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Relative Risk Analysis in Regulating the Use of Radiation-Emitting Medical Devices

A Preliminary Application

Prepared by
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Lawrence Livermore National Laboratory

Prepared for
U.S. Nuclear Regulatory Commission

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ABSTRACT

This report describes a preliminary application of an analysis approach for assessing relative risks in the use of radiation-emitting medical devices. Results are presented on human-initiated actions and failure modes that are most likely to occur in the use of the Gamma Knife,* a gamma irradiation therapy device. This effort represents an initial step in a U.S. Nuclear Regulatory Commission (NRC) plan to evaluate the potential role of risk analysis in regulating the use of nuclear medical devices. For this preliminary application of risk assessment, the focus was to develop a basic process using existing techniques for identifying the most likely risk contributors and their relative importance. The approach taken developed relative risk rankings and profiles that incorporated the type and quality of data available and presented results in an easily understood form. This work was performed by the Lawrence Livermore National Laboratory for the NRC.

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

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EXECUTIVE SUMMARY

Introduction

This report describes the development of a risk analysis approach for evaluating the use of radiation-emitting medical devices. The work was performed by Lawrence Livermore National Laboratory for the U.S. Nuclear Regulatory Commission (NRC). The assessment approach was initially applied to understand the risks in using the Gamma Knife,* a gamma irradiation therapy device. This effort represents an initial step in an NRC plan to evaluate the potential role of risk analysis in developing regulations and quality assurance requirements in the use of nuclear medical devices. The risk approach identifies and assesses the most likely risk contributors and their relative importance for the medical system. The approach uses expert screening techniques and relative risk profiling to incorporate the type, quantity and quality of data available and to present results in an easily understood form.

Risk Analysis Approach

A team of risk experts reviewed several engineering-system risk analysis approaches for their applicability to radiation emitting devices such as the Gamma Knife. The results of a comprehensive review concluded that the limited data base for the Gamma Knife does not permit the accurate estimation of individual risk contributor values and that absolute values were not necessary for an effective understanding and regulation of the system. The review also concluded that the use of a relative risk analysis approach was applicable to the Gamma Knife. After further considerations, a relative risk profiling process was planned and developed for application to the Gamma Knife.

Figure 1 illustrates the relative risk profiling process used in the Gamma Knife application.

The folowing five-step process was used to identify and assess the most likely risk contributors and their relative importance to the Gamma Knife.

1. Review Gamma Knife equipment, functions, and operations

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

2. Identify risk contributors through modified task analysis

Potential threat scenarios (risk contributors), propagation paths, failure and error modes were identified through interviews with medical treatment experts, manufacturers, technician operators, and installation engineers.

3. Identify potentially high-risk contributors and tasks through expert screening process

Failure or error probabilities, threat/failure/error and consequences associated with tasks were determined and evaluated via experts and task analysis.

4. Assess high-risk tasks through relative ranking and profile analysis

Relative risk rankings and profiles for each error were developed based upon the task analysis and expert judgments of medical personnel who operate the Gamma Knife.

5. Estimate the importance and degree of uncertainty associated with high-risk tasks

The distributions-of-error data were utilized in uncertainty, sensitivity, and importance analyses.

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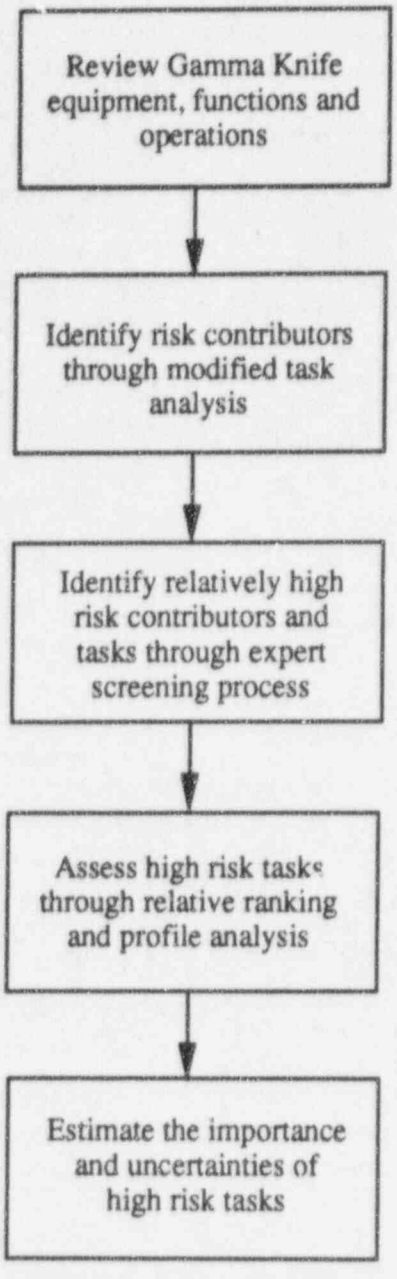

Figure 1. Relative risk analysis process used in the Gamma Knife application.

Relative Risk Profiling Overview

The information collected in Step 1 of the relative risk profiling process was analyzed to identify potential risk contributors to the Gamma Knife. From this effort, a list was developed which identified 102 tasks or subtasks with potential errors and 23 equipment failure modes that could result in risk. This list was reviewed and screened by experts experienced in the use of the Gamma Knife. The review and assessment resulted in a consolidated list of 24 relatively high-risk tasks, with a total of 66 subtask errors, and 23 equipment failures ranked by likelihood.

Through a formal elicitation process, the experts also provided relative estimates of the likelihoods and consequences of task errors or equipment

failures. This information helped to screen out the equipment failure modes as less risk-critical than error events in the 24 primary tasks.

Relative point estimates of likelihood, consequence, and risk for the primary tasks were compared by means of relative rankings and profiles, as illustrated in Figure 2. These aided the identification of the highest-risk or critical tasks, without requiring an absolute quantification of risk for each task. As shown in the figure, task 1.2 has the lowest consequence whereas task 1.1 has the highest consequence in the relative comparison. Task 2.9 has the highest probability and task 1.1 has the lowest probability in the relative comparison. An uncertainty and importance analysis was then performed, using the distributions of expert estimates for each of the 24 primary tasks. This analysis indicated the most critical tasks or those most likely to contribute to the highest-risk treatment scenarios. After the data collection and risk analysis were completed, new data became available on the error likelihoods of some Gamma Knife events. This actual data compared favorably—in both magnitude and relative values—with the expert estimates utilized.

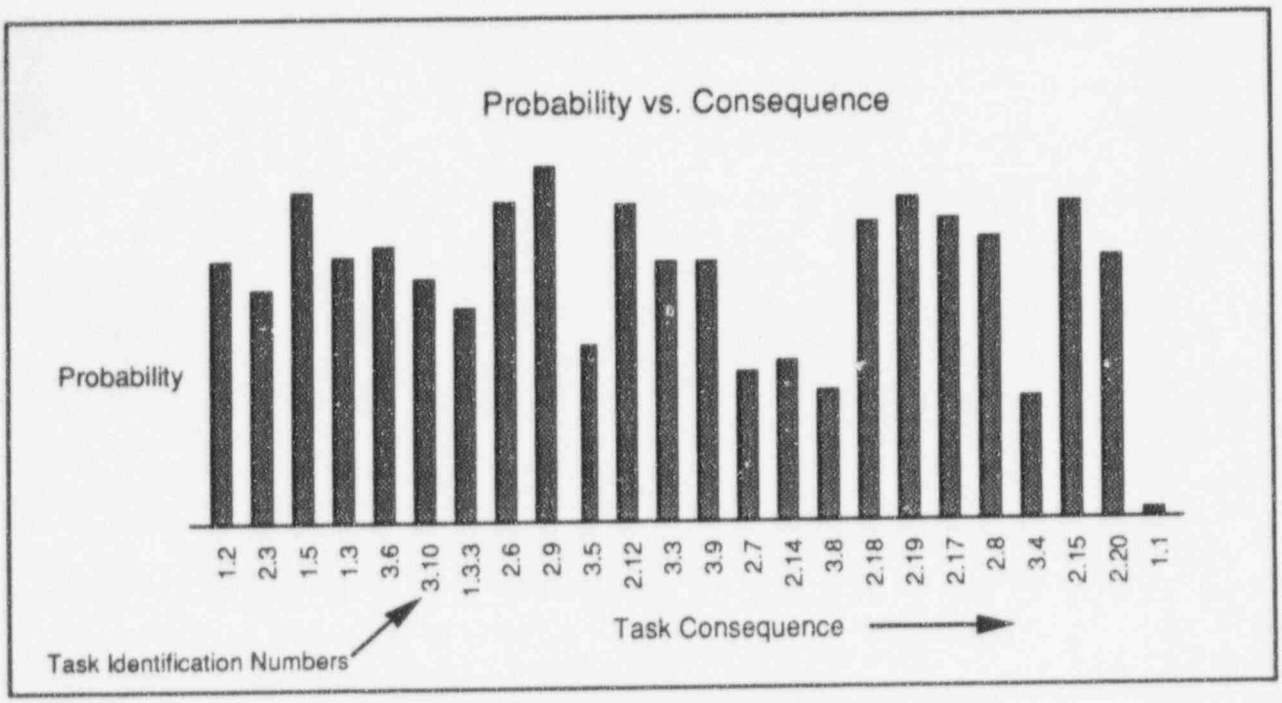

Figure 2. A risk domain profile for Gamma Knife tasks.
The probability of an error occurring (logarithmic scale) is along the ordinate, and the tasks are arranged by increasing consequence along the abscissa. The numerals along the abscissa are task identification numbers.

Conclusions and Recommendations

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

The relative risk profile process, as described in this report, can be applied to other radiation-emitting devices. For a specific device, it can only give relative risk information and rankings for that device. The process does not provide quantitative risk information for comparison with other devices. It can be used to identify weaknesses and support the development of positive measures for improving the treatment process for that device.

The use of the relative risk profile process may be most effective in nuclear medical applications that are not highly structured or have limited experience data bases. The process may be used to identify areas requiring additional regulations and guidelines for improving the safety of the patient, the administering staff, and the public.

FOREWORD

NRC has previously published information regarding patient treatment incidents involving gamma stereotactic radiosurgery units in Information Notices (IN) 94-39: *Identified Problems in Gamma Stereotactic Radiosurgery*, and IN 95-25: *Valve Failure During Patient Treatment with Gamma Stereotactic Radiosurgery Unit*. The following information from those documents concerns the two incidents.

IN 94-39. NRC was notified of an incident that occurred at an Agreement State licensee involving inadvertently inverting film of the treatment site for input into the treatment planning system and the subsequent overriding of the detection of the error by the treatment planning system. An arteriovenous malformation on the left side of the brain was being treated. An x-ray film was inverted before input into the treatment planning system. The treatment planning system initially rejected the image, recognizing it only as an older orientation system. Eventually, the neurosurgeon and physicist overrode the program and instructed the program to accept the reversed image. They then proceeded to generate treatment plans for two separate targets. After completing the first of two 8-minute shots for the first treatment plan and initiating the second, the physicist noticed that the X coordinates of the target points for the second treatment plan indicated a right-sided target, not left-sided as had been desired. He immediately terminated the second shot, with approximately 5 minutes remaining. After dose reconstruction, it was determined that the Y and Z coordinates were correct; however, the X offset resulted in a target miss of 16 mm. The licensee reported that the dose was delivered to areas of the brain "...with extremely high tolerance for deficit, and that the dose delivered was well below the dose-volume threshold for inducing any neurological damage."

IN 95-25. NRC was notified of an incident that occurred at an Agreement State licensee in which a patient undergoing gamma stereotactic radiosurgery received a dose, for a single fraction, that was 127 percent greater than the dose prescribed for that fraction. On October 25, 1994, a patient was prescribed to receive a series of 10 exposures in a Leksell Gamma System Model 23016 ("gamma knife") unit. At the end of the sixth exposure, the patient couch failed to retract from the treatment position because of a failure of a two-position, solenoid-operated valve on the hydraulic system of the unit.

The licensee's staff attempted to (1) manually pump the hydraulic system, and (2) shut the unit off. The latter action would normally turn the pump on and direct the pressure to allow the bed to retract. However, in this case, the valve was stuck in the 'bed-in' position and the internal spring could not reset the valve to allow the bed to move. The valve failure disabled both the normal and primary emergency patient retraction systems on the unit, resulting in the patient being irradiated for 3.8 minutes longer than the intended 3-minute treatment time. Medical personnel entered the room, pulled a pressure equalization latch on the bed, and were able to move the bed approximately 50 centimeters (20 inches). Subsequently, they manually disconnected the helmet from the unit to remove the patient from the treatment room.

When the patient couch failed to retract, the facility staff released the latch at the foot of the couch, thereby dropping the helmet to the lowest position corresponding to the low point of the couch tract. When the helmet is at the low point, the maximum dose rate at the focus of the primary collimator through the helmet is approximately 10 percent of the dose rate at the treatment position because of the lack of alignment with the helmet openings. Although the one exposure delivered a 127 percent overdose, it was delivered to a partial volume of the complete target volume with the result that there was a slight increase in the percentage of the target within the 45 percent isodose. However, changes in the isodose contour were minor at the 20 percent isodose contour. The maximum total dose delivered to the patient was approximately 33.5 Gray (Gy) (3350 rads) for all 10 exposures (fractions), compared with a planned dose of 33.33 Gy (3333 rads), therefore the medical consequences of this incident are minimal.

Furthermore, it appears that the medical staff who responded to the emergency all received less than 0.03 mSv (3 mrem) each.

The U.S. distributor, Elekta Radiosurgery, Inc., was notified of the event and subsequently replaced the valve. The distributor also notified all its customers of the event and attributed it to a valve failure, with no specific information on the cause of the failure.

ACKNOWLEDGMENTS

This work was sponsored by the U.S. Nuclear Regulatory Commission, Office of Nuclear Material Safety and Safeguards, Division of Industrial and Medical Nuclear Safety. The Technical Monitor was Dr. Patricia Rathbun who made significant contributions to the project team's efforts with her insights, ideas, experience, guidance, and management skills. The reviews of the project work and guiding comments provided by James Shepherd of the NRC are also appreciated.

Several professional people provided help, support, and cooperation in the conduct of this project. Elekta Instruments, 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 technically excellent and refreshingly candid in their comments and suggestions. 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 responding to our questions and arranging 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. Ladislau Steiner, Dr. Andrew Wu, and Ann Maitz.

RELATIVE RISK ANALYSIS IN REGULATING THE USE OF RADIATION-EMITTING MEDICAL DEVICES: A PRELIMINARY APPLICATION

1. INTRODUCTION

This report addresses a study conducted by Lawrence Livermore National Laboratory (LLNL) for the U.S. Nuclear Regulatory Commission (NRC) to develop a risk analysis approach for evaluating the use of radiation-emitting medical devices. This effort represents an initial step in an NRC plan to evaluate the potential role of risk analysis in developing regulations and quality assurance requirements in the use of nuclear medical devices. The risk analysis approach was initially applied to evaluate the use of the Gamma Knife.* The Gamma Knife is a commercially available external beam radiation therapy device used to deliver radiation to precisely defined intracranial targets. The analysis approach identified and assessed the most likely risk contributors (both human-initiated actions and equipment failure modes) and their relative importance in the use of the Gamma Knife.

1.1 Background

Since the early 1900's, radiation therapy has become one of the major methods of treatment in the management of cancer and other tumerous diseases. Radiation therapy is also used for palliative medical treatments. The objective of conventional radiation therapy using a teletherapy sealed source is to deliver a precisely measured dose of radiation to a defined tissue volume. The evolution of external beam radiation therapy has lead to the development of the Gamma Knife, a gamma (cobalt-60) stereotactic radiosurgery device. Stereotactic radiosurgery is the use of external radiation, in conjunction with a stereotactic guidance device, to very precisely deliver a dose to intracranial lesion volumes, such as brain tumors and arteriovenous malformations. Gamma Knife radiosurgery involves closed-skull, single-treatment session irradiation of a lesion by 201 stationary cobalt-60 sources (6600 Curies) geometrically arranged to converge into a dose volume. The Gamma Knife is a relatively new gamma therapy device which was commercially introduced into the U.S. for medical treatments in 1987.

The NRC has the authority to regulate the medical use of nuclear byproduct material or radiation from byproduct material to protect the health and safety of patients, while recognizing that physicians have the primary responsibility for the protection of their patients. Current NRC regulations—Title 10 of the Code of Federal Regulations, Part 35 (10 CFR 35)—address procedures for conventional cobalt-60 teletherapy devices (Subpart I), but do not necessarily address appropriate or comparable procedures for the Gamma Knife. Also, reports received by the NRC indicate that there are some cases of teletherapy misadministrations that have resulted from equipment malfunctions or human errors in treatment planning, dose calculations, and measurements. It is reasonable to project that comparable events may occur with Gamma Knives.

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 an evaluation of consequences. Risk assessments support risk management by producing a logical, integrated, and disciplined technical basis to support decision making. A major issue for the Gamma

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Knife project was determining which risk analysis approach and methods to employ.

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. Another class of risk methods focuses on the health effects of radioactive or 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 two 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 dangerous materials with certainty, i.e., a probability of one. Another difference is the types of consequences considered by each approach. The health risk assessment focuses on cancer fatalities. The engineering risk assessment considers system or component failures or human errors which can pose health risks, but not necessarily cancer fatalities. Since the dangers posed to the patient, practitioner, and public by the use of nuclear medical devices was of primary concern, the engineered-system risk analysis approach was selected and included the human error component.

The conventional engineering-system risk analysis approach normally estimates individual contributor risk values and requires large data bases and complex, detailed calculations. A team of risk experts reviewed several engineering-system risk analysis approaches for their applicability to the Gamma Knife. The results of a comprehensive review concluded that the limited data base for the Gamma Knife does not permit accurately estimating individual contributor risk values and that absolute values were not necessary for an effective understanding and regulation of the system. The review also concluded that the use of a relative risk analysis approach was applicable to the Gamma Knife. After further review, a modification of the relative risk profiling technique (Banks 1984) was selected for application to the Gamma Knife.

1.2 Regulations

Nuclear byproduct material, or radiation therefrom, is regulated by either federal or state laws. The Food and Drug Administration (FDA) provides market approval for cobalt-60 teletherapy units based on substantiated safety and effectiveness of the units. The FDA approves devices for sale and, prior to the passage of the Safe Medical Devices Act of 1990, monitored device use and performance through required manufacturer reports of safety-relevant incidents. There is now a medical device reporting requirement for users to notify the FDA directly about device malfunctions or abnormalities.

Twenty-eight states, known as Agreement States, have entered into an agreement with the NRC to regulate the use of byproduct material (as authorized by section 274 of the Atomic Energy Act). These states issue licenses and currently regulate about 4,000 institutions, e.g., hospitals, clinics, or physicians in private practice, while the NRC has about 2,000 byproduct licensees. The Agreement States' regulations for byproduct material are comparable to those of the NRC.

The NRC regulates the use of byproduct material in medicine by licensing and regulating institutions that use such material in diagnostic or therapeutic applications. The NRC issues regulatory requirements through the Code of Federal Regulations and by licensee conditions that authorize and control the use of byproduct material. The NRC also provides guidance regarding its regulatory requirements by means

of Regulatory Guides and Policy and Guidance Directives to the NRC staff. This system of rules, policies, and guidance implements the NRC's general policy (Federal Register, Vol. 44, p. 8242, February 9, 1979 (44 FR 8242)) of providing regulations necessary for the radiation safety of workers and the general public. The NRC tries to minimize intrusion into medical judgments affecting patients and into other areas traditionally considered part of the practice of medicine. NRC regulations are predicated on the assumption that properly trained and adequately informed physicians will make decisions that are in the best interest of their patients.

The NRC's regulations are published in Title 10 of the Code of Federal Regulations (10 CFR). Part 20 contains the standards for protection against radiation, while Part 35 deals specifically with the medical use of byproduct material. Subpart I—Teletherapy of 10 CFR 35 contains specific regulations for conventional cobalt-60 teletherapy facilities. Based on the results of this study, some of the quality control and calibration requirements for teletherapy facilities may not be appropriate for the external beam therapy technology of the Gamma Knife.

The NRC distinguishes between the unavoidable risks attendant in purposefully prescribed and properly performed clinical procedures and the unacceptable risks of improper or careless use. In 1991, the NRC amended 10 CFR 35 to require implementation of a quality management program—known as the Quality Management (QM) Rule (10 CFR 35.2 and 35.32)—to provide confidence that radiation will be administered as directed by an authorized user. Regulatory language specific to the Gamma Knife are contained in the QM rule.

NRC Regulatory guides are issued, after a formal review and comment process, to assist institutions in meeting the requirements of the regulations. The guides provide additional information and suggested procedures and programs; they do not require compliance. For instance, Regulatory Guide 8.33, "Quality Management Program" provides guidance to licensees and applicants for developing policies and procedures to establish their QM program required by the QM rule, including suggested policies and procedures for gamma stereotactic radiosurgery.

The NRC regulates the radiation safety of patients where justified by the risk to patients and where voluntary standards, or compliance with such standards, are inadequate (44 FR 8242). Voluntary or consensus standards are produced by professional or medical organizations. Many of the quality assurance and radiation safety voluntary standards concerning other external beam therapeutic procedures are relevant to the use of the Gamma Knife. This is especially true in the area of radiation safety, shielding, safety reviews, radiation surveys, interlock systems, exposure monitoring, good medical physics practices, et cetera.

1.3 Objective and Approach

The objective of this study was to identify the likely contributors to risk and their relative importance in the use of the Gamma Knife. This involves an assessment of:

1. What can go wrong in the process of using a Gamma Knife;
2. The relative likelihood of undesired events; and
3. The mis-delivery of radiation dose associated with an undesired event.

This project begins the development of a risk analysis approach for radiation-emitting medical devices. The approach should include, as much as is reasonable, the input of the regulated community, i.e., the device manufacturer and the medical practitioners.

A review of misadministration events and abnormal occurrences indicate that the risk analysis of an external beam therapy system should be balanced between equipment failures and human mistakes, if not directed toward the human errors. The Gamma Knife is a relatively simple hardware system with significant human control. Very little component failure data exists for the relatively new Gamma Knife. As of June 1993, there have been no misadministrations

with the device. Most operational information resides in the experience base of the manufacturer and users.

Given such considerations, a relative risk analysis approach was adopted, which would rely on anecdotal evidence, observations, and expert experience, and a relative risk profiling process was planned and developed. In the relative risk profiling process, an analysis of the Gamma Knife treatment tasks provided a systematic framework which could adequately account for and describe activities and equipment that may lead to undesirable events or consequences.

The relative risk profiling process is illustrated in Figure 1-1. It consists of a series of screening and ranking steps that progressively distill out the relatively high-risk tasks in the Gamma Knife application. After a thorough familiarization with the Gamma Knife, a preliminary analysis of all major tasks with potential risk contributions to the Gamma Knife operation was performed. Equipment failures were subsumed within the task analysis; only those components associated with task activities were examined. The preliminary task analysis postulated 102 tasks or subtasks (see Table 4-1) with potential consequences and 23 equipment failure modes (Table 4-2).

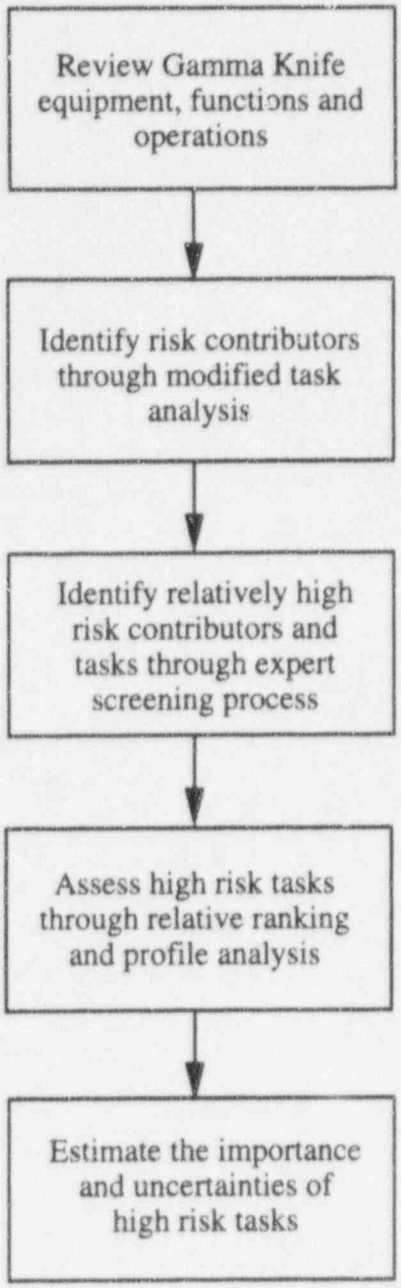


Figure 1-1. Relative risk analysis process used in the Gamma Knife application.

This list was reviewed and screened by experts experienced in the use of the Gamma Knife to validate, change, or refine the postulations. This resulted in a consolidated list of 24 relatively high-risk tasks (Table 5-1) (with a total of 66 subtask errors) and a list of 23 equipment failures ranked by likelihood (Table 5-2). Through a formal elicitation process, the experts also provided relative estimates of the likelihoods of task errors or equipment failures and the consequences of such undesired events. This information helped to screen out the equipment failure modes as less critical than error events in the 24 primary tasks.

Expert, relative point estimates of likelihood, consequence, and risk for the primary tasks were compared by means of relative rankings and profiles. These aided the identification of the highest-risk or critical tasks, without requiring

an absolute quantification of risk for each task. An uncertainty and importance analysis was then performed, using the distributions of expert estimates for each of the 24 primary tasks. This analysis indicated the most critical tasks or those most likely to contribute to the highest-risk treatment scenarios.

Figure 1-2 shows the layout of this report, consistent with the relative risk analysis process illustrated in Figure 1-1.

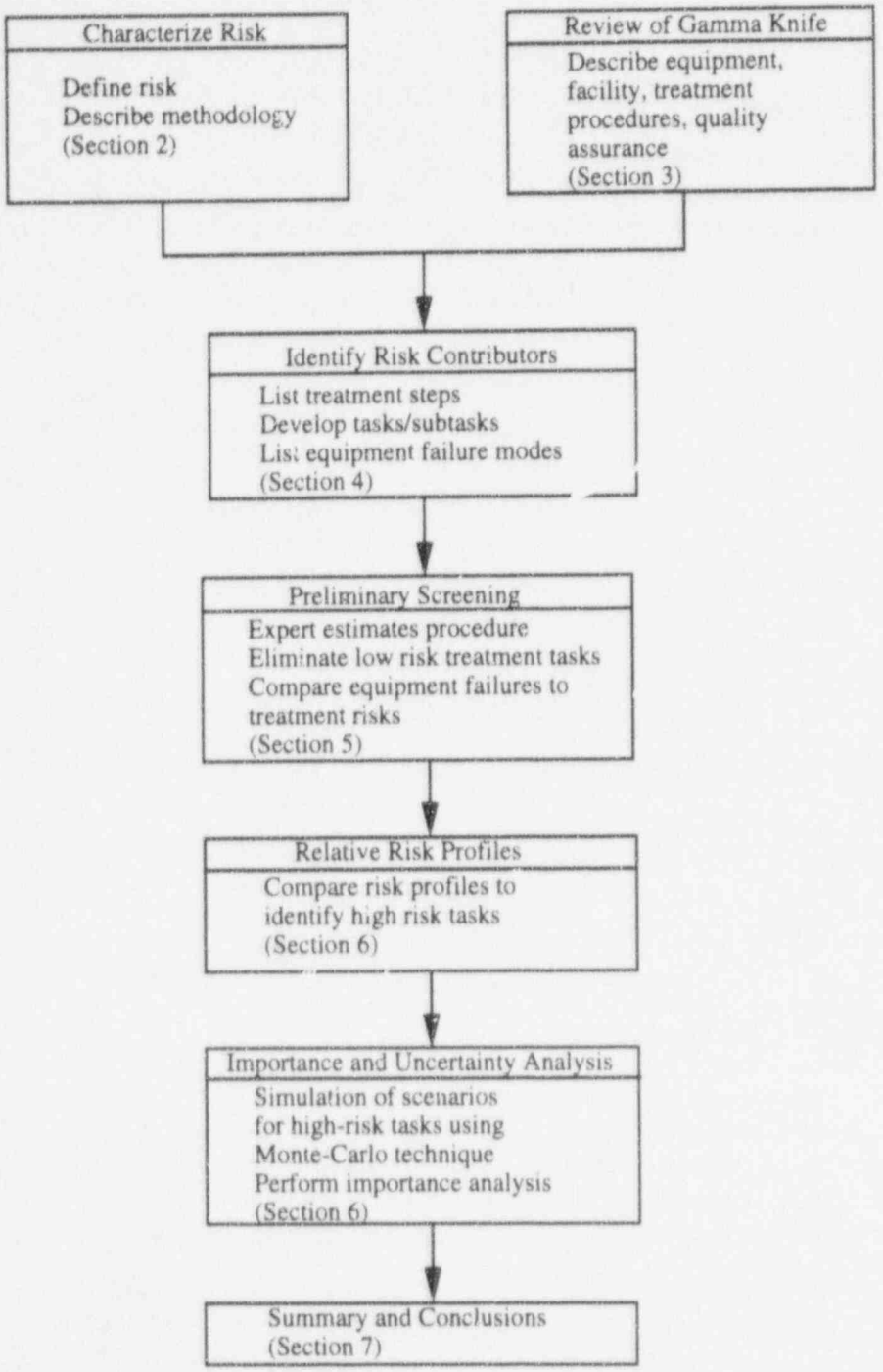


Figure 1-2. Schematic representation of report

In Section 2, issues critical to the risk analysis are reviewed. These include the definition of risk employed, and, especially, how consequence should be measured in terms of mis-delivery of dose and not in terms of radiobiological effects. General criteria for the risk analysis approach are summarized, and the relative risk analysis process is delineated.

Section 3 contains a discussion of the Gamma Knife unit, a typical treatment facility, treatment path procedures, and relevant quality assurance practices. The emphasis here is on aspects of the Gamma Knife operation relevant to risk, as well as information required to fully understand other discussions and results within the report.

A summary of observations leading to the initial identification of potential risk contributors is given. Risky tasks and equipment failure modes are identified by a top-down, iterative analysis process by examining the Gamma Knife functions and tasks in the context of the facility design, support equipment, and personnel interactions with the equipment, procedures, patients, data, administrative controls, and training. Hazards and component failures were associated with Gamma Knife subsystems examined in the context of the execution of specific operational tasks. The tasks are ordered in sequential steps paralleling the treatment process.

The role and results of expert opinions and estimations in the screening of the postulated risk contributors is discussed in Section 5. Throughout the relative risk analysis process, the analysts would develop an impression of or postulate potential risk contributors, and this view would then be presented to Gamma Knife experts for their review, verification, or refutation. The experts helped consolidate the preliminary risk-pertinent task list into a set of 24 primary, sequential, and independent tasks, each with its own set of subtasks or contributing events related by logic diagrams (fault trees). They also aided in the diminution and refinement of the list of equipment failure modes. A formal, and multi-modal, elicitation process was used to gather expert estimates of the relative likelihoods and consequences of task and equipment failures. These were used to determine that the equipment failures represented lower risks than task failures.

In Section 6, profiles of the relative mean values of the primary tasks' likelihoods, consequences, and risks are displayed. These serve to identify critical tasks as well as provide a pointwise topology of the Gamma Knife treatment path risk space.

In Section 7, the results from simulations of risky treatment scenarios are presented—consisting of concatenations of independent task errors. The full distributions, and hence uncertainties, of the experts' relative estimates for error rates and magnitudes are used in a Monte Carlo simulation approach. In addition, those tasks most likely to contribute to the highest-risk scenarios are extracted from the computerized simulations to determine the most critical tasks in the use of the Gamma Knife.

Section 8 includes a discussion of data on three event likelihoods that became available after the risk analysis was completed. This field data compared favorably—in both magnitude and relative values—with the expert estimates utilized.

Finally, Section 9 contains some closing observations and concluding remarks.

2. RISK CHARACTERIZATION AND METHODOLOGY

2.1 Definition of Risk Used

The definition of risk must be stated in operational terms. 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 terminal cancer or severe genetic defects). 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.

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 contrasting perspectives. In the Gamma Knife study, risk quantification results were presented 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 2-1. Each event quantified in the risk analysis would correspond to a point in this two-dimensional graph. Such a representation can aid 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. One role of risk analysis is to provide information to support regulatory decisions about what range of risks (regions of the risk domain) is acceptable.

2.2 Consequence Measure

Given our definition of risk, it is important in the risk analysis to clearly distinguish the probability of an event from its consequences. A major issue in estimating risk associated with the use of the Gamma Knife concerns 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 (deviation from expected) associated with an unintentional exposure or unintended deviation from the prescribed dose.

Adequate data on radiobiological complications associated with the mis-delivery of dose in the use of the Gamma Knife were not available during this study. The Gamma Knife delivers a focused beam of intense radiation to a biological target. 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 mis-delivery 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, attempts to measure consequences in terms of medical or biological effects were abandoned.

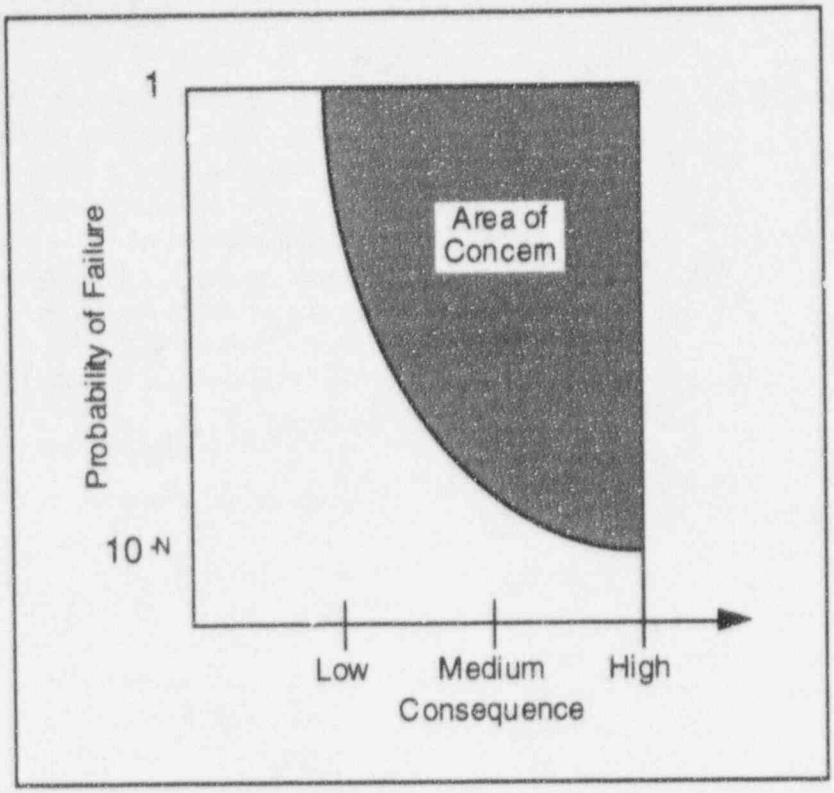


Figure 2-1. Illustration of the risk domain—probability of an event vs. its consequence

One consequence measure independent of medical considerations is the difference between the prescribed and delivered total absorbed dose to the target volume. This seemed a reasonable measure to use from a radiation protection perspective, as well as something that 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, it was decided that, for risk quantification purposes, 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.

2.3 Risk Analysis Approach

The type of risk analysis used depends on the type and quality of data available and the techniques 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 (ANS/IEEE 1983). 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 pre-defined 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. An HRA strives to model factors related to human error and performance and to estimate human error probabilities. An important aspect of an HRA is the qualitative assessment of the sources of human error. This may aid in identifying safety issues and provide 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, a team of risk experts reviewed several approaches. Some of these approaches, intended to integrate HRA into a nuclear-reactor-like PRA, were considered to be 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. Therefore, an analysis methodology must be used that can identify those mistakes or events that can cause undesirable endpoints.

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

- Focus on failure modes and human mistakes as primary causes of undesired events
- Provide a flexible framework for performing analyses
- Be able to incorporate both qualitative and quantitative data

The methodology should not be a rule-based methodology but should be a systematic approach to uncovering risk for a range of activities. It 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 should be equanimity between human and equipment elements: the method cannot be simply machine- or human-centered in its orientation.

After considering potential risk analysis methodologies, it was decided that the above criteria could best be met by 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.

2.3.1 The General Process of Relative Risk Profiling

Relative risk profiling is both a qualitative and quantitative technique for assessing relative risk associated with task or process execution. The basic method of task analysis is typically employed after failure scenarios are identified in order to determine what people actually do, what they are supposed to do, how they do it, where they do it, when they do it, what tools they use to do it, and under what conditions of time, urgency, lighting, training, and supervision they do it.

After the tasks associated with the identified failure paths are sequentially defined and bounded by the failure scenarios of interest, task experts and human factors engineers either observe, systematically rate, estimate, or measure the relative likelihood of error as a function of each task, as it is typically performed. After the relative probabilities of task failure (or success) are determined (using past records of incidents or failures) or estimated (using job content experts), the consequence associated with each failure is identified and then rated by magnitude relative to other possible consequences.

At this point, the analyst has two estimated or measured relative quantities: the probability of failure and the magnitude of various consequences. These two point estimates are then multiplied to produce a product reflecting the relative risk associated with each task in a sequence of tasks to be performed. Relative probability distributions can be generated along with variance estimates, by developing a frequency distribution of the actual historical data if it is available or of the expert's estimates. The degree of dispersion among expert estimates or different data sources is typically used to produce an estimate of the variance.

The central differences between relative risk profiling and the more traditional PRA approaches used in nuclear power plants lay in the fact that the actions of people are first studied, and equipment failures are the last to be assessed. Equipment, pumps, electrical systems, etc., are all viewed as an extension and augmentation of the human controller.

2.3.2 Relative Risk Profiling Steps

A detailed implementation plan (Banks and Jones 1992, Banks et al., 1992) for a relative risk profiling process was developed in this study. The major steps of the process (See Figure 1-1) are :

1. Review Gamma Knife equipment, functions, and operations

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

2. Identify risk contributors through modified task analysis

Identify potential threat scenarios (risk contributors), propagation paths, failure and error modes through interviews with medical treatment experts, manufacturers, technician operators, and installation engineers.

3. Identify potentially high-risk contributors and tasks through expert screening process

Determine and evaluate failure or error probabilities and consequences associated with tasks via experts and task analysis.

4. Assess high-risk tasks through relative ranking and profile analysis

Develop relative risk rankings and profiles for each error based upon the task analysis and

expert judgments of medical personnel who operate the Gamma Knife.

5. Estimate the importance and degree of uncertainty associated with high-risk tasks

The distributions-of-error data collected were utilized in uncertainty, sensitivity, and importance analyses.

The listing of these steps may imply a sequential and orderly investigative process, but the actual activities were often iterative. The first project plan prepared was very general, since the project team did not know what sort of information or data would be available, or what systematic tools would be best utilized to collect, organize, and analyze the information.

2.3.3 The Detailed Process of Relative Risk Profiling

Review Gamma Knife equipment, functions and operations

Background research on the Gamma Knife involved reading documents and user manuals provided by Elekta, and conducting literature searches. The user manuals and literature contained descriptions of the Gamma Knife components, cautionary notes with regard to safety, 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 articles on radiation safety and quality assurance.

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. The presentations provided a sound theoretical and practical understanding of how the Gamma Knife systems work; potential hazards or safety concerns; quality assurance, maintenance, and emergency procedures; and tasks performed as part of the treatment process.

On a two-day site visit to a Gamma Knife facility, 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. A mock acceptance test procedure, along with routine calibrations and checks, were performed. The medical physicist walked through the treatment procedure, noting all the checks performed to ensure accuracy in the treatment. As the walk-through was conducted, many questions were asked concerning why a particular activity was performed and what would happen if it was not correctly performed. This experience helped to refine an understanding of what system sequences were pertinent to potential risks, the relative importance of hazards and failure modes, and the tasks in the treatment procedure. Notebooks were created to record the sequences and hazards.

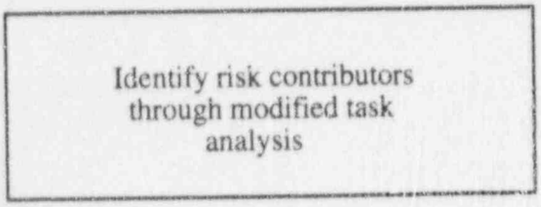
On the second day, a Gamma Knife patient treatment was observed, from imaging and lesion localization, to treatment planning, and patient positioning and treatment. This permitted a verification and validation of what was learned the day before.

During the course of the project, about half (five sites) of the then-existing Gamma Knife facilities (new facilities are steadily being established) were visited and patient treatments observed. These empirical experiences further refined the sequence identifications, failures evaluations, and task analyses, as well as the collection of data on the chances of occurrence of human errors and the consequences of those errors.

The University of California at San Francisco (UCSF) Medical Center had acquired a Gamma Knife and hosted many LLNL visits since it is near Livermore and convenient for further detailed investigations. This also afforded the LLNL team an opportunity to share in UCSF's learning experience with the use of the Gamma Knife.

Essentially all known aspects of the device and its use were examined, and a variety of questions

were posed to determine what could go wrong in the treatment planning, operation, and maintenance of the system, and where it could fail without regard to the root cause of the failure. The study was directed at those conditions or events that could lead to or trigger a mis-delivery of dose, or, postulating a consequence, the conditions that must exist to experience that consequence.



Based on observations, interviews, and questions answered by medical experts and engineers of the Gamma Knife, a comprehensive set of potential scenarios (risk elements) were identified which constituted abnormal operating modes and human errors.

Each threat scenario was systematically identified and evaluated using task analysis as a mechanism to determine task sequences and critical human failures. The medical experts provided many of the scenarios based upon their experience and treatment expertise. Relative probability and consequence estimations were acquired from the experience of the treating physicians who used the Gamma Knife. A traditional PRA was not performed nor was there any attempt made to assess the root cause of human error. The interest of this study was focused on phenomena and human actions that could lead to a misadministration, regardless of the reasons behind the event. The development of failure probabilities and subsequent risk rankings/profiles involved known and reliable rating techniques. Information was checked against multiple independent experts to ensure that the total analysis was thorough (content validity), balanced, and internally consistent.

Sequences pertinent to risk issues associated with the Gamma Knife were:

- 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; and
- Maintenance and servicing.

The types of potential hazards encountered and identified by the experts and later verified by the LLNL team 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; and
- Mechanical operations of the gamma unit and helmet hoist.

The products of the sequences and hazards analyses resulted, in the case of the Gamma Knife, in systems data concerning:

- Important quality assurance elements and their tolerances;
- Potential abnormal gamma unit events or failure modes and estimates of their frequencies of occurrence; and
- Preliminary task information for treatment paths.

The quality assurance elements pertained to the setting or calibration of timer accuracy and linearity, anticipated radiation output or profiles versus measured output, radiation monitors, interlocks, etc. The tolerances associated with these elements were based on documented and anecdotal information from Gamma Knife facilities.

The abnormal events or failure modes were associated either with the operation of the gamma unit itself or with facility systems and functions. Most of the events identified have relatively low likelihood ratings and consequences. These events, with their frequencies, were treated as basic events in the event or fault tree.

Once a process sequence was developed and the hazards identified, defined, and delineated, a task sequence list was developed for each step in the process of interest. The first task in each list is the initiating task for the process step, and the last task or subtask in each list must be completed successfully before the next step of the process can occur. Such task lists were developed for each of the Gamma Knife treatment path processes of imaging, localization, treatment planning, patient positioning, and treatment. All tasks had the characteristics of a purpose or goal, an input or stimulus, a decision or response by the operator, and a system or process change which can be fed back to the physician or technician.

For the purpose of the risk analysis, tasks were selected which were subjectively judged by medical experts to be the most pertinent activities affecting risks associated with the medical device. Based upon their knowledge and experience, the analysts then ascertained where errors most relevant to risk can or do occur. Each event and task sequence was clearly delineated. The selection of these "important" tasks was verified by medical experts' experiences. The types of task data collected are summarized in Table 2-1.

Note that the equipment or machine factors are not ignored by this 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 potential equipment failures can be applied. In this way, equipment or engineering risk analysis is contextually focused and hence economically efficient.

Appropriate information-gathering tools include literature searches, documentation analysis, both unobtrusive and participative observations, individual interviews, survey questionnaires, and both structured and unstructured group interviews. Quality assurance issues can be formulated in a protocol or survey format that establishes the criteria for information to be collected and a framework in which to collect, review, and analyze the information. The task analysis issues can be put in data forms or tables that are easily filled in task by task.

In the case of the Gamma Knife, data were collected from medical associations, standard-setting organizations, the manufacturer, Gamma Knife users, and experts. The team of professionals who inspected gamma units, attended acceptance tests, interviewed users, and observed patient treatments consisted of (1) a multi-disciplinary team of physicians and medical physicists with expertise in teletherapy, (2) risk assessment experts, and (3) scientists and engineers with extensive knowledge of task and safety analyses.

Table 2-1. Types of task data information

Task identification number	Most-likely human errors
Description or purpose of task	Error consequences
System components affected	Most-likely equipment failures
Support equipment	Consequences of equipment failures
Task frequency	Others involved in task
Hazards	Ways to lessen risk
Performance standards	Training/knowledge required

The task analysis data were verified for accuracy, completeness, and self-consistency by the use of subject matter experts, simulations, facility walk-throughs, and observation of actual practices.

Members of the medical community provided data, review, and comment to the project team. Data analyzed by the project team were subsequently reviewed, critiqued, and validated by medical community expert peer review teams.

In summary, the task analysis consists of the following iterated stages:

- Select the events or processes to be analyzed.
- Develop an understanding of each step of the process.
- Develop and complete task data forms.
- Verify the data for accuracy, completeness, and self-consistency.

Identify potentially high risk contributors and tasks through expert screening process

The following steps in the task analysis were used to identify the potentially most important risk contributors.

Step 1. Establish Task Analysis Objectives and Scope

Produce a first order set of operational tasks and operations sequences to be analyzed against potential hazards, misadministrations or other critical system failures.

Step 2. Establish Data Collection Model

The data collection model is embodied in the task analysis data form and a corresponding set of task analysis category definitions. The data forms are presented in Appendix A and the task category definitions are given below.

Step 3. Define Process Functions

Process functions were defined initially in the form of brief narrative statements that specify:

- Starting conditions
- Major activities resulting in changes in the operational status of the Gamma Knife operation and collateral facility conditions
- End conditions

The process function descriptions serve to bound the tasks to be included in each process step and to indicate major task groupings. Modifications were made as the task list is developed. When filling in the detailed steps of a process, task

groupings that may initially be overlooked are identified, and better ways of bounding processes and allocating or ordering activities within Gamma Knife process steps emerge.

Step 4. Analyze Process Functions to Develop Task List

The initial task list was developed by members of the data development, risk assessment team. The process function descriptions provide a framework for discussion. These descriptions identified the major changes in Gamma Knife status or conditions to be accomplished during the process. The purpose of the effort was to help the medical experts remember, visualize, and express the specific steps that would need to be performed by the medical personnel. Discussion of the layout of the treatment facility, and of the equipment, process, and exposure control requirements were also addressed. A schematic of the facility and equipment design was used as an aid. The experience of medical team members facilitated task identification and the identification of any hazards associated with each task element.

Step 5. Conduct Review of Task List

The completed task list was distributed to all members of both the data development and review groups for review and comment. Changes were agreed upon by the data development and review groups. The resulting task list was completed and later served as the starting point for completion of the task analysis data forms.

Late additions and other changes in the task lists were identified and inserted as the forms were iteratively reviewed and completed. Additional information, not included on the data collection forms, was obtained about the Gamma Knife design and equipment options. Another iteration of the task list development session was conducted, which involved all participants, to resolve issues identified in the detailed analysis, incorporate additional information, and establish a final, approved task list which appeared to be at the necessary level of resolution.

Thereafter, minor modifications were made in the wording and grouping of task elements to meet the requirements of the data collection model.

Step 6. Analyze Tasks, Complete Task Analysis Data Forms

A series of interview/discussion sessions were conducted to complete the task analysis data forms in accordance with the task category definitions (see the end of this section).

Step 7. Review Task Analysis Data Forms

A review was performed by members of the Gamma Knife operations staff in addition to those who participated in the detailed analysis and completion of forms. Review comments were incorporated into the task listing.

Step 8. Synthesize/Analyze Data

The final treatment of the data to meet project objectives is straightforward. The method of analysis was designed so that the task descriptors would constitute procedural steps which could simply be listed to provide the first order profile of risk. A risk profile was generated using the standard formulation of rated, relative probability of error in task performance multiplied by the rated severity of potential error consequences. In addition, lists of types of errors intrinsic to task requirements were generated. The risk profile and error lists were then used to identify tasks that should be given particular attention for mitigation measures. Human factors engineering evaluations of relatively high-risk tasks identified from the risk profile were not conducted nor were they required for purposes of this study. The purpose was not to make suggestions for the possibility of reducing risk through facility design/equipment enhancements or other risk mitigation methods, but simply to determine the relative risk associated with Gamma Knife operations at the time of the study.

The items of information recorded during the task analysis are explained below. When analyzing a task, only some of the information may be appropriate for some items (e.g., no

"support equipment" is needed to perform a specific task if the task does not require physical equipment).

Task Number

Each task and subtask must be assigned a number. This number identifies the process in which the task/subtask occurs and its position relative to other tasks/subtasks in the process.

Task Description Purpose

This describes what must be done to complete each task or subtask. The task description column should be filled out first since all other columns refer to it.

Support Equipment

Support equipment is any essential item that is required to perform the task.

Task Frequency

In this column, the frequency of task performance is given on a per-patient basis.

Potential Human Errors

This requires documentation of the most likely serious human errors that could be made in regard to an omission of a critical task or improper performance of a task.

A serious error is one that may lead to a potential consequence. Sometimes the consequence of an error depends upon system conditions or other situational factors when the error occurs. For example, medical technicians may forget to check the hydraulic system fluid level before patient treatment. This error would not matter unless the patient is in the device.

There may be many conceivable errors. As a rule, they can usually be limited to three per task that are both likely and serious.

Potential Significant Error Consequences

This is usually an unintended dose of radiation.

Error Probability Rating

This is a judgment made by subject matter experts. The procedure for this internal rating scale is to rank the likelihood of error, relative to all other potential human errors. Nominal values are assigned to the scale definitions as a guide to medical experts and as a mechanism for soliciting and documenting their comments and opinions.

It is stressed that the probability rating should not be viewed as a prediction of event errors, but simply as a relative ranking of the likelihood of the error or failure. The use of this rating is to identify relatively high-risk tasks.

Severity of Consequence

A judgment was made by each medical expert to rank order the severity of the consequences of each type of error. The rating scale was defined based on expert inputs.

Ways to Lessen Risk

This information is used to indicate how the potential for human errors and their consequences can be minimized.

There are four categories to choose from: (1) Equipment (referring to equipment selection/design and workspace design), (2) Procedures, (3) Training, (4) Supervision. One or more may be chosen. The choices indicate where provisions can be made most effectively to assure safe and successful performance of the task.

Training/Knowledge Required to Perform This Task

For this, subject matter experts are requested to determine the elements of knowledge essential to perform each task effectively. Knowledge requirements are broadly defined here to include knowing how to do something (i.e., skill mastery) as well as knowing information and concepts.

Performance Standards

This information is used to identify the criteria for satisfactory task performance. Performance standards should be objective and verifiable. They may be quantitative.

Assess high-risk tasks through relative ranking and profile analysis

Once the tasks are analyzed and selected for errors pertinent to risk, it is possible to identify those tasks associated with the highest risks. Since sufficient quantitative data were available, identification of the highest-risk factors was performed by direct calculation of the risk equation: probability of error times measure of consequence. If quantitative data are substantially lacking, qualitative judgments could have been used to formalize the rankings on a relative basis.

The advantage of a relative ranking scheme is its ability to compare both qualitative and quantitative data. The best method and data available should be used to estimate a likelihood of error or measure of consequence for each risk contributor. There can be a wide variation in the quality of estimation from risk contributor to contributor, but all measures can be compared by means of relative rankings.

In the first-order risk analysis, likely error rates and consequences for each task were treated as independent from other tasks, and were estimated as if they were independent. However, many errors or consequences are mitigated by verification or checking procedures. Such procedures must be adequately reflected in the task list, so that final ranking schemes can incorporate recovery factors. Scenarios involving concatenations of tasks were examined to validate or adjust the rankings for each task to ensure appropriate relative rankings.

The relative likelihood of error and the degree of consequence were estimated by subject matter experts. Evaluations have provided encouraging support for the use of expert judgment (Comer et al. 1983). Experts may be reliable at making relative estimates on limited scales, and relative rankings are reproducible. One may not conclude, however, that the expert judgments have predictive validity, if no true error probabilities are available for comparison or calibration. An advantage of direct numerical estimation is that it can be used to obtain estimates of uncertainty bounds.

Ranking data was collected for each task by asking relevant experts to provide their estimations of error frequencies or likelihoods and error magnitudes (dose deviations) associated with those errors. Experts were asked to make estimates based on their personal knowledge or experience. At this level of analysis, the issue is not how or why errors occurred, but how often errors have in fact occurred. Relative ratings or discrete distributions can be used; continuous distributions are desirable, but not necessary.

Both individuals and teams of experts were asked to numerically estimate error frequencies and error magnitudes for each risk-pertinent task. Data from several sources were assimilated by the project team into discrete error distributions for each task. These, in turn, were reviewed and validated by a medical expert peer review team.

The error likelihood was based on a percentage of patient cases and was applicable to all events and tasks of interest in the Gamma Knife study. Consequences of Gamma Knife errors were rated by the magnitude of error of dose delivered or of the position/volume of the delivered dose. However, the magnitudes of dose and position/volume errors may not be rationally compared, if dose and volume effects are independent. Fortunately, dose and volume radiobiological responses appear to obey power law relationships for volume elements in intracranial radiosurgical treatments. This dependence was exploited to formulate a linear metric of consequences incorporating both dose and position/volume errors in appropriate proportions.

Estimate the importance and uncertainties of high-risk tasks

The discrete error distributions developed for each risk-pertinent task in the Gamma Knife study do not represent true probability distributions in the classical sense. They were based on the experts' actual experiences (of varying degrees) and thus of uncertain probability. Rather, the relative probabilities more accurately represent density functions in the Bayesian sense. In this sense, the attempt was to include all information that is relevant, and such information may be conveyed as a distribution in which height reflects belief and width reflects uncertainty. In the Gamma Knife study, the distributions of error rates were utilized as estimates of the relative probabilities of errors occurring.

The relative rankings of probability of error and magnitude of consequences for each task are aggregated and assimilated to obtain consistency. A critique by an expert peer review team was employed to ensure appropriate and consensual relative rankings.

Relative rankings and error distributions can be used in computerized Monte Carlo simulations. Monte Carlo simulations of risk scenarios can provide a higher level of analysis than the point profiles, because concatenations or interactions among diverse tasks can be simulated and evaluated. Relative measures are sufficient for the Monte Carlo technique, since only weighted stochastic choices are used. The Monte Carlo simulation technique can be used with the error and consequence data to:

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

The Monte Carlo technique can simulate error combinations in a process and provide a statistical evaluation of complicated scenarios.

Often, such simulations expose unexpected combinations among events that would not otherwise be apparent. Thus, additional insights into what is important and why, and whether the input data are adequate to support the insights developed, can be gained from simulations using relative rankings or error distributions (discrete or continuous).

A computerized Monte Carlo simulation can be used to generate distributions representing, for instance, the effects of uncertainty or the propagation of errors, or to perform worst-case/best-case analyses. (However, worst-case/best-case estimates of risk can be misleading in the absence of some valid indicator of how extreme those estimates should be.)

For the risk analysis, Monte Carlo-generated distributions can be used to identify the highest-risk error scenarios, as well as those tasks most likely associated with the highest-risk scenarios.

To evaluate and effectively use risk assessments, it is important to understand how different sources of uncertainty contribute to the overall variability of the risk estimates. Uncertainty may occur in the estimation of variables and result from either natural variations or models that do not accurately reflect the process being investigated.

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. It made full use of the developed error rate and error magnitude distributions and could model the interactions among any number of tasks, logically combining distributions. It was used to aggregate subtasks and their error distributions, determine best- and worst-case extremes, and perform uncertainty and importance analyses.

The Monte Carlo computer code was essentially used as a tool for handling the uncertainties associated with human errors. In general,

estimates of human error probabilities are only good within one to two orders of magnitude. For a new device, there is a limited experience base which can expand the uncertainty. The code was used to model the propagation of uncertainties in the error rate and error magnitude data for each task, resulting in an overall risk uncertainty for a given task.

Logic diagrams were constructed with the primary tasks as contributing events to the top event, a misadministration. This tree consisted of all the primary tasks connected by a logical 'or' operand to the top gate. The probability and consequence distributions of the top event could then be determined by logically combining (union) the distributions associated with each primary task. This approach was found to be nonproductive, since the top distributions were relative values and provided little qualitative insight and no quantitative insight.

Another approach to generating the top event distributions, which was adopted, was to calculate distributions for possible combinations of errors in treatment scenarios and then combine those distributions into the top distribution. This approach again provided no quantitative insight to the risk of misadministration, but offered substantially more qualitative insights. In the process of making such calculations, the highest risk scenarios could be identified, as well as those tasks most often contributing to the high-risk scenarios. This was subsequently used by the team to indicate which tasks were the most significant to risk.

2.3.4 Participation of Medical Community

An objective in this work was to enlist the cooperation and participation of the manufacturer and members of the medical community. The manufacturer, Elekta Instruments, gave 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 safety analyses inspected Gamma Knife units, attended acceptance tests, interviewed users, observed patient treatments, and visited the manufacturing facility.

The visit to the manufacturer was very important, since certain quality aspects of the equipment can only be examined at this facility. Manufacturing practices are essential to the safe operation of the Gamma Knife. They determine and fix, for the life of the machine, the possible limits of accuracy and precision for radiosurgical incisions. The visit allowed an understanding of the design and manufacturing process; component and manufacturing quality control; accuracy measurements; and functional and acceptance testing. Also, the engineers responsible for the development and design of the Gamma Knife, including the implementation and testing of the computerized treatment planning system are located at the manufacturing facilities.

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. Specific review and commentary on this project were provided by (in alphabetical order) Dr. Brian Copcutt, Richard Grome, Martin Knotts, Dr. David Larson, Dr. John Lyman, Dr. Michael Schell.

3. REVIEW OF THE GAMMA KNIFE

3.1 Equipment and Facility

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 7000 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 Gamma Knife is pictured in Figure 3-1, and its major components are illustrated in Figures 3-2 through 3-4. The radiation unit has 201 cobalt-60 sources that are arranged in a large, heavily shielded sphere (18,000 kg) (see Figure 3-1 and 3-2). 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 cause the irradiation beams to converge 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.

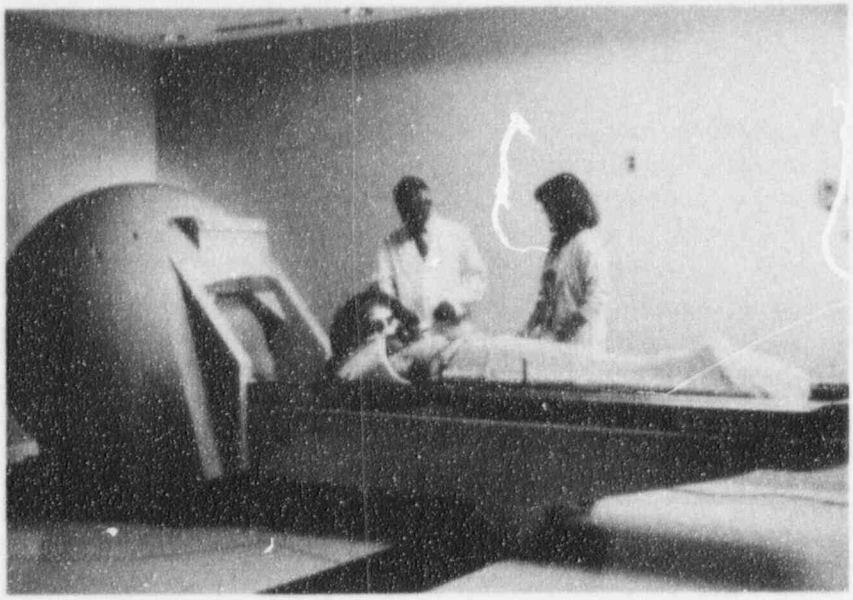


Figure 3-1. The Gamma Knife

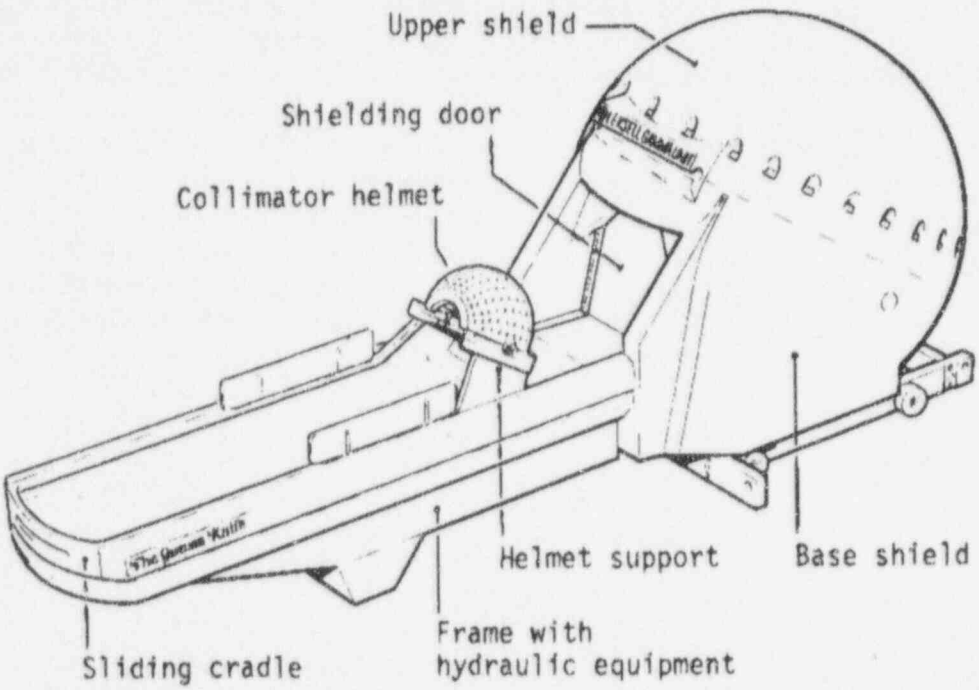


Figure 3-2. Major components of the Gamma Unit
(Adapted from materials supplied by Elekta Instruments)

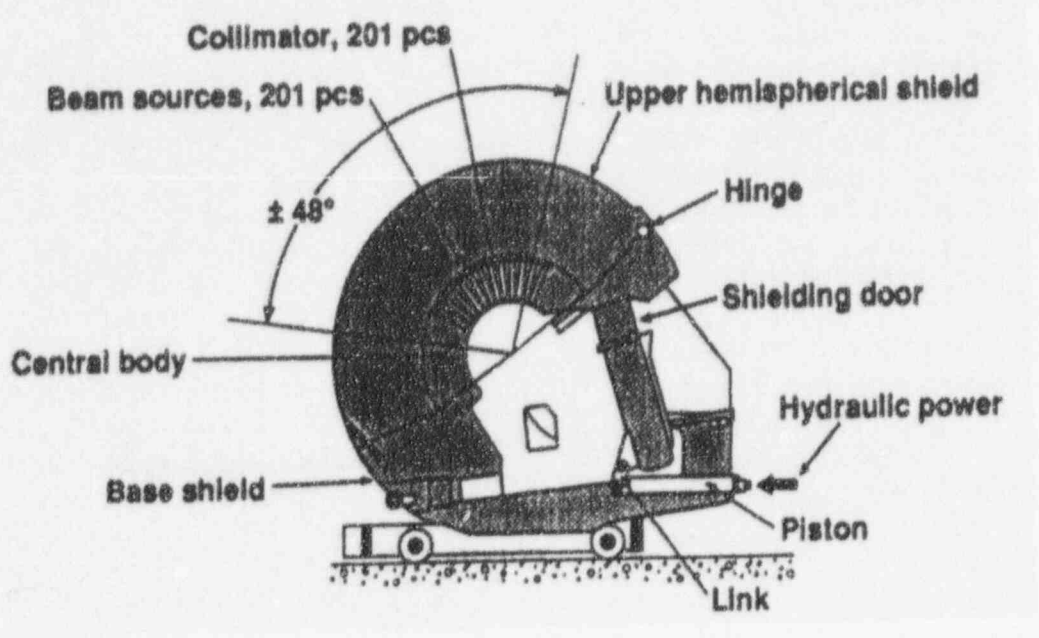


Figure 3-3. Major components of the radiation unit
(Adapted from materials supplied by Elekta Instruments)

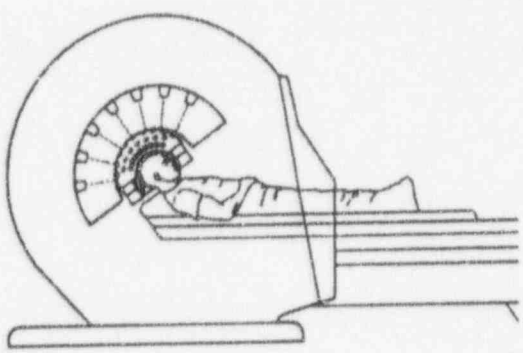


Figure 3-4. Schematic of the Gamma Knife treatment position
(Adapted from materials supplied by Elekta Instruments)

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.

A typical Gamma Knife facility or suite (Figure 3-5) 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 used only for Gamma Knife source loadings and treatments. 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. Normal operations constitute a maximum workload of two patients per day, five days per week. The control console is usually placed just outside the treatment room door to provide easy access to the treatment room and the hydraulic room. The control console is equipped with two separate event counters 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.

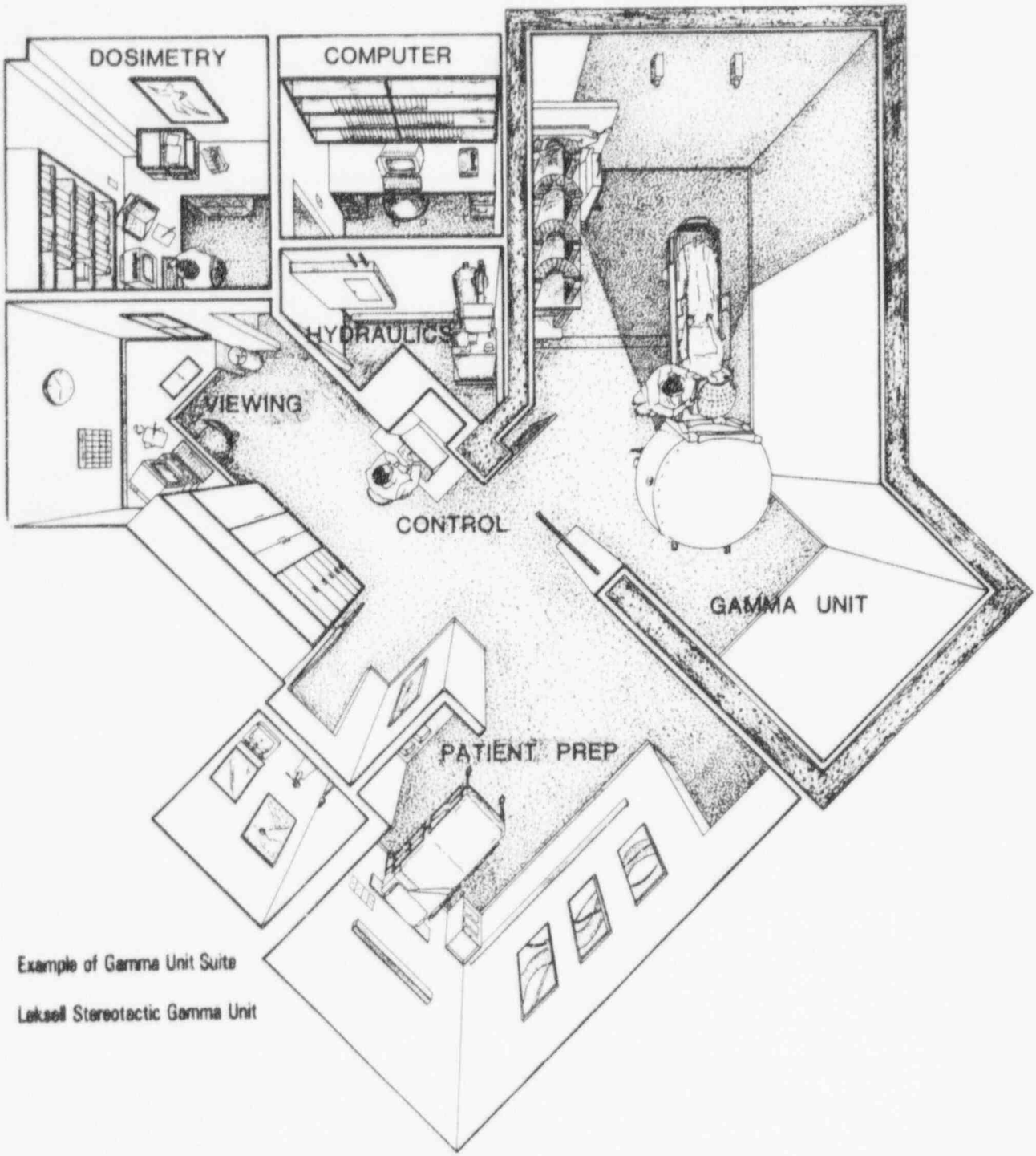


Figure 3-5. A typical Gamma Knife suite or treatment facility

3.2 Treatment Process

The Gamma Knife treatment process utilizes resources and facilities under the control of different hospital departments. Gamma Knife medical teams consist of a neurosurgeon, radiation oncologist, medical physicist, and a radiotherapy technician or a registered nurse. The team is usually a dedicated team, with authorized substitutions when necessary. Some facilities have more than one team. Attachment of the stereotactic frame to the patient's skull is performed by the neurosurgeon. Radiological images are taken in the CT, MRI, and angiography facilities. The Gamma Knife facility itself may be under the control of neurosurgery or radiation oncology or both, while personnel from medical physics perform quality assurance on the gamma unit and the treatment planning equipment. In consultation with the NRC, it was decided that organizational reliability issues were beyond the scope of the study.

Flow diagrams of the major Gamma Knife treatment activities are displayed in Figures 3-6 to 3-9. The process steps used by different facilities were very similar. The Gamma Knife treatment process is well-defined and includes a series of steps that have to be done in the correct order. The treatment procedure consists of three phases: imaging and localization of lesion; treatment planning; and patient positioning and treatment. A single treatment may include several Gamma Knife "shots." Each shot corresponds to a set of patient positioning, dose profile, and time parameters. The shot parameters are selected during the treatment planning process so that their superposition or aggregated effects meet the desired treatment plan of the medical team.

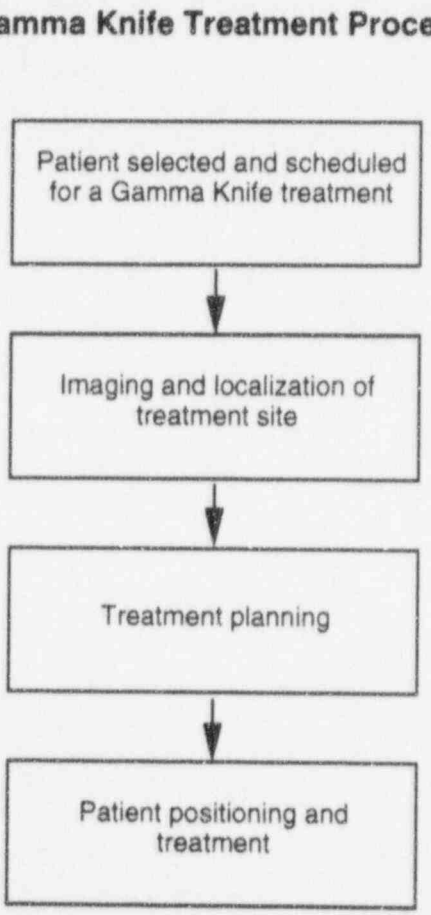


Figure 3-6. Flow diagram of major Gamma Knife treatment activities

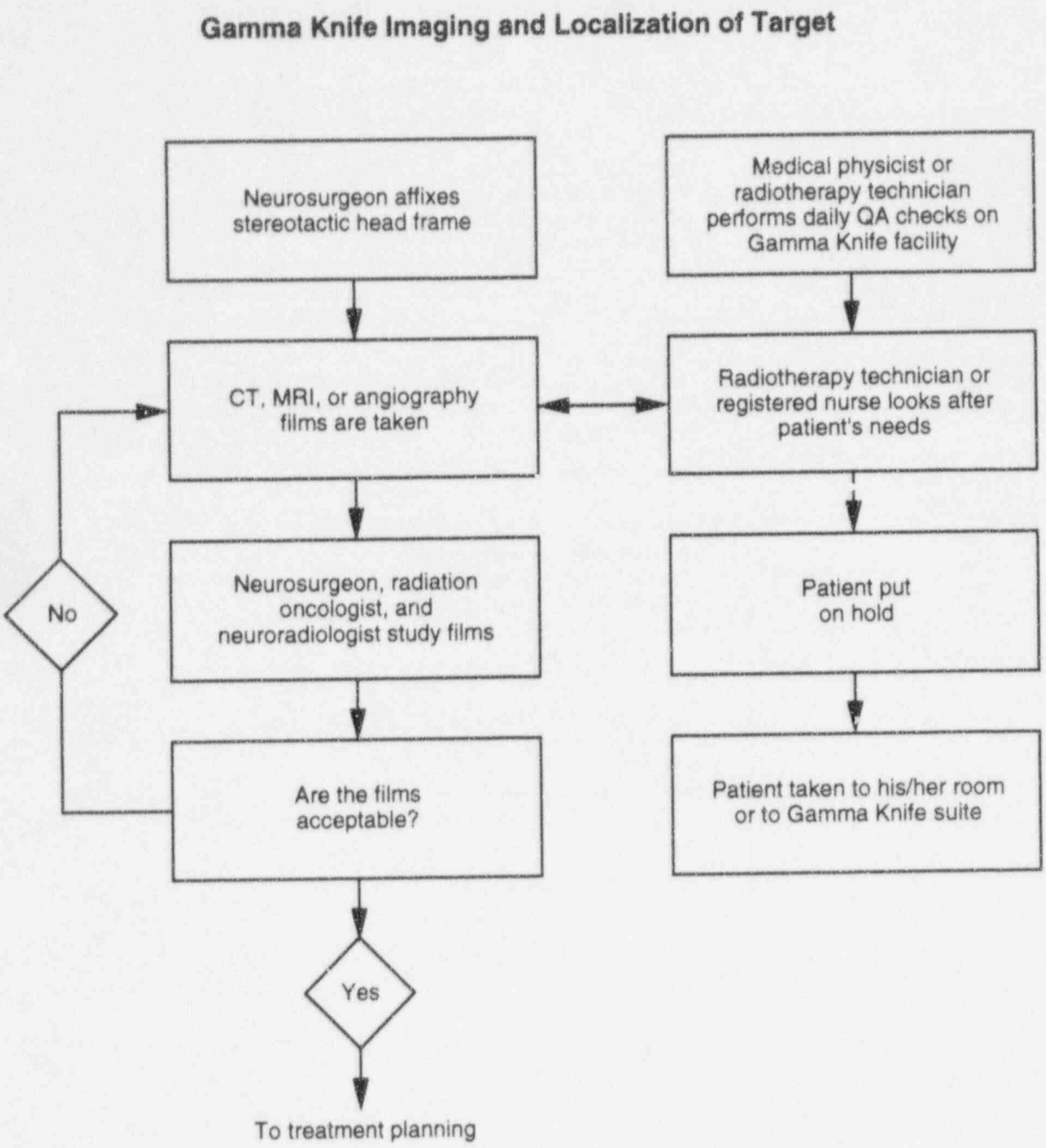


Figure 3-7. Flow diagram of major activities during Gamma Knife target imaging and localization

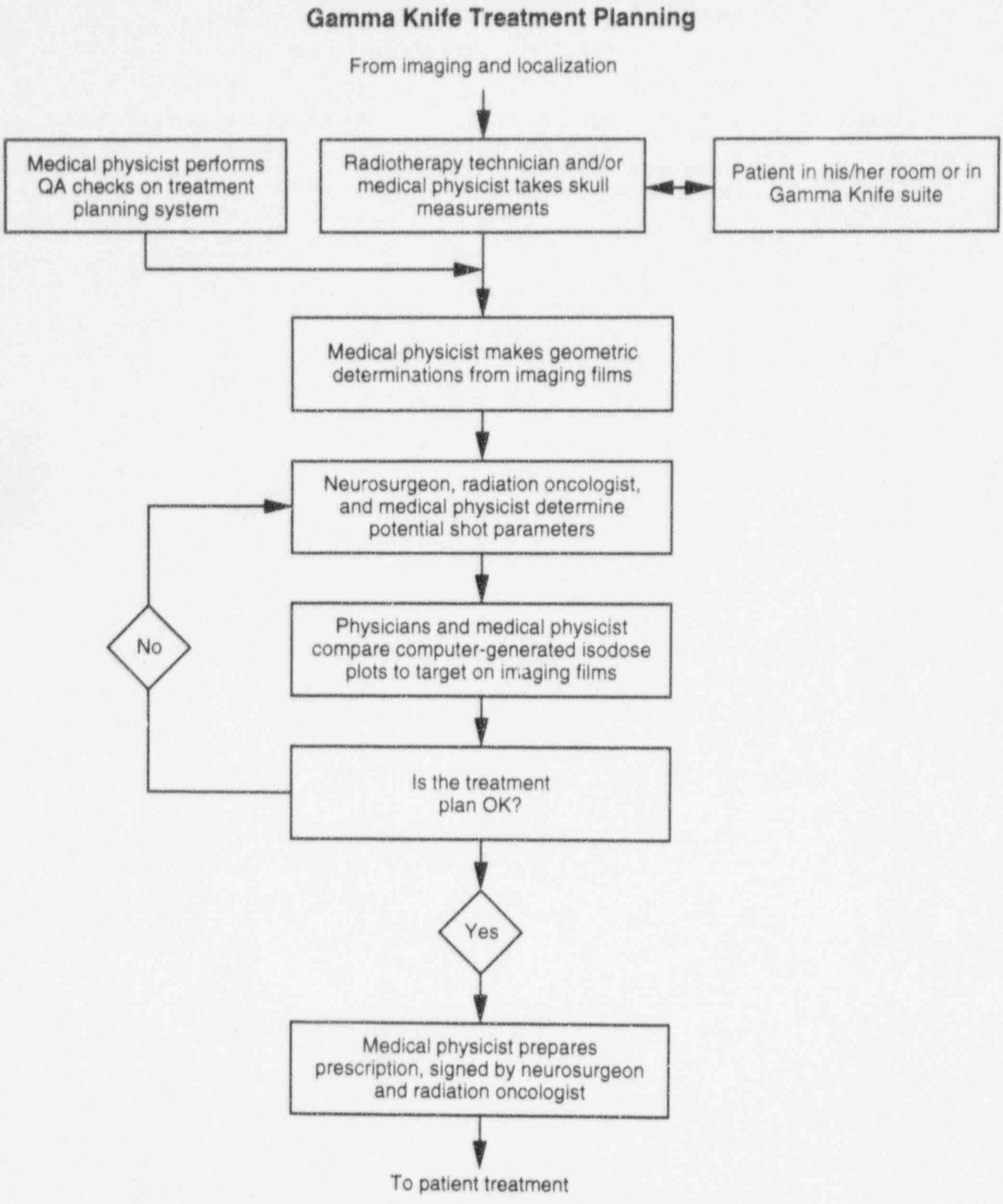


Figure 3-8. Flow diagram of major activities during Gamma Knife treatment planning

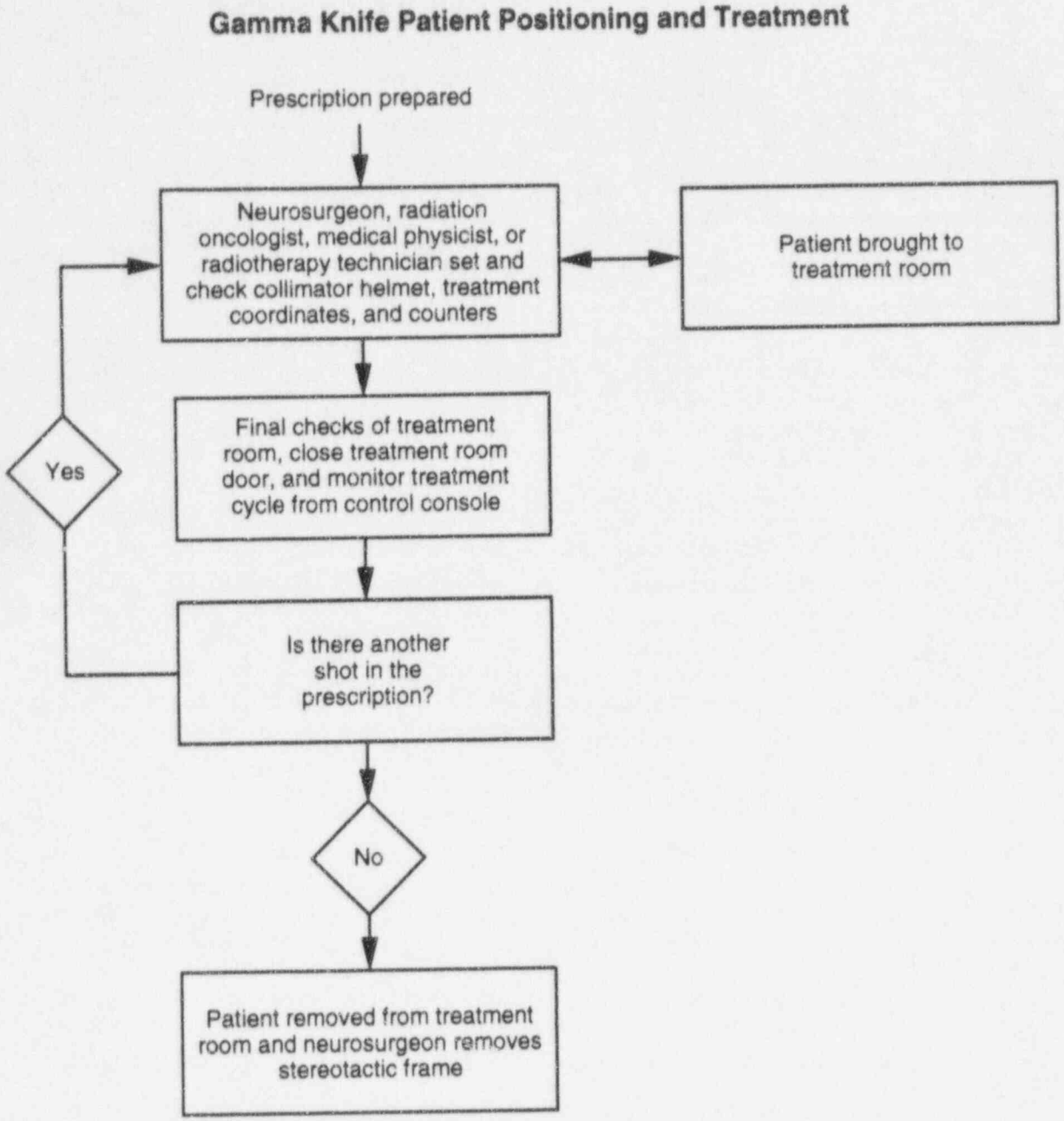


Figure 3-9. Flow diagram of major activities during Gamma Knife treatment session

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 contributing to the treatment are determined. Multiple shots are often needed in a single treatment to irradiate lesions either too large to cover with a single shot or sufficiently irregular in their geometry to require a combination of various-sized isocenters. The proposed shots, i.e., the coordinates, collimator sizes, gamma angles (defined as the angle of the patient's head with respect to the frame), and required dose are entered into the computerized treatment planning system 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.

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.

The patient lays on a treatment table during treatment with the stereotactic frame attached by trannions to the 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 hydraulic fluid reservoir provides sufficient pressure to release the treatment table so that it exits the radiation unit and closes the shielding door.

All personnel leave the patient in the treatment room and engage the door interlock. The treatment procedure begins by setting the counters 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 counters 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.

In Section 4.1, more detailed observations are described within each treatment step.

4. IDENTIFICATION OF POTENTIAL RISK CONTRIBUTORS

This section reviews salient observations from the data collection. The observations reviewed center on equipment failure modes, human mistakes, and procedures and activities that may mitigate the impacts of potential risk elements.

4.1 Discussion of Observations

The Gamma Knife and its treatment process are reviewed in Section 3.0. The subsections below summarize information gathered regarding steps in the Gamma Knife treatment planning process. The included information is germane to the preliminary selection by the project team of risk-pertinent tasks and equipment failure modes. The preliminary list of treatment tasks is provided in Table 4-1, and task data is contained in Appendix A. A list of the selected abnormal operating modes is contained in Table 4-2.

4.1.1 Patient Identification

The Gamma Knife patient must be correctly identified at least four times during the treatment process: before the stereotactic frame is affixed to the patient's head; before treatment planning to ensure the correct imaging films are used; before skull measurements are taken from the patient; and to confirm the correct prescription or treatment plan for the patient before positioning the patient for treatment. Members of the Gamma Knife team use at least two methods to identify the patient, and those methods are facility specific.

The correct identification of the patient is enhanced by the fact that the patient is a constant companion to the treatment process, which is normally completed in less than a day. Though sometimes two patients are treated in one day, it is common for only one patient to be treated per day. Thus, the Gamma Knife team is very aware of the patient and the patient's records.

If two patients are treated in the same day, there may be parallel activities, and some of the records and data can be confused. For instance, both patients could have their lesions imaged in the morning, and both sets of films are sent to the Gamma Knife suite. A member of the team might begin treatment planning using the data for one patient while the other is scheduled to be treated first.

4.1.2 Stereotactic Head Frame

The stereotactic frame consists of a base ring with four vertical posts, two frontal and two occipital. The base ring is engraved with scales used for setting coordinates and making measurements from CT, MRI, and angiography images. The frame's design is coordinated with the collimator helmet design so that the patient can be positioned in the Gamma Knife unit by attaching the frame to the helmet.

The frame is affixed to the patient by four pins inserted through the vertical posts and screwed into the patient's skull. The affixed frame defines the Gamma Knife reference coordinate system used throughout the operative procedure: once the frame is properly attached, it is not removed until the treatment is completed. The orthogonal coordinate system consists of the patient's right-left coordinate (x), posterior-anterior coordinate (y), and cephalad-caudad or axial coordinate (z). The origin of the coordinate system is at the patient's back, upper, right.

The stereotactic frame is attached to center the lesion, as much as is possible, within the frame coordinate system. This helps to position the patient later within the Gamma Knife unit and reduce the chance of errors associated with extreme coordinate values. However, medical considerations of the neurosurgeon override such mechanical concerns, and how the frame is affixed is a medical judgment.

To ensure that the coordinate system is orthogonal, the integrity or "squareness" of the frame should be verified, e.g., by properly tightening screws holding together the machined pieces of the frame. Since the coordinates determined by the fixation of the frame must remain constant throughout imaging, treatment planning, and treatment, the frame is checked for movement during the operative procedure. If the

frame is seen to shift, or comes off, then the frame must be re-affixed and the treatment process begun again. Such major shifts are possible since the patient has the frame on for several hours, and in some cases overnight if the treatment is extended from one day to the next.

4.1.3 CT, MRI, and Angiography Imaging

Once the stereotactic head frame is attached to the skull, the Gamma Knife team must locate the lesion to be treated within the frame's coordinate system. The Gamma Knife comes with CT, MRI, and angiography localizer or indicator boxes that attach to the stereotactic head frame and provide reference fiducials for localization of images. Angiography is used for AVMs, while CT and MRI are used for tumors and other lesions. (CT and MRI images of AVMs are sometimes made to provide complementary information to angiography.)

The indicator box fiducials are used to determine the lesion position within the Gamma Knife coordinate system. Thus, the indicator boxes must be orthogonal when attached to the stereotactic frame. This is accomplished by adjusting screws on the box adapter. Also, in setting up for imaging, the patient must be correctly aligned with respect to the imager. The axial coordinate should be parallel to the imager base with the patient level, not angled. The patient's head movement has to be restricted so as not to disturb the alignment with the imager. No document or checklist for these set-up procedures was observed.

CT and MRI image slices are taken in the sagittal, coronal, or axial planes. Preliminary scans for gross localization of the lesion are usually at 5 mm slice resolution; for imaging the lesion itself, 1.5 mm resolution is common. The magnification factor of the CT or MRI imager is machine specific and is provided by the computerized display. Lateral and frontal angiography images are used to locate AVMs. The geometry of the angiography set-up determines the magnification factor of the images.

The films obtained for treatment planning are labeled with all pertinent information. This includes patient identification, film orientations (coordinate plane), fiducials, CT/MRI and angiography coordinates, and magnification factors. The CT and MRI computerized display systems can provide this information directly on the films, but it should be checked. Labeling of the angiography films is mostly manual and is very important with respect to distinguishing frontal from lateral views as well as patient's left from right. The older Gamma Knife X-ray indicator boxes have an extra fiducial to distinguish left from right. The newer boxes do not have such a fiducial but can only be attached to the head frame in one way. It is also important to record the geometry of the angiography set-up so that the magnification factor can be properly calculated.

The reliability of the computerized imager systems was not investigated. Computer and software reliability and safety is an involved issue and was beyond the scope of this project.

4.1.4 Determine Lesion

Once acceptable imaging films are obtained, the neurosurgeon, neuroradiologist, or radiation oncologist determine and mark (with a lead or wax pencil) the outline of the lesion on orthogonal images. This is based on medical judgment. Subsequent treatment planning involves determining how to deliver a dose to this selected volume.

4.1.5 CT, MRI Film Center

The computerized CT and MRI imaging systems can be used to deposit a mark in the center of the CT/MRI image. The CT/MRI coordinates of this center mark are also provided. This center serves as a convenient reference point from which to measure the lesion position, especially if the lesion has been placed near the center of the stereotactic frame. The center CT/MRI coordinates are transformed into Gamma Knife coordinates, and hence any measurements from that center position are expressed in Gamma Knife coordinates. Thus, the use of a center mark greatly reduces the number of coordinate

transformation calculations and, subsequently, chances for error.

On the other hand, if a mistake is made in determining the center coordinates, the error can propagate to subsequent measurements made relative to that center. Thus, the medical physicist checks the center deposited by the CT/MRI computerized system by drawing lines connecting diagonal fiducials or by manually measuring fiducial distances. This serves as a check on the orthogonality of the indicators and any computer-based distortions.

There are some inherent sources of uncertainty in performing this center check. The center may shift infinitesimally from image slice to slice. The fiducial distances may not be even exact from image to image. The checker might use the wrong fiducial in cases where an extra left-right fiducial is provided. Also, the checker may not always be consistent in using the center of the fiducial images from which lines are drawn or measurements are taken.

Center marks on angiography films are determined manually by using fiducials and images of the engraved scales from the X-ray indicator box system. These determinations are subject to the same mistakes as for CT/MRI.

4.1.6 Initial Selection of Shots

Before beginning the treatment planning process, the neurosurgeon, radiation oncologist, or medical physicist will mark some initial shot positions on the films, based on experience and medical judgment. This will enable the initiation of the iterative treatment planning process.

4.1.7 Treatment Simulation

Sometimes the patient, with affixed stereotactic frame, is taken to the Gamma Knife treatment facility to simulate a treatment before treatment planning is completed. This is done especially if the lesion is in a position that may require some extreme coordinate settings.

The patient is placed on the sliding couch with the head and frame inside the collimating helmet. The potential range of lesion coordinates is checked for accessibility. It is determined whether the patient can be treated in the prone or supine position. The supine position is preferred, but if the lesion is in the direction of the lower back of the head, it may be best to treat with the patient in the prone position. Approximately 15% of treatments are in the prone position. The best gamma angle (see 4.1.11) is selected for shot accessibility and patient comfort. Also, the possible transmission of radiation into the patient's eyes or lenses is checked, by passing a flashlight over the outside of the helmet while the patient is fixed inside. Any offending collimators can be removed and replaced with collimator plugs. If there are more than a few (5 - 10) plugs used to protect the lenses, the Gamma Knife team may perform manual or computer calculations to reckon the effects of the plugs (each collimator corresponds to 0.5% of the total transmitted radiation).

4.1.8 Treatment Planning Equipment

The treatment planning equipment consists of a dose planning computer and software called Kula, a plotter for printing isodose plots, and film digitizing equipment. Some sites also have separate and supplementary software to perform target volume calculations (see 4.1.14). (Elekta instruments has recently introduced a new three-dimensional, computerized treatment planning system called GammaPlan, a registered trademark of Elekta Instruments, Inc. Facilities visited during the study were not using GammaPlan, so no consideration of this treatment planning system was made.)

Treatment day checks of the planning equipment are made by the medical physicist or radiotherapy technician or both. A computer point dose calculation is made to check the current dose rate from the computer with a table generated manually using yearly and monthly calibration data and the decay law. The plotter integrity is checked (given that the computer dose calculation is accurate) by plotting a simple computer isodose curve calculation and comparing it to a standard profile of the same calculation. The digitizer accuracy and linearity is evaluated by making some simple geometric determinations from imaging films using the digitizer and comparing the results to manual

determinations of the same geometric measures. There should be independent verifications of each of these checks.

4.1.9 Treatment Planning Software

The Gamma Knife comes with a custom treatment planning computer program named Kula. (Elekta now also supplies a treatment planning code, called GammaPlan, which can use computer based, three-dimensional images. This system was not in use during the data collection activities.) Kula runs on a dedicated VAX computer, i.e., the computer is only used to run Kula and no other software. The treatment planning system is kept in the Gamma Knife suite. Access to the code is controlled by use of a password, and the correct date must be entered to initiate the program. The correct date is required to ensure the use of the current dose rate of the Cobalt-60 sources. Also, if the correct date is entered and the program doesn't respond positively, there may be a problem with the computer clock or the program.

A patient data file must be created to perform treatment planning. The patient data file will eventually contain all pertinent information required to generate a treatment plan or prescription. This information includes patient name, patient identification number, skull measurements, gamma angle, dose matrix parameters and calculation mode, and shot parameters (coordinates, time weightings, collimators, plug patterns, and total dose). Only one patient file can be open at a time. If a patient file is closed, it can only be opened by typing the exact name in the data file. If there is more than one file for that exact patient name, then the latest created file will be opened by default. So, to have more than one file accessible for each patient requires a different patient name for that patient on each file. This practice may lead to confusion about which file to use for the prescription generation. Kula has a menu that allows the user to check any contents of the data file at any time during treatment planning. This provides an opportunity to verify data and inputs and recover from any errors.

Typical checks on the program, as mentioned in 4.1.8, are to run dose calculations that can be checked manually against standards. Kula has two modes for calculating dose profiles. The cut-and-modify method is an approximation algorithm which interpolates between intervals in the dose matrix. The exact calculation mode runs slower than the cut-and modify mode. There can be a difference in the dose calculation between the two modes by as much as 7%, depending on the size of the dose matrix. The dose algorithm in Kula has an idiosyncrasy that can cause a calculational blow-up for lesions near the skull boundary. This blow-up prevents the completion of the dose calculation. It can be avoided by re-defining the dose matrix near the skull boundary.

Software reliability is a significant issue in dose calculation: software errors can have very serious consequences to patients. This project was not scoped to analyze the software reliability of Kula. The Kula software, as part of the Gamma Knife medical device, is approved for sale by the FDA. The FDA has review guidelines for computer software used with medical devices.

4.1.10 Skull Measurements

The skull geometry, in Gamma Knife coordinates, needs to be assessed for the Kula dose calculation to properly account for attenuation of radiation between the skull and the target. There is an attenuation of about 5% per centimeter of brain tissue.

The Gamma Knife system includes a Plexiglas hemisphere or 'bubble" which attaches to the stereotactic frame. The attached hemisphere provides a reference surface, in Gamma Knife coordinates, to determine a set of distances between the bubble exterior and the outside of the skull. This set of distances defines the dimensions of the skull geometry for purposes of calculating the attenuation of radiation between the skull and the target lesion. The bubble is attached to the affixed stereotactic frame of the correctly identified patient. The bubble must be attached correctly, flush with the stereotactic frame. The bubble fits only one way on the

frame and assumes a supine treatment position. Thus, the skull data taken with this bubble needs to be transformed (manually) if the patient is to be treated in the prone position, so as not to have an incorrect orientation of the skull relative to the gamma sources.

The bubble contains 24 holes through which a scaled measuring stick ("dip-stick") is inserted to determine the set of distances between the bubble exterior and the outside of the skull. There appears to be a natural variance of plus or minus 3–4 mm in the bubble measurements. Errors can occur due to a mis-read of the measurement scale or by not holding the measuring stick orthogonal to the skull. The data are collected on a paper form. The data are usually verified by a second person.

For entering the skull data into Kula, the program, when requested, presents a template, similar to the paper data form, on the computer screen. The data are then entered manually using the keyboard, usually by the medical physicist. The person entering the data often does a self-check of the entered data, although some teams require an independent check. This information on the skull geometry becomes a part of the patient data file. Given this data, Kula can generate a skull profile to allow a check on the reasonableness of the measurements. If a measurement is grossly wrong or there has been a transposition of data, the skull profile will look odd and the data will be re-examined.

4.1.11 The Gamma Angle

The gamma angle is the angle at which the positive y-axis (posterior-anterior) of the stereotactic frame meets with the central axis beam of the Gamma Knife. It is selected for patient comfort and fit, depending on the location of the lesion, prior to treatment planning. The gamma angle is not a significant source of potential error compared to the isocenter coordinate settings, but it is usually double-checked.

The gamma angle influences the position of the isodose lines at the target, and hence, to first order, the dose at a point, and secondly, the volume treated. The influence of the gamma angle is inversely proportional to the number of shots in a treatment session.

Sometimes the gamma angle is changed during a treatment session—which can have multiple shots—to accommodate a patient's needs. In such cases, the treatment plan should be recalculated, with adjustments made for shots already administered.

4.1.12 Geometric Determinations From Films

Kula requires shot or isocenter positions to be in Gamma Knife x-, y-, and z-coordinates for treatment planning (see 4.1.16). This in turn requires geometric information from the imaging films to ensure that measurements in the localization indicator's coordinate system are properly translated to Gamma Knife coordinates.

Of primary importance is that the films are not reversed or the right and left are not confused. Also, the magnification factor depends on the imaging system arrangement and must be consistent with the film orientations. The CT and MRI computerized systems can provide a distinguishing mark on the films, but if this was neglected, the orientation should be verified. Some hospitals use more than one angiography set-up for taking images for the Gamma Knife. The left-right orientation of the camera or the magnification factor may differ among angiography, CT, and MRI systems. The films are marked to indicate film orientation and set-up geometry. Older Gamma Knife X-ray indicator boxes have a left-right distinguishing fiducial, but the newer boxes do not.

The CT and MRI computerized systems provide the user with the magnification factor and can be marked on the image. The magnification factor of the angiography images is determined by means of a calculation requiring parameter values from the imaging set up and measurements of the imaged indicator scales. Errors associated with such determinations include manual or digitizer measuring errors, misreading of film markings, using the wrong

fiducial, and not consistently using the fiducial centers.

CT/MRI image slices used for treatment planning are usually taken in one plane (e.g., the x-y plane) so that the value of the coordinate in the direction perpendicular or axial to the imaging plane (e.g., the z-coordinate) is determined from the slice resolution value. The translation of the CT/MRI image axial coordinate into the corresponding Gamma Knife coordinate requires the proper use of the magnification factor and a coordinate system origin transfer factor (since the origin of the CT/MRI coordinate system is not the origin of the Gamma Knife coordinate system).

For determination of image centers, see section 4.1.5.

4.1.13 Computerized Dose Calculations

To perform a dose calculation with Kula, the user needs to specify a dose matrix, in which the dose calculation is made, about the lesion of interest. This specification includes correctly entering the Gamma Knife coordinates of the center of the square matrix (as marked on the imaging film) and its dimension. The user can also specify a reference absolute dose or, as is common, use Kula's default value. The value of the absolute dose does not matter for calculating the geometry of the isodose lines. The treatment dose is usually selected after an acceptable isodose configuration is developed in the treatment planning process. But Kula requires some dose value to generate isodose curves.

As mentioned in 4.1.9, Kula has two modes for calculating dose profiles. The dose calculation algorithm divides the dose matrix into 31x31x31 bins, regardless of the matrix dimension, and interpolates between bins. The algorithm thus is less accurate the larger the dose matrix. The cut-and-modify mode is an approximation algorithm that interpolates between every third bin. The exact calculation mode interpolates between every bin and runs much slower than the cut-and-modify mode. Most treatment planners use the cut-and-modify mode to speed the treatment planning process along. The exact method is usually utilized to produce the final treatment plan. There can be a difference in the dose calculation between the two modes by as much as 7%, depending on the size of the dose matrix. The user can make a comparison by performing a point dose calculation within the dose matrix using both modes. A rule of thumb is that if these point calculations differ by 5% or more, use the exact mode.

In Kula, the user selects the dose calculation mode by changing a parameter value in the Kula initialization file. There is no indication to the user of which calculational mode Kula is in except by checking the parameter in the initialization file. Since this is an initialization parameter, it does not return to a default value when the program is terminated. Thus, the user may think Kula is in the exact mode, because that is what was used last time, but the parameter may have been changed in the interim. The user also must not get confused about which parameter value (1 or 0) corresponds to which mode. The Kula initialization file is an ASCII file that contains all the Kula program parameters. If the user, in selecting a calculation mode, changes one character of the initialization file incorrectly, then the file is corrupted and the consequences of all subsequent calculations could be severe. This is an unfortunate arrangement. GammaPlan obviates these difficulties by always using the exact mode algorithm with a faster processor.

4.1.14 Target Volume

Some treatment planners use separate and supplementary software to make target volume calculations based on measurements (digital or manual) of the lesion boundaries from the imaging films. The target volumes help the physicians determine the prescribed dose, based on considerations of dose-volume formulae or histograms.

4.1.15 Isocenter Determinations

The treatment planners mark shot positions or isocenters on the imaging films in iterative attempts to select the best combination of isocenters to treat the lesion. (The shot locations

are usually marked with a lead pencil.) The Gamma Knife coordinates of these isocenters have to be determined from the films and entered into Kula to perform isodose calculations. Errors in this process include making measurement errors and switching coordinates. The possibility of transposing coordinates is enhanced if orthogonal films are used to determine the coordinates; you have to ensure that you are extracting the correct coordinate from the correct planar image. The coordinate determinations are independently checked, especially before the final prescription is generated.

4.1.16 Shot Parameters

Kula shot parameter values needed to make isodose curve calculations are the isocenter coordinates (Gamma Knife x, y, and z), gamma angle, collimator sizes, collimator plugging patterns, and the shot superposition and weighting factors. The isocenter coordinates are discussed in 4.1.15. For each shot, the collimator size or helmet (4 mm, 8 mm, 14 mm, or 18 mm) must be specified. Also, any plug pattern for each shot is designated. Kula has a utility that allows the user to design or enter a plug pattern and give that pattern a label. This pattern is then specified by designating its label. Kula permits the treatment planner to make dose calculations from a subset of shots in a treatment plan. This is often helpful to the treatment planners: it allows sensitivity studies of the plan. The subset selection is made by changing the weighting factors for the shots. Kula gives each shot a default weighting factor of one. If a shot is to be excluded from the shot superposition pattern, its weighting factor can be set to zero, or another plan can be established using only the subset of shots. The weighting factors for each shot can be varied (from 0 to 1) to change the contribution of each shot to the overall dose profile. The weighting factors are reflected in the time for each shot in the treatment plan. All these parameters should be carefully checked upon entry into Kula, especially before the final treatment plan is generated.

4.1.17 Plot Isodose Curves

Kula can plot, on screen and using the plotter, the isodose lines resulting from a dose profile calculation. Plots using the plotter are made on acetate so the isodose curves can be overlaid on the imaging films for comparison to the lesion. To make such isodose plots, the user must specify the coordinate plane intersecting the dose profile; the isodose (dose percent) lines to be plotted; and the scaling factor of the plot. The scaling factor should conform to the magnification factor of the images relative to the standard Gamma Knife coordinate frame size. If the scaling factor and magnification factors don't conform, an incorrect dose profile may be delivered to the patient. The planner can also select the degree of labeling information on the plot. If the *de minimus* labeling option is selected, the chance of confusing overlays with images is enhanced.

4.1.18 Verification of Treatment Plan

Treatment plans are evaluated and verified by overlaying acetate isodose plots on the film images. It is obviously important to superimpose the correct plot over the correct image. The coordinate plane of the plot must match that of the image and the axial coordinates must be the same. Also, the isodose plots for the current shot selection must be used, as well as the correct imaging film, i.e., CT versus MRI. This last statement may seem trivial, but it reflects the fact that the treatment planning process usually requires several iterative steps of trial and error. In this process, many images are utilized and several more plots are generated. The treatment planners do not always manage all this information in a systematic way (they can be messy) and it isn't too difficult to get confused about which plot goes where.

Assuming the correct plot is used for the correct image, the plot must be overlaid correctly on the image. This involves superimposing the center mark of the dose matrix, printed on the plot, with the mark of the center of the dose matrix on the imaging film. The center mark of the dose matrix on the imaging film can be confused with shot position marks, resulting in a gross

misalignment of the dose profile. A minor misalignment of the dose profile can occur, if the superposition of the two dose matrix center marks is correct but one is not careful to properly match the marks (which are usually a + sign).

The overlays must be constantly checked as correct, especially for the plan that is accepted for treatment.

4.1.19 Prescription Preparation

Once a treatment plan is accepted, the treatment data or prescription is generated by Kula. The final treatment plan should be the last plan in the patient's data file, and all its parameter values should be correct. The physicians choose a dose for the treatment, and this must be correctly entered into the prescription template on the computer. The user can also select the mode in which the prescription is presented: either by shot number or by collimator size, with more than one shot for a collimator ordered by treatment time.

Kula produces a printout of the prescription which should be checked in all its particulars. The prescription contains the patient name, patient identification number, dose, gamma angle, shot number, x, y, and z shot coordinates, shot time, collimator size, and plug pattern, if any (about 90% of treatments are unplugged). If the patient is to be treated in the prone position, the default supine shot coordinates have to be transformed outside of Kula and rewritten on the prescription form. This requires a correct calculation, a correct transposition of coordinates, and a correct transcription.

Once the prescription is deemed verified, it is signed by at least two authorized users.

4.1.20 Treatment System Quality Assurance Checks

On the day of and before a treatment, the Gamma Knife systems within the treatment facility are checked by the medical physicist, radiotherapy technician, or both. These daily checks augment monthly, semi-annual, and annual quality assurance activities (which are described in a separate report on the quality assurance for Gamma Knives). Typical daily quality assurance activities consist of:

1. A visual inspection of the hydraulic room, console area, and treatment room. These are to ensure all necessary equipment is present. Hydraulic fluid on the floor may indicate a leak that can lead to underpressurization of the gamma unit.

2. The gamma unit power is turned on as are the video monitors.

3. With an active survey meter in hand, a radiation check source is taken into the treatment room and placed on the radiation monitors to verify in-room flashing. While in the room the unit is inspected and verified all right for treatment. The shielding cover at the rear of the helmet is opened, thereby breaking a safety interlock and simulating a condition for no treatment.

4. The treatment room is exited and it is verified no one is in the treatment room. Then at the control console several checks are made. These include verification of the alarm of the remote radiation monitor; setting and re-setting of counters; lamp tests; verification of "cover open" light and an attempt at treatment start which should fail, since a safety interlock was interrupted in step 3.

5. The treatment room is re-entered to close the rear helmet shielding cover (connecting a safety interlock) and to remove the radiation check source.

6. The treatment room is exited and verified empty of personnel. The counters are set (usually to a minute) and the treatment cycle initiated. With the treatment couch in motion, the emergency interrupt button is pushed to verify that the couch freezes in place until the interrupt is released and the treatment cycle is continued. When the unit is in the treatment position, the "treatment yes" light should be on. The treatment stop button then is tested to

verify that the treatment terminates and the couch is withdrawn to a safe position.

7. The treatment door interlock system is tested by opening the door and trying to initiate treatment.

8. Finally, the counters are set for a short treatment and a proper treatment cycle and completion (without interruption) is verified.

9. The proper functions of the communication and visual systems are verified.

10. Also the daily quality assurance protocol for the computerized treatment planning system Kula is run and verified (see 4.1.8 and 4.1.9).

4.1.21 Collimator Helmets

The interchangeable four-collimator helmets are heavy and require a specially designed, manually pneumatic hoist to move them from the gamma unit to their holding table and vice versa. The hoist lifts or lowers the helmets and moves on the floor. The treatment room floor is constructed as flat as possible to not hinder movement of the helmet hoist. The earlier hoist models, loaded with a helmet, are top heavy and require at least two people to stop toppling of the hoist. The newer models are easier for one person to handle. Before a retrofit, the older hoist helmet fixtures had a tendency to break off electrical connections at the back of the treatment couch helmet support when a helmet was lowered onto the support with the hoist. Treatment can not begin if those electrical connections are not sound.

Each helmet has two microswitches, one on each side of the helmet, to verify the proper mating of the helmet with the internal collimator in the treatment position. The microswitches have to be adjusted within a 0.1 mm tolerance of a perfect mating. If this tolerance is not met, the switches aren't activated during mating of the collimators, and the treatment couch is automatically withdrawn from the radiation unit. The Gamma Knife comes with a special tool to adjust the microswitches. If a switch is adjusted too low, it won't be activated at mating. If a switch is adjusted too high, it may be broken off during mating.

A helmet is selected, according to the prescription, and properly placed on the gamma unit before a patient can be positioned inside the helmet for a treatment shot. Each helmet is identified by an imprinted mark and by the size of the collimators. Practitioners usually try to minimize the number of helmet handlings, so they arrange the order of shots by collimator size. There can be confusion of helmets with shots if the prescription is not simply ordered. Also, one may mis-identify a helmet.

If a particular shot includes a plugging pattern, the pattern has to be formed on the appropriate helmet by replacing the removable tungsten collimators with tungsten plugs. The pattern is usually provided by a printout from the Kula utility for designing pluggings. The pattern is made before the patient is positioned and should be carefully and independently checked. All the plugs should also be checked to ensure they are properly seated; if not, they can become dislodged or broken while entering the radiation unit.

4.1.22 Patient Positioning for Treatment

For a treatment shot, the patient, with affixed stereotactic frame, is placed on the treatment couch and inside the appropriate collimating helmet on the gamma unit. The head frame is affixed to the collimating helmet at the proper shot coordinates by means of pillars and trunnions.

Usually the y-coordinate is set first, by sliding a trunnion support pillars along the y-coordinate scale on each side of the head frame and tightening their screws with a hexagonal wrench. The z-coordinate is adjusted by sliding the central parts of the same pillars along their engraved z-coordinate scale and tightening them in place with screws. Errors in setting the y- or z-coordinates on one side of the stereotactic frame of more that 20 or 50 mm, respectively, will absolutely prevent fixation of the trunnions

used to hold the stereotactic frame within the collimator helmet and to set the x-coordinate. If the x-coordinate is properly set on one side of the patient's head, the maximum errors possible in the x-coordinate setting on the opposite side are -1 mm or + 6.5 mm. Errors separating the trunnions by more than 6.5 mm will not allow support of the stereotactic frame in the helmet. The normal tight fit of the trunnions against the pillars attached to the frame, when the x-coordinate is correctly set on both sides, allows less than 1 mm error due to the mechanical rigidity of the frame. The gamma angle is set by rotating the trunnions after they are set into the pillars attached to the stereotactic frame.

The shot coordinates are set and checked by a team of 3–4 people consisting of the neurosurgeon, radiation oncologist, medical physicist, radiotherapy technician, or registered nurse. One person sets and secures the coordinates while another or two check the coordinate values and the security of the settings. An impressive double-blind checking routine consists of one person setting the shot coordinates from the prescription, which are left unknown to the checkers. Each of two checkers separately records their inspection of the set coordinates. Then both checks are compared to each other and the prescription. If there is any discrepancy among all three records, the coordinates are reset and the checking procedure is repeated.

Mistakes in coordinate settings can occur due to using coordinates from the wrong shot, mis-readings of the scales, or transposition of coordinates. The z-coordinate is the hardest to set and secure, because it holds up the weight of the patient's head. The x-trunnions are precisely machined and can be damaged if people do not follow procedures correctly or do not keep the trunnions clean. Their scales can become obscured or stuck in the helmets.

After data collection was completed, a study was published (Flickinger et al. 1993) on the potential errors and their magnitudes in setting Gamma Knife stereotactic coordinates.

Final checks are performed before leaving the patient in the treatment room. The collimator size and plug pattern are verified once more. A final check is made of the potential radiation exposure of the patient's eyes or lenses (see 4.1.7). A TLD may be placed on the lens or thyroid to measure exposure. The couch should be cleared of all unnecessary items. The helmet rear shielding plate is closed and the microswitches' electrical connections are secured. A microphone is attached to hear the patient speak and breathe. Sufficient light is made available to view the patient's face with the remote cameras and monitors. Side guards are attached to the couch. Finally, the room is cleared of all personnel, and the interlock door is closed.

4.1.23 Treatment Timing

Two digital counters or timers on the control console are set before starting the treatment shot. One counter is set for the shot time to count up, while the other is set to count down to zero. One could incorrectly set the counter or use a time from another shot, by, for instance, mis-reading the prescription. Thus, the counter settings are verified.

The two counters are on the same power supply, so are not independently redundant. However, one counter keeps the elapsed time if the other counter fails. This has happened due to a faulty microchip in some of the counters. The counters will display the elapsed shot time if the emergency interrupt or treatment stop function is invoked. If the treatment is interrupted for any reason, it's important to have the elapsed time to adjust or re-calculate the overall treatment plan. The timer reset button will reset the counters to the last set time, even during a treatment shot. A backup battery keeps the counters ticking in the event of an electrical failure.

4.1.24 Monitor Treatment

The treatment cycle is monitored from the console area by means of the remote audio and monitors and indications on the control console. The stop-treatment cycle is automatically initiated 1) if the couch has not reached the

treatment position within 90 seconds after treatment start, 2) if correct contact between the helmet and the central body is not confirmed (by the helmet microswitches) within two seconds after full movement of the couch into the radiation unit, or 3) the treatment room door interlock is broken.

Emergency procedures may be invoked if the patient is in difficulty, the machine is not performing adequately, or there is an electrical or a hydraulic failure. The layout of the facility, the emergency procedures, and training exercises are designed to extract the patient from the gamma unit in less than two minutes.

If a power failure occurs during irradiation (about 50% of the facilities have emergency power), the couch will be removed automatically out of the radiation unit (because microswitches have to be activated for the treatment to proceed). The unit shielding door is then closed by manually shifting the shielding door closure lever on the hydraulic unit in the hydraulic room. Without recent training, the user may not readily identify which lever to shift since there are two very similar and closely positioned levers. The wrong lever releases the reserve pressure from the hydraulic system reservoir. This can be precluded by removing the wrong lever. Closing of the shielding door is prevented by an interlock until the couch is fully removed.

If hydraulic pump failure occurs during treatment, there is enough reserve pressure to complete the treatment cycle. If there is not enough reserve pressure, the operator enters the hydraulic room and re-establishes pressure with the auxiliary hand pump. If the hydraulic failure is due to an electrical failure that affects the couch microswitches, the operator must also shift the radiation unit shielding door closure lever on the hydraulic unit after the patient couch has exited to its outer position and before the door can be closed by means of the hand pump. Again, shifting the wrong (reservoir release) lever will increase the need for hand pumping. Hand pumping is a lengthy process, requiring about 300 cycles to close the shielding door. Also, the hand pumping may not generate enough positive pressure to close the door if there is a failure in the hydraulic system.

If there is insufficient reserve pressure during treatment, the stop treatment cycle is automatically initiated. The reserve pressure level when the hydraulic pump is activated during the start treatment is sufficient to complete the stop treatment cycle. In the event reserve pressure is not sufficient at any time during the treatment cycle and the pump fails to restore sufficient hydraulic reserve pressure within one minute, the stop treatment cycle is automatically initiated.

A primary interest of the physicians in the case of an emergency is to remove the patient from the treatment room as soon as possible, even though the unit shielding door may still be open. The manual removal of the patient is effected by entering the treatment room, pulling the pressure release handle at the end of the couch, having two people retract the couch, and removing the patient from the helmet fixation trunnions. This procedure is designed and practiced to occur within two minutes.

If the couch gets stuck in the radiation unit and it is not possible to withdraw it with hydraulic hand pumping or manual retraction, the patient must be brought out manually from the high level radiation area, by loosening the bolt locking one or both head fixation trunnions with a special, long Allen key and pulling out the patient. When the couch is in the treatment position and is ordered out (either by end of treatment or treatment stop), it must have left the treatment position within five seconds or an alarm will be activated.

The prescription is marked to signify a successful completion of a shot. Care must be taken to mark the correct successfully completed shot. Also, it is a good idea to re-inspect the coordinate settings after the shot to see if they have slipped.

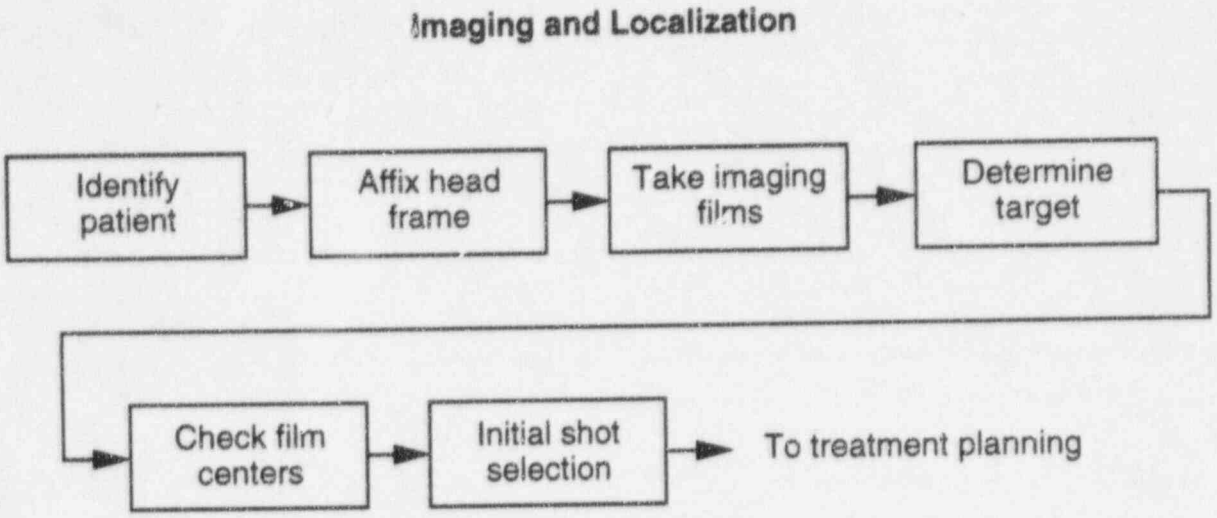


Figure 4-1. Flow diagram showing temporal relationships of tasks in the Gamma Knife treatment process—imaging and localization phase.

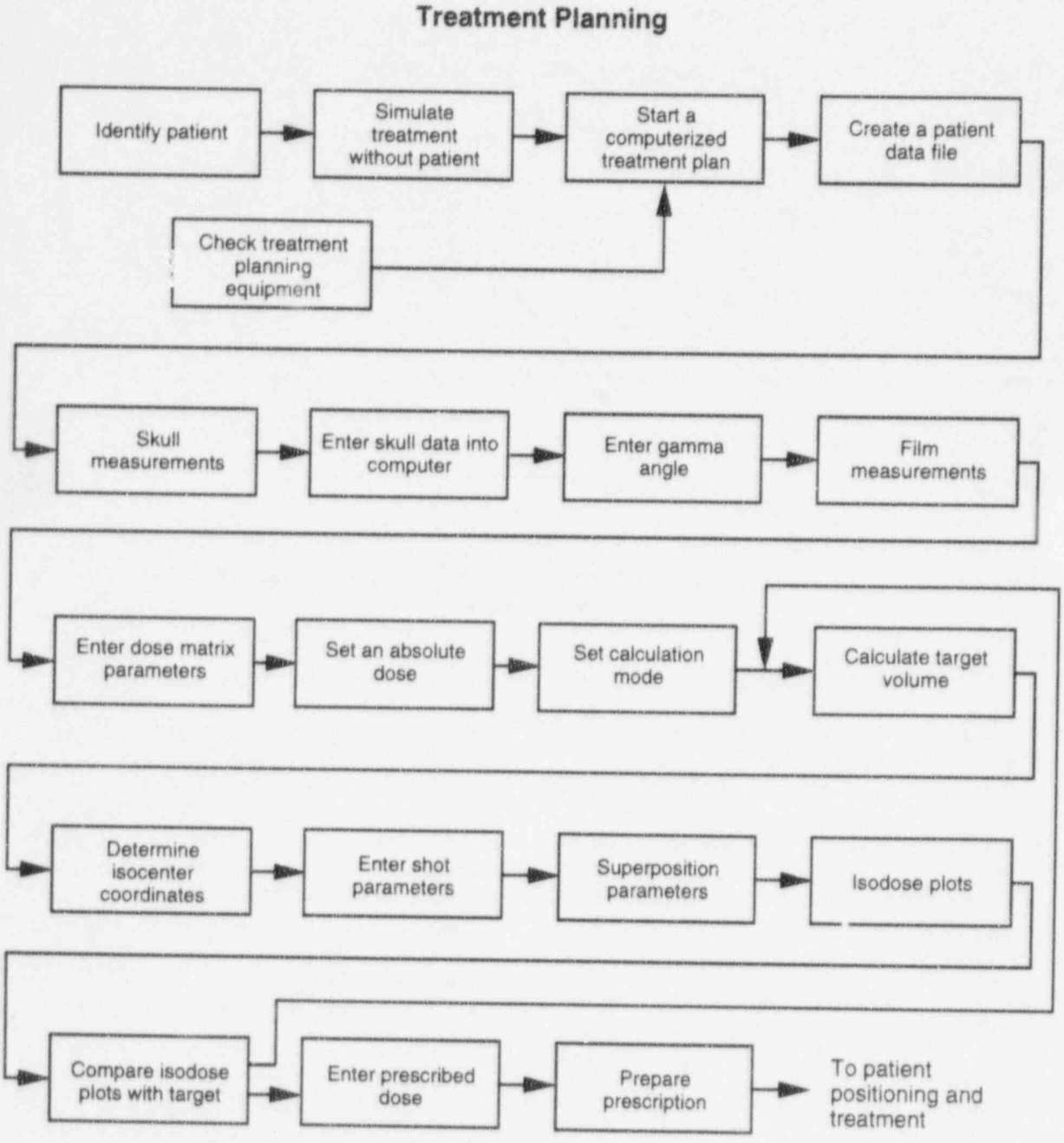


Figure 4-2. Flow diagram showing temporal relationships of tasks in the Gamma Knife treatment process—treatment planning phase.

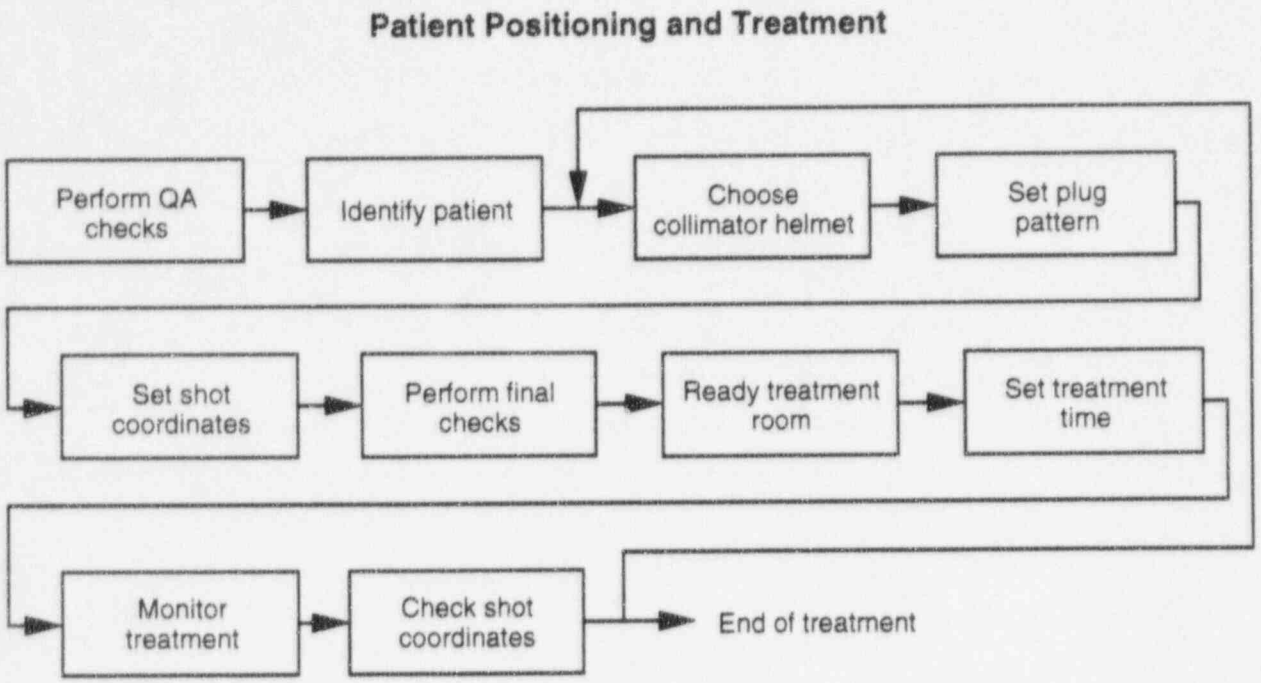


Figure 4-3. Flow diagram showing temporal relationships of tasks in the Gamma Knife treatment process—treatment phase.

4.2 Modified Task Analysis

Flow diagrams showing the temporal relationships of tasks in the three phases of the Gamma Knife treatment process are displayed in Figures 4-1 to 4-3. Note that the treatment process is highly serial with two major feedback loops: one in treatment planning to iterate the selection of a treatment plan; and the other for the administration of more than one shot during a treatment.

Section 2.3 describes the methods employed for the modified task analysis. A preliminary list of treatment tasks and subtasks perceived as pertinent to patient risk is given in Table 4-1. Specific data were collected for each task:

Task Description/Purpose

Task Frequency

Performance Standards

Support Equipment

Training/Knowledge Required

Ways to Reduce Errors/Risk

The data are assembled in Appendix A. The information on training was acquired to support the quality assurance work reported in a separate document. Information on human performance shaping factors was not collected for two reasons. The determined scope of the project did not include an assessment of causes of human errors. Also, there were adequate human factors, as defined by ASEP (Swain 1987), during the Gamma Knife treatment process. These include good overall attention to administrative controls and emergency and operating procedures; good training; and sufficient human-machine interfaces.

The data were collected from individual interviews, group interviews, and observation of patient treatments. The task data were verified by using 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 and their familiarity with the nature of this project.

Table 4-1 Preliminary list of Gamma Knife treatment tasks and subtasks

Process 1.0: Imaging and Localization	
1.1	Identify correct patient
1.2	Affix stereotactic frame
1.2.1	Verify integrity of head frame
1.2.2	Center lesion in stereotactic frame
1.2.3	Ensure frame is immovable on patient's head
1.3	Set up CT, MR, Angiography
1.3.1	Verify attachment and alignment of CT, MR, or X-ray indicators
1.3.2	Ensure correct alignment (orthogonality) with respect to imager
1.3.3	Label films: patient id.; film orientation; fiducials; left/right; etc.
1.3.4	Select image slice resolution (CT, MR)
1.4	Determine outline of lesion
1.5	Center correctly deposited on CT, MR films
1.6	Determine initial isocenter locations/coordinates

Process 2.0: Treatment Planning	
2.1	Identify correct patient with planning data (e.g., films)
2.2	Simulate treatment
2.2.1	Check range of lesion coordinates
2.2.2	Check supine vs. prone
2.2.3	Check gamma angle
2.2.4	Check lenses - need for collimator blocking
2.3	Check treatment planning equipment
2.3.1	Computer software calculations (e.g., today's dose rate)
2.3.2	Plotter integrity
2.3.3	Digitizer accuracy and linearity
2.4	Start up of treatment planning software
2.5	Create patient data files
2.6	Take skull measurements for supine or prone position
2.6.1	Verify identity of patient
2.6.2	Attach measuring bubble correctly
2.6.3	Use measuring stick
2.6.4	Enter scale readings on data form
2.6.5	Verify skull data
2.7	Enter skull data into patient's computer file
2.7.1	Verify computer skull data (skull profile)

2.8	Enter the gamma angle
2.9	Make geometric determinations from films
2.9.1	Make sure fiims are not reversed
2.9.2	Find center of image
2.9.3	Determine film slice (e.g., z) coordinate (CT, MR)
2.9.4	Determine magnification factors
2.9.5	Verify geometric determinations
2.10	Enter dose matrix center and size
2.11	Set absolute dose at a specified reference point (or use default)
2.12	Set cut-and-modify or exact calculation mode
2.12.1	Make point calculation to compare error between modes
2.13	Calculate target volume
2.14	Determine x, y, z isocenter coordinates
2.15	Enter shot parameters
2.15.1	Isocenter coordinates
2.15.2	Collimator sizes
2.15.3	Plug patterns
2.16	Enter shot superposition parameters
2.16.1	Shot numbers for superposition
2.16.2	Weighting factors
2.17	Plot isodose curves
2.17.1	Select coordinate plane
2.17.2	Select isodose levels
2.17.3	Select scaling factor
2.17.4	Label isodose plots
2.18	Overlay isodose plots on films (use for validation and verification)
2.18.1	Ensure that plot overlaid on correct image
2.18.2	Align center of frame with center mark on plot
2.18.3	Compare isodose curves to lesion
2.19	Enter prescribed dose
2.20	Print and sign prescription
2.20.1	Select mode (ordered by shot number or by collimator size)
2.20.2	Print skull measurements
2.20.3	Check printout against written directive
2.20.4	Make coordinate transformations between supine and prone positions if necessary
2.20.5	Sign prescription

Process 3.0: Patient Positioning and Treatment	
3.1	Perform daily QA checks
3.2	Identify correct patient with prescription
3.3	Choose helmet (collimator size) and/or change helmet
3.4	Set plug pattern
3.5	Set isocenter coordinates and gamma angle
3.5.1	Set y-, z-coordinates on stereotactic frame
3.5.1.1	Secure y-, z-settings
3.5.1.2	Check y-, z-coordinate settings
3.5.2	Set x-coordinate with trunnion settings
3.5.2.1	Secure x-setting
3.5.2.2	Check x-coordinate setting
3.5.3	Set and verify gamma angle
3.6	Perform final checks
3.6.1	Verify collimator size
3.6.2	Verify plug pattern
3.6.3	Check lenses
3.6.3.1	Adjust treatment time if collimators plugged
3.6.4	Place lens or thyroid TLDs
3.6.5	Clear couch of unnecessary items
3.6.6	Close back shielding plate and connect microswitches
3.6.7	Attach microphone to hear patient
3.6.8	Attach couch side-guards
3.6.9	Light patient's face
3.7	Clear room and close interlock door
3.8	Set treatment time on timers/counters from prescription
3.8.1	Verify time settings
3.9	Initiate and monitor treatment cycle
3.9.1	Ensure patient's fingers are safe
3.9.2	Make sure treatment docking occurs and treatment timers start
3.9.3	Make sure treatment stops and patient withdraws at correct time
3.9.4	Mark prescription shot as completed
3.9.5	Wait for shielding door to close before re-entering room
3.10	Check isocenter coordinates after treatment

4.3 Summary of Equipment Failure Modes

A distillation of the more important potential failure modes or abnormal operating events associated either with the operation of the gamma unit itself or with facility systems and functions are listed in Table 4-2.

These events could lead to undesired radiation exposures of either patients, personnel, or the public.

These events occurred in the past or the users and manufacturer were concerned they could happen in the future. Also, several possible scenarios were verified 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.

Table 4-2 Failure modes associated with the Gamma Knife.

Shielding door fails to close fully
Treatment table halts in transit
Helmet doesn't mate with internal collimator
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 can not pull out treatment table in an emergency
Electrical component failures
Electrical power loss
No emergency lights or monitors
Hydraulic component failures
Hydraulic fluid depressurization

5. PRELIMINARY SCREENING OF POSTULATED HIGH-RISK CONTRIBUTORS

5.1 Expert Estimations

To quantify the relative importance of the risk contributors, a measure of the probability of errors or abnormal events and their consequences was needed. Absolute measures were not determined, given the limited operating experience with the Gamma Knife and the absence of any misadministrations prior to the completion of the risk analysis (see Section 8). Also, the project scope did not permit the extensive research required to determine human error probabilities associated with the use of the Gamma Knife. However, as discussed in Section 2, it is plausible to develop relative risk rankings based on expert estimations.

In this study, the experts were professionals, experienced in the use of the Gamma Knife. They were Gamma Knife physicians, medical physicists, and Elekta engineers. Radiotherapy technicians and nurses were not asked to make numerical estimations. The expert pool consisted of individuals who understood the purpose of the elicitations and had appropriate backgrounds to develop numerical estimates.

Once the undesired events were understood by the project team, users were asked how often they experienced these events, i.e., what were the event frequencies. Initially, no scale was provided, because their answers were to help establish a metric for more formal solicitations later. Preliminary estimates from six experts were collected to determine the range or scale of probability estimates. This data is illustrated in Figure 5-1. The chances of occurrence of undesired events ranged from 1 in 5 patients to 1 in more than 1,000 patients. The reported probabilities tended to clump into five different bins, regardless of which facility provided the data. This consistency is probably due 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.

Based on the data represented in Fig. 5-1, the following template or metric for estimating event probabilities was established:

1. 1 in 1000 (.001)
2. 1 in 500 (.002)
3. 1 in 100 (.01)
4. 1 in 50 (.02)
5. 1 in 10 (.1)
6. Specify other rate

To establish a scale for consequences, information was elicited from a subset of users (six experts) and some deterministic analyses were performed. As discussed in Section 2.2, consequence is measured in terms of the magnitude of the unintended deviation from the expected radiation exposure. Experts were asked: If a certain undesired event occurred, how large of an unintended radiation exposure would result? Given the phenomenology of the Gamma Knife, some of these answers were determinable by the project team.

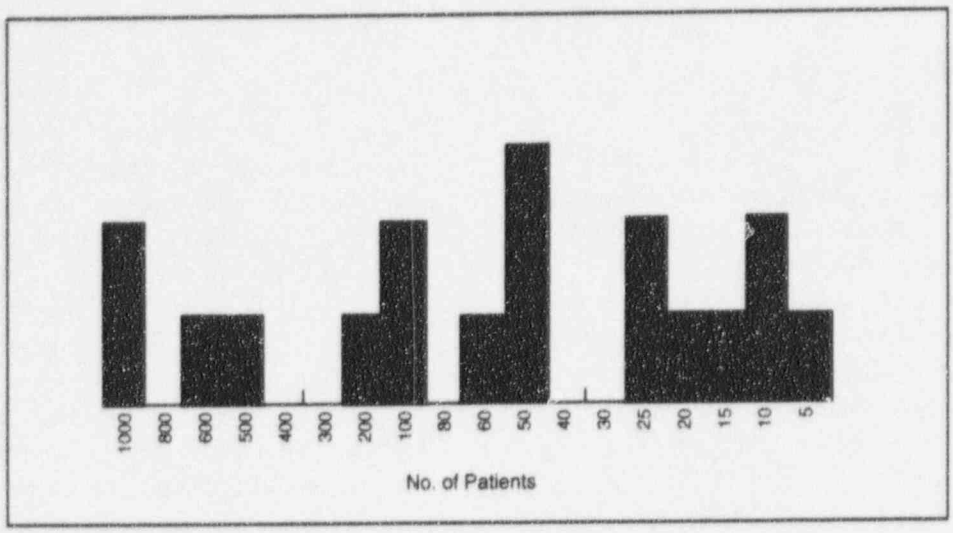


Figure 5-1. Reported chances of occurrence (1/No. of patients) of undesired events.

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. The distribution of radiation within the Gamma Knife suite was known, with and without the radiation unit shielding door being closed. Estimates were also available for how long the emergency procedures take (approximately 2–5 minutes). Thus, a range of potential personnel overexposures could be established and 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 problematic, 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, the error can translate into absolute dose or treatment position/volume errors in the patient. Thus, the kind of error needs to be specified along with the magnitude of the error. Assuming a certain error, it could be determined 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. 2% (.02)
2. 5% (.05)
3. 10% (.1)
4. 20% (.2)
5. 50% (.5)
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 radiobiological responses appear to obey power law relationships for volume elements in radiosurgical treatments (Flickinger 1989). Flickinger's integrated logistic formula provides a probability of necrosis as a function of dose and treatment volume. The logarithmic derivative of his formula provides a weighted relationship between fractional changes in dose and fractional changes in volume:

$$M = (W)DD/D + DV/V.$$

An average Gamma Knife treatment dose is 36–38 Gy (Flickinger 1992; private communications). For this dose value, the weighting factor, W, is 1.5.

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

Once these templates were established for estimating event probabilities and consequences, they were used to elicit expert estimations. 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.

The methodology practiced to collect expert estimates is summarized by the flow diagram of Figure 5-2. As discussed above, preliminary data was collected from six experts to establish appropriate error probability and consequence scales. The metrics were then used in formal elicitations of 14 experts (the original six plus eight others). The elicitations included individual and group interviews. The group interviews were unstructured, insofar as there were open discussions of people's opinions until each expert was polled for his or her estimation. In these interviews, the experts were asked about each primary task in Table 4-1:

1. Is this task pertinent to risk?
2. Is this task substantially a matter of medical art and practice?
3. What are the potential errors associated with this task?
4. Given these errors, in your experience what are the probabilities of them occurring?
5. In your experience, what is the likely magnitude of these errors?
6. Is there anything else we should know about this task?

The estimates were checked by observing patient treatments. The observed likelihoods were, in general, higher than the experts reported, but the relative values seemed to be consistent with the collected data.

For the abnormal operating events or equipment failure modes, the experts were asked to estimate the likelihood of their occurrences using values from the probability template. This was problematic, since some of the events had not been experienced by all the experts. Thus, they were asked to only make a relative ranking of the probabilities of occurrence. For events that had not occurred in their experience, the experts were asked to select the .001 value from the template.

All the data on event probabilities 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 two days, the review team systematically discussed, critiqued, and rationalized the data. The expert team also used preliminary versions of risk 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.

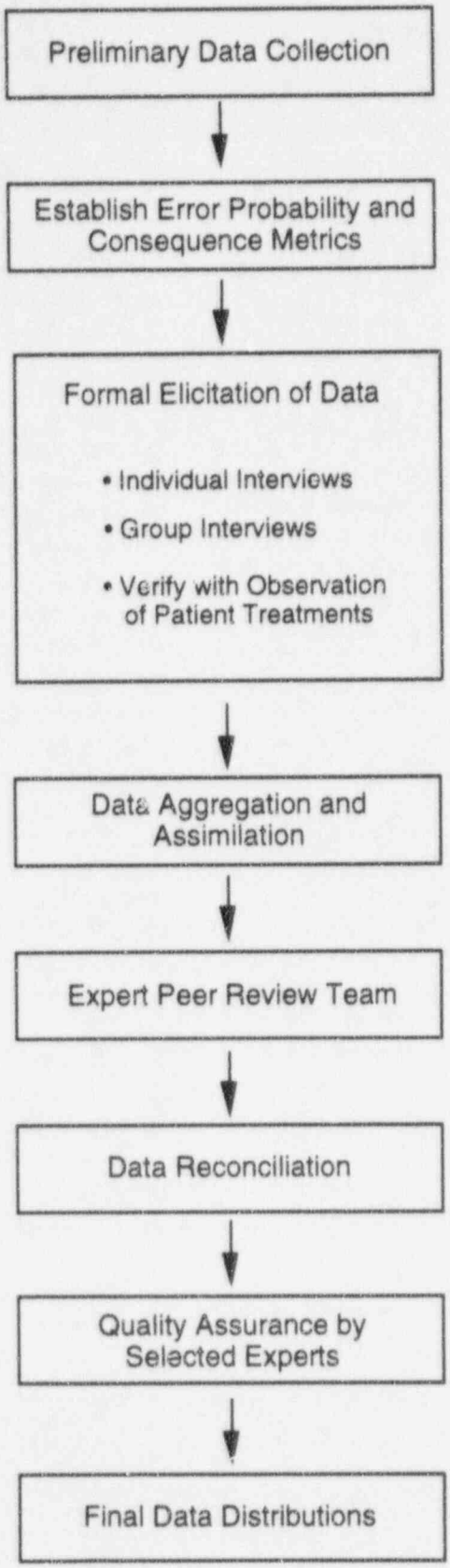


Figure 5-2. Flow diagram of expert elicitation process.

5.2 Consolidation of Critical Tasks

The expert elicitation experiences helped to consolidate and rationalize the tasks in Table 4-1. Some tasks were eliminated, because they only involved medical practices (1.4, 1.6, 2.13), or did not impact patient risk (2.2, 2.4, 2.5, 2.11, 3.1, 3.7). Some tasks were combined with or subsumed by others (2.10 subsumed by 2.12, and 2.16 by 2.15). The consolidated list of primary tasks is given in Table 5-1.

Fault trees were developed for each primary task showing the logical relationships of its subtasks or errors, i.e., its contributing fault events. The task logic diagrams are presented in Appendix C. The tasks were modeled as independent. The Gamma Knife treatment process is basically a sequential process, and it was adjudged by the project team, in consultation with Gamma Knife and human factors experts, that there were no dependencies among human errors in the different steps of the treatment process. This conforms to observations that once one sequence step is considered satisfactorily completed, the practitioner assumes all is well up to that point and moves on to the next step.

The treatment planning iterative process was modeled as if there was only one pass through the planning steps. This is because only one pass, the last pass, really counts: checks on the last treatment plan can correct, or fail to correct, any errors before moving on to administration of the treatment. The multiple-shot treatment loop is not modeled, because risk is considered on a per-shot basis.

The expert estimation data for each contributing event were assimilated by the project team into discrete distributions for each event, such as those represented in Figure 5-3. For each error, there was a discrete distribution for its probability of occurrence and a discrete distribution for its magnitude. For example, consider the distribution histograms in Figure 5-3. The height of the column above each error value represents the percentage of experts sampled who selected that value 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.

Appendix B shows the unit normalized probability and consequence distributions for each contributing event to the primary tasks of Table 5-1.

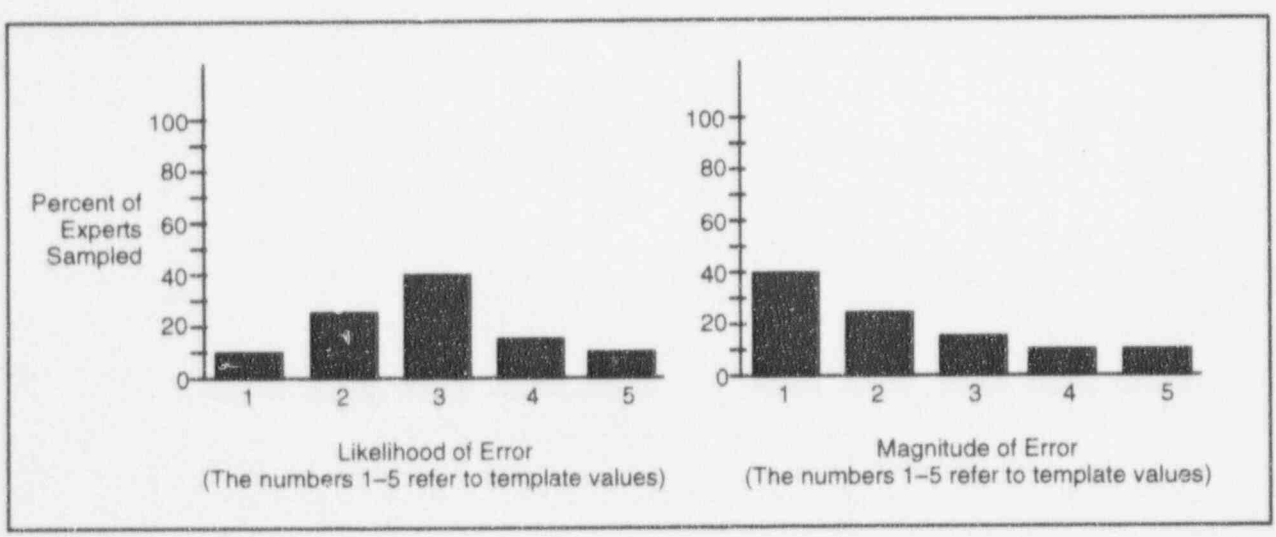


Figure 5-3 Representative error distributions for each task.

Table 5-1 Consolidated primary tasks in the Gamma Knife treatment path.

Imaging and Localization:	
1.1	Identify correct patient (also used for 2.1 and 3.2)
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	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
2.20	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
3.10	Check isocenter settings after treatment

Table 5-2 Failure modes—ranked by likelihood—associated with the Gamma Knife.

Event/failure mode	Likelihood Rating
Audio/visual communication failures	.1, .02
Treatment intervention by personnel (treatment stop or emergency interrupt)	.01, .02
Door interlock interrupted while shielding door still open	.01, .02
Emergency procedures invoked	.01
Inadvertent activation of operating modes	.01, .002
Personnel can not pull out couch	.01, .002
Shielding door fails to fully close	.001, .002
Counters/timers fail (e.g., power loss/restart test)	.001, .002
Console operating buttons inoperable	.001, .002
Radiation monitors inaccurate/inoperable	.001, .002
Electrical component failures	.001, .002
Electrical power loss	.001, .002
Hydraulic component failures	.001, .002
Hydraulic fluid depressurization	.001, .002
Couch halts in transit	.001
Helmet does not mate appropriately with internal collimator	.001
Helmet microswitches malfunction	.001
Door interlock fails	.001
Motion safety timers fail	.001
Status lights fail	.001
Emergency stops not operable	.001
Emergency release rod fails to work	.001
No emergency lights or monitors	site dependent (approx. 20% of sites)

5.3 Equipment Failure Modes

The experts' estimates of the likelihood of abnormal operating events or equipment failure modes are ranked in Table 5-2. The likelihood numbers .001, .002, .01, .02, and .1 refer to the template values. The order of the numbers reflects the experts' opinions about the relative ranking of the likelihoods.

A primary concern associated with the failure modes was the possibility of the patient's head being unnecessarily exposed to radiation inside the radiation unit during an abnormal operating event (Smith et al. 1993). 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.

A fault tree for the patient being incorrectly exposed within the radiation unit is displayed in Figure 5-4. The tree contains equipment failures only. If such faults occurred, staff members would have to enter the room and remove the patient from the machine. Under these circumstances, it might take a few minutes to remove the patient, and so it is important to determine whether irradiation of the patient might occur in this non-standard situation.

To check for background and extraneous radiation fields that may affect patients during a system failure or abnormal operating mode, several measurements were taken. 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 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. The most likely result of hydraulic unit failure is that the helmet would fall into its lowest position at the bottom of the track. The consequences to the patient if this should happen are probably minimal, since the hot spot from the focus of the primary collimator then lies just under the inner surface of the helmet and substantially superior to the treatment position. It is virtually certain that this would place the hot spot outside the patient. The hot spot would lie inside the head of the patient, if the helmet could stop at some point intermediate between the treatment position and the low point, but it is difficult to conceive of circumstances which would lead to this situation. 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 their treatment room for radiation hot spots—with the shielding door open—outside of the radiation unit. They found there were two collimated radiation beams, one on each side of the shielding door opening, entering the room over the treatment couch. The beams had separate sources, each being one of the 201 cobalt-60 sources whose emitted radiation is collimated by its primary collimator within the radiation unit. According to the Gamma Knife device registry, all such primary beams should be scattered at least once off the walls of the radiation unit before entering the treatment room. (The problem with the two unscattered radiation beams has now been corrected at all U.S. Gamma Knife facilities.)

It was imperative to estimate the risks of these hot spots. 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 5-5). The whole-body exposure to members of the staff and public should remain below 5 rem (10 CFR Part 20). The patient's brain should not receive more than 600 rem to avoid any indications of damage (NCRP 1991).

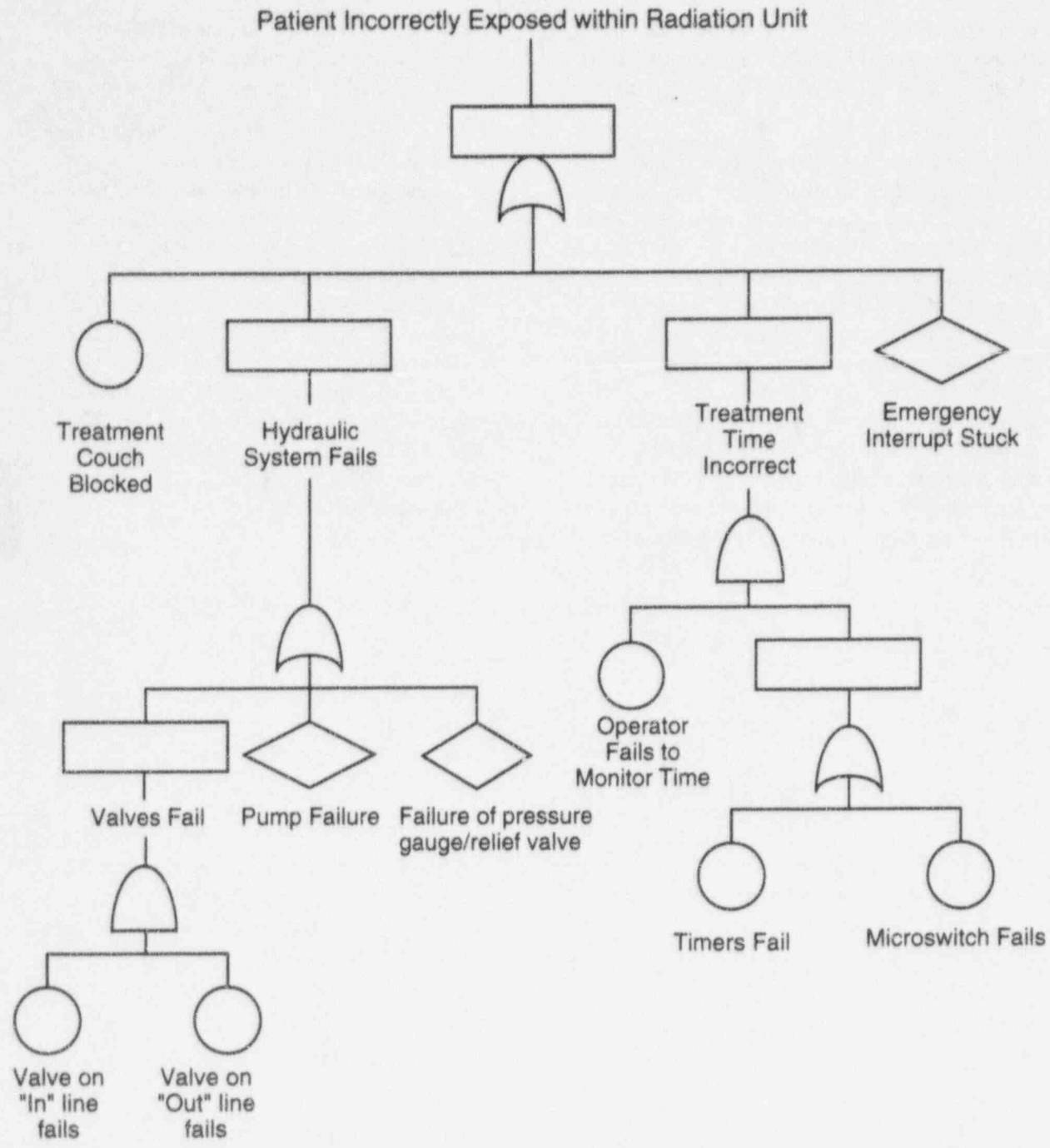


Figure 5-4 Fault tree for undue radiation exposure of the patient.

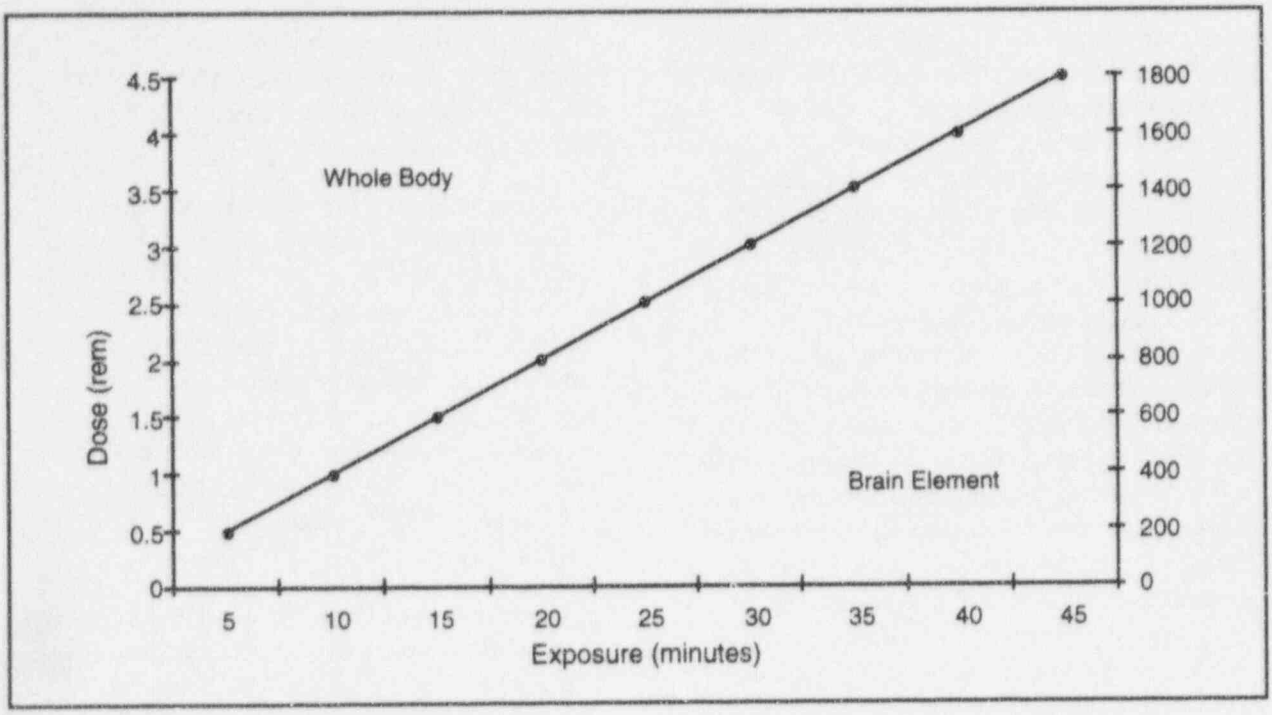


Figure 5-5 Dose consequence as a function of exposure time for Gamma Knife hot spots.

Thus, based on the graph in Figure 5-5, there are up to 15 minutes to extricate the patient from a stuck position for both staff and the patient to remain below the appropriate radiation safety thresholds. The Gamma Knife emergency procedures should take on the order of 2–5 minutes, so the consequences to the patient and personnel are low should there occur an abnormal operating event.

5.4 Comparison of Highest Risks of Treatment Tasks to Equipment Failures

Once the project team had identified the risk-pertinent events and estimated their probabilities and consequences, it was incumbent to rank the risks against one another to determine the relative importance of the risk contributors. Two basic kinds of risk contributors were considered: abnormal operating events and treatment path task errors. To perform a zero-order comparison of their risks, a qualitative, relative ranking scheme was utilized. Relative ratings of probability of occurrence and of consequences were assigned to four events or conditions corresponding to (1) the patient's head stopped in the off-target hot spots; (2) the patient unduly 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. Based on a review of the risk estimation data associated with events or tasks pertinent to each condition, a relative rating (from 0–10) was assigned to each condition's risk. The relative rankings of the four conditions are as follows:

Condition	Risk Ranking
Characteristic errors in normal treatment	10
Patient stuck in treatment position	5
Patient's head in off-target hot spot	3
Emergency personnel exposure	2

Emergency personnel exposure has the least significant risk of the four conditions. Even if the likelihood of invoking the emergency procedures is as high as 1 in every 100 patients, the staff radiation exposure consequences are low or very low, perhaps a half rem in the worst case. The likelihood of the patient's head being stopped in the off-target hot spot is very low: it hasn't occurred for over 7000 patients. The consequences of this condition are greater than for the emergency personnel, since the hottest radiation spot is 8-10% of maximum dose rate. The likelihood of the patient being unduly stuck in the treatment position is also very low, not happening for over 7000 patients. It is extremely difficult for the patient to reach the treatment position, unless the unit is operating properly. The patient can be released from the treatment position, in the worst case, by turning the unit off or by releasing the hydraulic pressure with a safety latch at the foot of the treatment couch.

The consequences to the patient of being stuck in the treatment position are potentially severe, since the brain would be irradiated at a maximum dose rate.

The most risk significant condition considered is that of characteristic treatment errors associated with a normal unit operation. In the treatment position, the patient is subject to intense, unintended radiation from any errors made in the imaging and localization, treatment planning, patient positioning, or treatment administration processes. The likelihood of such errors is greater than for any of the other three ranked conditions, and the consequences can be as great as being unduly stuck in the treatment position.

The comparison of risk significance helped to screen out the equipment failure modes as less critical than treatment error events in the 24 primary tasks.

6. RELATIVE RISK PROFILES OF CRITICAL TASKS

Before comparing the risks of the primary treatment tasks of Table 5-1, the probability and consequence distributions of their contributing fault events had to be combined to obtain aggregated error probability and consequence distributions for each primary task. The distribution combinations had to respect any logical relationships among the contributing events as reflected in the fault trees. To accomplish the appropriate combinations, the discrete distribution propagation method used in the Zion and Indian Point PRAs (Zion 1982, Indian Point 1982) was employed.

After obtaining the aggregated error distributions for the primary tasks, the mean values of the probability and consequence distributions for each task were used 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. Plots of the relative point estimates of probability, consequence, and risk are shown in Figures 6-1 to 6-4. Such comparisons of risks among tasks are referred to as "risk profiles." These relative risk profiles aid the identification of the high-risk, high-consequence, or critical tasks, without requiring an absolute quantification of probability, consequence, and risk for each task.

Figure 6-1 shows the relative error probabilities for the 24 primary tasks. Tasks 1.5 (center of imaging film) and 2.9 (geometric determinations from films) have the highest error probabilities, while task 1.1 (patient identification) has by far the lowest probability. Figure 6-2 displays the relative consequence measures of the task errors. Task 1.1 has by far the highest consequence, and task 1.2 (affix stereotactic frame) has the lowest consequence. Figure 6-3 shows a relative comparison of the probability of each task, ranked by increasing consequence along the abscissa. This is a bar chart form of the more familiar risk space plots of probability vs. consequence (cf. Figure 2-1). It helps to reveal the high-consequence and high-probability tasks, such as 2.15 (enter shot parameters) and 2.19 (enter prescribed dose).

Figure 6-4 shows the point estimates of relative risks of the primary tasks. The relative risk point estimates are products of the mean values of the error probability and consequence distributions. Several of the highest-risk tasks are associated with the treatment planning process (task identification numbers beginning with the number 2). The highest-point risk tasks are 2.15 (enter shot parameters), 2.19 (enter prescribed dose), and 2.9 (geometric determinations from films).

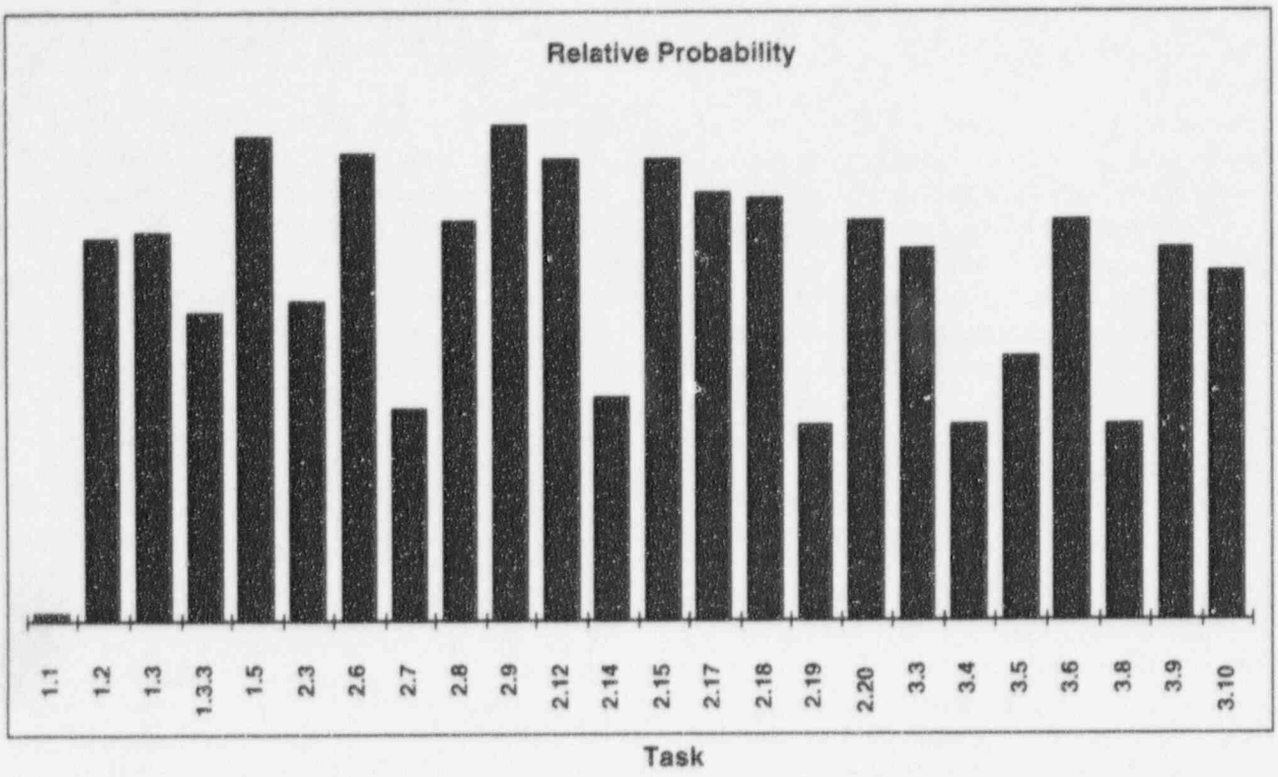


Figure 6-1 Relative probability (logarithmic scale) profile for Gamma Knife tasks. The numerals along the abscissa are task identification numbers.

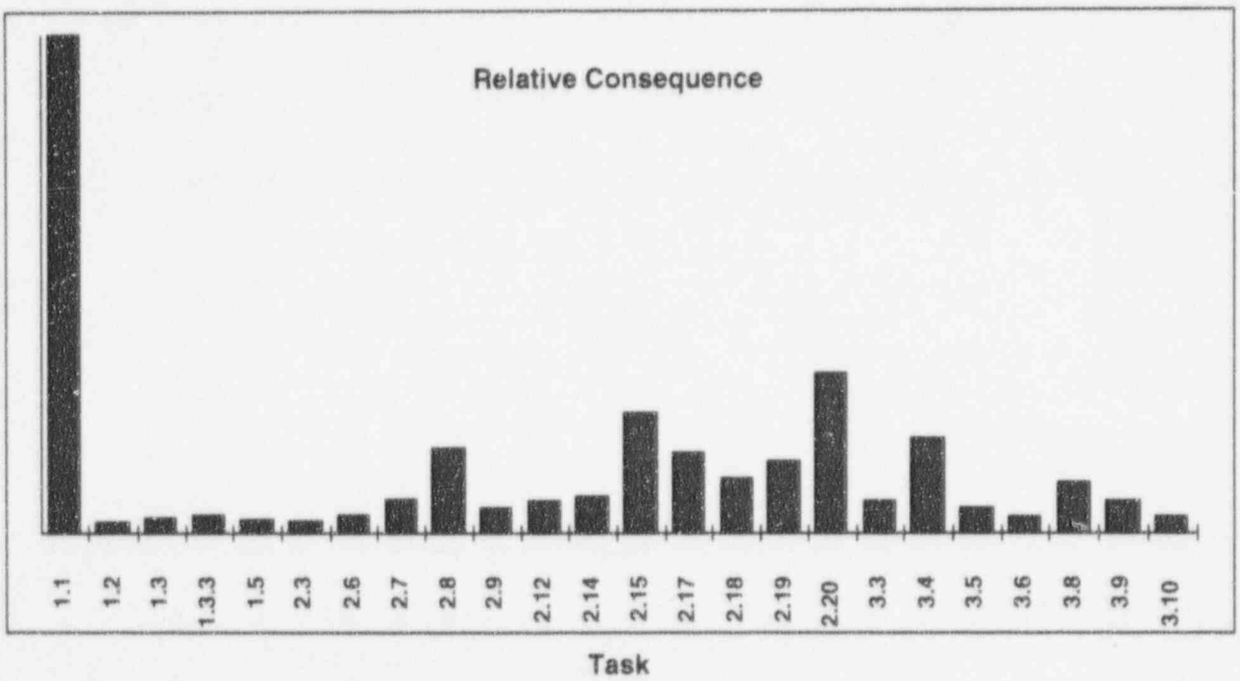


Figure 6-2 Relative consequence (linear scale) profile for Gamma Knife tasks The numerals along the abscissa are task identification numbers.

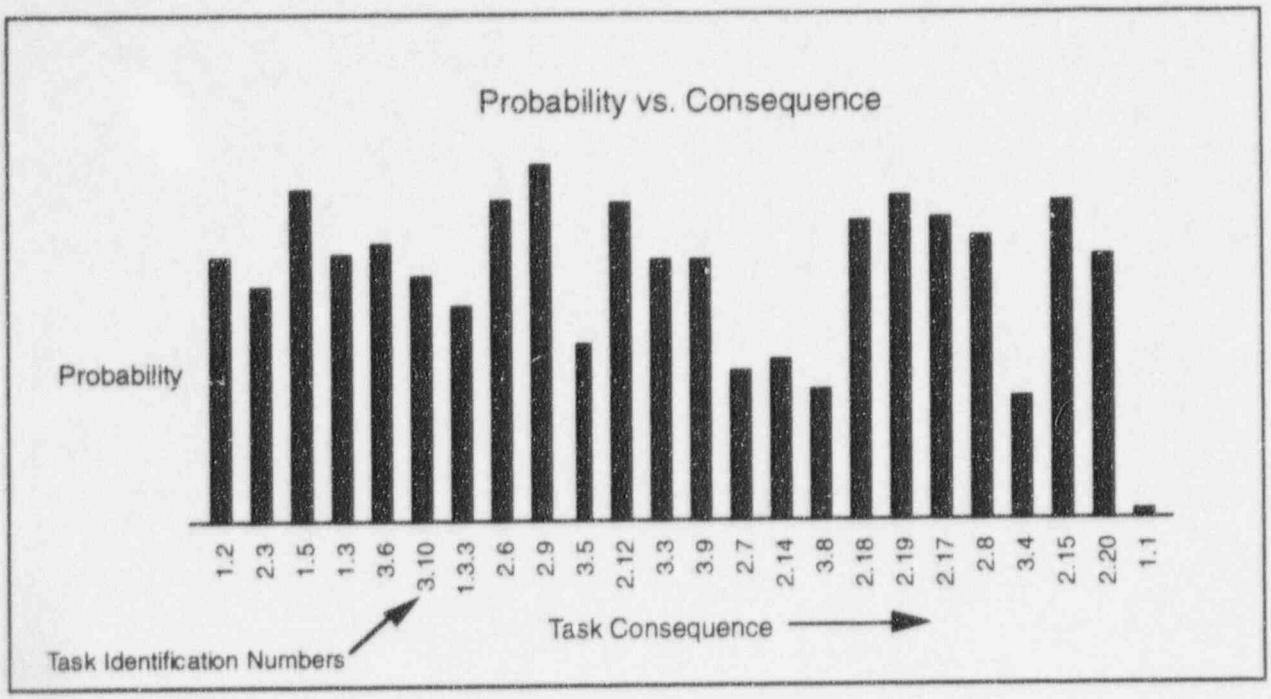


Figure 6-3 A risk domain profile for Gamma Knife tasks.
The probability of an error occurring (logarithmic scale) is along the ordinate, and the tasks are arranged by increasing consequence along the abscissa. The numerals along the abscissa are task identification numbers.

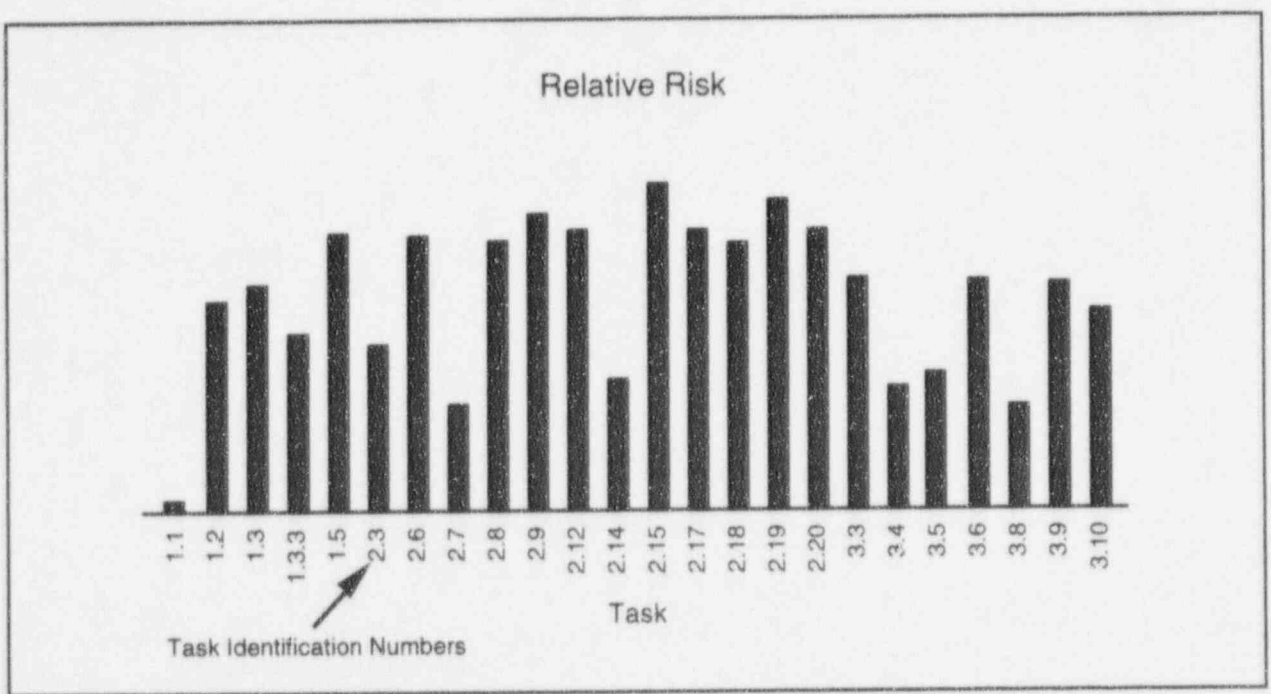


Figure 6-4 Relative risk (logarithmic scale) profile for Gamma Knife tasks.
The numerals along the abscissa are task identification numbers.

7. IMPORTANCE AND UNCERTAINTY ANALYSES OF CRITICAL TASKS

7.1 Simulations of Risk Scenarios

The risk profiles of Section 6 provide a "snapshot" of point estimates of relative risks of the primary tasks in the Gamma Knife treatment process. 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 5, these spreads reflect the uncertainties in the experts' estimations, uncertainties which also should be reflected in risk distributions for each task. Risk distributions were generated for each task by combining the task's probability and consequence distributions. The risk uncertainty associated with each risk distribution was measured by calculating its coefficient of variation. The *coefficient of 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 7-1. The large values of uncertainty and the wide variability in the uncertainties[1] from task to task indicate that the first-order risk analysis discussed in Section 6, 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.

An evaluation to determine the risks of misadministrations for Gamma Knife treatments requires that the probability and consequence distributions of the primary tasks (Table 5-1) be combined. One way to accomplish this is to construct a logic diagram or fault tree with the primary tasks as contributing events to the top event, a misadministration. This tree would simply be all the primary tasks connected by a logical 'or' operand to the top gate. The probability and consequence distributions of the top event could then be determined by logically combining (union) the distributions associated with each primary task. This would not be very instructive, since the top distributions would be of relative values and provide little qualitative insight and no quantitative insight.

Another approach to generating the top event distributions is to calculate distributions for statistically representative combinations of errors in treatment scenarios and then combine those distributions into a top distribution. This approach would again provide no quantitative insight to the risk of misadministration, but would offer substantially more qualitative insights. In the process of making such calculations, the highest risk scenarios could be identified, as well as those tasks most prevalent in the high-risk scenarios.

Therefore, it was decided to use the probability and consequence distributions in simulations of potential risk scenarios.

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

- Generate a statistical sample 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

[1] The data were not statistically sufficient to determine the sources of uncertainty. For instance, it could not be discerned if the uncertainties were due to variations among facilities or due to the vagaries of human error estimates.

such as latin hypercube did not seem appropriate given the nature of the discrete distributions—assumptions about the distributions for which no justification would have to be made. Hence, sampling methods that were more appropriate for discrete distributions were sought.

It was concluded that the Monte Carlo method would be a good way to randomly sample the discrete distributions. The Monte Carlo 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. A typical method is to sample a distribution is by transforming 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, a range of numbers between 0 and 1 will have been selected and the distribution will have been "sampled."

This technique was readily applied to the discrete distributions. For example, if there is a 30% chance that an error consequence is 0.02, and a 70% chance that it is 0.05, then values of the unit-normalized CDF between 0 and 0.3 would correspond to a 0.02 consequence and values between 0.3 and 1 correspond to a 0.05 consequence. When a randomly generated number between 0 and 1 falls into one of these 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 and the 0.05 consequence in 70% of the trials.

A computerized Monte Carlo technique can quickly generate a large set of representative error combinations and thus provide a statistical evaluation of treatment scenarios.

In the Gamma Knife project, a Monte Carlo-based computer code was used to simulate and evaluate the relative risks of possible error scenarios. It made use of the error probability and consequence distributions, and could model concatenations of tasks and combine their distributions.

The program logic flow to simulate each risk scenario is illustrated in Figure 7-2 and described below:

1. The analyst selects the tasks and their data to be included in a scenario evaluation. The scenario is defined by the tasks and their logical relationships. Task data to be included in the scenario simulation are entered into a file accessed by the program.
2. The unit normalized probability of error distribution is randomly sampled to select an error probability.
3. To determine if an error occurs for the current task, a random number is generated to compare to the selected error probability. If the random number is less than the error probability, then the error is deemed to have occurred. If the random number is greater than the probability, then the error is deemed not to have occurred. In the latter case, if there are more tasks included in the scenario, the code returns to Step 1 and considers the next task; otherwise, the program ends.
4. If a task error is deemed to occur, its error probability is recorded and saved.
5. If an error occurred, it is necessary to determine the consequence associated with that error. This is 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. The error probability and consequence measure for each task with an error in this scenario are logically combined with those measures from other tasks with errors in this scenario.

7. 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 computer clock resets the random number generator seed, and the scenario simulation is repeated.

The sequential event selection process in the simulation is represented by the 'decision tree' heuristic in Figure 7-3. For each task, it is decided whether an error occurs or not based on its probability. If it doesn't occur, there is no consequence and hence no contribution to risk, and the program moves on to the next task and repeats the decision making process. The endpoints of all the tree's branches correspond to unique outcomes of the scenario.

For further exemplification, the results of repeated simulations of a heuristic scenario with five tasks are represented in Figure 7-4. In the first simulation of this process, errors occurred (as represented by x's) in tasks 1, 2, and 4, and the relative risk measure for the scenario was 0.7. In the second simulation, errors occurred in tasks 2 and 3, where the risk measure was 0.3, and so on. The results of repeated simulations permit the identification of the highest relative risk error outcomes and of those tasks most likely to be associated with the highest-risk outcomes. Figure 7-5 is the same as 7-4 except for the shadings applied to the results of the first and third simulations. The dark shading highlights those two simulations with the highest relative risk values, 0.7 and 0.8, respectively. The diagonal-line shading highlights those task errors, tasks 1 and 4, that are common to the two highest-risk simulations. Thus, the simulation process helps identify the highest-risk scenarios and the errors most likely to be associated with those scenarios.

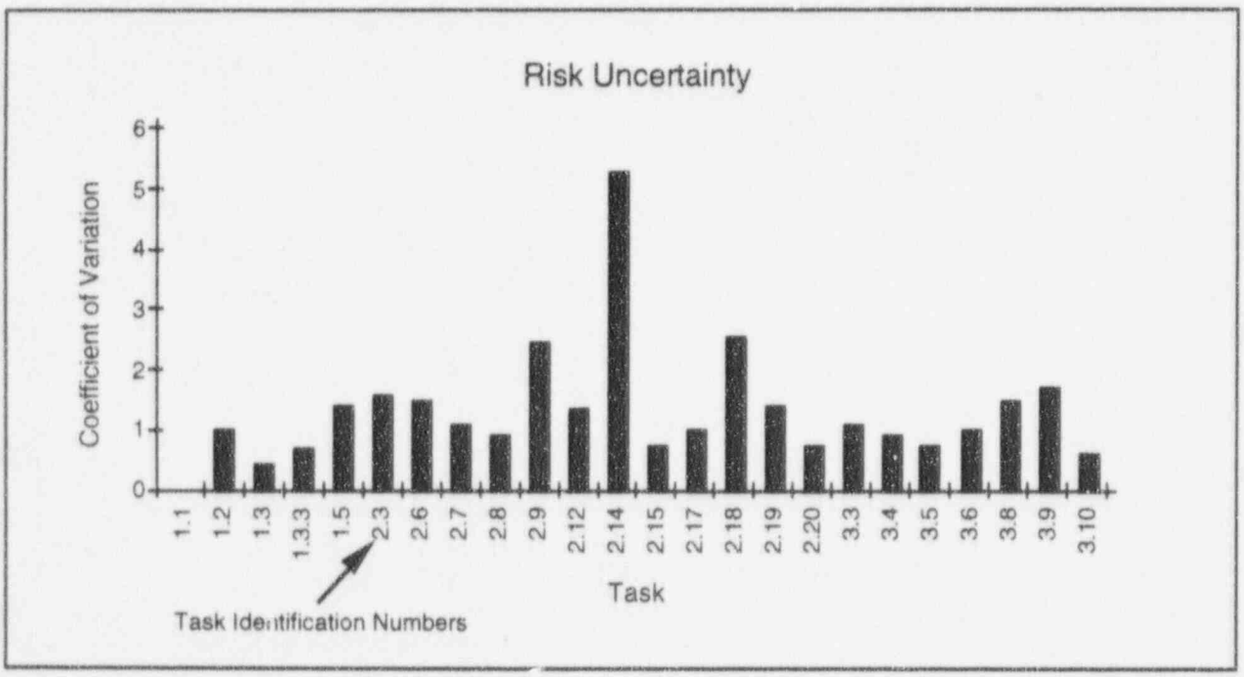


Figure 7-1 Risk uncertainty for Gamma Knife tasks.
The coefficient of variation is the ratio of the standard deviation over the mean. The numerals along the abscissa are task identification numbers.

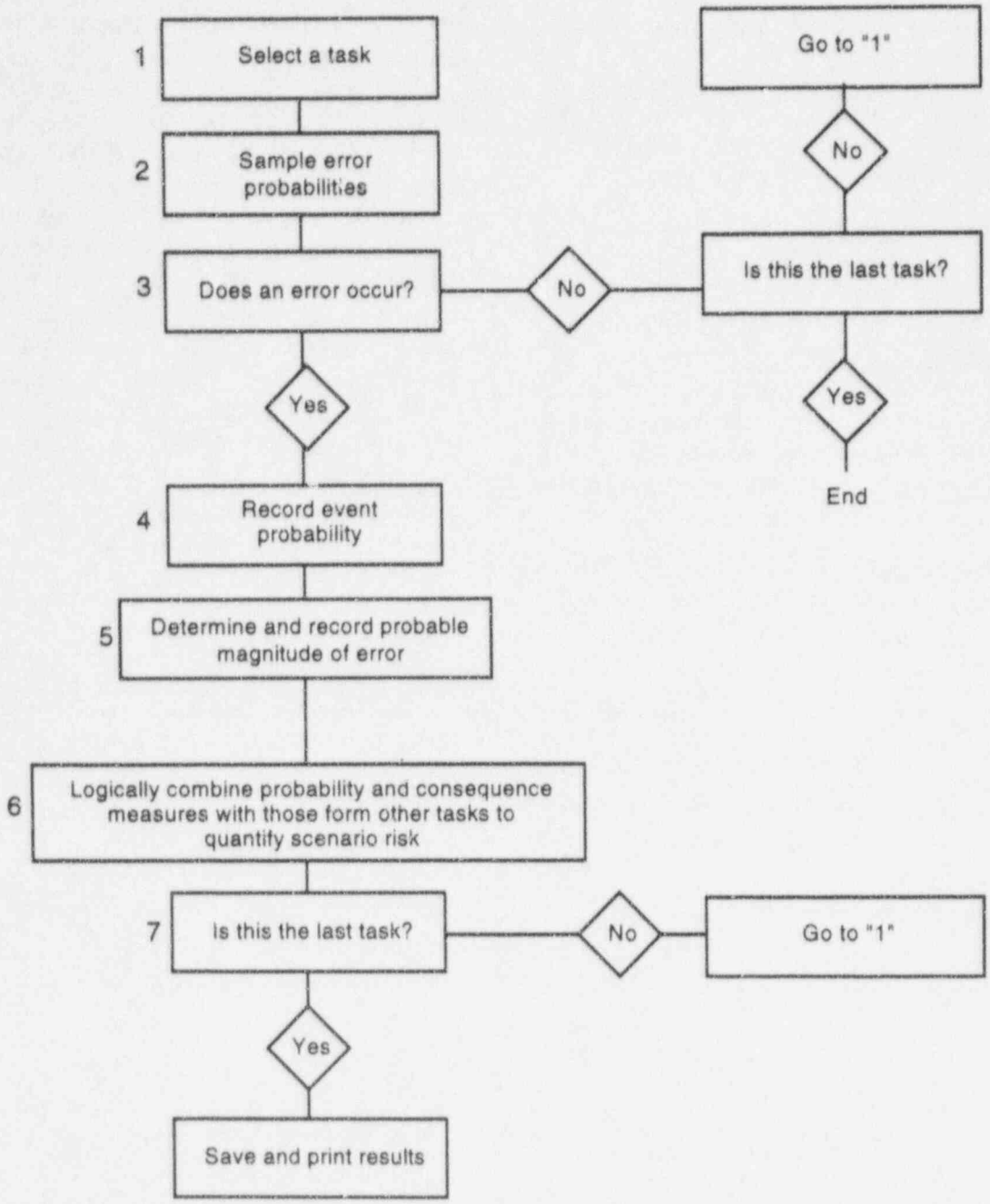


Figure 7-2 Risk scenario simulation logic flow

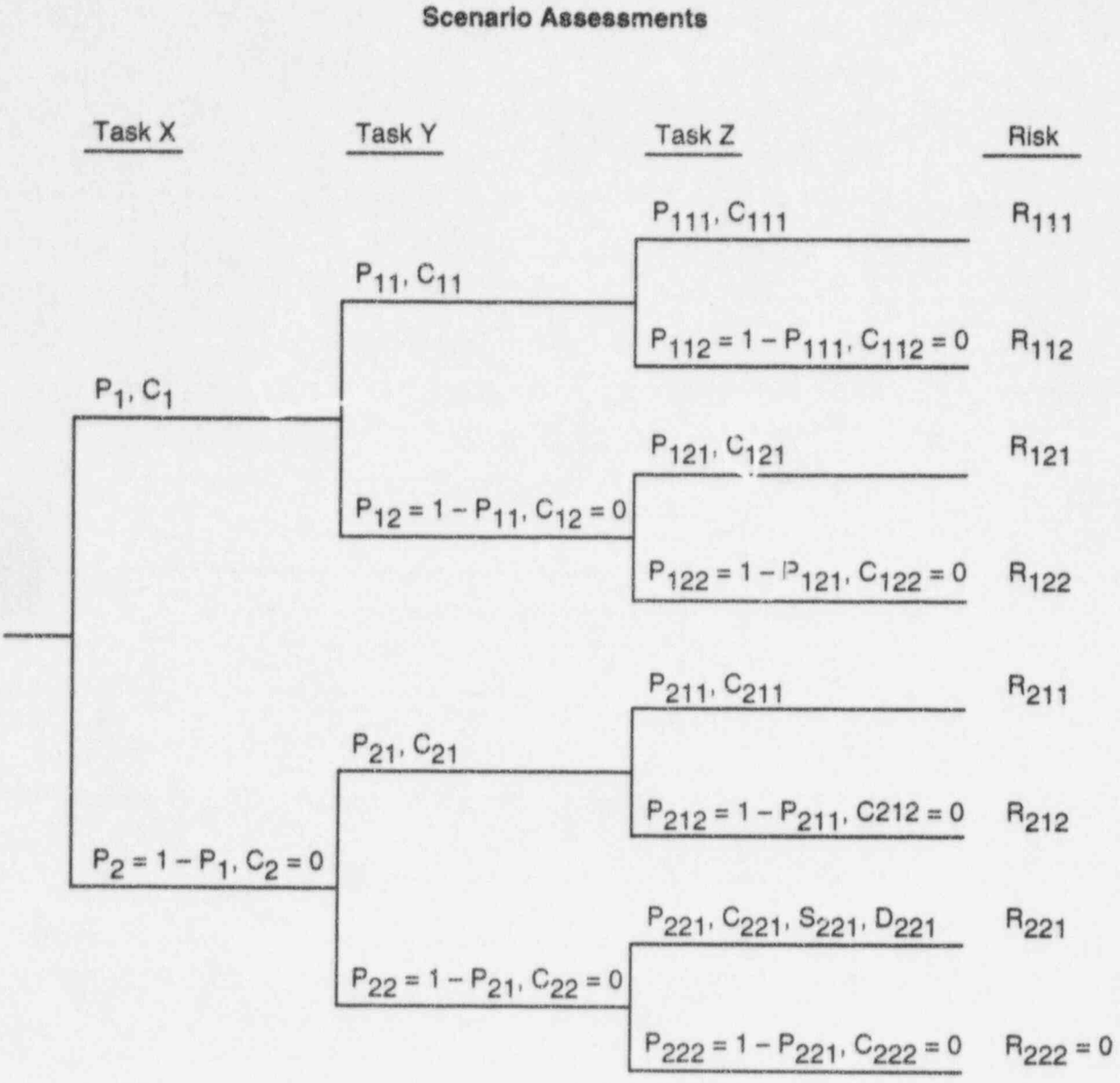


Figure 7-3 Decision tree heuristic for sequential event occurrences

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 7-4 Example results for simulations of a process with five tasks

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

Figure 7-5 Example identified tasks most likely associated with the highest risk scenarios.

7.2 Importance Analysis

The scenario simulation code was used to analyze the relative risks associated with the Gamma Knife treatment path. The treatment path was modeled to consist of the 24 primary, independent tasks listed in Table 5-1. Subtask error probability and consequence distributions in Appendix B were aggregated for each primary task to provide single probability and consequence distributions for each primary task.

The Monte Carlo simulation can introduce additional uncertainty into the risk analysis if insufficient trials are executed. To obviate this problem, enough simulations were performed to ensure at least a 5% accuracy in the 95% wings of the generated risk scenario distributions. Such an error is negligible compared to the uncertainties in the task error estimates. The convergence criteria stated that the totaled average of scenario risk values not vary more than 1 part in 10,000. The Monte Carlo simulation displayed good convergence or stability characteristics. The distributions, when simulating 24-task scenarios, stabilized after about 50,000 simulations. This study considered up to 100,000 simulations to try ensuring against any outlier scenarios.

The total error probability and consequence value for each simulated scenario was recorded. Based on the range of these values, seven error probability bins and seven consequence bins were established to help aggregate the results. Thus, the results of each simulation were associated with one of 49 bins.

The distribution of risk scenarios as a function of total error probability and consequence is shown in Figure 7-6. The plot shows two domains associated with the majority of risk scenarios: (1) relatively high-probability and high-consequence scenarios, and (2) relatively high-probability and low-consequence scenarios. One domain is in the upper-left quadrant of Figure 7-6. Several outcomes reside in this domain, because there are many task errors that can occur relatively often but have small error magnitudes. Examples of such errors are those that occur in measurement tasks. The other domain is in the upper-right quadrant of Figure 7-6. It contains scenario outcomes associated with relatively frequent task errors of moderate consequence. The events in this domain are thus of particular concern.

The simulation code was then used to generate the distribution of tasks with errors associated with scenarios in each of four quadrants of the Figure 7-6 risk domain. The results are shown in Figures 7-7 through 7-10.

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 6, 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 Figures 6-1 and 6-2, the error of task 2.15 has both relatively high consequences and probability of occurrence. Hence, it is expected to be a prevalent task among high-probability, high-consequence risk scenarios. According to the results in Figure 7-7, task 2.15 is prevalent, but not as prevalent as task 2.9, even though the point estimates in Figure 6-2 show the consequences of task 2.9 to be lower than those for task 2.15. The reason is revealed by Figure 7-1. The risk variation for task 2.9 is over three times higher than that for task 2.15. By looking at the error probability and consequence distributions combined to give the risk uncertainty, it is clear that most of the uncertainty was propagated from the consequence distribution. Task 2.9 has very small contributing errors, like ruler measurements, and very large contributing errors, such as imaging film reversals. Hence, even though tasks 2.9 and 2.15 have comparable error probabilities, as shown by Figure 6-1, the greater variation in the consequences of task 2.9 cause it to be more prevalent in the high-probability, high-consequence scenarios than in task 2.15. The same phenomenon applies for the high-probability, low-consequence risk scenarios (see Figure 7-8). Here, task 2.9 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, task 2.9 was focused on as potentially critical to risk in Gamma Knife treatments. Task 2.9 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. Errors would cause the wrong area of the patient's brain to be irradiated.

Sensitivity and risk mitigation studies were performed on task 2.9 by investigating ways to lower the error probabilities and consequences of the subtasks. Modified subtask error distributions were then combined to see what effect the changes had on the risk distribution for task 2.9. The mean risk associated with task 2.9 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. With both of these preventive measures, the coefficient of variation of the risk distribution for task 2.9 is reduced by almost 50%.

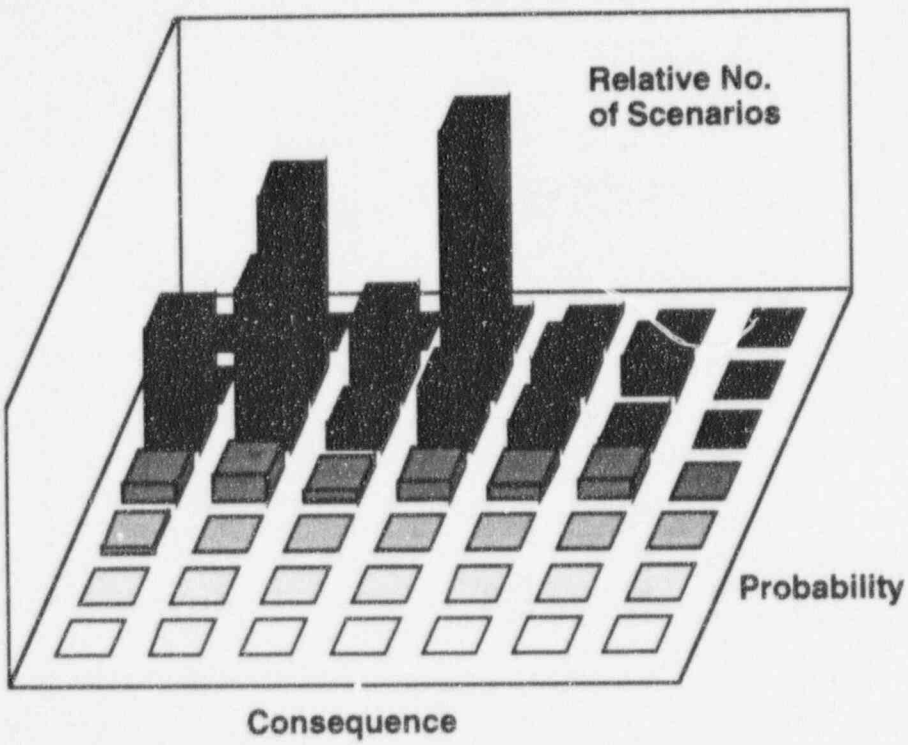


Figure 7-6 Distribution of risk scenarios for the Gamma Knife

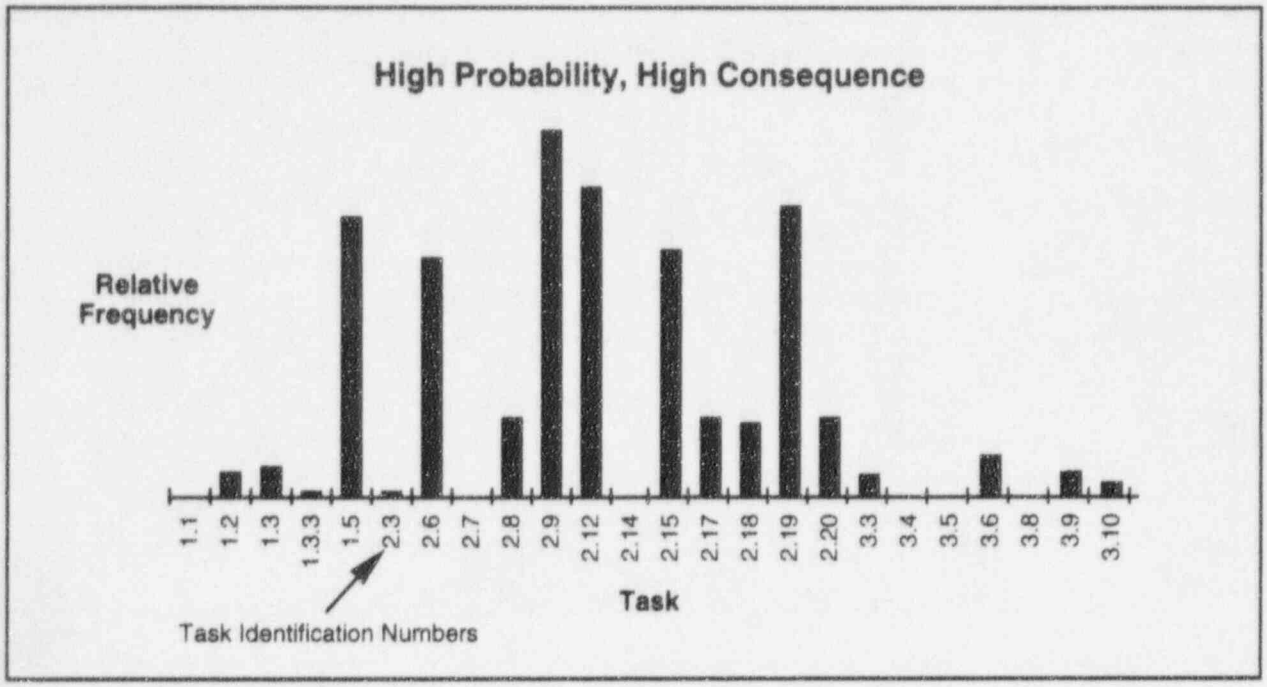


Figure 7-7 The relative frequency of individual tasks* associated with scenarios in the high-probability, high-consequence domain of risk space.

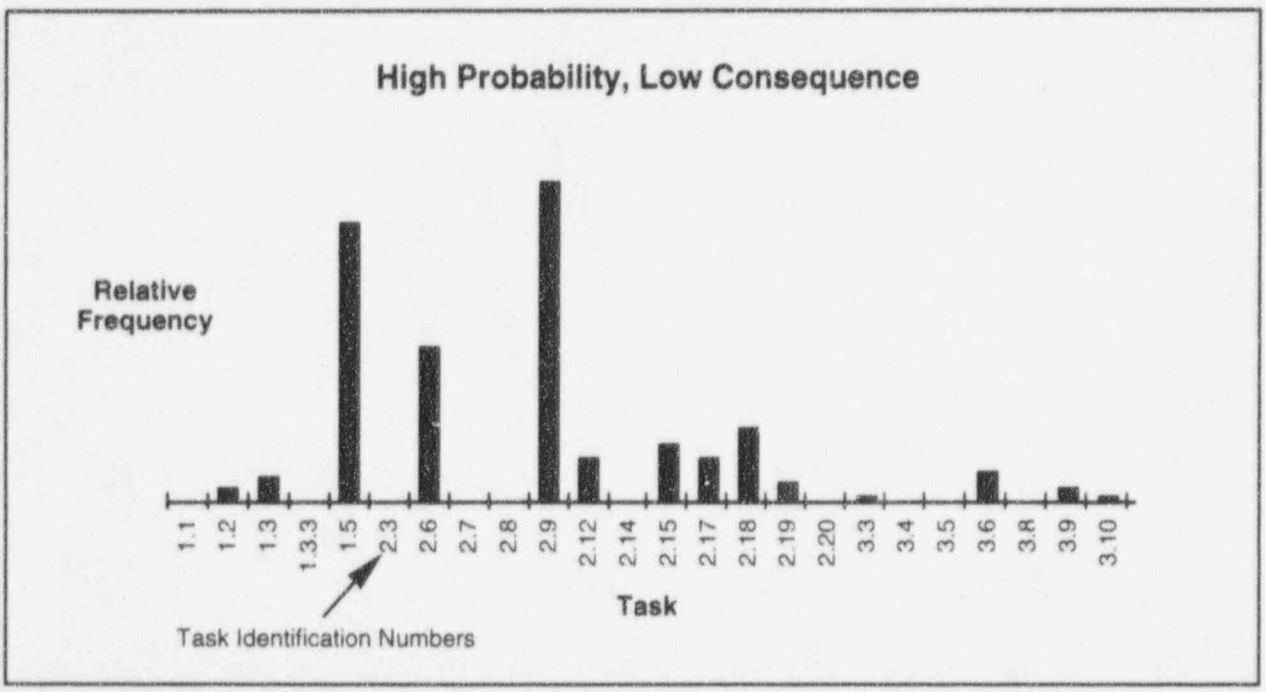


Figure 7-8 The relative frequency of individual tasks* associated with scenarios in the high-probability, low-consequence domain of risk space.

***Numerals in abscissa are task identification numbers.**

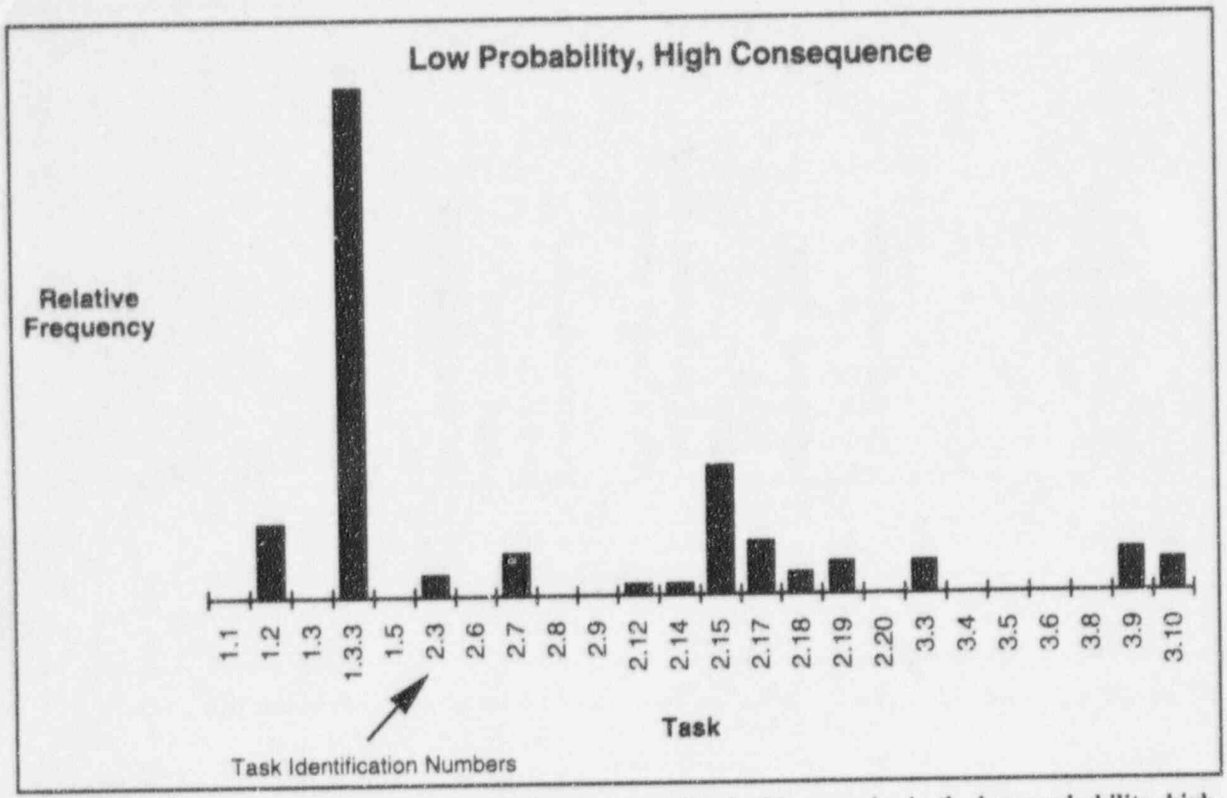


Figure 7-9 The relative frequency of individual tasks* associated with scenarios in the low-probability, high-consequence domain of risk space.

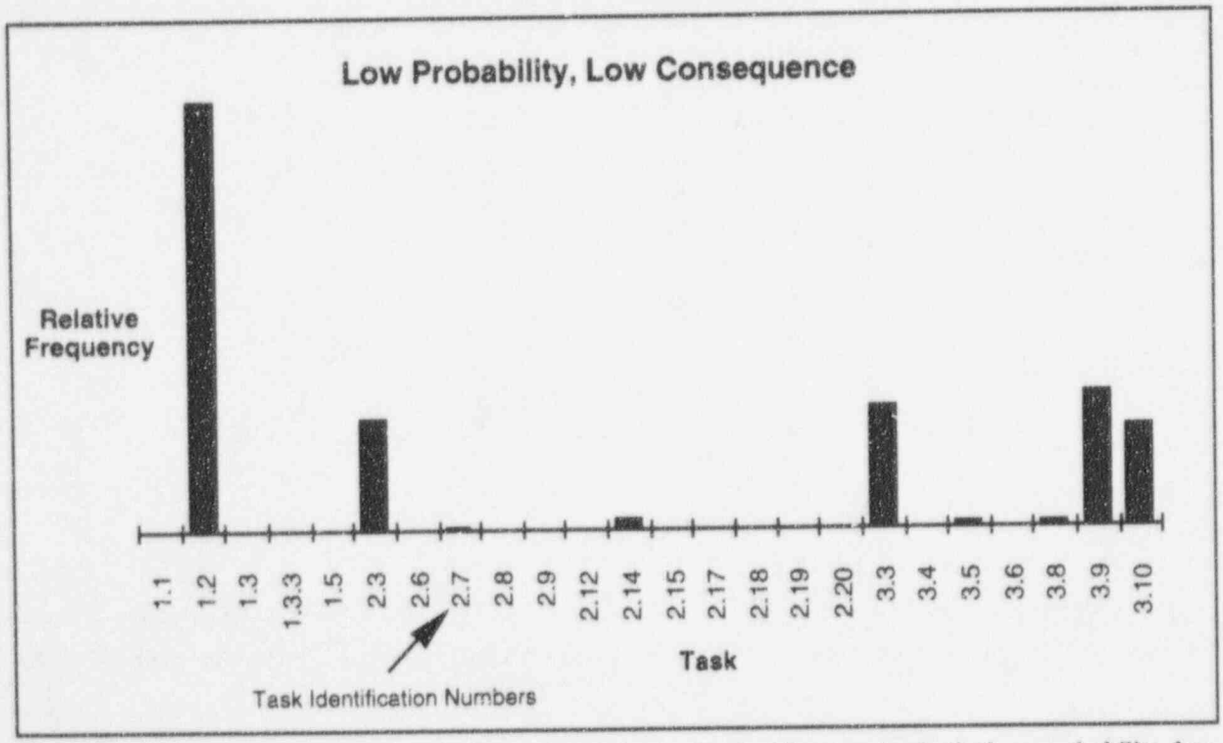


Figure 7-10 The relative frequency of individual tasks* associated with scenarios in the low-probability, low-consequence domain of risk space.

***Numerals in abscissa are task identification numbers.**

Tasks 2.12 and 2.19 were also prevalent tasks associated with high-risk scenarios. These tasks' relatively high risks (see Figure 6-1) 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. While observing patient treatments, it was noticed 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.

An apparent solution for reducing this risk was: before signing the prescription, the dose distribution calculated exactly from the prescription should be compared with the intended treatment 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 or added recovery factor 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.

Note that the manufacturer of the Gamma Knife now sells a more powerful computerized treatment planning system, called GammaPlan. 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, a risk evaluation of GammaPlan by LLNL has not been performed.

The scenario simulation code 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. The distribution of risk scenarios for the Gamma Knife treatment path with modified tasks is presented in Figure 7-11. It can be seen that the relatively high-probability, high-consequence scenarios have been substantially mitigated.

Sensitivity studies were performed 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 outcomes with respect to risk, shown both before and after the reduction strategy in Figures 7-12 and 7-13, respectively. (The nine risk values along the abscissas of these plots are bins used to aggregate the relative risk values.) There is a complete reversal in the accumulation of scenarios from high to low risks. 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%.

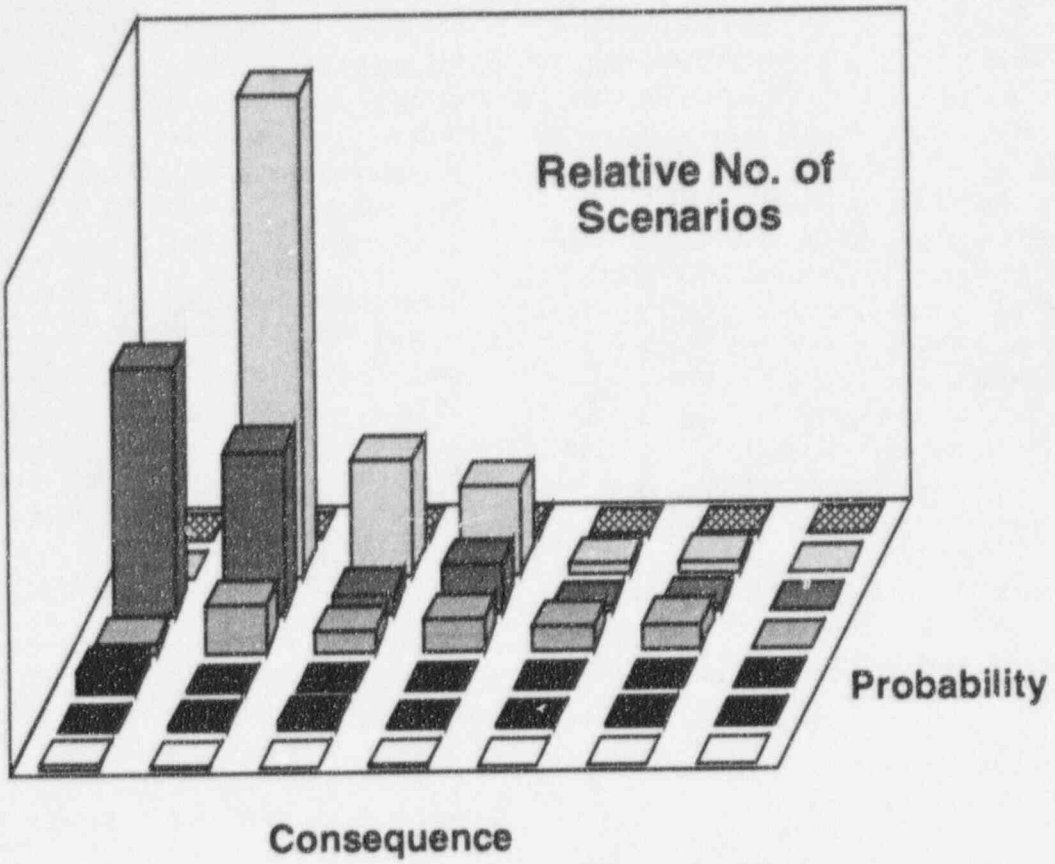


Figure 7-11 Distribution of risk scenarios with modified tasks.

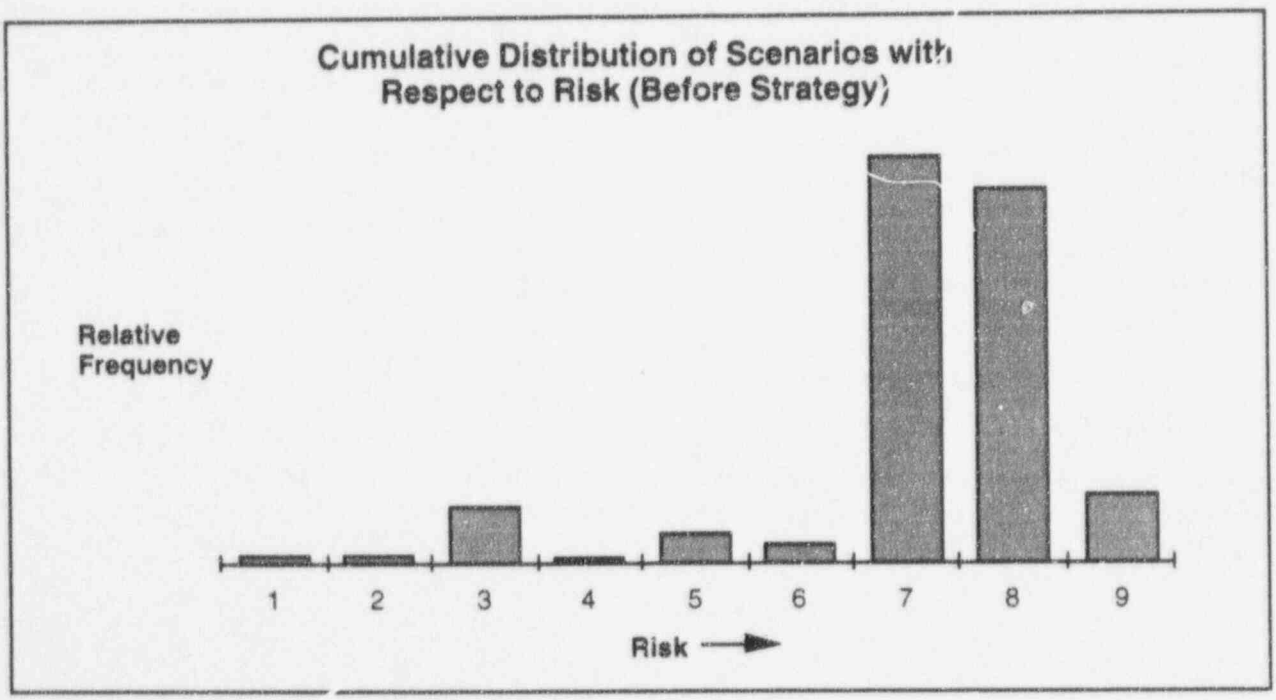


Figure 7-12 Relative frequency of Gamma Knife scenarios as a function of risk.

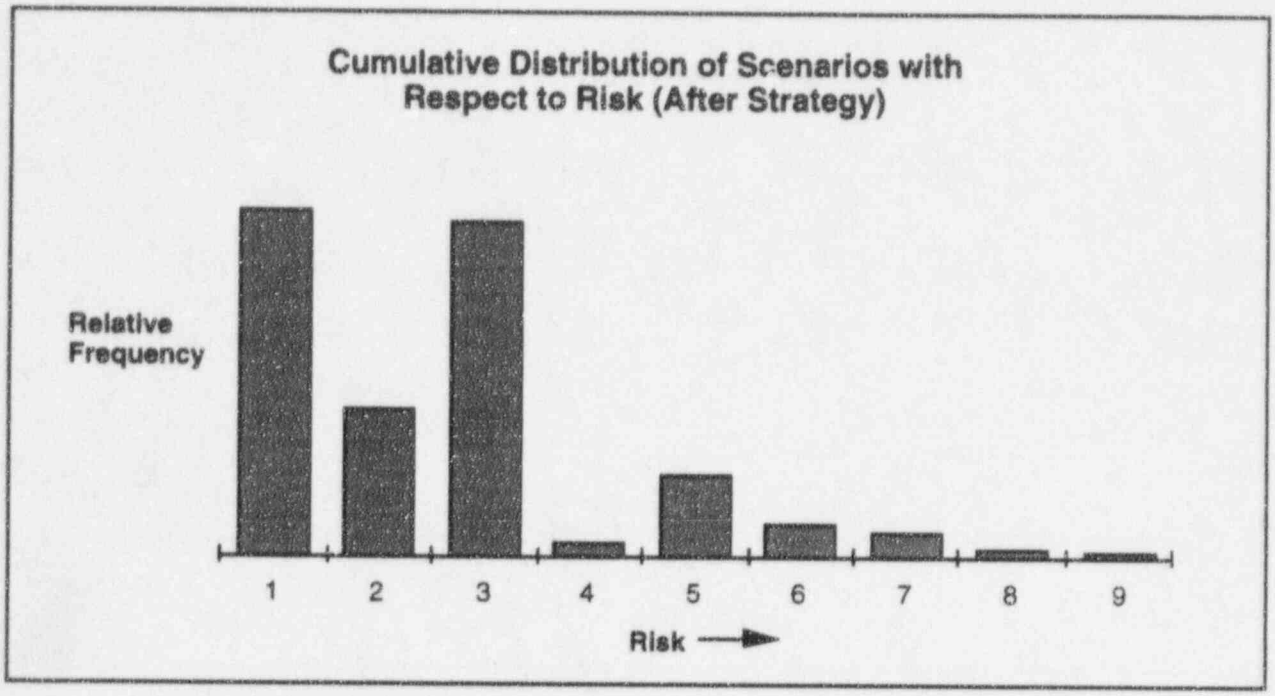


Figure 7-13 Relative frequency of scenarios with modified tasks as a function of risk.

8. DISCUSSION OF POST-ANALYSIS EVENTS

After the data collection and analyses were completed for this project, new data became available on the likelihood of three Gamma Knife events. It is worthwhile to compare this 'actual' data with the prior expert estimates utilized in the risk analysis of the Gamma Knife.

Shortly after the completion of the risk analysis, the first misadministration associated with the use of the Gamma Knife was reported (NRC 1994). This incident involved a misunderstanding of the orientation of angiography films, resulting in a left-right reversal of the images during treatment planning. Consequently, a treatment shot was delivered in the wrong place - on the opposite side of the brain from the lesion. Film reversal (Task 2.9.1) was considered as a contributing fault event to Task 2.9, and was highlighted as a potential high-risk event by the risk analysis in Section 7.2.

At the time of this incident, approximately 6000 patients had been treated using the Gamma Knife in the U.S. without a misadministration. Since then another, approximately 4000 patients have been treated without a misadministration. The statistics provided by this sample size indicate a 99% confidence that the probability of misadministration due to film reversal is not greater than 2E-3, with a width factor of 2, i.e., the probability is less than or equal to (1-4)E-3. The prior expert point estimate (mean value) of such an event used in our risk analysis was 3E-3.

Subsequent to this risk analysis, a Gamma Knife unit failed to retract from the treatment position, because of a failure of a solenoid-operated valve on the hydraulic system of the unit (NRC 1995). This is the sort of equipment failure anticipated by the analysis in Section 5.3. In this event the staff attempted to: 1) manually pump the hydraulic system; and 2) shut the unit off. The latter action would normally direct the pressure to allow the bed to retract. However, in this case, the valve was stuck in the 'bed-in' position. The valve failure disabled both the normal and primary emergency patient retraction systems on the unit, resulting in the patient being irradiated for 3.8 minutes longer than the intended 3--minute treatment time. Medical personnel entered the room, pulled the emergency pressure release latch on the bed, dropping the helmet to the lowest position corresponding to the low point of the couch track, and were able to move the bed approximately 20 inches. Subsequently, they removed the patient from the unit and treatment room.

This event occurred after an approximate cumulative total of 9000 patient treatments with the Gamma Knife in the U.S. The statistics provided by this sample size indicate a 99% confidence that the probability of such an event is not greater than 2E-3, with a width factor of 2, i.e., the probability is less than or equal to (1-4)E-3. The prior expert point estimate of such an event used in our risk analysis was 1E-3.

After the completion of the risk analysis, a study was published (Flickinger 1993) on the potential errors in setting the Gamma Knife shot coordinates during patient positioning prior to treatment. This experiment determined the error frequency in setting and checking the isocenter coordinates, which corresponds to Subtasks 3.5.1 - 3.5.2 of Task 3.5 (see Appendix C, Figure 20). It was found that the probability of an undetected error $\geq$ 0.25 mm, given verification by two observers, was 1/1,392 or 7E-4. The prior expert point estimate used in our risk analysis for incorrectly setting and checking isocenter coordinates was 2E-4.

One of the purported features of relative risk rankings is that each rank can be calibrated by rescaling all values, if an actual value for one or more ranked elements is known (assuming the elements are correctly and consistently ranked). It is possible, however, that actual values for different elements will produce conflicting calibrations. To check and compare calibrated values based on the new data, the actual probability for each event was used to calibrate the probability of the other two events. Based on the film reversal likelihood, the calibrated

likelihood for the hydraulic component failure was 1E-3, and for the coordinate setting error 1E-4. Calibrations determined by the hydraulic component failure probability gave 6E-3 and 4E-4 for the film reversal and coordinate setting error probabilities, respectively. The coordinate setting likelihood value provided a calibrated value of 1E-2 for the film reversal and 4E-3 for the hydraulic component failure.

The probability values—expert estimate, actual, and calibrated—for each of the three events are tabulated below for comparison. Note that the values for each event are well within an order of magnitude.

Table 8-1 Comparison of Event Probabilities

	Expert Estimate	Actual Value	Calibrated Values
Imaging film reversed (2.9.1)	3E-3	≤ 2E-3 (2)	6E-3, 1E-2
Hydraulic component failure	1E-3	≤ 2E-3 (2)	1E-3, 4E-3
Set and check isocenter coordinates error (3.5.1 - 3.5.2)	2E-4	7E-4	1E-4, 4E-4

9. SUMMARY AND CONCLUSIONS

This initial effort in applying risk analysis to a gamma irradiation medical device resulted in the development of a relative risk profile process that provides a basic means for identifying the most likely risk contributors and their relative importance. Relative risk profiles and distributions were developed which offered insights into the critical tasks of the Gamma Knife treatment process.

It was concluded that the limited data base for the Gamma Knife does not permit the accurate estimation of individual risk contributor values and that absolute values were not necessary for an effective understanding and regulation of the system. Thus, the use of a relative risk analysis approach was applicable to the Gamma Knife, and a relative risk profiling process was planned and developed.

The risk approach provides a flexible analysis framework that can incorporate both qualitative and quantitative data about human and equipment factors. Five steps were used in the relative risk profiling process applied to the Gamma Knife: (1) Review Gamma Knife equipment, functions, and operations, (2) Identify risk contributors through modified task analysis, (3) Identify potentially high-risk contributors and tasks through an expert screening process, (4) Assess high-risk tasks through relative ranking and profile analysis, and (5) Estimate the importance associated with high-risk tasks.

The first three steps systematically identify elements most likely to contribute to risk. The last two steps evaluate the relative risk importance of each of the identified risk contributors. The process consists of a series of screening and ranking techniques that progressively distill out the relatively high-risk elements in the Gamma Knife application. After a thorough familiarization with the Gamma Knife, a preliminary analysis of all major tasks with potential risk was performed. Equipment failures were subsumed within the task analysis. As part of this process, radiation hot spots were discovered to which a patient would be subject while being transported within the radiation unit. Gamma Knife experts reviewed and screened postulated risk contributors. Through a formal elicitation process, the experts also provided relative estimates of the likelihoods and consequences of human-initiated errors and equipment failure modes. This information helped to screen out the equipment failure modes as less risk significant than treatment error events. An importance and uncertainty analysis further identified the most critical tasks.

The type of products resulting from application of the relative risk profiling process include systems information, event/task data, and risk data. The systems information includes details about quality assurance elements, potential hazards, and potential abnormal operation events or modes. The task data helps characterize potential errors and can be used to develop preventive or mitigative measures. The risk data includes relative estimates of failures or errors and of consequences of undesired events. The risk data is manipulated into relative rankings or risk profiles and risk distributions.

The relative risk profiles showed that several of the highest-risk tasks are associated with the treatment planning process. The uncertainty and important analyses further indicated that particularly critical tasks are 2.9 Geometric determinations from films, 2.12 Selections of calculation mode, 2.15 Enter shot parameters, and 2.19 Enter prescribed dose.

Task 2.9 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 and performing coordinate transformations. These errors would cause the wrong area of the patient's brain to be irradiated. Sensitivity and risk mitigation studies demonstrated that the mean risk associated with task 2.9 could be

reduced by 20% by modifying the task to prevent film reversals, and reduced another 10% by making the correct coordinate transformations. As it happened after this analysis was completed, the first U.S. misadministration with the Gamma Knife concerned an angiography film reversal.

Tasks 2.12, 2.15, and 2.19 concern the accuracy of the dose calculations. A simple solution for reducing the risks is to require an additional check—before signing the prescription—comparing the treatment plan to the dose distribution calculated exactly from the prescription.

This final check would also provide an opportunity to discover and correct other data-manipulation errors that could occur during the treatment planning process.

The analysis showed that with the above-mentioned three procedural changes—(1) prevent film reversals, (2) correctly determine coordinate transformations, and (3) compare post-prescription dose profiles to the treatment plan—the number of incorrect treatments could be reduced by 23%, and dose errors greater than 10% could be reduced by 66%.

After the data collection and risk analysis were completed, new data became available on the error likelihoods of some Gamma Knife events. This actual data compared favorably—in both magnitude and relative values—with the expert estimates utilized.

The results of applying the developed relative risk profiling process to the Gamma Knife are device-specific, but the process can be applied to other radiation-emitting devices. It may be most effective in nuclear medical applications that are not highly structured or have limited experience data bases. The techniques can employ both qualitative and quantitative data. They exploit the expertise of professionals who have operating experience with the medical device. The simple tools used provide a powerful screening process. Risk profiles are expeditiously developed and enable an easy understanding of the most critical tasks.

The relative risk profile process, however, does not provide a quantitative risk of misadministration, nor does it permit a comparison of risks among different medical devices.

The relative risk techniques used to study the Gamma Knife can identify weaknesses in processes and support the development of positive performance measures, rather than predict the risk associated with poor performance. This approach could serve to produce reliable processes and procedures to prevent misadministrations resulting from mistakes.

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APPENDIX A: Gamma Knife Task Data

This appendix contains data collected for Gamma Knife treatment tasks. The data were collected as part of the modified task analysis efforts described in Section 2.3. The data were collected by 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. The team inspected gamma units, attended acceptance tests, interviewed users, and observed patient treatments. Subject matter experts used simulations, facility walk-throughs, and observations of actual practices to verify the task analysis data for accuracy, completeness, and self-consistency.

The data were collected with task data forms and a corresponding set of task analysis category definitions. The task category definitions are:

Task Number - Each task and subtask must be assigned a number. This number identifies the process in which the task/subtask occurs and its position relative to other tasks/subtasks in the process.

Task Description Purpose - This describes what must be done to complete each task or subtask. The task description column should be filled out first, since all other columns refer to it.

Task Frequency - In this column, the frequency of task performance is given on a per-patient basis.

Performance Standards - This information is used to identify the criteria for satisfactory task performance. Performance standards should be objective and verifiable. They may be quantitative.

Support Equipment - Support equipment is any non-essential item required to perform the task.

Training/Knowledge Required to Perform This Task - Subject matter experts are requested to determine the elements of knowledge essential to perform each task effectively. Knowledge requirements are broadly defined here to include knowing how to do something (i.e., skill mastery) as well as knowing information and concepts.

Ways to Lessen Risk - This information is used to indicate how the potential for human errors and their consequences can be minimized.

There are four categories to choose from: (1) Equipment (referring to equipment selection/design and workspace design), (2) Procedures, (3) Training, and (4) Supervision. One or more may be chosen. The choices indicate where provisions can be made most effectively to assure safe and successful performance of the task.

PROCESS: Imaging and Localization, Treatment Planning, Treatment

1. Task ID Number	1.1, 2.1, 2.6.1, 3.2
2. Task Description/Purpose	Identify correct patient
3. Task Frequency (No. of times per patient; 0 if not performed)	4
4. Performance Standards	Absolute correct identification At least two independent checks
5. Support Equipment	Patient records Films, planning data Written directive and prescription
6. Training/Knowledge Required (Academic, Equip., OJT, etc.)	Academic (nursing) OJT
7. Ways to Reduce Errors/Risk (Procedures, Equip., Training, etc.)	Management oversight/supervision Procedures Training

PROCESS: Imaging and Localization

1. Task ID Number	1.2 (1.2.1–1.2.3)
2. Task Description/Purpose	Affix sterotactic head frame
3. Task Frequency (No. of times per patient; 0 if not performed)	1
4. Performance Standards	Frame affixed securely—immovable
5. Support Equipment	Stereotactic frame Skull posts Wrenches, screwdrivers
6. Training/Knowledge Required (Academic, Equip., OJT, etc.)	Academic (neurosurgery) Medical expertise
7. Ways to Reduce Errors/Risk (Procedures, Equip., Training, etc.)	Departmental QA/QC and maintenance for frame Checks on frame integrity and affixation

PROCESS: Imaging and Localization

1. Task ID Number	1.3 (1.3.1–1.3.4)
2. Task Description/Purpose	Set up CT, MR, Angiography
3. Task Frequency (No. of times per patient; 0 if not performed)	1-2
4. Performance Standards	Patient aligned correctly Films labeled correctly
5. Support Equipment	CT, MR, Angiography units CT, MR, or X-ray indicators Computer systems
6. Training/Knowledge Required (Academic, Equip., OJT, etc.)	Academic (medical imaging) Equipment training Apprentice training, experience
7. Ways to Reduce Errors/Risk (Procedures, Equip., Training, etc.)	Departmental QA/QC and maintenance of equipment Procedures (including independent checks) New employee and refresher training

PROCESS: Imaging and Localization

1. Task ID Number	1.4
2. Task Description/Purpose	Determine outline of lesion
3. Task Frequency (No. of times per patient, 0 if not performed)	1-2
4. Performance Standards	Medical judgment
5. Support Equipment	Imaging films
6. Training/Knowledge Required (Academic, Equip., OJT, etc.)	Academic (medical)
7. Ways to Reduce Errors/Risk (Procedures, Equip., Training, etc.)	Independent checks/conferences Image enhancement equipment

PROCESS: Imaging and Localization

1. Task ID Number	1.5
2. Task Description/Purpose	Check that center of frame deposited correctly on CT, MR films
3. Task Frequency (No. of times per patient; 0 if not performed)	0–10
4. Performance Standards	0.8–2 mm
5. Support Equipment	CT, MR computer systems
6. Training/Knowledge Required (Academic, Equip., OJT, etc.)	Equipment operation and interpretation OJT—apprentice training
7. Ways to Reduce Errors/Risk (Procedures, Equip., Training, etc.)	QA/QC and maintenance of imaging/computer systems Independent checks by drawing lines

PROCESS: Imaging and Localization

1. Task ID Number	1.6
2. Task Description/Purpose	Determine initial isocenter locations/coordinates
3. Task Frequency (No. of times per patient; 0 if not performed)	1
4. Performance Standards	Medical judgment
5. Support Equipment	Imaging films
6. Training/Knowledge Required (Academic, Equip., OJT, etc.)	Academic (medical) Gamma Knife training
7. Ways to Reduce Errors/Risk (Procedures, Equip., Training, etc.)	Independent checks/conferences Gamma Knife training

PROCESS: Treatment Planning

1. Task ID Number	2.2 (2.2.1–2.2.4)
2. Task Description/Purpose	Simulate treatment—determine range of treatment parameters
3. Task Frequency (No. of times per patient; 0 if not performed)	0 -1
4. Performance Standards	Medical judgment
5. Support Equipment	Stereotactic frame and Gamma Knife
6. Training/Knowledge Required (Academic, Equip., OJT, etc.)	Academic (medical) Experience with Gamma Knife
7. Ways to Reduce Errors/Risk (Procedures, Equip., Training, etc.)	Conferences/independent checks

PROCESS: Treatment Planning

1. Task ID Number	2.3 (2.3.1–2.3.3)
2. Task Description/Purpose	Check treatment planning equipment
3. Task Frequency (No. of times per patient; 0 if not performed)	1
4. Performance Standards	< 2%
5. Support Equipment	Treatment planning hardware/software Digitizing equipment Plotter
6. Training/Knowledge Required (Academic, Equip., OJT, etc.)	Gamma Knife training
7. Ways to Reduce Errors/Risk (Procedures, Equip., Training, etc.)	QA/QC and maintenance programs Procedures Independent checks

PROCESS: Treatment Planning

1. Task ID Number	2.4
2. Task Description/Purpose	Start up of treatment planning software
3. Task Frequency (No. of times per patient; 0 if not performed)	1
4. Performance Standards	Must start up correctly and enter correct date to use software
5. Support Equipment	Micro Vax or HP Workstation
6. Training/Knowledge Required (Academic, Equip., OJT, etc.)	Kula training
7. Ways to Reduce Errors/Risk (Procedures, Equip., Training, etc.)	Follow start-up procedures

PROCESS: Treatment Planning

1. Task ID Number	2.5
2. Task Description/Purpose	Create patient data file in treatment planning program
3. Task Frequency (No. of times per patient; 0 if not performed)	1-2
4. Performance Standards	Enter patient name correctly Enter correct administrative data
5. Support Equipment	Kula software Patient records
6. Training/Knowledge Required (Academic, Equip., OJT, etc.)	Training in patient record procedures and use of Kula
7. Ways to Reduce Errors/Risk (Procedures, Equip., Training, etc.)	Management oversight/supervision Independent checks Periodic revie ws

PROCESS: Treatment Planning

1. Task ID Number	2.6 (2.6.1–2.6.5)
2. Task Description/Purpose	Take skull measurements (supine or prone position)
3. Task Frequency (No. of times per patient; 0 if not performed)	1–2
4. Performance Standards	± (3-4) mm
5. Support Equipment	Skull measuring bubble Measuring stick Data form
6. Training/Knowledge Required (Academic, Equip., OJT, etc.)	OJT—apprentice training
7. Ways to Reduce Errors/Risk (Procedures, Equip., Training, etc.)	Verification procedures Refresher training

PROCESS: Treatment Planning

1. Task ID Number	2.7 (2.7.1)
2. Task Description/Purpose	Enter skull data into treatment planning program
3. Task Frequency (No. of times per patient; 0 if not performed)	1–2
4. Performance Standards	Data entered correctly
5. Support Equipment	Skull data forms Treatment planning software
6. Training/Knowledge Required (Academic, Equip., OJT, etc.)	Gamma Knife treatment planning training
7. Ways to Reduce Errors/Risk (Procedures, Equip., Training, etc.)	Verification checks Periodic reviews

PROCESS: Treatment Planning

1. Task ID Number	2.8
2. Task Description/Purpose	Enter gamma angle into treatment planning program
3. Task Frequency (No. of times per patient; 0 if not performed)	1–2
4. Performance Standards	Enter exact value ± 5 degrees
5. Support Equipment	Kula computer software
6. Training/Knowledge Required (Academic, Equip., OJT, etc.)	Treatment planning training
7. Ways to Reduce Errors/Risk (Procedures, Equip., Training, etc.)	Independent checks

PROCESS: Treatment Planning

1. Task ID Number	2.9 (2.9.1–2.9.5)
2. Task Description/Purpose	Make measurements/determinations from films
3. Task Frequency (No. of times per patient; 0 if not performed)	1–2 (many for isocenter coordinates)
4. Performance Standards	± .5-1 mm
5. Support Equipment	Digitizing equipment Computer programs Straight edges/rulers
6. Training/Knowledge Required (Academic, Equip., OJT, etc.)	Gamma Knife treatment planning training
7. Ways to Reduce Errors/Risk (Procedures, Equip., Training, etc.)	Independent checks Procedures Refresher training

PROCESS: Treatment Planning

1. Task ID Number	2.10
2. Task Description/Purpose	Enter center coordinates and set dose matrix size for dose calculation matrix
3. Task Frequency (No. of times per patient; 0 if not performed)	1–2
4. Performance Standards	Enter correct data for adjuged choices
5. Support Equipment	Kula software
6. Training/Knowledge Required (Academic, Equip., OJT, etc.)	Treatment planning training Experience
7. Ways to Reduce Errors/Risk (Procedures, Equip., Training, etc.)	Verification/conference

PROCESS: Treatment Planning

1. Task ID Number	2.11
2. Task Description/Purpose	Set absolute dose at a specified point or use default
3. Task Frequency (No. of times per patient; 0 if not performed)	1
4. Performance Standards	Use adjudged value
5. Support Equipment	Kula
6. Training/Knowledge Required (Academic, Equip., OJT, etc.)	Treatment planning training Experience
7. Ways to Reduce Errors/Risk (Procedures, Equip., Training, etc.)	Periodically check software use of value Verification procedures

PROCESS: Treatment Planning

1. Task ID Number	2.12 (2.12.1)
2. Task Description/Purpose	Set cut-and-modify or exact calculation mode
3. Task Frequency (No. of times per patient; 0 if not performed)	1–2
4. Performance Standards	Set mode correctly
5. Support Equipment	Kula
6. Training/Knowledge Required (Academic, Equip., OJT, etc.)	Treatment planning training Experience
7. Ways to Reduce Errors/Risk (Procedures, Equip., Training, etc.)	Independent checks

PROCESS: Treatment Planning

1. Task ID Number	2.13
2. Task Description/Purpose	Calculate target volume for dose—volume considerations
3. Task Frequency (No. of times per patient; 0 if not performed)	0–5
4. Performance Standards	± 5%
5. Support Equipment	Computer programs Digitizers/measuring tools
6. Training/Knowledge Required (Academic, Equip., OJT, etc.)	Apprentice training
7. Ways to Reduce Errors/Risk (Procedures, Equip., Training, etc.)	QA/QC on volume programs Verification procedures

PROCESS: Treatment Planning

1. Task ID Number	2.14
2. Task Description/Purpose	Determine isocenter (x,y,z) coordinates
3. Task Frequency (No. of times per patient; 0 if not performed)	2–many times
4. Performance Standards	± 0.5 mm
5. Support Equipment	Computer programs Measuring equipment Digitizing equipment
6. Training/Knowledge Required (Academic, Equip., OJT, etc.)	Gamma Knife/apprentice training
7. Ways to Reduce Errors/Risk (Procedures, Equip., Training, etc.)	Procedures Independent checks

PROCESS: Treatment Planning

1. Task ID Number	2.15 (2.15.1--2.15.3)
2. Task Description/Purpose	Enter shot parameters into treatment planning program
3. Task Frequency (No. of times per patient; 0 if not performed)	2–many times
4. Performance Standards	Enter as adjudged
5. Support Equipment	Kula
6. Training/Knowledge Required (Academic, Equip., OJT, etc.)	Treatment planning training
7. Ways to Reduce Errors/Risk (Procedures, Equip., Training, etc.)	Independent verifications

PROCESS: Treatment Planning

1. Task ID Number	2.16 (2.16.1–2.16.2)
2. Task Description/Purpose	Enter shot superposition parameters into treatment planning program
3. Task Frequency (No. of times per patient; 0 if not performed)	2–many times
4. Performance Standards	Enter adjudged parameters
5. Support Equipment	Kula
6. Training/Knowledge Required (Academic, Equip., OJT, etc.)	Treatment planning training Experience
7. Ways to Reduce Errors/Risk (Procedures, Equip., Training, etc.)	Independent checks/conferences

PROCESS: Treatment Planning

1. Task ID Number	2.17 (2.17.1–2.17.4)
2. Task Description/Purpose	Select parameters and plot isodose curves
3. Task Frequency (No. of times per patient; 0 if not performed)	2–many times
4. Performance Standards	Use adjudged parameters
5. Support Equipment	Kula Plotter Transparencies
6. Training/Knowledge Required (Academic, Equip., OJT, etc.)	Treatment planning training Experience
7. Ways to Reduce Errors/Risk (Procedures, Equip., Training, etc.)	Independent checks Periodic reviews

PROCESS: Treatment Planning

1. Task ID Number	2.18 (2.18.1–2.18.3)
2. Task Description/Purpose	Overlay isodose plots on films
3. Task Frequency (No. of times per patient; 0 if not performed)	2–many times
4. Performance Standards	Overlay correct plots correctly on films
5. Support Equipment	Imaging films/data Plot transparencies
6. Training/Knowledge Required (Academic, Equip., OJT, etc.)	Treatment planning training Academic (medical)
7. Ways to Reduce Errors/Risk (Procedures, Equip., Training, etc.)	Verification procedures Periodic reviews

PROCESS: Treatment Planning

1. Task ID Number	2.19
2. Task Description/Purpose	Enter prescribed dose
3. Task Frequency (No. of times per patient; 0 if not performed)	1–3 or more
4. Performance Standards	Enter adjudged value
5. Support Equipment	Kula
6. Training/Knowledge Required (Academic, Equip., OJT, etc.)	Treatment planning training
7. Ways to Reduce Errors/Risk (Procedures, Equip., Training, etc.)	Independent checks

PROCESS: Treatment Planning

1.	**Task ID Number**	2.20 (2.20.1–2.20.5)
2.	**Task Description/Purpose**	Print and sign prescription
3.	**Task Frequency (No. of times per patient; 0 if not performed)**	1-2 or more
4.	**Performance Standards**	Prescription correct in all respects (conforms to written directive)
5.	**Support Equipment**	Kula
6.	**Training/Knowledge Required (Academic, Equip., OJT, etc.)**	Treatment planning training Academic (medical)
7.	**Ways to Reduce Errors/Risk (Procedures, Equip., Training, etc.)**	Verification/conferences Periodic reviews

PROCESS: Patient Positioning and Treatment

1. Task ID Number	3.1
2. Task Description/Purpose	Perform daily QA checks
3. Task Frequency (No. of times per patient; 0 if not performed)	Once per treatment day
4. Performance Standards	See Quality Assurance Tolerances
5. Support Equipment	Dose, position, timing , etc., calibration devices
6. Training/Knowledge Required (Academic, Equip., OJT, etc.)	Academic (medical physics, radiation therapy) Gamma Knife training Experience
7. Ways to Reduce Errors/Risk (Procedures, Equip., Training, etc.)	Management oversight (RSC) Procedures Refresher training Periodic reviews

PROCESS: Patient Positioning and Treatment

1. Task ID Number	3.3
2. Task Description/Purpose	Choose and/or change helmet (collimator size)
3. Task Frequency (No. of times per patient; 0 if not performed)	0–3
4. Performance Standards	Correctly identify and choose helmet
5. Support Equipment	Helmet hoist
6. Training/Knowledge Required (Academic, Equip., OJT, etc.)	Gamma Knife training OJT
7. Ways to Reduce Errors/Risk (Procedures, Equip., Training, etc.)	Use at least two people Verification procedures

PROCESS: Patient Positioning and Treatment

1. Task ID Number	3.4
2. Task Description/Purpose	Change plug pattern
3. Task Frequency (No. of times per patient; 0 if not performed)	0–2 for every shot
4. Performance Standards	Exact plug pattern
5. Support Equipment	Collimator plugs Collimator tools Plug pattern printout
6. Training/Knowledge Required (Academic, Equip., OJT, etc.)	Gamma Knife training OJT
7. Ways to Reduce Errors/Risk (Procedures, Equip., Training, etc.)	Independent checks Procedures Periodic reviews

PROCESS: Patient Positioning and Treatment

1. Task ID Number	3.5 (3.5.1–3.5.3)
2. Task Description/Purpose	Set isocenter and gamma angle coordinates
3. Task Frequency (No. of times per patient; 0 if not performed)	2–many times
4. Performance Standards	± 0.3 mm
5. Support Equipment	Stereotactic frame X-axis trunnions y-z pillars Tightening tools
6. Training/Knowledge Required (Academic, Equip., OJT, etc.)	Gamma Knife training OJT
7. Ways to Reduce Errors/Risk (Procedures, Equip., Training, etc.)	Independent checks Procedures Periodic reviews/refresher training Torque wrenches

PROCESS: Patient Positioning and Treatment

1. Task ID Number	3.6 (3.6.1–3.6.9)
2. Task Description/Purpose	Perform final checks before treatment
3. Task Frequency (No. of times per patient; 0 if not performed)	1–many times
4. Performance Standards	All checks must be satisfactorily completed
5. Support Equipment	
6. Training/Knowledge Required (Academic, Equip., OJT, etc.)	Gamma Knife training OJT–experience
7. Ways to Reduce Errors/Risk (Procedures, Equip., Training, etc.)	Procedures Periodic reviews

PROCESS: Patient Positioning and Treatment

1. Task ID Number	3.7
2. Task Description/Purpose	Clear room of personnel and close interlock door
3. Task Frequency (No. of times per patient; 0 if not performed)	1–many times
4. Performance Standards	All personnel must be out of treatment room and door interlock engaged
5. Support Equipment	Door interlock system Viewing cameras/monitors
6. Training/Knowledge Required (Academic, Equip., OJT, etc.)	Radiation safety training Gamma Knife training OJT
7. Ways to Reduce Errors/Risk (Procedures, Equip., Training, etc.)	Management oversight (RSC) Procedures

PROCESS: Patient Positioning and Treatment

1. Task ID Number	3.8
2. Task Description/Purpose	Set treatment times on timers/counters
3. Task Frequency (No. of times per patient; 0 if not performed)	1–many times
4. Performance Standards	Set times exactly as per prescription
5. Support Equipment	Gamma Knife console
6. Training/Knowledge Required (Academic, Equip., OJT, etc.)	Gamma Knife training OJT
7. Ways to Reduce Errors/Risk (Procedures, Equip., Training, etc.)	Independent check

PROCESS: Patient Positioning and Treatment

1. Task ID Number	3.9 (3.9.1–3.9.5)
2. Task Description/Purpose	Initiate and monitor treatment cycle
3. Task Frequency (No. of times per patient; 0 if not performed)	1–many times
4. Performance Standards	Follow all treatment monitoring procedures
5. Support Equipment	Gamma Knife console Viewing monitors Microphone and speaker
6. Training/Knowledge Required (Academic, Equip., OJT, etc.)	Gamma Knife training OJT–experience Academic (medical)
7. Ways to Reduce Errors/Risk (Procedures, Equip., Training, etc.)	Procedures Management oversight (RSC) Periodic reviews More viewing angles Emergency power for lights and cameras

PROCESS: Patient Positioning and Treatment

1. Task ID Number	3.10
2. Task Description/Purpose	Check isocenter coordinate settings after treatment cycle
3. Task Frequency (No. of times per patient; 0 if not performed)	0–number of shots
4. Performance Standards	Settings must not have shifted (± 0.3 mm)
5. Support Equipment	Prescription
6. Training/Knowledge Required (Academic, Equip., OJT, etc.)	Gamma Knife training OJT–experience
7. Ways to Reduce Errors/Risk (Procedures, Equip., Training, etc.)	Independent checks/procedures Periodic review Torque wrenches

APPENDIX B: TASK RELATIVE PROBABILITIES

This appendix contains error data collected for the primary tasks in the Gamma Knife treatment process. There are 24 such primary events, which are listed with their task identification numbers in Table 5-1. Contributing events due to equipment failures were screened out, as relatively low-risk events, early in the analysis (see Section 5.4) and thus are not included in these treatment task data tables. These data are used for analyses of the relatively highest-risk events.

To quantify the relative importance of the task risk contributors, a measure of the probability of errors and their consequences was needed. Absolute measures were not determined, given the limited operating experience with the Gamma Knife and the absence of any reported misadministrations. Also, the project scope did not permit the extensive research required to determine human error probabilities associated with the use of the Gamma Knife. However, as discussed in Section 2, it is plausible to develop relative risk rankings based on expert estimations.

The experts in this study were professionals, experienced in the use of the Gamma Knife. They were Gamma Knife physicians, medical physicians, medical physicists, and Elekta engineers. The expert pool consisted of individuals who understood the purpose of the elicitations and had appropriate backgrounds to develop numerical estimates.

Once the undesired treatment events were understood by the project team, the experts were asked how often they experienced these events, i.e., what were the event frequencies, and what were their corresponding magnitudes of deviation in dose delivered. The templates used for the likelihood and magnitude ratings are those discussed in Section 5.1.

For the Error Likelihood Ratings:

Bin 1 = .001

Bin 2 = .002

Bin 3 = .01

Bin 4 = .02

Bin 5 = .1

For the Error Magnitude Ratings:

Bin 1 = .02

Bin 2 = .05

Bin 3 = .1

Bin 4 = .2

Bin 5 = .5

The numbers lined up with the Error Likelihood and Error Magnitude headings in the enclosed tables correspond to the normalized percentage of experts preferring that bin value.

Consequence magnitudes associated with dose are to be weighted by a factor of 1.5 to be in the appropriate correspondence to position/volume errors (see Section 5.1).

TASK ID NUMBER: 1.1, 2.1, 2.6.1, 3.2 - Identify correct patient

Most Likely Errors	Error Likelihoods					Error Magnitudes				
	0.001	0.002	0.01	0.02	0.1	0.02	0.05	0.1	0.2	0.5
Mix-up in identification of documents with patient	1.0	0	0	0	0	X Dose X Pos./Vol. __Other:				
						0	0	0	0	1.0
Do not use independent check of patient identity	1.0	0	0	0	0	X Dose X Pos./Vol. __Other:				
						0	0	0	0	1.0

TASK ID NUMBER: 1.2 (1.2.1 - 1.2.3) - Affix stereotactic frame

Most Likely Errors	Error Likelihoods					Error Magnitudes				
	0.001	0.002	0.01	0.02	0.1	0.02	0.05	0.1	0.2	0.5
Frame not immovable on head and patient treated (1.2.3)	0	0.7	0.3	0	0	_ Dose X Pos./Vol. __Other:				
						0.8	0.2	0	0	0
Frame not 'square' (e.g., screws not tightened properly) (1.2.1)	0	0.6	0.4	0	0	_ Dose X Pos./Vol. __Other:				
						0.8	0.2	0	0	0

TASK ID NUMBER: 1.3 (1.3.1 - 1.3.4) - Set up CT, MR, Angiography

Most Likely Errors	Error Likelihoods					Error Magnitudes				
	0.001	0.002	0.01	0.02	0.1	0.02	0.05	0.1	0.2	0.5
Alignment not orthogonal to imager (1.3.2)	0	0	1.0	0	0	_ Dose _x_ Pos./Vol. __Other:				
						0.4	0.6	0	0	0
Films not labeled correctly (1.3.3)	0.4	0.6	0	0	0	_ Dose _x_ Pos./Vol. __Other:				
						0	0	0	0.2	0.8
Indicators not aligned properly (1.3.1)	0.6	0.4	0	0	0	_ Dose _x_ Pos./Vol. __Other:				
						0.8	0.2	0	0	0

TASK ID NUMBER: 1.5 - Center correctly deposited on CT, MR films

Most Likely Errors	Error Likelihoods					Error Magnitudes				
	0.001	0.002	0.01	0.02	0.1	0.02	0.05	0.1	0.2	0.5
Center shifts from image slice to slice	0	0	0	0.3	0.7	_ Dose _x_ Pos./Vol. __Other:				
						1.0	0	0	0	0
Fiducial distances not even	0	0	0.3	0.7	0	_ Dose _x_ Pos./Vol. __Other:				
						0.7	0.2	0.1	0	0
Use wrong fiducial (when an extra L/R fiducial)	0	0.2	0.5	0.3	0	_ Dose _x_ Pos./Vol. __Other:				
						0	0.4	0.6	0	0
Don't use center of fiducial images	0	0	0	0.6	0.4	__Dose _x_ Pos./Vol. __Other:				
						1.0	0	0	0	0

TASK ID NUMBER: 2.3 - Check treatment planning equipment

Most Likely Errors	Error Likelihoods					Error Magnitudes				
	0.001	0.002	0.01	0.02	0.1	0.02	0.05	0.1	0.2	0.5
Independent calculations inaccurate or inadequate to verify software/hardware performance (2.3.1)	1.0	0	0	0	0	x Dose _ Pos./Vol. __Other:				
						0.2	0.2	0.2	0.2	0.2
Don't adequately check digitizer linearity and accuracy (2.3.3)	0	0	0.5	0.5	0	_ Dose x Pos./Vol. __Other:				
						0.8	0.2	0	0	0
Don't correct for distortions in plotter (2.3.2)	0	0.2	0.5	0.3	0	_ Dose x Pos./Vol. __Other:				
						0.8	0.2	0	0	0
Don't use independent checks	0	0	0	0.2	0.8	x Dose x Pos./Vol. __Other:				
						0.8	0.2	0	0	0

TASK ID NUMBER: 2.6 - Take skull measurements

Most Likely Errors	Error Likelihoods					Error Magnitudes				
	0.001	0.002	0.01	0.02	0.1	0.02	0.05	0.1	0.2	0.5
Mis-read measurement scale (2.6.3)	0	0	0	0.7	0.3	x Dose _ Pos./Vol. __Other:				
						0.8	0.2	0	0	0
Do not hold measuring stick orthonormal to skull (2.6.3)	0	0	0	0.7	0.3	x Dose _ Pos./Vol. __Other:				
						1.0	0	0	0	0
Enter wrong data on data form (2.6.4 - 2.6.5)	0	0	0	1.0	0	x Dose _ Pos./Vol. __Other:				
						0.6	0.4	0	0	0
Put bubble on incorrectly	0	0	0.4	0.6	0	x Dose _ Pos./Vol. __Other:				
						1.0	0	0	0	0

TASK ID NUMBER: 2.7 - Enter skull data into computer

Most Likely Errors	Error Likelihoods					Error Magnitudes				
	0.001	0.002	0.01	0.02	0.1	0.02	0.05	0.1	0.2	0.5
Enter wrong data	0	0	0.4	0.6	0	x Dose _ Pos./Vol. __Other:				
						0.2	0.5	0.3	0	0
Don't check skull profile	0	0.3	0.7	0	0	x Dose _ Pos./Vol. __Other:				
						0.2	0.5	0.3	0	0

TASK ID NUMBER: 2.8 - Enter gamma angle

Most Likely Errors	Error Likelihoods					Error Magnitudes				
	0.001	0.002	0.01	0.02	0.1	0.02	0.05	0.1	0.2	0.5
Enter gamma angle incorrectly or use default value incorrectly	0	0	0.6	0.4	0	X Dose _ Pos./Vol. __Other:				
						0	0	0.6	0.4	0

TASK ID NUMBER: 2.9 - Geometric determinations from films

Most Likely Errors	Error Likelihoods					Error Magnitudes				
	0.001	0.002	0.01	0.02	0.1	0.02	0.05	0.1	0.2	0.5
Measurement errors (digitizer or manual) (2.9.2 - 2.9.5)	0	0	0	0.6	0.4	_ Dose X Pos./Vol. __Other:				
						0.7	0.3	0	0	0
Wrong axial (z) factor (2.9.3)	0	0	1.0	0	0	_ Dose X Pos./Vol. __Other:				
						0.4	0.5	0	0	0.1
Wrong magnification factor (2.9.4)	0	0	0	0.6	0.4	_ Dose X Pos./Vol. __Other:				
						0.7	0.3	0	0	0
Use wrong fiducial (films not reversed)	0	0	1.0	0	0	_ Dose X Pos./Vol. __Other:				
						0	0.3	0.7	0	0

TASK ID NUMBER: 2.9 - Geometric determinations from films *cont'd*

Most Likely Errors	Error Likelihoods					Error Magnitudes				
	0.001	0.002	0.01	0.02	0.1	0.02	0.05	0.1	0.2	0.5
Films reversed	0.3	0.5	0.2	0	0	_ Dose _x_ Pos./Vol. __Other:				
						0	0	0	0	1.0
Mis-read film markings (2.9.1 - 2.9.5)	0	0	0	0.6	0.4	_ Dose _x_ Pos./Vol. __Other:				
						0.7	0.3	0	0	0
Don't use center of fiducials	0	0	0	0.4	0.6	_ Dose _x_ Pos./Vol. __Other:				
						1.0	0	0	0	0

TASK ID NUMBER: 2.10 - Enter dose matrix parameters

Most Likely Errors	Error Likelihoods					Error Magnitudes				
	0.001	0.002	0.01	0.02	0.1	0.02	0.05	0.1	0.2	0.5
Parameters not entered correctly or use default values incorrectly	0.7	0.3	0	0	0	_ Dose _x_ Pos./Vol. __Other:				
						0	0.6	0.4	0	0

TASK ID NUMBER: 2.12 - Setting calculation mode

Most Likely Errors	Error Likelihoods					Error Magnitudes				
	0.001	0.002	0.01	0.02	0.1	0.02	0.05	0.1	0.2	0.5
Don't make point calculation to check error between modes (2.12.1)	0	0	0	0.4	0.6	.X Dose _ Pos./Vol. _ Other: 0.2	0.6	0.2	0	0
Set mode incorrectly in Kula initialization file	0	0.4	0.6	0	0	X Dose _ Pos./Vol. __Other: 0.2	0.6	0.2	0	0
Corrupt Kula initialization file	0.8	0.2	0	0	0	X Dose _ Pos./Vol. X Other: 0	0	1.0	0	0 6. may affect other calculations

TASK ID NUMBER: 2.14 - Determine isocenter coordinates

Most Likely Errors	Error Likelihoods					Error Magnitudes				
	0.001	0.002	0.01	0.02	0.1	0.02	0.05	0.1	0.2	0.5
Measure coordinates incorrectly	0	0	0.3	0.5	0.2	_ Dose X Pos./Vol. __Other: 0.6	0.4	0	0	0
Confuse coordinates	0	0.6	0.4	0	0	_ Dose X Pos./Vol. __Other: 0	0	0	0.4	0.6
No final check	0	0.5	0.4	0.1	0	use magnitude associated with error, above				

TASK ID NUMBER: 2.15 - Enter shot parameters

Most Likely Errors	Error Likelihoods					Error Magnitudes				
	0.001	0.002	0.01	0.02	0.1	0.02	0.05	0.1	0.2	0.5
Parameters not entered correctly (or defaults used incorrectly):	0	0	0	0	0	_ Dose _ Pos./Vol. __Other:				
						0	0	0	0	0
Isocenter coordinates (2.15.1)	0	0	0	1.0	0	_ Dose x Pos./Vol. __Other:				
						0	0.6	0	0.3	0.1
Collimator sizes (2.15.2)	0	0	0	1.0	0	_ Dose x Pos./Vol. _ Other:				
						0	0	0.8	0.2	0
Plug patterns (2.15.3)	0	0	0	1.0	0	x Dose _ Pos./Vol. _ Other:				
						0	0	0	0.3	0.7

TASK ID NUMBER: 2.16 - Enter shot superposition parameters

Most Likely Errors	Error Likelihoods					Error Magnitudes				
	0.001	0.002	0.01	0.02	0.1	0.02	0.05	0.1	0.2	0.5
Enter wrong values or use defaults incorrectly	0	0	0.6	0.4	0	_ Dose x Pos./Vol. __Other:				
						0	0.6	0	0.3	0.1

TASK ID NUMBER: 2.17 - Plot isodose curves

Most Likely Errors	Error Likelihoods					Error Magnitudes				
	0.001	0.002	0.01	0.02	0.1	0.02	0.05	0.1	0.2	0.5
Use incorrect parameters:										
1) scaling and magnification factors (2.17.3)	0	0	0.4	0.6	0	_ Dose _x_ Pos./Vol. __Other:				
						0	0.6	0.4	0	0
2) coordinate plane (2.17.1)	0	0	1.0	0	0	_ Dose _x_ Pos./Vol. __Other:				
						0	0	0	0.4	0.6
No overlay check	0	0.5	0.4	0.1	0	use magnitude associated with error, above				

TASK ID NUMBER: 2.18 - Overlay isodose plots

Most Likely Errors	Error Likelihoods					Error Magnitudes				
	0.001	0.002	0.01	0.02	0.1	0.02	0.05	0.1	0.2	0.5
Centers of frame and plots not aligned (2.18.2)	0	0	0.4	0.6	0	_ Dose _x_ Pos./Vol. __Other:				
						0.5	0.3	0	0.2	0
Plot overlaid on incorrect image (e.g., incorrect plane, wrong isodose curves of a set, plots not labeled sufficiently) (2.18.1)	0	0.7	0.3	0	0	_ Dose _x_ Pos./Vol. __Other:				
						0	0	0	0.3	0.7
No final overlay check	0	0.5	0.4	0.1	0	use magnitude associated with error, above				

TASK ID NUMBER: 2.19 - Enter prescribed dose

Most Likely Errors	Error Likelihoods					Error Magnitudes				
	0.001	0.002	0.01	0.02	0.1	0.02	0.05	0.1	0.2	0.5
Dose value not entered correctly and not checked	0	0	1.0	0	0	x Dose _ Pos./Vol. _Other:				
						0	0	0.6	0.3	0.1

TASK ID NUMBER: 2.20 - Produce prescription

Most Likely Errors	Error Likelihoods					Error Magnitudes				
	0.001	0.002	0.01	0.02	0.1	0.02	0.05	0.1	0.2	0.5
Make error in coordinate transformation calculation (supine to prone)(2.20.4)	0	0	0.6	0.4	0	_ Dose x Pos./Vol. _Other:				
						0	0	0	0.3	0.7
Prescription not correct (e.g., used wrong parameters or patient file) (2.20.1 - 2.20.3)	0.7	0.3	0	0	0	x Dose x Pos./Vol. _Other:				
						0	0	0	0	1.0

TASK ID NUMBER: 3.3 - Choose helmet

Most Likely Errors	Error Likelihoods					Error Magnitudes				
	0.001	0.002	0.01	0.02	0.1	0.02	0.05	0.1	0.2	0.5
Attach wrong helmet (e.g., mis-read prescription or choose incorrectly)	0	0.4	0.6	0	0	_ Dose x Pos./Vol. _Other:				
						0	0.4	0.6	0	0

TASK ID NUMBER: 3.4 - Set plug pattern

Most Likely Errors	Error Likelihoods					Error Magnitudes				
	0.001	0.002	0.01	0.02	0.1	0.02	0.05	0.1	0.2	0.5
Plug pattern not correct	0	0	1.0	0	0	x Dose _ Pos./Vol. __Other:				
						0	0.4	0.2	0.2	0.2
Plug(s) not seated properly	0.6	0.4	0	0	0	_ Dose _ Pos./Vol. x Other: shearing of plugs				
						0	0	0	0	0
Correct checks not made	0	0	1.0	0	0	use magnitude associated with error, above				

TASK ID NUMBER: 3.5 (3.5.1- 3.5.3) - Set isocenter coordinates and gamma angle

Most Likely Errors	Error Likelihoods					Error Magnitudes				
	0.001	0.002	0.01	0.02	0.1	0.02	0.05	0.1	0.2	0.5
Coordinates not set correctly (3.5.1, 3.5.2)	0	0	0.6	0.4	0	_ Dose x Pos./Vol. __Other:				
						0.6	0.4	0	0	0
Gamma angle not set correctly (3.5.3)	0	0	0	1.0	0	x Dose _ Pos./Vol. __Other:				
						0	1.0	0	0	0
Settings not adequately secured (3.5.1.1, 3.5.2.1, 3.5.3)	0	1.0	0	0	0	_ Dose x Pos./Vol. _ Other:				
						0.4	0.5	0.1	0	0
Settings not correctly checked (3.5.1.2, 3.5.2.2, 3.5.3)	0	0	0.6	0.4	0	use magnitude associated with error, above				

TASK ID NUMBER: 3.6 (3.6.1 - 3.6.9) - Perform final checks

Most Likely Errors	Error Likelihoods					Error Magnitudes				
	0.001	0.002	0.01	0.02	0.1	0.02	0.05	0.1	0.2	0.5
Time for treatment not adjusted for lens plugs (3.6.3 - 3.6.3.1)	0	0	0.4	0.6	0	x Dose _ Pos./Vol. __Other:				
						0.7	0.3	0	0	0
Couch not cleared (3.6.5)	0	0.3	0.5	0.2	0	x Dose _ Pos./Vol. x Other: treatment stop				
						0	0	0	0	0
						6. exposure time affected				

TASK ID NUMBER: 3.8 - Set treatment time

Most Likely Errors	Error Likelihoods					Error Magnitudes				
	0.001	0.002	0.01	0.02	0.1	0.02	0.05	0.1	0.2	0.5
Set time for wrong shot (mis-read prescription list)	0	0.6	0.4	0	0	x Dose _ Pos./Vol. __Other:				
						0	0	0.6	0.4	0
Set time incorrectly (3.8 - 3.8.1)	0	0.6	0.4	0	0	x Dose _ Pos./Vol. __Other:				
						0.7	0.3	0	0	0
Treatment time not verified	0	0	1.0	0	0	use magnitude associated with error, above				

TASK ID NUMBER: 3.9 (3.9.1 - 3.9.5) - Monitor treatment

Most Likely Errors	Error Likelihoods					Error Magnitudes				
	0.001	0.002	0.01	0.02	0.1	0.02	0.05	0.1	0.2	0.5
Interrupt treatment cycle (3.9.1 - 3.9.3)	0	0.4	0.6	0	0	X Dose _ Pos./Vol. _Other:				
						0.3	0.4	0.3	0	0
Mis-mark shot completed on shot list (3.9.4)	1.0	0	0	0	0	X Dose _ Pos./Vol. _Other:				
						0.3	0.4	0.3	0	0

TASK ID NUMBER: 3.10 - Check isocenter settings after treatment

Most Likely Errors	Error Likelihoods					Error Magnitudes				
	0.001	0.002	0.01	0.02	0.1	0.02	0.05	0.1	0.2	0.5
Settings moved during treatment	0	1.0	0	0	0	_ Dose X Pos./Vol. _Other:				
						0.4	0.5	0.1	0	0

APPENDIX C: Task Logic Diagrams

This appendix contains logic diagrams, in the form of fault trees, developed for the primary tasks in the Gamma Knife treatment process. These tasks are modeled as independent and are connected by logical 'or' operands to the top event, a misadministration. There are 24 such primary events which are listed with their task identification numbers in Table 5-1. These task numbers are reflected in the top event fault tree contained in this appendix. Contributing events due to equipment failures were screened out as relatively low-risk events, early in the analysis (see Section 5.4) and thus are not included in these treatment task logic diagrams.

Each primary task also contains subtasks or errors that constitute contributing fault events to the primary task. These events, for each primary task, are listed in the data forms of Appendix B. The contributing faults were combined in fault trees for each primary task and are contained in this appendix. The subtask numbers are not recorded in the primary task trees. The subtask events are also modeled as independent. Some of the events are logically combined with the 'and' operand which usually reflects a case of an independent check of some action.

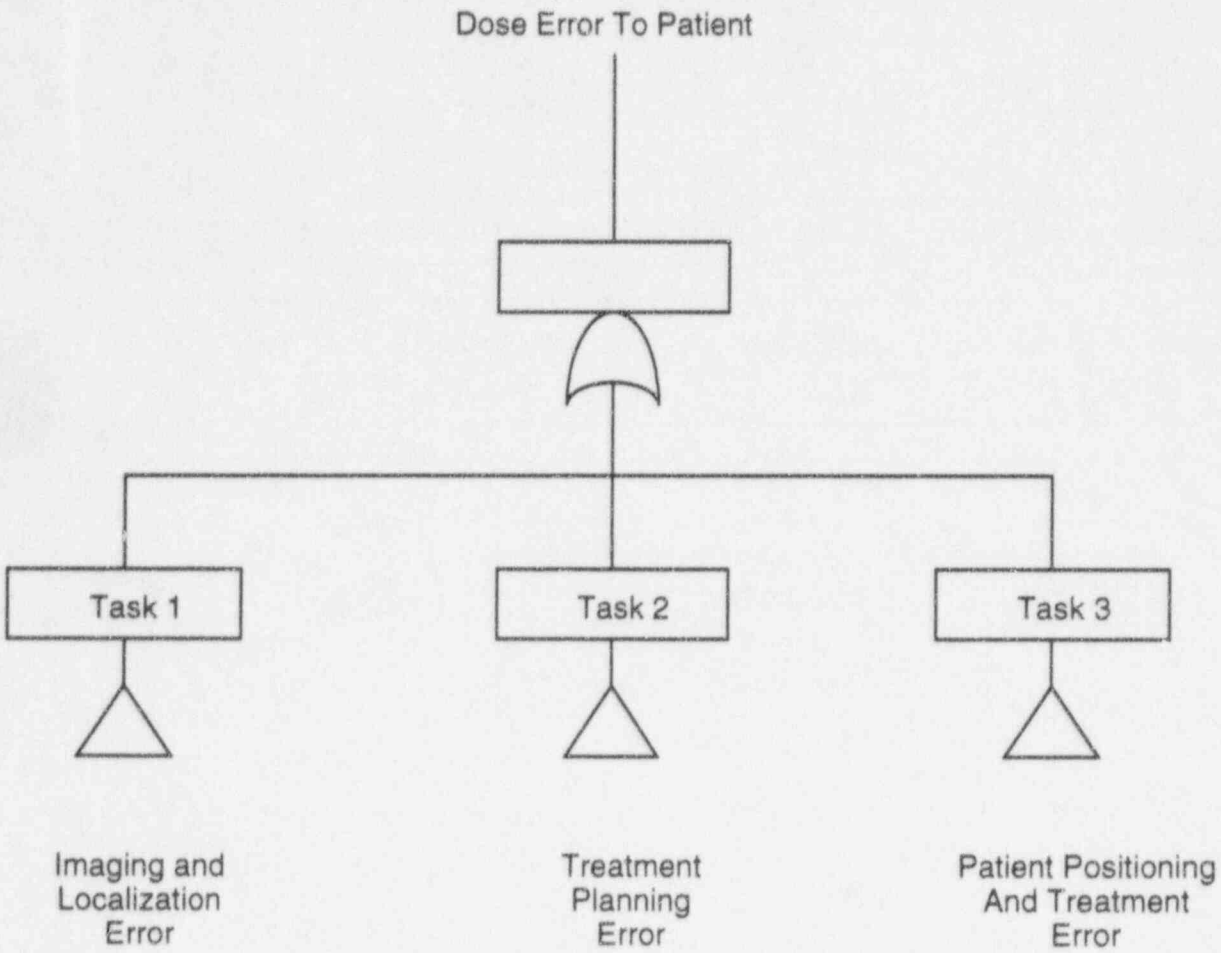

Figure 1. Dose Error to Patient

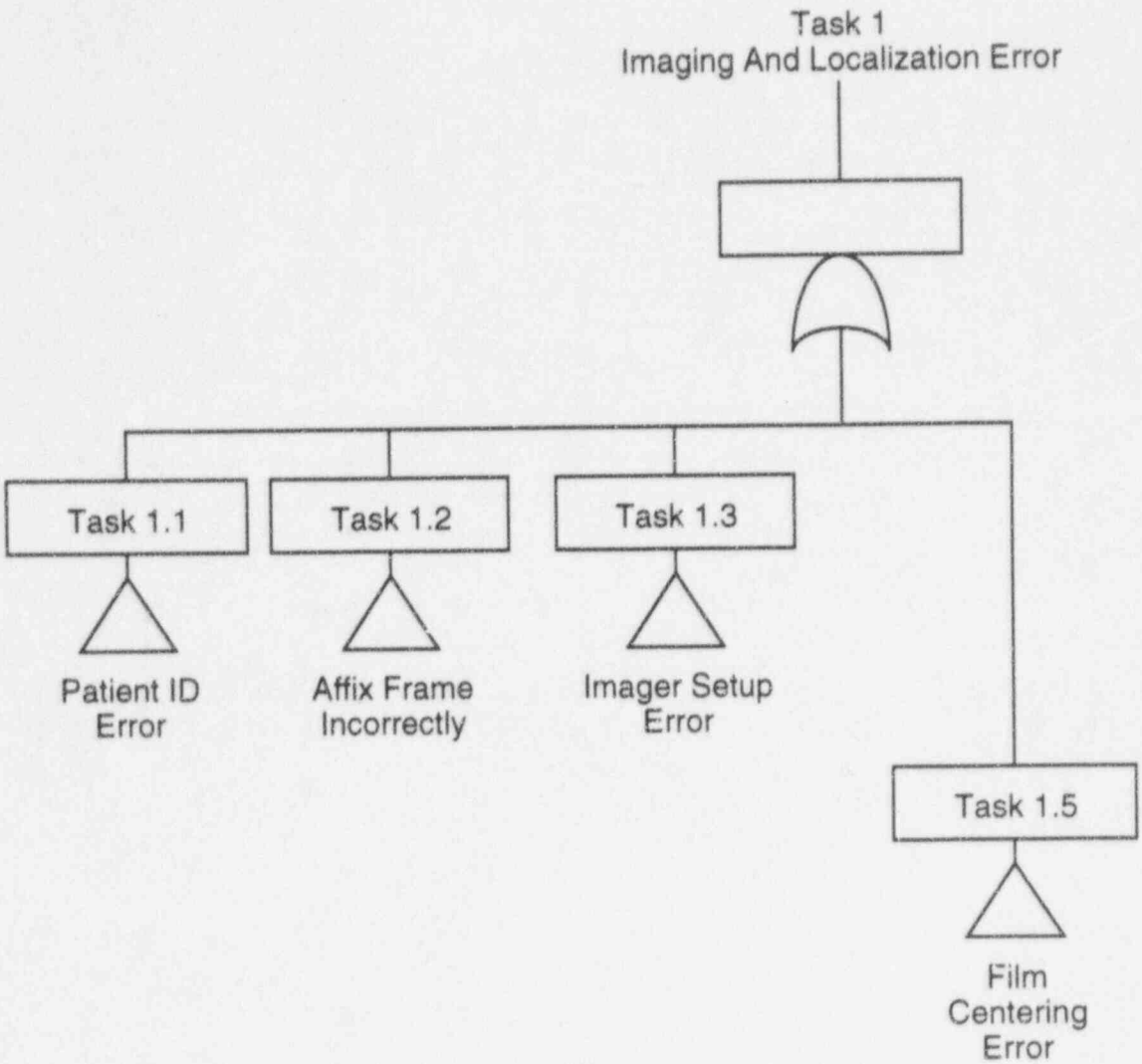

Figure 2. Task 1–Imaging and Localization Error

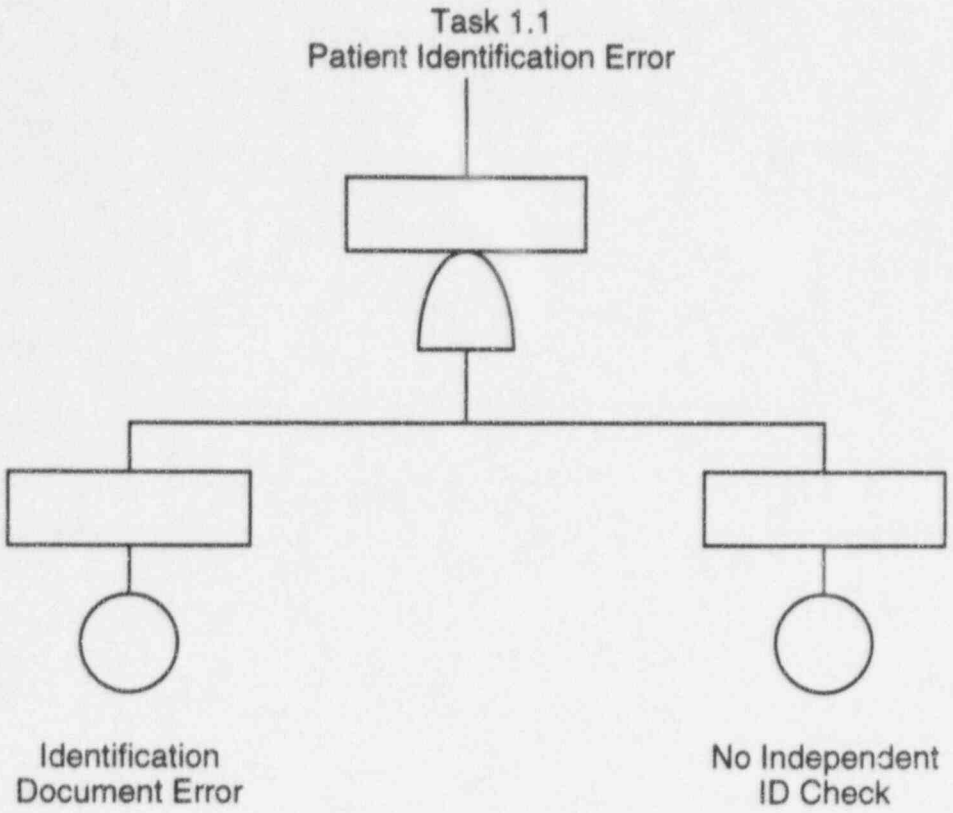

Figure 3. Task 1.1–Patient Identification Error

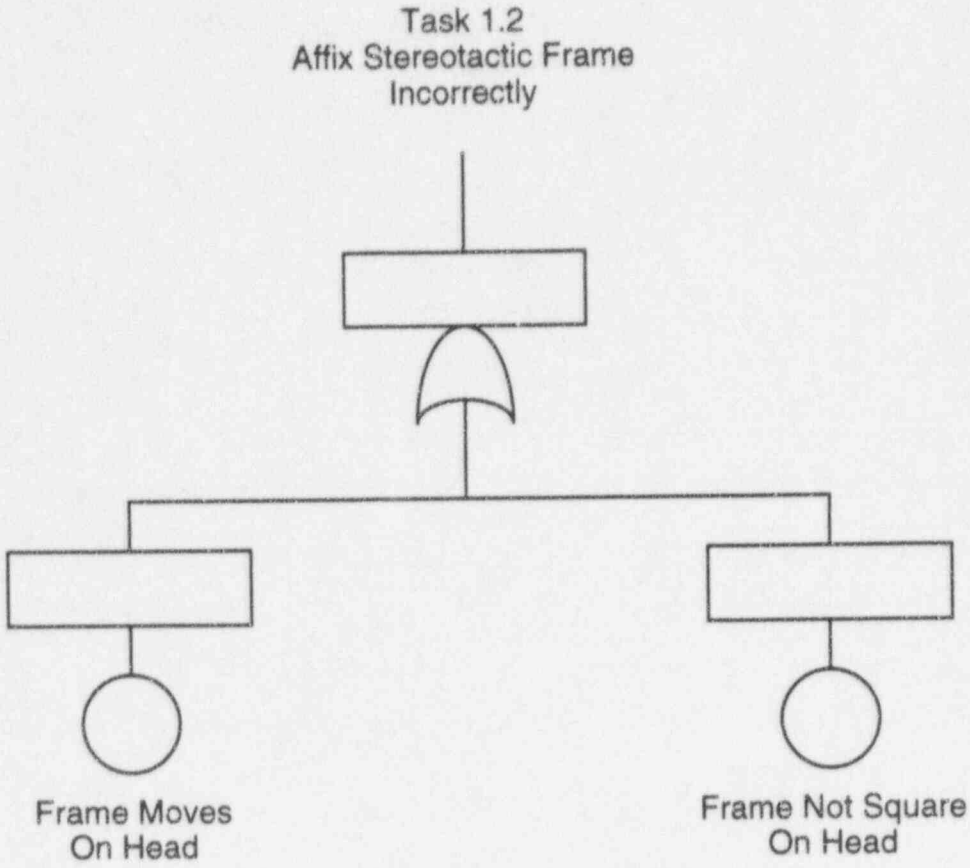

Figure 4. Task 1.2–Affix Stereotactic Frame Incorrectly

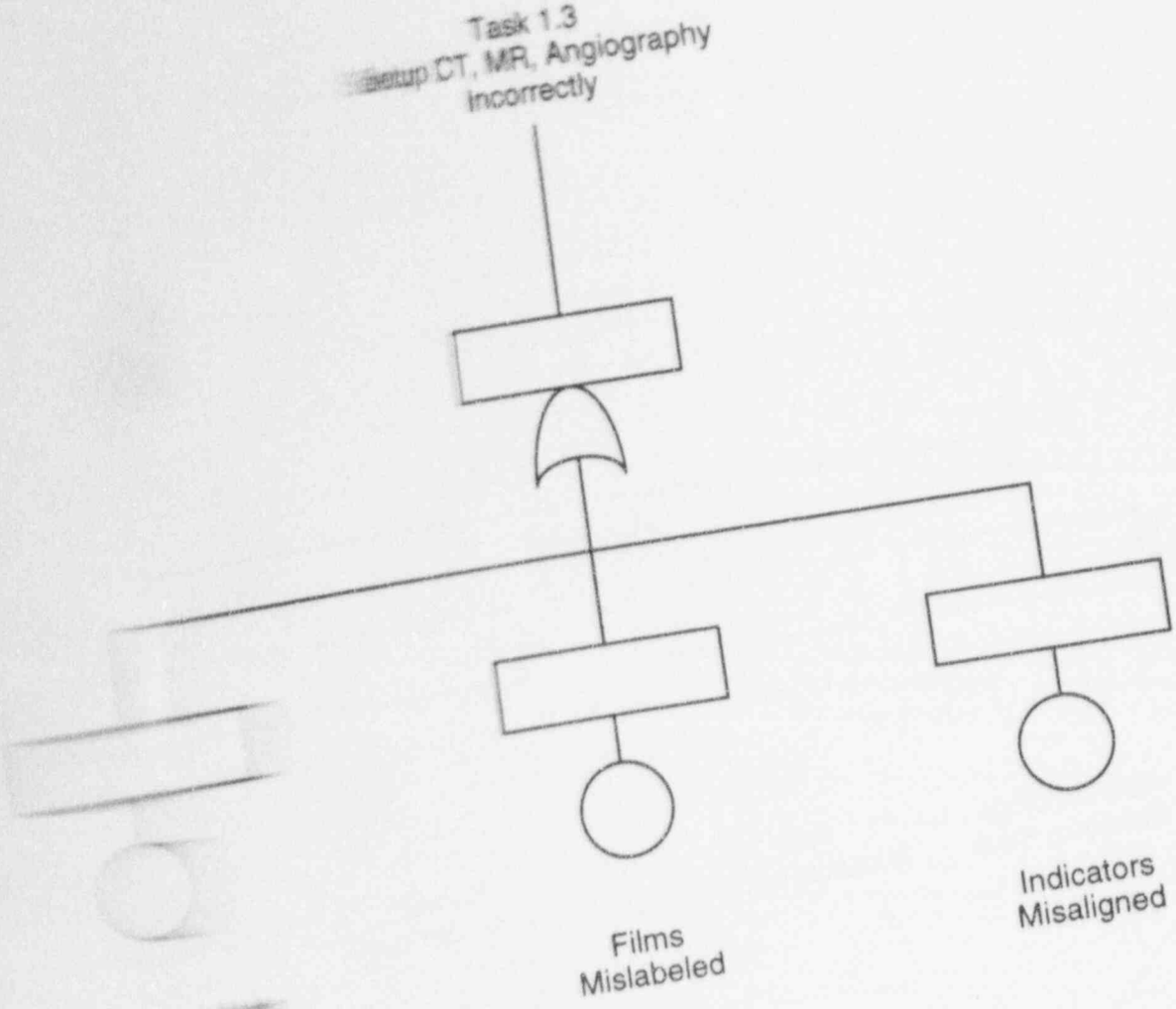

Figure 8. Task 1.3–Set Up CT, MR, Angiography Incorrectly

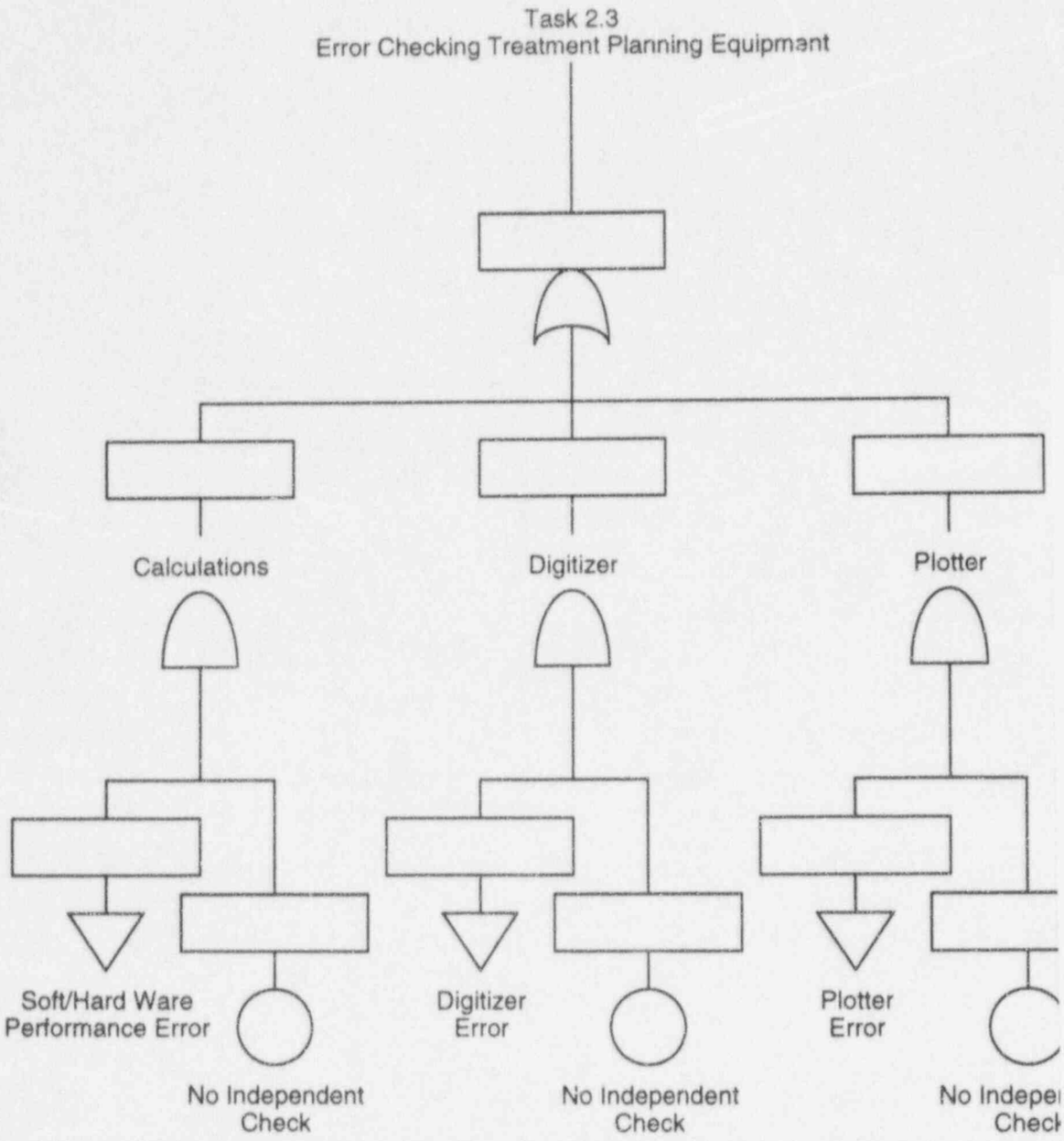

Figure 8. Task 2.3–Error Checking Treatment Planning Equipment

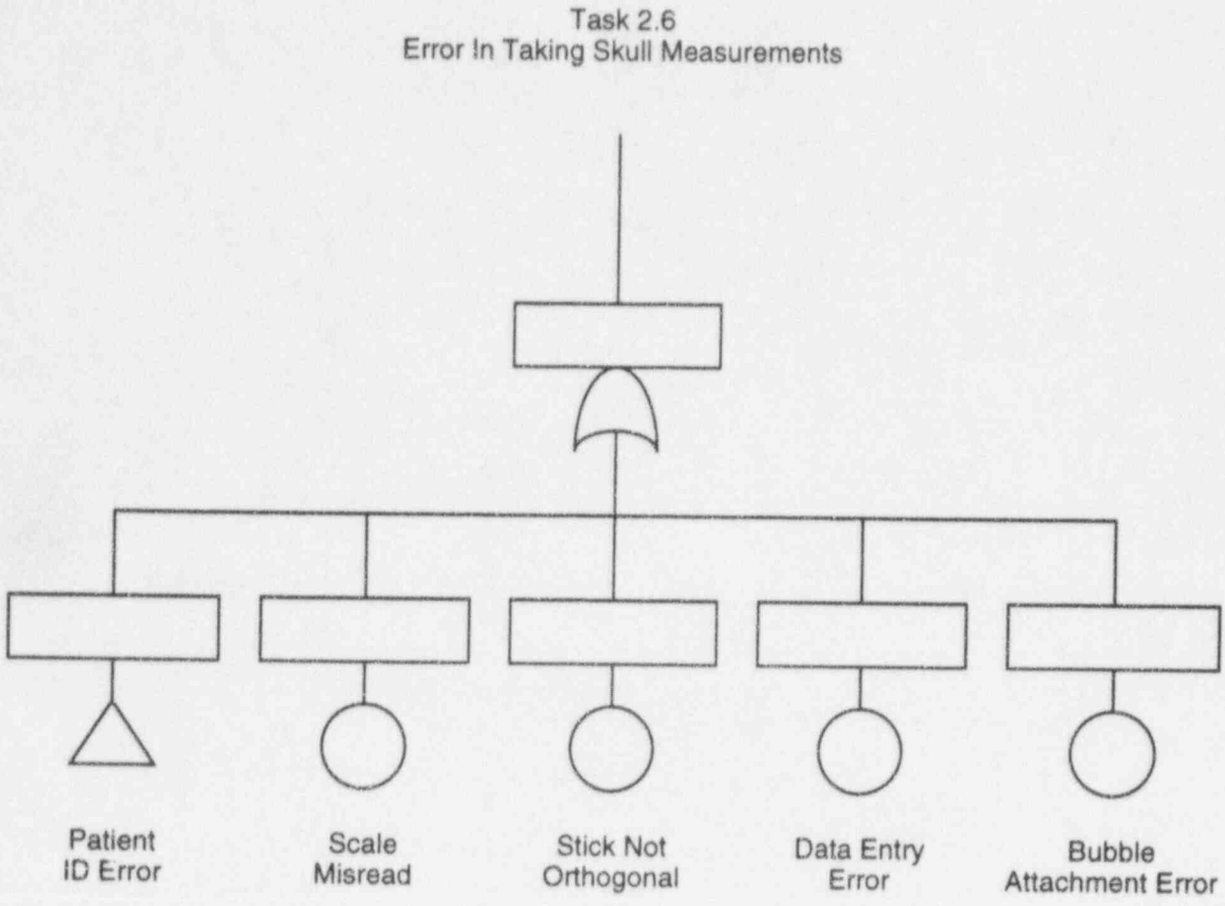

Figure 9. Task 2.6–Error in Taking Skull Measurements

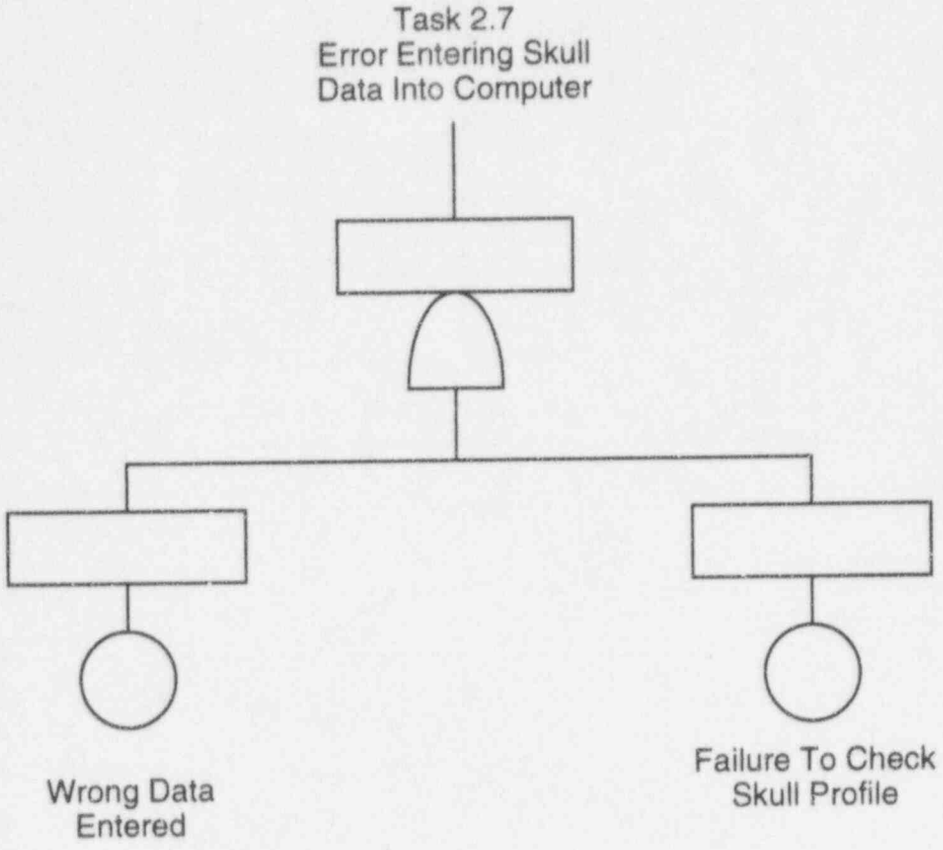

Figure 10. Task 2.7–Error Entering Skull Data Into Computer

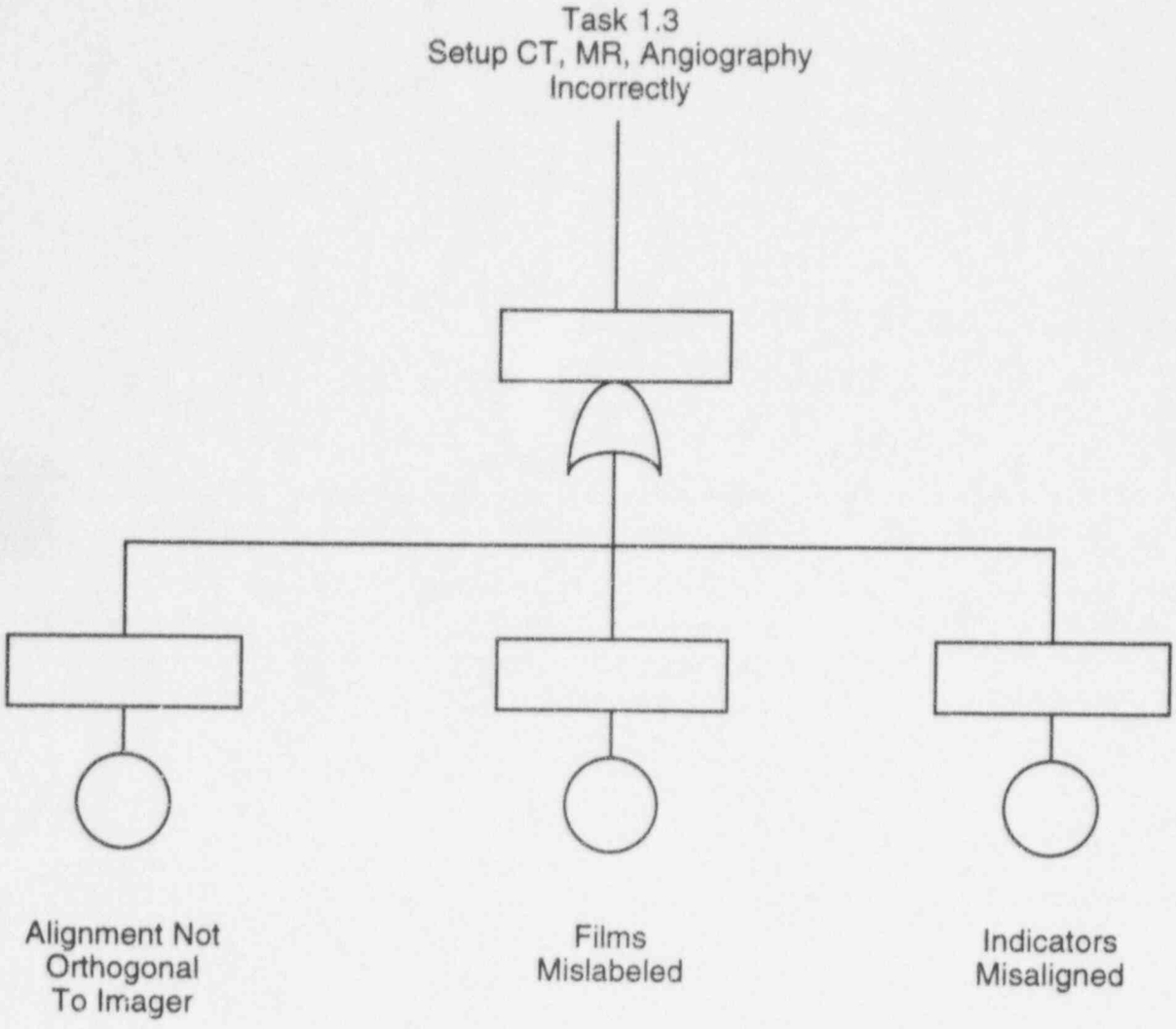

Figure 5. Task 1.3–Set Up CT, MR, Angiography Incorrectly

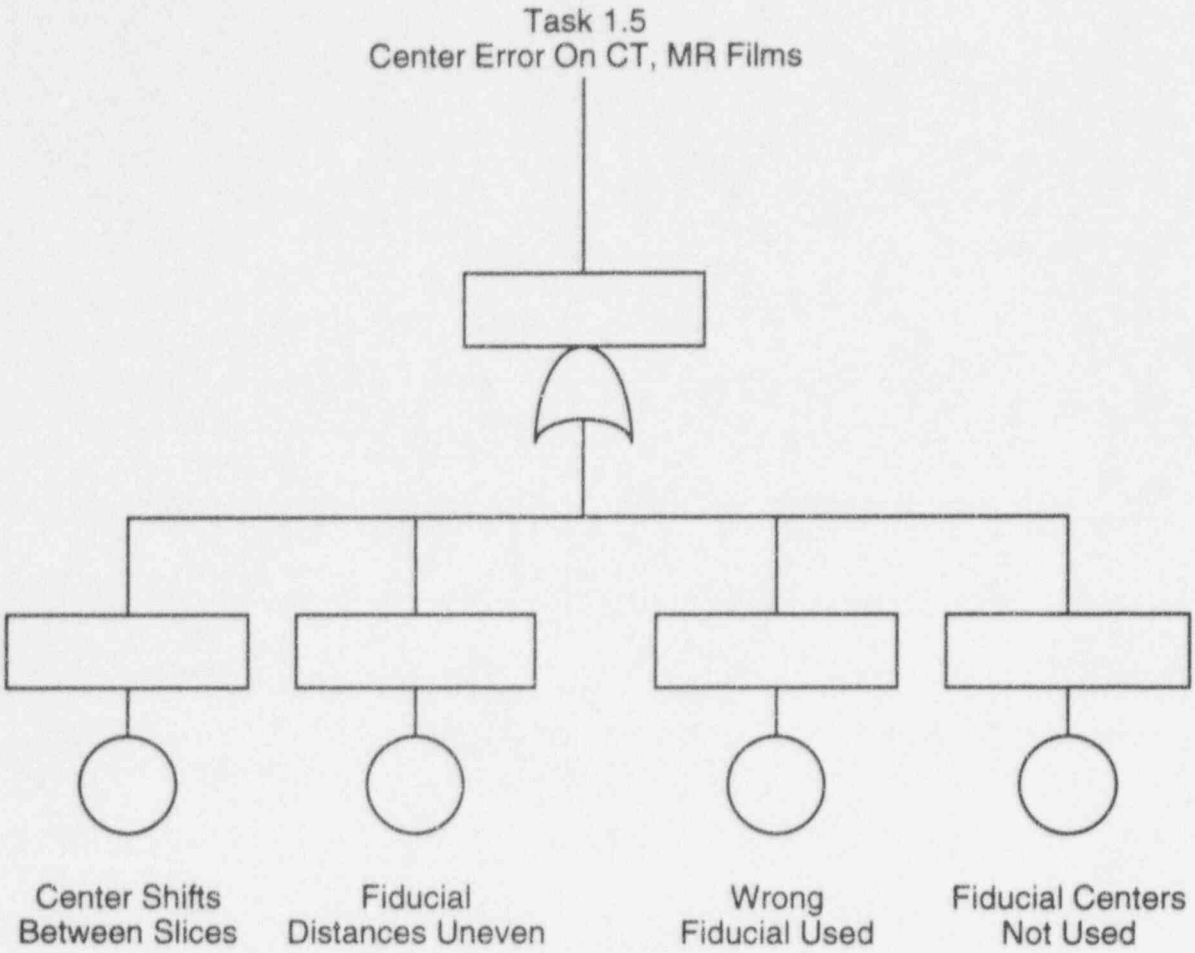

Figure 6. Task 1.5--Center Error on CT, MR Films

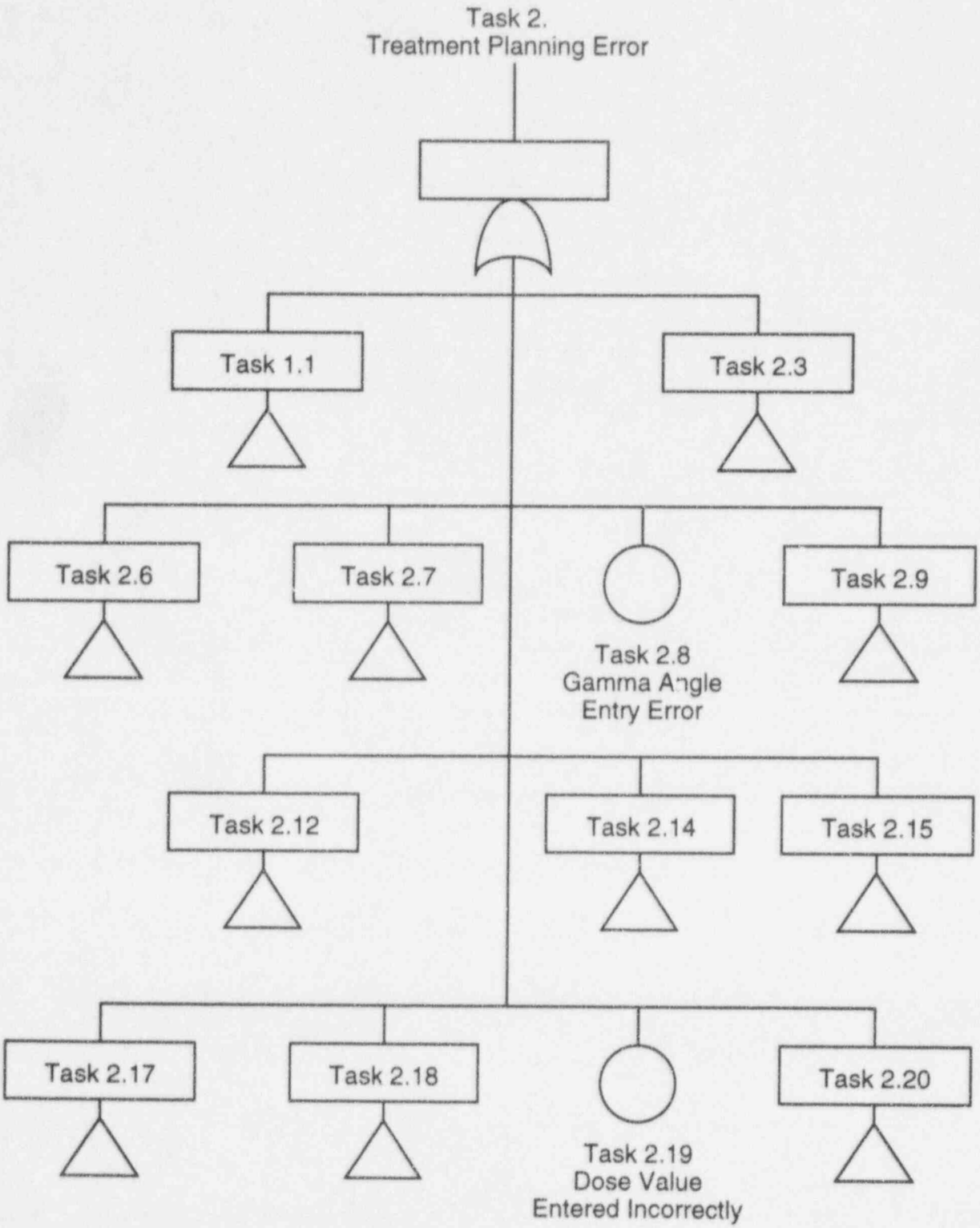

Figure 7. Task 2.0–Treatment Planning Error

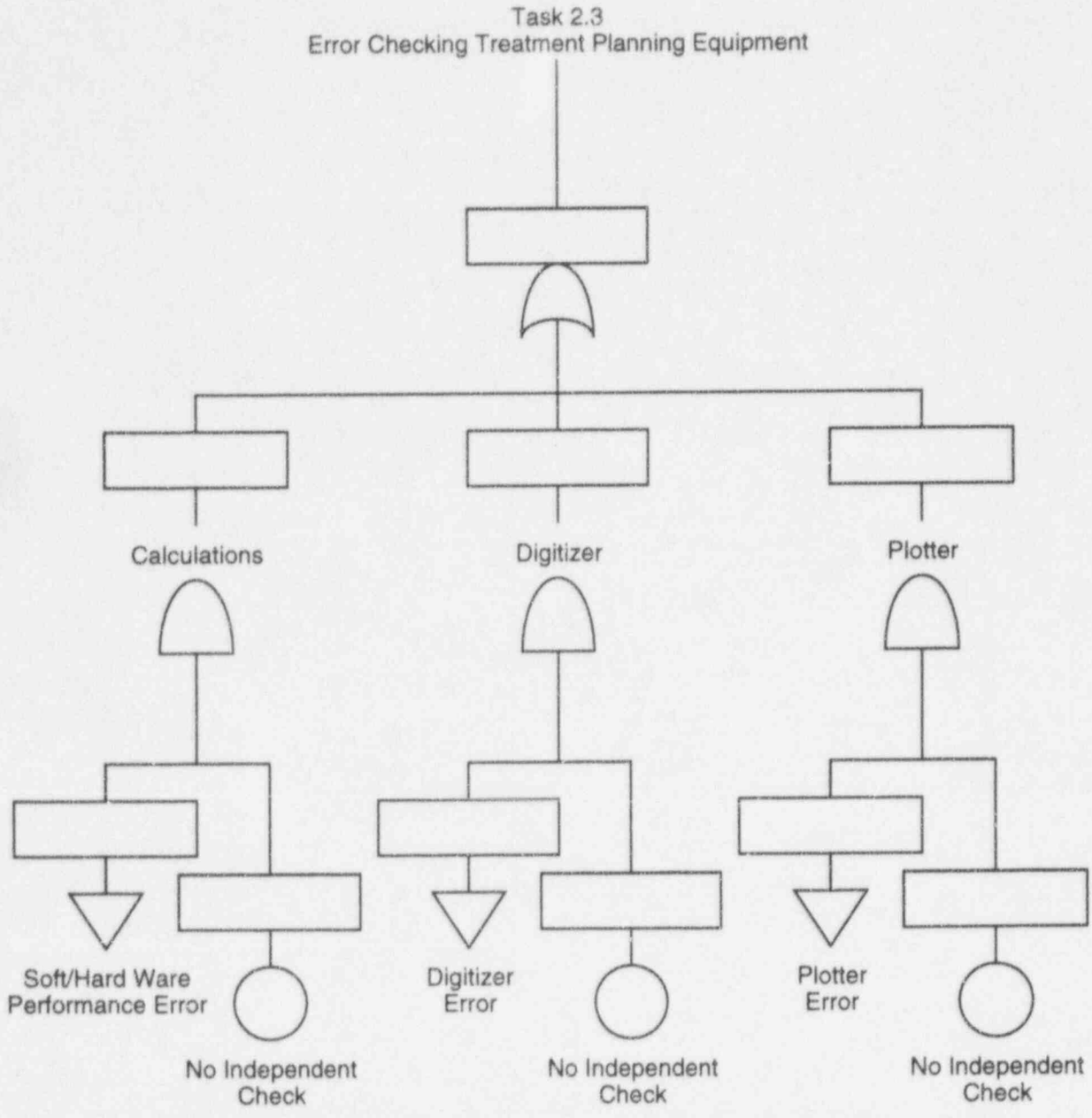

Figure 8. Task 2.3–Error Checking Treatment Planning Equipment

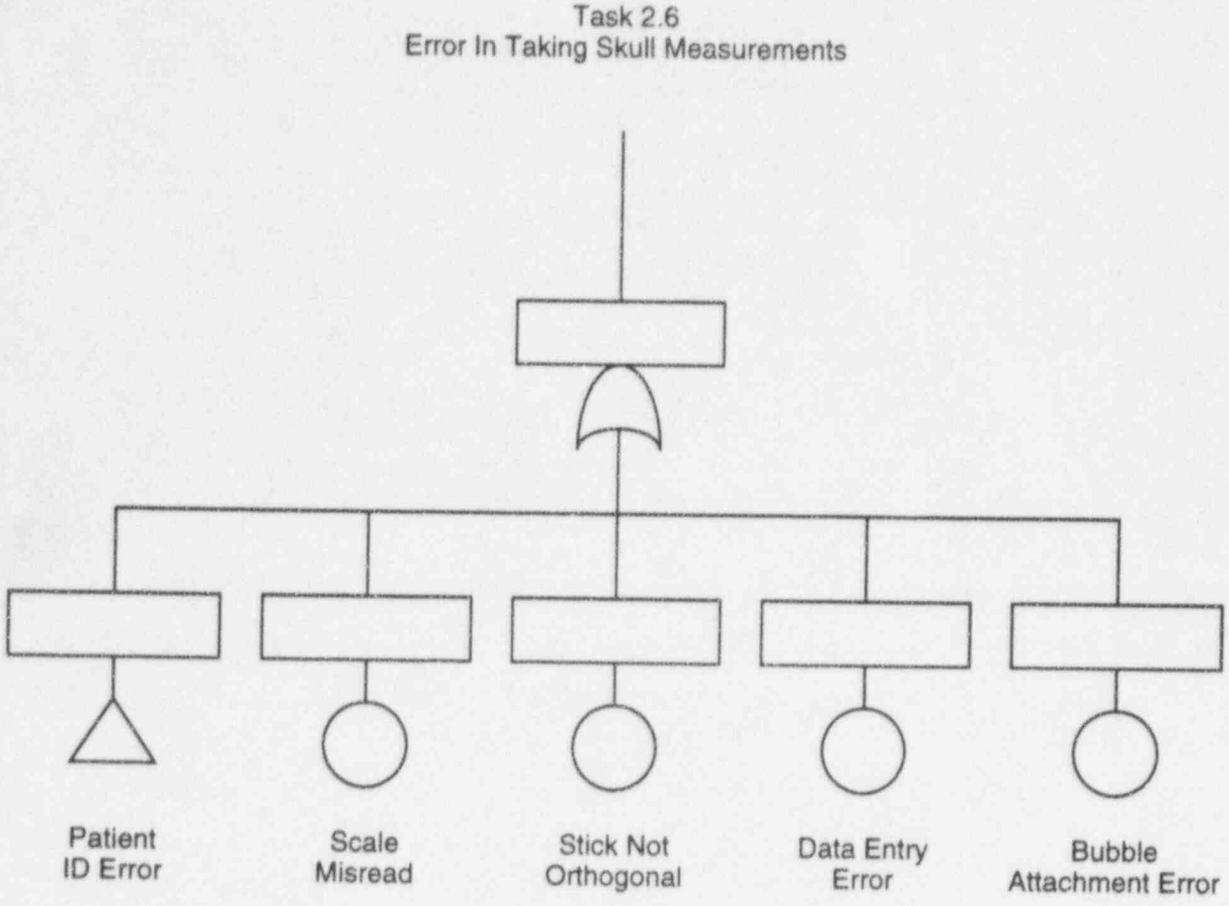

Figure 9. Task 2.6–Error in Taking Skull Measurements

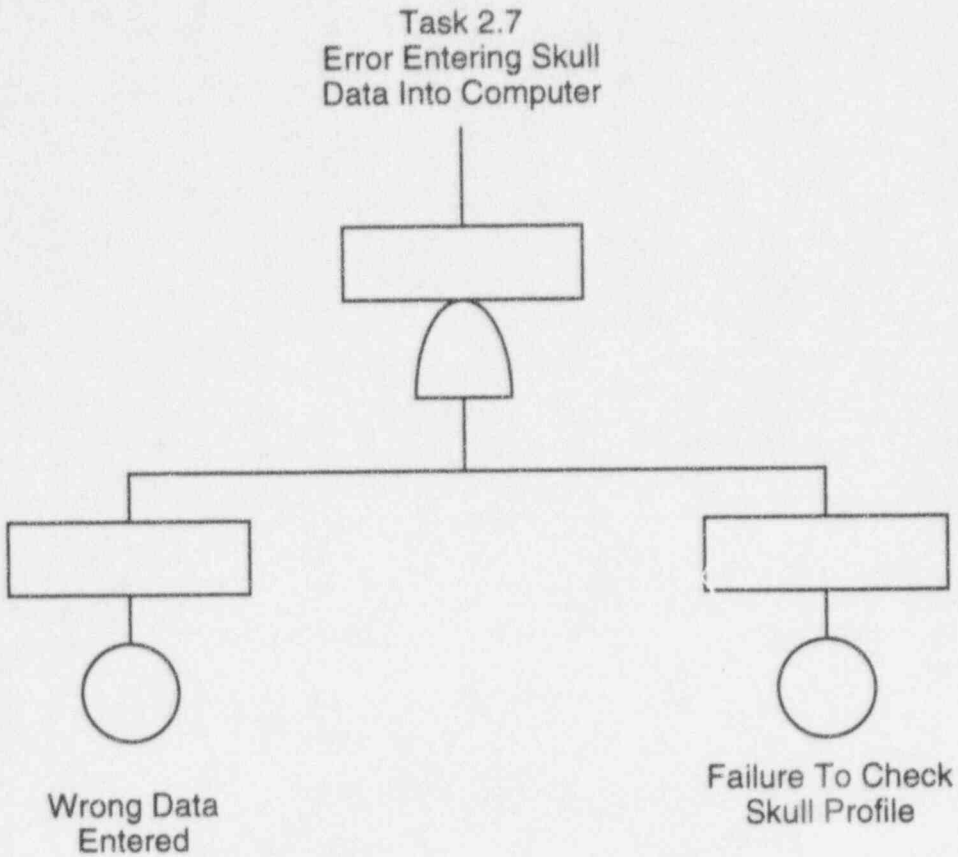

Figure 10. Task 2.7–Error Entering Skull Data Into Computer

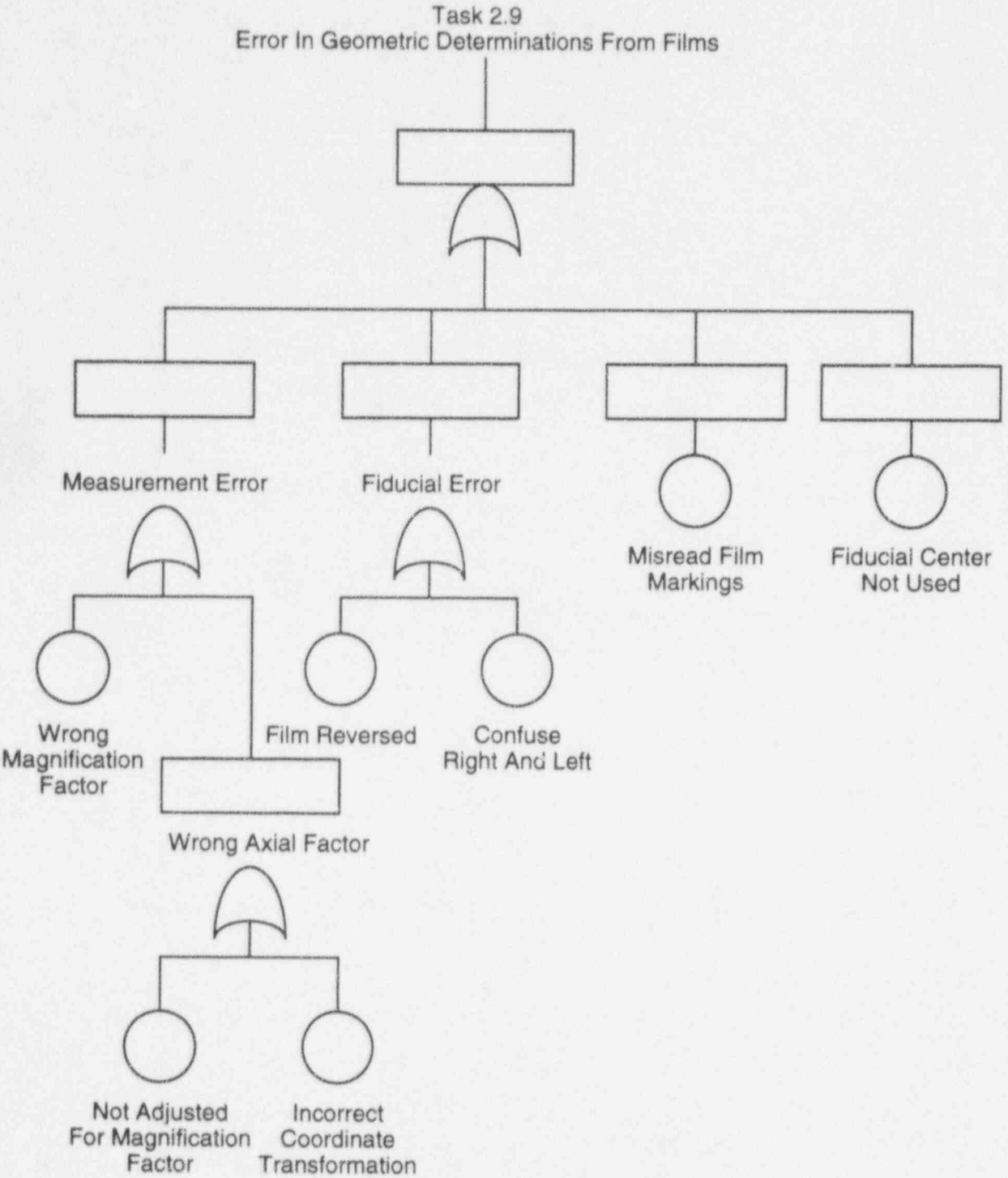

Figure 11. Task 2.9–Error in Geometric Determinations from Films

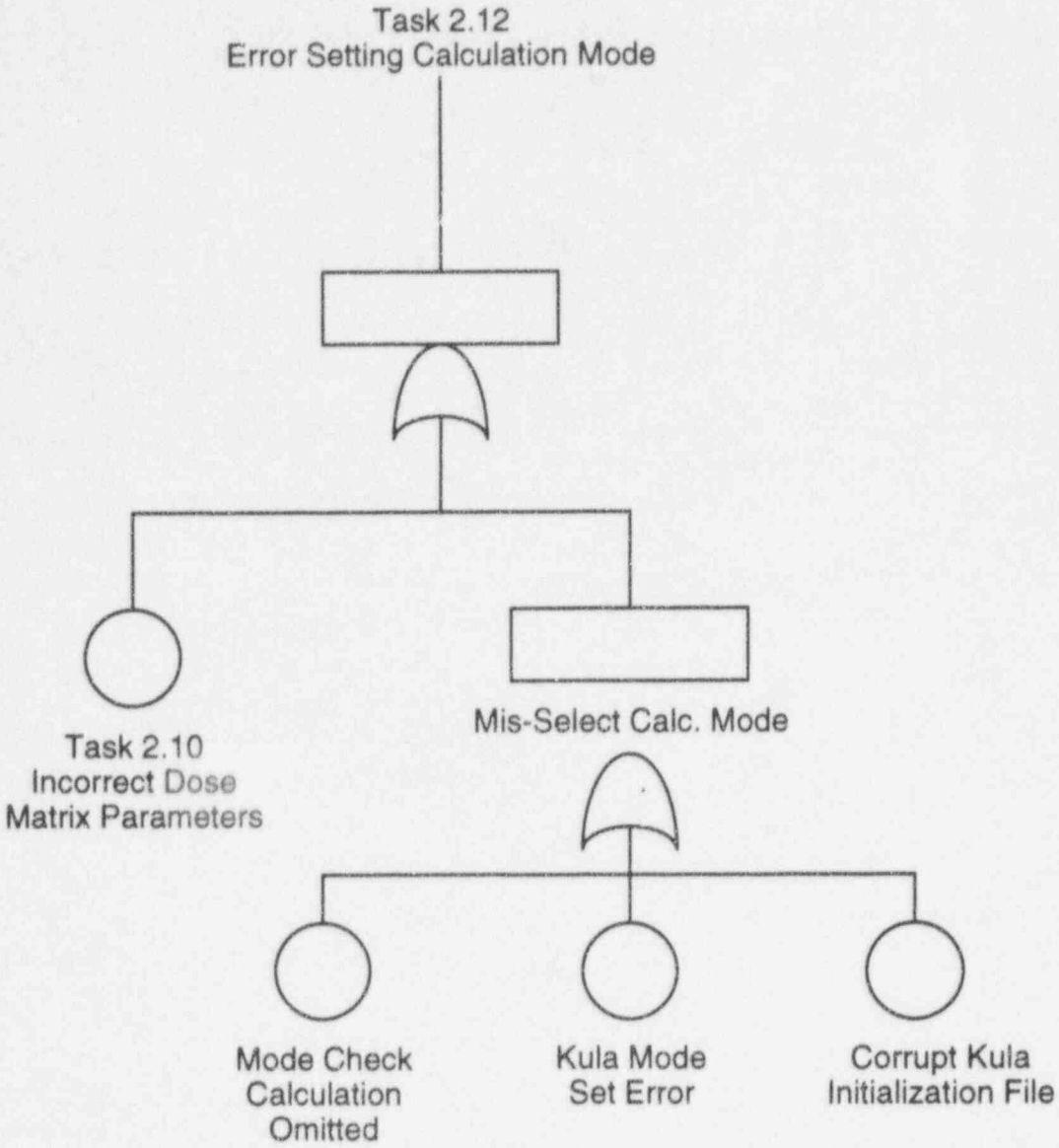

Figure 12. Task 2.12–Error Setting Calculation Mode

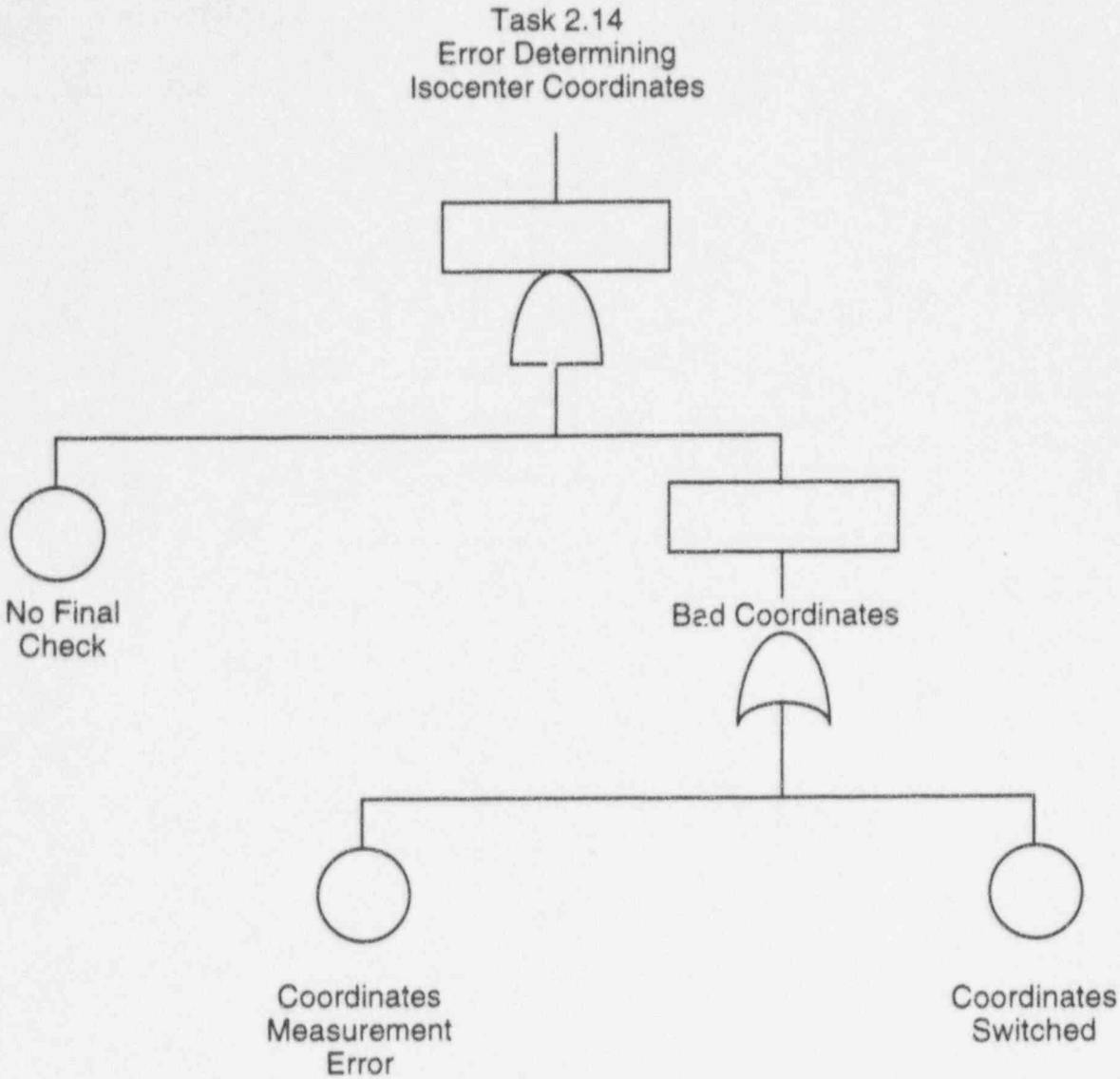

Figure 13. Task 2.14–Error Determining Isocenter Coordinates

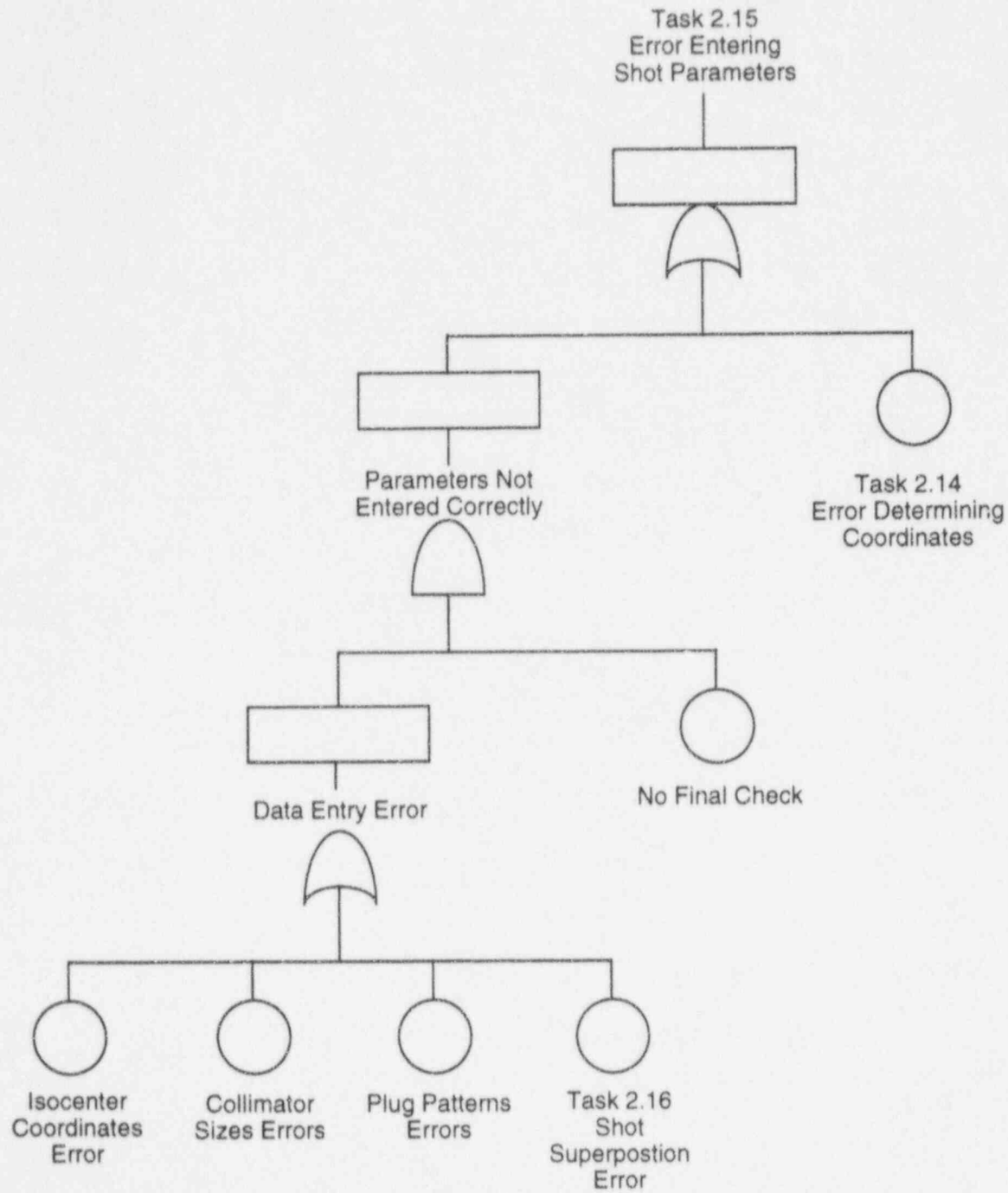

Figure 14. Task 2.15–Error Entering Shot Parameters

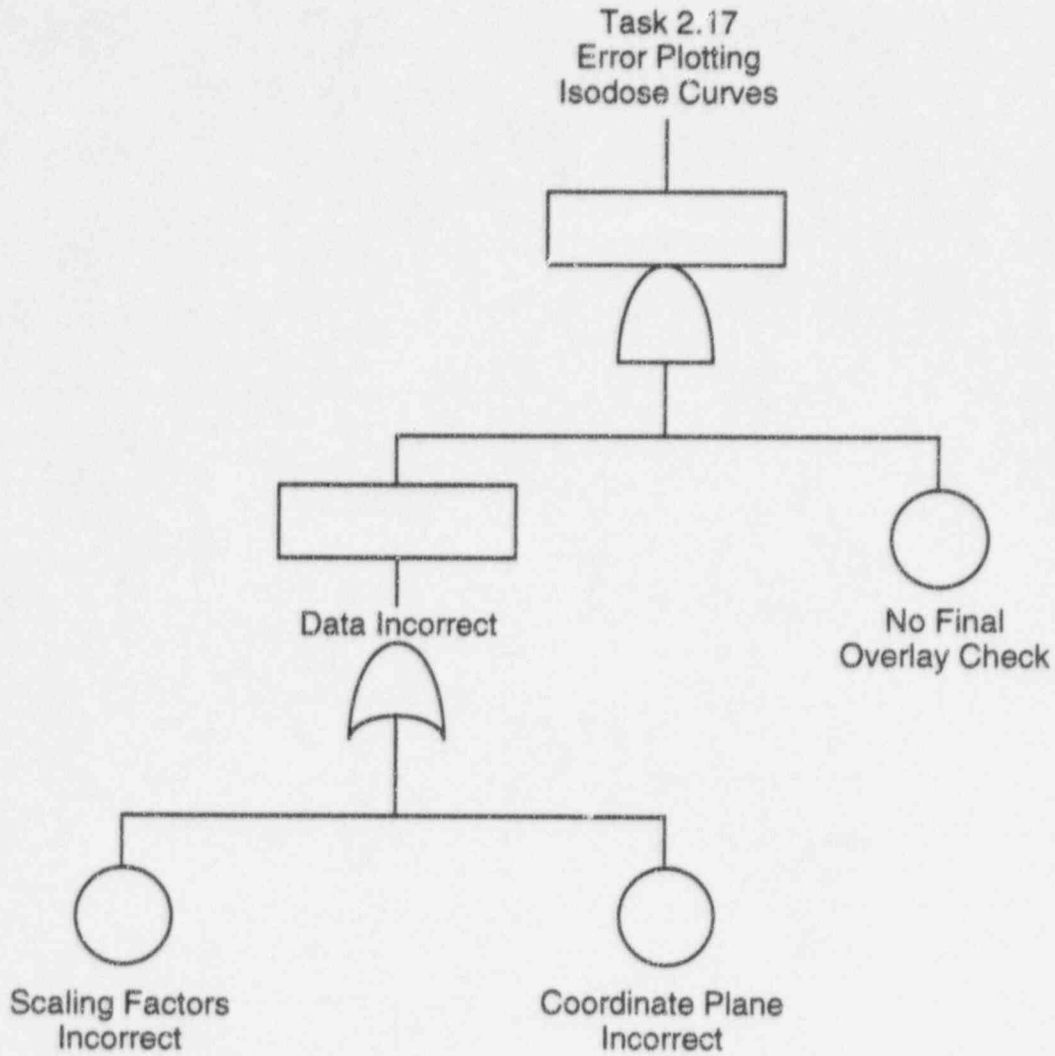

Figure 15. Task 2.17--Error Plotting Isodose Curves

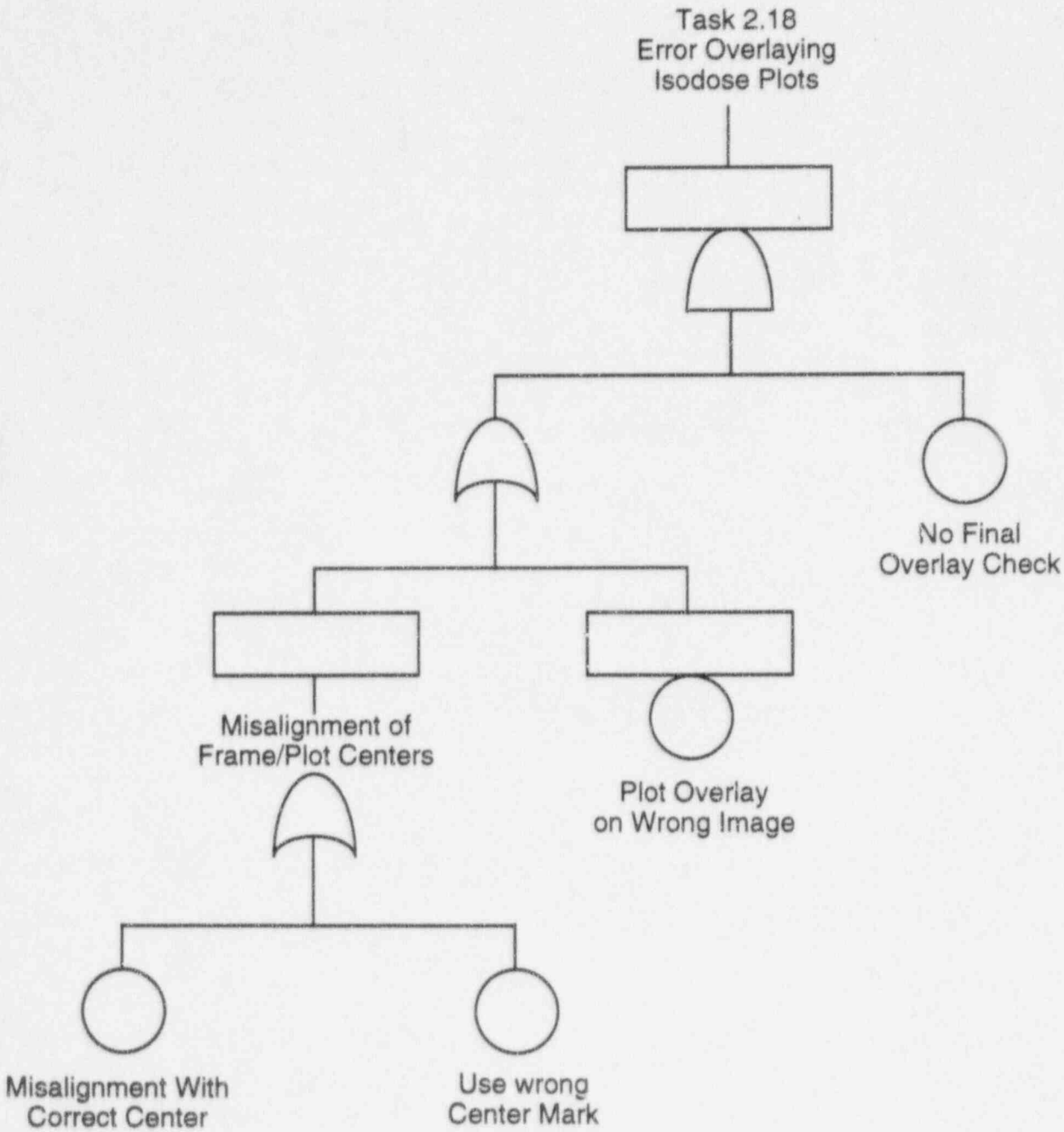

Figure 16. Task 2.18–Error Overlaying Isodose Plots

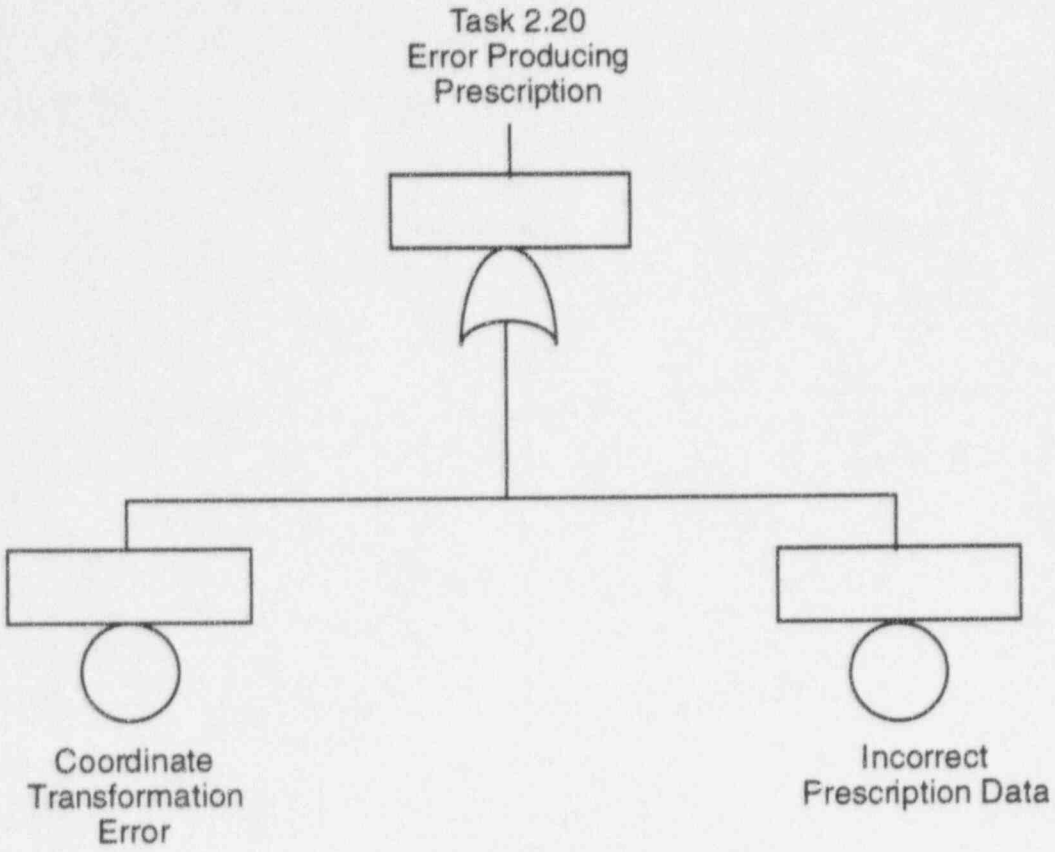

Figure 17. Task 2.20–Error Producing Prescription

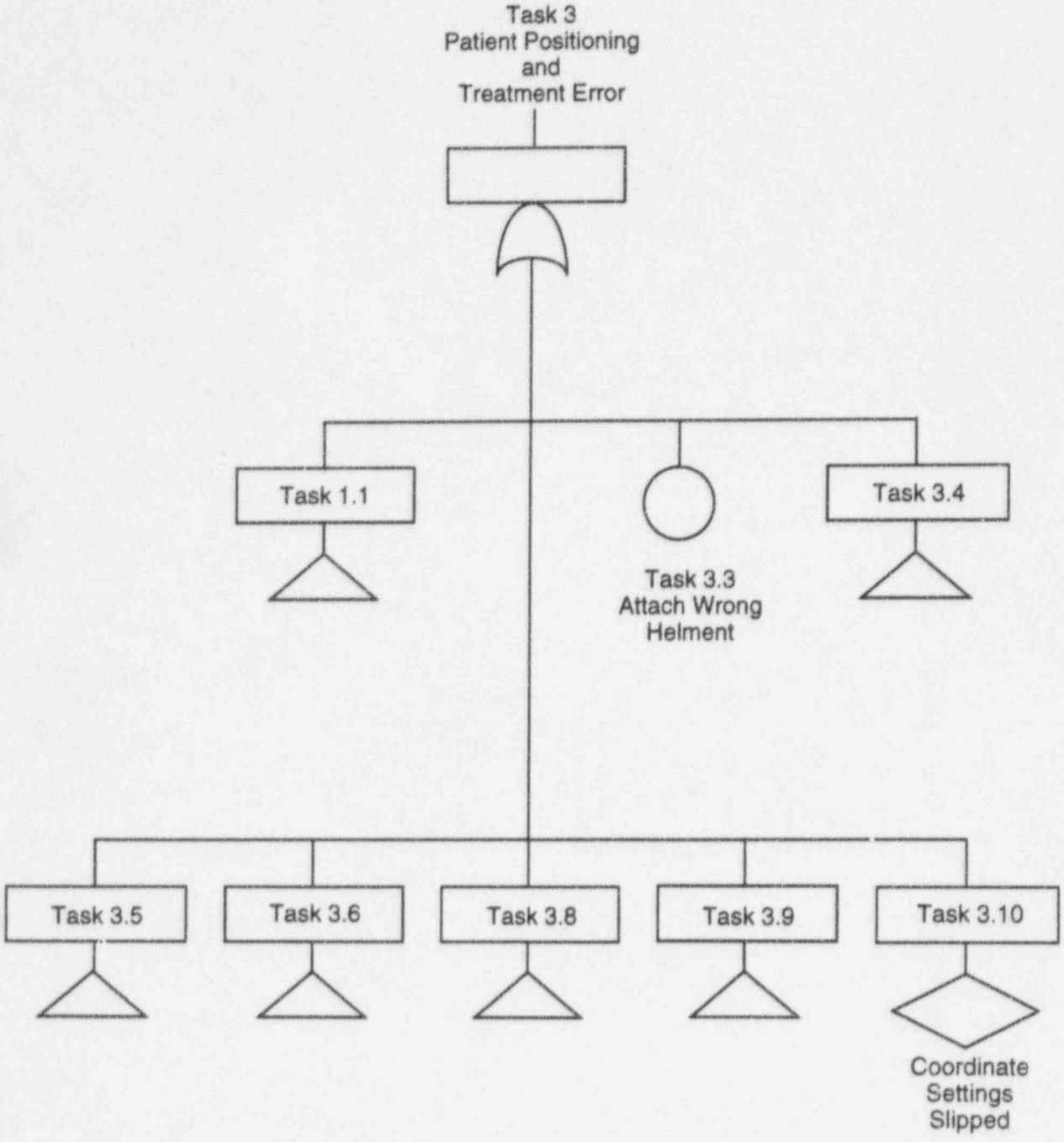

Figure 18. Task 3–Patient Positioning and Treatment Error

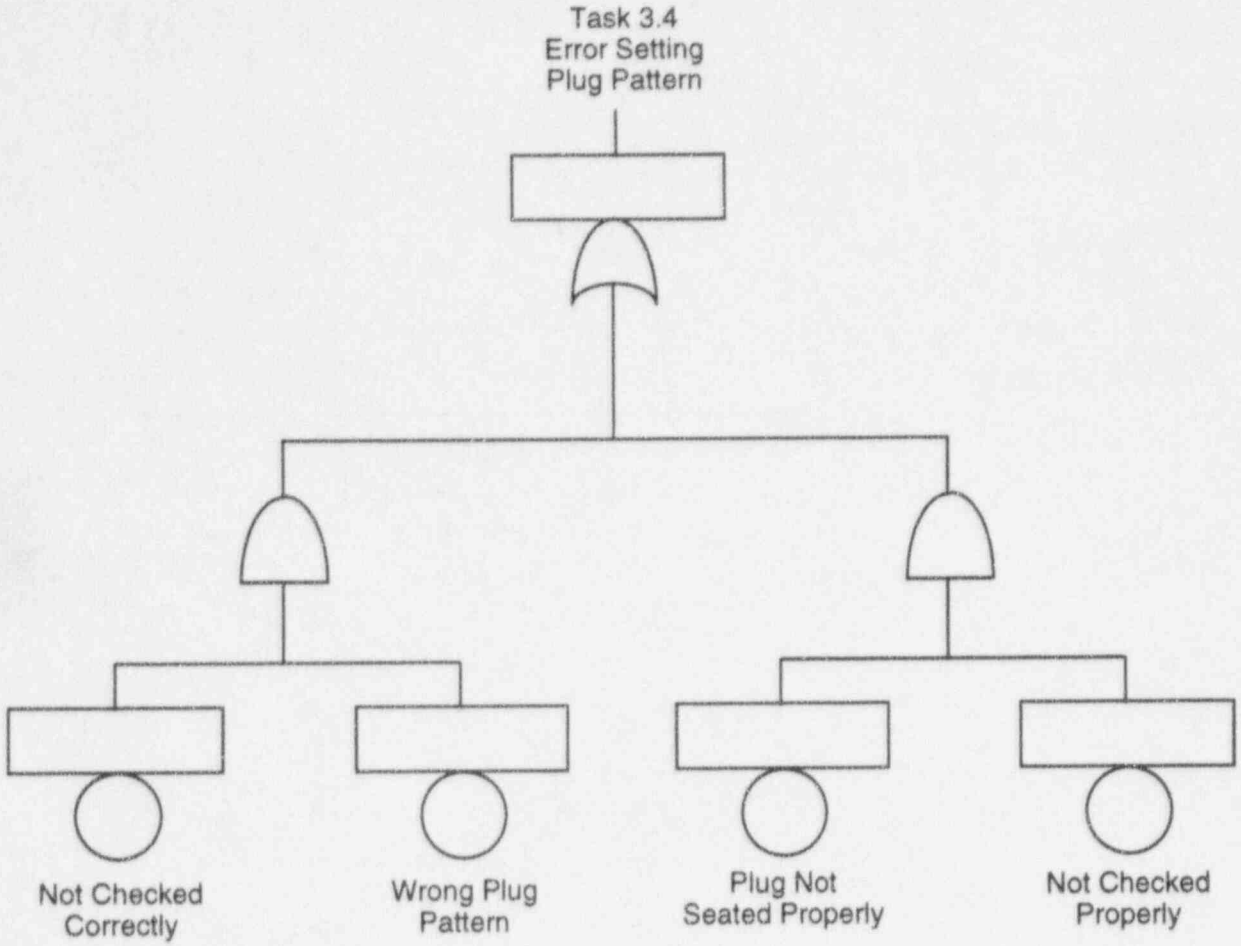

Figure 19. Task 3.4–Error Setting Plug Pattern

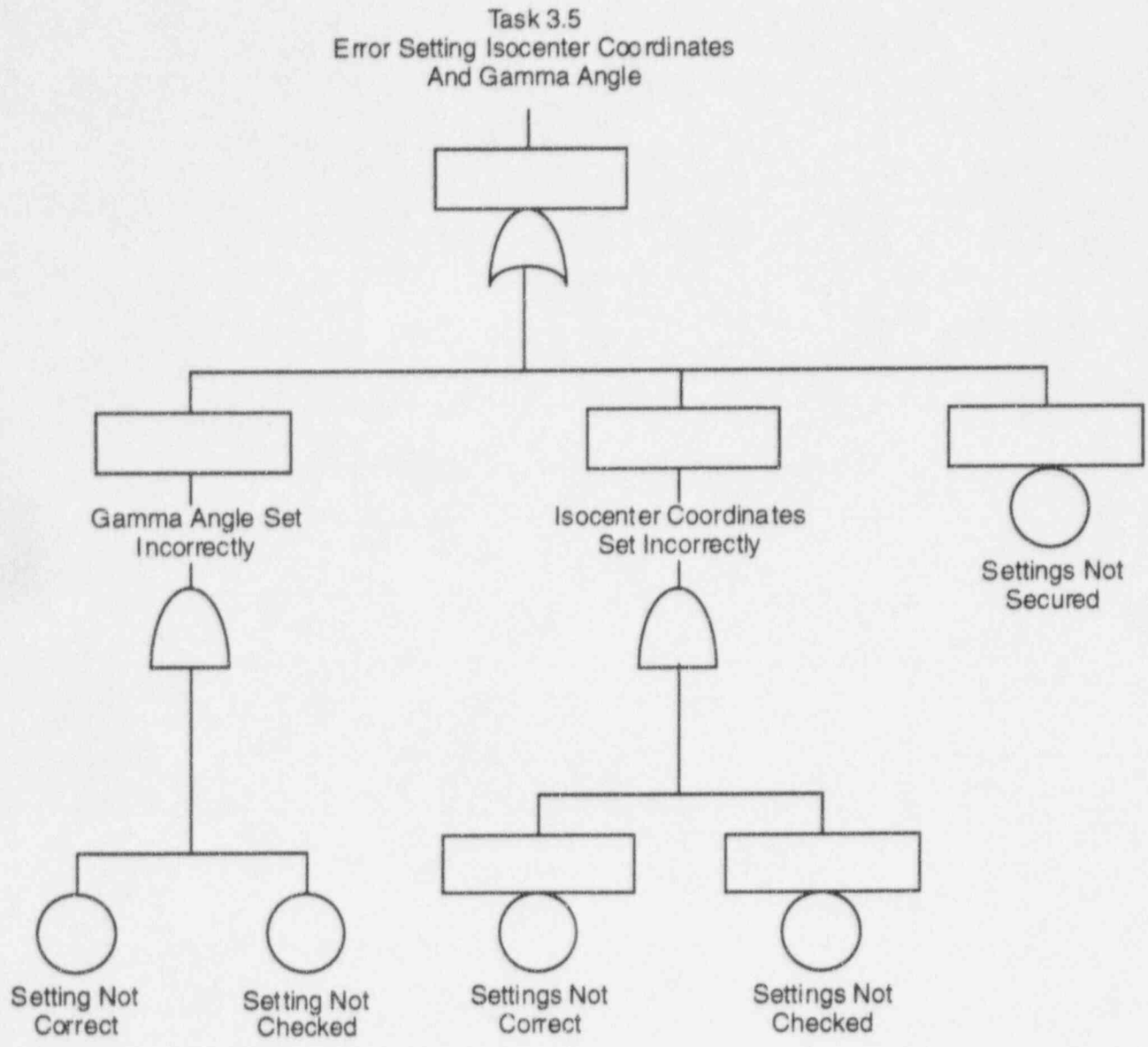

Figure 20. Task 3.5–Error Setting Isocenter Coordinates and Gamma Angle

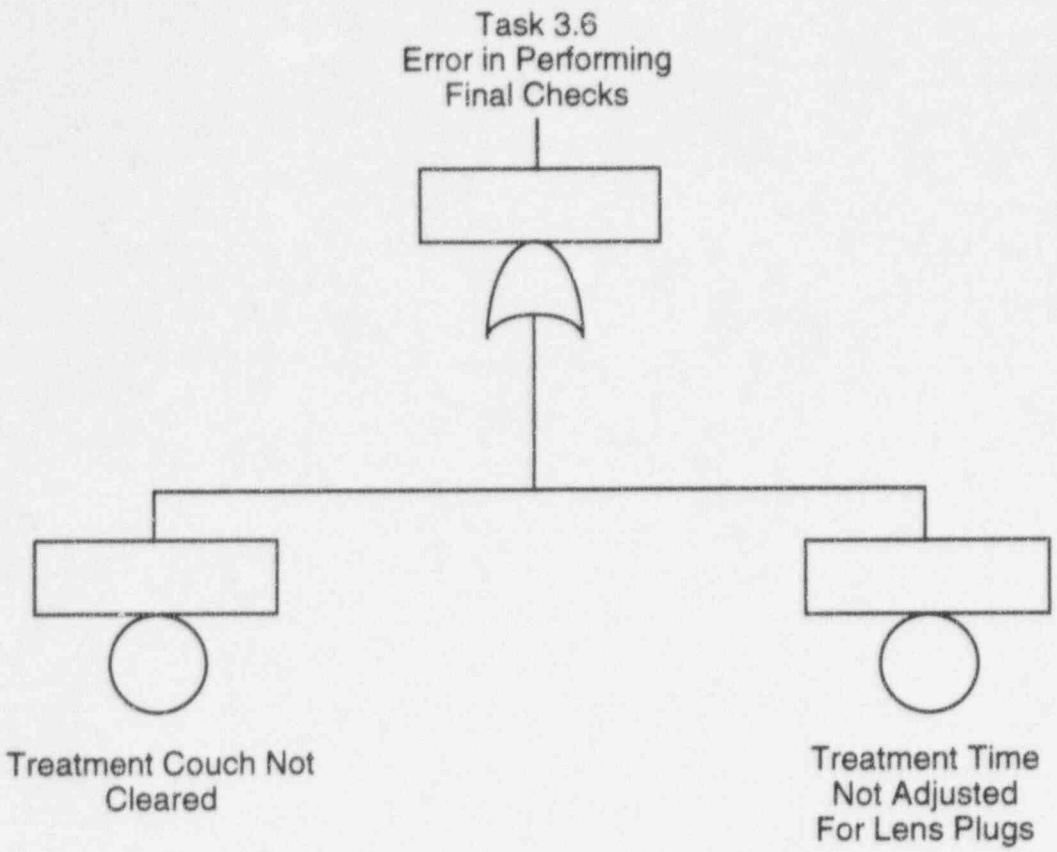

Figure 21. Task 3.6–Error in Performing Final Checks

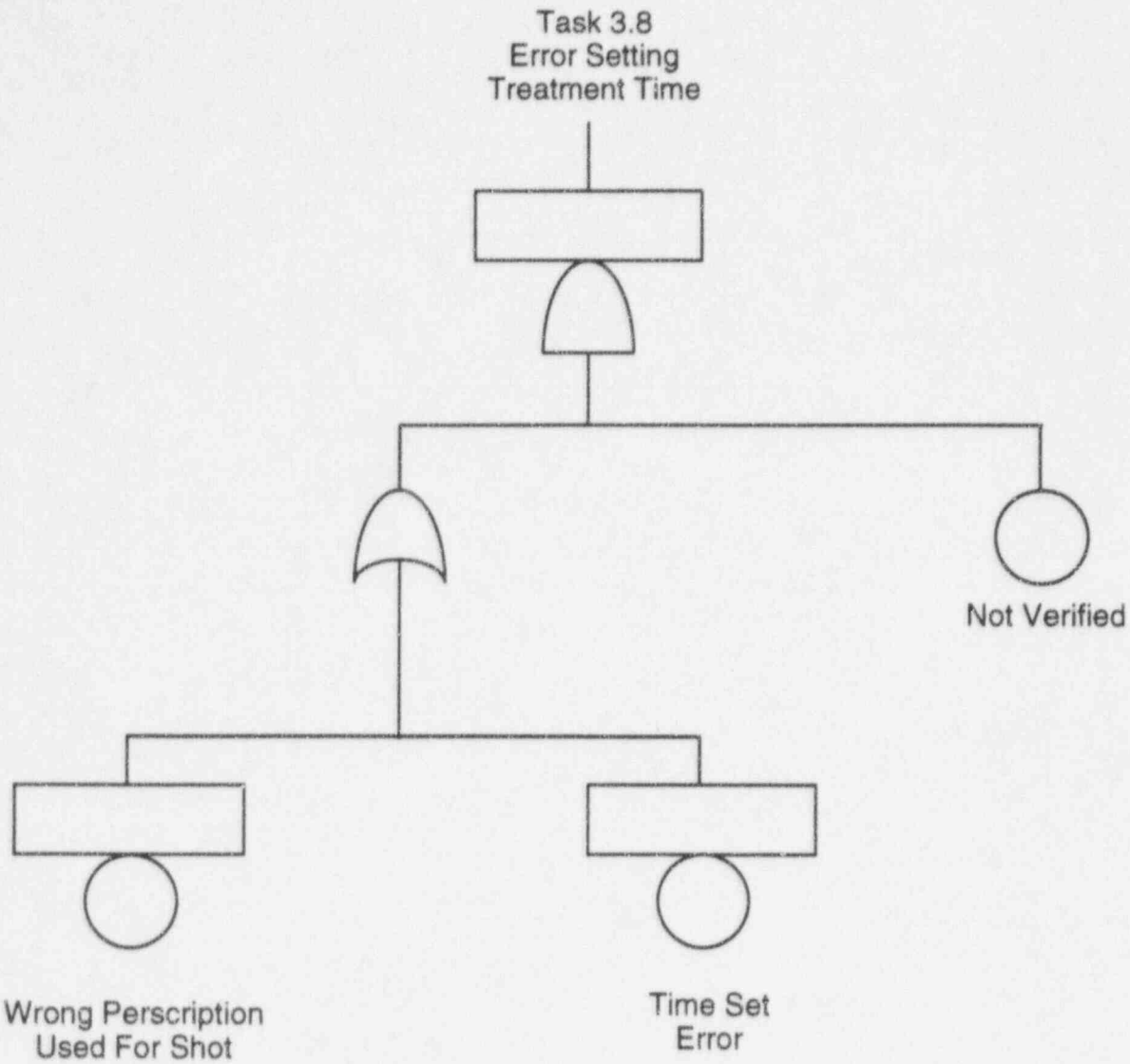

Figure 22. Task 3.8–Error Setting Treatment Time

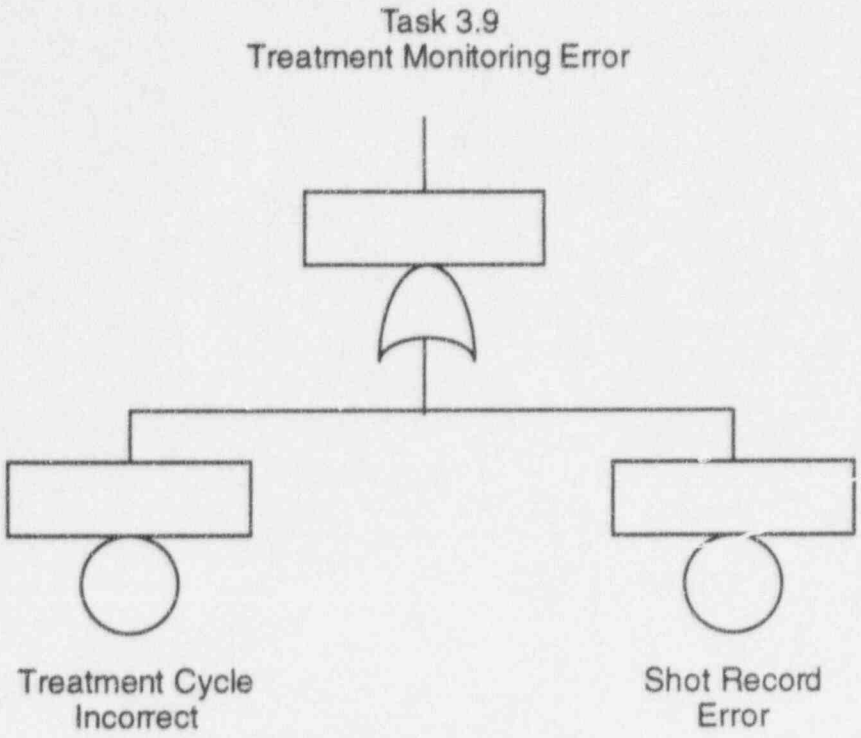

Figure 23. Task 3.9–Treatment Monitoring Error

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11. ABSTRACT *(200 words or less)*

This report describes a preliminary application of an analysis approach for assessing relative risks in the use of radiation-emitting medical devices. Results are presented on human-initiated actions and failure modes that are most likely to occur in the use of the Gamma Knife*, a gamma irradiation therapy device. This effort represents an initial step in a U.S. Nuclear Regulatory Commission (NRC) plan to evaluate the potential role of risk analysis in regulating the use of nuclear medical devices. For this preliminary application of risk assessment, the focus was to develop a basic process using existing techniques for identifying the most likely risk contributors and their relative importance. The approach taken developed relative risk rankings and profiles that incorporated the type and quality of data available and could present results in an easily understood form. This work was performed by the Lawrence Livermore National Laboratory for the NRC.

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

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