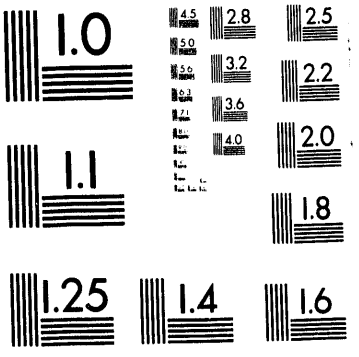

1.0
1.1
1.25
1.4
1.6
1.8
2.0
2.2
2.5
2.8
3.2
3.6
4.0
4.5
5.0
5.6
6.3
7.1

1 of 1

Conf-940312--54

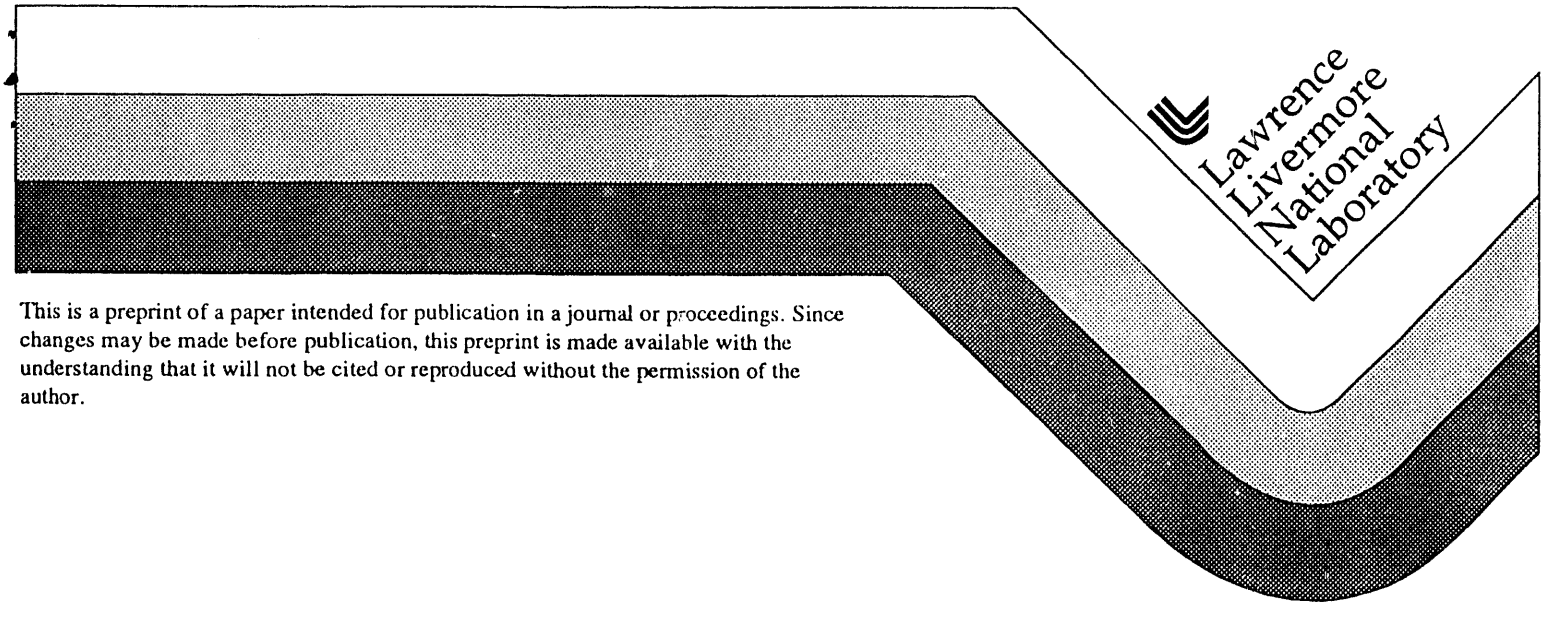
UCRL-JC-115429
PREPRINT

RISK EVALUATION OF MEDICAL AND INDUSTRIAL RADIATION DEVICES

Edwin D. Jones
Richard E. Cunningham
Patricia A. Rathbun

This paper was prepared for submittal to the:
Probabilistic Safety Assessment Meeting
March 20-24, 1994
San Diego, CA

March 1994



FIN L-1938

Risk Evaluation of Medical and Industrial Radiation Devices

Edwin D. Jones
Richard E. Cunningham
Patricia A. Rathbun

March 1994

RISK EVALUATION OF MEDICAL AND INDUSTRIAL RADIATION DEVICES*

Edwin D. Jones

Fission Energy and Systems Safety Program
Lawrence Livermore National Laboratory
P.O. Box 808, L-632
Livermore, CA 94551-9900

Richard E. Cunningham and Patricia A. Rathbun

Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Mail Stop 6H3, OWFN
Washington, D.C. 20555-0001

INTRODUCTION

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

Traditional methods of assessing risk in nuclear power plants may be inappropriate to use in assessing the use of by-product devices. The approaches used in assessing nuclear reactor risks are equipment-oriented. Secondary attention is paid to the human component, for the most part *after* critical system failure events have been identified.

This paper describes the risk methodology developed by Lawrence Livermore National Laboratory (LLNL), initially intended to assess risks associated with the use of the Gamma Knife,+ a gamma stereotactic radiosurgical device. For relatively new medical devices such as the Gamma Knife, the challenge is to perform a risk analysis with very

* This work was supported by the U.S. Nuclear Regulatory Commission, Office of Nuclear Material Safety and Safeguards, under the Interagency Agreement DOE 40-550-75 with the U.S. Department of Energy, and performed by Lawrence Livermore National Laboratory under Contract W-7405-Eng-48.

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

little quantitative data but with an important human factor component. The method described below provides a basic approach for identifying the most likely risk contributors and evaluating their relative importance.

The risk analysis approach developed for the Gamma Knife and described in this paper should be applicable to a broader class of devices in which the human interaction with the device is a prominent factor. In this sense, the method could be a prototypical model of nuclear medical or industrial device risk analysis.

RISK ASSESSMENT METHODOLOGY

The risk approach used is motivated by a need to have a flexible analysis framework that can incorporate both qualitative and quantitative data about human and equipment factors, and that is consistent with the ALARA principle (reducing risk to a level "as low as reasonably achievable"). The methodology should not be a rule-based methodology, but should be a systematic approach to uncovering risk at various levels of resolution for a range of levels of effort. The methodology must also be able to accommodate a variety of medical practices and devices. It thus must be empirically based and must 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. Thus, the risk analysis must not rely on only quantitative data to be useful. It should be able to compare a range of data types and data quality. In the methodology, there must be equanimity between human and equipment factors: the methodology cannot simply be machine- or human-centered in its orientation. The notion of ALARA provides a principle of relativity for the risk analysis: to lower risks to a level as low as reasonably achievable. This can be accomplished without absolute measures of risk (which, after all, are very difficult and costly to ascertain): only relative improvements in apparent risks are needed.

After a few iterations of considering potential risk analysis methodologies, it was decided that the above criteria could best be met by the approach of developing relative rankings of risk or risk profiles. Profile analysis is a general analytic tool which has been employed since the late 1940s. In the last decade, profile analytic techniques have been applied to the evaluation of both machine failures and human errors in nuclear facilities (Seaver and Stillwell, 1983; Banks and Paramore, 1983).

The risk assessment methodology is an empirically based, systematic approach to uncovering potential risks. It consists of a hierarchy of iterated stages: (1) process and sequence identification; (2) hazards evaluation; (3) event/task analysis and data collection; and (4) relative rankings and risk profiles. The first three stages serve to systematically identify elements most likely to contribute to risk. The last stage provides a measure of the relative risk importance of each of the identified risk contributors. Even though each stage requires its own analysis techniques and tools, the stages are not independent, and each requires iterated inputs from previous and subsequent stages. In this way, the total analysis is thorough, balanced, and self-consistent. Documented and anecdotal information as well as subject matter expertise is used, as much as possible, at every stage of the methodology.

Identifying Risk Contributors

The first stage is to define the problem to be analyzed, which involves selecting the series of events or process to be evaluated. The selection requires familiarity with the system of interest, its operational requirements and functions, and the role of the human operator. A process should be selected that can be separated, by a reasonable person, into a sequence of steps. The criteria for the delineation of a sequence step is that the step must be completed successfully before the next step can be initiated.

Identifying and judging hazardous elements or conditions associated with the use of the device is a very important stage. It provides the boundary conditions or circumscription for subsequent analyses. Insufficient resources are available to analyze everything, ad infinitum, so a clear understanding of hazardous situations is necessary to direct, focus, and constrain the analysis efforts. The hazards evaluation helps identify those sequence elements that deserve further evaluation.

As part of the risk identification effort for the Gamma Knife, it was important to search for extraneous radiation fields that may affect people during system failures or abnormal operating modes (Smith et al, 1993). First, the radiation levels were checked at the intended treatment target as a function of patient positioning during a normal treatment cycle. Then fields were checked during a failure mode of the hydraulic system while a phantom was within the radiation unit. (The primary concern was extraneous radiation to the patient close to the primary sources.)

Two kinds of radiation hot spots were discovered to which a patient would be subject while being transported 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) is due to transmission of the primary beams through the stainless steel of the collimating helmet. Other hot spots (approximately 1–2% of maximum) are due to inadvertent, non-attenuated transmission through misaligned collimators. These effects disappear at the treatment position, because the tungsten collimators are aligned and they prevent transmission of the primary beams.

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

Once a process sequence is developed and the hazards are well defined and understood, a human-oriented task sequence list needs to be developed for each step of the process of interest. The first task in each list should be the initiating task for the process step, and the last task or subtask in each list needs to 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 and localization, treatment planning, and patient positioning and treatment. All tasks have 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 operator.

For the purpose of a risk analysis, tasks should be selected that are judged to be the most pertinent activities affecting risks associated with the device. The analyst must ascertain where errors most relevant to risk can or do occur. Then each event or task sequence must be clearly delineated. Each task should have a well-defined error and a measurable consequence associated with that error. The selection of tasks should be based on expert actual experience with the use of the device.

In the case of the Gamma Knife, data were collected from medical associations, standard-setting organizations, the manufacturer, users, and experts. A multidisciplinary team of physicians and medical physicists with expertise in teletherapy, risk assessment experts, and scientists and engineers with extensive knowledge of task and safety analyses inspected Gamma Knife units, attended acceptance tests, interviewed users, and observed patient treatments. The data were verified for accuracy, completeness, and self-consistency by the use of subject matter experts, simulations, facility walk-throughs, and obs -ving actual practices. Data analyzed by the project team were subsequently reviewed, critiqued, and validated by medical community expert review teams.

Once the tasks have been analyzed and selected for errors pertinent to risk, it is possible to identify those tasks associated with the highest risks. In a first-order risk analysis, likely error rates and consequences for each task are treated as independent from other tasks, and estimated as if they are associated with isolated events. 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 logically combine probability and magnitude of errors for a concatenation of tasks, in order to accurately represent potential error propagations. Scenarios involving concatenations of tasks are examined to validate or adjust the rankings for each task, in order to ensure appropriate relative rankings,

The relative likelihood of error and the degree of consequence can be estimated by subject matter experts. Evaluations have provided encouraging support for the use of expert judgment (Comer et al, 1983). Experts are good 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 statistics 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 were collected for each task by asking relevant experts to provide their estimation 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 was not how or why errors occurred, but how often errors have in fact occurred. Relative ratings or discrete distributions were used — absolute values and continuous distributions are desirable, but not necessary.

Comparing rankings among tasks is done by means of a "risk profile." There are various ways to compare tasks. One instructive representation is to graph the tasks by their probabilities versus their consequences, by using the mean values from the discrete data distributions. Another first-order risk profile results from multiplying the probability of error by the magnitude of consequence for each task. Such profiles clearly identified the high risk tasks: those with relatively high probability and high consequence.

The relative rankings and error distributions also can be used in computerized Monte Carlo simulations of scenarios that provide a higher level of risk analysis, 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.

In the Gamma Knife project, a Monte Carlo computer code was developed and used to simulate and evaluate the relative risks of possible error scenarios. The code was named the Monte Carlo Risk Scenario Code or MCRSC ("McRisk"). It makes full use of the developed error rate and error magnitude distributions and can model the interactions among any number of tasks, logically convolving distributions. It was used to aggregate subtasks and their error distributions, determine best- and worse-case extremes, and perform the analyses outlined below. It is important to have a tool like MCRSC for handling the uncertainties associated with human errors in the use of medical devices. The large values of uncertainty indicate that the first order risk analysis, where only the mean values were used, may not be adequate to represent interacting errors among tasks.

The Monte Carlo simulations generated a multitude of error scenarios and their associated risks. Such simulations exposed synergies or scenarios that otherwise may have gone unnoticed. MCRSC produced distributions that enabled the identification of high-risk scenarios and tasks most likely associated with the highest risk scenarios.

Uncertainty, sensitivity, and mitigation studies were performed by analyzing the changes in risk profiles that were due to variations in task or error data. Thus, evaluations were made on the risk impacts of system design changes, site and device variabilities, potential risk mitigation and management measures, and regulatory requirements.

If costs are associated with proposed changes in tasks or error rates and magnitudes, then risk cost-benefit studies are also possible, e.g., risk vs. cost utility curves can be generated. The Monte Carlo simulations can generate risk outcomes for a variety of risk mitigation strategies in such a way that minimax criteria (and hence linear programming techniques) can be applied to determine the optimal mix of strategies. The mixed strategies may involve, for instance, a combination of changes in design, procedures, and training.

SUMMARY AND CONCLUSIONS

The efforts in applying probabilistic risk techniques and methods to the use of by-product devices show promise for developing indices of risk importance and effective risk management practices. The methods provide a flexible, basic approach for identifying most likely risk contributors and the relative importance of each contributor. The risk analysis tools also provide a platform for evaluating the effectiveness of regulatory practices.

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

REFERENCES

Banks, W.W., and Paramore, B., October 1983, Systems integration: a pilot task analysis of the DOE size reduction facility; EGG-REP-6440, Idaho National Engineering Laboratory.

Comer, M.K., Kozinsky, E. J., Eckel, J.S., and Miller, D.P., February 1983, A data bank conception and system description, *in:* "Human Reliability Data Bank for Nuclear Power Plant Operations," Vol. 2; NUREG/CR-2744, General Physics Corporation and Sandia National Laboratories.

Seaver, D.A., and Stillwell, W.G., March 1983, Procedures for using expert judgment to estimate human error probabilities in nuclear power plant operations; NUREG/CR-2743, Decision Science Consortium and Sandia National Laboratories.

Smith V., Verhey, L., Jones, E., and Lyman L., 1993, Consequences to the patient in the event of hydraulic unit failure; *to appear in:* "Stereotactic and Functional Neurosurgery," Vol. 61, Supplement 1.

DATE
FILMED
3/11/94
END