NUREG/CR-6277
Vol. 1

Human Factors Evaluation of Teletherapy

RECEIVED
AUG 01 1995
OSTI

Identification of Problems and Alternative Approaches

Prepared by
K. Henriksen, R. D. Kaye, R. Jones/Hughes Training, Inc.
D. S. Morisseau, D. I. Serig/NRC

Hughes Training, Inc.

Prepared for
U.S. Nuclear Regulatory Commission

AVAILABILITY NOTICE

Availability of Reference Materials Cited in NRC Publications

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

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

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

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

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

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

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

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

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

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

DISCLAIMER NOTICE

This report was prepared as an account of work sponsored by an agency of the United States Government. Neither the United States Government nor any agency thereof, nor any of their employees, makes any warranty, expressed or implied, or assumes any legal liability or responsibility for any third party's use, or the results of such use, of any information, apparatus, product, or process disclosed in this report, or represents that its use by such third party would not infringe privately owned rights.

DISCLAIMER

Portions of this document may be illegible in electronic image products. Images are produced from the best available original document.

Human Factors Evaluation of Teletherapy

Identification of Problems and Alternative Approaches

Manuscript Completed: June 1995
Date Published: July 1995

Prepared by
K. Henriksen, R. D. Kaye, R. Jones, Hughes Training, Inc.
D. S. Morisseau, D. I. Serig, Nuclear Regulatory Commission

Hughes Training, Inc.
5111 Leesburg Pike, Suite 300
Falls Church, VA 22041

Prepared for
Division of Systems Technology
Office of Nuclear Regulatory Research
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001
NRC Job Code L1532

DISTRIBUTION OF THIS DOCUMENT IS UNLIMITED

me

MASTER

ABSTRACT

A series of human factors evaluations was undertaken to better understand the contributing factors to human error in the teletherapy environment. Teletherapy is a multi-disciplinary methodology for treating cancerous tissue through selective exposure to an external beam of ionizing radiation. The principal sources of radiation are a radioactive isotope, typically cobalt-60 (Co-60), or a linear accelerator device capable of producing very high energy x-ray and electron beams. A team of human factors specialists, assisted by a panel of radiation oncologists, medical physicists, and radiation technologists, conducted site visits to radiation oncology departments at community hospitals, university centers, and free-standing clinics. A function and task analysis was initially performed to guide subsequent evaluations in the areas of user-system interfaces, procedures, training and qualifications, and organizational policies and practices. The final phase of the project focused on identification of the most significant human factors problems with respect to safe and effective operation of the teletherapy system and an identification and assessment of alternative approaches for resolving the problems. This report presents the findings of this final phase.

TABLE OF CONTENTS

	Page
ABSTRACT	iii
TABLE OF CONTENTS	v
LIST OF FIGURES	viii
LIST OF TABLES	ix
EXECUTIVE SUMMARY	xi
ACKNOWLEDGEMENTS	xvii
FOREWORD	xix
1.0 INTRODUCTION	1
1.1 Purpose of the Project	1
1.2 Human Factors Evaluation	2
1.3 Human Factors Problem Resolution	4
1.4 Brief Overview of the Teletherapy Process	5
2.0 METHODOLOGY	7
2.1 The First Five Phases	7
2.1.1 Site Sampling Strategy	7
2.1.2 Contacting Candidate Centers	8
2.1.3 Data Collection Preparation	8
2.1.4 Data Collection Procedures	9
2.1.5 Data Analyses	9
2.2 Summary and Prioritization of Problems	9
2.2.1 Create Inventory of Potential Human Factors Problems	9
2.2.2 Evaluate Impact of Potential Human Factors Problems on Teletherapy Functions/Tasks	10
2.2.3 Assess Error Detectability and Error Consequences	11
2.2.4 Generate and Assess Alternative Approaches for Resolving Problems	11

	Page
3.0 RESULTS	13
3.1 Summary of the First Five Phases	13
3.1.1 Function and Task Analysis	13
3.1.2 Human-System Interfaces	14
3.1.3 Procedures and Practices	16
3.1.4 Training	17
3.1.5 Organizational Factors	18
3.2 Identification of Critical Task Areas	19
4.0 CRITICAL TASK AREAS AND ALTERNATIVE APPROACHES	20
4.1 Critical Task Area 1 — Pre-treatment Planning	20
4.1.1 Tasks That Could Be Compromised	20
4.1.2 Contributing Factors	21
4.1.3 Alternative Approaches and Their Assessment	22
4.2 Critical Task Area 2 — Treatment Planning Computer Data Files	23
4.2.1 Tasks That Could Be Compromised	24
4.2.2 Contributing Factors	24
4.2.3 Alternative Approaches and Their Assessment	25
4.3 Critical Task Area 3 — Use of Patient Chart	27
4.3.1 Tasks That Could Be Compromised	27
4.3.2 Contributing Factors	29
4.3.3 Alternative Approaches and Their Assessment	30
4.4 Critical Task Area 4 — Patient Positioning and Immobilization	31
4.4.1 Tasks That Could Be Compromised	31
4.4.2 Contributing Factors	32
4.4.3 Alternative Approaches and Their Assessment	33
4.5 Critical Task Area 5 — Treatment Set-Up	35
4.5.1 Tasks That Could Be Compromised	35
4.5.2 Contributing Factors	36
4.5.3 Alternative Approaches and Their Assessment	37
4.6 Critical Task Area 6 — Data Transfer	39
4.6.1 Tasks That Could Be Compromised	39
4.6.2 Contributing Factors	41
4.6.3 Alternative Approaches and Their Assessment	41

	Page
4.7 Critical Task Area 7 — Equipment Checks and Calibration	43
4.7.1 Tasks That Could Be Compromised	44
4.7.2 Contributing Factors	44
4.7.3 Alternative Approaches and Their Assessment	46
4.8 Critical Task Area 8 — Radiation Field Alignment Accuracy	47
4.8.1 Tasks That Could Be Compromised	48
4.8.2 Contributing Factors	49
4.8.3 Alternative Approaches and Their Assessment	50
4.9 Critical Task Area 9 — Radiation Treatment Delivery	51
4.9.1 Tasks That Could Be Compromised	52
4.9.2 Contributing Factors	52
4.9.3 Alternative Approaches and Their Assessment	53
4.10 Critical Task Area 10 — Quality Assurance Procedures	54
4.10.1 Tasks That Could Be Compromised	55
4.10.2 Contributing Factors	56
4.10.3 Alternative Approaches and Their Assessment	57
 5.0 CONCLUSION	 59
 6.0 REFERENCES	 65
 7.0 GLOSSARY	 69

LIST OF FIGURES

Figure No.	Title	Page
2.1	Sequence of Activities for First Five Phases	7
3.1	Overview of Function and Task Analysis	13
5.1	Relative Pervasiveness of Contributing Factor Citations to Critical Task Areas	61

LIST OF TABLES

Table No.	Title	Page
3.1	Critical Task Areas	19
4.1	Daily, Weekly, Monthly and Annual QA Checks	45
5.1	Citation of Contributing Factors with Respect to Critical Task Areas	60

EXECUTIVE SUMMARY

Background

Teletherapy is a multidisciplinary, multiphased methodology for treating cancerous and other tissue through selective exposure to an external beam of ionizing radiation. A radioactive isotope, typically Co-60, or a linear accelerator capable of producing very high energy x-ray and electron beams are the principal sources of radiation. Treatment typically takes place on a daily basis over a period of weeks and is planned and administered by a team of specialists including a radiation oncologist, a radiation physicist, a radiation therapist, and possibly a dosimetrist. Effective treatment depends upon successful performance of functions and tasks involving people, machines, and procedures. Records maintained by the NRC have identified cases of teletherapy misadministration where the delivered radiation dose has differed from the radiation prescription. Misadministrations include instances where the treatment was to the wrong patient, the wrong body part, or the dose was too great or too little. Both human error and machine malfunction have led to misadministrations. Misadministration above the prescribed dose may destroy healthy tissue and organs; misadministration below the prescribed level may result in ineffective treatment. Either way, the consequences can be life threatening.

Objective

The objective of the present effort is to summarize the findings of a series of human factors evaluations sponsored by the NRC to identify the contributing causes of human error in teletherapy. There were six major parts to the overall study: 1) a function and task analysis of the teletherapy activities, 2) evaluation of human-system interfaces, 3) evaluation of the procedures used by teletherapy staff, 4) evaluation of the training and qualifications of teletherapy staff, 5) evaluation of organizational practices and policies, and 6) identification of human factors problems in terms of their impact on task performance and safe operation of the teletherapy system, and an identification and assessment of alternative approaches to resolve the problems. A review of relevant teletherapy and human factors literature also was conducted. The present report, *Human Factors Evaluation of Teletherapy: Volume I Identification of Problems and Alternative Approaches*, focuses mostly on the sixth phase of the study, although brief summaries of the preceding phases also are provided.

Methodology

The methodology centered around six major activities. First, a site sampling strategy for visiting departments of radiation oncology was developed to ensure geographic dispersion of sites within the U.S., a good representation of different types of facilities (e.g., university-based centers, large community hospitals, and smaller free-standing or satellite facilities), and the inclusion of Co-60 units where possible. Second, candidate radiation oncology departments were contacted by telephone and in writing to request their participation in the study. The level of cooperation was considered high. Third, research personnel prepared for data collection activities by examining background information on teletherapy functions and tasks, human-system

interfaces and procedures, and relevant training and organizational issues, and by developing the necessary data collection forms. Fourth, site visits were conducted, treatment equipment was examined, on-going treatments were observed, and interviews were held with teletherapy staff. And fifth, collected data were analyzed to reveal general trends.

The sixth activity focused on identifying the most significant human factors problems that contribute to human error in the teletherapy setting. A four-step process was followed. The first step was the creation of an inventory of human factors problems based on the findings of the first five phases of the study. The second step was the evaluation of the impact of the inventoried problems on the teletherapy functions, sub-functions and tasks identified in the first phase. Impact ratings on task performance were made by human factors and teletherapy personnel to screen out insignificant problems. Task areas that received high impact ratings with respect to human error and system safety consequences were retained for further examination. The third step was an assessment of the task areas with high impact ratings with respect to the likelihood of the error being detected and the likely adverse consequences of the error. Task areas with higher combined ratings (indicating that the associated error was unlikely to be detected and/or that the adverse consequences were serious enough to be considered a misadministration) were retained and regrouped into critical task areas. The fourth step comprised generation and assessment of alternative approaches for alleviating the problems.

Critical Task Areas and Alternative Approaches

The following identification of critical task areas and alternative approaches resulted from implementation of the methodology.

Pre-treatment Planning — This task area involves discussion of essential aspects of treatment among key personnel prior to simulation, treatment planning, and treatment delivery tasks. Not all facilities conduct pre-treatment planning conferences. In these instances, not all members of the team have the same understanding regarding intended treatment plan parameters, patient-related factors, unusual procedures that are planned or special equipment that is needed. Pre-treatment planning conferences are advised for all unusual treatments. Educational workshops, organized or endorsed by the facility's quality assurance program, also are suggested for sensitizing staff to communication problems that contribute to human error and to the deleterious effect of heavy workload and understaffing.

Treatment Planning Computer Data Files — Treatment planning computers contain data files that are specific to the treatment machines for which plans are developed. Treatment data files corresponding to older Co-60 sources have been mistakenly used for calculation of treatments for new patients, resulting in doses in excess of what was prescribed. The operations involved in the electronic storage and transfer of data are essentially opaque to the user, jeopardizing safe performance of treatment planning computer tasks involved in data file set-up. Alternative approaches call for modifying the interface of the treatment planning computer to make hidden operations more visible, establishing procedures to ensure the accurate updating of data files, and introducing competency-based training on new equipment for personnel rather than leaving mastery of new treatment planning technology to self-initiative.

Use of Patient Chart — The patient's chart is updated, reviewed, modified and used by a number of different staff members throughout the duration of therapy. Chart-related problems include changes to the prescription that go unnoticed, illegibility of handwritten information, transfer of information errors, and ambiguous prescription instructions that can compromise task performance and potentially lead to misadministrations. One recommendation is to redesign or make modifications to the lay-out of the chart and evaluate the new design's ability to reduce certain types of errors. A second recommendation focuses on modifying the behavior of individuals who are introducing illegible or ambiguous information on the chart by portraying good practices and bad practices within the context of the department's quality assurance program.

Patient Positioning and Immobilization — In external beam applications, reproducing the patient's position during each treatment is essential to effective therapy. Given repeated administrations, concern arises over the cumulative effects of imprecision where it is possible to underexpose the tumor volume and overexpose radio-sensitive healthy tissue. Alternative approaches recommended for addressing patient positioning and immobilization problems include achieving a better understanding of the significance of the problem through outcome studies, better sharing of information across departments on promising treatment aids and innovations, taking advantage of new technology rather than solely relying on skin marks as a way of setting treatment field margins, and designing patient scheduling systems that are more conducive to careful and precise positioning of patients.

Treatment Set-Up Slips and Lapses — Slips and lapses are actions that deviate from what is intended, usually as a result of working memory difficulties. Given the numerous routine parameters and adjustments (e.g., monitor units, field size, gantry and collimator angles, insertion of blocks and/or wedges) that need to be set for each treatment field for each patient, the setting of treatment parameters constitutes fertile ground for various slips and lapses. Several alternative approaches that may help mitigate slips and lapses during treatment set-up tasks include: dedicated efforts to ensure adequate staffing so that double-checking procedures are not sacrificed during periods of heavy workload; better job design for eliminating sources of interruption that compete with treatment administration; better workspace design and physical lay-out to reduce unnecessary workplace distractions; use of computer-based record and verify (R&V) systems for detecting inaccurately set parameters; better patient scheduling systems to reduce periods of peak workload; and education efforts for sensitizing managerial personnel to the latent effects that decisions and policies have on the day-to-day activities of front-line personnel.

Data Transfer — Because of the large number of steps and the number of team members involved in the planning, preparation, and delivery of external beam treatment, errors that result from inaccurate or inadequate information will be passed along to each subsequent phase of therapy and can ultimately affect treatment outcome. Once perpetuated, some of these errors are very difficult to check and correct. Several alternative approaches are offered for alleviating the factors that contribute to transfer error. Rather than allowing initial beam-on time calculations to be performed at the therapist's treatment console while the patient is waiting to be treated, a more reasonable procedure would be for the dosimetrist to calculate beam-on time and have it verified by another qualified person a day before treatment is scheduled. It is recognized that

there are times when this may not be medically feasible (e.g., emergencies). All input parameters and calculations that are part of the computer plan need to be verified independently by qualified personnel to avoid uncritical acceptance of computer-generated data. Training should help people become aware of weak links in the data transfer process; initiation of checking procedures should improve detection of errors. Innovation and experimentation for enhancing the detection of transfer error or for minimizing its occurrence is needed.

Equipment Checks and Calibration — There is a high level of consensus among radiation departments today that a set of systematic procedures for checking beam output and other treatment parameters is essential to guard against miscalculations and misadministrations. Lessons learned from earlier mishaps have underscored the potential for error whenever there is a change in the materials, test equipment, measurement conventions, or in personnel doing the checks and calibrations. Continuous and systematic vigilance is a requirement for safety, but differences exist among departments with respect to organizational commitment and continued adherence to recommended procedures. Most departments do a fine job, but some departments are lax. For maintaining vigilance, one approach is to examine the techniques that other industries use where safety is a paramount concern. In terms of changes in test equipment, measurement conventions, or personnel, monitoring (i.e., in a parallel and independent mode) should be enhanced during the transition period to ensure continuity of operation. Periodic reviews to ensure that personnel are performing their assigned tasks to the standards should be implemented.

Radiation Field Alignment Accuracy — Because of the steep dose-response characteristics of both tumor and normal tissues, the extent of field placement uncertainties as well as their potential influence on treatment outcome need to be better understood. Two major sources of variation underlie field placement errors: discrepancies between the way treatment is planned on the simulator unit and the way it is delivered on the treatment machine; and day-to-day variations of the treatment field alignment. Comparison of portal films with their corresponding simulator films suggests that the discrepancy between the films is greater than the variation resulting from day-to-day registration of the treatment field. Comparing portal and simulator films is not an easy process, partly because of the poor quality and uncertain magnification factors of portal films. In a busy therapeutic setting, quantitative comparison of the films is especially difficult for therapists. Continued development and evaluation of on-line electronic portal imaging devices hold promise as viable alternatives for improving the detection of field alignment error and reducing the likelihood of error on subsequent treatments. The random day-to-day variations in field alignment are best addressed by a systematic program that reviews portal and verification images for each site treated and by establishment of a work climate that is conducive to careful and precise field alignment procedures.

Radiation Treatment Delivery — Once all the treatment parameters have been entered correctly and the patient is in a stationary position, the actual delivery of the radiation treatment is typically uneventful. The therapist's primary task while the beam is on is to keep visual and audio contact with the patient by means of a TV monitor and intercom at his or her workstation. If the therapist is distracted or engaging in competing tasks during this period, there can be a delay in detecting patient movement or distress. Each department should determine those tasks that compete with the monitoring function for reallocation to non-treatment hours. Another treatment delivery problem can occur with Co-60 machines when the source gets stuck in an

unshielded position. In this situation, therapists must respond quickly and proficiently to avoid unintended irradiation of the patient and to themselves. It is possible for the therapist to enter the treatment room without noticing the cues associated with the unshielded source as a result of automatically responding to unintended competing cues that signal the termination of treatment (e.g., timer clicking off). Unless the therapist has received practice in responding to stuck sources, inappropriate actions and additional unnecessary radiation exposure can be the consequence. Alternative approaches include redesign of the cues that signal unshielded sources so that they serve a better discriminative stimulus function (e.g., an audio alarm) and introduction of realistic, performance-based training exercises for taking the guesswork out of responding to unshielded sources.

Quality Assurance (QA) Procedures — Because errors, once initiated, can be propagated through successive phases of the therapeutic process, quality assurance is the concern of all staff members. At the teletherapy sites visited before publication of NRC's (1991) *Regulatory Guide 8.33 Quality Management Program*, there was considerable variation with respect to implementation of formal QA programs. Some departments espouse the value of QA, but fall short in providing an internal structure for it. There are costs and resource requirements associated with QA that are likely to compete with efforts to keep operational expenses as lean as possible. Another problem has been sustaining QA programs — maintaining continuous emphasis on quality — once programs are initiated. A necessary alternative for those departments whose QA efforts need further development is the involvement and commitment of upper management. Efforts at QA are likely to have limited impact if they just reside in one discipline and do not emanate from the leadership of the department or institution. Management needs to initiate and provide the continuing structure for such programs. Fortunately, the momentum of the quality assurance movement remains strong in hospitals. Plenty of guidance is available for implementation of QA programs. In addition to NRC's (1991) regulatory guide, the radiation oncology professional societies offer well-formulated guidance for establishing QA programs.

ACKNOWLEDGEMENTS

The authors wish to express their gratitude to the administrative and professional personnel in the various radiation oncology departments visited during data collection activities. Their voluntary willingness to participate, interrupt their own busy schedules, and provide useful information is, indeed, appreciated. The authors also would like to acknowledge the contribution of subject matter experts at various stages throughout the project — a group of highly knowledgeable radiation oncologists, radiation physicists, and radiation therapists who served as consultants to the project and were able to enhance its technical accuracy.

FOREWORD

This report is prepared for the Office of Nuclear Regulatory Research of the U.S. Nuclear Regulatory Commission as part of the work performed under NRC-04-90-053, Human Factors Evaluation of Teletherapy. Teletherapy is a treatment methodology in which cancerous tissue is selectively destroyed by exposure to an external beam of ionizing radiation. The source of radiation may be a radioactive isotope, typically Co-60, or a linear accelerator capable of producing very high energy x-ray and electron beams. As practiced in departments of radiation oncology, teletherapy (or radiation therapy) is a complex, multi-phased, multi-disciplinary process involving the teamwork of radiation oncologists, radiation physicists, dosimetrists, and radiation therapists.

The present report is Volume I in a series of human factors evaluations for identifying the diverse array of factors that contribute to human error in the teletherapy setting. This volume contains the findings of the evaluations, an identification of problems, and alternative approaches to solving them. There are five major reports to this overall series, *Human Factors Evaluation of Teletherapy*:

Volume I Identification of Problems and Alternative Approaches

Volume II Function and Task Analysis

Volume III Human-System Interfaces and Procedures

Volume IV Training and Organizational Analysis

Volume V Literature Review

1.0 INTRODUCTION

In 1975 and early 1976 a teletherapy facility over-irradiated nearly 400 cancer patients. Subsequent reviews suggested that excessive radiation may have caused or hastened the deaths of many of those patients (Rubin, 1978). In the ensuing years, a number of teletherapy patients have received radiation doses that differed markedly from the prescribed dose or that were administered to the wrong location. Most of the events involved human error.

1.1 Purpose of the Project

As part of its mission to protect public health and safety, the Nuclear Regulatory Commission (NRC) and its agreement states regulate the use of nuclear byproduct material including that used in teletherapy (primarily Cobalt-60). The use of linear accelerators in teletherapy is regulated by the states.

One area of regulatory concern is misadministrations. For teletherapy, misadministrations are defined as radiation doses: 1) that involve the wrong patient, wrong mode of treatment, or wrong treatment site, 2) where the treatment consists of three or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose, 3) where the calculated weekly administered dose is 30 percent greater than the weekly prescribed dose, or 4) where the calculated total administered dose differs from the total prescribed dose by more than 20 percent of the total prescribed dose (U.S. Nuclear Regulatory Commission, July 1993).

Teletherapy misadministrations are often attributed to human error. Their consequences can be severe, as noted above. The purpose of the current project was to identify factors that cause human error in teletherapy through conduct of a human factors evaluation. The teletherapy device itself is only one element of the system for teletherapy. Other elements (e.g., personnel, facilities, supporting equipment, software, procedures, training, and organization) are no less important to the success of the teletherapy process and were also addressed in the evaluation.

The project was specifically designed to identify factors (root causes) that contribute to errors in teletherapy systems, to evaluate the impact of those factors on the performance of functions and tasks essential to meet system goals, and to prioritize function and task performance problems related to human errors in terms of their safety significance. Beyond that, it was designed to identify and evaluate alternative approaches for resolving safety significant problems related to human errors.

Radiation oncology facilities often house both Cobalt-60 (Co-60) and linear accelerator devices for teletherapy. The same personnel are typically involved in the use of both types of device. This project encompassed both nuclear byproduct devices and linear accelerators because differences between devices and their use may cause confusion leading to human error.

1.2 Human Factors Evaluation

Accident reports often conclude that human error was the cause of some disaster. For many, such a finding is acceptable as an end in itself. The idea that human error can be the result of the context within which it occurs is often difficult to grasp and poorly understood. In contrast, human factors practitioners are reluctant to conclude that an accident is simply the result of human nature. For them, the suggestion of human error is just the beginning. A human factors evaluation designed to assess the relationship between human performance and system performance seeks to answer the following questions.

- What performance is expected of people within a system?
- What factors within the system or its environment might lead to failure to meet those human performance expectations?
- What are the potential consequences of failing to meet various human performance expectations?
- How can human error leading to important system failures be reduced?
- How can the consequence of unavoidable human error be mitigated?

Human error is viewed as the result of mismatches between the human performance requirements of a system and what humans working within that system can reasonably be expected to do. For example, successful performance of a system may require error-free keyboard entry of data into a computer. At the same time, factors such as distractions and unfamiliar entry formats may make it unreasonable to expect that every keyboard entry will result in error-free performance. Successful performance of a system may also require that anyone suspecting an unsafe condition act to terminate operation. At the same time, emphasis on production and position in the workplace hierarchy may make it unreasonable to expect that everyone within the system will always exhibit such behavior.

The human factors discipline offers an approach for systematic evaluation of human-machine systems for potential errors and their consequences. The approach begins with a function and task analysis that:

- Identifies the system's purpose and other important goals,
- Identifies functions required to satisfy the system's purpose and goals,
- Identifies tasks, subtasks, and task steps necessary for users to fulfill their roles with respect to executing system functions, and
- Analyzes tasks, subtasks, and task steps for the performance requirements placed on the users.

The result is a detailed description of what people within a system are required to do in relation to the system's purpose, goals, and functions. The function and task analysis makes explicit many human performance requirements which may not otherwise be obvious. For example:

- Data entry requirements may deviate from conventional practice, requiring users to adopt unaccustomed procedures.
- The order of execution of a sequence of task steps may be conditional upon the outcome of certain intermediate steps in that sequence.
- Task performance may require complicated, precise, and subtle movements and positionings of the system's hardware components.

The function and task analysis process also specifically identifies many of the things necessary to support the required level of task performance (e.g., needed information, control capabilities, time, step-by-step directions, skills, knowledge, abilities, and environmental conditions).

Systematic human factors evaluation also includes evaluations of the system's workspaces, human-machine interfaces, procedures, training, and organizational policies and practices against available standards and guidelines. Results of those evaluations, in conjunction with the results of the function and task analysis, are then used to identify human factors problems. A human factors problem is defined as a task that humans within the system are not likely to perform to the level required by the system. Human factors problems may exist if the expected performance is simply beyond the human performance capabilities of people within the system (e.g., sense the presence of radioactivity). More often human factors problems are due to the unavailability of things necessary to support the expected performance (e.g., lack of a direct indication that a radioactive source is in its storage position) or the unsuitability of things that are available (e.g., displays indicating that a radioactive source is in a shielded storage position that are not based directly on the source's location). Human factors problems can be due to the unavailability or unsuitability of necessary human-machine interfaces, training, procedures, and organizational policies and practices.

Following identification of human factors problems, the impact of those problems is assessed. Impacts depend very much upon the specific task and upon the design and operation of the system being reviewed. For a given system, failure to perform some tasks adequately may be noticed immediately and corrected prior to an adverse system outcome. Failure to perform other tasks adequately may only cause one-time deviations in system performance that are easily noticed and compensated for. Failure to perform still other tasks adequately may have broad effects, lead to high consequence, irreversible, adverse outcomes, and may be noticed only through an accumulation of adverse outcomes. Assessing human factors problems in terms of their impact on the satisfaction of system goals provides a basis for prioritizing those problems. When prioritization is complete, plans for resolving significant problems can be developed.

1.3 Human Factors Problem Resolution

The goal of human factors problem resolution is to eliminate mismatches between what a system requires of people and what those people can be reasonably expected to do. One approach to meeting that goal is to modify the system to eliminate the human task or to reallocate that task to non-human elements of the system that might perform it more reliably (e.g., electronic collection and transfer of data rather than repeated keyboard entry of that data reduces one type of opportunity for human error). Such an approach is necessary when neither the performance required of people in the system nor the performance capabilities of those people can be sufficiently modified to eliminate the mismatch. Even in cases where it is not necessary, it may be preferred.

Other approaches to eliminating mismatches involve modifying the system to reduce human performance requirements or to enhance human performance capabilities. Modifying human-system interfaces to make things that support adequate task performance both available and suitable for the intended use tend to reduce human performance requirements. Modification of task specific procedures and of organizational policies and practices can also reduce human performance requirements. Modifying training or selection qualifications can improve the performance capabilities of people within the system.

The selection of alternative approaches for resolving human factors problems is based upon a number of considerations. Among these are:

- Approaches that are possible given the system in question.
- The near and long term effectiveness and cost of possible approaches.
- The possible introduction of new human factors problems.
- Coordination with approaches selected for the resolution of other human factors problems.

A combination of approaches is often used to resolve human factors problems. For instance, human-system interfaces may be enhanced (e.g., direct indication that a radioactive source has returned to its storage position may be provided). In turn, procedures may be developed to ensure that failure to get that indication leads to a technically adequate and complete sequence of human actions. Finally, training may be instituted or modified to address particular aspects of using the new human-system interfaces and procedures.

Elimination of mismatches between the human performance requirements of a system and what humans working within that system can reasonably be expected to do is not always possible. In such cases, the goal of the human factors problem resolution process is to reduce the impact of the human factors problem. Approaches that lead to early detection of a human error may lessen the consequences of that error.

1.4 Brief Overview of the Teletherapy Process

Teletherapy is a multidisciplinary, multiphased treatment methodology for treating cancerous and other tissue through selective exposure to an external beam of ionizing radiation. A radioactive isotope, typically Co-60, or a linear accelerator device for producing very high energy x-ray and electron beams are the principal sources of radiation. Treatment is planned and administered by a team of specialists consisting of a radiation oncologist, radiation physicist, dosimetrist, and radiation therapists. Effective treatment requires a concern for precision and consistency in human-human and human-machine interactions.

Once malignancy is confirmed, the oncologist conducts a clinical evaluation to stage the disease or determine its extent. After clinical evaluation, a therapeutic decision is made that determines the intent of therapy. A curative intent seeks to eradicate the tumor; a palliative intent seeks to relieve suffering and prolong life. Tumor localization defines the tumor volume and is the first step in defining the treatment volume as well. The treatment volume is always larger than the tumor volume in order to cover microscopic extensions of the tumor and other factors such as movement caused by the patient's respiration. This phase also must consider the normal tissue and structures that will be exposed to radiation and what the safe limits are for such exposure.

Treatment planning consists of developing the best treatment plan for each patient. The oncologist specifies the overall dose to the tumor and critical normal tissues. The physicist and dosimetrist then design potential treatment delivery approaches in conjunction with the oncologist for satisfying the treatment requirement. Patients are measured, body contours are drawn, and isodose curves are generated either manually or, more recently, with the aid of treatment planning computers. To achieve maximum accuracy, the treatment set-up is first simulated on a separate device that resembles the treatment machine and enables precise and accurate location of treatment fields. The patient is marked externally with tattoos to define the treatment fields or portals. Radiographic films can be taken to ensure that the defined fields include the tumor. Simulation thus allows for verification of the treatment technique and resolution of planning issues before actually using the treatment machines. Treatment aids also are likely to be needed. The fabrication of custom lead alloy blocks (for shielding radiosensitive structures from the beam) and immobilization devices (for keeping the patient in the same position treatment after treatment) are quite common.

After all the details of treatment planning have been worked out, the patient proceeds to treatment. Treatment is fractionated on a daily basis over a period of weeks. Radiation therapists now have the greatest contact with patients. Their workload varies with respect to organizational setting; however, patients need to be positioned accurately, numerous machine parameters entered, treatment accessories put in place, patients monitored while the beam is on, accurate daily records of administered dose kept, and attention paid to the unique needs of individual patients. Since the possibility of human error — treating the wrong patient, leaving out a block, entering a wrong machine parameter, imprecise patient positioning, failing to record a treatment — is always present, radiation therapists must also confirm that patient and equipment set-up is consistent with the treatment plan prior to treatment. Patient evaluation and

follow up are the last phases and involve assessment of tolerance to treatment, evaluation of tumor response, and assessment of complications.

The radiation oncology literature, as well as records maintained by the NRC, have implicated human error in cases where the delivered radiation treatment has differed from the radiation prescription. Misadministration of prescribed radiation dose, whether by human error or machine malfunction, can have serious consequences. Doses delivered below the prescribed level can lead to ineffective treatment; those delivered above the prescribed level can lead to damage of healthy tissue and critical structures.

This report describes the methods and findings of a human factors evaluation of teletherapy and presents and evaluates alternative approaches for dealing with safety-significant human factors problems.

2.0 METHODOLOGY

The methodology is discussed in two major parts. The first part addresses the site sampling strategy and data collection procedures used for conducting the first five phases of the overall study. The phases are: 1) the function and task analysis, 2) the analysis of human-system interfaces, 3) the analysis of procedures and practices, 4) the training analysis, and 5) the organizational analysis. The second part of the methodology focuses on the procedures used for identifying human factors problems associated with teletherapy tasks, identifying the major contributing factors that influence task performance and human error, and identifying and assessing alternative approaches for resolving the human factors problems.

2.1 The First Five Phases

Common to each of the first five phases of the study was developing a site sampling strategy, contacting the candidate centers, preparing data collection instruments, performing the data collection procedures, and analyzing the data. Figure 2.1 portrays the general sequence.

Figure 2.1 Sequence of Activities for First Five Phases

2.1.1 Site Sampling Strategy

The first step of the methodology was to develop a sampling strategy for visiting sites that was both practical and responsive to the needs of each phase of the study. An essential consideration was obtaining the cooperation of a broad spectrum of teletherapy organizations. Three major factors were taken into account in identifying potential sites:

- geographic dispersion
- type of teletherapy facility
- inclusion of Co-60 units, where possible.

Selection of geographically dispersed sites for visits minimized any disproportionate influence that might be associated with a given center or region (in terms of treatment practices or philosophy). Different types of facilities such as university-based centers, large community

hospitals, and smaller free-standing or satellite facilities were included to accommodate differences in management styles, organizational factors, personnel, patient load and other factors likely to vary among facility types. Finally, efforts were made to include centers with Co-60 units because of the NRC's regulatory responsibilities.

2.1.2 Contacting Candidate Centers

Given the above sampling considerations, candidate radiation oncology departments were selected from the Membership Directory of the American Society of Therapeutic Radiology and Oncology. The director of the facility, usually a radiation oncologist, or a radiation physicist was initially contacted by telephone. The telephone request for participation was followed by a formal letter further stating the purpose of the study. Important aspects of the letter were contractor-stated assurances with respect to anonymity of information sources and the NRC Project Manager's phone number in the event further assurances or questions needed to be addressed. The level of cooperation of the candidate centers was favorable; fewer than 15% of those contacted chose not to participate. No differences were discerned between participating and non-participating centers.

A total of twenty-four facilities were visited from the Northeast, Southeast, Northwest and Southwest segments of the continental United States. Eight facilities were visited for performance of the first phase, the function and task analysis. This phase provided a necessary foundation and understanding of the teletherapy process for performing the subsequent phases. To make the best use of available resources, phases 2 and 3, the analysis of human-system interfaces and the analysis of procedures and practices, were combined and conducted at the same time. Eight sites were visited with each site providing information on phase 2 and phase 3 issues. The fourth phase, the training analysis, and phase 5, the organizational analysis, also were combined and conducted at the same time with each of eight sites providing information. A site visit also was made to Theratronics International Limited (formerly known as Atomic Energy of Canada Limited Medical) in Ottawa, Canada. Theratronics is a manufacturer of Co-60 treatment units and planning systems.

2.1.3 Data Collection Preparation

Data collection personnel first familiarized themselves with the most salient issues pertaining to the particular phase under investigation. This involved relying on interactions with subject matter experts (SMEs), an on-going review of incident reports provided to the NRC by licensees, and a review of the human factors and radiation oncology research literature in relation to human error. A panel of six subject matter experts (two radiation oncologists, two radiation physicists, and two radiation therapists) was established to provide clarification of technical issues when needed. Concurrent with the conduct of phases 2 through 5 was the conduct of the literature review. The combined use of subject matter experts, incident reports, and the literature review were valuable in identifying a broad spectrum of relevant issues for inclusion in the data collection instruments. The function and task analysis findings, reported in *Human Factors Evaluation of Teletherapy: Volume II Function and Task Analysis*, NUREG/CR-6277 (1995), further served as an inventory of essential teletherapy activities likely to be influenced by relevant

variables from the subsequent phases. Using the information collected from these diverse sources, structured interview forms and data collection instruments were prepared and used as the primary data collection tools. The data collection tools were reviewed and checked for technical accuracy and content by the panel SMEs before initiation of data collection activities.

2.1.4 Data Collection Procedures

Site visits were generally scheduled on the basis of one center a day. For the most part, interviews were conducted with the radiation physicists, chief therapists, dosimetrists, staff therapists, radiation oncologists, training coordinators, and administrative personnel. Most interviews were conducted on a one-to-one basis when personnel were available. Interviews were supplemented with observations of on-going treatments and examination of policy and procedures manuals, treatment and simulation manuals, operator's manuals, patient charts, quality assurance reviews, calibration checklists, performance appraisal forms, and other documentation.

2.1.5 Data Analyses

The data collected from participants consisted primarily of responses to questions from the interview forms. Because of the small samples and the open-ended interview questions, no attempt was made to analyze the collected information with descriptive statistical techniques. Instead, corroborating evidence or points of convergence from the different sources of information were used to identify potential human factors problems. The results of these analyses were provided to the NRC as separate volumes, specifically NUREG/CR-6277, *Human Factors Evaluation of Teletherapy: Volume II Function and Task Analyses*; *Human Factors Evaluation of Teletherapy: Volume III Human-System Interfaces & Procedures*; *Human Factors Evaluation of Teletherapy: Volume IV Training and Organizational Analyses*; and *Human Factors Evaluation of Teletherapy: Volume V Literature Review*. A brief summary of the results from these five phases is presented in section 3.0 Results.

2.2 Summary and Prioritization of Problems

Based upon the findings documented in the above reports, the methodology described below identifies the most significant human factors problems in the teletherapy setting. The methodology comprises a four-step process.

2.2.1 Create Inventory of Potential Human Factors Problems

The first step was the creation of an inventory of human factors problems based upon the findings of phases 1 through 5. To create the inventory, Volumes II through V were reexamined for cited human factors problems, and descriptive human factors problem statements were prepared. The outcome of this step was a list of potential problem areas that could have an adverse impact on teletherapy performance.

2.2.2 Evaluate Impact of Potential Human Factors Problems on Teletherapy Functions/ Tasks

Once the inventory was established, the next step was to evaluate the impact of the potential human factors problems on the teletherapy tasks, sub-functions, and functions. Each of the potential problem areas was evaluated in terms of the impact the problem would likely have on successful and safe performance of the teletherapy tasks. The impact ratings, serving to screen out insignificant problems, consisted of three qualitative levels that increased in level of confidence the extent to which an impact could be inferred or stated. The three levels are defined as follows:

- No Discernable Impact (NI) No evidence from any of the data sources that identified problem has an impact on task performance or is likely to contribute to human error.

- Potential Impact (PI) Some evidence, frequently of an anecdotal nature, that identified problem has an impact on task performance and is likely to contribute to human error. Evidence must come from at least two independent sources (e.g., two respondents or a respondent and a researcher observation).

- Actual Impact (AI) A stronger form of evidence, documented independently of the present study, that the problem has an impact on task performance and has contributed to human error. Evidence comes from two independent sources (e.g., the research literature, incident reports, or quality assurance reviews).

This step combines the information from the potential problem areas that were reported in phases 2 through 5 and assesses the impact of the potential problems on actual task performance. A panel of human factors and teletherapy personnel made the impact assessments using a Nominal Group Technique (NGT). The NGT has panel members make their assessments independently of one another and then come together to discuss their assessments. Given discussion and further clarification of key issues, panel members then reconsider their initial assessments. Discrepant assessments (i.e., discrepancies between NI and the other assessments) were resolved by group consensus. Those task areas that received task impact ratings of PI or AI were retained and considered significant enough to warrant further examination in terms of human error and system safety consequences. The outcome of this step was the identification of tasks or task areas that may not be performed to the level required by the system.

2.2.3 Assess Error Detectability and Error Consequences

Each of the task areas that received a PI or an AI impact assessment was evaluated in terms of the extent to which the associated human error was detectable. Two levels of detectability assessment were made by the panel:

- Level 1 Error results from a dose of radiation that differs from the radiation prescription and has a **greater than 50%** likelihood of being detected within a five-day treatment period, and
- Level 2 Error results from a dose of radiation that differs from the radiation prescription and has a **less than 50%** likelihood of being detected within a five-day treatment period.

Each of the task areas also was evaluated in terms of the consequences of the associated human error. The assessment of consequences by the panel also consisted of two levels:

- Level 1 Adverse consequences of human error to patient or personnel are minimal in terms of harmful, irreversible effects, and
- Level 2 Adverse consequences of human error are serious enough to be considered a misadministration.

Both assessment levels for error detectability and error consequences as stated above refer to patients who have a prescription to receive radiation; however, the same assessment levels apply to accidental radiation exposures to teletherapy staff who, of course, do not have prescription to receive radiation.

In order to focus on the critical task areas, those task areas with combined ratings indicating that the associated error was likely to be detected and that the adverse consequences were minimal were dropped from further analysis. The remaining task areas with the higher ratings were further discussed and regrouped into critical task areas.

2.2.4 Generate and Assess Alternative Approaches for Resolving Problems

With the critical task areas identified, the next step was to generate alternative courses of action for resolving or alleviating the problems. From these alternatives, the most relevant were retained for further assessment. Once the alternative approaches were identified, their potential effects were assessed with respect to various criteria, such as: reducing the likelihood of error, improving the detection of error, limiting the adverse consequences of error, feasibility in terms of costs and resource constraints, robustness in helping to resolve related problems, and risk with respect to introducing new sources of error.

The critical task areas are identified in Section 3.2. Section 4.0 elaborates on the critical task areas by describing the tasks that may be compromised within each critical task area, identifying the major factors that contribute to the potential or actual errors, and describing and evaluating the alternative courses of action and an assessment of their potential for alleviating the problem.

3.0 RESULTS

This section provides a summary of the major findings of the overall study. Section 3.1 focuses on the findings of the first five phases: 1) the function and task analysis, 2) the analysis of human-system interfaces, 3) the analysis of procedures and practices, 4) the analysis of training, and 5) the analysis of organizational factors. Section 3.2 identifies the ten critical task areas as derived by the methodology described in Section 2.0.

3.1 Summary of the First Five Phases

3.1.1 Function and Task Analysis

Function and task descriptions were prepared upon completion of data collection activities for the first phase. Tasks were defined as discrete units of operator behavioral or cognitive activity having a discernable starting point, duration, and end point. Those tasks that were related in terms of their contribution to an output goal of the teletherapy system were aggregated, and the aggregated entities were treated as system functions or subfunctions. A dBASE IV file of functions, subfunctions, tasks, and associated information was developed for use during performance of subsequent parts of the project. All function/task descriptions and associated data were reviewed for technical accuracy by SMEs, serving as consultants to the project. Figure 3.1 shows the ten functions under which the subfunctions and tasks were organized.

Figure 3.1 Overview of Function and Task Analysis

Altogether, 176 discrete tasks were identified as integral components of the teletherapy process. The functions were divided into subfunctions in order to adequately organize the range of tasks performed and to allow analyses to focus on related sets of activities. Tasks, in turn, were divided into sub-tasks when it was appropriate.

The organization of the task data in the data base is as close as possible to the most likely flow of functions and tasks in a teletherapy facility. At the same time, the study found significant variations between and within teletherapy facilities in how tasks are performed, which tasks are performed, and in what order. The factors causing these variations include facility-specific issues such as unique practices and policies, use of different equipment, and differences in preferred practice between oncologists and staff members. These differences are further complicated by the finding that specific function and task performance procedures at the various facilities are not typically documented.

Each record in the data base corresponds to an individual task statement. Each record also includes fields which contain the following type of information: position of individual performing the task, equipment used during task performance, cues, conditions, standards for task performance, interactions with other staff members, communications required and communication mode, task difficulty, frequency of performance, time required to perform, likelihood of error, consequences of error, pervasiveness of error, and qualifying comments. The data contained in the data base provided the necessary foundation for the analyses performed in the subsequent phases of the project.

For a more detailed description of the function and task analysis, the reader is encouraged to consult *Human Factors Evaluation of Teletherapy: Volume II Function and Task Analysis*, NUREG/CR-6277 (1995).

3.1.2 Human-System Interfaces

With respect to human-system interface issues, the following findings were most germane:

- Interfaces of Co-60 treatment units were more consistent with the Association for the Advancement of Medical Instrumentation (AAMI) design guidelines than the interfaces of linear accelerators and simulators. Since the method of radiation delivery is simpler with Co-60 machines, fewer operator functions are incorporated on the control console that could potentially violate interface guidelines. Representative guideline deviations found on Co-60 machines include the absence of a label for the emergency button (rectangular red strip) used to turn the machine off, skip/arc thumbwheels that move system components up by turning the wheel down rather than up, and a keypad for digital treatment time entry (which was an after purchase add-on device) that was separated farther from the corresponding display than guidelines suggest.

- Representative deviations from AAMI guidelines for linear accelerators included labelling control console selector switches with numbers so small that reading them was difficult. Infrequently used controls occupied a central position on the control console. Representative guideline deviations for simulators included fluoroscopy controls that must be adjusted while looking at a monitor which was located in a position that precluded simultaneous use of the controls, and unused push buttons that were located in the primary visual area of the control panel.
- A number of potential problems became evident upon review of record and verify systems, treatment planning systems, and computer controlled treatment machines. Some earlier record and verify systems exhibited inflexible interlocks resulting in poor user acceptance among a number of therapists. Treatment planning systems enable the printing of isodose curves in different colors corresponding to the different percent dose levels; however, there is no standard color scheme across manufacturers that allows visual separation of the adjacent isodose curves. There was considerable variation in the level of security provided treatment machine parameter data files (e.g., from open access to password access), raising a question about the level of security that is needed.
- Discussions with commercial manufacturers of computer controlled treatment and treatment planning equipment indicate a lack of recognized universal formats or design guidelines for optimum user interfaces. Improvements are needed in the procedures for assessing software quality, equipment usability, and in establishing interface design guidelines for software-controlled medical equipment.
- Observation of Co-60 equipment in use occasionally revealed components that were missing or in a state of disrepair (typically position indicators). Compared to the control consoles for linear accelerators, the clock timers on Co-60 control consoles have different scale conventions which can be confusing. The mechanical control knob on some Co-60 consoles has a lash-back characteristic which can result in time settings that are less than accurate.
- Variations in conventions for position of equipment components (e.g., gantry angle) and beam status indication among manufacturers of treatment equipment create the potential for negative transfer as therapists rotate from one machine to another. Therapists indicate that the variation of conventions is not a source of error; however, differences in position indication conventions as a patient moves from simulator to treatment machine causes additional conversion and transfer of information steps to be taken. These additional steps are a potential source of error.
- Indicators of stuck sources may be overlooked by therapists. Given the highly automatic, skill-based routines performed by therapists, it is possible for the therapist to enter the treatment room after the timer clicks off without checking the lighted displays on the control console or above the treatment room door.

- The use of Ellis compensator measurement devices for measuring patient anatomy and fabricating compensators for individual patients requires measurement data to be transcribed in a reverse direction from measurements taken from the device. The reversal of direction in two dimensions can be confusing and lead to transcription errors.
- Unnecessary competing tasks brought about by placement of phones at therapists' workstations were observed. Therapists were expected to answer calls from other hospital departments; such interruptions were considered disruptive to treatment administrations and record keeping.

3.1.3 Procedures and Practices

The major findings with regard to procedures and practices are as follows:

- With respect to manuals containing policy and procedures, respondents indicated they use such documents infrequently. When they are referred to, they are typically used by new therapists or interns rotating into the department. Larger facilities generally had well documented manuals while smaller facilities generally did not. Following unwritten procedures was the rule at all facilities visited. The only exceptions were in the use of treatment protocols and periodic maintenance and calibration procedures.
- Communication errors occur under conditions when therapists rotate from one machine to another or have to take over a new group of patients being treated on a machine, when aspects of treatment are changed during the course of treatment, and when oncologists and physicists are unavailable to respond to treatment-related questions. Considerable variation exists among hospitals with respect to the formality of written and face-to-face communications.
- As required by the NRC, emergency procedures for a cobalt source stuck in an unshielded position are posted outside each treatment room that contains a Co-60 treatment machine. Although these procedures are usually clear and concise, none of the respondents indicated that dry-run exercises were ever conducted for responding decisively to stuck sources.
- The physics department is responsible for periodic maintenance procedures as well as maintenance performed on an as-needed basis. Although some variability existed among sites, the maintenance and data recording procedures that supported calibration and output tests were generally comprehensive and well documented.

- In terms of practices, all of the sites visited took port verification films during the first treatment while a wide majority used diode devices for dose verification on the surface of the patient (linear accelerator treatments only). Therapists were accustomed to using custom blocks and standard wedges as beam modification devices, and engaged in double-checking procedures for verifying the accuracy of calculations. Other widespread practices included the use of quality control checklists for maintaining the patient's chart, the use of record and verify systems on linear accelerators, and conducting chart round meetings on a weekly basis.
- A small number of sites utilize physics personnel on a contract basis whereby physicists rotate to sites on a periodic schedule. There is currently a diversity of opinion on the desirability of such a practice. Opponents of the practice maintain that checks of treatment plans and dose calculations can be delayed, and some treatments may be started without a physicist checking the calculations. When physicists are absent, questions requiring their expertise may remain unasked. Proponents maintain that it is an efficient and economical way of providing the services of physicists without impairing quality treatment of patients.

A further enumeration of human-system interface and procedural factors that can contribute to human error can be found in *Human Factors Evaluation of Teletherapy: Volume III Human-System Interfaces and Procedures*, NUREG/CR-6277 (1995).

3.1.4 Training

The following training factors were found to have a potential impact on human performance and human error in the teletherapy setting.

- The formal training that radiation therapy technologists, physicists, and dosimetrists receive prior to employment was reviewed, and while major deficiencies were not found, a need for a greater conceptual understanding of dosimetry and treatment planning by technologists was mentioned by respondents.
- Once hired, extensive reliance on informal on-the-job training (OJT) for newly hired technologists makes it difficult to determine if technologists have acquired the necessary skills and knowledge for unsupervised job performance.
- When new equipment or software is purchased by a facility, the training received by staff members is frequently less than adequate (e.g., left to the individual's initiative, an operator's manual, or vendor's ability to provide training).
- None of the respondents indicated they received any special training (e.g., emergency training) for responding to machine malfunctions such as stuck sources in Co-60 machines.

- Formal training in quality assurance procedures did not occur at many of the sites visited. It is noted that visits were made prior to publication of NRC's *Regulatory Guide 8.33* (1991) on quality management.
- Most teletherapy personnel focus on the active errors that technologists are likely to make and neglect the latent role that organizational policy and management decisions are likely to play in human error. Training programs that enhance greater awareness of these latent contributing factors from a system's perspective are needed.

3.1.5 Organizational Factors

A wide array of organizational factors were found to have the potential to influence teletherapy performance.

- Approximately 25 percent of the sites visited had at least one less therapist than considered desirable, thereby necessitating that a single technologist be assigned to a machine at times. Staffing shortages increase the workload of technologists; excessive workloads can increase the likelihood of treatment delivery errors.
- Favorable organizational climates for the self-reporting of errors were described by respondents at most of the sites visited. At these sites, emphasis was placed on reducing error and maximizing the quality of patient care rather than affixing blame. At the same time, respondents indicated there are hospitals where the organizational climate for the reporting of errors is not so favorable.
- Errors were cited by all members of the teletherapy team. They included calculation errors by dosimetrists and physicists, communication errors by oncologists, and charting and patient set-up errors by therapists.
- In terms of quality assurance, most sites were acquainted with various QA guidelines. Less easy to determine was the extent to which a given site was seriously committed to the QA process.
- Respondents identified the following organizational factors as contributing to human error: understaffing, old equipment that breaks down, management aloof to daily operations, salaries not competitive with the national average, oncologists not accessible, complexity of cases, and treatment schedules with too many patients per hour.
- Finally, it was noted that many of the active errors that technologists make likely have their origins in the less recognized latent errors spawned by organizational decision-makers. Many of these latent organizational factors are present in the system long before the actual occurrence of human error (e.g., understaffing, high patient load per treatment machine, lack of commitment to quality assurance).

A more detailed discussion of training and organizational factors that can lead to human error can be found in *Human Factors Evaluation of Teletherapy: Volume IV Training and Organizational Factors*, NUREG/CR-6277 (1995).

3.2 Identification of Critical Task Areas

As indicated in the methodology section, those task areas found to be associated with errors that were less likely to be detected and more likely to lead to misadministrations were selected as critical. Table 3.1 shows the ten critical task areas, listed in the relative order in which they occur in the teletherapy process.

Table 3.1 Critical Task Areas

Pre-treatment Planning
Use of Treatment Planning Computer Data Files
Use of Patient Chart
Patient Positioning and Immobilization
Treatment Set-Up
Data Transfer
Equipment Checks and Calibrations
Radiation Field Alignment Accuracy
Radiation Treatment Delivery
Quality Assurance (QA) Procedures

4.0 CRITICAL TASK AREAS AND ALTERNATIVE APPROACHES

This section discusses ten critical teletherapy task areas that were identified through the methodology. Each of the ten critical task areas is introduced, followed by identification of the tasks that could adversely affect safe and effective operation of the teletherapy system if not performed correctly. Also discussed are the major factors that contribute to potential or actual errors, alternatives for resolving problems caused by the errors, and an assessment of each with respect to improved safety. The critical task areas are discussed in the order in which they occur during the teletherapy process.

4.1 Critical Task Area 1 — Pre-treatment Planning

Pre-treatment planning involves discussion of essential aspects of treatment among key staff members prior to simulation, treatment planning, and other treatment delivery tasks. As noted in a recent report by the American Association of Physicists in Medicine (AAPM) Radiation Therapy Committee Task Group 40 (1994), a new patient planning conference should be attended by radiation oncologists, radiation therapists, dosimetrists, and medical physicists. It is a function performed prior to treatment and is typically initiated by the oncologist, especially for unusual treatments. Discussion at the conference should include pertinent medical history, physical and diagnostic findings, tumor staging, prior radiotherapy, past or intended surgery or chemotherapy, and treatment strategy (i.e., prescribed dose, consideration of limits to critical healthy organs, field arrangements and patient positioning). This information is of considerable value to the radiation therapists since it influences proper identification of the patient, scheduling, special care during set-up, and changes in the patient that need to be monitored throughout the course of therapy. Reports of misadministrations (e.g., treating the wrong patient or anatomical site) and near-misadministrations have implicated failures to convey critical information, non-communication, and incorrectly held assumptions about the intended approach as causal factors.

Not all facilities conduct pre-treatment planning sessions. When pre-treatment planning sessions are not conducted, it is reportedly because the case to be treated is performed routinely by teletherapy staff, and the treatment methodology is well understood by all staff members. However, problems are likely to occur when there is a departure or deviation from the standard, routine treatment. This is where unstated, implicit assumptions about what is intended, in the absence of explicit discussion about what is actually intended, can result in misadministrations. Pre-treatment planning conferences are a way of providing team members with a common shared mental model of how a particular patient is to be treated, thereby lessening the likelihood of confusion and potential misadministration.

4.1.1 Tasks That Could Be Compromised

The tasks and task-steps of the pre-treatment planning function that could have an adverse impact on satisfactory performance of the teletherapy system if not performed properly are listed below. These tasks and task-steps were taken from the function and task analysis phase of the

study and are reported in *Human Factors Evaluation of Teletherapy: Volume II Function and Task Analysis*, NUREG/CR-6277 (1995).

Pre-Treatment Planning

- Outline initial treatment plan parameters and any important patient-related factors.
 - Discuss critical structures and their dose limits for course of treatment.
 - Discuss total dose, dose fractionation, and dose distribution for target volume required for case.
- Review the use of department equipment for unusual situations that can have an impact on patient treatment (e.g., the use of specialized shielding).

There is considerable variation in the degree of formality for conducting pre-treatment planning conferences — from not conducting them at all, to informal discussions that occur on an impromptu basis, to formal meetings that occur at a predesignated time and place. Questions about the extent to which pre-treatment planning conferences should occur likewise triggered a diversity of opinion at the hospitals visited.

4.1.2 Contributing Factors

Potential errors associated with this task area involve failure to communicate in an unambiguous manner the essential components of the treatment such as the location of critical structures and unusual aspects of the intended treatment (e.g., treating the patient in the prone position rather than the usual supine position). Factors that contribute to the potential for human error among pre-treatment planning tasks include:

- The facility does not include pre-treatment planning sessions as part of standard treatment-related activities. Procedures for this activity have not been put in place or there may not be a perceived need for this activity.
- The oncologists and other team members are too rushed to prepare and present aspects of treatment. This factor is likely compounded by other factors such as patient load and a facility being understaffed.
- Treatment staff members converse in English, which may be their second language. Because of difficulties in both speaking and understanding English as a second language, interpersonal transfer of treatment planning information is jeopardized.

Given the presence of these factors, treatment staff may misunderstand key aspects of the treatment or may make assumptions about the treatment that are not intended by the oncologist. Proceeding with wrong assumptions may cause staff to fail to address atypical aspects of the intended treatment. Although there is opportunity for incorrect assumptions to be detected and

corrected during treatment planning, simulation, and delivery, there is no guarantee that they will be. A lack of communication or miscommunication during pre-treatment planning can lead to treatment of the wrong area, or administration of the wrong dose per fraction or the wrong number of fractions. Reason's (1990) distinction between active and latent errors is quite useful here. Treatment of the wrong area or administration of the wrong dose per fraction is considered an active error made by the therapists; however, such errors actually have their origins in latent errors made further upstream (e.g., failure by the oncologist to conduct a pre-treatment planning session to discuss and make clear the tasks identified in Section 4.1.1).

4.1.3 Alternative Approaches and Their Assessment

Three alternative approaches are suggested for helping to insure that the pre-treatment planning tasks are performed at a level required by the teletherapy system. The alternative approaches include:

- As part of a facility's efforts for continuous quality improvement, a worthwhile goal could be the conduct of pre-treatment planning sessions for treatments that the oncologist considers difficult or complex (e.g., intricate treatments to the head, neck or upper thoracic area). Since the purpose of pre-treatment planning sessions is to carry forward to subsequent tasks essential information, vehicles for doing so need to be considered (e.g., special forms containing diagrams and instructions).
- Educational efforts need to be directed at facility management to increase sensitivity about the deleterious effects of heavy workloads and understaffing in relation to pre-treatment planning activities. Since heavy workloads and understaffing are pervasive contributors to a number of teletherapy problems, this suggestion appears under other task areas as well.
- Also under the umbrella of a facility's quality assurance program, facility management could initiate communication process reviews and workshops for assessing and increasing staff awareness of communication problems that are common in today's diversified workplaces. Barriers to upward, downward, and lateral organizational communication, the development of better procedures and tools, and problems associated with inter-cultural differences could be addressed.

The first approach, stipulating the conduct of pre-treatment planning conferences for difficult or complex treatments, is considered to have the greatest potential effectiveness in terms of detecting and reducing the likelihood of errors that are otherwise initiated during this phase. By designating a time and place for pre-treatment planning considerations to be discussed and described, errors involving misinterpretations of prescriptions, using the wrong depth in calculations, or failure to modify treatments on schedule can be detected and prevented once treatment staff are made more acutely aware of the nature of the intended treatment. In addition to providing a record of pre-treatment planning considerations, the use of a pre-treatment planning form that carries the information forward should help to reduce the probability of downstream errors. Limiting factors may be the time and costs associated with the conduct of

such meetings; however, clarification of intended treatment issues up front is likely to save time and costs later because of the likelihood of setting up and administering the treatment correctly the first time around.

For significant long term gains in reducing the likelihood of error in this task area as well as other task areas, addressing the problem of heavy workloads and understaffing is likely to be the most robust alternative. Unless the workload can be undertaken more efficiently (perhaps through better workflow and job design) to allow time for pre-treatment planning sessions, this suggestion would likely entail hiring additional staff or restricting the number of patients that can be treated at any given time.

The third alternative of conducting communication process reviews and workshops for teletherapy personnel stems from an increasing awareness that misconstrued communication efforts are a major contributing cause of many system disasters. It is not just those individuals who use English as a second language that could benefit from a workshop on basic principles of communication. In a busy teletherapy work environment that involves frequent interactions and transfer of needed information among a number of people, effective communication should be a major concern. The purpose of the process reviews is to identify the weak points in the communication process and to solicit suggestions for improvement. Workshops can then be directed at the targeted weaknesses. When the review process is offered within the framework of the facility's quality assurance program, mechanisms can be put in place for monitoring and correcting communication practices when they break down.

4.2 Critical Task Area 2 — Use of Treatment Planning Computer Data Files

Treatment planning computers contain data files that are specific to the treatment machines for which plans are developed. Because sources are changed every five years or so in Co-60 machines, a most important data element is the activity of the source within the treatment machine at the facility. A new source will be much more active than a source that has been in the machine for three or four years. Thus exposure time for a newer, more active source will be shorter than for an older source.

Treatment data files corresponding to older sources have been mistakenly used for calculation of new treatments for patients. Most treatment planning computers automatically compute exposure times for a given dose based on source strength. In one incident, the times computed were incorrect and 33 patients received doses in excess of the prescribed dose. In this case, the physicist was directed to forego the updating of files which were used with beam trimmers (i.e., special accessories that shape the beam). The chief oncologist later decided to use beam trimmers for brain tumor therapy, and the old files corresponding to the older weaker source were used in treatment planning.

Another treatment planning computer incident involved parameter file data corresponding to a wedge filter. In this case, a facility purchased a new and different wedge filter. Although the old wedge was labeled "do not use," the facility failed to update the data file in the treatment planning computer corresponding to the new wedge. Use of the treatment planning data corresponding to the wedge that was no longer in use continued. Because the wedge filter

absorbs radiation consistent with its physical dimensions and these dimensions were different for the new wedge, the intensity of the beam passing through the new wedge was now different. This difference was not accounted for in the treatment time calculations. Consequently, treatment plans generated on the computer resulted in doses that were significantly lower than intended over a period of four to five years.

4.2.1 Tasks That Could Be Compromised

Tasks that are subject to these types of oversights were organized under the function referred to as Treatment Planning Computer Data File Set-Up in the function and task analysis report, *Human Factors Evaluation of Teletherapy: Volume II Function and Task Analysis*, NUREG/CR-6277 (1995). Of the six tasks listed below, the first task is a data file set-up that is specific to Co-60 machines, the second task is a data file set-up that is specific to linear accelerators, and the remaining data file set-up tasks are common to both Co-60 machines and linear accelerators.

Treatment Computer Data File Set-Up

Data file set-up specific to Co-60 machines

- Enter Co-60 source parameters in treatment planning computer data files.

Data file set-up specific to linear accelerators

- Enter beam energies and parameters in treatment planning computer data files.

Data file set-up common to Co-60 machines and linear accelerators

- Enter treatment machine identification in treatment planning computer data files.
- Enter necessary dose distribution files for each beam.
- Enter wedge identification and beam attenuation factors for all wedges to be used in treatment machines into treatment planning computer data files.
- Enter physical properties of treatment machine such as source-to-surface (SSD) into treatment planning computer data files.
- Remove old data file from treatment planning computer, or render it inaccessible.

4.2.2 Contributing Factors

Given the opaque nature of electronic storage and transfer of data, users and managers are somewhat removed from the actual storage and transfer operations. With most software-controlled systems, there are very few things that need to be verified at the user level. Only a

limited number of actions have immediate visible effects. Because of the opacity of treatment planning systems, users frequently do not have a good understanding of the validity of stored data or of the full functionality of the system.

As a consequence of not having a good appreciation of the problems to which opaque systems can give rise, there is frequently an absence of procedures that personnel can rely on for performing hidden, yet essential, tasks such as updating the treatment planning computer files. In terms of procedures, considerable variation was found among the sites visited with respect to having or following written procedures. Larger facilities were found to rely more on written procedures and documented modes of communication than smaller sites. However, even at facilities that value the use of procedures, one must first realize what the deficiencies, blind spots, or hidden sources of potential error actually are before a procedure can be prepared to rectify it. With the introduction of opaque technology, there is a possibility that the deficiency or error may not be detected until after many months of successful operation. This was clearly the case with the much cited "Malfunction 54" incidents in which the software governing the operation of the Therac 25 linear accelerator was found to be flawed, but only after two people died and another was severely burned by extremely high overdoses (e.g., Jacky, 1989). Even though a new piece of equipment is tested by the manufacturer before release, and even though many hospital departments will bench-test new equipment in a mode parallel to the existing system for a period of time, software flaws that are buried in code and program logic may remain undetected.

Yet another contributing factor that influences the likelihood of maintaining consistency between treatment planning computer data files and treatment machine and beam modification devices is the type of new equipment training that personnel receive. Most sites indicated that the vendor would provide applications training for a couple of days or a week. For a new treatment planning system, for example, the chief or lead physicist might receive the initial training, and then he or she would train other staff physicists and dosimetrists. The content not trained would have to be self-taught. It is noted that the quality of vendor-based training on their own product lines is likely to vary as is the ability of in-house personnel to train themselves and cross-train co-workers. While self-initiative to learn new systems and a willingness to share knowledge with others are both admirable qualities, they do not provide the foundation needed for comprehensive mastery of the new system. In brief, too much is left to chance.

4.2.3 Alternative Approaches and Their Assessment

Three alternative approaches are proposed to help insure that treatment planning computer data files are updated when they need to be. The alternative approaches are:

- Modify the interface of the treatment planning machine to make those functions that are invisible to the user a bit more visible. Computer data files need to be conspicuously mapped to specific treatment machines and accessories and displayed to the user.
- The incorporation of electronic interlocks on treatment planning systems needs to be considered. An electronic interlock refers to computer-driven logic and sensors that

prevent the continuation of subsequent steps when there is an inconsistency between treatment planning computer data files and the treatment machines and accessory devices for which they are intended.

- Establish or modify facility procedures to ensure the updating of treatment planning computer data files, and to keep outdated parameter files inaccessible to those performing treatment plans on a day-to-day basis.
- When new technology is introduced into the workplace, provide competency-based training to personnel who will be using the equipment. Training should include the proper use of that technology and the known safeguards for avoiding potential human error. This is a combined manufacturer/hospital responsibility and needs to be performed more systematically than it currently is to ensure an acceptable standard of performance.

For greatest effectiveness, the above three suggestions are best considered complementary and to be used as part of an overall quality assurance program rather than as quick fixes that can be incisively introduced in singular fashion. To be sure, the first suggestion of providing a better interface that clearly displays the appropriate relationship between the treatment planning computer data files and the machines and devices for which they are intended would reduce the likelihood of using inappropriate treatment data files. Norman (1988) makes a strong case for maximizing the use of display technology in taking the complexity out of everyday devices such as VCRs and microwaves. The same principles and technology can be used for assisting the dosimetrists or medical physicists with respect to data that is maintained on treatment planning computers. By incorporating the principles of visibility (i.e., making relevant operations more visible) and feedback (i.e., giving each action an immediate and obvious consequent), the ability to detect such errors would be improved and their likelihood reduced.

The incorporation of electronic interlocks on treatment planning computers to detect inconsistencies between actual parameter settings and what is intended would improve the detection of error considerably. Such a modification would enable corrective actions to eliminate the possibility of delivering too much or too little radiation. In the competitive medical device market, this is a safety feature that most manufacturers should be quite willing to incorporate. As is true for any device that stores data for subsequent use, considerable attention needs to be given to the accuracy of the initially entered data.

Given that inappropriate data files maintained on treatment planning computers can result in misadministrations, the suggestion of putting procedures in place (again within the framework of the department's overall quality assurance program) that will check for inconsistencies also needs to be considered. While the detectability of inconsistencies by human checking procedures may not be as reliable as an electronic interlock system, this alternative involves minimal cost and requires no new resources.

The alternative of a more systematic and competency-based approach for new equipment training rather than leaving it to the self-initiative of users would probably be more resource

intensive than the other approaches, but not overly so. First of all, hospitals as prospective buyers would be wise to place a fair share of the training responsibility on the shoulders of the manufacturer. The point of greatest negotiation leverage is before the order is placed. Manufacturer-provided training needs to address such training issues as the essential learning objectives that need to be mastered, an acceptable standard of performance before the new equipment confidently can be turned over to the facility, and procedures for evaluating the effectiveness of training. The extent to which such training improves the detection of error or reduces the likelihood of it is difficult to assess. However, if the appropriate feedback loops are incorporated into competency-based training (i.e., feedback from job incumbents after training), sources of error can be emphasized and remediated through continued training. In addition, competency-based training has a robust quality in that the same methods can be used to address other training concerns that the department may have.

4.3 Critical Task Area 3 — Use of Patient Chart

The patient's radiation chart is the focus of a great many teletherapy activities and its use cuts across several task areas. It is updated, reviewed, modified and used by a number of different staff members throughout the patient's therapy. Radiation therapists use it on a daily basis to set-up and record the fractionated radiation for each field that they are responsible for treating. Dosimetrists or medical physicists review all charts on a weekly basis to determine whether all doses have been correctly summed since the previous chart review and whether new treatment fields have been started or previous fields modified. Oncologists also access the chart on a frequent basis: at initial set-up, during on-going medical examinations, and at chart reviews. Also using patients' charts at times are nurses, social workers, dieticians, secretaries, and billing personnel. Given the number of people making new entries in the chart and extracting vital patient information from it, its design, function in the teletherapy process, and use by multiple team members requires close examination.

Poorly designed forms and the legibility of the data on the forms constitute human factors problems in many organizations. In the teletherapy setting, it is fairly easy to understand how problems related to obtaining accurate treatment data from the patient's chart (e.g., changes to the prescription that go unnoticed for a number of days, illegibility of handwritten information, transfer of information errors, and prescription instructions written in abbreviated form that can be interpreted in more than one way) can compromise task performance and potentially lead to serious misadministrations.

4.3.1. Tasks That Could Be Compromised

Tasks that faulty chart design and practices are most likely to compromise fall under three functional areas: treatment planning, treatment set-up and treatment administration.

Treatment Planning

Set-up and verify patient chart

- Set-up treatment chart.
- Check patient chart for completeness and accuracy periodically during course of treatment.

With respect to treatment set-up, three major sub-functions are involved: verify patient identity and critical treatment parameters, patient set-up, and treatment machine set-up. Each sub-functional area has its own set of tasks. Those that were considered likely to be impeded as a result of chart design and legibility problems include:

Treatment Set-Up

Verify patient identity and critical treatment parameters

- Ensure that set-up information and dose specified in treatment plan are appropriate for prescription.
- Ensure patient identity is consistent with patient named in treatment plan.

Patient set-up

- Move patient into correct anatomical position (i.e., supine, prone) prior to set-up of treatment field.
- Apply bolus material and immobilization devices to patient's body.

Treatment machine set-up

- Program computer-controlled linear accelerator control system prior to treatment.
- Rotate gantry and collimator to correct angle for treatment.
- Set correct field size.
- Place correct blocks and wedges.

Regarding treatment administration, the task performance most likely to be jeopardized was organized under the entry of treatment parameters sub-function.

Treatment Administration

Entry of treatment parameters

- Select beam type on linear accelerator control console.

- Select beam energy for beam type selection.
- Select rotating (moving) or fixed treatment.
- Enter treatment dose in "monitor units" or "exposure time".
- Ensure all treatment parameters are correct.

4.3.2 Contributing Factors

The location of the oncologist's prescription and the location of changes to the prescription in the treatment chart have been cited as a problem in both incident reports and by the study's respondents. A prescription error can be propagated throughout the entire course of therapy as evidenced by one patient who had the wrong side of his neck treated. Although the oncologist assisted with and approved simulation films for the incorrect side of the neck, the prescription on the chart clearly stated the correct side of the neck for treatment. Subsequent chart reviews did not catch this error. Contributing to such oversights is the tendency at some facilities to focus on the correctness of the dose calculations rather than verification of the prescription. Furthermore, verification of the prescription is less likely when the lay-out of the chart places the prescription block in an inconspicuous location. Chart lay-out and design factors also are suspected contributors to transfer of information errors, one type of which results from the orthographic similarity of recorded numbers representing different parameters but placed in contiguous locations on the chart.

Another incident, which implicated adequacy of handwritten information, involved a prescription that called for 300 rads to be administered per day to the head of a pediatric patient. The dosimetrist assumed the oncologist wanted 300 rads delivered per treatment field to each side of the head, while the oncologist assumed that the dosimetrist would set up the treatment plan to give 150 rads per treatment field. Both the inadequate information of the prescription and differing mental sets of the oncologist and dosimetrist (i.e., the oncologist's mental set is likely to be on the total daily dose the tumor needs to receive, while the dosimetrist is more concerned with the operational route of delivery) combined in allowing unintended dosages to be administered. The importance of unambiguous prescriptions and other treatment set-up information is underscored when treatments depart from standard protocols in ways not anticipated by the staff.

Yet another opportunity for error is present when oncologists occasionally request that treatments begin upon verbal request, before a written prescription is provided. Here the appropriateness of the intended treatment relies on the interpretation of the verbal communication and the memory of the individual therapist. Refusal by therapists to begin treatments with only verbal requests occasionally causes conflict between therapists and oncologists. In one incident, the oncologist issued a verbal prescription for 600 rads per treatment for three treatments. The oncologist later signed a written prescription for 300 rads to be given in five treatments. The therapist confused the two versions of the prescription and calculated a treatment plan for 600 rads in five treatments. A physicist then checked the accuracy of the mathematical calculations

(but not the validity of them) and transferred the data to the treatment sheet. Incorrect performance of these tasks resulted in the patient receiving a dosage beyond what was intended. Although it is difficult to predict exactly what tasks will be compromised by failure to prepare a written prescription, the impact methodology described in Section 2.2.2 identified treatment set-up and treatment administration tasks as those that may not be performed to the level required by the system.

4.3.3 Alternative Approaches and Their Assessment

Two alternative approaches are proposed for reducing the occurrence of error resulting from poorly designed forms or poor legibility of data entered on the form. The first approach is aimed at altering the lay-out of the form while the second approach focuses on modifying the behavior of individuals who enter information on the form that can be interpreted as ambiguous.

- It is recommended that facilities examine the lay-out of the chart and determine where changes would make the greatest potential improvement. To adequately assess the changes, error data would need to be recorded, preferably in accord with a quasi-experimental design (e.g., that first collects data for a baseline period with the existing form, then for a comparable period with the new form, and then a return to baseline using the existing form). Examination of the radiation oncology professional literature should also be part of this effort. At a recent American Society for Therapeutic Radiology and Oncology (ASTRO) annual meeting, one of the exhibits consisted of a large comparative display of charts with different lay-outs that allowed attendees to examine their relative strengths and weaknesses.
- The second approach of modifying the behavior of those individuals that are introducing ambiguous or illegible information on the chart also should be undertaken within the framework of the department's quality assurance (QA) program. One approach would be to identify, portray, and compare bad practices with good practices. By graphically contrasting (perhaps on a departmental bulletin board) practices that can lead to error with practices that are designed to prevent error, individuals that engage in risky practices should receive the message.

The first approach of altering the form (e.g., changing the location where the prescription and changes to the prescription are entered) would seem to stand the best chance of eliminating or reducing certain types of errors, but to be convincing, it needs to be demonstrated empirically. To empirically demonstrate the effectiveness of a change in a busy hospital setting takes time, resources, and a receptive organization. At the same time, whenever changes are made in the design of an interface, the potential for other errors may be introduced. Treatment staff will need to be alert to this. When assessing the feasibility of this approach, the length of time required for collecting the baseline and change data may be considered a limiting factor at some facilities. Given the relative infrequency with which these errors occur, it is important to note that sufficient amounts of time need to be scheduled for the separate data collection phases if error differences are to be found. Suggestions of this nature may find greater acceptance and resources at the university-based or research-oriented hospitals.

The second approach of departmental postings of bad practices and good practices, by itself, may be less likely to have a major impact on eliminating or reducing charting errors. The approach should not be considered by itself, however, but rather as a complementary alternative or as one of many tactics for demonstrating a serious concern for continuous improvement in providing teletherapy services. Its advantages are low cost, ease of implementation, high visibility, and potential educational value. It also has a robust quality and can be used for highlighting other unacceptable and acceptable practices.

4.4 Critical Task Area 4 — Patient Positioning and Immobilization

Uncertainty associated with patient positioning and immobilization has received a fair degree of attention in the literature (e.g., Bentel, Nelson & Noell, 1989; Hendrickson, 1982; Svenson, 1989). In external beam applications, precision and reproducibility of treatment are essential to effective therapy. Given repeated administrations, concern arises over the cumulative effects of imprecision where it is possible to underexpose the tumor volume or overexpose radio-sensitive tissue. As noted by Perez and Brady (1992), the only effective irradiation is that which strikes the clonogenic tumor cells.

Whatever the patient's treatment position and whatever immobilization device is used, the combined effect must not be so uncomfortable and cumbersome that it precludes reproducibility or encourages movement. If these goals are not achieved, the dose distribution across the field edge widens when the patient moves during treatment or is imprecisely placed from treatment to treatment. The effect is for tissue outside the field edge to receive a dose higher than what was intended and for the tissue inside the target volume to receive less than what was prescribed. While the target volume encompasses a small margin of clinically uninvolved tissue to accommodate such uncertainties as physiologic movements related to breathing and heart action, inadvertent patient movement, inexact tumor localization, and microscopic extensions of the tumor, the degree of accommodation depends upon the anatomy under treatment. For example, a high degree of precision is required in patient positioning and immobilization for tumors in the head and neck area because of the closeness of the orbita, brain, and cervical spinal cord (Hendrickson, 1982).

4.4.1 Tasks That Could Be Compromised

Treatment tasks and task-steps that could be subject to patient position and immobilization inconsistencies are those that are reported under the Treatment Set-Up functional area and Patient Set-Up sub-functional area in *Human Factors Evaluation of Teletherapy: Volume II Function and Task Analysis*, NUREG/CR-6277 (1995).

Treatment Set-Up

Patient set-up

- Assist patient into treatment room.

- Explain treatment process to patient.
- Assist patient onto treatment table.
- Move patient into correct anatomical (e.g., supine, prone) position prior to set-up of treatment field.
- Secure patient in treatment position.
- Apply bolus material to patient's body.
- Position TV monitor so that visual contact is made with patient.
- Assist technologist with difficult patient and treatment machine set-ups.

Also during the simulation function, tasks that are organized under the sub-functional area of patient immobilization or positioning devices are likely to be involved.

Simulation

Patient immobilization and positioning devices

- Detect need for patient immobilization or positioning devices.
- Construct immobilization or positioning devices.

4.4.2 Contributing Factors

There have been impressive improvements with the precision of external beam therapy over the years given the advent of isocentric therapy machines, linear accelerators, computed tomography (CT), treatment planning computers, and custom beam shaping blocks. For a number of practitioners, however, the weakest link in the entire process remains patient positioning and immobilization (Bentel et al., 1989). The nature of the task is such that it is quite difficult for therapists to achieve the same patient position treatment after treatment and for patients themselves to remain motionless during treatment. Part of the problem, according to Reinstein and Meek (1987), is that much of the quality assurance focus has been on the physical dosimetric aspects of therapy and less emphasis has been placed on geometric treatment set-up problems. Because the radiation therapy community has placed less emphasis on patient positioning problems, Reinstein and Meek contend that research and design criteria for optimal patient support systems (e.g., treatment couches) are needed to facilitate reproducible set-ups. Interestingly enough, some of the greatest improvements in immobilization devices have come from the low-end of the device market with the use of plastic casting material (tradename Aquaplast) and styrofoam-based, form-fitting molds (tradename Alpha Cradle Mold Maker) that are easy to make and comfortable for the patient.

A certain amount of trial and error experimentation with respect to positioning and immobilization aids is evident at different facilities. A variety of treatment aids (e.g., biteblocks, slant boards, centimeter scale graticules, body casts and cradles, arm supports, and contouring devices) have been developed to assist in accurate positioning, yet little is known about the optimal use of these aids or the most effective versions. It is not unusual for different facilities in the same city to be using different treatment aids and approaches to patient set-ups without much inter-facility discussion on the strengths and weaknesses of these aids.

Another source of difficulty in achieving accurate patient set-ups is reliance on skin tattoos which are used for marking the field margins in conjunction with the optical distance indicator (ODI), triangulation lasers, field demarcation light and central ray cross-hair shadow. Skin marks or tattoos can be unreliable due to weight changes or fading, while the precision of the ODI is variable (typically ± 0.5 cm) on sloped skin surfaces. Moreover, this sort of imprecision is not captured by current record and verify systems.

While greater attention to the design of treatment couches and immobilization devices should facilitate reproducible set-ups, design is not the only factor that needs to be examined. Precision, reproducibility, and double-checking is bound to suffer when therapists start to experience a back-log of patients waiting to be treated, when the treatment is complex and time-consuming, when competing tasks are directed at them, and when the equipment fails or is difficult to manipulate and set-up. It is not difficult to understand how these factors may interact and accrue in a short period of time. In a high volume clinic, controls and displays of the treatment machine that are cumbersome to manipulate and read can add to the therapist's workload; if complex treatments or competing interruptions occur, further time pressures are experienced in addition to the back-log of patients waiting to be treated. If the workload pressures that impinge upon therapists is such that precise patient positioning is sacrificed to maintaining a high patient volume, this is a management problem that deserves to be treated on its own accord.

4.4.3 Alternative Approaches and Their Assessment

Several approaches are proposed for addressing the problems associated with patient positioning and immobilization. These approaches are directed towards achieving a better understanding of the significance of the problem, sharing information on the effectiveness of treatment aids, avoiding sole reliance on skin marks as a way of setting treatment field margins, and ensuring that departments are not so busy that they sacrifice precision of patient positioning.

Whether or not one grants Reinstein and Meek's contention that the radiation therapy community has placed less emphasis on patient positioning compared to the physical characteristics of the beam, few would deny patient positioning is a serious challenge. The more that occurrences of positioning and immobilization imprecision can be documented and shared with the practicing community, the more likely additional resources will be devoted for attending to the problem. Studies should attempt to show the relationship between imprecision and outcome measures. Once the exact nature of the positioning and immobilization problems in relation to clinical outcome is determined, equipment and system designers will have better

information to initiate improvements in the patient-treatment machine interface and in associated procedures. While conducting empirical studies may seem like a long term effort without any guarantee of immediately reducing the likelihood of error, research of this nature should be encouraged on a steady and continuing basis so that decision makers in radiation oncology departments have a solid foundation upon which to make intelligent decisions.

Since therapists and physicists are typically most aware of the techniques and specialized devices used at their own centers or where they were trained, a better means of communicating effective practices and technical innovations across centers is suggested. There is probably no singular communication vehicle that would fill the void of technical transfer entirely. Instead, a multi-channel approach for communicating innovations is advocated that employs such outlets as articles in professional journals, papers at professional conferences, computer conferencing networks, and show and tell demonstrations at the local or regional meetings of professional organizations. It would not be unreasonable for certain professional organizations in radiation therapy to assume a leadership role in providing an on-going communication mechanism since promoting the effective application of radiation therapy techniques and facilitating more direct lines of communication among their memberships are frequently part of their mission statements. Since a professional society's journal has wide circulation among the society's membership, a section of the journal devoted to innovations and effective practices is a practical way of sharing information for improving the detection of error, reducing the likelihood of error, or limiting the adverse consequences of error.

Because of the problems associated with skin marks (e.g., weight loss, confusion with earlier marks, patients that are obese, breathing), new alternatives to patient positioning and treatment localization need continued exploration. Potential alternatives include the use of advanced technology for assisting in patient positioning such as new field referencing in place of dyes, incorporating CT image data and beams-eye-view techniques, the development of more precise and usable patient movement indicators, and expanding the record and verify concept for confirming correct patient positioning. For example, in the thorax area, breathing can lead to considerable changes in the patient's contour. Although there are no commercial systems at present that are capable of measuring directly the patient's movement, there have been prototypes of such a system. By using a line image that is projected on the patient from a laser in combination with two video cameras positioned at fixed right angles relative to the light source, the cameras can record the amount of light reflected from the patient's contour surface. An analog-to-digital device feeds the information to a microcomputer, enabling 25 contour profiles per second. Once changes in the patient's contour are determined on-line reliably, the microcomputer can be programmed to turn off the treatment machine if predetermined limits are exceeded. Corrective actions are taken with the patient (e.g., repositioning, specific breathing instructions) and treatment resumes as long as movement is within specified limits (J.A. Deye, personal communication, October 28, 1994). Research and development in new technology also is a long-term approach; however, once new developments are successfully tested and implemented, they frequently have the potential to eliminate a cluster of interrelated problems associated with error detection and reduction.

It was noted that reproducibility of patient positioning is also likely to depend upon the workload of the therapists (Reinstein and Meek, 1987). Conscientious and consistent performance of therapists is crucial in attaining precise positioning throughout the duration of therapy. Each center needs to develop a reasonable patient scheduling system that avoids peak loads and provides therapists with sufficient time to ensure precise patient positioning. This is a concern that can be addressed within the center's quality assurance program. Given there is some evidence (Swann-D'Emilia, Chu & Daywalt, 1990) that suggests a disproportionate number of errors occur at high levels of patient volume, efforts directed at avoiding peak patient volume on treatment machines should improve the detection of error and reduce the likelihood of its occurrence.

4.5 Critical Task Area 5 — Treatment Set-Up

Skill-based slips and lapses can occur anywhere in the teletherapy process; however, one place where the evidence is quite clear that numerous slips and lapses occur is during treatment set-up. As used in the human factors literature, slips and lapses are actions that deviate from current intention as a result of working memory difficulties (Reason, 1979; Norman, 1981). Slips, according to Reason (1990), can occur through workplace distraction or preoccupation whenever something else captures one's attention. Slips, such as using a wrong block in teletherapy, are quite unpredictable since they involve momentary interruptions of highly skilled, automatic routines. Lapses are a more covert form of error, usually referred to as memory failures, yet still involving a discrepancy between what was intended and what was performed. If a therapist fails to chart a treatment and thus gives an extra treatment, a lapse has occurred.

Given the numerous parameters and adjustments that need to be set for each treatment field for each patient, it is not surprising that the setting of treatment parameters constitute fertile ground for imprecision and error. These set-up tasks fall under the direction of the therapists and include such parameters as monitor units or exposure time, field size, gantry and collimator angles, insertion of blocks and/or wedges, source-to-surface distance (SSD) and use of correct tattoos.

4.5.1 Tasks That Could Be Compromised

Tasks that are subject to the occurrence of slips and lapses occur throughout the teletherapy process, but are most evident in two functional areas: treatment set-up and treatment administration from the control console. Many of these tasks are of a routine, highly practiced nature.

Treatment Set-Up

Treatment machine set-up

- Rotate gantry to correct angle for treatment.
- Adjust collimator and angle to prescribed values.

- Readjust field light (via collimator) to field borders and/or marks on patient's skin.
- Position patient for proper SSD.
- Position standard (non-custom) blocks on block template.
- Attach custom block assembly to treatment head.
- Attach wedge to wedge holder in treatment head.
- Position tissue compensator in treatment beam.
- Attach electron cone to treatment machine head.

Several tasks that involve treatment administration from the control console that may be susceptible to the same types of skill-based errors include:

Treatment Administration from Control Console

Entry of treatment parameters

- Select beam type on linear accelerator control console.
- Select beam energy for beam type selection.
- Select rotating or fixed treatment.
- Enter degree of rotation on moving field, "start" and "stop" angles.
- Enter treatment dose in "monitor units" or "exposure time."
- Ensure all treatment parameters are correct.

4.5.2 Contributing Factors

According to Rasmussen's (1982) taxonomy, slips and lapses are very likely to occur at a skill-based level of performance. Skill-based behavior "represents sensorimotor performance during acts or activities that, after a statement of an intention, take place without conscious control as smooth, automated, and highly integrated patterns of behaviour" (Rasmussen, 1986, p.100). As such, slips and lapses are the common execution errors made by therapists during treatment set-up (e.g., selecting the wrong block, reversing the X-Y field coordinates, setting the wrong monitor units or treatment times, using the wrong tattoos) given momentary interruption of or distraction from these highly practiced, automatic routines. Slips and lapses are quite unpredictable and seemingly difficult to control or reduce. Serving as contributing factors, however, are those workplace variables and occurrences that have the effect of interrupting or

distracting therapists from the successful completion of these routines. Workplace factors that may contribute to the occurrence of these errors include the following:

- Excessive workloads and rapid-paced patient treatment schedules can increase the likelihood of treatment set-up errors. While workload varies between facilities and time of day, Swann-D'Emilia, Chu and Daywalt (1990) have shown a greater occurrence of treatment set-up errors with increases in patient load.
- Inadequate levels of staffing can serve to increase the workload for therapists when only one therapist is assigned to a machine rather than two as is recommended. Approximately 25% of the sites visited were understaffed by one therapist.
- Unnecessary workplace distractions stemming from poor physical layout of the therapist's workstation (e.g., workstations in heavily trafficked aisle-ways or near entrance areas for patients) were found at some facilities.
- Unnecessary competing tasks such as requiring therapists to answer phones at their stations while simultaneously administering treatments was observed. Therapists considered such interruptions disruptive to treatment administrations, record keeping, and treatment set-ups.

Much of the focus in the literature is on the active errors that therapists and dosimetrists are likely to make to the neglect of the latent role that management decisions, environmental factors (both physical and social), and organizational policy can have on human error. Reason (1990) has made a strong case that the active errors of overstressed operators are, in large part, the delayed combined effects of managerial mistakes and system design failures that occur further upstream in the greater socio-technical system. Many of the contributing factors to what is regarded as random, unpredictable error result from these less recognizable antecedent influences that combine and exert their effects in unanticipated ways.

4.5.3 Alternative Approaches and Their Assessment

There are several alternative approaches that may help mitigate the occurrence of slips and lapses during treatment set-up. These alternative approaches include:

- To reduce periods of peak workload that therapists frequently experience, the function of patient scheduling needs to be re-examined by department heads to ensure a more evenly distributed method of scheduling patients.
- Dedicated efforts to ensure adequate staffing need to be taken by facility management at those hospitals that are understaffed. By having two therapists assigned to a machine and by employing double-checking procedures (i.e., one therapist calls out settings from a checklist while a second therapist makes the settings and reads them back), the slips and lapses that one therapist makes are more likely to be detected and corrected by the other.

- To help reduce unnecessary workplace distractions, workspace design and physical layout efforts need to be considered as ways of keeping sources of distraction to a minimum.
- Better job design (i.e., the assignment of tasks to personnel) can help ensure that interruptions and tasks that compete with treatment administration and chart keeping are held to a minimum during treatment hours.
- To detect and prevent deviations in the delivered radiation dose that result from parameter input errors during treatment set-up, manufacturers offer computerized record and verify (R&V) systems that inhibit a machine from being turned on when the parameters set on the machine do not agree with the prescribed ones to within specified tolerances. About a third of the facilities were using R&V systems on their linear accelerators at the time the authors visited. Very few had such systems on their Co-60 machines.
- Education efforts are recommended to help sensitize department heads and managerial personnel on the latent effects that their decisions and policies can have on the day-to-day activities of those that have the greatest contact with patients.

There is considerable merit in the human factors expression that "it is easier to bend metal than to twist arms." The above approaches suggest that the likelihood and consequences of error can be reduced by the appropriate design of equipment, workstations, and jobs that exclude such errors or at least makes their occurrence more unlikely. An R&V system is a good example of designing error out of the job. In one study of R&V systems, 416 significant deviations (e.g., verification failures involving monitor units, collimator angle, blocking tray, gantry angle, energy, field size, and wedges) were detected over a one-year period on three treatment machines incorporating R&V systems (Mohan, Podmanoczky, Caley, Lapidus & Laughlin, 1984). This equated to 60% of the patients that would have encountered one significant deviation throughout their course of treatment had the deviations not been caught. Scheduling patients in a manner to avoid peak loads, ensuring that two therapists work on a machine, designing the physical layout of the therapist's workstation away from sources of distraction, and eliminating tasks that compete with treatment administration from the job description of therapists are ways of designing the work environment to reduce error.

As before, for greatest effectiveness these recommendations are best considered as complementary under the aegis of a fully coordinated quality assurance program rather than introduced singularly. Since therapists' performance of treatment set-up tasks is highly skill-based and likely occurring at asymptotic level, the recommendation of additional training for these tasks would be questionable. The education of department heads and those in decision-making positions on the more latent and subtle aspects of human error (and on its multiple contributing factors) is a recommendation that deserves consideration, however.

4.6. Critical Task Area 6 — Data Transfer

Because of the large number of steps and the various treatment team members involved in the planning, preparation and delivery of radiation treatment, the transfer of error-free information from one phase or step of therapy to the next is extremely important. Errors that result from inaccurate or inadequate information will be passed along to each subsequent step and phase of the teletherapy process and may ultimately affect the outcome of treatment. Once perpetuated, some of these errors gain a validity of their own that is difficult to check and correct. Procedures for checking typically cover a well-defined sub-set of steps at a particular point of therapy, but do not exhaustively and progressively work backwards through the chain of therapeutic steps and decisions to the very beginning of therapy. In practice, the checking procedures also tend to focus more on the accuracy of the data rather than the validity of it (e.g., obtaining the correct cumulative dose for a given field, rather than examining whether the field should still be treated).

Leunens and associates studied the inadequate transfer of information at different points throughout the teletherapy preparation chain and were able to trace data transfer errors to treatment simulation, input of data to the treatment planning system, preparation of the patient's treatment chart, input of treatment parameters to the R&V system, and during modification to parameters made at the first session (Leunens, Verstraete, Van den Bogaert, Van Dam, Dutreix, & van der Schueren, 1992). Many of the data transfer errors were attributed to inattention; that is, the slips and lapses addressed by Norman (1981) and Reason (1990). Others were attributed to transcription steps (e.g., copying data from a digital display during treatment simulation onto paper; entering data into the treatment planning computer or into the R&V system). Respondents in the present study also confirmed the presence of these types of errors.

4.6.1 Tasks That Could Be Compromised

Tasks that are susceptible to data transfer errors can occur almost anywhere; however, a large number of them fall under three functional areas: simulation, treatment planning, and treatment set-up. As before, these functions, sub-functions, and tasks have been extracted from *Human Factors Evaluation of Teletherapy: Volume II Function and Task Analysis*, NUREG/CR-6277 (1995), and are listed below.

Simulation

Simulation planning

- Obtain appropriate data and/or worksheets and ensure availability for simulation.

Simulate treatment

- Take manual measurements of patient's external anatomy.
- Obtain contour of patient's body.

- Measure anatomy of treatment area with calipers.
- Mark field borders with dye or colored markers.
- Produce appropriate quality radiographs.

Treatment Planning

Obtain treatment data

- Acquire prescription and simulation data, and ensure completeness and internal consistency.
- Acquire essential treatment related data to enable emergency treatment.

Treatment plan calculations without treatment planning computer

- Produce treatment plan calculations.

Treatment Plan Calculations on Treatment Planning Computer

- Select patient name in computer directory, or enter name if not in directory.
- Obtain patient's body contour strip from simulation technologist, or from storage area.
 - Enter patient contour into treatment planning computer file.
 - Enter dose limiting (critical) structures within patient's body contour entered previously.
 - Enter the identification of the treatment machine.
- Enter beam parameters into treatment planning computer's treatment plan file.
- Enter beam position relative to graphic representation of patient contour and target area on treatment planning computer screen.
 - Produce alternate treatment plans (dose levels and beam positions) that maximize desirable or minimize undesirable aspects of treatment.

Treatment Set-Up

Treatment machine set-up

- Program computer control system prior to course of treatment.

4.6.2 Contributing Factors

At centers that determine initial beam-on time calculations with a computer program, it is sometimes the practice to have therapists perform the calculations at their treatment machine consoles. Sometimes patients are treated immediately following simulation. When this is the case, beam-on times are frequently calculated by the therapist while the patient is waiting. As noted by Gastorf, Harris & Horton (1991), with a patient on the table and the therapist pressed for time, this is not the best circumstance in which to make the calculation. Fewer errors would be expected under less stressful conditions.

Aggravating this problem is the uncritical acceptance of treatment plan data that is generated by computer. Few people would take exception to the tremendous improvements made possible with computers, but far too often sources of error are overlooked. When it is so easy to make errors with the input parameters, the output of the computer plan warrants greater skepticism than it normally receives. A somewhat ironic feature of the Leunens et al. (1992) data is that "nearly half of the major deviations were introduced during the input of data in the check-and-confirm system, demonstrating that a system aimed to prevent accidental errors, can lead to a considerable number of systematic errors if used as an uncontrolled set-up system" (1992, p. 217). The work of Leunens and associates also serves as a reminder that tasks that involve a human-initiated transfer or input of information are especially susceptible to error.

The pervasiveness of these errors suggests that they are relatively resistant to modification and change. The nature of these tasks conforms to Rasmussen's (1986) skill-based level of performance; their sensorimotor, routine, and automatic quality often leads to such descriptions as tedious or monotonous. Often the dosimetrist's immediate visual field is composed of highly similar stimuli (e.g., look-alike numbers or characters in a table or column), providing a rich source of interference. If visual spacing suffers or tracking aids are absent, then computational error becomes more understandable. When this type of routine task occurs in a visual field with a high loading for interference and in an organizational environment that expects rapid-paced work, then computational error becomes almost inevitable.

4.6.3 Alternative Approaches and Their Assessment

It was noted that initial beam-on time calculations are sometimes performed at the therapist's treatment console with the patient waiting to be treated. Even though these calculations are facilitated by a menu-driven computer program, calculations performed with the patient on the table waiting to be treated should be minimized (Gastorf et al., 1991). The basic concern is the possibility of parameter input errors when the therapist is under pressure to maintain a treatment schedule. To reduce the likelihood of such errors, a preferred alternative is a more distributed method for scheduling patients that lessens the need to work under pressure. At the same time, it is recognized that there are times when unexpected patients need to be scheduled and set-up on short notice.

Another alternative would be for the dosimetrist to calculate the beam-on time and for the calculation to be verified by the physicist the day before the patient is to appear for treatment.

This relieves the therapist of performing calculations under pressure. Whatever procedure is adopted, part of it should include the provision of verifying all calculations within 48 hours after the initial calculation (using a different instrument than used for the initial calculation whenever possible) and verifying the correctness of all treatment parameters (using a different dosimetrist or physicist, if available). The greatest value of this alternative is early error detection.

A related alternative with respect to inaccurate input parameters and calculations that are part of the computer plan is to have another qualified person verify independently all inputs. Uncritical acceptance of treatment plan data that is generated by computer allows input errors to go unnoticed. To enhance early error detection, the computer hard copy should allow identification of the input for a given patient. This should make it easier for treatment staff to be vigilant of input entries; however, they also must realize the importance of being vigilant. Training and adherence to procedures are two complementary alternatives for increasing sensitivity to the weak links in the process. Training helps people become aware that weak links exist and adherence to procedures should improve the detection of errors. Both approaches can be implemented within the context of the department's quality assurance program.

Although training and adherence to procedures may be necessary components of a program for increasing concern about detection of data transfer error, they may not be sufficient to bring about a permanent change. Vigilance to an anomalous event, whether on a radar screen or in a computer print-out, has always been a difficult task to maintain for any period of time. Innovative, experimental approaches need to be tried as alternatives. For example, to enhance long-term vigilance for error detection, one facility initiated an incentive program with encouraging results by monthly rewarding the staff member who detected the most errors. New methods for maintaining vigilance and detecting errors (e.g., incentive systems, random interval inspections) need to be tried and put to the empirical test. The success of these methods frequently depends on how well they are implemented and how well they are supported by the organization.

With respect to errors that result from poorly organized visual fields composed of similar stimuli that are found in tables and display screens, the most direct alternative is to correct the likely sources of interference (e.g., crowded spacing and poorly organized perceptual cues). The use of color or shading may help separate columns of numbers that might otherwise be transposed. Although this may not be possible with software packages or printed matter that has already been purchased, the ease of reading tables and extracting information from display screens need to be included in the evaluation criteria that decision makers use when making purchases. When incorporated in the design phase of a product development effort, properly designed tables and screens typically are no more costly than poorly designed interfaces, yet the potential for reducing the likelihood of transfer error is much greater.

An encouraging sign is that research and development efforts among the major medical equipment manufacturers is likely to continue in a very competitive market. Value will be added to new treatment planning computers and software when they contain features that minimize the amount of data transfer and entry of treatment parameters that is required by dosimetrists and therapists. New devices may replace many of the error-prone transfer tasks currently performed

by humans. However, for the present, the best defense is a conscientious implementation of the practices and procedures discussed above. With the possible exception of new devices, the implementation of any one alternative by itself is likely to have limited impact. For this reason, a more programmatic effort consisting of a combination or integrated set of well founded practices has the greatest likelihood of reducing data transfer error.

4.7 Critical Task Area 7 — Equipment Checks and Calibration

One of the more routine tasks for the radiation physicist is to periodically check the output of the treatment machines. The importance of this task area was underscored a number of years ago in a highly publicized event whereby nearly 400 patients were inadvertently over-irradiated at a hospital in Ohio (Rubin, 1978). In this situation, the output of the hospital's cobalt-60 machine required periodic measurement (i.e., every month or two) with a probe to compare measured radiation against predicted values. Since cobalt-60 is a radioactive isotope, physicists can use the decay rate in conjunction with tables and graphs to determine appropriate exposure times for the prescribed radiation dosage. Yet during a 27 month period until discovery that close to 400 patients had been over-irradiated, it appears the output of the source was measured only twice very early in this period (Rubin, 1978).

In subsequent investigations, the physicist explained that a higher priority project — the acquisition, installation, and testing of a new linear accelerator for the department — took precedence amidst an increasing workload and that calibrating the cobalt-60 source never ranked high on his list. Also in error was the methodology used for determining the predicted output curve for cobalt-60. The decay rate of cobalt-60 can be accurately measured on either semi-logarithmic graph paper or linear graph paper; however, since the decay rate of cobalt-60 is an exponential rather than linear function of time, most physicists advocate the use of semi-log graph paper since the decay rate shows up as a straight line enabling easy detection of any deviation. In hindsight, the physicist recognized three things he did wrong. First, he used linear graph paper where the decay rate slopes gradually making a variation more difficult to detect. Second, he inadvertently switched from linear paper with five squares per division to linear paper with six squares per division, making the decay rate appear faster than it really was. And third, for nearly two years, he failed to take periodic measurements of radiation output which would have indicated that something was wrong with his graphic projections.

The effect of these errors was an output curve showing the cobalt-60 source losing its strength far faster than it really was. This divergence progressively increased with the passage of time so that by the time the problem was finally discovered, exposure times had increased considerably, resulting in overdoses as high as 40 percent. As far as the records show, no one ever checked the physicist's output curves or inquired whether periodic calibrations were being made.

Because radiation therapy frequently results in some undesirable side effects and because the initial overdoses were marginal, complaints from patients about fatigue, sore throat and diarrhea were not unusual enough to suspect that something was wrong. It was only when the number and intensity of complaints about severe radiation reactions (e.g., skin burns, acute

diarrhea) became inordinate that someone suggested, nearly two years later, that the output of the cobalt-60 machine be checked.

4.7.1 Tasks That Could Be Compromised

Tasks that are most likely compromised are the daily, weekly, monthly and annual constancy checks, calibrations and adjustments that are listed in *Human Factors Evaluation of Teletherapy: Volume II Function and Task Analysis*, NUREG/CR-6277 (1995), under the functional area, "Treatment and Safety Equipment Checks, Adjustments and Maintenance." It should be noted that since the above tragedy became known in 1976, quality assurance procedures for checking and monitoring beam output and other parameters have become much more comprehensive and systematic. There are many recent excellent guidelines for establishing such tests, including: 1) American College of Medical Physics (ACMP) Report #2, *Radiation Control and Quality Assurance in Radiation Oncology: A Suggested Protocol*, 2) the American Association of Physicists in Medicine (AAPM) Report #13, *Physical Aspects of Quality Assurance in Radiation Therapy*, and 3) AAPM's *Proceedings of a Symposium on Quality Assurance of Radiotherapy Equipment*. As noted by Purdy (1991), the actual equipment checks and calibration tasks implemented at a given institution depends upon the particular complex of treatment machines, simulators, and test equipment. Table 4.1 is adopted from Purdy (1991) and provides general guidance regarding the daily, weekly, monthly, and annual QA checks that need to be performed for maintaining the teletherapy system in a safe and operational state. Calibration of dosimetry equipment should be traceable to guidelines established by the National Institute of Standards and Technology (NIST).

4.7.2 Contributing Factors

Karzmark (1987) has noted that radiation overexposure can be the result of equipment failures, inadequate or non-existent procedures, or operator error. The above mishap in Ohio clearly underscores what can go wrong in the face of inadequate procedures, human error, and other contributing factors.

Respondents from the radiation oncology departments agreed that a set of procedures for systematically checking beam output and other treatment parameters is essential to guard against the type of miscalculation that skewed the predicted output graph at the hospital in Ohio. Although expert opinion no doubt varied during the mid-1970s on how often a cobalt-60 source should be checked, even then most hospitals realized the need for doing it on a periodic basis. Currently, the NRC requires that the dose rate be corrected mathematically for physical decay at intervals not exceeding one month and that this correction be verified by measurement each month. With the abundance of guidelines today for performing quality assurance tests, there is no absence of requisite knowledge for ensuring safe treatments. What was absent at the hospital in Ohio and is still absent today at some centers is a strong organizational commitment that ensures that the recommended procedures are effectively implemented. Recall at the hospital in Ohio that no one ever checked the physicist's calibrations or directed him to make a calibration.

Table 4.1 Daily, Weekly, Monthly and Annual QA Checks

Daily Checks

- Computer-control system self-diagnostic tests
- Machine operating parameters
- Interlock lamp test
- Laser-localization lights
- Optical distance indicator (ODI)
- Patient audio-visual communication
- Radiation warning lights
- Photon beam output constancy

Weekly Checks

- Light-radiation field congruence
- Radiation beam symmetry
- Electron beam radiation output constancy

Monthly Checks

- Emergency off switches and interlocks
- Mechanical and digital indicators (gantry, collimator, field size)
- Inspection of mechanical parts of the accelerator incl. blocking tray and treatment aids
- Constancy check of daily dosimetry system
- Photon beam energy (off-axis ratio)
- Electron beam energy (ionization depth ratio)

Annual Checks

- Emergency off switches and interlocks
- Mechanical and digital indicators (gantry, collimator, field size)
- Inspection of mechanical parts of the accelerator incl. blocking trays and treatment aids
- Machine alignment (isocenter check)
- Light-radiation field congruence
- Radiation beam symmetry
- Monitor chamber linearity and end effect
- Photon dose calibration (cGy/monitor unit)
- Electron dose calibration (cGy/monitor unit)
- Output field size dependence
- Percent depth doses for several field sizes
- Wedge factors
- Tray factors
- Off-axis factors
- Arc therapy

Source: Purdy, J.A., "Quality Assurance of External Beam Megavoltage Radiotherapy Equipment." In G. Starkschall & J. Horton (Eds.), *Proceedings of the American College of Medical Physics Symposium - Quality Assurance in Radiotherapy Physics*, Madison, WI: Medical Physics Publishing, 1991; Reprinted with permission of The American College of Medical Physics

It is not as likely that the above mishap would occur in today's teletherapy environment with its emphasis on quality assurance. However, the mishap identifies some other contributing sources of error that can still plague radiation oncology departments today. In the above mishap, the physicist inadvertently switched from linear graph paper with five squares per division to linear graph paper with six squares per division. In this case, something as benign as graph paper wreaked havoc. Whenever there is a change in the materials, test equipment, or other devices that may necessitate change in the measurement conventions, there is a cause for concern. Also when a task or procedure is transferred from one person to another, there is an element of risk that the procedures will be performed differently. In subsequent investigations of the Ohio mishap, the previous physicist indicated that he always used semi-log paper to chart the decay rate, not the linear paper. Also since the previous physicist was hired on a contract basis and interpersonal relationships were somewhat strained between him and hospital management when the new physicist was hired, the transfer or transitioning of operating procedure was less than it should have been between the two physicists.

There was also a question about the qualifications of the new physicist in the Ohio mishap. Although part of his training involved working with cobalt-60 at a university-based medical center, his limited clinical experience did not qualify him for certification from the American Board of Radiology. Inadequate qualifications and training may have been contributing factors in this situation.

4.7.3 Alternative Approaches and Their Assessment

The lack of organizational commitment rather than the availability of useful guidelines was identified as a continuing factor that helps explain why some departments may be lax in implementing a rigorous schedule of equipment checks and calibrations. Karzmark (1987) has noted that a "distinguishing feature of safety is the need for eternal vigilance" (p. 1600); however, eternal vigilance is not that easy to maintain. How does one encourage departments that may be lagging in their commitment to the necessary procedures? Once a new set of procedures are implemented, how does one ensure continued adherence to them? One approach is for a panel made up of administrators, oncologists, physicists, therapists, and human factors specialists to do some brainstorming on the organizational commitment issue. It would also be quite instructive to examine what techniques are employed for maintaining vigilance in other disciplines and industries where safety concerns are paramount. Although the above suggestion does not provide an immediate solution, it does follow a direction that a few hospitals are currently taking. Also in terms of acceptance, the suggested approach has the advantage of coming from the user population that would eventually implement it.

The lack of continuity that can occur whenever there are changes in procedure, test equipment, measurement conventions, or task reassignment constitutes a second contributing factor. Whenever changes in procedure occur or tasks are transferred from one person or group to another, there is renewed opportunity for error. Greater vigilance or monitoring needs to occur during the transition period to ensure continuity of operation. This is best accomplished by an evaluator or monitor that is independent of the involved parties. Once the new procedure has been established as viable and reliable, the period of transition monitoring can be ended. Another

approach is to run the two procedures in parallel until the viability of the new procedure becomes established and people demonstrate the necessary proficiency and comfort with it. Both approaches have the advantage of directing resources toward the change segment of the operation that is known to be susceptible to error. Resources are being targeted where needed. A disadvantage lies in the requirement for additional monitoring capability, thereby potentially increasing departmental resources and costs.

Inadequate qualifications and training were cited in the Ohio incident as potential contributing factors for not recognizing the importance of a systematic schedule of equipment checks and calibrations. Certification from professional certifying boards is frequently recommended or required. It is also endorsed here, but not as the final solution for training. Given the continuous introduction of new technology into the workplace, there are new skills and knowledge that must be acquired by personnel. For these new skills and knowledge, the most sensible alternative for reducing the likelihood of error is a systematic and orderly training process. In the training literature, systematic approaches to training are often known as *Systems Approach to Training* (SAT) or *Instructional Systems Development* (ISD). Most training approaches that claim the SAT or ISD label typically contain five phases: 1) analysis (to determine the tasks that need to be trained), 2) design (to specify the training objectives, conditions and standards), 3) development (to create the instructional materials based on the training objectives), 4) implementation (to conduct the actual training), and 5) evaluation (to provide feedback to training personnel regarding how well training objectives are achieved by students). The SAT and ISD approaches have been adopted by the military services, by private industry, and by a wide cross-section of government agencies. Their value for radiation oncology departments is that they take the guesswork out of training by specifying what needs to be trained, to what standards of performance, and to what level of effectiveness. It is ultimately the responsibility of the clinical department head to ensure that teletherapy personnel can perform newly acquired tasks to the standards expected. This is a managerial function most reasonably accomplished through periodic review and feedback to the training function regarding deficiencies in performance and changes in tasks.

4.8 Critical Task Area 8 — Radiation Field Alignment Accuracy

Precise placement of the radiation field relative to the patient's anatomy is a continuous concern throughout the course of therapy. Two imaging techniques used to assess radiation field position and target volume are portal images and verification images. Portal images are taken by exposing an x-ray film to only a small fraction of the daily treatment dose. Typically a double exposure image is taken, whereby the first exposure is made in the treatment field aperture mode (i.e., with blocks or multileaf collimator in place) and the second image is taken with the x-ray jaws fully opened (i.e., with the blocks removed or multileaf collimator retracted) to capture some of the patient's surrounding anatomy. The advantage of double exposure portal imaging is that the surrounding anatomy makes it easier to assess consistency of field placement; the disadvantage is that the patient is imaged under set-up rather than treatment conditions (i.e., it does not show the effect of patient motion during treatment). There is also some concern about the dosage contribution from the port films, especially on critical anatomical structures, given the trend of increasing the number of port films during the course of therapy (Jones, 1991).

Verification images, on the other hand, are single exposure images which are placed under the patient and record the delivery of the entire dose for a given field. Verification films record what happens during treatment. This includes the presence of radiation beam modifiers and the patient's motion. One limitation is that the viewing of the film comes after the treatment rather than before. Another limitation is the inability to view surrounding anatomy since the image is taken in the treatment field mode.

There is an accumulating body of empirical studies that show the occurrence of significant localization errors (approximately 1 cm or greater) is not that infrequent. Depending on the treatment site, they can occur 10 - 36% of the time (e.g., Byhardt, Cox, Hornberg & Lierman, 1978; Lam, Partowmah, Loo, & Wharam, 1987; Marks, Haus, Sutton & Griem, 1976; Rabinowitz, Broomberg, Goitein, McCarthy & Leong, 1985). There also is evidence (Marks et al., 1976) of an inverse relationship between frequency of localization errors and the number of portal films taken (e.g., the number of cases with errors greater than 1 cm decreased from 36% to 15% as the number of portal films increased from 9 to 24 throughout the treatment regime). If one can assume the relationship is causal, the results underscore the value for taking portal films more frequently than the conventional one time before the onset of treatment. There is considerable variation among treatment facilities in terms of the frequency of portal imaging. Given time, cost, and other pragmatic factors, most facilities do not regard daily imaging as feasible.

4.8.1 Tasks That Could Be Compromised

Tasks from the function and task analysis upon which field alignment errors have the most direct impact were organized under the subfunction of Portal Localization Films. This subfunction, in turn, was placed under the function Treatment Administration from the Control Console. Field alignment deviations also will impede the oncologist's efforts to monitor patient progress and treatment adequacy, which is the last function from the function and task analysis.

Treatment Administration from the Control Console

Portal localization films

- Place localization (x-ray) film in film receptacle on treatment machine.
- Enter exposure time in monitor units (linear accelerator) or exposure time (Co-60) required for film.
- Make film exposure.
- Open collimator fully.
- Make second exposure of open treatment field rectangle.
- Mark patient's name, date, and treatment parameters on film.

Monitor Patient Progress and Treatment Adequacy

- Review port localization film.
- Communicate unacceptability of treatment field location and document acceptable modification.

4.8.2 Contributing Factors

Because of the rather steep dose-response characteristics of both tumors and normal tissues, it is important that the extent of field placement uncertainties be appreciated as well as their possible influence on the outcome of therapy understood. Contributing factors to field placement errors include the day-to-day variations of the treatment field alignment, discrepancies between the conditions under which treatment was planned (on the simulator unit) and delivered, mechanical changes over time to equipment and accessories that have an impact on field alignment (e.g., alignment of laser lights, blocks shifting), and changes in the patient's position or anatomy. Although the factors that contribute to day-to-day variations associated with field alignment may overlap to some extent with the factors that contribute to variations in patient immobilization and positioning (Section 4.4), this earlier section focused on problems associated with achieving the same patient position (e.g., use of treatment aids, reliance on skin marks, therapist workload) while the present section focuses on problems associated with the taking of portal and verification films, and with comparing portal films to simulator films. These tasks are performed after the patient has been immobilized.

With respect to variations in the placement of the radiation field relative to the patient's anatomy, Rabinowitz et al. (1985) found a relatively modest average standard deviation of 3mm which was independent of anatomical site (e.g., brain, thorax, abdomen, pelvis). In their carefully executed study, Rabinowitz and associates were interested in examining day-to-day variation of portal films *per se* (i.e., uninterrupted by intended changes in set-up); however, in a typically busy department where a research protocol is not being implemented, day-to-day variations can result from numerous factors such as prescribed changes in the set-up procedure, rotating therapists, and by differing interpretations of poor quality portal films. Deviations in the registration of radiation fields also can be caused by gradual changes in tumor size or body contour.

On the other hand, variations that result from transferring a treatment plan from the simulator to the treatment machine are larger. By comparing portal films with their corresponding simulator films, Rabinowitz et al. (1985) were able to conclude that the "magnitude of the typical discrepancy between simulator and portal films is considerably greater than the typical variation from one portal film to the next" (p. 1862). It is commonly known that the quality of portal films is relatively poor; however, this may be only part of the problem. According to Rabinowitz and associates, even when the landmarks are clearly identified and highlighted on the portal films, the process of comparing portal films to simulator films is tedious and not that straight forward. Measurement of discrepancies is made more difficult by anatomic distortions (i.e., change in flexion of the head relative to the neck) that can occur and by

uncertain magnification factors of the portal films. These investigators also note that if research-oriented personnel who had unlimited time to make detailed quantitative comparisons found the task difficult, how much more so it must be for therapists in a busy therapeutic environment.

4.8.3 Alternative Approaches and Their Assessment

As noted above, there are differences among treatment facilities in terms of the frequency of portal imaging. Small departments more likely take the conventional approach of one port film at the beginning of treatment. Larger departments take weekly port films and a new port film with every change of set-up. Realistically, there is no universal number or dictum that can be issued for all departments to follow. The most recent report of the American Association of Physicists in Medicine (AAPM) Radiation Therapy Committee Task Group 40 (1994) on quality assurance recommends that portal or verification films of all fields be obtained at least once a week, while at the same time recognizing that "the frequency with which portal and verification films should be obtained depends upon the site treated, the immobilization device used, the individual patient's condition, and the degree of reproducibility that is sought" (p. 612).

On-line electronic portal imaging devices may soon serve as a viable alternative for improving patient imaging before and during treatment (e.g., Boyer, Antonuk, Fenster, Van Herk, Meertens, Munro, Reinstein & Wong, 1992). Advantages include viewing of the radiation fields on a video monitor within seconds, enhancing images and possibly improving the contrast of internal anatomical landmarks, and overall facilitating of image taking. Such advantages would certainly improve the detection of field alignment error and thereby reduce the likelihood of error on subsequent treatments. Quite desirable would be the capability to make easier quantitative comparisons between simulator and portal images by electronically overlaying the two images. At present, electronic portal imaging devices are quite expensive and somewhat cumbersome in size. Another challenge is avoiding information overload and learning how to effectively assimilate the wealth of information that is available.

With the current imaging technology, the most direct way to reduce the dose per portal image is to use a faster film/screen system. Jones (1991) recommends X-omatic G film with a copper screen system offered by Kodak made especially for port filming, claiming that the faster system has reduced port film dosage in other departments by 75%. While there were no stated advantages in using the faster film/screen system for greater detection or reduction of field alignment error, such a system merits closer examination, given the promise it holds for reducing the adverse consequences of unnecessary irradiation to critical structures while at the same time appearing quite feasible in terms of cost and resource constraints.

The random day-to-day variations in patient set-up are best controlled by an on-going systematic recording and review of portal and verification images for each site as part of the facility's QA program. In this regard, the AAPM Radiation Therapy Committee Task Group 40 (1994) report cautions against an overzealous correction of daily random position errors that if "overcorrected" may lead to larger, systematic errors. The Task Group's recommendation is to monitor the positioning errors that are observed for a few days and if they are persistent, then take corrective action. The task force also recommends weekly treatment film review conferences attended by all members of the planning team as a way of more effectively

controlling day-to-day variations as well as the inconsistencies between simulation and portal images. Given the sizable reported inconsistencies between simulation and portal images, orthogonal films which image the isocenter also should be obtained (in addition to images of the treatment field) when oblique or noncoplanar fields are used. Keeping track of the number of repeat films also is recommended as a way of providing an impetus for identifying persistent set-up problems and for making subsequent improvements (e.g., better patient marking systems, clearer instructions, or more effective immobilization devices). Finally, alternative corrective actions need to be discussed openly and the selected course of action documented and communicated to the appropriate staff members rather than allowing well-intended recommendations to be disregarded because of lack of accountability and follow-through.

4.9 Critical Task Area 9 — Radiation Treatment Delivery

Given sufficient attention to all the preceding functions and tasks that need to be performed, the actual delivery of the radiation treatment appears quite uneventful. Assuming that all the treatment parameters have been entered correctly and that the patient is not moving about on the treatment couch, treatment is initiated by pressing the "beam on" button from the control console. The therapist's primary task while the beam is on is to keep visual contact with the patient by means of the TV monitor at his or her workstation. The therapist and patient also are both able to initiate audio contact through a speaker system. Treatment is stopped by pressing the beam stop or emergency stop button if the patient is moving about, distressed or experiencing medical problems. Although most patients do not noticeably move about while the beam is on, various accounts related to the research team indicate that it does happen, especially with older, incoherent, or confused patients. If the therapist is distracted during this period or is engaged in competing tasks, there can be a delay in detecting that the patient is in distress or that the treatment machine is malfunctioning. Another reason the therapist needs to be very attentive is possible dislocation of beam altering devices (e.g., standard blocks, custom blocks, and wedges) just prior to or during treatment. Although occurring infrequently, the latch that holds the block tray assembly in place can weaken with continued use. When not checked periodically, block assemblies have been known to fall from the treatment head. If this happens, the patient can be injured and healthy, non-target tissue is exposed to radiation.

A situation that can have serious consequences with some Co-60 units is for the source to occasionally stick in the unshielded position. When a source gets stuck in an unshielded position, the radiation therapists have to intervene decisively to minimize radiation exposure both to the patient and to themselves. Two major factors that influence the ability of radiation therapists to intervene decisively are detection of the unshielded source and proficiency in the appropriate actions. Does the therapist receive an immediate or very early indication of the malfunction and can the therapist perform knowledgeably and swiftly during this infrequent but stressful event? There is evidence to suggest that improvements are needed with respect to both factors.

4.9.1 Tasks That Could Be Compromised

Several tasks are noted from the treatment administration function that could be jeopardized and not performed as effectively or as safely as the teletherapy system requires.

Treatment Administration from the Control Console

Radiation treatment delivery

- Monitor patient visually on TV monitor.
- Monitor patient on audio monitor.
- Stop treatment as necessary.
- Detect that source is stuck in open position.
- Re-shield source stuck in open position with emergency re-shielding capability from control console (if available).
- Escort patient from treatment room when source is stuck open.
- Manually re-shield source stuck in open position in treatment room.

4.9.2 Contributing Factors

At many facilities, technologists are given a number of ancillary tasks, some of which are performed during the radiation delivery period while the beam is on. For example, therapists can be observed receiving telephone calls from patients, from resident or attending physicians requesting information on patients, and from other departments within the hospital. They also have been observed performing dose calculations, billing patients, and doing other paperwork during the beam-on period. The performance of additional duties during the radiation treatment period is a work condition cited by therapists that adds to their workload and results in stress. If these tasks compete with the therapist's monitoring function while the beam is on (and it is difficult to assume there is no interference), there could be a delay in detecting and carrying out the appropriate actions for a patient who was visually in distress.

With respect to the occurrence of a stuck source, the more preoccupied therapists are with ancillary tasks during the radiation treatment period, the greater the likelihood that the indication for a stuck source in an unshielded position may go temporarily unnoticed. In the event that a source fails to be re-shielded at the end of the planned treatment time, the mechanical or digital timer counts down to zero, and the beam-on indicator on the control console remains lit or goes to an in-transit indication depending on the convention used by the manufacturer. If these indicators go unnoticed, the indication to the therapist that the radiation source is unshielded is the red indicator light over the door to the treatment room. The mechanical clock timer usually

clicks, serving as a signal that treatment is over. Upon hearing the click, the therapist may habitually get up from the control console and turn the console key to the off position without looking at the beam status indicator on the control console. The red light over the door should be on; however, this light comes on so many times during the day (whenever the door is opened) it may no longer serve a signaling function. In addition, the light is often located high, out of the field of normal vision. When the therapist enters the treatment room and is unaware of the stuck source, he or she should notice the scattered radiation detector in the treatment room that will be flashing red when the source is not completely shielded. Some therapists may become anxious at this point and act inappropriately. Given that habituation (i.e., a decrease in responsiveness given repeated presentation of stimuli) can occur in the monitoring of critical cues as a result of administering so many treatments day after day, combined with the rarity of an unshielded source situation, it is quite possible for such a condition to go unnoticed for several seconds. It is also possible for the therapist to unknowingly enter the treatment room while the source is unshielded.

Emergency procedures for responding to a source stuck in the unshielded position are typically posted outside each treatment room that contains a cobalt-60 treatment machine. Although these procedures appear to be clear and concise, none of the respondents that were interviewed indicated they ever received any training or dry-run exercises for responding decisively to unshielded sources. Incident reports have cited inappropriate actions on the part of the therapist that have resulted in unnecessary radiation exposure to patient and therapist alike. The relative infrequency of occurrence and the very stressful nature of such an event combine to make more difficult what may appear to be a simple sequence of actions. The likelihood that therapists will be able to perform these tasks confidently is greater if they first receive realistic, performance-based training that requires these activities to be practiced.

4.9.3 Alternative Approaches and Their Assessment

Three alternative approaches are proposed for improving the monitoring function during radiation treatment delivery and for responding decisively to those infrequent occasions when the Co-60 source remains unshielded.

Since the performance of tasks that may compete with the monitoring function during the radiation delivery period is a practice that is tacitly condoned or expected at some facilities, it is a work-related issue that is best resolved within the department, most reasonably within the context of the department's quality assurance program. Each department should be able to decide which tasks, if performed during the radiation treatment period, are likely to compete with patient monitoring. Those tasks that compete with this function can be reallocated to other qualified personnel or to non-treatment hours. New procedures may also need to be identified and tested for reducing the number of telephone calls to the therapist's workstation during treatment periods. Since the performance of ancillary tasks is just one factor that increases the therapist's workload during the treatment period, other factors that contribute to therapist stress (e.g., high patient load, getting behind schedule, complex treatments, machine malfunction) are also worth discussing within the quality assurance context. This recommendation has the advantage of not being resource-intensive and it is something that can be addressed by staff members in the department.

As mentioned above, it is quite possible for the therapist to become less responsive to cues that are associated with a stuck source since they are also present at other times. Due to the infrequent occurrence of stuck sources and the repetitive, automatic actions in response to control console and associated stimuli, it is possible for the therapist to enter the treatment room after the timer clicks off without noticing the lighted displays that indicate a stuck source. An audio alarm that is unique and specific to the stuck source condition is recommended. This would preclude the habituation effect and would allow the therapist to recognize the malfunction immediately, thereby eliminating several seconds or more of unintended exposure to the patient. An audio alarm has the advantage of directly addressing the potential problem and is relatively inexpensive.

Rather than allowing inappropriate actions to compound the adverse consequences of responding to an unshielded source, a more farsighted strategy would be to design and implement exercises that would specifically train therapists for responding to critical high-pressure and unexpected circumstances. Through realistic, simulated exercises — similar to airline cockpit emergency procedures training — therapists could be trained in scenarios that involve source malfunctions. Using very similar notions, Gaba and DeAnda (1988; 1989) have recreated the operating room environment for simulated anesthesiology training and research. Surgeons, anesthesiologists, and operating room nurses participate in exercises with simulated equipment faults and patient complications. Such training takes the guesswork out of what to do in an emergency and also helps to identify procedures that may look good on paper but fail when actually practiced. Just as good pilot training should strive to never let a pilot encounter a situation that has not been practiced before in simulated runs, therapists likewise should never be expected to respond to emergency situations that they have not practiced before. With such training, emergencies are reduced to a more manageable problem of situation recognition. Experienced therapists would recognize the situation they are in and respond automatically. While it may be somewhat expensive to build a training device that simulates a cobalt-60 machine with a stuck source at a high level of fidelity, using lower cost mock-ups with lesser levels of physical fidelity or dry-run exercises with existing machines are feasible alternatives. From a training perspective, functional fidelity is more important. Simulations and training exercises are most effective when they require the operator to process the same cues, make the same decisions, carry out the same actions, and be informed of the same consequences as would occur in their operational environments.

4.10 Critical Task Area 10 — Quality Assurance Procedures

A decade or so ago, quality assurance (QA) was considered the province of the physics department and focused primarily on the output and mechanical parameters of the treatment units. At that time, quality assurance was largely a facility-specific, voluntary effort of sound practices rather than today's more formalized practices and their inherent documented standards. While physics staff continue to play a central role in comprehensive quality assurance programs, it has become increasingly evident that effective quality assurance can not be limited to any one discipline or to any particular phase of teletherapy. Because errors, once initiated, can be propagated through successive phases of the therapeutic process, quality assurance is the concern of all staff members.

Peters and colleagues (1991) note that the "most essential ingredient of a QA program is the right state of mind. All staff — physicians, physicists, dosimetrists, therapists, nurses, and administrators — must be committed to QA. Once such a commitment is made, however, QA also requires resources" (p. 107). A similar requirement for commitment is expressed by Potocsny (1991) who states "before a department begins to design a QA program there should be philosophic agreement that QA is an essential part of quality treatment delivery and sound medical practice — not just bureaucratic lip service to licensing or accrediting agency regulations. A positive approach to QA has to emanate from the top — from the leadership of the department or institution" (p. 365).

It is noted that site visits were made before publication of NRC's (1991) *Regulatory Guide 8.33* on quality management programs. Not all the radiation therapy sites visited at the time of the study had implemented formal QA programs. In fact, there was considerable variation with respect to formal implementation of QA programs. Some facilities had limited QA procedures in place yet espoused the importance of QA; other facilities were proud of their QA efforts and were able to provide on-going records and documentation attesting to the accountability aspects of QA.

4.10.1 Tasks That Could Be Compromised

The absence of a comprehensive quality assurance program can affect a very wide range of tasks across all the teletherapy functional areas. The approach to this point has been to identify those task areas that, if compromised, would most likely affect human performance adversely and place the safe and effective operation of the teletherapy system in question. Because of the successive and interrelated nature of the teletherapy functions and tasks, it would be very difficult to isolate a smaller sub-set of functions and tasks as especially susceptible to lax quality assurance procedures. In brief, the absence of a comprehensive quality assurance program can adversely affect all the tasks performed as part of the teletherapy system. For this reason, and to underscore the requirement for pervasive and comprehensive quality assurance programs, all ten function areas are listed below.

- Diagnosis, Tumor Localization, and Identification of Initial Treatment Concerns
- Pre-Treatment Planning
- Treatment and Safety Equipment Checks, Adjustments and Maintenance
- Simulation
- Treatment Computer Data Files Set-Up
- Treatment Planning
- Custom Blocks
- Treatment Set-Up
- Treatment Administration from Control Console
- Monitoring of Patient Progress and Treatment Adequacy

4.10.2 Contributing Factors

A few reasons can be offered for the variation that was found at the sites visited with respect to implementation of quality assurance programs. These include the resources required for implementing a dedicated quality assurance program, the knowledge and skill-base for initiating a quality assurance program, and the sustainment of such programs.

A comprehensive quality assurance program that involves oncologists, physicists, dosimetrists, and therapists will seek continuous improvements in the way the department delivers therapy in order to minimize the difference between prescribed and delivered dose, prevent the delivery of unintended doses, and minimize the time between occurrence of an error and corrective action (Lane, Chow, Loyd, Laxton & Rosen, 1991). It is generally accepted that the active commitment of upper management is a necessary condition for successful quality assurance programs and that individual efforts at QA without full departmental support, guidance, resources, and procedures are likely to have limited impact. Part of the problem is the cost and resource requirements associated with quality assurance that are likely to compete with the goal of the business side of teletherapy to keep operational expenses as lean as possible. The costs/benefits of a comprehensive QA program are difficult to establish and not all department heads are convinced that the benefits justify the costs. While all departments are likely to espouse the value of quality assurance, only some commit to it in a real sense in terms of people, time, materials, and test equipment.

Of those facilities that make a decision to seriously commit to quality assurance, there is no guarantee they will be successful, have an impact, and realize the quality benefits. It is possible they may just increase operating expenses and lower profit margins. In brief, there is an execution or implementation aspect to quality assurance that can not be ignored. Some facilities are likely to execute their programs better than others and this accounts for a certain amount of the variance across programs. Both knowledge of the individual components of a QA program and skill in implementing these components in the treatment environment are required. Also complicating matters is the delicate task of introducing change into the workplace without the workforce resenting it.

Once started, quality assurance programs are difficult to sustain. At one site visited, the chief physicist indicated that the difficulty with implementing QA programs was in following through and in maintaining continuous emphasis on quality rather than allowing the program to "fizzle out." Many QA tasks are of a low visibility, mundane, and somewhat thankless nature. Many tasks are performed before or after treatment hours. It seems as though QA becomes most important after a mishap occurs, not before. Then renewed efforts are made for broader participation and discipline. No one is likely to be reinforced or told they did a great job in performing the calibration checks, in doing the chart reviews, or performing constancy source checks on the ion chambers. One can appeal to professional dedication and conscience, but even these qualities can wane if staff members perceive that higher status members in the department are giving lip service to QA. To maintain QA behavior, there is a need for multiple and interacting mutual support systems at all levels in the department.

4.10.3 Alternative Approaches and Their Assessment

In addressing the needs of those facilities that do not currently have well-formulated and implemented QA programs, a necessary alternative to the status quo is the active commitment and involvement of upper management. Management needs to initiate and provide the continuing structure for such programs. How does one get management to commit to the QA concept? There is no simple answer nor singular fix; however, the QA movement has gained momentum in recent years. Those people who advocated such programs years ago are no longer ignored. Starting with successes abroad and in non-medical industries, QA has become part of the American lexicon. Organizations that do not show evidence of improving their own internal processes are less likely to be well-received. Decisions of this nature are rarely made at a single point in time by an individual manager or in a purely rational manner, but instead are likely to be characterized by smaller incremental trends, uncertainty, political maneuvering, and gradual consensus among different sub-units in the organization (McCall, Kaplan & Gerlach, 1982; Simon, 1987). Successful advocates of change are sensitive to their own organizational climate; they know who the key stakeholders are, how to integrate and reconcile special interests, and how to take advantage of emerging forces that are shaping their disciplines. Likewise, the NRC has provided a nudge in the right direction. It has recognized the importance of quality assurance by amending regulations (10 CFR 35.32) governing therapeutic administrations of by-product material to require development and implementation of a basic quality management program. For each treatment modality involving by-product material (e.g., radiopharmaceutical therapy, teletherapy, brachytherapy, gamma stereotactic radiosurgery), NRC's *Regulatory Guide 8.33* has specific policies and procedures to ensure compliance with 10 CFR 35.32.

If there are multiple inputs to the decision-making process, the formal decision is merely a capstone to all the factors that have been taken into account through the informal consensus building period. The problem now becomes how one designs and implements a QA program. Fortunately, there is plenty of guidance available. In addition to NRC's *Regulatory Guide 8.33 Quality Management Program*, the professional societies offer well-formulated guidance for establishing QA programs. For example, to assist radiation oncology departments in meeting QA standards, the American College of Radiology has prepared *Quality Assurance Program in Radiation Oncology* (1989). A recent report, *Comprehensive QA for Radiation Oncology: Report of AAPM Radiation Therapy Committee Task Group 40* (1994), addresses advances in radiation oncology during the past decade and developments in the principles of QA. The American College of Medical Physics and the American Association of Physicists in Medicine also have issued reports and suggested protocols on the physical aspects of radiation therapy. Proceedings of dedicated conferences on QA as well as writings and observations of experienced practitioners/investigators are quite valuable. There are also workshops and consulting groups that provide training in necessary QA processes. Once a QA program is put into place, it will then be possible to determine how well it is serving the functions and tasks performed in a given department. Do some functions and tasks have reliable QA procedures, but others not? For example, if the number of treatment machine set-up errors made by therapists exceeds a certain criterion, it may be necessary to establish more formal procedures such as reading back machine settings to a second therapist once they are made. After corrective action is taken, monitoring and evaluation occur which provide documented evidence of the success or failure of the action.

If no improvement occurs, other potential contributing factors (e.g., patient scheduling system, labels on the machine interface, competing tasks) are examined for improvement. Further corrective actions are taken, and in turn, monitored and evaluated. Other troublesome functions and tasks that do not meet acceptable standards will necessitate different corrective actions drawn from a full array of potential human-system interface, procedural, training, and organizational solutions. These human factors solutions will have their greatest impact in reducing error in those departments that have well designed and implemented QA programs.

How does one maintain a continuous interest in QA once the initial enthusiasm starts to decline? To provide the on-going QA emphasis, first the program needs to provide the structure (i.e., new procedures, materials, test equipment, measurable criteria, review meetings) that becomes the departmental infrastructure for seeking continuous improvement. Without the structure, efforts at QA amount to little more than good intentions. Once the structure is in place, the next critical component for maintaining the program is to ensure that all levels within the department are complying with the QA procedures. This lets everybody in the department know that the program is intact and all members of the department have responsibility for it. With everybody performing QA procedures, the sources of maintenance for QA behavior become multiple and reciprocally supporting, thus making it easier to internalize basic QA principles.

5.0 CONCLUSION

The present report summarizes a series of human factors evaluations undertaken to identify the contributing causes of human error in teletherapy. Teletherapy (or external beam radiation therapy) was defined as a multi-disciplinary and multi-phased methodology for treating cancerous and other tissue through selective exposure to an external beam of ionizing radiation. The principal sources of radiation are a radioactive isotope (typically cobalt-60) or a linear accelerator device. To be safe and effective, treatment requires a concern for precision and consistency of human-human and human-machine interactions since it takes place on a daily basis (in fractions) over a period of weeks.

There were five preceding phases of this study which provided the foundation and framework for the present effort: 1) a function and task analysis of the teletherapy activities, 2) evaluation of human-system interfaces, 3) evaluation of the procedures used by teletherapy staff, 4) evaluation of training and qualifications of teletherapy staff, and 5) evaluation of organizational practices and policies. As a summary report, the present effort focused on the most significant critical task areas that if compromised could contribute to human error in the teletherapy setting, and also on an identification and assessment of alternative approaches to the problems.

Table 5.1 identifies the ten critical task areas (starting with pre-treatment planning and ending with quality assurance procedures) that were considered to have significant consequences for effective treatment and teletherapy system safety if not performed properly. Along the left hand margin are arranged the major contributing factors which serve to have an adverse impact on task performance and contribute to human error. The list of contributing factors was generated by examining and consolidating the contributing factors that were cited in the preceding section. The cell entries refer to frequency of citation.

The table shows that for any given critical task area, there are two to four major contributing factors that if present, either singly or in combination, can jeopardize safe and effective operation of the system. There are very likely other factors of a less obvious nature and not reported in the table that are also exerting their influence on task performance. This multiplicity of contributing factors limits the usefulness of alternative approaches that focus on singular fixes to the neglect of factors that interact and permeate the system. The pervasiveness of the contributing factors also suggests that approaches that address the problem in one task area also are likely to be beneficial for performance in another task area.

Figure 5.1 displays the relative pervasiveness of the individual contributing factors. The bar chart was derived by dividing the number of citations or references to each contributing factor (as portrayed in Table 5.1 and as discussed throughout Section 4.0) for the critical task areas by the total number of citations. Although generalization of the citation values beyond the confines of the study is unwarranted, the actual relative ordering of contributing factors has good face validity and is compatible with the internal assessments of research and subject matter expert personnel.

Table 5.1 Citation of Contributing Factors with Respect to Critical Task Areas

Contributing Factors	Critical Task Areas									
	Pre-treatment Planning	Treatment Planning Computer Data Files	Use of Patient Chart	Patient Positioning and Immobilization	Treatment Set-Up	Data Transfer	Equipment Checks and Calibration	Radiation Field Alignment Accuracy	Radiation Treatment Delivery	Quality Assurance Procedures
Workload	1			1	1	1		1		
Design of Equipment/ Materials		1	1	1		1			1	
Inadequate Procedures	1	1		1			1			
Inadequate Communication	1		2				1			
Inadequate Resources/Staffing	1				1		1			1
Qualifications and Training		1					1		1	
Repetitive Data Input						2				
Competing Tasks					1				1	
Physical Layout					1					
Task Difficulty								1		
Day-to-Day Variation								1		
Implementation Skill										1

The major contributing factors, the multiple task areas upon which they have an impact, and suggested alternative approaches are summarized below.

Workload — Excessive workload probably can jeopardize performance in all the task areas; however, workload was cited specifically as a contributing factor in pre-treatment planning, patient positioning and immobilization, treatment set-up, data transfer, and radiation field alignment. When workload pressures impinge upon teletherapy staff, it is not surprising that pre-treatment planning conferences are neglected, that patient positioning errors are made, that the wrong block is selected for treatment set-up, that the wrong data are transferred to the Record and Verify system, or that hasty judgements are made regarding the accuracy of radiation field alignment. Alternative approaches for alleviating excessive workload included adequate staffing, better patient scheduling systems that avoid peak load conditions, better job design for eliminating sources of interruption, reallocation of tasks to other personnel, and incorporating new portal imaging technology once it has been tested and shown to be cost-effective.

Figure 5.1 Relative Pervasiveness of Contributing Factor Citations to Critical Task Areas

Design of Equipment/Materials — The design of the equipment and materials was cited as a potentially compromising factor to satisfactory task performance during treatment planning, use of the patient chart, treatment set-up, data transfer, and radiation treatment delivery. Among the problems are the opaque nature of electronic storage of treatment data files, chart lay-out and legibility as sources of confusion, less than optimal patient support systems (i.e., treatment couches and immobilization devices), lack of visual spacing cues on computational tasks, and Co-60 machines where the source can get stuck in an unshielded position. Among the offered alternatives were improved interfaces to treatment planning computers for making opaque operations more visible, modifying the design of the chart and improving legibility of entries, greater research and design efforts to focus on reproducible patient support and immobilization systems, and initiating performance-based training procedures for responding to stuck sources.

Inadequate Procedures — Inadequate procedures (or lack of procedures) were found to contribute to sub-standard task performance in a number of areas. Among those task areas were pre-treatment planning, treatment planning computer data files, patient positioning and immobilization, and equipment checks and calibration. In brief, inadequate procedures can result in teletherapy staff not having a full understanding of the treatment parameters for an impending treatment, or in not setting up the correct parameters in the treatment planning computer. In the absence of clearly written procedures, different therapists can set-up, position and immobilize the same patient in different ways. Without a periodic measurement procedure, the radiation physicist is less likely to compare the output of a Co-60 treatment machine against predicted values and ensure that the treatment is safe. Alternative approaches for alleviating procedure deficiencies include establishing and implementing new procedures where absent, eliminating ambiguity and lack of specificity with existing procedures, and obtaining the necessary organizational commitment for a system-wide on-going implementation of the procedures. These approaches are best addressed within the context of the facility's quality management program.

Inadequate Communication — Inadequate communication is another factor that can degrade performance in many if not all of the task areas. The adverse effects of inadequate communication were especially noted during pre-treatment planning, use of the patient chart, and equipment checks and calibration. Speaking and comprehending English as a second language, interpersonal conflict, cultural diversity, and status differentials can serve as barriers to verbal communication. Written communication can be compromised by illegible handwriting, lack of detail in instructions, unwarranted assumptions, failure to disseminate changes in procedure, or using a verbal channel of communication to begin treatment rather than a written prescription. Suggested alternatives included establishing effective communication protocols for both written and spoken communications, expecting and training staff to engage in effective communication practices (e.g., repeating back directives before taking action), and offering workshops for becoming more sensitive to the daily barriers to effective communication.

Inadequate Resources/Staffing — Table 5.1 shows that inadequate levels of staffing and resources can have an adverse impact on pre-treatment planning, treatment set-up, equipment checks and calibration, and quality assurance procedures. With increasing health-care costs, hospitals are moving to decrease operational expenses including using fewer therapists and dosimetrists. The services of the medical physicists are increasingly acquired on a contract basis. Understaffing was one of the work conditions reported by therapists as most stressful. Approximately one-quarter of the sites visited were understaffed by one therapist. When a therapist leaves out a wedge while treating a patient, it is a bit simplistic to focus solely on human error as the culprit when the organizational setting and work conditions — understaffing, high patient load, complex treatments, getting behind schedule, environmental distractions — combine in such a way to promote the occurrence of such errors. It was recommended that radiation oncology departments undertake renewed efforts to ensure adequate staffing levels (i.e., more in line with the guidelines established by the *Radiation Oncology in Integrated Cancer Management - Report of the Inter-Society Council for Radiation Oncology*, 1991) and that educational efforts help inform department heads on the latent effects that staffing and resource decisions can have on quality care of patients.

Qualifications and Training — The qualifications that one brings to the job as a result of formal education and the training received once hired are essential for satisfactory performance in all of the critical task areas. In the present analysis, deficiencies in personnel qualifications and training were cited in treatment planning computer data files set-up, equipment checks and calibration, and radiation treatment delivery. For example, there is no systematic form of training to learn a new treatment planning software package or for setting up and maintaining data files other than vendor-provided training and self-learning. Questions were raised about the qualifications and training of the physicist in the Ohio overdoses. Inappropriate actions on the part of therapists in responding to stuck Co-60 sources have implicated a need for training. Alternative approaches called for initiating more systematic and accountable methods for new equipment training, hiring individuals who are certified through professional certifying boards, and conducting realistic, dry-run exercises for responding to stuck Co-60 sources.

Repetitive Data Input — The inherent characteristics of some tasks make them susceptible to error. The repetitive quality of data input operations contributes to data transfer errors at various points throughout the teletherapy process (e.g., during input of data to the treatment planning system, when preparing the patient's treatment chart, during input of parameters to the Record and Verify system, and while modifying parameters at the first session). These tasks are characterized by a skilled sensorimotor, repetitive, and automatic quality, performed in an immediate visual field of highly similar stimuli (e.g., look alike alpha-numeric characters) that provides an ample source of interference. Compounding the problem, such tasks are frequently performed under time-pressured conditions. These types of errors are fairly resistant to change. A multi-prong programmatic effort that has the following components merits consideration: re-scheduling the performance of data transfer tasks to less time-pressured conditions, removing sources of distraction, improving visual spacing and perceptual cues of numerical tables and forms, trying out innovative vigilance procedures for early detection of errors, and relying less on manual data input through incorporation of new technology.

Competing Tasks — Competing tasks are not independent of the other contributing factors. They no doubt are influenced by conditions of understaffing, and in turn, serve to increase workload. Two task areas where their presence is especially noticeable are treatment set-up and radiation treatment delivery. The slips and lapses that can occur during treatment set-up (e.g., setting the wrong field size, omitting a wedge, using the wrong tattoos) have their origin in the diversion of attention that competing tasks promote. Likewise, therapists that perform ancillary tasks during treatment delivery while the beam is on may not be that attentive to patients in distress or malfunctioning treatment machines. Departments that tacitly condone or expect therapists to perform ancillary tasks during the radiation delivery period need to re-examine the practice. Renewed efforts at judicious job design (i.e., where competing tasks can be reallocated to someone else or to non-treatment hours) represents a viable alternative. Since the performance of competing tasks is just one factor that increases the therapist's workload, it is best addressed along with other workload factors (e.g., patient load, getting behind schedule, complex treatments) within the context of the facility's quality management program.

Physical Layout, Task Difficulty, Day-to-Day Variation, and Implementation Skill — Occurring less frequently as contributing factors to sub-standard task performance, yet serving to interact and combine with other factors are the physical layout of the therapist's workspace, the difficulty of performing certain tasks such as comparing simulator films with portal films, the day-to-day variation that exists in treatment field alignment, and the implementation skill required for effectively executing a quality management program. The design of workspace needs to be such that patient and co-worker traffic flow does not interfere with the therapist's primary treatment tasks and that the physical proximity of team members is such that they are accessible to one another. To alleviate the difficulty of comparing simulator and portal films, new electronic imaging technology that has the capability of overlaying simulator and portal images needs to be explored and further developed for cost-effective utilization. The day-to-day variation that exists in radiation field alignment is best controlled by a systematic recording of portal images and holding of weekly film review conferences attended by appropriate members of the treatment team. And finally, the implementation skill that is required for initiating and sustaining successful quality management programs is greatly aided by departmental commitment and an infrastructure (i.e., new procedures, materials, test equipment, measurable criteria, and review meetings) that allow all members of the department to have an active role in seeking continuous improvement.

6.0 REFERENCES

- American Association of Physicists in Medicine, "Comprehensive QA for radiation oncology: Report of AAPM Radiation Therapy Committee Task Group 40," *Medical Physics*, 21, pp. 581-618, 1994.
- American Association of Physicists in Medicine, *Physical Aspects of Quality Assurance in Radiation Therapy*, Report No. 13, New York: American Association of Physicists in Medicine, 1984.
- American College of Medical Physicists, *Radiation Control and Quality Assurance in Radiation Oncology: A Suggested Protocol*, Report No. 2, Reston, VA: American College of Medical Physicists, 1986.
- American College of Radiology, *Quality Assurance Program in Radiation Oncology*, Reston, VA: American College of Radiology, 1989.
- Bentel, G.C., C.E. Nelson, & K.T. Noell, *Treatment Planning & Dose Calculation in Radiation Oncology*, Elmsford, NY: Pergamon Press, 1989.
- Boyer, A., L. Antonuk, A. Fenster, M. Van Herk, H. Meertens, P. Munro; L.E. Reinstein, & J. Wong, "A Review of Electronic Portal Imaging Devices (EPIDs)," *Medical Physics*, 19, 1-16, 1992.
- Byhardt, R.W., J.D. Cox, A. Hornberg, & G. Lierman, "Weekly Localization Films and Detection of Field Placement Errors," *International Journal of Radiation Oncology/Biology/Physics*, 4, 881-887, 1978.
- Gaba, D.M. & A. DeAnda, "A Comprehensive Anesthesia Simulated Environment: Recreating the Operating Room for Research and Teaching," *Anesthesiology*, 68, 387-394, 1988.
- Gaba, D.M. & A. DeAnda, "The Response of Anesthesia Trainees to Simulated Critical Incidents," *Anesthesia and Analgesia*, 68, 444-451, 1989.
- Gastorf, R.J., M.R. Harris, & J.L. Horton, "Patient Calculations and Radiotherapy Chart Review," In G. Starkschall and J. Horton (Eds.), *Quality Assurance in Radiotherapy Physics - Proceedings of an American College of Medical Physics Symposium*, Madison, WI: Medical Physics Publishing, 1991.
- Hendrickson, F.R., "Precision in Radiation Oncology," *International Journal of Radiation Oncology/Biology/Physics*, 8, 311-312, 1982.

- Henriksen, K., R.D. Kaye, R. Jones, D.S. Morisseau & S.I. Serig, *Human Factors Evaluation of Teletherapy: Volume IV Training and Organizational Analysis*, NUREG/CR-6277, Washington, D.C.: U.S. Nuclear Regulatory Commission, 1995.
- Henriksen, K., R.D. Kaye, R. Jones, D.S. Morisseau & S.I. Serig, *Human Factors Evaluation of Teletherapy: Volume V Literature Review*, NUREG/CR-6277, Washington, D.C.: U.S. Nuclear Regulatory Commission, 1995.
- Jacky, J. "Programmed for Disaster," *The Sciences*, 29, 22-27, 1989.
- Jones, L.W., "Port Film Dosage in Radiation Therapy," *Radiologic Technology*, 62(5), 362-368, 1992.
- Karzmark, C.J., "Procedural and Operator Error Aspects of Radiation Accidents in Radiotherapy," *International Journal of Radiation Oncology/Biology/Physics*, 13, 1599-1602, 1987.
- Kaye, R., K. Henriksen, R. Jones, D.S. Morisseau & S.I. Serig, *Human Factors Evaluation of Teletherapy: Volume II Function and Task Analysis*, NUREG/CR-6277, Washington, D.C.: U.S. Nuclear Regulatory Commission, 1995.
- Kaye, R., K. Henriksen, R. Jones, D.S. Morisseau & S.I. Serig, *Human Factors Evaluation of Teletherapy: Volume III Human-System Interface and Procedures*, NUREG/CR-6277, Washington, D.C.: U.S. Nuclear Regulatory Commission, 1995.
- Lam, K.S., M. Partowmah, D.J. Loo & M.D. Wharam, "On-line Measurement of Field Placement Errors in Extended Beam Radiotherapy," *British Journal of Radiology*, 60, 361-367, 1987.
- Lane, R.G., C.H. Chow, M.D. Loyd, J. Laxton & I.I. Rosen, "One Perspective of Quality Assurance in Radiation Therapy," In G. Starkschall and J. Horton (Eds.), *Quality Assurance in Radiotherapy Physics - Proceedings of an American College of Medical Physics Symposium*, Madison, WI: Medical Physics Publishing, 1991.
- Leunens, G., J. Verstraete, W. Van den Bogaert, J. Van Dam, A. Dutreix, E. van der Schueren, "Human Errors in Data Transfer during the Preparation and Delivery of Radiation Treatment Affecting the Final Result: 'Garbage In, Garbage Out,'" *Radiotherapy and Oncology*, 23, 217-222, 1992.
- Marks, J.E., A.G. Haus, H.G. Sutton, & M.L. Griem, "The Value of Frequent Treatment Verification Films in Reducing Localization Error in the Irradiation of Complex Fields," *Cancer*, 37, 2755-2761, 1976.
- McCall, M.W., Jr., R.E. Kaplan, & M.L. Gerlach, *Caught in the Act: Decision Makers at Work*, Technical Report No. 20, Greensboro, N.C.: Center for Creative Leadership, 1982.

- Mohan, R., K.C. Podmaniczsky, R.Caley, A. Lapidus, & J.S. Laughlin, "A Computerized Record and Verify System for Radiation Treatments," *International Journal of Radiation Oncology/Biology/Physics*, 10, 1975-1985, 1984.
- Norman, D.A., "Categorization of Action Slips," *Psychological Review*, 88, 1-15, 1981.
- Norman, D.A., *The Design of Everyday Things*, New York: Doubleday, 1988.
- Peters, L.J., D. Browning, A.S. Potocsny, & J.L. Horton, "Departmental Support for a Quality Assurance Program," In G. Starkschall and J. Horton (Eds.), *Quality Assurance in Radiotherapy Physics - Proceedings of an American College of Medical Physics Symposium*, Madison, WI: Medical Physics Publishing, 1991.
- Perez, C.A., & L.W. Brady, "Overview," In Perez, C.A. & Brady, L.W. (Eds.), *Principles and Practice of Radiation Oncology*, Philadelphia, PA: J.B. Lippincott Company, 1992.
- Potocsny, A. "Quality Assurance: A Technologist's Point of View," In G. Starkschall and J. Horton (Eds.), *Quality Assurance in Radiotherapy Physics - Proceedings of an American College of Medical Physics Symposium*, Madison, WI: Medical Physics Publishing, 1991.
- Purdy, J.A., "Quality Assurance of External Beam Megavoltage Radiotherapy Equipment," In G. Starkschall & J. Horton (Eds.), *Proceedings of the American College of Medical Physics Symposium - Quality Assurance in Radiotherapy Physics*, Madison, WI: Medical Physics Publishing, 1991.
- Rabinowitz, I., J. Broomberg, M. Goitein, K. McCarthy, & J. Leong, "Accuracy of Radiation Field Alignment in Clinical Practice." *International Journal of Radiation Oncology/Biology/Physics*, 11, 1857-1867, 1985.
- Rasmussen, J., "A Taxonomy for Describing Human Malfunction in Industrial Installations," *Journal of Occupational Accidents*, 4, 311-333, 1982.
- Rasmussen, J., *Information Processing and Human-machine Interaction - An Approach to Cognitive Engineering*, New York: North Holland, 1986.
- Reason, J.T., "Actions Not As planned: The Price of Automatization," In G. Underwood & R. Stevens (Eds.), *Aspects of Consciousness, Volume I: Psychological Issues*, London: Wiley, 1979.
- Reason, J., *Human Error*, Cambridge: Cambridge University Press, 1990.
- Reinstein, L.E., & A.G. Meek, "Recommendations of the Workshop on Geometric Accuracy and Reproducibility in Radiation Therapy," *Medical Dosimetry*, 12, 27-33, 1987.

Rubin, L.S., "The Riverside Radiation Tragedy," *Columbus Monthly*, 52-65, May, 1978.

Simon, H., "Making Managerial Decisions: The Role of Intuition and Emotion," *Academy of Management Executive*, 1, 57-64, 1987.

Starkschall, G., (Ed.), *Proceedings of a Symposium on Quality Assurance of Radiotherapy Equipment*, New York: American Association of Physics in Medicine, 1983.

Svensson, G.K., "Quality Assurance in External Beam Radiation Therapy," *Radiographics*, 9, 169-182, 1989.

Swann-D'Emila, B., J.C.H. Chu, & J. Daywalt, "Misadministration of Prescribed Radiation Dose," *Medical Dosimetry*, 15, 185-191, 1990.

U.S. Nuclear Regulatory Commission, "Quality Management Program," *Regulatory Guide* 8.33. Washington, DC: U.S. Government Printing Office, 1991.

7.0 GLOSSARY

<i>Absorbed dose</i>	Energy per unit mass imparted by ionizing radiation to a small mass of material.
<i>Beam</i>	Directed radiant energy, such as an x-ray or electron beam, normally limited in cross section by the mechanism of generation or by collimating apertures or other beam-shaping devices.
<i>Block</i>	A piece of metal (lead or lead alloy) that is positioned under the beam to prevent radiation from reaching a specific part of anatomy. These can be standard blocks which come in a variety of shapes and are positioned on the block tray during each treatment, or custom blocks which are specially made for a specific patient's treatment, and attached to a block tray. Custom blocks are most often used to define an irregular field.
<i>Block tray</i>	A square flat piece of plastic on which blocks are attached (custom blocks) or positioned (standard blocks).
<i>Bolus</i>	Tissue equivalent material placed on the surface of the patient to even out irregular contours for adjusting dose distribution to the tissues beneath it.
<i>Calibration</i>	Process of determining the exposure rate or absorbed dose rate at a calibration point in the beam under a closely specified set of conditions.
<i>Cobalt-60</i>	A radionuclide with a half-life of 5.27 years used as a gamma radiation source in teletherapy.
<i>Collimator</i>	An arrangement of shielding material designed to define the dimensions of a beam of radiation.
<i>Divergence</i>	The geometric spreading of a beam's field size with increasing distance from the source.
<i>Dosimetrist</i>	An individual who has received specific training in the aspects of dosage measurement and calculation as related to radiation therapy.
<i>Field size</i>	The dimensions of the treatment field (<i>width x length</i>) as indicated by the collimator setting.
<i>Fluoroscopy</i>	Examination by means of an instrument (the fluoroscope) that projects x-ray shadows on a fluorescent screen, used to visualize the form and motion of deep structures of the body.

<i>Gantry</i>	The portion of the treatment machine that supports the treatment head and rotates about the isocenter on a horizontal axis.
<i>Gantry angle</i>	The angle of the isocentrically mounted gantry relative to its vertical downward position.
<i>Gray (Gy)</i>	Unit of absorbed dose ($1 \text{ Gy} = 1 \text{ J/kg} = 100 \text{ rads}$).
<i>Inverse square law</i>	Mathematical relation that describes the decrease in radiation intensity as the beam diverges. The intensity is inversely proportional to the square of the distance from the source.
<i>Ionization</i>	The process by which a neutral atom acquires a positive or negative charge. Ionization can be caused by high temperatures, electrical discharges, or nuclear radiations.
<i>Isocenter</i>	The imaginary point in space around which the treatment head (more precisely, the center of the collimator on the treatment head) rotates. This point is used as a reference for isocentric treatments.
<i>Isocentric treatment technique</i>	A treatment technique whereby the tumor center is positioned at isocenter with the aid of the adjustable treatment couch, side and ceiling laser lights, and skin marks. With the tumor positioned at isocenter, it can be accurately and conveniently irradiated from any desired gantry angle.
<i>Isodose chart</i>	A family of isodose curves usually drawn for equal increments of percentage depth dose, representing the distribution of absorbed dose in a specified plane for a specified beam.
<i>Isodose curve</i>	A line typically depicted in a plane along which the absorbed dose is constant.
<i>Light field</i>	A light projected on the patient's body surface which geometrically mimics the surface area of the treatment beam. The illuminated area is used to identify the area of treatment beam entry when setting up the patient for treatment.
<i>Linear accelerator</i>	Device used for accelerating charged particles using microwave radiation.
<i>MU</i>	Linear accelerator units specify amount of radiation exposure by monitor units (MU), while the counterpart for cobalt-60 machines is treatment time.
<i>Optical distance indicator</i>	A light device used to indicate the distance of the patient from the treatment source.

<i>Phantom</i>	A volume of tissue-equivalent material, usually used to measure the characteristics of radiation beams as they pass through the material.
<i>Port film</i>	An x-ray image taken with the patient interposed between the treatment machine and x-ray film. The film helps to determine the adequacy of the treatment beam with respect to encompassing the intended volume and minimizing exposure to adjacent critical structures.
<i>Positioning laser</i>	Small laser beams located in the treatment room that converge on the isocenter. They are used to position the patient. Tattoos frequently are used to mark the position at which positioning lasers shine on the patient when the patient is in the proper position.
<i>Quality assurance</i>	The combined department-wide systematic activities that seek to ensure the safe and effective implementation of therapy. This includes a continuing evaluation of the adequacy and effectiveness of therapeutic operations through feedback, timely correction, and periodic auditing mechanisms.
<i>Rad</i>	Unit of radiation absorbed dose which equals 0.01 Gray or 1 cGy (1 Gy = 100 rad).
<i>Radiation field</i>	Surface area on the patient defined by the passage of the treatment beam through the skin surface.
<i>Radiation oncologist</i>	A physician who has specialized in radiation oncology and is responsible for clinical consultation and evaluation of patients to determine suitability for therapy, the appropriate dose prescription, the optimal plan of treatment, the required treatment supervision, weekly reviews to evaluate changes in clinical status, and follow up evaluations for assessing tumor response.
<i>Radiation oncology</i>	A clinical medical specialty with a specific interest in the study and treatment of tumors, particularly as it relates to treatment with ionizing radiations.
<i>Radiation physicist</i>	A physicist recognized by professional education or certification as qualified to secure the safe and effective delivery of radiation therapy through such activities as calibration and maintenance of the equipment in accord with accepted protocols; acceptance testing and commissioning of therapy units and planning systems; and contribution of subject matter expertise to treatment planning and quality assurance (QA) procedures.

<i>Radiation therapist</i>	A skilled professional qualified by education that provides radiation therapy-related services under the supervision of a radiation oncologist or radiation physicist. Responsibilities most closely associated with radiation therapists are the daily setting-up, delivery, and recording of radiation treatments.
<i>Record and Verify System</i>	A computer-based program that compares the treatment that has been set up with a record of the intended treatment. Treatment parameters that may be verified include field size, collimator and gantry angles, couch position, daily dose for a given field, and preset monitor units that provide the dose. Such systems identify and prevent set-up errors prior to treatment when the errors exceed a preset magnitude (e.g., more than one degree of arc).
<i>Regulatory Guide 8.33 Quality Management Program</i>	In recognizing the importance of quality management, the NRC has amended regulations governing therapeutic administrations of by-product material. For each treatment modality involving by-produce material (e.g., radiopharmaceutical therapy, teletherapy, brachytherapy, gamma stereotactic radiosurgery), guidance is provided to licensees and applicants for developing a quality management program acceptable to the NRC for complying with 10 CFR 35.32.
<i>Rotation therapy</i>	External beam teletherapy in which the source of radiation moves circumferentially relative to the patient (while centered in the volume of interest).
<i>SAD</i>	Source-to-axis distance (i.e., source-to-isocenter distance) is the distance from the front surface of the source to the isocenter.
<i>Simulation</i>	The use of a simulator (diagnostic-quality x-ray beam on a therapy mounting) to determine the various treatment field outlines and orientations to be used in a course of radiation therapy.
<i>Simulation film</i>	An x-ray taken on the treatment simulator that shows the position of the treatment field with respect to bony landmarks.
<i>Simulator</i>	A radiation generator operating with a diagnostic x-ray beam that has the mechanical capability to orient this beam toward a patient using parameters that imitate those proposed for therapy. It often provides direct x-ray fluoroscopic visualization of the area in question.
<i>SSD</i>	Source-to-surface distance, or the distance measured along the beam axis from the front surface of the source to the surface of the irradiated object.

<i>Tattoos</i>	Small indelible marks made on the patient's skin to indicate field centers and edges. These marks often are indicated on the set-up diagram in the patient's chart, on photographs of the patient, and on the x-ray films taken by the simulator unit.
<i>Teletherapy</i>	The delivery of radiation treatments to the patient from a machine located remote from the body.
<i>Treatment Head</i>	The housing for the radioactive source (typically Co-60) constructed of high density shielding material. The treatment head most often attached to the treatment machine via the gantry.
<i>Treatment Port or Treatment Field</i>	The area on the patient's body at which the treatment beam penetrates. Generally referred to as the location of a treatment field on a patient.
<i>Wedge or Wedge Filter</i>	A metal wedge-shaped accessory placed beneath the treatment beam which causes a progressive decrease in the dose rate across the whole or part of a beam.

Note: Two sources needing to be acknowledged for their usefulness in constructing the above glossary are Mizer, S., Scheller, R.R., & Deye, J.A., *Radiation Therapy Simulation Workbook*, Elmsford, NY: Pergamon Press, 1986, and Stanton, R., D. Stinson, *An Introduction to Radiation Oncology Physics*, Madison, WI: Medical Physics Publishing, 1992.

BIBLIOGRAPHIC DATA SHEET

(See instructions on the reverse)

1. REPORT NUMBER
(Assigned by NRC. Add Vol., Supp., Rev.,
and Addendum Numbers, if any.)
NUREG/CR-6277
Vol. 1

2. TITLE AND SUBTITLE

Human Factors Evaluation of Teletherapy

Identification of Problems and Alternative Approaches

3. DATE REPORT PUBLISHED

MONTH YEAR

July 1995

4. FIN OR GRANT NUMBER

L1532

5. AUTHOR(S)

K. Henriksen, R. D. Kaye, R. Jones, Hughes Training, Inc.
D. S. Morisseau, D. I. Serig, Nuclear Regulatory Commission

6. TYPE OF REPORT

Technical

7. PERIOD COVERED (Inclusive Dates)

1990 - 1995

8. PERFORMING ORGANIZATION - NAME AND ADDRESS (If NRC, provide Division, Office or Region, U.S. Nuclear Regulatory Commission, and mailing address; if contractor, provide name and mailing address.)

Hughes Training, Inc.
5111 Leesburg Pike, Suite 300
Falls Church, VA 22041

9. SPONSORING ORGANIZATION - NAME AND ADDRESS (If NRC, type "Same as above"; if contractor, provide NRC Division, Office or Region, U.S. Nuclear Regulatory Commission, and mailing address.)

Division of Systems Technology
Office of Nuclear Regulatory Research
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

10. SUPPLEMENTARY NOTES

11. ABSTRACT (200 words or less)

A series of human factors evaluations were undertaken to better understand the contributing factors to human error in the teletherapy environment. Teletherapy is a multi-disciplinary methodology for treating cancerous tissue through selective exposure to an external beam of ionizing radiation. A team of human factors specialists, assisted by a panel of radiation oncologists, medical physicists, and radiation therapists, conducted site visits to radiation oncology departments at community hospitals, university centers, and free-standing clinics. A function and task analysis was initially performed to guide subsequent evaluations in the areas of system-user interfaces, procedures, training and qualifications, and organizational policies and practices. The present work focuses solely on training and qualifications of personnel (e.g., training received before and during employment), and the potential impact of organizational factors on the performance of teletherapy. Organizational factors include such topics as adequacy of staffing, performance evaluations, commonly occurring errors, implementation of quality assurance programs, and organizational climate.

12. KEY WORDS/DESCRIPTORS (List words or phrases that will assist researchers in locating the report.)

Teletherapy	Human-System Interfaces
Medical Device(s)	Training and Qualification
Human Factors Evaluation	Task Analysis
Human Error	Teletherapy Procedures
Teletherapy Errors	Organizational Policies and Practices
Medical Misadministration	Teletherapy Training
Organizational Analysis	
Medical Quality Management	
Medical Systems	
Radiation Therapy	

13. AVAILABILITY STATEMENT

Unlimited

14. SECURITY CLASSIFICATION

(This Page)

Unclassified

(This Report)

Unclassified

15. NUMBER OF PAGES

16. PRICE