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Human Factors Evaluation of Teletherapy

Human-System Interfaces and Procedures

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ABSTRACT

A series of human factors evaluations was undertaken to better understand the contributing factors to human error in the teletherapy environment. Teletherapy is a multidisciplinary methodology for treating cancerous tissue through selective exposure to an external beam of ionizing radiation. The principal sources of radiation are a radioactive isotope, typically cobalt-60 (Co-60), or a linear accelerator device capable of producing very high energy x-ray and electron beams. A team of human factors specialists conducted site visits to radiation oncology departments at community hospitals, university centers, and free-standing clinics. In addition, a panel of radiation oncologists, medical physicists, and radiation technologists served as subject matter experts. A function and task analysis was initially performed to guide subsequent evaluations in the areas of user-system interfaces, procedures, training and qualifications, and organizational policies and practices. The present report focuses on an evaluation of the human-system interfaces in relation to the treatment machines and supporting equipment (e.g., simulators, treatment planning computers, control consoles, patient charts) found in the teletherapy environment. The report also evaluates operating, maintenance and emergency procedures and practices involved in teletherapy. The evaluations are based on the function and task analysis and established human engineering guidelines, where applicable.

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EXECUTIVE SUMMARY

Background

Teletherapy is a multidisciplinary, multiphased methodology for treating cancerous and other tissue through selective exposure to an external beam of ionizing radiation. A radioactive isotope, typically Cobalt-60, or a linear accelerator capable of producing very high energy x-ray and electron beams, are the principal sources of the radiation. Treatment typically takes place on a daily basis over a period of weeks. It is planned and administered by a team of specialists including a radiation oncologist, a radiation physicist, a therapist, and possibly a dosimetrist. Effective teletherapy 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. Those involving the wrong patient or body part are clearly of no value to the patient and may increase medical risk to the patient. Misadministrations above the prescribed dose may destroy healthy tissue and organs; misadministration below the prescribed level may result in ineffective treatment of the disease. With either deviation, the consequences can be life threatening.

Objective

The present effort, sponsored by the NRC, is part of a human factors evaluation designed to identify the root causes of human error in teletherapy. The six phases to the study included: 1) a function and task analysis of teletherapy activities, 2) an evaluation of the human-system interface, 3) an evaluation of departmental procedures and practices, 4) an examination of the training and qualifications of treatment staff (excluding the oncologists), 5) an evaluation of organizational practices and policies, and 6) an identification of human factors problems in teletherapy, and identification and evaluation of alternative approaches to resolve significant problems. In addition, a comprehensive review of the radiation oncology and human factors literature was conducted. The present report, *Human Factors Evaluation of Teletherapy: Volume III Human System Interfaces and Procedures*, NUREG/CR-6277, focuses solely on human-system interfaces and the procedures and practices that are likely to have an impact on the treatment process.

Methodology

The scope of the methodology for evaluating human-system interfaces and procedures and practices included the major components of the equipment and an array of procedures and practices by which teletherapy personnel carry out their functions and tasks. The major equipment components included treatment machines, simulators, control consoles, treatment planning systems, record and verify systems, patient charts and various accessory devices. Procedures focused on operating, emergency, and maintenance routines that were most often documented and derived from departmental policy, while practices were typically unwritten and showed considerable variation in their execution. Practices that were addressed included the use of port films, beam modification, double checking of calculations, quality assurance of patient charts, use of record and verify systems, pre-treatment planning, and staffing levels.

To support the human-system interface evaluation of teletherapy equipment, an interface checklist was derived from the *AAMI (Association for the Advancement of Medical Instrumentation) Recommended Practice, Human Factors Engineering Guidelines and Preferred Practices for the Design of Medical Devices* (1988). Equipment interface evaluations also were supported by visual inspection of the equipment components and results of inquiry directed at equipment users and SME consultants. A structured interview guide was developed for software usability assessment of treatment planning and treatment machine software interfaces. Data collection for procedures and practices relied on structured interview instruments, observations of treatment-related activity, and follow-up inquiries.

Inspection of equipment and interviews with teletherapy personnel occurred at six sites for this phase of the study. As was true for the other phases of the study, participation was voluntary on the part of the hospital and information collected was non-attributable. Because of possible differences in practice or management style as a result of type of facility, university-based centers, large community hospitals, and smaller clinics were sampled. Given NRC's regulatory responsibilities for by-product materials, efforts also were made to include centers with Cobalt-60 units as well as linear accelerators.

Results

Human-System Interfaces

Human-system interface findings were compiled from application of the human-system interface guideline checklist and from administration of structured interviews and observations of the equipment in operation. With respect to the human-system interface guideline checklist, several findings emerged. First, the interfaces of Co-60 treatment units were generally more consistent with AAMI design guidelines than the interfaces of linear accelerators and simulators. This was attributed to the fewer operator functions and simpler control consoles of Co-60 machines that could potentially violate interface guidelines. Representative guideline deviations found on Co-60 machines included the absence of a label for the emergency "off" button, thumbwheels used to increase values by turning the wheel in a downward direction, and a

keypad, added on after purchase, that was displaced too far left of the corresponding display. Representative AAMI guideline deviations on linear accelerators included control console selector switches with numbers small enough to impair reading and infrequently used controls occupying a central position on the control console. Fluoroscopy controls on a simulator also were misplaced, precluding ease of use. Second, a number of human factors deviations were found on record and verify (R&V) systems, treatment planning systems and computer controlled treatment machines. Inflexible electronic interlocks were found on some of the earlier R&V systems resulting in poor acceptance by the therapists. There was no standard color scheme for allowing visual separation of adjacent isodose curves among various treatment planning systems. Also the level of security provided for treatment machine parameter data files varied from open access to password access, raising concern about the appropriate level of security. Third, follow-up discussions with commercial manufacturers of computer controlled treatment and treatment planning equipment indicated a lack of recognized universal formats or design guidelines for optimum user interfaces.

The structured interviews and observations of the equipment in operation further uncovered human factors deficiencies. Observation of Co-60 equipment in use occasionally revealed components that were missing or in a poor state of repair (e.g., position indicators). The mechanical clock timer on some Co-60 control consoles had a slight lash-back characteristic that could result in less than accurate time settings. It is possible that lighted displays for stuck Co-60 sources could be overlooked or not responded to immediately given the highly automatic, skill-based performance routines of therapists. Variations in conventions for position of equipment components (e.g., gantry angle) and beam status indication among different manufacturers introduce the potential for negative transfer as therapists rotate from one machine to the next. Although therapists indicate that the change of conventions is not a source of error, changes in convention cause additional conversion and transfer of information steps to be taken which are subject to error. Likewise, transcription errors can result at those facilities that use the Ellis compensator measurement device for measuring patient anatomy and fabricating compensators since the measurement data is transcribed from the device in a reverse direction on two dimensions. Other human-system interface problems resulted from therapists performing unnecessary competing tasks while treatment was being administered. Communication errors also were found when therapists rotate from one machine to another, when treatment is modified during the course of therapy, and when oncologists and physicists are unavailable to respond to treatment-related questions.

Procedures and Practices

Procedures and practices refer to specific approaches for accomplishing a group of tasks or sub-system goals. Procedures are generally written or documented, endorsed by higher organizational authority, and allow limited deviation in their execution. Practices also are approved by supervisory personnel as the accepted way to perform tasks, but compared to procedures, they are typically unwritten and are likely to show greater variation in their execution.

While it was not always possible to distinguish between procedures and practices at the teletherapy facilities visited, there were three areas for which the existence of procedures were clearly evident. First, all facilities had a Policy and Procedures Manual; however, the manuals frequently varied with respect to completeness and quality. Larger facilities generally had well documented manuals; smaller facilities generally did not have well documented manuals. Respondents at both large and small facilities indicated they did not use the manual very much. When used, it was used by new therapists or interns rotating into the department. Second, as required by the NRC, emergency procedures for a Co-60 source stuck in an unshielded position were posted outside treatment rooms that contained a Co-60 machine. These procedures were usually clear and concise, yet none of the respondents reported that dry-run exercises were ever conducted to validate the procedures for responding decisively to stuck sources. Posting these procedures on the wall in the form of a job aid may not be sufficient for optimum performance when a stress-producing machine malfunction occurs. Treatment machine maintenance and calibration was the third area for which procedures were well established. Although variability existed across the facilities visited, maintenance and data recording procedures to support calibration and output tests were generally comprehensive and well documented.

Practices, to a certain extent, depend on the clinical preferences of the oncologists in charge. Since accurate placement of the radiation field relative to the patient's body is a paramount concern, all facilities took port films during the first week. Most facilities took them weekly thereafter. The radiation oncology literature reports that field localization errors are inversely related to the number of port films taken. The practice of beam modification with standard or custom blocks ranged from 65% to 90% of patients treated at the facilities visited. With respect to human error, the use of standard blocks is subject to difficulty in precisely positioning the blocks in the same position for each subsequent treatment. Dose calculations are subject to the slips and lapses of skill-based performance. All facilities indicated they had a double check program in place; however, the operation of other factors (e.g., rapid pace of work, crowded data tables) can combine to adversely affect the accuracy of dose calculations. The use of a quality assurance checklist with respect to information in the patient's chart also was a standard practice, yet errors sometimes go unnoticed given the tendency at some facilities to focus on the mere presence of required components rather than verification of the prescription. The use of record and verify (R&V) systems that inhibit a treatment machine from being turned on when the parameters set on the machine do not agree with the prescribed parameters is becoming a common practice. Used predominantly with linear accelerators, R&V systems have caught many set-up errors. It was noted that a number of errors can be made at the time of data entry into the R&V system, demonstrating that systematic errors can result from a system that is designed to eliminate random errors. A wide range of variability in the actual conduct of pre-treatment planning sessions was found among facilities. The value of pre-treatment planning sessions is that they provide team members with relevant medical history and a preliminary understanding how a particular patient is likely to be treated, thereby reducing the likelihood of subsequent miscommunication. And finally, one quarter of the departments visited had one less therapist than would have been desirable and the services of physicists were frequently acquired on a part-time contract basis. Understaffing and resulting increases in workload were work conditions reported by therapists as most stressful.

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

FOREWORD

This report is prepared for the Office of Nuclear Regulatory Research of the U.S. Nuclear Regulatory Commission as part of the work performed under NRC-04-90-053, Human Factors Evaluation of Teletherapy. Teletherapy is a treatment methodology in which cancerous tissue is selectively destroyed by exposure to an external beam of ionizing radiation. The source of radiation may be a radioactive isotope, typically Co-60, or a linear accelerator which produces 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 requiring the teamwork of radiation oncologists, radiation physicists, dosimetrists, and radiation therapists.

The present report, *Volume III Human-System Interfaces and Procedures*, is part of a study designed to identify factors that can contribute to human error in the teletherapy setting. There are five major reports resulting from this study, *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

The human-system interface refers to the manner in which two sub-systems—humans and equipment (whether computerized or non-computerized)—interact or communicate within the boundaries of the entire system. The interface is the hyphen in the expression *human-system interface*. In the past, the burden of a successful interface rested very much with the user. "Fit the person to the task" was very much the credo. Even with the introduction of software-driven technology, early computer systems were not very flexible or adaptable. Precisely formatted input was a troublesome requirement that allowed few exceptions. Computer experts, exercising their superior adaptability, accepted the burden of mastering obscure commands and languages so that the two sub-systems could communicate while less inclined users were left befuddled by their ineffectual efforts to communicate. All this has started to change, however. An increasing awareness of the importance of good interface design has started to shift responsibility for the human-system interaction to individuals who specialize in interface issues. Rather than forcing users to adapt to the equipment, it is now possible to design systems that are more compatible with the unique ways that humans work and think. While today's modern interfaces have benefitted considerably from the new design principles, the discipline itself is still poorly understood by equipment manufacturers and there is a lot of existing equipment in operation that was designed without human-system interface concerns in mind. This premise was found to be the case in the teletherapy environment. For this reason, the purpose of this part of the study was to identify human-system interface problems that have the potential to adversely affect the performance of functions and tasks that are essential to meet teletherapy system goals or that lead to error. The evaluation is based on the function and task analysis reported in *Volume II Function and Task Analysis*, NUREG/CR-6277 (1995), and covers the following human-system interface areas and issues:

- Use of computer controlled systems
  - Record and verify systems
  - Treatment planning systems
- Emerging environment for Cobalt-60 machines
- Human interface issues from the manufacturer's perspective
- Government guidelines for approval of new equipment
- Cobalt-60 mechanical clock timers
- Differences between Cobalt-60 machines and linear accelerators
- Multiplicity of equipment conventions
- Modifications of treatment machine control console
- Accessory tray mount
- Beam-on indicators and a stuck source condition
- Ellis compensators
- Patient charts
- Hand calculators
- Equipment condition

- General workplace and environmental factors
- Lighting and noise

Beyond one's immediate workstation or control console are other systems, not always well defined, with which humans interact. The presence of these other systems requires investigators to look beyond traditional paradigms of interface design to better understand the intricacies of human-system interaction. There are interfaces with various procedures and practices in which the human-system interactions are embedded. Procedures are typically documented approaches for accomplishing a group of tasks, endorsed by the organization, and complied with fairly closely. Practices also refer to accepted ways of accomplishing tasks; however, they are usually not documented and allow for deviation in their execution. Both procedures and practices, in turn, are influenced by the organizational and managerial milieu that exists at a given facility. To be sure, there are ways in which procedures and practices can serve to facilitate or impede the success of human-system interactions or system performance overall. As a consequence, the purpose of the second part of the present study was to perform a human factors evaluation of the operating, emergency and maintenance procedures and practices involved in teletherapy. This evaluation also is based on the results of the function and task analysis cited above. The following procedures and practices were examined:

- Operating procedures
- Emergency procedures
- Maintenance procedures
- Use of port films
- Beam modification and verification
- Double checking of calculations
- Quality assurance of patient chart information
- Use of record and verify systems
- Pre-treatment planning
- Staffing levels

2.0 METHODOLOGY

The scope of the human-system interface and procedures and practices evaluations included the major components of teletherapy equipment with which staff members performed their daily functions and tasks. Specifically, this included treatment machines, simulators, software interfaces, communications with other professional staff, and procedures and practices. Data were collected at teletherapy facilities using direct observation, photographs, inspection and interview techniques.

2.1 Human-System Interface Data Collection

The data collection methodologies for the human-system interface evaluation included a Human Interface Checklist for hardware components, a Software Usability structured interview, and Communications Analysis data collection sheets. The data collection instruments were developed by project scientists with assistance from subject matter experts (SME) consultants as required. In developing these instruments, it was essential that they be brief enough to be successfully applied during teletherapy site visits, yet include information and criteria so that relevant issues within the teletherapy system could be evaluated. With the data collection forms kept as brief as possible, it was not always possible to investigate all three of the data collection areas during any one site visit due to time constraints and availability of the professional staff at these facilities.

In addition to the human-system interface checklist, equipment interface evaluations were also based on visual inspection of equipment components and results of inquiries directed at professionals at teletherapy facilities and SME consultants. The results of these inquiries addressed specific instances of equipment interface design inadequacies as well as concerns pertaining to the status of teletherapy equipment in general.

2.1.1 Human-System Interface Checklist

The human-system interface checklist was derived from the AAMI (Association for the Advancement of Medical Instrumentation) *Human Factors Engineering Guidelines and Preferred Practices for the Design of Medical Devices* (1988). These guidelines were developed by the AAMI Human Engineering Committee, and represented contributions from pre-existing human interface guideline documents. These documents included AFSC DH 1-3, MIL-HDBK-759A, and particularly MIL-STD-1472C. Because these guidelines were intended for application to all medical devices, they contained portions that were not applicable to teletherapy equipment. However, these are the only interface guidelines available that apply specifically to medical equipment. They were recent and represented the consensus of human factors engineers and medical professionals. Therefore, these interface guidelines were considered the best source to support a human factors evaluation of teletherapy equipment.

The first step in developing the Human-System Interface Checklist was to select criteria which were potentially applicable to teletherapy. This selection was based on the significant range of teletherapy equipment observed by project personnel during the execution of the function and task analysis. A total of 140 criteria considered to be potentially relevant were culled from the AAMI document for the review of teletherapy hardware. The checklist was used by project staff with some input from SMEs regarding clarification of specific aspects of the equipment interface. The research team maintained the same alpha-numeric designation of guidelines used in the AAMI document. Not all of the 140 criteria were used for each device. Instead, only those criteria from the major categories (e.g., controls, visual displays, consoles, audio signals) that provided the closest mapping to the components of the device under consideration were used.

2.1.2 Software Usability Interview Guide

Because software is becoming an increasingly important aspect of the teletherapy equipment interface, a structured interview guide was developed for software usability assessment of treatment planning and treatment machine software interfaces. This interview guide was developed from computer interface criteria in NUREG-0700, "Designing user interfaces" (Powell, 1990), from discussions with SMEs of the use of treatment planning, treatment machine computer control and record and verify software, and from the research team's experience in performing usability analyses. The interview guide consisted of 11 subject areas including such areas as documentation, screen prompts, and function keys.

2.1.3 Communications Data Collection

A communications data collection form was adapted from communication structure and evaluation considerations described by Fisher (1981) and in Downs (1988). The intent of this form was to determine patterns and content of treatment-related communications that occur within teletherapy departments. Because it was already evident that communication patterns, modes, and content were quite variable within teletherapy departments, the goal was to determine the subject matter of typical and essential communications, their mode, and the participants in order to identify shortcomings within department communications. In addition, facility staff members were asked to describe typical communication failures.

2.2 Procedures and Practices Data Collection

The data collection for teletherapy procedures and practices relied on structured interview data collection instruments, unstructured interviews, observations, and direct inspections of procedures. The structured interview data collection instrument was developed based on preliminary evaluations of the use of procedures at teletherapy sites during the conduct of the function and task analysis as well as on specific guidance provided by SME consultants. The procedures data collection forms assessed the extent to which general operating, emergency, and maintenance procedures were followed. Specific aspects of the procedures also were assessed

such as accessibility, maintainability, accountability, readability, compliance, technical accuracy and completeness. With respect to practices, data collection forms were devised to assess the extent to which radiation oncology departments engaged in use of port films, custom blocks and other bean attenuation devices, dosimetry double-checking systems, record and verify (R&V) systems, and quality assurance checklists among other practices. In keeping with the exploratory nature of the present research, unstructured observations and interviews with personnel engaged in various practices also were made when such opportunities arose.

2.3 Linkage of Findings to Function and Task Analysis Data

Given that human factors problems typically have an adverse impact on task performance, the problems and results identified in the human-system interface and the procedures and practices evaluations are linked or tied to the functions and tasks identified in the NUREG/CR-6277 (1995) *Volume II Function and Task Analysis* data base. Repeated references are made in the sections that follow to the function and task analysis data base to identify where in the overall flow of teletherapy activities that task performance can be compromised.

3.0 HUMAN-SYSTEM INTERFACE: RESULTS AND DISCUSSION

This section presents the major human-system interface problems that were identified. The presentation of these findings is organized into three sub-sections: 1) findings generated from the application of a human-system interface guideline checklist and generated from administration of structured interviews on software usability as well as inspection of the use of software, 2) findings generated by interviews and observation regarding other human-system interface problems and 3) findings regarding communication patterns across the different phases of teletherapy, for transferring treatment-related data, and for reporting errors and equipment malfunction.

3.1 Human-System Interface Guideline Checklist Results

The human-system interface checklist was applied to Cobalt-60 treatment units, linear accelerators, and one simulator for comparison. With a few exceptions, it was found that the interfaces of Cobalt-60 treatment units were more consistent with design guidelines than linear accelerators and the simulator. The major reason for this is almost certainly the relative simplicity of the Cobalt-60 operator console compared to that of the linear accelerator and simulator. Since the method of radiation delivery is simpler with Co-60, these machines have fewer components incorporated into the user console that could potentially violate interface guidelines. However, issues concerning inconsistencies among Co-60 interfaces come to light when multiple configurations represented by different manufacturers and models are compared. These inconsistencies are presented in section 3.2.3.

The following is a list of deviations from guidelines identified through the application of the tailored human-interface checklist. Each deviation contains a guideline number from the AAMI (Association for the Advancement of Medical Instrumentation) *Recommended Practice, Human Factors Engineering Guidelines and Preferred Practices for the Design of Medical Devices* (1988). Findings are separated by equipment type (i.e., Cobalt-60, Linear Accelerator, Simulator), manufacturer, and model. A brief summary of the guideline deviation follows each finding.

Cobalt-60: AECL Theratron 80

Guideline Number: 4.10

Summary: The emergency off button, a long rectangular red strip, is not labeled. To prevent confusion and delay of response, all buttons on control console should be clearly labeled.

Guideline Number: 4.12.8 (3)

Summary: Lamp test or dual lamp/filament reliability is not provided.

Guideline Number: 7.

Summary: The console was placed 20.25" back on the table. This may be too far (16" recommended) for some operators.

Cobalt-60: AECL Theratron 780

Guideline Number: 4.7.2 (2)

Summary: The keypad for digital treatment time entry is well to the left (4") of the corresponding display. The keypad on this unit is an after market add-on. Such modifications to older Co-60 equipment are not unusual. In this case the treatment time entry keypad replaced the previous circular mechanical timer clock typical of most Co-60 control consoles. The keypad rejects entries that exceed a pre-set tolerance (e.g., treatment times of 50 minutes which would never be appropriate); however, the keys seem to be temperamental, there is no clear feedback for entry (Guideline 4.12.5.2) and attempted entries are frequently not taken resulting in an "error" display. There is the potential that an incorrect entry could be made that would not exceed the tolerance of the device (e.g., an appropriate treatment time for another patient). If unnoticed, this could result in an incorrect treatment time.

Guideline Number: 4.12.2

Summary: Skip/Arc degree input thumbwheels increase by turning thumbwheel down which can be confusing to therapists. The thumbwheels are approximately one half (1.5 mm) of the recommended diameter thus requiring longer turning times.

Cobalt-60: AECL Eldorado 76

Guideline Number: 3.4, 4.11.1 (1)

Summary: The emergency stop button on the control console protrudes (2") making it easy to hit inadvertently. This would cause the beam to be stopped prematurely.

Linear Accelerator: Mitsubishi Model 14 EXL

Guideline Number 3.2

Summary: Output variability of approximately 8% was detected by the facility's physicist. The machine gave no indication of this condition and did not interlock. The physicist stated that interlocks do not occur on this equipment for deviations in output and field symmetry. It was noted that similar deviations in beam characteristics would cause other

linear accelerators (e.g., Siemens, Varian) to interlock. It was the opinion of the physicist that such uncontrolled deviations in the treatment beam pose a potential to reduce the accuracy of treatment.

Comparison to Co-60 treatment machines: Due to the manner in which the beam is generated in Co-60 equipment (from a radioactive source rather than electronically induced) this kind of problem is unique to linear accelerator equipment.

Guideline Number: 3.4 (6)

Summary: The "Dose/Deg" selector and output check adjustors are labeled with numbers that are quite small (about 1 mm) and difficult to read.

Comparison to Co-60 treatment machines: Not directly comparable. Because the control console of Co-60 equipment is much simpler, there is less requirement to crowd so many controls and features on the control panel. As a result, the stroke width used on dials is easier to read.

Guideline Number: 4.1

Summary: A keypad or thumbwheel would be an easier to use alternative for the "Dose/Deg" selector mentioned in the deviation to guideline 3.4 (6) above.

Comparison to Co-60 treatment machines: Not directly comparable. There is no "Dose/Deg" selector control on Co-60 machines.

Guideline Number: 4.3

Summary: The "Dose/Deg" selector is quite small (about 1 cm) and somewhat difficult to manipulate comfortably.

Comparison to Cobalt-60 treatment machines: Not directly comparable.

Guideline Number: 4.7.1 (3), 4.11.1 (1)

Summary: The control panel layout is configured such that when reaching for the "X-Ray" selection button (a frequently used control selection), it is easy to overshoot the "X-Ray" button and hit the "Off" button which is located just to the left. This is due in part to the location of the chair with respect to the control console; the chair is on the right side of the control console causing a reach approximately 65 deg. to the left.

Comparison to Cobalt-60 treatment machines: Not directly comparable.

Guideline Number: 4.8.1

Summary: Monitor Unit (M.U.) selection thumbwheel increases by turning thumbwheel down.

Comparison to Cobalt-60 treatment machines: Not directly comparable.

Guideline Number: 5.11.1

Summary: The beam output level display pointer needle exceeds the shorter scale gradations.

Comparison to Cobalt-60 treatment machines: Not directly comparable.

Linear Accelerator: Siemens Mevatron

Guideline Number: 4.7.2 (4)

Summary: The physical proximity between controls and associated displays requires improvement. Proper spatial relationships (e.g., each control should be placed below its related display) enable the therapist to associate a control with the correct display. In the absence of improving the physical proximity between controls and displays, framing or outlining control-display combinations can improve the ability of the user to associate a control with the correct display. The above manufacturer also neglected to use framing techniques.

Comparison to Cobalt-60 treatment machines: Similar spatial relationship problems between controls and displays were observed on some Co-60 equipment.

Guideline Number: 4.7.3 (8)

Summary: Infrequently used controls for moving treatment (i.e. rotation, skip, arc) occupy a central location on the control panel. At many facilities, these treatments are infrequently or never performed.

Comparison to Cobalt-60 treatment machines: Not considered a problem among the Co-60 control consoles examined.

Guideline Number: 7.2.2, 7.2.4

Summary: The operator's chair was a stool with no arm or backrest. It is noted that stools and chairs are switched around quite freely in teletherapy facilities. This is most likely a characteristic of the workplace rather than a characteristic that is uniquely associated with a given manufacturer.

Comparison to Cobalt-60 treatment machines: The same practice regarding use of stools and chairs was evident with Cobalt-60 machines.

Simulator: Varian Ximitron C series

Guideline Number: 4.7.3 (7)

Summary: Fluoroscopy controls must be adjusted while looking at monitor; however, these controls are not close enough to reach without moving away from monitor.

Guideline Number: 4.7.3 (9)

Summary: There are two unused push buttons located in the primary visual area of the control panel.

Guideline Number: 4.9.1

Summary: The thumbwheel for adjusting KVp for X-ray, fluoroscopy, and exposure time is difficult to adjust (high resistance). In addition, the values displayed proceed in an upward direction from 1, to 2, 3, then 4, but if a value is exceeded in the adjustment and the control is adjusted back down, the value goes from 4 back to 1 and the operator has to then adjust up.

Guideline Number: 4.11.1 (2), (3)

Summary: The switch to activate the fluoroscopy is located on the floor. The shielded control area for the simulator is kept dark so that the fluoroscopy monitor may be viewed better. It is possible to inadvertently step on the fluoroscopy switch. Although this doesn't typically activate the beam (the machine has to be set up before activation is possible), inadvertent activation is possible.

Guideline Number: 4.12.8 (5)

Summary: Legend caps are used on pushbuttons and are physically interchangeable between the X-ray and fluoroscopy consoles.

In summary, the use of a human-factors interface checklist based on AAMI guidelines has resulted in the identification of several potential interface problems. At the same time, it is best to remember there are a vast number of equipment configurations in use and the present study was able to visit but a limited number of facilities. While site sampling procedures were designed to be as representative as possible, it is difficult to assess how representative the above findings are of the teletherapy industry as a whole.

3.1.1 Use of Computer Controlled Systems

Since the early 1980s there has been a progressively increasing trend among major treatment equipment manufacturers toward computer control of treatment equipment and 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. There are inherent challenges, however, for users of computer controlled 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. Relegated more to a monitoring function, the user is somewhat removed from the actual storage, processing, and transfer of data and may have only a limited understanding of the full functionality of the system. In addition, the problem of opaque software control may be compounded by poorly designed user interfaces. Given these potential problems, this section focuses on record and verify (R&V) systems, treatment planning systems, and electronic transfer of treatment-related data.

3.1.1.1 Record and Verify Systems

The delivery of radiation treatments is a complex process as was shown in *Volume II Function and Task Analysis* NUREG/CR-6277 (1995). A patient may have up to four fields exposed per treatment. Each treatment field requires the setting of between 15 and 20 parameters resulting in the possibility of the occurrence of an error that can have an impact on the welfare of the patient. To prevent entry of an inaccurate parameter value from enabling the wrong dose to be delivered, R&V systems inhibit a treatment machine from being turned on when the parameters set on the machine do not fall within specified tolerances based on prescribed parameters. Equipment that incorporates the capability to automatically verify patient set-up parameters prior to treatment represents a significantly increased margin of safety for patients.

Record and verify systems are much more likely to be found on linear accelerators. None of the SME consultants or individuals at facilities visited were aware of a Cobalt-60 machine connected to a record and verify system, nor were any computer controlled Cobalt-60 machines available for observation. Research personnel were able to observe computer controlled Cobalt-60 equipment being manufactured at Theratronics International Limited (formerly Atomic Energy of Canada Limited), although a fully working model was not available for evaluation. The new computer controlled Cobalt-60 treatment machines are the T-1000 and 780C models. The operator console CRT for a 780C is shown in Figure 3.1. Both machines have a verify capability for gantry angle, collimator settings, treatment time, wedge presence and identification; however,

there is no associated recording system. Is it noted that the T-1000 has a source-to-axis (SAD) distance of 100 cm which is consistent with linear accelerators, the only Cobalt-60 machine with this SAD (most use 80 cm, some 60 cm). Only a few facilities have computer controlled Co-60 treatment machines. These machines are all custom modified versions of a previous Theratronics Co-60 treatment machine (model 780) which included a computer control interface provided by Theratronics and a record and verify system developed at the facilities.

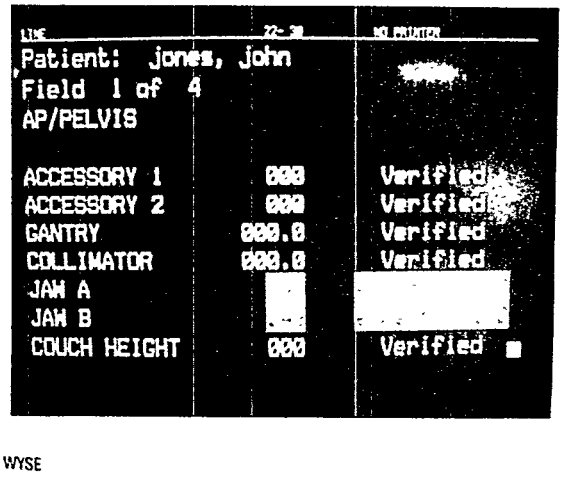

Figure 3.1 Operator console CRT for Co-60 machine (Theratronics 780C)

Record and verify systems require a data flow of essential treatment machine position and radiation output parameters. It is therefore necessary for electronic sensors to be present on treatment machines to transmit this information. Treatment machines equipped with electronic controls for positioning essential components and displaying these positions at the control console lend themselves more readily to record and verify interface than those treatment machines that rely largely on mechanical control. Most linear accelerators fall into the former group and most Co-60 machines fall into the latter. Treatment machines that are largely controlled by computer provide the best interface for record and verify systems. In addition to the required data corresponding to actual treatment machine position and output parameters, R&V systems must be provided with the correct settings of these parameters to enable verification that the current set of treatment machine conditions is correct. If not correct, the R&V system prevents treatment from continuing (i.e., by initiating an electronic interlock condition) and displays the nature of the interlock on the therapist's monitor. Finally, the record and verify system records the treatment data in a data file.

Record and verify systems dedicated to a single treatment machine store data on a mini or microcomputer. Typically, the data for each patient is stored on an individual cassette, diskette, paper tape, card or other media. Systems connected to a department-wide computer system store data in a central location thus reducing the likelihood of damaging or misplacing the patient data.

Optimally, record and verify systems should have the ability to record and verify all critical aspects of treatment administered, provide reports containing data of an entire patient population treated within a given period, provide statistical analysis of data, allow for patients to be transferred from one treatment machine to another with ease, and provide a consistent operator interface to other R&V systems at a facility. With respect to all but the first of these capabilities, R&V systems connected to a central computer provide a more robust overall capability compared to those connected to a single dedicated computer.

Providing the R&V system with a set of correct treatment parameters is performed in two general ways depending on the treatment machine control interface characteristics. If the treatment machine is not computer controlled, each treatment machine parameter must be individually set on the first treatment and encoded into the R&V system as the correct setting for the course of treatment. Each treatment thereafter must be set up to match these parameters, or the system will interlock. This is typically performed by a physicist or dosimetrist working with one or two treatment therapists. Any changes in the course of treatment require this process to be repeated and for the previous file of treatment parameters to be replaced by a new one containing the necessary modifications to parameters.

If the treatment equipment is computer controlled, the setup may be performed as described above, or by importing the data through a direct data link from the treatment planning computer or simulator. The computer control will allow for selected machine parameters to be adjusted automatically. The therapist must still ensure that the treatment field is correctly positioned on the patient's body and make small adjustments in the treatment table position as necessary. The decision of how much leeway to allow within the system is the responsibility of the physicist when defining and setting or specifying tolerance levels on record and verify software. These decisions are made in light of professional guidelines from groups such as the American Association of Physics in Medicine (AAPM) and specific requirements of the facility.

Problems and potential problems with record and verify systems are varied. Tasks that could be most directly affected are those that involve entry of treatment parameters. These tasks are listed under the subfunction, "Entry of Treatment Parameters," which is found under function number 9.00, "Treatment Administration from the Control Console" in the *Volume II Function and Task Analysis* data base. Since some systems are provided by commercial manufacturers and some are developed in-house at a facility, not all the tasks are affected in the same manner. Some early systems developed by manufacturers tend to be inflexible to the specific requirements of a facility, and may exhibit nuisance interlocks for parameters that are of no importance to treatments typically performed at that facility. Thus, some therapists may view record and verify systems as an intrusive nuisance, while others prefer these systems.

Although R&V systems can prevent many set-up errors, they do not catch all errors and their use can even introduce new errors 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, studies have found a number of errors can be 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 (e.g., Leunens, Verstraete, Bogaert, Van Dam, Dutreix & van der Schueren, 1992). These findings underscore the importance of verifying the accuracy of the original values that are entered.

3.1.1.2 Treatment Planning Systems

The initial steps of the treatment planning process involve setting up a file containing information about each field to be planned for a given patient. This information includes the outline of the edges of the field, critical structures in the patient, the outline of the external anatomy, and the target area. To place this information into the typical treatment planning system (i.e., to set up the patient's treatment file), a simulation film (x-ray) is placed on the digitizer consisting of a lighted holder for the simulation film and a stylus (a pen-like device connected to the system) for marking portions of the film. The digitizer is connected to the treatment planning computer. The center of the film is marked, three corners of the simulation film may be specified, and the outlines of the patient's external anatomy as well as internal features such as bony landmarks are traced. This information is transferred to the treatment planning computer's file. Some systems use a sonic sensor to detect the position of the stylus on the simulation film (the stylus is clicked down for specific points), others use an electromagnetic stylus. With the sonic sensor, individual points must be entered to describe a line. These points are then marked through a sequence of menu-selected commands and cursor adjustments and the system draws the line of best fit through the points. The electromagnetic system uses a device that continuously senses the position of the stylus, thereby circumventing the line drawing step. The latter methodology seems to be the most preferred and represents the technology which has evolved more recently. One area of concern with the digitizer is the possibility of the simulation film moving when the patient data is being entered into the machine.

Although most treatment planning equipment uses simulation films, some systems are equipped to download computed tomography (CT) images. These may be used instead of or in addition to simulation films. Variation in the sophistication of these systems results from budgetary and departmental capability differences among radiation oncology departments. In general, major treatment centers or other facilities with budgets that will allow for more expensive equipment will have systems that are reportedly more accurate, and will allow for more detailed information to be handled regarding the treatment field. However, these systems require more expertise to operate and more sophisticated treatment protocols to achieve the advantages in treatment delivery that they offer. Subject matter experts report that advances in medical imaging, especially computed tomography (CT), provide the necessary data to more accurately model the patient and to address a wider range of treatment planning issues.

Most treatment planning systems did not have color coding on the user's monitor; however, all provided printouts with isodose curves which do have different colors corresponding to different isodose curves and supporting data. There is no consistent standard color scheme for specific percent dose levels of isodose curves; the major intent of the use of different colors is

to allow adjacent isodose curves to be visually separated from each other. Such a standard, if implemented, might prove helpful. Although some less-than-optimal color coding exists, color systems are much more easily interpreted than monochrome systems.

Keyboards range from specialized reduced keyboards with dedicated function keys to full microcomputer-style keyboards with function keys and alphanumerics. Individuals typically liked the kind of keyboard they were using. There were no discernable differences between the use of any of the keyboards in terms of task performance (or error likelihood) on the data entry tasks reported in the *Volume II Function and Task Analysis* data base under the subfunction "Treatment Plan Calculations on Treatment Planning Computer," which is listed under function 6.00 "Treatment Planning."

With respect to misidentification of patients, all systems observed contained a feature whereby no more than one patient could have the same name. Assuming that the software performs correctly, this would not allow a new file to be cloned from a previous patient file and maintain the same patient identification. Evaluation of the specific algorithms used by the software code for patient identification was beyond the scope of this investigation; however, the systems that were reviewed specifically for this project would not allow two names of "Smith, R." If this was attempted when a treatment plan was to be initiated for a patient and there was already a file and a plan for a patient with the same name, the machine would immediately state that a file already exists as soon as the individual attempted to enter the name. At this point it is incumbent on the staff member doing the treatment plan to realize that a change must be made in the patient's name to keep the files separate. Chances are that this has already occurred in the paperwork associated with the patient, but if it has not, the staff member would call the new patient "Smith, Robert", or "Smith R.E.", for example. Interviews with staff as well as reviews of teletherapy misadministration reports did not indicate actual confusion of patient names on facility computer systems, although all personnel interviewed were aware of the possibility.

Professional staff interviewed concerning the usability of treatment planning software, namely dosimetrists and physicists, tend to be quite appreciative of the equipment, although some expressed interest in more advanced systems with greater capabilities. There were reports that some facilities used outdated treatment planning software with outdated manuals, and that some software in use was not completely tested and still contained bugs. The existence of these problems was rarely volunteered, evidenced or admitted to at any of the facilities visited. One facility did report problems with a manufacturer updating manuals consistent with software revisions, or because of errata in previous manuals. There seemed to be some ambiguity with respect to which manual information was updating which versions of the software. Personal communications with the manufacturer were occasionally of limited assistance.

The availability and extensiveness of on-line help varied on different systems. The users of these systems used them so much that they felt they knew the system well enough that they rarely or never used help functions. As computer systems in teletherapy departments continue to become more complex, it is likely that the help capability will become more important.

Interesting variability was found to exist with respect to the security of treatment machine parameter data files. Security ranged from open access to password access. In many situations, anybody using the computer system could access these data files, but only dosimetrists and physicists who should be accessing them, knew how to use the necessary components of the software. Some systems (as designed by manufacturers) incorporated the use of separate keyboards to access treatment parameter data files; keyboards which were devoted to physicist or dosimetrist tasks and maintenance engineers were different than those used by treatment technologists. Finally, security passwords were sometimes required to access these files. No facility visited kept treatment planning equipment in a locked room during business hours. No facility reported having had an occurrence of an unauthorized individual accessing these files and creating a problem, though some facilities took security quite seriously (i.e., those that used security passwords). The existing range of levels of security poses a question as to what level is actually necessary. If only the knowledge of how to access the files is truly sufficient, then why are other levels of security sometimes used? Given the crucial nature of treatment machine parameter files, the potential impact of inappropriate access on teletherapy safety requires closer examination. All the subfunctions and tasks listed under function 5.00 "Treatment Computer Data Files Setup" in the *Volume II Function and Task Analysis* data base could be potentially affected.

Evaluations revealed that a variety of interface configurations exist for software and hardware components of treatment planning computers, treatment machine control, and record and verify systems. Observations of the use of these interactive systems have revealed no obvious usability flaws. Both commercial and in-house systems have been developed and modified by intensive, though not systematic, evaluation of user needs. Users of these systems do not have many criticisms of the software systems. These systems are consistently praised by the physicists who have primary responsibility for their presence in the department and their maintenance. Oncologists are also appreciative of their potential to allow more rapid patient set-up times, and to record and verify treatments. Therapists appreciate the ability to observe and control treatment machine parameters from a single location, and to monitor the readout of equipment parameters compared to set-up values displayed on a CRT in the treatment room. If good interfaces could be assured, computer controlled treatment machines have the potential to be more efficiently and easily operated than predecessor equipment.

Different systems vary in assignment of function keys, color codes, and menu selection formats that are similar to differences between commercially available word processing systems. As with commercial word processors, users tend to like the system that they are more familiar with, having adjusted to its idiosyncracies. Some are resistant to the possibility that someone will force them to learn another system.

3.1.2. Emerging Environment for Cobalt-60 Treatment Machines

The current trend among treatment equipment manufacturers is toward extensive use of electronic data transfer of treatment related data and software control of treatment equipment. Computer control of linear accelerators is now fairly common, and computer control of Cobalt-60

equipment seems to be beginning. Many manufacturers are developing software, or software and hardware systems to link patient scheduling on treatment machines, simulation, treatment planning, record and verify, and control of treatment throughout the department. This will result in a stream of crucial treatment-related data passing from one piece of equipment to another.

One recent innovation is the dynamic multi-leaf collimator (presently only available on linear accelerators) which allows the shape of the treatment field to be modified without the use of custom blocks. After the collimator leaf positions are established in treatment planning, these parameters are fed to the treatment machine electronically, thus eliminating the paper based and verbal communications involved with creating blocks, the blocks themselves, and the steps required to place the blocks in the treatment head before each treatment. Some facilities have the CRTs for computer controlled linear accelerator treatment machines connected to a facility-wide computer system on which patient scheduling and treatment records, record and verify data and treatment machine parameters reside. Although Co-60 equipment is generally not incorporated in this kind of comprehensive data flow environment, the newest Co-60 equipment developed by Theratronics includes two computer controlled Co-60 models and a treatment planning system with a record and verify interface which is intended to allow for record and verify systems to be connected to it. In the United States, the trend of replacing Co-60 equipment with linear accelerators is continuing, if not accelerating. If for some reason this trend reverses, some Cobalt-60 treatment equipment may be fully integrated into computer controlled environments. They will then be provided with the advantages offered by such systems as well as the potential problems (e.g., system opacity, initial data entry error) inherent to any computerized environment. However, if computer controlled Co-60 equipment does not become a reality in the United States and if the current reduction of Co-60 treatment machines continues, the proliferation of record and verify systems, computer control and automatic transfer of simulator data on linear accelerators will increasingly become the norm for teletherapy facilities. Cobalt-60 equipment will frequently not be provided with the convenience and safety margins provided by the computerized environments. Reliance by operators on the convenience of operation and the safety margins associated with the more typical computer control environments surrounding linear accelerators may result in an increased potential for error commission in the use of Co-60 equipment. In essence, the interface and the treatment tasks associated with older Co-60 equipment are likely to become more and more dissimilar to that of linear accelerators and simulators at the same time that Co-60 equipment becomes more scarce.

Use of electronic data storage and transfer systems increases reliance on the design and integrity of the software that controls them, and the mechanical sensors that electronically communicate treatment machine parameters. A significant portion of the responsibility for ensuring accurate treatment application is shifted from the capabilities of the treatment planning and technology staff to the physics and maintenance personnel responsible for ensuring that the system is performing correctly. In addition, there is currently no standard for data exchange formats. Manufacturers may create a treatment planning system that can interface with a CT system, though new CT versions or alternative CT systems may format data differently causing unknown consequences when the two systems are interfaced. In addition, reliance on overall computer control provides the potential for unnoticed file mixups, a situation observed earlier

whereby a treatment planning system was connected via a LAN system to a central computer, and treatment machine parameter files were occasionally mixed up in the plans created by the system.

3.1.3 Human Interface Issues from the Manufacturer's Perspective

Interviews with commercial manufacturers of computer controlled treatment and treatment planning equipment revealed that there is no recognized universal format for optimum user interface characteristics or design guidelines. Indeed, there seems at times to be some tendency for developing unique formats that will induce facilities to purchase all of their equipment from the same manufacturer. Usability or human factors departments *per se* do not exist at any of the three treatment equipment manufacturing facilities contacted. There are mechanisms in place in which customers may fill out a sheet describing problems encountered with software which are typically reviewed and incorporated in the next software release as the manufacturer sees fit. Only rarely are human factors professionals contracted to provide input for specific issues. No ongoing systematic human interface evaluation program has been observed.

3.1.4 Government Guidelines for Approval of New Equipment

Review of Government approval requirements and discussions with SMEs and employees at radiation oncology equipment manufacturers indicate that the present stance of the Government with respect to approval of new software controlled medical systems could be improved. Technology advancements are continuously being integrated into the teletherapy environment. Multiple competing manufacturers are providing high-tech treatment and treatment-related equipment. A variety of interface and data transfer formats exist. Standardization is an important issue which receives a lot of attention by manufacturers and teletherapy professionals alike. Government approval programs that pertain to software controlled medical equipment lack definition, recommendations of specific interface design guidelines, and procedures for testing equipment usability. A central component of this evaluation, human error considerations, is not addressed. Also lacking is direction for the components of the software interface that should be tested, how this testing should be carried out (i.e., using a population of test participants similar in background to the intended user population, using scenarios representative of actual use), how data should be handled, evaluated and reported, how inadequacies should be dealt with, and the qualifications of the individuals who should do this. Acceptance processes presently do not include human interface characteristics at a level remotely comparable to the emphasis applied to other hardware and software systems such as air traffic control equipment or nuclear power station control room equipment which are used by a comparatively large population and for which errors can be dangerous. Furthermore, data reviewed for acceptance purposes is generated by the manufacturers themselves rather than from impartial third parties or the Government. Failure to properly assess equipment usability has the potential to adversely affect a wide range of tasks in such function areas as Treatment Computer Data Files Set-Up, Treatment Planning, Custom Blocks and Compensators, Treatment Set-Up, and Treatment Administration from Control Console.

3.2 Other Human-System Interface Problems

The issues presented below were not identified through the application of the human-system interface checklist. Some were identified before the checklist was developed, while others did not match well with any of the criteria in the checklist or required a more thorough explanation in terms of their context within the teletherapy environment for proper understanding.

3.2.1 Cobalt-60 Mechanical Clock Timers

The control consoles (as originally configured) of most existing Cobalt-60 treatment machines were equipped with a circular mechanical clock, as shown in Figure 3.2. Treatment time is set by moving a flange on the outer scale ring around the clock to the desired position for the treatment time. The outer scale frequently reads in 1/100 min. and the inner scale reads in whole minutes (one counter-clockwise revolution of the outer flange would return to the zero position, but would indicate a "1" (one minute) on the inner ring).

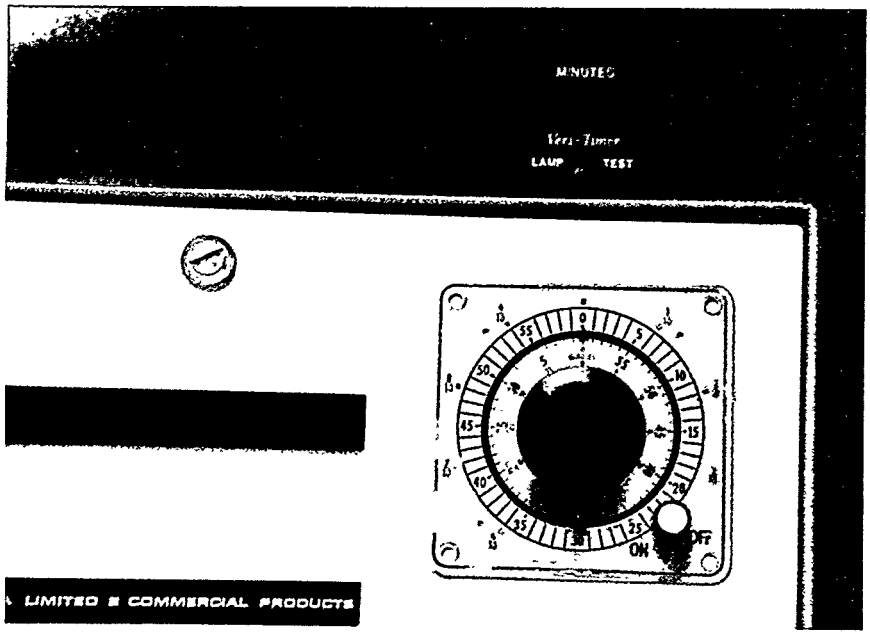

Figure 3.2 Mechanical clock timer

There are several issues associated with these mechanical clocks. First, most therapists prefer digital entry of treatment times when this is available. There is also some concern that this method of setting treatment time may be less accurate than digital entry of the treatment time because of the frequent lash-back characteristics (a movement when the flange moves back a bit after letting go) of the flange, and the requirement for demanding manual dexterity and visual monitoring when setting the flange to the proper position.

Another problem is the multiplicity of scales used on the clock. Some mechanical clock timers define the outer scale in 1/100 minute and the inner scale in 1 minute intervals. Others use seconds for the outer scale and minutes for the inner scale. Some Co-60 machines have been altered to incorporate digital input of treatment time in minutes and seconds by using small keypads. A facility using a Co-60 machine frequently also has a linear accelerator which requires treatment time to be entered in monitor units (MU), again a different unit. With the multiplicity of conventions for setting treatment time between Co-60 units (although two different conventions for Co-60 units were not observed at the same facility) and the presence of linear accelerators, it could be expected that the potential for error of setting treatment times exists at the level of the therapist (i.e., task number 5.00 "Specify dose in exposure time" listed under the "Entry of Treatment Parameters" subfunction which, in turn, is listed under function 9.00 "Treatment Administration from the Control Console" in the *Volume II Function and Task Analysis* data base) and also upstream in the treatment planning task of the process (e.g., a dosimetrist forgetting to convert .5 minutes into 30 seconds).

As indicated, the mechanical time clocks on most Co-60 control consoles (in their original configuration) represent two sources of error. One source is the potential for confusion between existing scales for specifying treatment time, and the other is the degree of mechanical lash-back in the time setting mechanism of the mechanical clock.

3.2.2 Differences Between Cobalt-60 Machines and Linear Accelerators

A major difference between linear accelerators and Co-60 treatment devices is the units by which the amount of exposure is specified. Cobalt-60 treatments are specified by treatment time, while linear accelerator treatments are specified in monitor units. Therapists at treatment facilities where both types of equipment were used were frequently asked whether this difference caused any confusion, and the response was consistently that it did not. Therapists stated that it was obvious whether a linear accelerator or cobalt unit was being used, and that they were well aware of how to enter the amount of exposure for treatments, and the respective numerical quantities that were appropriate.

In addition to the difference in exposure units, another consistent difference between Co-60 and linear accelerator machines was that all observed linear accelerators incorporated audio feedback while the beam was on. This audio feedback is a series of somewhat soft but very noticeable beeps which begin as soon as the beam is activated and end as soon as the beam stops. Standard Co-60 equipment had no comparable feedback mechanism, although there was a muffled sound when the source is unshielded or exposed and another when it was re-shielded. A physicist at one facility retro-fitted the control console on the Co-60 unit at that facility so that the control console would provide audio feedback while the treatment beam was exposed. The intent was to ensure that the therapists were aware that the source was unshielded (e.g., task number 5.00 "Detect that source is stuck in open position" listed under the "Radiation Treatment Delivery" subfunction which, in turn, is listed under function 9.00 "Treatment Administration from the Control Console" in the *Volume II Function and Task Analysis* data base).

A significant difference between linear accelerators and Co-60 treatment machines, and one which will certainly continue to become more pronounced, is the tendency for linear accelerators to be coupled with a computer operated control system. Linear accelerators present the therapist with a graphic display of machine and associated equipment parameters such as collimator jaw position, gantry angle, treatment table height, and the presence of beam modification devices. This information is typically presented to the therapist in a format which allows it to be easily viewed and interpreted. These systems are usually linked to files which include the entire profile of the patient's treatment parameters. Much of the patient set-up may be performed from the treatment console (e.g., adjusting the collimator jaw settings and rotation). In the next treatment room may be a Co-60 unit with none of these advanced features. All patient treatment parameters are set manually on the treatment machine itself, and there are no interlocks present to remind the therapist of a forgotten beam modification device, or indications of incorrect gantry angle. There are a number of treatment machine set-up tasks (found respectively under the treatment set-up function and treatment machine set-up subfunction in the *Volume II Function and Task Analysis* data base) that could be adversely affected.

An additional difference between Co-60 and linear accelerators is the source-to-axis distance (SAD) used by these machines. Cobalt-60 machines usually use an SAD of 80 cm or sometimes 60 cm, while linear accelerators use an SAD of 100 cm. This is important because in the set-up and transfer of simulation results, an incorrect simulator setting for SAD will result in inappropriate field size and dose to the target area. It is therefore important that the identity of the intended treatment machine be clearly marked on the simulation data sheets for departments that have both kinds of treatment equipment.

In brief, there are consistent differences between the use of Co-60 machines and linear accelerators. Computer-controlled linear accelerators with advanced safety features continue to play a more dominant role in treatments at facilities in general. Does reliance on these features make it likely that the same therapists will be less attentive to manual checking procedures when performing treatment set-up tasks on Co-60 machines? One could also hypothesize just the opposite — that is, the advanced safety features on linear accelerators might make therapists more sensitive to the need for manual checking procedures when performing these same tasks on Co-60 machines. There are no empirical data that shed light on this issue. Clearly, there is a need to have a better understanding of the transfer effects that may exist when moving from one type of machine to another.

3.2.3 Multiplicity of Equipment Conventions

An important issue related to the equipment interface of the teletherapy environment is the multiplicity of conventions for aspects of equipment position indication. Both cobalt and linear accelerator units use a multitude of scale conventions and coordinate graduations. This was determined through observation of teletherapy equipment at working facilities and at a manufacturer's facility, and through discussions with consultant SMEs. The differences in convention are most pronounced between manufacturers; however, differences also exist between different models of equipment or options of the same model for a single manufacturer.

Because of the scarcity of older, non-isocentric machines currently in operation, only isocentric-mounted machines were examined. The primary motions involved with isocentric equipment for which position indication conventions vary include the following:

- Gantry rotation about the isocenter
- Collimator rotation
- Collimator adjustment for field size determination
- Treatment couch rotation about the isocenter
- Treatment couch rotation about the pedestal axis supporting the table
- Treatment table longitudinal travel
- Treatment table lateral travel

Examples of different conventions are presented in Figures 3.3 and 3.4 for gantry rotation and and collimator rotation respectively. Note that the scale size differences are arbitrary; the meaningful part of the graphic is the direction of the scales. Essentially, the conventions for indicating the position of an equipment component differ in three ways. One area of difference is the location of the zero point, or the position at which the component is reported to be zero degrees or centimeters. Another is the direction of the change of numerical values applied to changes in equipment position (i.e., does the degree indication increase in magnitude for motion in a clockwise or counterclockwise direction for a left or right movement?). Finally, there are differences in the sign of the numerical values applied to positions as motion is applied from the zero point. For example, if there is a movement 10 degrees clockwise from 0 degrees this may be position "10"; however, for motion 10 degrees counterclockwise this can be position "10" in some cases or position "-10," depending on the convention used.

Multiple conventions also have been observed in indicators concerned with the status of the source in Co-60 equipment. Theratronics presently uses a European standard for source status indication on the control console for current models 1000, 780C, and Phoenix. In this case, "beam on" status is indicated by a yellow lighted display. "Beam off" is indicated by a green lighted display, and "in transit" (source is in the process of being shielded or unshielded) is indicated by a red lighted display. This contrasts with other uses of red and green. An older AECL model, the Theratron 80, uses two lights on the display console, a red which is lighted when the beam is unshielded (or on), a green which is lighted when the beam is shielded (off), and both lights are illuminated when the beam is in transit. Note that the major difference is the inconsistent use of red in one case indicating beam in transit and in another indicating beam on. Machines from other manufacturers that have since stopped production of Cobalt-60 equipment use other conventions. The Picker C4M/60 and C8M/80 also used both red and green indicators on the control console. In this case the green light indicates beam off and is also lighted (without the red) when the beam is in transit. The red light indicates a beam-on condition. The Picker C/9, however, uses the simultaneous red and green convention for the in transit condition. Conventions

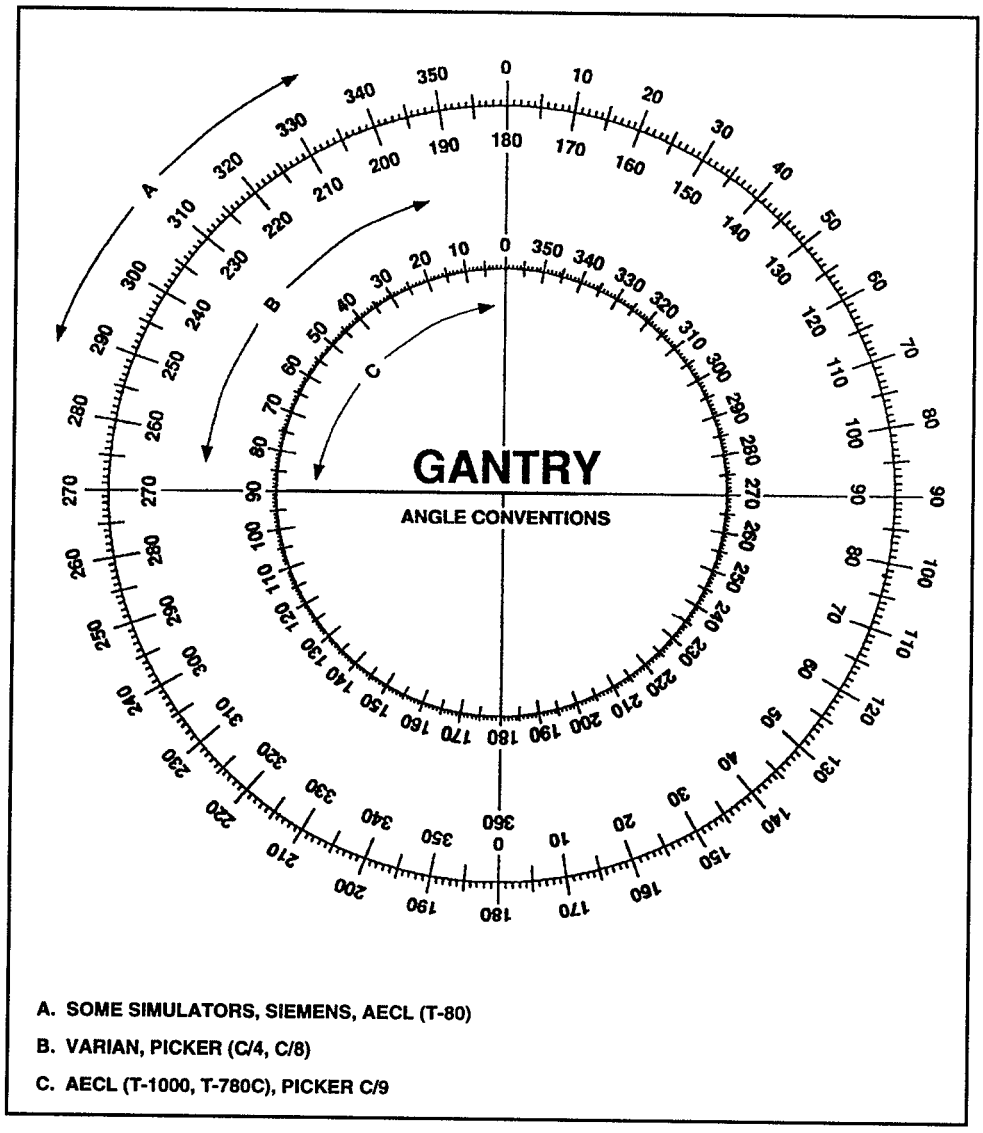

Figure 3.3 Varying gantry angle conventions

discussed for these treatment machines are summarized in Table 3.1. The differences in conventions represented by these treatment machines is not necessarily exhaustive of all those that exist for Co-60 equipment.

Given the variation in conventions for position of equipment components and status indication, it is clear that the potential for negative transfer of training exists. Even if negative transfer is nominal, the insertion of additional steps that conversions from different conventions require raises the opportunity for transcription error. Once again, there are a number of treatment machine set-up tasks — "Rotate gantry to correct angle for treatment," "Adjust collimator size to prescribed size," and "Readjust field light (via collimator) to field borders and/or permanent marks on patient's skin as prescribed before treatment" — that could be performed in error.

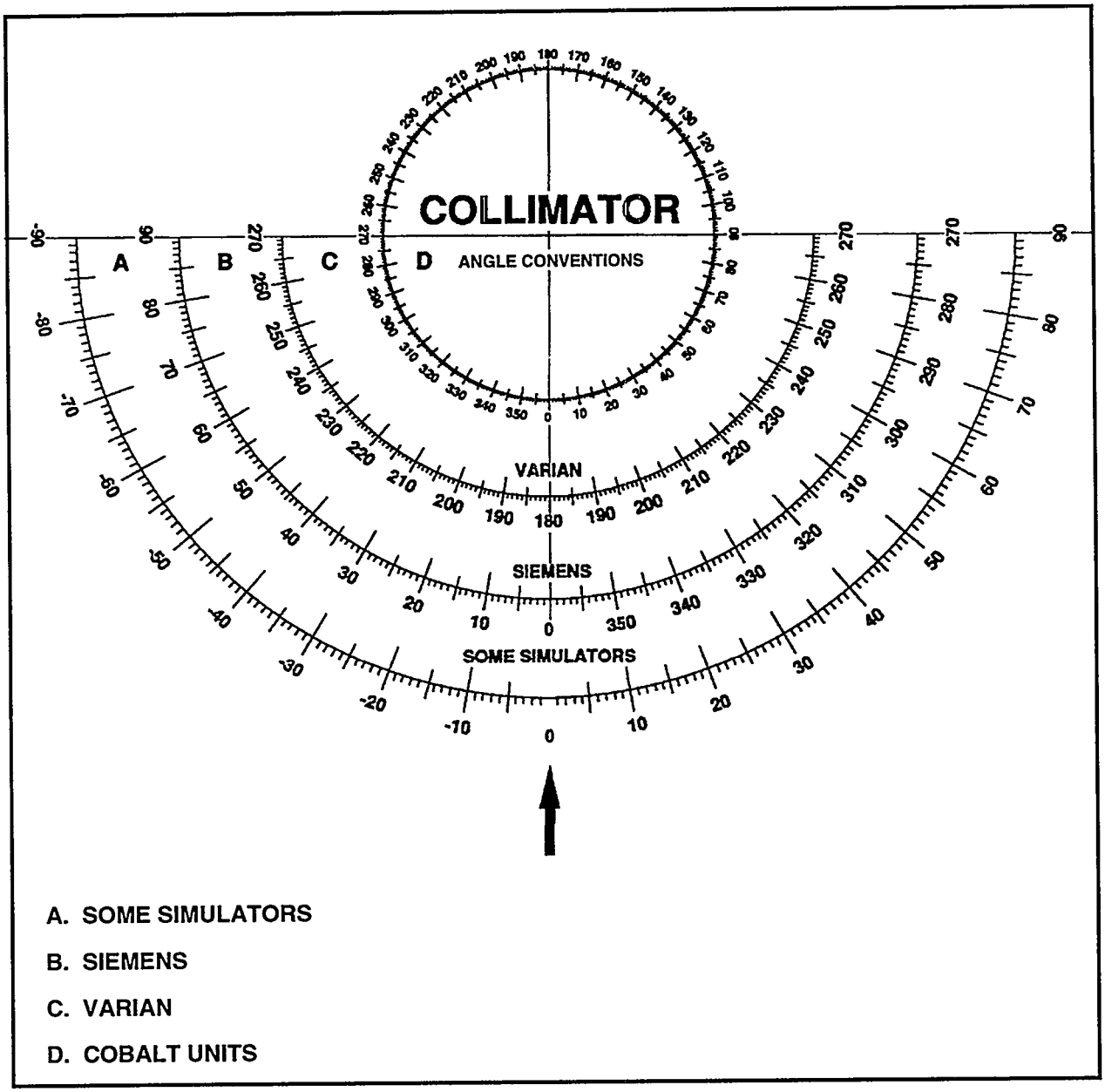

Figure 3.4 Varying collimator angle conventions

These tasks are found under the treatment set-up function and treatment machine set-up subfunction in the NUREG/CR-6277 (1995) *Volume II Function and Task Analysis* data base.

It is interesting that very few therapists reported that these deviations in conventions provided them with any significant problems. Therapists as a whole seem to feel that it is part of their professional responsibility to adjust to changes in equipment conventions. In addition, most treatment therapists would typically use not more than two or three different treatment machines in addition to a simulator. Therapists almost unanimously indicate that they know the operation

Table 3.1
Beam Status Indication Conventions for Manufacturers/Models

Indicator Light	Beam Status: Beam Off	Beam On	Source in Transit	Source "Ready"
Red	None	Picker C4M/60, Siemens G-2 C8M/80, C/9. T80. Linear Accelerators	T1000, T780C, Phoenix, Siemens G-2	None
Yellow	None	T1000, T780C, Phoenix.		Siemens G-2
Green	T1000, T780C, Phoenix T80, Siemens G-2, Picker C4M/60, C8M/80, C/9. Linear Accelerators.	None	Picker C4M/60 C8M/80	None
Red & Green Simultaneous	None	None	Picker C/9. T80.	None

of all of the treatment machines in their department well enough that they are not apt to make an error due to different position indication conventions although they would prefer the conventions to be consistent. Individuals in a supervisory capacity are frequently not as complacent with respect to these issues. Some have contacted manufacturers and requested modifications to their equipment to make it consistent with other equipment at that facility. Others have conversion charts in the simulation room which are used to translate simulation data to appropriate data for treatment machines. One facility worked with three different conventions, one for the simulator, one for a linear accelerator, and one for a Co-60 treatment machine.

3.2.4 Modifications to Treatment Machine Control Consoles

An AECL T-80 control console was observed at a facility that refurbishes used Co-60 equipment and then resells it. The console had not yet been refurbished and was in the same condition as when it was purchased from a teletherapy facility. It is not known where the machine was used. The labels that were affixed to the machine (most likely by treatment personnel) were quite noteworthy. None of the facilities visited had equipment that was modified in this way.

First, the selector switch pointer for the fixed position had been enhanced with two lines (actually red) to show more clearly the required position for a fixed treatment. Also for a moving treatment in which the gantry moves while the beam is exposed, the selections are "Fixed", "Rotational", "Arc", and "Skip". These square mode labels are supposed to light up when the selector switch is pointed to them. An unplanned rotation of the gantry would cause exposure to areas of the patient's body other than the intended target area, and could also cause a possible collision between the treatment head and the treatment couch. It is likely that some incident prompted modification of the control console. This is supported by a message directly under the

mechanical clock timer. This message stated "IS IT SUPPOSED TO BE ROTATING". One possibility is that one or more of the indicator lights for treatment mode had failed, although these are reportedly easy to repair.

Another message on the control console asked "HAVE YOU PUT IN THE SPINAL SHIELD". Another message is in red tape, asserting "WARNING". Directly under this message is another in black tape. This message warns "ASSURE THAT SWITCH IS IN 'ON' POSITION AND NOT IN START POSITION BEFORE ATTEMPTING TO USE EQUIPMENT". The manual for the Theratron 80 states that when the equipment is first energized, the key switch must be turned all the way to the right and then let go (apparently to the normal "on" position).

These modifications to the face of the control console may have resulted from one or more errors committed while using the equipment. The modifications raise questions about the adequacy of the original design. Although the present investigators did not see the control console in operation, the need for so many add-on labels suggests that the interface (as it originally existed) was not sufficient for error-free performance.

Other modifications observed on control consoles are after-market modifications of the mechanical clock timer. As an example, a digital treatment time entry clock was observed that was located where the mechanical clock timer used to be. This clock was installed by a refurbishing company (not the refurbishing company visited in this study) and was present when the research team visited the facility. The clock exhibited some idiosyncracies. It was unreliable in accepting treatment time data (i.e., some numbers would not appear on the display even though they had been pushed or would not appear unless the buttons were pushed in just the right way). (see the departure from AAMI guidelines in the Human-System Interface Guideline Checklist Results for the T-780 above). After-market modifications that are unreliable add an unnecessary source of stress to therapists as they attempt to accommodate busy treatment schedules.

3.2.5 Accessory Tray Mount

The accessory tray mount holds block trays and wedges or compensators under the treatment head for custom beam modification. The mount that holds the accessory trays, sometimes referred to as a "jig" or "accessory mount," has the capacity for two beam modification trays. This device is shown below in Figure 3.5. Most manufacturers make the tracks that hold accessories of different widths so that only compensators or wedges can fit into the upper track, and only block trays can fit in the lower, consistent with a universally observed convention. If installed, verification systems will interlock the treatment process if an incorrect beam modification device is inserted.

In one case, a treatment machine was equipped with an accessory tray that could hold either a block tray, a compensator, or wedge in either of two tracks. Though unlikely, the possibility exists that the accessory devices could be reversed in terms of their position in the mount. This would cause errors with respect to unplanned radiation dose distribution to the treatment area. A more likely scenario would be that only one beam modification device is to be used (e.g., a

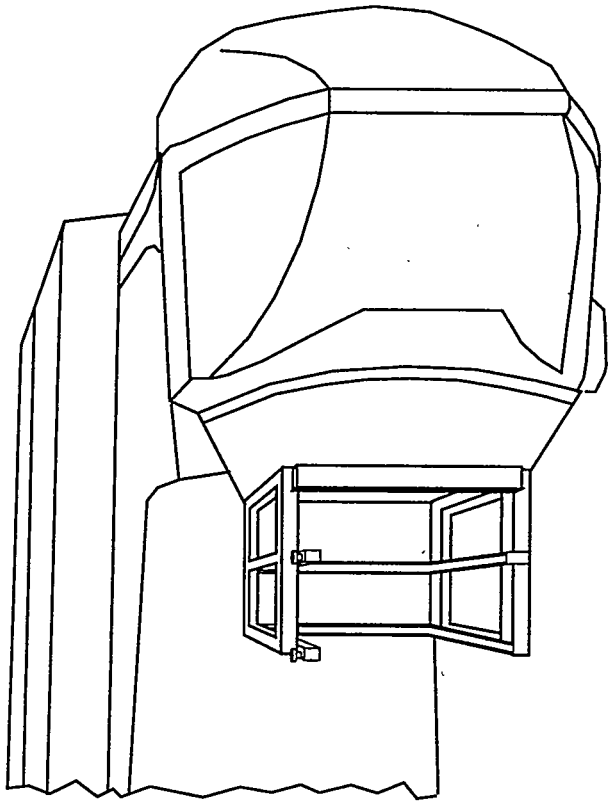

Figure 3.5 Accessory tray mount

wedge or a compensator), and this device is placed in the wrong track. This would cause the characteristics of the resulting beam to be greatly different from what is intended. In the case of a wedge, the divergence of the beam by the time it reached the wedge could conceivably be large enough that portions of the beam would not pass through the wedge, resulting in a much higher dose than planned to a portion of the treatment area. In the case of a compensator, the compensation for the surface of the patient's body would be thrown off significantly, possibly resulting in a deviation in planned dose distribution to the treatment area. Although no facility reported that this has ever occurred, it is possible, and such errors may go unnoticed and unreported. The tasks that are directly involved — "Position standards blocks on block template," "Attach custom block assembly to treatment head," "Attach custom block assembly to treatment head," "Attach wedge to wedge holder in treatment head," "Position tissue compensator in treatment beam" — are found in the treatment machine set-up subfunction under the treatment set-up function in the *Volume II Function and Task Analysis*, NUREG/CR-6277 (1995) data base.

3.2.6 Beam On Indicators and a Stuck Source Condition

As noted in the preceding section, there is typically no audio feedback while a Co-60 source is exposed. The therapist knows that the source is exposed from three indications: 1) the mechanical timer is in motion (or the digital timer is counting down), 2) the beam-on indicator is illuminated, and 3) the red radiation indicator light (required by the NRC) over the treatment room door is illuminated. It is noted that the indicator light is connected to a scattered radiation detector in the treatment room and activates any time the source is unshielded. At the conclusion of the treatment, the source is re-shielded with an accompanying characteristic sound; however, this sound is not loud and is easily obscured by a ringing phone or a nearby conversation.

In the event that a source fails to be re-shielded at the end of the planned treatment time, the mechanical or digital timer shows that the treatment has stopped (it has counted down to zero). It provides the same information whether or not the source is shielded. At the same time, the beam-on indicator on the control console will remain lit, or go to an "in transit" indication depending on the convention employed by the manufacturer. If the beam-on indicator goes unnoticed, the only indication to the therapist that the radiation source is unshielded is the red indicator light over the door of the treatment room.

The mechanical clock timer usually clicks when the treatment is over. Upon hearing this click, the therapist may habitually get up from the control console and turn the console key to the off position without looking at the beam status indicator on the control console. The red light over the door of the treatment room may or may not be on; this light comes on and goes off so many times during the day that it loses meaning. When the therapist enters the treatment room and is unaware of the stuck source, he or she may notice the scattered radiation detector in the treatment room that will be flashing red because the source is not completely shielded. Due to the habituation of motion resulting from treating patient after patient, day after day, the rarity of a stuck source situation, and the audio cue of the mechanical clock as it reaches zero time, it is possible for a stuck source condition to go unnoticed for several seconds. It is also possible for the therapist to unknowingly enter the treatment room while the source is unshielded. There is at least one documented deviation of dose incident that illustrates such an occurrence, and there are likely many incidents that resulted in deviation of dose less than that required to be considered a misadministration.

The indication of a stuck source may not always be attended to by the therapist. Due to the infrequency of this occurrence, it is possible for the therapist to enter the treatment room after the timer clicks off without checking lighted displays that could indicate a stuck source. An audio signal would more likely allow the therapist to understand the situation quickly. At a minimum, several seconds of additional exposure to the patient could be saved.

3.2.7 Ellis Compensators

The Ellis compensator is a custom beam modification device for counteracting (compensating for) variations of the surface of a patient's anatomy so that the beam reaching the target area within the patient's body beneath the surface will be of uniform intensity. Each compensator is

custom assembled from stock pieces for a specific treatment area for a single patient. The compensator is made by applying a measurement device to the patients external anatomy. This device is shown in Figure 3.6.

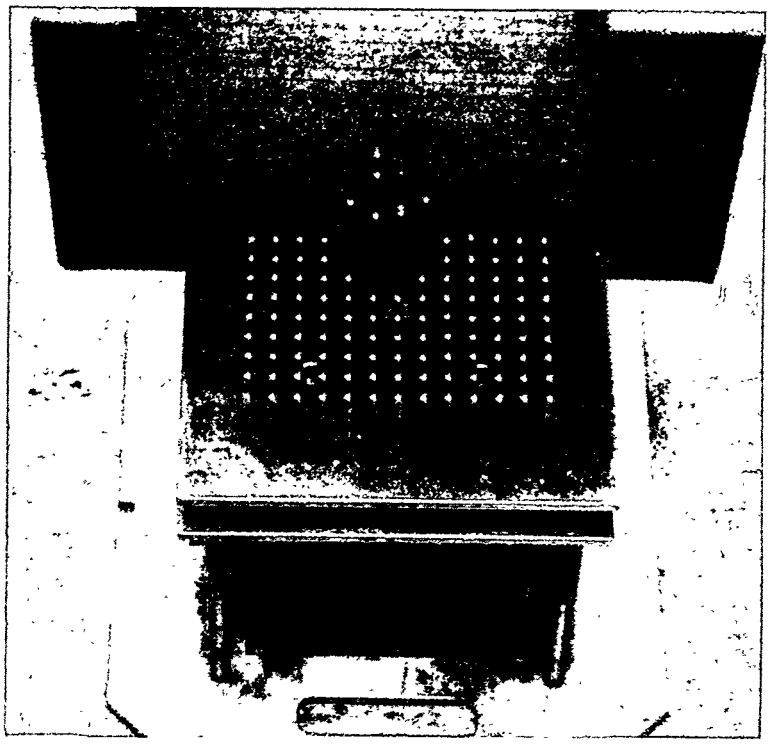

Figure 3.6 Ellis compensator measurement device

The measurement device consists of a rectangular array of metal rods that slide in and out of a metal plate. The device is placed in the treatment machine treatment head and the metal rods are pulled down to the surface of the patient at the treatment area. The differences in rod positions are measured and transcribed to a data sheet. The data sheet is then placed under a clear plastic compensator tray on which brass and aluminum cubes are attached. The thickness and thus beam attenuating ability of the cubes varies at different locations, depending on the rod measurement at that location. The shorter the rod distance, the smaller the metal cubes placed on the compensator tray. The metal cubes modify the beam to adjust for areas at which the beam passes through comparatively less tissue before reaching the target. It is also noted that the Ellis compensator device provides modification of the treatment beam in two dimensions as opposed to a wedge filter which shapes the beam in only one dimension. A completed Ellis compensator is shown in Figure 3.7.

The major problem with the Ellis compensator is that the process for transcription of measurement data is somewhat confusing. After the measurement device is applied to the patient, it is removed and placed in an inverted position before measurements are taken. The rods which were pointing down in the direction of the beam are now pointing up. Metal cubes are placed on

the compensator tray, depending on the position of the rods in the measurement device. The compensator tray is created consistent with the up-to-down orientation of the beam. Therefore, when the rod measurement data is transcribed on the measurement data sheet from the inverted measurement device, the individual performing this task has to transpose the left to right directions for the rods measured and the data recorded. When asked if this process can lead to confusion and errors, the one therapist interviewed replied that it can be confusing but "another person usually checks it before it is used."

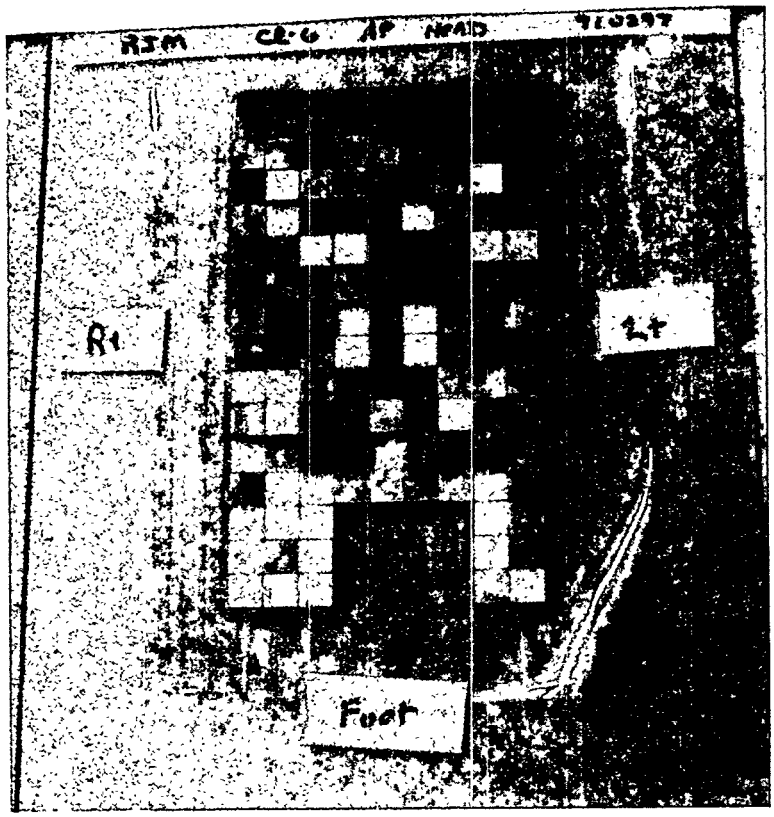

Figure 3.7 Completed Ellis Compensator

Errors that occur in the process of developing the compensator would result in some portions of the treatment area receiving more or less radiation than intended by the physician. If the error were for only one or two of the compensator cube positions, this would correspond to one or two 1 cm x 1 cm portions of the treatment area. Tasks that are directly affected include: "Take measurements required to make compensator," "Measure measurement rod position and transcribe to data sheet," "Attach data recording sheet to compensator tray," and "Place metal cubes on compensator tray and secure." These tasks are found under the "Create Ellis Compensator" subfunction which, in turn, is found under the "Custom Blocks and Compensators" function in the *Volume II Function and Task Analysis* NUREG/CR-6277 (1995) data base.

The Ellis compensator is useful for modifying beam characteristics in two dimensions. It is therefore more sensitive to variations in external anatomy in its beam modification characteristics than is a wedge filter. Site visits indicate that this device is not frequently used. Some departments use other methodologies for the development of compensators. At those facilities where it is used, the recording of measurements of patient anatomy leading up to the creation of compensators for individual patients require measurement data to be transcribed in a reverse direction from measurements taken from the measurement device designed for this process. This reversal of direction for recording the data is somewhat difficult and is likely to lead to transcription errors.

3.2.8 Patient Charts

There are a variety of forms for patient charts in use. At a recent American Society for Therapeutic Radiation Oncology (ASTRO) conference in Washington DC, an exhibit booth displayed about 10 different versions of patient charts. Most facilities have their own charts printed locally, creating even more versions. Patient charts observed at facilities almost always exhibit some differences in format. Some facilities visited had recently changed the format of their patient charts in response to potential human factors problems. In one case, the therapists could not see the prescription when they were recording daily doses. This led to a higher possibility of recording daily doses for the wrong patient. The therapists liked the new chart better. At another facility, a therapist related that a year prior to our visit, the department changed the format of patient charts. During the course of the change to the new charts, there were two charts for some patients, and the data in some of the charts were "full of mistakes," resulting from the transition to the new charts.

There are likely to be administrative reasons for certain information to be contained and presented in different locations in a patient chart. To an extent, the patient chart reflects the unique aspects of the organization that uses the chart. Chart format seems to be influenced by the preferences of the staff. A major consideration or concern regarding chart design is the extent to which therapists performing treatments and staff members performing chart checks can see the initial prescription and the recorded daily treatments without turning the chart over or turning a page.

3.2.9 Hand Calculators

Hand calculators are used frequently in teletherapy facilities. In accordance with specific facility practices, some treatment plans are hand-calculated rather than being planned on a computer-based treatment planning system. Hand-calculation entails using a hand calculator along with other accessories that are sometimes taken for granted (e.g., pencils, dose calculation forms, dose tables). Hand calculators are also used by physicists and dosimetrists for checking treatment plans. All facilities state that they check computer generated treatment plans by hand—that is, with a hand calculator. Hand calculators are also used for checking accumulated daily dose in patient charts.

The calculators used are variable in size and format as with the use of calculators in the general population. There are usually several calculators available in a department. No staff reported difficulty in using calculators. In some cases, it may be of benefit for a paper print-out of calculations performed during a chart check to be attached to the chart by the staff member checking the chart; however, in terms of preventing treatment error, this practice would likely be of limited value. It would result only in illustrating how a calculation was performed when it did not catch an error—likely identical to the way the erroneous calculation was performed in the first place.

In general, the calculators used varied in size, shape and format, but this seems to be insignificant in terms of its impact on the performance of the staff who use them. Of greater concern are the programmable calculators for which small companies develop algorithms for dose calculations and sell the programmed calculator to teletherapy facilities. The physicist on-site may also develop an unreviewed program for a hand calculator. Reportedly, no specific guidelines exist at State or Federal Government level for verification that these programs are correct, and that the devices themselves are reliable. A review of existing guidelines supports this concern.

3.2.10 Equipment Condition

At some facilities visited, treatment equipment was observed that was not fully operational. In one case, the field defining light on a Co-60 machine seemed so dim for larger fields that it was more difficult to use than the investigators considered appropriate, a sentiment supported by professional staff at that facility. The dimness of the light made the treatment machine set-up task of adjusting the field light to the field borders or to marks on the patient's skin more difficult to perform.

In another case, a mechanical table height scale for the treatment couch was mounted upside down, so that the reading was meaningless. The staff was not even aware of this because they never used the scale. They always used the optical distance indicator which is projected out of the treatment head to measure the distance of the source from the patient. This is a more reliable method for determining this distance because variability in patient set-up position and the size of the patient throughout the treatment process can cause the source-to-surface distance (SSD) to change. Therefore, the SSD must be measured each time. For isocentric treatments, the position of the side pointing lasers with respect to tattoos or marks on the patient ensure that the patient is at the correct level. As the patient is moved into position for final treatment, minute adjustments of the treatment table are usually necessary, and are always done with respect to marks on the patient. These tasks can be found in the *Volume II Function and Task Analysis* NUREG/CR-6277 (1995) data base under the "Patient Set-Up" and "Treatment Machine Set-Up" subfunctions of function 8.00 "Treatment Set-Up."

There are more sophisticated treatments in which a patient is treated from both the AP (from above) and the PA (from below) directions and the treatment area is located above the midline of the patient (not at the isocenter). In these cases, the AP treatment is set up and treated, the gantry is then rotated 180 degrees (treatment head now under the patient) for the PA treatment.

At this point, it is necessary to raise the treatment table to ensure that the center of the treatment area is at the same distance from the source. This is done by using the table height indicator. At this point the treatment head is directly under the patient, so the optical distance indicator is of no use. The indication is projected on the "tennis racket" portion of the treatment table, and the therapist would have to get under the table and look up to see it even if it were readable.

In another case, the indicator scale for degrees of rotation of the treatment table pedestal located on the floor of the treatment room had been removed (or never installed). There was a pointer with no scale. When the table position was straight, it was marked on the floor with black marker. Again, because the vast majority of treatments are performed with the treatment table in the straight position (i.e., 90 deg. from the plane of gantry rotation), and because the treatment field is typically marked on the patient's body and patient position is verified with the field defining light before treatment, lack of this scale would have little effect on delivery of most standard treatments. Concerning the angle of the patient with respect to the plane of gantry rotation, a therapist should not rely on the crude measure of treatment table position allowed by a table rotation degree indicator. Variance could occur due to the position of the patient on the table which would not be accounted for by this indicator. This scale, however, would help speed the patient setup process in some cases. This scale is required for some unusual treatments, though the facility stated that the treatments performed on this machine were always done with the table in the straight position.

Another facility was using a treatment machine on which the optical distance indicator was temporarily not operational. Patients were being set up for the proper SSD (listed as task number 5.00 under the "Treatment Machine Set-Up" subfunction of function 8.00 "Treatment Set-Up" in the *Volume II Function and Task Analysis* data base) using a tape measure to measure the SSD. Subject matter experts indicated that although the optical distance indicator is an important device for measuring SSD, SSD can be determined in this way assuming one is careful. The present authors suspect that the reliability of accurately measuring SSD using a tape measure is less than that of using the optical distance indicator.

Yet another treatment facility had a Co-60 machine that was generally not used and that was scheduled for decommissioning. The side pointing lasers had been removed from the treatment room. The chairman of the department stated that the machine was used occasionally for treatment of certain non-isocentric palliative cases. Discussion with consultant SMEs indicated that it would be very poor practice to use a treatment machine equipped in such a manner for isocentric treatments. Non-isocentric treatments could also be affected, although to a lesser extent, because lining up the field defining light using only the field marking on the patient could result in some inaccuracy due to the thickness of the field marking on the patient and the tendency of the field defining light to stretch over anatomy that is curved toward or away from the beam.

The above observations indicate that teletherapy facilities occasionally use Co-60 equipment that has some components that are missing or not functional. These components were not associated with the radiation source, but are typically position indications for the treatment table or other components that define the position of the treatment equipment. In some cases, the

condition is stated to be temporary; however, it is occasionally clear that the status of the equipment has not changed for quite some time and is not likely to change soon. The features found to be in disrepair did not seem to be serious, unless individuals trained to use such devices were asked to perform certain procedures on this equipment and were not prepared to use other methodologies for performing these tasks.

3.2.11 General Workplace and Environmental Factors

As with so many aspects of teletherapy, variations in workplace layouts are essentially unique to each facility. Some facilities did not have armrests on the therapist's chair at the treatment machine control console, while others did. Some therapists insist on a certain kind of chair; others do not care, and sometimes several kinds of chairs circulate from one treatment area to another. Some placed the control console on a desk in front of the portion of the desk that had drawers so that the operator could not roll the chair directly in front of the console. Most therapists do not seem overly concerned with chairs, and frequently perform treatment machine control tasks in a standing (stooped) position, and do not often sit. Others always sit down before manipulating the treatment control console. One facility placed the operator console (for a linear accelerator) in such a narrow space that there was not room for a chair. One of two staff members would have to turn sideways to pass, and there was only one entrance. The therapists in this facility did not like this arrangement. These different spatial arrangements can affect viewing angles and distances, and even the accessibility of controls.

3.2.12 Lighting and Noise

Lighting was consistently adequate at all facilities visited. No staff member ever responded that ambient lighting level was a concern in a facility. Noise was a distraction in some of the busier facilities and appeared to be directly related to the number of treatment units and patient volume per treatment unit. Internal furnishings influenced ambient noise levels. Facilities with carpeting were noticeably quieter. At one university-based facility that was quite noisy, the most distracting aspect of the ambient noise was frequent paging of individuals on the public address system. Another facility had phones located at the treatment workstations. This was a significant problem because part of the duties of the therapists in that facility was to answer calls concerning treatment scheduling for patients under care in other departments in the hospital. The therapists at this facility unanimously stated that such interruptions were disruptive to their treatment administrations and record keeping. Although these general workplace and environmental factors may be singly insufficient by themselves to result in error, when combined with other factors that are less than optimal they have the potential to adversely affect a wide range of treatment set-up and treatment administration tasks.

3.3 Communications Evaluation

The main components of communications between different staff specialties include: (1 scheduling patients for simulation, treatment planning, and treatment, 2) transferring treatment

related data, 3) calling attention to errors, clarifying and adjusting patient related treatment data, and 4) reporting equipment malfunctions and requesting maintenance. These critical communications are recorded in a variety of ways and locations depending on the facility. The communication patterns between facilities are so variable and diverse that it was difficult to identify sub-components of communication for comparison and evaluation. Facilities have differing needs for formality of communication depending on the complexity of the department structure. Larger facilities use more written communications in which the message is received with limited associated verbal explanation or follow-up. Smaller facilities addressed many of the same issues in a face-to-face manner between staff members. As the numbers of professional staff increased, there appeared to be fewer face-to-face communications between professional staff. More paper- or telephone-based communication occurred, and the face-to-face component was reduced. Communication efficiency is more of a concern for staff members at larger sites where the pace of treatment is rapid. These facilities made more of an effort to standardize communications with department-specific forms.

Interview respondents reported that significant miscommunications were most likely to occur when 1) therapists rotated from one treatment machine to another and had to take over a new group of patients being treated on that machine, 2) aspects of treatments were changed during the course of treatment, and 3) interns rotated through a treatment facility. The formality of the information exchange process during these times varies.

Communications were found to be most problematic when the staff members at a facility were busy. Occasionally, a therapist may be uncertain of a change in treatment that is noted in the chart and would like to discuss it with a physicist or the oncologist before starting the treatment. Another typical problem that occurs is a treatment prescription that has not been signed by the oncologist. The therapist is then placed in the position of proceeding with treatment or backing up the treatment schedule. In cases in which the schedule is already behind, there is significant pressure perceived by the therapist to not delay a treatment for a situation that is not clearly serious.

Another factor is whether or not a facility is part of a group of facilities. Such a facility would include a central location that manages and shares professional resources with a number of satellite locations. As with staff size, the presence of one or more satellite facilities increases the tendency for communications to be made via paper, phone, or in one case, via FAX. The use of the FAX for staff communication presented an interesting problem. Treatment calculations were performed by therapists at the satellite facilities and then sent over FAX to the central facility where physicists would check them. If the physicist found problems, corrections would be sent back over FAX. If no FAX was returned, then therapists would assume that the calculations were correct. This system does not take into consideration the scenario in which a FAX is lost at either end of the communication. Under this system, a therapist could proceed with treatment assuming the calculations have been checked when there has been a problem in the FAX transfer process. In other instances in which there is no resident physicist, communications concerning dose calculations and treatment plans may be time consuming to the point that treatments may begin before problems are corrected, or plans may be made overly simplistic to avoid a large requirement of the physicist consultant.

A situation was reported at a facility concerning communications between hospital departments that had an impact on a patient's intended treatments. In some cases, the department performing chemotherapy desired some patients to have radiation therapy simultaneously with chemotherapy. In one instance, the radiation oncology department was contacted to schedule radiation therapy treatment to coincide with chemotherapy. The patient was set up to begin radiation treatments. Meanwhile, the department performing chemotherapy had to postpone their treatment for some reason, but failed to contact the radiation oncology department. The patient was well into the course of radiation treatment before the communications disconnect was discovered. In one sense, this situation is peripheral to the purpose of this study; however, it does, at least theoretically, have an impact on the well-being of the patient. Clearly this is not a misadministration; however, it is still an error. One could argue that if considerations are made for radiation treatment assuming that the patient will be undergoing chemotherapy, then the absence of chemotherapy could require the treatment to be different.

4.0 PROCEDURES AND PRACTICES EVALUATION

Procedures and practices are not that easy to distinguish in operation. Their variation is best represented by gradations along a continuum. Written procedures that allow limited deviation and that are dictated by formal organizational authority represent one end of this continuum. Unwritten practices represent the other end of the continuum; they are typically endorsed by supervisory personnel as the accepted way to accomplish a group of tasks, but are usually communicated by word-of-mouth and allow for considerable variation in their execution.

It was found that procedures and practices reflect, to a certain extent, a facility's formally stated policies. A facility typically has a written Policies and Procedures manual, although it is usually quite general. It is typically not useful to refer to on a daily basis particularly with respect to treatment-related tasks. Procedures and practices also are influenced by job descriptions and generally accepted expectations for performance by individual professional positions within a teletherapy facility. The presence of specific equipment also has a strong influence on what procedures and practices are implemented.

4.1 Teletherapy Procedures

Two types of procedures were reviewed: those that defined departmental processes in general terms, and others that described or implied the performance of specific tasks in a certain way. An example of a general guideline would be a Quality Assurance Plan that assigns overall responsibilities for achieving quality assurance goals to the various positions in the department. Examples of task performance procedures found in the Policies and Procedures Manuals were not that plentiful, but might include simulation workup data/instruction sheets. At the sites visited, no specific guidelines were found for the development of procedures. Given this absence of standard guidelines for writing and maintaining procedures, this responsibility rests solely with each facility. Content of procedures ranged from quite general to specific depending on the subject area.

Written procedures at teletherapy facilities were evaluated by structured interview (with criteria adapted from relevant guidelines such as NUREG-0899, "Guidelines for the Preparation of Emergency Operating Procedures", 1981), visual examination, and discussion of the use of procedures with members of the teletherapy staff. The inspections of the procedures and informal discussion surrounding the administration of the structured interview were of considerable value to the evaluation process. Individuals at different facilities called procedures different names. Some procedures were grouped or separated in a manner that also was variable. Attempts to obtain specific rating information on procedures relied to some degree on imposing the structure of the interview form on participants; however, research personnel considered it necessary to establish common denominators in the procedures area as an important first step in the evaluation.

4.1.1 Operating Procedures

The overall picture with respect to the use of written procedures for treatment delivery and related tasks is addressed before individual procedures are discussed. The closest approximation to what one would expect for a procedure for day to day activities in a teletherapy facility is the Policies and Procedures (P&P) document. Although this document might be referred to by other names, all the departments visited understood what was being referred to by the term Policies and Procedures document or manual. It frequently consisted of a three-ring notebook that explained what is done in the department, how it is done and who does it. The existence of the P&P document is largely due to requirements by the Joint Commission for Accreditation of Health Care Organizations (JCAHO) for accreditation. Completeness and maintainability (i.e., keeping the document up to date) varied considerably across facilities. Another consistent finding with respect to written P&P manuals was that they are referred to very infrequently by therapists. Respondents typically said they were used about once per month, probably less. When this document was used, it was usually by newly hired individuals or by oncologist trainees rotating through the department as part of a training program. Resident therapists were typically aware of the P&P manual in the department and had read it, but it was not uncommon that they do not know exactly where a copy was located. Therapists were never observed reviewing a procedure intended for use in an unusual situation.

Operating procedures include treatment protocols, therapist protocols, quality control procedures and other non-treatment related procedures such as infection control, nursing procedures, and administrative procedures. In terms of guidelines for day to day activities that are actually used, calculation worksheets, patient measurement worksheets, patient charts, and dose calculation worksheets for individual treatment machines comprise the majority of such guidelines. Although these items do not guide the user with explanations, the data they require causes the individual using them to perform specific actions. Structured interviews indicated that these procedures and worksheets are quite variable among facilities. Readability and design of these forms and documents were usually rated as excellent. Assessment by visual inspection of the documents usually coincided with these ratings. However, the overall level of effort expended to achieve completeness, accountability and maintainability seemed to be much higher at the larger centers than at community hospitals and smaller facilities.

The ability to operate treatment machines and to use treatment associated materials and equipment seems analogous to the ability to drive a car. After the basic skill is mastered, the function of driving is performed without consulting procedures. No step-by-step operating procedures to be followed by teletherapy staff members were identified during site visits (with the exception of the operator's manual to a given treatment machine). For this reason, the evaluation of procedures includes not only written procedures, but also unwritten activities which stem from job descriptions, specific needs and practices of the teletherapy department and performance expected by the profession for a given position. In fact, it was frequently difficult to determine if teletherapy personnel were referring to procedures or practices since they were not accustomed to making the same distinction between the two terms that is typically found in nuclear power plant operations (i.e., procedures referring to step-by-step documented sequences

that closely guide task performance and practices referring to undocumented patterns of task performance that are likely to be shared by members of a work group, but also allow a fair degree of departure from the norm). Although much of the information reported in this section on procedures may seem like practices, the authors opted to report exactly the information provided by respondents when inquiries were made with respect to operating, emergency, and maintenance procedures.

As indicated above, much of the actual treatment-related process specific to a department seemed to exist as patterns of behavior learned and taught by staff members. These guidelines for appropriate performance are passed verbally to new employees and are maintained by rehearsal and communication between staff members. Policies and procedures manuals provide the general framework only. Task sequences with very little or no accompanying documentation were found to be the rule at the teletherapy facilities visited, with the exception of some physics tasks such as periodic maintenance, calibration and troubleshooting. At the same time, it was found that some departments back up the verbally transmitted routines with written procedures that describe the activities in the department more completely. Other facilities had limited written procedures. The factors driving this variability in procedures appeared to be the size of the facility, and the extent to which the facility was associated with satellite facilities. The larger, well known facilities take the development, maintenance, and distribution of procedures more seriously than most of the smaller facilities. In cases where satellite facilities are managed from a central facility, the emphasis on procedure quality is more pronounced to ensure that all facilities operate in the same manner, use the same forms, and perform treatments and treatment-related activities in the same way. As with communications, larger facilities tend to be more paper-based, and expend more effort on written forms and documents than do the smaller facilities.

A finding that was evident at all the facilities visited was that the equipment purchased by a facility had a direct influence on departmental procedures and practices. The actions required of all treatment staff and decisions by the oncologist on how to treat a case are profoundly influenced by the presence, capabilities, features, and idiosyncratic aspects of treatment and treatment planning equipment. Consistent with the previous findings, larger departments tend to have more expensive and therefore more complex equipment. The actions required to use this equipment are correspondingly more complex; therefore, there are more requirements for these actions to be specified and kept consistent throughout the staff by the use of written procedures. Smaller departments using state-of-the-art equipment may not have extensive written procedures. While the scope of the present study does not allow conclusions to be drawn on the relationship between the presence/absence of written procedures and teletherapy system performance, the latitude that exists along the procedure-practice continuum makes the variation in teletherapy system performance that can be attributed to this component difficult to assess. The empirical question remains: can teletherapy system performance be improved (e.g., significantly reduce identifiable errors) if formal, documented procedures are more consistently implemented?

4.1.1.1 Manufacturer Supplied Manuals

To some extent operator manuals for specific treatment machines may be viewed as procedures. Manuals are typically present at operators' workstations. Like other written procedures, they are referred to only rarely, although therapists always knew where to find them. Operator manuals vary in quality, but seem to be adequate as a source of reference for the therapists. Therapists indicate that if something confuses them about the equipment and the manual does not immediately help them, they usually consult with the physicist. Some physicists feel that therapists tend to come to them immediately without even looking at the manual.

At one facility visited, there was a Cobalt-60 machine that had just been removed and sold, but was manufactured in France. When the unit was delivered, all of the accompanying documentation (e.g., the operators, maintenance, and technical specifications) were in French. The facility was unable to obtain this information in English and was obliged to create these materials in-house. It was only due to the competence of the physics staff that the situation was resolved adequately. Indeed, the physicist provided a copy of the in-house maintenance procedure to the manufacturer for approval and they indicated that it was excellent. The same situation in another facility may not have been dealt with as well. A similar, but much less serious case was observed for a linear accelerator. The machine was manufactured in Japan. The maintenance engineer said that the technical manuals were written in Japanese. Review of these documents indicated that, although also translated into English, the translation was not always correct or clear.

4.1.1.2 Operating Procedures (Therapist)

The essential skills of the therapist are developed in the training program required of therapists, are refined during the internship portion of their training, and then further refined as a new employee. After being hired, most aspects of the therapist's job are learned under the supervision, or with the assistance of, another more experienced employee. There is significant variability at the task level in administering treatment and performing treatment related activities among facilities. In adjusting to a new department, the therapist will typically be given a copy of the departmental procedures book to read, but a large proportion of the procedures are actually learned through on-the-job experience and assisting with the treatment of patients. The capabilities of the therapist are assessed periodically by the supervisor responsible for the therapists. When acceptable performance is demonstrated, the therapist is then allowed to set up and administer treatments to patients unsupervised. At most of the facilities visited, determination of acceptable performance resulted from the subjective judgement of the supervisory therapist rather than a more formal assessment procedure (e.g., assessment of skills against a performance-based checklist).

At one facility, there was a procedure that required therapists to refrain from taking the patient's chart into the treatment room during patient set-up. There had been occurrences of therapists leaving these charts in the room during treatment, forgetting that they had done so, and recording the patient's daily dose in the next patient's chart. At another facility, a therapist was observed who took a great deal of pride in announcing the treatment time for each patient

without looking into the chart. Another therapist present always checked the chart before this therapist pressed the beam on button, and the therapist was always correct. However, it was clear from the attitude of this therapist that she might easily treat a patient based on her memory of the treatment time in the chart if left alone to do so.

It was occasionally reported that oncologists, in a rush to begin treatment, request treatments to begin before filling out a prescription form. Therapists usually resist this; however, oncologists have the formal authority and status to expect treatment to begin on a verbal request. Such requests in the past have led to treatment set-up and treatment administration errors, resulting, in large measure, from ambiguous communication. Although respondents stated that it is against written policy or practice at their facilities to start treatments without a prescription, they also acknowledged that not all oncologists comply.

4.1.1.3 Operating Procedures (Dosimetrist)

An examination of organizational structure found that dosimetrists typically report to and follow the guidance set by the physicist if there is one on the staff. For facilities at which there is no full-time physicist, the dosimetrist frequently has experience at another facility under the direction of a physicist. Until recently, there have not been specific training programs for the dosimetrist position. Many dosimetrists have been trained on the job. Some are highly regarded former therapists, while others have a B.S. degree in a natural science. Similar to therapists, dosimetrists learn a significant portion of their job by initially performing their duties under supervision.

Functions performed by dosimetrists include fulfilling requirements for use of software controlling the treatment planning equipment, providing treatment plan alternatives to the physicist and/or oncologist, calculating or assisting with the calculations required for beams, modifying treatment plans, performing initial dose calculations, checking and modifying these calculations as necessary, and carrying out department-specific requirements for other support activities such as assisting with difficult patient set-ups, and developing treatment aids such as patient immobilization devices and blocks. At the facilities visited, dosimetrists used several procedures to fulfill the requirements of the job including dose calculation methodology sheets, the user's manual, and documentation of the treatment planning computer and additional data recording and data transfer sheets developed by the physicist.

4.1.2 Emergency Procedures

As stipulated by the NRC, emergency procedures for a cobalt source stuck in an unshielded position were found posted on a wall near the therapist's control console. These procedures were always clear, concise and accurate at the departments visited. The tasks most directly involved are reported under subfunction "Radiation Treatment Delivery" which, in turn, is found in the "Treatment Administration from Control Console" function in the *Volume II Function and Task Analysis* NUREG/CR-6277 (1995) data base. Emergency procedures for linear accelerators were not posted as frequently nor as consistently compared to the Co-60 machines.

For linear accelerators, the analogous situation to a stuck source is a failure of the radiation measurement device that converts radiation output into monitor units. These units are counted up to the number set by the therapist and then the beam stops automatically. These monitors (ion chambers) almost always have a backup which will stop the beam if the first monitor fails. If for some reason both monitors fail simultaneously, the therapist can stop the beam with an emergency "off" button which stops electricity being fed to the beam apparatus. If the emergency "off" button also does not work, there is usually an emergency "off" switch that controls all power coming into the unit.

Facilities have fire procedures, some that are posted, and others that are not. To be consistent with JCAHO, departments based in accredited hospitals require employees to be tested on their knowledge of fire and other emergency procedures. The essential components are turning off the treatment beam, and escorting the patient out of the treatment area immediately.

At some facilities, there were special procedures for therapists working with linear accelerators that were not exactly emergency procedures, but were for use in response to abnormal conditions. For example, at one facility when the output varied between 5% and 10%, the therapist was allowed to start the first patient's treatment, but had to contact the physics department immediately. If the output variance was greater than 10%, then the therapist could not perform any treatment until the machine had been serviced and approved by the physics department. Most of the facilities had a standing rule that the physics department was to be notified if output varied by 3-5%. These modified procedures are similar to limiting conditions of operation (LCO) found in nuclear power settings.

There are typically no corresponding set of emergency procedures for Cobalt-60 treatment machines for different levels of variation in output because there is very little danger of a cobalt beam varying its output characteristics from day to day. Cobalt output is checked weekly in some facilities; however, it is more typical for it to be checked monthly. An unexpected fluctuation in dose for a Cobalt-60 machine would immediately cause the staff to suspect the timer device or incomplete opening of the shield. A deviation would be reported to physics if it was greater than 3%, although in actual practice, this occurrence would be so unusual that smaller deviations also would likely be reported.

4.1.3 Maintenance Procedures

At most of the sites visited, it was the primary responsibility of the physicist to develop preventive maintenance procedures and ensure that they are followed. Maintenance includes periodic maintenance and maintenance performed on an as-needed basis. Maintenance procedures for Cobalt-60 machines are developed from maintenance specified by the manufacturer and may be modified as required at a facility. Guidelines for periodic calibrations and output tests are specified by Report 13 of the American Association of Physicists in Medicine (AAPM). Beyond these guidelines, the responsibility for equipment maintenance rests with the professional judgement and preferred practices of the physicist. The physicist creates maintenance procedures and data recording formats to support calibration and output test data. There is no guidance or

standard concerning the format of these forms. Physicists frequently stated that their procedures meet the AAPM requirements. A visual inspection of these forms found them to be readily accessible, usable, and complete. An example, reproduced from one of the visited facilities, of a physicist's activities and output checks can be found in Figure 4.1. Tasks that involve maintenance and equipment safety checks can be found under the "Treatment and Safety Equipment Checks, Adjustments and Maintenance" function in the *Volume II Function and Task Analysis* NUREG/CR-6277 (1995) data base.

4.2 Teletherapy Practices

As indicated earlier, practices refer to specific approaches for accomplishing groups of tasks or sub-system goals. They are typically unwritten, but are endorsed by departmental supervisory personnel as the generally accepted way to perform a group of tasks. A certain latitude is evident in the performance of practices. They can be executed differently from one person to the next in a given locale, or can be even executed differently by the same person at different times. This variability results in differences in the manner in which tasks are performed, their frequency, or if they are performed at all in facilities. Variability in practices may indicate variability in overall quality of treatment. The relationship between variability of practices, quality of treatment, and the likelihood of error is less than obvious and is likely to involve clinical judgement. One facility may make compensators for certain treatments and may be more likely to commit an error due to the intricate manner in which a compensator is developed. It might be advisable for this facility to use certain aids or verification procedures during the development of their compensators. At the same time, the practice at another facility may be to never use any kind of compensators. Such a facility does not run the risk of committing an error while developing a compensator; however, one can contend the entire treatment delivered by this facility may include more undesirable aspects of dose distribution than the use of a flawed compensator at the first facility.

The areas discussed next are those for which variation associated with practices was found to be evident. These areas included use of port films, beam modification and verification, double checking of calculations, quality assurance of patient charts, use of Record and Verify Systems, pre-treatment planning and staffing levels.

4.2.1 Port Films

Accurate placement of the radiation field relative to the patient's anatomy is a continuous concern throughout therapy. All facilities where practices were sampled (6 total) took port films during the first treatment. The frequencies reported in response to the interview represent the best estimates available from personnel at the facilities. After the first port film, most facilities took port films weekly, but this depended on the type of case. In one facility, only head and neck films were taken weekly, and other treatment areas were filmed 2-3 times over the course of treatment. One facility stated that palliative cases did not receive port films. *Volume V Literature Review*, NUREG/CR-6277, reported that the occurrence of localization errors is not insignificant. There is evidence of an inverse relationship between frequency of localization errors and the

	Mon	Tues	Wed	Thur	Fri
Wk 1	Physics Conference	Spot Check 4 MV 10 MV 18 MV	Spot Check ELECTRON 6,9,13,17,20 MeV	Spot Check 4 MV 10 MV 18 MV	Physics List Spot Check Co-60
Wk 2	Physics Conference	Spot Check 4 MV 10 MV 18 MV	Spot Check ELECTRON 6,9,13,17,20 MeV	Spot Check 4 MV 10 MV 18 MV	Physics List
Wk 3	Physics Conference	Spot Check 4 MV 10 MV 18 MV	Spot Check ELECTRON 6,9,13,17,20 MeV	Spot Check 4 MV 10 MV 18 MV	Physics List
Wk 4	Physics Conference	Spot Check 4 MV 10 MV 18 MV	Spot Check ELECTRON 6,9,13,17,20 MeV	Spot Check 4 MV 10 MV 18 MV	Physics List

1st Qtr	2nd Qtr	3rd Qtr	4th Qtr
Isotope Inventory Spot Check Superficial	Isotope Inventory Spot Check Superficial	Isotope Inventory Spot Check Superficial	Isotope Inventory Spot Check Superficial

SPOT CHECKS include checks of output, depth stick, light and radiation fields, light scale, beam flatness and lasers.

ISOTOPE INVENTORY is the physical counting of all isotopes in the department.

PHYSICS LIST is the list of patients who have had treatment plans, implants, or maximum permissible doses during the past week. It is needed at noon on Friday.

PHYSICS CONFERENCE is the discussion of the patients on the list. It is held at noon on Monday

Other Dosimetry procedures (done as needed):

TREATMENT CARD CHECKING, TREATMENT PLANS, CONTOUR VERIFICATION, BLOCKMAKING, FIELD JUNCTION DOSIMETRY, SPECIAL FIELD DOSIMETRY, TREATMENT PLAN/SET-UP VERIFICATION, ISOTOPE APPLICATOR LOADING, Cs-137/Ir-192/I-125/Au-198 DOSIMETRY, & PATIENT ROOM SURVEYS.

Figure 4.1 Physics Procedure

number of port films taken. Assuming the relationship is causal, the results underscore the value of taking portal films more frequently than the conventional one time before the onset of treatment. Tasks associated with the sub-function, "portal localization films," are found in the "Treatment Administration from the Control Console" function in *Volume II, Function and Task Analysis*, NUREG/CR-6277 (1995) data base.

4.2.2 Beam Modification and Verification

Four of six facilities occasionally used a diode (a small, accurate device for measuring radiation) for treatment dose verification on the surface of the patient. All of these facilities used the diode for linear accelerator treatments only, none on Cobalt-60. This was because of the lack of daily fluctuations in the Cobalt-60 beam. Estimates of the use of custom or standard blocks for modification of the shape of the beam ranged from 65% to 90% of patients across all facilities interviewed. For facilities using blocks, the use of custom blocks ranged from 70% to 100%. Use of beam modification other than blocks ranged from 10% to 55% of patients with the most common method for beam modification being wedge filters. Tissue bolus was the next most frequent beam modifier used with estimates ranging from 2% to 25% of patients. Five of the six facilities stated that they did not use Ellis compensators, and one facility used them for about 1% of patients. Ellis compensators were observed at other facilities during the function and task analysis, although no percentage for frequency of use was obtained at that time. These facilities also stated that the Ellis compensator was used infrequently.

The use of standard versus custom blocks involves a clinical judgement. In relation to human error, the use of standard blocks is subject to difficulty in precisely positioning the blocks in the same position treatment after treatment. It is sometimes necessary to stack the blocks on top of each other to achieve the desired contour. In addition to being a somewhat precarious practice in terms of patient safety, there is little likelihood that the therapist will be able to reproduce exactly the field shape day after day. These difficulties are eliminated with the use of custom blocks. With custom blocks, the shape of the treated field is easily reproduced treatment after treatment. Since these blocks are attached to a lexan tray, they can be safely used when the beam is directed horizontally without the risk of falling on the patient.

4.2.3 Double Checking of Calculations

All facilities interviewed stated that they had a double check program in place. All but one facility checked dose calculations, calculations of modifications to dose, and graphic treatment plans before the first treatment (or before the first treatment after modification). One facility double checked these items. Others checked within the first three days after the first treatment. Some facilities visited during the function and task analysis also stated that these items were checked within two or three days after the first treatment day, while others stated that these items were checked before the first treatment. Calculation errors are known to occur with a certain frequency. The nature of calculation tasks conforms to Rasmussen's (1986) skill-based level of performance; these are highly practiced, routine and automatic performances with a somewhat monotonous quality. In addition, the dosimetrist's immediate visual field is composed of highly

similar stimuli (e.g., look-alike numbers in a table or column), providing an ample source of interference. If visual spacing is poor, and tracking aids are unavailable, and the pace of work is rapid, then computational error is likely facilitated. For these reasons, it is unwise to take short-cuts with the practice of independent double checking.

4.2.4 Quality Assurance of Patient Chart Information

The patient's radiation chart is the focus of numerous teletherapy activities that cut across several task areas. It is reviewed, modified, updated and used by various staff members throughout the patient's therapy. When asked, all facilities interviewed reported that a quality assurance checklist is contained in every patient's chart. The quality assurance checklist was designed to assure that the paperwork in the chart is complete. An example of a quality assurance checklist is provided in Figure 4.2. Although use of such checklists are common practice, errors continue to occur with respect to the patient's chart. In using such a checklist, there is a tendency at some facilities to focus on the mere presence of required components rather than verification of the prescription. For example, verification of the prescription is less likely when the lay-out of the chart places the prescription block in an inconspicuous location. Chart lay-out and design factors also are suspected contributors of transfer of information errors, one type of which results from the orthographic similarity of recorded numbers representing different parameters, but placed in contiguous locations on the chart. Legibility of the handwritten prescription is another potential problem. The importance of legibility of the prescription and other treatment set-up information is underscored by treatments that depart from standard protocols in ways not anticipated by the staff. Another potential opportunity for error is present when oncologists occasionally request that treatments begin upon verbal request, before a written prescription is provided. Here the intended treatment relies on the interpretation of the verbal communication and the memory of the individual therapist.

4.2.5 Use of Record and Verify Systems

Record and verify (R&V) systems inhibit a treatment machine from being turned on when the parameters set on the machine do not agree with the prescribed ones to within specified tolerances. Four of six facilities visited during this phase indicated that they used an R&V system. It is very unusual for a facility to operate a Co-60 machine that is attached to an R&V system. Only one was found during the course of this study. While the *Volume V Literature Review*, NUREG/CR-6277 (1995), found that R&V systems have proven their value in catching many set-up errors, it should be noted they do not catch all errors and their use can even introduce new errors of the type they were designed to eliminate. 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, and treatment couch position. 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 is designed to prevent random errors. These

findings underscore the importance of verifying the accuracy of the original values that are entered in the R&V system—a practice that was not consistently followed at the sites visited.

RADIATION ONCOLOGY
TREATMENT CHART SCREEN

NO	YES		
[ ]	[ ]	1.	Is the diagnosis stated?
[ ]	[ ]	2.	Is the stage of disease stated?
[ ]	[ ]	3.	Is the pertinent histopathology report in the chart?
[ ]	[ ]	4.	Is the relevant history of the disease stated?
[ ]	[ ]	5.	Are the physical findings relevant to the disease stated?
[ ]	[ ]	6.	Was a treatment plan or prescription dated and signed by the responsible physician at the beginning of treatment?
[ ]	[ ]	7.	Was planned dose stated?
[ ]	[ ]	8.	Was method of delivery stated?
[ ]	[ ]	9.	Was treatment site or treatment volume stated?
[ ]	[ ]	10.	Were fields documented by port films?
[ ]	[ ]	11.	Are dosimetry calculations in the chart?
[ ]	[ ]	12.	Is there a summary or a completion of therapy report?
[ ]	[ ]	13.	Is there a follow-up plan stated?
[ ]	[ ]	14.	Was the treatment record checked weekly by a designated reviewer?
[ ]	[ ]	15.	Was there evidence of periodic examination of the patient by the responsible physician?

Figure 4.2 Quality assurance checklist for patient chart

4.2.6 Pre-treatment Planning

This task area involves discussion of essential aspects of treatment among key personnel prior to simulation, treatment planning, and treatment delivery tasks. Discussion at pre-treatment planning sessions typically involve pertinent medical history, physical and diagnostic findings,

tumor staging, prior radiotherapy, past or intended surgery, chemotherapy, and preliminary treatment strategy. Five of six facilities had pre-treatment planning meetings which included members of the treatment staff and the oncologist; however, the percentage of cases for which formal meetings were held at specified times in a designated meeting area were 100%, 20%, 15%, 0%, 0%, 0% for the six facilities. In brief, a wide range of variability in the actual practice of this function was found among facilities. When pre-treatment planning sessions were not conducted, it was reportedly because the case to be treated was performed routinely by teletherapy staff, and the treatment methodology was well understood by treatment staff. However, problems can occur when there is a departure from standard, expected routines. Misadministrations have resulted from unstated, implicit assumptions about what was expected, in the absence of explicit discussion about what was actually intended. The value of pre-treatment conferences is that they provide team members with common shared mental model of how a particular patient is to be treated, thereby reducing the likelihood of confusion and potential misadministration.

4.2.7 Staffing Levels

Although staffing practices are also discussed in *Volume I Identification of Problems and Alternative Approaches* and *Volume IV Training and Organizational Analysis*, their pervasive impact on pre-treatment planning, treatment set-up, equipment checks and calibration, and quality assurance warrants discussion in more than one volume. With increases in the costs of providing medical services, hospitals have been attempting to decrease operating expenses in a variety of ways. Reductions in personnel is one method. In departments of radiation oncology, this means using fewer therapists, dosimetrists, and medical physicists. Approximately one quarter of the hospitals visited were understaffed by one therapist. Understaffing was one of the work conditions reported by therapists as most stressful. The services of medical physicists and dosimetrists are increasingly acquired on a contract basis—a practice giving rise to a diversity of opinion. In those facilities that have contracted out the physics function, physics personnel rotate to the department on a periodic basis (e.g., once a week) to check treatment plans and dose calculations, perform equipment checks, and to consult with the oncologist. While in some communities, this practice may serve as an efficient use of professional personnel, the question remains is effective treatment and safety compromised in any way as a result? The authors know of no empirical data on the consequences of the practice. Given the lack of any evidence to the contrary, the staffing guidelines established by the *Radiation Oncology in Integrated Cancer Management - Report of the Inter-Society Council for Radiation Oncology* (1991) represent, at present, the best collective wisdom on staffing.

5.0 CONCLUSION

Teletherapy was defined as a multi-phased and multi-disciplinary methodology for treating cancerous and other tissue through selective exposure to an external beam of ionizing radiation. Since treatment takes place on a daily basis (in fractions) over a period of weeks, effective treatment requires a concern for precision and consistency of human-machine and human-human interactions found in few other occupations. The present report focuses on the human-system interfaces as teletherapy staff operate and maintain treatment machines, simulators, treatment planning software, and ancillary equipment. The report also focuses on procedures and practices as teletherapy staff interact and communicate in carrying out the successive phases of the treatment regime. The following conclusions summarize the findings from the human-system interfaces and procedures and practices areas.

5.1 The Human-System Interfaces

- Interfaces of Co-60 treatment units were more consistent with AAMI design guidelines than the interfaces of linear accelerators and simulators. Since the method of radiation delivery is simpler with Co-60 machines, fewer operator functions that could potentially violate interface guidelines are incorporated on the control console. Representative guideline deviations found on Co-60 units include the absence of a label for the emergency "off" button (rectangular red strip), skip/arc thumbwheels with values that increase by turning the wheel down rather than up, and a keypad for digital treatment time entry (which was an after market add-on) was well to the left of the corresponding display.

- Representative AAMI guideline deviations on linear accelerators included labelling control console selector switches with numbers small enough to make reading difficult and infrequently used controls occupying a central position on the control console. Representative guideline deviations for simulators included fluoroscopy controls that must be adjusted while looking at a monitor that was located in a position that precluded reaching those controls and unused push buttons that were located in the primary visual area of the control panel.

- A number of human factors issues became evident upon review of record and verify systems, treatment planning systems, and computer controlled treatment machines. Some earlier record and verify systems exhibited inflexible interlocks resulting in poor user acceptance among some therapists. Treatment planning systems enable the printing of isodose curves in different colors corresponding to the different percent dose levels; however, there is no standard color scheme that allows visual separation of the adjacent isodose curves. There was considerable variation in the level of security provided treatment machine parameter data files (e.g., from open access to password access), raising the question of what level of security is really needed.

- Discussions with commercial manufacturers of computer controlled treatment and treatment planning equipment indicate a lack of recognized universal formats or design guidelines for optimum user interfaces. In a similar vein, government approval programs that pertain to software controlled medical equipment also lack definition, interface design guidelines, and procedures for testing equipment usability.

- Observation of Co-60 equipment in use occasionally revealed components that were missing or in a state of disrepair (typically position indicators). Mechanical clock timers on Co-60 control consoles have different scale conventions which can be confusing, while the flange on some consoles have a lash-back characteristic resulting in time settings that are less than accurate.

- Variations in conventions for position of equipment components (e.g., gantry angle) and beam status indication among manufacturers of treatment equipment introduce the potential for negative transfer as therapists rotate from one machine to another. Therapists indicate that the change of conventions is not a source of error; however, differences in position indication conventions as a patient moves from simulator to treatment machine causes additional conversion and transfer of information steps to be taken which are subject to error.

- Indicators of stuck sources can be overlooked by therapists. Given the highly automatic, skill-based routines performed by therapists, it is possible for the therapist to enter the treatment room after the timer clicks off without checking the lighted displays on the control console or above the treatment room door.

- The use of Ellis compensator measurement devices for measuring patient anatomy and fabricating compensators for individual patients requires measurement data to be transcribed in a reverse direction from measurements taken from the measurement device. The reversal of direction in two dimensions can be confusing and lead to transcription errors.

- Unnecessary competing tasks brought about by placement of phones at therapists' workstations were observed. Therapists were expected to answer calls from other hospital departments; such interruptions were considered disruptive to treatment administrations and record keeping.

- Communication errors occur under conditions when therapists rotate from one machine to another or have to take over a new group of patients being treated on a machine, when aspects of treatment are changed during the course of treatment, and when oncologists and physicists are unavailable to respond to treatment-related questions. Considerable variation exists among hospitals with respect to the formality of written and face-to-face communications.

5.2 Procedures and Practices

- With respect to Policies and Procedures Manuals, respondents indicated they use such documents infrequently. When they are used, they are used by new therapists or interns rotating into the department. Larger facilities generally had well documented manuals; smaller facilities generally did not have well documented manuals. Following unwritten procedures and practices was the rule at all facilities visited, with the exception of treatment protocols and periodic maintenance and calibration procedures.

- As required by the NRC, emergency procedures for a cobalt source stuck in an unshielded position are posted outside each treatment room that contains a Co-60 treatment machine. Although these procedures are usually clear and concise, none of the respondents indicated that dry-run exercises were ever conducted for responding decisively to stuck sources.

- The physics department is responsible for periodic maintenance procedures as well as maintenance performed on an as-needed basis. Although some variability existed among sites, the maintenance and data recording procedures that supported calibration and output tests were generally comprehensive and well documented.

- In terms of practices, all of the sites visited took port films during the first treatment while a majority used diode devices for dose verification on the surface of the patient (linear accelerator treatments only), were accustomed to using custom blocks and standard wedges as beam modification devices, and engaged in double-checking procedures for verifying the accuracy of calculations. Other practices included the use of quality control checklists for maintaining the patient's chart, the use of record and verify systems, and the conduct of pre-treatment planning sessions for some patients.

- Approximately one quarter of the departments visited were understaffed by one therapist—a working condition that therapists cite as very stressful. A number of sites use physics personnel on a contract basis whereby physicists rotate to sites on a scheduled basis. There is currently a diversity of opinion on the desirability of such a practice. Opponents of the practice maintain that checks of treatment plans and dose calculations can be delayed, and some treatments may be started without a physicist checking the calculations. When physicists are absent, questions requiring their expertise may remain unasked. Proponents maintain that it is an efficient and economical way of providing the services of physicists without impairing quality treatment of patients.

6.0 REFERENCES

American Association of Physicists in Medicine, "Physical Aspects of Quality Assurance in Radiation Therapy." *AAPM Report No. 13,* New York, NY: American Institute of Physics, Inc., 1984.

Association for the Advancement of Medical Instrumentation, *Human Factors Engineering Guidelines and Preferred Practices for the Design of Medical Devices*, Arlington, VA: Association for the Advancement of Medical Instrumentation, 1988.

Downs, C. W., *Communication Audits.* New York: Harper-Collins, 1988.

Fisher, D., *Communications In Organizations.* St. Paul, Minnesota: West, 1981.

Henriksen, K., R.D. Kaye, R. Jones, D. Morisseau & D. Serig, *Human Factors Evaluation of Teletherapy: Volume I Identification of Problems and Alternative Approaches,* NUREG/CR-6277, Washington DC, Nuclear Regulatory Commission, 1995.

Henriksen, K., R.D. Kaye, R. Jones, D. Morisseau & D. Serig, *Human Factors Evaluation of Teletherapy: Volume III Training and Organizational Analysis,* NUREG/CR-6277, Washington DC, Nuclear Regulatory Commission, 1995.

Henriksen, K., R.D. Kaye, R. Jones, D. Morisseau & D. Serig, *Human Factors Evaluation of Teletherapy: Volume V Literature Review,* NUREG/CR-6277, Washington DC, Nuclear Regulatory Commission, 1995.

Kaye, R.D., K. Henriksen, R. Jones, D. Morisseau & D. Serig, *Human Factors Evaluation of Teletherapy: Volume II Function and Task Analysis,* NUREG/CR-6277, Washington DC, Nuclear Regulatory Commission, 1995.

Leunens, G., J. Verstraete, W. Van den Bogaert, J. Van Dam, A. Dutreix, E. van der Schueren, "Human Errors in Data Transfer during the Preparation and Delivery of Radiation Treatment Affecting the Final Result: 'Garbage in, Garbage Out'." *Radiotherapy and Oncology*, 23, pp. 217-222, 1992.

Mohan, R., K.C. Podmaniczky, R. Caley, A. Lapidus, & J.S. Laughlin, "A Computerized Record and Verify System for Radiation Treatments." *International Journal of Radiation Oncology/Biology/Physics,* 10, 1975-1985, 1984.

Powell, J.E., *Designing User Interfaces.* San Marcos, CA: Slawson Communications, 1990.

Rasmussen, J., *Information Processing and Human-Machine Interaction - An Approach to Cognitive Engineering,* New York: North Holland, 1986.

Report of the Inter-Society Council for Radiation Oncology, "Radiation Oncology in Integrated Cancer Management," Philadelphia, PA: American College of Radiology, November, 1991.

U.S. Nuclear Regulatory Commission, "Guidelines for Control Room Design Reviews," NUREG-0700, Washington, D.C., 1981.

U.S. Nuclear Regulatory Commission, "Guidelines for the Preparation of Emergency Operating Procedures," NUREG-0899, Washington, D.C., 1981.

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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.

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