NUREG/CR-6277
Vol. 5

Human Factors Evaluation of Teletherapy

Literature Review

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Prepared for
U.S. Nuclear Regulatory Commission

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Manuscript Completed: June 1995
Date Published: July 1995

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Washington, DC 20555-0001
NRC Job Code L1532

ABSTRACT

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 performed initially to guide subsequent evaluations in the areas of workplace environment, system-user interfaces, procedures, training, and organizational practices. To further acquire an in-depth and up-to-date understanding of the practice of teletherapy in support of these evaluations, a systematic literature review was conducted. Factors that have a potential impact on the accuracy of treatment delivery were of primary concern. The present volume is the literature review. The volume starts with an overview of the multiphased nature of teletherapy, and then examines the requirement for precision, the increasing role of quality assurance, current conceptualizations of human error, and the role of system factors such as the workplace environment, user-system interfaces, procedures, training, and organizational practices.

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EXECUTIVE SUMMARY

Background

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 cobalt-60 (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 Nuclear Regulatory Commission (NRC) have identified cases of teletherapy misadministration where the delivered radiation dose has differed from the radiation prescription (e.g., 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 present literature review was undertaken in support 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 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 safety and identification and evaluation of alternatives to resolve significant problems. The present report focuses solely on the findings of the literature review, especially as they relate to accuracy of treatment delivery.

Methodology

There were five principal sources of information used for the literature review. First, a wide assortment of radiation oncology textbooks, journal articles and reprints were reviewed at the outset of the project to gain a better understanding of the terminology and scope of the field. Second, the research team's panel of subject matter experts (two radiation oncologists, two medical physicists, and two radiation therapists) provided guidance from the perspective of their separate disciplines on content areas and sources of relevant information. Third, given the understanding obtained from the first two sources, key words were generated and a systematic computerized literature search, using the databases of the MedLine service, was conducted. PsycINFO was the service used for the psychological and human factors literature. Fourth, conference proceedings from professional associations provided another source of information.

Finally, the authors' own libraries and networks of professional contacts were used. All titles and articles were evaluated for their relevance to radiation treatment error.

Findings

The Multiphased Nature of Teletherapy

To understand the wide assortment of human factors that have an impact on teletherapy first requires a good understanding and appreciation of the multiphased nature of teletherapy. Good overviews of the process can be found in Bentel, Nelson and Noell (1989) and Perez and Brady (1992). Once malignancy is confirmed, the oncologist conducts a clinical evaluation to determine the extent of the disease. A therapeutic decision is made regarding the intent of therapy. A curative intent seeks to eradicate the tumor; a palliative intent seeks to relieve suffering and prolong life to the extent possible. Next the oncologist starts the process of localizing the tumor and preparing a treatment prescription. In this phase radiation levels to which normal tissue and structures can be exposed safely during treatment must also be considered. Treatment planning specifies the best configuration of beam and dosage for a specific patient in order to target the tumor effectively and to minimize damage to surrounding healthy tissue. The oncologist specifies the overall dose to the tumor and critical normal tissues. The physicist then designs potential treatment delivery approaches in conjunction with the oncologist. Patients are measured, body contours are drawn, and isodose curves (i.e., a family of lines representing the distribution of absorbed dose in a specified plane whereby the absorbed dose is constant along each line) are generated either manually or with the aid of treatment planning computers.

To achieve maximum accuracy, the treatment set-up is first developed using a simulator which is a separate device that resembles the treatment machine and enables precise and accurate location of the treatment fields. Radiographic films are taken to position the fields appropriately. Treatment fields or portals are marked for subsequent treatment by applying tatoos or dyes to the patient's body. Simulation thus allows for verification of the treatment approach and resolution of treatment planning issues before actually using the treatment machines (Mizer, Scheller and Deye, 1986). Special treatment aids 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 (Glasgow and Purdy, 1992).

After all the details of treatment planning have been worked out, the patient begins a course of treatment that will include daily treatment doses or fractions over a period of weeks. The radiation therapists now have the greatest degree of contact with the patient. Their workload varies with respect to the given facility; however, patients need to be positioned accurately, numerous machine parameters entered, treatment accessories put in place, patients monitored while the beam is on, and accurate daily records of administered dose need to be kept. While efforts are made to avoid any deviation from the treatment plan 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. Patient evaluation and

follow up are the last phases and involve assessment of tolerance to treatment, evaluation of tumor response, and assessment of complications (Bentel et al. 1989).

The Requirement for Precision

As noted by Perez and Brady (1992), the only effective irradiation is that which strikes the cancerous cells. Since the total dose is typically delivered in fractions on a daily basis over a period of weeks, precision and consistency are essential to effective treatment. Clinical evaluation is the first place that a concern for precision is evident. How confident is the oncologist that the tumor has been localized given the information imparted by the various examinations, diagnostic studies, pathology reports and imaging services? A second area where precision is a major concern is the medical physics of the treatment process. Here the focus is on issues such as dosimetric uncertainty of beam monitoring and calibration, inexact treatment field placements, lack of knowledge of tissue inhomogeneities, and incorrect dose calculations (Goitein, 1985; Hendrickson, 1982). Patient positioning and immobilization is the third area of uncertainty that has received considerable attention in the literature. The patient's treatment position can not be so awkward and uncomfortable as to preclude reproducability. If the dose distribution widens across the field edge as a result of patient movement or imprecise positioning, the effect is for the tissue outside the field edge to receive a dose higher than calculated and those organs inside the target volume to be under dosed. The fourth area of concern with respect to precision is the daily input of treatment parameters. The radiation therapists are called upon to enter numerous parameters and adjustments — field size, gantry and collimator angles, timer settings, insertion of blocks and/or wedges — for each treatment field for each patient. Simple input errors on routine patient set up tasks are not uncommon; such errors increase with increases in patient load (Swann-D'Emila, Chu & Daywalt, 1990). In recent years, computerized record and verify systems have gained greater acceptance as a way to preclude many of these set-up errors. These systems inhibit a machine from being turned on when the parameters set on the machine do not agree with those prescribed to within specified tolerances (Mohan, Podmaniczky, Caley, Lapidus & Laughlin, 1984; Muller-Runkel & Watkins, 1991).

Improving Geometric Accuracy

In the past, much of the effort for insuring accuracy in radiation therapy has focused on the physical dosimetric aspects of therapy with less emphasis on the geometric treatment problems. Geometric treatment problems refer to a broad array of factors — reproducibility of patient set-ups, adequacy of portal verification films, incorporation of new technology — that have a bearing upon the correct placement of the tumor volume within the geometric definition of each treatment field. A study group headed by Reinstein and Meek (1987) recommended that further efforts be made to document geometric treatment problems in the literature, improve training of therapists and oncologists in the geometric facets of therapy, stress the importance of careful set-ups and quality assurance, and encourage communication between departments to promote a greater sharing of knowledge and techniques.

Increasing Role of Quality Assurance

A decade or so ago quality assurance was largely concentrated on the physical aspects of treatment — to regular dosimetric checks of machine output and to the proper functioning of the treatment machine's mechanical parameters (Starkschall & Horton, 1991). Assisted by the creation of well-formulated guidelines, very much in evidence today are more comprehensive and formalized quality assurance (QA) programs. In order to maintain their accreditation, hospitals must meet minimum standards of quality assurance established by the Joint Commission for Accreditation of Health Care Organizations (JCAHO). To assist radiation oncology departments in meeting QA standards, the American College of Radiology prepared *Quality Assurance Program in Radiation Oncology* (1989). Recently, the NRC has issued *Regulatory Guide 8.33* which serves to provide guidance to licensees and applicants for developing a quality management program acceptable to NRC in complying with 10 CFR 35.32. Despite the presence of these guidelines, Henriksen, Kaye, Jones, Morisseau and Serig (1995) found considerable variation in terms of commitment to quality assurance programs at the radiation oncology departments they visited (visits were made prior to publication of NRC's regulatory guide).

Examining the Concept of Human Error

Rather than automatically assigning blame to the front-line operator after a mishap occurs, a human factors perspective forces investigators to look further upstream from the operator and examine the role of unsuspected contributing factors such as poorly designed interfaces, ambiguous procedures, lack of training, or indecision by management. As noted by Reason (1990), operators tend to inherit the defects of everyone who has played a role in the design of the overall system. Moreover, investigations of human error can be error-prone themselves. The potential for *hindsight bias* (evaluating the event after the fact) and *attribution error* (tendency to neglect situational factors and attribute the mishap to the human deficiencies of others) are always present. Rasmussen (1987) points out the arbitrary and pragmatic nature of human error analyses, while Perrow (1984) focuses on inherent characteristics of systems that make some industries more prone to accidents. Various models and taxonomies for classifying human error have been proposed. One recent taxonomy (Rasmussen 1982, 1986), based on the relationship between performance levels (skill-based, rule-based, and knowledge-based) and error types (slips and lapses, rule-based mistakes, and knowledge-based mistakes) was considered helpful in understanding the types of errors made in the teletherapy environment. A multiple factor model of Sanders and Shaw (1988) also was of special interest because of its focus on managerial and social-organizational factors as well as traditional human factors areas (e.g., user-system interfaces, workplace environment).

Workplace Environment

Both the human factors and architectural communities have long understood the benefits of a work environment that is purposefully designed for the nature of the work that is performed. Building and facility design start with an inventory of activities that are performed by building occupants (Harrigan, 1987). Individuals and groups that must share information such as oncologists, physicists and therapists need to be co-located to efficiently resolve treatment-related

questions. The design of individual workplaces needs to take into account human capabilities for standing and seated positions, distances traveled, work surfaces, the lifting of weighted objects, visual requirements, and communication flow. With the rapid introduction of video display terminals (VDTs) in the workplace in the early 1980s, initial interest focused on potential harmful effects of continuous use. Given the proper design of VDT displays, workplace lighting, seating and other workstation practices (e.g., visual breaks from the screen), continued VDT work does not appear to present serious visual problems. However, repetitive motion injury (e.g., carpal tunnel syndrome) remains a problem for some people who use VDT keyboards and mouse devices.

User-System Interfaces

As the user-system interface has dramatically changed in the past 15 years with the introduction of microprocessor-based technology, various concerns about the role and level of understanding required of the human operator have been expressed (Bainbridge, 1987; Norman & Draper, 1986; Weiner & Curry, 1980). With automation, humans have been assigned a monitoring role, but one of the ironies of automation, to use Bainbridge's phrase, is the inability of operators to exercise proficient manual control on those rare occasions when it is required. Because of their accustomed hands-off role, operators are frequently ill prepared to respond to system emergencies when they occur. Likewise, there is a range of opinion in terms of how the user-system is to be evaluated. One approach is to rely on written guidelines such as the *Human Factors Engineering Guidelines and Preferred Practices for the Design of Medical Devices* from the Association for the Advancement of Medical Instrumentation (AAMI) for assessing the adequacy of various controls, visual displays, audio signals, and consoles. Cook and his associates, on the other hand, have advocated a more dynamic, interactive, user-centered testing of medical devices under the widest possible range of human interaction (Cook, Potter, Woods, and McDonald, 1991). Emphasis is placed on the human-device interaction and whether the user can formulate an appropriate mental model that will facilitate a dialogue between user and device. Flawed mental models are likely to exact their toll in the form of inappropriate operator actions when the device fails.

Kaye, Henriksen, Jones, Morisseau and Serig (1995) used a checklist methodology combined with incident reports, observations of the equipment in use, and information provided by physicists and therapists for evaluating the interfaces of Co-60 machines and linear accelerators. Overall, Co-60 units are much simpler machines than linear accelerators and have fewer components incorporated in the user console that could violate AAMI guidelines. Labeling inadequacies and thumbwheels that turned down rather than up were human engineering discrepancies that were common to the control consoles of both types of treatment units.

In teletherapy, improved user-system interfaces can prevent errors that would otherwise go unnoticed. In setting up a patient, as many as 15 to 20 machine parameters may need to be entered for each field that is treated. To detect and prevent deviations in the delivered radiation dose, some manufacturers offer computerized record and verify (R&V) systems. These systems 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. In one study, 416 deviations occurred

over a one-year period on three treatment machines that otherwise would have likely gone undetected (Mohan, Podmaniczky, Caley, Lapidus & Laughlin, 1984).

As noted above, there are inherent challenges for users of computerized systems. Computer systems are essentially opaque; their function cannot be easily discerned on the basis of the structure of the system (Weinhous, 1991). Very few things need to be tweaked, and only a limited number of actions will have immediate effects. Since the control system of today's linear accelerator is implemented in software which is likely to be unfamiliar territory for the physicist, Weinhous recommends that the manufacturer provide a series of quality assurance (QA) scripts (i.e., for acceptance testing and for monthly and annual QA) as well as the necessary hardware/software components for conducting the tests.

Procedures and Practices

Procedures typically refer to an approved ordered sequence of tasks or steps that are documented in a form that provides a reference for appropriate performance, while practices may or may not conform to an approved sequence of steps that are documented. Practices may vary between sites as well as among individuals within a given site. The two terms are sometimes used interchangeably in both the human factors and radiation oncology literature. When an activity involves a large number of tasks distributed across several people, good procedures can facilitate the accurate transfer of information. At the same time, transfer of information tasks are a fertile source of errors. Leunens and associates traced teletherapy transfer errors to five places in the treatment preparation process: during treatment simulation, during input of data to the treatment planning system for calculation of dose distribution and monitor units, during preparation of the treatment chart, during input of data to the record and verify system, and during modification of parameter values to the record and verify system (Leunens, Verstraete, Bogaert, Van Dam, Dutreix & van der Schueren, 1992). If undetected, errors due to inaccurate transfer of information will be propagated in every subsequent step and have the potential to affect eventual outcomes adversely. Recommended practices that aid accurate transfer of information include the use of clear instructions, well designed forms, comprehensible and legible labels, and use of meaningful symbols and codes (Caplan, Lucus & Murphy, 1983).

In terms of communication procedures, larger facilities generally rely more on written procedures and communications while smaller facilities handle many of the same issues on an individual, face-to-face basis. As staff size, workload, and number of satellite facilities increase, direct interpersonal communication becomes more difficult. Kaye et al. (1995) found that larger facilities make a greater effort in standardizing procedures in the form of comprehensive Policy and Procedures manuals and department-specific forms for transferring information. However, even in departments with good documentation, communication failures can occur when the treatment plan changes during the course of treatment, when therapists are rotated to a new machine, when patient set-ups are complicated, or simply when one person makes unwarranted assumptions about what another person knows.

Training and Qualifications

The formal training or schooling that radiation therapists, dosimetrists, and physicists receive prior to employment constitutes the major component of their preparation to perform teletherapy services. The typical preparation for therapists is a two year program at a community college that combines classroom instruction with clinical experience at a near-by hospital. Some individuals who become radiation therapists have first worked as x-ray technicians. These individuals typically attend a one year program for their formal training. Many facilities require that therapists be certified or eligible for certification through the American Registry of Radiologic Technologists at the time of hire. There are facilities, however, that may require no formal training for their therapists. With respect to dosimetrists, many hospitals train their own (usually an experienced therapist), while radiation physicists have a masters or doctoral degree with a concentration of coursework in radiologic physics, anatomy, physiology, oncology, and radiobiology. Once hired, most of the training that occurs in departments of radiation oncology is on-the-job training (OJT). This usually refers to a newly hired employee working side-by-side with a senior employee for a few months. OJT is the principal means of training for orienting new personnel to the department, to new equipment and software, and to new procedures. With many OJT programs, it is very difficult to determine what is being learned despite the good intentions of the person in charge of training (Henriksen et al., 1995).

Organizational Policies and Practices

The role of organizational policies and practices is starting to receive greater recognition in the literature on human error, accidents, and system safety (Reason, 1990; Sanders & Shaw, 1988; Weiner, 1989). Different organizational factors may lie dormant for a while only to combine later in unsuspected ways that give rise to error. Staffing shortages among therapists and dosimetrists continue today as they did a decade ago (Gerber, 1984). At the same time, therapists frequently work under stressful treatment schedules. To maximize the use of expensive treatment machines and to be of service to as many patients as possible, the existing practice is to schedule patients back-to-back, with as many as four to five patients an hour, given the demand. The level of commitment to quality assurance (QA) programs also is an important organizational factor. As a relatively recent movement, several centers report successful experiences with QA programs as well as some lessons to be learned (Starkshall & Horton, 1991). Experience in other sectors of the economy have implicated the active commitment of upper management and the existence of formal procedures as necessary conditions for the effective implementation of QA programs. Otherwise, individual efforts are likely to have limited impact. Another essential organizational factor is the quality of communication within the organization. Understanding and resolving the barriers to communication is especially necessary in multiphased, multidisciplinary environments such as teletherapy. Organizational barriers to communication include such factors as information loss from serial transmission of messages sent up and down the chain of command, task specialization resulting in non-overlapping frames of reference, and mistrust among personnel resulting from differences in authority and status. On the interpersonal level, barriers include implicit assumptions under which the sender operates without being fully aware of them and failing to receive feedback to confirm that the message has been received and understood. Teletherapy personnel also mention

organizational climate, environmental distractions, and accessibility of oncologists as organizational factors that can potentially impede or facilitate therapeutic performance (Henriksen et al., 1995).

Errors that occur at the organizational level are typically made by those in decision-making positions (e.g., department heads and hospital administrators), far removed from the control consoles and treatment machines of the therapist. As noted by Reason (1990), these are the fuzzy, ill-defined and often unrecognized errors that lie dormant for some time in the greater socio-technical system. For example, the adverse consequences of ignoring the need for a quality assurance program may only become evident when this error of judgment aligns itself with poor communication practices, staffing shortages, and stressful treatment delivery schedules.

ACKNOWLEDGEMENTS

Since this review is based upon the work of others, the authors wish to acknowledge the considerable contribution of the radiation oncology, human factors, and research personnel whose investigations have made the practice of teletherapy safer and more effective.

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 originate from a radioactive isotope, typically Co-60, or a linear accelerator device for producing very high energy x-ray and electron beams. As practiced in departments of radiation oncology, teletherapy (or radiation therapy) is a complex, multiphased, multidisciplinary process involving the teamwork of radiation oncologists, radiation physicists, dosimetrists, and radiation therapists.

The present report is part of a series of human factors evaluations for identifying the diverse array of factors that contribute to human error in the teletherapy setting. 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

Teletherapy is a treatment methodology in which cancerous or other tissue is selectively destroyed by exposure to an external beam of ionizing radiation. The source of radiation may originate from a radioactive isotope, typically Co-60, or a linear accelerator. As a treatment methodology, teletherapy is a multiphased, multidisciplinary process influenced by a broad range of human factors variables. Treatment is delivered repeatedly over a number of days (i.e., total dosage is divided into daily fractions) and involves communication and coordination among treatment personnel. It also involves the operation and maintenance of equipment which has become increasingly automated and computer-driven. To ensure proper delivery of the external radiation beam, all equipment associated with treatment planning, simulation, and treatment must undergo a series of periodic checks to ensure reliable and accurate functioning. Successful therapeutic outcome requires a concern for precision and consistency in human-human and human-machine interactions found in few other occupations. The workload varies with respect to organizational setting; however, at certain facilities the front-line workers of the system (the radiation therapists) may experience the stress associated with being called upon to set-up and treat from four to five patients an hour. Patients have to be positioned accurately, numerous machine parameters entered, treatment accessories put in place, accurate daily records of administered dose maintained, and the unique needs of individual patients attended to in a compassionate manner.

That errors occur in the teletherapy environment is understandable and not surprising from a human factors perspective, yet the occurrence of errors is not very acceptable to the teletherapy treatment community nor to the patients themselves. The radiation oncology professional literature as well as records maintained by the U.S. Nuclear Regulatory Commission have implicated human error in cases where the delivered teletherapy 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; doses delivered above the prescribed level can lead to damage to healthy tissue and critical structures. The following three case histories illustrate one area of human factors concern: the integrity of software control of the treatment process.

1.1 Three Case Histories

The stories of three individuals undergoing treatment shocked the radiation therapy community during the second half of the 1980s. For a 61 year-old woman in Georgia, the daily treatments for her breast cancer had been uneventful until one day she experienced a tremendous, red-hot sensation penetrating the left side of her body during the treatment. Despite her protests of having been burned, the therapist claimed it was impossible. After all, the center's state-of-the-art computerized linear accelerator — a Therac 25 manufactured by Atomic Energy of Canada, Ltd. (AECL) — had delivered thousands of previous treatments without incident. Although she was hospitalized for what was thought to be muscle spasms and a frozen shoulder, she continued to receive radiation for her cancer until she ultimately refused further treatments because the welt above her breast began to break down (Richards, 1990).

It was not until almost a year later and after two more cancer patients in a different part of the country had similar experiences that the puzzle started to come together. A 33 year-old Texas oil field worker was undergoing his ninth Therac 25 treatment after having a tumor removed from his back when he felt a sudden jolt of heat. As he flinched, he got hit again, and again much more powerfully. When he inquired if he had accidently received too much radiation, his oncologist stated that the machine indicated that he had not even received his prescribed dose. The machine had turned itself off. Left on the therapist's control console was an error message "Malfunction 54" - a cryptic computer code that has come to epitomize the hidden problem of software reliability at its worst (Joyce, 1987). The oncologist contacted the clinic's physicist to inspect the machine, who in turn called AECL. Following the suggestions of AECL, the physicist checked various functions, but could find nothing wrong. The machine was put back into use. The oil field worker's condition worsened, AECL was called again, and the Canadian firm sent its senior engineer and a service technician to examine the machine. Once again, nothing wrong could be found.

Twenty-two days after the oil field worker's overdose, a 66 year-old bus driver was receiving one of his last four treatments for skin cancer to his ear in a treatment regime that had successfully irradiated the targeted area 30 times previously. On this particular occasion, he screamed in pain as he felt a powerful jolt to the ear. The therapist immediately informed the physicist of another Malfunction 54 incident. This time the physicist had the therapist step through the actions that triggered Malfunction 54 and was able to determine what happened.

To understand the malfunction, it is important to note that the Therac 25 is capable of delivering either X-ray or electron-beam therapy. When X-ray therapy is used, the machine produces a much higher intensity beam that strikes a tungsten target and converts the beam to X-rays. In the latter two examples, the therapist erroneously selected X-ray rather than the intended electron beam therapy mode. The Therac software instructed the machine to set up the high current beam, put the tungsten target in place, and enter other parameters appropriate for X-rays. When the therapist noticed her error and corrected it, the simple, intuitive method used to correct the error created a situation that the software was not designed to recognize. Using the "up" arrow on her keyboard to get to the edit function, she changed the "x" mode for X-ray to the "e" mode for electrons — a correction that should dramatically lessen the intensity of the beam. Using the return key to go to the bottom of the screen, she waited for the "beam ready" command and entered "b" to turn the beam on when the command appeared. The machine's computer display then signalled Malfunction 54 and shut itself off in less than a second, but not until it had delivered a dose of radiation likely to have been 100 times higher than it should have been. By duplicating the therapist's keyboard commands, the physicist was able to determine the Therac scrambled the two energy modes, retracting the target as it should for electron mode, but leaving the beam intensity on high for X-rays. A portion of the software "turned its back on the world for a while" according to AECL's quality assurance chief and was not able to respond properly to changes made at the keyboard (Richards, 1990).

Both the oil field worker and the bus driver died within a period of months after their misfortune. Radiation damage deprived the 61 year-old woman of her left breast and use of her left arm.

1.2 Why Study the Human Factors of Teletherapy

A critic could justifiably assert that the above three cases are atypical and that little notice is given to the thousands and thousands of patients that have been successfully treated. Indeed, the typical errors that occur in teletherapy are ones that allow for easy adjustments and which do not have any adverse impact on the well-being of patients. In fact, during the past 15 years, many departments of radiation oncology in various community hospital and university-based settings have initiated impressive quality assurance programs to curtail human error, machine malfunction, and imprecision of treatment.

While impressive improvements have been made with quality assurance programs and advances in technology, there remains a need for a better understanding of the role of human factors in teletherapy. Given the complexity of the teletherapy work environment and the deleterious consequences of error, it is quite reasonable to seek a better understanding of the nature of human error, the major human factors likely to contribute to it, and the different forms by which it may manifest itself. With respect to the teletherapy environment, the following questions merit consideration.

- How is human error currently conceptualized?
- What is the relationship between equipment design and human error? What sort of errors do computerized record and verify systems catch?
- Do differences in the geometries and procedures used for Co-60 and linear accelerators cause any problems for therapists?
- How are personnel trained on the newer treatment planning software and treatment systems?
- Does the new equipment/software introduce new, unanticipated sources of error?
- Does the organizational climate serve to facilitate or impede the self-reporting of errors?
- What organizational factors serve to differentiate successful quality assurance programs from unsuccessful quality assurance programs?

Avoidable errors no doubt will continue to occur in the teletherapy environment until we have a better understanding of the range of human factors that influence their occurrence. The purpose of the present volume is to examine systematically what is currently known about these factors. The first objective, however, is to describe the multiphased nature of the treatment process, as shown below.

The remainder of the review is organized in the following major sections:

- The Multiphased Nature of Teletherapy
- The Requirement for Precision
- Improving Geometric Accuracy
- Increasing Role of Quality Assurance
- Examining the Concept of Human Error
- Workplace Environment
- User-System Interfaces
- Procedures and Practices
- Training and Qualifications
- Organizational Policies and Practices

A final section of the review draws conclusions about the range of factors that affect safe and effective treatment based on a summarization and integration of information from the literature.

2.0 THE MULTIPHASED NATURE OF TELETHERAPY

The effective use of external beam ionizing radiation for therapy requires a multiphased and multidisciplinary process that depends upon many complex interactions among trained personnel, equipment, and prescribed procedures. Personnel come from the disciplines of radiation oncology, medical physics, dosimetry, and radiation therapy technology. Equipment may consist of Co-60 machines (which are becoming fewer in number), linear accelerators, simulators, control consoles, special immobilization devices, treatment planning computers and software from different manufacturers. Procedures can vary from following formal, written documentation to relying on rules of thumb or memory. Figure 2.1 shows multiple phases of teletherapy, key and support staff, and the variety of interrelated functions as recognized in the *Report to the Director of the National Cancer Institute of Health by the Committee for Radiation Oncology Studies,* (1981).

The following description of the treatment process characterizes the multiple phases of teletherapy as practiced in a generic or ideal sense. It should be noted that actual practice varies from one facility to the next and often deviates from the ideal.

2.1 Clinical Evaluation

As shown in the figure, the radiation oncologist first conducts a clinical evaluation, usually after a diagnosis of malignancy has been confirmed. Pertinent information from various sources (e.g., physical examination, diagnostic studies and reports from pathology, imaging services, and the laboratory) is gathered for a better understanding of the biologic characteristics of the cancer and to serve as a basis for staging the disease. An assessment of the primary tumor (T), regional lymph nodes (N), and distant metastases (M) enables the extent of the disease to be classified. In brief, the malignancy at diagnosis may be at an early, intermediate, or late stage of its development. The extent or stage of the tumor, in turn, determines in large part the choice of treatment as well as the prognosis (Bentel, Nelson, & Noell, 1989). Because tumors vary by anatomical site and type, other staging systems may be used. To provide an international basis for categorizing cancers and to enable comparable end results to be reported, both the American Joint Committee on Cancer (AJCC) and the International Union Against Cancer (IUCC) have played key roles in attempting to develop meaningful staging systems which incorporate TNM sub-categories. With the publication of the third edition of *Manual for Staging of Cancer* (1988) and the fourth edition of *TNM Classification of Malignant Tumors* (1987), better agreement has been reached regarding classifications (Rubin, McDonald & Keller, 1992).

2.2 The Therapeutic Decision

A therapeutic decision is next made by the oncologist regarding appropriate treatment. If there is no possibility of eradicating the tumor, treatment typically is palliative, to relieve suffering and extend life. With hope for tumor eradication, the therapeutic decision will have a curative intent. When the intent of therapy is curative, it is extremely important to deliver the highest possible dose to the tumor volume to achieve maximum tumor control while at the same time limiting dose to surrounding healthy tissue to the lowest possible level. This is a trade-off that the radiation oncologist must consider with each patient.

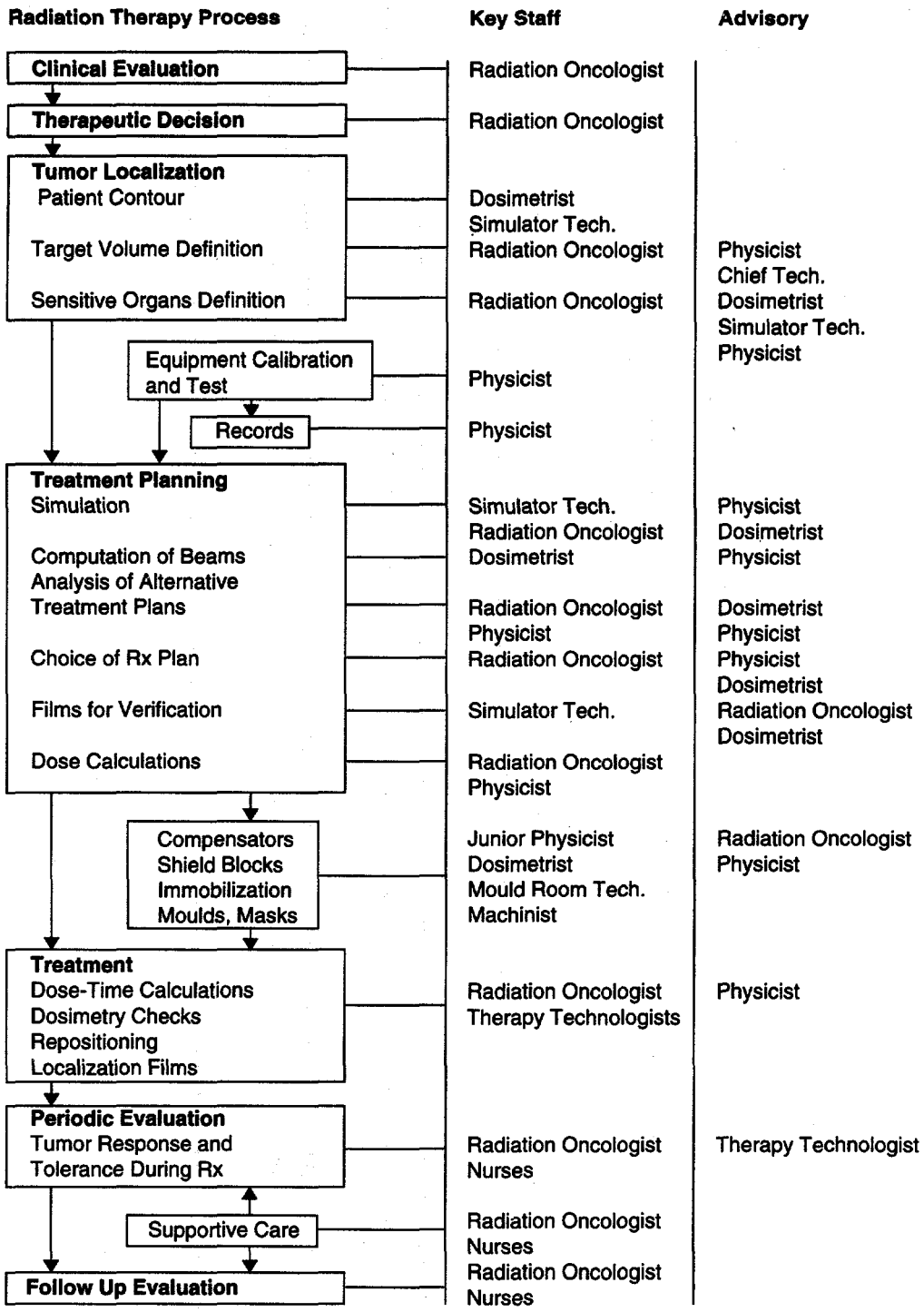

Figure 2.1 Key Staff Functions In Radiation Therapy (Adopted From Report to the Director of the National Cancer Institute of Health by the Committee for Radiation Oncology Studies, 1981).

2.3 Target Volume Localization

When the therapeutic decision has been made, the oncologist starts the process of localizing the target volume and preparing a treatment prescription. It is here that the oncologist is assisted by other members of the treatment team, such as the dosimetrist or physicist who are called upon for patient measurement and construction of patient contours.

It should be noted that the term volume is used selectively in localizing and treating the tumor. Tumor volume refers to the gross tumor and any expected microextensions, whereas target volume includes the tumor volume plus a biological margin of subclinical disease assumed to be present but not detectable by microscope. Treatment volume provides an additional margin to cover the preceding volume specifications adequately and to compensate for geometric inaccuracies during radiation exposure (Perez & Brady, 1992). Figure 2.2 shows the relationships among tumor volume, target volume and treatment portal volume.

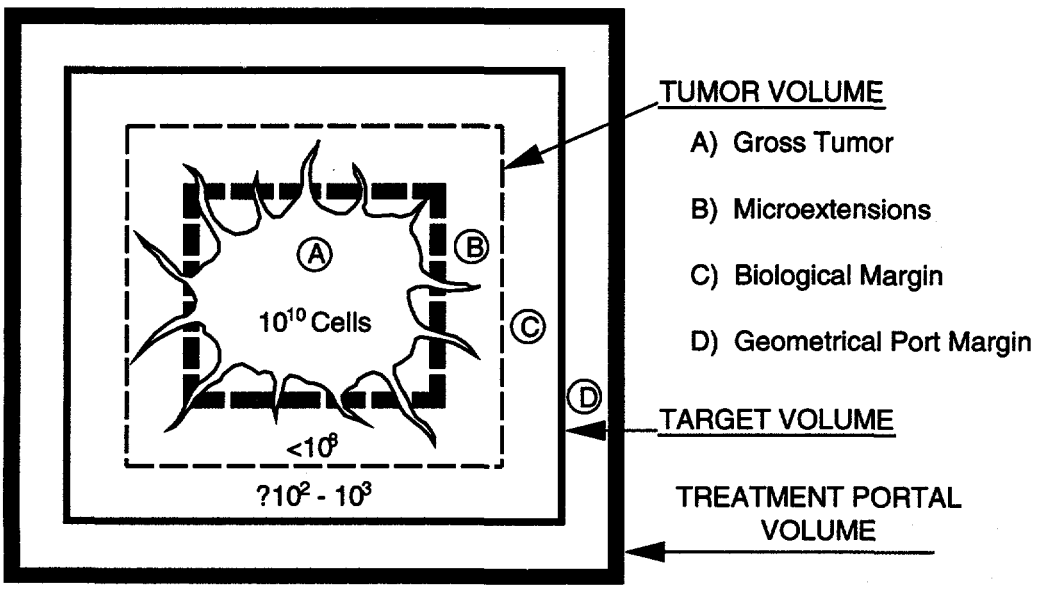

Figure 2.2 Definition of "Volumes" in Radiation Therapy (Perez, C.A., & L.W. Brady, "Overview." In Perez, C.A. & Brady, L.W. (Eds.), *Principles and Practice of Radiation Oncology,* Philadelphia, PA: J.B. Lippincott Company, 1992; Reprinted with permission of Lea & Febiger)

All radiation sensitive structures within the irradiated volume need to be clearly identified along with their maximum acceptable doses. For example, tables prepared by Rubin (1975) and reported in Bentel et al. (1989) show the lens of the eye as one of the most radiosensitive structures (i.e., a tissue dose of 1200 cGy is associated with a 50% injury rate within 5 years) whereas mature cartilage, large arteries and veins are quite tolerant of higher radiation doses (i.e., tissue doses up to 10,000 cGy are cited before moderate to mild morbidity occurs). Other vital organs such as kidney, liver, lung, heart and brain fall between these extremes. Knowledge

regarding tolerance of normal tissue organs to irradiation is extremely important to the practice of teletherapy. Information on the tolerance of normal tissue to therapeutic irradiation is periodically updated, as exemplified by the work of a recent task force on tolerance effects (Emami, Lyman, Brown, Coia, Goitein, Munzenrider, Shank, Solin & Wesson, 1991).

2.4 Treatment Planning

Target volume localization is followed by treatment planning which requires the efforts of the oncologist, physicist, dosimetrist, and simulation therapist. The treatment set-up is first simulated to insure precise and accurate location of treatment fields. Simulation is a focal planning event which allows questions of patient set-up and planning to be resolved without actually using the treatment machines (Mizer, Scheller, & Deye, 1986). Considerations include appropriate positioning of patient, selection and preparation of immobilization devices, selection of radiation field shapes and beam entry/exit points, preparation of shielding blocks, and the need for beam modifiers such as wedges and compensators for missing tissue (Glasgow & Purdy, 1992). By replicating the geometries, functions and motions of a treatment unit, simulators serve as indispensable treatment planning tools. They further enable the treatment machines to be used solely for therapy.

Careful attention to detail is needed during treatment planning to ensure the precision of subsequent radiation therapy. Precision has been increased significantly over the years with the availability of isocentric treatment machines, linear accelerators, simulators, treatment planning computers, CT scanners, magnetic resonance imaging (MRI) and improved diagnostic techniques. All these advances collectively reduce the uncertainty associated with determining the size and location of the target volume. Despite these advances, a remaining problem involves ensuring that the treatment beam traverses the specified anatomy consistently treatment-after-treatment for the duration of treatment. According to Hendrickson (1982), "the problem of possible patient movement during the course of treatment and the ability to reproduce the patient position on subsequent treatments may be one of the major problems in radiation oncology" (p. 311). The importance of this routine but difficult-to-replicate aspect of treatment has been noted by other authors as well (Barish & Lerch, 1978; Bentel et al. 1989; Kartha, Chung-Bin, Wachtor & Hendrickson, 1975; Goldson, Young, Espinoza & Henschke, 1978; Huaskins & Thomson, 1973; Verhey, Goitein, McNulty, Munzenrider & Suit, 1982, and Williamson, 1979). Alignment lasers are used to enhance the reproducibility of the patient's position; a number of positioning and immobilization devices — body casts, Alpha Cradle, Aquaplast, Scotchcast, arm boards, head and neck cradles, bite blocks — have become an integral part of patient set-up that is reflected in treatment planning.

Once the dose tolerances of critical anatomical structures in the vicinity of the tumor have been considered and other issues resolved, the oncologist specifies the doses to the tumor and critical normal structures. The physicist or dosimetrist designs potential delivery approaches that satisfy the dose requirements, typically with the assistance of treatment planning computer software. The calculation of doses and mapping of isodose patterns are reviewed with the oncologist to select the best treatment plan for a given patient. Adjustments may be made; however, before the start of treatment, each patient's prescription defines the treatment volume,

total dose, number of treatments, dose per treatment and frequency of treatment. Detailed discussions of treatment planning approaches for different tumor sites can be found in Perez and Brady (1992), while more generalized discussions of this essential phase can be found in other sources (Bentel et al., 1989; Bleehen, Glastein & Haybittle, 1983; Glasgow & Purdy, 1992; Mould, 1981; and Wright & Boyer, 1983).

Recent advances in medical imaging, especially computed tomography (CT), and computer graphic display capabilities have spawned the development of three dimensional (3D) treatment planning systems that can address a range of treatment planning tasks in addition to dose calculation (Goitein, 1979; Goitein & Abrams, 1983a; Goitein & Abrams, 1983b; McShan, Silverman & Lanza 1979; McShan, Fraass, & Lichter, 1990); Perez & Brady, 1992; Purdy, Wong, Harms, Drzymala, Emami, Matthews, Krippier & Ramchandar, 1987; Purdy, Wong, Harms, Emami & Matthews, 1987). Given the advanced computer and display capability, contiguous CT slices can be used to depict anatomic structures and target volume. Perez & Brady (1992) list the following capabilities that 3D systems are intended to provide: diagnostic information relevant to patient's disease, delineation of normal tissue, definition of tumor and target volume, simulation of therapy by means of digitally reconstructed radiographs, design of treatment aids such as compensators and blocks, calculation of 3D dose distributions and dose optimization, and critical evaluation of the treatment plan. Another feature of these systems is the "beam's eye-view" (BEV) display in which patient contours are viewed as if the observer's eye is placed at the source of radiation looking out along the axis of the radiation beam (Goitein & Abrams, 1983; McShan, Fraass & Lichter, 1990). At the same time, Perez and Brady (1992) warn that the BEV, while necessary for 3D viewing, is not sufficient for optimal planning, especially for more complex beam arrangements.

2.5 Treatment

Once consensus is reached on the most reasonable treatment plan, the patient is scheduled for treatment. Treatment occurs on a daily, fractionated basis and is administered by the radiation therapists who now have the greatest degree of contact with the patient. The therapists are responsible for setting up and positioning the patient on the treatment couch, entering and setting the treatment machine parameters (e.g., energy level, gantry rotation, field size, insertion of blocks/other beam modifiers), turning the external treatment beam on, monitoring the patient, and maintaining an accurate daily chart of the doses administered. Since treatment occurs on a daily basis over a five- to six-week period, the possibility of unintentionally deviating from the treatment plan always exists. Treatment delivery errors — using the wrong block for the treatment field, using the wrong wedge, setting the wrong field size, selecting wrong photon energy level, giving an extra fraction through failing to chart a treatment — do occur (Swann-D'Emila, Chu & Daywalt, 1990). For this reason, many radiation oncology departments have installed computerized record-and-verify systems that automatically check the correct machine parameters before permitting activation of the beam (Mohan, Podmaniczky, Caly, Lapidus & Laughlin, 1984). It should be noted that most record and verify systems are used primarily in conjunction with linear accelerators, not Co-60 machines. Also, record and verify systems check machine parameters, but do not check patient set-up errors. If a treatment unit does not have a record and verify system, the therapist is typically the last line of defense between proper

administration and misadministration. It is possible that unless some errors (e.g., always misreading a handwritten number) are caught at the time they occur, they may have little or no chance of being detected prior to the end of treatment. Many departments have initiated quality assurance programs which involve the reporting of treatment errors, monitoring their occurrence, and implementing quality control measures for avoiding their recurrence (Swann-D'Emila et al., 1990).

2.6 Periodic Evaluation

Periodic evaluation during treatment needs to occur on different levels. The patient is treated and observed on a daily basis by the therapists. Treatments are charted on a daily basis, and then weekly chart rounds are conducted by the oncologist and team members to monitor the patient's progress. Weekly portal verification radiographs are taken and reviewed. As observed by Gastorf, Harris and Horton (1991), one of the least exciting but absolutely necessary periodic tasks for the medical physicist or dosimetrist to perform is rechecking the patient's treatment record. In brief, the patient's chart needs to be reviewed initially, after each change in set-up, weekly, and at the end of treatment to verify that the final dose delivered is as prescribed. Errors involving numbers and transfer of information are not unusual given daily fractionated treatments across several weeks involving multiple fields and modalities and given that the chart is used by different treatment team members. While a conscientious periodic quality control procedure that incorporates redundant checks of calculations and input parameters may not prevent errors from initially being made, it should catch them before they are detrimental to the patient (Gastorf et al., 1991).

2.7 Follow Up Evaluation

Post-treatment follow-up of the results and sequelae of radiation therapy is conducted under the purview of the oncologist. Any post-irradiation tumor activity and radiation-induced changes to normal tissue need to be detected early for additional curative efforts and to avoid serious subsequent complications.

3.0 THE REQUIREMENT FOR PRECISION

In radiation therapy, precision is essential to effective treatment. As noted by Perez and Brady (1992), the only effective irradiation is that which strikes the cancerous cells. Although most deviations from intended treatment are relatively small, concern arises over the possible cumulative effects of imprecision across the successive phases and levels of the treatment process. For a given patient, what is the likelihood that these inaccuracies will cascade or accumulate such as to underexpose the tumor volume or overexpose radio-sensitive tissue? Even small discrepancies in dosage to the tumor volume can have a dramatic effect on probability of a cure, given the steepness of the dose response curve (Hendrickson, 1982; Herring & Compton, 1971).

3.1 Clinical Evaluation

The first place that a concern for precision is realized is during clinical evaluation and therapeutic decision making. How closely does the information provided by the various examinations, diagnostic studies, pathology reports, and imaging services come in providing a good understanding of the nature and extent of the cancer? This is influenced by the knowledge domain of the attending radiation oncologist and represents a challenge to his or her skills at synthesizing information and problem solving. How complete is the existing medical knowledge base? Are the correct hypotheses being explored? Is the interpretation of the data correct? What possibilities have been overlooked? What is the level of confidence in localizing the tumor? These questions focus on the adequacy of the therapeutic decision making process and how knowledge is used and activated during problem solving and decision making. During the past decade there has been an increasing interest in medical decision making and in the various decision making flaws of practitioners. Cook and Woods (1994), for example, discuss the problems of dealing with medical complexity through the use of simplifying heuristics. Medical practitioners resort to simplifying heuristics most likely because they generally work and they reduce the cognitive demands that result from a complex subject matter and busy practice (Woods, 1988). Tversky and Kahneman (1974) have shown that heuristics do not always lead to the most desirable outcomes and that under certain circumstances they can be incorrect. An uncritical use of heuristics can lead to such oversimplifications as evaluating different disease entities as more similar than they actually are, treating multidimensional phenomena as unidimensional, and treating highly interconnected concepts as separable (Cook & Woods, 1994; Feltovich, Spiro, & Coulson, 1993).

Two other decision making biases that can occur in medical practice are failure to revise an assessment or evaluation in the face of new evidence and overconfidence in an evaluation once it has been made. There is an accumulating body of research which suggests that humans selectively discount and ignore information that is incompatible with readily available assessments of the situation (Arkes & Harkness, 1980; Freedman & Sears, 1965). Once individuals arrive at an assessment or are given a diagnosis of a situation, they are more likely to process information relevant to the situation in a biased fashion. Once a diagnosis had been supplied, subjects in the Arkes and Harkness (1980) experiment became more likely to falsely

recognize symptoms that were consistent with their diagnosis and less likely to recognize actual symptoms that were inconsistent with their diagnosis. Further complicating the possibility of considering inconsistent symptoms and alternative interpretations are findings that show that individuals have an unwarranted or excessive degree of confidence once they have arrived at an interpretation of a problem situation (Einhorn & Hogarth, 1978; Gettys, Fisher & Mehle, 1979; Slovic, 1982). One interpretation is that because of the cognitive dissonance that uncertainty creates, individuals compensate by becoming overconfident or overprotective in their assessment.

3.2 Realm of Medical Physics

A second area where precision is of major concern and is treated extensively in the literature is the medical physics of the treatment process (e.g., Goitein, 1985; Jayaraman, 1988; Kahn, 1984; Purdy, 1991a; Svensson, 1989). Here the focus varies from the dosimetric uncertainty of beam monitoring and calibration, inexact treatment field placements, lack of knowledge of tissue inhomogeneities, incorrect dose calculations, to discrepancies between what was planned and what was therapeutically delivered. Given that these and other sources of imprecision exist, there is actually a range of possible doses that the tumor volume may receive rather than a single dose distribution that represents the patient's treatment. For this reason, Goitein (1985) has proposed incorporating error analysis — identifying each source of uncertainty, assessing its magnitude, and estimating its impact — into the planning process. The result would be an estimate, at some specified level of confidence, of the range of dose likely at any point. Such efforts attempt to make more explicit the uncertainty of our knowledge of the dose at any point rather than relying on implicit understanding and intuition which is oftentimes inadequate. Other efforts for dealing with uncertainty emphasize preventative measures. As discussed previously, erroneous numbers used for calculations that make their way to the patient's chart can be reduced by redundant systems of double-checking (Gastorf et al., 1991; Hendrickson, 1982; Kartha, Chung-Bin, Hendrickson, 1973).

3.3 Patient Positioning and Immobilization

The next area of uncertainty that also has received considerable notice in the literature is patient positioning and immobilization (e.g., Barish & Lerch, 1978; Bentel et al. 1989; Hendrickson, 1982; Kartha, Chung-Bin, Wachtor & Hendrickson, 1975; Goldson, Young, Espinoza & Henschke, 1978; Huaskins & Thomson, 1973; Rabinowitz, Broomberg, Goitein, McCarthy & Leong, 1985; Svensson, 1989; Verhey, Goitein, McNulty, Munzenrider & Suit, 1982, and Williamson, 1979). Whatever the patient's treatment position, it can not be so awkward and uncomfortable that it precludes reproducibility or encourages movement. On the basis of a limited number of studies (Svensson, 1984; Rabinowitz, et al. 1985; Verhey et al. 1982), Svensson (1989) was able to conclude that normal immobilization procedures for set-up precision have standard deviations of 3-5mm while in special treatment procedures the standard deviations may be less than 2mm. As the dose distribution widens across the field edge 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 calculated and those organs inside the field edge or target volume to be under dosed. While the target volume encompasses a small margin of clinically uninvolved tissue to accommodate such uncertainties as the

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. A high degree of precision is required in patient positioning and immobilization for tumors in the head and neck area because of the proximity of the orbita, brain and cervical spinal cord (Hendrickson, 1982).

A Patterns of Care Study reviewed patients treated with radiation for Hodgkin's disease and found that set-up errors were correlated with decreased tumor control. Kinzie, Hanks, Maclean, and Kramer (1983) found that 33% of patients whose treatment portals were inadequate (i.e., later judged as failing to encompass the tumor) subsequently developed in-field or marginal recurrences compared to only 7% percent of those treated with adequate portals. Similar findings of the relationship between localization error and recurrence have been reported for upper airway carcinoma (Doss, 1979), Hodgkin's disease and malignant lymphoma with extended mantel fields (Marks, Haus, Sutton & Griem, 1974), and nasopharyngeal carcinoma (Marks, Bedwinek, Lee, Purdy & Perez, 1982).

Portal and verification films are used to ensure the accuracy of the position of the treatment portal and in making subsequent improvements. By analyzing the incidence and magnitude of treatment portal errors ascertained by verification films during mantle field irradiation for patients with Hodgkin's disease, Hulshof and colleagues (cited in Perez & Brady, 1992) found the first verification film at the beginning of treatment uncovered localization errors of 1 cm or greater in 13 % of the cases. An adequate treatment set-up was obtained in 60% of the cases after the first correction and in 84% of the cases after the second correction. If modifications are not made during the first or second day set-up with the aid of initial portal imaging, positioning errors may persist as systematic deviation throughout the course of treatment.

A limitation of portal films is that the patient is imaged with a small fraction of the daily treatment dose under set-up rather than actual treatment conditions. Since portal films are taken over a brief interval of time just prior to treatment, they do not show the effect of patient movement during treatment or slight changes in patient position from end of set-up to onset of treatment. Verification images, on the other hand, record what occurred during treatment (including motion) since they are single exposure images which record the delivery of the entire fraction. As noted in a recent report by the American Association of Physicists in Medicine (AAPM) Radiation Therapy Committee Task Group 40 (1994), periodic review and recording of portal and verification films is an essential aspect of a facility's QA program. The same report warns against an overzealous correction of small random positioning errors which cannot be controlled since such errors can be magnified if overcorrected and subsequently lead to larger, systematic errors. The patient's position should be modified only if such errors persist in which case they have lost their random quality. While it is recognized that the frequency with which portal and verification films should be taken depends on a number of factors (e.g., anatomical site treated, immobilization device used, patient's condition), the AAPM Radiation Therapy Committee Task Group 40 (1994) recommends that portal and verification films of all fields be taken at least once a week.

3.4 Input of Treatment Parameters

The fourth area underscoring the importance of precision is the daily input of treatment parameters which is performed by the therapists. Numerous parameters and adjustments need to be set for each treatment field for each patient. These set-up parameters include field size, gantry and collimator angles, timer settings, insertion of blocks and/or wedges, use of correct tatoos, proper charting and so forth. Given the ease with which it is possible to make mistakes in performing simple input tasks (such as dialing a telephone), it is not surprising that the setting of treatment parameters constitutes fertile ground for imprecision and error. Hendrickson (1978) suggests that accidental errors of this sort may be related to intensity of work pressure. He presents data showing that the error rate drops considerably from 3.5% when one therapist is responsible for monitoring the parameters to 0.82% when two therapists work together. He attributes this improvement to the therapists having less to do and working more carefully rather than rechecking the other's efforts. Data collected by Swann-D'Emilla, Chu, and Daywalt (1990) showing a disproportionate number of misadministrations at the higher patient census levels also support Hendrickson's interpretation. While the redundant system of double checking may reduce calculation and set-up errors, such a procedure is not flawless. First of all, therapists do not always work in pairs, but are sometimes required to enter parameters and set up patients without the assistance of a second therapist. Second, it is not uncommon for two therapists to miss the same errant parameter. And third, it is also not uncommon for two therapists to be jointly susceptible to the demands of a high pressure work environment.

In more recent years, computerized record and verify systems have been introduced as a way to preclude many of the set-up errors. These systems 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. It has been found that treatment errors can be reduced considerably and that some of these errors would have been missed by relying on traditional checking procedures (Mohan, Podmaniczky, Caley, Lapidus & Laughlin, 1984; Muller-Runkel & Watkins, 1991; and Podmaniczky, Mohan, Kutcher, Kestler & Vikram, 1985). While record and verify systems are regarded as valuable quality assurance tools, they do not catch all set-up errors. They do not verify, for example, that the patient is positioned on the treatment couch correctly. Although the vast majority of record and verify systems are found on linear accelerators, such systems also have been made available for Co-60 machines.

4.0 IMPROVING GEOMETRIC ACCURACY

Geometric accuracy refers to "the correct inclusion of the target volume within the planned treatment volume" (Reinstein and Meek, 1987, p. 28). In other words, treatment accuracy is obtained when the target volume is entirely contained within the geometric edges of the planned treatment field. A positioning error (also referred to as field placement error, localization error, misregistration, geometric miss), according to Reinstein and Meek, occurs when there is a deviation beyond an arbitrary standard (e.g., 5mm) between "the placement of a delivered treatment field (as demonstrated by the portal film) and the planned treatment field," (p. 28). Recent studies have shown an increasing awareness of the frequency and significance of field placement errors (Byhardt, Cox, Hornburg & Liermann, 1978; Dunscombe, Fox & Ryder, 1991; Dunscombe & Fox, 1989; Goitein & Busse, 1975; Griffiths, Pearcey, & Thorogood, 1987; Huizenga, Levendag, DePorre & Visser, 1988). According to Reinstein and Meek (1987), in the past much of the effort for quality assurance in radiation therapy has focused on the physical dosimetric aspects of therapy with less emphasis on the geometric treatment problems. While it is widely recognized that systematic and random localization errors can have an adverse effect on tumor control, there is a limited number of studies that demonstrate the effects of such errors (e.g., Kinzie, Hanks, Mcclean & Kramer, 1983; Marks, Bedwinek, Lee, Purdy & Perez, 1982; White, Chen, McCracken, Kennedy, Seydel, Hartman, Mira, Khan, Durrance & Skinner, 1982). In an effort to address more adequately the geometric aspects of treatment, a multidisciplinary study group, headed by Reinstein and Meek (1987), examined and made recommendations regarding relevant aspects of treatment simulation, set-up, execution and verification. Performance of each of these functions has a bearing on the correct placement of the tumor volume within the geometric definition of each treatment field.

In terms of the significance of geometric accuracy, the multidisciplinary group reported that the problem was not fully appreciated by the radiation therapy community and that there was a need to: 1) document the problem in the literature, 2) improve the training of therapists and oncologists in the geometric facets of therapy, 3) ensure that departments are not too busy to perform careful set-ups and quality control procedures, and 4) encourage communication between departments to promote greater sharing of knowledge and techniques (Reinstein & Meek, 1987). To address these issues, the study group recommended specific working groups, further research on the relationship between geometric accuracy and outcome, and the conduct of symposia to address the issues.

4.1 Problems with Attaining Geometric Accuracy

Reinstein and Meek (1987) noted several problem areas in achieving geometric accuracy and made recommendations to address them. Inconsistencies between the simulator and the treatment unit (e.g., differences in couches; source-to-skin distance (SSD) lights mounted at different locations and angles; differing ranges of couch motion; and reversal of field lengths/field widths and gantry angle conventions) were cited as having the potential to create patient set-up difficulties. It was recommended that a working group study the design issues of simulators with respect to the accurate transfer of set-up data to the treatment unit and make their findings known

to simulator manufacturers. It was noted that reproducibility of patient set-ups is bound to suffer in busy clinics when the pressure of waiting patients is experienced by therapists. The Reinstein and Meek group recommended that design criteria for optimal patient support systems (i.e., treatment couches) be established to facilitate reproducible set-ups.

While better design of treatment couches and immobilization devices should facilitate reproducible set-ups, it is not the only factor that needs to be examined. If reproducibility of patient set-ups suffers because of workload pressures impinging on the technologists, this is a patient scheduling and departmental issue that merits addressing on it own. In this regard, the Reinstein and Meek group recognized the performance of therapists as a crucial factor in attaining precise treatment, and recommended a study to determine the impact of the number of patients treated per day by a single therapist on the accuracy and reproducibility of treatment.

Another cited source of difficulty in achieving geometric accuracy is reliance on skin marks for patient positioning with the optical distance indicator (ODI), triangulation lasers, field demarcation light and central ray cross-hair shadow. Skin marks or tatoos are often unreliable due to weight changes or fading while the precision of the ODI is variable (typically $\pm$ 0.5 cm) on sloped skin surfaces, and can not be captured by current record and verify systems. The Reinstein and Meek group called for working groups and a national workshop for the study and dissemination of new approaches to accurate patient positioning and treatment localization. It was also noted that a variety of treatment aids (e.g., bite blocks, slant boards, centimeter scale graticules, body casts and cradles, arm supports, and contouring devices) have been developed to assist in accurate positioning, yet the best versions of such aids are frequently not available or well publicized. The recommendation was to disseminate this information in the form of an annual report.

4.2 Verification of Geometric Accuracy

As a way of verifying geometric accuracy, the use of portal films has received considerable attention (e.g., AAMP, 1988; Byhardt et al., 1978; Hendee, 1981; Marks, Davis & Haus, 1974; Marks, Haus, Sutton & Griem, 1974). Portal verification films are X-ray films exposed under treatment conditions with the actual treatment unit serving as the energy source. Portal films are double-exposed. The first exposure encompasses only the actual treatment field while the second exposure is made with an enlarged field with all beam shaping blocks removed, thus making it easier to recognize anatomical landmarks. Because the quality of high energy port films is markedly less than that of diagnostic or simulation films, there has been a steady effort to improve the imaging characteristics of port films (Droege, 1977; Galkin & Wu, 1978; Hammoudah & Henschke, 1977, Reinstein & Orton, 1979; and Strubler, Galkin & Suntharalingam, 1977). Although portal films render poorer quality images compared to other radiographs, they are considered to contain sufficient information for determining accuracy of beam placement (Stanton & Stinson, 1992). They also serve as legal records of the defined treatment volume under treatment conditions. While a survey of 158 radiation therapy facilities (cited in Reinstein & Meek, 1987) found that 91% of the centers took portal films on the first day of treatment, only 41% indicated they did so on a regular basis (once a week). The Reinstein and Meek group concluded there is a need for better information concerning frequency

of port film verifications based upon different treatment categories (e.g., head and neck, pediatric) and use of treatment verification aids such as the port film graticule (Van de Geijn, Harrington & Fraass, 1982).

At the same time that the quality control benefits of portal verification have led many departments to implement weekly port film policies for each patient, questions concerning the significance of port film dosage, once considered to be negligible, have been raised. By examining clinical data from 100 patients, Jones (1991) found that the impact of port film dosage borders on the significant and offers alternatives for decreasing dosages (e.g., deducting port film time from prescribed dosage, modified weekly schedules, faster port film speed).

4.3 Incorporating New Technology

Reinstein and Meek (1987) also noted the advantages of on-line, real-time megavoltage imaging which was initially explored over a decade ago (Bailey, Horn & Kampp, 1980). Advantages include elimination of time delays in processing the image, filtering and enhancing images for greater anatomical detail, and overlaying the images electronically on the simulation film for direct comparison of treatment intention. Continued improvements in resolution, speed, and maneuverability can no doubt be expected in subsequent models. In their experience with a prototype system, Wade and Nicholas (1991) report that the images were easy to obtain and they regard the technique as superior to the standard practice of using verification radiographs. Other accounts of improved precision in the delivery of multiple fractions with on-line imaging systems can also be found in Graham, Cheng, Geer, Binns, Vannier and Wong (1991) and Wong, Binns, Cheng, Geer, Epstein, Klarmann and Purdy (1990). Recommendations also are made by Reinstein and Meek to support the development and evaluation of a fully integrated treatment planning and verification scheme, which would bring under one comprehensive system the emerging technologies of imaging, CT-planning and simulation, and digital megavoltage portal imaging.

5.0 INCREASING ROLE OF QUALITY ASSURANCE

In their introduction to a set of papers presented at a symposium on quality assurance in radiotherapy physics, Starkschall and Horton (1991) comment on the increasing requirement for quality assurance (with the increasing sophistication of radiotherapy equipment) and on the increasing role of the physics staff in comprehensive quality assurance programs. According to Starkschall and Horton, a decade or so ago physics quality assurance was limited to regular checks on the output and mechanical parameters of the treatment units. At that time, quality assurance was characterized as largely an informal, voluntary effort rather than reflecting the more formalized and documented standards of practice that are in evidence today.

5.1 Quality Assurance Guidelines

Coincident with technical innovations in the planning and delivery of therapeutic radiation were the creation of some well-formulated guidelines for establishing quality assurance programs, namely: the American College of Medical Physics (ACMP) Report #2, *Radiation Control and Quality Assurance in Radiation Oncology: A Suggested Protocol* (1986); the American Association of Physicists in Medicine (AAPM) Report #13, *Physical Aspects of Quality Assurance in Radiation Therapy* (1984); the American Association of Physicists in Medicine's *Proceedings of a Symposium on Quality Assurance of Radiotherapy Equipment* (1983); as well as a more recent collection of papers, American College of Medical Physics's *Quality Assurance in Radiotherapy Physics* (1991). Over the past several years, the Joint Commission for Accreditation of Health Care Organizations (JCAHO) has set minimum standards of QA that hospitals must meet in order to maintain their accreditation (1989). To assist radiation oncology departments in meeting QA standards, the American College of Radiology prepared *Quality Assurance Program in Radiation Oncology* (1989). The World Health Organization also considered it necessary to prepare a document on quality assurance (WHO, 1988). Recently, a new task group of the Radiation Therapy Committee within AAPM has been set up to review the impact that QA programs are having and to assess recommended revisions to AAPM Report #13, published in 1984 and perhaps due for an update a decade later (Kutcher, 1991).

In addition to the guidelines established by professional organizations, the experience and observations of practitioners/investigators as reflected in their writing has helped to gain wider acceptance for quality assurance procedures (e.g., Gastorf, Horton & Harris, 1991; Gastorf, Harris & Horton, 1991; Horton, Davis & Gastorf, 1991; Purdy, 1983, 1991; Purdy, Harms & Gerber, 1987; Rassow, 1988; Svensson, 1989; and Wizenberg, 1982). In his discussion of the essential features of a treatment machine QA program, Purdy (1991a) lists the following key ingredients:

- A commitment by the staff to QA
- Adequate staffing levels
- Adequate test instrumentation
- Regularly scheduled QA and preventive maintenance reviews
- Adequate time on the treatment machine for QA and PM reviews

- Agreed-upon QA machine performance tests and acceptance criteria
- Accurate and complete documentation of the treatment machine
- Bound archival records

Purdy's placement of "a commitment by the staff to QA" at the top of the list is consistent with other authors in underscoring the importance of staff involvement as an essential component of successful quality assurance programs. 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). Or, in the words of Potocsny (1991), "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 generally accepted that successful quality assurance programs implicate the active involvement of upper management as a necessary condition and that individual efforts at QA without full departmental approval, support, resources and procedures are likely to be short-lived. The requirement for resources includes having adequate staffing levels in all the relevant disciplines as well as the necessary test equipment for checking the treatment machines. The "Blue Book" of the Inter-Society Council for Radiation Oncology (1991) contains staffing guidelines, while Purdy (1991a) provides a list of the type of test equipment considered most useful for checking beam alignment, field symmetry, and the output of the machine. In terms of regularly scheduled QA and preventive maintenance, Table 5.1 lists the Daily, Weekly, Monthly and Annual tests recommended by Purdy (1991a). It should be noted that the above guidelines and lists provided useful background information for the conduct of other phases of the present study (e.g., user-system interfaces and procedures; training and organizational analysis).

Purdy maintains that QA tests should be designed to be quick and reproducible so that checks on key parameters can be performed regularly. He notes that the daily checks take about 15 to 30 minutes per machine to complete, while the weekly and monthly checks may take from one to two hours depending on the number of tests conducted and the number of modes and energies to be examined. Purdy also recommends the establishment of performance criteria for each of the constancy checks performed. The criteria should be in accord with recognized guidelines such as those provided by the American College of Medical Physics (ACMP) Report 2, *Radiation Control and Quality Assurance in Radiation Oncology: A Suggested Protocol* (1986). Those parameters whose measurements fall outside the criteria should be adjusted until they conform with the criteria. Also underscored in the Purdy (1991a) article are the requirements for the full calibrations and monthly spot check measurements of licensed Co-60 units as established by the U.S. Nuclear Regulatory Commission (NRC) in Title 10, Part 35 of the Code of Federal Regulations, Subpart I (1990).

Table 5.1 Daily, Weekly, Monthly and Annual 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

5.2 Regulatory Guide 8.33 Quality Management Program

The NRC 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 (QM) program (U.S. NRC, 1991). For each treatment modality involving by-product material (e.g., radiopharmaceutical therapy, teletherapy, brachytherapy, gamma stereotactic radiosurgery), Regulatory Guide 8.33 has specific policies and procedures to ensure compliance with 10 CFR 35.32.

With respect to teletherapy, the regulatory guide recommends that licensees have policies and procedures for:

- Having an authorized user date and sign a written directive prior to the administration of any dose.
- Verifying, by more than one method, the identity of the patient as the individual named in the written directive.
- Having an authorized user approve a treatment plan that provides sufficient information and direction to satisfy the written directive.
- Verifying, before each administration of dose, that specific administration details agree with the treatment plan and written directive.
- Workers to seek guidance if they do not understand how to carry out a written directive.
- A qualified person under supervision of an authorized user, after each administered fraction, to make, date, and sign or initial a written record of patient's chart that contains for each treatment field, the treatment time, dose administered, and cumulative dose administered.
- Having a weekly chart check by qualified supervised person to detect errors (e.g., arithmetic errors, miscalculations, or incorrect transfers of data) resulting from daily and cumulative administrations from all treatment fields or from changes in written directive or treatment plan.
- Checking the dose calculations within three working days after administering the first fractional dose when the prescribed dose is to be administered in more than three fractions.
- Independently checking certain full calibration measurements as specified in the guide.
- Having full calibration measurements to include the determination of transmission factors for trays and wedges.

- Having a physical measurement of output prior to first administered fraction if the patient's treatment plan includes 1) field sizes or treatment distances that fall outside the range measured in the most recent calibration or 2) transmission factors for beam-modifying devices (exceptions listed in guide) that have not been measured in the most recent full calibration measurement.
- Providing the prescribed treatment without first performing the checks of dose calculations or physical measurements.
- Performing acceptance testing by a qualified person on each treatment planning or dose calculating computer program that could be used for dose calculations.
- Performing periodic reviews of the quality management program.

The above listing is an abbreviation of the suggested policies and procedures for teletherapy described in *Regulatory Guide 8.33*. For a complete description, the reader is encouraged to consult the regulatory guide. The guide serves to provide guidance to licensees and applicants for developing a quality management program acceptable to NRC in complying with 10 CFR 35.32.

6.0 EXAMINING THE CONCEPT OF HUMAN ERROR

In the everyday world of serious accidents and mishaps, human error is an easily accessible term that comes to the rescue of managers and investigators who are trying to make sense of the incident. Far too often, the term is used as a convenient label that lacks explanatory power. For example, an article in *The Washington Post* (September 11, 1982) informs its readers that "Metro Blames Human Error for Train Derailment." A three-man crew, performing routine maintenance, failed to properly lock and block a switch. Did the crew know how to operate the switch? Was the switch designed in such a way that its locked and unlocked positions were clearly discernable? Does management provide quality assurance programs for the continued performance of sound maintenance practices — even routine practices such as setting a switch? Too frequently the answer is no; yet, accidents happen, investigations are held, and human error is cited. Investigations need to be made in more depth than the mere citing of human error. Attributing accidents to human error and going no further not only provides a false sense of understanding, but it also impedes further investigation into the role of potential contributing factors.

6.1 Human Error and Human Bias

When considered within the context of the prevailing conditions of the overall system, human error is simply an inappropriate human action, failure to act, or decision, or a series of such inappropriate occurrences that has the potential to have an adverse impact on system performance. The phrase "within the context of prevailing conditions" is crucial since the same human action or decision when combined with a different set of conditions might not have the potential to degrade system performance or cause injury to people. Whether one's actions or decisions are said to be in error depends, to a large extent, on the status of the system and on other prevailing situational and organizational conditions.

Instead of automatically stopping with a finding of human error, a systems perspective forces investigators to look further upstream from the operator and examine the possibility of other types of error: faulty maintenance procedures, misdirected training, poorly designed interfaces, or indecisiveness of management. Rather than being the first line of defense in the operational system as is often claimed, operators are actually the last line of defense (and probably the most vulnerable) for it is operators who inherit the less recognized errors of omission and commission of everyone else who has played a role in the design of the greater socio-technical system. Reason (1990) perhaps makes this point best: "Rather than being the main instigators of an accident, operators tend to be the inheritors of system defects created by poor design, incorrect installation, faulty maintenance and bad management decisions. Their part is usually that of adding the final garnish to a lethal brew whose ingredients have already been long in the cooking" (p. 173).

Another disturbing quality regarding many investigations of human error is the hidden role that human bias may play. Despite the best of intentions, humans do not always make fair and impartial assessments of events and other people. A good example is the research on *hindsight*

bias by Fischhoff and colleagues (Fischhoff, 1975; Slovic & Fischhoff, 1977) which also is discussed by Reason (1990). Proclamations about human error are most always made "after the fact," rarely before. The most significant psychological difference between individuals who were involved in events leading up to a disaster and those who are called upon to investigate after it occurred is knowledge of outcome. Investigators have the luxury in hindsight of knowing how things were going to turn out; the operators and their supervisors did not. While most people would not expect much credit for picking a horse after it has won the race, many investigators are unaware of the influence of outcome knowledge on their perceptions and reconstructions of the incident. Given the advantage of a known outcome, what would have been a bewildering array of non-convergent events becomes assimilated into a coherent, causal framework for making sense out of what happened. In fact, it may be difficult to imagine it happening any other way. "Why couldn't they see it?" is the question that is often asked. Such hindsight results in expectations by investigators that participants should have anticipated the incident by foresight; it also blinds them to what actually would have been known had the roles been reversed. If investigations of human error are to be fair and impartial, appropriate actions and decisions need to be determined before the mishap; not from the comfortable vantage point of hindsight.

Investigations of accidents also are susceptible to *attribution error.* When human observers or investigators set out to determine the causal factors of someone else's misfortune, they tend to make a fundamental error, known as the *attribution error* (Jones & Nisbett, 1971). Rather than giving careful consideration to the prevailing situational and organizational factors that are present when misfortune befalls someone else, the observer tends to make dispositional attributions and views the mishap as evidence of some inherent character flaw or defect in the individual. On the other hand, when misfortune befalls the observer, he or she is more likely to attribute the cause to situational or environmental factors rather than dispositional ones.

6.2 Pragmatic and System Characteristics

Rasmussen (1987) points out the arbitrary and somewhat pragmatic aspects of investigations of human error and system performance. When system performance is below some specified standard, an effort is made to backtrack the chain of events and circumstances to find the causes. How far back to go or when to stop are open questions, the answers to which are likely to vary among different investigators. One could stop at the operator's actions and claim operator error, or one could seek to identify other reasons — incomplete procedures, confusing controls and displays, malfunctioning components, management oversights — that may have served as contributing factors. Rasmussen notes that the search for causes will stop when one comes across one or more factors that are familiar and therefore are acceptable explanations, and for which there are available corrections or cures. Since there is no well-defined start point to which one is progressively working backwards through the causal chain, how far back one is willing to search is likely to depend on pragmatic considerations such as resources, time constraints, and internal political ramifications. Rasmussen also observes that some human actions become classified as human error simply because they are performed in unkind work environments; that is, work environments where there is not much tolerance for individual experimentation and where it is not possible for individuals to correct inappropriate actions before they lead to undesirable consequences. In some unkind environments, it may not be possible to reverse the

inappropriate actions while in others it may not be possible to foresee the undesirable consequences. Rasmussen's unkind work environment is quite similar to Perrow's (1984) notion of *tightness of coupling* in complex systems.

Perrow's (1984) analysis of system disasters in high risk industries also shifts the burden of responsibility from the front-line operation of the system to actual properties of the system. Using the concepts of *tightness of coupling* and *interactive complexity*, Perrow focuses on the inherent characteristics of systems that make some industries more prone to accidents. Tightness of coupling refers to dependencies among operational sequences that are relatively intolerant of delays and deviations, while interactive complexity refers to the number of ways system components (i.e., equipment, procedures, people) can interact, especially unexpectedly. It is the multiple and unexpected interactions of malfunctioning parts, inadequate procedures, and unanticipated actions — each innocuous by itself — in tightly coupled systems that give rise to accidents. Such accidents are rare but inevitable, even "normal," to use Perrow's terminology. By understanding the special characteristics of high-risk systems, decision-makers might be able to avoid blaming the wrong components of the system and also refrain from technological fixes that only serve to make the system riskier. In the same vein, the application of task network models (e.g., Laughery & Laughery, 1987) merits consideration as a way of understanding the dynamic effects on human performance of varying levels of *tightness of coupling* and *interactive complexity*.

6.3 Taxonomies of Human Error

Those who attempt to derive workable taxonomies for classifying human error find that it is not an easy task (e.g., Senders & Moray, 1991). There are task-oriented schemes (Swain & Guttmann's (1983) errors of omission, errors of commission, sequence errors, and timing errors); information-processing models that emphasize the role of the operator as hypothesis-tester (Rouse & Rouse, 1983); and environmental schemes that go beyond the operator's immediate environment of controls and displays and examine the role of the social-managerial-organizational influences as well (Sanders & Shaw, 1988). There is no universally accepted scheme that will satisfy everyone's needs. Some obviously are more useful for a particular setting than others. One recent taxonomy, based on the relationship between performance levels and error types, that has application to the teletherapy environment can be traced to the work of Norman (1981), Rasmussen (1982; 1986), and Reason (1987; 1990). Table 6.1 is adopted from Reason (1990) and shows a basic relationship between performance levels and error types.

Table 6.1 Performance Levels and Error Types

Performance Level	Error Type
Skill-based (SB) level	Slips and lapses
Rule-based (RB) level	RB mistakes
Knowledge-based (KB) level	KB mistakes

Source: Reason, J., *Human Error*, Cambridge: Cambridge University Press, 1990; Reprinted with permission of Cambridge University Press

Errors depend on the level of behavior involved. The three performance levels are based on a distinction made by Rasmussen (1982; 1986). Skill-based performance represents intended sensorimotor activity that takes place "without conscious control as smooth, automated, and highly integrated patterns of behaviour" (Rasmussen, 1986, p. 100). Such activities are of a routine, nonproblematic nature that take place in familiar surroundings. This is the performance level that characterizes a large percentage of the tasks performed by the radiation therapists as they enter treatment parameters in the machine and set up the patient. Errors that occur during skill-based performance are termed slips and lapses. 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 whenever there is the opportunity for attentional capture through workplace distraction or preoccupation. Slips, such as using a wrong block in teletherapy, are quite unpredictable since they involve momentary interruptions of highly practiced, automatic routines. Lapses are a more covert error form, 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 fraction, a lapse has occurred. The value of recommending additional training for therapists who commit slips and lapses would be questionable since they are quite proficient at inserting blocks and recording the daily treatment. To the extent possible, it makes more sense to detect and remove the environmental or organizational distractors that contribute to slips and lapses rather than try to improve task performance that is already at asymptotic level.

Rule-based behavior, according to Rasmussen (1986), is "controlled by a stored rule or procedure that may have been derived empirically during previous occasions, ... or it may be prepared on occasion by conscious problem solving and planning" (p. 102). Knowledge-based behavior occurs in unfamiliar situations and refers to the control of performance at a higher conceptual level where a goal is explicitly formulated and alternative plans are considered for reaching the goal. Consistent with Rasmussen's approach, rules may be explicitly stated, formally learned, and shared among operators (e.g., procedures which are specifically trained and

practiced). They might, however, more frequently be informally learned through experience and different from one operator to the next (e.g., an idiosynscratic but normally effective sequence of activities used by physicists during treatment planning). The plans that guide knowledge-based behavior tend, by their nature, to vary with the knowledge available to the person or group and with the conditions under which the plan is formulated. Many treatment planning activities and dose distribution determinations of the physicist are examples of rule-based performance since a body of explicit goal-directed rules already exists and can be described. Other treatment planning activities of the physicist or the conceptual model used by the oncologist in deriving the suspected tumor volume may best conform to knowledge-based performance.

Errors that occur at the rule-based and knowledge-based levels are labelled mistakes. Unlike slips and lapses, mistakes occur when intended actions proceed as planned; however, the intended action, plan, or means of implementation is inappropriate. Mistakes thus refer to inadequacies in the planning process, to some deficiency of judgment in the selection of an objective, or in the means or set of rules used to achieve the objective (Reason, 1990). As with planning failures, mistakes often involve the less understood and less easily recognized higher mental processes used for problem-solving. The consequences of mistakes can be quite insidious over the long term. While the intention is desirable and compelling, the harmfulness of the consequences may accumulate gradually and become perceptible only after a prolonged period (Woods, 1984). Unlike slips and lapses that are frequently caught in the near-term through a system of redundant and independent checks, there is no near-term detection of mistakes since the consequences of plans are often delayed and obsfucated by time and other events. When checks are made against the rule or plan, performance may be appropriate; however, the rule or plan itself may be inappropriate. The plan also is dependent upon the resources available to implement it. Who is responsible, for example, if the treatment does not fully encapsulate the tumor volume and malignancy continues to spread after treatment? Clearly the radiation oncologist is responsible for the adequacy of the treatment plan; however, the oncologist is dependent upon the skills of the medical physicist in mapping out alternative delivery approaches, and the physicist, in turn, is dependent upon the sophistication of the treatment planning equipment in the department, the presence of which is dependent upon the financial health of the hospital.

The appropriateness of rules and plans is more difficult to evaluate since their true effectiveness is known only after the consequences become known. Given vagaries of the situation, inadequate rules or plans can sometimes succeed and good plans can sometimes fail. Some investigators have made a distinction between the logical soundness of the plan and the effectiveness of the plan (Nickerson & Feehrer, 1975). Logical soundness is the extent to which the plan is congruent with established criteria, up-to-date information, and optimal use of available resources at the time of decision. This allows the quality of the plan to be evaluated before setting it to action. Effectiveness of a plan is evaluated in terms of the extent to which outcomes are achieved after the plan is executed.

6.4 Contributing Factors to Human Error and Accidents

In their research to determine the contribution of system factors in the occurrence of underground injury accidents for the Bureau of Mines, Sanders and Shaw (1988) reviewed several different models and then proposed the model of contributing factors in accident causation (CFAC) shown in Figure 6.1. Although the model was developed to address accident causation in the underground mining industry, the major factors identified have direct application to occurrences of human error in the teletherapy setting as well. The model shows that a certain element of chance is involved in accidents. Unsafe behavior, like human error, is a deviation in human performance from an accepted standard. The term unsafe behavior typically is used when the consequences of the deviation have safety implications (i.e., injury to personnel, damage to equipment). Human error does not always result in unsafe behavior, nor does unsafe behavior always lead to an accident. But sometimes it does, especially in hazardous or unforgiving environments. In Figure 6.1, the first tier, labelled *worker/coworker*, shows a number of organismic variables (alertness, physical capabilities, fatigue, motivation, illness) that may contribute to unsafe behaviors. These same variables in a coworker with whom one shares system performance dependence also can lead to unsafe behavior. The influence of coworkers is important to recognize (as seen in the earlier discussion of the need for having two therapists work together to perform double-checking procedures), but has been somewhat neglected in the past. The second tier variables are under the major headings of *physical environment, equipment design*, the *work itself*, and the *social/psychological environment*. These variables reflect different dimensions of the worker's immediate environment that have an influence on the worker's organismic state. The immediate environment may be the ambient physical one within which the individual works, the layout and arrangement of workplace equipment, the nature of the work itself, or prevailing social norms and organizational climate. It is very likely that variables in these environments do not exert their effects in an isolated, singular manner. Instead, they combine with one another to lead to complex and difficult-to-decipher interactions. The third tier variables — safety orientation, production pressure, incentive systems, staffing, resource availability and so forth — in turn, exert their effects on the separate environments in which workers dwell and interact. As indicated elsewhere, the role of management as a contributor to human error and accidents is starting to be recognized. The noteworthy aspect of the Sanders and Shaw (1988) model is that the importance of managerial and social-organizational factors are fully recognized while not overlooking the significance of classical human factors categories of the physical environment, equipment design, and the work itself.

A similar model adapted from the work of Reason (1990) on accident causation was introduced by Henriksen, Kaye and Morisseau (1991) to account for the intricate concatenation of major factors that can lead to human error in the teletherapy setting. Figure 6.2 shows the limited but possible opportunity for slipping through the defenses provided by treatment delivery, human system interfaces, training, procedures, and organizational factors once the crank of daily operations sets the major factors in motion. Furthest downstream in the figure is the line of defense of treatment delivery. These are the tasks performed by the radiation therapists. As front-line workers of the teletherapy system, they set up patients on the treatment couch, enter the necessary machine parameters to deliver the correct dose to the treatment fields, turn the beam on, and record the administered daily fractionated dose and accumulated dose for each field.

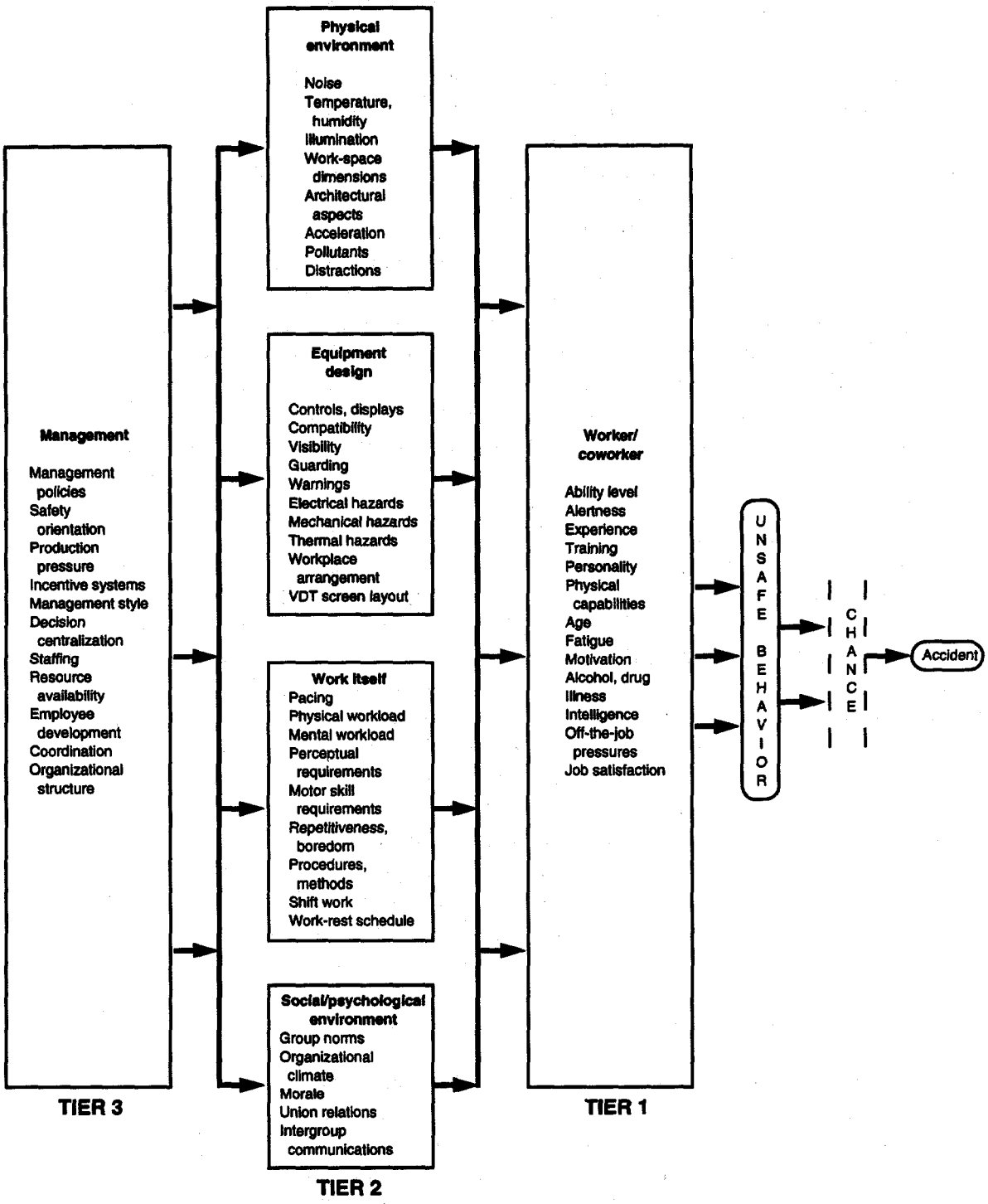

Figure 6.1 A Model of Contributing Factors in Accident Causation (Sanders, M.S. & E.J. McCormick, *Human Factors Engineering and Design*. New York: McGraw-Hill, 1993; Reprinted with the permission of McGraw-Hill, Inc.)

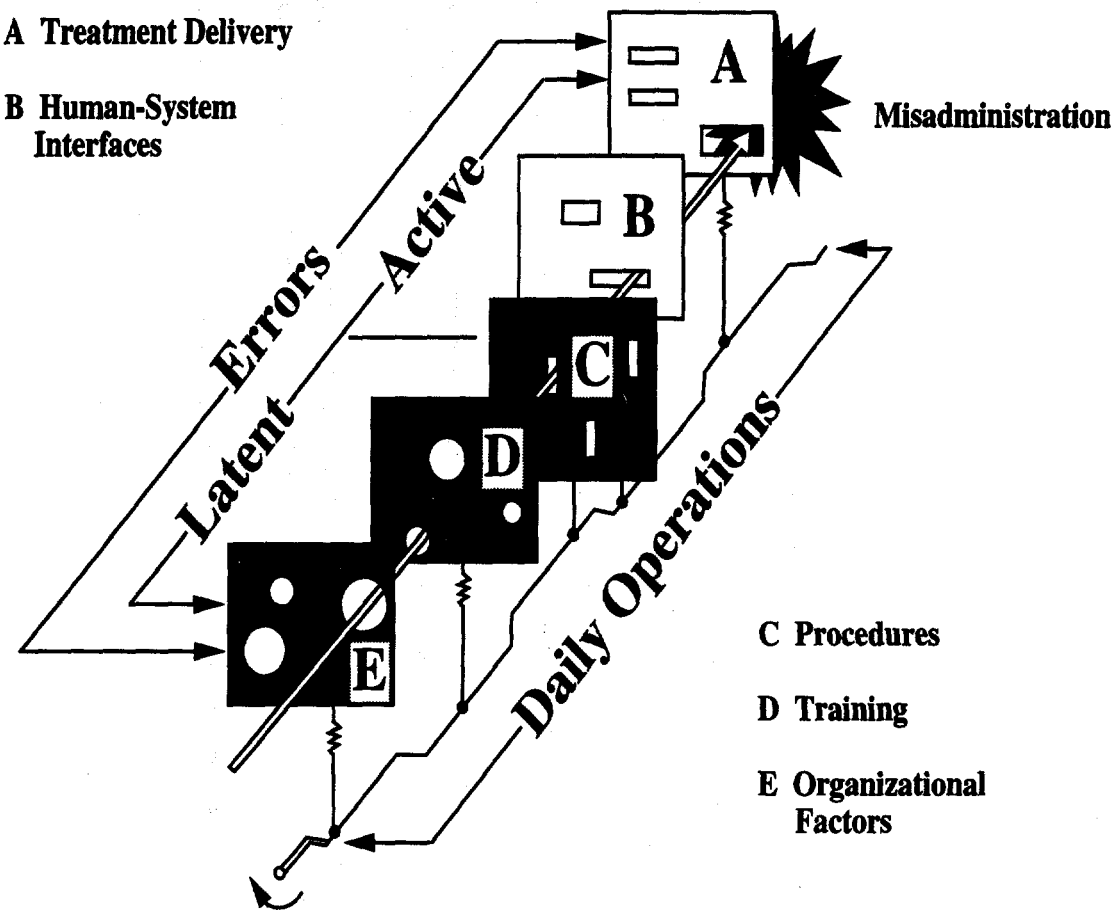

Figure 6.2 Conceptualization of Human Error in Teletherapy (Adapted from Reason, 1990)

Errors that occur here are termed active errors; their occurrence is noticed typically in the near term, although some errors may go unnoticed for some time or never be identified. These are the slips and lapses discussed above. Many of the treatment delivery errors can be compensated for in subsequent treatments. Furthest upstream in the figure are the organizational policies and practices that may either curtail or facilitate the opportunity for human error. Errors that occur at the organizational level are propagated by those in decision-making positions (e.g., department heads, hospital administrators), far removed from the treatment machines and control consoles of the therapist. These are fuzzy, difficult-to-trace, and often unrecognized errors that antecede and lie dormant for some time in the greater socio-technical system. For example, the absence of a credible quality assurance program would be an error of omission occurring at the decision-making level. As Figure 6.2 implies, the adverse consequences of ignoring the need for a quality assurance program may become apparent only when this organizational "error of judgment" aligns itself with marginally trained personnel, ambiguous operating procedures, poorly designed user-system interfaces, and a rapid-paced production schedule for treating patients. The figure portrays the dynamic aspects of human error and underscores the notion that accidents may result from a unique interaction of several necessary but singly insufficient factors. Many of these factors are present in the system long before the actual occurrence of an incident (Reason, 1990).

7.0 WORKPLACE ENVIRONMENT

The benefits of a work environment that is purposefully designed for the nature of the work that is performed has been well understood by the military and aerospace industries for a number of years. Other professions, including the various medical disciplines, have only recently begun to examine the relationship between workplace variables (e.g., design of jobs, equipment, and physical lay-out) and employee performance (e.g., efficiency, reduction of error, job satisfaction). It is generally accepted that one's immediate physical environment can serve to facilitate or impede the tasks performed in that environment (Deasy, 1974; Harrigan, 1987; Lueder, 1983; McCormack; 1970; Pellow, 1981). The central contention of much of the literature reviewed in this section is that intelligent design of the workplace environment will not only eliminate unnecessary effort in the actual execution of jobs, but also can improve the way information is transferred from people to people and between people and machines. Increased concern about the latent or less recognized contributory factors to human error will likely lead to increased appreciation of the role of factors that make up our immediate work environment.

7.1 Building and Facility Design

The proper starting place, before workplace layout is considered, is with the design of the building and facilities. This assumes, of course, that the design and construction have not already been completed. Organizations do expand, redesign, and build anew, and thus it is important to know something about the building type, what design features have proved successful in the past, and what features have failed (Harrigan, 1987; Harrigan & Harrigan, 1979). A good familiarity with user requirements and with the existing range of possible options for each design element is critical. The premise that the user is the starting point in building design is not new to architecture. Known as the performance approach, and generally accepted since the early 1970s, architects have developed methods — not dissimilar to function and task analysis techniques — for inventorying the activities that are performed by building occupants (Brill, 1974; Wright, 1971). Cronberg (1975) notes that activities are the link between the user and the physical environment. Listed below are a few of the questions that should be answered if one intends to design and plan environments from the perspective of user expectations and requirements (Harrigan and Harrigan 1979; Harrigan 1987):

- What programs, services, and operational schedules will be in effect during the period of facility use?
- What are the relationships between groups and organizations that use the facility and influence activities within the facility?
- What individuals and groups must exchange information and what is the nature and frequency of this exchange?
- How many people will be entering, leaving, and moving about within the facility, for what purpose, and how frequently? What facility spaces are likely to be subject to particularly heavy user flow?

- What user groups require special equipment, fixtures, furnishings, placement, signage, safety features, and security components?
- What are the recommended circulation patterns for facilitating information, users, equipment, and material flow between spaces?
- Who will be using the facility? How may these users be grouped into categories? How many individuals would each category include?
- What are the characteristic activities of users? What is known about the extent, time of occurrence, and duration of anticipated activities?
- What are the norms (e.g., gender, age), traditions, and special characteristics of users? Are these trends likely to continue in the future?
- What spaces are needed to support user activities? What space layouts are most compatible with requirements and characteristics of users? What is the estimated square footage for each facility space?
- What equipment, fixtures and furnishings, both stationary and mobile, are required for each facility space?
- What is the best way of meeting space adjacency and circulation flow requirements for the facility?
- What provisions with respect to users should be made for temperature, humidity, airflow, illumination, noise, distraction, hazards, and climatic conditions?

The implications that the above questions have for the design of radiation oncology departments are fairly clear. In some of the older facilities, one can find inappropriate spatial arrangements with respect to personnel who need to be close to one another. Physicists and oncologists need to be located close to the work stations of therapists to respond to questions regarding treatment. When these personnel are located on separate floors or in out-of-the-way locations, questions regarding treatment clarification are frequently left unasked.

7.2 Workplace Layout

Workplaces are those locations where personnel perform a series of tasks for an extended period of time. Given the length of time spent at the workplace and the number of repetitive activities involved, the layout of the workplace has a direct bearing on performance levels and efficiencies realized. When designing the workplace, human capabilities need to be considered in terms of the work envelope for standing and seated positions, distances traveled, work surfaces, the lifting of weighted objects, visual requirements and communication flow. Unnecessary travel distances to retrieve needed information or to perform enabling tasks can waste the valuable time of an operator who needs to maintain a schedule. Repetitious, unnecessary motor activity may facilitate fatigue. Information needed by several people should be placed in a central location, communication and coordination should be maximized by suitable

spatial arrangements, and clear lines of sight need to be maintained for monitoring tasks (Cushman, Nielsen & Pugsley, 1983).

In addition to general workplace design guidance, there are also specific considerations that need to be given to selective aspects of the workplace. Specific design considerations can be found for workplaces where there is a predominance of sitting or standing (Cushman, Nielsen & Pugsley; 1983, Lueder, 1983; Mandal, 1982); biomechanical stress and manual lifting (Chaffin & Andersson, 1984; Ayoub, 1982a, 1982b); noise (Davies & Jones, 1984; Jones & Broadbent, 1987; Webster, 1984) and visual work (Cushman & Crist, 1987; Grandjean, Hunting & Pidermann, 1983; Helander, 1987; Fulkner & Murphy, 1973; Murch, 1984; National Research Council, 1983).

Workplace guidelines have not always been based on a foundation of empirical investigation, however. Mandal (1982) explores the myth of the proper right-angled, upright seating position that has been handed down generation after generation and has even found its way into national and international standards. Mandal notes:

> In 1884, the German ortopaedic [sic] surgeon Staffel constructed the forerunner of the modern working chair. He stressed the importance of lumbar back support (kreuzlehne) to give the right-angled, upright position.
> . . . But no normal person has ever been able to sit in this peculiar position for more than 1-2 min., and one can hardly do any work as the axis of vision is horizontal. As soon as we have to read, write or do precision work, we bend over the table in order to position our eyes at 20-40 cm distance from the book or the item. This compared with the 50-60 cm of the upright position. It is here that the crucial problem of the seated position is to be found.
>
> Staffel never gave any real explanation why this particular posture should be better than any other posture. Nevertheless, this posture has been accepted ever since quite uncritically by all experts all over the world as the only correct one.

In departments of radiation oncology, one can find a variety of chairs and stools used by therapists, physicists, and oncologists. Like many organizations, little thought is given to seating requirements; however, well-designed chairs for operational personnel are one of the most important components of the workplace. Different styled chairs will have different effects on posture, circulation, amount of pressure on the spine, and amount of effort to maintain a position. A good backrest that adjusts up and down and forward and backward is an essential feature of well-designed chairs. The backrest helps maintain the inward curve of the lower spine (lumbar) and encourages good sitting posture which results in even pressure on the spinal disks. Grieco (1986) warns readers of the problem of postural fixity; that is, the tendency to sit in one position for prolonged periods of time. A fixed posture, if maintained too long, may in the long term lead to degenerative processes in the discs. More detailed information on seated workplaces can be found in Andersson, 1987; Cushman, Nielsen & Pugsley, 1983; Mandal, 1985; and Shute & Starr, 1984).

7.3 Health Related Issues of Video Display Terminals

Concurrent with the widespread growth and use of computers in the workplace in the 1980s, considerable interest was initially focused on the health-related effects of prolonged use of video display terminals (VDTs). Eye strain, headaches, and lumbar muscular discomfort are some of the more frequently occurring complaints that individuals have reported (IBM, 1984). In a five-year study conducted by the Association of Ophthalmologists of Quebec (1982), people working on VDTs were compared with people not working on VDTs. It was concluded that continuous work on cathode ray tube (CRT) terminals for a period of five years has no harmful effect on the ocular and visual systems. Studies conducted in Scandinavia have produced conflicting results, thereby making it difficult to develop a body of practical guidelines on the safe and productive use of VDTs with which everybody will agree.

Given the proper design of VDT display characteristics, workplace lighting, seating and other workstation features, the current thinking (in the United States and Canada) is that VDT work need not cause any unique visual problems. While guidelines and standards (e.g., Human Factors Society, 1988; Grandjean, 1987; Lueder 1986a) have been developed for the design and use of VDT workstations, several investigators have noted the lack of agreement among these efforts and the difficulties involved in trying the establish standards (Dainoff & Dainhoff, 1986; Helander & Rupp, 1984; and Sanders & McCormick, 1993). The attempt to establish standards in isolation of a number of relevant factors with which the particular dimension may interact is likely to run into difficulty. The following recommendations are those for which there appears to be greatest agreement; specific dimensions or ranges for features such as keyboard heights or viewing angles have not been included:

- Adequate non-glare overhead lighting
- Adjustable heights for keyboard and terminal
- Adjustable back support for the lower lumbar region
- Arm rests
- Moderate intensity screen phosphor
- Keyboard height relative to right angle arm position; keyboard plane slightly raised
- Display screen viewing distance should be a sufficient distance from screen depending upon size of characters (many users still sit too close to screen)
- Display screen line of sight is below the horizontal
- Frequent visual breaks from the screen
- Regularly scheduled breaks from the workstation

Because VDTs provide immediate feedback to data entry input, there is a tendency among many individuals for the use of VDTs to become so self-sustaining that it is difficult to separate them from their workstations. This often happens among highly proficient individuals who spend long periods at the workstation and who may need to be encouraged to take more frequent

breaks. In a review of factors influencing performance in continuous-work situations, Krueger (1989) found that effectiveness on sustained vigilance tasks declines noticeably within 20-35 minutes of initiation and then diminishes even further after two hours. In machine-paced jobs, Krueger finds that short rest breaks reduce fatigue as well as increases job satisfaction. Decrements in performance on monitoring tasks that may endanger worker or public safety has always been a major concern. Weinger and Englund (1990) note that in some occupations, union agreements and legislation may limit the duration of monitoring tasks while other recommendations have limited monitoring tasks to sessions of less than four hours (Warm, 1984). Although there have been attempts to determine the optimal timing and duration of rest breaks (Janaro & Bechtold, 1985), it is generally realized that optimal scheduling is likely to interact with a number of other variables (e.g., intensity of the workload, design of the workstation, and individual differences). It is also recognized that teletherapy personnel, by the diverse nature of their jobs, do not spent inordinate amounts of time solely on monitoring tasks.

8.0 USER-SYSTEM INTERFACES

The user-system interface refers to the manner in which two sub-systems — humans and computers or humans and non-computerized equipment — interact or communicate within the boundaries of the whole system. The interface is the hyphen in the expression *user-system interface*. Or, as might be depicted in a Venn diagram, it is the intersection of two overlapping circles separately labelled human and equipment. Mayhew (1992) observes that in the past the burden for a successful interface rested very much with the user. Computer systems, for example, were not very flexible or adaptable; precise and correctly formatted input was a troublesome requirement that allowed few exceptions. Computer jockeys, exercising their superior adaptability, accepted the burden of mastering obscure languages so that the two subsystems could communicate while less inclined users suffered guilt over their ineffectual efforts to communicate. All this has started to change in the last decade, however. A new discipline of user interface design has shifted the responsibility for the success of the human-computer interaction to computer software designers who specialize in interface issues. Rather than forcing users to adapt to the computer, it is now possible to design computer systems that are more compatible with the unique ways that humans work and think. Today's modern interfaces have benefitted considerably from a collection of design principles — know thy user, internal consistency, anticipation of user's actions, familiarity, direct manipulation, user control, error robustness, responsiveness, accessible documentation — that have been elaborated upon by a number of authors (Gardiner & Christie, 1987; Mayhew, 1992; Norman & Draper, 1986; Powell, 1990; Rubinstein & Hersh, 1984; Shneiderman, 1987).

Beyond the screen or panel of one's immediate workstation, however, are numerous other systems, not always well defined, with which humans interact. Brown (1986; 1991) has been an advocate of looking beyond traditional paradigms of interface design in order to understand the intricacies of user-system interaction. There are interfaces with a physical environment, social environment and organizational environment as well. As a consequence, there are likely to be subtle ways in which social or organizational factors can serve to facilitate or hinder the success of human-computer interactions (e.g., does the social infrastructure of the organization encourage users to share information and play an active learning role in understanding and mastering complex information systems?).

8.1 The Two-Sided Nature of Automation

Everybody is in favor of improved user-system interfaces whether the operational environment be a heavily shielded radiation therapy treatment facility, an aircraft cockpit, or the control room of a nuclear power plant. Not everybody is in agreement in terms of what this entails, however. As the user-system interface has dramatically changed in the past 15 years with the proliferation of microprocessor-based devices, numerous concerns about the role and level of understanding required of the human operator have been expressed (Bainbridge, 1987; Moray, 1986; Norman & Draper, 1986; Shneiderman, 1987; Weiner & Curry, 1980). At one extreme, the operator is seen as losing both monitoring and control functions with increases in automation. Reduced to boredom and complacency, the operator is viewed as little more than a passive

custodian for a complex system that he or she poorly understands. On the other hand, the purported benefits of automation are to relieve operators of the drudgery of repetitive, time-consuming and error-prone tasks, thereby freeing them to use their higher level cognitive and supervisory functions to respond to unanticipated system anomalies and failures.

Doubting the notion of human-as-able-supervisor of malfunctioning systems, Bainbridge (1987) and Reason (1990) make note of some ironies and "Catch 22s" of automation. If the system designers view their mission as supplanting the inefficiencies of fallible operators with automation, what happens to the design errors of the system designers themselves? In brief, the consequences of these errors are inherited by the operators. They reside in the system to combine eventually with other latent defects to cause performance problems or accidents. What happens to those "tasks which the designer cannot think how to automate" (Bainbridge, 1987, p. 272)? Once again, they are passed along to the operator to perform. How proficient is the operator likely to be when given manual control after the automated system fails? Not very, given that proficiency requires practice. To respond successfully to atypical and rare events in a system that has suddenly become dynamic and uncertain, operators need considerable practice. Exercising knowledge-based, problem-solving skills on a dynamic system is incongruous with the operator's accustomed, passive hands-off role in the automated setting. Recall the *Malfunction 54* incident cited earlier with AECL's state-of-the-art computer controlled linear accelerator (the Therac 25) and the initial difficulty that even the company's service technician had in tracing the source of the error message. As wryly noted by Reason, a consequence of automation is that "operators become de-skilled in precisely those activities that justify their marginalised existence" (1990, p.180).

8.2 Evaluation of the Interface

There also is a range of opinion in terms of how the user-system interface is to be evaluated. Most human factors professionals are quite familiar with the use of written criteria and guidelines for the evaluation of equipment design. The early work of Van Cott and Kinkade (1972) and Woodson and Conover (1973) is well known. For human factors personnel working on military systems, *Human Engineering Design Criteria for Military Systems, Equipment, and Facilities (MIL-STD-1472D)* also is well known. The Association for the Advancement of Medical Instrumentation (AAMI) has likewise published a set of human factors guidelines for medical equipment entitled, *Human Factors Engineering Guidelines and Preferred Practices for the Design of Medical Devices* (1988). Based on predecessor human factors engineering criteria, the AAMI guidelines provide ergonomic information and advice for controls, visual displays, audio signals, and consoles for the promotion of patient and user safety, operator effectiveness, and system safety and performance.

As an example of this approach, Cook, Potter, Woods and McDonald (1991) evaluated a humidification device (i.e., Marquest SCT 2000 Servo Controlled Tracking Heated Humidification System) using the AAMI's 1988 guidelines. The AAMI guidelines contained approximately 180 testable criteria that could be applied to a device. Not all the items applied to a given device since individual devices do not contain all the features that the guidelines covered. Sixty items were found applicable to the humidifier and all but eight satisfied the guidelines. The human

engineering discrepancies (HEDs) detected through use of the guidelines related primarily to the positioning of controls in relation to displays, the coloring of messages, and legibility of warning signals. Such evaluations are relatively straightforward once the irrelevant items have been discarded.

As one result of their effort, Cook and his associates have argued against relying solely on a checklist or set of guidelines to evaluate a device. Instead, they have advocated a more dynamic, interactive, and user-centered testing of medical devices (Cook, Potter, Woods & McDonald, 1991; Cook, Woods & Howie, 1990; Cook, 1989). Drawing on his work in anesthesiology and emerging developments in user-centered design (Norman & Draper, 1986; Norman, 1988), Cook prefers to vary operational conditions, insert faults, and map out device performance under the widest possible range of human interaction. Emphasis is placed on the human-computer interaction and whether the user can determine the current state of the device, identify controls for altering the state of the device, and maintain a mental model of device operation that reflects the actual operation of the device. Human-computer interface knowledge and principles are used to uncover flaws that might otherwise go unnoticed. For example, the apparent simplicity of devices with few controls may mislead users, especially when designers assign multiple functions to single controls, hide system states from the user, and devise complex and arbitrary control sequences (Cook et al., 1991). Such characteristics can wreak havoc with the user's mental model of the device's behavior. Flawed mental models typically exact their toll when the device fails. With an inaccurate and incomplete mental model, the failure remains a mystery, knowledged-based behavior is misguided, and the probability of user recovery is slim. To what extent does the user-system interface encourage the formation of appropriate mental models and facilitate the dialogue between user and device? Such issues, according to Cook, are most likely to be addressed under test conditions that stress dynamic operation; that is, those to which users are actually exposed.

This is not to imply that the traditional human engineering guidelines such as those of the AAMI are obsolete or of limited value. For one thing, new equipment manufacturers continue to need guidance in the design of various controls, displays, and consoles. It would be foolish to overlook the accumulated human engineering knowledge-base that these guidelines represent. In addition, our knowledge of the far-reaching, user-system interface issues, spawned by the advent of microprocessor-based technology, is still in a state of infancy despite the intellectual vigor of cognitive engineering efforts. As a consequence of increasing system opacity, Brown (1986) advocated new interface design strategies that "make evident to users the relationships between their activities in using the system and the system's underlying structural and functional characteristics" (p. 459). Increased use of opaque electronic data transfer and control systems places greater reliance on the integrity of the software that controls them and on the sensitivity of sensors that encode treatment machine parameters. Given our imperfect state of knowledge, efforts for establishing guidelines for many user-system interface issues would be premature. At the same time, to supplement the knowledge and principles already established, investigators need to be especially alert to new methodologies for evaluating issues that will certainly arise with the introduction of new technology. Relying solely on one method would be short-sighted.

8.3 Evaluation of Teletherapy Equipment

Using relevant items from the AAMI guidelines in conjunction with other data collection methods, Kaye et al. (1995) also used a checklist methodology for evaluating Co-60 treatment units, linear accelerators, and a simulator. Overall, the interfaces of the Co-60 units were found to be more consistent with the guidelines than the linear accelerator or the simulator. Compared to linear accelerators, the Co-60 units are much simpler machines and have fewer components incorporated in the user console that could violate AAMI guidelines. Table 8.1 reports some representative HEDs associated with Co-60 units and linear accelerators using the AAMI guidelines. It is interesting to note that although the underlying technologies and resultant interfaces differ between Co-60 units and linear accelerators, the HEDs uncovered by Kaye et al. (1995), with the AAMI guidelines, are similar. Given any set of guidelines that is applied to diverse technology, the evaluator is forced to consider the level of detail that the guidelines provide in filtering out deficiencies. To capture discrepancies that the guidelines may have missed, Kaye et al. (1995) also relied on incident reports, observations of the equipment in use, and information provided by therapists, physicists and other subject matter experts. In addition to deficiencies derived from checklists, such user-system interface issues as equipment condition, mechanical clock timers, differences between Co-60 units and linear accelerators, multiplicity of conventions for equipment position indication, interface modifications to control consoles, Ellis compensators, patient charts, and general workplace anthropometrics also were analyzed.

8.4 Record and Verify (R&V) Systems

External beam radiation therapy is a complex process that involves numerous tasks including the setting of 15 to 20 machine parameters for each treatment field. A patient may have up to four fields exposed per daily treatment. Even under the most favorable work conditions, there is a possibility that errors can be made that will have adverse consequences. To prevent entry of an inaccurate parameter value from enabling the wrong dose to be delivered and to provide a complete and accurate record of treatments, a centralized record and verify (R&V) system was developed at Memorial Sloan-Kettering Cancer Center in which four treatment machines (from three different manufacturers) were connected to a host computer, a dual VAX 11/780 (Mohan, Podmaniczky, Caley, Lapidus & Laughlin, 1984). Operationally, the treatment machine and couch parameters that are entered by the therapist are monitored by the system and compared with prescribed values. The system inhibits a machine from being turned on when the parameters set on the machine do not agree with the prescribed ones to within specified tolerances. Table 8.2 lists the parameters that are monitored by the Memorial Sloan-Kettering R&V system.

Table 8.1 Representative Human Engineering Deficiencies Associated with Co-60 Units and Linear Accelerators (Adapted from Kaye et al., 1995)

Co-60 Units

- the emergency off-button, a long rectangular red strip, was not labeled
- the console was placed too far back on the table for some operators, in excess of 16 inches
- the keypad for digital treatment time entry (an after market add-on which replaced the circular mechanical clock timer) was too far to the left of corresponding display
- thumbwheels used for skip/arc degree input increase by turning thumbwheel down
- the emergency stop-button on the control protruded 2", making it easy to hit inadvertently

Linear Accelerators

- Output variability of approximately 8% was detected by physicist; machine gave no indication of deviation and did not interlock
- "Dose/Deg" selector and output adjustors were labeled with numbers that were too small (about 1 mm) and difficult to read
- Thumbwheel used for monitor unit (MU) selection increased by turning down
- The display pointer for beam output level exceeded the shorter scale gradations
- Infrequently used controls for moving treatment (e.g., rotation, skip arc) occupied a central position on the control panel; these treatments are infrequently performed
- Operator's chair was a stool with no arm or back rest

Not all of the parameters in Table 8.2 are relevant to all machines. For example, the head swivel parameter is only applicable to the Center's Co-60 machine, a Theratron-780. In the event that one or more treatment parameters do not agree with prescribed values within the tolerances, the treatment is prevented, and a message is displayed on the screen indicating the prescribed value, the entered (set) value, and the tolerance limit of each parameter failing verification. On the same screen, a menu of options for resetting the parameters is presented to the therapist.

Mohan et al. (1984) were able to compile the significant verification failures that occurred over a one-year period on three of the treatment machines. Table 8.3 lists the frequencies of the various types of error that could have occurred had not the record and verify system been in place.

Table 8.2 Parameters Monitored by the Record and Verify System

Monitor units (or minutes) set	Couch pedestal rotation
Monitor units (or minutes) delivered	Fixed or rotational beam
Radiation type (X-rays, electrons or mass-dose)	Arc of rotation
Energy	Arc direction
Field width	Selector switch position
Field length	Dose rate
Collimator angle	Gantry speed
Gantry angle	Monitor units back-up
Wedge number	Source to diaphragm distance
Blocking tray number	Head swivel angle
Couch X axis	Starting angle of first arc
Couch Y axis	Ending angle of first arc
Couch Z (height)	Starting angle of second arc
Couch isocentric rotation	Ending angle of second arc

Source: Reprinted from *International Journal of Radiation Oncology/Biology/Physics*, 10, Mohan et al., "A Computerized Record and Verify System for Radiation Treatments" pp.1975-1985, 1984 with permission of Elsevier Science Ltd, The Boulevard, Langford Lane, Kidlington OX5 1GB UK

Table 8.3 Record and Verify System Verification "Significant" Verification Failures

Monitor unit	223
Collimator angle	3
Blocking tray	26
Gantry angle	18
Energy	120
Field size	12
Wedge	14
Total no. of failures	416

Source: Reprinted from *International Journal of Radiation Oncology/Biology/Physics*, 10, Mohan et al., "A Computerized Record and Verify System for Radiation Treatments" pp.1975-1985, 1984 with permission of Elsevier Science Ltd, The Boulevard, Langford Lane, Kidlington OX5 1GB UK

The significance of an error actually requires a clinical assessment based on the parameters involved, the anatomical location of the field, and the treatment techniques. For example, a field size error of half a centimeter that borders a critical structure (e.g., lens, spinal cord) is

significant; bordering a non-critical structure, the same magnitude of error would not be considered clinically significant. As noted by Mohan et al. (1984), the 416 errors represent 1.2 percent of all fields treated. What does such a percentage mean? If one assumes an average of 50 field treatments throughout the entire course of treatment for the typical patient and that the errors are likely to be randomly distributed, approximately 60% of the patients will encounter one significant error. Early concerns that R&V systems would cause the therapists to rely on the system too much and become less vigilant appear to be unfounded. In fact, Mohan et al. (1984) report that the failure verification rate gradually diminishes as the therapists become more sensitive to the common types of set-up errors. Although record and verify systems fall short of verifying the patient's position on the treatment couch, the avoidance of the types of errors found in Table 8.3 provide a good example of the beneficial application of automated systems. Because the Memorial Sloan-Kettering system uses a common data base for all treatment machines, it permits statistical analyses and generation of reports on data that encompass the entire patient population (Podmaniczky, Mohan, Kutcher, Kestler & Vikram, 1985). Patterns of verification failure can be identified, thus providing well-targeted direction to subsequent quality assurance efforts. Such systems are viewed as serving a major role in departments seeking to improve quality assurance efforts and in generating data likely to be useful in management and clinical research.

At yet another facility, treatment errors also were found to be considerably reduced using a record and verify system connected to a Varian CL-1800 accelerator. Muller-Runkel and Watkins (1991) compiled treatment errors before and after the introduction of an R&V system and found a reduction of 90% and 75% for major and minor treatment errors respectively. Errors not detected and errors introduced by the record and verify system also were noted. Because the CL-1800 does not encode block trays, missing or incorrect blocks could not be verified by the record and verify system. Errors that were introduced by the R&V system through wrong data entry at the host station included the transposition of field widths and lengths and a wrong code for wedge orientation. Correct entry of all treatment parameters at the host station is of utmost importance since all subsequent treatments depend upon the validity of initial entry parameters. Leunens and associates also found a sizable number of data entry errors (Leunens, Verstraete, Bogaert, Van Dam, Dutreix & van der Schueren, 1992). Other errors were only detected by the R&V system, having escaped all chart checks. The system detected one patient receiving one treatment less than was prescribed because a treatment was charted twice on the same day and another patient received one more treatment than prescribed because one treatment given had not been charted (and the overdose warning on the R&V system had been overridden).

Muller-Runkel and Watkins (1991) report that it was originally intended that manual charting would be replaced by computer charting in order to realize time savings and to eliminate errors like recording the same treatment twice or not recording a treatment that was actually given. The plan to rely on automatic charting was abandoned because of the cumbersome procedure for resetting faults when the accelerator developed technical problems. Also therapists stated a preference for manual charting since it enhanced their alertness and involvement in daily treatments. Furthermore, the redundancy function provided by manual charting was viewed as a valuable quality assurance procedure.

Record and verify systems initially made their debut in research-oriented facilities. With increasing emphasis on quality assurance and the importance of eliminating set-up errors, R&V systems are becoming more widely used in community-based hospitals. Muller-Runkel and Watkins (1991) note several obstacles that radiation oncology departments face when considering R&V systems. First of all, the purchase price is likely to require capital equipment funding. R&V systems do not generate revenue in and of themselves, but only serve a quality assurance function. Furthermore, most R&V systems are manufacturer specific, making networking an additional hurdle needing to be worked out if a department operates treatment units from different manufacturers. Also therapists may initially feel threatened by the monitoring capability of R&V systems or be apprehensive that the system will slow up patient treatment flow. According to Muller-Runkel and Watkins' experience with the R&V system, after a two-month transition period of learning, therapists felt that the system was easy to use and helped them prevent errors. Treatment times were longer when therapists worked alone because of the second keyboard, but were unchanged when therapists worked in teams of two. It also takes additional time for the dosimetrist or therapist to set-up the initial R&V file for each patient, to re-enter parameter values when treatment is modified, and to maintain the files (J.A. Deye, personal communication, September 28, 1994).

As indicated above, R&V systems can catch many set-up errors, but they do not catch all errors and their use can even introduce new errors of the very type they were designed to eliminate. While different manufacturers and models of R&V systems encode different parameters, typical parameters not encoded include patient position on the treatment couch, the presence of blocks, the wrong set of blocks, treatment couch position, and patient identification. With respect to introducing new errors, Leunens et al. (1992) found a number of errors were made at the time of data entry into the R&V system, demonstrating that systematic errors can result from a system that was designed to prevent random errors. These findings underscore the importance of verifying the accuracy of the original values that are entered. Such systems also would benefit from the dynamic test and evaluation procedures that Cook et al. (1991) advocate.

8.5 Software Control and its Challenges

There is a strong trend among major treatment equipment manufacturers toward software control of treatment equipment and the electronic transfer of treatment-related data. Manufacturers are developing software products and hardware/software systems that provide transfer linkages among system components for integrating such functions as patient scheduling, treatment planning, simulation, parameter set-up, and record and verify. A good example of the flow of treatment data from one component to another is the electronic control of the multi-leaf collimator, a recent innovation for custom shaping the treatment field without the fabrication of custom blocks. Collimator-leaf parameters are transferred to the treatment unit electronically once the leaf positions are established during treatment planning. This has eliminated a number of treatment-related tasks — the transfer of written and verbal communication involved in block design, the fabrication of the block, and the repeated attachment of the block tray to the treatment head — each with their opportunity for human error. Given the steady decline of Co-60 units in the U.S., it is typically the linear accelerator product line that is moving toward a more-integrated, computerized environment. The exceptions are two computer-controlled Co-60

models from Theratronics, Inc., the T-1000 and T-780 models, that can be configured to accommodate a record and verify system. As Co-60 units become increasingly scarce in the U.S., the interfaces and treatment tasks associated with these units are likely to become more dissimilar to those of linear accelerators.

There are inherent challenges, however, for the user of computerized systems. Unlike simpler electro-mechanical systems, computer systems are essentially opaque; that is, their function cannot be easily discerned on the basis of the structure of the system (Brown, 1986; Reason, 1990; Weinhous, 1991). Relegated to a monitoring function, the user is somewhat removed from the actual storage, processing and transfer of information. There are very few things that need to be "tweaked" and only a limited number of actions that will have immediate visible effects. Given the opaque nature of computerized systems, operators frequently do not have a good understanding of the full functionality of the system or even what state the system is in. Recall that the therapist in the *Malfunction 54* incident described earlier had no way of knowing that her corrections made at the keyboard (i.e., changing the "x" mode for X-ray to the "e" mode for electrons) were ineffective in lessening the intensity of the beam. The fact that service technicians and engineers could not duplicate the malfunction when initially called out to inspect the unit further attests to the system's opacity.

Consider Weinhous's (1991) very apt description of the plight of the radiation oncology department's physicist as he or she tries to understand the hidden control functions of today's computer-controlled treatment units:

> Prior to the introduction of computer controlled accelerators, physicists could easily understand most control systems. One had a set of prints and could "touch" the components (relays, switches, potentiometers, etc.). One could trace circuits and discern intent and function. Additionally, the control systems were hard-wired, i.e., not mutable.
>
> Today's computer controlled accelerator is not easily understood. The control systems are "hidden" within proprietary software. Typically, the end user does not receive a copy of the source code - the accelerator ships with only the executable image (machine-language version) of its software. There is nothing tangible for the physicist to touch! Additionally, the entire system is mutable. Should the manufacturer install a software update, the user is left with a machine that generally looks the same on the surface but which can be vastly different in its control logic or operation. Even if the manufacturer were to provide the source code for the accelerator's control system, it would be of little use to the end user. It is simply too difficult to abstract specific information from possibly 100,000 lines of unfamiliar code (let alone from code written in an unfamiliar language) (p.45).

So what is the physicist to do? How does one ensure the safe operation of a system that has such poor possibilities for being understood? Weinhous notes that traditional acceptance testing/ quality control methods can be applied to the more familiar electromechanical or modularized components of the unit's control system where they exist (Wootton et al., 1975; Svensson et al., 1984; and Horton, 1987). However, when the control system of the treatment unit is largely implemented in software, the physicist is now in the unfamiliar territory of software quality

assurance (SQA), a branch of computer science and engineering. Without specific training in software engineering, there is always recourse for the physicist to the various articles and publications that address the subject (e.g., ANSI/IEEE, 1984; Brannigan, 1985; Chow, 1985; FDA, 1987; Gelperin & Hetzel, 1988; Hamlet, 1988; Herrick & Berthrong, 1989; Leveson, 1986 and Zelkowitz, 1990). Although these materials impart the lesson that quality assurance in control systems needs to be designed in at the outset rather than tacked on later as an afterthought, it is still going to take more than the individual initiative of the physicist to ensure that the software provides for safe and effective machine operation. Since it is unreasonable to expect physicists to decipher the software details of computer-control systems, Weinhous (1992) maintains that greater cooperation and guidance is needed from the manufacturers of such systems. Weinhous recommends that the manufacturer provide a series of QA scripts (i.e., for acceptance testing, monthly QA, annual QA) as well as the necessary hardware/software components for conducting the tests. To ensure that the system is meeting all functional specifications, the scripts would need to provide the necessary detail of all the operations that QA personnel need to perform and the exact actions that should result from the operations. To ensure that the radiation oncology department has maximum leverage with the manufacturer, it is recommended that the department address these issues (i.e., put the appropriate language regarding hardware, software and QA scripting components in the purchase order) before the treatment unit is ordered.

In their review of the Therac 25 incidents cited earlier, Leveson and Turner (1993) cite as a contributing factor an "overconfidence in the software and removal of hardware interlocks (making the software into a single point of failure that could lead to an accident)." Since software design errors are difficult to detect and eliminate, the lesson to be learned from the Therac 25 accidents is the increased risk that occurs when software is assigned sole responsibility for system safety. Although software was implicated in the Therac 25 accidents, Leveson and Turner (1993) warn against falling into the single cause trap because of the complex and unpredictable manner in which contributing factors to accidents interact. Other major contributing factors to the Therac 25 accidents cited by the authors were: management inadequacies and lack of procedures for following through on reported incidents; less than acceptable software engineering practices; and overconfidence in unrealistic risk assessments. Reducing the occurrence of such accidents will require addressing more than one factor. Related discussions of software control issues as they pertain to safety of radiation therapy treatment units can be found in Jacky and Kalet, 1987; Jacky, 1988, 1989, 1990; Jacky and White, 1990; Parnas, van Schowen and Kwan, 1990; Starkschall, Steadham, Bujnowski and Harris (1989); Ting, 1987; and Weinhous, Purdy and Granda, 1990.

To help ensure that software-controlled teletherapy systems function as intended, individuals with expertise in software quality assurance procedures are likely to play a greater role. In an effort to test all the functions of a large 3-D radiation therapy planning program, Jacky and White (1990) conclude that systematic testing can uncover errors not found by informal testing, routine program use, or by comparison with other measurements; however, some errors will remain and only be discovered by actual use. Jacky and White estimate that a large planning system containing 30,000 lines of code may still contain more than 100 errors when it is released for clinical use. As noted by several investigators (e.g., Curran & Starkschall, 1991; Jacky & White,

1990), it is unlikely that any test plan can catch all the errors or that any software of this magnitude will be 100% correct. Jacky and White recommend that the results calculated by treatment planning computers should always be checked by a method independent of the planning program. Despite continued improvements in software quality assurance techniques (Chow, 1984; Fairley, 1985) and compliance by manufacturers to FDA development activities, the thorny issue of what to do about an imperfect product in clinical use remains. A greater societal issue is the willingness of developers of software, manufacturers of software-controlled equipment, and the general public (which expects flawless medical treatment) to devote the necessary resources for a more exhaustive testing of the software products that are bound to govern the outcomes of a wider range of medical treatment.

9.0 PROCEDURES AND PRACTICES

As systems become more and more complex, it is not enough to rely solely on the most experienced or skillful personnel. In many occupations, the wealth of seasoned expertise has been steadily declining over recent years. Many of the tasks involve long and complex sequences, are performed infrequently, and stretch the limits of human memory. Nor is it practical to always establish formal training programs for every skill area that involves complex performance. Oftentimes, the consequences of inadequate performance are quite severe, involving injury or death to people, damage to expensive equipment, or both. For many of these reasons, work on complex systems is often guided by written procedures or prescribed ways of doing things.

A procedure can be regarded as an ordered sequence of tasks or steps that are followed in pursuit of a system or sub-system goal. They typically are approved by higher organizational authority (i.e., higher than the person performing the tasks), are documented, allow for minimal deviation, and serve as a reference or guide for acceptable task performance. On the other hand, a practice can also refer to an ordered sequence of tasks or steps; however, greater latitude is usually evident in the execution of the tasks. Practices can vary from one locale to the next, or from one person to the next within the same locale. In brief, practices can be guided by procedures, but do not necessarily conform to them. In the literature, one sometimes finds the terms used interchangeably.

The airline industry is known for the importance it places on following procedures. Sears (1986), cited in Nagel (1988), analyzed airline accident statistics for a 24 year period (1959-1983) and developed a classification scheme for organizing the data. Of the 93 major worldwide accidents examined, 30 (33%) of them were attributed to a failure of the flight crew to follow standard operating procedures. Such a statistic points to the importance of procedures for the safe operation of airlines. At the same time, it forces us to go beyond a purely descriptive level and ask some penetrating questions about the procedures. How well do crew members know the procedures? Is there skill decay for procedures not exercised frequently? How easily retrievable are the procedures? What operational or environmental factors are likely to interfere with the expected execution of standard operating procedures? Indeed, there is likely to be a host of behavioral, medical, operational, task, equipment, and environmental variables with which the execution of procedures is likely to interact (NTSB, 1983).

9.1 Types of Procedures

Procedures vary considerably with respect to level of specificity and complexity. Some investigators distinguish between two types of procedures: algorithms and heuristics (Merrill, 1982). The series of steps of an algorithm is precisely defined and, if followed, will lead to a correct result (Landa, 1974). By contrast, a heuristic involves greater ambiguity, depending on "rules of thumb" which cannot guarantee a correct result (Geis, 1984). Simple procedures involve only a few operations, are performed in a linear sequence, and contain few decision steps.

More complex procedures entail many operations and many conditional decision points. Decision steps lead to alternative paths in a procedure.

In terms of their format (either paper-based or electronic), procedures can be represented in a number of ways: job aids, structured outlines, decision trees, flowcharts, decision tables and structured writing techniques (Jonassen, 1982). Job aids are a well known technology for supplementing the user's capacity for information storage and retrieval, and frequently are used for maintenance and troubleshooting applications (Swezey, 1987). Job aids are most useful for tasks that involve long and complex sequences, are performed infrequently, would normally rely on memory, and that may be clarified with the use of illustrations. Structured outlines show both sequential and hierarchical relationships and are read from top to bottom as with normal expository text (Merrill, 1982). Decision trees, flowcharts, and decision tables are frequently used in conjunction with the other techniques. Structured writing, or Information Mapping® as it has become known, has proved especially useful for procedures documentation where a premium is placed on the ability to quickly retrieve, skim, and comprehend needed information. Information is presented in blocks with each block containing a label that reveals the block's content (Horn, 1982). As a consequence, the user is able to locate quickly and retrieve the needed information on a page without having to read the entire page.

9.2 Transfer of Information

Procedures that involve the transfer of information between people can take various guises: written instructions, forms, labels and signs, and codes (Caplan, Lucas & Murphy, 1983). When there are a large number of steps and there are several people involved in the procedure, the transfer of accurate information is no longer as simple as it may first appear. As occurs in radiation therapy, errors due to inaccurate transfer of information will be reflected in every subsequent step and have the potential to affect adversely eventual outcomes.

Each major phase of the treatment planning and treatment delivery process involves an inevitable amount of uncertainty (Dutreix, 1984; Goitein, 1985; Hulshof, Vanuytsel & Van den Bogaert, 1989; WHO, 1988). Given the large number of steps and the number of people involved in treatment planning and delivery, the transfer of accurate information from one step to the next and from one person to another is not a process that can be taken for granted. Errors due to inaccurate transfer of information can be systematically passed along to each subsequent step and can have undesirable effects on the final result of treatment (Sutherland, 1980). Leunens and associates studied the frequency and sources of transfer errors for 464 new treatments over a nine month period (Leunens, Verstraete, Bogaert, Van Dam, Dutreix & van der Schueren, 1992). Erroneous data transfer was detected in less than 1% (139/24,128) of the transferred parameters; however, this affected 26% (119/464) of the checked treatments. It was estimated that each new treatment involved about 52 data transfers. The origin of the transfer errors was traced to one of five places in the treatment preparation chain: 1) during activities involved in treatment simulation, 2) during the input of data to the treatment planning system for calculating the dose distribution and the monitor units, 3) during preparation of the treatment chart, 4) during the input of parameters in the check-and-confirm system (i.e., Leunens' terminology for record and verify systems), and 5) during therapists' modification of the parameters introduced in the

check-and-confirm system. Table 9.1, adopted from Leunens et al. (1992), shows how the deviations were distributed according to their place of origin and as a percentage of the total number of deviations.

Table 9.1 Percentage of the Total Number of Deviations

Originating Step	All Deviations	Major Deviations
Treatment simulation	37% (51/139)	2% (3/139)
Dose distribution and calculation of monitor units	17% (24/139)	4% (5/139)
Treatment chart	14% (19/139)	4% (5/139)
Check-and-confirm system	25% (35/139)	9% (12/139)
First session	7% (10/139)	0% (0/139)

Source: Reprinted from *Radiotherapy and Oncology*, 23, Leunens et al., "Human Errors in Data Transfer during Preparation and Delivery of Radiation Treatment Affecting the Final Result: 'Garbage In, Garbage Out'" pp. 217-222, 1992 with permission of Elsevier Science Ltd, The Boulevard, Langford Lane, Kidlington, OX5 1GB UK

Major deviations refer to deviations which would, if uncorrected, cause the final tumor dose or dose to critical organs to be wrong by $\pm$ 5% or more at the completion of treatment, while minor deviations are defined as less than $\pm$ 5% at the completion of treatment. The table shows a large contribution of data transfer errors introduced during treatment simulation. Many of these errors were due to inconsistencies between preplanning data and the treatment actually simulated, according to Leunens et al. (1992). The erroneous data transfers in the middle three places of origin (i.e., dose distribution and calculation of monitor units, treatment chart, and check-and-confirm system) are attributed to transcription errors, rounding off errors, and forgotten data or exchange of data. First session deviations were decisions made by the therapists who changed or by-passed a parameter because of patient set-up difficulties. Many of the minor deviations were consciously made decisions to deviate from the intended treatment.

In 5% (25/464) of the checked treatments, major deviations occurred which could have led to a target volume miss or an over- or under-dosage in the irradiated volume. If not corrected, such deviations could have resulted in complications or a decreased probability of adequate tumor control. A large number of the major deviations (11/25) are associated with the use of wedge filters (e.g., mistakes in the choice of a wedge filter, forgotten wedge filter, or misorientation of the wedge filter in the beam). Leunens et al. (1992) underscore the vulnerability associated with the use of beam accessory devices and recommend careful quality control. A somewhat ironic feature of the Leunens data is that "nearly half of the major deviations were introduced during input of the 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). It is especially important to initiate a procedure that verifies that the data in the verification system are the same as the data on the treatment chart. To eliminate a sizeable proportion of the major errors, Leunens recommends that the irradiated volume be checked with portal imaging and the actually given dose with *in vivo* dosimetry during the first treatment session (Leunens, Van Dam, Dutreix, van der Schueren, 1990b; Leunens et al., 1992). Once all the parameters are confirmed, then they can be set in the automatic verification system.

Table 9.2, adopted from Caplan et al. (1983), gives examples of transfer-of-information errors that occur in a production setting. Many of these tasks and errors have parallels in the teletherapy setting. The first two columns identify the tasks and errors most likely to occur, while the third column lists the information display characteristics that may contribute to the error.

Table 9.2 Transfer-of-Information Errors

Task	Error	Opportunity for Error
Labeling	Mislabel	Illegible product ID Inadequate label storage and retrieval system
Packaging	Mix Product	Simultaneous handling of similar product Switch control cards Product change: improper clearing of line Shift change: communication failure

Continued on next page

Source: Caplan et al., "Information Transfer." In *Ergonomic Design for People at Work*, Volume I, Belmont, CA: Lifetime Learning Publications, 1983; reprinted with courtesy of Eastman Kodak Company

Table 9.2 — *Continued*

Task	Error	Opportunity for Error
Order Picking	Mix Order	Similar items adjacent to each other Similar product IDs
Sorting	Mixed Kinds	Incorrectly identified Poor handwriting Distraction during the task
Transcribing, Keying	Substitute, Transpose, Omit	Poor handwriting Memory overload Incompatibility of format Look-alike characters
Following Instructions	Misinterpret	Poor comprehensibility Poor legibility Poor readability
Filling Out Forms	Enter Information at Wrong Place; Enter Wrong information	Too much information on form Poor layout of form Lack of instructions
Looking Up Tables	Mistrack Across Columns	Incorrect spacing between columns; Lack of tracking aids (spaces or lines)
Monitoring Control Panels	Misread Dial; Misjudge Trend	Parallax problem (difficult to line up) Look-alike dials with different scales Information overload; inadequate sampling Inadequate knowledge of results

9.3 Recommended Practices for Transfer of Information

Anybody who has ever attempted to install a household appliance will appreciate the value of clear, concise and easy to follow written instructions. Instructions should be designed and written by personnel who are trained in the creation of instructions rather than the project engineer who was unfortunate enough to draw the shortest straw. For those seeking to master the skill, there are general guidelines (Caplan et al., 1983; Miller, 1975; Payne, 1951). It is recommended that the ordering of instructions follow the sequence of actions required. Short sentences, flow diagrams, illustrations, and algorithms are preferable to blocks of text (Miller, 1975). As mentioned above, the information mapping techniques of Horn (1982), where essential information is presented in blocks to facilitate quick retrieval, have gained a wide following. Szlichcinski (1979) advocates the embedding or integration of instructions on the actual equipment, a practice now followed by the vast number of office equipment manufacturers. Broadbent (1977) informs us that it is best to use the active tense and be affirmative (rather than the passive tense and the negative), while the classic by Payne (1951) is still considered required reading for those who have a need to write clear and unambiguous survey questions and instructions. In addition, one should not overlook the necessity of pilot testing the instructions on a group of test subjects that are representative of the user group.

Poorly designed forms constitute another human factors deficiency in many organizations (Caplan et al., 1983). How much wasted energy is expended on responding to information blocks on forms when no one really needs the information? A number of critical questions need to be asked before granting approval for the creation of forms. Is the form actually needed? How serious are the consequences of not having the form? Is every item on the form needed? What is going to be done with the information? Is there a procedure for evaluating the continued necessity of the form so that it does not live beyond its usefulness? Once the need for the form has been clearly demonstrated, then, and only then, should one become concerned about design considerations for optimizing information yield.

In transmitting short messages, labels and signs have their own requirements for effective communication. The sender must ensure that the message is comprehensible, legible, and readable. Comprehensibility depends, in part, on a person's prior knowledge of a situation and thus the message designer should have a clear purpose in mind for the message, gear it to the least knowledgeable user, and keep the message concise and unambiguous (Caplan et al., 1983). Legibility refers to the receiver's ability to discriminate among letters and numbers. Legibility can be improved on labels and signs by attending to guidelines on font styles, font sizes and color found in Cornog and Rose (1967) and McCormack and Sanders (1982). Guidelines also are available for readability and address such features as use of uppercase and lower case, spacing, borders, and layout (Caplan et al., 1983). Not to be overlooked are environmental factors that can affect message transmission. Among these are viewing distance, viewing angle, illumination, physical deterioration and competing displays (Caplan, 1975).

To help identify various items of a given class or to abbreviate and streamline the transfer of information, coding systems are used. Commonly used systems for coding are alphanumerics, symbols, and color. Alphanumerics are subject to various error opportunities necessitating

recommended preventive measures in code design (Caplan, 1975). To more easily detect the omission or addition of characters, the code should be of uniform length and composition. To recognize a substitution between numbers and letters, the location for numbers and letters in the code should be consistent. To help reduce the transposition of letters, the use of familiar acronyms is recommended. Transposition of numbers, in certain situations, can be decreased by introducing rules or patterns for adjacent numbers. Illegibility due to poor handwriting can be addressed, in part, by using consistent locations for letters and numbers and by using individual blocks for letters and numbers.

Symbols are best used when they meaningfully represent their referents and there is good strength of association between symbol and referent. The symbol designer can take advantage of well-established, existing associations (Cairney & Siess, 1982), and if that is not possible, seek to create symbols that ease the amount of new learning involved. Easterby (1967, 1970) underscores the importance of perceptual principles (e.g., strong figure-to-ground articulation, closure, simplicity, unity) for effective symbolic design. Alternative designs for the same referent can be developed and tested. In a simulated emergency setting, Collins and Lerner (1983) presented subjects with 18 designs of exit symbols under different levels of viewing difficulty and asked them to indicate whether or not the symbol was an exit sign. An analysis of errors showed that certain symbols for "No Exit" were confused with those for "Exit". Design properties of the best symbols tended to be: filled figures rather than outlined figures, figures with square or rectangular backgrounds were more reliably identified than circular figures, and simplified figures were less error prone compared to figures with a greater number of symbol elements. Once an effective symbol has been determined, Sanders and McCormick (1993) note the need for standardization (i.e., a given symbol is always associated with the same referent), especially when the symbol referent is likely to be encountered in a variety of circumstances (e.g., rest room signs, do not enter signs).

Color can also be the basis for coding systems, and is known for its usefulness in searching tasks (Christ, 1975). Given a visual field of many competing stimuli, color does an excellent job of commanding our attention. There are a number of distinct colors that individuals with normal color vision can discriminate. Jones (1962) finds that there are 8 to 15 colors that can be absolutely discriminated at least 90% of the time. Other research has found that individuals can learn to increase the number of discriminations when trained on combinations of hue, saturation and lightness (Feallock, Southard, Kobayashi & Howell, 1966). Color also can be combined with other dimensions if there is a need for multidimensional coding; however, if rapid interpretation is required, it would be unwise to combine more than two dimensions (Heglin, 1973). One needs to exercise a certain degree of caution with the use of color. Potential pitfalls include using too many colors, introducing color codes in environments that have other color coding systems, and overlooking the fact that not all workers have full color vision. The immediate environment where the color coding occurs also needs to be kept in mind. Because the cones (i.e., receptors or specialized cells responsible for seeing color and small detail under daylight conditions) in the retina must be activated to see color, color vision is reduced in dimly lit environments. For example, the usefulness of a color coding scheme in the teletherapy treatment room would need to be questioned since there are several tasks assisted by the use of laser lights for which room illumination is maintained at a low level.

With the rapid proliferation of desk top computers and software packages in the workplace, on-the-spot coding systems are being devised by greater numbers of people for a variety of purposes. Appearing in charts and graphs, the coding systems oftentimes take on a character that only the originator can readily decipher or appreciate. Rather than succumb to the "chartjunk" and "glitz" that Tufte (1983) and Wickens (1992) warn about when generating computer graphics, it is the responsibility of the designer to apply accepted human factors principles when using codes and graphics for information display. A number of sources are available for a more detailed and comprehensive discussion of effective coding and information display techniques (Caplan et al., 1983; Cleveland & McGill, 1984; Kosslyn, 1989; Sanders & McCormick, 1993; Wickens, 1992).

9.4 Communication Failures

One area of radiation therapy in which the adverse consequences of an absence of well established procedures becomes quite apparent is communication failure. It is not surprising that radiation therapy facilities have differing needs for formality of communication given considerations of size and organizational structure. Larger facilities are likely to rely more on written procedures and communications while smaller facilities will deal with many of the same issues on a verbal, one-to-one basis. As the size of the radiation oncology staff increases, as workload increases, or as the number of satellite facilities increase, direct face-to-face communication between staff members becomes more problematic. Greater reliance is placed on written messages, the telephone, or the facsimile machine. Larger facilities appear to make a greater effort in standardizing procedures in the form of comprehensive *Policy and Procedures* manuals and department-specific forms for transferring information. These findings are in agreement with what the literature reports on the relationship between organizational size and communication patterns (Fisher, 1981).

Failures of communication occur in radiation therapy departments in a manner similar to the ways they occur in all organizations. Verbal communication failures can take many forms (e.g., inadequate transfer of clinical information to appropriate personnel, inaccurate transfer of clinical information, and information overload which can lead to memory storage failure). Written communications can suffer the same problems. In the radiation therapy environment, communication failures have been reported when the treatment plan changes during the course of treatment, when therapists are rotated to a new machine, when residents and interns rotate to the department, when the patient set-ups are difficult and complex, and when one person simply assumes that the other person understands what is intended, when, in fact, he or she does not. Even written instructions may not be adequate for some tasks. For example, the complexity of and precision required for proper positioning of the patient for some treatments may be too much to put in writing. In busy departments, a therapist may seek clarification regarding a treatment, but not be able to find the attending oncologist or physicist. Given organizational pressures to minimize falling behind schedule, the therapist will go ahead and treat the patient without the assuring clarification. Other times, the communication process may be constrained by poor interpersonal relations between staff members.

Communication errors have received a great deal of attention in the aviation field because of the impact on safety margins. The imprecision of natural language combined with strong situation-dependent expectancies on the part of pilots have lead to erroneous interpretations of controller instructions (Nagel, 1988). Monan (1986) notes that pilots hear what they expect or want to hear and frequently do not hear what they do not anticipate hearing. Incident reports on aborted take-offs, missed mid-air collisions, and avoidable go-arounds implicate communication as a complex and subject-to-error process. To provide a needed redundancy for an imprecise process, Monan (1986) advocates active listening which refers to a two-way flow of information (i.e., from sender to receiver and then from receiver to sender) for the participants in the controller-pilot dialogue. Monan uses the term *hearback* to refer to the process whereby a controller actively listens to the pilot's response to an air traffic control clearance. Listeners are not merely passive receptacles of incoming information, but actively manipulate, enhance and filter the information in accord with their own organizing schemas. The more we become aware of the pitfalls of communication and the sources of confusion, the more likely we will be able to devise procedures to preclude the communication mishaps.

9.5 Formality of Procedures in Teletherapy

The development and implementation of procedures to guide on-the-job behavior are manifested in a variety of ways in different occupational settings. In teletherapy, as in many other settings, there is a continuum of procedures: from formally written documentation maintained at the therapist's workstation (e.g., operator's manual for a given treatment unit; job-aid on how to respond to a stuck source on a Co-60 unit) to unwritten procedures (typically supervisory verbal directions for performing a job in a certain way) and practices (successful modes of activity that become part of an organization's or individual's *modus operandi*). Kaye et al. (1995) found considerable variation in the extent to which procedures were documented in a nationwide study of various departments of radiation oncology. There was likely to be less reliance on written documentation at the smaller facilities; however, at some of the larger or nationally recognized centers, procedures were well documented. Table 9.3 lists a number of procedure manuals that were in evidence at one large university-based center that was affiliated with several smaller community clinics. The written procedures were placed in 3-ring notebooks and kept at the workstations of appropriate personnel for ease of access. Some were in a state of revision, reflecting a concern to keep them current.

Table 9.3 Procedure Manuals in Use at a Large University-Based Center

Policy & Procedures Manual
Treatment & Simulation Manual
Therapist Supervisor's Procedures Manual
Quality Assurance Log Book
Operating Procedures and Residents' Manual
Operator's Manual (per machine)
"Brain" Book on Machines for Dose Calculations
Daily Calibration Manual
Operator's Weekly Inspection Report
Protocol Management Manual
Nursing Procedure Manual
Planning Conference
Earthquake Preparedness

9.6 Evaluation of Procedures

How does one recognize effective procedures once they are in place? What criteria does one use for evaluating procedures? Although each organizational setting is likely to have specific criteria that directly address unique requirements, there are several criteria that apply to a wide range of teletherapy facilities. Table 9.4 summarizes the criteria that were used in the Kaye et al. (1995) study. It was generally the smaller community-based facilities that were likely to receive lower evaluations with respect to comprehensiveness, maintainability, accountability, compliance and completeness of written procedures.

Table 9.4 Evaluation Criteria for Procedures

Comprehensiveness	An assessment of the extent to which written procedures are in place across the major functional areas.
Accessibility	The degree to which procedures are located in a place that permits ease of access by operational personnel.
Maintainability	The degree to which procedures are kept up-to-date and are maintained on a periodic basis.
Accountability	The extent to which someone or some group is responsible for initiating, implementing, and evaluating procedures.

(Table continued on next page)

Table 9.4 — *Continued*

Readability	The extent to which procedures can be easily, rapidly, and precisely read.
Document design	The extent to which layout of information in the document facilitates useability and retrieval of information.
Emergency highlighting	The extent to which emergency procedures, warnings, cautions are consistently highlighted or posted to capture the attention of operational personnel.
Compliance	The extent to which personnel are complying with procedures and have a positive attitude regarding implementation.
Technical accuracy	The extent to which procedure is technically accurate.
Completeness	The extent to which procedure is complete and serves as a comprehensive guide for appropriate action.

10.0 TRAINING AND QUALIFICATIONS

Training refers to the systematic change in behavior, cognition or attitudes that is intended to result in improved performance in the work environment. Training implies a well defined, structured sequence of learning activities — frequently some combination of instruction, practice or experiential exercises — designed to raise the proficiency level of employees on specified tasks (Caro, 1988; Goldstein, 1986). In most training programs, there is a mechanism for determining whether the objectives of the program have been realized. Although it is usually the case that training involves the acquisition or performance enhancement of tasks that are currently marginally performed or not performed at all, training also could involve learning not to do something that may be occurring too frequently, such as the commission of errors. Training furthermore involves the development, management and effective utilization of training resources (e.g., personnel, materials, media, equipment) as well as the performance of administrative duties such as the keeping of trainee records.

10.1 Training Before Employment

The formal training or schooling that radiation therapists, dosimetrists, and physicists receive prior to employment constitutes the major component of their preparation and readiness to perform teletherapy services. The brief description provided here on the types of training experiences required for employment in a teletherapy setting is based on recent studies performed for the NRC (Brodsky, Cehn, Thomas, Inge, McIndoe & Goldin, 1989; Henriksen et al., 1995).

10.2 Training of Radiation Therapists

The traditional career path for radiation therapists is to enroll in a two-year program that is affiliated with a local community college or community hospital whereby students receive a combination of classroom instruction at the college and clinical experience at near-by hospitals. Another path into radiation therapy is through previous training and employment in diagnostic radiology. Individuals with this experience typically, but not always, undergo a one-year program. The minimum standards for accrediting educational programs are described in *Essentials and Guidelines of an Accredited Educational Program for the Radiation Therapy Technologist* (1988) which have been adopted by the American College of Radiology, American Medical Association, and the American Society of Radiologic Technologists.

To determine that individuals are qualified to practice the profession of radiation therapy technology, the American Registry of Radiologic Technologists (ARRT) administers a national certification examination. The examination is designed to assess the knowledge and cognitive skills underlying performance of the major tasks required of staff therapists at the entry level. To establish a close relationship between the knowledge and skills that underlie entry-level tasks and the examination content, ARRT updates and revises an existing job analysis every five years. Employment practices at radiation therapy facilities vary considerably on a state-by-state basis and by place of employment. Most states require that therapists be certified or eligible for certification at the time of employment, but many do not. Eligibility refers to satisfying the requirements of one of the approved one- or two-year programs. If eligible for certification,

therapists may be hired provisionally without certification, but will be expected to take the exam in the first year.

10.3 Training of Dosimetrists

With respect to dosimetry, there are a limited number of university-based programs providing both classroom and clinical experience. Entry into these programs typically requires a B.S. degree or certification as a therapist and one year of experience. The average program takes one year to complete. Rather than entering dosimetry through a university program, it is common for hospitals to train their own dosimetrists, usually an experienced therapist. The therapist-in-training-for-dosimetry is likely to be selected on the basis of his or her track record and will have a very good understanding of the teletherapy environment. Although most hospitals do not require certification for dosimetrists, individuals can seek certification by passing the exam administered by the Medical Dosimetrist Certification Board.

10.4 Training of Physicists

In terms of education, the radiation physicist typically has a masters of science or doctoral degree in physics or closely aligned science or specialty area. In addition to a concentration in radiologic physics, it is important for the radiation physicist to have coursework in anatomy, physiology, oncology, and radiobiology. Currently, certification for physicists is not a requirement at many hospitals, but there is a movement for either licensing or certification in some states. Physicists that seek certification can do so through either the American Board of Radiology or the American Board of Medical Physics.

10.5 Training After Employment

As indicated above, most of the formal training of personnel in teletherapy occurs prior to employment. Once hired, personnel receive most of the training that occurs in departments of radiation oncology through on-the-job training (OJT). When properly implemented, OJT has some distinct advantages. Some transfer-of-training problems are avoided since individuals are trained in the same social and physical environment in which they perform job tasks. OJT also appears ideal for those situations where teamwork is involved and the physical layout requires proximity of coworkers. Unfortunately, many employers reporting that their training is done on an informal OJT basis provide a newly hired employee with little more than the opportunity to work with a more senior employee for a few months (Goldstein, 1986). Accountability is absent with respect to establishing specific training objectives or to structuring the trainee's work environment such that it systematically promotes learning. With many OJT programs, it is very difficult to determine what is being learned despite the good intentions of the training coordinator.

OJT has been identified as the principal means by which radiation therapists meet a variety of training requirements: orientation of new personnel to the department, orientation to new equipment and software, and orientation to new procedures (Henriksen et al., 1995). With respect to new equipment and software, respondents at most sites indicated that the vendor would

provide operations and/or maintenance training for a couple of days. The lead physicist or lead therapist would receive the initial training, and then he or she would train other staff members.

Worthy of consideration for the radiation therapy community are the instructional systems development (ISD) approaches to training that have been successfully employed by the military services, a wide variety of government agencies, and private industry. Instructional systems development (ISD) procedures evolved during the late fifties with the conviction that a systems approach would take the guesswork out of training and ensure its job relevance. Most approaches to training that claim an ISD or competency-based label contain five sequential major phases: analysis (i.e., identification of tasks that make up the job), design (i.e., preparation of learning objectives for the tasks that have been selected for training), development (i.e., creation of training materials and media based on characteristics of the learning objectives), implementation (i.e., determination of how the training program is best conducted and administered) and evaluation (i.e., determination of whether training objectives are being realized and satisfying organizational needs). Although the ISD process it not immune to criticism (e.g., internal inconsistencies of the process and lack of adequate how-to-do-it information have been cited by Montague & Wulfeck, 1986; deficiencies with objectives, tests and course materials are noted by Vineberg & Joyner, 1980), the fact that various ISD versions have been adopted by the military services, private industry, and a broad cross-section of government agencies attests to its versatility and robustness.

10.6 Learning to Avoid Human Error

Some work environments are well known for their complex, dynamic, and hazardous operations (e.g., combat, aircraft, nuclear power plant) and, as a consequence, have developed special training procedures for handling unexpected problems and for reducing the occurrence of human error. While many departments of radiation oncology have active quality assurance programs, Henriksen et al. (1995) report no evidence of the use of special training procedures for the avoidance of human error or for responding to machine malfunction. For example, a machine malfunction that can have serious consequences with Co-60 units is for the source to stick in the exposed position. If this rare but known event occurs, the radiation therapists must act decisively to minimize radiation exposure to the patient and departmental personnel. Although many facilities have the correct procedure posted on the wall (next to the therapist's control console) in the form of a job aid, the likelihood of responding decisively and correctly during this stress-producing event could be much greater if the therapists have first received realistic simulated training exercises for responding to stuck sources. Rather than waiting for human error to compound the adverse consequences of such an incident, a more active strategy is to design training that specifically trains therapists for responding to critical and unexpected circumstances.

Recently there has been of surge of research interest in the range of human factors that affects performance of anesthesiology tasks in the operating room, the role of human error in anesthetic mishaps, and the effectiveness of particular training interventions (Cook, 1989; Gaba, 1989; Weinger & Englund, 1990). With respect to training interventions, Gaba and DeAnda (1988, 1989) have used hands-on simulation techniques to investigate the rapid and pressured

decision-making responses by experienced and inexperienced anesthesia residents, and by faculty and private practitioners to critical incidents. In the simulated context of head and neck surgery, Gaba and DeAnda exposed subjects to incidents ranging from minor (e.g., IV catheter kink) to major significance (e.g., breathing circuit disconnect). Individual performances were videotaped and response times from the onset of each event to its detection and subsequent correction were recorded. Although there was considerable performance variability in each group, experienced residents generally corrected problems faster than did junior residents. It was noted that most subjects responded in a stereotyped fashion, resulting in correction delays when the problem turned out to be something else. Furthermore the investigators found that the use of redundant information was poor, appropriate corrective actions were not always taken, and major deviations from standard advanced cardiac life support protocols (e.g., failure to administer epinephrine) occurred in 58% of the subjects. Also noteworthy was the finding that during the observation period, 135 new, unplanned incidents occurred of which 88% were the result of human error by the anesthesiologist.

Actually a variety of simulations and games have been used to train personnel in the health care professions. Sleet and Stadsklev (1977) annotated a number of simulated games used in a variety of health care areas (e.g., disease management, drug use and abuse, health care planning). Unlike Gaba's simulated anesthesia environment, many of these simulations did not aspire to high levels of physical fidelity (i.e., faithful representation of the physical aspects), but focused on the functional fidelity of the situation and the transfer of needed information. Functional fidelity is achieved by enabling players to process the same cues and information, make the same decisions, and be informed of the same consequences as would occur in their actual job setting.

11.0 ORGANIZATIONAL POLICIES AND PRACTICES

As indicated earlier, the role of organizational policies and practices — once neglected in human factors research — is starting to be recognized in the literature on human error, accidents and system safety (e.g., Sanders & Shaw, 1988; Senders & Moray, 1991; and Weiner, 1989). Reason (1990) has been quite articulate in noting that the lessons learned from major disasters — Three Mile Island, Bhopal, Challenger, Chernobyl, Herald of Free Enterprise, and King's Cross Underground Fire — have implicated latent error conditions spawned by management as a very significant contributing factor. In this section, different organizational factors likely to have an impact on therapeutic performance will be examined.

11.1 Staffing

The increasing complexity of radiation therapy equipment, the precision required of intricate treatment techniques, and the public expectation of quality health care are progressively placing greater demands on radiation therapy professionals. At the same time, the considerable shortage of personnel, especially radiation therapists and dosimetrists, which was identified a decade ago, continues today (Gerber, 1984). The question arises as to whether there are accepted standards or minimal staff requirements for facilities administering radiation therapy. Guidelines can be found for optimal staffing in a well known booklet, referred to frequently as the "Blue Book" or more formally as *Radiation Oncology in Integrated Cancer Management - Report of the Inter-Society Council for Radiation Oncology* (1991). Among other guidelines, the "Blue Book" provides minimal personnel requirements for radiation therapy. For example, the "Blue Book" recommends two staff therapists per megavoltage unit up to 25 patients treated daily per unit. For many facilities, the staffing recommendations found in the "Blue Book" represent the ideal rather than the reality. In visiting over 20 facilities nationwide, Henriksen et al. (1995) found that a majority of the facilities reported that their staff therapists have worked alone in treating patients on a given machine. The estimated percentage of time that this occurs ranged from 10-50%. Understaffing also was one of the work conditions cited by therapists as most stressful.

There is good reason to suspect that the level of staffing is one of those organizational factors that may lie dormant for awhile, yet eventually combine with other unsuspected variables and give rise to a treatment error. When a therapists leaves out a wedge while treating a patient, it is a bit simplistic and misleading to solely focus on human error as the culprit when the organizational setting and work conditions — understaffing, high patient load, complex treatments, very ill patients, getting behind schedule, environmental distractions — may interact in such a way as to promote the occurrence of such errors.

11.2 Patient Census

Patient census refers to the number of patients that are treated on a given treatment unit on a daily basis. The number of patients treated per day with a given machine depends on a number of factors. One of these factors is the efficiency and quickness with which the therapists can set up, treat, and then get ready for the next patient. To maximize the use of the very sophisticated and costly treatment units and to be of service to as many patients seeking treatment as is possible, the existing practice is to schedule patients back-to-back, with as many as four or five an hour given the demand. As a consequence, therapists perceive a need to work as efficiently as possible. Making efficient use of resources constitutes good management practice, but only up to a point. If management personnel become overly ambitious in the number of patients they decide to treat, work conditions are likely to become stressful for therapists and errors more likely to occur.

An empirical study by Swann-D'Emilia, Chu, and Daywalt (1990) reports a disproportionate number of errors as patient census increases. These investigators recorded both frequencies of occurrence of the average monthly census within successive intervals of patient load (e.g., 20-24, 25-29, 30-34, 35-39 patients) and misadministrations occurring within those intervals for the treatment machines in operation at their facility in 1988 and 1989. For both their 1988 and 1989 data, there was a disproportionate number of misadministrations at the higher census intervals even though these higher census intervals occurred less frequently.

Although there are very few studies in the radiation oncology therapy literature showing a relationship between workload and misadministrations, the issue is significant enough to be of concern in other medical disciplines. In anesthesiology, Gaba (1989) has noted that the anesthesiologist is susceptible to time pressure during preoperative evaluations, and in preparing for and administering anesthesia. Adding to the time pressures, according to Gaba, "are financial pressures to anesthetize the maximum number of patients possible, which may lead anesthesiologists to cut corners and ignore potential danger signals (1989, p. 145)." Inadequate preoperative evaluations associated with time pressured conditions were also observed and noted by Cooper, Newbower, and Kitz (1984) in their analysis of major errors in anesthesia management.

11.3 Organizational Commitment to Quality Assurance

Quality assurance (QA) programs are a relatively recent organizational initiative that have received quite a bit of attention in the radiation oncology literature. There are numerous articles and publications that underscore the importance of the clinical and physical aspects of quality assurance (Chaffey, 1984; Cunningham, 1984; Hanks, 1984; Purdy, 1991a, 1991b; Starkshall & Horton, 1991; Suntharalingam, 1984; Svensson, 1984). The emphasis placed on quality assurance by the Joint Commission on Accreditation of Health Care Organizations (JCAHO) and the American College of Radiology, no doubt, has played a significant role. In those facilities that formally implement QA programs, a Quality Assurance Committee typically oversees QA activities and includes a chairperson, radiation oncologist, physicist, chief radiation therapist, and other interested staff members. Areas of focus can include clinical QA, treatment machine QA,

treatment planning QA, chart review, and on-going monitoring and evaluation of the program. Weekly case review meetings are scheduled and the pertinent details of patients undergoing treatment are discussed, including treatment plans, portal and simulation films, dose distributions, and any unusual histological factors or problems encountered during treatment. A log is maintained on all cases presented and any problems requiring corrective action are documented and followed-up in subsequent meetings. In terms of monitoring and evaluating the QA program itself, procedures are implemented which identify prospective problems, delineate quality indicators that reflect current knowledge and experience, and initiate preventative and/or corrective actions for improving patient care.

At the time of their studies, Henriksen et al. (1995) and Kaye et al. (1995) reported substantial variation with respect to formal implementation of QA programs in the facilities they visited. It should be noted that actual site visits in these studies were made before implementation of NRC's *Regulatory Guide 8.33* on quality management. Some facilities had limited QA procedures in place (yet espoused the importance of QA), while 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. The greatest emphasis thus far appears to be on machine QA, stemming from the strong QA initiatives of physics department personnel. The success of a comprehensive QA program, however, requires the full support of the department's decision makers as well as the commitment and involvement of all treatment personnel. Individual efforts at QA without full departmental approval, support, resources and procedures are likely to fall short of what is required to be make a significant difference. According to one physicist, the difficulty in implementing QA programs is in following through and in maintaining continuous emphasis on quality rather than allowing the program to "fizzle out." Experience with total quality management (TQM) and QA programs in the non-health sectors of the economy have implicated the active commitment of upper management and the existence of formal procedures to follow as necessary conditions for the effective implementation of such programs (Juran, 1988). The organizational climate and level of commitment within which QA efforts are initiated and maintained serve as very important factors, even if difficult to measure and assess.

11.4 Organizational Barriers to Communication

Barriers to communication in organizations serve to distort, impede the quality, or block the flow of needed information (Fisher, 1981). To avoid communication failures, it is not enough to exhort that different functional groups should start to communicate. There is always communication of some sort, but there is not always quality communication — the level of communication that is necessary for effective performance. Understanding and resolving the barriers to communication are essential requirements for any organization. One investigator generated a list of 130 barriers (e.g., perceptual selectivity, implicit assumptions, lack of feedback, task specialization, language differences, geographic factors, task specialization, status differences) accumulated from the management literature (Lewis, 1975). Brown (1976) made a distinction between microbarriers which refer to small scale person-to-person communication and macrobarriers which include the broader, more encompassing organizational obstacles. Microbarriers include such impediments as selectively perceiving limited aspects or amounts of the message, implicit assumptions that the communicator operates from without being fully aware

of them or thinking them through, and failing to receive feedback to confirm that the message has been received, acknowledged and understood. Implicit assumptions are especially troublesome because they are part of one's unstated, taken-for-granted conception of the world. Since they are not directly observable, they have to be inferred from behavior or some behavioral deficit. Table 11.1 is adapted from Nilson (1954) and shows the inferred nature of implicit assumptions.

Table 11.1 Relationship between Communicative Behavior and Implicit Assumptions (Adapted from Nilson, 1954)

Behavior	Assumptions
Lack of inquiry into the nature and causes of problems.	I know all I need to know.
Not checking for reception and understanding.	My listeners understand what I said.
Not providing opportunities for others to express themselves.	My listeners feel (or should feel) as I do.
Treating problems once solved as if they will stay solved.	The environment is (or should be) unchanging.
Failure to examine or study communications procedures.	The process of communication itself does not need to be examined.

Macrobarriers, on the other hand, involve such obstacles as information loss from serial transmission of messages sent up and down the organization's chain of command, task specialization resulting in non-overlapping frames of reference, and mistrust among personnel resulting from differences in authority, status, and power. For example, macrobarriers are associated with the direction in which messages are sent. Downward communication, or superior to subordinate, can be quite ineffective in a serial transmission mode. In an earlier study, Nichol (1962) showed that only 20% of downward directed communication reached the bottom organizational level. A common source of dissatisfaction for lower level personnel is the lack of timely and adequate receipt of information, while a recurring tendency of upper level management is to overestimate the amount of information received by people below them. Further support for the operation of implicit assumptions comes from upper management's surprise when they hear complaints from below regarding the need for more information.

Other limiting characteristics of downward communication include its one-way nature which precludes receipt of feedback or any opportunity for clarification. Furthermore, there are likely to be differences in values and perceptions along the chain of command which serve to filter the information (Allen, 1979). Mistrust of superiors or the perception that they are a source of biased information also can serve to block the relay of downward information (Mellinger, 1956). Among the several things that supervisors can do to improve downward communication are the following: use multiple channels of communication, including face to face; maintain adequate contact with subordinates and encourage two-way communication; keep informed of subordinate's values and perceptions; share personal points of view; and build trust by letting subordinates know how decisions are made that are important to them (Fisher, 1981).

Just as there are problems with downward communication, there also are problems with upward communication, from subordinates to superiors. A major barrier is for employees to selectively transmit information that will enhance their standing with their superiors while withholding or minimizing the impact of messages that might damage their standing (Rosen & Tesser, 1970; Rosen & Tesser, 1972; Athanassiades, 1973). Minimizing unpleasant messages, identified as the MUM effect in the research of Rosen and Tesser, refers to the tendency by subordinates to only pass along good news up the chain of command, thus giving superiors a false sense that all is well. If the norms and culture of the organization are such that upper management only wants to hear about successful outcomes, not problems, then successful outcomes will be what gets transmitted upward.

As before, perceptions of subordinates and superiors can be far apart on the same issue. Likert (1961) reports that higher managers view the quality of upward communication as quite favorable (e.g., 73% of the foremen indicated they always or almost always obtain subordinate ideas) whereas subordinates do not consider the quality of upward communication as good (e.g., only 16% reported that their foremen always or almost always obtained subordinate ideas). In a similar vein, 95% of the foremen reported they understand subordinates' problems well, whereas only 35% of the subordinates indicated that foremen understand their problems well. Efforts worthy of consideration for improving the quality of upward communication include: increasing the willingness of subordinates to build relationships with superiors; increasing sensitive, objective listening skills on the part of superiors; attempting to extend the range of input by superiors for a more balanced receipt of information; acknowledging the existence of problems and the dedicated efforts of all to solve them, and increasing the number of informal contacts with subordinates (Fisher, 1981).

To enable coordination, sharing of information, and joint problem solving, communication also occurs in a lateral direction. In a traditional vertical organizational hierarchy, to communicate across functional boundaries, managers in one line of command would need to go up their respective chain of superiors, cross over at perhaps a vice-president level, and then descend to the appropriate level in the recipient's chain of command. To reply, the recipient's return communication would then need to go back up his or her chain of command, cross over at the higher level, and then descend back down the other side. To avoid this cumbersome and inefficient path of communication, mid-level managers in different departments bridge the formal hierarchical structure and communicate directly as co-laterals. Known as Fayol's bridge (1949),

direct co-lateral communication saves considerable time and reduces distortion and information loss involved in a series of upward and downward communication links. Ponder (1968) found that effective managers spent more time communicating with co-laterals, while less effective managers focused more time and attention on their subordinates. While some of the earlier research reported that organizations are more likely to recognize and reward hierarchical communication (Albaum, 1964; Schwitter, 1965), increasing specialization in the workplace has added the requirement for efficient communication across organizational boundaries.

11.5 Other Organizational Factors

Table 11.2 summarizes a wide range of organizational factors that were cited by teletherapy personnel as factors that potentially serve to impede or facilitate task performance in the teletherapy setting (Henriksen et al., 1995). The entries in the table are reported without any indication of importance or priority; they are based on interviews with teletherapy personnel to establish the organizational factors that have the most impact on therapeutic performance.

As noted earlier, errors that can be traced to managerial and organizational factors remain poorly understood due, in large measure, to their dormant and delayed nature (Rasmussen & Pedersen, 1984; Reason, 1990; Senders & Moray, 1991). To use Reason's (1990) metaphor, these are the resident pathogens that lie dormant for some time, yet combine with other unsuspected pathogens to thwart the system's defenses and lead to error. Errors of indecision or omission, more likely to be made by managers and administrators, are termed latent errors because they occur further upstream in the sequence of events and are more difficult to trace. Frequently, decisions are made in a loose, diffuse, incremental, somewhat disorderly fashion (Kotter, 1982; McCall, Kaplan & Gerlach, 1982; Simon, 1987). Decision-making consequences accrue gradually over time, interact with other variables, and are not that easy to isolate and determine. Yet organizational practices regarding staffing, communication, workload, patient scheduling, and quality assurance procedures surely have their impact. The near-term errors that therapists make result, in some measure, from the delayed effects of organizational shortcomings. These errors likely result from the delayed effects of several necessary but singly insufficient factors that combine in unanticipated ways. Many of these factors are present in the system long before the actual occurrence of human error.

Table 11.2 Organizational Factors that can Affect Task Performance

- Staffing levels
- Organizational climate for self-reporting of errors
- Communication practices among team members
- Coordination of satellite sites
- Workload for treatment personnel
- Environmental distractions
- Scheduling of patients
- Accessibility of oncologists
- Clarity of treatment plans
- Commitment to QA procedures
- Patient census
- Equipment replacement/procurement
- Professional growth opportunities

12.0 CONCLUSION

The present literature review was undertaken in support of a series of human factors evaluations to identify the contributing causes of human error in teletherapy. Teletherapy (or external beam radiation therapy) was defined as a multidisciplinary and multiphased treatment 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 Co-60, or a linear accelerator. Since teletherapy entails a large number of steps, involves a number of people, and is delivered (in fractions) across a number of days, effective and safe treatment requires a concern for the factors that affect precision and consistency of human-human and human-machine interactions. The following conclusions are derived from the literature review:

- The multiphased nature of teletherapy involves the interactions of radiation oncologists, medical physicists, dosimetrists and radiation therapists in a complex sequence of interrelated activities. These activities include clinical evaluation, therapeutic decision-making, target volume localization, treatment planning, simulation of treatment, fabrication of treatment aids, treatment, patient evaluation during treatment, and follow-up evaluation. The consequences of errors made during an early phase may or may not become evident at a later phase.

- Precision of treatment is a major requirement; otherwise the tumor cells may remain undestroyed. Major areas of concern for precision include localization of the tumor, the medical physics of the treatment process (e.g., dosimetric uncertainty of beam monitoring and calibration), reproducibility of patient positioning and immobilization, and consistency in the correct daily input of treatment parameters (e.g., field sizes, gantry angles, insertion of wedges).

- Greater awareness of the need to ensure geometric treatment accuracy as well as the physical dosimetric aspects of therapy is evident. Geometric treatment issues include a variety of factors that influence the correct placement of the tumor volume within the geometric definition of the treatment field (e.g., reproducibility of treatment set-ups, adequacy of portal verification films).

- The increasing role of quality assurance (QA) programs has become evident during the past decade. Various QA guidelines have been prepared by professional associations. Hospitals must meet minimum standards of quality assurance established by the Joint Commission for Accreditation of Health Care Organizations (JCAHO) in order to maintain accreditation. Recently, the NRC issued *Regulatory Guide 8.33* which serves to provide guidance to licensees and applicants for developing a quality management program acceptable to NRC in complying with 10 CFR 35.32.

- Notions of human error also have changed over the years. Rather than automatically assigning blame to the front-line operator, a systems perspective avoids the single-cause mentality of earlier studies and forces investigators to examine the role of other unsuspected contributing factors such as poorly designed interfaces, ambiguous procedures, and questionable management practices.

- With respect to the workplace environment, individuals and groups that must share information such as oncologists, physicists and therapists need to be co-located to efficiently resolve treatment-related questions. Designers of individual workplaces need to take into account human capabilities for standing and sitting, distances traveled, the lifting of weighted objects, use of special tools, visual requirements, and communication flow.

- With the advent of microprocessor-based technology, the user-system interface has changed considerably in the past 15 years. Both advantages and new challenges can be cited. In teletherapy, improved user-system interfaces can prevent errors that would otherwise go undetected through the use of computerized record and verify systems. At the same time, computer systems are essentially opaque, making troubleshooting difficult. The control systems of linear accelerators are implemented in software which is likely to be unfamiliar to personnel responsible for performing monthly and annual QA.

- In terms of procedures, larger facilities rely more frequently on written procedures and documented communication while smaller facilities address the same issues on an individual face-to-face basis. Even with documented procedures, transfer-of-information tasks are a fertile source of errors. In teletherapy, transfer errors have been traced to treatment simulation, input of data to the treatment planning system, preparation of the treatment chart, input of data to the record and verify system, and modification of parameters introduced in the record and verify system.

- The formal training or schooling received by therapists, dosimetrists, and physicists prior to employment constitutes the major component of their preparation to perform teletherapy services. Once hired, on-the-job training (OJT) is the principal means of training for orienting personnel to the department, to new equipment and software, and to new procedures. Because of the informal way in which OJT is implemented, it is often not possible to determine what is being learned and how well it is being learned.

- The role of organizational policy and practices has received greater recognition in investigations of human error, accidents and system safety than in the past. Different organizational factors — staffing, treatment schedules, quality assurance, communication practices, accessibility of oncologists — may lie dormant for a while only to combine later in unanticipated ways to give rise to error. Therapists are the last, not the first, line of defense in the teletherapy system. In other words, the less recognized errors of everyone else who has played a role in the design of the overall system are likely to accrue, be inherited by therapists, and appear as treatment errors.

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NRC FORM 335 (2-89) NRCM 1102, 3201, 3202

U.S. NUCLEAR REGULATORY COMMISSION

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. 5

2. TITLE AND SUBTITLE
Human Factors Evaluation of Teletherapy

Literature Review

3. DATE REPORT PUBLISHED
MONTH: July
YEAR: 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
Medical Device(s)
Human Factors Evaluation
Human Error
Teletherapy Errors
Medical Misadministration
Organizational Analysis
Medical Quality Management
Medical Systems
Radiation Therapy
Human-System Interfaces
Training and Qualification
Task Analysis
Teletherapy Procedures
Organizational Policies and Practices
Teletherapy Training

13. AVAILABILITY STATEMENT
Unlimited

14. SECURITY CLASSIFICATION
(This Page)
Unclassified
(This Report)
Unclassified

15. NUMBER OF PAGES

16. PRICE