	RES
2.5 GENERIC ISSUES PROGRAM	* Provide technical support to agency users of risk assessment in the form of support for risk-based regulation activities, technical reviews, issue risk assessments, statistical analyses and such, and develop guidance for agency uses of risk assessment.	* Continue to prioritize and resolve generic issues.	Continuing	RES

3.0 ANALYSIS AND EVALUATION OF OPERATING EXPERIENCE, AND TRAINING

Regulatory Activity	Objectives	Methods	Target Schedule	Lead Office(s)
3.1 RISK-BASED TRENDS AND PATTERNS ANALYSIS	* Use reactor operating experience data to assess the trends and patterns in equipment, systems, initiating events, human performance, and important accident sequence.	* Trend performance of risk-important components. * Trend performance of risk-important systems. * Trend frequency of risk-important initiating events. * Trend human performance for reliability characteristics.	Annual rpt Annual rpt Periodic Draft 1/95	AEOD
	* Evaluate the effectiveness of licensee actions taken to resolve risk significant safety issues.	* Trend reactor operating experience associated with specific safety issues and assess risk implications as a measure of safety performance.	TBD	
	* Develop trending methods and special databases for use in AEOD trending activities and for PRA applications in other NRC offices.	* Develop standard trending and statistical analysis procedures for identified areas for reliability and statistics applications. * Develop special software and databases (e.g. common cause failure) for use in trending analyses and PRA studies.	LOSP-8/95 CCF-12/94 Periodic updates, others as appropriate	AEOD
3.2 ACCIDENT SEQUENCE PRECURSOR (ASP) PROGRAM	* Identify and rank risk significance of operational events.	* Screen and analyze LERs, AITs, IITs, and events identified from other sources to obtain ASP events. * Perform independent review of each ASP analyses. Licensees and NRC staff peer review of each analysis. * Convert ASP analyses to IRRAS. * Improve recovery and uncertainty methods for use with IRRAS.	Plan-10/94 Annual rpt Peer review implemented for 1993 events analysis Complete 4/95	AEOD
	* Determine generic implications of ASP events and characterize risk insights.	* Develop engineering and risk insights from ASP events.	Initial rpt 6/95, then annually	AEOD

3.0 ANALYSIS AND EVALUATION OF OPERATING EXPERIENCE, AND TRAINING(CONT.)

Regulatory Activity	Objectives	Methods	Target Schedule	Lead Office(s)
	* Provide supplemental information on plant specific performance.	* Share ASP analyses and insights with other NRC offices and Regions.	Annual rpt	AEOD
	* Provide a check with PRAs.	* Compare ASP quantitative and qualitative insights with PRAs and IPEs.	6/95	AEOD
	* Provide an empirical indication of industry risk and associated trends.	* Rebaseline selected ASP events. * Develop relationship between ASP CCDPs and core damage frequency.	11/95 Annual rpt	AEOD
3.3 INDUSTRY RISK TRENDS	* Provide a measure of industry risk that is as complete as possible to determine whether risk is increasing, decreasing, or remaining constant over time.	* Develop program plan which integrates NRR, RES, and AEOD activities which use design and operating experience to assess the implied level of risk and how it is changing. * Implement program plan elements which will include plant-specific models and insights from IPEs, component and system reliability data, and other risk-important design and operational data in an integrated frame work to periodically evaluate industry trends.	Plan-11/94 11/95, then annually	AEOD
3.4 RISK-BASED PERFORMANCE INDICATORS	* Establish a comprehensive set of performance indicators and supplementary performance measures which are more closely related to risk and provide both early indication and confirmation of plant performance problems.	* Identify and evaluate new or improved risk-based PIs which use component and system reliability models & human and organizational performance evaluation methods. * Develop and test candidate PIs/performance measures. * Implement risk-based PIs with Commission approval.	Plan-12/94 6/97 12/97	AEOD
3.5 COMPILE OPERATING EXPERIENCE DATA	* Compile operating experience information in database systems suitable for quantitative reliability and risk analysis applications. Information should be scrutable to the source at the event level to the extent practical and be sufficient for estimating reliability and availability parameters for NRC applications.	* Manage and maintain SCSS and the PI data base, provide oversight and access to NPRDS, obtain INPO's SSPI, compile IPE failure data, collect plant-specific reliability and availability data. * Revise LER rule to eliminate unnecessary and less safety-significant reporting and to better capture ASP, CCF, and human performance events. * Develop, manage, and maintain agency databases for reliability/availability data (equipment performance, initiating events, CCF and human performance data).	Ongoing Draft 9/95 Final 8/96 ASP,CCF,& HP database-12/95	AEOD

Regulatory Activity	Objectives	Methods	Target Schedule	Lead Office(s)
3.6 STAFF TRAINING	* Present PRA curriculum as presently scheduled for FY 1994.	* Continue current contracts to present courses as scheduled. * Maintain current reactor technology courses that include PRA insights and applications. * Improve courses via feedback. * Review current PRA course material to ensure consistency with Appendix C.	Ongoing	AEOD
	* Develop and present Appendix C training courses.	* Prepare course material based on Appendix C. * Present courses on Appendix C.	12/94	RES and PRA Working Group
	* Determine staff requirements for training, including analysis of knowledge and skills, needed by the NRC staff.	* Review JTAs performed to date. * Perform representative JTAs for staff positions (JTA Pilot Program). * Evaluate staff training requirements as identified in the PRA Implementation Plan and the Technical Training Needs Survey (Phase 2) and incorporate them into the training requirements analysis. * Analyze the results of the JTA Pilot Program and determine requirements for additional JTAs. * Complete JTAs for other staff positions as needed. * Solicit a review of the proposed training requirements. * Finalize the requirements.	12/96	AEOD
	* Revise current PRA curriculum and develop new training program to fulfill identified staff needs.	* Prepare new courses to meet identified needs. * Revise current PRA courses to meet identified needs. * Revise current reactor technology courses as necessary to include additional PRA insights and applications.	12/97	AEOD
	* Present revised PRA training curriculum.	* Establish contracts for presentation of new PRA curriculum. * Present revised reactor technology courses. * Improve courses based on feedback.	12/97	AEOD

4.0 NUCLEAR MATERIALS AND LOW-LEVEL WASTE SAFETY AND SAFEGUARDS REGULATION

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. * Examine the use of Monte Carlo simulation and its application to relative risk profiling. * Examine the use of expert judgment in developing error rates and consequence measures.	8/94 6/95 9/95	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/ RES
	* Extend the application of the methodology and its further development into additional devices, including teletherapy and the pulsed high dose rate afterloader.	*Develop generic risk approaches.	10/96	NMSS/ RES
	* Develop user friendly computerized guidance for materials licensees in risk analysis techniques for industrial and medical radiation devices.	* Conduct a series of HRA benchmarking and cross-validation exercises, including THERP and recent methodological developments in support of LP&S.	10/96	NMSS/ RES
4.2 Continue use of risk assessment of allowable radiation releases and doses associated with low-level radioactive waste and residual activity.	* Develop decision criteria to support regulatory decision making that incorporates both deterministic and risk-based engineering judgment.	* Conduct enhanced participatory rulemaking to establish radiological criteria for decommissioning nuclear sites; technical support for rulemaking including comprehensive risk based assessment of residual contamination. * Work with DOE and EPA to the extent practicable to develop common approaches, assumptions, and models for evaluating risks and alternative remediation methodologies. (Risk harmonization). * Work with NCRP 87-2 to develop risk based waste classification recommendations.	6/95	RES & NMSS
4.3 Develop guidance for the review of risk associated with waste repositories.	* Develop a Branch Technical Position on conducting a Performance Assessment of a LLW disposal facility.	* Mixture of deterministic and risk-based engineering judgment.	TBD	NMSS & RES

4.0 NUCLEAR MATERIALS AND LOW-LEVEL WASTE SAFETY AND SAFEGUARDS REGULATION(CONT.)

Regulatory Activity	Objectives	Methods	Target Schedule	Lead Office(s)
4.4 Revise SRP.	* BTP to be revised to reflect the Branch Technical Position for a Low-Level Waste Disposal Facility. This is a lower priority effort.	TBD	TBD	NMSS

5.0 HIGH-LEVEL NUCLEAR WASTE REGULATION

Regulatory Activity	Objectives	Methods	Target Schedule	Lead Office(s)
5.1 REGULATION OF HIGH-LEVEL NUCLEAR WASTE	* Develop guidance for the NRC and CNWRA staffs in the use of PA to evaluate the safety of HLW programs.	* Assist the staff in pre-licensing activities and in license application reviews. * Develop a technical assessment capability in total-system and subsystem PA for use in licensing and pre-licensing reviews. * Combine specialized technical disciplines (earth sciences and engineering) with those of system modelers to improve methodology. * Identify and prioritize user needs in PA (i.e., the basis for research projects) for RES, and to monitor progress towards meeting those needs.	Ongoing	NMSS & RES
	* Use PA and PSA methods, results and insights to support development of the Licensee Application Review Plan for HLW geologic repository.	* IPA analyses complement the Systematic Regulatory Analysis process used to develop the License Application Review Plan; results of IPA analyses provide feedback into SRA process.	Ongoing	NMSS
	* Use PA and PSA methods, results and insights to evaluate proposed changes to regulations governing the disposal of HLW.	* Assist the staff to maintain and to refine the regulatory structure in 10 CFR Part 60 that pertains to PA. * Apply IPA analyses to 10 CFR 60 (especially to sections 60.111, 60.112, 60.113, and 60.122) to maintain and refine the regulatory structure.	Ongoing	NMSS
	* Continue PA activities during interactions with DOE during the pre-licensing phase of repository development, site characterization, and repository design.	* Provide guidance to the DOE on site characterization requirements,s ongoing design work, and licensing issues important to the DOE's development of a complete and high-quality license application.	Ongoing	NMSS

A.3. RISK EVALUATION OF HIGH DOSE RATE REMOTE AFTERLOADING BRACHYTHERAPY AT A LARGE RESEARCH/TEACHING INSTITUTION

Dana L. Kelly, Lon N. Haney, George P. Simion, Patricia A. Rathbun, Jack L. Auflick

ABSTRACT

The Idaho National Engineering Laboratory (INEL) has been tasked by the NRC to evaluate the misadministration risks associated with high dose rate (HDR) remote afterloading brachytherapy in the U. S. This paper describes the results of INEL's visit to a large research/teaching institution. The purpose of this visit was to collect information on the HDR treatment process at this institution. This information will form a part of the HDR risk analysis knowledge base needed to provide quantitative data on the risks of brachytherapy misadministrations.

A.3.1 Introduction

Brachytherapy (from the Greek brachy = short) is a term used to describe various procedures for the treatment of cancer using small sealed radioactive sources. Afterloading techniques are those in which non-radioactive applicators or guide tubes are placed in the patient and the radioactive sources are then manually loaded into the applicators. Remote afterloaders are devices that use a remote control mechanism to insert and withdraw the sources. These devices have been designed for various dose rates. This paper focuses on high dose rate (HDR) remote afterloaders, in which doses of greater than 0.2 Gy/min are achieved. HDR remote afterloaders employ iridium-192, cobalt-60, or cesium-137 sources, with a combined maximum activity of 1.85 x 1011 to 7.4 x 1011 Bq.

Current NRC regulations address quality control procedures for conventional brachytherapy procedures, but do not address comparable procedures for remote afterloaders. The objectives of the risk assessment program being performed by INEL are to evaluate the risk significance of faults that could occur during clinical applications of remote afterloading brachytherapy and to provide information that the NRC can use in its consideration of regulations applicable to these devices. This paper describes the first phase of the INEL program: the use of risk assessment techniques to identify, model, and evaluate hardware faults and human errors with the potential to lead to brachytherapy misadministrations.

The initial portions of this task will focus on establishing a brachytherapy knowledge base for answering the following questions.

1. What is the HDR treatment spectrum, that is, devices employed, modalities of treatment, treatment settings, etc.?
2. What steps are involved in the HDR process and do they vary significantly across the treatment spectrum?
3. How reliable is the hardware?
4. What are the important human factors and human reliability issues that can contribute to or protect against human errors leading to misadministrations?
5. What is the role of quality assurance (QA) in preventing misadministrations?

A.3.2 Institute A Treatment Spectrum

Institute A is a large clinic for the radiotherapeutic treatment of cancer. A relatively small part of this clinic is devoted to use of the Nucletron microSelectron HDR remote afterloader for the palliative treatment of lung and esophageal cancers. At present, Institute A performs on the order of 20 such treatments a year, each consisting of 3-7 dose fractions. The medical physics staff at Institute A is actively engaged in brachytherapy research,

also, and the Nucletron HDR plays an important role in this research.

Institute A is also a teaching institution, affiliated with a nearby school of medicine. Institute A runs a physician residency program in radiation oncology and also provides training in brachytherapy for dosimetrists, radiation therapy technicians, and radiation oncology nurses. This amount of diverse activity and the availability of highly trained staff personnel probably places Institute A at one end of the spectrum in regard to treatment setting. On the other hand, Institute A performs relatively few HDR treatments, all of which are palliative, and treats a limited range of cancers in comparison with the intended role of the Nucletron device. As an example, Institute A does not use HDR brachytherapy to treat gynecological tumors. It is expected that the risks of misadministration will be, at least to some extent, a function of the treatment modality employed, so this finding may limit the generic applicability of results derived for Institute A

A.3.3 The HDR Process at Institute A

Figure 1 shows a block diagram of the HDR treatment process in place at Institute A at the time of the INEL visit in early 1992. The process is highly serial; very few actions occur in parallel. The process is also characterized by recovery actions involving the medical physicist and radiation oncologist. The relevant details of the process are discussed in the sections that follow.

A.3.4 Hardware Reliability

Based on anecdotal evidence from the manufacturer and the users at Institute A, the Nucletron microSelectron HDR appears to be a highly reliable device, with numerous features that guard against functional failures. However, this finding must remain preliminary until detailed design data is received from the manufacturer.

A.3.5 Human Factors and Human Reliability Issues

A screening human reliability analysis (HRA) was performed for the Institute A HDR process shown in Figure 1. In conjunction with the logic model described below, HRA was used to model the predominant human errors associated with significant human actions.

To familiarize themselves with the Institute A HDR process, the PRA and HRA analysts reviewed the following:

- descriptions of the Nucletron HDR microSelectron;
- Institute A procedures (including abnormal, emergency, maintenance, administrative, and especially quality assurance) and operational practices,
- staff composition and level of training and experience.

This training/familiarization process was enhanced by a one-week visit to Institute A where behavioral observations were made of the brachytherapy staff. The analysts also examined human actions entailing detection, diagnosis, and recovery actions following a hypothesized problem in the HDR process.

These activities identified a group of important human actions described in generic, functional terms (e.g., operators recover system). Next, the analysts expanded the description of each of these key human actions into specific high-level operator tasks and subtasks which were included in the logic model used to analyze the HDR process model. Decomposing each human action into specific tasks associated with individual equipment and procedures allowed the analysts to begin to identify specific failure modes, root causes, and failure effects. The description of each task also referenced significant recovery factors identified in the ASEP (Accident Sequence Evaluation Program) methodology[1] and relevant performance shaping factors for relatively poor human factors issues associated with the Nucletron computerized treatment planning system. These data were derived from an evaluation of the human-machine interface and direct observations of operator performance during an actual treatment.

The ASEP methodology was chosen as the primary technique for HRA modeling and assignment of screening probabilities. ASEP was designed specifically for situations, like this analysis, where detailed HRA task analysis information can not be collected. ASEP

allows systems analysts to make conservative estimates of human error probabilities (HEPs) without performing a detailed task analysis. This HRA procedure goes beyond a generic human factors approach to analyze, predict, and evaluate work-oriented human performance in quantitative terms. HRA can be applied to any activity which has a goal, a set of more or less fixed procedures which personnel perform to accomplish that goal, and some output or consequence of the performance which can be used to determine success or task accomplishment. HRA uses a human factors approach, but broadens its focus within a systems context. HRA examines the impact of unsuccessful human performance on the system or subsystem, while identifying feedback loops from the system, recovery actions (which return the system to a success path), and the effect of negative performance shaping factors (which increase the likelihood of human error). For each task, this data is used to a) build logic models of the system, b) derive estimates for HEPs, and c) combine HEPs with hardware failure rates to generate estimates of overall system reliability.

The analyst has several options from which to choose in using ASEP. This particular analysis used an option which gives greater credit for recovery factors and a more detailed consideration of dependence effects (compared with more general screening analysis approaches). As used in ASEP, dependence refers to the level of interaction between two or more workers or two or more tasks. Dependence is usually modeled on a scale which ranges from complete dependence (e.g., where a second worker fails at a given task because a primary worker failed at the same task) to complete independence (zero dependence).

It should be noted, however, that ASEP gives a more conservative assessment of HEPs than analyses based on a detailed task analysis, such as the Technique for Human Error Rate Prediction (THERP).2 Most of the ASEP HEPs represent total failure probabilities of 0.03 for original errors (0.02 for each error of omission plus 0.01 for each error of commission), multiplied by failure probabilities for various recovery factors. By comparison, if a detailed HRA-oriented task analysis were performed for the Institute A process, HEPs would generally be reduced by at least an order of magnitude. This reduction stems from the inclusion of other performance shaping factors not modeled in ASEP.

The ASEP procedure requires an expert assessment of a) the quality of administrative controls and the extent to which they are carried out, b) human factors issues such as the quality of the human-machine interface, c) the quality of procedures, training, and operator skill level, and d) the presence or absence of four specific recovery factors.

ASEP allows basic HEPs to be adjusted upwards for unusually poor human factors elements or poor written procedures. Significant human factors problems were identified in the Nucletron computerized treatment planning system (CTPS), which was given a reasonably poor rating by the analysts. According to its users at Institute A, the human-machine interface for the CTPS is confusing, difficult to use, and limits the ability to detect and quickly correct human errors. Consequently, human actions involving the use of the CTPS were adjusted upwards by a factor of 2.

While most human actions were modeled and quantified using ASEP, a few HEP values came from the Systematic Human Action Reliability Procedure (SHARP).3 These human actions were associated with medical practices and physician skills, which are not covered in ASEP. As a result, a skill-based screening HEP of 0.005 from SHARP was used for these actions.

Results from the screening HRA should be considered in relative terms only (i.e., not as absolute estimates of the probability of human error). The reason is two-fold: there is considerable conservatism built into the ASEP procedures and a detailed HRA-oriented task analysis was not performed at Institute A. An HRA-oriented task analysis would examine the impact of unsuccessful human performance on the system or subsystem, while identifying feedback loops from the system, recovery actions (which return the system to a success path), and the effect of various performance shaping factors, which either increase or decrease the likelihood of human error.

A.3.6 Institute A Quality Assurance for HDR Brachytherapy

Institute A has established a very detailed, written quality assurance (QA) protocol for both low and high dose rate brachytherapy. For HDR remote afterloading brachytherapy, the protocol describes required activities for

1. acceptance testing, commissioning, and source calibration,
2. quarterly QA review,
3. daily device QA,
4. treatment procedures,
5. roles and responsibilities of various personnel, and
6. review of treatment planning calculations, simulator films, and HDR programming.

In addition to these protocols, Institute A has also prepared a Quality Management Program to ensure compliance with new NRC regulations regarding quality management and misadministrations (10 CFR parts 2 and 35, Federal Register 56, No. 143, 34104-34121, and NRC Regulatory Guide 8.33). The main intent of the Quality Management Program is to provide written policies and auditable records to demonstrate compliance. Listed below are some items from the Quality Management Program that apply specifically to HDR brachytherapy:

1. two forms of patient ID required prior to administering treatment,
2. physician must sign and date prescription prior to start of treatment,
3. physicist must review entire treatment record prior to start of treatment, and
4. prior to implementing previously unused features of the treatment planning program, the physicist must test the feature for accuracy.

A rather surprising result pertaining to HDR QA was the importance of the activities performed by the physicist in association with the quarterly change-out of the Ir-192 source. In particular, the analysts did not suspect ahead of time that source strength calibration would be an important issue; it was assumed that the vendor would supply accurate data on the strength of each Ir-192 source. However, this is not the case. The Institute A physics staff provided information on the relative inaccuracy of vendor source strength calibrations and stressed the need to perform an independent check of source strength. A confounding factor is the lack of an accepted calibration standard for Ir–192. The importance of this QA task is reflected in the misadministration logic model discussed below, where failure to perform the quarterly source change QA activities is assumed to lead directly to a misadministration. This is an issue that might have escaped notice without the visit to Institute A.

A.3.7 Logic Models for Dose Error Misadministration

Deductive logic models were employed to estimate the potential for a dose-in-error misadministration with the Nucletron Micro Selectron HDR remote afterloader, as it is used at Institute A. These models are based on the process in place at Institute A during the INEL visit in early 1992. The results of the evaluation are summarized in this section.

Deductive logic models, in which the basic faults (and combinations of faults) leading to a misadministration are deduced by the analyst, were used (instead of an inductive approach, for example) because they were felt to be better-suited to the regulatory perspective being assumed in this project.

The top event in the model represents a dose to a patient that differs from the prescribed dose by 20% or more (this is the current regulatory definition of a misadministration). From this top event, the basic error combinations, or fault paths, that can lead to this type of misadministration are deduced. It should be emphasized that this model is specific to the HDR process in place at Institute A during the first quarter of 1992; it is not yet known whether this model would be applicable without modification to other HDR procedures performed at other institutions or clinics, perhaps employing remote afterloaders from other manufacturers. Answering this question will require visits to other institutions representing different points in the HDR treatment spectrum.

Analysis of the logic models produced 44 failure paths leading to a dose-in-error misadministration. None of these paths involved only a single error. In other words, there is no single error that can lead directly to a misadministration. This finding evinces the Institute A practice of independently reviewing the output of critical steps in the process, thus providing numerous opportunities to recover from prior errors. There were 23 failure paths involving two errors. These 23 paths contributed approximately 91% of the misadministration screening probability of 0.05. There were 17 paths involving 3 errors, with a combined probability of 2 x 10-3, 4 paths with 4 errors, with a combined probability of less than 10-4, and 1 path involving 5 errors, with a probability of less than 10-4.

The important role played by the Institute A medical physicist is illustrated by removing the independent review of the computerized treatment plan from the logic model and reanalyzing the model. There are again 44 failure paths, but the misadministration screening probability increases from 0.05 to 0.30 and 7 of the paths now involve a single error. These 7 failure paths all involve errors by the dosimetrist in generating the computerized treatment plan. They contribute approximately 96% of the misadministration probability. In the original case, these 7 paths contained two errors, because the medical physicist performs an independent review of the treatment plan prior to treatment.

The medical physicist also plays a vital role in the quality assurance (QA) activities associated with the quarterly replacement of the Ir-192 source (see above, also). At Institute A, the physicist is required at each source replacement to perform a source strength calibration, a check of HDR positional accuracy, and a check of timer accuracy and linearity. These steps are vital to preventing a dose-in-error misadministration. They do not appear as major contributors to the probability of a misadministration because of the low screening probabilities assigned to them. However, these errors are at the top of the risk increase importance list, meaning that the probability of a misadministration is very sensitive to increases in the probabilities of these errors. Note: a failure to perform any of the quarterly QA checks leads automatically to a misadministration. This is a conservative assumption that is based on interviews with Institute A medical physicists in which anecdotal evidence was obtained indicating that each of these steps is crucial to preventing a misadministration. For example, the source strength provided by the vendor has been found to be in error by an amount significant enough to lead to a dose-in-error misadministration. While it is true that the vendor source strength is not always in error by such a large amount, detailed data on the frequencies and magnitudes of these errors are not available; hence, failure to perform an independent calibration was assumed to lead directly to a dose-in-error misadministration.

A.3.8 Conclusions

The analysis of HDR remote afterloading brachytherapy at Institute A has provided the first piece of the misadministration risk puzzle. The model developed to describe the Institute A process is felt to be reasonably complete (with the exception that more hardware design details are needed) and accurate and should be useful as a starting point for examining other elements in the treatment spectrum and for investigating future HDR brachytherapy misadministrations.

The screening HRA and logic model analysis demonstrate the human factors deficiencies of the Nucletron CTPS and, consequently, the important role played by the Institute A medical physics staff in preventing misadministrations that are a potential result of this relatively poor human-machine interface. The human factors observations also point out the importance placed upon the skill and knowledge of the physician, parameters that are especially difficult to quantify with present HRA methodologies.

The staff interviews at Institute A served to illustrate the important role played by the medical physicists during the quarterly QA activities associated with source change-out. To reiterate, this insight might not have been obtained without the visit to Institute A.

The use of deductive techniques (e.g., fault trees) has proven to be an effective and efficient way to model and estimate the potential for a dose-in-error misadministration at a specific medical institution. In addition, the fault

tree methodology added to the credibility and auditability of the analysis performed while identifying and evaluating

a. possible combinations of faults (or failure paths) in the case-specific HDR process,

b. significant human errors associated with specific portions of the brachytherapy process,

c. dependencies between significant human errors in the process,

d. important recovery actions, and

e. performance shaping factors adversely influencing human errors.

A.3.9 Future Analysis Efforts

The next step in the HDR risk analysis will be to make additional site visits, construct process models and (perhaps) logic models for these sites, and compare their processes to that at Institute A. Of particular interest will be the role of the medical physics staff at these other sites; based on anecdotal evidence provided by the Institute A staff, one can expect to see the medical physicist perform disparate functions at the different sites. At least for the Nucletron system, the role of the medical physicist appears to be vital to preventing misadministrations, so it will be interesting to see how other institutions and clinics utilize the skills and talents of their physics staff, if indeed they draw upon a dedicated physics staff at all.

Some of the activities planned for the next phase of this analysis are

1. Expand Knowledge Base -- High dose rate and/or low dose rate remote afterloading brachytherapy is performed on at least 12 treatment sites (e.g., esophagus, bronchus, cervix, endometrium). The details of the treatment process depend heavily on the specific application performed, the treatment modality used, the model of remote afterloader employed, and on the facility-specific procedures and personnel involved in the process. The limited information collected from visits to two manufacturers has indicated that significant design variability exists among the three remote afterloaders currently licensed in the U.S.

2. Review Quality Assurance Activities -- Treatment-specific and periodic quality assurance activities will be reviewed. Key steps and tasks performed in QA activities will be identified and included in the process and logic models.

3. Evaluate Human Behavior -- Human behavior data and insights gleaned from Institute A will be supplemented by data collected by INEL human reliability analysts with the direct support of medical experts.

4. Examine Key Hardware -- The brachytherapy remote afterloader is a relatively simple hardware system. Its performance requires (and is dependent upon) significant human control. System features designed to prevent or mitigate misadministrations will be examined and performance criteria will be developed for each of the principal device designs considered. If available, device-specific failure and incident data will be evaluated.

5. Develop Process and Logic Models -- Process models will be developed to represent significant brachytherapy applications, afterloader types and models, and medical facility environments. To assess the risk significance of the use of remote afterloaders, both established risk assessment methods (e.g., fault trees) and novel techniques will be considered.

6. Determine Possible Consequences -- A range of possible consequences (e.g., acute and latent detrimental health effects, including physical injury and death) associated with each significant failure path in the brachytherapy process will be estimated qualitatively by a panel of radiation oncology physicians with expertise in brachytherapy.

A.3.10 References

1. A. D. SWAIN, *Accident Sequence Evaluation Program Human Reliability Analysis Procedure*, NUREG/CR-4772, Sandia National Laboratories, February 1987.

2. A. D. SWAIN and H. E. GUTTMAN, *Handbook of Human Reliability Analysis with Emphasis on Nuclear Power Plant*

Risk Applications, NUREG/CR-1278, Sandia National Laboratories, August 1983.

3. G. W. HANNAMAN and A. J. SPURGIN, *Systematic Human Action Reliability Procedure (SHARP),* EPRI-NP-3583, Electric Power Research Institute, 1984.

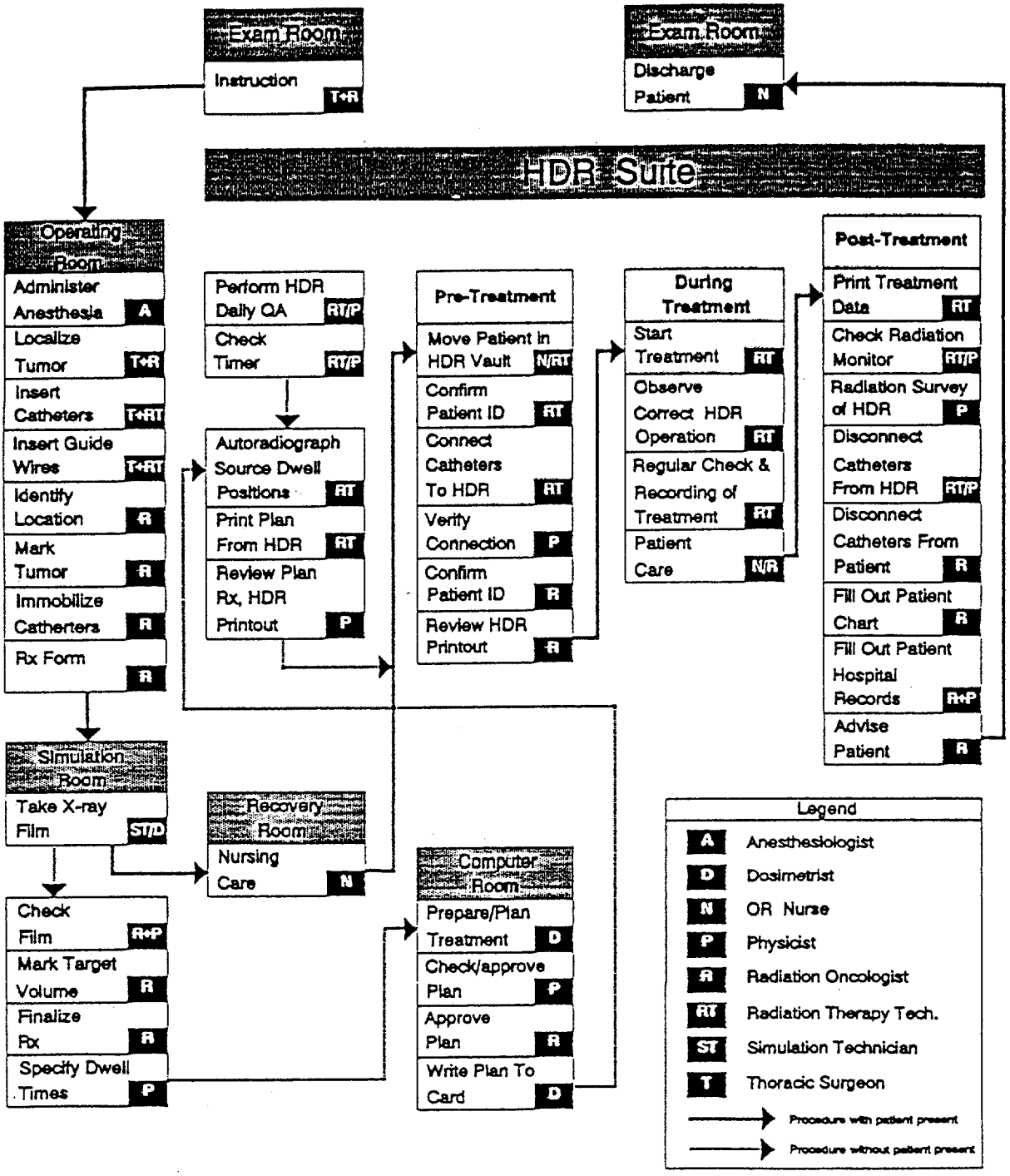

Figure 1. Procedural flow Chart for Endobronchial HDR Brachytherapy at Institute A.

A.4. THE PROS AND CONS OF USING HUMAN RELIABILITY ANALYSIS TECHNIQUES TO ANALYZE MISADMINISTRATION EVENTS

Lee T. Ostrom, Ph.D., CSP

ABSTRACT

This paper discusses the risk assessment methodologies applied to data collected during investigations of incidents in medicine involving nuclear by-product materials. These are called misadministration events. The risk assessment methodology applied to the data is fault tree analysis augmented with human reliability analysis. The results of the analysis has been beneficial for further elucidating the causal factors of the misadministration event analyzed. The risk assessment methodology did not provide all the benefits desired, however. For example, the methodology did not provide a good quantitative estimate of the risk of future misadministrations.

A.4.1 Introduction

Medical applications of radionuclides involve both therapeutic and diagnostic procedures. Therapeutic procedures may include the use of relatively intense radioactive sources and have the potential for significant detrimental health effects if mistakes occur. The Nuclear Regulatory Commission (NRC) regulates these medical applications of radionuclides under 10 CFR 35. In this regulation, misadministration events are defined; licensees are required to report these events to the NRC.

Misadministration events generally involve errors in therapeutic or diagnostic applications resulting in the wrong dose being administered, the wrong site being treated, or the wrong patient being treated. In order to better understand the potential causes of these events, and to help examine the regulatory basis, the NRC Office of Nuclear Materials Safety and Safeguards (NMSS) is undertaking a risk assessment of misadministration events as part of an event investigation activity. This work represents one of the first applications to the safety of medical radioisotope devices of Probabilistic Risk Assessment (PRA) techniques developed to evaluate reactor safety. This paper discusses the methodology used to date, the problems encountered, preliminary insights from this first analysis, and possible future directions of the project.

This project was funded by the U.S. Nuclear Regulatory Commission and for the U.S. Department of Energy under DOE Idaho Field Office Contract DE-AC07-76ID01570. Views expressed in this report are not necessarily those of the Nuclear Regulatory Commission.

A.4.2 Methodology

The methodology applied to the data discussed in this paper was PRA fault tree analysis augmented with human reliability analysis (HRA). The data to conduct the analyses were collected during site visits to facilities that had experienced misadministration events and from visits to facilities that performed similar procedures. These visits were beneficial because they enhanced the understanding of the medical procedures. The risk assessment methodology dealt only with the top event observed during the event. The three possible top events were:

- Wrong treatment site
- Wrong dose administered
- Wrong patient being treated.

The event discussed in this paper was a wrong treatment site event.

A.4.3 Description of the Event

This event involved the manual brachytherapy treatment modality. A patient undergoing treatment for cervical cancer received an unin-

tended 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 Ostrom, Leahy, and Novack[1].

A.4.4 Analysis Methodology

The risk assessment methodology used to perform the analysis was a combination of probabilistic risk assessment (PRA) and human reliability analysis (HRA). The process for conducting the analysis involved six steps. These were: 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; 6) conducting a sensitivity analysis. The sensitivity analysis (Step 6) involved iterating on Steps 4 and 5 in order to model the process while varying performance shaping factors and postulating changes in the process. The following discusses each of these steps in more detail:

Process Model

A process model was developed using functional flow diagram (FFD) techniques[2]. The model basically shows the steps in the process in the order of their performance. The process model was developed using data collected from a misadministration site visit and a visit to a cancer center that performs similar treatments. This model was used as the basis for the rest of the analysis.

Fault Trees

There were three fault trees developed using standard PRA techniques Figure 1 shows an example of the types of fault trees developed.

The human errors shown on the tree were determined in two ways. First, by input from the misadministration investigation site visit and, second, by postulating errors from the process steps shown on the process model. Medical professionals helped postulate these errors. HRA event trees were developed for sequences of human errors, such as the placement of the afterloader.

Human Reliability Event Trees

Figure 2 shows an example of the HRA event trees developed from the analysis of the process that existed at the time of the event. This tree was developed using the techniques described in THERP[3]. There were two sequences of human errors postulated. These were the Source Control Sequence (SCS) and the Afterloader Placement Sequence (APS). The SCS shown in Figure 2 depicts the event that was investigated during the site visit. The failure paths on these trees proceed diagonally from upper-left to lower-right. Success paths proceed diagonally from upper-right to lower-left. Recovery paths are dashed lines and proceed from right to left. The capital letters denote errors and the lower-case letters denote successful actions.

There were three failure paths determined in the SCS. These were: ABC, aDEF, and AbDEF. There were also three failure paths in the physician placement sequence.

Quantifying the Model

THERP[3], SHARP[4], and ASEP[5] methodologies were used to quantify the human error probabilities. The hardware failure data were developed using a generic hardware failure rate of 1.0E-3. This is a screening value and actual failure rates will be sought from the manufacturer. The hardware failure rates are probably high because there is no force placed on the welds and the material the afterloader is made of is high grade stainless steel. High grade pipe has a failure rate on the order of 2E-5 failures per hour and springs have failure rates on the order of 4E-5 failures per hour[6].

Factors that were considered during the quantification of the human errors were the Radiation Technologist's lack of training, the poor labeling on the source safe, and the dependencies between the Radiation Technologist and the Radiation Technologist Supervisor. The Radiation Technologist (RT) and Radiation Technologist Supervisor (RTS) errors were quantified using the data tables and methodologies contained in THERP. Although there were not one-to-one correlations between the errors that were postulated in the model and those listed in the

THERP tables, the categories were generally similar. It was assumed that 36% of the Cs–137 sources in the safe were small enough to migrate through the end of the spring. This was calculated by taking the number of 10 mg Cs-137 sources of the diameter used in the event and dividing by the total number of sources in the source safe at the time of the event. This value is an estimate; the exact number would vary depending on the age of the spring and whether the opening was damaged. The physician errors were more difficult to quantify, so SHARP skill-based screening values were chosen. It was assumed that the physician was well skilled; a value of 5.0E-4 was chosen as the HEP. This is the middle of the range for a skill-based error, which is from 5.0E-5 to 5.0E-3. The patient errors were the most difficult to quantify. These were quantified by using ASEP pre-accident screening values. The value initially used was 0.03; however, this value was postulated to be too high because patients are medicated and instructed not to touch the afterloader. In fact, patients are afraid to touch the afterloader because of the fear of radioactivity. The medical consultant stated that in his twenty years of work in the field he has only heard of one case where a patient got up from bed. In this regard, we reduced the HEP for the patient actions by a factor of ten, which is the error factor, and used the value 0.003. This is the lower tolerance bound. This still made the value conservative, but more realistic. An ASEP screening value of 0.03 was also used for errors involving the nurse and transportation of the patient.

Generating the Cut Sets

IRRAS 4.07 was used to generate the cut sets.

Sensitivity Analysis

The sensitivity analysis involved varying performance shaping factors and postulating changes in the process. These changes were then quantified and an estimate in the change in the overall probability for failure was calculated. Two separate analyses were conducted.

The first analysis involved improving the level of stress of the workers, improving their training level, reducing the dependence between staff members, and adding independent verification steps to the process. The second analysis involved postulating the process with the incorrect sources removed from the source safe.

A.4.5 Results and Discussion

The risk assessment was interesting because it highlighted (a) the failure path that lead to the event, (b) the estimated effects of licensee's corrective actions on the failure path, and (c) another failure path that is not only reasonably probable, but could go undetected. The evaluation process suggested the need for a reliable, independent verification of afterloader placement, to reduce the probability of this failure path.

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.

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

A.4.6 Future Direction

From these results it has been decided to retain elements of the risk assessment methodologies tried to date, plus orient the data analysis to more of a human factors approach. For example, a process model and event trees will be developed for the events investigated.

The investigation itself will be oriented more towards a human factors approach since the events investigated to date have primarily involved human error. This entails collecting more information about the human factors aspects of the process including:

- Communications
- Training
- Human-machine interface
- Organizational culture.

Also, the possibility of maintaining a data base of all medical procedures using nuclear by-product materials and how many of those

result in misadministration in order to get a better understanding of the true risk for misadministrations will be explored.

A.4.7 Conclusions

Applying risk assessment methodologies to misadministration events has proven useful because it shows how the system can fail and how changes to the system can help prevent misadministrations.

The risk assessment methodologies tried to date have not provided all the information desired. Therefore, a hybrid risk assessment approach is going to be applied to data collected during future misadministration events.

A.4.8 References

1. L. T. Ostrom, T. J. Leahy and S. D. Novack, *Summary of 1991 and 1992 Misadministration Events,* EG&G-2707, NUREG/CR-6088 (1993).
2. D. Meister, *Behavioral Analysis and Measurement Methods,* John Wiley and Sons, New York, (1985).
3. A. D. Swain and H. E. Guttman, *Handbook of Human Reliability Analysis with Emphasis on Nuclear Power Plant Applications,* NUREG/CR-1278, (1983).
4. G. W. Hannaman and A. J. Spurgin, *Systematic Human Action Reliability Procedure (SHARP).* EPRI NP-3583, Palo Alto, CA, (1984).
5. A. D. Swain, *Accident Sequence Evaluation Program Human Reliability Analysis Procedure,* NUREG/CR-4772, SAND86-1996, (1987).
6. D. I. Gertman, W. F. Gilmore, W. J. Galyean, M. R. Groh, C.D. Gentillon, B. G. Gilbert, and W. J. Reece, *Nuclear Computerized Library for Assessing Reactor Reliability (NUCLARR).* NUREG/CR-4639, EG&G-2458, Vol. 1, Rev. 1, (1990).
7. K. Russell, et al., *Integrated Reliability and Risk Analysis System (IRRAS), Version 4.0,* NUREG/CR-5813, January (1992).

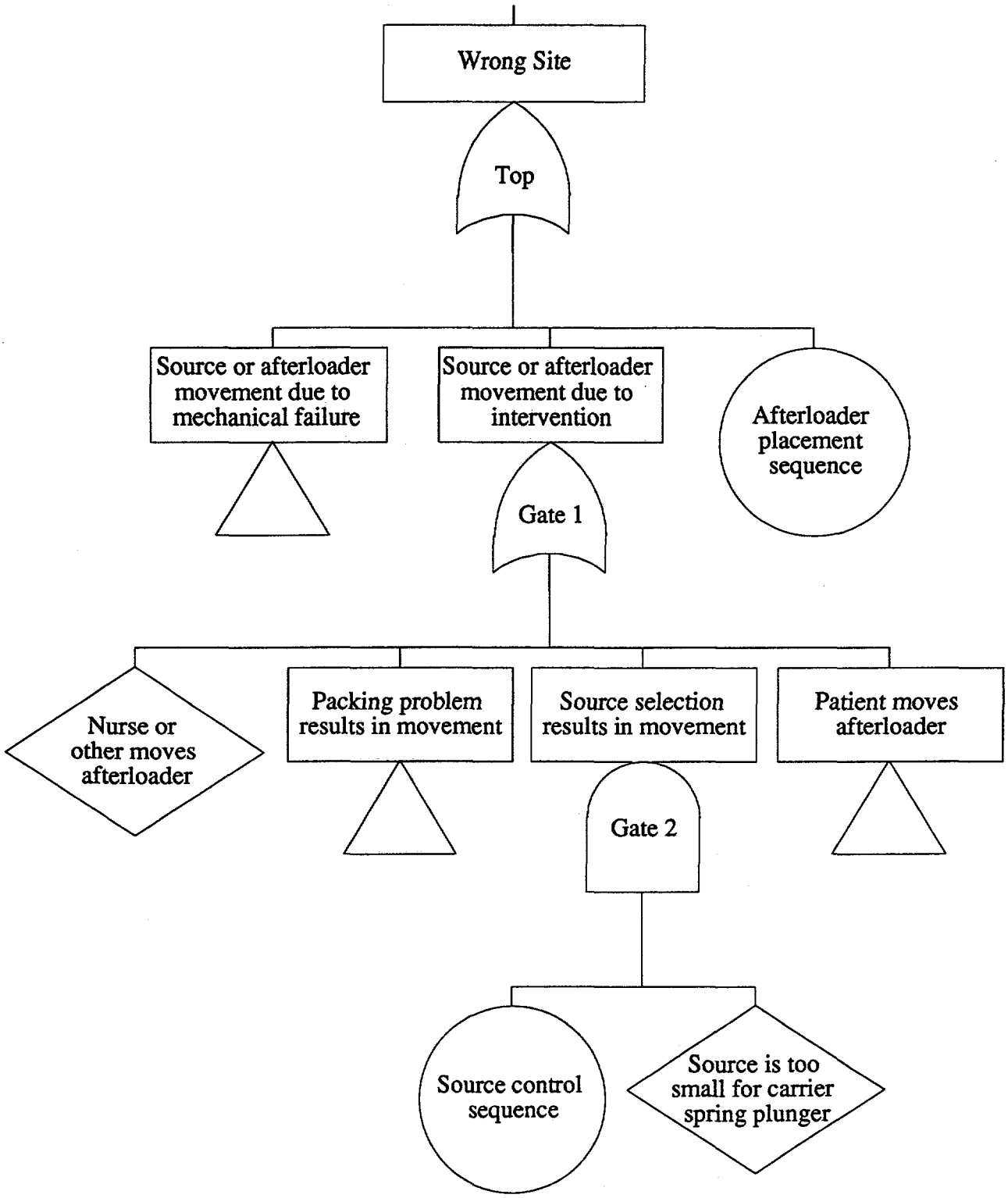

Figure 1. Fault tree developed for the event.

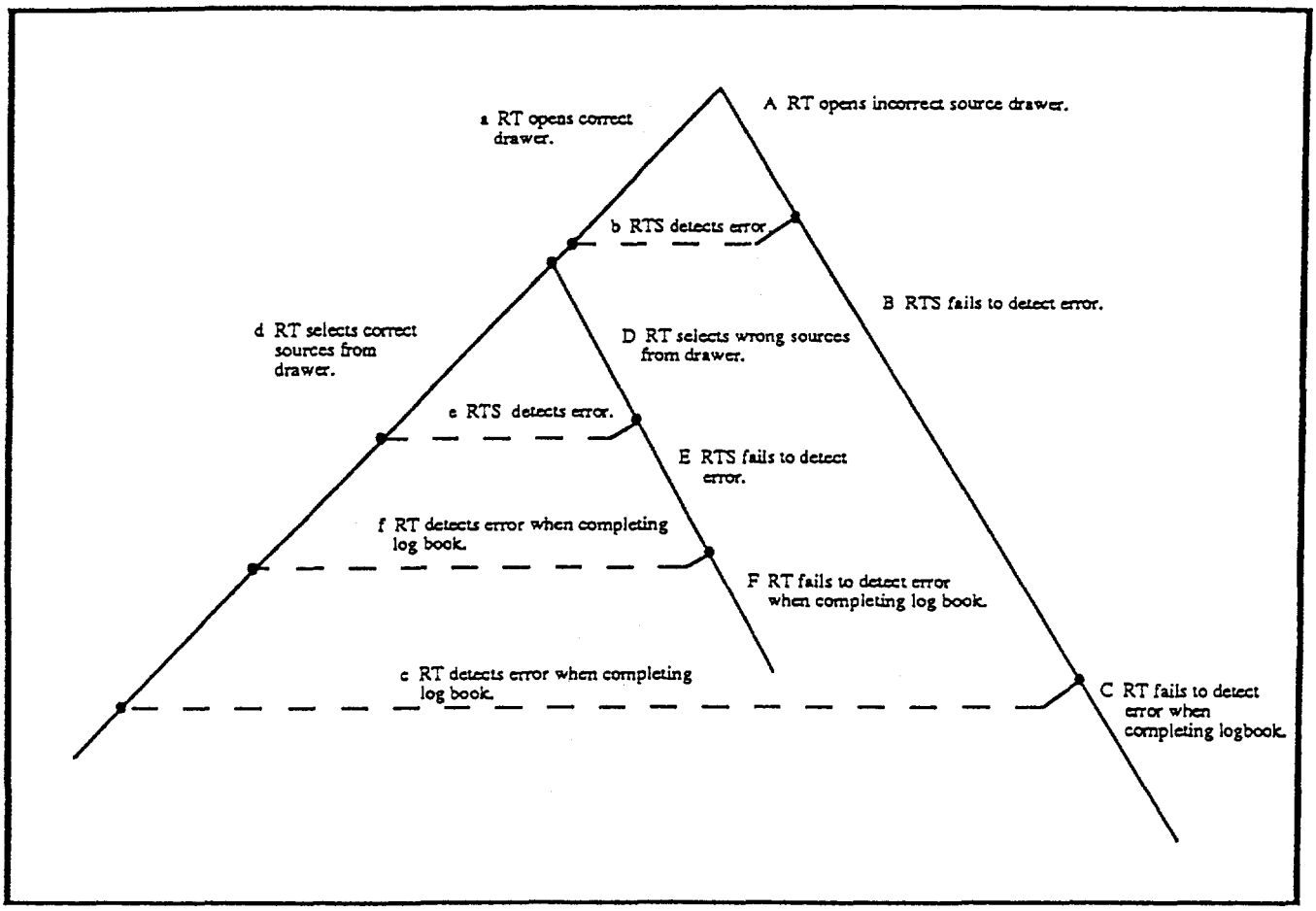

Figure 2. Source selection sequence.

A.5. REVIEW OF MEDICAL MISADMINISTRATION EVENT SUMMARIES AND COMPARISON OF HUMAN ERROR MODELING

John Wreathall

A.5.1 Purpose

The purpose of this work is to describe: an analysis of medical misadministration events using a generic error modeling framework, an evaluation of the benefits of this method of analysis, and to compare the use of this method with the THERP method. (Technique for Human Error Rate Prediction)

A.5.2 Summary of Generic Error Modeling Framework

This framework has been developed under funding from the U.S. Nuclear Regulatory Commission (NRC) as part of the creation of a new human reliability analysis (HRA) method for the analysis of human errors during low-power and shutdown operations at commercial nuclear power plants. The framework in its present form has been published in a draft letter report (Draft Task 6 letter report) to NRC. The most recent publicly available form of the framework was presented at the 1994 Probabilistic Safety and Management (PSAM II) conference.[1] This section provides a summary of the principal features of this framework related to the analysis of medical misadministrations, and the various taxonomies associated with the framework.

The graphical representation of the framework is a flow diagram shown in Figure 1. The arrows in this figure indicate influences. For example, the occurrence of error mechanisms is influenced by the performance shaping factors (PSFs). This influence is shown by an arrow from PSFs to error mechanisms.

A.5.3 Unacceptable Outcomes

Unacceptable outcomes are self-descriptive; they represent the results of the misadministration that are deemed unacceptable by some position of authority or regulation. In the case of medical misadministrations reviewed by NRC, there are identified a range of unacceptable outcomes that are used as the basis for this analysis. These are: dose to the wrong patient, dose to the wrong site, wrong dose, and wrong isotope used.

A.5.4 Human Failure Events

Human failure events (HFEs) represent the interactions with equipment or patients that result in the unacceptable outcome. These are often expressed in terms of the state of the equipment being incorrect, as in the case of "Incorrect treatment program entered in HDR machine." The focus of the HFEs is on the consequence of one or (usually) more unsafe actions ("errors") that represented the immediate cause of the unacceptable outcomes.

A.5.5 Unsafe Actions

Unsafe actions are those actions taken by people that lead the plant into a less safe state. Unsafe actions also include the unsafe consequences of actions not taken (the so-called errors of omission). These are often called "human errors" in typical event investigations. The distinction in this framework is that many unsafe actions do not involve "errors" in the narrow sense (often actions taken that were not intended); rather, they may involve mistaken intentions or deliberate rule-breaking. As described later, people can be "set up" by circumstances and conditions to take the actions that led to unsafe consequences. In those circumstances, the people did not commit an error in the every-day sense of the term; they were doing what was the "correct" thing as it seemed at the time.

Reason[2] provides a taxonomy of the classes of unsafe actions. Slips and lapses lead to unsafe actions where the outcome of the action was not what was intended. Skipping a step in a procedure or reversing the numbers in an identification label are examples of lapses and slips respectively. Both are errors associated with what Rasmussen[3] has termed skill-based level of performance. This level of performance is associated with the

predominantly "automatic control" of routine and highly practiced actions. The significance to risk of these unsafe actions generally seems to be quite small for the simple fact that these actions, not as intended, are easily recognized by the person involved and (in most circumstances) are easily corrected.

For unsafe actions where the action is as intended, there are two broad classes of unsafe actions. The first relates to intentional actions in which the intention is wrong. For example, the operator may have misdiagnosed the plant condition and is following the procedure for the wrong condition. The consequential actions are mistakes. The second is where a person decides to break some rule (even though the rule is known to them) for what seems to be a good (or at least benign) reason, such as reversing the steps in a procedure to simplify the task. Unsafe actions in this last category are circumventions.(Referred to as "violations" in Reason's terminology. However, "violations" has a distinctly different meaning in NRC investigations from that intended here.) It should be noted that acts of sabotage are distinct from circumventions in terms of the intended consequence.

Mistakes can be considered rule-based or knowledge-based depending on whether the task is demanding rule-based or knowledge-based performance. For rule-based performance, documented, task-specific instructions are being followed (usually contained in procedures for almost all power-plant activities important to safety). For knowledge-based performance, the person involved is relying on ingrained technical and specialist knowledge (as in generalized troubleshooting). Rule-based mistakes are further subdivided as to whether the wrong rules are being followed (for example, following misdiagnosis), or the rules are appropriate but contain technical omissions or flaws.

Mistakes are perhaps the most significant to risk because they are being followed purposefully by the user, who has limited cues that there is a problem. Indications contradicting the diagnosis are often dismissed as "instrument errors", for example. Often it takes an outsider to the situation to identify the nature of the problem as happened at Three Mile Island.

Circumventions are distinctly different in their causes from the other kinds of unsafe actions and are not be considered "human errors' in many psychological analyses. Reason provides the following interpretation: circumventions "can be defined as deliberate but not necessarily reprehensible deviations from those practices deemed necessary (by designers, managers and regulatory agencies) to maintain the safe operation of a potentially hazardous system." Circumventions are potentially significant contributors to risk in that unanalyzed conditions can result from unexpected combinations of errors and circumventions. However, the person committing the circumvention is (usually) aware that the action has occurred and may be able to take actions themselves or alert other staff.

A.5.6 Error Mechanisms

Different unsafe actions can come about from different psychological mechanisms that lead to the same unsafe outcome. For example, a physicist could mis-program an HDR machine for several reasons. First, he may inadvertently skip a step in the dose planning calculation (a lapse). Second, he may incorrectly read the instructions in the prescription (for example, reversing two digits a slip). Third, the software could contain an error in the coding or look-up tables (a machine failure that has resulted in some cases from a lack of knowledge on the part of the physicist). Fourth, the plan may have been developed for a different patient (a rule-based mistake). From the outcome perspective, the human failure event is still "incorrect treatment program in HDR machine." As will be discussed, the opportunities for these different mechanisms to be corrected before treatment starts are significantly different.

These different reasons for performing an unsafe action represent different error mechanisms. There are important differences between these error mechanisms, both as to the conditions under which they can occur and the potential for recovery.

Error mechanisms are not observable in themselves, only by their consequences as

unsafe actions. Therefore data sources such as event reports will not provide information specific to this classification. However, the classification is important in that consideration of error mechanisms provides a logical basis for considering the influence of clusters of PSFs and contingent conditions on different unsafe actions. The following is based in large part on the discussion by Reason in Ref. 3.

Reason has identified error mechanisms associated with the different kinds of unsafe actions. For the purposes of this project, these can be classified into two groups: failures associated with cognitive processes, and circumvention-related factors. For example, the failures associated with cognitive processes (and their most likely-to-be-associated types of unsafe action) include:

- failures in attention (mainly slips)
- failures of memory (lapses)
- failures of recognition (mainly lapses)
- failures of situational appraisal (misapplications of "good rules" [rule-based mistakes] and knowledge-based mistakes)
- failures of verification (misapplications of "good" rules and knowledge-based mistakes)
- motor program failures (applications of bad rule [rule-based mistakes])
- incomplete knowledge (rule-based and knowledge-based mistakes)
- inaccurate knowledge (rule-based and knowledge-based mistakes).

It should be noted that confirmation bias and overconfidence, for example, are subsumed under verification failures.

Given these error mechanisms, it is possible to identify some of the situational influences that are likely to give rise to the mechanisms. These are not considered to be formally complete. Rather, these are intended just to indicate the kinds of linkages that may be important in the medical misadministration events.

Precursors of attentional failures: distraction, high workload, stress, changes in work routines, situations, or plans.

Precursors of memory failures: distraction, high workload, stress, and task items in which necessary knowledge must be kept in the head rather than being inherent in the task.

Precursors of recognition failures: poor "signal-to-noise ratio" (e.g., poor human-machine interface or communications), distraction, high workload, stress, etc.

Precursors of situational appraisal failures: counter-indications to application of appropriate rule embedded in a mass of other signals some of which are indicating the use of a "strong-but-wrong" rule, inadequate training, inadequate procedures, inadequate supervision, stress, distractions, etc.

Precursors of verification failures: as above, with greater emphasis on distraction, stress, workload, and other things likely to disturb or preempt "on-line" reasoning.

Precursors of motor program failures: a "forgiving" environment in which bad work habits are not corrected by supervision, experience, training, or adequate procedures.

Precursors of knowledge failures: inadequate procedures, training, and leadership.

In the case of circumventions, it is recognized that only limited research exists as to error mechanisms and the conditions that influence their occurrence. Data reported in a paper by Reason & Free,[4] that describes several research programs aimed at understanding this area of behavior, is attached for information in Appendix A.

A.5.7 Performance Shaping Factors

Given the differences between the possible error mechanisms that could be the cause of one unsafe action, the use of a single set of performance-shaping factors (PSFs) for all mechanisms is inappropriate. As discussed above, each error mechanism has a primary set of factors. In addition, the rates and locations of circumventions are strongly influenced by the task design and the occurrence of incompatible goals or requirements, and the rewards and penalties for compliance.

The important point is that no single set of PSFs apply to all error mechanisms, and that

using a single set of PSFs would be appropriate if only that particular error mechanism were the most risk-significant.

A.5.8 Contingent Conditions

The distinction between PSFs and contingent conditions is a pragmatic one, since both influence the rates and types of unsafe actions. Contingent conditions are those aspects of performance at the facility that are distinctly different from the routine of other similar opportunities for similar unsafe outcomes. They often represent aspects of a treatment plan or facility operation for which normal planning and procedures prove inadequate in some significant way. In contrast, the PSFs are often related to ergonomic aspects of the situation, which can often be evaluated by techniques such as walk-throughs, use of human-factors checklists, and so on.

A.5.9 Analysis of Medical Misadministration Events

Three misadministration events for analysis were selected jointly with the INEL project team. These events are identified as Events A, C, and D in NUREG/CR-60886. These events are analyzed below.

Event A, Misadministration of a High Dose Rate Remote Brachytherapy Treatment, November 1991

Summary of Event

In this event, a male patient was due to receive his fifth and final radiation therapy treatment for cancer of the nasal septum. Following its attachment to the patient's nose a catheter was connected to the high dose rate (HDR) unit by a resident physician. The medical physicist who had programmed the previous four treatments was not available so a second physicist programmed the HDR unit using the treatment chart adjacent to the HDR console. The physician and the physicist verified the data programmed into the HDR unit corresponded to the information in the chart and the unit was activated. Shortly after the treatment began, an observer asked the duration of the treatment. The physician indicated that it should last about 90 seconds, whereas the physicist indicated more than 400 seconds. Because of the difference, the physician directed that the treatment be stopped. Subsequently it was found that the wrong chart had been used to program the treatment. Two charts were located by the HDR console. The physicist had selected the wrong one, and no verification of patient identity was made. As a result, the patient received an unintended dose of 76 cGy to the lips.

Analysis

This analysis discusses the various elements of the framework as they occurred in this event. The framework in flowchart format corresponding to this event is shown in Figure 3.

Unacceptable Outcome

The unacceptable outcome in this case is defined by the NRC's category of dose to the wrong site.

Human Failure Event

This event was the result of the incorrect program being entered into the HDR device by a medical physicist. The program that was entered was designed for a different patient.

Unsafe Actions

Two unsafe actions led to the HFE. First the physicist selected and entered data from the wrong patient's chart. This was a rule-based mistake in that the data were entered purposefully according to the correct procedure; it was the wrong data source that was used. Second, the physician present, while reviewing the printout from the HDR programmer, failed to identify that the data entered in the HDR program were incorrect. This was a knowledge-based mistake. The physician did not know how to read the HDR data printout and so did not understand that these data did not correspond with the prescription.

Error Mechanisms

Two different error mechanisms contributed to the physicist entering the wrong data. First was the selection error between the two charts left by the HDR machine. This selection error was encouraged by the absence of clear identification marks as to which chart applied to which patient (see PSFs). The second error mechanism related to the

physicist was the absence of any attempt to verify the patient's identity. Depending on whether the physicist was trained and required to check the patient's identity, this represented a circumvention (knew the rules but did not follow them) or a lapse (forgot about the rule), or, if no such training or rule was provided, a motor-program failure (an inadequate rule concerning patient identification). In this case, reference 5 identifies that the facility lacked any procedure requiring verification of patient identity versus the treatment plan, and therefore this error mechanism is a failure in verification.

The inability of the physician to interpret the HDR machine program was a result of incomplete knowledge; he simply did not have the knowledge to make the correct interpretation.

Performance Shaping Factors

For the first error mechanism of the physicist, mis-selection of the patient's chart, the principal contributions come from poor control of the charts (Procedure), and an inadequate labeling system associated with the location of "next patient" charts (Labeling [part of Human-System Interface]). For the second error mechanism, the physicist's failure to verify the patient identity, was shaped by the lack of facility requirements (Procedure) and (probably) by a failure in training.

The incomplete knowledge on the part of the physician is the result of inadequate training.

Contingent Factors

Several factors created the opportunity for this event. First, the facility was normally operated with a small number of patients; two patients being treated with the HDR unit (and, hence, two charts being near the unit) in the same day was unusual. Most HDR treatments (~ 90%) were gynecological, with most others being endobronchial. Hence two patients involving nasal catheters on the same day was very rare. (However, two patients having a similar preparation for gynecological treatment may not be so rare.) Second, the physicist who previously treated the patient considered he would have recognized the patient, possibly because of the small number of patients. However he was not available and the second physicist did not confirm the identity of the patient.

All of these factors created the opportunity for the physicist to select the incorrect chart.

Event C, Misadministration of Manual Intracavity Brachytherapy Treatment, February 1992

Summary of Misadministration

In this event, a female patient was undergoing the second of two brachytherapy treatments using a Henschke afterloading applicator with cesium-137 sources as part of a treatment plan for cervical cancer. The features of a Henschke applicator and other aspects of the treatment are described further in Reference 5. A "new" radiation technologist (RTA) was being trained in active-source loading procedures including those associated with the Henschke applicator by an experienced technologist (RTB), who was also performing other, separate duties. RTA, on observing that the experienced technologist was busy, decided to proceed with the source-loading process in the source-storage room without waiting for RTB. As she started, she saw the radiation therapy supervisor (RTS) and requested her help. As a result, RTA and RTS selected sources from a drawer in the safe labeled "10 mg" and "15 mg" sources, the correct sizes of sources for the therapy. RTA then installed these sources into the source carrier associated with the Henschke applicator and carried them in a "pig" to the simulation room. The sources were subsequently used in the treatment. On leaving the source storage room, RTA entered data into the source log-book. Rather than enter the data corresponding to the actual sources, she copied an earlier entry for sources used in a previous similar procedure.

However, the sources used were not the correct sources for the source carrier. Because of a different geometry, the selected sources were not retained by the helical springs in the Henschke source carriers. During treatment (planned for 40 hours+) the sources relocated within the carriers to the capped ends, causing radiation doses to the labia and upper thighs. The error in selecting the sources was strongly influenced by the assistance of RTS, who had not performed a loading of a Henschke

applicator for eight years. The sources selected by RTA were those that were in use eight years earlier, but were no longer the correct ones. The mis-selection was compounded by the labeling on the source safe. The drawer from which the sources were removed was the only one labeled with the source sizes. However the drawer was not intended to be used and a piece of unlabeled tape had been placed to prevent the drawer being opened.

The incorrect location of the sources was found because of a separate problem with the initial setup of the applicator. In accordance with the original plan, a straight intrauterine tandem was prepared and loaded with dummy sources for the simulation films. However, during insertion, the physician decided that a curved tandem would be more suitable so one was used in stead of the straight tandem. However, the dummy sources were left in the straight tandem. When the simulation film was read, the dummy sources were observed to be missing. According to procedures, the treatment could continue anyway and was allowed to proceed. The medical physicist, on observing the lack of dummy sources, decided that this was an opportunity to train a "new" medical physicist in the dosimetry procedure, and requested a second film to be taken. Because of the workload in the X-ray department, the second film was taken about 6 hours after the medical physicist's request. Once this was reviewed, it was seen that the cesium sources were not in the correct location. The patient's physician ordered the removal of the sources. This was done about 24 hours after the start of the treatment.

Analysis

This analysis discusses the various elements of the framework as they occurred in this event. The framework in flowchart format corresponding to this event is shown in Figure 3.

Unacceptable Outcome

The unacceptable outcome in this case is defined by the NRC's category of dose to the wrong site.

Human Failure Event

One human-failure event occurred: the wrong sources were installed in the Henschke applicator, which were then relocated to the wrong site because of the incompatible geometry between these sources and the source carriers.

A sub-optimal recovery occurred in that the location of the sources was discovered during the treatment, but only after 24 hours after the sources were loaded. However, there was no requirement to repeat the film before the treatment started (since other means existed to calculate the treatment dosimetry), failure to repeat the film is not a failure.

Unsafe Actions

Two unsafe actions led to the wrong sources being installed in the Henschke applicator. The first was more important; the second removed a potential, though unlikely, recovery opportunity.

The first unsafe action was the unauthorized removal of the incorrect sources from the safe. RTA knew that she was not authorized to remove sources from the safe. This was to be her training period for such an action. Her action to remove the sources (a circumvention) was compounded by the advice of the supervisor, RTS, whose knowledge of the location and sources to be used was outdated. As a result, RTA removed the wrong sources from the safe and installed them in the source carriers. Without the circumvention the incorrect sources would not (in all likelihood) have been selected.

The second unsafe action was the failure of RTA to record the data associated with the sources actually removed from the safe in the log book, rather than copying the data from a previous entry. This was again a circumvention of the rules concerning logbooks. Since RTA was a qualified radiation technologist (just not trained in this particular area), it can be assumed that she understood the need for logbook record-keeping. The contribution of this action was to remove one potential recovery opportunity. That is, if the sources actually removed had been logged and someone else (say, RTB) had subsequently inspected the log book, it was possible that the error would have been found. However, there is no indication that a periodic check of the selected sources be performed other than during a source-log book audit, which would

have identified the mis-identification of the sources in the log book.

Auditing of the source log book was required only once every six months according to the Radiation Oncology's Quality Assurance Program. It is considered unlikely that the error would have been found during the treatment period; the probability of a six-monthly test occurring within the planned 42.5 hour treatment period is approximately 1/100. Nonetheless, the potential existed.

Error Mechanisms

The first unsafe action, the unauthorized removal of the sources, resulted from three error mechanisms associated with two people, RTA and RTS. The first error mechanism associated with RTA was the error in judgment in deciding to proceed with the removal of the sources despite not being so authorized (error in judgment leading to a circumvention). The second was the selection error that led to the incorrect sources being inserted in the source carrier. The error mechanisms associated with RTS was the use of inaccurate knowledge in that she relied on her out-of-date experience in helping select the sources.

The cause of the second unsafe action, entering incorrect data into the log book, is not described specifically in the report. However, one might suspect that this approach to record-keeping was not uncommon on the part of the individual; it may have been common for other personnel.

Performance Shaping Factors

The factors associated with RTA's judgment error, to select the sources, are not identified in the report. Potential PSFs would include: workload (since RTB was busy), the penalties/rewards system (as it was applied at that facility for "rule-breaking"), and overconfidence on the part of RTA (she was a qualified radiation technologist). Additionally, the event may indicate that training about acceptable behavior during training may have been absent.

The PSFs associated with the selection error by RTA are identified in the report. These are: the inadequate labeling of the source safe drawers and her lack of training (recognizing that she was in training when this event occurred).

The PSFs associated with the inaccurate knowledge associated with RTS are the labeling of the source safe drawers (the same PSF as above), and a lack of training associated with changes in procedures in the area supervised by RTS.

Again, there are no identified PSFs associated with RTA's decision to copy the previous log-book entry. The same potential PSFs associated with the source-selection error (workload, penalties/rewards system and overconfidence) could similarly apply here.

Contingent Factors

Several contingent factors played a role in creating the potential for this misadministration. The first (and possibly the most significant) was the continued storage of the out-dated sources in the same safe as the current sources. The use of two lengths of unmarked tape to indicate that drawer was not to be opened was a very weak alternative to removal of the outdated sources, as reflected in the "labeling" PSF above.

The second was the unfortunate combination of the supervisor's outdated knowledge with the change in configuration of the Henschke source carriers. Other changes would not have led to a patient misadministration (such as if the outdated sources were too big, rather than too small, for the source carriers).

The third contingent factor that increased the likelihood of early detection was the presence of a "new" medical physicist. Because of his need to be trained, the staff medical physicist decided to have a repeated film taken for the dosimetry calculations. But for this reason, it appears likely that the medical physicist would have used the original film without the dummy sources. In that case, the treatment would have continued for the planned 42.5 hours.

A.5.10 Discussion of Generic Error Modeling Framework Results

This section discusses the advantages gained from the use of the Generic Error Modeling

Framework and compares these with another human-error modeling method, THERP.

Advantages Gained from Use of Generic Error Modeling Framework

The advantages gained from the use of this framework are in several areas. These are:

- presentation of results of investigations;
- explanation for causes of misadministration events;
- identification of modifications to investigation protocols; and
- adaptation of investigation results for other users.

Presentation of Results of Investigations

As shown in the example analyses in Section 3, the framework provides a hierarchical structure to presenting the results of the investigations. This structure helps make clear the dimensions and different contributing factors that simple narrative descriptions provide. One important distinction is what were the observable actions that people took (unsafe actions) that led to the defenses in medical uses of nuclear devices failing, versus the states of mind (error mechanisms) that precipitated the action. A second is to provide a description of how specific performance-shaping factors influenced specific unsafe actions. A third is a description of the contingent conditions came to play their significant roles. It has been found that, by representing

Of particular benefit, it has been found in other applications of the framework that the use of the hierarchy in describing the events and their causes helps communicate the key elements to people not expert in the areas of human factors or (in this case) nuclear medicine and radiation therapy. This applies particularly to regulatory agency management.

Explanation for Causes of Misadministration Events

The framework at the levels of unsafe actions and error mechanisms reflects concepts developed in the psychological community; specifically those described by Reason in Ref. 3. Many of the actions and mechanisms described there have existed for some time in the literature, and therefore are implicit in existing event reports (whether or not they use the same taxonomy). However, Reason introduced a class of unsafe actions that rarely had been considered explicitly in event analyses. These are circumventions, the deliberate though non-malevolent breaking of safety rules and procedures. This class of unsafe actions appears to play an important role in the occurrence of several misadministration events, particularly the manual brachytherapy misadministration described in Section 3.2. Another case where circumventions played an important role was the remote brachytherapy misadministration at Indiana, Pennsylvania.[6]

The distinction between circumventions and other types of unsafe actions is important. First, the circumstances associated with circumventions are largely different from those associated with the more traditional forms of errors. Even though the description for circumventions is not yet as developed as those for other types of unsafe actions, the more traditional areas of human-factors engineering do not seem to be so important here. These would include procedures' content and presentation, design of displays, and so on. Circumventions are typically associated with motivational and management issues.

It is recognized that ways of evaluating and modeling circumventions are not yet complete. However, the notion of circumventions as a factor in significant misadministration events seems important in the explanation of their occurrence.

Identification of Modifications to Investigation Protocols

Given that the framework brings a structure to the description of the events, and that it introduces a new class of unsafe action, then it is possible to use its concepts to modify and extend the protocols used during the on-site investigations. These suggestions are not intended as any form of criticism of the present protocols, but are simply intended to indicate how the framework can supplement the concepts already in use.

First, by providing a nominal set of PSFs that are considered more likely to be linked

with certain error mechanisms and types of unsafe actions (see Section 2.4), these could be used as a focused area for investigation, possibly prompting a search for influences that would be otherwise overlooked or minimized. In addition, negative findings would also be important in the development of improved databases for these events. Second, the new types of unsafe actions, particularly circumventions, are not considered explicitly in the current protocols. As a result, the causes of the circumvention discussed in Section 3.2 are based on supposition rather than evidence.

Adaptation of Investigation Results for Other Users

One of the uses of the misadministration event investigations is to provide information to other users for regulatory applications, such as the use of probabilistic risk assessments. One difficulty in using event investigations in their "native" form is that the circumstances surrounding an event are often unique and are described in terms of what Hudson[7] has labeled "tokens". Tokens are the specific causes and factors that occur uniquely in individual events, such as the misleading drawer labeling coincident with the out-of-date knowledge of RTS discussed in Section 3.2.2. In contrast, regulators and risk analysts need to draw more general conclusions from these occurrences to prevent classes of events and failures; what Hudson has called "types". In order to generalize, it is appropriate to apply taxonomies to the various dimensions of these events, such as the types of unsafe actions and their contributing PSFs.

This framework provides a suitable set of taxonomies. For example, during discussions with INEL staff it was found that application of the framework to the events described in [5] provided significant help in expressing the events in ways that PRA and HRA analysts could relate the event data to the modeling of the classes of events into PRA trees. A comparison of this method with one of the standard HRA techniques is discussed in Section 4.2.

A.5.11 Comparison with the THERP Method

The Technique for Human Error Rate Prediction (THERP) is one of the longest established methods for estimating the probabilities of human errors. It was developed and first applied as part of the U.S. NRC's Reactor Safety Study (WASH-1400) in the early 1970's. Since then it has been modified and updated once by its authors; the last documented version of the method[9] was published in 1983.

In order to compare the methods discussed in Section 2 with THERP, there are a few points of clarification to be made. First, most analysts (including the INEL staff) do not simply apply the methods and data presented in [8] when performing an HRA study. Rather they use the concepts contained in THERP as a spring-board for their own analyses, often involving expert judgment beyond the THERP database for providing influences of shaping factors and calculating probabilities of errors. The one feature of THERP that is most frequently followed by most analysts is the use of detailed task analyses to describe the various actions required by plant (or medical personnel) to perform some task safely. Error probabilities are then assigned to each step in the task analyses to represent the likelihood that particular step is (in effect) omitted. All such probabilities can then be summed to provide a probability that the overall task is not completed correctly. (This is a simplification of the mathematical process. Details of the actual mathematical manipulations are provided in standard references for probabilistic risk analysis.) Therefore the application of THERP tends to vary between analysts in terms of the actual PSF data used and the exact form of the task analysis (level of decomposition, stop-rules for recovery, etc.). This inter-user variability has been considered one of the principal factors in limiting the repeatability of THERP results,[9] which has demonstrated variations of more than 103 in estimates of error probabilities for the same sample case, for example. For this comparison, the emphasis is on THERP as documented; there are simply too many variations in its application to use any other basis.

Second, the method described in Section 2 does not constitute a working HRA method. The framework has been developed as one of several steps towards an improved HRA method, but several major tasks remain

including the development of the quantification process. Therefore the comparison cannot be made on the basis of what each estimates as error probabilities for the same setting. Rather, the comparison can only be based on the degree to which each identifies important aspects of human errors as seen in "real-world" events. Given the nature of how different groups use THERP as a framework rather than as a complete HRA procedure, this comparison is reasonable. It must also be recognized that research on the elements of the framework is not yet finished. More work is planned in two areas important in medical misadministrations: the causes of circumventions, and a taxonomy for contingent conditions. Both require additional data analyses.

Interpretation of Probability of Human Failure

The first fundamental difference between THERP and the Generic Error Modeling framework lies in the embedded belief in THERP that opportunities for human errors occur continuously through all steps in a detailed task analysis, and that (for the most part) these are separable and "independent". (By independent, it is implied that the principles of superposition [lineal addition] can be applied to error probabilities, not that rules for dependence analysis are not provided.) Further, the influences represented in the THERP PSFs are, for the most part, considered independent. These properties of the modeling represent, in effect, that human reliability is a stochastic variable; that is, people's performance randomly varies through time and is modulated by the various PSFs.

In contrast, it is the view represented in the Generic Error Modeling framework that (on the whole) people are highly reliable except when placed in settings where the conditions and the PSFs combine in such a way as to make failure virtually certain (at least, highly likely!). The practical significance of this view is that what have been termed the contingent conditions are an equal influence in determining outcomes as are any PSFs. It is the contingent conditions that set up the opportunities for errors to result in human failure events. Therefore, in assessing any scenario, it is critical to assess what conditions represent "business as usual" and what are significant departures from those conditions where the normally adequate PSFs are no longer adequate (or may even be adverse). Such departures are represented by the contingent conditions, though these need to be further systematized.

The distinction can be summarized by the following two interpretations of the probability of a human error in some task. In effect, THERP is implying that, for the given task and PSFs, a failure probability of 10-2 means that for every hundred times the task is performed, on average a person will fail to perform the task correctly once. For the Generic Error Modeling approach, such a number would be interpreted as that for every hundred times the task is performed, the combination of PSFs and contingent factors will result in almost certain failure. Therefore the probability is determined principally by how often the combination of PSFs and contingent factors will occur. For comparatively high probabilities (such as 10-2 per event), the practical difference in interpretation may not be too important. However, as probability estimates decrease, our imagination limits our ability to consider the range of abnormal contingent factors that may negate such probabilities. For example, with a failure estimate of 10-5, we must be assured that there are no conditions that can occur more frequently that 1 in 100,000 that can "force" a human error. This is why the new method will include a significant effort to identify the potential for such conditions.

Consideration of Error Types

THERP provides no real classification of error types. It does distinguish errors of omission and commission, though these are differences in consequence, not in the underlying mental processes. For the most part, the errors described in the THERP data represent slips and lapses. They are principally errors committed in following procedures (written or oral) where steps are omitted, controls are mis-selected, or indications or labels are misread. Mistakes are considered only in terms of misdiagnosis using a time-reliability correlation. Circumventions are not considered. The recovery mechanisms are primarily associated with slips and lapses

(walk-round checks of displays, alarm annunciators, and the like), with some limited consideration of one person checking another (a potential recovery against some rule-based mistakes).

The error types considered in THERP represent the concerns during the period of its development. Prior to the accident at Three Mile Island (TMI) in 1979, much concern about operator behavior was focused on layout of displays, labeling, and meter reading. This was reflected in the focus of human-factors guidelines then in use in the nuclear industry. (See, for example, the bibliography contained in The Human. The Key Factor in Nuclear Safety: Conference Record for 1979 IEEE Standards Workshop on Human Factors and Nuclear Safety, IEEE, New York, 1980.) The "nominal diagnosis" module was added post-TMI, when a variety of similar (at least in principle) time-reliability based methods emerged in the early to mid-1980's to address the concern of misdiagnosis. Circumventions represent a new area. Their importance has become recognized following Chernobyl and such non-nuclear catastrophes as the Challenger explosion, the petrochemical accidents at Bhopal, Institute (West Virginia), and Channelview (Texas), and the transportation accidents at Valdez (Alaska), Zeebrugge (Belgium), and at Kings Cross and Clapham Junction (London, U. K.). The significance of the "off-normal" contingent conditions has also been recognized in these events.

In summary, the THERP method has considered in detail only one class of the range of error types (slips and lapses), and provides a simplistic consideration of one class of rule-based mistakes (misdiagnosis). In contrast, it is intended that the Generic Error Modeling method will consider all presently identified error types.

This distinction is not only important in terms of quantification. Perhaps more important is the way the errors are described qualitatively. These qualitative descriptions play an important role in shaping people's perceptions of the important human-factors concerns. These perceptions then influence which regulatory forces are brought to bear.

Use of Operational Experience

The final distinction between THERP and the Generic Error Modeling (when complete) is that THERP provides data tables representing the (unquestioned) expertise of the method's authors. However no mechanism was provided for incorporating operational experience into the database. Therefore, as experience with man-machine technologies has developed and expanded, this has not been reflected in the THERP method (at least as published). In contrast, error probability quantification in the Generic Error Modeling method as now planned will be based on expert judgment that is formally based on a two-stage incorporation of operational experience.

A.5.12 Conclusions

In conclusion, it is believed that the Generic Error Modeling method, through its framework, provides a more realistic description of the contribution of human behavior to significant accidents. Its development has been strongly influenced by the experience of severe accidents in several technologies; it is consistent with recent work in psychology, and provides a logical basis for parsing human errors and their causes into different levels of description. Its interpretation of the probability of human failure is logical and consistent with experience in several fields. Additionally, it will be a "living" method where operational experience will be constantly factored in. This should reduce the problems associated with the developments in the underlying man-machine technologies. It is recognized that there is considerable work required to convert this method into a practical HRA method. This work is continuing, however, with a prototype method being available in the next 12 to 18 months.

In contrast, THERP analyses are focused on a limited set of error types, which was the focus of concern at the time of its development; it must be recognized that these types are not the only one of concern today. Its implicit interpretation of error probability does not seem to accord with our experience in major accidents, where consistently the presence of "off-normal" conditions were a significant factor and almost guaranteed

failure. There are no mechanisms for it to incorporate operational experience nor address new technologies. Because of these shortcomings, many analysts have had to adapt the THERP concept to their own applications. However, experiments in the application of THERP in this way have indicated a high degree of variability in the estimated of human error probabilities.

A.5.13 Some Preliminary Data on Circumventions

(Taken from Reference 5)

These results are based on evaluations of circumventions during shunting (a railroad activity involving the coupling up of goods trains).

"Time pressure, high workload, and a quicker way of working featured as reasons for all rule circumventions. These were designated as general factors. When these general factors were excluded, three specific factors appeared, relating to particular rules. These were as follows.

Factor 1: Competence

- Inexperience
- Laziness
- Management turns a blind eye

N.B. Experienced shunters saw these circumventions as being more the result of errors than deliberate non-compliance.

Factor 2: Attitude

- A skilled shunter can work safely this way
- It's a macho way to work
- Management turns a blind eye

N.B. These were high-frequency and low-risk circumventions, later classified as routine circumventions

Factor 3: Work conditions

- Design of sidings makes circumvention necessary
- Rules can be impossible to work to
- Inexperience

N.B. These were high-frequency and high-risk circumventions, later classified as situational circumventions."

A.5.14 References

1. Wreathall, J., et al, *The Development Of A New HRA Method On A Principled Basis, Proceedings of the Second Probabilistic Safety and Management* (PSAM II) Conference, San Diego, California, In Press.
2. Reason, J., *Human Error,* New York: Cambridge University Press, 1990.
3. Rasmussen, J., *Models of Mental Strategies in Process Plant Diagnosis, in Human Detection and Diagnosis of System Failures,* (J. Rasmussen & W. Rouse, Eds.), New York: Plenum Press, 1981.
4. Reason, J. and Free, R., *Bending the rules: The psychology of violations,* New Technology & Work (NeTWork) Meeting, Werner Reimers Foundation, Bad Homburg, Germany, 1993.
5. Ostrom, L.T., Leahy, T.J., and Novack, S.D., *Summary of 1991-1992 Misadministration Event Investigations,* NUREG/CR-6088, Idaho National Engineering Laboratory, Idaho Falls, Idaho, March 1994.
6. U.S. Nuclear Regulatory Commission, *Loss of an Iridium-192 Source and Therapy Misadministration at Indiana Regional Cancer Center, Indiana, Pennsylvania, on November 16, 1992,* NUREG-1480, Washington, D.C., February 1993.
7. As reported in [2] above.
8. Swain, A.D., and Guttmann, H.E., *Handbook of Human Reliability Analysis with Emphasis on Nuclear Power Plant Applications, Final Report,* NUREG/CR-1278, Sandia National Laboratories, Albuquerque, New Mexico, August 1983.
9. Poucet, A., *Human Factors Reliability Benchmark Exercise: Synthesis Report, EUR 12222 EN,* Office for Official Publications of the European Communities, Commission of the European Communities, Luxembourg, 1989.

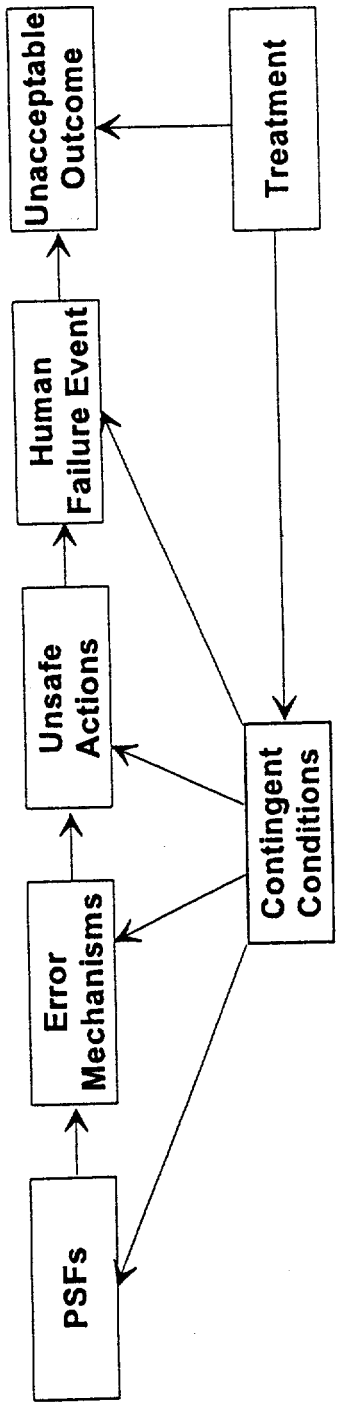

Figure 1. Generic Error Modeling Framework

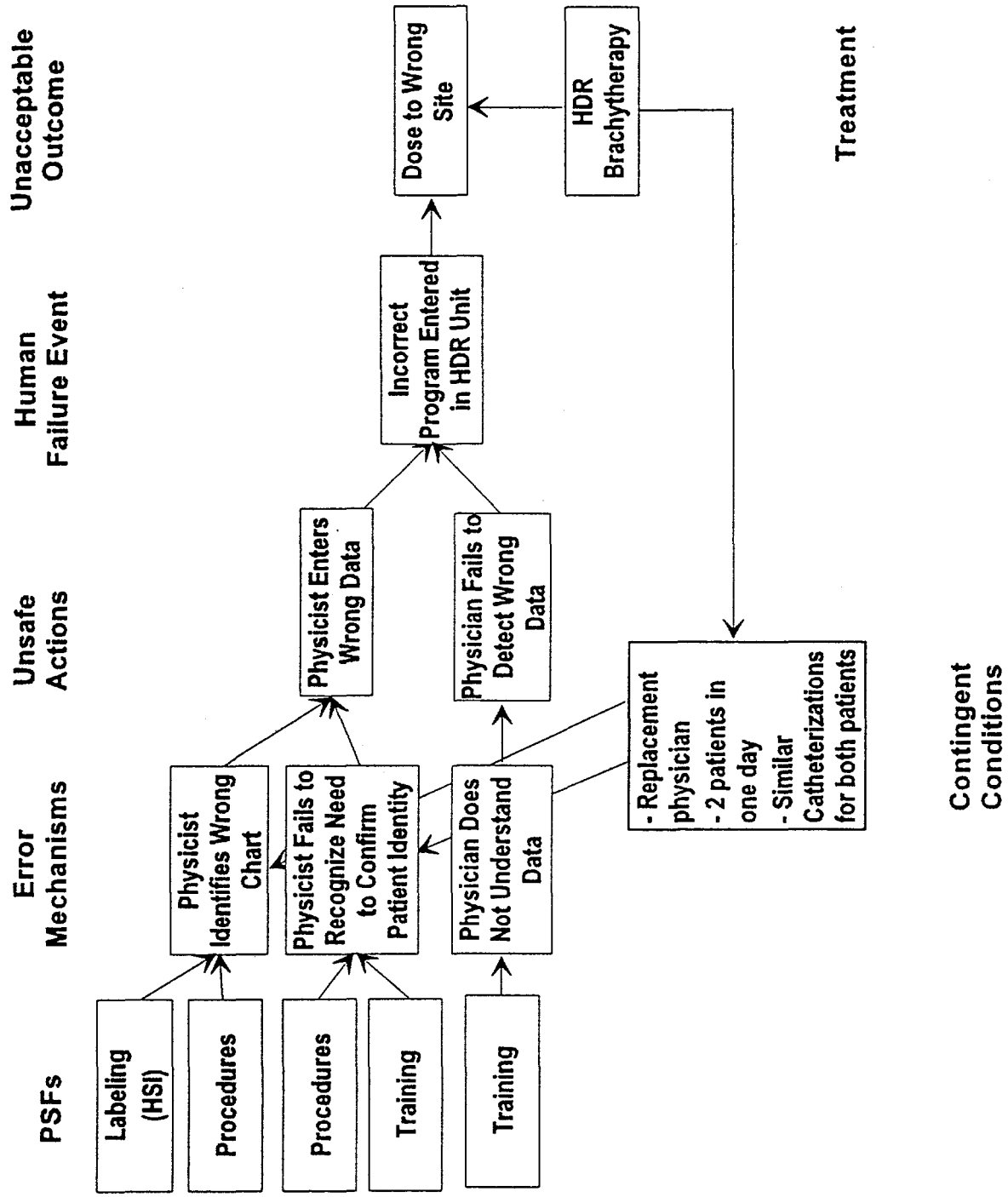

Figure 2. Analysis of Event A, Remote Brachytherapy Misadministration

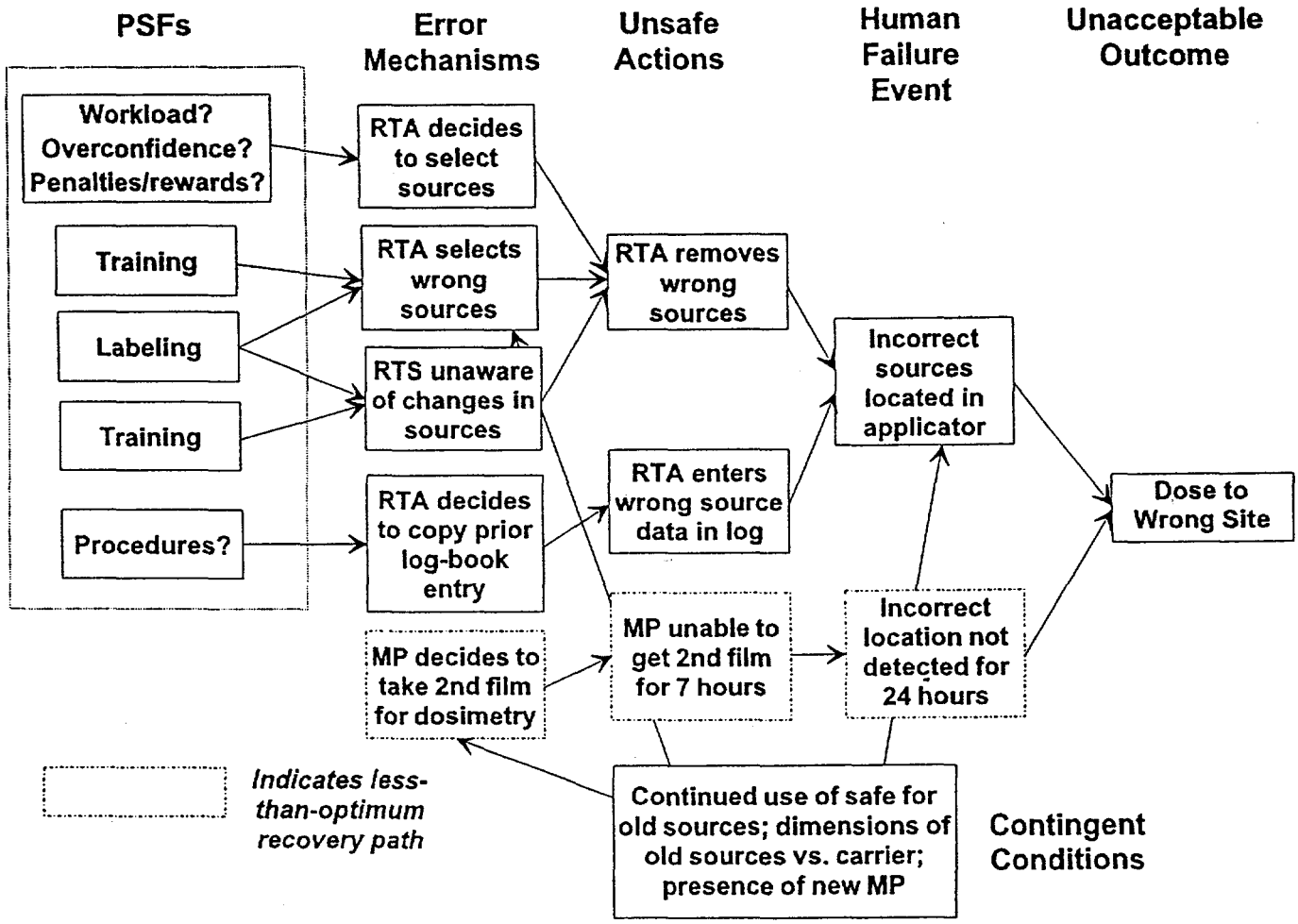

Figure 3. Analysis of Event C, Intracavity Manual Brachytherapy Misadministration

A.6. PRELIMINARY EXAMPLES OF THE DEVELOPMENT OF ERROR INFLUENCES AND EFFECTS DIAGRAMS TO ANALYZE MEDICAL MISADMINISTRATION EVENTS

Tami A. Thatcher, Harold S. Blackman, and Lee T. Ostrom

ABSTRACT

An error modeling framework described by John Wreathall[1] has been modified and applied to depict the human errors associated with medical misadministration events. Identifying the factors that affect human performance are essential for understanding and helping to prevent these medical misadministration events because human errors are often a direct cause of the event. Additionally, recovery actions taken by humans are often the only way to prevent a misadministration when a human error, computer-related fault, or hardware failure has occurred. The diagrams resulting from this error modeling are called error influence and effects diagrams.

Error influences and effects diagrams provide a way of guiding the analysis of human performance, and subsequently documenting and communicating the results. Analysis of actual events using this approach can provide an important link between past misadministrations and the refinement of risk assessment models including fault tree logic modeling and human reliability analyses (HRA). The approach shows how various performance-shaping factors (PSFs) such as administrative policies, routine and abnormal event procedures, and human-machine interfaces influence human errors and potential recovery actions. The significance of the error (or combination of errors or hardware faults) is indicated by a description of the misadministration type.

This report describes the approach and provides taxonomies associated with the framework. Examples of the approach developed for brachytherapy misadministration events from NUREG/CR-6088 are provided.

A.6.1 Error Influences and Effects Diagrams

The general framework for the error influences and effects diagram is shown in Figure 1. This framework has been adapted from Reference 1 with some variations in structure and terminology. Briefly, the main parts of the diagram are as follows. On the left side of the diagram, the performance-shaping factors (PSFs) that influence the occurrence of errors (or hardware failures) are listed. Although generally addressed in other performance-shaping factors, also included in this column are any atypical conditions such as non-English speaking patients, staffing discontinuities, unusual treatment site, etc. These conditions often provide a context that influences the occurrence of errors. The next column to the right, Error Mechanisms, identifies the human error mechanisms, or in some cases, the hardware failure mechanisms. Lines connecting the PSFs to the error mechanisms indicate the correspondence of PSFs that influence particular error mechanisms.

The Unsafe Actions correspond to those actions taken (or not taken) that, if unmitigated, will lead to a misadministration. An unsafe action may not seem to be an "error" because the intended action was carried out; however, it would be included here if it may lead to an undesired state because of the circumstances surrounding the event. Hardware faults may be included in this category for the purpose of understanding the influences contributing to the failure and

understanding the potential recovery actions that could prevent the hardware fault from causing a misadministration event.

For a misadministration event to occur, potential recovery paths such as a review step required by standard work practices that would be expected to detect the error must also fail. The recovery path may fail for reasons such as the review was not performed (an omission), or because the review is not sufficient in scope to detect the problem. Often a review to find possible errors is the only way to prevent a misadministration when an unsafe action (or hardware fault) has occurred; therefore, understanding what factors limit the effectiveness of the review are of interest. Based on current fault tree models of misadministrations developed at the INEL, the events in the unsafe actions column would typically correspond to basic events in fault trees because the failure of recovery actions to mitigate an unplanned event have been specifically represented in the fault trees.

When an unsafe action occurs and potential recovery paths fail, the actions or faults that will produce a misadministration are stated under the heading of Unrecovered Event. The effect of the Unrecovered Event is stated under the heading of Misadministration Type; for example, dose to the wrong site, wrong dose, etc.

Generally, when two lines feed into one box of text, moving from left to right on the page, both of the contributors are necessary in order to produce the mechanism, unsafe action, or unrecovered event. Using fault tree logic terminology, this would correspond to AND gate logic. A weak influence can be indicated with a dashed line.

Examples of five misadministration events that were documented and analyzed in NUREG/CR-6088 are provided in Figures 2 through 6. Detailed descriptions of the events are not provided here, but they would normally accompany the Error Influence and Effects diagrams. As in any event or fault tree structure, the interpretation of the event is dependent upon the information available about the event and upon the judgment of the analyst.

In representing actual misadministration events, failed recovery paths that were omitted or unsuccessfully attempted can be depicted. For purposes of analyzing the misadministration event further, potential recovery paths and the influences affecting their success can be postulated. Additionally, if the effects of an actual misadministration event are known, then potential effects if a similar event were to occur can also be postulated.

Also, in analyzing an actual misadministration event, the post-event corrective actions taken by the licensee can be shown on the far left of the diagram to indication correspondence of the corrective actions with the PSFs influencing the event. This can indicate where the effectiveness or comprehensiveness of the corrective actions may be limited. An example of post-event corrective actions correspondence to the PSFs is shown in Figure 7.

A.6.2 Error Influences and Effects Modeling Taxonomies

Performance-Shaping Factors

Performance-shaping factors (PSFs) can include institutional factors such as organizational factors, training, supervision, and human-machine interfaces as well as human behavior influences such as stress or workload. A taxonomy adapted from Reference 3 is provided in Table 1. Regarding PSFs associated with failed recovery paths, the following issues should be considered:

- What procedures or written guidance direct that a review be performed?
- Is performance of the review documented?
- Are reviews typically performed?
- Who performs the review?
- How much time is allotted for the review?
- What is the main intent of the review?
- What signs would indicate that a problem exists?
- Are steps taken to ensure that the review is independent?
- What is done to ensure that the review is of sufficient scope to detect a problem?

Included in the PSFs column are the atypical conditions (those conditions that deviate from normal conditions) that have contributed to the event. Examples of atypical conditions include inexperienced staff, new staff, substituting staff, non-English speaking patients, etc. By identifying atypical conditions present in past misadministration events, insights into deficiencies in institutional PSFs may be discovered. These provide additional data necessary to understand the context in which the event took place. For example, a quality procedure used by an untrained therapist is not nearly as effective. Thus, influence and likelihood of atypical events can be addressed in the misadministration risk assessment.

The PSFs (and atypical conditions) influencing specific error mechanisms are then indicated by drawing a line from the PSF to the corresponding error mechanism(s). In some instances, the line from the PSF may be drawn directly to the unsafe action. One PSF may influence several error mechanisms, and an error mechanism may be influenced by several PSFs.

Error Mechanisms

The consequence of an error mechanism is an unsafe act. Decomposing unsafe actions into error mechanism can allow a clearer linkage to influences and can aid characterization (and quantification) of the error. Two groups of error mechanisms are considered: failures associated with cognitive processes, and circumvention-related actions. failures associated with cognitive processes (and their most likely-to-be-associated types of unsafe action) include:

- failures in attention (mainly slips)
- failure of memory (lapses)
- failure of recognition (mainly lapses)
- failure of situational appraisal (misapplications of "good rules" [rule-based mistakes] and knowledge-based mistakes)
- failure of verification (misapplication of "good" rules, knowledge-based mistakes, confirmation bias, and overconfidence)
- motor program failure (applications of bad rule [rule-based mistakes] incomplete knowledge (rule-based and knowledge-based mistakes)
- inaccurate knowledge (rule-based and knowledge-based mistakes)

Circumventions are actions that intentionally break the "rules"; however, there is not intent to cause harm. It may be the only way to perform the task in practice, or be the more efficient or convenient way to perform the task. The identification of circumventions which have not typically been considered by HRA techniques can provide important insights that affect the estimation of human error probabilities. Influences upon circumventions include the perceived likelihood of incurring a penalty for circumventing rules, and working conditions that encourage circumvention because of the difficulty of working within the rules.

Unsafe Actions

Unsafe Actions correspond to those actions taken (or not taken) that, if unmitigated, will lead to a misadministration. For a misadministration event to occur, potential recovery paths such as a review step required by standard work practices that would be expected to detect the error must also fail. Reason[4] provides a taxonomy of the classes of unsafe actions. Slips and lapses lead to unsafe actions where the outcome of the action was not what was intended. Skipping a step in a procedure or reversing the numbers in an identification label are examples of lapses and slips, respectively. Both are errors associated with what Rasmussen[5] has termed skill-based level of performance. This level of performance is associated with the predominantly "automatic control" of routine and highly practiced actions. These actions are easily recognized by the person involved and (in most circumstances) are easily corrected.

For unsafe actions where the action is as intended, there are two broad classes of unsafe actions: (1) when the intention is wrong (because of misinterpretation of the situation), and (2) circumventions.

Mistakes can be considered rule-based or knowledge-based depending on whether the

task is demanding rule-based or knowledge-based performance. For rule-based performance, written instructions are being followed. For knowledge-based performance, the person involved is relying on ingrained technical and specialist knowledge. Rule-based mistakes are further subdivided as to whether the wrong rules are being followed, or the rules are being followed but the rules are flawed.

Unrecovered Event

The Unrecovered Event includes a statement that summarizes the combinations of human errors (and equipment failures) that will cause the unacceptable outcome, a misadministration event. Recovery actions have failed to prevent the "unrecovered event".

Misadministration Type

The misadministration type represents the unacceptable outcome of the event. It is suggested that this category include the following outcomes:

- dose to the wrong patient
- dose to the wrong site
- wrong dose
- wrong isotope
- lost source
- unplanned staff exposure
- unplanned public exposure.

Further statement of the consequence severity of the event or the potential severity range for a postulated event can be added.

A.6.3 Discussion of Limitations and Benefits

This framework can be used to represent actual misadministration events and to represent postulated events developed to model misadministrations. The depiction of the error influences, particularly the influences upon potential or failed recovery actions, is very useful for both misadministration investigations and for risk assessment development and documentation.

By sharing the same format, communication of the key influences is greatly enhanced. Additional documentation will of course be necessary to describe the events, but the diagrams provide a concise focus for the event. The level of detail in the diagrams will provide important information for assessment of regulatory issues. Misadministration investigations can benefit from the information that would be provided by the misadministration risk assessment, and the risk assessment can be improved based on insights obtained from misadministration investigations.

The Error Influence and Effects diagram thus far does not include quantification of human error rates or recovery probabilities; however, the approach provides a useful focus that will complement the quantification of human error based on existing theoretical techniques augmented with human reliability analysis (HRA) expert judgment.

A preliminary taxonomy of error mechanisms and unsafe acts has been developed to provide guidance for Error Influence and Effects diagram construction.

This approach addresses NRC regulatory needs because it accommodates in a logical, traceable way, the impact of changes in design, procedures, training, man-machine interface, and other PSFs. The development of risk assessment models can provide a way to target areas for improvement, allow sensitivity studies to be performed, and allow the comparison of different treatment types. By improving the ability to communicate the important PSFs, the risk assessment brings the human reliability issues to the forefront so that their influences can be understood. This provides a level of detail that can indicate the PSFs that should be improved and also the PSFs that limit the effectiveness of proposed changes.

The key attributes of error influence diagrams include to following:

- Depiction of the relationship of various performance-shaping factors (PSFs) to human errors and error mechanisms to aid understanding and communication of causes and contributing factors of undesired events.
- Identification of atypical conditions that contribute to the event.

- Depiction of failed recovery paths and potential recovery paths and their corresponding PSFs.
- Identification of the dependencies between error causes and potential error recovery actions.
- Comparison of show post-event corrective action correspondence to PSFs to communicate coverage of the corrective actions and insight into the potential effectiveness of the corrective actions.

A.6.4 References

1. John Wreathall, *Review of Medical Misadministration Event Summaries and Comparison of Human Error Modeling*, May 1994
2. L. T. Ostrom, T. J. Leahy, and S. D. Novack, *Summary of 1991-1992 Misadministration Event Investigations*, NUREG/CR-6088, March 1994.
3. D. I. Gertman, and H. S. Blackman, *Human Reliability and Safety Analysis Data Handbook*, New York: John Wiley and Sons, Inc., 1994.
4. J. Reason, *Human Error*, New York: Cambridge University Press, 1990.
5. J. Rasmussen, *Models of Mental Strategies in Process Plant Diagnosis, Human Detection and Diagnosis of System Failures*, (J. Rasmussen & W. Rouse, Eds.), New York: Plenum Press, 1981.

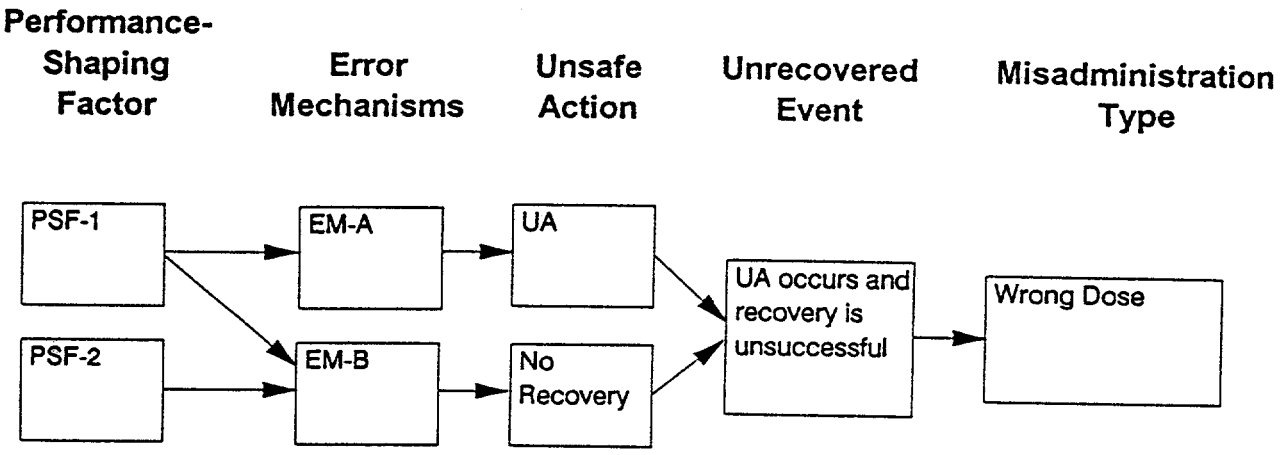

Figure 1. Error influences and effects diagram framework.

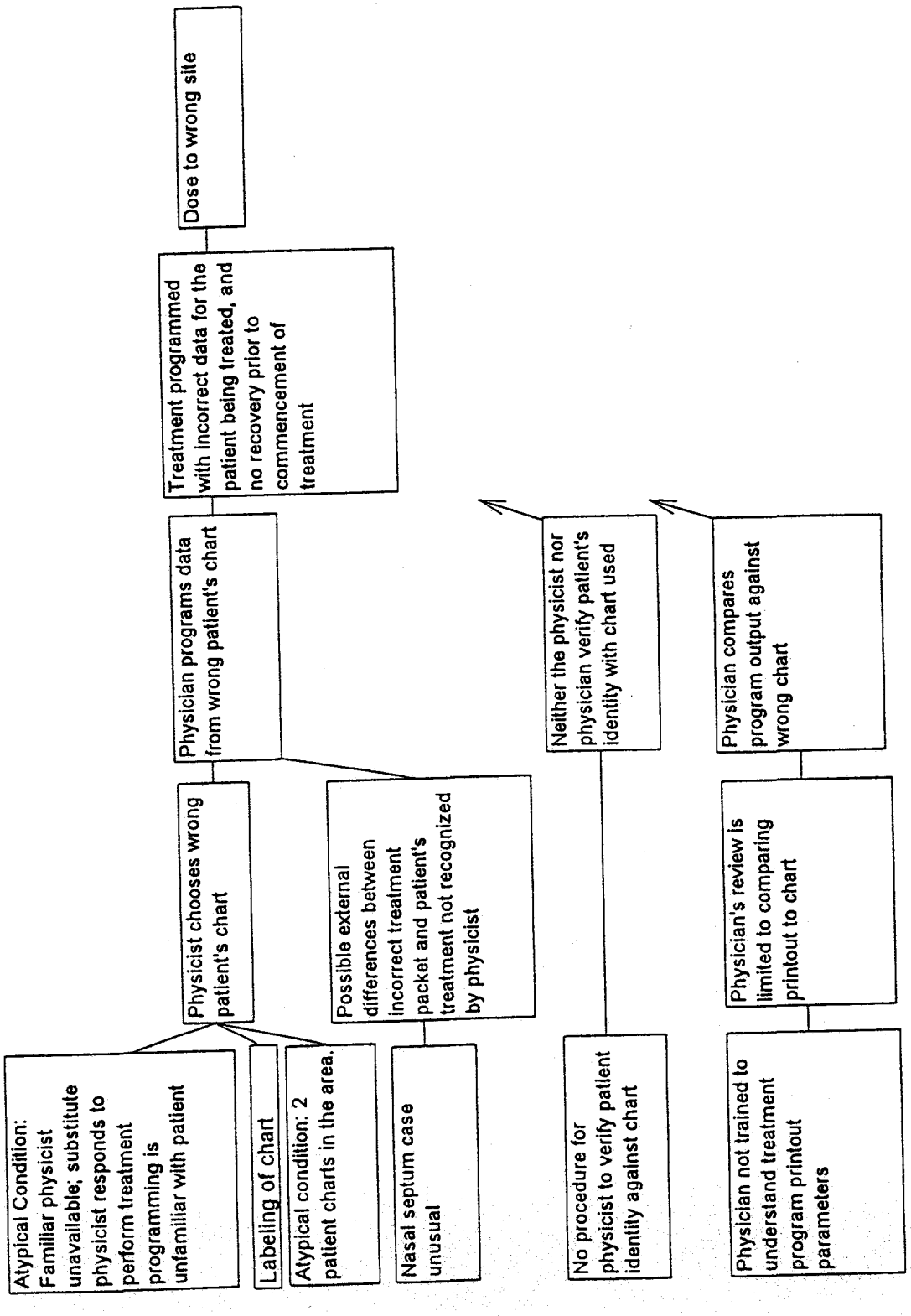

Figure 2. Example diagram for HDR remote afterloader brachytherapy Event A from NUREG/CR-6088.

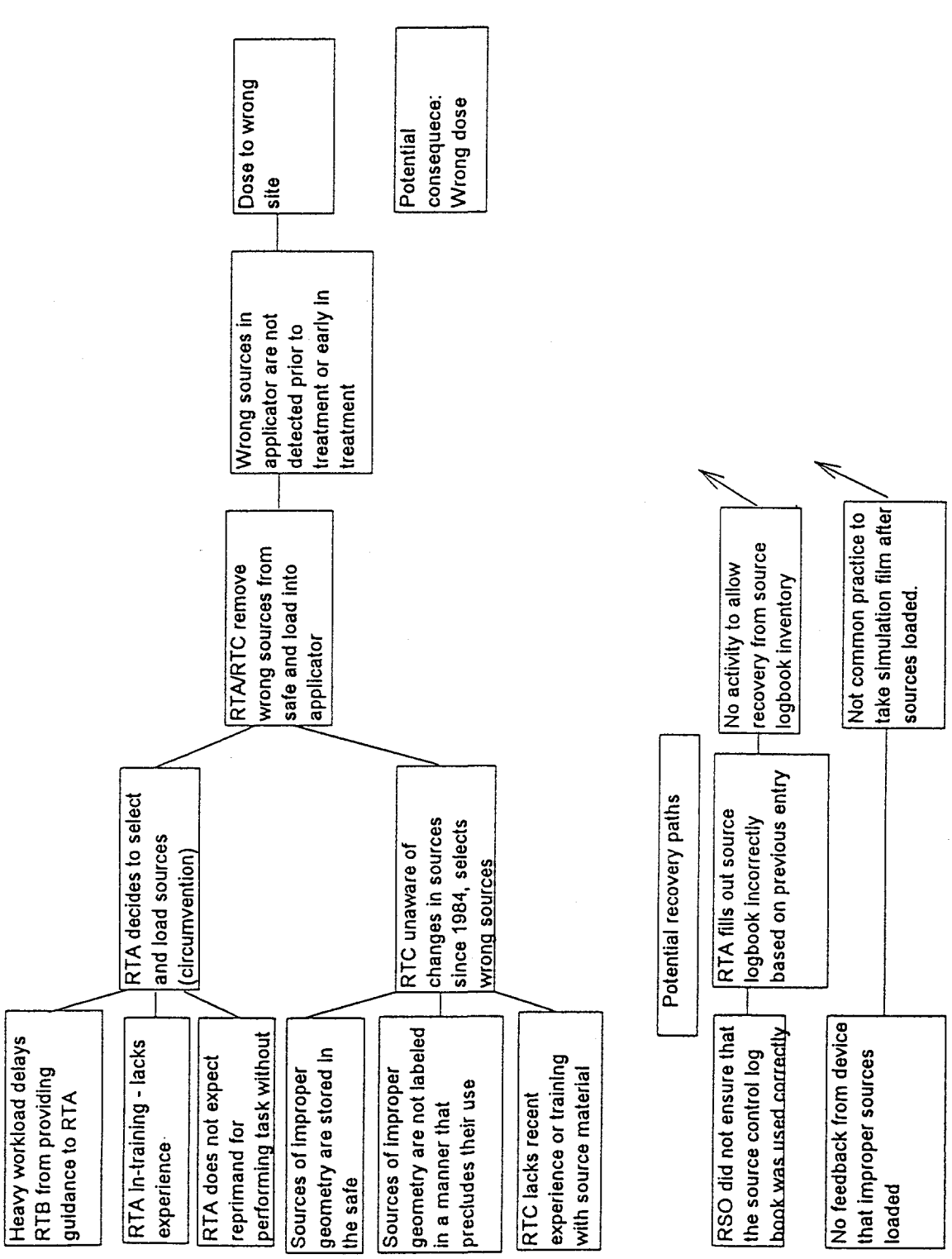

Figure 3. Example diagram for manual brachytherapy Event C from NUREG/CR-6088.

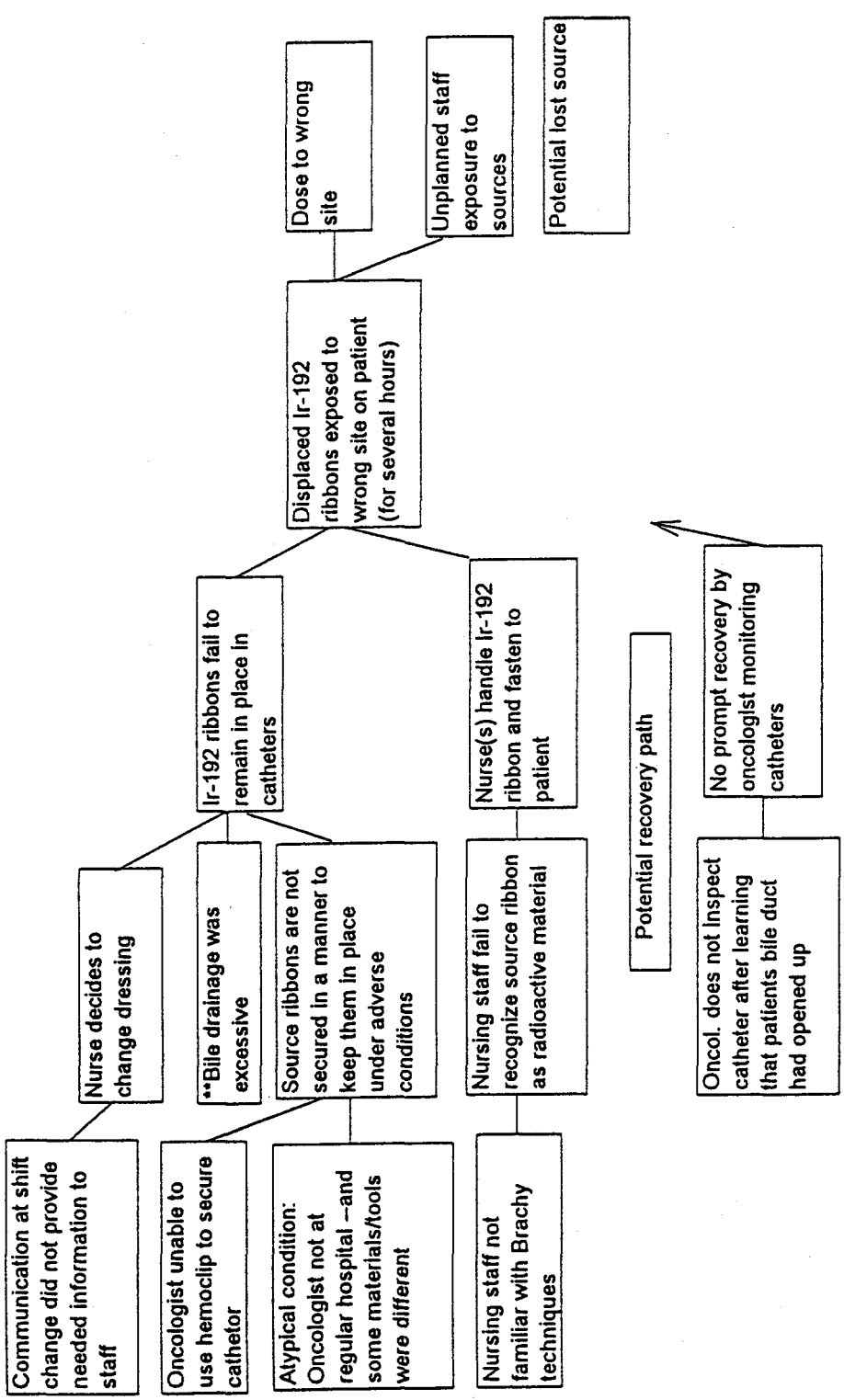

Figure 4. Example diagram for manual brachytherapy Event E from NUREG/CR-6088.

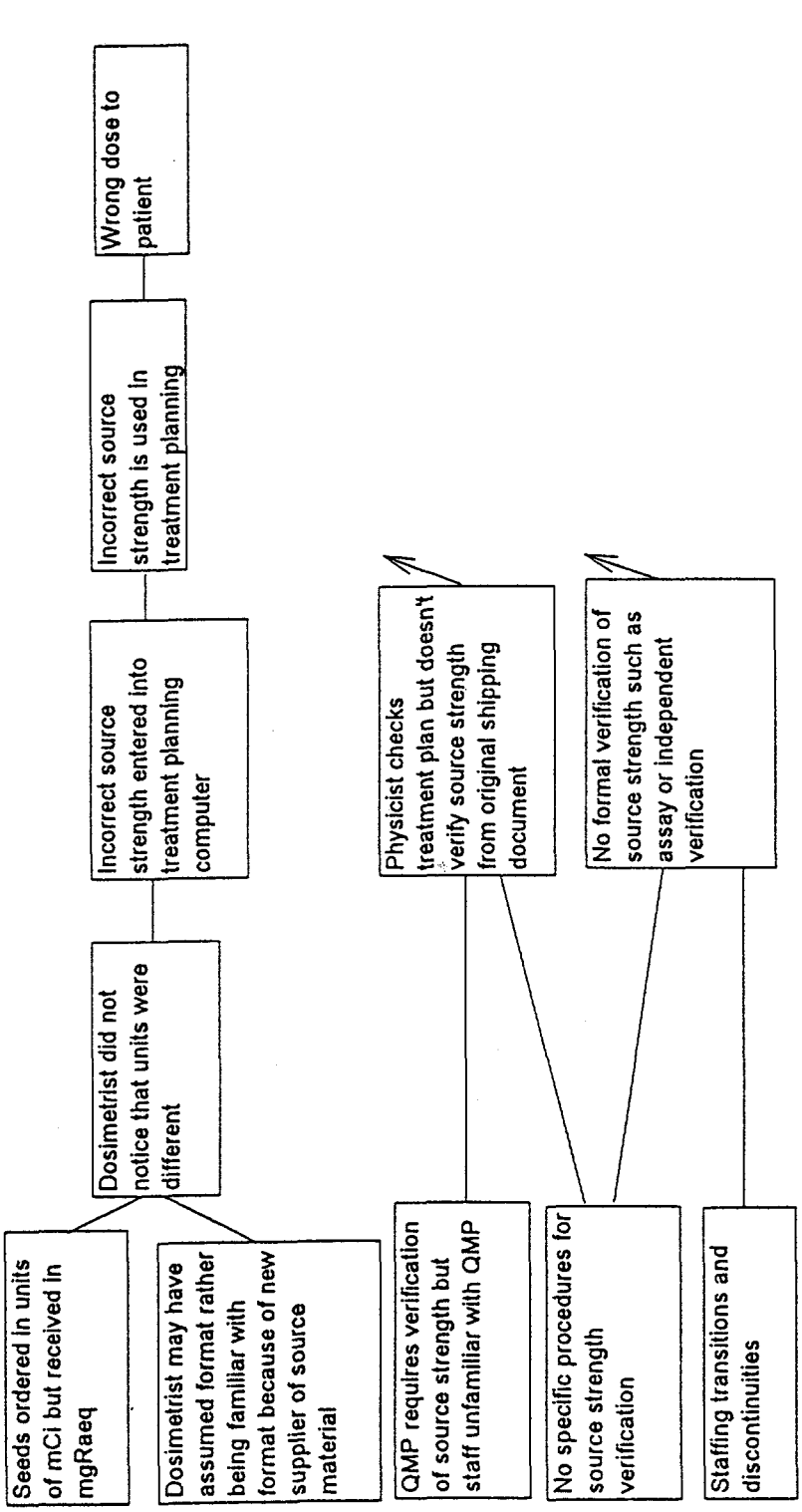

Figure 5. Example diagram for manual brachytherapy Event F from NUREG/CR-6088.

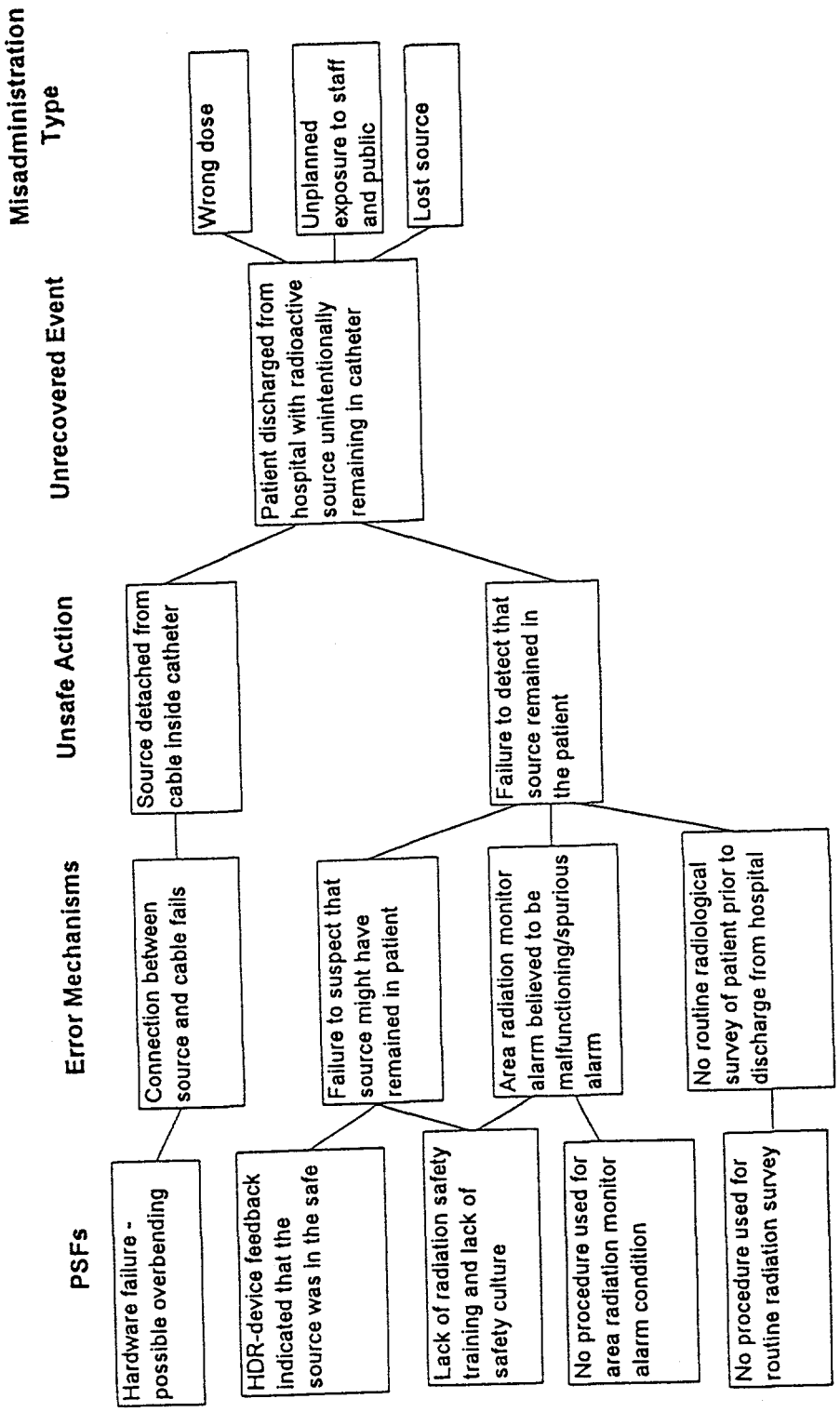

Figure 6. Example diagram for HDR remote afterloader brachytherapy Event G from NUREG/CR-6088.

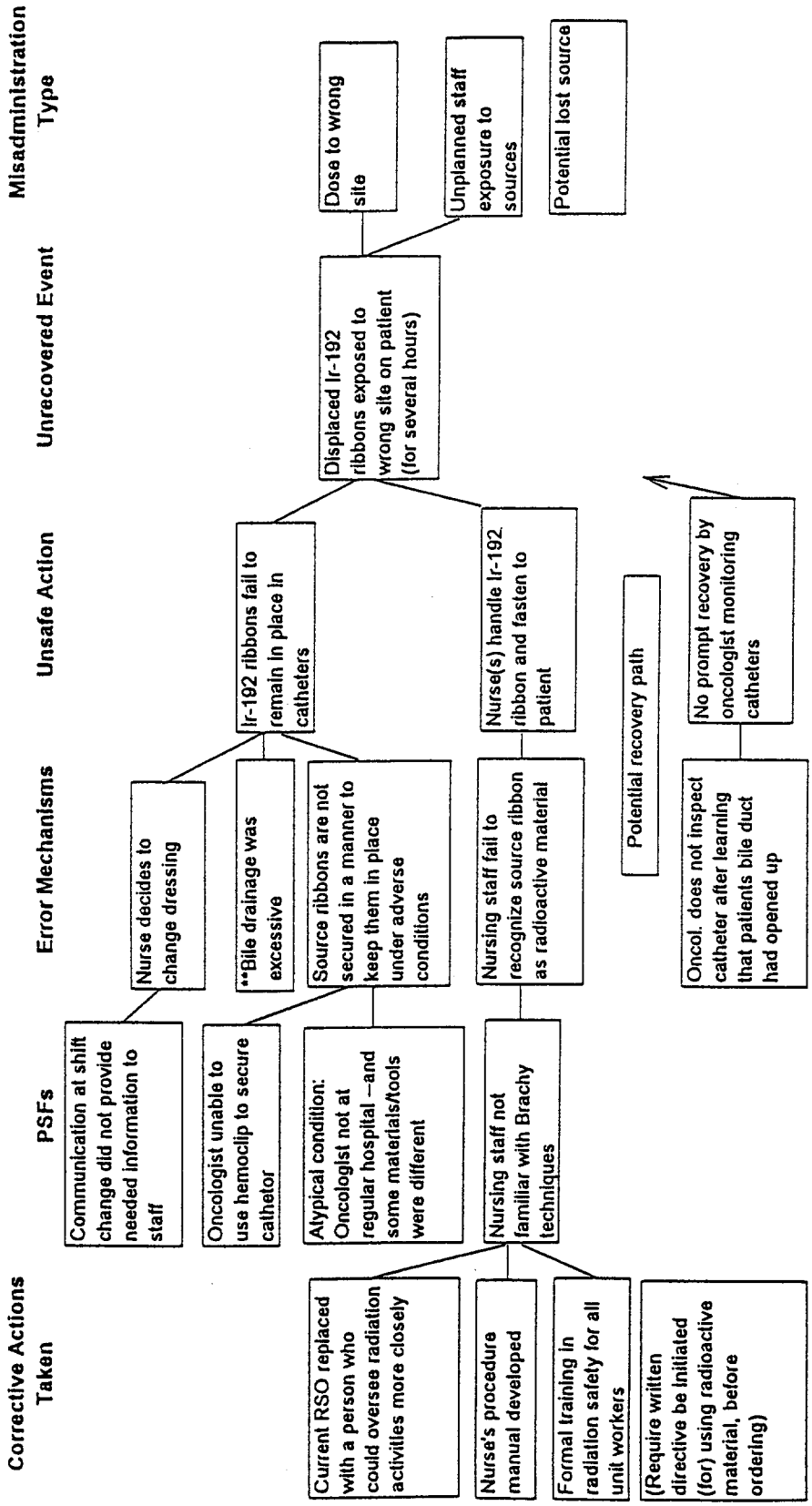

Figure 7. Example diagram for manual brachytherapy Event E from NUREG/CR-6088 including post-event corrective actions.

Table 1. Performance-shaping factors (PSFs) taxonomy.

PSF	Definition
General Staff Experience	What characterizes the experience of the staff?
Experience Performing The Task	Is the task routine or infrequent?
Training	What specific training applies to the task?
Means Of Obtaining Basic Task Instructions And Any Special Instructions	Are written instructions (such as an Rx) or medical chart read, or are instructions verbally transmitted?
Time-Pressure	Time to perform versus time available.
Stress	What stress is being experienced by the task performer
Feedback To Operator Action	What type of feedback does the operator receive after a control action?
Procedure Required	Is a procedure required? type of procedure?
Procedure Applicability To Action/Situation	Does the procedure apply to the action or situation?
Procedure Quality	Is the procedure perceived as accurate and complete? Is the procedure understandable and easily followed?
Procedure Familiar/Understood	Are staff familiar with the procedure? Do they understand the procedure?
Procedure Practiced	Is the procedure used routinely or practiced in emergency drills?
Clothing Required	What special clothing is required? Does it impair the ability to perform the task?
Tools Required	What special tools are required? Are they available?
Work Place Design	Does the workplace hinder the ability to perform the task?
Type Of Human-Machine Interface	What device, machine, or computer hardware is used in performing the task, and what are the interfaces?
Quality Of Human-Machine Interface	Are basic ergonomic standards met? Characterize the quality of the interface.
Local Versus Remote Control	Is the action performed at a remote location or locally (at the patient)
Tasks Dynamic Aspects	Is the task performed concurrently with other tasks or is it performed independently, step by step?
Task Dependency	Does the correct performance of this task depend on the performance of another task? On other individuals?
Safety Culture	Do the cultural norms of the organization affect the safe performance of tasks?
Environment	Temperature, radiation level, etc.

A.7. Brachytherapy Risk Assessment Program Plan

W. J. Galyean, S. D. Novack

Risk assessment is a tool designed to aid decision makers in the face of uncertainty. In the case of brachytherapy treatment, risk assessment can be used to address a variety of issues, including the overall risk to the public associated with potential accidents during the treatment process, the safety level of a specific treatment process, and the risk significance of past events. This paper describes the process proposed to develop and validate risk models for brachytherapy treatment; it includes work to develop simple generic models (to assess overall risk) and facility-specific models (aimed at supporting the development of the generic model and generating detailed risk management insights for a specific facility/process).

Two technical objectives must be achieved to ensure project success. First, the generic model must be able to accommodate the wide range of machines, modalities (i.e., prescriptions and target organs), and facilities in use or contemplated for near-term use. A functionally based generic event tree identifying the sequential phases involved in the treatment is proposed. (Facility-specific fault trees or other supporting models for the event tree top events, can be used to tailor the generic event tree to specific applications.) Second, both generic and facility-specific analyses must be performed in the face of sparse data suitable for estimating error rates. A number of approaches to maximize the use of available information (including expert elicitation techniques) will be employed.

A.7.1 Generic Model Development

Process Familiarization

The purpose of the generic modeling task is to develop a model that reasonably represents a wide range of machines, treatment modalities, and facilities. This subtask gathers the information needed to develop the generic model. It includes a formal review of past brachytherapy misadministration events to identify key tasks, functions, and safety barriers. Because the risk associated with events not yet observed might be important, the subtask also involves: i) interviews with experts to identify important sources of facility-to-facility variability, ii) the identification of key facilities from which additional information on their specific processes for administering brachytherapy treatments can be gathered, and iii) the collection of information from these facilities. (In principle, it is desirable to select these facilities using a carefully designed sampling plan; in practice, facility access by the analysis team may be an overriding constraint. Nevertheless, to ensure completeness in the analysis, it is important to select as diverse a set of facilities as possible.) This work will build upon previous misadministration event investigation work and analyses performed by the INEL for the NRC.

Develop Event Tree Model

The generic model will use the graphical event tree method because of its scrutability and facility in presenting information.[a] The event tree organizes the progression of possible failure events in the treatment in a chronological fashion with the failures grouped by phases of the medical process. Each failure scenario is then classified according to the expected severity of the resulting misadministration. In the present version of the event tree, this classification

---

a. Unlike more literal Monte Carlo event simulation models, the event tree model structure and, therefore, the risk-dominant scenarios, are readily apparent to the analyst. Monte Carlo simulation is, in general, a more flexible modeling approach. However, this flexibility is often not needed unless complex, dynamic interactions among processes must be explicitly represented. Of course, Monte Carlo simulation techniques are commonly used to propagate uncertainties through an event tree; such a use does not affect the essential discrete character of the event tree.

takes the form of three adverse consequence categories, namely High, Moderate, and Low. A draft event tree was completed as part of this report (see attachment). It is expected that the development of the final generic event tree will be an iterative process since the model must adequately represent events and facilities characterized in the familiarization subtask.

Data Development

Data for model quantification (i.e., failure rate information) will be difficult to obtain and likely will not be based on extensive operating experience. Although failure information on misadministrations is available from the AEOD database, it provides only the failures and not the number of opportunities for failure (i.e., the denominator needed to calculate rates). In addition, for the level of detail needed in the present analysis, the data are likely too sparse to support high confidence in the results. Hence, the approach proposed here utilizes a combination of the historical data and expert opinion to maximize the utilization of available resources.

Review AEOD Database

Now that a draft event tree has been developed providing a taxonomy, the available data from the AEOD database can be reviewed in a structured manner. This review will collect all the brachytherapy misadministrations and segregate them into groups corresponding to the events appearing on the event tree. This will have two purposes. First, the review of the data will provide a check of the event tree model ensuring as much as possible that the model indeed represents the reality of the treatment process and includes the errors that are likely to occur. Second, grouping the available data by event tree heading will generate a frequency histogram that can be used to provide initial prioritization and input to the expert elicitation process (see below). Because the data are relatively scarce and information on the number of treatments given is not readily available (efforts will be made to obtain this information), quantitative failure rate estimates will be quite uncertain. Relative frequencies will therefore be employed in the initial phases of the analysis to focus subsequent efforts and to reduce the uncertainty in the quantitative frequencies.

Expert Elicitation

To supplement the experience data (i.e., to deal with as yet unobserved but potentially significant events), an expert elicitation process will be used. To ensure a high quality elicitation, a two-step, well defined process is proposed. The first step will prioritize the identified misadministration scenarios using a pair-wise ranking scheme. (Note that this step can use the relative frequency information generated from the AEOD database as either an initial input to the experts, as a check on the results, or both.) The expert panel will consist of Radiation Oncologists and Medical Physicists (including Radiation Safety Officers). Disparities between these values and the results from the AEOD database and model prediction will be investigated and resolved. For example, the misadministration events in the AEOD database might be re-examined to ensure they are correctly characterized. In addition, several events will be reviewed with the expert panel to verify these types of scenarios were considered when they formulated their opinions.

Although a relative ranking of possible misadministration scenarios can be useful for identifying where to allocate future resources and for evaluating the applicability of current rules and regulations, it cannot be used for determining conformance with safety goals or for performing cost/benefit analyses. Hence, the second step of the expert elicitation will be the estimation of absolute failure probabilities and frequencies for the individual failure events. This will utilize the results produced previously from the AEOD database and the pair-wise ranking. However, this time the experts will be asked to estimate the frequency of human errors and/or equipment failures (e.g., the chance of an error or failure might be once in a thousand treatments). We will also elicit estimates from the experts on the extent of their experience. For example, how many treatments have they participated in, how many treatments have been performed at their facility? This information will then be used to quantify the impact of their opinions through a Bayesian update process.

A.7.2 Analysis

Quantify Generic Model

Once all failure rates and other model parameters are estimated, the model will be quantified to provide both relative and quantitative values for the generic event tree. This information will be used to guide the remaining tasks. Specifically, comparing risks of brachytherapy treatments to the risk posed by other medical procedures (obtained from the open literature) and various "safety goals" (such as has been suggested for the commercial nuclear power industry, and in use in other countries); evaluating the coverage of current rules and regulations; and performing cost/benefit analyses to calculate the value of possible risk reduction strategies. This last item will be conducted through the application of the generic models to a treatment at a specific facility.

Facility Specific Analyses

This task achieves three goals. First, it provides a means to formally validate the generic model produced previously. Second, it facilitates the cost/benefit evaluation of any proposed process changes and/or changes in regulations relevant to a selected facility. Third, it provides important application lessons that will assist future facility specific analyses.

This task starts with the generic event tree developed and quantified previously, and tailors it to assess the risk associated with a specific treatment at a specific facility. This will likely take the form of expanding the evaluation of the event tree events by developing specific and detailed fault trees, which in turn will be quantified by a detailed human reliability analysis (for the human errors) and any available hardware data supplemented by engineering judgment. Alternate modeling approaches (e.g., direct simulation) will be investigated if necessary. If the basic structure of the generic event tree is not applicable to the specific application being examined, the generic event tree will be modified to make it consistent. Results from the facility-specific analyses will be factored into the generic model to refine its structure and to help define ranges of possible failure rates for each of the generic failure events. This process (i.e., performing facility-specific analyses) will be repeated as many times as is felt necessary to produce an industry-wide generic event tree (with associated failure rate probability distributions) that can be used for evaluating the coverage and adequacy of rules and regulation.

A.7.3 Compare Risk Results to Regulations

Using the results of both the generic event tree evaluation as well as the specific applications, current rules and regulations will be reviewed to determine their efficacy and efficiency. The prioritized listing of potential misadministration scenarios from the generic model will be compared to the current rules and regulations. The rules and regulations that address potential errors and failures in each scenario will be identified in a matrix along with an evaluation of their adequacy (i.e., qualitatively evaluate coverage or completeness). Possible approaches for redressing any perceived deficiencies will be discussed with the NRC PM. Quantitative evaluations of any changes to the treatment process or regulations can only be measured by cost/benefit analyses. These would require the use of the treatment-specific models developed by this study.

A.8. PRINCIPLES OF BRACHYTHERAPY QUALITY ASSURANCE

Glenn P. Glasgow, Ph.D.

A.8.1 Introduction

Q! QA! QC! QM! TQM! We all recognize the meanings of each term in this queue of Q terms and realize there is no escape from the insidious Q lexicon. So, the author asks the readers forbearance as we again use the Q word in Principles of Brachytherapy Quality Assurance, with the emphasis on principles and applied to conventional low dose rate manually (not remote) performed brachytherapy using therapeutic radioactive materials (TRAM).

Recent references (Williamson 1991, Kutcher 1994) offer comprehensive reviews on these topics and it is difficult to find ideas or topics not previously discussed. Nevertheless, the author offers the following materials, divided into two categories: Quality assurance of the products (TRAM and ancillary equipment) and quality assurance of the processes (medical and radiation control protocols, planning, source localization, dose distribution data, and treatment documentation) of use of TRAM in patients. A prior Proceedings (Glasgow 1990a) emphasized features of a radiation control program for brachytherapy.

It is necessary to distinguish quality assurance (QA) from quality management (QM). Task Group 40 (Kutcher 1994) reports the widely accepted definition of QA as "All those planned or systematic actions necessary to provide adequate confidence that a product or service will satisfy given requirements for quality." A documented QA program in brachytherapy is good practice, useful for Joint Commission on Accreditation Healthcare Organization site visits, but it is not a legal requirement of any agency. Quality management, as used here, refers specifically to the United States Nuclear Regulatory Commission (NRC) recent regulatory QM program (NRC 1991) and is a license requirement for those federal hospitals and non-agreement state hospitals using by-product TRAM under NRC regulatory control. Agreement state have three years from January 27, 1992 to agree to adopt a QM program. Some features of a good practice QA program are legally required in the NRC's QM program.

A.8.2 Quality Assurance of the Product: Conventional Low Dose Rate Therapeutic Radioactive Materials And Ancillary Equipment

Radionuclides And Their Physical Properties

Eleven radionuclides (Ra-226, Rn-222, Co-60, Cs-137, Au-198, Ta-182, Ir-192, I-125, Pd-103, Sr-90, and Ru-106) are considered conventional; they have, at some time, been used extensively in brachytherapy. The use of Ra-226 and Rn-222 has been all but abandoned in the United States; Co-60 use generally is confined to eye plaque therapy; Ir-192 has replaced Ta-182 as an interstitial source; and Ru-106, used in Europe for eye plaque therapy, has found little use in the United States. Au-198 is used for interstitial seed implants at a few facilities. Many facilities possess a permanent inventory of Sr-90 eye plaques and Cs-137 tubes for gynecologic brachytherapy, order Ir-192 seeds for temporary interstitial use, and order I-125 seeds for eye plaques, permanent, or even temporary implants. Pd-103 seeds, the most recently approved NRC by-product source, are used for permanent implants and eye plaques. The physical properties of these radionuclides are well known (Glasgow 1992b) and are presented elsewhere in these Proceedings.

Radionuclides Source Inventories

a) Permanent Sources

Quality assurance of the main product, the radioactive sources, begins with the simple task of establishing and maintaining an master inventory of the sources that a facility already possesses. This master inventory should include as complete a description as possible of known source parameters. The manufacturer's name,, the source model type

and model number, chemical configuration of the radionuclide and its physical state (e.g. Cs-137 resin in microspheres), the physical dimensions (physical length, active length, outer diameter, inner diameter, wall thickness) of any encapsulating materials, including capsules end welds or plugs, date of purchase, certificate of activity or other equivalent statement of strength, individual source identification numbers and/or color codes, and any other pertinent information, such as storage location. As permanent sources likely have a longer useful life at a facility than a physicist, this master inventory must be a permanent file readily available to any physicist assuming the facility's responsibility for these sources.

b) Temporary Sources

The data needed for the sources in a temporary inventory is no different from that for the sources in the permanent inventory, except the actual number of these sources present at any time varies, as well as their exact location. A quarterly inventory of both permanent and temporary sources is a long standing regulatory requirement (NRC 1990).

Source Control

a) Facilities

As the concerned parent must know the whereabouts of their small children at all times, the physicist must always know the physical locations of all radioactive sources in their facility. And, like a parent, we have our moments of temporary panic when we believe our small sources are missing.

Control of permanent or previously purchased temporary sources begins with knowing where they are stored. Facilities, equipment, and techniques for the storage, preparation, use, and disposal of TRAM are little changed from prior descriptions (Broadbent 1984). The locked source room should be well lighted, have wall mounted pegboard to hold forceps and other tools, and have colored surfaces that allow easy identification of a dropped seed. An area radiation monitor with both visible and audible alarms, set to trip at a preselected exposure rate, is an excellent protective tool that will alert personnel to the presence of an unshielded source. While it may have to be defeated during some source preparation procedures, it must be returned to service at the end of all source preparations. A Geiger-Mueller counter must always be available in the source room for use in locating sources, for surveys of all trash that leaves the room, and for determining if any catheters removed from patients still contain seeds. Radiation surveys within the source room and around the source room are required at the frequencies specified in the license, usually not less than quarterly and possibly as often as weekly. A standard survey form that clearly identifies the physical location at which each exposure rate is measured should be used, along with the proper identification of the survey instrument.

Generally, the permanent inventory of sources are stored in a dedicated storage safe with individual drawers for source of each type designed to keep surface exposure rates to less than 20 mSv/h (2 mR/h). All safe drawers must be clearly labeled as to content and arrangement of TRAM within the drawers. Temporary sources, such as Ir-192 seeds, usually are stored in their shipping containers or other lead containers are stored in a lead brick well or cave in the source room. To prevent the loss of dropped seeds, all small openings in the room should be covered with tape or other material. A lead block with a leaded glass window is commonly used to shield those preparing sources. Sources are manipulated from behind the block using long handled (8" to 12") forceps. A lighted magnification lens is useful for close work, such as identifying source serial numbers.

b) Visual Systems

A visible inventory control board similar in arrangement to the safe and its drawers, with different colored markers corresponding to different types and /or activities of sources, is a useful tool to keep track of the removal/return of sources to the safe. Each time a source is removed/returned to the safe, a corresponding colored marker is removed/returned from the inventory control board. Removed markers can be used to indicate which sources are in specific patients.

c) Purchase

Control of temporary sources begins with their purchase. Standard order forms should

be prepared for each radionuclide source commonly ordered, with appropriate statements regarding type, form, activity or strength per seed, seed spacing or strength, total activity, total units (seeds, ribbons) ordered, necessary accessories, and other information. A log book or electronic record system in the source room should record receipt, calibration, use, and disposal of all purchased sources. The log should include sequential numbered entries (2-'94; i.e., second order of '94) identifying invoice number, type of TRAM, batch or lot numbers, physical forms and amounts (number of seeds, number of ribbons, and their activities or strengths). In addition to the calibration (discussed later) of the TRAM, a qualitative inspection of the order is required to confirm that it is the material ordered and that it is appropriately configured.

d) Use Records

The use logbook records the flow of the TRAM from the source room to the patient's room or other administration area and its return. Using a sequence entry number to track the use of orders, a suggested use record would include: the patient's name and identifying hospital number; the radiation oncologist and resident; the activity or strength of the sources at the time of administration; the physical form (number of ribbons, seeds) removed from the source room; time, date, and person removing the sources; physical form of sources returned to the source room immediately after administration (those planned for use, but not used); the physical form and activity or strength of the sources actually used in the patient; physical form, number, and activity or strength of the sources returned to the source room at the end of therapy; and date, time, and individual returning the sources. Careful physical counting of the sources removed from the room, not used and returned, and used and returned obviously is required. The cardinal rule of counting: Never delay the count of sources. Count them when removed from the patient and count them again immediately when returned to the source room.

e) Transport

Numerous devices are available for transporting sources from the storage room to the administration room. Surface exposure rate on transport devices generally should be less than 100 mSv/h (10 mR/h). Multicompartmental transport devices allow one to keep track of different types, colored coded sources, or sources of different activities of TRAM used in a single patient. A transport record should accompany the transport device to identify the sources while in transport. Diagrams of the physical arrangement of TRAM in the transport container eliminates possible confusion than can occur in the patient's room when the TRAM is transferred to the physician authorized user for placement in the patient. A similar diagram and transport record is required for the transport of the sources back to the source room.

f) Disposal

At disposal, regroup sources using the original entry number, placing all used sources from a given order back into the original shipping containers if possible. The disposal record should identify the sources by the sequence entry number and invoice number, the physical form (number of ribbons, seeds) in the container, the number of days held and the decayed activity, and the method of disposal (usually return to vendor). Sources intended for the radioactive waste disposal sites generally are turned over to the radiation safety officer who keeps final records and prepares the source for proper shipping and disposal at these sites.

Source Activity

a) Permanent Sources

A prior speaker, and Task Group 40 (Kutcher 1994), have addressed the methodologies of the assignment of a clinical numerical value (activity, air kerma strength) to a specific radioactive source or a source from a batch of sources. To eliminate redundancy we focus on application of these recommendations rather than the recommendations themselves.

For permanent inventory sources (Cs-137 tubes and needles; Sr-90 plaques) it is necessary to know the history to the clinical numerical values assigned to the sources. Often such sources are several years old, and while the assigned clinical numerical values may have been carefully decayed for several

years, the knowledge of the selection of the original clinical numerical values (most likely, their activities) may not be clear. A departmental statement of the current clinical numerical values (usually obtained by decaying the original assigned clinical numerical values) of a radioactive source must have attached to it a synopsis of the how and when these original, clinical, numerical values were assigned. If changes occurred over the years (e.g., changes in the half-life used in the decay calculation) these changes should be carefully noted on the current departmental statement of the clinical numerical values. There should be no ambiguity in the knowledge of the current assigned clinical numerical values. Moreover, there should be a clear departmental policy on the frequency (monthly, quarterly, semi-annually, or annually) and half-lives used for decaying the clinical numerical values. When a current clinical numerical value is calculated (often by decaying the prior assigned value), one should check that the calculated value is consistent by decaying the original assigned value, accounting for any documented changes in methodology over time.

b) Temporary Sources

For ordered temporary TRAM, there should be a clear methodology, consistently applied, for the adoption of the clinical numerical value. One must not adopt a certificate value for one order, a dose calibrator value for the next order, or use the average of the two for the third order. Task Group 40 (Kutcher 1994) allows the adoption of either the certificate value or the institution's measured value if they agree to within 3%; however, one must be consistent in the choice. (N.B. In the case of agreement, I personally prefer the adoption of the certificate value even if one has direct traceability to an Accredited Dosimetry Calibration Laboratory and a redundant dosimeter system per TG 40. I presume the manufacturer has a better, more consistent calibration method than I do.) Unfortunately, many facilities still do not have even the two component (dose calibrator plus either one long lived radioactive source or the manufacturer's source certificate) redundant brachytherapy dosimetry system recommended in the TG 40 Report. Purchase of a dose calibrator for brachytherapy quality assurance is strongly recommended, as the cost of these instruments has decreased markedly in recent years. For those facilities that do have dose calibrators, the quality assurance program for dose calibrators outlined in the TG 40 report is essential.

Source Physical Integrity

There are three critical tasks required to confirm the integrity of a radioactive source: (1) performing leak tests to confirm that the source is intact and is not releasing radioactive material, (2) confirming that the spatial distribution of the radioactive material inside any encapsulated source is correct and remains unaltered as the source is used, and (3) determining that the source has the activity or strength assigned at the time of use. The first task is reasonably simple; the second and third less so.

a) Leak Tests

For encapsulated sources in the permanent inventory (Cs-137, Sr-90) semi-annual leak tests usually are a legal requirement by license unless the facility's license authorizes a different leak test frequency. Moreover, the leak test methodology (using facility leak-testing equipment, properly calibrated or using a commercial firm whose license must be on file in the facility) must be included in the license application and subsequently followed. DeLuca's (DeLuca 1984) remarks on in-house facility leak-tests are an excellent introduction to the topic. Generally, unused I-125 sources held in inventory for less than 6 months do not legally require a leak-test; however, if held for over six months they must be leak tested. If I-125 seeds are used as a temporary source, and potentially used more than once for multiple patients, the sources should be leaked tested before each use. These I-125 seeds can rupture if handled improperly. Ir-192 seeds are not considered encapsulated and need not be leak-tested under current NRC regulations (NRC 1990).

b) Autoradiographs

For permanent sources, such as Cs-137 tubes, one should know the radiation distribution around the source is that intended by the manufacturer and, once known, it should be monitored for changes. Determination of the absolute dose

distribution for brachytherapy sources generally is a difficult project; nevertheless, numerous reports document the dosimetry for sources of specific design. Most users trust and use published literature data, either measured or calculated, rather than perform their own specific model source dosimetry. A simpler task is to determine that a batch of sources of the same design have the same linear activities, realizing that the activities for the individual sources is not identical, but varies within the reported standard deviation of the batch. A simple test uses both radiography and autoradiography. Design a large sheet of plastic with grooves or other indentations on the top to hold all, if possible, sources of a specific design; the device should have a means of holding a film below the sources without air gaps between the film and the source holder. The sources must be spaced far enough apart to avoid cross irradiation. At the simulator, obtain a radiograph of the sources with a simultaneous autoradiograph. Some experimentation with a single source before hand should be done in order to determine proper radiography and autoradiography techniques. This film can be scanned on a densitometer, to determine isodensity profiles away and along the sources. With proper normalization of the optical density to the center of each source, one can quantitatively compare the profiles to determine if the sources match. Once baseline data is obtained, this same project can be repeated annually to determine if any changes the radioactive material matrix within each source has changed. Similar devices can be constructed for testing arrays of Ir-192 seeds in ribbons in order to determine if the seed spacing is correct; usually only autoradiography is performed for such tests. Such test will quickly identify a cold seed that could be overlooked by using a dose calibrator to monitoring a ribbon for total activity.

c) Dose Calibrators

As this topic is presented elsewhere in these Proceedings, we only note that a dose calibrator can be used to confirm, over time, that permanent sources are decaying correctly, and that ordered temporary sources, either individual seeds or ribbon seed arrays, satisfy stated source certificate values. Consistent procedures and techniques are required, however, in using a dose calibrator. Source positioning within the calibrator is critical. For testing the relative strength of seeds, a simple collimator system with 1" x 1" NaI scintillation crystal may be designed (Ling 1981); used properly, it can be used to test for both relative source activity and identify errors in seed spacing.

Applicators

Applicators used in bracytherapy are subject to two major procedures that can alter applicator integrity: Repeated cleaning and sterilizations, and repeated insertions into patients. The applicator quality assurance program begins with the receipt into the department of any type (gynecologic applicator, seed placement guns, interstitial needles, etc.) of new unused applicator. It is essential to determine, by visual inspection and often radiographs, the features and performance characteristics of the applicator before it is used, and to determine that it meets stated design standards. For gynecologic applicators one determines that the applicator assembly is structurally sound and welds are properly formed, that source insert carriers seat correctly in the colpostats, and that all clamps, screws, and retaining devices function properly. Baseline radiographs of the applicator with and without sources in the applicator should be performed to determine that internal shields are properly located and that the source carriers seats correctly. If a department has applicators of different designs, some without internal shields and some without, they should be clearly marked in some manner lest confusion arise regarding their use. Several radiographs made from multiple views may be required to see all internal features of the applicator assembly. Radiographic film techniques used must be carefully recorded so that subsequent quality assurance radiographs of the same applicators can be compared to the originals.

For interstitial applicators using stainless steel needles, check all needles for strength and straightness. Pay attention to the type of needle end as some needles have, by design, different degrees of sharpness (i.e. blunt, 30o slant, 45o slant) for different applications. Needles with different tips must be separated by type on any prepared surgical tray and

clearly marked so the different types are distinguishable. For plastic needles, make certain that the tips are intact and cannot separate from the needle body. Seed guns must be checked for proper function to determine if they deposit seeds at the specified spacing; usually this is done by performing an implant with dummy seeds in super-flab or similar translucent material.

The intent of any of these procedures is to determine if applicators of all types function properly so that subsequent deviations in features or performance can readily be identified. Repeated cleaning of applicators can cause damage. Most plastics are not compatible with steam sterilizing, particularly, "flashing". Sterilization of nylon materials by ethylene oxide gas is the preferred method. However, plastic components of applicators or plastic applicators and needles experience small deformations from repeated gas sterilizations. Liquid disinfectants and cold sterilizing solutions can be corrosive to the silver brazing used to assemble some metal applicators. Where brazed, metal components should be manually tested to ensure the brazed joint is not loose. Visually inspect the joints for hair line cracks. For brazed tubes, such as ovoids brazed to handles, immerse the joint in water and blow air into the tube and watch for air bubbles that would indicate a failing brazed joint. Needle points become dull from repeated insertions; if resharpened, care must be taken to retain the original angle of cut on the needles.

A.8.3 Quality Assurance Of The Process Of The Use Of The Products

Protocols

The use of TRAM requires forethought, and that forethought is best summarized in protocols. We consider here departmental protocols for use, protocols for source control in preparation and transportation of TRAM, protocols for patient control while the TRAM is in the patient, nursing service protocols, and the protocol for quality management.

a) Departmental Use

We refer here not to a medical protocol; rather, to a protocol for the specific uses of TRAM in a facility. The intent is to identify all features for the proper use of TRAM so that incidents that result from the improper use of TRAM are avoided. This protocol, with many component parts, may require the approval of the Radiation Safety Committee. While the components of such a protocol will vary among facilities, it should address at least three concerns regarding the use of TRAM: What, where, and who! The protocol should identify for use in the facility the available radionuclides and their physical form; new radionuclides should be added to the protocol after details of their use have been developed. It should identify where (operating rooms, patient rooms, departmental examination rooms, diagnostic x-ray rooms, the simulator, etc.) in the facility specific radionuclides may be used. Are you allowed to hot load TRAM in the operating room? Can you really place a surface mold on a patient's hand and have them set all day in a departmental waiting room or must they be admitted to a private room? Having established this protocol will prevent incidences that are sure to arise when physicians wants to use TRAM in locations normally not allowed. The protocol should identify authorized users and their designates. The authorized users for humans are our physician colleagues and their duties are clearly identified in NRC regulations (NRC 1990). Designates (N. B. my term, not the NRC's) refers to the supporting medical staff (physicists, dosimetrist, radiation therapists, nurses) all of whom have a designated role in the medical procedure with TRAM. In some facilities, those who prepare and transport the radioactive materials must be approved for its non-human use by the Radiation Safety Committee. A clear definition of individual roles and responsibilities facilitates training and avoids difficulties.

b) Source Control

The previous discussion about source control should exist as a component of the TRAM protocol. This component describes the preparation of TRAM of different types, describes the inventory control methods, describes that allowed methods of transportation, establishes a procedure, with acknowledging signatures, for transferring the TRAM to the physician authorized user for insertion into the patient, and a similar

procedure for the removal of the TRAM from the patient and return to the source room. This purpose is to make certain that the correctly prescribed TRAM is given to the physician authorized user, and that the same recognizes it, and acknowledges and concurs that it is the material desired for the planned procedure.

c) Patient Control

This protocol address all of the features of a radiation control program required once the TRAM is in the patient. Components of such a program are described in a prior Proceedings (Glasgow 1990a). Whole the forms used for such patient control programs are unique to each facility, they generally have the following components. A Nursing Information form, kept at the nursing desks, identifies the pertinent information about the source, its insertion time and planned removal time, identifies emergency telephone numbers, and contains primary instructions regarding radiation control procedures. Door room posting forms include a necessary "Caution: Radiation Materials" sign and other instructions to personnel and visitors (N.B. We now use English-Spanish-Polish multilingual instructions), a room diagram with location exposure rates and working times, and nursing instructions specific to the patient care for the type of TRAM in the patient. The latter form includes instructions on the use of bed shields, patient care, housekeeping personnel and visitor time limits, and emergency medical instructions.

d) Nursing Service Protocol

Most Nursing Services will have a nursing procedures manual that will address questions such as the giving of daily baths, obtaining vital signs, and related nursing concerns. These issues must be addressed for each type of TRAM procedure allowed in a facility. For example, nursing patient care procedures for a prostate I-125 implant patients are different that those for a gynecologic implant patient. Details of patient care must be addressed in these Nursing Service protocols; there may be significant overlap with components of the Patient Control protocol.

c) The Quality Management Program

The NRC's Quality Management Program (NRC 1991) requires a set of written procedures addressing each item in the QM rule. Specifically, a written directive must identify the radioisotope, number of source, source strength, and the anatomic site, total prescribed dose (at dose prescriptions points or distances to the sources or specific anatomy) and nominal duration of therapy. Two-way patient identification confirms the brachytherapy patient's identification by comparison with a photograph, birth date, addresses, social security or hospital identification numbers, or identifying data on the patient's ID bracelet. Treatment plan compliance with the written directive consists of verifying the identification of the radionuclide, source activity or other related parameter, the number of sources, the sources relative spatial configurations, sequence arrangements, and nominal duration of use. Verification of the spatial dose distribution for the plan of therapy should be obtained by having a second knowledgeable individual document by signature that the resulting spatial dose distribution is correct. A record of therapy, documenting the components of the treatment plan, should be generated before temporary sources are removed from the patient and for permanent implants, before the patient is released from the hospital. Radiographs of non-radioactive sources for temporary implant should be used to verify source positions relative to target volumes in anatomic sites. Primary dose calculations should be cross-checked by a second individual before temporary sources are removed, or, for permanent implants, before the patient is released.

Planning The Use Of Tram

Specific methods of planning treatments with TRAM are presented elsewhere in these Proceedings; here, we review the most basic of principles in the planning process. These principles are used in planning forms for general categories of implants based on anatomic site (gynecologic, interstitial, etc.) These forms are designed to facilitate the sharing of information between the physician and others who will have a role in the implant

process, and to gather more information than " I'm going to implant Mrs. Jones next Tuesday".

a) Planning Forms

The first section of the form collects patient information (name, medical record, proposed date of implant) and physician information (authorized user physician, resident, referring physician). The second section collects data on the diagnosis and, very importantly, prior external beam treatments and prior brachytherapy treatments. The third section of the form addresses the known information about the anatomic area and a volume estimate of the tumor and a volume estimate of the target, and allows areas to sketch both. The fourth area of the forms asks for information on the proposed dose and its method of prescription, and the limiting doses to adjacent critical organs. The fifth area of the form lists, for temporary implants, the current inventory of sources that could be used for the patient, and indicates if new sources are to be ordered. The next area of the form identifies that equipment needed to be prepared for the procedure.

b) Treatment Philosophies

Forms are easy enough to prepare; but the real questions in bracytherapy that require answers are much more difficult to control. Is the planning (before sources are inserted) by your physicians ad-hoc or systematic? Is there a clear understanding of the desired spatial dose distribution to be achieved and the dose uniformity for that distribution? Is any system being followed? Forms used to plan cases will help the physician focus on their plans for that case and the physicist can play a vital role in assisting the physicians in developing consistent methods of brachytherapy in a facility.

Source Localization

Normally, the first interaction of the physicist with the patient occurs during source localization procedures. As methods of source localization are presented elsewhere in these Proceedings, we will not repeat them here. However, quality assurance procedures need to be developed for source localization. Generally, the QA involves having a QA program established for the imaging system and devices used, and having a QA program established for the isodose computation computer into which the imaging data is entered and from which the isodose curves are produced. A simple approach is to have imbedded in plastic phantoms fixed arrays of seeds or wires that mimic simulated source arrangements so that a fixed geometry is achieved and so the same device can be used repeatedly for radiographic tests. Quality assurance of the isodose computation system involves establishing baseline reconstructed spatial source arrays from these processed radiographs and, of course, determining at specified intervals that the computer continues to produce the same source array patterns from the same original films.

Dose Distribution Data

As others are presenting dose distribution data for radionuclides, we focus only on the use of such data in the isodose computation computer. Each type of isodose planning computer will have a brachytherapy menu. Often these are separated into sections on planning with linear sources, seeds, and possibly moving sources in high dose rate remote afterloaders.

Generally, a set of files, either as tables or as analytical functions, for each radionuclide, are stored in the computer. These data files are used to generate the isodose curves around sources. Quality assurance begins with developing an absolutely clear understanding of the method of generating these files, and understanding the computer algorithms for the use of such files to construct the isodose curves. In a review (Smith, 1990) of ten brachytherapy computers seven different algorithms were used to computer the doses around brachytherapy sources. Often, the format of these files is not the format of the literature data. The user generating the original files must clearly document the literature data that is being used to generate the files. Moreover, there must be a clear documentation of the basic assumptions used in the algorithm, regarding source encapsulation, end effects that produce dose anisotropy, tissue attenuation and multiple scattering corrections, and corrections for heterogeneous (bone, air) mediums. The computer models can be as simple as a point

source in air to a algorithm that accounts for numerous known processes that change the dose distribution. There are numerous possibilities for errors to arise as these files are used over time. First, if similar files exist for the same radionuclide with different filtration or encapsulation, confusion can arise as to which is the correct file to be used. Some files in the computer may have been provided by the software manufacturer for demonstration purposes, but are not intended for actual patient treatment. The origins of any such files must be clearly understood. Often, if the software manufacturer announces a new software release, errors are introduced in transferring or entering files for the new release. Often, files are inadvertently eliminated in this process, and a new user may begin planning with an improper file. Such files must be inspected after software upgrades, or other planned changes in the software program. Computer file reviews may (if the facilities QM program requires) be included in the annual QM audit. Obviously, in order to determine if the computer software produces consistent isodose distributions, one must prepare performance standards, usually by looking at the data produced for a single source and comparing these computer generated data to the known dose distribution data for a single source. Once such a comparison is made, it establishes a baseline for future comparisons.

Our knowledge of brachytherapy source dosimetry is much greater today that in years past; changing the basic source data file to represent the best and most recent data set is common, but one must carefully document these changes. Additionally, newer terms (Williamson 1993) have been introduced to describe the physics of brachytherapy sources, while computer software may use older terms and definitions. Great care must be exercised as confusion can arise regarding exactly what is meant by a particular old or new definition. One common way to test files is to share a set of data with others that have the same computer, and who are using the same data files, to determine if the same results are produced. The computer user groups often promote such projects.

Treatment Documentation

a) Dose Prescriptions (Written Directives) and Source Removal Times

One difficulty unique to brachytherapy has been the lack of definitive prescriptions prior to source insertion. Generally, the control of source placement is not sufficiently accurate for the physician to say absolutely what dose can be delivered until films reveal the spatial distribution of the sources, and the subsequent isodose patterns. Often, there is more of an intent of therapy than a prescription. The recent NRC QM program (NRC 1991) addresses this problem. A brachytherapy written directive, prior to implantation, must identify the radioisotope, number of sources, and the source strength. After implantation, but prior to the completion of the procedure, one must add to the written directive the treatment site, total source strength, and exposure time (or, equivalently, the total dose). The physicians may alter the intent of brachytherapy after reviewing the isodose curves (viz. allowing the sources to be removed earlier or later than originally intended). However, such decisions must be appear in a written directive before the sources are removed. While not a specific requirement of the QM program, as with all dose calculations, good practice requires this source removal time calculation must be double-checked and signed by a second knowledgeable individual.

A recordable event constitutes performing brachytherapy without a daily dose record or written directive, or delivery of a calculated dose greater than 10% (but nor more than 20%) of the prescribed dose. The more serious misadministration constitutes treatment of the wrong patient, use of the wrong radioisotope, implanting the wrong anatomic site, using leaking sources, failing to remove temporary sources, or allowing a calculated administrated dose 20% greater than the prescribed dose.

b) Source Transfers

While previously discussed, we stress again the importance of this step in brachytherapy. Physicians, as authorized users, have the responsibility to insert the TRAM into the

patient. Usually, knowledge of what TRAM has been prepared for this procedure lies with a designate. It is essential that there be no confusion during this important step. Good practice requires that the physician should sign a statement acknowledging the TRAM prepared so that there is not confusion about the number of sources, their activities, and other important data. When sources are removed from the patient, a similar procedure should be followed to document that all sources have been removed and are being returned to the source room. The patient survey must be done after the sources are removed.

c) Documentation of Treatment

The American Endocurietherapy Society (Anderson 1991) has prepared sample forms for documenting patient's treatments. In additional to the conventional patient identity information, and required previously discussed data required for a written directive, the forms collect data on total air kerma strength, stresses the methodology (films, CT scans, MR scans) used to determine target volume definitions, doses of various descriptions (prescribed, treatment, minimum, etc.) and dose rates, recommend methods of estimated volumes (cylindrical, ellipsoid, spherical) of tissue treated, doses to special interest points, and summarizes the differences between the doses planned and those delivered. While each facility will have their own forms, it is highly recommended that the component information included in these AES forms be included in the treatment summary forms of each facility.

A.8.4 Literature Cited

1. Anderson, L.L. , Nath, R., Olch, A. and Roy, J.. (1991). *American Endocurietherapy Society Recommendation for Dose Specifications in Brachytherapy*. Endocurietherapy/ Hyperthermia Oncology 7: 1-12.
2. Broadbent, M.V. (1984) *Brachytherapy Source Storage, Room Design and Shielding*. In Thomadsen B., (ed.) *Radiotherapy Safety*. New York: American Institute of Physics; 99-116.
3. DeLucas, P.M. (1984). *Leak Test Analysis - A Few Remarks*. In Thomadsen, B., (ed.) *Radiotherapy Safety*. New York: American Institute of Physics; 76-89.
4. Glasgow, G.P. and Perez, C.A. (1992a). *Physics of Brachytherapy*. In Perez, C.A. and Brady, L.W. (eds.). *Principles and Practices of Radiation Oncology (2nd Ed.)*. Philadelphia, PA, J.B. Lippincott Company, 267.
5. Glasgow, G.P. (1992b). *Radiation Safety Program For Radiation Oncology*. In Purdy, J.A. (ed.) *Advances in Radiation Oncologyy Physics*. American Institute of Physics, Woodbury, NY, 596-622.
6. Kutcher, G.J., Loia L., Gillin, M., Hanson, W.F., Leibel, S., Morfon, R.J., Palta, J.R., Purdy, J.A., Reinstein, L.E., Svenson, G.K., Weller, M., Wingfield, L. (1994) *Comprehensive QA For Radiation Oncology Report of AAPM Radiation Therapy Committee Task Group 40*, (In Press).
7. Ling, C.C. and Gromaedzki, Z.C. (1981). *Activity Uniformity of Ir-192 Seeds*. Int J Radiation Oncology Biol Phys 7: 669-669.
8. Smith, V. (1990). *Brachytherapy Software Systems*. American Associations of Physicists in Medicine Newsletter 15: 8-10.
9. Nuclear Regulatory Commission (1990). *Title 10, Chapter 1, Code of Federal Regulations, Part 35, Medical Use of By-product Material*, Washington D.C., Government Printing Office.
10. Nuclear Regulatory Commission (1991). *Quality Management Program and Misadministrations*. Federal Register 56 (143): 34104-34122, Thursday, 25 July.
11. Williamson, J.F. (1991). *Practical Quality Assurance for low dose rate brachytherapy*. In: Starkschall, G., Horton, L. (eds.). *Quality Assurance in Radiotherapy Physics*, Medical Physics Publishing, Madison, WI , 1239-182.
12. Williamson, J.F., (1993). *American Endocurietherapy Society Recommendations for Specification of Brachytherapy Source Strength*.

Endocurietherapy/Hyperthermia Oncology
9: 1-7.

NRC FORM 335 (2-89) NRCM 1102, 3201, 3202

U.S. NUCLEAR REGULATORY COMMISSION

BIBLIOGRAPHIC DATA SHEET

(See instructions on the reverse)

1. REPORT NUMBER (Assigned by NRC, Add Vol., Supp., Rev., and Addendum Numbers, if any.)
NUREG/CP-0144
INEL-94/0111
Vol. 1

2. TITLE AND SUBTITLE
A Workshop on Developing Risk Assessment Methods for Medical Use of Radioactive Material

Summary

3. DATE REPORT PUBLISHED
MONTH: August
YEAR: 1995

4. FIN OR GRANT NUMBER
L1939

5. AUTHOR(S)
Edited by J. P. Tortorelli

6. TYPE OF REPORT
Technical

7. PERIOD COVERED *(Inclusive Dates)*

8. PERFORMING ORGANIZATION – NAME AND ADDRESS *(If NRC, provide Division, Office or Region, U.S. Nuclear Regulatory Commission, and mailing address; if contractor, provide name and mailing address.)*
Idaho National Engineering Laboratory
Lockheed Idaho Technologies Company
Idaho Falls, ID 83415

9. SPONSORING ORGANIZATION – NAME AND ADDRESS *(If NRC, type "Same as above"; if contractor, provide NRC Division, Office or Region, U.S. Nuclear Regulatory Commission, and mailing address.)*
Division of Industrial and Medical Nuclear Safety
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

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.

12. KEY WORDS/DESCRIPTORS *(List words or phrases that will assist researchers in locating the report.)*
risk assessment
radiation
nuclear medicine
radiation oncology
human factors
workshop

13. AVAILABILITY STATEMENT
Unlimited

14. SECURITY CLASSIFICATION
(This Page)
Unclassified
(This Report)
Unclassified

15. NUMBER OF PAGES

16. PRICE