UNITED STATES
NUCLEAR REGULATORY COMMISSION
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MEMORANDUM FOR: Lawrence C. Shao, Director
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Brian W. Sheron, Director
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Warren Minners, Director
Division of Safety Issue Resolution

FROM: Eric S. Beckjord, Director
Office of Nuclear Regulatory Research

SUBJECT: SURVEY OF PRA USES IN RES

In a July 1991 letter, the NRC's Advisory Committee on Reactor Safeguards (ACRS) identified a number of problems with the staff's uses of PRA. In response, the NRC's Executive Director for Operations formed a working group of staff management to:

> consider what improvements in methods and data analysis are possible and needed, the role of uncertainty analysis in different staff uses of PRA, if improvements are needed in the allocation of existing PRA staff, and the need for recruitment of more staff (or for identifying other means for supplementing staff resources).

This PRA Working Group has developed and is implementing a plan, which is being provided to you under separate cover. The plan's Task 1 relates to the definition and categorization of present staff PRA uses. An initial list of RES uses has been developed (Enclosure 1), as well as a use survey (Enclosure 2). Please take two actions to support the Working Group's completion of Task 1:

- Review the list of uses provided in Enclosure 1 for completeness and update it as necessary (the list should include not only current activity that utilize PRA but also any major activities completed in the last 2 years); and

- Provide the survey to appropriate staff members for each use identified on the updated list. In cases such as generic issue analyses, where PRA is used to support resolution of a number of issues, it is not necessary to have the survey completed for each issue. Rather, a small representative sample of issues (e.g., normal case, very complex study, simple study) will be sufficient.

Please ensure that the survey is completed and returned to the Working Group Chair, Mark Cunningham, DSIR, by April 3, 1992. If you have any questions, please contact Mr. Cunningham on X23965.

Eric S. Beckjord, Director
Office of Nuclear Regulatory Research

Enclosures:
As stated

Enclosure 1

Summary of PRA Uses

Office of Nuclear Regulatory Research

- Review of licensee IPE/IPEEE or PRA submittals (DSIR)
- Reviews of advanced reactors (PIUS, CANDU, etc.) (DSR)
- Regulatory analyses in support of rulemaking or regulatory guide development:

  Examples include:

  - License renewal rule (part 54) (DSIR)
  - Maintenance rule (DSIR)
  - Part 100 update (DSIR)
  - Part 100 Appendix A update (DE)
  - Part 20 update (DRA)
  - Rules and regulatory guides in support of NMSS (DRA)
  - Part 50 update to reflect latest ASME code (DE)
- Definition of safety goal large release (DSIR)
- Prioritization of generic issues (DSIR)
- Generic issue resolution (DSIR)
- Analysis of severe accident issues (e.g., direct containment heating) (DSR)
- Analysis of accident management (DSR)
- Prioritization of research

  Examples include:
  - Materials (DE)
  - Aging (DE)
  - Severe accidents (DSR)
  - Human Factors (DSR)
  - Seismic (DE)
  - Waste management (DRA)
- Low power/shutdown risk evaluation (DSIR)
- Risk-based performance indicator research (DSR)
- Risk-based technical specification research (DSR)
- Support for ASME code changes (DE)

Enclosure 2

A Survey Of NRC PRA Uses

In late 1991, the Executive Director for Operations established an interoffice group (the "PRA Working Group") to review present staff uses of PRA and to consider what additional guidance to the staff would assure the consistent development, content, and use of PRA within the NRC. This review was initiated by the EDO in response to ACRS comments on the staff's uses of PRA.

The Working Group has developed this survey to help in the characterization of present staff uses of PRA. This survey has two sections. The first section relates to the process of PRA use in the agency. The second section relates to the technical attributes of the PRA applications. After evaluating the results of this survey, some of the respondents may be asked to provide additional information; in this case, a more detailed survey will be sent to the respondent.

This survey covers both PRA applications and studies, as well as non-PRA applications and studies which use PRA as a support tool. It also covers those applications that adapt results of PRA studies.

If you have any questions please call:

Mark Cunningham
Chief, DSIR/PRAB

X23965

Name of The Respondent:

Affiliation:

Mail Stop and Telephone Number:

INSTRUCTIONS

1) If, for a particular type of application, (e.g., generic issue analysis), the PRA methods used vary considerably, please fill out individual surveys for a representative sample of applications (e.g., normal case, very complex study, simple study)

2) Check the appropriate answer whenever possible; if desired, provide further information or clarifications in a brief form.

3) Only include applications or studies in which PRA was used and which were initiated or completed in the past 2 years.

I. The Process of PRA Use

I.1 Description of the Application or Study

a) Name of the application or study.

b) Applicable references.

I.2 Objectives of the Application or Study

a) Briefly describe the objectives of the overall project for which the PRA application or study was performed.

b) Briefly describe the specific objectives of the PRA application/study portion of the project.

c) Indicate the approximate level of effort involved:

- Total staff-weeks spent on the PRA portion of the project.

- Fraction of project's overall effort spent on the PRA portion.

I.3 Uses of the PRA Results

a) How were the PRA application/study results used to reach a regulatory conclusion?

____ - PRA results directly used to reach a regulatory decision.

____ - PRA results indirectly used to reach a regulatory decision.

____ - PRA results not used to reach a regulatory decision.

____ - Other _____

b) What was the principal form of output from the PRA application/study?

____ - Core damage frequency or risk.

____ - Change in core damage frequency or risk.

____ - Importance or other relative ranking.

____ - Review and comment on PRA performed by others.

____ - Qualitative insights.

____ - Other _____

c) Does formal guidance exist on how <u>to perform</u> the PRA application?

____ - Guidance does not exist.

____ - Guidance exists (briefly describe and reference).

d) Does formal guidance exist on how to use the results of the PRA in the agency's decisionmaking process?

____ - Guidance does not exist.

____ - Guidance exists (briefly describe and reference).

e) Do formal decision criteria exist for this use of PRA?

____ - Formal decision criteria exist (briefly describe and reference).

____ - Decision criteria do not exist.

I.4 Staff and Contractor PRA Experience

a) Identify the level of PRA knowledge of the people who performed this application or study. Please answer the questions with respect to the NRC project manager here and, if a contractor was used, with respect to the principal investigator in question I.4.b.

Name of NRC Project Manager _____ _____

- PRA Related Experience	Yrs.	No. of Studies
Event Tree/Fault Tree Development		
* Fault Tree Construction	___	_____
* Event Tree Construction	___	_____
* Review of ET/FTs	___	_____
* Project Management	___	_____
* Other (please specify) _____ _____	___	_____
Data Analysis		
* Screening/Rev./Categorizing	___	_____
* Bayesian Analysis	___	_____
* Statistical Analysis	___	_____
* Common Cause Data	___	_____
* Human Performance Data	___	_____
* Other (please specify) _____	___	_____
Quantification of Sequences (or fault trees)		
* Quantified Fault Trees	___	_____
* Quant. Accident Sequences	___	_____
* Performed Uncertainty Anal.	___	_____
* Performed Sensitivity Anal.	___	_____
Human Performance	___	_____
Containment Failure Analysis	___	_____
In-Vessel Phenomena/Source Term	___	_____
Offsite Consequence Analysis	___	_____
External Events		
* Qualitative Analysis	___	_____
* Probabilistic	___	_____
* Other (please specify)	___	_____

- Non-PRA Background/Experience

	Yrs
Reactor Systems	___
Auxiliary Systems	___
Instrumentation and Control	___
Electrical Systems	___
Thermal-Hydraulics	___
Containment Analysis	___
Source Term Analysis	___
Reactor Operation	___
Inspection	___
Chemistry	___
Materials Science	___
Consequence Analysis	___
Statistics	___
External Events	___
Other (Please Specify)	___
_____	

- Type of PRA Education

_____ * NRC courses
_____ * Formal PRA education
_____ * Experience
_____ * Other (please specify)_____

b) If a contractor was used, describe the experience of the principal investigator.

Name and Affiliation of Principal Investigator _____

- PRA Related Experience	Yrs.	No. of Studies
Event Tree/Fault Tree Development		
* Fault Tree Construction	___	_____
* Event Tree Construction	___	_____
* Review of ET/FTs	___	_____
* Project Management	___	_____
* Other (please specify) _____	___	_____
Data Analysis		
* Screening/Rev./Categorizing	___	_____
* Bayesian Analysis	___	_____
* Statistical Analysis	___	_____
* Common Cause Data	___	_____
* Human Performance Data	___	_____
* Other (please specify) _____	___	_____
Quantification of Sequences (or fault trees)		
* Quantified Fault Trees	___	_____
* Quant. Accident Sequences	___	_____
* Performed Uncertainty Anal.	___	_____
* Performed Sensitivity Anal.	___	_____
Human Performance	___	_____
Containment Failure Analysis	___	_____
In-Vessel Phenomena/Source Term	___	_____
Offsite Consequence Analysis	___	_____
External Events		
* Qualitative Analysis	___	_____
* Probabilistic	___	_____
* Other (please specify)	___	_____

- Non-PRA Background/Experience Yrs

Reactor Systems	___
Auxiliary Systems	___
Instrumentation and Control	___
Electrical Systems	___
Thermal-Hydraulics	___
Containment Analysis	___
Source Term Analysis	___
Reactor Operation	___
Inspection	___
Chemistry	___
Materials Science	___
Consequence Analysis	___
Statistics	___
External Events	___
Other (Please Specify)	___
_____	

- Type of PRA Education

____ * NRC courses
____ * Formal PRA education
____ * Experience
____ * Other (please specify)_____

c) In performing this PRA application/study, what other technical skills did you occasionally or routinely make use of (check all that apply):

- In the staff of your division:

Occasionally	Routinely	
_____	_____	- Level 1 analysis
_____	_____	- Statistics
_____	_____	- Human reliability analysis
_____	_____	- Fire analysis
_____	_____	- Seismic (or other external event) analysis
_____	_____	- Level 2 analysis
_____	_____	- Level 3 analysis

- In other parts of NRC:

Occasionally	Routinely	
_____	_____	- Level 1 analysis
_____	_____	- Statistics
_____	_____	- Human reliability analysis
_____	_____	- Fire analysis
_____	_____	- Seismic (or other external event) analysis
_____	_____	- Level 2 analysis
_____	_____	- Level 3 analysis

- From contractors

Occasionally	Routinely	
_____	_____	- Level 1 analysis
_____	_____	- Statistics
_____	_____	- Human reliability analysis
_____	_____	- Fire analysis
_____	_____	- Seismic (or other external event) analysis
_____	_____	- Level 2 analysis
_____	_____	- Level 3 analysis

I.5 Review of application or study

a) Describe the level and type of review performed for this application or study.

- Extent of review
  - ____ * Spot checks
  - ____ * Detailed review
  - ____ * Independent verification
  - ____ * Other _____
  - ____ * None

- Reviewers
  - ____ * NRC staff (include their names)
  - ____ * ACRS
  - ____ * Contractors (include their names)
  - ____ * Universities (include their names)

- Major areas included in the review (check all that apply).
  - ____ * Fault trees
  - ____ * Event trees
  - ____ * Initiating events
  - ____ * Data
  - ____ * Common cause failures
  - ____ * Quantification
  - ____ * Plant damage states
  - ____ * Source term
  - ____ * Uncertainty analysis
  - ____ * Human reliability
  - ____ * Containment analysis
  - ____ * External events
  - ____ * Others _____

I.6 Documentation

a) What form of documentation was developed for the application?

- ____ - None
- ____ - Informal note
- ____ - Memorandum
- ____ - Letter report
- ____ - NUREG or NUREG/CR
- ____ - Other _____

II. Technical Attributes of the PRA Application/Study

a) Was this application or study a generic application?

____ - It was a generic study.

What makes it generic?

____ * Multiple plants studied; how many?
____ * Hypothetical plant studied
____ * Other _____

____ - It was a plant specific study

____ - Other _____

b) Did the application or study generate its own unique PRA calculations, adapt results of previously performed PRAs, or was it a mixture?

____ - Unique PRA calculations were generated.

____ - It adapted PRA results from other PRAs, or was a mixture. Which of the following are unique or adapted (check as many as apply):

Unique	Adapted	
____	____	* Fault trees
____	____	* Event trees
____	____	* Initiating events
____	____	* Data
____	____	* Common cause failures
____	____	* Human reliability
____	____	* External events
____	____	* Dominant sequences
____	____	* Only specific sequences
____	____	* Overall CDF, conditional containment failure, and/or offsite consequences
____	____	* Plant damage states
____	____	* Source term
____	____	* Uncertainty analysis
____	____	* Containment analysis
____	____	* Others _____

- If the results were mainly adapted, identify the PRA sources.

____ - NUREG-1150 (which plant?)

____ - WASH-1400 (which plant?)

____ - Industry PRA (which plant?)

____ - Other _____ _____

c) Identify the relevant PRA level and methodology used.

- Check the appropriate level:

____ - Level-I
____ - Level-II
____ - Level-III

- Methodology: check applicable methods (check as many as apply)

____ - Large fault tree-small event tree
____ - Small fault tree-large event tree
____ - Support systems are included
____ - Sequences are modified and adapted
____ - Sequences are adapted without modification
____ - Cut sets of systems or sequences are adapted without modification
____ - Cut sets of systems or sequences are adapted with modifications
____ - Fault trees are adapted without modifications
____ - Fault trees are adapted with modifications
____ - Plant damage states are created

- Initiating events. Check all applicable initiators:

____ - LOCAs (what sizes?)

____ - Transients (which ones?)

____ - Support system initiators (which ones?)

____ - Internal fire and flood
____ - External events
____ - Other initiating events (which ones?)

- What sources of data were used? Check all applicable items:

____ - Only generic data (identify the source)

____ - Only plant specific data

____ - Combination of generic and plant specific

____ - Used that in existing PRA (which one?)

- Plant conditions evaluated:

____ - Full power
____ - Low power
____ - Snutdown
____ - Refueling
____ - Other _____

d) Identify the degree of conservatism employed in this application:

____ - Strictly best estimate inputs used for models, data base, assumptions, etc.

____ - Conservative values were employed in the following areas:

e) Did this application or study perform uncertainty or sensitivity analysis?

____ - No uncertainty analysis was performed; only point estimates were used as inputs.
____ - A full scope uncertainty analysis was performed.
____ - A limited scope uncertainty analysis was performed. What was the scope?

____ - No sensitivity study was performed.

____ - A sensitivity analysis was performed. (For which elements of the application or study?)

____ - If an uncertainty analysis was performed, identify the following:

* Types of distributions used

____ • Log-Normal
____ • Maximum Entropy
____ • Empirical
____ • Others_____

* Method of propagating distributions

____ • Monte-Carlo
____ • LHS
____ • Moments Method
____ • Others_____

* Model uncertainty

____ • Qualitatively considered
____ • Quantitatively considered
____ • Not considered

* How is uncertainty information used?

____ • Only displayed the range
____ • Factored into the conclusion of the application/study (explain how)
____ • To calculate mean value
____ • Other _____

* Were experts used to estimate uncertainty distribution or were they derived from data?

____ • Experts estimated uncertainty
____ • Uncertainty derived from data
____ • Both
____ • Uncertainty taken from existing PRA (which one?)

f) Did this application or study incorporate the effects common cause failures (CCF), and how did it do so?

- Did the application or study consider CCF?

_____ * Yes
_____ * No

- How were CCFs treated?

_____ * Implicitly
_____ * System level
_____ * Train level
_____ * Component groups within a system
_____ * Other _____

- Method of CCF treatment

_____ * Generic beta factor
_____ * Plant specific beta factor
_____ * Alpha factor method
_____ * Multiple Greek letter
_____ * Basic parameter
_____ * Shock model
_____ * Stress-strength model
_____ * Other _____

- CCF data sources

_____ * Generic (source?)

_____ * Existing PRA
_____ * Plant-specific
_____ * Other _____

g) Did this application or study consider probability of human failures?

_____ - Yes
_____ - No

- Pre-accident human errors were considered

_____ - Yes
_____ - No

- Post-accident human errors were considered

____ - Yes
____ - No

- Types of errors considered

____ - Procedural
____ - Control room errors
____ - Ex-control room errors
____ - Errors of omission only
____ - Errors of omission and commission
____ - Equipment restoration errors
____ - Others _____

- Analysis methods used

____ - Expert judgment
____ - THERP
____ - SLIM-MAUD
____ - HCR
____ - TRC
____ - Other _____

- Human reliability data source

____ - Generic data (source?)

____ - Simulator data
____ - Expert judgment
____ - Other _____

- Identify the following aspects of the recovery actions considered:

____ - Only recoveries from a control room were considered.
____ - Ex-control room recoveries were included.

- Data used
____ * Plant specific
____ * Generic
____ * Other_____

____ - Recovery actions were added after the initial quantification.

____ - Recovery actions were an explicit part of the model.

h) Were external events considered?

____ - No
____ - Yes (which ones?)

____ * External floods
____ * External fires
____ * Seismic events
____ * High wind
____ * Tornadoes
____ * Human-made hazards (e.g., aircraft, explosion, sabotage)
____ * Lightning
____ * Others _____

- For those external events consider, what method was used?

____ * Fragilities developed

____ o generic
____ o plant specific

____ * Event trees adapted
____ * Event trees developed
____ * Initiating event frequency
____ • Generically considered
____ • Plant specifically considered
____ • Other _____
____ * Fault trees developed
____ * Fault trees adapted
____ * Margins approach

i) Describe the applicable aspects of the application or study's quantification process:

____ - Cut sets of sequences generated and quantified.
____ - Cut sets of fault trees developed and quantified.

____ - Average, time independent unavailabilities calculated for input events.
____ - Point-wise time dependent unavailabilities developed for input events.

____ - What codes were used in the quantification?

____ * IRRAS
____ * SETS
____ * FRANTIC
____ * SARA
____ * Other _____

____ - Calculations were made by hand.

____ - What form of truncation was used?

____ * Probability or frequency based truncation (describe the level).

____ * Cut set size truncation (describe the level).

____ * Other _____

j) Identify the method of accident progression and containment loading analysis used in this application or study.

____ - Not modeled
____ - Explicitly modeled

- What computer models were used for the loading analysis?
____ MELCOR
____ STCP
____ MAAP
____ Other _____

____ - Adapted from other study (what study?)

____ - Other _____

k) Identify the method of fission product release and transport (source term) analysis used in this application or study.

____ - Not modeled
____ - Explicitly modeled

- What computer models were used for the analysis?
____ MELCOR
____ STCP
____ MAAP
____ Other _____

____ - Adapted from other study (what study?)

____ - Other _____

1) If offsite consequences were analyzed, indicate the nature of such calculations and the form of the results.

- Codes used

____ - MACCS 1.5
____ - MACCS 1.4
____ - CRAC2
____ - Other _____

- Consequence measures estimated:

____ - Early fatalities
____ - Latent cancer fatalities
____ - Population dose (50 mile)
____ - Safety goal measures
____ - Others _____

- Site parameters

____ - Site specific
____ - Generic (how developed?)

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UCRL-ID-XXXXXX

Risk Analysis in Regulating the Use of Nuclear Medical Devices

DRAFT (February 1994)

Prepared by
E.D. Jones

Prepared for
U.S. Nuclear Regulatory Commission

FESSP
Fission Energy and Systems Safety Program

Lawrence Livermore National Laboratory

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Risk Analysis in Regulating the Use of Nuclear Medical Devices

DRAFT

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ABSTRACT

This report describes the development of a risk analysis approach designed and used to identify and assess high-risk, human-initiated actions and failure modes that are most likely to occur in the use of the Gamma Knife, a nuclear medical device. This effort represents an initial step in an overall NRC plan to evaluate the use of risk analysis in regulating the use of nuclear by-product materials. The methodology and tools show promise for developing indices of risk importance and effective risk management practices. The methods provide a flexible, basic approach for identifying most-likely risk contributors and the relative import nce of each contributor. The risk analysis tools also provide a platform for evaluating regulatory practices and reductions in the risk of misadministrations.

CONTENTS

EXECUTIVE SUMMARY

In 1991, the U.S. Nuclear Regulatory Commission (NRC), Office of Nuclear Material Safety and Safeguards, began a program to evaluate the use of probabilistic risk assessment (PRA) in regulating nuclear medical devices. This program represents an initial step in an overall plan to evaluate the use of PRA in regulating the use of nuclear by-product materials. The NRC envisioned that the use of risk analysis techniques could assist staff in ensuring that the regulatory approach was standardized, understandable and effective.

Traditional methods of assessing risk in nuclear power plants are inappropriate for assessing the use of nuclear medical devices. The approaches are equipment oriented with only secondary attention paid to the human component, and mostly after critical system failure events have been identified. However, investigations of medical misadministrations indicate that most treatment errors are human related.

Three areas were selected for inclusion in a risk analysis pilot program: the brachytherapy remote afterloader; the Gamma Knife, a gamma stereotactic radiosurgical device; and an examination of misadministration events. Lawrence Livermore National Laboratory (LLNL) was instructed to examine quality assurance issues for the Gamma Knife, with an overall goal of developing a generic risk methodology for use in by-product materials regulation. This report describes the development by LLNL of a methodology initially intended to assess risks associated with the use of the Gamma Knife.

The methodology and its tools show promise for developing indices of risk importance and effective risk management practices. The assessment methodology is an empirically based, systematic approach to uncovering potential risks. It is a flexible framework that can incorporate both qualitative and quantitative data about human and equipment factors and can rely on only relative measures of risk. Radiation safety improvements can be accomplished without absolute measures of risk (which are difficult to determine): only relative improvements in apparent risks are needed. The method uses both deterministic and probabilistic techniques to identify the most likely risk contributors and the relative importance of each contributor.

The risk analysis tools provide a platform for evaluating regulatory practices and reductions in the risk of misadministrations. The tools can be used to evaluate the effectiveness of preventive or risk-mitigating measures. They can also support alternative, more detailed, or higher-level assessments such as uncertainty and sensitivity studies. For these reasons, the potential exists to extend the current approach to radiography and other areas in which a reduction in potential unintended exposures can be realized.

The potential regulatory impacts of the risk analysis methodology are significant, as it may play a role in:

- Quantifying the risk of misadministrations.
- Developing regulations and guidelines to reduce the frequency and magnitude of errors.
- Evaluating the effectiveness of quality improvement practices.
- Reviewing the design of new devices.

ACKNOWLEDGMENTS

This study came a long way from a beginning in which the LLNL project team knew little about how to analyze the risks associated with the use of a nuclear medical device and knew even less about the Gamma Knife. The successes of this effort are attributable to the help, support, and cooperation of several very professional people. Elekta Instruments and, in particular, Richard Grome, Hans Sundquist, and Martin Knotts, extended extraordinary time and effort in cooperating with this project. Our primary consultants, Dr. David Larson and Dr. John Lyman were excellent, refreshingly blunt, and maintained refined senses of humor. We would also like to thank the Radiation Oncology staff at the University of California, San Francisco, especially Dr. Lynn Verhey and Dr. Vernon Smith, for so graciously tolerating our persistent questions and visits to their Gamma Knife facility. Other selected Gamma Knife users whose experiences were invaluable to our study, included Dr. Brian Copcutt, Dr. Harold Berk, Dr. L. Dade Lunsford, Dr. L. Steiner, Dr. Andrew Wu, and Ann Maitz. Our NRC Technical Monitor, Dr. Patricia Rathbun, played a significant role as a *de facto* project team member. Her insights, ideas, experience, and guidance were invaluable components to the team's success, and we appreciate her involvement. We also appreciate the reviews of our work and guiding comments provided by James Shepherd of the NRC. Finally, but not least, William Banks contributed crucial and creative ideas to the risk analysis and to the project team. He also presented a supportive and encouraging management style which allowed the team to flourish. Any deficiencies in this project are the sole responsibility of the author of this report.

RISK ANALYSIS IN REGULATING THE USE OF NUCLEAR MEDICAL DEVICES

1. INTRODUCTION

1.1. Goals and Objectives

This report describes a risk analysis approach that was developed to identify and assess high-risk, human-initiated actions and failure modes that are most likely to occur in the use of the Gamma Knife*, a nuclear medical device. The approach is being developed by the Fission Energy and Systems Safety Program of Lawrence Livermore National Laboratory (LLNL) under the auspices of the U.S. Nuclear Regulatory Commission (NRC), Office of Nuclear Material Safety and Safeguards (NMSS). Aspects of the methodology that could prove useful in the regulatory process are emphasized.

In 1991, the NRC, Division of Industrial and Medical Nuclear Safety, began a program to evaluate the use of probabilistic risk assessment (PRA) in regulating medical devices. This program represents an initial step in an overall plan to evaluate the use of PRA in regulating the use of nuclear byproduct materials.

The NRC envisioned that the use of risk analysis techniques could assist staff in ensuring that the regulatory approach was standardized, understandable, and effective. The staff could build upon the results of a risk analysis to produce procedures and inspection guidance to help avoid potentially risky situations and to continually lower risks. It was also felt that the use of risk assessments could lead to the development of various indices of risk importance of medical processes, thus permitting more effective risk management.

Three areas were selected for inclusion in a risk analysis pilot program: the brachytherapy remote afterloader; the Leksell Gamma Unit (LGU) or Gamma Knife, a gamma stereotactic radiosurgical device; and an examination of misadministration events. Contracts were placed with two National Laboratories: Lawrence Livermore National Laboratory (LLNL) and the Idaho National Engineering Laboratory (INEL). LLNL was instructed to examine quality assurance procedures for the Gamma Knife, with an overall goal of developing a generic risk methodology for use in byproduct materials regulation.

1.2. Scope and Organization of Document

This document describes a risk methodology developed by LLNL and its application to assessing risks associated with the use of the Gamma Knife. The design of the Gamma Knife makes it a relatively simple mechanical machine with very few moving parts. However, a great deal of care must be taken by the Gamma Knife medical team to plan the treatment, locate and position lesions, and administer the correct dose and treatment to the patient. Hence, the use of the Gamma Knife was considered to be a human task-driven operation. The method provided a basic approach for identifying the most likely risk contributors and their relative importance, and for evaluating the effectiveness of preventive or risk-mitigating measures.

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

For relatively new medical devices such as the Gamma Knife, very little data exists concerning component performance. Most information resides in the experience base of the manufacturer and users. Furthermore, preliminary investigations of this experience base indicated that most treatment errors are human-related. Thus, the challenge was to perform a risk analysis with very little quantitative data but with an important human factor component. The risk analysis approach developed for the Gamma Knife and described in this document may be applicable to a broader class of medical devices in which the human interaction with the device is a prominent factor.

The description in this document of the risk analysis approach essentially follows its process of development. Section 2 provides a brief discussion of the Gamma Knife device and its use. Section 3 discusses the up-front risk evaluation issues that had to be addressed before embarking on the development of a risk approach. These issues included the consideration of characterizing risk for the Gamma Knife and how to deal with consequence measures. Traditional PRA and human reliability analysis (HRA) techniques were reviewed before selecting general criteria and a technique to analyze risk for the Gamma Knife. The role of quality assurance and peer review is also discussed. Section 4 describes the risk analysis methodology as applied to the Gamma Knife. The systematic and iterative hierarchy of the method's stages is delineated and representative results are explained. Results that can support the regulatory process are emphasized. Section 5 concludes with a summary of the capabilities of the methodology as developed.

2. THE GAMMA KNIFE

The Gamma Knife is a gamma radiation device designed to perform stereotactic radiosurgery of the brain. Dr. Lars Leksell, a neurosurgeon at the Karolinska Institute in Stockholm, Sweden, first proposed the use of external radiation beams with the guidance of a stereotactic frame to precisely locate and treat surgically inaccessible lesions within the brain (Leksell 1971). Leksell's early work used proton beams, a linear accelerator, and a cobalt unit. The first Gamma Knife (using 179 cobalt-60 sources) was installed at Karolinska in 1968. It was designed for the treatment of functional neurosurgical symptoms. A second unit was designed in the early 1970s to produce a spherical radiation dose for treatment of tumors and arteriovenous malformations (AVMs). The unit that was designed for and used by the Karolinska Institute in 1968 was donated to the University of California at Los Angeles (UCLA) in 1981, entering the United States as a research unit on a broad byproduct license. In the 1980s, the third and fourth gamma units, which had 201 cobalt-60 sources, were installed in Buenos Aires, Argentina, and Sheffield, England, respectively. The fifth Gamma Knife was the first 201 cobalt-60 source unit in the U.S. and was installed at the University of Pittsburgh Medical Center in 1987 (Maitz et al 1990, Lunsford et al 1989). To date, there are approximately 15 Gamma Knives installed in the U.S., and more than 2?00 U.S. patients have undergone radiosurgical treatments with Gamma Knives.

The U.S. Gamma Knife model consists of a radiation unit, four interchangeable collimator helmets, a patient treatment table, a hydraulic system, a control console, and a treatment planning computer system. The radiation unit has 201 cobalt-60 sources that are arranged in a large, heavily shielded sphere (18,000 kg) (see Figure 2-1 and 2-2). Radiation from each cobalt-60 source is collimated into narrow beams that focus at the center of the sphere. A movable external collimator device or helmet is advanced hydraulically to align with the fixed internal collimators inside the sphere. The combined collimators restrict the irradiation beams that are focused at the center of the sphere. The cross-sectional diameter of the beams at the focal point can be varied by changing the size of the circular apertures of the collimators in the helmet. In addition, any of the removable collimators can be replaced with an occlusive plug to prevent irradiation of the lens or critical structures near the target. For each helmet, a pair of trunnions serves as fixation points for the stereotactic frame, which in turn is attached by four pins to the outer surface of the patient's skull.

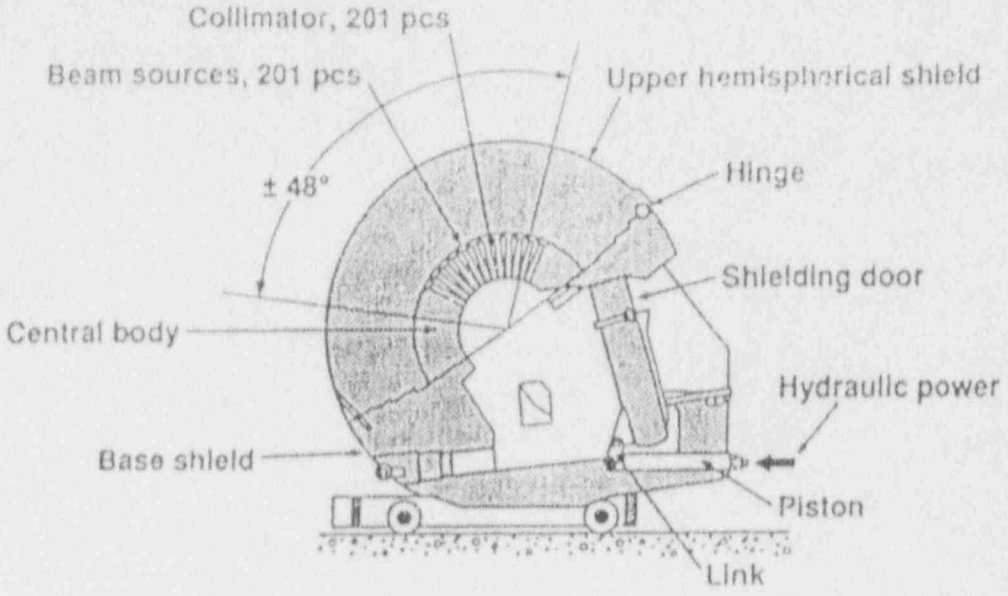


Figure 2-1. Major components of the Gamma Knife
(Adapted from materials supplied by Elekta Instruments)

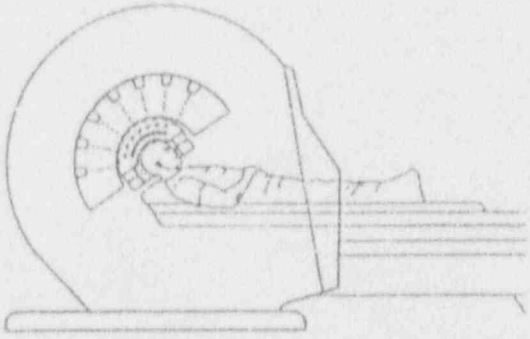


Figure 2-2. Schematic of the Gamma Knife radiation unit (Adapted from materials supplied by Elekta Instruments)

The cumulative radiation from 201 beams results in a concentrated radiation dose at the center of the sphere (with a rapid exponential dose falloff in all directions from the center) while sparing tissue along the 201 individual beam entry paths. In other words, a high level of radiation is delivered in the precise center of the sphere, and a very low dose of radiation is delivered to regions away from the center. The concentrated dose or beam profile occupies a volume in three-dimensional space. Each isodose line, determined as a percentage of the total dose, defines an isodose volume. In a Gamma Knife treatment, the patient's head, held in the stereotactic head frame, is positioned so that the center of an intracranial target volume is at the beam focal point. Ideally, a radiation isodose volume should superimpose on the three-dimensional volume of the intracranial lesion. The total dose delivered to the external contour target volume depends on the activity of the cobalt-60 sources, the isodose line

that conforms to the lesion contour, and the length of time the patient's head remains positioned in the gamma unit.

The patient lays on a treatment table during treatment while the stereotactic frame is attached to a collimating helmet. A hydraulic system controls the opening and closing of the steel shielding door of the radiation unit and the movement of the treatment table in and out of the unit. In the event of a power or hydraulic failure, a reserve hydraulic pressure releases the treatment table so that it exits the radiation unit and closes the shielding door.

A typical Gamma Knife facility or suite consists of a treatment room, hydraulic room, control console, treatment planning area, patient preparation area, medical physics area, a bathroom, and storage. A Gamma Knife suite is a dedicated facility and is designed for Gamma Knife source loadings and treatments only. The gamma unit is isolated in a shielded treatment room with a shielded door interlock system. The room shielding is designed to meet NRC requirements for teletherapy units (Maitz et al 1990). Recommendations in Report 49 of the National Committee on Radiation Protection and Measurements (NCRP 1976) are used as guidelines. Exposure rates are limited to 2 mR/hr in both controlled and non-controlled areas. A maximum workload of two patients per day, five days per week is usually assumed. The control console is usually placed just outside the treatment room door to provide easy access to the hydraulic room. The control console is equipped with a redundant timer as well as treatment control and interrupt push-button switches. A television monitor is connected to cameras within the treatment room and a microphone system for two-way verbal communication with the patient is included.

The typical Gamma Knife medical team consists of a neurosurgeon, radiation oncologist, medical physicist, radiotherapy technician, and a registered nurse. The team is usually a dedicated team, with authorized substitutions when necessary. Some facilities have more than one team.

A generic Gamma Knife treatment path is displayed in Figure 2-3. The treatment procedure is divisible into three major parts: imaging and localization of lesion; treatment planning; and patient positioning and treatment. Stereotactic radiosurgery begins with the patient's head fixed in a Leksell stereotactic frame system. This is applied to the patient, under local anesthesia, via a four pin fixation. Once affixed, the frame remains in place as a reference coordinate system until treatment is completed.

Depending on the type of disease to be treated, various diagnostic imaging techniques can be used for localization. Computed tomography (CT) or magnetic resonance imaging (MRI) are used for tumors. For AVMs, the most common disorder treated with radiosurgery, a set of orthogonal angiographic images of the brain is taken. The stereotactic frame's rectilinear fiducial coordinate system is realized on the images, from which three-dimensional coordinates and magnification factors of the target lesion's position are determined.

Based on the size, shape, and location of the target lesion as seen on the localization images, the coordinates of each proposed radiation shot or isocenter at the target are determined. Multiple shots are often needed to irradiate lesions either too large to cover with a single shot or sufficiently irregular to require a combination of various-sized isocenters. The proposed shots, i.e., the coordinates, collimator sizes, and gamma angles (defined as the angle of the patient's head with respect to the frame), are entered into the computerized treatment planning system that is provided with the gamma unit. The computer system can calculate and display the composite isodose distribution for all three principal axes. In treatment planning, the computer-generated isodose contour plots are superimposed upon the imaging study on which the target volume has been defined, until selected dose contours are aligned with the boundary of the lesion (Flickinger et al 1990, Flickinger et al 1990a, Wu et al 1990). In practice, final shot parameters are selected only after several iterations of proposed treatment plans.

LAWRENCE LIVERMORE NATIONAL LAB

GMSS GAMMA KNIFE PROJECT

REPRESENTATIVE TREATMENT PATH

GK: Gamma Knife
MP: Medical Physicist
NS: Neurosurgeon
RN: Registered Nurse
RO: Radiation Oncologist
RT: Radiotherapy Technician

IMAGING AND LOCALIZATION

TREATMENT PLANNING

PATIENT POSITIONING AND TREATMENT

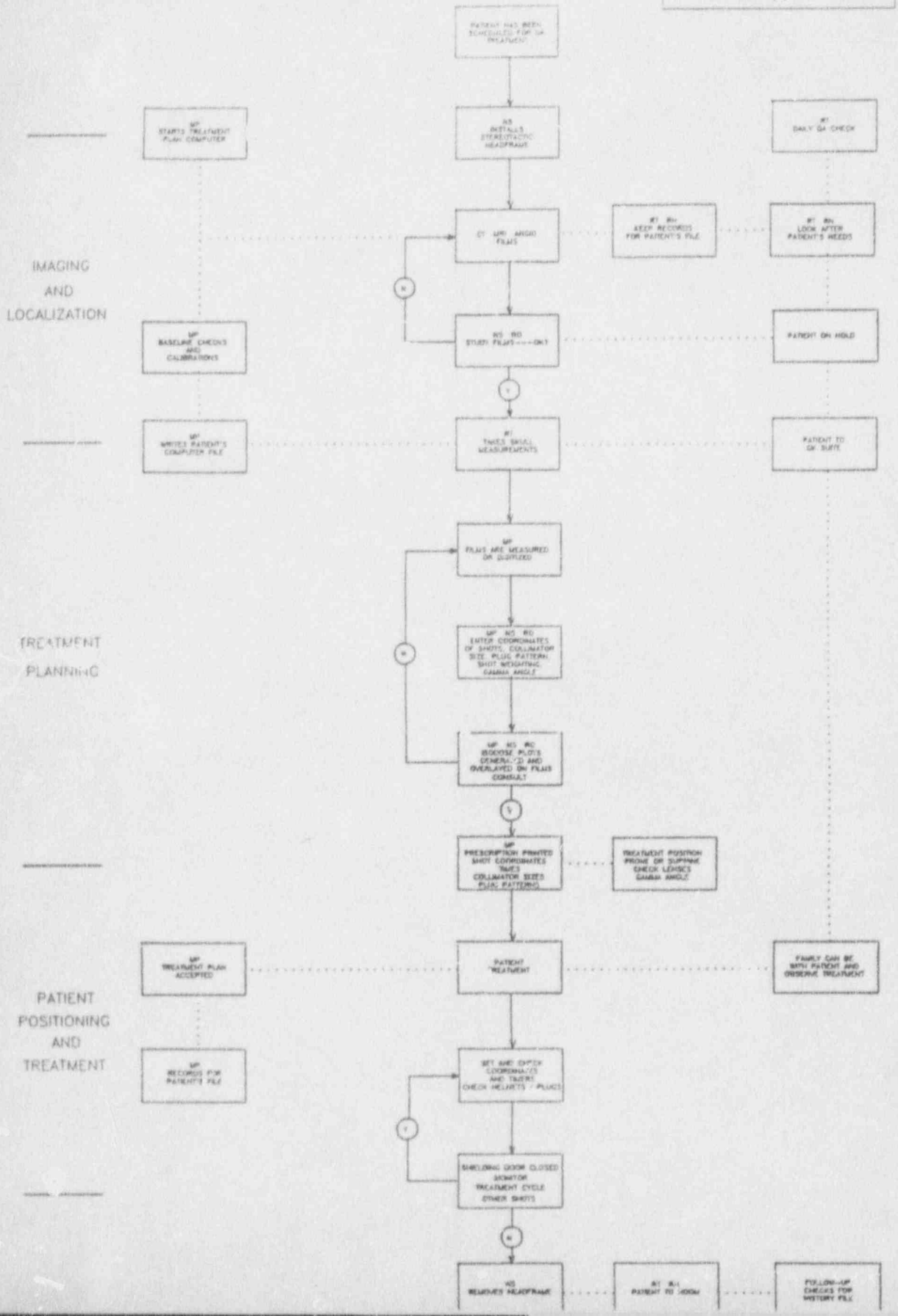


Figure 2-3

An important issue in radiosurgery, beyond determining the dose that is given to the target, is determining the dose that can be tolerated by the brain tissue surrounding the lesion. Given a dose chosen by the physicians for a treatment plan, the computer calculates the time that the target volume must remain in the focal point of the gamma unit in order to deliver the desired amount of radiation.

After all these calculations have been made, the patient is placed in one of four collimator helmets. The choice of collimator helmet depends on the size and configuration of the lesion to be treated. The previously determined stereotactic coordinates are then set on the Leksell frame by means of side bars and a trunnion. These settings are checked by members of the Gamma Knife team.

All personnel leave the patient in the treatment room and engage the door interlock. The treatment procedure begins by setting the timers on the console and pushing a button. The radiation unit shielding door opens as the table holding the patient and external collimator helmet is advanced hydraulically into the unit. When the collimator helmet is aligned with the internal collimator, the radiation treatment commences. After the prescribed amount of time has elapsed, the collimator helmet and the patient are automatically withdrawn from the unit and the shielded door closes. If additional shots are required by the treatment plan, then the coordinates, collimators, and timers are reset, and the treatment process is repeated. All shots are usually given in a single treatment session.

Treatment times can be as short as 5 to 15 minutes in a Gamma Knife with new cobalt-60 sources, but can be much longer in an older unit after the sources have decayed over time.

3. RISK EVALUATION ISSUES

3.1 Introduction

In the past decade, the concepts and methods of risk analysis have seen increasing use in agencies of the Federal Government (NRC 1992). A risk analysis provides a systematic and coherent framework for answering questions about systems and their safety, including what can go wrong, the relative likelihood of undesired events, and the evaluation of consequences. Risk assessments support risk management by producing a logical, integrated, and disciplined technical basis to support decision making. A major issue in the Gamma Knife project was determining which risk analysis approach and methods should be used for a nuclear medical device.

One class of risk assessment methods focuses on engineered systems. This type considers facilities and equipment that can, under certain conditions, pose health risks. A major application area of engineering risk assessment methods, supported by the NRC over the last 20 years, has been in nuclear power plants. However, traditional methods of assessing risk in nuclear power plants may be inappropriate in assessing the use of nuclear medical devices. The approaches used for nuclear reactor risks are equipment-oriented, with only secondary attention being paid to the human component, for the most part after critical system failure events have been identified. However, investigations of medical misadministrations indicate that most treatment errors are human-related.

Another class of risk methods focuses on the health effects of toxic substances introduced into the environment. In 1983, the National Academy of Sciences published what has become known as the *Red Book*, or *Risk Assessment in the Federal Government: Managing the Process*. This approach is used by the Environmental Protection Agency, the Food and Drug Administration, the Consumer Product Safety Commission, and the Occupational Safety and Health Administration (NRC 1992).

There are some significant differences between engineered-system risk assessment and the process promulgated by the *Red Book*. Engineered-system risk assessments explicitly involve the consideration of event frequencies and the probabilities of system failures, which are not included in the *Red Book* process. The health risk assessments assume that systems release toxic materials with certainty, i.e., a

probability of one. Another difference is the types of consequences considered by each approach. The health risk assessment is very specific to toxic materials and thus focuses on cancer fatalities. The engineering risk assessment considers all types of system failures which can also pose health risks, but not necessarily cancer fatalities.

Since the NRC is interested in dangers posed to the patient, practitioner, and public by the *use* of nuclear medical devices, it seemed more appropriate to employ an engineered-system risk analysis approach with a prominent human factor component. In particular, as mentioned in Section 1.1, this project represents an opportunity to begin to evaluate the use of probabilistic risk analysis in regulating nuclear medical devices. PRA explicitly considers the probabilities of system failures and considers a range of possible consequences. So, an appropriate PRA approach needed to be developed for nuclear medical devices like the Gamma Knife.

Before deciding how to analyze risks associated with Gamma Knife treatments, it was necessary to formulate an appropriate quantification of risk, including the measure of consequences associated with treatment failures.

3.2. Characterizing Risk

The adopted definition of risk is crucial to the viability of a risk analysis. The definition must be unambiguous, easy to understand, meaningful, and measurable. The International Commission on Radiological Protection (ICRP) discusses risk in ICRP Publication 60 (ICRP 1990). Before the publication of this document, the ICRP had defined risk as the probability of a harmful effect (mainly lethal cancer and severe hereditary harm). However, outside the field of radiation protection, "risk" has several other meanings, such as the threat of an undesirable event, including the probability and character of the event. The risk of an engineered system is quantified by combining the probability of an event occurrence and the consequences of that occurrence. A common approach is to multiply the probability by the consequence measure, resulting in the expected value of a particular consequence (NRC 1992). In ICRP 60, the concept of risk is expanded to include the definition used by engineering disciplines: the product of the probability that an event occurs and some measure of the potential loss or consequences associated with that event. This is the definition of risk we adopted for the Gamma Knife study.

A problem with this risk definition is that high-probability events with low consequences may have the same risk quantification as low-probability events with high consequences. From a risk management perspective, the high-consequence event may be more important to control, e.g., to mitigate public perception and concerns about risk. Thus, two events of equal risk quantification may be of different risk "significance" when viewed from other perspectives. In using this risk quantification formula, we were mindful to present results in terms of the two components of risk: the probability of an event and its associated consequences.

A standard representation of the two risk components is illustrated in Figure 3-1. Each event quantified in the risk analysis would correspond to a point in this two-dimensional graph. Such a representation can aid the regulatory agency in identifying those events or risks of most concern. For instance, low-consequence events may have a lower priority than high-consequence events, regardless of their respective probabilities. We think the role of risk analysis is to provide information to support regulatory decisions about what range of risks (regions of the risk domain) are acceptable.

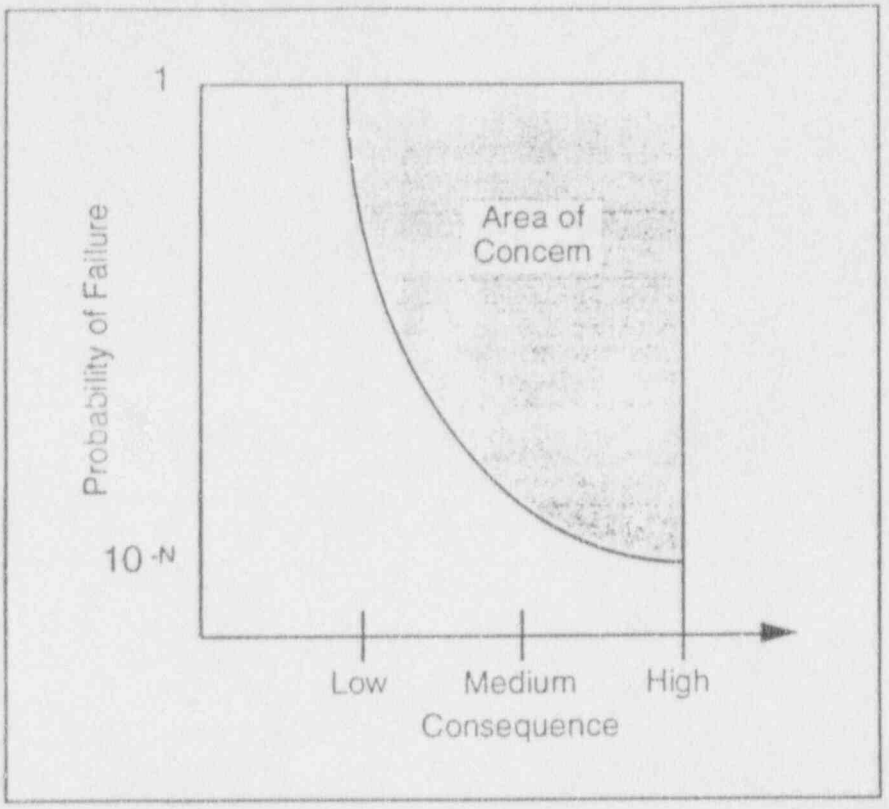


Figure 3-1. Illustration of the risk domain: probability of an event vs. its consequence

3.3. Dealing with Consequence Measures

In performing a risk analysis, it is important to clearly separate the probability of an event from its consequences. A major issue in estimating risk associated with the use of the Gamma Knife concerned the definition and measurement of consequences. For misadministrations, there are two ways of measuring consequences: (1) the biological or medical consequences of a misadministration; and (2) the magnitude of the error associated with an unintentional exposure or unintended deviation from the prescribed dose.

Measures of biological consequences are particularly problematic for the Gamma Knife. Significant statistics on complications are not available, and what data exists is highly conditioned by the type of treatment procedure or patient specifics. The Gamma Knife delivers a focus of intense radiation to a treatment volume. The Gamma Knife is often used for lesions not operable by surgical intervention due to their proximity to sensitive or eloquent areas of the brain. Depending on the location of the target lesion, a misdelivery of dose in one part of the brain may have a nominal effect, while in another area it may be deadly. Therefore, even if there was a good radiobiological model for Gamma Knife treatments, the medical consequences of a misadministration would vary from specific case to case. For these reasons, we abandoned attempts to measure consequences in terms of medical or biological effects.

One consequence measure independent of medical considerations is the difference between the prescribed and delivered total absorbed dose to the target volume or the amount of unintentional radiation exposure to the patient, practitioner, or public. This seemed a reasonable measure to use from a radiation protection perspective, as well as something we felt could be determined from a study of the Gamma Knife.

Measuring consequences in this objective way has additional benefits. It keeps the analysis of mistakes separate from judgments about medical art and practice: the risk issue becomes whether the prescription, as formulated by the physician, is faithfully rendered, rather than whether the patient was harmed. Also, measuring consequences in terms of unintended deviations provides a simple metric for the ranking of consequences. Given such a measure, the NRC can concentrate on ensuring that the frequency and magnitude of unintended deviations are reduced. In the development of the Quality Management (QM) Rule (10 CFR 35.2 and 35.32), this was in fact the basis for the revised misadministration reporting requirements, with the primary focus on the occurrence of a significant error that should be evaluated because of its potential for harm. By setting thresholds below which permanent functional disabilities are unlikely to result, errors can be identified and corrected to avoid harmful consequences.

Based upon these considerations, we decided for risk quantification that the probability of an undesired event would be associated with an unplanned radiation exposure, and the consequence of that event would be the magnitude of the unintended deviation from the patient's prescribed dose or from the expected radiation exposure to practitioners or the public.

3.4. Analyzing Risk

The type of risk analysis used depends on the kind and quality of data available and the methodology employed. Probabilistic risk assessments require component failure data to estimate system failure. The traditional PRA process begins with an initial accident definition and delineates probability and consequence paths that result in risk (Fullwood and Hall 1988). The event tree plays a central role in modeling potential accident sequences that may result following an initiating event. The initiating event may be a combination of system or equipment failures or human errors. The event tree successively displays scenarios of the successes or failures of system safety functions that respond to the initiating event. In most PRAs, the success or failure branching probability at a node in the event tree is determined by either a fault tree analysis of the relevant system or by data from operating experience. A fault tree analysis is a technique to find all credible ways in which a system could fail. The fault tree is a graphic model of the logical interrelationships of all the parallel and sequential combinations of faults that result in a predefined system failure. It is particularly appropriate for hardware systems where the logical interrelationships are fixed and the possible combinations of faults are denumerable.

A human reliability analysis (HRA) is included in a PRA to consider the human as well as the hardware components in identifying and quantifying risk. This is important because human error has been found to be a dominant risk in nuclear power plant operations (Haney et al 1989). An HRA strives to model factors related to human error and performance and to estimate human error probabilities. An important aspect of a HRA is the qualitative assessment of the sources of human error. This may aid in identifying safety and regulatory issues and provides a means for evaluating the risk impact of proposed changes in equipment design, operations, or procedures. HRA techniques are numerous (Haney et al 1989) and continue to be developed.

To analyze risk in the use of the Gamma Knife, we initially proposed an approach that was intended to integrate human performance factors into a traditional nuclear-reactor-like PRA. After consultation with the NRC/NMSS staff, they concluded that this approach was overly focused on methods for nuclear power plant risk analysis. These methods were developed for complex hardware systems designed to operate with a minimum of human interference. They are also predicated on a single defined end state and assume a significant knowledge base (such PRAs require quantitative inputs). These conditions were not applicable for the Gamma Knife. The Gamma Knife is a relatively straightforward hardware system with significant human control. It is also a relatively new system and has little operating experience base or data about component performance. Most information resides in the experience base of the manufacturer and users. Furthermore, preliminary investigations of this experience base indicate that most errors are human-related. Therefore, an analysis methodology must

be used that can model the human interactions and identify those events that can cause undesirable endpoints. With the Gamma Knife, we were challenged is to perform a risk analysis with very little quantitative data but with an important human factor component.

These considerations led to the establishment of general criteria for the development of a risk analysis approach. The methodology should:

- Provide a flexible framework for performing analyses.
- Be able to incorporate both qualitative and quantitative data.
- Consider both human and equipment factors.

The methodology should not be a rule-based methodology but should be a systematic approach to uncovering risk at various levels of resolution for a range of levels of effort. The methodology must also be able to accommodate a variety of medical practices and devices. It thus must be empirically based, and not rely on preconceived notions of system processes. For relatively new devices, most of the operating experience data will be qualitative, i.e., anecdotal, rather than quantitative. Therefore, the risk analysis must not rely only on quantitative data in order to be useful; it should be able to compare a range of data types and data quality. In the methodology, there must be equanimity between human and equipment factors: the method cannot be simply machine- or human-centered in its orientation. A notion of this project was that risk analysis could be used to improve radiation safety by discovering ways to lower risks. This goal can be accomplished without absolute measures of risk (which, after all, are very difficult and costly to ascertain): only relative improvements in apparent risks are needed. Hence, the methodology would be useful if it at least used relative measures of risk.

After considering other potential risk analysis methodologies, it was decided that the above criteria could best be met by the approach of developing relative rankings of risk or risk profiles. Profile analysis is a general analytic tool which has been employed since the late 1940s. In the last decade, profile analytic techniques have been applied to the evaluation of both machine failures and human errors in nuclear facilities (Seaver and Stillwell 1983, Banks and Paramore 1983, Comer et al 1984, Banks 1984). Relative rankings are particularly amenable to expert estimation techniques. We anticipated that relative risk rankings and profiles could readily incorporate the type and quality of data available about the Gamma Knife and could present results in an easily understood form.

3.5. Quality Assurance and Peer Review

A major objective in this work was to enlist the cooperation and participation of the manufacturer and members of the medical community. These efforts were very successful and resulted in active participation in the project from its inception by the regulated community.

The manufacturer, Elekta Instruments, made presentations on technical aspects of their device, and provided opportunities for the quality assurance and risk assessment experts to examine the Gamma Knife and its operation. Facility visits were arranged to observe patient treatments and interview medical practitioners. A multi-disciplinary team of physicians and medical physicists with expertise in teletherapy, risk assessment experts, and scientists and engineers with extensive knowledge of task and safety analyses inspected Gamma Knife units, attended acceptance tests, interviewed users, and observed patient treatments. Data and information gathered were reviewed for accuracy, completeness, and self-consistency by the use of subject matter experts, simulations, facility walk-throughs, and the observation of actual practices.

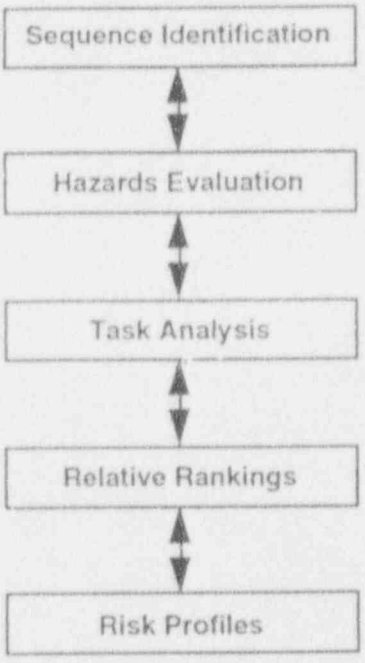
Members of the medical community provided data, review, and comment to the project team. Data analyzed by the project team was subsequently reviewed, critiqued, and validated by medical community expert peer review teams. This up-front participation by the manufacturer and the medical community helped the project gain acceptance both within and without the NRC.

4. RISK ASSESSMENT METHODOLOGY

4.1. Overview of Methodology

As discussed in section 3.4, the risk approach used was motivated by a need to have a flexible analysis framework that could incorporate both qualitative and quantitative data about human and equipment factors, and would support attempts to increase radiation safety. We felt these criteria could be met by the approach of developing relative rankings of risks or risk profiles.

The risk assessment methodology adopted (Banks and Jones 1992, Banks et al 1992) is an empirically based, systematic approach to uncovering potential risks. It consisted of a tightly coupled set of activities. A heuristic representation of these activities is:



The double directional lines between activity elements indicate that information was iterated among all elements of the analysis.

The first three activity elements represent the deterministic processes we went through to really learn about the Gamma Knife and its use. At the beginning of this project we knew virtually nothing about the Gamma Knife or stereotactic radiosurgery. A multi-discipline team of physicians and medical physicists with expertise in teletherapy, risk assessment experts, and scientists and engineers with extensive knowledge of task and safety analyses was organized. We were fortunate that the manufacturer of the Gamma Knife, Elekta Instruments, was very cooperative in this project. Elekta encouraged us to learn about the Gamma Knife in a rational and systematic way and offered their support in formulating a plan to acquire the information needed to perform a risk analysis.

The plan started with background research on the Gamma Knife using documents and user manuals provided by Elekta, as well as results of literature searches. Also, Elekta made presentations to LLNL and NRC personnel on the design and use of the Gamma Knife, its manufacturing process, and the loading of the cobalt-60 sources. This research provided a sound theoretical understanding of how the Gamma Knife systems work; potential hazards or safety concerns; quality assurance, maintenance, and emergency procedures; and tasks in the treatment process. At this point, we were quite ready to examine a Gamma Knife.

Elekta Instruments arranged a two-day site visit to a Gamma Knife facility. The facility was not in use the first day, and the Gamma Knife's lead design engineer and the facility's medical physicist were present. This afforded an opportunity to inspect the Gamma Knife and ask questions. We became familiar with the facility and operation of the Gamma Knife. A mock acceptance test procedure and routine calibrations and checks were performed, and the medical physicist also walked through the treatment procedure, noting all the checks he performs to ensure accuracy in the treatment. This experience helped to refine our understanding of what system sequences were pertinent to potential risks, the relative importance of hazards, and the risk-pertinent tasks in the treatment procedure. The second day we observed a Gamma Knife patient treatment, from imaging and lesion localization, to treatment planning, and patient positioning and treatment. This permitted a verification and validation of what we had learned the day before.

During the course of this project, we visited and observed patient treatments at about half of the then-existing Gamma Knife facilities (new facilities are steadily being established). At all facilities, the personnel were very helpful, especially when they appreciated we were trying to find ways to mitigate risk and not inspect the users. On these site visits we were able to further refine our sequence identifications, hazards evaluations, and task analysis, as well as collect data on human error rates and error magnitudes. We also observed the cobalt-60 loading procedure at a new Gamma Knife site and visited the Gamma Knife manufacturing facility.

Near the start of this project, the University of California at San Francisco (UCSF) Medical Center, a sister organization to LLNL only 40 miles away, acquired a Gamma Knife. Thus, there was nearby Gamma Knife on which to perform further investigations, and we could share in UCSF's learning experience with the use of the Gamma Knife.

The Gamma Knife community is small and networks very well. We were able to establish good relationships with individuals in this network which allowed us to collect anecdotal and experiential information, learn about unusual events, and have any questions answered.

The iterative sequence identification, hazards evaluation, and task analysis activities in the risk analysis approach served to identify elements most likely to contribute to risk. The error data collection and expert experience base provided, via a ranking and profiling process, the probable relative risk importance of each of the identified risk contributors. The ranking and profiling process also caused us to reconsider some of the judgments about the elements most likely to contribute to risk. Hence, all elements of the analysis were iterated and reconciled. In this way the total analysis was thorough, balanced, and internally consistent.

4.2. Identifying Risk Elements

4.2.1. Sequence Identification and Hazards Evaluation

As noted above, we started with very little knowledge of the Gamma Knife, its use, and its operation. The challenge was to sufficiently understand the Gamma Knife as a nuclear medical device to identify those aspects pertinent to radiation risks.

The first step was to apprehend how the Gamma Knife operates and the hazards associated with its operation. The objective was to select a set of system processes or operational event sequences to be included in the risk analysis. This required familiarity with the Gamma Knife system, its operational requirements and functions, and the role of the human. We had an understanding of radiation safety issues from a previous study of documents from standard-setting organizations, including the American National Standards Institute (ANSI), Food and Drug Administration (FDA), American College of Radiology (ACR), American Association of Physicists in Medicine (AAPM), Hospital Physicists Association (HPA), National Council on Radiation Protection and Measurement (NCRP), International

Commission on Radiological Protection (ICRP), Institute of Physical Sciences in Medicine (IPSM), International Atomic Energy Agency (IAEA), American Society of Therapy, Radiology, and Oncology (ASTRO), National Institute of Standards and Technology (NIST), and the International Electrotechnical Commission (IEC). Documents from these organizations had precious little, if anything, to say directly about the Gamma Knife. However, many of the issues addressed were relevant to our study.

Since we had no preconceived notions about the Gamma Knife, we began by looking at all aspects of the device and its use. We analyzed materials obtained from literature searches and materials provided by the manufacturer, including user manuals and blueprints. We were looking to identify elements pertinent to radiation safety or risk. The user manuals and literature searches were particularly helpful; they contained descriptions of the Gamma Knife components, cautionary notes with regard to safety and maintenance, and step-by-step descriptions of how to operate the Gamma Knife and perform treatments. While most of the published literature on the Gamma Knife concerns medical issues, there were several excellent articles on radiation safety, quality assurance, and calibration issues

Our preliminary list of processes or sequences pertinent to risk issues associated with the Gamma Knife were:

- Device functional and acceptance tests,
- Quality assurance procedures for gamma unit physics,
- Dosimetry and safety measures,
- Pre-therapy performance checkouts,
- Patient treatment path, including imaging and localization, treatment planning, and patient positioning and treatment,
- Abnormal events during gamma unit operation,
- Emergency procedures, and
- Maintenance and servicing.

The pertinence of this list of elements was, for the most part, borne out by our subsequent familiarization with the Gamma Knife, visits to facilities and the manufacturer, and discussions with users. However, the identified sequences or events were distilled and refined with experience. In particular, how the functional and acceptance tests and the maintenance and servicing was performed were dropped from consideration. The manufacturer does not ship the Gamma Knife unless all manufacturing functional tests are satisfied. When the Gamma Knife is installed, functional and acceptance tests are performed by the manufacturer, and the device is not transferred to the buyer unless it is working perfectly. Thus, any faults uncovered by these tests would only show up as abnormal operating events, and such events already were being considered in our study. Similarly, how the maintenance and servicing is performed was not as risk-pertinent as the identification of abnormal operating events due to faulty maintenance. The relationships among the quality assurance, calibrations, performance checks, and the treatment path are illustrated in Figure 2-3.

In order to clarify those processes or sequence elements that are relevant to risk, it was important to identify hazards associated with the Gamma Knife. In the process of familiarizing ourselves with the gamma unit, we came to perceive the hazards as associated with a machine system that uses hydraulic and electrical components to control its mechanical movement intended to expose an affixed patient to focused beams of gamma radiation. The familiarization process included the study of blueprints, facility walk-throughs, interviews of and demonstrations by the Elekta maintenance and servicing personnel, and discussions with users. We were particularly interested in those hazards that could lead to radiation exposure accidents.

The types of hazards we considered for the Gamma Knife included:

- Ionizing radiation to the patient during the treatment cycle, the practitioner during normal operating and emergency conditions, and the public,
- Hydraulic pressure in containers and components under rapid pressure changes,
- Electrical inadvertent activation and de-activation and electrical component and power source failures,
- Mechanical movements of the gamma unit.

The identifications of risk-pertinent sequences and hazards were really a dual exercise, carried out in tandem. We would identify a sequence of events and then consider if there were any hazards associated with those activities. Or we would recognize a hazard and try to identify all those activities with which it may be associated. This iterative process served to enhance and refine our analysis. Our analysis was continually focused by the objective of finding the elements most likely to contribute to the risk of an unplanned radiation exposure. The products of these efforts resulted in systems data on:

- Important quality assurance elements and their tolerances,
- Potential abnormal gamma unit events or failure modes,
- Preliminary task information for treatment paths.

Some of the more important quality assurance elements and their tolerances are listed in Table 4-1. The quality assurance elements are designed to check the dosimetry and physics parameters that affect the accuracy of dose delivery or to maintain safety and compliance with 10 CFR Part 35. The tolerances associated with these elements were based on documented and anecdotal information from Gamma Knife facilities. Every facility we visited had good records on the quality assurance activities and calibration data. The tolerances varied slightly among facilities depending on who performed the checks and what methods were used. The data could have been tabulated and continually updated in such a way as to provide a basis for statistical quality control of the dosimetry and physics parameters. However, only a few facilities had committed the manpower to such an effort. The facility-determined tolerances established for us the minimum standard of variation or uncertainty that could be reasonably achieved. This kind of data is important for regulators to understand, so as not to have unrealistic expectations of the regulated.

Table 4-1. Gamma Knife Quality Assurance Tolerances

QA Element	Frequency	Tolerance
Timer accuracy	Monthly	≤2sec
Timer linearity	Monthly	≤2%; Correl.=0.999
On-off error	Monthly	- (0.03 - 0.05) min.
Radiation output	Monthly	≤ 2%
Anticipated output vs. measured	Monthly	≤ (2 - 3)%
Computer output vs. measured	Monthly	≤ (2 - 4)%
Dose profiles	Annual	±1 mm on 50% line
Radiation/mechanical isocenter coincidence	Annual	± (0.3 - 0.4) mm
Trunnion centricity	Monthly	± (0.2 - 0.5) mm
Collimator factors	Annual	≤ (2 - 5) %
Helmet microswitch test	Monthly	± 0.1 mm of trip point
Couch movement time	Monthly	± 10 sec. from initial calibration
Radiation monitors	Daily	≤ 10% of annual calibration
Door interlock	Daily	≤ 0.5 cm of trip position
Leak tests	Semi-annual	< 0.005 μCi

Some of the more important abnormal events or failure modes associated either with the operation of the gamma unit itself or with facility systems and functions are listed below:

Shielding door fails to close fully
Treatment table halts in transit
Helmet microswitches malfunction
Treatment intervention by personnel
Emergency procedures invoked
Door interlock interrupted while shielding door still open
Door interlock fails
Counters/timers fail
Motion safety timers fail
Status lights fail
Console operating buttons fail
Inadvertent activation of operating modes
Audio/visual communication failures
Radiation monitors inaccurate/inoperable
Emergency stops not operable
Emergency release rod fails to work
Personnel cannot pull out treatment table in an emergency
Electrical component failures
Emergency power not available
No emergency lights or monitors
Hydraulic component failures
Hydraulic fluid depressurization

These events were selected because they could lead to undesired radiation exposures of either patients, personnel, or the public. We determined the events by asking Elekta personnel and Gamma Knife users what sort of events had occurred in the past or what events they were concerned about happening in the future. Also, we proposed several event scenarios, based on the project team's investigations, that we thought were possible and verified these via discussions with the manufacturer and users. It was decided early in the study, in consultation with NRC staff, not to consider external events except power outages.

A primary concern in our risk study was the possibility of the patient's head being unnecessarily exposed to radiation inside the radiation unit during an abnormal operating event. The overriding design principle of the Gamma Knife is that the patient cannot be in the treatment position unless the unit is operating properly. To achieve this, the hydraulic system pushes the treatment table or couch up a literal hill into the treatment position. (The tracks that constrain the motion of the couch are curved upwards inside the radiation unit.) This motion is monitored by switches and safety timers. The patient only receives background radiation until the external collimator helmet, to which the patient is affixed, properly aligns with the primary collimator for the 201 cobalt-60 sources. Helmet microswitches ensure the proper alignment. If all motion safety checks are not satisfied, the hydraulic pressure pushing on the couch is released and it is automatically pulled by hydraulic pressure out of the radiation unit.

As part of our risk identification effort, we wondered what would happen if a hydraulic unit failure occurred during a treatment (Smith et al 1993). In this event the helmet and the patient would drop

from the highest position, where the helmet is mated with the primary collimator, and would probably stop at the low point of the track that constrains the motion of the couch. The assumption is that staff members would then have to enter the room and remove the patient from the machine. Under these circumstances it might take up to two minutes to remove the patient, and so it is important to determine whether irradiation of the patient might occur in this non-standard situation. A potentially worse situation would be if the couch got stuck between the low and high points of the track inside the radiation unit. (This could only happen if the couch got mechanically stuck, for example, by a "freezing" of the hydraulic system or some mechanical obstruction such as a tool or pillow that was not properly removed.)

To check for extraneous radiation fields that may affect patients during a system failure or abnormal operating mode, we performed several measurements. First, the radiation levels were checked at the intended treatment target as a function of patient positioning during a normal treatment cycle. The levels were checked with an ion chamber centered within a phantom, i.e., located at the intended treatment target position. A film was then placed in the center of a helmet to record any off-target foci of radiation. With this film in place, a treatment cycle was carried out, but it was interrupted by a simulated hydraulic unit failure. When the film was developed it showed the expected treatment focus but also a much fainter focus off-target that no one could readily explain.

Further measurements were made (Smith et al 1993) to elucidate the nature of this anomalous radiation hot spot outside the normal irradiation volume. Two kinds of radiation hot spots were discovered to which a patient would be subject while in between the shielding door and the treatment position, but not while in the treatment position. One hot spot (approximately 8–10% of maximum dose rate) was due to transmission of the primary beams through the stainless steel of the collimating helmet. The primary collimator produces an irradiation volume at the focus of the primary collimator holes, regardless of where the helmet is located and regardless of which secondary collimator diameter helmet is in place. Thus, this focus passes through a patient's head, in an off-target position, during transport of the patient within the radiation unit. Other smaller hot spots (approximately 1–2% of maximum) were due to inadvertent, non-attenuated transmission through misaligned collimators. These effects disappeared at the treatment position, because the tungsten collimators were aligned and they prevented transmission of the primary beams. (However, there is leakage from the collimators on the order of 0.3–0.4% of maximum dose (Wu et al 1990).)

After these determinations, Rhode Island Hospital carefully checked for radiation hot spots (with the shielding door open) outside of the radiation unit. They found a collimated beam coming out of each side of the open shielding door due to a systemic design flaw. The radiation outside of the shielding door was therefore not purely scattered radiation. (This problem has now been successfully corrected at all U.S. Gamma Knife facilities.)

We realized early in the project that a very important set of activities, with respect to risk to the patient, were those associated with the treatment path. Mistakes in imaging and localization, treatment planning, or patient positioning and treatment could cause a misadministration. Using our usual tools—documents, site visits, manufacturer's and users' experiences, and observing patient treatments—we tried to identify those tasks within the treatment path most likely to contribute to patient risk. Invariably, we found potential errors to be human-initiated.

Our sequence identification and hazards evaluation activities resulted in a preliminary risk-pertinent task list of about 100 tasks. The analyses of these tasks were enhanced and refined over time as we collected error data and began the ranking processes. As discussed below, we eventually ended with 23 primary risk-pertinent tasks and 56 subtasks, for a total of 79 tasks.

4.2.2. Empirical Event/Task Analysis

The products of the sequence identifications and hazard analyzes were risk-pertinent quality assurance activities, abnormal operating events, and a preliminary list of tasks in which human errors could occur. These events were adjudged to be the most likely contributors to risk. Before we could quantify the relative importance of these risk contributors, we needed to formally collect more information and data about the tasks, the frequency of abnormal events or errors, and consequences.

In the scope of this study, we were not able to perform a traditional task analysis of the Gamma Knife treatment path. Instead, we adopted an empirical and pragmatic approach of selecting only those tasks that were judged to be the most pertinent activities affecting risk associated with the use of the Gamma Knife. Such judgments were based on ascertaining where errors most relevant to risk can or *do* occur and not on *why* the errors occur. This was accomplished by a several means. A dual approach was to postulate that an error occurs and then examine the consequences of that error, or postulate that a misdelivery of dose happens and then examine the errors that would have to have occurred for that consequence. We asked the manufacturer and users to tell us what errors they had experienced, and we asked a lot of "what if" questions of them. We also observed actual treatment processes, from a human factors perspective, to witness errors that did or could occur. Each task was defined in the usual way of having a specific purpose, an input, and a human action. We tried to identify tasks that had a well-defined human error and a measurable consequence associated with that error.

As noted above, our preliminary investigations resulted in about 100 tasks associated with the treatment path. To further analyze and refine this empirical task list, we formally collected data for each of these tasks. The types of data collected are as follows:

Task ID number
Task description/purpose
Dependency on other tasks
Task frequency (number of times per patient)
Performance standards
Support equipment
Training/knowledge required
Ways to reduce errors/risk.

These types were selected to not only to help us clarify the role of each task, but also to provide a basis for establishing the effectiveness of error mitigation measures. As an expert task analyst will observe, this list is not as comprehensive as would be required for a traditional task analysis.

Note that the equipment or machine factors are not ignored by this human-based task analysis. Rather, the human-initiated actions are used to highlight those equipment factors that are most relevant to preventing failures. Once these identifications are made, techniques appropriate to estimating risks associated with equipment failures may be applied. In this way, equipment or engineering risk analysis is contextually focused and hence economically efficient.

The data was formally collected using three complementary methods: individual interviews, both structured and unstructured group interviews, and the observation of patient treatments. The task analysis data were verified by the use of subject matter experts, simulations, and facility walk-throughs. The information was also reviewed and reconciled, as needed, by an expert review team consisting of physicians and medical physicists familiar with the Gamma Knife, representatives of the manufacturer, NRC staff, and human factors experts. The members of this team were selected on the basis of their expertise as well as their familiarity with the nature of this project.

Based on the formal task data collection the task list was modified. Some tasks were eliminated, others were combined, and some were redefined. Another iteration of task modifications occurred after the analysis of error frequency and consequence data for the tasks (see below). The primary tasks finally used in the relative risk rankings are listed in Table 4-2. The non-sequential numbers of the primary tasks are an artifact of the task list modifications; we maintained the original task IDs so as not to confuse list versions. There are a total of 55 subtasks associated with these primary tasks, an average of over two subtasks for each primary task. Each of these subtasks corresponds to a specific activity in which a human error can occur, but does not necessarily detail why an error occurs. Some subtask errors are as simple as not performing an independent check. Others, for instance task 2.9.1, are more subtle and numerous. In task 2.9.1, Geometric determinations from films, subtask errors include an incorrect determination of the magnification factor, the axial coordinate (z) factor, misreading film markings, and confusing or reversing the orientation of films.

4.3 Evaluating Risk Contributors

In order to quantify the relative importance of the risk contributors, the project team needed to measure the frequency of errors or abnormal events and their consequences (see Section 3.2). There was little hope of determining absolute values, given the limited operating experience with the Gamma Knife and the absence of any reported misadministrations. Also, the project scope did not permit the massive research required to determine human error probabilities associated with the use of the Gamma Knife. However, as discussed in Section 3.4, relative risk evaluations would be adequate for identifying safety issues and prioritizing the allocation of resources to reduce risk.

Once we had an understanding of the undesired events, we began to ask users how often they experienced these events, i.e., what were the event frequencies. Initially, we provided no metric, because we wanted their answers to help us establish a metric for more formal solicitations later. The responses were remarkably uniform. Almost everyone reported their frequency estimates in terms of one event per a number of patients, e.g., error "a" occurs once every 20 patients, while error "b" occurs once every 500 patients. We collected preliminary information from a subset of users to determine the range or scale of frequency estimates. This data is illustrated in Figure 4-1. The reported error rates tended to clump into five different bins, regardless of which facility provided the data. We attributed this consistency to uniformity in the use of the Gamma Knife. All sites were constrained to use the same treatment procedures and most people had the same training. This uniformity among sites may change as Gamma Knives proliferate and the manufacturer loses some oversight control.

Table 4-2. Primary Tasks in the Gamma Knife Treatment Path

1.1	Identify correct patient (also used for 2.1 and 3.2)
Imaging and Localization:	
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 CT, MR films
Treatment Planning:	
2.3	Check treatment planning equipment
2.6	Take skull measurements
2.7	Enter skull data into computer
2.8	Enter gamma angle
2.9.1	Geometric determinations from films
2.12	Select calculation mode
2.14	Determine isocenter coordinates
2.15	Enter shot parameters
2.17	Plot isodose curves
2.18	Overlay isodose plots
2.19	Enter prescribed dose
2.21	Produce prescription
Patient Positioning and Treatment:	
3.3	Choose collimating helmet
3.4	Set plug pattern
3.5	Set isocenter coordinates and gamma angle
3.6	Perform final checks
3.8	Set treatment time
3.9	Monitor treatment
3.11	Check isocenter settings after treatment

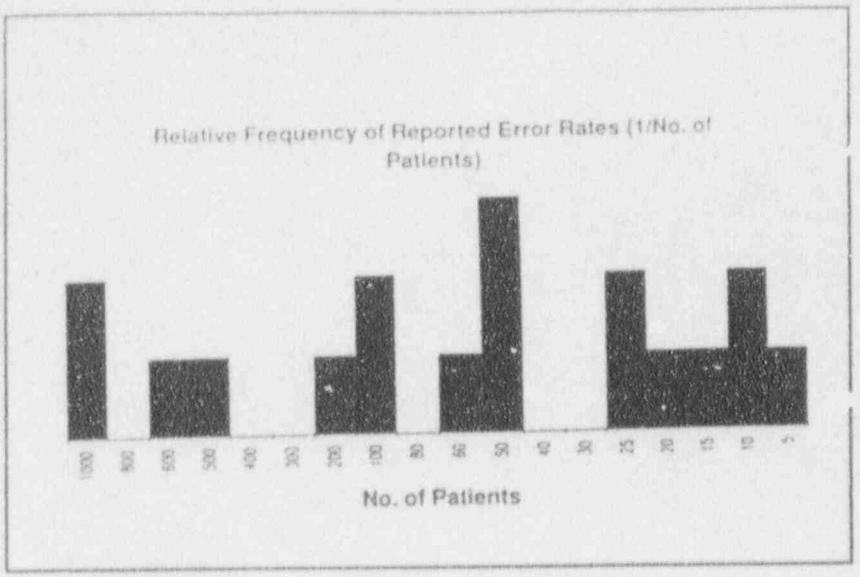


Figure 4-1. Reported Error Rates

Based on the data represented in Fig. 4-1, we established the following template or metric for estimating error likelihoods:

1. 1 in more than a 1000 patients
2. 1 in 500–700 patients
3. 1 in 100–300 patients
4. 1 in 50–60 patients
5. 1 in 10–25 patients
6. Specify other rate

To establish a similar scale for consequences, we elicited information from a subset of users and performed some deterministic analyses. Consequence is measured in terms of the magnitude of the unintended deviation from the expected radiation exposure. Users were asked if a certain event occurred how large of an unintended radiation exposure would result. Given, our understanding of the Gamma Knife, we were able to determine some of these answers ourselves.

Unplanned personnel exposures due to abnormal operating events depend on the position of the personnel relative to the cobalt-60 sources, the shielding between personnel and the sources, and the time of exposure. We knew the distribution of radiation within the Gamma Knife suite with and without the radiation shielding door being closed. We also had estimates of how long the emergency procedures should take. Thus, we could establish a range of potential personnel overexposures expressed as a percentage of the suite's normal background radiation.

The determination of unintended dose to the patient given an error in the treatment path was more problematical, because the absorbed dose depends on the absolute dose (the dose rate of the gamma radiation multiplied by the time of exposure) and on the volume of brain tissue receiving the radiation. Depending on the nature of the error in the treatment path, it can translate into absolute dose or treatment position/volume errors in the patient. Thus, the *kind* of error needs to be specified along with how large the error is in terms of affecting the value of the absolute dose or volume treated. Assuming a

certain error, we could analyze how the error would propagate through the Gamma Knife system and result in either an unintended deviation in absolute dose or treatment volume. Based on such deterministic studies and expert elicitations, the following template for estimating error magnitudes was established:

> The error under consideration will most likely lead to an error in
>
> ___Dose
>
> ___Treatment position/volume
>
> The most likely magnitudes of the error are:
>
> 1. 0 to 2%
> 2. >2 to 5%
> 3. >5 to 10%
> 4. >10 to 20%
> 5. > 20%
> 6. Specify other

This metric is not the end of the consequence measure problem. The magnitudes of dose and position/volume errors may not be rationally compared, if dose and volume effects are independent. But dose and volume radiological responses appear to obey power law relationships for volume elements in radiosurgical treatments (Flickinger 1989). By taking the logarithmic derivative of Flickinger's integrated logistic formula, we derived a linear, weighted relationship between fractional changes in dose and fractional changes in volume (assuming the average Gamma Knife treatment is 36–38 Gy):

$$M = (1.5)\Delta D/D + \Delta V/V.$$

This means that the consequences of dose errors should be weighted by a factor of 1.5 relative to the consequences of volume errors.

Since we were only interested in relative measures of consequence, we used this weighting scheme to quantify consequence magnitudes associated with dose and position/volume errors. For instance, if the magnitude of a volume error was 5%, we gave it a consequence measure of 0.05. But, if the magnitude of a dose error was 5%, we gave it a consequence measure of 0.075.

Once we had these templates for estimating event likelihoods and consequences, we used them to formally collect data on our previously identified risk-pertinent events. The data were acquired by essentially the same methods used in the empirical task analysis: expert estimations based on the templates were elicited in individual and group interviews, and these estimations were checked by observing patient treatments. Studies (Comer et al 1983, Comer et al 1984) have provided encouraging support for the use of expert judgment. Experts are good at making relative estimates on limited scales. Their relative estimates are also reproducible. The Gamma Knife experts were asked to make their estimates based on their actual experience. At the level of analysis of this project, the issue was not how or why errors occurred but how often they occurred and what was their magnitude. During patient

treatments, we observed that, in general, error rates were higher than people had reported. However, the relative error rates seemed to be consistent with what we were told. This was fine, since we could only estimate relative values.

Data from several sources were assimilated by the project team into discrete distributions for each event, such as those represented in Figure 4-2. For each event or potential error, there was a discrete distribution for the likelihood of occurrence of the error and a discrete distribution for the magnitude of the error. For example, consider the error likelihood distribution histogram in Figure 4-2. A column is associated with each of the five error likelihood estimates delineated in the error likelihood template described above. The height of each column represents the percentage of experts sampled who selected that error likelihood as the most appropriate. If no expert thought a particular template value was likely, then the column height above that value is zero and does not appear. Thus, speaking heuristically, the "width" of the distribution reflects uncertainty in the experts' estimations. If the error likelihood was certain, 100% of the experts would agree, and there would be only one column in the discrete distribution.

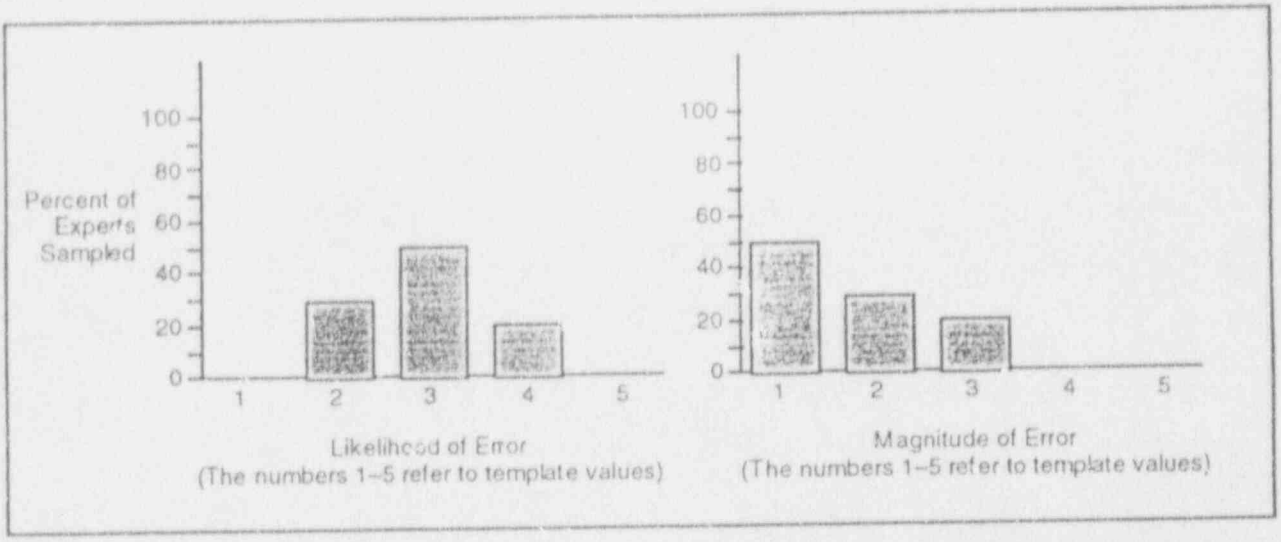


Figure 4-2. Representative Error Distributions for Each Task

All the data on event likelihoods and consequences were reviewed and reconciled by an expert review team consisting of physicians and medical physicists familiar with the Gamma Knife, representatives of the manufacturer, NRC staff, and human factors experts. The members of this team were selected on the basis of their expertise as well as their familiarity with the nature of this project. Members of the team received all data to be reviewed two weeks prior to meeting. Together for an intensive two days, the review team systematically went through the data and discussed, critiqued, and rationalized the data. As described below, the data can be formulated into relative risk profiles. The expert team also used preliminary versions of these profiles to critique the data and ensure its consistency. The results of this expert review were subsequently shared with selected individuals in the Gamma Knife community to provide quality assurance on the expert review team.

4.4. Relative Rankings and Risk Profiles

Once the project team had identified the risk-pertinent events and quantified their likelihoods and consequences, it was necessary to rank the risks against one another to determine the relative importance of the risk contributors. We had three basic kinds of risk contributors: quality assurance

activities, abnormal operating events, and treatment path task errors. To perform a first-order comparison of their risks, we utilized a qualitative, relative ranking scheme for both likelihood of an event's occurrence and its consequences.

To exemplify this first order analysis, consider the situation of the extraneous radiation hot spots discussed in Section 4.2.1. It was imperative to estimate the risks of these hot spots and compare them to the risks to the patient and practitioners under normal treatment exposures. We considered four conditions corresponding to (1) the patient's head stopped in the off-target hot spots; (2) the patient stuck in the treatment position; (3) emergency personnel exposed during extraction of a patient with the shielding door open; and (4) characteristic treatment errors associated with a normal gamma unit operation.

To aid in the evaluation of consequences to the patient and emergency personnel, a chart was derived showing the amount of effective dose received over time by a whole body external to the radiation unit, or by a brain tissue element inside the radiation unit, given the dose rates of both the internal and external radiation hot spots (see Figure 4-3). The whole-body exposure should remain below 5 rem to avoid any clinical or stochastic effects, and the brain should not receive more than 600 rem to avoid any indications of damage (NCRP 1991). Thus, based on the graph in Figure 4-3, there are up to 15 minutes to extricate the patient from a stuck position to remain below these radiation safety thresholds. The Gamma Knife emergency procedures should only take 2–5 minutes, so the consequences to the patient and personnel are small during an abnormal operating event.

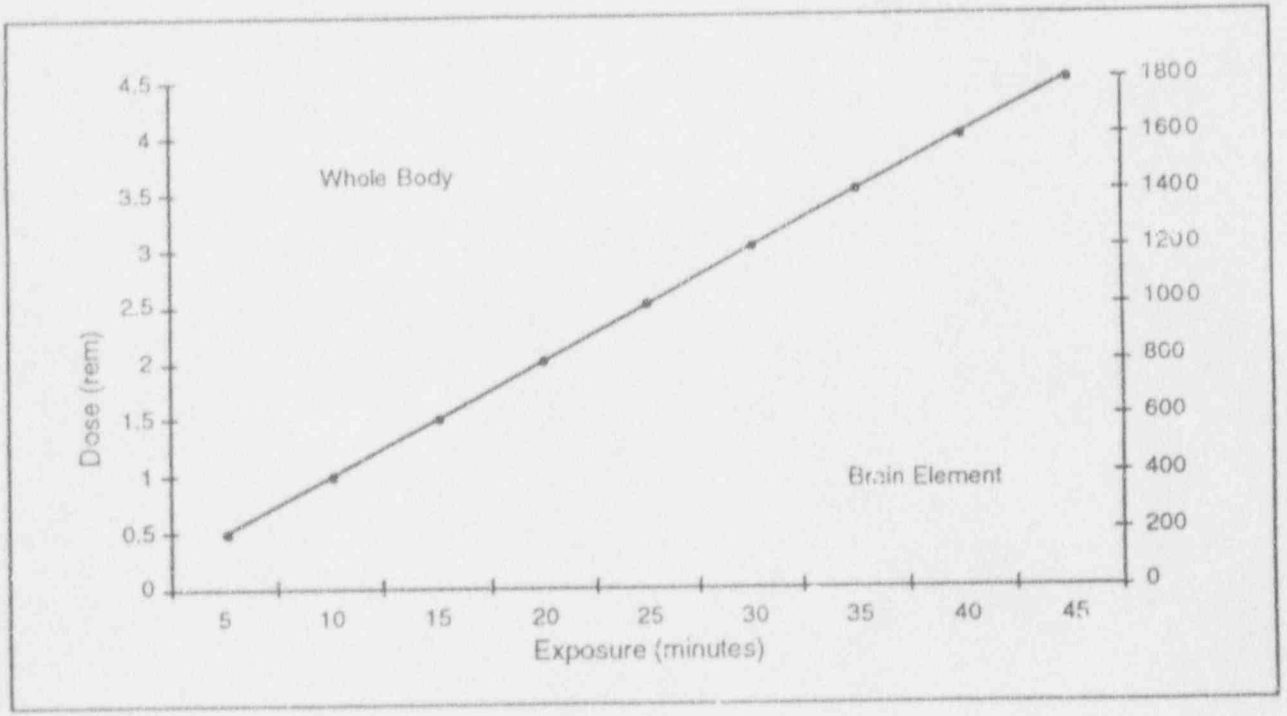


Figure 4-3. Dose Consequence as a Function of Exposure Time for Gamma Knife Hot Spots

Based on a review of the risk quantification data (see Section 4.3) associated with events or tasks pertinent to each condition, we assigned a relative rating to each condition's likelihood of occurrence and consequences. The relative rating scheme had five values: (1) very low; (2) low; (3) medium; (4)

high; and (5) very high. The product of the likelihood and consequence ratings provided values to rank the risks of the four conditions:

Condition	Likelihood	Consequences	Ranking
Characteristic errors in normal treatment	3–4	2–3	6–12
Patient stuck in treatment position	1	4–5	4–5
Patient's head in off-target hot spot	1	2–3	2–3
Emergency personnel exposure	1–?	1–2	1–4

The conclusion drawn from this analysis is that the Gamma Knife is relatively more risky when it operates properly than when it does not. This seems counter-intuitive from an engineering perspective—in which a system usually is safest when operating properly. For the Gamma Knife, it is extremely difficult for the patient to be in the treatment position unless the unit is operating properly. Thus, the probability of being stuck in the treatment position is extremely low. On the other hand, in the treatment position the patient is subject to intense radiation from any errors made in the imaging and localization, treatment planning, patient positioning, and treatment administration processes. An analogy would be the risk associated with a cardiovascular surgeon's scalpel. If the surgeon drops the scalpel on the floor, it is no danger to the patient. It is only dangerous when used in an eloquent area.

The results of this example analysis are indicative of the general conclusions from our first-order comparison of risks among quality assurance activities, abnormal operating events, and treatment tasks. The risks associated with quality assurance and calibration activities are relatively low because errors in these activities are rare and the magnitudes of any errors are small. The tolerances for these activities are well known and understood by the Gamma Knife personnel, and any deviation from them likely would be noticed and investigated. Also, the calibrations are subject to independent checks. The risks of abnormal operating events are also relatively low. The frequency of such events is very low or low, and, as evidenced in the worse-case radiation hot spot example above, the consequences are relatively minor to both the patient and practitioners. Hence, the main remaining effort of our risk analysis centered on determining the relative importance of the treatment path risk contributors.

In order to directly compare risks among the treatment path tasks, we needed to convert, for each task error, the discrete error likelihood distributions to discrete probability distributions, and the discrete error magnitude distributions to discrete consequence distributions. This was required to facilitate mathematical manipulations and the calculation of risk as the product of the probability of an event and its consequence. To make these conversions, the estimated error likelihood bins were replaced by single-valued probabilities. For consistency and conservatism, the highest likelihood in each bin was chosen as the single-valued probability for that bin, so the error likelihood template became the probability template:

1. 0.001
2. 0.002
3. 0.01
4. 0.02
5. 0.1

Similarly, the error magnitude bins were replaced by the highest percent error. The position/volume error magnitude template was replaced by the consequence template:

1. 0.02
2. 0.05
3. 0.1
4. 0.2
5. 0.5

As discussed in section 4.3, the dose errors are weighted 1.5 times higher than the position/volume errors for the purpose of consequence measures. Thus, the dose error magnitude template was replaced by the consequence template:

1. 0.03
2. 0.075
3. 0.15
4. 0.3
5. 0.75

All the task error data was transformed to conform to these templates. We then had for each task error a discrete distribution of its probability of occurrence and of its consequences.

Before we could compare the risks of the primary treatment tasks of Section 4.2.2, we had to logically combine or convolve the probability and consequence distributions of their subtasks to obtain aggregated probability and consequence distributions for the primary task. These distribution convolutions had to respect any dependencies among the subtasks. To accomplish the appropriate convolutions, we employed the discrete distribution propagation method used in the Zion and Indian Point PRAs (Fullwood and Hall 1988).

After obtaining the aggregated distributions for the primary tasks, we used the mean values of the probability and consequence distributions for each task as point estimates of their probability of error occurrence and associated consequence. The product of these two numbers then provided a first-order risk estimate for the task.

The comparison of risks among tasks is referred to as a "risk profile." The risks of the primary tasks are shown in a column graph in Figure 4-4. This profile shows the relative magnitude of risks among all the primary tasks. The primary tasks we ended up with are, to a good approximation, independent of one another. As mentioned above, preliminary versions of this risk profile were critiqued and reconciled by the expert review team to help clarify the data on which these profiles are based. The dependencies in the Gamma Knife treatment path are contained within the subtasks of any one primary task, i.e., a primary task's subtasks may be dependent on each other, but the primary tasks are considered to be independent of each other. Recall that the dependencies among the subtasks were accounted for in the convolution of the subtask error distributions to develop aggregated distributions for the primary tasks. The independence of the primary tasks is due to the serial nature of the Gamma Knife treatment process: each primary task has to be successfully completed before the next primary task can begin.

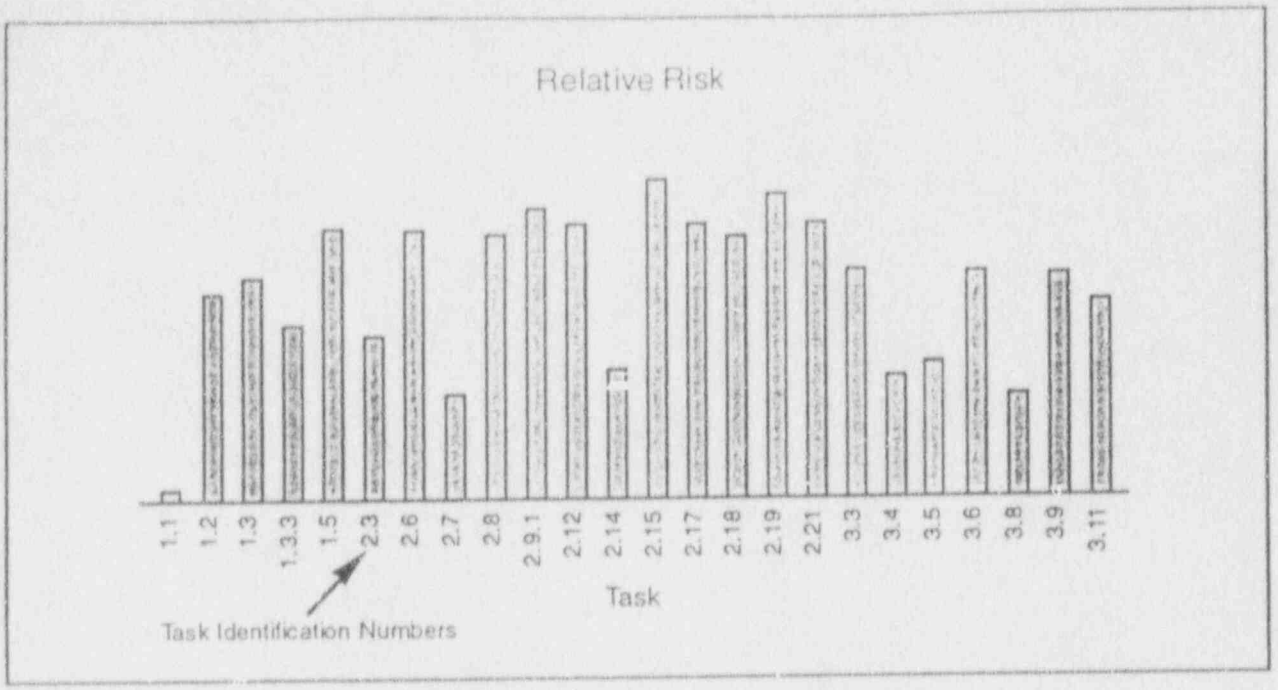


Figure 4-4. Relative risk (logarithmic scale) profile for Gamma Knife tasks. The numerals along the abcissa are task identification numbers.

The risk profile of Figure 4-4 helps to identify the relatively high-risk or critical tasks. One can see that several of the highest-risk tasks are associated with the treatment planning process (task identification numbers beginning with the number 2). If one had a regulatory standard that set an acceptable risk limit, this could be superimposed over the risk profile to identify those tasks with risks above the acceptable limit. Unfortunately, this can not be done until the relative risk values are calibrated to provide absolute risk values that can be compared to the regulatory standard. An advantage of using relative risks, though, is that if only one or two of the risk values are calibrated then all the risks quantities can be determined, since the relative measures among the risks have already been estimated. To calibrate the risks, data are required from investigations of misadministrations or from studies to determine human error probabilities.

Another instructive risk profile is to graph the tasks by their probabilities versus their consequence as shown in the column graph of Figure 4-5. The tasks are ordered by increasing consequence along the abscissa and the height of the columns reflect their probabilities. This allows the analyst to discern among tasks with, say, low and high consequences but with the similar relative risks. Recall that a problem with our risk definition is that high-probability events with low consequences may have the same risk quantification as low-probability events with high consequences. From a risk management perspective, the high-consequence task may be more important to control. The risk profile in Figure 4-5 permits the determination of the highest-consequence events as well as their relative probabilities.

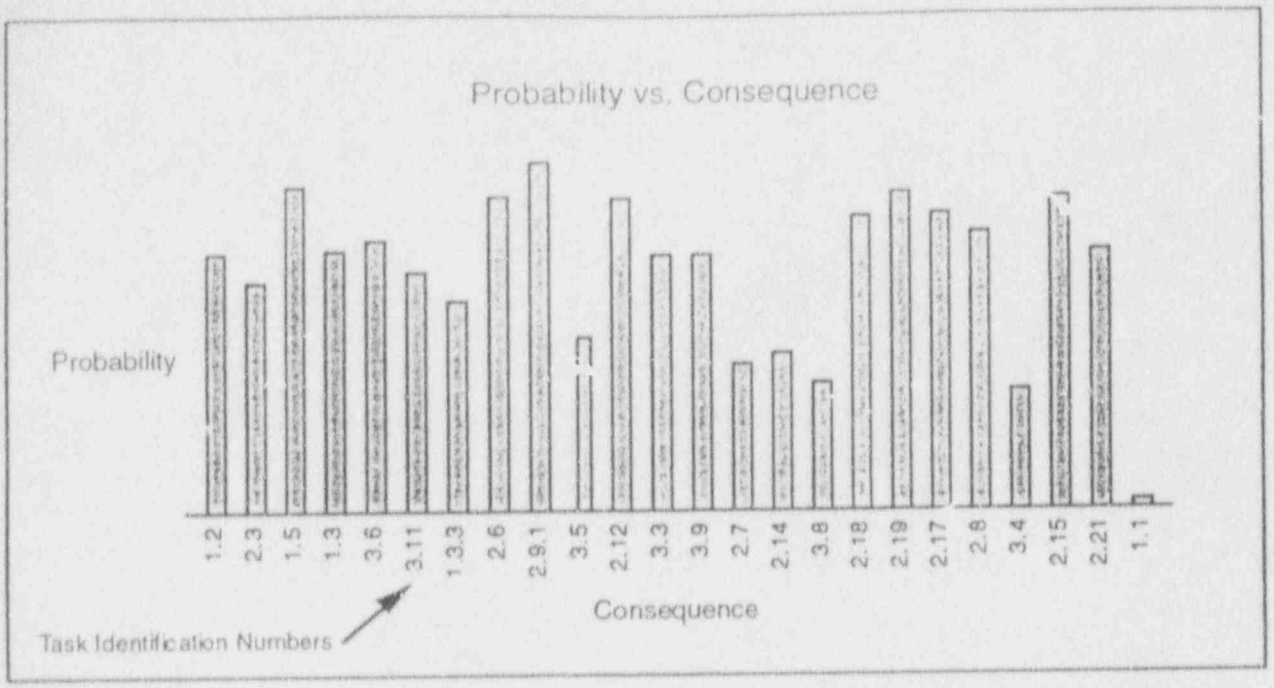


Figure 4-5. A risk domain profile for Gamma Knife tasks. The probability of an error occurring (logarithmic scale) is along the ordinate, and the tasks are arranged by increasing consequence along the abscissa. The numerals along the abcissa are task identification numbers.

The risk profiles provide a first-order view of high-risk events and might be used to prioritize the allocation of regulatory resources. If the risks were calibrated, the profiles could provide a framework for estimating the relative benefits of regulations by measuring the changes in risk profiles associated with proposed mitigating or preventive measures.

4.5. Simulations of Risk Scenarios

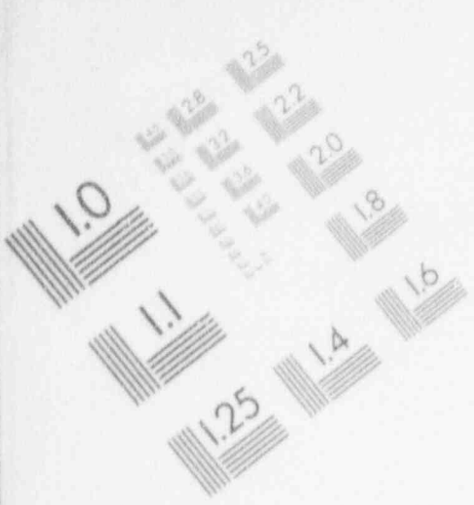
4.5.1. Overview

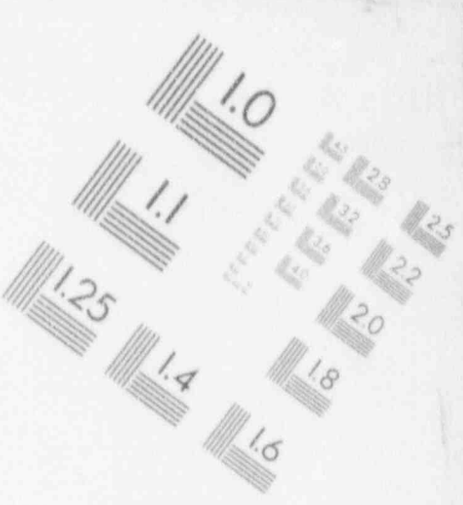
The risk profiles of Section 4.4 provide a "snapshot" of point estimates of relative risks of the primary tasks in the Gamma Knife treatment process. However, to determine the risks of misadministrations for Gamma Knife treatments, it is necessary to model concatenations of tasks representing possible treatment scenarios. Given the tasks and their error data, we have the information needed to generate possible treatment error scenarios and their associated risks. In principle, we could generate all possible risk scenarios by hand, but this is unreasonable since the number of possible scenarios is multitudinous. Another approach would be to model only those treatment scenarios with the highest risks, but, except for the case in which every possible error occurs, it is not apparent which these scenarios are until they are modeled.

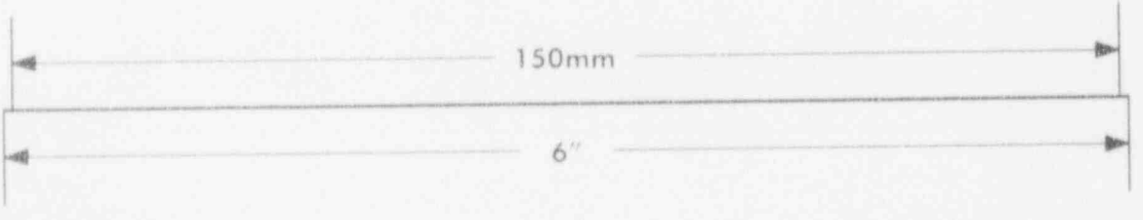
Also, it is important to perform uncertainty analyses on the treatment scenarios. The relative risk point estimates are products of the mean values of the error probability and consequence distributions, and contain no information about the standard deviations or spreads of these distributions. As discussed in Section 4.3, these spreads reflect the uncertainties in the experts' estimations, uncertainties which should be reflected in risk distributions for each task. We generated risk distributions for each task by convoluting the task's probability and consequence distributions. We measured the risk uncertainty associated with each risk distribution by calculating its coefficient of variation. The coefficient of

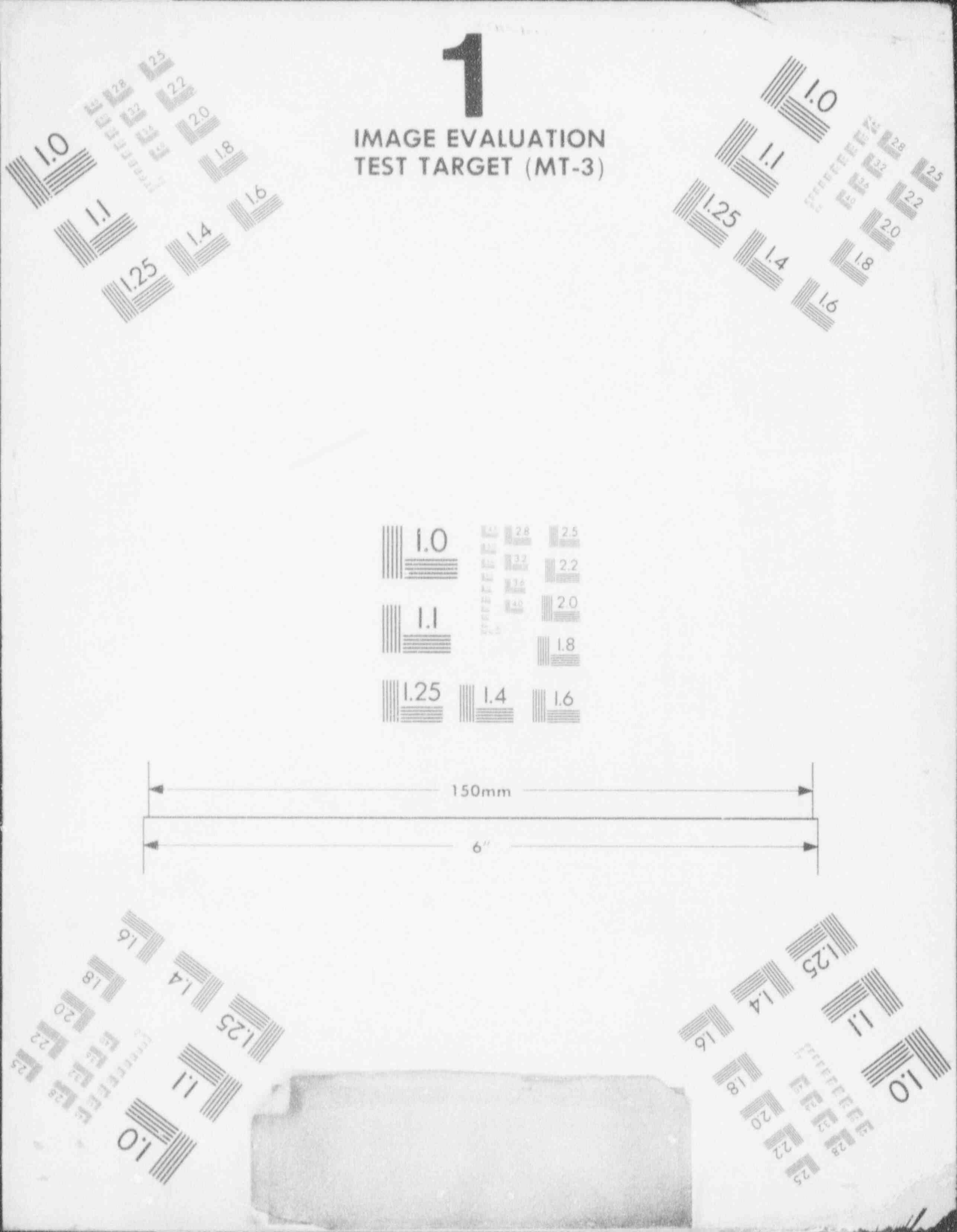
1

IMAGE EVALUATION
TEST TARGET (MT-3)



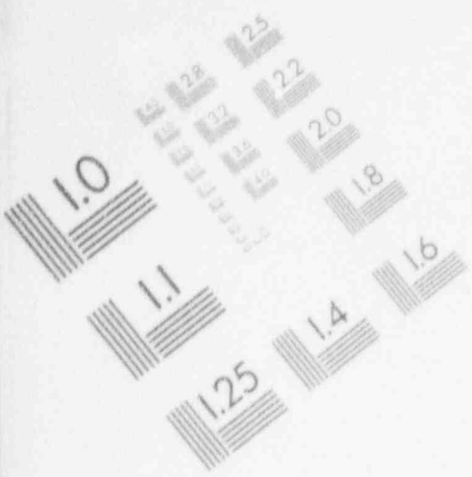


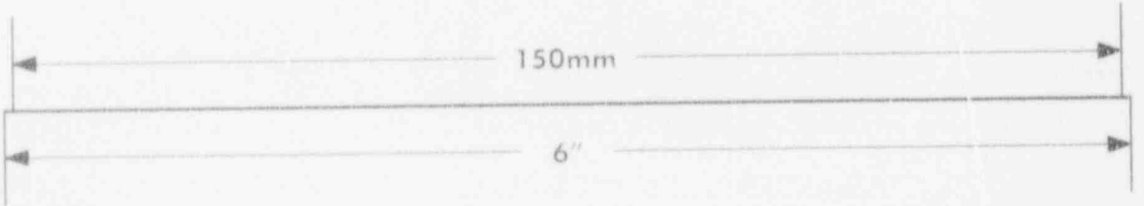


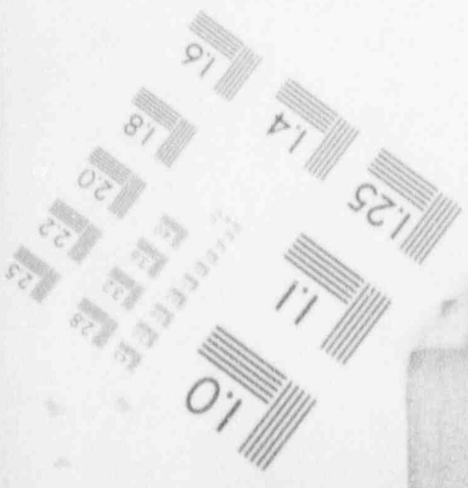

1
IMAGE EVALUATION
TEST TARGET (MT-3)
1.0
1.1
1.25
1.4
1.6
1.8
2.0
2.2
2.5
2.8
3.2
3.6
4.0
150mm
6"

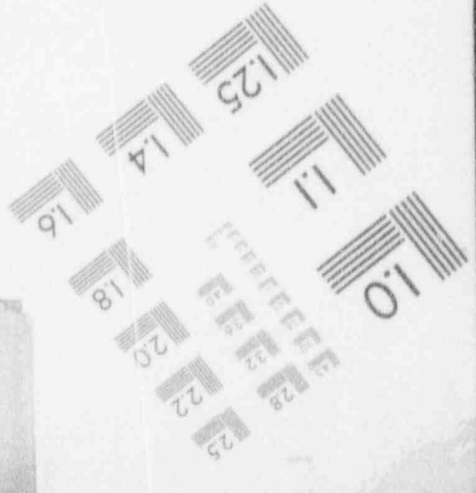
1

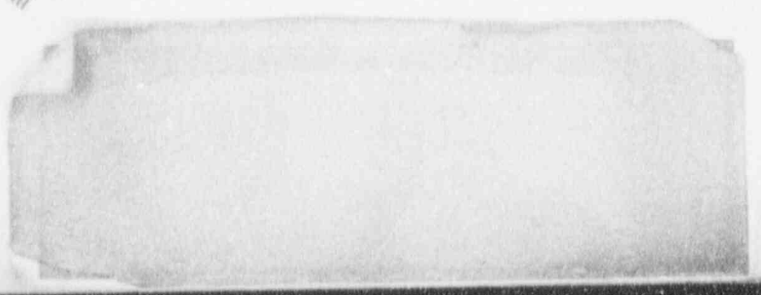
IMAGE EVALUATION TEST TARGET (MT-3)





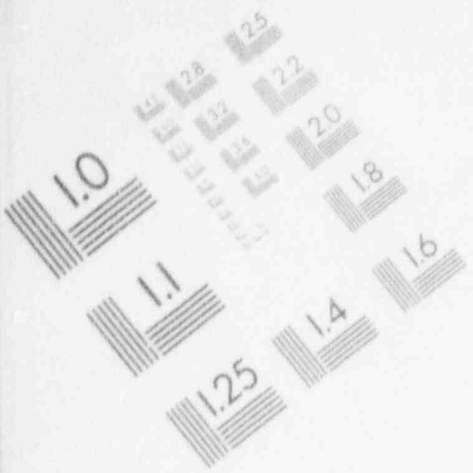


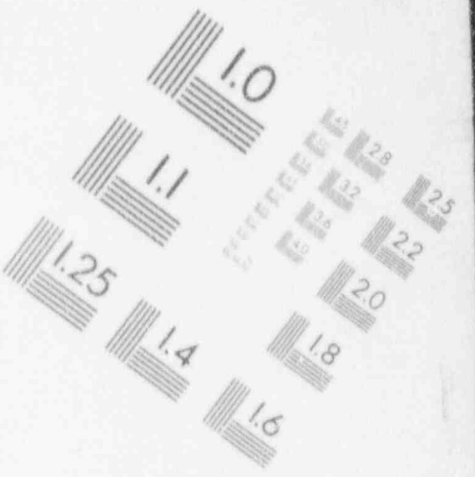


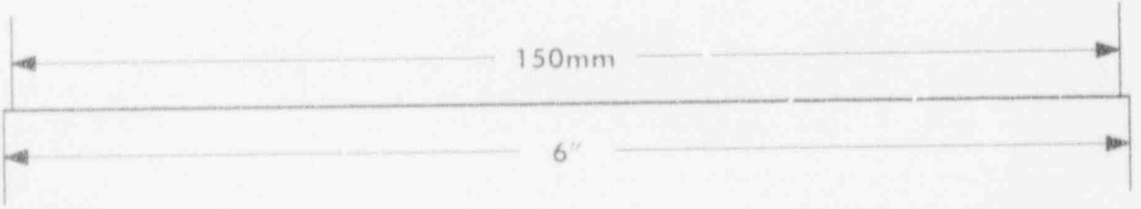


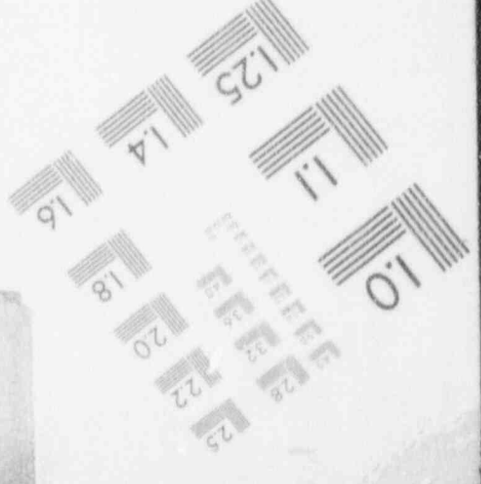
1

IMAGE EVALUATION TEST TARGET (MT-3)









variation is the ratio of the standard deviation over the mean for the distribution. Usually, the standard deviation is a fraction of the mean, so the coefficient of variation is less than one unless there is a great deal of uncertainty in the data. The coefficients of variation for the primary Gamma Knife tasks are shown in Figure 4-6. The large values of uncertainty and the wide variability in the uncertainties[1] from task to task indicate that the risk analysis discussed in Section 4.4 in which only the mean values were used, may not be adequate to represent the combinations of errors among tasks in a treatment scenario. Thus, the full error probability and consequence distributions should be used when estimating risks of treatment scenarios.

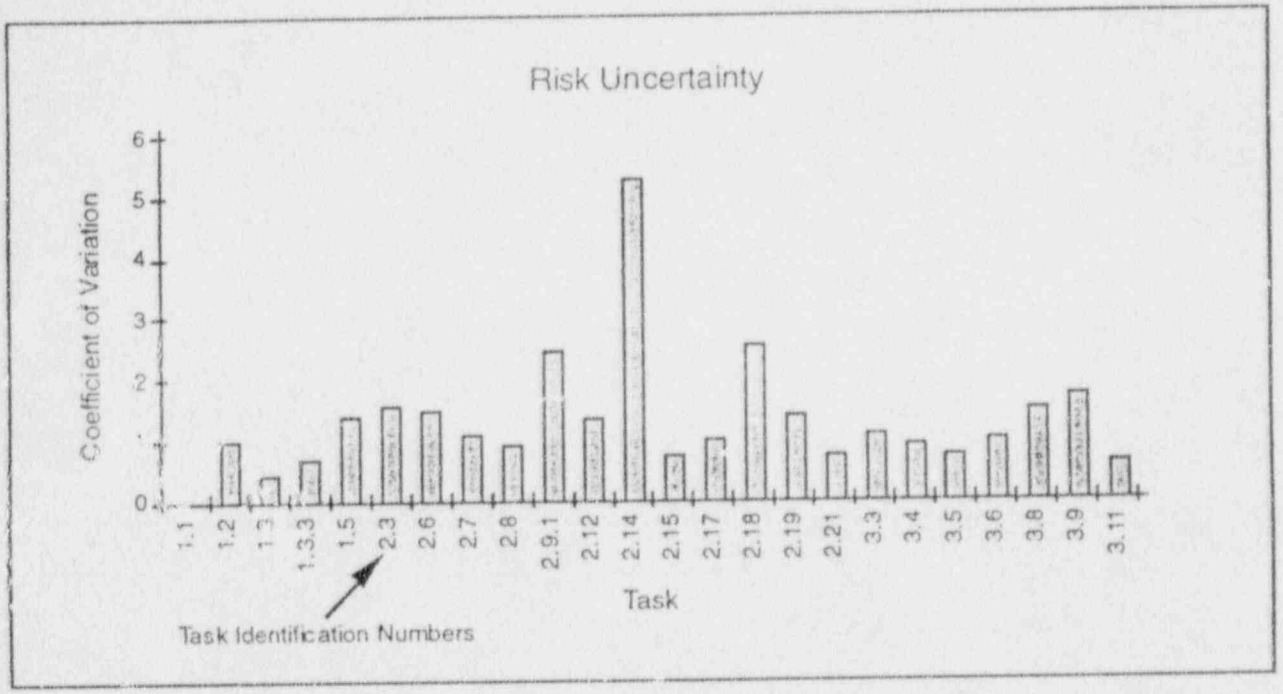


Figure 4-6. Risk uncertainty for Gamma Knife tasks. The coefficient of variation is the ratio of the standard deviation over the mean. The numerals along the abscissa are task identification numbers.

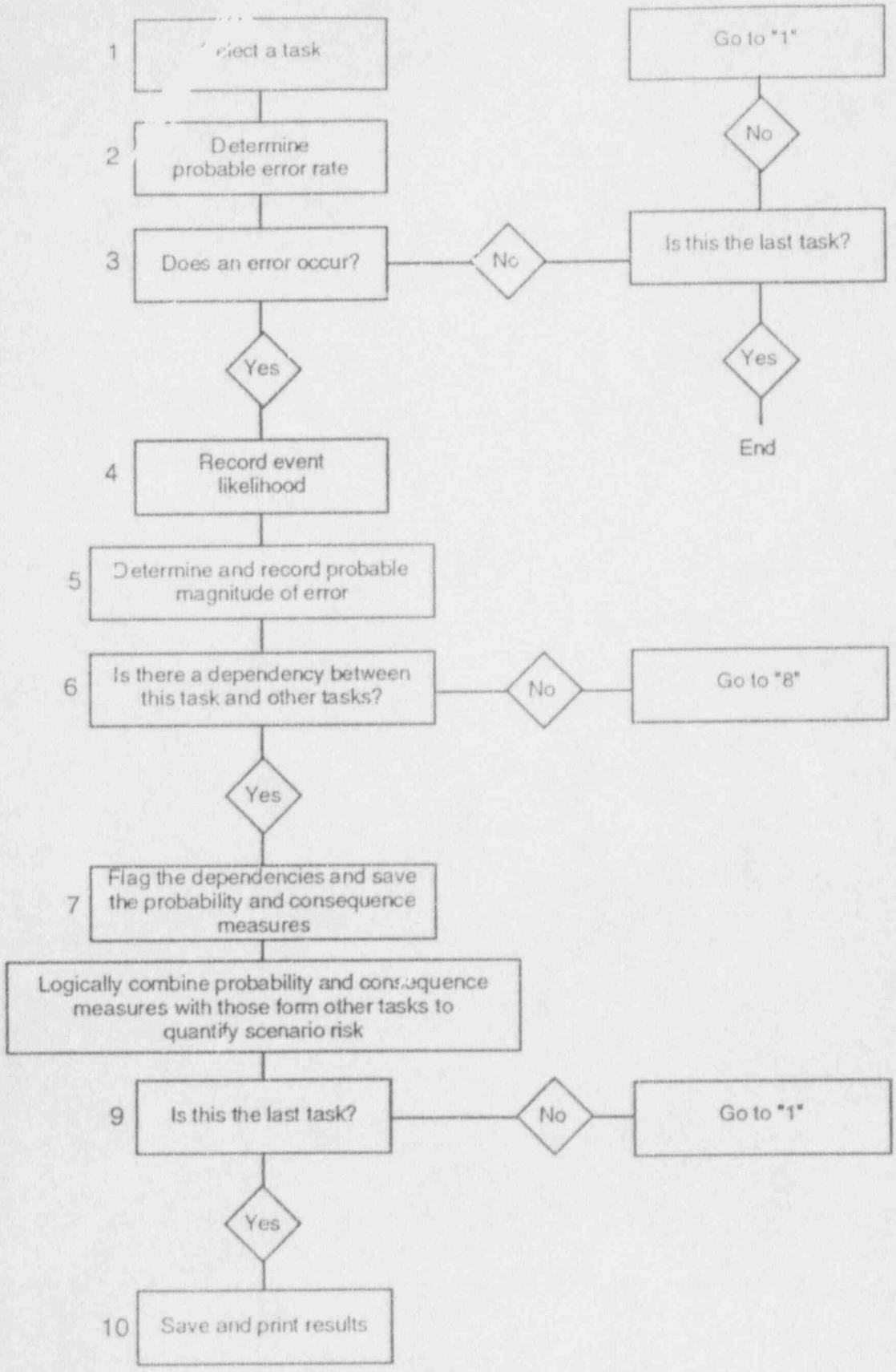
The most efficient way to accomplish these analytical objectives is to use a computer program to:

- Generate a multitude of error scenarios and their associated risks,
- Generate scenario risk distributions for evaluation purposes,
- Perform uncertainty, sensitivity, and mitigation studies by changing tasks or error distributions.

In order to do these things, a technique for sampling the probability and consequence distributions must be incorporated into the program code. Distribution sampling techniques such as latin hypercube did not seem appropriate given the nature of our discrete distributions—we would have to make assumptions about our distributions for which we did not have justification. Therefore, we searched for sampling methods that were more appropriate for our discrete distributions.

The Monte Carlo technique was developed for simulating stochastic physical processes, in particular, neutron transport in atomic bomb design. Like its gambling namesake, it uses random number processes.

[1]Our data was not statistically sufficient to determine the sources of uncertainty. For instance, we could not discern if the uncertainties were due to variations among facilities or due to the vagaries of human error estimates.


1
Select a task
2
Determine probable error rate
3
Does an error occur?
No
Is this the last task?
Go to "1"
No
Yes
End
Yes
4
Record event likelihood
5
Determine and record probable magnitude of error
6
Is there a dependency between this task and other tasks?
No
Go to "8"
Yes
7
Flag the dependencies and save the probability and consequence measures
8
Logically combine probability and consequence measures with those form other tasks to quantify scenario risk
9
Is this the last task?
No
Go to "1"
Yes
10
Save and print results

The technique utilizes a pseudo-random number generator to randomly sample a distribution. If enough random samples are taken, the distribution can be replicated and hence modeled.

We thought the Monte Carlo method would be a good way to randomly sample our discrete distributions. A typical way the method is used to sample a distribution is to transform the distribution into a unit-normalized, cumulative distribution function (CDF)—whose values are constrained to lie between 0 and 1. A number between 0 and 1 is randomly selected, and a distribution value is inferred from the CDF. After many such random trials, "all" numbers between 0 and 1 will have been selected and the distribution will have been "completely" sampled.

This technique was easily applied to our discrete distributions. For example, if there is a 30% chance that an error consequence is 0.02, a 50% chance it is 0.05, and a 20% chance it is 0.10, then values of the unit-normalized CDF between 0 and 0.3 would correspond to a 0.02 consequence, values between 0.3 and 0.8 correspond to a 0.05 consequence, and values between 0.8 and 1.0 correspond to a 0.10 consequence measure. When a randomly generated number between 0 and 1 falls into one of these three ranges, the corresponding consequence measure is selected. If this selection process is repeated several times, each time with a new randomly generated number between 0 and 1, then, on average, the 0.02 consequence will be selected in 30% of the trials, the 0.05 consequence in 50% of the trials, and the 0.10 consequence in 20% of the trials.

A computerized Monte Carlo technique can quickly generate a large set of possible error combinations and thus provide a statistical evaluation of treatment scenarios. Embracing this viable approach, our efforts focused on developing a computer code to generate risk scenarios.

4.5.2. MCRSC: A Monte Carlo Risk Scenario Code

In the Gamma Knife project, a Monte Carlo computer code was developed and used to simulate and evaluate the relative risks of possible error scenarios. The code was named the Monte Carlo Risk Scenario Code, or MCRSC ("McRisk"). It made full use of our error probability and consequence distributions and could model the interactions of any number of tasks, logically convolving their distributions.

The logic flow of MCRSC to simulate each risk scenario is illustrated in Figure 4-76 and described below:

1. Tasks to be included in the scenario simulation were listed with their data by the analyst in a spreadsheet format. The data for each task included: the task ID; the IDs of all the dependent tasks (these tasks must be included in the scenario); the percent of experts estimating each error probability; the error probabilities (from the templates in Section 4.4); the percent of experts estimating the consequence measures; and the consequence measures (from the templates in Section 4-4). All these data were read into MCRSC as part of its initialization. To start the scenario simulation, the program selected the data from the first task in the list.
2. By using the distribution sampling technique described in the previous section, MCRSC generated a random number between 0 and 1 to compare to the percent of experts estimating an error probability and thus selecting an error probability.
3. To determine if an error occurs for the current task, MCRSC generated a random number to compare to the selected error probability. If the random number was less than the error probability, then the error was deemed to have occurred. If the random number was greater than the probability then the error was deemed not to have occurred. In this case, if there were more tasks to consider in the scenario, the code returned to Step 1 and considered the next task, otherwise the program ended.
4. If a task error was deemed to occur, its error probability was recorded and saved.

5. If an error occurred, it was necessary to determine the consequence associated with that error. This was achieved by the Monte Carlo sampling technique: compare a random number to the percent of experts estimating a consequence and select the corresponding consequence. This number is also recorded and saved.

6 and 7. If this task has any dependencies among other tasks, then these must be duly noted to ensure its probability and consequence values are properly combined with the values from the dependent tasks.

8. The error probability and consequence for each task with an error in this scenario are logically combined with those from other tasks with errors in this scenario. For independent errors, the probabilities are summed and the consequence measures are added vectorially. For totally dependent errors, the probabilities are multiplied and the consequences are summed. The total probability and consequence values for this scenario are then recorded and multiplied to give the risk value for the scenario.

9. If this is the last task to be considered in the scenario, then the results are saved and printed to a file. Otherwise, the code returns to Step 1.

To generate other risk scenarios, the scenario simulation program is repeated. To illustrate what MCRSC can do, the results of repeated simulations of an example scenario are heuristically represented in Figure 4-8. This example is for a process with five tasks. In the first simulation of this process, errors occurred (as represented by x's) in tasks 1, 2, and 4, and the risk measure for the scenario was 0.7. In the second simulation, errors occurred in tasks 2 and 3, the risk measure was 0.3, and so on. The results of repeated simulations permit the identification of the highest relative risk error scenarios and of those tasks most likely to be associated with the highest-risk scenarios. See Figure 4-9. The highest-risk scenarios selected in this example are the two with relative risk values 0.8 and 0.7. These scenarios have in common errors in tasks 1 and 4. Thus, MCRSC helps to identify the highest-risk scenarios and the errors most likely to be associated with those scenarios.

Tasks					Risk
1	2	3	4	5	
X	X		X		0.7
	X	X			0.3
X		X	X	X	0.8
X			X	X	0.4
	X	X			0.2

Figure 4-8

Tasks					Risk
1	2	3	4	5	
X	X		X		0.7
	X	X			0.3
X		X	X	X	0.8
X			X	X	0.4
	X	X			0.2

Figure 4-9. [Karen: this is the same matrix but with the shading added]

4.5.3. A Risk Analysis Using MCRSC

The capabilities of MCRSC were used in a grand fashion to perform an analysis of the relative risks associated with the Gamma Knife treatment path. The treatment path was modeled to consist of the 24 primary tasks listed in Table 4-2. The error probability and consequence distributions (aggregated from the subtask distributions) for each task were utilized.

100,000 simulations of the treatment process were run to provide a good statistical evaluation of the risk scenarios. The Monte Carlo simulation can introduce additional uncertainty into the risk analysis if insufficient trials are executed. To obviate this problem, we performed enough simulations to ensure at least a 5% accuracy in the 95% wings of the MCRSC generated risk scenario distributions. Such an error is negligible compared to the uncertainties in our task error estimates. The Monte Carlo simulation displayed good convergence or stability characteristics. The distributions, when simulating 24-task scenarios, stabilized after about 50,000 simulations. We went up to 100,000 simulations to marginally improve the accuracy of the results and to ensure we captured any outliers. 100,000 simulations of the 24-task treatment process took about 1.5 hours on a 25-MHz, 486 personal computer.

The total error probability and consequence value for every scenario was simulated. Based on the range of these values, we established seven error probability bins and seven consequence bins to help aggregate the results. Thus, each scenario was associated with one of 49 bins, and we could represent 200,000 data by 49 bins and the number of scenarios belonging to each bin, i.e., we could represent the results of 100,000 simulations by 98 parameters.

The results are represented in Figure 4-10. There are two humps in the distribution of risk scenarios as a function of total error probability and consequence. These are highlighted by a contour plot of the relative number of scenarios as shown in Figure 4-11. The contour plot two domains in risk space associated with the majority of risk scenarios: (1) relatively high probability and relatively high-consequence scenarios, and (2) relatively high-probability and relatively low-consequence scenarios.

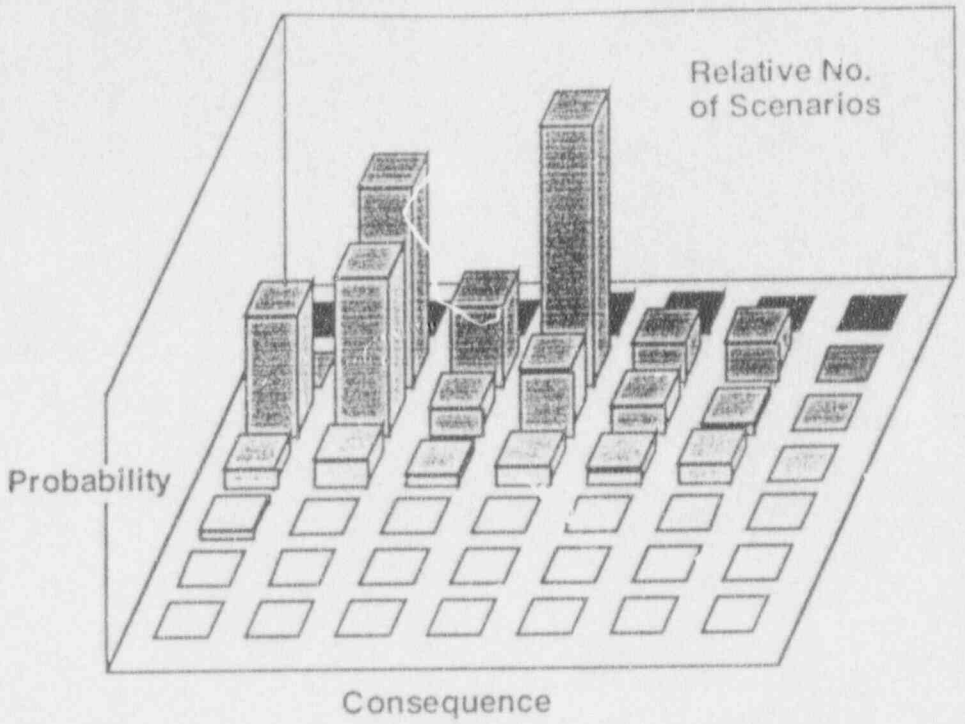


Figure 4-10. Distribution of risk scenarios for the Gamma Knife

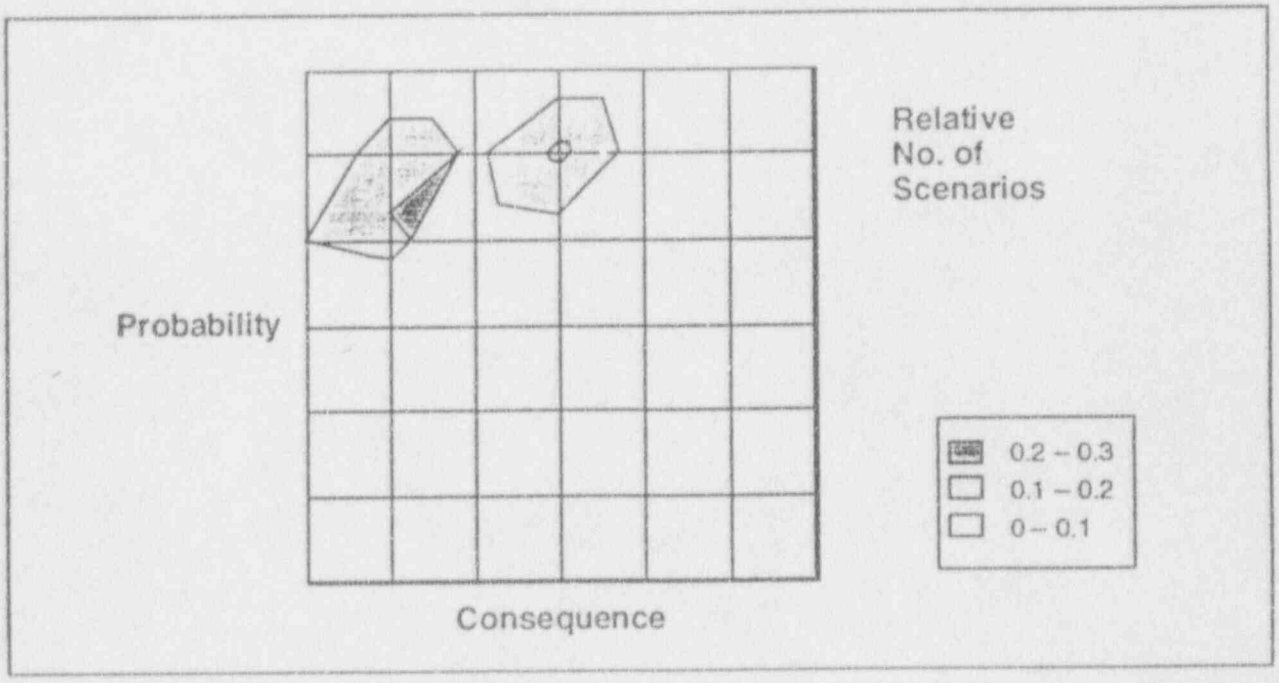


Figure 4-11. Contour plot for distribution of Gamma Knife risk scenarios

In order to determine the major contributors to these risk scenarios, MCRSC was utilized to generate the distribution of tasks with errors that were associated with the scenarios in each of the two risk domains. The results are shown in Figures 4-12 and 4-13.

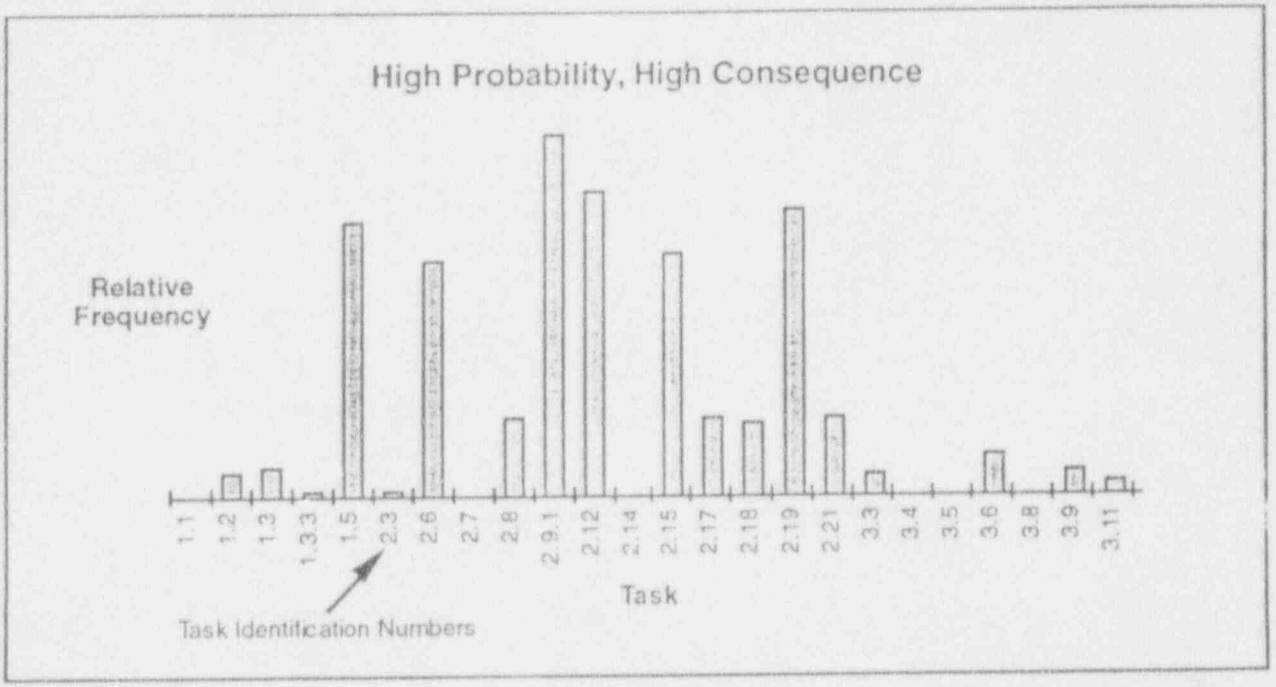


Figure 4-12. The relative frequency of individual tasks (numerals in abscissa are task identification numbers) associated with scenarios in the high-probability, high-consequence domain of risk space.

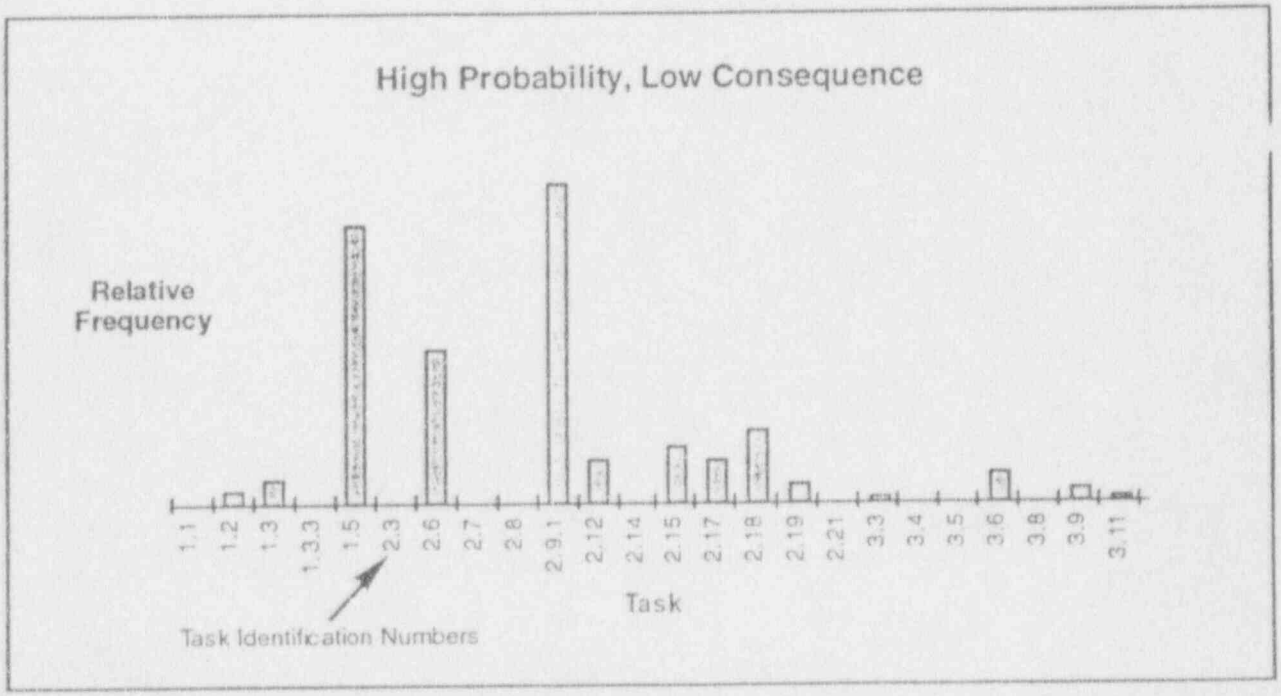


Figure 4-13. The relative frequency of individual tasks (numerals in abscissa are task identification numbers) associated with scenarios in the high-probability, low-consequence domain of risk space.

These results are interesting from a couple of perspectives. First, they indicate prevalent tasks in the higher-risk scenarios. Second, in comparison to the point risk estimates of Section 4.4, they show the effects of using the error distributions rather than just the means. Consider, for instance, task 2.15. According to the point estimates in Figure 4-5, the error of task 2.15 has both relatively high consequences and probability of occurrence. Hence, we would expect it to be a prevalent task among high-probability, high-consequence risk scenarios. According to the results in figure 4-11??ed, task 2.15 is prevalent, but not as prevalent as task 2.9.1. Why is this, when the point estimates in Figure 4-5 show the consequences of task 2.9.1 to be lower than those for task 2.15? The answer is revealed by Figure 4-6. The risk variation for task 2.9.1 is over three times higher than that for task 2.15. By looking at the error probability and consequence distributions convolved to give the risk uncertainty, it was clear that most of the uncertainty was propagated from the consequence distribution. Hence, even though tasks 2.9.1 and 2.15 have comparable error probabilities, as shown by Figure 4-5, the greater variation in the consequences of task 2.9.1 cause it to be more prevalent in the high-probability, high-consequence scenarios than task 2.15. The same phenomenon applies for the high-probability, low-consequence risk scenarios (see Figure 4-13??ed). Here, task 2.9.1 is prevalent due to its relatively high error probability and wide range of possible consequences. Meanwhile, task 2.15 is barely present even though it has a comparable error probability. This is because task 2.15 only has small variations about a relatively high consequence.

Based on these analyses, we focused in on task 2.9.1 as a potential major contributor to risk in Gamma Knife treatments. Task 2.9.1 entails acquiring geometric data from imaging films. Analyses of its subtask error distributions indicated that the highest consequences were associated with the errors of reversing image orientations (in particular, angiography films) and determining the Gamma Knife z-axis coordinate for CT and MR scans. This coordinate determination is problematic, because the treatment planner must remember to correctly include a magnification factor and a coordinate transformation factor in the calculation.

We performed sensitivity and risk mitigation studies on task 2.9.1 by investigating ways to lower the error probabilities and consequences of the subtasks. Modified subtask error distributions were then convolved to see what effect the changes had on the risk distribution for task 2.9.1. We determined that the mean risk associated with task 2.9.1 could be reduced by 20% by modifying the task to prevent film reversals, and reduced another 10% by making sure that the z coordinate was always determined correctly.[2]

Tasks 2.12 and 2.19 were also prevalent tasks associated with high-risk scenarios. These tasks' relatively high risks (see Figure 4-5) were related to the accuracy of dose calculations. Kula, the computerized treatment planning system evaluated during the Gamma Knife study, had two modes for calculating dose distributions—the "fast" mode and the "exact" mode. The fast mode used an interpolation scheme that is less accurate than the exact calculation algorithm. The difference between the two calculations was usually in the range of 4–7%. Treatment planners typically used the fast mode during the treatment planning stages to expedite the process, and they used the exact mode to produce the final prescription. We noticed while observing patient treatments that the dose profiles associated with the final exact calculation were often not checked. Hence, the dose actually delivered to the patient could be different from that intended by the physicians, who based their treatment plan on dose profiles from the inexact calculations.

A solution for reducing this risk was apparent to us: before signing the prescription, the dose distribution calculated exactly from the prescription should be compared with the intended treatment

[2]If one can associate costs with making these changes, then a risk reduction per unit spent resource can be determined.

plan. This final check would also provide an opportunity to recover from other data manipulation errors that could occur during the treatment planning process. The net result of this single check was to reduce the probability of occurrence of errors associated with tasks 2.12, 2.19, 2.15, 2.17, and 2.18 by one to two orders of magnitude.

It must be noted that the manufacturer of the Gamma Knife now sells a more powerful computerized treatment planning system, called GammaPlan.[3] This software always uses the exact dose calculation algorithm, thereby obviating the potential error of using the approximate calculation in Kula. GammaPlan also facilitates the manipulation of data during the treatment planning process. GammaPlan not only makes the job of treatment planning more efficient, it may also be less risky than Kula. However, we have not performed a risk evaluation of GammaPlan.

MCRSC was then used to simulate 100,000 treatments as before, except some of the 24 tasks were modified as per the aforementioned strategies for reducing risks .he distribution of risk scenarios for the Gamma Knife treatment path with modified tasks is presented in Figures 4-14 and 4-15. It can be seen that the relatively high-probability, high-consequence scenarios have been substantially mitigated.

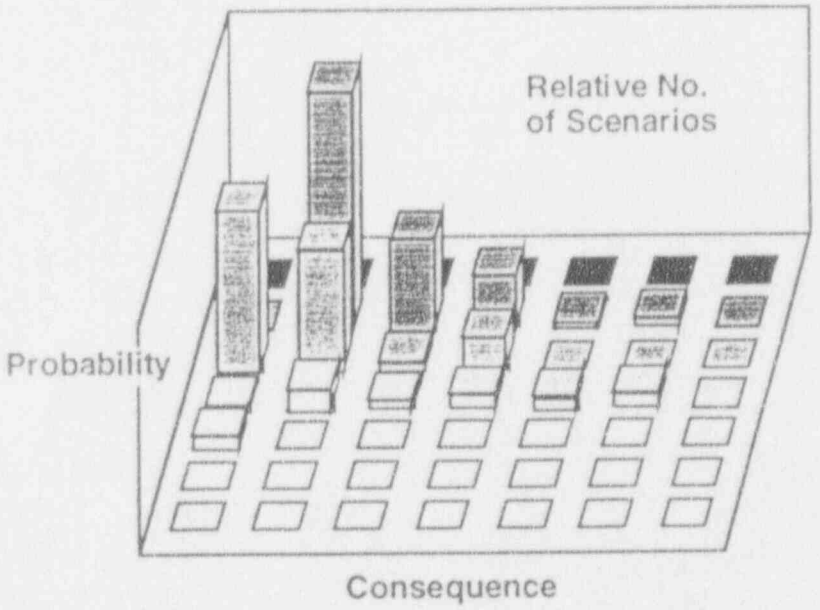


Figure 4-14 . Distribution of risk scenarios with modified tasks

[3] GammaPlan is a registered trademark of Elekta Instruments, Inc.

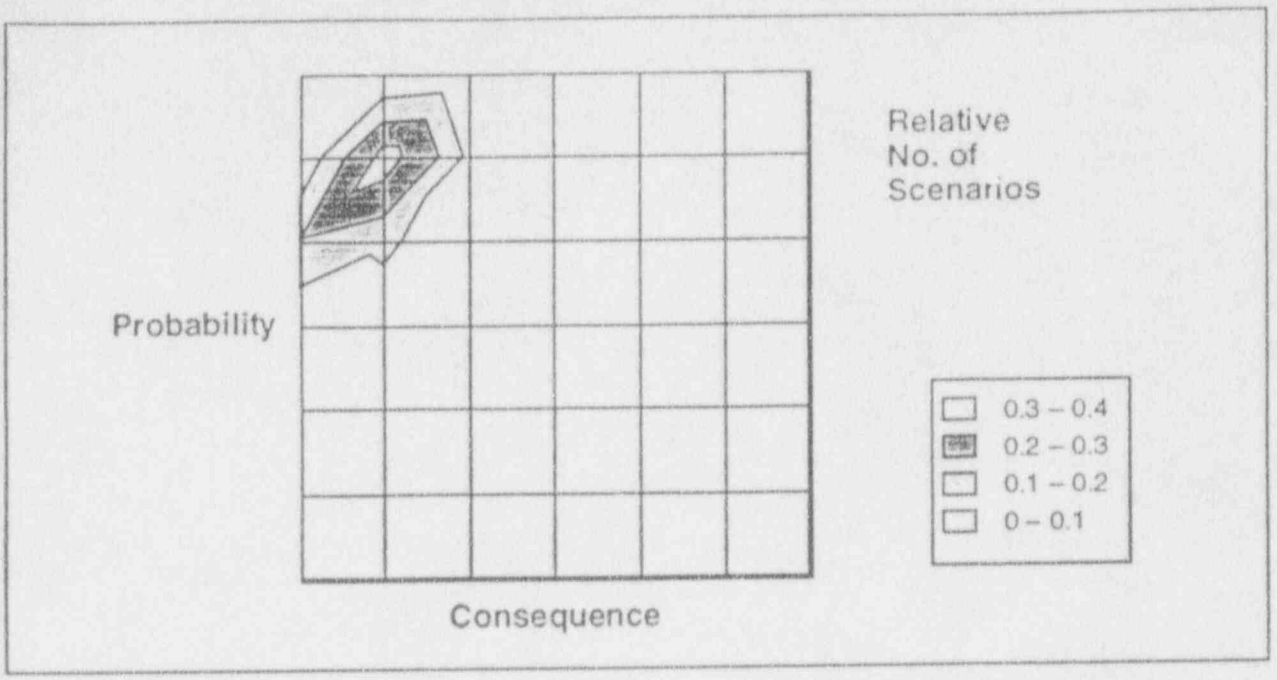


Figure 4-15. Contour plot for distribution of risk scenarios with modified tasks

We also performed sensitivity studies on task distributions to try to reduce the risks of the remaining high-probability, low-consequence scenarios. This turned out to be unsuccessful, since the consequences were already very small and the probabilities were constrained by human error rates.

Another demonstration of the impact of the risk reduction measures is provided by the cumulative distribution of scenarios with respect to risk, shown both before and after the reduction strategy in Figures 4-16 and 4-17, respectively. (The nine risk values along the abscissas of these plots are actually bins used to aggregate the relative risk values.) There is a complete reversal in the accumulation of scenarios from high to low risks. Our analyses indicated that if the Gamma Knife users could prevent film reversals, correctly determine the z coordinate, and would compare post-prescription dose profiles to the treatment plan, the number of incorrect treatments would be reduced by 23%, and dose errors greater than 10% would be reduced by 66%.

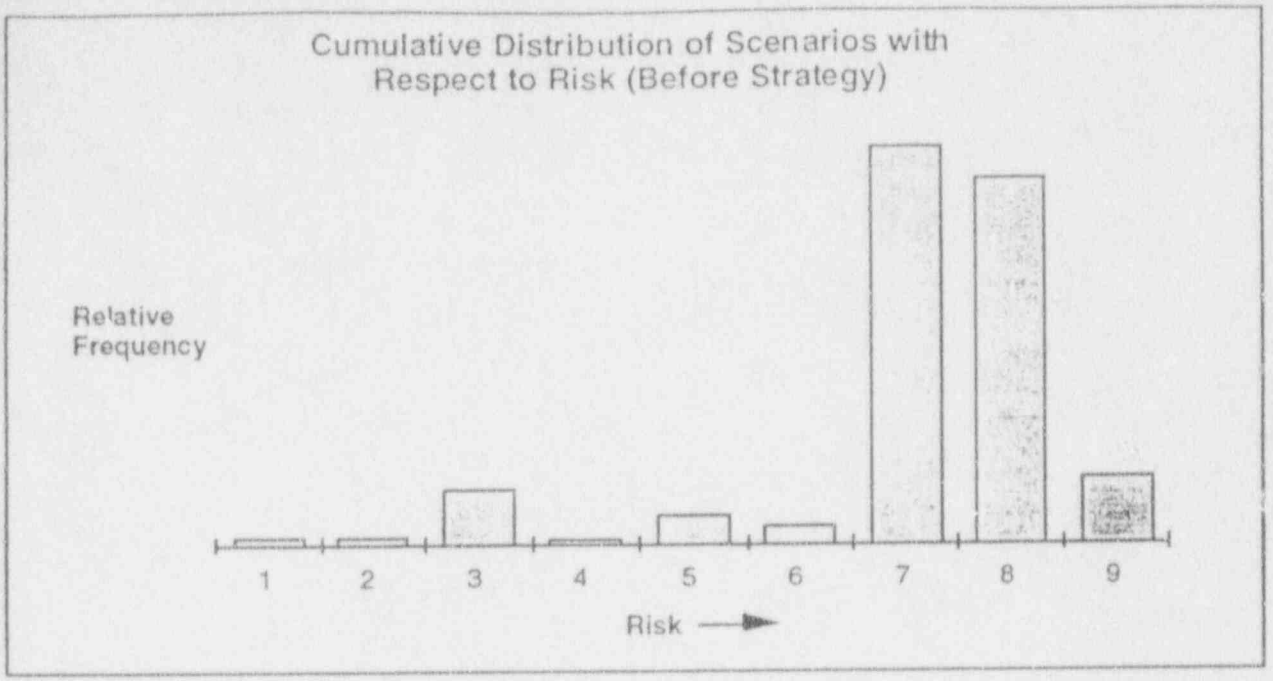


Figure 4-16. Relative frequency of Gamma Knife scenarios as a function of risk

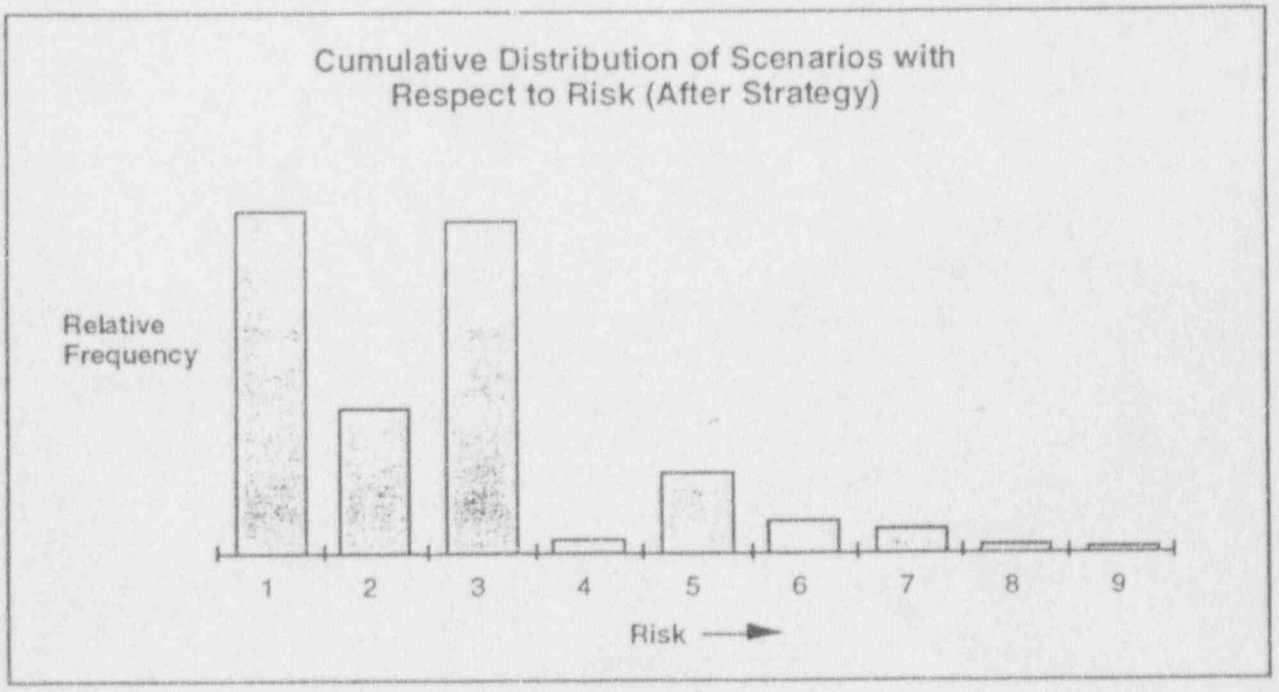


Figure 4-17. Relative frequency of scenarios with modified tasks as a function of risk

5. SUMMARY AND CONCLUSIONS

This initial effort to evaluate the use of PRA in regulating nuclear medical devices resulted in the development of a methodology and tools that show promise for developing indices of risk importance and effective risk management practices. The methods provide a flexible, basic approach for identifying most-likely risk contributors and the relative importance of each contributor. Several standard risk analysis techniques, including the armamentarium of PRA and HRA methods, might be utilized once the high-risk events are identified and characterized. For instance, event/fault tree techniques may be employed to understand how errors occur. HRA or human factor studies could help determine human error probabilities. The risk analysis tools also provide a platform for evaluating regulatory practices and reductions in the risk of misadministrations. For these reasons, the potential exists to extend the current approach to radiography and other areas in which a reduction in potential unintended exposures can be realized.

The results obtained have their limitations, however, because the work is new and innovative. The results so far are device-specific, and it remains to test the validity, consistency, and applicability of the methods to other devices. Other, or deeper, analyses may reveal shortcomings of the methodologies, or lead to the development of improved analysis techniques. Finally, because of the qualitative nature of the data available for the device studied, uncertainty bounds are not well understood.

The potential regulatory impacts of the risk analysis methodology are significant, and it may play a role in:

- Quantifying of the risk of misadministrations.
- Developing regulations and guidelines to reduce the frequency and magnitudes of errors.
- Evaluating the effectiveness of quality improvement practices.
- Enabling cost-benefit analyses of regulatory actions.
- Reviewing the design of new devices.

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UNITED STATES
NUCLEAR REGULATORY COMMISSION
ADVISORY COMMITTEE ON REACTOR SAFEGUARDS
WASHINGTON, D. C. 20555

November 10, 1993

The Honorable Ivan Selin
Chairman
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Chairman Selin:

SUBJECT: DRAFT FINAL REPORT OF THE PRA WORKING GROUP

During the 403rd meeting of the Advisory Committee on Reactor Safeguards, November 4-6, 1993, we heard presentations by the NRC staff on the draft final report of the PRA Working Group and its recommendations to the Commission. We also had the benefit of the documents referenced, of which we call special attention to the November 2, 1993 letter of the NRC Office Directors to the Executive Director for Operations.

In general, we were favorably impressed by the report, and of course gratified that the final version took account of many of the concerns expressed by the external reviewers and by us. In some cases, the responses were aspirational (i.e., to the pivotal concern that there is as yet no NRC policy on how PRA should be used in regulation, the report acknowledges that that is important and needs to be addressed), but even aspirational responses are better than denials that there is a problem. What really matters, of course, is the extent to which NRC will in fact enhance its capabilities, tune its regulatory activities to the risk posed by the objects of regulation, and adjust its life style to the new awareness of the implications of probabilistic analysis.

In this context we welcome the November 2, 1993 letter mentioned above, which records the intent of the Office Directors to develop a plan for the application of PRA throughout the agency, and to do so by December 30, 1993. In such a short time span, especially at this time of year, it is not possible to do more than establish a program plan, and make the commitment of resources. Given the magnitude of the job, the history of inconsistency and unevenness in the use of PRA, the frequent misunderstandings, etc., those resources will have to be substantial if the job is to be taken seriously. We have to reserve judgment until we can see if the actions match the words.

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Still, we think that the PRA Working Group has done a creditable job, especially given the limited resources it had available, and we are heartened by the positive response accorded its report by the senior staff.

Some of the problems left for the future are, though acknowledged, extremely difficult and fundamental. A central issue since the beginning is to find a mechanism for the incorporation of risk-based, and therefore probabilistic, considerations into a deterministic regulatory structure. The Committee has only hinted at the existence of techniques for doing this, and the question is left entirely open by the PRA Working Group. It will not be simple, especially in an agency whose staff has limited training and experience in such matters.

We are therefore pleased that the Working Group has produced a valuable report, and that the senior staff appears to be taking it seriously. After the battle at El Alamein in World War II, Winston Churchill said that it was not the end, nor even the beginning of the end, but that perhaps it was the end of the beginning. We have the same cautious hope. We remain interested in this activity, and would like to be kept aware of the progress.

Sincerely,

J. Ernest Wilkins, Jr.

J. Ernest Wilkins, Jr.
Chairman

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1. Memorandum dated October 8, 1993, from Warren Minners, NRC, for John T. Larkins, ACRS, Subject: PRA Working Group Draft Final Report (Draft Predecisional)
2. Memorandum dated November 2, 1993, from NRC Office Directors (NRR, RES, AEOD, NMSS) for James M. Taylor, NRC Executive Director for Operations, Subject: Agency Directions for Current and Future Uses of Probabilistic Risk Assessment (PRA)
3. Letter dated May 20, 1993, from Paul Shewmon, ACRS Chairman, to James M. Taylor, NRC Executive Director for Operations, Subject: Draft Report of the PRA Working Group
4. Letter dated July 19, 1991, from David A. Ward, ACRS Chairman, to the Honorable Ivan Selin, NRC Chairman, Subject: The Consistent Use of Probabilistic Risk Assessment