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Relative Risk Analysis of the Use of Radiation-Emitting Medical Devices: A Preliminary Application

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Introduction

This report describes the development of a risk analysis approach for evaluating the use of radiation-emitting medical devices. This effort was performed by Lawrence Livermore National Laboratory for the U.S. Nuclear Regulatory Commission (NRC). The assessment approach has been applied to understand the risks in using the Gamma Knife,* a gamma irradiation therapy device. This effort represents an initial step to evaluate the potential role of risk analysis for developing regulations and quality assurance requirements in the use of nuclear medical devices.

The risk approach identifies and assesses the most likely risk contributors and their relative importance for the medical system. The approach uses expert screening techniques and relative risk profiling to incorporate the type, quantity, and quality of data available and to present results in an easily understood form.

* The Gamma Knife is a registered trademark of Elekta Instruments, Inc.

Risk Analysis Approach

A team of risk experts reviewed several engineering-system risk analysis approaches for their applicability to radiation-emitting medical devices, such as the Gamma Knife. The results of this comprehensive review concluded that the limited data base available for the Gamma Knife, as with other radiation-emitting medical devices, did not permit an accurate estimate of the value of individual risk contributors, and that absolute values were not necessary for an effective understanding of the system. The review also concluded that the use of a relative risk analysis approach was applicable to these types of systems. After further considerations, a relative risk profiling process was developed for application to the Gamma Knife device.

The relative risk profiling process used in this application is illustrated in Figure 1. The process consists of five steps to identify and assess the most likely risk contributors and their relative importance. The remainder of this paper will briefly discuss each step in the process as applied to the Gamma Knife device followed by a discussion of conclusions and recommendations.

1. Review Equipment, Functions, and Operations

Information collection activities were undertaken in order to develop an understanding of the treatment functions, processes, facilities, operations, hazards, and procedures. A multi-discipline team of physicians, systems engineers, human factors engineers and medical physicists with aggregate expertise in teletherapy, risk assessment, task analyses, and human reliability analysis, was organized to gather information. A data collection plan was developed that included background literature reviews and research, interviews with medical treatment experts, operators, installation engineers and the manufacturer, and visits to multiple Gamma Knife facilities.

2. Identify Risk Contributors Through a Modified Task Analysis

The information gathered in the previous step was used to identify a comprehensive set of potential threat scenarios through a systematic application of task analysis as a mechanism to determine task sequences, propagation paths, failure modes, and human actions. The threat scenarios included both normal and abnormal operating modes.

Potential risk significant threat scenarios were developed for:

1) quality assurance procedures including calibrations, timer accuracy, interlocks, and radiation output and monitoring,

2) dosimetry and safety measures,

3) pre-therapy checkout,

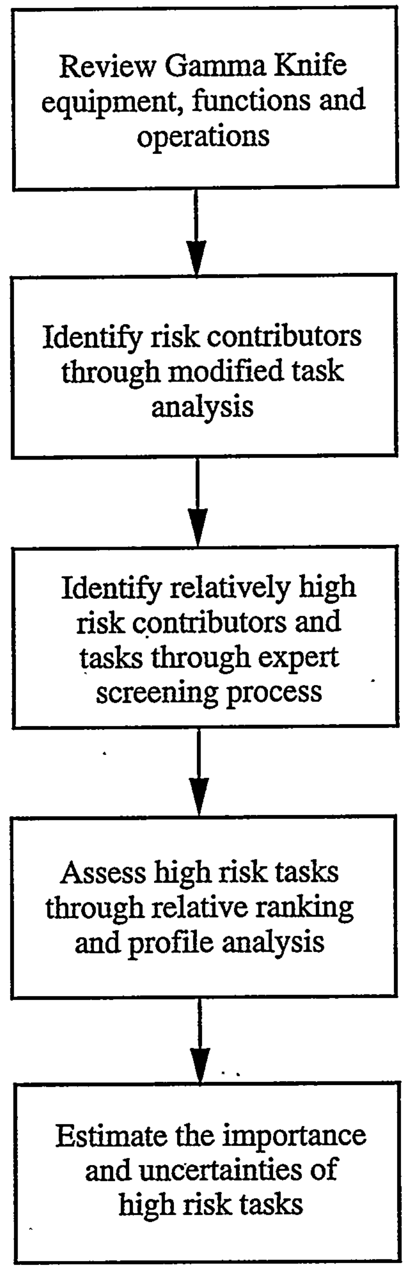

Figure 1. Relative Risk Analysis Process used in the Gamma Knife Application.

4) patient treatment including planning, positioning, localization, and imaging,

5) abnormal events, and

6) maintenance and servicing.

The types of potential hazards encountered in the evaluation included: ionizing radiation to patients and practitioners, hydraulic pressure under rapid changes, inadvertent activation of electrical components, power source failures, mechanical operation, and helmet hoist failure.

For the Gamma Knife device, the task analyses and threat scenarios development efforts identified 102 tasks or subtasks with potential human errors and 23 equipment failure modes.

3. Identify Potentially High-Risk Contributors and Tasks through an Expert Screening Process

The task analyses used to identify potential threat scenarios were also employed to evaluate equipment failure and human error likelihoods, and identify potential consequences associated with the failure of each tasks. This was accomplished through a step-by-step process of information elicitation from medical experts familiar with Gamma Knife operation.

The elicitation process involved interview and discussion sessions using descriptions of the functional process flow and individual tasks with schematic representations of the facility layout and equipment drawings. Individuals and teams of experts were asked to provide numerical estimates that were combined into discrete distributions for each task. This process resulted in data concerning task frequencies, the use of support equipment, equipment failure and human errors rates, potential consequences, and consequence severities. In addition, the elicitation process was used to indicate how potential human errors and their consequences could be minimized (prevented or mitigated).

The information collected was used to assign relative estimates of likelihood and consequence to each of the identified human errors and equipment failures. This evaluation resulted in a consolidated list of 24 relatively high-risk tasks, with a total of 66 subtask errors. The information was also used to screen out the equipment failures as less risk-critical than the human error events in the 24 primary tasks. Table 1 provides a list of the 24 primary tasks identified for the Gamma Knife treatment path.

4. Assess High-Risk Tasks through Relative Ranking and Profile Analysis

Since sufficient quantitative data was available from the previous task, the identification of high-risk task and subtasks was conducted by a direct calculation of risk: task probability times consequence severity. However, in the absence of quantitative data, qualitative judgements could have been used to formalize the ranking on a relative basis.

The initial risk evaluation assumed independence between tasks. However, many errors or resultant consequences are prevented (or mitigated) by "checking" procedures during the treatment process. These procedures were addressed by incorporating recovery factors into the final task rankings. Threat scenarios involving concatenated tasks were adjusted to ensure appropriate relative rankings.

Table 1 - Consolidated Primary Tasks in the Gamma Knife Treatment Path

Imaging and Localization	
1.1	Identify correct patent
1.2	Affix stereotactic frame
1.3	Set up CT, MR, Angiography
1.3.3	Films not labeled correctly
1.5	Center correctly deposited on film
Treatment Planning	
2.3	Check planning equipment
2.6	Take skull measurements
2.7	Enter skull data into computer
2.8	Enter gamma angle
2.9	Determine geometry from film
2.12	Select calculation mode
2.14	Determine iso-center coordinates
2.15	Enter shot parameters
2.17	Plot iso-dose curves
2.18	Overlay iso-dose plots
2.19	Enter prescribed dose
2.20	Produce prescription
Patient Positioning and Treatment	
3.3	Choose collimating helmet
3.4	Set plug pattern
3,5	Set iso-center coordinates and gamma angle
3.6	Perform Final checks
3.8	Set treatment time
3.9	Monitor treatment
3.10	Check iso-center settings after treatment

Relative point estimates of error likelihood, consequence severity, and risk for the primary tasks were compared by means of relative rankings and profiles, as illustrated in Figure 2. These profiles aided in the identification of the highest-risk or critical tasks, without requiring an absolute quantification of risk for each task. As shown in the Figure 2, Task 1.2, Affix Stereographic Frame, had the lowest consequences whereas Task 1.1, Identify Correct Patent, had the highest consequence in the relative comparison. Task 2.9, Determine Geometry from Film, had the highest error likelihood, and Task 1.1 had the lowest error likelihood in the relative comparison.

5. Estimate the Importance and Degree of Uncertainty Associated with High Risk Tasks

To gain and understanding of the importance and degree of uncertainty associated with high-risk tasks, a logic diagram (event tree) was constructed that modeled the sequential occurrence of each primary task as the top event. Individual subtasks for each primary task were combined using various logic modeling methods to aggregate their error and consequence distributions into single error and consequence distributions for the primary task.

The discrete error distributions of relative probabilities based on the experts' actual experiences (of varying degrees) do not represent true classical probability distributions but more accurately represent density functions. Therefore, all relevant information was used to develop distributions based on belief and uncertainty. For the Gamma Knife study, the distribution of error rates were utilized as estimates of the relative occurrence likelihoods.

Evaluation of the overall logic diagram involved propagating both probabilities and consequences of task errors along each threat scenario. A Monte Carlo simulation was used to evaluate the relative risk of the possible scenarios. High-risk scenarios were examined to determine the relative importance of the individual primary tasks. The important primary tasks were then decomposed to identify dominant subtasks.

For the Gamma Knife study, these evaluations indicate that most of the uncertainty in the results were propagated from consequence distributions. In addition, Task 2.9, Determine Geometry from Film, was shown to have the highest relative risk, even compared to Task 2.15, Enter Shot Parameters, which has a comparable relative probability and higher consequences. This result was due to the fact that Task 2.9 has a wide range of possible consequences compared to a small variation about a relatively high consequence for Task 2.15.

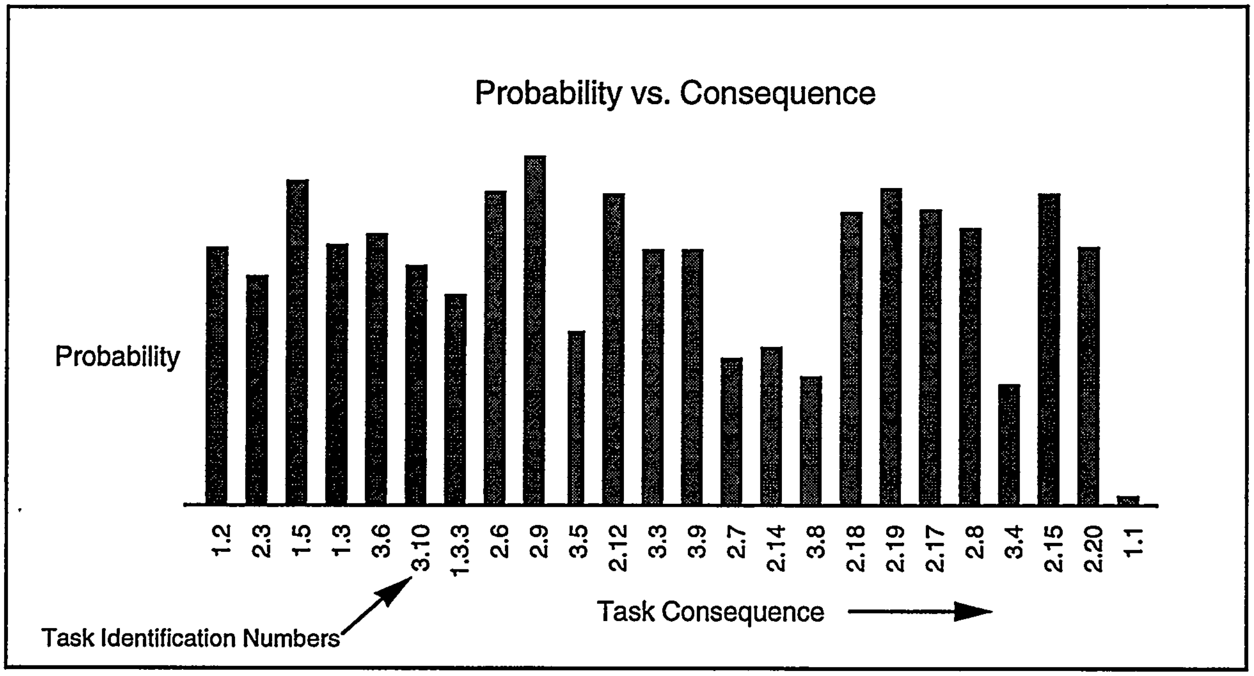

Figure 2. A risk domain profile for Gamma Knife tasks. The error occurrence probability (logarithmic scale) is shown along the ordinate, and the tasks are arranged by increasing consequence along the abscissa. The numerals along the abscissa are task identification numbers.

Sensitivity and risk mitigation studies were performed on Task 2.9 by investigating ways to lower the error probabilities and consequences of associated subtasks. Modified subtasks and their representative error distributions were then combined to evaluate changes to the risk distribution. Administrative changes to two subtasks of Task 2.9 resulted in a reduction in the mean risk of about 30% with a reduction in the coefficient of variation of the risk distribution of almost 50%.

Participation by the Medical Community

One object of this effort was cooperation and participation by the manufacturer and members of the medical community. Along with participating in the data and information gathering efforts, every step in the process was reviewed for accuracy, completeness and consistency by subject matter experts and by conducting simulations, facility walk-throughs, and observations of actual practices.

Members of the medical community provided reviews and comments to the project team. All data utilized was subsequently reviewed, critiqued, and validated by expert peer review teams.

Conclusions and Recommendations

A relative risk profiling process has been developed for evaluating the risk of radiation-emitting medical devices. It has been initially applied to assess the Gamma Knife treatment operations. Relative risk profiles and distributions were developed which offer insights into the critical tasks of the treatment process. The relative risk profiles show that several of the highest-risk tasks are associated with treatment planning activities. Specific aspects of the treatment process were identified for improvements to reduce the risks, particularly those task and subtask errors that can result in relatively high consequences.

The relative risk profile process can be readily applied to other radiation-emitting devices. For these specific applications, this analytical approach can give relative risk information and rankings but will not provide quantitative risk information for comparison with other devices. This process can be used to identify weaknesses and support the development of positive measures for improving treatment.

The use of a relative risk profile process is most effective in nuclear medical applications that are not highly structured or that have a limited experience base. The process can be used to identify areas requiring additional requirements and implementation guidelines for improving the safety of patients, administering staff, and the public.

Acknowledgements

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