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Human Factors Evaluation of Remote Afterloading Brachytherapy

Human Error and Critical Tasks in Remote Afterloading Brachytherapy and Approaches for Improved System Performance

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Abstract

Remote Afterloading Brachytherapy (RAB) is a medical process used in the treatment of cancer. RAB uses a computer-controlled device to remotely insert and remove radioactive sources close to a target (or tumor) in the body. Some RAB problems affecting the radiation dose to the patient have been reported and attributed to human error. To determine the root cause of human error in the RAB system, a human factors team visited 23 RAB treatment sites in the U.S. The team observed RAB treatment planning and delivery, interviewed RAB personnel, and performed walk-throughs, during which staff demonstrated the procedures and practices used in performing RAB tasks. Factors leading to human error in the RAB system were identified. The impact of those factors on the performance of RAB was then evaluated and prioritized in terms of safety significance. Finally, the project identified and evaluated alternative approaches for resolving the safety significant problems related to human error.

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Introduction

Remote afterloading brachytherapy (RAB) is a medical process employed in the treatment of cancer that uses a computer to control the insertion and removal of radioactive sources in the vicinity of tumors in the body. RAB allows precise and reliable placement of radioactivity in the body while minimizing staff exposure to radiation. Some problems in the conduct of RAB have been noted in recent years, many of which have been attributed to human error.

As provided by a mandate to assure public health and safety, the U.S. Nuclear Regulatory Commission (NRC) reviews and investigates reports of certain errors and problems in the medical use of by-product materials. The predicted expansion of RAB, coupled with documented evidence of human error, demonstrates the need to improve the safety of this process. To better understand the nature of the RAB process and the potential for human error in RAB, the NRC sponsored a human factors study of RAB.

The project was designed to achieve the following specific goals:

- identify root causes of human error in RAB systems
- evaluate the effects human errors have on the performance of RAB functions and tasks
- identify and prioritize tasks with significant safety problems
- identify and evaluate alternative approaches for resolving those problems

A Human Factors Approach to RAB

Human factors is an applied science that evaluates human performance in interaction with technology and the environment. Human error is seen as the result of mismatches between what users are expected to do and what they are able to do. Human factors experts evaluate the demands placed on people by a system, identify actual and potential human errors, determine the consequences of those errors, and propose ways to minimize errors and their consequences. The result is a detailed description of what people within a system are required to do in relation to the system's purpose, goals, and functions.

The analysis of the functions and tasks performed by people also specifically identifies many of the things necessary to support the required level of task performance (e.g., needed information, control capabilities, sufficient time, step-by-step procedures, skills, knowledge, abilities, and environmental conditions). Systematic human factors evaluation also includes evaluations of the system's workspaces, human-system interfaces, procedures, training, and organizational policies and practices against available standards and guidelines. Results of those evaluations, in conjunction with the results of the function and task analysis, are then used to identify potential "human factors problems." A human factors problem is defined as a task which humans are not likely to perform to the level required by the system. Human factors problems can be due to the unavailability or unsuitability of necessary human-system interfaces, procedures, training, and organizational practices and policies.

Following identification of human factors problems, the impact of those problems is assessed. Assessing human factors problems in terms of their impact on the satisfaction of system goals provides a basis for prioritizing those problems. When prioritization is complete, plans for resolving significant problems can be developed.

Overview of RAB

Brachytherapy is a cancer treatment that uses radioactive materials to retard or destroy tumors with ionizing radiation. The process involves placing radioactive sources into a tumor, or in the area around the tumor, and then removing them after the prescribed dose of radiation has been delivered.

Brachytherapy has become increasingly automated over the past two decades. In RAB, a remotely controlled device inserts and withdraws radioactive sources from source holders that have been placed in a patient. Two types of RAB are currently practiced in the United States; they differ in the activity of their sources. High dose rate (HDR) RAB treatments use a high activity iridium-192 source to irradiate the target tissue for 5–10 minutes. HDR treatments are often conducted on an outpatient basis. Low dose rate (LDR) RAB treatments use several lower activity radioactive sources, such as cesium-137, and are conducted as inpatient procedures, typically lasting 2–3 days.

Method

Since all facilities involved in RAB could not be visited, a representative sample of twenty-three RAB facilities was chosen for visits to collect data on RAB. Facilities were chosen by afterloader manufacturer, geographic region, dose rate, licensing authority, caseload, and RAB experience.

During the first data collection stage, the two distributors of RAB devices and seven facilities using those devices were visited. A function and task analysis of the RAB process was produced using data from those visits. During the second stage, another eight facilities were visited to identify and evaluate the human-system interfaces and the procedures and practices used in the RAB process. During the third and final stage of data collection, an additional eight facilities were visited to determine the training and organizational support provided for RAB.

A comprehensive data collection protocol was devised prior to the site visits in order to ensure that data from those sources would meet the needs of the study. In addition, several data collection tools were developed specifically for this study. Those tools allowed human factors analysts to gather information about the characteristics of the devices and of each medical facility (e.g., personnel employed, equipment used, training and organizational factors, and practices and procedures used during remote afterloading). Unique aspects of each facility were also noted. These included its physical layout, potential distractors, organizational and administrative structures, jobs performed by various categories of workers, and local organizational, training, and treatment goals. Emphasis, throughout, was on identifying factors that could lead to patients receiving radiation dosages that differed significantly from the prescribed dosage or to inadvertent staff exposure.

Data were collected from the following sources:

- documentation supplied by the manufacturers and distributors of RAB equipment
- documentation used on-site by RAB staff, including locally developed documents
- interviews with all available RAB staff at each site
- observation and recording of RAB activities as they were being performed or demonstrated
- directed walk-throughs in which RAB staff performed tasks on simulated cases

A human factors research team analyzed all the data gathered during the project and identified factors that contribute to human error in RAB. The consequences of each error were then determined, and alternative approaches for resolving safety significant problems related to human error were identified and evaluated.

Results

Phase 1: RAB Function and Task Analysis

A human factors evaluation of the overall RAB process was conducted in Phase 1. It consisted of three major parts: a function and task analysis, an error analysis, and a skills assessment. The function and task analysis provided a detailed description of the tasks, equipment, materials, and personnel involved in performing RAB. The error analysis determined which RAB tasks are most susceptible to human error, identified actual and potential errors, and made preliminary determinations of their causes. The skills assessment identified the cognitive, perceptual, and motor skills needed to perform RAB functions and tasks.

The function and task analysis organized the RAB process into five major functions:

(1) Patient Preparation

(2) Treatment Planning

(3) Treatment Delivery

(4) Post-Treatment

(5) Quality Assurance and Maintenance

The skills needed for RAB were determined using a structured procedure that covered cognitive, perceptual, and motor skills. Two especially important cognitive skills were identified: the ability to detect and anticipate problems; and the ability to follow explicit rules in order to perform sequential actions. Certain functions and tasks were estimated to be more error prone than others. For example, treatment planning was considered to be the most difficult function, being highest in mental workload demands, and the function in which distractions were most likely to impair task performance.

Phase 2: Human-System Interfaces

Phase 2 evaluated the human-system interfaces used by RAB staff. These evaluations followed established human factors standards and guidelines for interface design. Four classes of human-system interfaces were evaluated based on the results of the Phase 1 function and task analysis: equipment, software, documents, and workspaces. Deficiencies that impede error-free human performance were identified for each of these four types of interfaces.

General human-system interface findings across all RAB functions and tasks showed that

- RAB staff were often unfamiliar with RAB interfaces that they had not used frequently.
- Operators could not see some essential treatment controls and displays from their workstations.
- System status information often was unavailable to system operators.

Phase 3: Procedures and Practices

Phase 3 evaluated the procedures and practices used to perform RAB tasks. The only tasks that were performed in exactly the same way at different facilities were those involving the actual operation of the RAB treatment delivery equipment. Very little written documentation was found that could be used to guide RAB task performance. Instead, verbal communication and demonstration was used to guide staff in RAB activities.

Phase 3 also identified the methods used to link the tasks together and the communications procedures used to pass information and material between the tasks. These linkages were crucial but often overlooked aspects of task performance. Without a well-established system of linking tasks, information that is critical to the correct performance of RAB can be lost. Similarly, verification procedures are often needed to confirm that certain actions occurred at the appropriate time and place in the RAB process. Verification procedures tended to either be absent, poorly structured, or inconsistently used at many facilities.

Phase 4: Training Practices and Policies

Phase 4 evaluated the training and qualifications of RAB staff. Although all RAB staff at the visited sites had received on-the-job training in RAB, most sites had no formal training programs, little written training material, and little, if any, follow-up or refresher training of any type. In addition, there are currently no state or national standardized training programs that RAB staff are required to complete, nor are there standardized assessment procedures for RAB training.

Certification examinations for RAB staff positions were required only for radiation therapy technologists at most sites (national certification is offered by the American Registry of Radiologic Technologists; in addition, some states have their own registry examinations). However, these certification procedures do not substantially address RAB-specific topics. Most RAB staff had therefore not been required to take formal written or oral examinations on RAB skills and knowledge. At the present time, there are no certification procedures specifically designed for RAB.

Phase 5: Organizational Practices and Policies

Phase 5 evaluated the organizational support provided RAB at each site. Eight organizational functions for RAB were identified and the way they affect RAB performance was assessed. These eight functions were

- Establishing Goals
- Defining Tasks
- Acquiring Staff and Equipment

- Designing Procedures
- Allocating Tasks
- Communicating Goals and Procedures
- Monitoring Progress Toward Goals
- Directing Progress Toward Goals

RAB was found to have been organized to meet different production, service, and treatment goals depending on local requirements and pre-existing staffing, workspace, and organizational structures. Although RAB staff and equipment had been acquired and assigned tasks, only a few sites had formally defined those tasks or produced written procedures to guide staff in performing them. Communication linkages during RAB task performance were particularly error-prone. Quality assurance procedures designed to identify RAB errors and address their consequences were incomplete and often failed to pass the information needed by staff to verify that the RAB process had been performed correctly.

Phase 6: Identification and Prioritization of Human Error in RAB

Phase 6 identified seventy-six opportunities for human error in RAB. The consequences of these errors could propagate through the RAB system and adversely affect patients or staff. A conceptual model of RAB was developed using data collected during Phases 1 through 5. The model allowed the consequences of human error to be identified and specified the information needed to detect and correct those errors. This was an important finding because the task linkages described in the model had often not been previously recognized as vital components of the RAB process.

Next, a panel of RAB subject matter experts used the analysis and task linkages to identify and prioritize consequences of human error on RAB. The panel also identified critical tasks and linkages in which a performance error was judged likely to result in undesirable consequences.

Critical RAB Tasks

The following ten RAB tasks and task linkages were determined to be critical in terms of their error likelihood and the consequences of those errors:

Patient Scheduling, Identification, and Tracking

This task involves identification of patients and their records as they move through the RAB system. Errors in these tasks include scheduling patients for the wrong treatment, bringing patients to the wrong treatment area, and substitution of patient documents or treatments.

Applicator Selection, Placement, and Stabilization

This task requires that applicators be selected, placed near a target in the body, and secured to prevent movement. Information on applicator characteristics (e.g., length) and applicator placement must be given to the treatment planners and to the staff who connect the applicators to the treatment delivery equipment. Errors in this task include failure to place the applicator so that the desired dose can be delivered to the targets, failure to stabilize the applicator after placement, and failure to transfer accurate information on the placement to other tasks.

Target Volume Localization

This task involves identification and specification of the volume of tissue that is to be irradiated. Errors in this task include failure to identify all the radiation targets and failure to specify the exact locations of the targets.

Dwell Position Localization

This task involves selection, specification, and communication of the positions that sources will occupy in the applicator during treatment. Errors in performing this task include incorrect identification, specification, or transfer of information about source positions between treatment planners and the treatment delivery system.

Dosimetry

This task involves calculation of the dose distributions that are produced by sources placed at specified dwell positions for specified times. Errors in dosimetry include failure to calculate the dose accurately or failure to describe the dose that will be received by each target from sources placed at the dwell positions.

Treatment Set-up

This task involves connection of patients to the afterloading treatment unit. Errors in treatment set-up include swapping two or more treatment channels so that treatment planned for one applicator will be delivered through another, connection of improper source guide tubes so that the planned treatment distance does not correspond to the planned dwell positions, or modification of the spatial relationship between the applicator and the targets so that the target tissues do not receive a correct dose.

Treatment Plan Entry

This task involves transfer of treatment parameters from the treatment plan to the treatment delivery unit. Errors in treatment plan entry include entry of values different from those in the treatment plan or the entry of the wrong treatment plan.

Quality Assurance and Maintenance

Quality assurance in RAB involves testing equipment and procedures to identify and correct malfunctions or problems before they impair treatment or compromise patient and staff safety. Maintenance involves changes to equipment or procedures that are designed to prevent or eliminate problems. Errors in quality assurance and maintenance include failures to detect, deal with, or communicate problems during the performance of quality assurance or maintenance.

Source Exchange

Errors committed during source exchange can result in inadvertent exposure of staff to the source during the exchange procedure, or produce changes in RAB equipment that can cause problems in source positioning accuracy, equipment integrity, or treatment delivery.

Source Calibration

Source calibration involves the measurement of the characteristics of a radioactive source and the transfer of that information to RAB task in which those characteristics are used. Examples of source calibration errors include failure to measure accurately the activity of a radioactive source or failure to communicate accurately the calibration results to staff and treatment planning systems.

RAB Problem Resolution

Alternative approaches were developed to reduce the impact of human error on each of these ten critical tasks. Each alternative was then evaluated to determine how it might be used to reduce the likelihood of human error in RAB, to improve the opportunity for error detection, or to aid in the correction of error consequences. Promising alternatives were grouped into four categories:

(1) Human-Systems Interface and Equipment Modifications

- tag readers for patient identification tags
- automatic comparison of patient and treatment plan identifications
- prominent labels on applicators that might be misidentified
- applicator stabilization aids
- digitization aids (e.g., scanners and target superimposition aids)
- improved feedback and visualization aids for treatment planners
- unambiguous data entry formats
- dwell positions referenced to the applicator instead of the treatment unit
- pre-treatment dose estimation based on treatment plan parameters
- direct calibration chambers for RAB radionuclides
- automatic calibration while the source is in its stored position
- source position sensors (minimum would detect a source in the safe)
- measurement of dose delivered (to some reference volume) during treatment
- performance certification packages for software and hardware

(2) Job Performance Aids

- highly visible identification tags on patients and all their documents
- applicator identification labels
- an applicator-channel map
- QA checklists that highlight failed or omitted checks
- visual aids for treatment planning
- improved access to emergency source containment safes

(3) Procedure Modifications

- tagging procedures for patients and their documents
- use of an applicator-channel map for treatment planning and treatment setup
- standardization of dosage units
- target marking in simulation views (when applicable)
- minimization of patient movement between simulation and treatment
- erasure of magnetic media used to transfer treatment plans

(4) Training and Organization Modifications

- identification of error opportunities
- a multi-tiered quality assurance program stressing early error detection
- display of information needed for error detection to all staff
- communication procedures that pass redundant information needed for error correction
- verification of task linkages prior to treatment
- certification of all RAB equipment and software after maintenance
- integration of QA with refresher training in emergency and planning procedures
- multiple source calibrations
- training in local task performance and linkage procedures
- training in error detection and allocation of error detection duties

- monitoring the efficacy of procedures and training in preventing errors
- monitoring the efficacy of RAB error detection and correction

Conclusion

Taken together, alternative approaches to HSIs, job performance aids, procedures, and training would reduce the likelihood of errors in most of the critical tasks. The hardware modifications could also reduce the burden on staff by automatically performing some of the currently difficult procedures, automating error-prone linkages, and providing needed feedback to staff on their performance and on system integrity. The remaining organizational modifications could improve quality assurance and increase the opportunity for detecting and correcting human errors.

These alternatives could eliminate many existing opportunities for human error. They could also improve quality assurance and safety by making errors easier to detect, and by providing staff with the information they need to identify and address the consequences of error in the RAB process.

Although the alternative approaches provide some direction to solve problems in the critical tasks, they do not include the level of detail that would be required for implementation. In many cases, more than one alternative has been suggested for a single problem to allow for interim improvements until more technically challenging but potentially better solutions can be achieved.

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The authors thank the many members of the radiation therapy community who generously contributed their time, knowledge, and expertise to this project. The radiation oncologists, medical physicists, dosimetrists, radiation therapists, and department administrators consulted during this project were helpful and informative. The efforts of these individuals have resulted in increased understanding of human factors aspects of remote afterloading brachytherapy. This understanding can aid in making remote afterloading brachytherapy safer, more reliable, and more effective for both patients and the dedicated workers who serve them.

1 Introduction

Brachytherapy (Greek: *brachy*, short range + *therapia*, medical treatment) is a cancer treatment process that uses radioactive materials ("sources") to retard or destroy tumors with ionizing radiation. Depending on the area to be treated, radioactive sources are placed within a body cavity adjacent to the tissue to be exposed (intracavitary or intraluminal), externally adjacent to the tissue to be exposed or directly into a tumor or surrounding tissue (interstitial). In general, brachytherapy sources are intended to be removed after the treatment area has received its prescribed dose of radiation. In remote afterloading brachytherapy (RAB), a remotely controlled device inserts and withdraws the sources from source holders that have been placed in a patient.

On November 21, 1992, a patient who had been treated with a RAB device died after the brachytherapy source was left in an implanted source holder following treatment. In the past five years, other patients being treated with RAB devices have received radiation doses which differed from the prescribed dose or which were administered to the wrong location. All the events involved "human error."

1.1 Purpose of the Project

The Nuclear Regulatory Commission (NRC) and its agreement states regulate brachytherapy as part of their mission to protect public health and safety. One area of regulatory concern is misadministrations. A brachytherapy misadministration means the administration of a brachytherapy radiation dose

(1) involving the wrong patient, wrong radioisotope, or wrong treatment site (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site),

(2) involving a sealed source that is leaking,

(3) when, for a temporary implant, one or more sealed sources are not removed upon completion of the procedure, or

(4) when the calculated administered dose differs from the prescribed dose by more than 20 percent of the prescribed dose (U.S. Nuclear Regulatory Commission, January 1994).

Misadministrations are often attributed to human error. Their consequences, as shown by the example above, can be severe. The purpose of the current project was to conduct a human factors evaluation of RAB to identify factors which could lead to human error. The remote afterloader itself is only one element of the RAB system. Other elements (e.g., personnel, facilities, supporting equipment, software, procedures, training, and the organization) are no less important to the success of brachytherapy and were also addressed in the evaluation.

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

1.2 Human Factors Evaluation

Accident reports often end with a finding that human error was the cause of some disaster. However, that finding may be only the first step in determining the actual root cause of the disaster.

A human factors evaluation designed to assess the relationship between human performance and system performance seeks to answer the following questions:

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

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

The human factors discipline offers an approach to systematic evaluation of human-machine systems for

potential errors and their consequences. The approach begins with a function and task analysis which

- identifies the system's purpose and other important goals
- identifies functions required to satisfy the system's purpose and goals
- identifies tasks and task steps necessary for users to accomplish their roles with respect to the system functions
- analyzes tasks and task steps for the performance requirements placed on the users

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

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

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

Systematic human factors evaluation also includes evaluations of the system's workspaces, human-system interfaces, procedures, training, and organizational policies and practices against standards and guidelines (e.g., American National Standards Institute, 1988; Association for the Advancement of Medical Instrumentation, 1993; Department of Defense, MIL-STD-1472D, 1989; National Aeronautics and Space Administration, NASA-STD-3000, 1987; Nuclear Regulatory Commission, NUREG-0700, 1981). Results of those evaluations, in conjunction with the results of the function and task analysis, are then used to identify potential "human factors problems." A human factors problem is defined as a task which humans are not likely to perform to the level required by the system. Human factors problems may exist if the expected performance is simply beyond the human performance capabilities of people within the system (e.g., sense the presence of radioactivity). More often human factors problems are due to the unavailability of system components necessary to support the expected performance (e.g., lack of a direct indication that a radioactive source is in its storage position) or the unsuitability of system components which are available (e.g., displays indicating that a radioactive source is in a shielded storage position which are not based directly on the location of the source). Human factors problems can be due to the unavailability or unsuitability of necessary human-system interfaces, training, procedures, and organizational policies and practices.

Following identification of human factors problems, the impact of those problems is assessed. Impacts depend upon the specific task and upon the design and operation of the system being reviewed. For a given system, failure to perform some tasks adequately may be noticed immediately and corrected prior to an adverse system outcome. Failure to perform other tasks adequately may cause only a single adverse outcome that can be easily detected and corrected. Failure to perform still other tasks adequately may have broad effects and lead to irreversible, adverse consequences. Such failures may not be noticed until there has been an accumulation of adverse outcomes. Assessing human factors problems in terms of their impact on the satisfaction of system goals provides a basis for prioritizing those problems. When prioritization is complete, plans for resolving significant problems can be developed.

1.3 Human Factors Problem Resolution

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

Other approaches to eliminating mismatches involve modifying the system to reduce human performance requirements or to enhance human performance capabilities. Modifying human-system interfaces to make system components which support adequate task performance both available and suitable for the intended use tend to reduce human performance requirements. Modification of task specific procedures and of

organizational policies and practices can also reduce human performance requirements. Modifying training or selection qualifications can improve the performance capabilities of people within the system.

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

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

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

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

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

1.4 Remote Afterloading Brachytherapy

Several methods for implanting and removing brachytherapy sources have evolved over the years. Manual brachytherapy originated in the early 1900s, shortly after the discovery of radium. In its earliest applications, radium was implanted directly into the tissue to be treated. Subsequently, treatment versions were developed using lower activity and shorter lived isotopes such as gold and cesium. More refined forms of manual brachytherapy then were developed in which sources were loaded into pre-positioned applicators. This approach, termed manual afterloading, reduced the radiation exposure of medical personnel during brachytherapy procedures. Nevertheless, there remained some occupational exposure to radiation during the manual loading and removal of sources and during nursing care.

RAB was developed in Europe during the 1960s and introduced to the United States 10–15 years later. RAB provides a greater degree of safety for medical and staff personnel because a remotely controlled device inserts and withdraws the source material. Medical and staff personnel remain outside a shielded treatment room. This report addresses RAB only.

Two types of RAB are currently practiced in the United States and are classified on the basis of the intensity of their sources: high dose rate (HDR) and low dose rate (LDR). HDR RAB uses a high activity (nominally 10 curies) source such as iridium-192 (^{192}Ir) to deliver a therapeutic absorbed dose of 500–1000 centiGray in 5–10 minutes. HDR treatments can be conducted on an outpatient basis due to their short treatment times. To enhance the biological effectiveness and patient tolerance of a HDR treatment, patients often receive the treatment dosage in 2–3 fractions separated by a few days.

LDR RAB uses lower activity sources consisting of cesium-137 pellets (^{137}Cs) or iridium wire of a few hundred milliCuries of activity, depending on the number of pellets or length of wire chosen. Low dose rate treatments are conducted using inpatient procedures that duplicate manual afterloading brachytherapy treatment times (2–3 days).

RAB is a complex system comprised of components that must function in a coordinated manner. These components include facilities, RAB functions (with their associated equipment) personnel, and patients.

1.4.1 RAB Facilities

RAB facilities include HDR treatment suites, LDR treatment suites, treatment planning areas, simulation rooms, and various control stations, waiting rooms, examination rooms, operating theaters, and storage and shop areas. HDR and LDR treatment rooms and treatment planning areas are briefly described below.

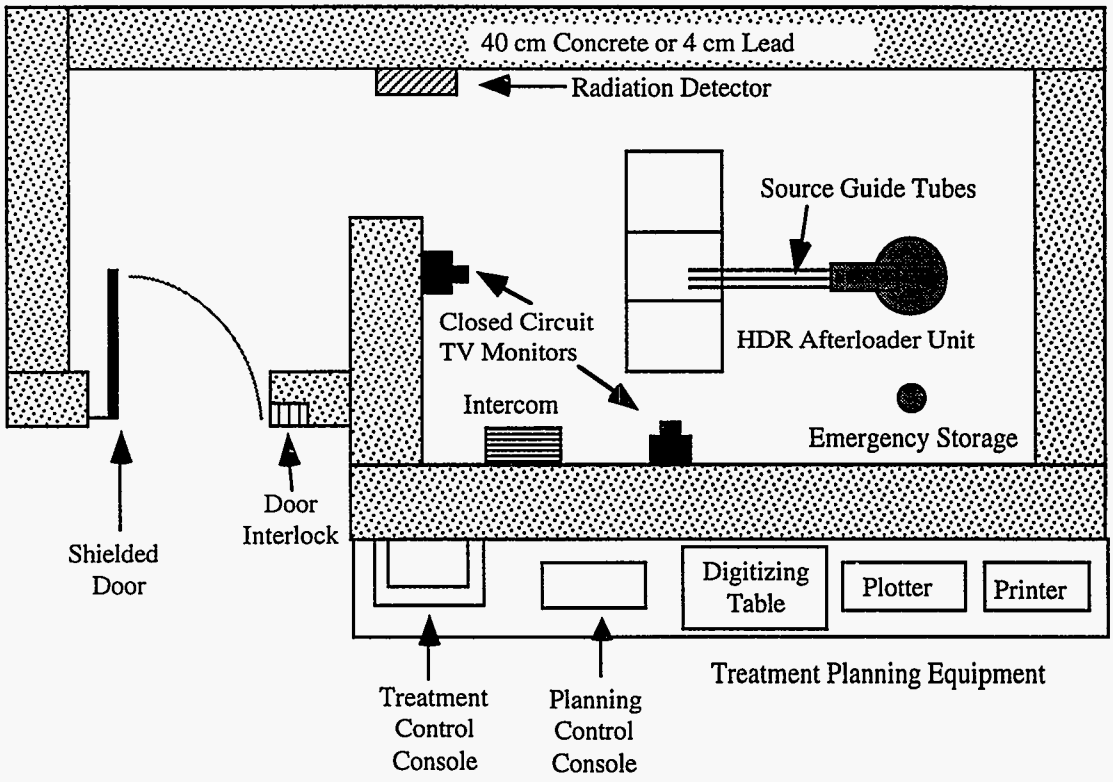

Figure 1. Floor-plan of a representative HDR brachytherapy suite

1.4.1.1 HDR Treatment Suite

Figure 1 shows a representative, dedicated, HDR brachytherapy suite. This floor-plan incorporates the essential treatment planning and treatment delivery facilities used in HDR RAB. Treatment planning and treatment delivery facilities usually are not located in such close proximity; for illustrative purposes, however, they are shown adjacent to the treatment room in the figure.

The treatment room shows typical components of a HDR facility. The remote afterloader unit is positioned next to the patient, who is usually in a wheelchair or on a bed. The height of the afterloader's source head can be adjusted to aid in connecting the source guide tubes to the applicators that have been placed in the patient. A radiation detector that illuminates whenever ionizing radiation is present in the room is shown on the wall of the treatment room. Closed circuit TV cameras can be oriented to include both the patient and the radiation detector in their field of view. This enables the brachytherapy staff to observe the patient during the treatment session as well as to check for the presence of radiation before entering the treatment room. The emergency storage container is positioned close to the afterloader to expedite emergency shielding of the source.

The afterloader treatment control console is located outside the treatment room along with a closed circuit TV monitor and controls to abort a treatment session manually should the need arise. Treatment planning facilities are located in a separate room. HDR facilities are often collocated with teletherapy equipment in a remote area of the hospital, usually a basement or isolated ground floor location. This provides distance and shielding to limit personnel exposure to radiation. The patient, therefore, usually must be transported to the brachytherapy suite from another area of the hospital where applicators, (catheters, needles, or other source holding devices) have been inserted. Figure 1 shows equipment placement in a room dedicated to brachytherapy treatments. In cases where the brachytherapy device is collocated with a teletherapy device, the teletherapy device occupies a fixed location within the room and the brachytherapy device is rolled into position when needed.

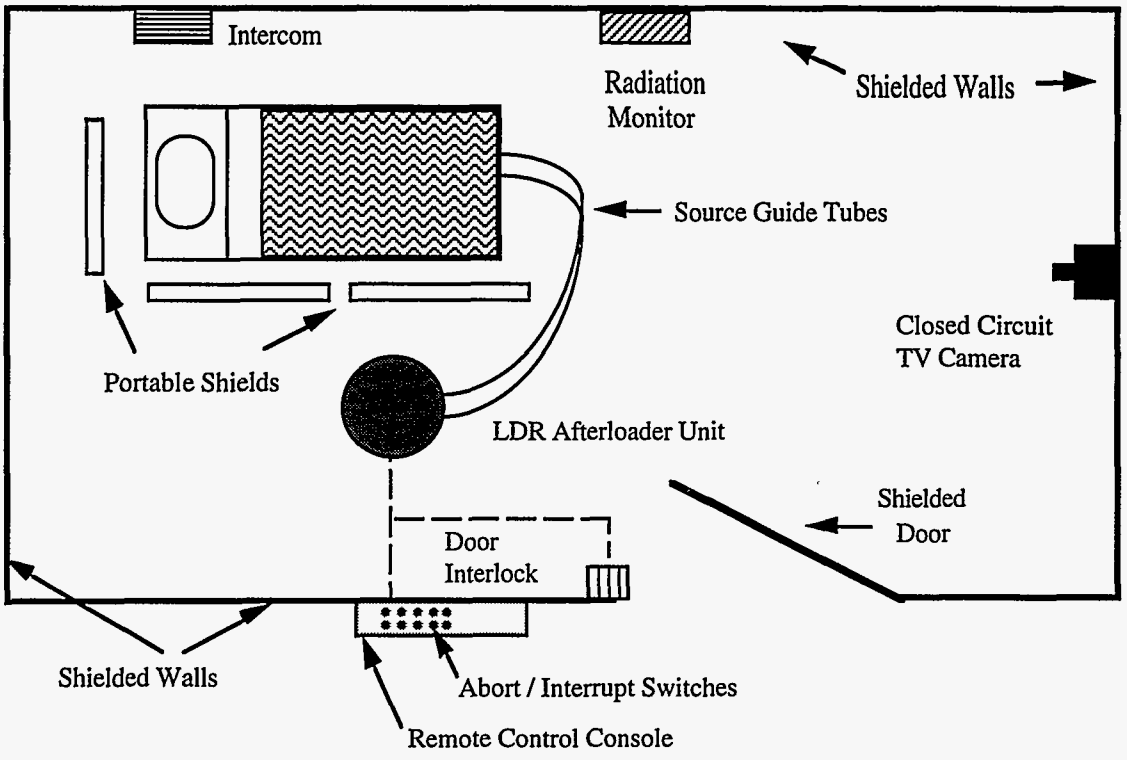

Figure 2. Floor-plan of a representative LDR brachytherapy suite

1.4.1.2 LDR Treatment Suite

Figure 2 shows a representative treatment room for LDR applications. This room is usually a conventional hospital room that has been converted for radiation treatment through the addition of shielding, a radiation monitor, a closed circuit TV system, and intercoms. The remote control console outside the treatment room is used to start and interrupt treatment sessions, communicate with the patient, and monitor the status of the afterloader unit.

1.4.1.3 Treatment Planning Area

For illustrative purposes, treatment planning facilities are shown adjacent to the treatment room in Figure 1. They are usually located in a separate room and are often shared by the HDR, LDR, and teletherapy planning activities. The treatment planning control console, digitizing table, computer and its peripheral devices (e.g., printer, plotter) are used to generate a treatment plan which is then programmed into the afterloader control computer.

1.4.2 RAB Functions and Associated Equipment

The operations necessary to accomplish RAB include clinical evaluation, therapeutic decision making, patient preparation, treatment planning, treatment delivery, quality assurance, maintenance, and follow-up evaluations of patient progress. Clinical evaluation, therapeutic decision making, and follow-up evaluations were beyond the scope of this study. The functions performed in preparing, planning, and delivering an RAB treatment include

- Patient Preparation
- Treatment Planning
- Treatment Delivery
- Post-Treatment
- Quality Assurance and Maintenance

These functions and their associated equipment are summarized below in Sections 1.4.2.1 to 1.4.2.5.

1.4.2.1 Patient Preparation

Preparation for RAB includes patient scheduling, tracking, identification and instruction. Equipment set-up, life support attachment, and other tasks that must be accomplished before treatment begins are included in patient preparation. Checks and calibrations of the RAB system for treatment readiness are addressed under QA and Maintenance.

1.4.2.2 Treatment Planning

Treatment planning is the process whereby the dose distribution specified by the radiation oncologist's prescription is operationalized. The process involves determining appropriate dwell positions and times for the sources relative to the patient's treatment area. In order for a treatment plan to be implemented successfully, the position of applicators must be accurately determined relative to the cancer tissue and other anatomy. Figure 3 illustrates a straight applicator placed near a tumor and a cylindrical isodose of radiation that might be delivered to tissue surrounding the applicator during treatment.

Treatment simulation is the part of treatment planning that determines the location of applicators and sources relative to the cancer tissue. Treatment simulation is performed using an x-ray machine and simulated sources made of inert, radio-opaque material such as lead. The simulated sources are inserted into the applicators that have been pre-positioned in the patient. X-ray images are then taken and the actual position of the simulated sources is evaluated relative to the desired position. If necessary, the simulated sources or applicators are repositioned, and another set of x-ray films is made. This process continues until the applicators are in the desired treatment location.

The treatment planning computer and its peripheral devices (e.g., printer, plotter) are used to generate a treatment plan which is then programmed into the afterloader control computer. Specially designed software is used to determine the dwell positions and dwell times for the sources. Coordinate points related to patient anatomy and the tumor are entered into the planning program from simulation x-ray images. The output of treatment planning is a set of recommended source dwell positions and a dwell time for each position. Results are displayed on a printer or a plotter. Computer printouts serve as records of the treatment planning session.

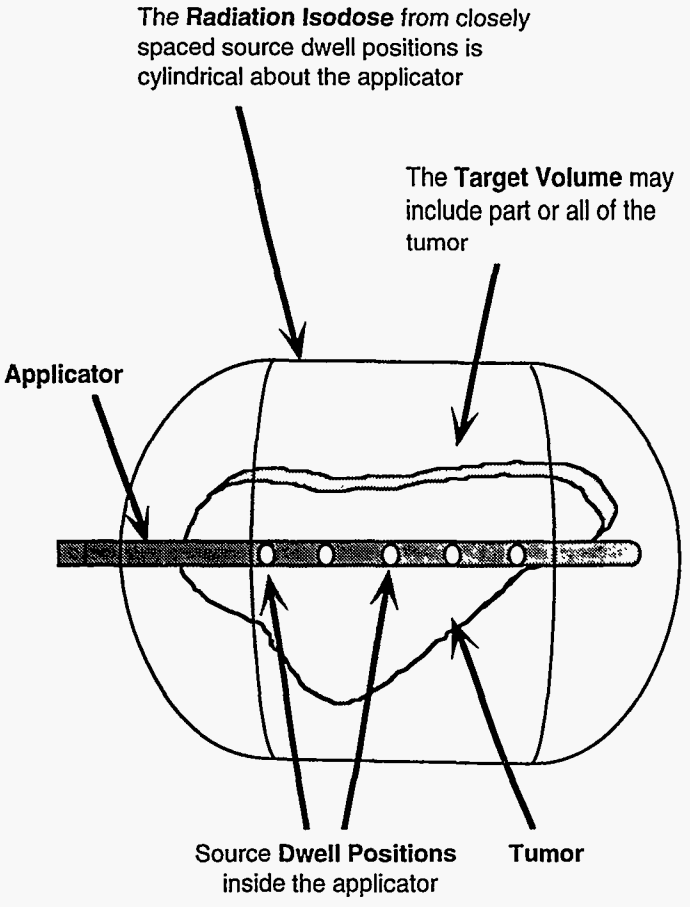

Figure 3. Some treatment planning terms

Treatment planning computers are produced by various companies in the U.S. and abroad, including RAB device manufacturers. The computers are versions of general purpose micro and minicomputers with specialized software for the analysis of radiation activity, dose, decay, distribution in tissue, and optimization. Most treatment planning systems can be used for manual brachytherapy and teletherapy as well as RAB.

1.4.2.3 Treatment Delivery

RAB treatment delivery is accomplished by remotely positioning the source(s) within the tissue to be irradiated for the prescribed period of time. The sources are automatically removed to a safe repository upon command from the control console following treatment. Sources may also be restored temporarily to safe storage during periods of interruption such as when staff must be in the treatment

room. Remote afterloaders perform all of these source transport functions.

Representative models of HDR afterloaders* are shown in Figures 4 and 5. Figure 4 shows a GammaMed model 12i HDR afterloader and Figure 5 shows a microSelectron HDR afterloader. These two models, and an earlier model of GammaMed HDR afterloader were evaluated in detail during the course of this study.

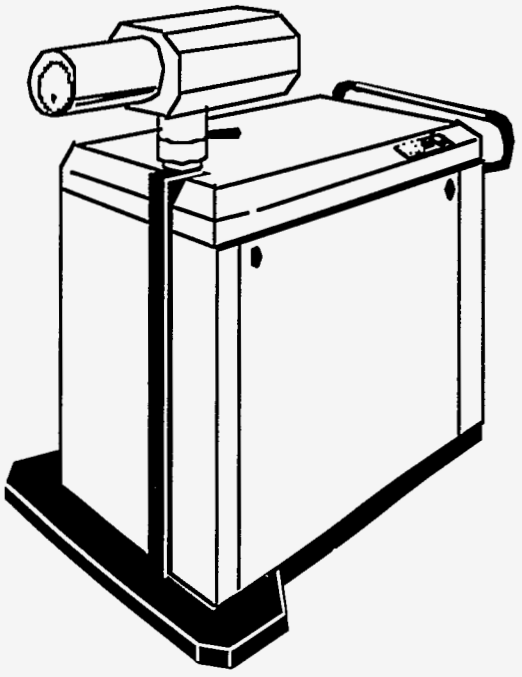

Figure 4. GammaMed® 12i HDR afterloader

HDR afterloaders move their radioactive source mechanically by means of a steel cable or wire attached to a precision stepping motor. All current HDR remote afterloaders use a single source composed of iridium-192 with a nominal activity of 10 Curies (Ci). In the majority of HDR afterloaders, the source is implanted in a metal capsule about 1 millimeter in diameter and about 5 millimeters in length. One model of HDR afterloader incorporates the source into the end of the wire used to move it to different positions. To achieve the prescribed dose distribution, the source is moved precise distances along the source guide tubes and held at each position for a specified length of time, typically only a few minutes.

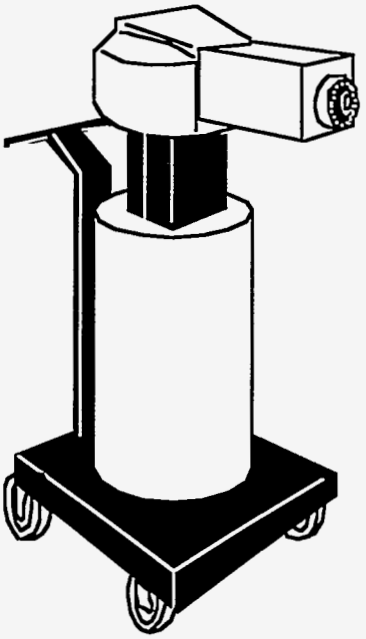

Figure 5. Nucletron® HDR afterloader

LDR afterloaders use source trains of cesium-137 in 10–40 milliCurie (mCi) pellets or iridium in ribbon assemblies of 1–2 mCi seeds. Low dose rate sources are assembled according to the prescribed dose distribution and held stationary during a prolonged (2–3 day) treatment session. The LDR remote afterloaders move iridium elements or cesium pellets using combinations of pneumatic and mechanical power. Two LDR afterloader models are displayed in Figure 6 and 7. Figure 6 shows a Selectron LDR afterloader and Figure 7 shows a MicroSelectron LDR afterloader. Both models of LDR afterloader are distributed by the Nucletron corporation.

The movement of the source between the afterloader and the patient is controlled by the afterloader control console. For HDR afterloaders, this console is located outside and adjacent to the treatment suite; for LDR afterloaders, it is integrated into the afterloader console. The treatment plan is entered into the treatment delivery computer at this console. The treatment session is monitored and can be interrupted or terminated at the console or, in some cases, at another remote station. Status indicators convey the condition of the afterloading system during a treatment session. Figure 1 shows the location of the HDR treatment

* Nucletron®, Selectron®, and MicroSelectron® are registered trademarks of Nucletron International B.V. GammaMed® is a registered trademark of Isotopen-Technik DR. Sauerwein GMBH.

control console in the vicinity of the HDR brachytherapy suite.

Applicators are transport and container devices that are placed in the patient in the desired proximity to the tissue to be treated. They are used to guide movement and ensure the proper positioning of the radioactive source(s). Applicators may be flexible tubes (catheters) whose shape can be changed to allow them to reach and conform to tumor locations within the body, or may be rigid appliances that can be used to deliver standardized treatment patterns. Multiple applicators can be used to generate complex dose distributions that may be needed to treat particular tumors.

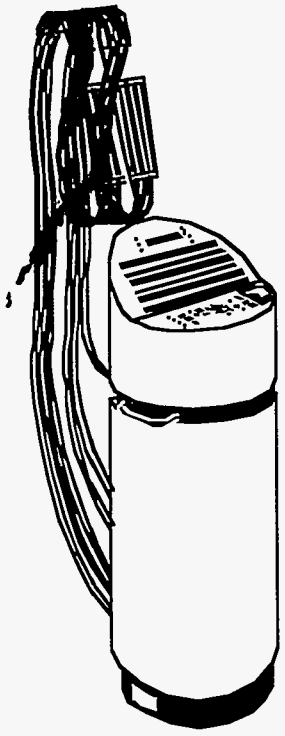

Figure 6. Selectron® LDR afterloader

Source guide tubes connect the treatment channels of the afterloader to the applicators that have been placed in a patient. It is important to ensure that each applicator is connected to the correct afterloader channel. Manufacturers and RAB staff often use mechanical interlocks and labeling to help prevent source guide tubes from being connected to the wrong channel.

All remote afterloaders have multiple safeguards for protecting patient and staff from unintended radiation exposure. These include:

- a door interlock that causes the afterloader to return the source to a shielded position when the door to the treatment room is opened
- automatic source return by a backup system in the event of a power failure, and
- in the case of HDR afterloaders, a manually operated crank to return the sources to the afterloader should primary and backup power fail.

Although they vary in details, all afterloader control consoles have an alphanumeric display, a numeric keypad for entering treatment plan parameters, indicator lights showing what mode the afterloader has entered, and a key switch for restricting access to afterloader controls.

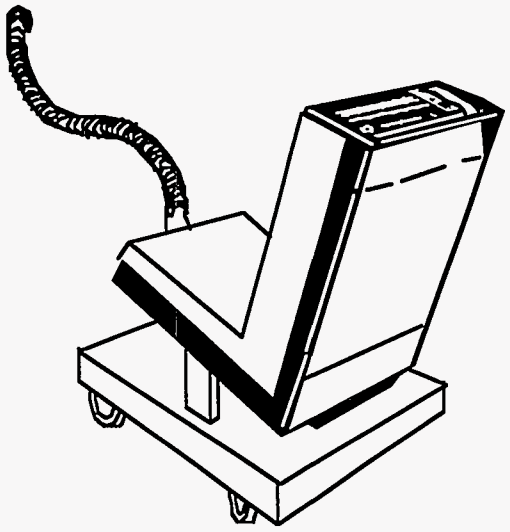

Figure 7. MicroSelectron® LDR afterloader

All RAB consoles also have a printer for generating a record of each treatment session. This record includes treatment plan parameters, patient identification data, interruptions of treatment sessions, and error codes.

1.4.2.4 Post-Treatment

The Post-Treatment function includes disconnecting the patient from the afterloader, removal of applicators, and preparing the patient for discharge or resumption of routine nursing care. The patient may be transported to a recovery room, allowing them time to recover from the treatment session and the effects of medication. Treatment data are

printed and the staff verifies that the prescribed radiation dosage was administered to the patient. Patient records are updated, checked for accuracy and filed.

1.4.2.5 Quality Assurance and Maintenance

Quality assurance and maintenance consists of all activities required to check system operation:

(1) source exchange

(2) source calibration

(3) equipment and software updates

(4) troubleshooting

(5) routine quality assurance

Performance of these tasks helps to assure that treatment sessions are conducted as safely and effectively as possible, for both patients and staff.

Miscellaneous quality assurance appliances are used to determine whether the remote afterloader system is performing according to specifications. Source position accuracy, activity level, and source travel distance are examples of critical factors that must be tested and calibrated. These devices include source position check rulers, calibration chambers, and source guide tube index rods.

1.4.3 RAB Personnel

Radiation therapy and radiation oncology departments are staffed with specially trained personnel needed for the safe and effective delivery of radiation in therapeutic doses. Staffs vary from place to place but can include physicians (radiation oncologists), nurses, medical physicists, radiation therapy technologists (also known as radiation therapists), dosimetrists, engineers, and clerical support personnel. Other important personnel components of the RAB system include those hospital departments which are served by or which serve the radiation oncology department. Personnel components important to RAB outside the medical facility include vendor personnel involved in training, information and engineering support.

1.4.4 RAB Patients

Finally, the patient also is a fundamentally important component of the RAB system. Patient understanding and cooperation is essential to safe RAB.

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2 Method

The RAB system described in Section 1 involves a complex process in which human error can contribute to misadministrations. The human factors discipline provides a systematic approach for evaluation of such systems to identify potential errors and their consequences. Once potential errors are identified, alternative approaches for reducing the frequency of errors and mitigating their consequences can be evaluated. In the current study, this systematic approach to systems analysis included the following six phases:

(1) Function and task analysis

(2) Human-system interface evaluation

(3) Procedures and practices evaluation

(4) Training and qualifications evaluation

(5) Organizational practices and policies evaluation

(6) Identification and prioritization of human factors problems and identification and evaluation of alternative approaches for resolving these problems

Phases 1 through 5 required data to be collected from facilities where RAB was performed (e.g., hospitals and free-standing radiation oncology services) and from facilities which supported the performance of RAB (e.g., equipment distributors). Phase 6 required integration and evaluation of the data collected in the first five phases.

2.1 Sampling Strategy

Since all facilities involved in RAB could not be visited, a representative sample of RAB facilities was chosen for visits to collect data in the first five phases of the study. Two distributors of RAB devices and twenty-three facilities using those devices were visited. Data were collected in three stages. During the first stage, the two distributors of RAB devices and a sample of seven facilities using those devices were visited to collect data for a function and task analysis of the RAB process. During the second stage, another eight facilities were visited to identify and evaluate the human-system interfaces and the procedures and practices used in the RAB process. During the third and final stage of data collection, an additional eight facilities were visited to determine the training and organizational support provided for RAB.

Although organized into three data collection stages with different emphasis for each stage, relevant data for prior analyses were also collected as the study progressed to increase the data sample for those analyses. In particular, data collected on procedures and practices in the second stage were augmented with additional data collected in the third stage to provide a sample of 16 sites for that evaluation.

Facilities were chosen by afterloader manufacturer, geographic region, dose rate, licensing authority, caseload, and RAB experience. The influence of these selection criteria on the sample chosen for the study is summarized in Sections 2.1.1 through 2.1.3.

2.1.1 Afterloader Distributors

At the beginning of this study there were two major brands (GammaMed and Nucletron) of afterloaders with widespread U.S. distribution. The U.S. distributors of both these brands were visited during the first phase of the study. A third brand, Omnitron* which was introduced at about the time this study began has subsequently also developed fairly wide U.S. distribution. Because initial U.S. distribution of the Omnitron devices occurred after start of the first phase of the study, these devices were not included in the study.

2.1.2 Facilities Using RAB Devices

One hundred and thirty-five medical facilities had installed RAB devices in the U.S. at the beginning of this study. A representative sample of 23 was selected for site visits. A sampling methodology termed stratified random sampling (Cochran, 1977; Kish, 1965) was employed in site selection. Stratified sampling involves dividing the population from which samples will be selected into groups that are defined by various criteria. A random sample is then chosen from each group. Stratified sampling is useful when, as in the present case, several characteristics of the individual population members are known before data collection begins. The characteristics chosen for sites selected in this study were manufacturer, geographic region, dose rate, licensing agency, case load, and RAB experience. In addition, as a secondary consideration, different types of medical facilities were visited including government hospitals, university hospitals, private hospitals, and free-standing clinics.

The data collection, interviews, and treatment walk-throughs performed by the site visit team required substantial participation by the facility. Two sites which were initially contacted elected not to participate when the data collection methods and visit requirements were explained. Two others were unable to participate due to scheduling difficulties. These four sites were replaced by others in the same region with roughly similar characteristics. To prevent bias, no site was dropped from the study after it had been visited.

* Omnitron is a registered trademark of Omnitron International, Inc.

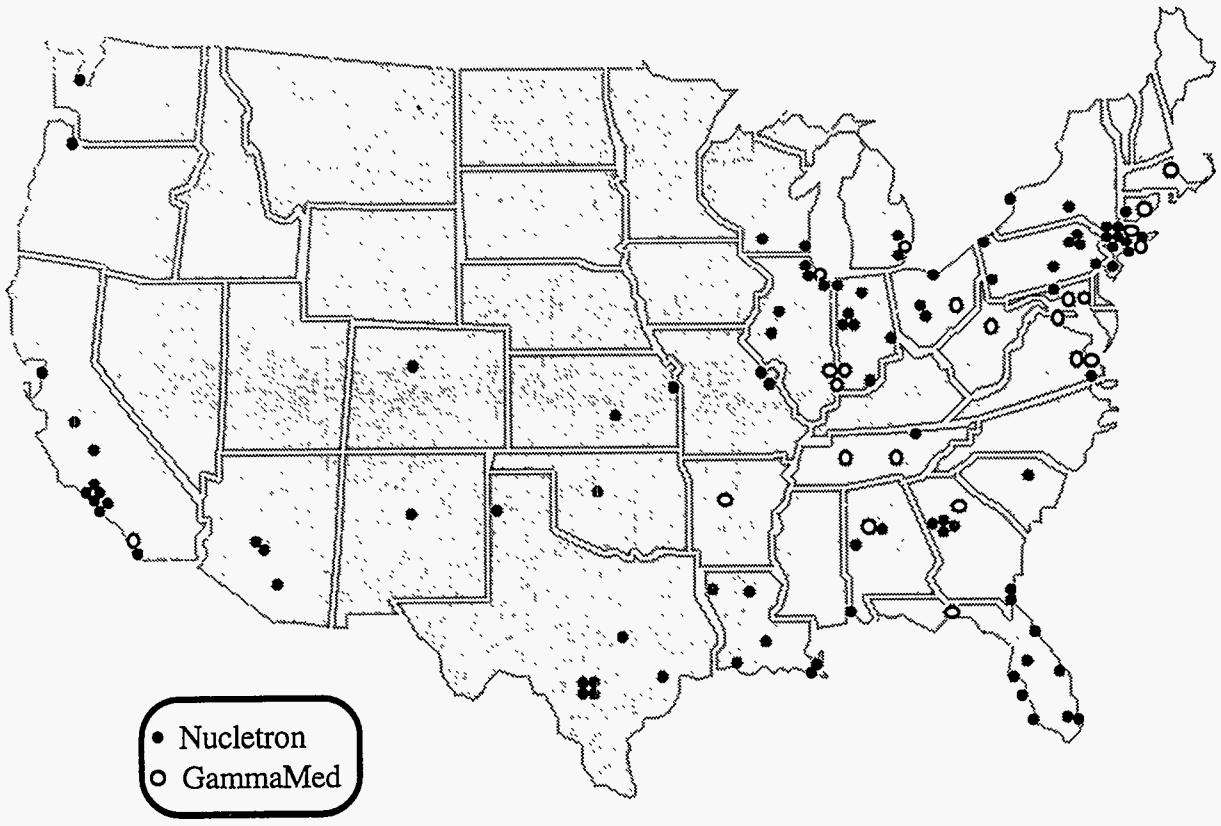


Figure 8. Remote afterloading brachytherapy equipment installations in the U.S. in 1990

2.1.2.1 Manufacturer

The visited sites included eighteen which used a Nucletron afterloader and five which used a GammaMed afterloader. The ratio of Nucletron to GammaMed sites visited approximated the ratio of afterloaders of each brand in use nationwide at the start of the study (about 110 Nucletron and 25 GammaMed). Several sites had more than one model of afterloader (e.g., an LDR and an HDR or two models of LDR) and three had more than one brand of afterloader. Two visited sites had recently installed an Omnitron afterloader and planning system in addition to the equipment they had originally acquired. Treatment planning equipment from five different manufacturers was used at the visited sites.

2.1.2.2 Geographic Region

Figure 8 shows the geographic distribution of RAB equipment in use in the U.S. at the beginning of this project. The sites to be visited were chosen from both urban and rural settings in each geographic region of the U.S. Care was taken to limit the number of sites chosen in any one state.

2.1.2.3 Dose Rate

Two of the visited sites performed only LDR remote afterloading treatments. Two others performed both HDR and LDR treatments. The remaining 19 sites performed only HDR treatments.

2.1.2.4 Licensing Authority

At the onset of this study, medical use of nuclear by-product material was licensed by the NRC in 21 states. The 29 other states licensed its use themselves in agreement with the NRC. Eleven of the sites visited in the study were in a state regulated by the NRC and twelve were in NRC-agreement states.

2.1.2.5 Case Load and RAB Experience

Sites with RAB case loads from less than one per month to greater than 30 per month were included in the study. Site selection was not distributed evenly by case load since one objective of the study was to learn from experienced users and such users were usually associated with sites having higher RAB case loads. Although it was assumed that experienced staff would have identified more RAB problems and developed more sophisticated RAB procedures than would be found at sites with little experience in RAB, data were also collected from five sites at which fewer than one RAB treatment a month was performed. These data were used to identify problems that might not occur with experienced RAB users.

2.2 Data Collection and Analysis

A comprehensive data collection protocol was devised prior to the site visits in order to ensure that data from those sources would meet the needs of the study. In addition, several data collection tools were developed specifically for this study. Those tools allowed human factors analysts to gather information about the characteristics of the devices and each medical facility (e.g., personnel employed, equipment used, training and organizational factors, and practices and procedures used during remote afterloading). Unique aspects of each facility were also noted. These included its physical layout, potential distractors, organizational and administrative structures, jobs performed by various categories of workers, and local organizational, training, and treatment goals. Emphasis, throughout, was on identifying factors that could lead to misadministrations or inadvertent staff exposure.

A typical site visit involved 2–3 project team members for 2–3 days. During visits, data were collected from the following sources:

- Documentation supplied by the manufacturers and distributors of the remote afterloaders, including operating manuals, equipment specifications, training manuals, and journal articles
- Documentation used on site by the people performing the RAB activities including operating or training manuals, written procedures, checklists, or other written job performance aids
- Interviews with afterloader distributors and the project team's RAB consultants from the Department of Radiation Oncology, University of California at San Diego
- Interviews with all available RAB personnel at each site including department chairs, radiation oncologists, nurses, medical physicists, radiation therapy technologists, dosimetrists, receptionists, and patient transporters. These interviews covered individual background and training information as well as discussion of local problems and practices
- Direct observation and recording of various aspects of remote afterloading while they were being performed or demonstrated at each site. These supplied a documentable record to analyze remote afterloading brachytherapy functions and case history information
- Directed walk-throughs in which staff were asked to perform their usual functions on simulated cases while being observed and questioned by members of the site visit team

Phase 1, the function and task analysis, was designed to characterize the RAB process and establish a framework for both data collection during Phases 2 through 5 and integration of findings during Phase 6. The following sections provide an overview of the data collection and analysis methods used throughout all phases of the study.

2.2.1 Phase 1: Function and Task Analysis and Error Analysis

The function and task analysis involved visits to two RAB equipment distributors and to seven medical facilities. To guide the research team's activities prior to medical facility visits, a skeleton function and task listing was developed from the literature, from radiation oncology experts on the project team, and from the visits to RAB equipment distributors. The team revised the skeleton function and task listing by building, amplifying, and modifying the structure and detail following each site visit. The final function and task structure and inventory was completed after the seventh site visit.

At medical facility site visits, the research team's approach to the function and task analysis was to observe and record the performance of all tasks performed by the RAB staff. In addition, those aspects of RAB that could not be observed objectively, or were difficult to review otherwise, were assessed through detailed, structured interviews with RAB staff at each site. An individual interview was conducted with each available member of the brachytherapy staff (e.g., department chair, radiation oncologists, nurses, medical physicists, radiation therapists, dosimetrists) to establish staff responsibilities, familiarity with various functions, training, and qualifications in brachytherapy. Interviews supplied valuable anecdotal information about equipment function, policy issues, and how personnel compensate for problematic aspects of their work environment that would have been difficult to obtain otherwise.

With the permission of the supervising oncologist and—when required—the patient, the research team observed and

recorded data during more than ten RAB treatments (cases). The practices and procedures followed by the RAB staff during all clinical functions (i.e., treatment preparation, treatment planning, treatment delivery, and post-treatment) were recorded. The team also observed and recorded preparation, equipment maintenance, and calibration activities, before and after treatments, and during four HDR source exchanges. This information was used to build the function, task, and step descriptions needed to develop a complete function and task inventory and to generate a comprehensive understanding of the RAB system.

The analysis first established the major system functions of RAB. These functions were arranged in the order in which they are performed. Next, each function was described in terms of the major tasks that must be carried out to satisfy the requirements of that function. Finally, each task was broken down into its component steps, resulting in the completed function and task structure and inventory (Function and Task Analysis, NUREG/CR-6125, Vol. 2).

The following information was recorded for each function and task:

- afterloader system used: Nucletron or GammaMed
- physical arrangement of equipment within the workspace
- space allocated for work and rest
- job titles of persons performing the task
- job titles of persons supervising the task
- equipment used to perform the task
- time required to perform the task (minimum, typical, maximum) as measured by stopwatch or elicited from staff. Video and audio tape recordings made at some sites were also used to determine task durations
- performance sequence
- distraction sources and distraction levels
- detailed function, task, and task step taxonomy and description
- input requirements for each task step
- outputs from each task step
- system feedback from each task step
- possible errors and likelihood of errors at each task step
- personnel workload allocation for functions and tasks
- effects of distraction on staff performance
- staff ratings of knowledge, experience, and/or familiarity with selected functions and tasks

The process began with a generic function and task analysis which was then tailored to each type of RAB system being analyzed. Analysts were especially sensitive to differences between HDR and LDR systems, and to how functions and tasks were allocated to different individuals and groups of personnel at the seven facilities visited.

2.2.1.1 Error Analysis

An error analysis was accomplished concurrently with the function and task analysis. It was based on the following information: (1) analysis of misadministration data from NRC and Food and Drug Administration (FDA) reporting systems, (2) error likelihood estimates by RAB staff, (3) workload information developed from the function and task analysis, and (4) information about potential distractions developed from the function and task analysis.

Misadministration Data

Misadministration and problem data from the following sources were reviewed for error type, brachytherapy type, and function:

- U.S. Nuclear Regulatory Commission, Office for Analysis and Evaluation of Operational Data (NUREG 1272): 1982–1991
- Radiological Health Bulletin, FDA Center for Devices and Radiological Health: August 1989–June 1991
- Medical Devices Bulletin, FDA Center for Devices and Radiological Health: August 1989–June 1991
- Medical Device Problem Reporting Program, FDA Center for Devices and Radiological Health: 1984–1990

Error Likelihood Estimates

The human factors team made qualitative estimations of error likelihood at each task step by assigning a score of high, medium, or low to that task step as established during interviews with RAB staff. After each subsequent site visit, the analysts revised the existing error likelihood assignments for each step, as necessary, based on the most recent observations.

Workload Analysis

The subjective measure of workload was developed from a standard instrument, the Subjective Workload Assessment Technique, in which three factors (time pressure, mental effort, and stress) were rated (Reid, Shingledecker, and Eggemeier, 1981). This instrument was administered to most RAB personnel at each site. Results were used to highlight functions and tasks that required the most effort, that would most likely be influenced by the potential distractions, and that would be potentially important

locations of error. Each workload factor was rated separately for treatment delivery and treatment planning. A questionnaire was used to obtain ratings on a three-point scale in accordance with established procedures (Reid, Shingledecker, and Eggemeier, 1981). The scales for each workload factor were as follows:

Time Pressure

1. Often have spare time. Interruptions or overlap among activities occur infrequently or not at all.

2. Occasionally have spare time. Interruptions or overlap among activities occur frequently.

3. Almost never have spare time. Interruptions or overlap among activities are very frequent, or occur all the time.

Mental Effort

1. Very little conscious mental effort or concentration required. Activity is almost automatic, requiring little or no attention.

2. Moderate conscious mental effort or concentration required. Complexity of activity is moderately high due to uncertainty, unpredictability, or unfamiliarity. Considerable attention required.

3. Extensive mental effort and concentration are necessary. Very complex activity requiring total attention.

Stress

1. Little confusion, risk, frustration, or anxiety exists and can be easily accommodated.

2. Moderate stress due to confusion, frustration, or anxiety noticeably adds to workload. Significant compensation is required to maintain adequate performance.

3. High to very intense stress due to confusion, frustration, or anxiety. High to extreme determination and self-control required.

Distraction Analysis

The research team collected information on potential distractions from RAB staff members to identify factors that contribute to errors and to validate independently the functions and tasks with the highest likelihood of error.

Background noise sources, such as intercoms, telephones, machinery noise, traffic noise, and conversational background were noted by the research team. Each workstation was measured for overall background noise level using a sound level meter. RAB staff supplemented these observations and measurements by describing the effects on job performance, if any, of each of the potential distractors. Information about other sources of distraction and the qualitative effects of distraction on staff performance also were solicited from the RAB staff.

Error Analysis Summary

After the last Phase 1 site visit an error likelihood validation was conducted. The project team's RAB consultants and two of the most experienced brachytherapy physicists from the visit sites (1 Nucletron site and 1 GammaMed site) independently selected the tasks with the greatest likelihood of error and rank ordered them. The remaining tasks were then assigned a medium or low likelihood of error based on the comments of the RAB staff supplemented by information from the distraction and workload analyses.

2.2.1.2 Skills Assessment

The completed task analysis furnished a detailed description of the functions and tasks of RAB. Following the task analysis, a structured procedure, the Job Comparison and Analysis Tool (JCAT; Seven, Akman, Muckler, Knapp, and Bernstein, 1991), was employed to determine the skills needed to perform each task. The JCAT is based on Fleishman's work in task taxonomies (Fleishman and Mountford, 1989; Fleishman and Quaintence, 1984) and has been used successfully in human factors projects similar to this one. Both cognitive and motor skills are included in the JCAT. As a result, it furnishes a comprehensive inventory of the skills required to perform RAB.

The JCAT assessment includes two major components, decision flow diagrams and a list of 50 skills and abilities. The decision flow diagrams, which are based on the work of Mallamud, Levine, and Fleishman (1980), were used to identify the critical skills required for each brachytherapy function and task. While it does not include every skill needed to perform all work-related tasks, the JCAT provides a set of skills that can be used reliably to discriminate RAB functions and tasks from other work activities.

Three human factors specialists from the research team, who were thoroughly familiar with RAB and human factors methodology, independently evaluated each RAB task using the JCAT. Raters referred to the function and task analysis to ensure that they clearly understood the detailed steps involved in each task. An inter-rater reliability coefficient of 0.89 was obtained for the JCAT ratings. After all tasks had been assessed independently, raters

reevaluated those few cases where their ratings differed. By discussing the rationale behind individual ratings, a consensus was reached for all RAB tasks.

This methodology made it possible to identify critical skills for performing RAB without being influenced by local practices or personnel qualification requirements at the medical facilities visited. The results of this assessment are directly relevant to the analysis of staff training and qualifications later in the project.

2.2.2 Phase 2: Human-System Interfaces

In the second phase of the study, eight additional medical facilities were visited to collect data on the workspaces and human-system interfaces used in performing the tasks identified in Phase 1.

2.2.2.1 Interface Classification

Four broad classes of human interfaces with other elements of the RAB system were defined based on observations made during Phase 1. Subclasses were then defined in order to create functionally meaningful groups for the interface evaluations. The classification scheme served both to organize the project team's understanding of the human interfaces with other elements of the system and to structure the interface evaluation in terms of recognized human factors engineering standards and guidelines. These standards and guidelines were derived from numerous technical sources, but especially those listed below:

- American National Standards Institute, "American National Standards for Human Factors Engineering of Visual Display Terminal Workstations," ANSI/HFS 100–1988
- Association for the Advancement of Medical Instrumentation, "Human Factors Engineering Guidelines and Preferred Practices for the Design of Medical Devices," ANSI/AAMI HE48–1993
- U.S. Department of Defense, "Anthropometry of U.S. Military Personnel (metric)," DOD-HDBK-743A
- U.S. Department of Defense, "Human Engineering Guidelines for Management Information Systems," MIL-HDBK-761A
- U.S. Department of Defense, "Human Factors Engineering Design for Army Materiel," MIL-HDBK-759B(MI)
- U.S. Department of Defense, "Manuals, Technical: General Style and Format Requirements," MIL-M-38784B
- U.S. Department of Defense, "Human Engineering Design Criteria for Military Systems, Equipment, and Facilities," MIL-STD-1472D
- National Aeronautics and Space Administration, "Man-System Integration Standards," NASA-STD-3000
- U.S. Nuclear Regulatory Commission, "Guidelines for Control Room Design Reviews," NUREG-0700

The interface classifications were:

(1) equipment
- simulation systems
- treatment planning systems
- high dose rate afterloaders
- high dose rate treatment control systems
- low dose rate afterloaders
- low dose rate treatment control systems
- auxiliary equipment

(2) software
- treatment planning software
- treatment control software

(3) user manuals*
- treatment planning manuals
- afterloader usage manuals

(4) workspaces
- simulation
- treatment planning
- high dose rate treatment
- high dose rate treatment control
- low dose rate treatment
- low dose rate treatment control

* Only user manuals were examined in Phase 2. Interface standards are less suitable for shorter forms of documentation, such as locally developed procedures, checklists, and forms, which were considered in Phases 3 and 4 of this project.

The way in which these four broad interface classes are associated with RAB functions and tasks is demonstrated in Table 1. The tasks of monitoring and controlling the treatment session have been combined in Table 1 and in subsequent analyses since they are performed together during treatment delivery.

2.2.2.2 Data Collection

Because of time constraints during site visits, workspaces and interfaces were not evaluated on-site. Instead, human

Table 1. RAB Functions and Tasks with their Associated Interfaces

	Equipment	Software	Documents	Workspaces
Patient Preparation				
Patient scheduling, identification, and tracking	–	–	Form	Var
Patient instruction	–	–	Proc	Var
Life support monitoring	Aux	–	–	Var
Applicator placement and stabilization	Aux	–	Manl	Var
Patient transportation	Aux	–	–	Var
Treatment Planning				
Simulation with dummy sources	Sim	–	Proc	Sim
Target volume localization	Plan	Plan	Manl	Plan
Radiation prescription	–	–	–	Var
Dwell position localization	Plan	Plan	Manl	Plan
Dosimetry	Plan	Plan	Manl	Plan
Treatment plan selection and approval	–	–	Form	Var
Treatment Delivery				
Treatment set-up	Aft	–	Manl, Cklst	Tmt, Ctrl
Treatment plan entry	Ctrl	Ctrl	Manl	Ctrl
Verify treatment data prior to treatment	Ctrl	–	Proc	Ctrl
Treatment session monitoring	Ctrl	Ctrl	Manl	Ctrl
Treatment session control	Ctrl	Ctrl	Manl	Ctrl
Post-Treatment				
Source guide tube disconnection	Aux	–	–	Tmt
Applicator removal	Aux	–	–	Tmt, Var
Patient transportation	Aux	–	–	Var
Treatment verification	Ctrl	–	Proc, Form	Ctrl
Record-keeping	Ctrl	–	Form	Ctrl
Quality Assurance and Maintenance				
Source exchange	Aft, Ctrl	Ctrl	Proc, Cklst, Form	Tmt, Ctrl
Source calibration	Aft, Ctrl, Aux	Ctrl	Proc, Cklst, Form	Tmt, Ctrl
Equipment and software updates	All	Plan, Ctrl	–	Plan, Tmt, Ctrl
Troubleshooting	Plan, Ctrl	Plan, Ctrl	Manl	Plan, Ctrl
Routine quality assurance	Aft, Ctrl, Aux	Ctrl	Form, Cklst	Tmt, Ctrl

Equipment	Software	Documents	Workspaces
Simulation (Sim)	Treatment Planning (Plan)	User Manuals (Manl)	Simulation (Sim)
Treatment Planning (Plan)	Treatment Control (Ctrl)	Local Procedures (Proc)	Treatment Planning (Plan)
Afterloader (Aft)		Checklists (Cklst)	Treatment Room (Tmt)
Afterloader Control Unit (Ctrl)		Forms (Form)	Treatment Control (Ctrl)
Auxiliary Equipment (Aux)			Various Other (Var)

factors engineering data were collected at each site for later analysis.

The human factors engineering standards and guidelines listed in the preceding section were first reviewed to identify data necessary to evaluate workspaces and human interfaces with other elements of the RAB system. Data collection forms, checklists, and interview questions were then developed to assure that the needed data were obtained. The completed data collection plan required quantitative measurements, observations by the site visit team, and interviews of RAB staff. In addition, engineering drawings and photographs provided some interface data. Some flexibility was required during site visits so that the

team could adapt the data collection plan to any unique characteristics of a particular site (e.g., workspace layout).

2.2.2.3 Data Analysis

Upon returning from the site visits, data on workspaces and on human interfaces were evaluated against relevant human factors engineering standards and guidelines that had been obtained from the sources listed in Section 2.2.2.1. The evaluations concentrated on aspects of the workspaces in RAB facilities that could affect function and task performance, and on the fundamental components of the interface (e.g., display size, button spacing, reach envelope). A formalized checklist was used in conducting these detailed and systematic evaluations, ensuring that all relevant aspects of each RAB interface were examined. Deviations from recognized human factors engineering design guidelines were noted in detail. In addition, seven current RAB user manuals were evaluated against human factors guidelines for instructional manual design and medical device labeling. These guidelines were derived from over 100 monographs and journal articles from the literature on human factors, document design, instructional technology, adult learning, reading, and human-computer interaction. Any differences between the manuals supplied by the distributors and those found at the medical sites were noted. As new or revised manuals became available, copies were requested from the distributors so that the analysis would reflect the most recent available versions of the documentation.

2.2.3 Phase 3: Procedures and Practices

Data on procedures and practices used in performing and verifying RAB tasks were collected during the same eight medical facility visits used to collect data on workspaces and human-system interfaces. Phase 1 identified verifications of some RAB tasks. Verifications were expanded and considered separately from the tasks used to perform RAB in Phase 3 and subsequent analyses.

2.2.3.1 Procedures and Practices Classification

Technically adequate and complete procedures and practices are valuable, often essential, elements of systems involving humans. The term 'procedure' has various meanings in human factors analysis, medicine, and training contexts. In this project, a 'procedure' was defined as:

'Procedure': An ordered sequence of tasks or steps that has been designed, approved, and documented for some purpose.

The steps in the procedure must be documented in a form that permits its use as a reference for task performers and allows deviations from the approved sequence to be detected. Approval of such a procedure may be informal. There may be more than a single procedure approved for a particular purpose.

In this project, a 'practice' was defined as:

'Practice': Any ordered sequence of tasks or steps used repeatedly for some purpose.

Practices may differ between individuals and may or may not conform to the approved sequence set out in a procedure. Thus both procedures and practices govern the performance of tasks, but procedures are documented while practices are not.

Historically, RAB evolved from manual brachytherapy through the allocation of some tasks previously performed by humans to machines, computer software, and specially designed hardware. As with most such evolutionary systems, users have been required to fill the gaps produced by the automation. Users continue to perform all the unautomated tasks. They also perform new tasks required for the transfer of information and material between equipment, and monitor and verify their own performance as well as that of the equipment.

Figure 9 shows a conceptual model of how information and materials flow through a portion of the RAB process. Four tasks involving patient contact (Applicator placement, Target volume localization, Treatment set-up, and Treatment session monitoring and control) are performed concurrently with four tasks that do not involve patient contact (Source calibration, Radiation prescription, Treatment plan selection and approval, and Treatment plan entry). These tasks are linked together by the movement of the patient and of information and materials between task performers. As a quality control check, a series of verification procedures determines whether the tasks and their linkages are performed without error.

Eight classes of procedures and practices relevant to the conduct of RAB were identified by reviewing the function and task analysis findings. As Table 2 shows, each class of procedure addresses a different part of the RAB treatment delivery process. Medical procedures were not evaluated for medical/technical adequacy because they were beyond the scope of this project.

2.2.3.2 Data Collection

Data about RAB procedures and practices were collected at each facility during the visits for later analysis.

Three forms of written documentation were accepted as evidence of locally approved procedures:

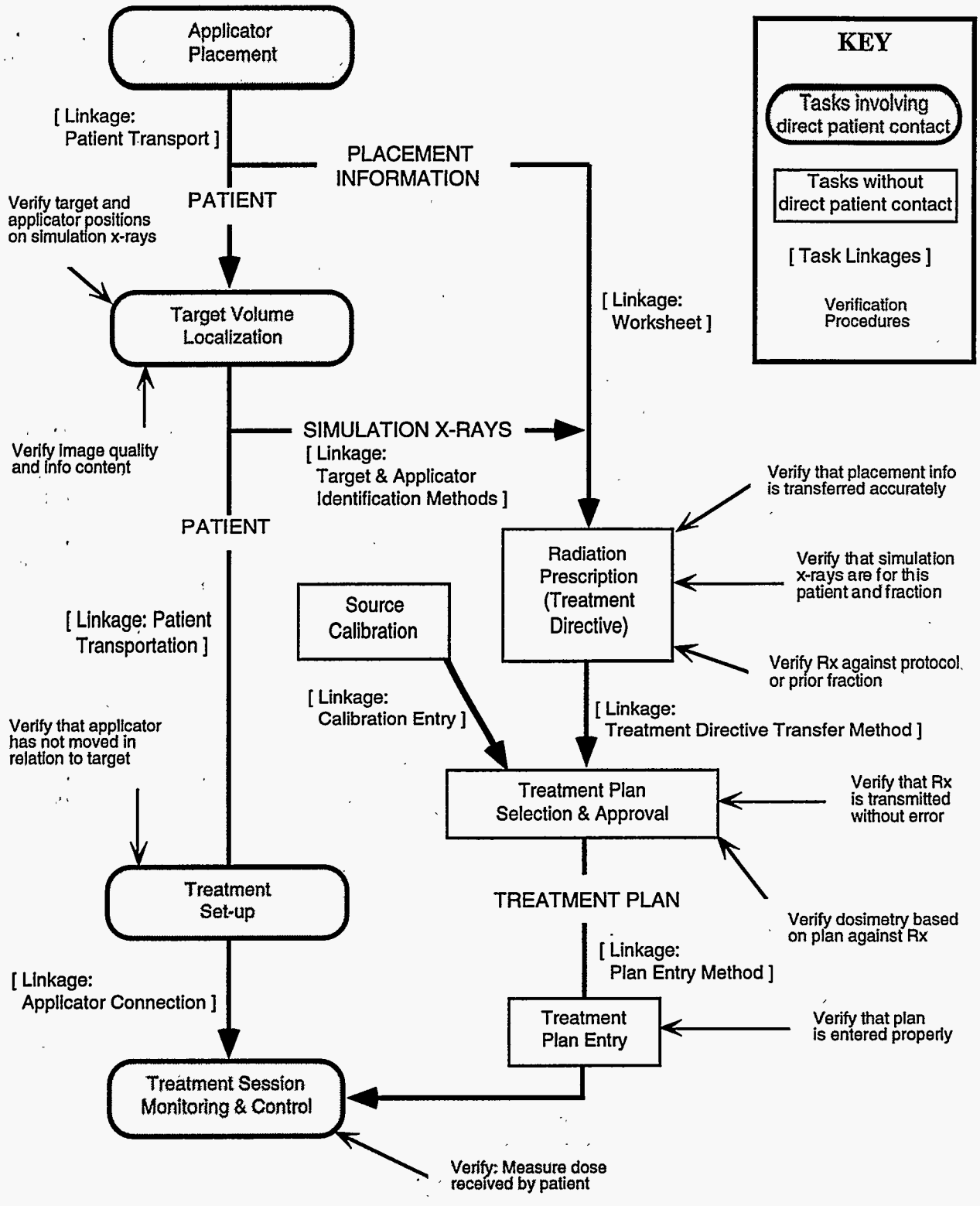


Figure 9. RAB conceptual model of information and material flow in major tasks and task linkages

Table 2. Types of Procedures Used in Remote Afterloading Brachytherapy

Procedure	Purpose
Medical[1]	Specifies a sequence of tasks or steps designed to treat a specific medical condition or body location.
Task Allocation[1]	Specifies who, or what, is responsible for performing each RAB task.
Task Ordering[1]	Specifies when and in what order each RAB task is to be performed.
Task Locating[1]	Specifies the work space to be used in performing an RAB task.
Task Performance[2]	Specifies a sequence of steps designed to perform a particular RAB task.
Task Linkage[2]	Specifies a sequence of steps designed to connect the output of one RAB task to the input of another RAB task.
Performance Verification[3]	Specifies a sequence of steps designed to detect and correct errors in RAB task performance.
Linkage Verification[3]	Specifies a sequence of steps designed to detect and correct errors in task linkage, or in the information transfer between tasks.

[1]These procedures deal with the design of an RAB treatment program.
[2]These procedures deal with the planning and delivery of an RAB treatment.
[3]These are QA procedures used to detect and correct errors.

- Descriptions—Written descriptions detailed the steps that must be performed to accomplish one of the classes of procedures and practices in Table 2. Either locally written descriptions or excerpts from manufacturer's manuals that had been compiled and adapted for local use met this criterion.
- Worksheets—Worksheets contained information identifying a task step and provided a place for the user to enter a derived value after performing that step in the procedure.
- Checklists—Checklists contained a check box that the user could mark during task performance in order to keep track of which steps had been completed.

The definition of a practice allowed data to be collected on the same categories for which procedures were identified. It also permitted collection of RAB data which had not been formalized in approved written documents. Since practices need have no written documentation, data on practices were collected through direct observation of RAB staff and/or interviews with RAB personnel at each site.

Although practices had no obvious written documentation, some were nevertheless structured in such a way that task performers would be unable to deviate from the ordered sequence of steps. Such constraints were noted separately for each identified practice. The project team collected the following types of data on-site for each class of procedure and practice:

(1) Task allocation procedures and practices

The project team determined the staff person and equipment assigned to perform each RAB task. Five job categories were investigated: MD, Physicist, Dosimetrist, Radiation Therapy Technologist, Nurse, and Clerical.

(2) Task ordering procedures and practices

The order in which the tasks were performed by procedure or practice and the time that elapsed between the performance of tasks was noted. Written procedures covering the order and interval between tasks were collected (when available).

(3) Task locating procedures and practices

Workspaces assigned by procedure or practice were identified for all RAB tasks.

(4) Task performance procedures and practices

Written procedures for task performance were collected (when available). The steps used in performing each RAB task by procedure or practice were noted.

(5) Task linkage procedures and practices

Written procedures for task linkage were collected (when available). Task linkages needed to perform

RAB were derived from the function and task analysis and were identified at the site using direct observation, user descriptions and walk-through demonstrations of task performance. The following information was collected:

- tasks performed
- order of task performance
- persons performing each task
- information and material passed between tasks
- personnel involved in the linkages
- number of times that control of the procedure or information was passed between individuals
- method of transferring control and information between individuals

(6) Task performance verification procedures and practices

Steps used to verify the correct performance of a task by procedure or practice were recorded. Written procedures for verifying that a task had been performed correctly were collected (when available).

(7) Task linkage verification procedures and practices

Procedures and practices used to verify that data transferred between tasks was transferred correctly were recorded. Written procedures for verifying task linkages were collected (when available).

RAB treatments performed at the site were investigated at the task linkage level to determine several characteristics:

- time at which verification was attempted
- verification method used
- format of the verification
- verifying agent
- redundant information that was preserved and was available for use in verification
- information actually used in verification

2.2.3.3 Data Analysis

Once procedures and practices had been collected at each site, they were compared with the RAB functions and tasks. Procedures were evaluated for their format, their availability, and their suitability for task performance. Practices were evaluated to determine whether they compensated for procedural inadequacies or missing procedures and whether they were in conflict with the approved procedures.

Seventy-two documents (i.e., procedural descriptions, worksheets, or checklists) collected from the RAB sites were evaluated on their form and content against procedural guidelines. The evaluation focused on six general criteria: legibility, language, format, illustrations, highlighting, and comprehensibility. Each criterion was divided into two or three specific items (e.g., simple, non-stylized font) that could be evaluated for each form with a "yes", "sometimes", "no", or "not applicable" response. The results for each category were tallied and the percentages for each response calculated. In the content evaluation, 45 worksheets and checklists used during patient preparation, treatment planning, treatment and quality assurance were evaluated.

2.2.4 Phase 4: Training

In the fourth phase of the study, eight additional medical facilities were visited to collect data on the training provided to the staff in the procedures and practices necessary to accomplish RAB. Information regarding training and qualifications was collected at each of the 23 sites and considered during the Phase 4 analysis. Data analysis concentrated on two areas:

(1) the training and qualifications of RAB staff

(2) the training materials available to the RAB staff

2.2.4.1 Data Collection

To evaluate the training and qualifications possessed by RAB staff, detailed interviews were conducted at each RAB site. All available staff members involved in RAB were interviewed. The interviews were conducted individually in a private location. Questions asked during these interviews were open-ended, encouraging extended discussions on training and qualifications issues. The interview approach allowed respondents an opportunity to elaborate on certain issues peculiar to their site, thus ensuring more complete data collection.

RAB functions and tasks identified in Phase 1 served as a basis for the development of specific training and qualifications related questions to be used in the RAB staff interviews. The questions addressed a wide variety of training and qualifications issues and covered the following topics:

- type of formal (college) education received and/or degrees held
- type(s) of medical certification held
- type and length of RAB training received in a "formal" setting (e.g., classroom instruction with qualified instructor and standardized course of instruction)
- perceived adequacy of the "formal" training

- instructional material used during the course of "formal" instruction
- type and length of RAB training received in an "informal" setting (e.g., OJT, apprenticeships, seminars, working groups, newsletters, videotapes, etc.)
- length of directly related RAB experience
- length of indirectly related manual afterloading brachytherapy experience
- length of indirectly related experience in other forms of radiation oncology treatments
- form and frequency of re-training received
- testing required and/or qualification procedures conducted prior to performing RAB
- form and frequency of performance feedback received
- perceived "transfer of training" that occurred between RAB tasks, and other tasks performed by an RAB staff member
- additional training desired

To evaluate training materials and programs available to RAB staff, the following items were collected from each equipment manufacturer and RAB site:

(1) technical documentation provided by brachytherapy equipment distributors

(2) training course materials provided at the Nucletron training facility

(3) training/advertisement video tapes produced by the brachytherapy equipment manufacturers

(4) "in-house" training material produced locally at each RAB site including

- written RAB related policies and procedures
- written evidence of a training course
- written testing material
- written qualifications standards
- performance checklists
- miscellaneous training materials, including background reading material, reports and protocols developed at other RAB sites, and general "nice-to-know" information that may be of value as supplementary training material

2.2.4.2 Data Analysis

The content of RAB training programs was evaluated by comparing each instructional system to a model training system specified by the "systems approach to training" (Gagne, Briggs, and Wager, 1988). This model requires that training needs be defined, that training objectives be stated, that specific knowledge, skills, and abilities be identified, and that those requirements be addressed with training material and testing methods designed to meet specific learning objectives.

To facilitate evaluation against the model system, the interview data were entered into a computer based training and qualification matrix, and organized according to five staff positions: Oncologist, Physicist, Dosimetrist, Technologist, and Nurse. RAB site, type of RAB equipment used, and site licensing agency (whether the sites were licensed by the NRC or by the State) were also included in the matrix. This additional information allowed factors that might affect local training and qualification requirements to be considered.

The matrix was then used to compare the training and qualifications of individuals within a staff position group; and also to consider the differences in training and qualification requirements across staff positions. The training requirements for each staff position were determined by using a structured protocol, the Job Comparison and Analysis Tool (JCAT; Seven, Akman, Muckler, Knapp, and Bernstein, 1991) to identify critical skills and abilities required for each RAB task. Skills and abilities required for RAB tasks performed by individuals in each staff position were then compared to the training provided to individuals in those positions. The results of the comparison are summarized in Section 3.

To obtain a rough estimate of the prevalence of RAB training materials at each site, a simple count was made of the types of training material collected. Collected training material was then categorized according to type, and evaluated on their availability, their content and their suitability for training purposes. Due to the brevity of many of the collected training materials, only a few items were selected for a full content/format evaluation.

The format of the selected training material was first evaluated against human factors guidelines for document design derived from the following sources:

- "Principles of Medical Device Labeling," NTIS PB 94-126851, 1993
- U.S. Department of Defense, "Manuals, Technical: General Style and Format Requirements," MIL-M-38784B, 1983
- U.S. Nuclear Regulatory Commission, "Guidelines for the Preparation of Emergency Operating Procedures," NUREG-0899, 1982

The evaluation focused on

- highlighting
- graphics

- information organization
- language and readability
- legibility
- physical media properties

The suitability of the material for training purposes was then evaluated by comparing its strengths and weaknesses in each of the above categories with the material's RAB training objectives.

2.2.5 Phase 5: Organizational Practices and Policies

A set of factors tailored to RAB organizations was developed to guide data collection in the Phase 5 site visits. They were used to gain a general understanding of organizational dynamics at the site. These factors were

- organizational structure
- staff selection criteria
- staff motivation methods
- staff training policies
- staff job satisfaction
- staff performance appraisal methods
- decision making methods
- decision communication methods

Data collected on RAB goals, the resources and staff allocated to RAB tasks, and the methods used to support, monitor, and direct RAB task performance, were used to identify the way in which each RAB system was organized and maintained.

2.2.5.1 Data Collected at all Sites

Basic organizational information regarding site composition, site licensing, number of treatments, types of treatments, staff background and staff composition, were collected from administrators at all 23 sites. Data collected at these sites included

- hospital affiliations
- the area and population served
- RAB case load
- RAB equipment
- size and staff of the departments performing RAB
- size and composition of the RAB teams
- organizational chart(s)
- organizational problems and suggested solutions to them
- training offered at the site for RAB task performers
- re-training and certification requirements for RAB task performers
- maintenance policies for RAB equipment
- radiation safety policies for RAB

Additional data on organizational practices dealing with staff (e.g., motivation, supervision, and communications) were collected during interviews with RAB staff at all sites.

2.2.5.2 Data Collected During Phase 5

In addition to the collection of basic organizational information at all sites, eight sites were selected for detailed investigation of RAB organizational practices and policies. These were the same sites visited to collect data on staff training programs. Interviews were conducted with the people who had defined the goals and objectives of the RAB treatment facility, and with those who had designed the system for delivering RAB treatments, selected the equipment, and selected and trained the RAB personnel. Interviews were also conducted with personnel who were responsible for defining or communicating procedures for RAB task performance or task linkage and with everyone responsible for monitoring and directing progress toward the departmental goals.

When possible, all persons holding administrative positions related to RAB organizational functions at the site were interviewed. Data were collected from all RAB task performers at the site on their participation in the organizational functions and the effect those functions had on their job performance.

Directed interviews with RAB administrators during Phase 5 covered the following organizational topics:

- goals of the RAB program
- facilities and resources provided for RAB
- composition of the staff and their qualifications
- medical and administrative structures used to direct RAB task performers
- communications structure set up between task performers and administrators
- methods used to allocate RAB tasks to staff and evaluate their performance
- training provided and required for RAB staff
- employee motivation methods used at the site
- workplace safety monitoring performed at the site
- methods used to report and resolve safety problems at the site

Since production, approval, and communication of procedures is an important organizational function, the person responsible for the definition and communication of procedures for performing each RAB task was interviewed (when available) regarding

- task performance procedures that were being used for each task
- problems that had been considered in designing the task performance procedures
- linkage and verification procedures designed for the RAB tasks
- methods used to monitor conformance with procedures

This study was particularly interested in the performance of the various organizations in directing and supporting RAB at each site. To assess the performance of the organization, both the administrators and the task performers at the site were interviewed separately about the organizational support for the staff and for each RAB task performed at the site.

Each task performer at the site was interviewed to determine his or her work schedule, job responsibilities, training received, working conditions, communication methods used with supervisors and other team members, feedback received on job performance, overall job satisfaction level, and suggested changes regarding local operating procedures.

In addition, the primary task performer for each RAB task was asked how he or she had learned to perform the task, whether there was a training program covering that task at the site, and whether he or she had learned to perform, link and verify the task from that program.

2.2.5.3 Data Analysis

The data collected on organizational performance from all sites was evaluated in Phase 5 of the study to identify RAB organizational functions and tasks that described

- how the organizational functions were performed at each site
- how the organization supported and directed the performance of the RAB functions and tasks

The analysis identified eight organizational functions related to operating an RAB facility. Data collected from all sites on organizational performance were then analyzed to determine the practices and policies needed to perform those functions.

2.2.6 Phase 6: Identification and Prioritization of Human Error in RAB

Phase 6 was designed to build upon information gained during the first five phases to

(1) Identify the factors which can contribute to human error in RAB.

(2) Evaluate the impact of these factors, both singly and in combination, on the performance of the functions and tasks essential to meet RAB goals.

(3) Prioritize function and task performance problems related to human errors caused by those factors in terms of their safety significance.

(4) Identify and evaluate alternative approaches for resolving safety significant problems related to human error.

A conceptual model of RAB treatment delivery was developed in Phase 6 based on the original function and task analysis, and the practices used at the RAB sites to perform the RAB tasks and link them into a treatment delivery system. The model was then used to describe and analyze error propagation through each RAB treatment delivery system.

The results of that model-based analysis were presented to a panel of experts on RAB treatment delivery. The experts used the data on error propagation to prioritize the problems created by human error in RAB treatment delivery. They identified ten critical RAB tasks and task linkages in which the consequences of human error were significant and unlikely to be corrected by current RAB practices. Equipment and methods used to perform these tasks and linkages were then evaluated to identify alternative approaches for reducing the frequency of human error and for making the consequences of those errors easier to detect and correct.

2.2.6.1 Identification of Factors Which Can Contribute to Human Error in RAB

RAB requires that certain actions be performed by users and other complimentary actions be performed by equipment under user control. Possible human errors in RAB fall into three categories:

(1) performance errors (e.g., failure to meet performance requirements for a task)

(2) linkage errors (e.g., failure to transfer information or material using appropriate interface, or linkage procedures)

(3) verification errors (e.g., failure to identify potential errors or failure to take appropriate action to address their consequences)

These three categories of human error were evaluated in terms of each of the RAB system components studied in this project: task performance requirements, human-system interfaces, task linkage procedures and practices, and training and organizational factors in order to assess the impact of actual as well as potential human error on RAB system performance.

Task Performance Requirements

Following the Phase 1 data collection, a comprehensive function and task analysis was conducted to identify the functions and tasks performed by people in delivering RAB. Each RAB task was then divided into task steps performed in sequence to accomplish the task.

Potential human errors in the performance of each step were identified and the likelihood of such an error was estimated. This initial error likelihood estimate was updated after each subsequent data collection stage.

Human-System Interfaces

Interfaces were evaluated for their adherence to human factors guidelines and for the way in which they supported the performance requirements of each function and task. Potential errors due to inadequate interfaces were identified and added to those identified in Phase 1. The feedback provided to staff to allow them to detect those errors were identified and evaluated.

Task Linkage Procedures and Practices

Communication linkages were identified following the second data collection stage involving human-system interfaces, workspaces and procedures and practices. Specification of these linkages allowed specific linkage errors to be identified. Task linkage errors usually involve information transfers between tasks but may also involve changes to equipment or other objects that are transferred between tasks or workstations. The likelihood of task linkage errors was estimated based on the way in which tasks were linked together. Since errors can also be made while attempting to correct other errors, methods used to address the consequences of task performance and task linkage errors were evaluated. This resulted in identification of additional QA-related potential errors involving

- failure to detect task performance or linkage errors
- failure to correct task performance or linkage errors
- correction of non-existent performance or linkage errors

These linkage errors were added to the original set of errors defined in Phase 1. The information required and available for detecting errors and the methods used to correct errors and to address their consequences were evaluated.

Training and Organizational Factors

Data on training and organizational support for RAB were used to identify errors that could occur due to the way in which the RAB process was organized or supported. Methods used by RAB facilities to assess staff performance and provide and assess training in task performance, linkage, and QA procedures were also evaluated.

2.2.6.2 Evaluation of the Impact of Factors on RAB

To evaluate the impact of factors on RAB system performance, a conceptual model of the RAB process was developed. The model linked RAB functions and tasks together by specifying the order in which tasks were performed and the linkages between the tasks. The conceptual model was then used both to describe different RAB treatment delivery systems and to analyze the mechanisms for the propagation of error consequences in those systems.

The impact of various factors on RAB system performance was estimated by analyzing the way in which each factor could affect other elements of the conceptual model. The errors which could occur in different systems were identified. The methods needed to detect each error and to limit its consequences were determined.

Error Propagation Analysis

The conceptual model was used to trace the propagation of the effects of potential errors through different RAB systems (e.g., HDR, LDR). The consequences of errors in task performance and task linkage errors depended on the performance, linkage, and verification practices used as well as on the training and organizational support provided. The mechanisms for propagation of error consequences within each modeled RAB system were identified so that the impact of each potential error or combination of errors on RAB treatment delivery could be evaluated. The conceptual model was then used to determine the information that would be needed to detect and correct potential errors at different stages of the RAB treatment delivery process.

Error Detection and Correction Analysis

The information needed to detect potential errors was defined. The model was then used to determine whether that information was transferred from task to task and available for verification of task performance and task linkage. If no detection procedure was specified at a particular transfer point in the model, the error or its consequences were allowed to propagate through the system into the next task.

Once an error is detected, additional information is usually needed to correct the error. For example, lack of a label can be detected easily, but more information is required to determine the missing label's contents. As with error detection, the information needed to correct errors in task performance or task linkage must be carried by the system to the place at which it is needed. The information required to correct potential task performance or task linkage errors was identified. The model was then used to determine whether that information was carried to the point at which correction of the error was possible.

2.2.6.3 Prioritization of Problems in Terms of their Safety Significance

As noted in Section 1.2, a human factors problem is a task (including task linkages) which humans within a system are not likely to perform to the level required by the system. In RAB, some such problems can have high safety significance. This study identified and prioritized such problems.

Identification of Safety Significant Problems

Safety significant problems were defined as human task performance or linkage errors whose consequences could propagate through the system and cause unintended radiation exposure to the patient or the RAB staff.

The conceptual model was used to identify all incidents in which human errors in task performance or task linkage could lead to inappropriate radiation exposure of the patient or staff. Those incidents included incidents which might not be detected by current QA practices as well as those which would be reported as misadministrations or reportable events under current reporting guidelines. Problems unrelated to radiation exposure and those which had no human task performance components (e.g., unexpected equipment failures) were not evaluated in this study.

Safety significant human factors problems were identified by a group composed of ten subject matter experts on RAB and human factors. The group included a physician/physicist, a physicist, a dosimetrist, specialists in training and organizational procedures, and the five members of the site visit teams.

At the first meeting, the group reviewed errors, potential errors and tasks susceptible to error (critical tasks) using the function and task analysis as a guide. Errors were classified and characterized by detectability, frequency, likelihood, and consequence. The critical tasks were identified within each function, based on error associations.

Prioritization of Error Consequences

A second meeting of the subject matter experts was used to review and discuss the contributions to critical task performance and error significance of: human-system interfaces, procedures and practices, training and qualifications, and organizational practices and policies. The group was asked to identify critical tasks in which a performance error was likely to result in a misadministration or other undesirable consequence to the patient or staff. The experts used their own mental models of RAB treatment delivery to gauge and assess the effect of task performance and linkage errors on the system. The potential contributions from each area were discussed and prioritized.

2.2.6.4 Identification and Evaluation of Alternative Approaches for Resolving Safety Significant Problems

Each task or linkage in which an error could propagate through the system to cause a safety significant problem was analyzed independently to determine items in the human-system interfaces, procedures, training, or organization that could be changed to reduce the likelihood of the error's occurrence or make it easier to detect and correct. Alternatives to current practice incorporating these changes were formulated and evaluated for their effect on RAB and their utility in reducing human error and its consequences during the RAB process.

3 Results

Phases 1 through 5 of this study were data collection and analysis efforts designed to characterize the RAB system as it currently exists. Phase 6 assessed the impact of aggregated Phase 1 through 5 results on RAB task performance and prioritized potential errors in terms of their safety significance. This section summarizes the findings of those phases. Phase 6 also identified and evaluated alternative approaches for resolving safety significant problems related to human error in RAB. The findings of that analysis are discussed separately in Section 5.

3.1 Phase 1: Function and Task Analysis

Phase 1 identified RAB functions and tasks performed in planning and delivering RAB treatments (NUREG/CR-6125, Vol. 2). It also provided a preliminary error analysis and skills estimate for performing those tasks. Clinical evaluation and therapeutic decision making tasks which precede or follow the RAB treatment session were not addressed in this study.

3.1.1 RAB Functions

Five RAB functions were identified:

- Patient Preparation
- Treatment Planning
- Treatment Delivery
- Post-Treatment
- Quality Assurance and Maintenance

These functions describe discrete stages in the planning, organization and delivery of a single RAB treatment. Each function was composed of several tasks. Figure 10 depicts the temporal flow between these functions and their associated tasks during an RAB treatment session. Quality assurance and maintenance tasks are not shown in the time sequence since they are performed at various times during this flow. Routine QA is not in sequence in Figure 10, since it can be performed throughout the treatment process. Each RAB function is described below along with its associated tasks.

3.1.1.1 Patient Preparation

This is the function in which a patient is prepared for treatment delivery. It involves treatment scheduling and tracking, patient identification, patient instruction, life support, applicator placement, and patient transport.

Patient Scheduling, Identification, and Tracking

The first task in patient preparation is to schedule a treatment session. Once a session is scheduled, the patient must be identified and tracked through the RAB process to ensure that the scheduled treatment will be received. RAB patients may be treated on an outpatient or an inpatient basis. Inpatients are those who have been admitted to the hospital and usually come to radiation oncology from another service. Outpatients may come directly into radiation oncology or be admitted through a central, outpatient admitting facility. The patient admission process varies among sites and determines subsequent patient scheduling, transportation, and tracking procedures.

Patient Instruction

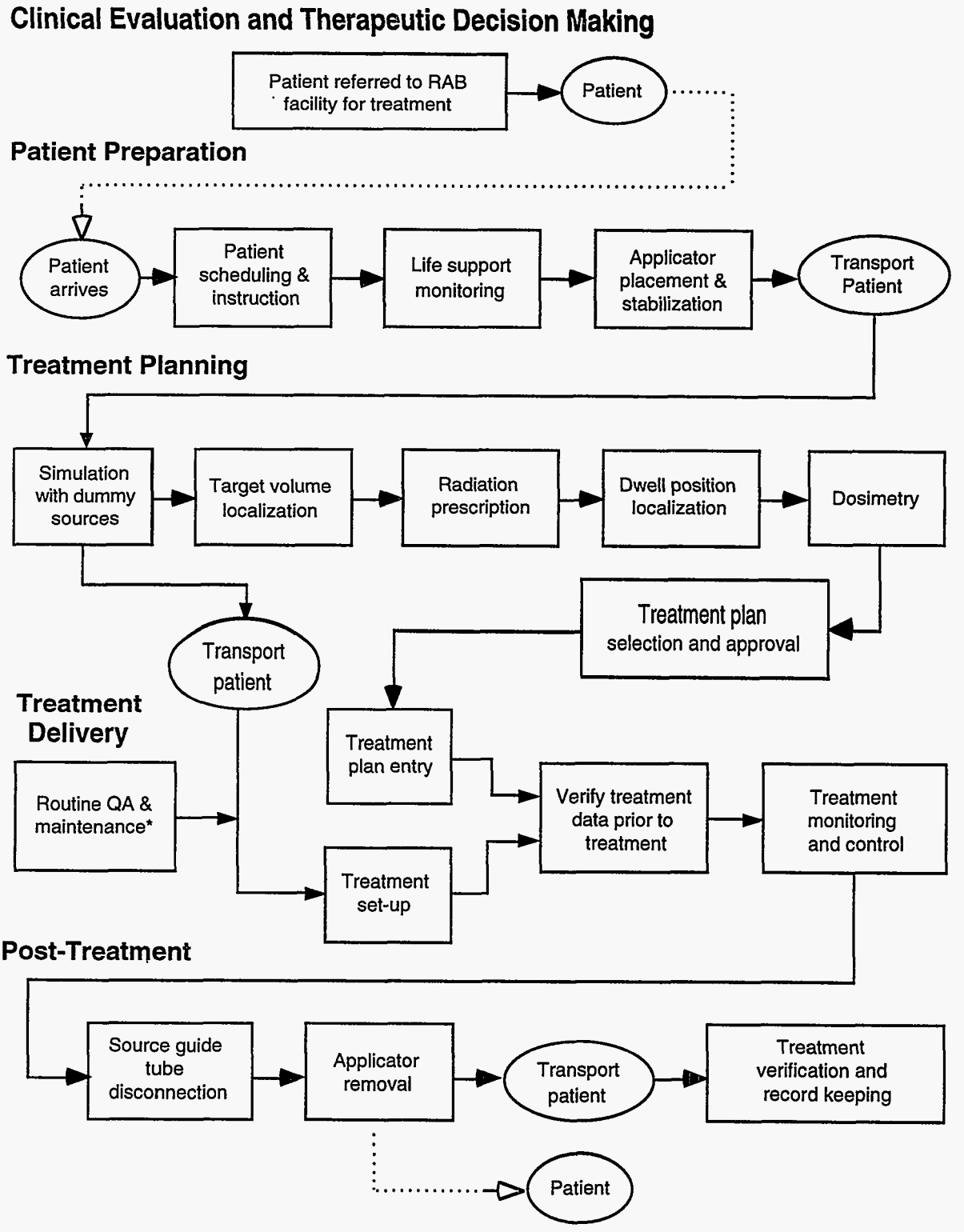
Patient instruction can be viewed as a training procedure in which the staff informs patients about the treatment process and then teaches them to perform any tasks that will be expected of them during the treatment process (e.g., movement between workstations, remaining in one position during the treatment, responding to instructions). Some assessment of the patient's understanding and task performance capacity is usually made in conjunction with the instruction. Instruction is particularly important for patients undergoing LDR treatments, since LDR treatments take place over several days and require patient participation throughout the treatment process.

Life Support Monitoring

Life support monitoring involves maintenance of the patient's vital functions such as heart rate and blood pressure. The RAB patient frequently needs no life support assistance, but assistance may be provided by medical staff for patients who require special care or who may be under medication, such as sedatives, analgesics, anti-anxiety drugs, or local anesthetics. Patient attendants or RAB staff are required to attach, monitor, and adjust life support equipment during this task which continues throughout the RAB treatment procedure.

Applicator Placement and Stabilization

Applicator placement and stabilization is a medical task in which the applicator is placed and secured close to the target. Placement of applicators may require collaboration with different medical specialists, depending on the location of the target and the route chosen to introduce the applicator into the patient's body. For example, lung catheters are applicators which are positioned by a pulmonary specialist, soft tissue needles are applicators that may be positioned by surgeons, and cervical applicators are usually positioned by gynecologists.



*QA and maintenance tasks may also occur as needed at other points in the RAB process.

Figure 10. Flow diagram of temporal relationships between major RAB functions and tasks

Patient Transportation

This task involves moving an RAB patient from one location to another. Important steps within this task include locating and identifying the patient, determining the transfer route, moving the patient from the transport equipment to the destination equipment, and passing information about the patient to the destination staff.

3.1.1.2 Treatment Planning

Treatment Planning is the function in which the dose distribution specified by the radiation prescription is transformed into instructions for positioning the source during treatment. It involves specification of each radiation source to be used, the linear distance to move that source into its treatment position and the amount of time that the source should be allowed to dwell at that position. LDR treatment plans specify a different source at each treatment position. HDR plans specify a single source which is then moved to different positions during treatment.

If the treatment directive specifies a radiation dose to be given to particular targets, then treatment planning requires localization of the applicator and targets within the same three-dimensional coordinate system. Calculations must then be performed to determine positions within the applicator at which the source or sources will be placed and allowed to dwell during treatment to produce the prescribed radiation dose distribution.

Treatment planning is often performed using computers with specialized software. The computer is used to reconstruct the positions of the applicator(s) and targets in space from simulation images, and to calculate and plot the dose distributions that would result from sources allowed to dwell at specified positions within the applicator(s). Staff enter information from the treatment directive and select and digitize the simulation images used to identify the expected positions of the targets, applicators, and sources.

Simulation with Dummy Sources

The purpose of simulation is to establish the position of the implanted applicator relative to the target. Simulation equipment consists of patient positioning devices, applicator, source and target locating devices, and imaging equipment.

Typical steps in this task involve insertion of radio-opaque dummy source strings into the applicators followed by exposure of two orthogonal x-ray images (usually anterior-posterior and lateral). These images show where the applicator has been placed in the patient's body. The dummy sources identify potential dwell positions within each applicator. Fluoroscopy is often used to position the patient so that the x-ray images will contain the desired information.

Target Volume Localization

This task defines the anatomical boundaries of the target volume (tumor) that is to be irradiated. Target volume determinations are usually based on qualitative clinical judgment using several factors: imaging techniques, surgical staging, and knowledge of the biological behavior of various tumors. Typically, heavy reliance is placed on the ability to form accurate three-dimensional mental images. Increasingly, treatment planning computers are being used to construct two or three-dimensional anatomical images for more precise tumor localization.

Radiation Prescription

Once radiation targets are identified, the dose to be given to each target is prescribed by a physician and incorporated in a treatment directive. The treatment directive specifies the prescribed dose distribution and the method to be used to deliver the dose to the targets. The treatment directive may include a specification of the source dwell positions to be used or may leave the choice of dwell positions to other treatment planning tasks. The physician may formulate his prescription using the case history of the patient and information about the target and applicator derived from the simulation x-ray.

The radiation prescription is often made in units of absorbed dose—in rads or centiGray (cGy)—to a volume surrounding the applicator. A typical radiation prescription might be to give a dose of 1200 cGy to a cylinder around the applicator. The treatment directive for this prescription might then direct that this dose be delivered in two separate fractions, of 600 cGy each, one day apart, using an HDR ^{192}Ir afterloading device.

Variations were found in the method by which the prescription was recorded and transmitted to treatment planning personnel. For example, oncologists at some sites marked the target and specified the prescription on the x-ray film, while oncologists at other sites used locally developed forms to transfer that information.

Dwell Position Localization

Dwell position localization involves selecting and specifying positions for sources to occupy along the treatment path defined by the source guide tubes and applicators. Typical HDR dwell positions for a single source are spaced at 5 or 2.5 mm intervals between

predetermined starting and stopping points. In HDR RAB, treatment planning takes far longer than treatment so the dwell times at each position must be calculated prior to positioning the source. In LDR, dwell positions are specified for multiple sources within source trains that are placed in applicators and then held in place for an extended period of time (up to several days). This permits LDR sources to be placed before specifying their dwell times and then removed after the time required to deliver the prescribed dose of radiation has been calculated.

Dosimetry

Dosimetry is the task that calculates the prescribed dose at specific anatomical or spatial locations due to radiation. In RAB, the radiation comes from one or more radioactive sources positioned in the applicator(s) during treatment. Although computer software is used to calculate the dose distributions from these sources, users are required to digitize the placement locations from simulation images (x-rays) so that the distances between the treatment positions and targets can be reconstructed by the computer. Those distances are then used to calculate the dose that would be delivered to the reconstructed targets by placing a known source at the measured position(s).

Dosimetry can be used to predict the dose distribution produced by a specific treatment plan or to generate a treatment plan by calculating treatment positions and/or dwell times. In the latter case, users enter the source characteristics and prescribed dose distribution and the treatment planning software iteratively chooses dwell times and/or positions until a plan that produces the requested dose distribution has been generated.

Treatment Plan Selection and Approval

The final task in treatment planning consists of selecting and approving a particular treatment plan and verifying that the plan will deliver the prescribed radiation dose to the radiation targets. Plans may be chosen from a dose atlas, generated for an idealized patient using standard treatment geometries, or for individual patients by inserting simulated sources into the patient's applicator(s) and taking x-ray views of the treatment field to define the positions of the sources and the radiation targets.

Once a tentative plan is selected, its dose distribution is compared to the dose distribution specified in the treatment directive to verify that it will deliver the prescribed dose. All automated treatment planning systems display isodose lines from the dose distribution in two dimensions. Some rotate these lines to aid in visualization of the three dimensional dose distribution. Once the distribution is verified, the plan is reviewed by the prescribing physician to ensure that the dose will be delivered to the desired targets. Approval of the plan for treating the patient is usually indicated by the physician's signature on a dose distribution plot or on a table of the plan's dwell positions and times.

3.1.1.3 Treatment Delivery

This is the RAB function in which the dose of radiation specified in the treatment directive is delivered to the patient. Tasks in treatment delivery involve connecting the patient to the afterloader, entering a treatment plan into the afterloader control unit, and monitoring and controlling the delivery process.

Treatment Set-up

Treatment set-up is the first task in treatment delivery. During this task the patient is placed and stabilized in a treatment position. The afterloader unit is then adjusted for height and fixed in position and the patient is hooked to the afterloader unit by attaching guide tubes between the applicators in the patient and the appropriate afterloader channels.

Treatment Plan Entry

Treatment plan parameters can be entered into the afterloader control unit either manually or by one of several automated or partially automated means:

- using the keyboard at the control console
- using a memory card
- recalling a treatment plan stored in the control unit memory
- direct transfer between the treatment planning system and the treatment delivery system

Verify Treatment Data Prior to Treatment

Verifying that the treatment plan parameters have been entered correctly into the afterloader control unit is accomplished by comparing the plan parameters that were generated by treatment planning with the values that were entered into the afterloader control unit. Verification can be performed either by the person who entered the treatment plan or, more preferably, by a second individual.

Treatment Session Monitoring

Monitoring a treatment session involves monitoring both the patient and the hardware in the treatment delivery system. Patients are monitored via closed-circuit television

and intercom. LDR patients are monitored in their hospital rooms from a nursing station. HDR patients are monitored from the afterloader control console area just outside the treatment room. The afterloader device monitors its own performance during treatment and provides a running account of system status on the operator's console. Indicator lights alert system operators of conditions that require attention. The printer provides a hard copy record of each source movement and status change during treatment.

Treatment Session Control

The position of the sources during treatment is controlled by the afterloading equipment. In HDR, the afterloader positions a single source at the first dwell position and then moves the source to the next dwell position whenever the dwell time for a position has been reached. In LDR, the afterloader positions multiple sources at different dwell positions.

In both HDR and LDR sources are automatically retracted into shielded parts of the afterloader after treatment is completed. Should this procedure fail, the afterloader operator can interrupt the treatment and retract the sources either by alternative automated means or by manual intervention. Interruptions are routine occurrences in LDR treatments where sources are retracted automatically each time someone enters the treatment room. This allows the nursing staff to tend to patient needs and visitors to enter the room without danger of exposure to radiation. In contrast, interruptions in HDR treatments occur only when an anomalous situation exists. Sessions are aborted automatically or by the operator when a serious condition arises and treatment must be stopped immediately.

3.1.1.4 Post-Treatment

This is the function in which the RAB patient is prepared for release or resumption of routine nursing care after the treatment has been delivered. Tasks in this function involve disconnecting the patient from the afterloader source guide tubes, removing the applicators from the patient, transporting the patient from the treatment delivery area, verifying treatment delivery, and record-keeping.

Source Guide Tube Disconnection

In this task, the source guide tubes are disconnected from the applicators and (usually) from the source head of the remote afterloader. They are then placed in storage locations and used in later treatments.

Applicator Removal

Applicators are usually removed by the staff who placed them, although removal procedures can be simpler than placement procedures since position information is often not collected during removal. Removed applicators are either discarded or sterilized for reuse.

Patient Transportation

Patient care after an HDR treatment usually involves moving patients to a recovery room, tending to their needs, and allowing them time to recover from the treatment session and the effects of medications. The patient undergoing LDR treatment usually remains in the hospital room in which the treatment was given. Regular nursing care can be resumed after removal of the sources.

Treatment Verification

Treatment verification is performed after treatment to detect mistakes that may not have been noticed earlier. All afterloaders evaluated in this study deliver a printout of treatment session parameters along with a running record of events (e.g., interruptions) that occurred during each session. The radiation therapy technologist or physicist can use these records to verify, after treatment, that the prescribed radiation dosage was administered to the patient. If discrepancies are detected, they are recorded in the appropriate forms and the prescribing physician is notified.

Record-Keeping

Patient and brachytherapy record-keeping involves gathering and collating all treatment planning and treatment delivery data. These data are placed in patient records, departmental records, and hospital records for storage and future access.

3.1.1.5 Quality Assurance and Maintenance

This function consists of five tasks that are performed to ensure that the RAB system is operating reliably, safely, and effectively. These tasks include exchanging the source, calibrating a newly installed source, performing equipment and software updates, troubleshooting problems in RAB equipment or process, and conducting routine quality assurance tests of the RAB system. Maintenance involves the diagnosis and repair of RAB equipment, software, and supplies; it occurs as needed in any of the QA tasks.

Source Exchange

Source exchange involves the ordering, receipt, storage and maintenance of new radioactive sources and the storage and

disposal of old ones. Source exchange is performed frequently for the short life LDR sources, never for long life LDR sources, and three to five times a year for HDR sources.

Source Calibration

This task involves measurement of the activity of a radiation source and the transfer of that measurement to the devices and into the activity units (e.g., Curies, milliCuries) used for planning and delivering RAB treatments.

Equipment and Software Updates

This task involves changes to the devices or programs used to perform RAB tasks. These include installation of software and hardware updates and any other changes to hardware or software that might change the interface with the equipment or the way in which the equipment or software operates.

Troubleshooting

This task involves the recognition and resolution of problems or difficulties in the RAB equipment or process. It includes dealing with problems detected during QA or maintenance activities as well as problems related to the support of the patient and staff during emergencies or other unexpected occurrences.

Routine Quality Assurance

Routine quality assurance involves tests conducted to determine whether the RAB system is operating properly, procedures have been followed, and whether those procedures have produced the intended results. Routine QA in RAB verifies that the patient is ready for treatment and is being treated properly, that the RAB treatment process is being used within its designed capacity, and that the system is meeting its operational and performance goals. Routine QA tasks include verifying the identity of the patient, testing the operation of the equipment, and verifying and monitoring the performance of the staff and the RAB process. Less routine QA tasks involve certification of performance of new or modified equipment, software, and procedures.

3.1.2 Preliminary Error Analysis

The preliminary error analysis involved a review of misadministration data for the period 1978–1992, error likelihood estimates, a workload analysis, and a distraction analysis. The analysis of NRC reports identified RAB tasks that should be examined more carefully for potential sources of error. For the most part, these tasks were within the treatment planning and treatment delivery functions.

The findings of the misadministration analysis were confirmed by the error analysis conducted during the site visits. Brachytherapy personnel cited treatment planning as the most difficult function, rated it highest in workload characteristics—time pressure, mental effort, and stress—and reported that they were most susceptible to distraction during treatment planning. RAB experts also rated treatment planning tasks with the greatest number of medium and high error likelihood scores.

3.1.2.1 Misadministration Review

The findings of the misadministration error analysis are summarized for each RAB function and task in Table 3. The number of reported misadministrations is shown for each task along with a brief description of each type of error.

Treatment delivery was the function associated with the greatest number of misadministration errors, with errors occurring in four of the five tasks. Treatment planning had the second largest number of problems, with most errors occurring in the dosimetry task and consisting of dose calculation errors.

3.1.2.2 Error Likelihood Estimate

The findings of the subjective error analysis conducted on site are summarized in Table 4. High dose rate treatment planning is the function associated with the highest likelihood of error, followed by treatment delivery. These likelihood estimates agree with the misadministration report data in Table 3 and the workload analysis presented in the following section. The consequence of an uncorrected error in HDR treatment planning is likely to be severe because of the high radiation dosages employed in HDR treatments. HDR errors may also be difficult to detect and correct due to the short duration of most HDR treatments.

3.1.2.3 Workload Analysis

Table 5 shows the results of the workload assessment for HDR and LDR during treatment planning and treatment delivery. Mental effort was judged to be greater in these activities than either time pressure or stress, both of which were rated equally. RAB staff subjectively experience greater workload in treatment planning than in treatment delivery. HDR treatments are associated with slightly higher levels of stress, mental effort, and time pressure than LDR treatments. HDR workload increases when the patient is in severe discomfort, is sedated, or is attended by clinical personnel who are anxious to proceed with the treatment session. Table 6 shows the workload assessments

Table 3. Misadministration Error Analysis

Function/Task	Number of Misadministrations	Description of Human Error
I. Patient Preparation		
1. Patient scheduling, identification and tracking	1	Misidentify patient
2. Patient instruction	0	
3. Life support monitoring	0	
4. Applicator placement and stabilization	0	
5. Patient transportation	0	
II. Treatment Planning		
1. Simulation with dummy sources	0	
2. Target volume localization	1	Poor mapping of target volume to tumor
3. Radiation prescription	0	
4. Dwell position localization	2	Interpretation of imaging data inaccurate
5. Dosimetry	4	Dose calculation error
6. Treatment plan selection and approval	1	Fail to independently verify plan
III. Treatment Delivery		
1. Treatment set-up	4	Wrong treatment site Wrong sources loaded
2. Treatment plan entry	4	Misenter plan values Wrong treatment site
3. Verify treatment data prior to treatment	1	Fail to verify plan
4. Treatment session monitoring	5	Wrong source placement in applicator Fail to detect dislodged source
5. Treatment session control	0	
IV. Post-Treatment		
1. Source guide tube disconnection	0	
2. Applicator removal	0	
3. Patient transportation	0	
4. Treatment verification	0	
5. Record-keeping	4	Fail to account for all sources Fail to maintain adequate records
V. Quality Assurance and Maintenance		
1. Source exchange	1	Improper packaging of source
2. Source calibration	1	Calibration units different
3. Equipment and software updates	0	
4. Troubleshooting	0	
5. Routine quality assurance	1	Fail to perform radiation survey
Total	30	

for three groups of RAB personnel: oncologists, physicists, and radiation therapy technologists. Dosimetrists were combined with radiation therapy technologists to generate a statistically meaningful category and because there often is overlap in their responsibilities.

3.1.2.4 Distraction Analysis

Distractions and potential distractions were observed in all stages of the brachytherapy process. These distractions can exert a significant impact on both subjective workload and

Table 4. Summary of Tasks with Highest Likelihood of Errors Based on Subjective Error Analysis

Function/Task	Task Summary	Error Likelihood Ranking*
Treatment Planning		
Target volume localization	Defining the geometry of the area to be irradiated by reconstructing applicator locations and anatomical points. This task is more likely to be a source of error in HDR than in LDR treatments because of the shorter time frame for planning in HDR.	1
Dwell position localization and dosimetry	Selecting source dwell positions in the applicators and a dwell time at each position so that the dose distribution specified in the treatment directive will be generated.	2
Simulation with dummy sources	Taking x-rays of implanted applicator(s) using dummy sources to show applicator position relative to the target volume.	3
Treatment Delivery		
Treatment plan entry	Manually entering a treatment plan (dwell positions and dwell times for each applicator) at the afterloader control console.	4
Treatment set-up	Attachment of source guide tubes to the afterloader and to the applicators, ensuring that each source guide tube is attached to its assigned channel and is fully seated.	5

* 1 = highest, 5 = lowest

error likelihood. The crowded conditions and high activity levels in most hospitals intrude to some degree into most clinical activities. Radiation therapy suites are often located in a basement or a remote wing because of the need for shielding. In spite of this isolation, intercoms, telephones, public address systems, and foot traffic still produce distractions and noise. The presence of family members, personnel involved in other radiation oncology activities, and others not directly involved in RAB also were observed to present potential distractions to the RAB staff.

Background activities and distractions were noted by the site visit team during all brachytherapy functions except QA and maintenance. In spite of the high level of staff activity and the competing demands placed on staff in a radiation oncology setting, RAB personnel reported that their performance was impaired by these factors only during treatment planning. This finding was supported by on-site observations.

Treatment planning requires intense concentration for a period of 10–30 minutes. More time is required in complex cases or when task steps must be repeated to detect errors or correct their consequences. Effective treatment planning depends on the execution of a series of sequential, inter-dependent steps. Ideally, treatment planning personnel can construct a plan from start to finish without being interrupted; however, this may be the exception rather than the rule.

QA and maintenance tasks were accomplished when time permitted, without need for outside clinical staff and were therefore relatively unaffected by background activities.

3.1.2.5 Tasks with Significant Error Probabilities

The combined results of these different methods for estimating error probabilities are shown in Table 7 which

Table 5. RAB Staff Judgments of Workload Factors

	Treatment Planning			Treatment Delivery			
RAB Type	Time Pressure	Mental Effort	Stress	Time Pressure	Mental Effort	Stress	Mean
HDR	2.0	2.6	2.1	1.7	2.3	1.8	2.1
LDR	2.0	2.2	1.5	2.0	2.2	1.8	1.9
Mean	2.0	2.5	2.0	1.8	2.3	1.8	

Note: Responses were made using a 3-point rating scale. A score of 1 corresponds to a perceived low level of the workload factor, 2 corresponds to a moderate level, and 3 corresponds to a high level.

Table 6. RAB Staff Judgments of Workload Factors by Job Category

	Treatment Planning			Treatment Delivery			
Job Category	Time Pressure	Mental Effort	Stress	Time Pressure	Mental Effort	Stress	Mean
Oncologists	2.0	2.4	1.8	1.5	1.8	1.5	1.8
Physicists	2.1	2.6	2.2	1.8	2.3	1.9	2.1
Radiation Therapy Technologists	2.0	2.5	1.8	1.9	2.4	1.7	2.1

Note: Staff judgments were made using a 3-point rating scale. A score of 1 corresponds to a low level of the indicated activity or perception, 2 corresponds to a moderate level, and 3 corresponds to a high level.

lists twenty-four different error opportunities and the task and step in which each error could be made.

3.1.3 Skills Assessment

The 27 tasks in RAB involve 19 perceptual, motor, or cognitive skills. Eight of the 19 apply to only a single task. Thus, 11 of these skills are needed to perform most tasks in RAB. Table 8 lists the skills required for each RAB task. The percentage of those RAB tasks which use perceptual, motor and cognitive skills is shown in Figure 11. The skills assessment confirmed the importance of cognitive skills in RAB. Problem sensitivity and information ordering are by far the most widely used skills. Problem sensitivity is the ability to detect and foresee problems and patterns of problems. Information ordering is the ability to follow explicit rules in order to perform actions in a particular order. Information ordering is an important skill because RAB tasks are performed in a highly structured, sequential manner. Treatment planning required more demanding skills than other RAB functions. Most of these required skills are cognitive in nature, corroborating the mental workload assessment reported in the previous section.

3.2 Phase 2: Human-System Interface (HSI) Evaluation

During Phase 2, analysts assessed the data on RAB equipment, software, documents, and workspaces from site visits to determine whether these factors facilitated or inhibited RAB task performance. Phase 2 results are presented in detail in NUREG/CR-6125, Vol. 3. Analysts considered several types of information in making their assessments, including the findings of the detailed human-system interface evaluation presented in Table 1, the steps involved in performing each task (as defined in Phase 1), the information and control capabilities required to perform the tasks, and the comments made by RAB staff during site

Table 7. Tasks with a Significant Probability of Human Error and Undesirable Error Consequences

Function/Task	Step	Possible Errors
Patient Preparation		
Patient Transportation	Transport after placing applicators	Applicator position changed
Treatment Planning		
Simulation with Dummy Sources	Select dummy source(s)	Wrong dummy source(s) inserted
	Insert dummy sources into applicators	Sources not fully inserted
	Visualize dummy source locations	Patient improperly aligned
Dosimetry	Calibrate x-ray images	Incorrect values entered
	Identify applicator and its position	Incorrect values entered
	Enter shield locations	Incorrect shield position entered
	Enter shield characteristics	Incorrect shield data entered
	Enter reference radiation dose	Incorrect dose level or units entered
	Select active dwell positions	Incorrect starting position entered
	Select active dwell positions	Incorrect position offset entered
	Select active dwell positions	Position entered for wrong applicator
	Enter dwell times	Incorrect values entered
	Select weighting factors	Incorrect weight entered
	Enter source characteristics	Wrong date entered
	Enter source characteristics	Wrong isotope entered
	Enter source characteristics	Wrong calibration data entered
Treatment Delivery		
Treatment Set-up	Attach source guide tubes	Guide tubes and channels mismatched
	Attach source guide tubes	Indexer ring not secured
Treatment Plan Entry	Enter channel number	Wrong channel selected
	Enter length	Wrong length entered
	Press position key	Wrong position selected
	Press cancel key	Wrong position selected
	Press time key	Wrong time selected

visits. General findings across all functions and tasks were that

- Staff were not familiar with infrequently used interfaces.
- Operators' views of essential displays and controls were often obscured.
- System status information was often not available to users of the equipment.
- When system status information was available, it was often difficult to understand.

The following sections present the results of the human systems interface evaluations for specific RAB functions and tasks.

3.2.1 Patient Preparation

Traditional HSI factors exerted minimal influence on the patient preparation tasks since, for the most part, equipment, software, and documents played only minor roles in these tasks. The tasks involved in Patient

Table 8. Skills Required to Perform Specific RAB Tasks

Function/Task	Skill: Oral Comprehension	Written Comprehension	Oral Expression	Problem Sensitivity	Pattern Recognition	Selective Attention	Visualization	Deductive Reasoning	Information Ordering	Number Facility	Time Sharing	Speed of Closure	Perceptual Speed & Accuracy	Near Vision	Finger Dexterity	Manual Dexterity	Arm-Hand Steadiness	Multi-Limb Coordination	Static Strength
I. Patient Preparation																			
1. Patient scheduling, ID, and tracking	•		•					•											
2. Patient instruction	•		•																
3. Life support monitoring				•				•							•				
4. Applicator placement and stabilization				•										•	•	•			
5. Patient transportation			•													•	•	•	
II. Treatment Planning																			
1. Simulation with dummy sources				•	•		•		•					•	•	•			
2. Target volume localization				•	•		•		•					•	•				
3. Radiation prescription				•			•		•					•					
4. Dwell position localization				•			•		•										
5. Dosimetry				•			•		•										
6. Treatment plan selection and approval		•	•	•			•			•			•						
III. Treatment Delivery																			
1. Treatment set-up				•					•						•				
2.Treatment plan entry				•					•										
3. Verify treatment data prior to treatment				•					•				•						
4. Treatment session monitoring				•		•					•								
5. Treatment session control				•					•										
IV. Post-Treatment																			
1. Source guide tube disconnection				•										•	•	•			
2. Applicator removal				•										•	•	•			
3. Patient transportation			•													•	•	•	
4. Treatment verification		•		•					•										
5. Record-keeping		•							•										
V. Quality Assurance and Maintenance																			
1. Source exchange				•					•					•					
2. Source calibration				•				•	•										
3. Equipment and software updates	•	•	•						•										
4. Troubleshooting				•					•			•							
5. Routine quality assurance				•					•										

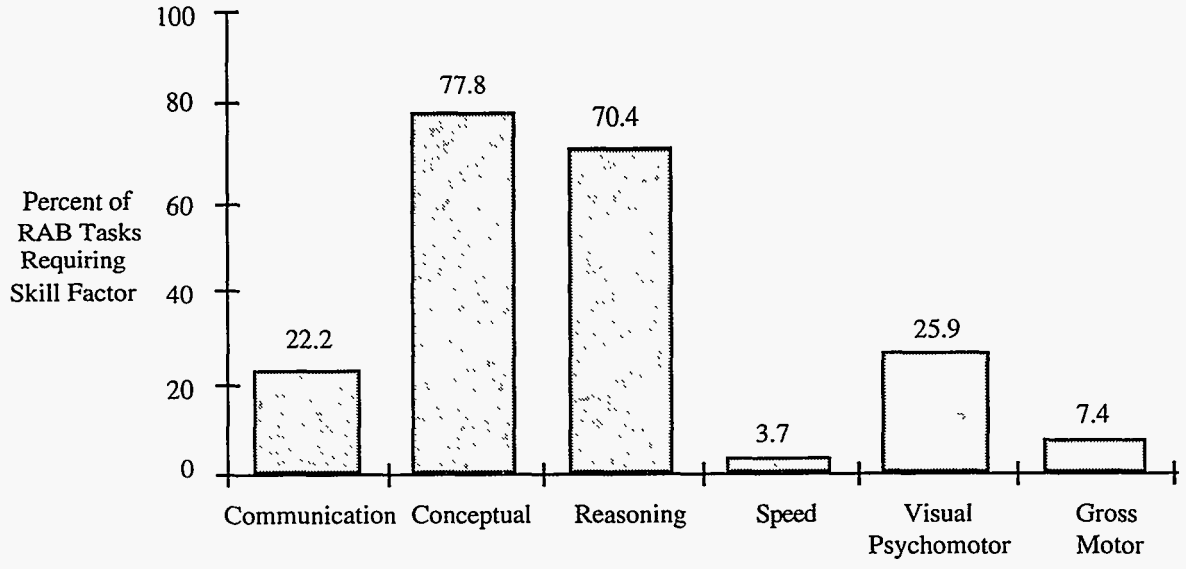


Figure 11. Percent of RAB tasks requiring various skill factors

Preparation are performed at various locations in the radiation oncology suite.

3.2.1.1 Patient Scheduling, Identification, and Tracking

Patient scheduling was performed by administrative staff within the radiation oncology suite. Patient scheduling results were often kept on large office calendars maintained by a receptionist, clerk or administrator. These schedules were filled out after using the telephone to contact and coordinate treatment times with patients and staff.

Patient identification was performed initially by verbal interchange with the patient or by inspecting records that accompanied the patient to the RAB facility. Within the RAB work area, identification and tracking of the patient and his records used photographs, identification labels, and the patient's name and treatment data written on records. The labels, names, and data were often difficult to read and interpret so that they were not suitable for rapid identification.

3.2.1.2 Patient Instruction

Most treatment facilities made special efforts to explain the nature and course of treatment to each patient. The radiation oncologist and nurse usually explained in general terms what to expect during an RAB treatment and summarized its expected effect on their disease. HDR patients are usually instructed to remain stationary during the brief period of treatment delivery and LDR patients are instructed to limit their movements. When patients were not capable of participating fully in treatment delivery, because of senility, sedation, or cognitive impairment, their ability to understand and follow the instructions was assessed so that these potential problems could be addressed prior to treatment. No interfaces or aids were used in this task.

3.2.1.3 Life Support Monitoring

Life support and monitoring equipment are highly variable in interface design, presenting potential human interface problems to staff. These potential problems were not evaluated in this study since most sites at which such equipment was used either restricted its use to physicians or provided other specialized staff from outside the RAB work group to deal with the life support equipment.

3.2.1.4 Applicator Placement and Stabilization

Many of the applicators used in RAB were adequately designed and labeled. Some, however, have no labeling whatsoever. This made it difficult to discriminate between them when they were used in a multiple applicator treatment. Discussions of applicator attachment in user

manuals and other documents were incomplete and generally unsatisfactory.

No mechanism was provided to assess the stability of applicators after they had been placed in treatment positions. To compensate for this deficiency, staff at some sites used tape and ink marks to match positions on the applicators to marks on the patient's skin so that they could detect applicator motion after placement.

3.2.1.5 Patient Transportation

Transport equipment for sedated patients was provided and restraints were available if needed. Staff at most facilities attempted to minimize patient movement after applicators were in place, with varying success. Two facilities limited patient movement during transport by placing and securing the patient on a hard frame prior to transport. The patient and frame were then moved together on subsequent transfers, allowing the patient to remain in a single position on the frame. Restraints and bed rails were available on transportation equipment at most sites to prevent semi-conscious patients from falling. No other standard interfaces were found to help prevent or detect applicator movement during patient transport. Positioning marks made at some sites during applicator placement could be used to detect gross movement of externally visible applicators during transport.

Identification labels on the patients and their records were used to verify each patient's identity and to match the patient with transported records. These labels were often difficult to read and interpret, or used codes (such as bar codes) that required machine translation before they could be compared after transport.

3.2.2 Treatment Planning

HSI influences on treatment planning tasks were more pronounced than on patient preparation tasks. Analysts evaluated the adequacy of equipment design and workspace layouts for simulation with dummy sources, target volume localization, dwell position localization, and dosimetry . The other treatment planning tasks, radiation prescription and treatment plan selection and approval, were performed by the radiation oncologist at various workspaces, which had no particular influence on their performance.

Treatment planning was found to be complex and mentally demanding. It was often performed under considerable time pressure with minimal performance feedback from software and hardware interfaces. Treatment directives and the worksheets used to transport information between planning tasks were often not standardized. Measurement units varied with individuals and between different tasks and equipment. Error opportunities increased each time staff was required to translate between incompatible information presentation and entry formats.

Treatment planning systems were not designed for physical comfort and often did not place needed information in the operator's line of sight. Non-standard labeling and data entry formats further increased the likelihood of human error.

3.2.2.1 Simulation with Dummy Sources

Several models of simulation equipment were used for simulation. In general, this equipment met human factors engineering design standards (e.g., MIL-STD-1472D, NASA-STD-3000) and promoted accurate usage by technologists who performed simulation tasks. Much of the older equipment, however, employed sub-optimal displays and ambiguous control labeling. These interfaces introduced a significant potential for error due to confusion about the actual (vs. intended) settings. Some protection against these errors was provided by extensive practice (repetition) in performing simulation tasks and by the standardization of task sequences, equipment settings, and staff roles.

Most workspaces for simulation were found to be arranged in an appropriate manner to support the simulation tasks. Workspace configurations at most sites had evolved based on the needs and suggestions of the staff. The ability to accommodate simulation was comparable for dedicated simulation rooms and for integrated simulation - RAB treatment rooms.

3.2.2.2 Target Volume Localization

Most treatment planning workspaces were not well arranged for target volume localization. This task often required projection of the image of the target onto a simulation x-ray. No interface aids were provided for this projection at some sites. At others, rulers and magnification scales were used to carefully measure distances between the target and other structures before transferring them to the simulation images. Rulers of different scale with often indistinguishable markings were found at several sites, increasing the likelihood of measurement and projection errors.

3.2.2.3 Radiation Prescription

Radiation prescriptions usually were written using units of radiation dose to tissue: rads, Gray, or centiGray. Some planning systems used units that were different from those typically used at the facility. Significant problems are likely if the treatment planner either fails to notice a difference in radiation units or miscalculates its conversion.

3.2.2.4 Dwell Position Localization

Dwell positions in the applicators were often chosen by comparing simulation images of dummy source strings with target localization marks. When simulation images were unavailable, fixed dwell positions were chosen based on measurement from a reference point within each applicator. These simulation images, localization marks, and measuring devices were the primary interfaces used in this task. Staff had difficulty matching the images of the same dummy source in different simulation views. They also found it difficult to estimate the actual distances between imaged structures from the two-dimensional projections of those structures in the simulation views.

Applicator labels were often not visible in x-ray images, leading to possible errors in identifying the images of the same applicator in different views

At many sites, treatment planning systems were used to reconstruct dwell positions in space from simulation images. These reconstructions helped staff to visualize the spatial arrangement of their chosen dwell positions. Use of these systems required that the selected dwell positions be digitized using dosimetry equipment and interfaces.

Once dwell positions within each applicator were selected, staff were often required to translate those positions into linear distances from the afterloader. These translations often required careful measurement of the length of the cable path used to bring the source to the applicator. Guide tube lengths were usually not well marked and similar guide tubes of different length were often poorly labeled. Standard path lengths through known guide tube connections were used at some sites to reduce the potential for error in these calculations.

Feedback was provided by some planning systems on the linear distances between source positions resulting from dwell position specifications. Typically, no feedback was provided on the distance between the sources and the radiation targets.

The manuals that pertained to dwell position localization were often inadequate. Sentences tended to be long, illustrations lacked clarity, and information was not ordered according to the actual sequence of task operations.

3.2.2.5 Dosimetry

The major strength of some treatment planning systems was their dose optimization ability, which greatly facilitated dwell time selection. Dose optimization was "built into" the dedicated RAB treatment planning systems and enabled them to choose dwell times designed to deliver specific radiation doses to a specified target. Generic treatment planning systems, which are used for both teletherapy and RAB, tend not to have dose optimization algorithms built in, thereby requiring treatment planners or physicians to perform the optimization themselves by repeatedly choosing tentative dwell times and then evaluating the resulting isodose distributions until an acceptable distribution is produced. The number of interactions and judgments required of operators in these systems can increase the potential for human error.

Many sites maintained several independent, dedicated treatment planning systems in a single, crowded room. As a result, RAB treatment planning systems were often configured to fit into available space rather than to adhere to ergonomics guidelines. RAB treatment planning workstations were often configured so that the computer, which was arranged for seated use, was beside the light table, which was arranged for standing use. This horizontal configuration not only required the treatment planner to alternate between sitting and standing but also made it difficult to observe the computer screen from the light table. The light table, was typically placed so that most treatment planners (particularly women and those of smaller stature) would need to stand and bend over it to avoid parallax problems while digitizing. This posture places unnecessary stress on the lower back, neck, and shoulders. Several planning systems were found to have significant parallax in their digitizing systems so that different coordinates might be entered depending on the angle between the operator's line of sight and the plane of the digitizing table. Also, treatment planning reference manuals, patient records, and other printed information were often stored in locations that required treatment planners to twist their torsos and/or to lift improperly.

These systems relied on treatment planning software, which had both good and poor features. The software often performed all the calculations required to reconstruct applicator and target geometries from simulation views. This eliminated numerous opportunities for human error in performing these complicated mathematical calculations. The speed and accuracy of the computer calculations allowed multiple dose distributions to be calculated so that a treatment plan could be optimized to match the dose specified in the treatment directive. The software interfaces, however, were often difficult for users to operate. Digitization and option selections required long sequences of manual data entry without feedback that would allow entry errors to be detected or corrected. Users reported that they often could not determine the appropriate response to software prompts. They found it easier to restart the software and re-enter all their data rather than to attempt to verify or correct their entries.

The user manuals for dosimetry were confusing, and difficult to use. Sentences were lengthy and difficult to read, illustrations were of poor quality, and information was not organized in the order in which it would be needed while performing dosimetry.

Most workspaces were arranged adequately to allow a single user to view the computer-based graphics used during dosimetry. However, the open or shared arrangement of many treatment planning workstations was incompatible with the need for quiet and intense concentration during RAB treatment planning.

3.2.2.6 Treatment Plan Selection and Approval

Dosimetry is an iterative process in which multiple candidate treatment plans are generated for a given treatment fraction. These plans are comparatively evaluated for their ability to meet the requirements of the radiation prescription. The most suitable plan is chosen from this pool of candidate plans, is approved by the attending physician, and is then used to enter treatment plan parameters into the afterloader control unit.

3.2.3 Treatment Delivery

The treatment delivery tasks were heavily influenced by HSI factors. In treatment delivery, the unique equipment, software, and workspaces for HDR and LDR exerted different influences on task performance.

The software in both HDR and LDR treatment delivery systems adequately supported the relevant tasks, providing several safety checks and back-ups. The LDR workspaces were considered to be suitable for the required tasks before and during treatment. HDR workspaces shared with other types of equipment occasionally restricted staff access to the patient and to the HDR controls.

3.2.3.1 Treatment Set-up

In general, the equipment and workspaces for treatment set-up facilitated task performance. Necessary RAB supplies and equipment were typically stored in the treatment room, near the location where they were to be used. In most cases, RAB supplies were labeled in a manner that maximized rapid and unambiguous understanding by users. User manuals were not particularly helpful for treatment set-up since they tended to omit procedures that were not directly associated with operation of the RAB unit. Consequently, most sites had developed their own procedures, often embodied in a checklist to facilitate their performance. The findings were that these self-developed procedures were highly variable.

A significant potential problem was the possibility of moving or stepping on guide tubes and power cables during treatment. This problem was more likely in LDR RAB where treatments are often interrupted to allow staff and visitors access to the treatment room.

3.2.3.2 Treatment Plan Entry

The impact of HSI factors on treatment plan entry varied depending on the method used to enter the data. Equipment that permitted treatment plans to be entered by recall from computer memory or by insertion of a pre-recorded program card clearly facilitated accurate data entry. On the other hand, they also made it easier to enter data from the wrong treatment plan. Cards and disks used to enter treatment plans were often unlabeled and difficult to distinguish visually from similar media containing incorrect plans. The interfaces used to enter treatment plans manually (e.g., series of printed dwell times and dwell intervals), increased the opportunity for human error in this task by requiring additional steps in the entry process.

Regardless of the entry mode, the software that drives the afterloader control units supported this task adequately and displayed the entered parameters so that they could be verified after entry. The user manuals described the treatment tasks and steps adequately, although their poor format and organization often made them difficult to use.

The 6-channel status display on the Selectron LDR provided an additional HSI strength for verifying treatment data prior to treatment.

Systems in which multiple treatment plans are stored prior to treatment can enable errors that might not occur otherwise. They provide ready access not only to the approved plan for the current treatment session but also to treatment plans intended for other patients or prior treatment sessions on the current patient. Operators using these systems require an unambiguous method to match each stored treatment plan with individual treatment sessions to reduce the chance of entering the wrong plan for a particular session.

3.2.3.3 Verify Treatment Data Prior to Treatment

Verification of treatment parameters was performed at the treatment control workspace using one of two methods. A manual check could be made to ensure that the correct values had been entered into the afterloader control unit. Alternatively, the printer in the afterloader control unit could print out a hard copy of treatment parameters. Both methods supported the task well by providing an immediate hard copy of treatment values and a record of events during a session (e.g., errors, incomplete insertions, interruptions).

Their correct execution was aided by following locally developed procedures using supporting documentation. After a treatment session, that record could be used to verify that a treatment had been performed. It was sufficiently detailed to allow the consequences of some treatment-related problems to be corrected by compensating for their consequences in subsequent treatment sessions. Some printers produced faint images that were difficult to read. Others failed to specify units for the printed values, leading to possible interpretation errors by staff unfamiliar with their content.

3.2.3.4 Treatment Session Monitoring

Control unit displays at many sites had narrow viewing angles that placed the operator out of TV monitor or window sight lines. At those sites, the patient and the afterloader control unit could not be monitored effectively by one person during treatment delivery. At LDR sites, the remote control consoles and nurse station displays facilitated the tasks involved in monitoring treatment by presenting the required information on the displays of a single workstation.

3.2.3.5 Treatment Session Control

Whether people other than the patient were in the treatment room was not always obvious to the person controlling the afterloading equipment. Since the room should be empty when the source is exposed for QA, and occupied only by the patient during treatment, this increased the potential for unintentional radiation exposure.

Different versions of some LDR controls were found to have conflicting color codes. Some units had red stop buttons and green start buttons, others reversed that coding. Patient call lights at the nursing station display were often unlabeled or ambiguously labeled. Some LED indicator lights on LDR units appeared to be illuminated when they were actually off. Others reflected light which made them difficult to read.

Emergency access to the afterloader and the patient was difficult due to the physical separation of the RAB staff from them during treatment delivery. This drawback can be partially offset by ensuring that the manual source retraction cranks in the afterloader can be accessed and operated during emergencies. Also, a patient should be able to be quickly disconnected from the afterloader and removed from the treatment room.

The manuals supporting treatment session monitoring and control were adequate, although it was difficult to locate specific troubleshooting information due to poor organization and indexing.

The opening of the emergency source storage container was a potential problem at some HDR sites. It was often only slightly larger than a source and too narrow to allow insertion of a source trapped inside an applicator or enclosed within a source guide tube.

3.2.4 Post-Treatment

For the most part, the post-treatment tasks were not strongly influenced by HSI factors. The major concerns during post-treatment pertain to patient welfare and completing and securing all forms and records needed to fully document the treatment session. Some potential opportunities for human error arising from inadequate interfaces are mentioned below.

3.2.4.1 Source Guide Tube Disconnection

The connectors and other auxiliary equipment used to disconnect source guide tubes were well designed to facilitate task performance. The work spaces where these tasks were performed were suitable. Provisions for storing the source guide tubes were haphazard at some sites, however, which can lead to subsequent treatment set-up errors when source guide tubes that are of different lengths are stored together. The lack of labeling on most source guide tubes also contributes to this problem.

3.2.4.2 Applicator Removal

Applicator removal is a medical procedure performed by the attending medical staff. In some cases, such as lung treatments, the applicator can be removed immediately following the treatment session; in other cases, applicators must be surgically removed. In the former situation, HSI factors are minimal, whereas in the latter situation, they lie beyond the scope of this project.

3.2.4.3 Patient Transportation

Patient transportation needs vary according to the type of RAB administered and the post-treatment condition of the patient. Patients who receive LDR RAB treatments do so in their hospital rooms, which eliminates any post-treatment transportation needs. Patients who receive HDR RAB treatments, in contrast, must be moved from the brachytherapy suite. Patients may either walk under their own power while being escorted or be transported in a wheel chair. In either case, HSI factors play a negligible role.

3.2.4.4 Treatment Verification

Treatment verification requires that an accurate record of the treatment session be obtained and incorporated with the patient's records. The afterloader control unit is the primary interface that is used to obtain a print-out of treatment session events and treatment plan parameters. RAB staff obtained this information from each of the afterloaders examined in this project with no problem. Treatment verification is performed in the treatment control area, often when other staff are preparing for the next patient. These crowded and time pressured conditions can encourage errors unless procedures for verifying a treatment session have been established and are followed. Checklists were used at some sites to facilitate error-free performance.

3.2.4.5 Record-Keeping

Each site used its own forms and procedures for record-keeping. As with treatment verification, the treatment control workspace used for this task tended to be crowded and cramped because it was shared with other radiotherapy modalities such as teletherapy. Opportunities for misplacing forms or for mismatching forms with patient and department records were thus presented. The use of job aids to guard against these errors, such as color coding schemes, was minimal or inconsistently applied at some sites.

3.2.5 Quality Assurance and Maintenance

Source exchange, source calibration, and routine quality assurance tasks were generally well supported by the equipment, software, and workspaces. Problems with individual interfaces are noted below.

3.2.5.1 Source Exchange

Because of the different types of sources and hardware configurations, different HSI considerations are relevant for the HDR and LDR source exchange tasks. For the MicroSelectron LDR system, source exchange involved using a source preparation station to build source strings. The interface for this device required users to assemble sources while viewing the assembly in a mirror. Problems with the interface of this device interfered with effective task performance. Users reported difficulties with cutters, with measuring lengths, and were observed to expose their eyes to radiation during walk-throughs of the source preparation procedure. The user manual was not considered helpful for this task, in contrast to the locally generated checklists and forms which were used to guide task performance.

Contents of intermediate safes used to store LDR source strings after their preparation could not be determined directly. Similarly, HDR systems failed to provide a way to detect the presence of a HDR source in the safe after source exchange (or treatment).

3.2.5.2 Source Calibration

Source calibration chambers were often difficult to position and secure at a fixed distance from the source during calibration. Since measured activity is a function of the distance to the measuring device, small positioning errors could have serious consequences on subsequent treatments. Sources were shipped labeled with activity values calculated by the vendor, but different calibration equipment and calibration algorithms made comparison of these calculations difficult. No aids for comparing the results of calibration differences were provided. As in source exchange, the locally generated checklists and forms were much more useful than the user manuals for performing this task.

3.2.5.3 Equipment and Software Updates

Software updates typically lacked adequate documentation. Documentation often failed to inform users of interface changes that accompanied software modifications. Modifications themselves were often undocumented, which prevented users from identifying and validating calculations that might be affected by the changes. Manufacturer telephone assistance constituted a back-up source of information that could be used to augment written material.

3.2.5.4 Troubleshooting

Troubleshooting was hindered by the use of cryptic software error codes and by hard-to-understand user manuals. The availability of diagnostics in the equipment and of a telephone in the workspace (to obtain on-line assistance from the manufacturer) helped to offset these weaknesses. Rapid and unambiguous tool access was hindered by cluttered and poorly organized workspaces at some sites.

3.2.5.5 Routine Quality Assurance

Routine QA involves tests performed on a regular basis to ensure that the RAB system is operating within its design tolerances. One of these tests determines the accuracy with which an HDR afterloader can move and position a check cable in a test applicator. The indicator on the Nucletron source position check ruler, which is pushed by the check cable, may fit too loosely and move further than the cable which pushes it—giving an inaccurate indication of cable

positioning. Routine QA tasks were often facilitated by the use of locally generated checklists and forms.

3.3 Phase 3: Procedures and Practices Evaluation

During Phase 3, analysts evaluated procedures and practices used to perform RAB. Phase 3 results are presented in detail in NUREG/CR-6125, Vol. 3. This section deals with the procedures and practices used to plan and deliver RAB treatments. Procedures and practices addressing task allocation, task location, task ordering and other organizational factors are summarized in Section 3.5.

Very few sites used written procedures to guide RAB task performance. Table 9 shows the percentage of sites at which some form of locally written task performance procedure was found for each RAB task. In general, QA and Maintenance had the most documentation. More than 60 percent of the sites had either worksheets or checklists for all QA and Maintenance tasks except for the Equipment and Software Update task. In contrast, tasks in the Patient Preparation function tended to have the least documentation. Only the patient scheduling and tracking task was documented at more than a very small number of sites. Tasks for the other three functions—Treatment Planning, Treatment Delivery, and Post-Treatment—had documentation support that was intermediate between QA and Maintenance and Patient Preparation, with 20 to 40 percent of the sites having either worksheets or checklists for most of these tasks. Staff at some sites referred to manufacturer's equipment manuals during RAB. Manufacturer's and distributor's manuals for afterloading equipment have been evaluated separately in Volume 3 of NUREG/CR-6125. Only a few of those manuals described procedures for using the equipment to perform RAB tasks. The manuals typically described only the steps required to interface with the equipment and omitted the steps in the tasks that did not use the equipment.

3.3.1 Evaluation of Procedural Documents

Procedural documents were classified as descriptions, checklists, or worksheets depending on whether the documents provided instructions without user annotation (descriptions), space for users to indicate that steps in a procedure had been performed (checklists), or space for results of the procedure to be entered (worksheets). Table 10 shows the percentage of sites at which each type of procedural document was found for individual RAB tasks. Some sites had no written procedures for most tasks. Some sites had a single type of written procedure to guide performance of selected tasks, while others had both procedural descriptions and checklists or worksheets for the same task.

Table 9. Tasks for which Procedural Documents were Found at 15 Sites

Function/Task	Percentage of sites at which written procedural documents were used to guide task performance
Patient Preparation	
Patient scheduling, identification, and tracking	33
Patient instruction	0
Life support monitoring[1]	0
Applicator placement and stabilization	13
Patient transportation	0
Treatment Planning	
Simulation with dummy sources	33
Target volume localization	7
Radiation prescription	47
Dwell position localization	27
Dosimetry[2]	0
Treatment plan selection and approval	20
Treatment Delivery	
Treatment set-up	27
Treatment plan entry	40
Verification of data prior to treatment	27
Treatment session monitoring and control	27
Post-Treatment	
Source guide tube disconnection and applicator removal[3]	13
Patient transportation	0
Record-keeping and treatment verification[4]	27
Quality Assurance and Maintenance	
Source exchange	67
Source calibration	60
Equipment and software updates	7
Troubleshooting	67
Routine quality assurance	67

[1] All tasks except for life support monitoring were performed at every site. Life support monitoring was performed only rarely by non-medical RAB staff. No written procedures were found for this task that were accessible to staff during task performance.

[2] Dosimetry is an automated task that is performed by the treatment planning software. As such, no written procedural documentation was available or needed to guide task performance.

[3] Source guide tube disconnection and applicator removal were combined into the same documents at all sites that had documentation for these tasks.

[4] Record-keeping and treatment verification were combined into the same documents at all sites that had documentation for these tasks.

Table 10. Types of Task Performance Procedures Found at 15 Sites

Function/Task	A document describing task performance was available (percent of sites)	Checklists were used during task performance (percent of sites)	Worksheets were used during task performance (percent of sites)
Patient Preparation			
Patient scheduling, identification, and tracking	13	20	–
Patient instruction	–	–	–
Life support monitoring	–	–	–
Applicator placement and stabilization	–	13	–
Patient transportation	–	–	–
Treatment Planning			
Simulation with dummy sources	33	–	7
Target volume localization	–	–	7
Radiation prescription	20	–	27
Dwell position localization	–	–	27
Dosimetry	–	–	–
Treatment plan selection and approval	13	7	13
Treatment Delivery			
Treatment set-up	27	–	7
Treatment plan entry	33	–	13
Verify treatment data prior to treatment	20	13	27
Treatment session monitoring and control	20	–	7
Post-Treatment			
Source guide tube and applicator removal	13	–	–
Quality Assurance and Maintenance			
Source exchange	13	13	7
Source calibration	47	27	33
Equipment and software updates	7	7	–
Troubleshooting	67	–	7
Routine quality assurance	60	53	27

3.3.1.1 Procedural Descriptions

Written procedural descriptions were found at only a few sites for most RAB tasks. Most were descriptions of general task goals or hardware interface guidelines rather than step-by-step descriptions of how to perform RAB tasks. Few of these descriptions were suitable for use as guidelines during task performance due to differences between the descriptions and the steps actually required to perform the tasks. Exceptions were noted for source calibration procedures and some troubleshooting procedures. These had usually been designed by the RAB staff who performed those tasks. They were useful to the RAB staff as a guide in performing steps in infrequently performed tasks, but were often privately maintained and not accessible to other staff. The suitability of these descriptions for others was questionable since the steps described were often limited to those in which the RAB staff anticipated difficulty. Simple equipment operating procedures and emergency procedures were also posted in several treatment control workspaces. Many of these descriptions were obscured from view. However, staff knew of their existence and were usually able to locate them when asked about them.

3.3.1.2 Worksheets and Checklists

Checklists and worksheets guided task performance at some sites. Seventy-two of these were collected and

evaluated for features that are known to affect the ease with which a document can be used and understood. These features include legibility, language, format, illustration usage and highlighting, and comprehensibility. Table 11 shows the percentage of worksheets and checklists that met, partially met, or failed to meet human factors document design standards and guidelines (e.g., MIL-M-38784B) for each of these features. Table 11 indicates that most documents were legible and comprehensible, but that they often failed to use illustrations, white space, and highlighting techniques, all of which could markedly improve their readability and usefulness to RAB staff. The following paragraphs discuss Table 11 findings in more detail.

Legibility

Most of the documents used a font that was simple and non-stylized. However, many documents (43 percent) lacked sharp and crisp printed characters. Most of these problems stemmed from bad photocopies in which smudges and fading made the print difficult to read. Thirty-eight percent of the documents were printed in font sizes that were too small to be easily read at normal working distances. Many were well below 12 points, and some were so small that they were almost illegible. Such small print poses a problem when rapid and accurate transfer of information is desirable.

Language

Forty percent of the worksheets and checklists contained abbreviations that might be misinterpreted by staff performing the task. Only 10 percent of the documents explained those abbreviations.

Format

In many instances, lines were used to separate text or to link text items. These lines were often difficult to follow. Worksheets and checklists, require enough space between lines for information to be easily written and seen. The spacing between lines of text was insufficient for these purposes in many of the documents. Insufficient space can lead to skipped items or misunderstood information.

Illustrations and Highlighting

Only twenty-one percent of these documents had illustrations to clarify the meaning of their descriptions. Several worksheets had space in which an illustration could be drawn by a task performer to amplify the information contained in the document.

Highlighting consisting of boldface type, font changes, underlining or color changes was used to emphasize important information in 35 percent of these documents.

Comprehensibility

Most of the documents were logically organized to follow an expected sequence of RAB events. Worksheets and checklists were occasionally difficult to follow due to inconsistent entry formats for adjacent items. Instead of always using a check to indicate a passed test or a completed procedure, some checklists required checks for failed tests. Others were inconsistent in their entry requirements. Not all checklists were arranged so that missing items or failed tests would be obvious at a glance.

Information Content

Table 12 shows the information contained in 27 worksheets and checklists used during patient preparation, treatment planning, and treatment delivery.

Most sites had some method (dates or fraction numbers) to identify the treatment fraction to which the document corresponded. Roughly half carried the radiation prescription and therefore provided enough information to verify adherence to the treatment directive. Several contained a description of applicator-channel connections, and a few had space to write planning calculations for later verification.

Table 13 shows the information contained in 22 additional worksheets and checklists dealing with routine quality assurance. All provided space for initials of the person performing the QA check. Most included the date the QA was performed and a check of the safety interlocks used during treatment. Some also noted whether the source activity and positioning accuracy had been verified.

3.3.2 Identification of RAB Task Performance and Linkage Practices

The methods used to perform the RAB tasks varied at each site. Staff at some sites followed detailed procedural guidelines while others had no written guidelines for task performance. Worksheets were used to carry information between tasks at some sites. Staff at other sites relied on memory or verbal communication for these task linkages. Verification of task performance and linkages was similarly formalized at some sites and performed informally or omitted at others. The following sections describe the practices identified for performing each RAB task and note when those practices were guided by a written procedure.

Table 11. Percent of RAB Worksheets and Checklists Meeting Evaluation Criteria

Criteria	Yes (percent of total)	Sometimes (percent of total)	No (percent of total)	Not Applicable (percent of total)
Legibility				
Simple, non-stylized font	88	1	11	0
Printed characters are sharp and crisp	57	21	22	0
Font size legible	62	21	17	0
Language				
Short line length	71	25	4	0
Familiar words	96	4	0	0
Clear meaning	52	42	6	0
Format				
Sufficient spacing between text	42	25	33	0
Caps and italics used appropriately	55	18	7	20
Lines separating text are easy to follow	44	31	19	6
Illustrations and Highlighting				
Drawings, or figures used to facilitate understanding	21	0	79	0
Boldface, font change, underlining, or color change used to emphasize important information	15	25	60	0
Comprehensibility				
Text is organized into logical statements and sections	82	3	4	11
Abbreviations are explained	10	14	39	37

3.3.2.1 Patient Preparation Practices

Scheduling, Identification, and Tracking

Scheduling logs for treatment rooms were used at all sites. The patient was photographed and carried a copy of the photograph during treatment at two sites. Another copy of the photograph was placed in the patient's medical records. This provided the redundant information needed to verify the patient's identity and match the patient to the records prior to treatment.

Patients were sometimes re-identified by different staff upon arrival at each RAB workstation. When the results of these workstation identifications were preserved, this practice served to track the patient's progress through the facility and allowed staff to detect identification or tracking errors. In that system, the patient was identified once and the initial identification was verified at each workstation. When the results of previous identifications were not preserved, workstation identifications provided an additional opportunity for making an identification error, but provided no way to detect the error. Staff generally interrogated the patient to generate the extra information needed to verify their identification in those circumstances.

Written descriptions of how to schedule an RAB treatment session were provided at two of the sites. A step-by step checklist was completed during scheduling at three other sites. A worksheet was completed after scheduling and passed, along with other information on the patient, to subsequent task performers at five of the sites.

Table 12. RAB Treatment Worksheet and Checklist Contents

Doc #	Document type	Tmt fraction identified by	Rx included	Target ID	App-site map	App-chan map	Dwell points	Dwell times	Planning calcs	Verification required
2	Worksheet	Date			• (D)	•	•	•		•
3	Worksheet	Date			•	•	•	•		•
4	Worksheet	Date			• (D)	•	•	•		•
5	Worksheet	Rx	•				• (MD)	• (dos)		•
6	Worksheet	Date/Fx	•		•		•			•
12	Worksheet	Date/Fx	•				•	•		
19	Worksheet	Date/Fx	•				•	•	•	
24	Worksheet/Checklist	Date/Fx								•
29	Worksheet	Date	•		•	•	•	•		
36	Worksheet	Date	•			NA (single)	•	•		•
37	Worksheet	Date/Fx			•		•	•		
38	Worksheet	Date			•		plan #	plan #		
39	Worksheet	Date/Fx		(maybe)	• (D)					
40	Worksheet	Date/Fx		(maybe)	• (D)					
41	Worksheet	Date/Fx					•	•		
50	Worksheet	Date/Fx				NA (single)	•	•		
51	Worksheet/Checklist									•
53	Worksheet	Date/Fx	•			NA (single)				
56	Worksheet	Date/Fx	•							•
58	Worksheet	Date	copy							•
64	Worksheet	Date/Fx								•
68	Worksheet	Dates	•	•						•
69	Worksheet	Dates								•
71	Worksheet/Checklist	Date					•	•		•
76	Worksheet	Date	•		•	•	•		•	•
77	Worksheet	Date	•		•	•	•		•	•
86	Worksheet	Date	copy				•	•		

Fx: Treatment fraction number
Rx: Radiation prescription number
copy: Rx copied onto form

(D): Printed diagram provided for annotation
(maybe): Printed diagram shows some possible targets
(single): Only one applicator used

MD: Selected by physician
Dos: Completed by dosimetrist
plan #: taken from a planning atlas

Table 13. Routine QA Checklist Contents

Doc #	Date	Checker Initials	Door Interlock	Inter-rupt	Console Lights	Source Activate	Source Retract	Cables	Inter-com	Camera/ Monitor	Timer	Printer Paper	Proc. Posted	Source Activity	Other
1	•	•	•			•							•		G
7	•	•	•	•	•	•	•		•	•					
9 - 10	•	•	•	•	•	•	•		•	•	•			•	D,R,G,B
21	•	•	•	•										•	B,R,C,Se
23	•	•	•	•	•		•	•			•				I,F,Ch
28	•	•	•	•	•				•	•			•	•	D,S
35	•	•	•	•	•	•	•			•	•		•		G,S
40a		•	•	•	•			•							F
44 - 46	•	•	•	•	•	•	•			•	•		•	•	R,F
49	•	•	•	•	•	•	•		•	•	•			•	D,G,B,S
52	•	•	•	•	•	•	•	•	•	•	•	•	•		Ch,S,A
55	•	•		•	•	•	•		•	•					B,A
65	•	•	•		•				•	•	•		•		Co,B,A,M
70	•	•	•	•					•	•		•	•		A,L,P,Co
73	•	•	•	•		•	•				•			•	R,M,A,C
74	•	•	•	•		•	•				•			•	R,A,C
75	•	•				•								•	R,A,C
78	•	•	•		•			•	•	•		•			B,Co
79	•	•						•	•		•				Co,B,E,Pn
total	18	19	16	14	12	11	10	5	10	11	10	3	7	8	
percent	95	100	84	74	63	58	53	26	53	58	53	16	37	42	

Legend for "Other" column:

A - Autoradiograph check
B - Battery check
C - Calibration procedures
Ch - Chirper
Co - Compressor
D - Date of last calibration
E - Electrical checks
F - Film check
G - Guide Tube check
I - Ion Chamber
L - Lead Shields
M - Procedures performed monthly
P - Patient supports
Pn - Pneumatical checks
R - Radiation Survey
S - Survey meter availability
Se - Source exchange procedure

Procedures and practices for identifying and tracking patient records were particularly weak at several sites. Simulation x-rays and treatment plans from previous treatment fractions were often stored and brought to the planning station along with the records for the current session. This increased the possibility that old records would be substituted for current ones during treatment planning.

Patient Instruction

Patients at most sites were given general verbal instructions by their examining physicians prior to undergoing RAB treatment. These were followed by more specific instructions from a nurse or technologist just prior to treatment delivery. Only a single site provided a written description of procedures to follow during patient instruction. In practice, these instructions ranged from advice to remain calm and not change body position to much more complicated instructions regarding self-positioning during simulation and self-transport between RAB workstations. Instructions given during HDR treatment delivery usually consisted of short messages from a technologist regarding the expected duration of treatment and admonitions to refrain from moving until the treatment was completed.

Life Support Monitoring

Life support equipment was found in the RAB work area at several RAB site. Use of the equipment, however, was restricted to physicians or critical care nurses and was not part of the duties of other RAB staff. Life support attachment by RAB personnel was not observed during any RAB treatment performed during a site visit for this study.

Patient life support equipment was usually transferred to the RAB work area already attached to the patient and accompanied by life support specialists. These specialists remained with the patient during most RAB activities and helped monitor the patient during treatment delivery. Although the use of life support equipment placed an additional burden on RAB staff by increasing the difficulty of dealing with the patient and the amount of equipment attached to the patient, no written procedures describing the performance of this task were found at any site.

Applicator Placement and Stabilization

Placement of applicators was a medical function that was based on experience rather than written procedures at most sites. Written procedures, when available, were used to augment clinical judgment of where the applicators should be placed and the best method for placing them in that location in an individual patient. Information from tomographic scans, clinical x-rays, and direct observation of the area in which the applicator was being placed were used along with knowledge of anatomical variation and measurements from prior teletherapy treatments and surgical interventions.

Written procedures for applicator placement were found at two sites. Discussions of applicator placement appear regularly in both manufacturers' newsletters and in the RAB literature. These procedural descriptions were not available to the task performers during the placement task, but were available at most sites for reference.

Undocumented placement and stabilization practices were used at many sites. Small gold seeds were inserted into soft physiologic structures at a few sites during placement of the applicators to act as radio-opaque reference points for positioning the applicators.

Lung applicators were often taped to the patient's nose for stabilization. Staff at some sites marked each applicator with ink where it exited the nostrils so that subsequent movement that changed the position of the mark could be detected. Corresponding ink marks on applicators and the patient's skin were used to detect applicator movement at other sites.

Patient Transportation

Patient contact tasks were physically linked by the transportation of the patient between the workspaces used for the RAB tasks. Transportation between other departments and the RAB area was only rarely performed by the RAB staff. Some hospitalized patients were sedated or on life support and unable to identify themselves to RAB staff. In such cases, non-RAB transporters were responsible for initial identification of the patient.

At most sites the transportation staff was aware that applicators might move and took care to avoid shifting an applicator's position during transport. Although this practice was dependent on the transporters' knowledge of applicator stabilization techniques, it was not generally supported by procedural descriptions, training, or performance feedback. Only one site had a written description of transportation procedures that included a warning that care should be taken to avoid moving applicators as the patient was moved between RAB workstations.

Transport procedures were formalized without written procedural documentation at several sites. At those sites a special transfer platform was placed under each RAB patient. The platform and patient were then transported

together so that the patient remained supine throughout the RAB process.

3.3.2.2 Treatment Planning Procedures and Practices

Simulation with Dummy Sources

Simulation results were used in treatment planning at most sites, although simulation was not always performed on all patients. Those sites selected treatment plans from a dose atlas that had been compiled for standardized applicator geometries. Other sites performed simulations to aid in radiation prescription and target and dwell point specification, but did not use the simulation results for dosimetry.

Task performance procedures for simulation were found at five sites. One of those sites also provided a worksheet that was completed during simulation.

Standard practice during simulation at most sites was to position the patient in the x-ray field and to expose two x-ray negatives of the treatment area. These negatives showed different (usually orthogonal) views of the projected images of applicators which had been placed in the patient. Strings of radio-opaque markers were inserted into the applicators prior to exposure of the negatives to simulate positions of radioactive sources during treatment. The magnification and viewing angle used in simulation were then written on one of the x-ray negatives prior to transmitting the two negatives to the remaining treatment planning tasks.

Variation was observed in the method of coding the magnification information and the degree of standardization of the process. Some sites used magnification rings or positioning frames to mark the magnification and view angle in the negatives. Some sites only produced orthogonal views, while others used non-orthogonal view angles. In some cases, particular dummy marker strings were always placed in specific applicators. In others, no order of placement was observed.

At sites that performed treatments with multiple applicators, more than two simulation images were sometimes made so that dummy strings could be removed from one set of images to facilitate identification of the individual applicators on the negatives.

The amount of anatomical information visible on the images also varied widely but was consistent within an individual site for a particular treatment procedure. For gynecological procedures some sites inserted contrast media into critical organs to render them visible on the x-ray negatives for dosimetric calculations.

Target Volume Localization

Physiological targets were specified at only 20% of the sites. At the other sites, the physicians chose to localize the target volume by specifying a distance from the applicator (usually 1 cm). That practice defined a target volume around the applicator rather than specific physiologic targets in the patient's body.

At most sites the prescribing physician described the physiological targets verbally to treatment planners. These verbal descriptions were sometimes accompanied by sketches drawn on a simulation negative to identify the radiation targets. These sketches provided an estimate of the projected area of the target on the negative rather than the actual target volume.

At sites at which simulation was performed for only the first treatment fraction, the initial target specifications were retained for all subsequent treatment fractions.

Procedures for performing this task were informal and undocumented at most sites. Only one site had a worksheet item dealing with target localization. Target localization practices were consistent for individual task performers at most sites, although variation among individuals was common.

Radiation Prescription

A specific target was specified along with the written radiation prescription at only three sites. At those sites, the physician wrote the radiation prescription on a simulation negative and also marked the negative with either tumor boundaries or a desired isodose around targets. The prescription format at these sites therefore consisted of a radiation dose plus one or more isodose outlines.

At other sites, individual radiation targets were not included in the treatment directive. The physician's prescription at those sites described the dose of radiation to be delivered to a surface at a fixed distance (usually 1 cm) from each applicator. That surface was designed to include the targets or to produce the desired distribution of radiation at each target's location. Target positions relative to the applicator were usually measured at the time the applicators were placed. This practice did not require simulation negatives and was used without them at several sites. Variation was seen in the dosage, in the distance of the surface from the applicator, in the reference for measuring that distance (starting from either the center or the surface of the applicator). Variation was also found in the number of fractions used to deliver the total prescribed dose.

Several sites had standard radiation prescriptions that specified the isodose to be delivered to a surface around the applicator (e.g., 500 cGy at 1 cm). Those prescriptions varied only in the length and location of the treatment region defined by the source dwell positions. The isodose distance was standardized at some sites (e.g., at 1 cm from the surface of the applicator) and varied between individual prescribers at others. When the surface of the applicator was referenced, the prescription also specified the size (diameter) of the applicator.

Seven sites out of fifteen provided some form of written procedure for radiation prescription. Three provided descriptions of radiation prescription steps and the other four had worksheets that were completed during task performance.

Dwell Position Localization

Dwell positions were chosen at most sites by having the person who had placed the applicator mark the images of dummy sources on simulation x-rays. For cases in which no simulation was performed, dwell positions were chosen from sets of standard pre-planned dwell positions based on applicator geometry. No written procedures describing the performance of this task were found at any site.

Dosimetry

Dosimetry was performed by using a manually positioned digitization device to transfer coordinates of

- body reference points
- the radiation targets
- the proposed source dwell positions

from simulation negatives to a treatment planning computer. Treatment planning software was then used to reconstruct the geometric distribution of the sources and targets in space from those digitized coordinates. The software also calculated the dose distribution due to sources placed at those positions.

Dosimetry was not performed during treatment planning at 20 percent of the sites. Staff at those sites selected treatment plans from a dose atlas that had been compiled for standardized applicator geometries prior to treatment. Dosimetry was performed during treatment planning at 60 percent of the sites and after treatment delivery at 20 percent of the sites (to verify that the prescribed dose had been delivered). Simulation images and dwell times printed out during treatment were used to calculate those dose distributions.

No written procedures describing the performance of this task were found at any site. The use of computer programs to perform calculation and display operations in dosimetry constituted a form of unwritten procedure. These programs consisted of ordered sequences of steps that were performed by the planning system to calculate and display dose distributions. Use of the same input commands to the program would result in the same sequence of steps being performed by the system.

Although the results of these computer procedures (usually an isodose distribution plotted in one or more planes passing through the sources) were presented to the users, the actual steps performed by the planning systems to create the results were usually hidden. This prevented verification of the suitability of the procedures for individual treatments. At three sites, staff had written their own planning system software so that the procedures used in the calculations would be accessible and could be validated by the staff.

Hand digitization of x-ray images (or in some cases needle templates) was usually performed with little or no feedback and provided multiple opportunities for human error. Parallax contributed to the potential for error in some digitization systems. A single digitization or stabilization error could result in marked discrepancies between the reconstructed distances between sources and targets.

Treatment Plan Selection and Approval

Some sites had compiled an atlas of treatment plans designed for standard source dwell positions and target distances. A treatment plan containing source positions and the dwell time at each position was selected from the atlas at those sites based on dwell positions and dose specified in the treatment directive.

Other sites generated one or more individual plans for each patient. Simulation negatives from the patient were used at those sites to identify dwell positions and radiation targets. Multiple plans were then generated by dosimetry until one or more met the requirements of the treatment directive. Optimization routines were often used in conjunction with dosimetry to calculate the dwell times needed to produce the dose distribution specified in the treatment directive. In either case, after a plan was selected, the plan (or its isodose plot in one or more planes around the sources) was compared with the treatment directive before it was approved for use.

Written descriptions of approved selection and approval procedures were found at two sites. Three sites provided worksheets or checklists to be completed while performing this task.

3.3.2.3 Treatment Delivery Procedures and Practices

Treatment Set-up

The usual convention for attaching applicators was to label the applicators in order of placement (1,2,3,...). An alternative (and sometimes complementary convention) was to label the applicators by placing numbered radio-opaque marker strings into them during simulation and leaving those markers in the applicators to identify them and match them to the treatment plan during setup. Connection practices were standardized at several sites. However, staff varied in their compliance with the standards so that errors in which connections were different from those required by the treatment plan were possible.

Four sites had written procedures or worksheets for setting up a treatment session.

Treatment Plan Entry

Task performance varied depending on the entry mode used and equipment available for performing this task. Three methods were available at the sites that were visited: Hand entry of each plan parameter; card or disk entry of an entire treatment plan; and recall of a treatment plan that had been previously entered and stored in the afterloader control unit.

Card or disk entry was used at eleven of the sites which had matched treatment planning and treatment delivery equipment. Two of these sites also entered some plans by hand from planning atlases. In no case was an atlas plan stored on a card. Eight sites produced a new card for each treatment fraction. One site did not generate a separate card for each treatment fraction. At that site, a card was produced by the planning system for the first treatment fraction and then stored in the patient's chart. That card was then removed from the chart and used to enter the original plan for each subsequent treatment fraction.

Staff at sites without card or disk entry either entered all plans manually or recalled standard plans that had been entered manually and then stored in the afterloader control unit. At one of these sites the entry procedure was further amended by the need to turn off the power to the control unit while the patient was positioned. At that site the plan was entered by hand, then stored in the afterloader control unit's memory, and finally recalled from memory after the power to the unit had been restored.

Written procedures for entering a treatment plan were found at six sites. Descriptions of steps used in treatment plan entry were available from manufacturers' instruction manuals. Magnetic cards or disks standardized some of the entry steps at ten sites.

Treatment Monitoring and Control

At all sites, the practice when starting a treatment was to check that the room was cleared, and then to check that the treatment plan entry verifications had been performed. The (memorized) manufacturer's procedure for starting the afterloading device was then performed.

Staff watched the patient on TV monitors and communicated with the patient via intercom during treatment at fourteen of the sites (14/15 = 73 percent). Staff at one site monitored treatment by visual observation through a leaded glass window. Staff at all sites reported that they monitored the course of treatment on the afterloader control unit display during each treatment session. They were observed to do so during treatment at seven sites (7/15 = 47 percent). The level of monitoring at these seven sites was highly variable and ranged from casual glances at the displays during treatment to prediction and documentation of each dwell position and dwell time during the course of the treatment. At four sites, monitoring consisted of being within range of the treatment control hardware so that alarms from either the hardware or verbal communications from the patient could be recognized. The displays were not monitored at these sites until an alarm sounded or the patient demanded attention.

Control and monitoring of the source position during treatment was handled by hardware that followed steps that were built into the equipment. Only the results of these steps (error messages or position displays) were displayed during treatment. The equipment recorded each source dwell position and provided a printed record of the dwell time at each dwell position. Some afterloaders checked channel connections prior to treatment and monitored resistance to the movement of the source during treatment. If an obstruction or a power failure was detected during treatment, the afterloader would abort the treatment session. Power failures were not experienced during any site visit, but obstructions and faulty connections were encountered. In these cases, the hardware monitoring equipment functioned according to manufacturer's specifications.

Written descriptions of steps to be followed in starting a treatment were found at three sites. Manufacturer's procedures were listed in the equipment control manuals.

3.3.2.4 Post-Treatment Procedures and Practices

Source Guide Tube Disconnection

The source guide tubes (SGTs) were disconnected from the patient's applicators following treatment at all sites. Staff also removed the guide tubes from the indexer head after treatment and stored them in racks or drawers at most sites. Source guide tubes were not disconnected from the indexer head at one site. At that site the tubes remained permanently connected to the indexer head of the afterloader.

Written procedures describing SGT removal were found at two sites.

Applicator Removal

Applicator removal practices varied depending on the type of applicator and the methods used to insert and stabilize the applicators. Sites at which applicators were re-used inspected the removed applicators visually for defects or wear. Staff at some sites reported that they performed an inventory of removed items and radiation surveys of surgically implanted applicators. No radiation survey of removed applicators was reported or observed for intracavitary applicators. The lack of written procedures or documentation for such inventories and surveys suggests that these practices might differ depending on who removed the applicator.

No written procedures describing the performance of this task were found at any site.

Record-Keeping

Treatment printouts, treatment plans, and simulation x-rays were retained at all RAB sites. Individual patient charts were retained for the duration of the patient's treatment. Worksheets filled out at some sites were entered into the patient's chart. A written summary of the treatment was required of the physics staff after treatment at two sites. Videotaped records of bronchoscopy were retained and used to gauge response to treatment at four sites.

Written procedures describing post treatment record keeping were found at two sites. Two other sites had worksheets used during post treatment record keeping that structured the performance of this task.

3.3.2.5 Quality Assurance and Maintenance Procedures and Practices

Source Exchange

Source replacement practices differed by manufacturer and by the type of equipment (low or high dose rate) used at the site. All three sites that performed their own HDR source exchanges used equipment from a single manufacturer. Licensing agreements and agreements with afterloader distributors at the other sites limited source exchange to the manufacturer's representatives. Radiation surveys were performed after the source exchange at all sites. Surveys were also performed prior to the replacement at most sites.

Some variation was observed in source exchange at the sites where the physicists performed their own exchanges. Two of the sites reported that engineering personnel were also authorized to participate in the source exchange.

Locally written procedures for performing source exchanges were found at two of the three sites which performed their own source exchanges. Both sites had step-by-step checklists and one also had a worksheet to be filled out during task performance. Written procedures in the manufacturer's instruction manuals were followed by the manufacturer's representatives when they performed source exchanges.

Source Calibration

HDR calibration was always performed in air at the visited sites although some had experimented with other methods (e.g., various phantoms, which consist of compounds such as water or plastic that mimic the radiation absorption properties of human tissue). Most sites reported using a Farmer chamber to measure the source activity although three sites used other chambers: (PTW, Thimble, and parallel-plates). Two sites used a cobalt reference for calculation of the source activity from the chamber measurements while the remainder interpolated values from copper, cesium and other references. All sites made multiple measurements of activity using different dwell times to check the transit time and positioning accuracy in moving the source to the measurement position.

Some form of local written procedure for calibration of the source was found at nine sites. Checklists were used at four of these, and worksheets were used at the other five. Descriptions of the procedures to be used were also found at seven of these sites. Manufacturer's instructions and professional journals that contained suggested calibration procedures were found at most sites.

The use of programmable calculators or computer programs to perform some of the calculations during source calibration provided a form of procedure which was used at several sites to direct task performance. These programs allowed a sequence of calculation steps to be stored and repeated for each calibration.

Troubleshooting

Physicists were "on-call" twenty-four hours a day to deal with emergencies at all of the visited sites. Troubleshooting practices were observed during walk-through demonstrations or observation of treatments at six sites.

Two primary methods for dealing with problems were observed. In the first, verification of the elimination of problems was required. At a site using this method all treatment procedures would be suspended until an identified problem had been diagnosed, corrected, and, in the case of a failed QA check, the check had been repeated and passed. At one site using this method, treatment was suspended during the visit for four hours due to a failure to pass a positioning accuracy check. In the second method, adjustments were made to compensate for problems or errors after they had occurred. At one site using this method, an error in positioning the patient during simulation was detected by the digitization software and adjusted by moving the measurement axes during planning instead of repeating the simulation.

No written procedures describing the performance of this task were found at any site.

Routine Quality Assurance

Routine QA checks for RAB were performed prior to treatments at all sites. At most sites simulator alignment, view angle and magnification were tested on a regular schedule by non-RAB personnel who used the simulator for other types of treatments. Two of the sites tested simulator equipment as part of their RAB QA procedures. Only a few sites performed QA on other than a daily basis. At six sites planning equipment software was checked after each software update and at another site the software was checked prior to each multi-channel treatment plan. One site checked the length of all new applicators. Another checked the length of all applicators and guide tubes as part of the QA performed when the source was exchanged. Console displays were checked weekly rather than daily at one site and emergency stop controls for the remote afterloader were checked monthly at one site and only at source exchange at another. All sites checked the source activity and performed a radiation survey at the time of source exchange.

Written procedures describing or dealing with routine QA were found at 10 sites. Eight of these had step-by-step checklists for use during task performance. Four sites had worksheets that were filled out during QA. Sites without checklists also performed a routine, but undocumented, QA assessment before each treatment.

3.3.2.6 Emergency and Safety Procedures

Although most sites had local procedures designed to deal with fires and fire alarms, few sites had designed procedures for the local facility to address other RAB emergencies. Manuals and emergency source retraction procedures supplied by the vendor of the remote afterloading equipment were the only emergency procedures at many sites.

A formal safety program including the procedures for reporting and resolving safety problems and regular monitoring of safety-related information was in place at 73 percent of the sites. Safety procedures were communicated using warning signs, posted notices, bulletin board notices, extensive safety checklists, and occasional meetings. All sites had instituted procedures by which staff who were likely to be exposed to radiation would wear sensors to allow that exposure to be measured. Most sites had specified a single individual to collect and evaluate reports on staff radiation exposures.

3.3.3 Evaluation of Task Performance Practices

Since few sites had written performance procedures for RAB tasks, it was impossible to compare practices to procedures at most sites. Staff performance of most RAB tasks followed manufacturer's guidelines for interfacing with afterloading equipment. When interface procedures were difficult to understand (e.g., treatment planning manuals and software), staff tended to follow consistent interface practices that had proved successful in the past. They sometimes did so without understanding why those practices had been successful.

Deviations from locally accepted practices were noted among individuals at several sites. In many cases, these were due to misunderstandings about what the accepted practice constituted or required. Some deviations were due to adherence to accepted practices without considering whether they would be appropriate in all circumstances (e.g., it is acceptable to position a patient prior to simulation but not between a pair of simulation views). Although procedures for task performance might have prevented some of these misunderstandings, most of them could also have been prevented by better training.

Documented procedures would make such a training program easier to design and implement.

3.3.4 Evaluation of Task Linkage Practices

Some information was transferred verbally between task performers at all sites. Several weak linkages in this transfer were identified in which neither a procedure nor a consistent practice could be determined. The most noteworthy of these was that information identifying an applicator, the prescribed dose to be delivered by that applicator, the treatment parameters designated to deliver that dose, and the channel to which the applicator must be connected was inconsistently transmitted between task performers at several sites. This meant that it could not be guaranteed that an applicator in a multiple applicator treatment would be connected to the correct treatment channel.

Weak linkages were also identified in the transmission of the radiation prescription, applicator size, simulation information, and calibration data. These linkages suffered from inconsistent terminology between task performers and inconsistent human interfaces used to transfer the information.

Detection of an error always requires that extra or redundant information be available to identify the error. In many RAB treatment delivery systems such redundant information was not transferred. In these cases, task performance errors could not be detected or reported after completion of the task.

Examples of these potentially undetectable errors include: Applicator-target positioning errors when no simulation was performed; movement of applicators between simulation and treatment; calculation errors in treatment planning software; and source guide tube connection errors in treatments using multiple treatment channels.

3.3.5 Evaluation of Verification Practices

Verification is a QA activity designed to ensure that tasks have been performed correctly and task linkages have been made successfully. Wide variation in verification practices was observed. Staff at some sites verified their own performance. Staff at other sites verified each other's performance. Some sites had formal verification procedures for a few tasks and linkages.

3.3.5.1 Verification of Task Performance

Verification of task performance entails the recognition that a task has been performed and judgment regarding the quality of task performance. All sites had some method of verifying treatment planning performance and verifying entry of the treatment plan into the afterloader control unit. These ranged from visual verification by the task performer to elaborate schemes in which a second verifier was required to make independent measurements which were then compared to the original measurements.

Not all tasks were formally verified. Written descriptions of verification procedures were found at only 33 percent of the sites and covered only ten of the RAB tasks. Most sites had procedural descriptions for only one or two tasks, although one site had written descriptions for seven RAB tasks. The procedure for verification of treatment plan entry was described most frequently. Checklists or worksheets were used at 27 percent of the sites to help guide verification of performance of a few RAB tasks. Descriptions of procedures for verifying treatment planning, treatment set-up, source calibrations, and software updates were found at only a single site. Applicator placement, target volume localization, and applicator connections were seldom verified at any of the visited sites.

Patient identification was never formally verified at some sites and subject to repeated verification at others. Staff at several sites reported that their patients became upset when they were asked repeatedly for personal identification information.

3.3.5.2 Verification of Task Linkages

In many cases, information was available to detect errors, but was unlikely to be used due to a lack of a consistent procedure for verification of task linkages. Examples of these sorts of errors include: applicator size mismatches between placement and planning; treatment distance errors; source dwell position errors due to improper placement of simulation markers; and selection of an inappropriate treatment plan. Staff at most sites verified that the parameters in the treatment plan had been correctly transferred to the afterloader control unit. Other linkages were verified only by the more diligent task performers. This situation was somewhat ameliorated by the practice at most sites of having a single individual perform most of the tasks so that problems of information transfer between individuals were minimized. The linkages were particularly weak when information was transferred between different individuals or when new individuals were added to the RAB team.

3.4 Phase 4: Training Evaluation

A systems approach to training in RAB would consist of a definition of training needs for each RAB position followed by a statement of learning objectives that specified the

skills and knowledge required for specific RAB tasks. Training needs would then be addressed using training materials and testing methods designed to meet the learning objectives. Most sites had no systematic training program for RAB staff although one site had developed a similar program for training RAB technologists.

Despite this lack of formal training and certification for RAB, the majority of the RAB staff reported that they had received adequate training for the RAB tasks that they performed. Many also indicated that they would welcome additional training in tasks which they did not perform regularly.

The following sections identify the training methods that were available to RAB staff and evaluate training issues related to those methods that might limit or increase the opportunity for human error in RAB. Phase 4 results are presented in detail in NUREG/CR-6125, Vol. 3.

3.4.1 Academic Training Programs

Although formal academic training in their specialties was required of physicians, nurses, and physicists, only one staff member reported that the academic training had dealt with RAB. In that instance, a physicist had learned about RAB during a clinical apprenticeship at an RAB site rather than as a formal part of the medical physics curriculum. Pre-employment certification examinations for RAB staff positions were required only for radiation therapy technologists at most sites. In most states, this certification requirement was met by passing a national certification examination for radiation therapy technologists offered by the American Registry of Radiologic Technologists (ARRT). Alternatively, some states had their own registry that offered its own certification examination. Both the national and individual state certification procedures did not address in depth any special requirements for RAB. It must be emphasized that this lack of a certification process for RAB does not mean that RAB staff are not qualified to perform RAB, only that it is difficult to comparatively evaluate their competence on a nationwide basis.

3.4.2 In-House Training Programs

Most sites visited during Phase 4 had no formalized training programs and little or no written training material. Only two sites had any sort of formal training and certification for RAB task positions. One had developed a training program to teach methods used to verify an RAB treatment plan and the other had developed a formal training program for the RAB radiation therapy technologist position. That program included a description of position qualifications and demands in relation to the major goals and objectives of the radiation therapy department and provided lectures and training material designed to meet those objectives. At that site formal certification of proficiency was required before a trainee was permitted to operate RAB equipment.

Training in RAB task performance at most other sites was neither formal nor systematic. This training often consisted solely of watching other staff members perform their duties. Apprenticeship (on-the-job) training methods were common. In RAB apprenticeship training an experienced task performer directs new staff members in RAB task performance until the new members demonstrate that they are qualified to perform independently. Other sites required their RAB staff to "self-train" by using available documentation and observing other staff. No formal testing was performed in conjunction with either training method.

3.4.3 Vendor Training Programs

Only one regularly scheduled RAB training course was identified during this project. That course was a manufacturer's course on RAB treatment planning provided by one RAB equipment distributor (Nucletron) to RAB sites that purchased their treatment planning systems. That course was organized as a one-week, hands-on, classroom training session to orient new users to the treatment planning system. Another distributor (GammaMed) provided on-site instruction during initial installation of the RAB equipment and instruction on demand afterward.

These vendor courses involved lectures and hands-on equipment usage to familiarize students with the vendor's equipment and planning software. They also provided an opportunity for students to ask questions of system designers and meet other equipment users. Neither constituted a complete training program since the RAB staff attending the courses were not tested on their understanding and comprehension of the course material. Classes, however, were reported to be small and personal, providing the opportunity for dedicated students to overcome these format and content difficulties by pursuing their own learning objectives. Experienced users were able to ask questions and to request clarification of material that had not been covered to their satisfaction in the user's manuals.

3.4.4 Training Materials

Professionally developed RAB training and testing material was not widely available. Much of the material used to train RAB staff was not training material per se but rather a collection of technical manuals, journal articles, checklists, forms, and manufacturer's literature and advertisements. In most cases the material had not been organized for either specific staff positions (i.e., RAB Technologist's Training

Course, RAB Nurse's Training Course) or for particular RAB functions and tasks. RAB staff was required to review both general references on RAB as well as documents on specific types of RAB equipment in order to discover information that applied to their jobs.

Little correlation was found between the number of RAB staff indicating an interest in additional training and the presence of training material at a given site. This suggests that the materials currently available to the staff may not meet their training needs.

3.4.4.1 Locally Produced Training Materials

Roughly 22 percent of the sites had developed some type of locally produced training material. Training materials which had been developed locally varied considerably in format and content from site to site.

Table 14 summarizes the locally-produced materials found at the sites that could be used for training. These materials included

- written policies, procedures, and user aids
- local training course material
- written testing materials
- qualification standards
- performance checklists
- miscellaneous training materials, such as reference publications, dosage charts, and safety information

The site with a training program for technologists provided a supplemental RAB training manual covering patient scheduling, programming the afterloader computer, communication with the patient during treatment, emergency procedures, post-treatment procedures, and data collection and recording.

Much of the information found in these documents at other sites was too general to be classified as training material. Few materials stated training objectives, specified performance requirements, or addressed other features expected in a systematic training program. Some sites had well-documented RAB policies and procedures, but few made those procedures available to the RAB staff as training aids. Most of these local training materials were found in storage areas that rendered them inaccessible to trainees.

3.4.4.2 Vendor Training Materials

The training materials provided by RAB manufacturers included user manuals, training course materials, and video tapes. Because of the limited opportunities for RAB staff to receive organized training courses, the user manuals for the RAB systems were de facto training materials. Physicists and dosimetrists commonly relied on user manuals to provide information on a new system or on new system features. They also referred to the manuals when troubleshooting RAB system problems. Thus, user manuals were used for both initial and refresher training.

Many of the commercially available documents written for specific models of RAB equipment varied in quality and format. Seven RAB user manuals were evaluated in Phase 2 against document design standards and guidelines (DOD, MIL-M-38784B; "Principles of Medical Device Labeling," NTIS PB 94-126851). Almost without exception, the manuals lacked important presentation and format features needed to facilitate understanding of their content. They were designed as equipment or software reference manuals rather than training manuals and none followed systematic training objectives. Serious deficiencies were noted in the areas of information organization, language and readability, illustrations, highlighting, and typography. Color, for example, was used in only one manual; white space and typographic cueing were used inconsistently; tables of contents lacked detail, and illustrations were rarely used. Some procedural descriptions in the manuals were incomprehensible even to RAB personnel already experienced in those procedures.

The content and format of written instructional material provided by the manufacturers were also evaluated. Although the material was found to constitute a resource of information on RAB, it was poorly organized for training purposes. There was little continuity from one section to the next, making it difficult to identify learning objectives. Much of the material was dated, and required the student to refer to separate handouts or equipment manuals for current information.

3.4.5 Skills Transfer

Many RAB staff performed RAB tasks after gaining extensive experience in teletherapy or manual afterloading brachytherapy. Some transfer of skills appropriate to RAB might be expected since these other treatment modalities also involve therapeutic application of radiation to tissue. This expectation was not well supported by team interviews with RAB staff. Many staff reported that there had been only slight positive transfer of skills (i.e. transfer facilitating task performance) from other radiation oncology tasks to RAB. Most also reported no negative transfer of skills (i.e., transfer interfering with task performance) between those tasks and RAB. Tasks in which there had been some carry-over of skills included scheduling and simulation. Both of these tasks use equipment and techniques that are often shared with other

Table 14. Sites with Locally Produced Training Materials (n = 16)

Training Material	Percent of Sites
Written procedures for some tasks	69
Training course material for some tasks	25
Written testing material	12
Written qualification standards for some positions	6
Performance checklists for some tasks	62
Miscellaneous training material	81

modes of radiation therapy treatment (e.g., teletherapy) used at a treatment facility.

3.4.6 Testing and Qualification

Testing determines whether facts, procedures, and relationships have been learned. Qualification ensures that persons in a specific staff position have acquired the skills needed to perform tasks assigned to that position.

Only 15 percent of the RAB staff reported that they had been tested or formally evaluated to qualify for their RAB positions. Most of these were at the one site with a formal training program for radiation therapy technologists. Three brief examinations were required for certification of technologists at that site:

(1) an operator's certification exam

(2) a general procedures checklist exam

(3) an emergency procedures checklist exam

Treatment planners at that site had also attended the courses and taken the certification examinations.

Most other RAB staff in this study had never been tested or otherwise formally evaluated on their skills and knowledge.

Without a qualification process, it is possible that some RAB staff will be inadequately prepared for certain tasks. Without testing, these deficiencies would not be apparent until they produced undesirable consequences. Such latent mismatches between position requirements and skills would be particularly important in tasks that were performed infrequently, such as those involving emergency procedures or unusual treatment protocols.

3.4.7 Refresher Training

Refresher training is an important part of a systematic training program. Refresher training is designed to limit the degradation of skills after they have been acquired. Because RAB is performed infrequently at many sites, RAB staff usually spend more time working in other radiation oncology activities (e.g., teletherapy) than they do in RAB. Some skill degradation is likely in such circumstances.

Few RAB staff reported that they had received refresher training in RAB or in any of their other duties. One exception was emergency procedures. Staff at several sites reported that they had undergone periodic retraining to handle fire drills and fire-related emergencies.

Most staff did not have similar formal opportunities to refresh their training for RAB tasks, although most refreshed some of their skills during the practice of RAB. Without refresher training RAB staff face the possibility that their skills eventually may not match the tasks that they must perform.

The sites with training programs included annual refresher training as part of their programs. However, those program had not been in place long enough for any refresher training to have been provided.

3.4.8 Supplemental Training

Desire for additional training in RAB procedures was expressed by personnel in all staff positions. Many dosimetrists, technologists, and nurses stated that they would welcome additional training in the RAB tasks that they performed regularly. They also expressed a desire to become more familiar with tasks outside their area of expertise. For example, several nurses expressed an interest

in learning simulation procedures and some technologists were interested in learning dosimetry because they felt it would aid them in their job performance.

Since most training in RAB occurred on the job, there was only limited opportunity for staff to cross-train on skills outside their job classifications. Within job classifications, several informal sources of supplementary training information were available to RAB personnel. Discussions with professional colleagues and with the RAB manufacturer's representatives were often used by staff to identify and evaluate new techniques and procedures. Seminars and workshops conducted at professional meetings were also mentioned as potentially valuable training opportunities. Some dosimetrists, physicists, and physicians reported augmenting their training by visiting other RAB sites to observe unfamiliar procedures and by viewing video tapes and reading commercially available literature on RAB.

3.4.9 Training for Error Reduction

Training is usually used to standardize performance by teaching compliance with approved task performance procedures. The form of apprenticeship training found in RAB, in which most training occurs during task performance, provides a means by which performance can be standardized and tailored to the characteristics of individual RAB systems. Since much of this training occurs without a statement of training objectives or testing to determine whether those objectives have been met, it can be difficult for either students or trainers to determine what has actually been learned. Since no record is kept of what has been learned, retention cannot be evaluated and retraining needs cannot be assessed. The need for additional training often becomes apparent after task performance errors have occurred and been identified. Training objectives and a course designed to meet those objectives would allow training to be used to prevent these task performance errors rather than to respond to them after they have occurred.

Training can also compensate for weaknesses in procedures or human system interfaces by teaching staff to recognize and deal with problems and their consequences. Without an analysis of system weaknesses and error opportunities, however, and without some testing of whether a trainee has learned and retained effective procedures to deal with them, the potential for training to compensate for other weaknesses in the RAB system is unlikely to be fully realized.

3.5 Phase 5: Organizational Practices and Policies Evaluation

Data on organizational activities collected during prior phases of the study were combined with data collected from eight additional sites in Phase 5. Based on this data, the research team identified organizational functions and tasks that were needed to support RAB. Phase 5 results are presented in detail in NUREG/CR-6125, Vol. 3.

3.5.1 Identification of Organizational Functions

Eight organizational functions were identified as being needed to support RAB:

Function 1: Establishment of Goals

Treatment, performance, and safety goals must be defined so that equipment and personnel can be acquired and procedures can be designed to meet them.

Function 2: Determination of Tasks

Both administrative tasks (related to these organizational functions) and RAB tasks (related to the RAB functions defined in Phase 1 of this study) must be determined before equipment can be acquired and procedures designed to perform those tasks. Safety and performance goals may require additional tasks to be performed by staff who are not directly involved in the planning and delivery of individual RAB treatments (e.g., radiation safety officers, QA and maintenance specialists, and administrators).

Function 3: Acquisition of Staff, Workspace, and Resources

Once tasks have been determined, personnel, workspace, equipment, and supplies needed to perform those tasks can be identified and acquired.

Function 4: Design of Procedures

Procedures for performing tasks, task linkages, and verifications must be designed so that the workspaces, staff, tasks, and resources can be combined into a system capable of meeting system goals.

Function 5: Allocation of Tasks, Workspaces, and Resources

Personnel, equipment and other resources must be brought together at a specific time and place so that the tasks can be performed. Management determines who will perform each task, specifies where and when it will be performed, and distributes the resources needed to perform it.

Function 6: Communication of Goals, Procedures, and Information

Performance goals, procedures for performing tasks, and information used in tasks must be communicated to the task performers. Training programs can be used to communicate procedures and some information. Testing programs can be used to assess the efficacy of the communication.

Function 7: Monitoring Progress Toward Goals

The performance of personnel, procedures, equipment, and other resources must be monitored to determine whether progress is being made in meeting the system's goals.

Function 8: Directing Progress Toward Goals

Based on information collected in Function 7, direct progress toward the current goals by specifying modifications in the tasks, personnel, procedures, training, equipment, and resources that are being used to achieve those goals.

3.5.2 Evaluation of the Performance of Organizational Functions

Once RAB organizational functions had been determined, an analysis based on those functions was conducted to determine the range of organizational practice at the visited facilities.

3.5.2.1 Function 1: Establishment of Goals

The reasons given for the initial introduction of RAB as a form of treatment involved reducing the radiation exposure to staff during brachytherapy (a safety goal) and, (for HDR RAB), shortening the time required to perform a brachytherapy treatment (a production goal). Since all RAB sites in this study were visited after they became operational, the goals which had led to the establishment of RAB at each site were not always discernible. Several administrative staff involved in starting an RAB program suggested that RAB had been instituted at their site in order to provide a service that had been requested by referring physicians (a service goal). Some mentioned that RAB allowed them to provide faster and more convenient treatments for patients, while also reducing staff exposure to radiation (combined service and safety goals). All sites appeared to have considered safety, service, and production goals for RAB and to have organized the local RAB process to balance those goals with other complimentary or conflicting organizational requirements (e.g., space, cost, licensing regulations).

Most of the sites received a significant proportion of their patients on referral and offered RAB as a service to referring physicians in conjunction with other forms of radiation therapy. Sites with large radiation therapy case loads often had to balance production goals for RAB with those of other radiation therapy treatments due to workspace limitations and caseload demands. At those sites, time spent performing RAB reduced the time available for other treatments; consequently, one goal was to conduct an RAB treatment session as rapidly as possible to minimize interference with other forms of radiation therapy.

Goals at some facilities involved training and research in addition to service, safety, and production goals. The way in which these different goals were balanced influenced the way in which RAB was conducted. Sites with training goals were more likely to assign tasks to less than fully trained staff. They were also likely to allow extra time for staff to perform the tasks and verify their performance. Sites with more dominant service and production goals were more likely to have experienced staff. They also often required their staffs to perform RAB tasks under extreme time pressure.

3.5.2.2 Function 2: Determination of Tasks

Determination of RAB Tasks

Each site performed all of the RAB functions described in Phase 1 of this study. Differences were found in organizations which had elected to omit certain tasks (e.g., simulation and dosimetry) for some medical procedures.

Determination of Administrative Tasks

Although organizational tasks had been defined, and staff, equipment, and resources allocated to RAB at all sites, there was little evidence at many sites that this had been accomplished in any systematic way.

Administrative responsibility for RAB was often assigned to individuals who were expected to perform organizational functions without explicit specification of those functions or their associated tasks. Administrative changes involving modification of RAB goals and procedures were usually performed on an ad hoc basis by staff in response to operational problems without explicit prior written definition of modification procedures or goals.

3.5.2.3 Function 3: Acquisition of Staff, Workspace, and Resources

No installation was found in which human and physical resources had been acquired solely to perform RAB treatments. At all sites, the radiation oncology department in which RAB was performed predated the RAB installation. RAB treatment delivery systems therefore had to be accommodated in the existing organizations. RAB

often added afterloaders, afterloader controllers, source guide tubes, and applicators to the equipment, material, workspace, and personnel already in use at those sites for other forms of radiological treatment.

Acquisition of Staff

Radiation oncology staff at the sites ranged from a minimum of 8 individuals to a maximum of 56. The greatest variation was in the positions of oncologist (1 to 16 per site), physicist (1 to 12 per site), and technologist (2 to 14 per site). RAB was carried out by a subset of these radiation oncology staff. A typical RAB team was comprised of several oncologists, one or two physicists, one dosimetrist, several technologists and one or two nurses. Five sites had no dosimetrists, and two sites had no nurses. Several sites had a dedicated RAB nurse but most staff had other duties in addition to RAB.

Most sites reported that one person, often the chief oncologist, was responsible for the hiring of all new employees. In many cases, the hiring of qualified employees who were already trained and experienced in RAB had been difficult. As a result, recruiting was often based on other criteria. These criteria for RAB employment often involved teletherapy experience, personal attitude, and interpersonal skills with patients.

Medical physicists with academic and research experience were preferred by some sites, although experienced RAB physicists were sometimes difficult to find. Two sites indicated a preference for less highly trained (M.S. rather than Ph.D.) medical physicists based on their belief that such individuals would be more likely to conform to local practices.

To overcome a local shortage of trained technical staff, several sites had programs for training radiation therapy technologists. Others provided support for technologist training programs in local community colleges.

Acquisition of Workspace

Most sites had met shielding requirements for RAB treatment areas by either converting areas previously used for other radiation therapy treatments or by sharing areas that were still in use for other types of treatment. Shared workspaces often presented a scheduling problem and markedly increased the time pressure during treatment planning for RAB staff at some facilities.

Acquisition of Equipment

RAB requires afterloading equipment for positioning the source and controlling that position during treatment. All sites had supplemented afterloaders with support equipment designed to aid staff in planning and monitoring RAB treatments. Policies on what equipment to acquire varied depending on the administrative structure at the sites and the degree of participation of the administrators in RAB. At some sites, the afterloading equipment was owned and maintained by the RAB staff under contract to the facility. At others the equipment was owned by the facility which then hired staff to operate it. Prior clinical experience was the main determining factor in the type of RAB equipment selected: administrators who had used one type of equipment usually acquired similar equipment for subsequent installations. Three sites had RAB equipment from more than one manufacturer.

External beam treatments (e.g., teletherapy) were performed in addition to RAB at all sites. Most sites used common scheduling, record-keeping and simulation equipment for both their RAB and external beam treatment programs. Shared equipment often limited the number of different interfaces staff were required to learn. Shared simulation equipment usually required transport of the patient from the simulation workspace to the RAB treatment workspace. This increased the potential for applicators or targets to shift position between simulation and treatment. At some sites, problems in scheduling shared equipment had been addressed by acquiring additional simulation equipment with different interfaces and usage requirements. These differences required additional training and verification procedures to be designed to insure that simulation results were correctly transmitted to RAB treatment planners.

Sites with active teletherapy programs often used their teletherapy planning systems to produce RAB treatment plans. Some of these systems were unable to optimize dose distributions for the curved source distributions common in RAB. This required additional planning procedures to be designed to adapt these treatment plans to RAB.

Administrators at several sites had acquired dedicated planning or simulation systems for RAB to eliminate these problems with shared equipment. In each case the dedicated systems were different from those used by the same staff for other radiation therapy treatments. This required additional procedures and training to be designed to deal with the differences.

Acquisition of Materials and Supplies

All sites had treatment programs other than RAB with which they shared supplies and materials for clinical procedures, x-ray, simulation and planning. Supplies that were specific to RAB were usually acquired from the afterloader vendors. Two sites had experimented with applicators from other sources than the RAB equipment manufacturer. Inventory maintenance and control practices for RAB supplies varied. Some sites re-ordered supplies as they were needed and others kept a large local stock of disposable, or reusable items. Disposable applicators were commonly used for lung treatments, although several sites sterilized and re-used the same lung applicator for each treatment fraction on a single patient. This practice was supported by standard practices for evaluating the used applicator for wear or damage at most sites. Staff at a few sites inventoried and tested each newly purchased applicator, guide tube, or software update before it was used in RAB. Although these practices were often adhered to rigidly by staff, no formal procedure linking purchases to pre-treatment quality assurance was identified.

3.5.2.4 Function 4: Design of Procedures

Once tasks are determined and the staff, workspace, and resources have been acquired to perform the tasks, an important organizational activity is to determine the procedures that will be used to perform the tasks. In addition, the communication and transport procedures that will be used to link the tasks together into a goal-directed process must be established. A complete procedure design cycle would include defining the initial requirements specification, completing the initial design, testing the prototype procedure against task requirements, modifying the procedure as needed, and obtaining approval of the procedure for performing a particular task or task linkage. Procedures can be designed both for RAB tasks and for tasks related to administrative functions.

All sites had designed formal procedures for some RAB tasks, although the function of designing the procedures was carried out informally and without documentation at most sites. This made it difficult to trace the sequence of organizational decisions and actions that resulted in the creation of procedures for tasks both for RAB and administrative functions.

Only two sites included procedure design as a stated job function (one for physicists and the other for a management position held by a physicist). Staff at all sites indicated that medical and nursing procedures could be changed by physicians or nurses without consultation with other staff. Most staff also felt that physicists would be responsible for deciding whether non-medical procedures needed to be changed and would also be responsible for implementing the changes. No site provided resources to assist in the design and documentation of RAB procedures. Few documented procedures were found at any of the sites.

Administrative Procedures

Administrative procedures govern the way in which the organizational functions are performed at a particular site. Administrative procedures were often formalized by organizational charts showing the relationship between different job categories at most sites. These organizational structures had from two to seven vertical levels with an average of between four and five levels per site. No pure "vertical" structures were seen although the lateral span of control was quite narrow in the taller structures. Most sites had separate departments for physics and medical staff and some had separate organizational branches for technologists and nurses as well.

One interesting deviation from this structure was found in hospitals that contracted for oncology services. At those facilities, tasks performed by oncologists and physicists were allocated to contract employees rather than to members of the hospital staff. Figure 12 shows a model organizational chart for such a facility with different contracted groups for physics and oncology in addition to a traditional organizational structure. Some problems in task allocation, performance verification and performance appraisal were encountered in these and in other structures when performance appraisers were not involved in the delivery of RAB treatments.

The functional organization for RAB differed from the formal organizational chart at most sites. RAB task performers were often members of an RAB team that had been assembled from different administrative hierarchies or departments. Figure 13 shows the relation of such a team (shown shaded) to a typical departmental structure. In this figure, teams that overlap the formal structure are formed to accomplish different tasks. The RAB work group is drawn from members of the physics, oncology, pulmonology, and nursing staff. In such a team structure, the person rating the performance of a staff member might be an administrative supervisor who was not involved with RAB treatment delivery.

Although most sites had one or more individuals in charge of monitoring progress and directing progress toward goals, those goals only rarely involved RAB directly and were more likely to involve overall safety, production, and service for the entire department or facility without specifying or considering the contribution of individual treatment modalities.

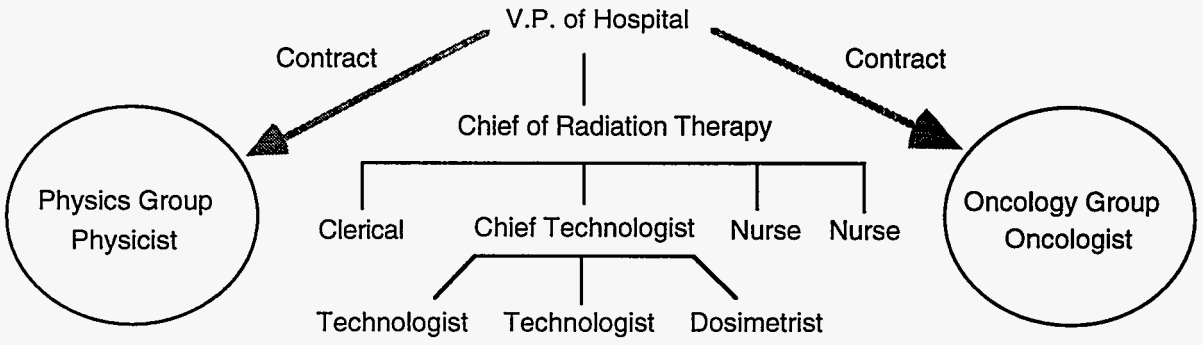


Figure 12. A four-level organization in a hospital with contracted staff

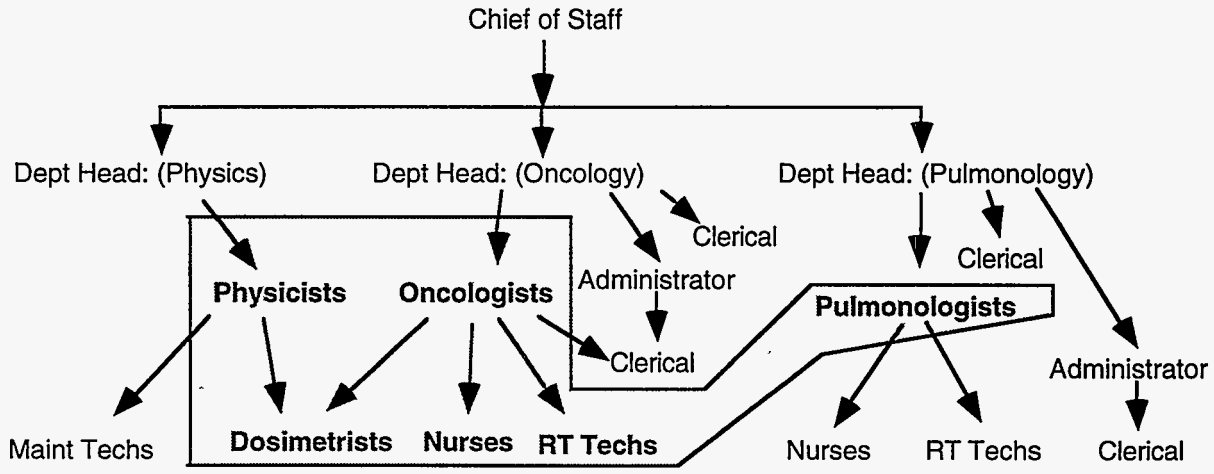


Figure 13. A work group organizational chart (large hospital)

RAB Procedures

RAB procedures specify and approve methods used to perform RAB functions, tasks, and task linkages. All sites performed the RAB functions described in Phase 1 of this study for at least some of their cases.

RAB Task Performance Procedures

Task performance procedures are methods that have been documented and approved by an organization for performing the tasks required to meet the organization's goals. Written task performance procedures, worksheets or checklists were found for some RAB tasks (primarily quality assurance and calibration) at 67 percent of the visited sites. No site had written procedures for each RAB task. At many sites with small staffs, task performance methods had been worked out independently by the task performers but had not been formally documented or approved. The format and content of the procedures that were used for performing RAB operational tasks has been reported in Section 3.3.

RAB Task Linkage Procedures

Task linkage procedures determine how information and material will be transferred between tasks. Linkage procedures are used by an organization to define the order of task performance and to link those tasks into a system that meets organizational goals. Linkage procedures can be designed to overcome or eliminate difficulties produced by administrative decisions regarding workspaces, equipment, and staffing.

Although experienced staff were all familiar with the information that had to be transmitted to perform RAB, only a few of the RAB administrators interviewed had formally identified that information. Information that had been formally identified was often carried between tasks by checklists or worksheets.

Organizational decisions had been made at all sites regarding the way in which RAB functions and tasks were to be performed. The nature of these decisions varied from one site to another and appeared to be a function of several factors including the physical characteristics of the facility, the level of experience and training of radiation therapy staff in RAB, the anticipated RAB caseload, the number of staff who were involved in some aspect of RAB, and the type of RAB treatments that were to be given (e.g., HDR, LDR).

The particular order in which RAB tasks are performed sets limits on the number of possible task linkages and determines the information that can be transmitted from one task to subsequent tasks. Although some variation was evident in terms of which persons in the organization established the task order and the sort of information that should be transmitted, a general pattern became evident. Physicians tended to establish and reinforce the preferred order of task performance. Physicians also determined the information that was required before a treatment directive would be written and a treatment plan approved. Physicists established the quality assurance and maintenance procedures that should be performed at various intervals. A common organizational strategy for obtaining compliance with the desired task order was the use of worksheets and checklists to guide task performance and the transmission of information from one task to another.

The treatment planning function varied from one site to the next depending on whether simulation was done prior to treatment delivery. At sites where simulation was performed prior to treatment, a common practice was to write information directly on the x-ray negative which was then transported between tasks. In contrast, sites that did not perform simulation before treatment used other methods to transmit needed information including worksheets, verbal communication, and hand written notes. It often appeared that no formal organizational directive had been issued regarding the medium in which information was transmitted from task to task; however, the content of that information had been unambiguously defined by certain individuals involved in the delivery of RAB treatments, usually physicians or physicists.

Task linkages which transferred information verbally between tasks were found to be arbitrary and inconsistent at several sites. Staff members at these sites often used linkage practices in which data were assumed to have particular values unless the task performers were informed otherwise (e.g., cylinder sizes and applicator hookup protocols were standardized). However, staff were found to disagree on the "standards" in use and to use different criteria to determine whether a deviation from the standard should be noted.

Several weak linkages were identified in which neither a procedure nor a consistent practice could be determined. In some cases terminology was confusing. In other cases task performers used different sources of information that might be contradictory.

Quality Assurance and Maintenance Procedures

All sites performed routine quality assurance checks on RAB treatment and monitoring equipment prior to starting a treatment session. The order in which other QA and maintenance tasks were performed varied, but was generally consistent at each site. Treatment plan approval was usually performed prior to treatment but was performed after the treatment session had ended at several of the visited sites.

Detecting and Correcting Errors

The means for detecting and correcting errors is a vital organizational concern when dealing with a hazardous technology such as RAB. Error detection requires that redundant information be available so that errors can be identified and, if possible, rectified. An important organizational function is to devise a reliable means of making information available to RAB staff that permits them to detect errors as soon as possible after the errors occur. This information should inform the RAB staff about the nature of the error, as well when and where it occurred. Given this specific knowledge, it may be possible to correct the error and so limit its consequences.

Both error detection and correction require that procedures be designed and implemented so that specific information about task performance is made available to RAB staff. This requires that a flow of information be maintained throughout the RAB process such that errors that occur in

one task or function are not overlooked when the output generated by that task or function is propagated through the system. Organizational decisions on how to detect and correct errors had been made at some but not all of the visited sites. These decisions had encouraged the development of two basic types of procedures for detecting and correcting errors. One type of procedure verified task performance, whereas the other type verified task linkages.

Task Performance Verification

Verification of task performance entails the recognition that a task has been performed. It may also require a judgment to be made regarding the quality of task performance and of the product generated by the task, if any. The organizations studied in this project differed in the extent to which they had identified a need for task performance verification. Thus, while all organizations had some means for verifying the treatment planning function, few of them verified each of the individual tasks that comprise treatment planning. An important implication of this finding is that an error could occur in a component task and fail to be detected and corrected before the treatment plan was used to administer a treatment fraction.

A prime organizational control for verifying task performance is to supply RAB staff with necessary documents to aid them in determining whether they have committed any errors. Documentation for task verification procedures was found at only 33 percent of the visited sites and for only ten of the RAB tasks.

Task Linkage Verification

Task linkage verification involves the determination that the flow of information between tasks has occurred in a reliable, timely, and accurate manner. This consideration is particularly critical in RAB, given the fact that RAB functions and tasks are frequently performed at physically separated locations and that information created at one location must be transmitted to another location in order for RAB to be conducted without error.

There was an overall low level of organizational awareness of the importance of task linkages. This shortcoming was reflected in the lack of formal documentation for verifying task linkages. Often, informal staff-generated techniques were used to verify task linkages, as when one individual entered the treatment plan parameters into the afterloader control unit and another individual checked that the correct values had been entered. Many RAB linkages were verified only by the more diligent task performers. This situation was moderated at sites where one person performed most of the tasks, minimizing the need to transfer information between task performers.

Errors in some tasks could not be traced to their point of origin because the information needed to detect them was not transmitted. In other cases, information was available to detect errors, but was unlikely to be applied due to a lack of procedures for verifying task linkages. The lack of organizational safeguards meant that task linkages were especially weak whenever information was transferred between RAB staff or when new individuals were added to established RAB teams.

Emergency and Safety Procedures

Organizational awareness of the need to make provisions for responding to emergency and safety situations was greater than the awareness of the need for task verification and linkage procedures. However, the formalization of procedures for responding to emergency and safety situations in RAB was not common at the visited sites. Thus, while nearly all sites had procedures for responding to fires and fire alarms, few sites had developed procedures specifically for RAB emergencies. In fact, documentation for RAB emergencies at many sites consisted primarily of source retraction procedures supplied by the vendor of the remote afterloading equipment. However, organizational decisions had been made regarding who should be notified in the event of a general radiation emergency. This person, usually the radiation safety officer, had determined in advance the course of action to follow depending on the nature of the emergency.

3.5.2.5 Function 5: Allocation of Tasks, Workspaces, and Resources

State or NRC licensing guidelines provide considerable leeway in implementation of this function and that leeway was reflected in the way that different organizations had responded to this function. Great variation was found in both the choice of suitable RAB workspaces and the staff who were assigned RAB duties. Often, these variations were made directly in response to the physical layout of the site, the RAB caseload, and the size of RAB staff. Some sites had dedicated RAB treatment and planning work areas while other sites used planning equipment for other types of radiation treatment in addition to RAB. Many sites delivered RAB treatments in the same shielded workspaces that were used for teletherapy treatments.

Administrative staff at all sites had performed these allocations prior to starting RAB and had documented some of the results in their applications for an RAB site license. State or NRC licensing guidelines had been followed for these initial allocations and were adhered to in changes introduced after the RAB system was operational (e.g., Tasks specified as allocated to a job category in the

licensing agreement continued to be allocated to individuals in that job category).

All sites had an administrator who was responsible for ensuring that the relevant job categories were filled and that supplies were available for performing RAB. In many cases this was a member of the RAB team (either a physician or a physicist). Administrative employees without RAB duties also performed that function in several departments.

Allocation of Tasks

Administrators at all sites followed pre-existing licensing and professional guidelines for determining which tasks would be allocated to equipment and staff. A few sites had procedural guidelines in addition to the specifications in their licensing agreements for which job categories would perform specific RAB tasks.

Tasks Allocated to Humans and Machines

The decision to perform RAB is itself a commitment to allocate some tasks to people and other tasks to machines. In RAB, the task of placing radioactive sources in the patient's body has been automated and is performed by hardware without human intervention.

Some performance verification tasks were also performed by equipment or software. These included checking connections between the patient and the RAB afterloader, performing calculations to verify the accuracy and consistency of human data entries, and checking for obstructions in the source path prior to treatment delivery.

Hardware and software were often used by humans during dosimetry and treatment plan generation to perform data collection, calculation, and precise mechanical manipulations. RAB staff performed the tasks that required data collection, manipulation, pattern recognition, and medical experience or knowledge. RAB staff were also required to transport the patient, information, and materials between workspaces. Many other human tasks were required to verify that the linkages between tasks and equipment were performed correctly.

Tasks Allocated to Different Job Categories

A common method of task allocation involved assignment of each RAB function to a particular job category. Most sites had only moderate crossover in task performance between job categories. Table 15 shows a breakdown of some of the RAB tasks performed by physicians, physicists, dosimetrists, technologists, nurses and clerical staff. Variations were observed between sites in the assignments of tasks to job categories. These variations may be attributed to organizational decisions including the workload levels assigned individual RAB staff, the possibility that staff members at different sites are trained to do different tasks, and whether RAB is done exclusively or other types of radiation therapy are done as well.

Although large staffs were common at the visited sites, RAB tended to be performed by small specialized teams within the larger department. At all sites applicator placement, target identification and radiation prescription were performed by physicians. At most sites, physicists or dosimetrists performed the tasks involving treatment planning software and technologists performed daily QA, simulation, linkage, and treatment delivery and monitoring tasks. There was great variability between different sites in the tasks assigned to physicists. Physicists at a few sites performed all the non-physician RAB tasks. At others physicists performed only administrative and troubleshooting tasks, taking little part in day-to-day RAB operations. This variability was due to several factors, such as the availability of other personnel to perform some of the non-physician tasks, the training the physicist had received either at that site or at some other site, the physical layout of a site in relation to the tasks to be performed, and the types of RAB treatments performed at a site.

Allocation of Workspaces for Task Performance

Workspaces for RAB can either be allocated from space dedicated to RAB or overlaid on existing allocations made for other purposes. Administrators at many sites had elected to add RAB to their existing workspaces rather than to allocate dedicated space for RAB. Treatment planning workspaces for RAB were shared with planning systems for other types of radiation therapy treatment at 29 percent of the sites. Treatment delivery workspaces for RAB were shared with other treatment units (teletherapy, hyperthermia, etc.) at all but four of the HDR sites. Workspace allocation decisions were based on pragmatic considerations. It is more feasible to use or modify existing workspaces than it is to build new workspaces. RAB is a relatively new technology, in contrast to teletherapy for which workspaces have existed for several decades. Also, the number of RAB treatments at a given site are much smaller than the number of teletherapy treatments. Hence, organizational decisions frequently were made to accommodate RAB in the context of existing teletherapy workspaces.

Simulation and treatment were performed in different workspaces at 20 percent of the sites. This allowed existing simulation equipment and resources to be used for RAB, but required transportation of the patient between the unshielded simulation room and a shielded treatment area.

Table 15. RAB Task Performance According to Job Category at 16 Sites

Function/Task	Job Category					
	MD (percent of sites)*	Physicist (percent of sites)*	Dosimetrist (percent of sites)*	Technologist (percent of sites)*	Nurse (percent of sites)*	Clerical (percent of sites)*
Patient Preparation						
Patient scheduling, identification, and tracking	7	7	–	47	60	33
Patient instruction	40	7	–	27	67	–
Life support monitoring	20	–	–	13	53	–
Applicator placement and stabilization	100	–	–	7	13	–
Patient transportation	–	7	–	47	47	7
Treatment Planning						
Simulation with dummy sources	13	7	7	100	–	–
Target volume localization	100	20	7	–	–	–
Radiation prescription	100	–	–	–	–	–
Dwell position localization	33	7	–	7	–	–
Dosimetry	13	67	27	7	–	–
Treatment plan selection and approval	87	20	7	7	–	–
Treatment Delivery						
Treatment set-up	13	33	13	60	20	–
Treatment plan entry	13	53	13	33	–	–
Verify treatment data prior to treatment	27	53	13	33	–	–
Treatment session monitoring	27	60	7	60	27	–
Treatment session control	20	53	7	47	–	–
Post-Treatment						
Source guide tube disconnection	20	13	7	47	27	–
Applicator removal	87	20	7	20	40	–
Patient transportation	–	7	–	47	47	7
Record-keeping**	13	47	13	67	20	–
Quality Assurance and Maintenance						
Source exchange	–	20	–	–	–	–
Source calibration	–	100	–	–	–	–
Equipment and software updates	–	80	–	–	–	–
Troubleshooting	–	100	–	–	–	–
Routine quality assurance	–	73	–	47	–	–

* Row sums can be greater than 100 since a task can be performed by more than one job category at some sites.
** Treatment verification has been included as part of record-keeping for the purposes of this summary.

A single workspace was provided for applicator placement, treatment, and simulation at 20 percent of the sites. This allocation of space eliminated transportation of the patient and reduced the opportunity for applicator movement between those tasks. At the remaining sites, workspaces for placement, simulation, and treatment tasks were combined for some RAB treatments and separated for others.

Allocation of the same workspace for RAB and other forms of radiation therapy treatment also presented some scheduling problems for the other types of treatment due to the variable length of RAB treatment planning sessions. Some administrators had addressed this problem by allocating space for RAB patients to remain outside the treatment area between simulation and treatment. This allowed teletherapy to continue during RAB treatment planning sessions, but increased the chance that RAB applicators might be moved as the patient was transported between the different areas.

Allocation of Resources

Resources and materials for RAB were allocated by administrators who also had responsibility for teletherapy and other radiation oncology operations. Allocation decisions were based on a combination of factors stemming from pragmatic and economic considerations. The fact that RAB must often compete with teletherapy for available workspaces, equipment, and personnel suggests that compromises are necessary in order for both types of treatment to exist side-by-side. These compromises are operationalized by organizational policies that give one type of treatment priority over the other, depending upon factors related to caseload, personnel availability, and the urgency of particular cases.

3.5.2.6 Function 6: Communication of Goals, Procedures, and Information

Once goals are determined, tasks defined, procedures designed, and staff and resources allocated to perform those tasks, the goals and task performance and linkage procedures must be communicated to the staff. Training programs can be used to communicate procedures for performing tasks. Information needed while performing the tasks must also be transmitted to the task performers. The communication systems used to pass information from the administration to RAB task performers and those that transmit information between task performers should meet several criteria. They should ensure that RAB staff understand the goals of the RAB system, have learned task procedures, and are provided the information they need at the appropriate time to perform their duties.

Communication of Goals

RAB staff meetings were used at all sites to communicate administrative goals and to discuss the implication of those goals for each job category. These meetings were particularly effective when adjustments of work schedules were made since RAB is practiced as a team effort and requires coordination between the different individuals on the team. Individual goals for staff were usually communicated during private conversations with supervisors rather than in meetings.

Communication of Administrative Procedures

Several of the larger facilities had employee handbooks describing administrative procedures at the site. Direct personal contact was the usual form of administrative communications between adjacent levels in all the organizations. Smaller facilities expected supervisors and co-workers to communicate procedures and procedure changes without written documentation.

Scheduled meetings were the most common form of communication between non-adjacent administrative levels. Staff meetings were used at all sites to communicate information on scheduling and to discuss and resolve departmental difficulties. Meeting frequency varied from weekly to "as needed" with the longest interval reported between meetings being three months.

Communication of RAB Procedures

RAB procedures were usually communicated to staff verbally during a short training period. The employee's task performance was then monitored by a supervisor or co-worker for a few cases before the new employee was allowed to perform RAB tasks without supervision.

At many sites some of the performance procedures for treatment planning tasks and many of the linkage procedures between those tasks were tailored to the requirements of individual oncologists or particular medical treatments. These special procedures were usually communicated verbally from the oncologists to the task performers. Since many of these procedures were undocumented, they provided an additional opportunity for substitution errors. Substitution errors can occur when procedures appropriate for one task or linkage can be used inappropriately in another.

> Examples: Dose prescriptions were sometimes provided in different units by different oncologists at the same site. Procedures for attaching applicators to the afterloader were often standardized, but might be different for each medical treatment procedure. One

staff member who performed the attachments had learned only one of the procedures and was unaware that a different procedure was required in some circumstances.

A few sites used posted notes and bulletin boards to transmit information about procedural changes or to provide examples of properly executed worksheets or checklists. A shortcoming of this practice was observed at one site where posted materials had not been updated to match procedure modifications that had been communicated verbally.

A card illustrating emergency procedures suggested by the vendor of the remote afterloading equipment to deal with afterloader problems during treatment was posted prominently in the control area at many sites. This card and some equipment manuals were available to suggest emergency procedures recommended by the vendor. At a few sites the card was placed behind equipment or stored in a notebook that was inaccessible during a treatment.

Communication of Information

At most sites, communication between individuals involved in RAB was verbal and informal. Formal communication procedures between RAB staff had been established at a few sites. At those sites staff reported that instead of initiating contact directly with individuals at different organizational levels or in different job categories, they would communicate with an immediate supervisor, who would then pass on their information or inquiries.

The only written communication reported or observed between RAB staff separated by a single organizational level was in the form of the worksheets that passed between treatment planning staff during the generation of an RAB treatment plan. Only two sites reported that written memos would be exchanged between RAB staff who were separated by two or three levels in the administrative organizational chart. Written communication between levels of RAB administration were found only in certain unusual circumstances in which documentation was necessary to show compliance or disagreement with written directives. Written communication in the form of memos was more common between administrative staff who were not involved in RAB.

The communication paths between the staff at a typical hospital are shown in Figure 14. Memos are used in the organization depicted in Figure 14 to transfer administrative information. Verbal communications are shown between RAB task performers.

Posted notes were used to transmit information on scheduled meetings at several sites. Staff meetings were used at most sites to transfer and discuss information between staff on both administrative and RAB issues. Individual verbal communication of time-sensitive information was encouraged within the RAB team at most sites. Wide variance was noted in communication practices despite this encouragement. Staff at some sites were eager to initiate discussions on RAB problems with other team members. At other sites, staff were reluctant to initiate conversations and preferred to limit their communications to certain individuals or to specific situations in which verbal communication was required. The reasons for this variability in communication practices among RAB staff reflect the way in which task linkage and verification information is transmitted, authority relationships at particular sites, and personality characteristics of RAB staff members.

3.5.2.7 Function 7: Monitoring Progress Toward Goals

RAB goals were only rarely explicitly described. No formal system for comparing progress with RAB goals was found at any site. In some cases, costs were monitored carefully. At many sites service and treatment goals were monitored by tracking the number of treatments performed for different physicians or different medical conditions. Immediate feedback was provided to most RAB staff when short-term goals were not met (e.g., when extra time was required for a specific treatment). Monitoring the efficiency of service and the ability of staff to perform their RAB tasks was usually informal. Formal evaluations of staff were required at many sites, but the relevance of these evaluations to RAB goals was often low. Formal evaluations were carried out by supervisors in the department in which the evaluee was employed regardless of whether that department was active in RAB. At sites in which administrative and RAB supervision duties were performed by the same individuals, performance was related to RAB task performance criteria. At many sites formal evaluations were often carried out by department administrators who were not involved in RAB task performance. Several staff reported that they were evaluated by administrators who they met with only for the purpose of performance evaluation. Neither the administrators nor the staff were clear on the criteria that would be used for evaluation in these cases although both felt that input on particularly poor performance would be provided by other supervisory personnel with daily contact with the RAB staff.

3.5.2.8 Function 8: Directing Progress Toward Goals

There was ample evidence that direction was taking place at RAB sites in spite of sporadic documentation of this

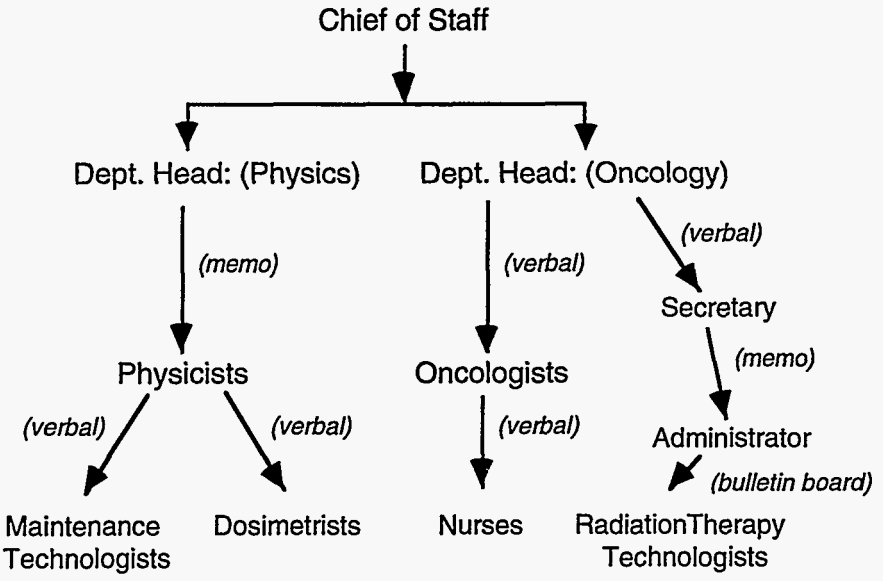


Figure 14. A typical flow diagram for communication of administrative information

function. Several sites reported that they had redefined the treatment goals that had led them to set up an RAB treatment facility. In many cases modifications were related to changes in the clinical practice of the referring physicians. Adjustments had been made when patient caseloads had changed. A few sites reported that the HDR afterloader had originally been intended for only one type of medical treatment (e.g., lungs) but had been subsequently used for other types of treatment (e.g., interstitial). Several sites reported that RAB was under evaluation as a potential replacement for manual brachytherapy treatments.

Two sites reported that the expected cost/benefit advantage of RAB had not been achieved due to the number of staff that were required to perform verifications to detect potential human errors in RAB. Since most patients at those sites were referred for treatment, production goals required to justified the cost of the RAB process could not be met. Administrators at both sites were in the process of modifying their RAB goals to include service as well as production.

3.5.3 RAB Staff Motivation and Job Satisfaction

Motivation and job satisfaction were measured at each site to assess the effect of organizational policies and practices on RAB staff. High motivation based on personal responsibility for patients was found at most sites. Job satisfaction levels were also high, although organizational policies contributed to a feeling of isolation for some staff.

3.5.3.1 Motivation

Motivation to perform well at RAB tasks was found to be high even at sites in which staff reported little or no feedback from supervisors. Interviews with individual RAB staff members at sites with reported communication and personnel problems determined that the major motivational factor for staff was a feeling of personal responsibility for the patients under their care. Consequences of poor task performance were most often discussed in terms of the perceived effect of that performance on the patient rather than its consequences for the staff member. In comparison, other potential sources of motivation, such as opportunities for promotion or increased pay, seemed to play only a minor role in motivating RAB staff to aspire to high levels of task performance.

3.5.3.2 Job Satisfaction

Job satisfaction levels varied across sites, although staff at only two sites reported low overall job satisfaction. Most dissatisfaction appeared to be due to either personality conflicts between the staff or to perceived isolation from control and decision processes. Four issues were mentioned frequently as sources of job dissatisfaction for RAB employees:

(1) Nurses' felt administratively isolated from the RAB treatment team.

(2) Technologists and physicists reported undesirable time pressure during treatment planning.

(3) Personality conflicts sometimes occurred between staff.

(4) Workspace limitations were sometimes difficult to accommodate.

3.6 Phase 6: Identification and Prioritization of Human Error in RAB

During Phase 6, potential human errors in RAB were identified along with the consequences that might follow each error. Critical tasks (i.e., tasks in which potential errors could have serious consequences to the patient or staff) were prioritized according to their safety significance. Next, current task performance techniques were analyzed, as were techniques for detecting and correcting human error. Finally, alternative techniques for performing critical tasks were proposed and evaluated for their ability to decrease the likelihood of human error, increase its detectability, and limit its consequences. In many cases, more than one alternative was suggested for a single problem to allow for interim improvements until more complex but potentially better solutions could be implemented.

3.6.1 Identification of Potential Human Errors in RAB

The Phase 1 function and task analysis was used to preliminarily identify task performance errors that could occur in RAB. A conceptual model of the RAB system was then developed so that the linkages between the tasks could be described and potential human errors in performing those linkages could be identified.

3.6.1.1 Errors Identified by Function and Task Analysis

The 24 task performance errors identified as part of the preliminary error likelihood estimates in Phase 1 have been shown in Table 7. Most of these errors were associated with the treatment planning and treatment delivery functions.

3.6.1.2 Error Consequences Identified by the Conceptual Model of the RAB Process

Potential consequences of human errors which could propagate through the RAB system were identified using a conceptual model of RAB. This model was developed by specifying the information and material passed between tasks using linkages and procedures identified in Phases 1 through 5. This allowed the consequences of an error in task performance or task linkage to be tracked so that the effect of those errors on treatment planning and treatment delivery could be evaluated. The conceptual model was also used to suggest procedures that could be used to identify and correct the consequences of error at different points in the RAB process.

Figures 15, 16, and 17 provide graphical representations of those parts of the model that deal with treatment plan generation, treatment plan selection, and treatment delivery. In each of these figures, the flow of information and materials through the RAB system is depicted by filled arrows. Patient movement between workspaces is shown by unfilled arrows. Transfer of information is represented by the movement of the physical medium which contains the information, and is shown as a 2-dimensional box. A 3-dimensional box signifies an RAB task or subtask; shaded boxes denote tasks involving patient contact, while unshaded boxes denote tasks without direct patient contact.

Figure 15 shows the process by which a treatment plan is generated for a patient. The patient is scheduled for a treatment session, applicators are placed in the patient, and treatment simulation with dummy sources produces a set of x-ray films that are used to determine applicator location and potential source dwell positions within the patient. During target volume localization, targets for the radiation dose are either identified in the x-ray images or added to those images using information from other target volume localization techniques. The x-ray images carry this information to the dwell position localization task where dwell positions are refined and limits on source travel are established. This information is used in the radiation prescription task, along with applicator information, to prescribe a dose of radiation for each target. A written prescription describing each radiation target and the dose to be delivered to that target carries the desired radiation distribution to the treatment plan generation task. In that task, treatment plans are produced by selecting precise source dwell times and dwell positions. The results are carried in three documents: the x-ray, the applicator map that specifies which applicator will be connected to each afterloader channel, and the plan that specifies source dwell positions and dwell times within each channel. Once a set of treatment plans has been generated, the most appropriate plan will be selected by the radiation oncologist.

Figure 16 represents the flow of information and material during the selection of a particular treatment plan for treatment delivery. Dosimetry software is used to calculate the dose that would be delivered to each target from each plan. To do this, the software uses position information transferred from the x-ray images to reconstruct the

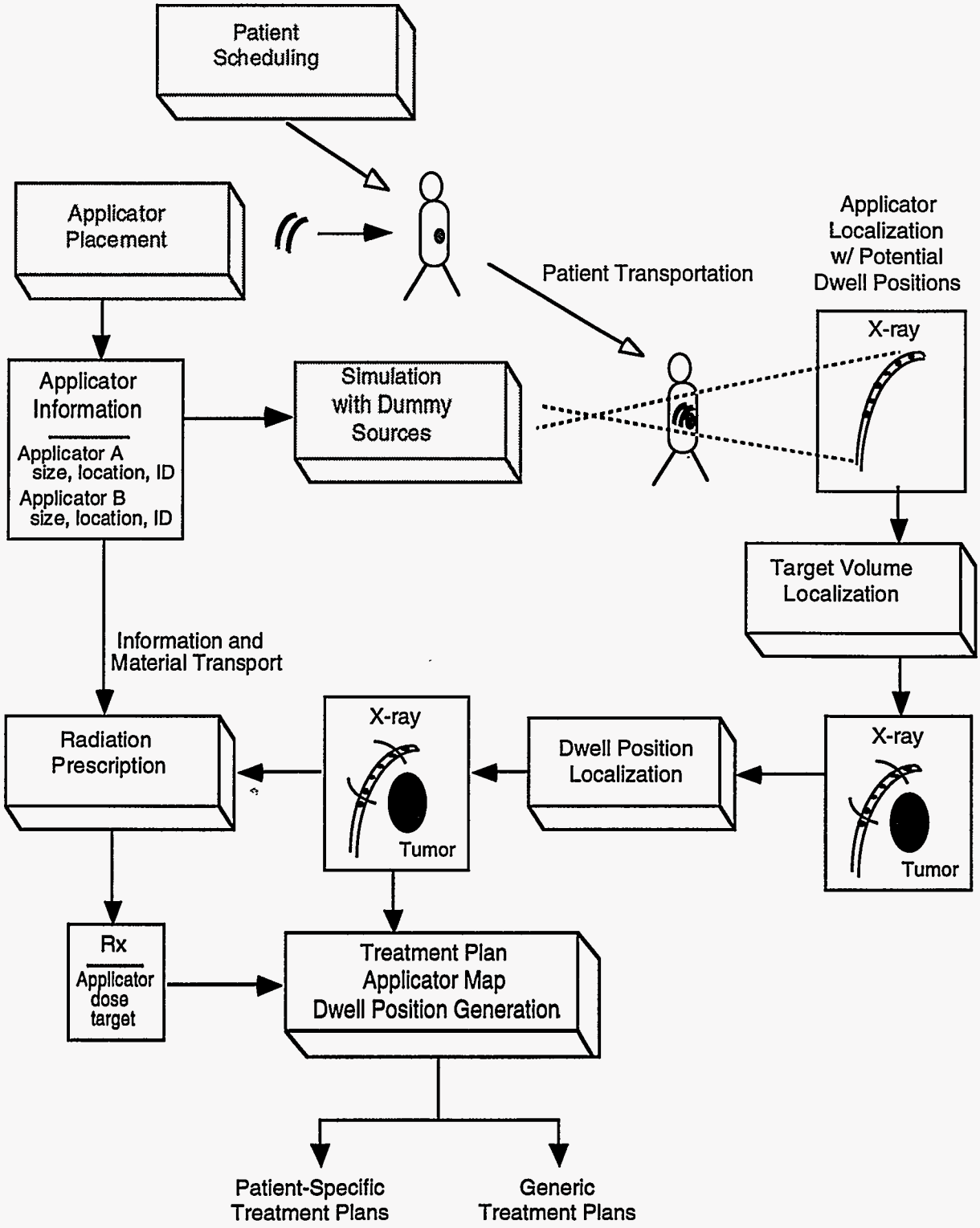


Figure 15. Treatment plan generation

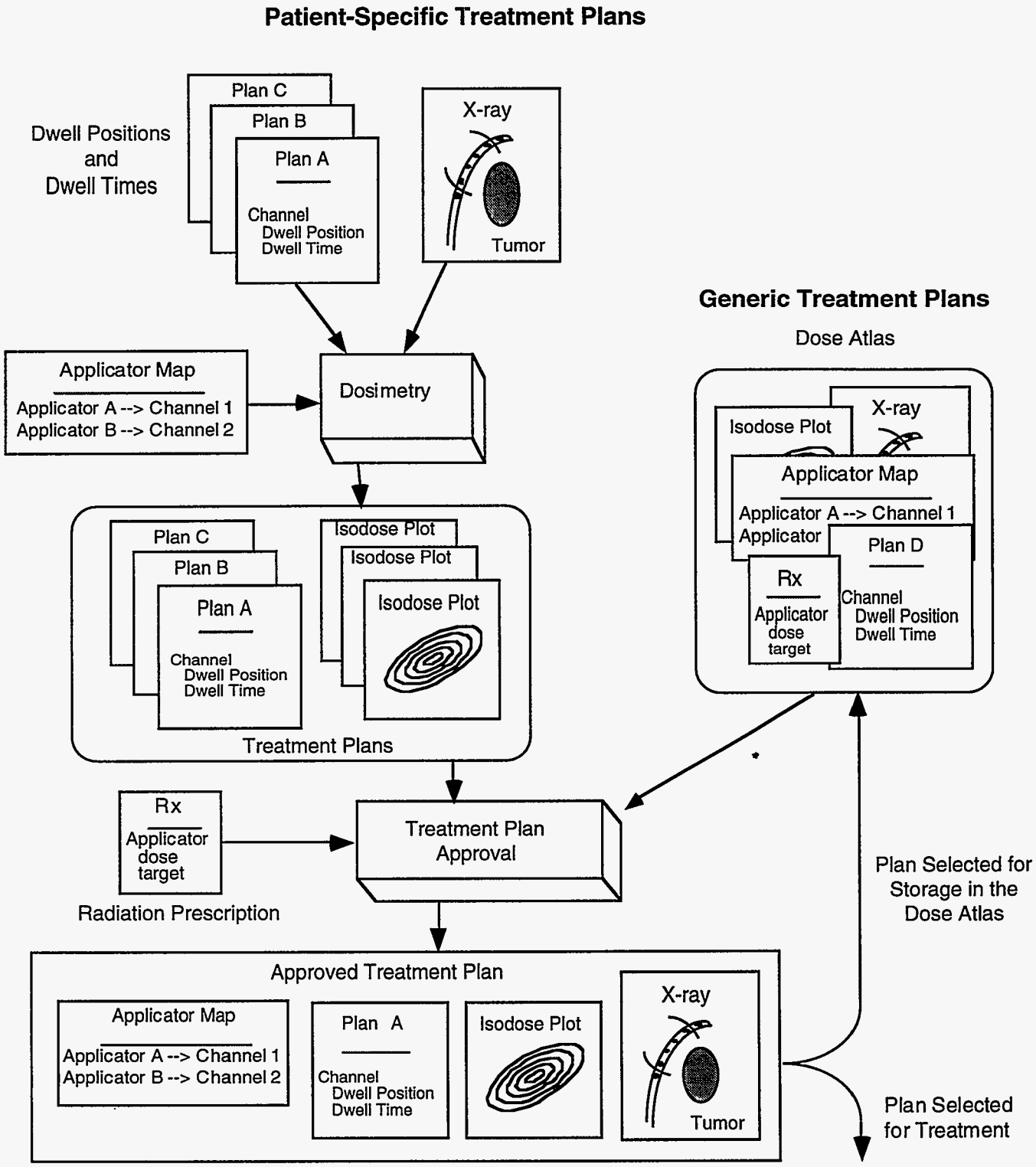


Figure 16. Treatment plan selection

geometric relationships between the dwell positions and the targets. The applicator map is used to match planned afterloader channels with specific applicators identified in the x-ray images. The dosages for each plan are plotted (the isodose plots) and compared with the desired radiation prescription.

In the plan selection and approval task, the dose distributions from the isodose plots for one or more treatment plans (from either the current planning session or from plans stored in a dose atlas) are compared with the radiation prescription. The most appropriate plan is selected on the basis of how well its isodose plot corresponds to the radiation prescription. When a plan is chosen and approved for treatment, the three major products of the treatment planning process are brought together: the radiation prescription, which specifies the dose to be delivered to each target; the applicator map, which specifies the connections between the afterloader channels and the applicators; and the treatment plan, which details the source dwell positions and times within each afterloader channel.

The same techniques can be used to generate reference plans for a dose atlas that catalogs distributions of sources and targets. An atlas can be used for cases involving generic treatment geometries and applicators. Unusual geometries and custom made applicators necessitate the formulation of treatment plans that take their special characteristics into account.

Figure 17 shows an approved treatment plan being used to deliver an RAB treatment to a patient. The plan is entered in the afterloader control unit, and the applicator map is used to connect the applicators to the correct afterloader channels.

Each task performed in this process, and each task linkage performed by the transport of information and materials is susceptible to error. Tables 16 and 17 show the 76 errors which the model identified as having consequences that were likely to propagate through an RAB system and produce potentially adverse effects on patients or staff. Table 16 shows the errors associated with treatment-related activities and Table 17 shows the errors associated with quality assurance and maintenance tasks. This analysis identified linkage errors and performance errors in addition to the original 24 task performance errors identified in Phase 1. Appendix A describes each of these 76 errors in detail and specifies the information needed to detect and correct their consequences.

3.6.2 Identification of Critical Tasks and Linkages

A panel of RAB subject matter experts used the tasks and linkages reported in Phases 1 and 3 of this study to identify the effect of errors on RAB treatment delivery. The panel initially identified critical tasks and linkages in which a performance error was judged as likely to result in a misadministration or other undesirable consequence to the patient or staff. These critical tasks and linkages are presented in Table 18.

The first column of Table 18 shows the RAB function and task in which an error was expected to occur. The second column specifies whether the error can be detected with currently available methods. Errors on critical tasks and linkages labeled "undetectable" were judged unlikely to be detected using either current capabilities or current capabilities augmented by simple procedural changes or job performance aids. The third column is an estimate of the frequency with which such an error might occur in RAB treatment delivery. The fourth column presents the experts' assessment of the consequences of the error. "Staff concern" indicates that the error was judged to be serious but in many cases was unlikely to result in a recordable event or reported misadministration since the error was judged to be difficult or impossible to detect. Ten critical tasks and linkages were identified.

In addition to the critical tasks listed in Table 18, the panel also identified two critical linkage verifications which are shown in Table 19. One of these was concerned with verifying and approving a treatment plan and the other involved checking plan parameters after they had been entered into the afterloader control unit. The panel stressed that each of these verifications should be performed but did not speculate on the incidence of verification failures. They felt that the consequence of verification errors would depend on what had gone undetected by the linkage verification process.

3.6.3 Prioritization of Errors by Safety Significance

The experts identified fewer significant errors than were identified by the conceptual model of RAB. However, all of the errors reported in Table 18 were judged likely to cause significant harm to patients or staff. Instead of reporting the critical errors or the errors whose consequences propagated through the system, the panel focused on the tasks in which significant errors might occur.

The panel regarded an error as significant if it was likely to result in either a markedly greater radiation dose to the patient than specified in the treatment directive or if it would result in an unintended dose to either the patient or the staff. Although a misadministration might also result from a lower dose of radiation than specified in the directive, the panel was reluctant to regard a situation in which a lower dose was delivered as critical unless it was likely to go undetected.

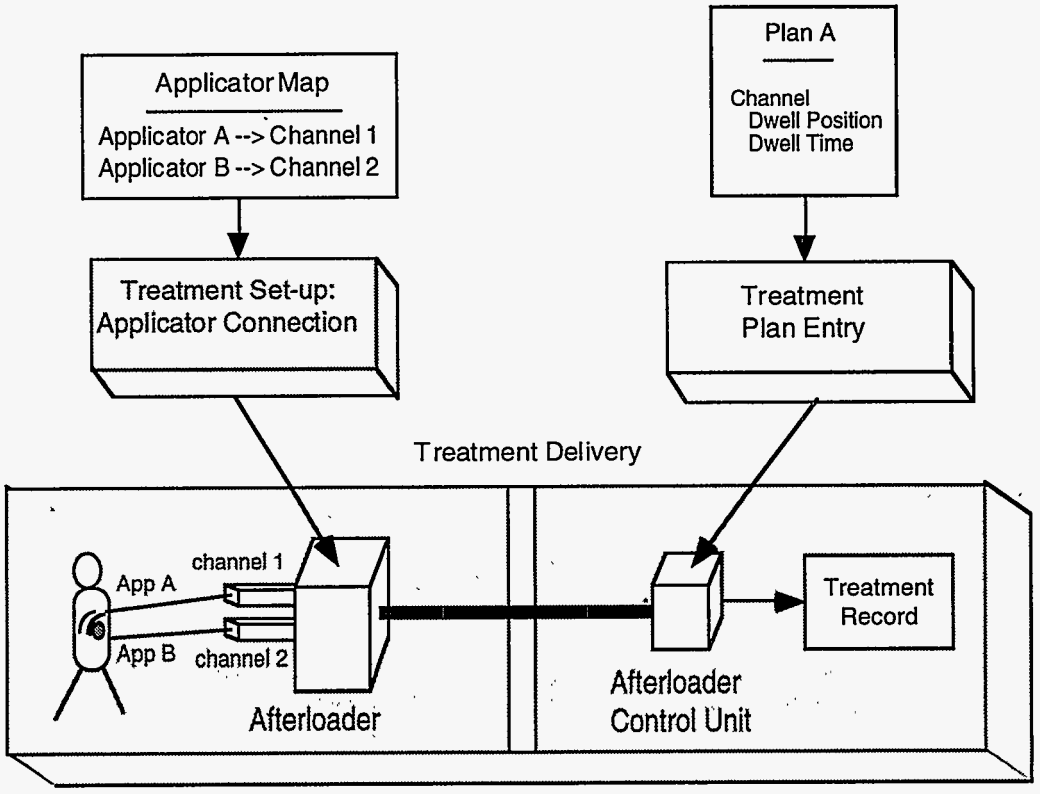


Figure 17. Treatment delivery based on treatment plan

Target volume localization and dosimetry were selected as the most critical treatment planning tasks, and source calibration as the most critical QA and maintenance task. The experts were particularly concerned about potential "systemic" errors in software, device maintenance and source calibration since they felt that such systemic errors could endanger all the patients treated in the interval between the occurrence of the error and its detection.

3.6.4 Comparison of Expert and Model-Based Assessments

The results from the conceptual model were compared with the results from the expert assessment presented in Section 3.6.1. Although there was general agreement on the tasks with significant error consequences, there were some interesting differences between the assessments of the experts and the model results. The model identified more potential errors and more ways in which these errors could contribute to undesirable outcomes, while the experts tended to focus on a representative or familiar path with fewer possible branches. The most significant difference was that the original conceptual model did not indicate that source exchange would be a likely cause of significant error for RAB staff. Since most HDR source exchanges were performed by the manufacturer, RAB staff often did not participate in this task. If an error was made during source exchange, the model suggested that the error would probably be detected during calibration or QA before its consequences could propagate. The experts pointed out that source exchange posed a serious hazard to the staff and patient whether or not any errors were later corrected since any source exchange failure was likely to require human intervention and exposure. They also advised against making any distinction between RAB staff and manufacturer staff when the source exchange occurred at the RAB site. The conceptual model was amended to incorporate these changes. Appendix A includes these modifications and an expanded analysis of errors related to source exchange.

3.6.5 Error Frequency Estimates

Since there were about 135 RAB installations in the United States at the beginning of this study, the four documented misadministrations in that year (U.S. Nuclear Regulatory Commission, NUREG-1272, 1990) correspond to a misadministration rate per site of 4/135 = 3 percent. Thus 3

Table 16. RAB Process Errors

Function/Task	Step	Human Error	Type of Error
Patient Preparation			
Patient scheduling	Schedule RAB treatment	Data entry error	Task performance
Patient identification	Identify patient	Patient misidentified	Task performance
Patient tracking	Route patient according to schedule	Patient routing error	Task linkage
Patient instruction	Instruct patient	Failure to instruct patient	Task performance
Life support	Attach equipment	Attachment error	Task performance
Applicator placement	Locate tumor	Tumor location misidentified	Task performance
	Select applicator	Inappropriate applicator selected	Task performance
	Place applicator	Applicator not placed near tumor	Task performance
	Secure applicator	Applicator inadequately secured	Task performance
	Affix channel connector	Connector incompletely connected	Task performance
Record-keeping	Label applicators	Applicator mislabeled	Task linkage
	Record applicator diameters	Recorded incorrectly	Task linkage
	Record applicator lengths	Recorded incorrectly	Task linkage
Patient transportation	Move patient to next area	Applicator dislodged	Task linkage
Treatment Planning			
Simulation with dummy sources	Place dummy sources in applicator	Dummy string forced into applicator	Task performance
	Place dummy sources in applicator	Dummy string not completely inserted	Task performance
	Place dummy sources in applicator	Dummy string of insufficient length	Task performance
	Secure dummy string after insertion	Dummy string not secured	Task performance
	Record dummy string in each applicator	Recorded incorrectly	Task linkage
	Record original dummy spacing	Dummy spacing misidentified	Task linkage
	Position patient for simulation view	Patient positioned incorrectly	Task performance
	Position patient for simulation view	Applicator moved	Task performance
	Position patient for simulation view	Dummy moved	Task performance
	Expose simulation image	Image exposed incorrectly	Task performance
	Record view angle and magnification	Recorded incorrectly	Task linkage
	Label simulation images	Patient misidentified	Task linkage
	Label simulation images	Treatment fraction misidentified	Task linkage
	Label simulation images	AP and lateral views mislabeled	Task linkage
	Transport simulation results	Wrong images transferred	Task linkage
Patient transportation	Transport patient to treatment area	Applicator moved	Task linkage
Target volume localization	Identify radiation targets	Target misidentified	Task performance
Radiation prescription	Specify dose for each target	Target doses miscalculated	Task performance
	Transfer treatment directive to planner	Communication error	Task linkage
Dwell pos'n localization	Identify dwell positions	Dwell positions misidentified	Task performance
Dosimetry	Choose dwell times	Inappropriate dwell time chosen	Task performance
Dosimetry	Calculate target doses	Doses calculated incorrectly	Task performance
Treatment plan selection	Select a plan	Inappropriate plan selected	Task performance
Treatment plan selection	Transfer plan to afterloader control unit	Wrong plan transferred	Task linkage
Treatment Delivery			
Treatment set-up	Position patient for treatment	Applicator moved	Task performance
	Position patient for treatment	Patient poorly positioned	Task performance
	Connect applicators to afterloader	Applicator moved	Task performance
	Connect applicators to afterloader	Applicator connected to wrong treatment channel	Task linkage
	Connect applicators to afterloader	Applicator connected with wrong guide tube	Task performance
	Connect applicators to afterloader	Applicator not connected properly	Task performance
Treatment plan entry	Enter treatment plan	Data entry error	Task linkage
Treatment monitoring	Monitor treatment session	Failure to detect system failure	Task performance
Treatment control	Start treatment	Treatment begun before setup completed	Task linkage
	Start treatment	Failure to clear room prior to treatment	Task performance
	Control treatment session	Failure to take appropriate action	Task performance
	Interrupt treatment	Treatment interrupted unnecessarily	Task performance
	Conclude treatment	Room entered while source is exposed	Task performance
Post-Treatment			
SGT disconnection	Disconnect applicators from afterloader	Entry procedures not followed	Task performance
	Disconnect applicators from afterloader	Failure to notice applicator movement	Task performance
Patient transportation	Move patient to recovery area	Damage/dislodge applicator	Task performance
Applicator removal	Remove applicators	Damage applicators	Task performance
Record-keeping	Record treatment parameters	Failure to record treatment data	Task linkage
	Document administration of treatment fraction	Treatment fraction recorded incorrectly	Task linkage
	Record treatment fraction for patient	Record treatment fraction for wrong patient	Task linkage
	Store patient treatment records	Lose treatment records	Task linkage

Table 17. Quality Assurance and Maintenance Errors

Function/Task	Step	Human Error	Type of Error
Quality Assurance and Maintenance			
Source exchange	Secure source	Source released or poorly secured	Task performance
	Replace source	Incorrect radionuclide inserted	Task performance
Source calibration	Measure source activity	Measurement or calculation error	Task performance
	Transfer calibration	Data entry error	Task linkage
Software updates	Change software	Software error introduced	Task performance
		Software changes not specified	Task linkage
		User interface changed	Task linkage
Routine quality assurance	Equipment & safety check	Failure to perform QA procedure	Task performance
		Failure to recognize QA problem	Task performance
		Failure to record QA problem	Task linkage
		Failure to report QA problem	Task linkage
		QA certification error	Task linkage
		Failure to record QA performance	Task linkage
		Source exposed in occupied room	Task performance
	Hardware maintenance	Maintenance performance error	Task performance
	Hardware modification	Hardware modification not tested	Task performance
		User interface changed	Task linkage

percent of the RAB sites reported misadministrations in 1990.

The number of RAB treatments performed in 1990 can be estimated by extrapolating the mean of 177 treatments per site observed in this study (1991) to the 135 reported RAB sites in 1990, and adjusting for the reported rate of increase from the sites of about 32 treatments per site per year. Using this formula: [sites]* [treatments/site/year] = treatments/year, produces the estimate that 19,575 RAB treatments were administered in 1990.

Four misadministrations in 19,575 treatments corresponds to a misadministration rate per treatment of 0.02 percent. Thus, approximately 0.02 percent of RAB treatments resulted in reported misadministrations in 1990.

Error checking and correction by RAB staff was observed at each facility visited. In addition, every medical facility visited in this study reported that errors were regularly caught and corrected by their error detection and performance verification procedures. These data suggest that the error rate per site may be substantially higher than the reported misadministration rate. A high rate of errors is not inconsistent with the low rate of misadministrations that have been reported in RAB. For example:

- Some errors may never be detected.
- Some errors may be detected and corrected before a misadministration occurs.
- Some errors may not produce enough difference from the prescribed dose for a treatment to be labeled a misadministration.
- Some errors may produce dosages which exceed the misadministration criteria for a single treatment but do not exceed the total dose prescribed for a series of treatment fractions. Under reporting rules in place at the time of our medical site visits, a dosage error on a single fraction that could be compensated for in subsequent fractions need not be reported.

A higher rate of errors than misadministrations is desirable, but does not provide a reliable index of system safety. Each error which has not yet resulted in a misadministration might do so in the future under slightly different circumstances. The only real difference in many cases may be in the magnitude of the error's consequences (e.g., an error in data input involving transposition of a "1" and a "2" might have greater consequences in the first digit of a number than in the last and might not have the same consequences as transposing a "1" and a "9"). In order to reduce the potential for undesirable consequences, the underlying errors must be addressed regardless of whether any particular instance of an error led to a misadministration.

Table 18. Critical Tasks and Linkages*

Critical Tasks and Linkages	Current Detectability	Problem/Error Frequency	Consequence
Patient Preparation			
Patient scheduling, identification, & tracking[1]	Current/Augmented	Once in a while	Recordable event
Applicator placement and stabilization	Current/Undetectable[2]	Once in a while	Concern/Recordable[3]
Treatment Planning[4]			
Target volume localization	Undetectable	Rare	Staff Concern
Dwell position localization[5]	Undetectable	Frequent	Concern/Recordable
Dosimetry[6]	Undetectable	Once in a while	Concern/Recordable
Treatment Delivery[7]			
Treatment set-up[8]	Undetectable	Frequent	Concern/Recordable
Treatment plan entry	Current capability[9]	Occasional/Frequent	Concern/Recordable
Post-Treatment			
No Critical Tasks			
Quality Assurance and Maintenance			
Source exchange	Current capability	Rare	Recordable event
Source calibration[10]	Current capability	Rare	Recordable event
Routine quality assurance[11]			

* Tables 16 and 17 describe the individual errors involved in each task or linkage in greater detail

1 Although "treating the wrong patient" is classically a problem in nuclear medicine, identification errors were considered to be less likely in RAB because of the intrusive medical procedure involved. This identification advantage for RAB is offset if the RAB team often does not see the patient beforehand, and the RAB patient does not have a wrist band or other hospital identification.

2 Problems in applicator placement are detectable with current technology; problems in applicator stabilization are largely undetectable.

3 Consequence depends on the site treated and on the degree of applicator movement.

4 Comments on the other Treatment Planning tasks: making sure that the prescription is understood is a linkage task that influences all the other tasks; problem with simulation include difficulties in determining the magnification factor from the images and the difficulty of interpreting sub-optimal x-ray films.

5 Second most critical of the Treatment Planning tasks. Mistakes in the magnification factor are influential here.

6 Tied for most critical of the Treatment Planning tasks. Also includes dose optimization.

7 Note that if there is an emergency stop of the GM 2i treatment, it is very complex (and error prone) to reprogram for a restart.

8 This primarily includes hooking applicators to the wrong treatment channels.

9 This is considered a high frequency error of major consequence, so there are usually steps in place to catch errors.

10 A systematic error endangering multiple patients is possible if the source strength is not properly measured and recorded after source exchange.

11 Included as a "critical" task for identifying potential RAB errors and addressing their consequences.

Table 19. Critical Verifications

Function	Verification
Treatment Planning	Verify and approve treatment plan
Treatment Delivery	Verify treatment data prior to treatment

3.6.6 Identification and Evaluation of Alternative Approaches

The final undertaking in Phase 6 was to identify and evaluate alternative approaches to solving safety significant problems in RAB. These approaches were generated by combining and integrating the opinions of the expert panel, the empirical data collected during the site visits, and the predictions of the RAB conceptual model. This process yielded a set of alternative approaches that could be implemented to reduce or eliminate radiation hazards to patients and staff. These alternative approaches are presented in detail in Section 5. These approaches suggested that changes be made in four aspects of RAB systems: equipment and software, job performance aids, procedures, and training. Each intervention was designed so that it would produce one or more of the following effects on RAB systems:

- decrease the likelihood of human error
- increase the detectability of human error
- limit the consequences of human error

Some of these approaches require a significant redesign or modification of various aspects of RAB hardware, software, procedures or training. In view of this fact, alternatives were formulated whenever possible to provide interim improvements in RAB system performance, while the more sophisticated approaches are being developed and implemented.

4 A General Approach to Human Error

A good case can be made that as long as it is possible for humans in a system to make errors, it will also remain a human function to detect and correct the consequences of those errors. A robust system ensures that errors and their consequences will be corrected before they can degrade system performance. A system can be considered robust with regard to human error if the consequences of a human error either cannot effect system performance, or will be detected and corrected by the system or its users before the output of the system is degraded.

Errors which are not detected cannot be corrected, except by chance, before their consequences affect other parts of the system. Error detection requires redundant information. A suspect result must be compared with something else before a difference can be detected. Correction of the consequences of an error requires even more information, since a difference between two values does not indicate which is correct.

The previous sections described human errors that are likely to occur in RAB. They also introduced a conceptual model of the RAB treatment delivery process that can be used to track how errors occur, and the paths by which their consequences can propagate through an RAB system. The results of that model were then used to described and prioritize the performance and safety consequences of those errors. Identification of the critical tasks and the paths by which the consequences of error in those tasks propagate through a system is an essential step in reducing the consequences of error. Once potential errors on critical tasks are identified, steps can be taken to

- decrease the likelihood of human error
- increase the detectability of human error
- limit the consequences of errors which do propagate through the system
- improve the error prevention and detection capabilities of quality assurance procedures

4.1 Decrease the Likelihood of Human Error

Human factors analysis attempts to identify the root causes of human error so that the factors leading to the error can be removed or reduced. Changes in the human-systems interface, procedures, training, or organizational practices and policies can be used to modify the influence of the factors contributing to an error so that the likelihood of that error is reduced. Sometimes, when machines can perform a task more reliably than humans, human error can be avoided by reallocating that task to a machine.

4.2 Increase the Detectability of Human Error

Although the likelihood of human error can be reduced by good system design, it is unreasonable to expect that all such error will be eliminated in a complex system. The ease with which errors are detected and the delay between occurrence and detection determine the effect that errors will have on system performance. An ideal system would be one in which errors are difficult to commit, easy to detect, and which was robust enough to allow recovery from errors after they had been detected. Unfortunately, human errors in many systems are difficult to detect. Thus, major safety gains can be expected from an increase in error detectability. Changes in the human-system interfaces, procedures, training, or organizational practices and policies can increase the chance of detecting errors.

4.2.1 Improve the Timing of Error Detection

If errors in task performance can be detected as the task performer completes a step of the task, the error can often be corrected at that time before it affects system performance. Immediate error detection requires three things:

(1) feedback from the system on the results of the latest step

(2) the expected result of the step

(3) a method to compare the system feedback with the expected result

Temporal contiguity with task performance is desirable since an error detected long after a task is completed may require many other tasks, each with its own sequence of steps, to be examined before the locus of the error can be identified. Just as the cost of error correction may rise as detection time increases, the number of things which can be corrected may be reduced. Immediate detection may allow the error itself to be corrected and system performance to continue with no degradation. Less prompt detection may permit damage control to mitigate error consequences. Late detection may only allow correction for future operations or, in the worst case, no correction at all.

4.2.2 Improve the Allocation of Error Detection Tasks

If task performers are already burdened to the point that performance errors are likely, the addition of error detection tasks to their workload will increase the potential for performance decrement. Ideally, errors should be

obvious to task performers with little or no additional effort expended in error detection. The additional effort can be reduced by providing procedures and training that facilitate error detection, or by allocating the detection of errors to other staff and accepting the staffing, communication and delay problems inherent in multi-person procedures. The burden on task performers can be substantially reduced if hardware and software are allocated the function of detecting task performance errors as they occur and providing timely feedback. The burden cannot be eliminated unless the equipment has some way other than user input to acquire the additional information used in error detection.

4.3 Limit the Consequences of Human Error

Detection of an error does not of itself guarantee that the error will be corrected or that its consequences will be limited. The consequences of an error depend on when the error is detected, and on what can be done to correct the error and block its effects.

4.3.1 Prevent the Propagation of the Consequences of the Error

If task performance or linkage errors can be detected before the consequences propagate to another part of the system, degradation of system performance can be limited or prevented. In many cases, a task or linkage can be repeated with only minimal effect on system performance and safety.

4.3.2 Damage Control After an Error is Detected

Errors which remain undetected make no immediate demands on the system, although they may have undesirable consequences and degrade system performance. Once an error is detected, degradation of system performance can be limited by correcting the error and taking actions to reverse its consequences. Damage control after an error is detected places an additional burden on staff since it requires that any propagating consequences of the error be identified and prevented from compromising other parts of the system.

4.4 Quality Assurance

One aspect of quality assurance involves additional procedures that are performed to prevent errors, to detect errors and their consequences, and to prevent those consequences from degrading system performance. A multi-tiered QA program involves steps designed to accomplish these goals sequentially so that each possible error is defined, then steps are designed to prevent as many errors as possible, other steps are designed to detect any errors which were not prevented, and further steps are designed to deal with the consequences of errors after they have been detected.

In systems in which tasks are performed sequentially, an event-oriented damage control procedure can be used to address error consequences. In such a QA system, the task containing an error is first identified, and then that task and all subsequent tasks in the sequence are repeated. Thus, in an event-based QA system in which an error is identified in the third of five sequential tasks, the output of the system can be corrected by repeating the third, fourth and fifth tasks. An alternative damage control procedure involves detecting the consequences of an error in subsequent tasks, and then using knowledge of the system to determine additional steps that can be performed to compensate for the effect of the error on the system. If some steps in the process are not reversible, as is the case after a radiation treatment has been delivered, the effects of an error may not be correctable, although steps may still be taken to limit the consequences of the error.

The following section describes alternatives to current practice in RAB that can be used in such a QA system to address human error in critical RAB tasks. Alternatives for preventing errors, detecting their consequences, and limiting the impact of those consequences will be considered and evaluated for each critical RAB task.

5 Addressing Human Error on Critical RAB Tasks

The error analysis presented in Section 3 identified ten critical tasks in which human error was likely to produce an unintended dose of radiation to the patient or staff. Previous phases of the project determined the contributions of human-systems interfaces, procedures, training and the organizational support of RAB to the root causes of error in those critical tasks.

A good human systems interface for task performance should indicate what the person is expected to do, make it easy to perform the required operations without error, and make it easy to detect and correct any errors which do occur.

Procedures can support a task by showing the proper way to perform each step in the task and by showing how materials and information should be transferred between different tasks. Training can support the task by ensuring that staff acquire the knowledge and skills needed to perform the task.

Organizational support ensures that the workspaces, resources, and equipment needed to support the task are available, that procedures have been designed to perform the tasks, to link them, and to verify task performance, and that staff are adequately trained to carry out those procedures.

In this section, alternative approaches for improving error prevention, error detection, error correction, and damage control in the ten critical tasks are suggested and evaluated. Modifications to current RAB interfaces, procedures, training, and organizational support for each task are considered. The alternatives provide some direction to solve problems in the critical tasks, but do not include the level of detail that would be required for implementation. In many cases, more than one alternative has been suggested for a single problem to allow for interim improvements until more technically challenging but potentially better solutions can be achieved.

Implementation of the alternatives would require coordination with existing procedures and in some cases would require support from RAB equipment manufacturers and software developers.

5.1 Critical Task 1: Patient Scheduling, Identification, and Tracking

This task involves the initial identification of the patient, scheduling the patient's movement through the RAB workspaces, and any transport, tracking and re-identification that is required as the patient and his records move within the RAB system. Errors in these tasks involve scheduling the patient for the wrong treatment, bringing the patient to the wrong treatment area, or delivering an inappropriate treatment to the patient due to misidentification of the patient or his records. (See Table A.1 in Appendix A for more complete error descriptions.)

The initial arrival of the patient in the treatment area is particularly important since identification aids are often attached to the patient and the patient's records at that time. After initial identification of the patient and his records, the staff need a rapid and reliable method to verify that the patient, the patient's records, and the patient's schedule correspond to those required by the current treatment directive.

To facilitate detection of errors, the identification mechanism should be available to all staff who work with the patient or the patient's documents without requiring staff to use complicated identification procedures.

5.1.1 Evaluation of Current Techniques

Patient wrist bands with patient identification codes are used to identify patients in many hospitals. Hospital identification bands have the advantage that they are difficult to remove or exchange, and use codes that can be compared with documents and scheduled procedures after transport. Since HDR RAB is often performed as an outpatient procedure, wrist bands are not currently placed on all RAB patients. Wrist band ID codes are usually a series of digits that facilitate computer identification of patient records, but are difficult for people to differentiate or recall. This difficulty can lead to errors in transcription and the need for time-consuming comparisons to match a patient's wristband code with records and scheduling information.

Some outpatient clinics require the patient to carry a magnetic card with identification information on it. This information can be read by a computer and compared with records and scheduling information entered at each workstation. The magnetic card eliminates problems that humans may have in identifying and transcribing strings of numbers. Unfortunately, cards can also increase the potential for other errors since each card is identical and differences between cards can be more difficult to determine than differences between patients.

Photographs of the patient were added to the records carried by the patient during RAB at some visited sites. These photographs had the advantage of allowing records to be visually matched to a patient without disturbing the

patient or requiring that written records be searched for identification codes. Photographs work particularly well when their images are large enough so that identification can be made at a glance. They are limited by their image quality, changes in patients' appearance over time, and the similarity in age, appearance, and attire of RAB patients at many sites. Photographs are also more easily dropped or switched than wrist bands and cannot be easily compared to printed identification codes on treatment records.

Patients at most of the RAB sites had made multiple visits to the site for treatment and were known to their physician and the RAB staff. This limited the opportunity for identification errors and provided a source of information (i.e., staff memory) for verifying identifications. Recall of the patient's name and previous treatments was also used by staff at many sites instead of identification codes as the redundant information needed to verify that documents transported with the patient were appropriate. These recognition methods served to limit, but not eliminate the opportunity for error in these tasks. They enabled errors in which patients with similar names or similar treatment histories might be confused. Tracking patients and documents using memorized information introduces an opportunity for old memory patterns to replace or modify recently stored items.

Some sites allocate a single staff member to accompany and track the patient during treatment so that the only opportunity for misidentification occurs when the patient initially arrives. This method does not address the problem of matching the patient to schedules and records and is not effective when records and the patient are separated.

5.1.2 Alternatives to Current Techniques

Approaches that could be used to reduce the potential for error in this critical task include provision of job performance aids, redesign of identification and linkage procedures, and additional staff training.

Since the patient may not be awake when a transfer or treatment takes place, the identification procedures must work without interaction between the patient and the staff. Since patients and their records can be separated, identification procedures must be able to match patients to their records.

Identification errors can be made whenever a staff member initiates or resumes contact with a patient, uses or modifies the patient's records, or passes control of the patient or his records to someone else.

Equipment and Software Modifications

Some of the burden on staff performing this task could be relieved by automating part of the identification and tracking process. If the patient and all patient records were automatically marked with identification information that could be read and verified by the planning and afterloading equipment, each step in the tracking process could then be verified automatically by software as the patient or documents arrived at each RAB workstation.

Job Performance Aids

Highly visible tags that identify the patient and his records could assist staff in determining whether the patient is the person for whom the treatment was scheduled, whether the records are for that patient and treatment fraction, and whether the patient has been transferred to the proper place.

Procedures

Task locating procedures could be modified to combine the workspaces for different RAB tasks. This would reduce the movement of the patient from one area to another and limit the subsequent number of identifications performed. Limiting the transport of the patient and the patient's records would reduce the likelihood of scheduling errors and limit the opportunities for misidentification after transport.

Task allocation procedures could also be modified to limit the number of different staff that take responsibility for the patient and records during the RAB process. Since the patient's identity is transferred each time responsibility for the patient or his records is passed between staff members, the number of possible identification errors could be reduced by limiting the number of these transfers.

Tagging procedures can be designed so that tags are applied to patients and patient records on entry to the treatment area and whenever a subsequent record is generated. Procedures can be designed to require these tags to be placed and compared before any records are separated from each other or from the patient.

Communication procedures can be designed to ensure that enough information is transmitted with the patient and with treatment documents to allow their identities and their suitability for the scheduled treatment to be verified.

Verification procedures can be designed to use that information to check for identification and transport errors in during RAB.

Training

Training staff in identification methods can reduce the incidence of errors related to patient identification and tracking. Training staff to recognize error opportunities and to use specific identification procedures to resolve scheduling and tracking ambiguities is a viable alternative in some situations.

5.1.3 Evaluation of the Alternatives

There is an opportunity for human error each time an RAB treatment procedure is scheduled or whenever patients and their records are transferred between RAB workspaces. Identification errors can also occur whenever patient records are created or when responsibility for the patient or the patient's records is passed between staff members during RAB.

Different identification information, and formats are often used for marking schedules, records, x-rays, and the patient during treatment. Current identification and tracking practices often involve searching the patient's records for identification numbers or repeatedly asking the patient for personal identifying information. These practices add substantially to the burden on the staff, are likely to increase the time needed to perform the treatment, and may cause some patients to wonder why the staff can neither remember them nor determine why they are there.

Decreasing the Likelihood of Human Error

Automatic tagging of patient records could be used to standardize the format of identification marks placed on patient records. Automatic tag reading would reduce the opportunity for human misidentification. Effective use of equipment with tagging and reading capability to eliminate human error in this task would require coordination between manufacturers of equipment used to make and read tags at different RAB workstations. Sites would also need to purchase new equipment with tagging and tag identification capabilities before automatic tagging could be used. Tagging standards would allow manufacturers to address these problems and coordinate their equipment development so that automatic tagging could be provided on new equipment models.

Until standards for automatic tagging are developed, and equipment offering automatic tagging and tag reading is coordinated, procedures and job performance aids for manual tagging can be used to reduce the opportunity for human error in scheduling and tracking patients and their records. In either an automatic or a manual tagging system, each patient would be tagged with an identifier upon arrival for treatment, and each document generated or received during treatment would be tagged with a corresponding identifier. Prominent tags on patients and patient records would reduce the burden on staff trying to identify records and match them with particular patients or treatment directives. Although tags could reduce the likelihood of errors in identifying the patient and the patient's records, four new errors would still be possible if tags were used in this task:

(1) the patient might be mis-tagged

(2) records might be mis-tagged

(3) tags might be misidentified

(4) properly tagged patients might be scheduled for the wrong treatment or delivered to the wrong workstations

Training in tagging procedures and in procedures for scheduling and tracking using tags could be used to reduce the incidence of these errors.

Since an opportunity for error occurs each time the patient or a patient record is transported, the alternative of combining workspaces and staff for different RAB tasks to reduce transport and limit the number of resulting identifications would also decrease the likelihood of error. This alternative cannot eliminate all chance of error since some transport and initial identification would still be required.

Increasing the Detectability of Human Error

Tags can be used to detect transport errors by comparing the tags on documents and patients arriving at a workstation. Scheduling errors cannot be detected from tags alone, since both the patient and the schedule may have the same tags on arrival at a workstation.

To detect mis-tagging, another identifier must be available to compare to the tag. Job performance aids can be used to provide these alternate identifiers. Matched ID tags can be attached to the patient and each record or form that is used for a particular treatment fraction. Treatment fractions might be indicated by tags with different color codes. This would help prevent documents from a previous treatment fraction from being confused with those used in subsequent treatment fractions. To facilitate detection of errors, the tags should be large enough to be seen from a distance of several feet and placed so that they are visible at a glance so that they can be matched at each error opportunity.

The burden placed on the staff for performing these comparisons can be limited substantially by making the tags visible and distinguishable at a glance without searching the patient or the patient's documents for

matching codes. Tags that identify patients and their treatment fraction can reduce this burden by allowing anyone at the site to identify them without interacting with the patient or searching for identification codes. To accomplish this, the tags must be placed prominently on the patient and on all patient documents used or modified during RAB.

Tags also make it possible to detect a previous identification or tracking error since the tag on the patient can be compared with the tags on the treatment directive, treatment plan, and treatment schedule. The likelihood of detecting these errors can be substantially increased if the tags allow errors to be detected by all staff at any time rather than by specified individuals at times when they may be too engrossed in their duties to notice that an error has occurred.

Verification procedures are particularly important during initial identification and scheduling since tags would be placed at that time.

Tagging of patients and their records could also be used when software is used in the identification process. Software could be designed to tag all stored or entered records with a unique patient ID and treatment fraction. The software could then compare the tags on its stored records to verify that they matched. The records could also be matched to the patient if the software could read the patient's identification tag.

Limiting the Consequences of Human Error

The consequences to the patient of an identification error depend on how far treatment has progressed between the time the error was made and it is detected. The primary method for limiting the consequences of an error is therefore to detect the error and correct it as early in the RAB process as possible. Any consequences of the error that may have propagated beyond the point at which the error was made must then be identified and addressed.

One way to detect tagging errors early in RAB would be to assign someone to verify the initial tagging of the patient and all tagged documents.

Another approach would be to design procedures that require verification of patient identity each time a staff member initiates or resumes contact with a patient, uses the patient's records, or passes control of the patient or records to someone else.

Many RAB errors can be corrected if they are detected prior to treatment delivery. An alternative to early error detection might be to perform all verifications just prior to treatment delivery. This method can either substitute for early detection or can be used as a final step to detect identification or scheduling errors before they produce unrecoverable consequences. If this alternative is used, correction procedures must be designed to deal with each possible consequence of an error in scheduling, identifying, or tracking a patient.

Identification procedures can be time consuming since re-identification must be performed each time that documents or patients are transported. Refresher training in identification procedures might be useful for staff who may be tempted to accelerate the identification process by bridging gaps in documentation with unverified assumptions.

> Example: A staff member who refers to a document from a previous treatment fraction may not recognize that it might be mistaken for a current document by another task performer. Documents that are in a workstation during treatment are often assumed to belong to the current patient. It requires training to overcome this assumption, to recognize error opportunities, and to re-identify and re-label documents whenever a possibility of error has occurred.

The alternative of providing suitable tags and the training and time needed to use them can provide the basis for a continuing support program for this important error detection activity. Since these tags would carry the results of the initial patient identification to subsequent tasks, the burden on staff to re-identify at each transfer would be reduced. Presentation of the prior identification results in a prominent tag would transform many opportunities for identification and tracking error into opportunities for detecting and correcting scheduling or transport problems.

5.2 Critical Task 2: Applicator Placement and Stabilization

These tasks require that applicators be selected, placed near a target in the body, and secured to prevent movement after placement. Information on the characteristics of the applicator (e.g., diameter, length) and applicator placement must be transmitted to the treatment planners and to the staff performing applicator connections.

Errors in these tasks involve failure to select the appropriate applicator for the intended target, failure to place the applicator near the tumor, failure to secure the applicator to prevent its movement after placement, or failure to transfer accurate information about the placement to other task performers. See Table A.2 in Appendix A for a more detailed error description.

5.2.1 Evaluation of Current Techniques

Since applicator selection, placement, and stabilization are medical procedures performed by physicians, the procedures used to perform this task were not part of this study. However, some of the aids used in performing the task were identified and are described below. The position of the applicator relative to radiation targets is crucial to treatment planning and most sites had developed procedures for checking that the placement was close to the tumor or methods for determining whether the applicator had moved since it was placed. These performance verification procedures, and the linkage procedures used to transfer placement information, whether performed by physicians or other RAB staff are discussed below.

Applicator Selection

The selection of an appropriate applicator for a given target requires knowledge of the dose distribution characteristics of different applicators in relation to the target volume. One consequence of selecting an inappropriate applicator is that shaping the dose distribution to cover the target may prove difficult. This error can have notable consequences for the patient, as when too high a dose is delivered to a region outside the target volume.

Applicator selection requires that discriminations be made among applicator shapes and sizes. These discriminations can be difficult when an applicator is selected from among several similar applicators that are used for the same type of treatment.

Applicator Placement Interfaces and Aids

The interfaces available for applicator placement varied depending on the applicators used and the sites in which they were placed. Since the object of this task is to place the applicator near the tumor and to secure it so that it remains in place until treatment is completed, the task involves both visualization and feedback on the location and the security of the placement. In some cases placement was performed surgically using direct visual feedback of the relationship between the applicator and the target. In others, fluoroscopic or other two dimensional representations of applicator position were used. Needles were placed using guide frames or by successive approximations with fluoroscopic or CAT scans. The primary problems observed in placement involved lack of feedback on the distance between the applicator and its target and the mental calculation needed to translate two-dimensional images of applicator and target positions (from fluoroscopy, x-rays or CAT scans) into three-dimensional spatial relationships. These problems were increased when the target was not visible on the same images as the applicator so that two sets of images, one of the target and the other of the applicator, were used. These independent images often used different scales and view angles for the target and the applicator.

Applicator Stabilization

Each type of applicator has different stabilization requirements. Lung catheters placed in the patient's airway may move each time the patient breathes or coughs. Other applicators may move when the patient changes position or uses certain muscles. Applicators that are placed using positioning racks usually have good stabilization interfaces, while unsupported needles and lung catheters often have none. A design for a lung catheter, with stabilization prongs to hold it in position after it was placed, was in use at one site.

The optimum stabilization interface for this task depends on who performs the stabilization, the method used to stabilize the applicator, and when the stabilization is performed. Since applicator placement is usually a medical procedure and therefore not within the scope of this study, stabilization procedures using surgical and other tissue-damaging methods were not evaluated. The need to detect and address the consequences of applicator movement (whether or not it is due to improper stabilization) remains an important part of the RAB process.

Error Detection and Correction Procedures

To detect errors in selecting, placing, and stabilizing an applicator after placement, information on the intended characteristics and position must be preserved so that it can be compared with later measurements. Interfaces therefore include the original applicator specifications and any tags, labels, and location devices used to determine an applicator's position and characteristics. These interfaces often offered inadequate support to the people performing the verifications.

Worksheets were used to carry placement information to other task performers at some sites. Other sites relied on verbal communications to transfer placement information. Either method can transfer the information needed for planning an RAB treatment although only the first allows independent verification of communication after the information has been transferred.

Mechanical methods for detecting applicator movement were often used. These usually entailed marking the position of the applicators with respect to some reference point on the patient at the time of placement. Tape was often used to indicate movement of applicators in lung treatments. These mechanical aids were used to verify

whether the applicator had been partially expelled or pulled from the lung prior to treatment, but did not allow movement of the applicators within the body in relation to the targets to be detected.

Placement errors and movement can be detected by simulation if the target and applicators can be identified on the simulation images. At many sites simulation images showing the applicators and some patient body structures were used to verify placement of the applicators prior to treatment. These views did not always have enough information to verify the applicator characteristics, target position, or stabilization. They often did not show the radiation targets, so no verification of the position of the applicators in relation to the targets could be performed.

Some sites accomplished the transfer of applicator characteristics to the simulation images by placing coded radio-opaque identification dots on each applicator. Some sites also tagged the targets with radio-opaque material prior to simulation so that both the targets and the applicators could be seen in the simulation views. Such tagging can be a useful aid in verifying applicator placement, but must be subject to clinical evaluation of its consequences to the patient and its relevance to the treatment procedure.

Applicator placement is a good example of an activity in which organizational decisions must be made to balance speed, efficiency, safety, and training. At some sites, distances between targets and applicators were measured by the physicians during placement, after which radiation doses were specified to the applicators rather than to the targets. This procedure assumed that the placement was stable enough so that the distances would not change appreciably before treatment was completed. At other sites, treatment directives specified the doses to be delivered to specific targets in the body. In those cases, simulation x-rays were used after placement to measure the distances between the applicators and the targets. This latter ordering of tasks had the advantage that movements of the applicator between placement and simulation could be detected but had the disadvantage that it took more time and introduced the opportunity for simulation or target localization errors. Neither method could detect applicator movement after simulation. This problem was addressed at some sites by performing both the simulation and the treatment in the same room to minimize patient movement between simulation and treatment.

5.2.2 Alternatives to Current Techniques

Selection of an appropriate applicator requires an interface between the applicator and the person doing the placement. Applicator labeling and tracking methods differed at the visited sites and were often insufficient to provide unambiguous selection information at the time of placement.

Alternatives to current techniques for placing and stabilizing applicators involve methods designed to help identify, preserve, and transfer information on applicator characteristics, and methods to detect and compensate for movement of the applicator between placement and treatment.

Equipment and Software Modifications

Applicators could be marked by the manufacturer so that their selection characteristics (e.g., size, diameter, shielding) could be determined easily.

Feedback could be provided during applicator placement by computerized reconstruction of applicator position so that the task performer could measure the distance between an applicator and other body structures as the applicator was being placed.

Many applicators (e.g., lung catheters) appear to be designed for ease of movement through body cavities. This makes them easy to position, but also increases the chance that they will move out of position after placement. Stabilization errors would be less likely if the applicator could be modified to have the opposite movement characteristics after placement so that movement out of the chosen position was more difficult than movement into it. Any such modification should also be reversible to allow the applicator to be removed easily after treatment.

Job Performance Aids

The likelihood of error in the transfer of information on applicator characteristics could be reduced if the applicators were labeled in such a way that their treatment related characteristics (length, diameter, etc.) could be determined easily during task performance. Errors in information transfer could be detected if those characteristics could be determined by either visual inspection after applicator placement or determined from their images in the simulation views.

It is of particular importance that applicator placement, radiation prescription, treatment planning, and applicator hook-up task performers have a common reference for applicators, treatment directives, and treatment channels. Worksheets are one method for applicator placement and stabilization characteristics to be transferred between tasks. An applicator-channel map that could be annotated during placement with the characteristics of each applicator would

provide a common reference for radiation prescription, treatment planning, and treatment setup.

Corresponding marks on the patient and applicator at the entry point of the applicator into the patient's body can be used to detect offsets in the applicator's position after placement. Tape can be placed on the body and on the applicator to standardize and highlight the marks..

Procedures

Although applicator placement and stabilization procedures involve medical expertise that was not part of this study, detection of placement and stabilization error, and procedures for dealing with the consequences of those errors are often performed by RAB staff.

If placement or stabilization errors are detected during applicator placement they can often be corrected before their consequences can affect other tasks. One method for limiting the consequences of stabilization errors (but not placement errors) would be to prevent applicator movement in the interval between the initial measurement of applicator-target distances and the delivery of a treatment based on those distances.

To detect the consequences of placement and stabilization errors on subsequent tasks, information on the applicator's current position, stability, and characteristics must be obtained and compared with their intended values. These needs could be addressed by ensuring that applicator characteristics are known and are preserved after placement. A method for measuring the current characteristics and location of each applicator would also be required.

Stabilization of the applicator with respect to one location in the patients body, or with respect to an external positioning frame, cannot guarantee that the distance between the applicator and the targets will not change. Targets and applicators can often move within the body in response to normal physiological processes (e.g., breathing, coughing, bladder distention, rolling over) that are unrelated to the RAB process. A few sites gathered information on the distance between applicators and targets by placing radio-opaque markers on the targets to make them visible on simulation views. When both the radiation targets and the applicators are radio-opaque, x-ray images of the target area can be used to measure the distances between the applicators and the targets. New images are required to re-measure the distances each time movement is suspected.

The measured applicator-target distances can also be used to generate a new treatment plan based on the actual applicator position after transport.

Training

Training or experience in placement and stabilization techniques is important for this task but falls outside the scope of this study since placement and stabilization are medical procedures and involve medical decisions. Training in those procedures, however, could help RAB staff deal with error consequences by emphasizing that unless the distance between an applicator and the targets is measured after placement, stabilization problems will remain hidden and stabilization performance cannot be improved.

Training in the detection of poorly placed or stabilized applicators and in the prevention of undesirable consequences of these errors would be useful for both physicians and RAB staff.

Consequences of applicator stabilization problems could be limited by training staff to limit their effect on the RAB process. Training in proper transportation procedures to minimize applicator-movement would be particularly useful at sites which transport patients between simulation and treatment. No official training program was found to teach these skills, although individual physicians and physicists were observed to discuss stabilization problems with other RAB staff.

The consequences of applicator movement could be limited by training RAB staff to measure applicator positions after transport and to re-plan the treatment if applicator-target positions have changed.

5.2.3 Evaluation of the Alternatives

Applicator selection, placement, and stabilization are performed early in the RAB process. Because subsequent functions and tasks usually occur in different areas of the medical facility than applicator placement, there is an opportunity for the applicator(s) to shift position as the patient is transported from one location to another. Since applicator position can be determined from visual inspection only in rare instances, the RAB personnel involved in actual treatment delivery are not able to detect any shifts in applicator position. It is thus imperative that the correct applicators be selected, placed, and secured in order for the patient to receive the prescribed radiation dosage.

Decreasing the Likelihood of Human Error

Applicators marked prominently with the characteristics needed in later stages of the RAB process (e.g., size, diameter, shielding) would reduce the likelihood of selecting and placing a different applicator than was originally intended. Since most applicators are hidden after placement, such labeling would not prevent errors in communication of those characteristics unless procedures were designed so that the information in the labels was recorded during the placement task. The likelihood of a transcription error during placement could be decreased if the information on the labels were not hidden after placement and could be accessed and verified at the end of the task when there might be more time available for reading the information and staff would be more likely to have their hands free to record the values.

Transfer of information on applicator characteristics is also subject to error that could be limited by the use of formalized information transfer procedures and job performance aids. A single worksheet used to carry this information between the tasks would eliminate the possibility that conflicting information would be used by different task performers.

Performance could be improved in the placement task if some method were devised to provide three-dimensional views of applicator and target position or if a method was devised to provide continual feedback on the distances between points on the applicator and target locations as each applicator is being placed. Feedback interfaces that allow measurement of the distance between an applicator and other body structures (e.g., CAT scans) are currently expensive and time consuming.

Stabilization performance could be improved if applicators were easier to stabilize and if performance feedback were provided on the position and stability of applicators during placement. Applicators with different stabilization characteristics during placement and removal (when they should be easy to position) than during treatment planning and treatment (when they should be difficult to move) would be desirable, but would require additional developmental effort. One manufacturer produces a lung applicator that can be modified after placement by extending prongs to keep it in position. Some sites used positioning racks and sutures to improve applicator stability. Use of such invasive stabilization methods involves clinical decisions that are outside the scope of this study.

The current lack of a generally suitable method for ensuring stabilization or detecting stabilization errors means that many changes in the distance between the applicators and the radiation targets during the RAB process will neither be detected nor corrected.

Increasing the Detectability of Human Error

Improved methods for applicator stabilization would reduce the incidence of applicator position changes but would not eliminate all stabilization problems. Detection of stabilization errors requires that some index of stability be derived and applied to the applicators and targets after placement. Until such an index is derived, stabilization problems must be identified by their consequences. This involves detection of the movement of the applicator in relation to the targets. When treatment and simulation workspaces are separated, additional transport increases the opportunity for these applicator-target position changes. A final movement check that measured the distance between the applicators and the targets just prior to treatment would be desirable to detect these position changes.

Tape used to mark applicator exit positions in lung treatments can help identify an applicator which has been moved in or out of the lung past the tape. Since external marks may not detect movement that takes place inside the body, this method does not indicate position changes within the lung that might occur when a patient coughs.

X-ray or CAT images of the treatment area are currently the only means available to measure the distances between applicators and targets. A less cumbersome process than simulation images for determining applicator-target distances in HDR treatments would be welcome, since current imaging and calculation procedures using treatment planning equipment are quite time consuming. These limitations are less severe in LDR treatments since treatment times are long in LDR and the actual source positions can be imaged during treatment.

Worksheets produced during applicator placement can be used to transfer applicator information to Planning and Setup tasks. When worksheets are employed to transfer placement information, additional error detection time must be spent by staff to determine that no transcription or substitution errors have been made in recording and using the worksheet information.

Limiting the Consequences of Human Error

Until applicator movement can be detected more easily, redesign of workspaces to minimize the need for transport, and training in transport and simulation procedures that minimize motion of the applicator in relation to the targets, can help prevent the consequences of poor stabilization.

X-ray simulation is currently the only way available at most HDR sites to measure the position of the applicator inside the body. Simulation used to detect placement or stabilization errors can also be used to compensate for their consequences if a new treatment plan can be generated using the actual positions of the applicator and the targets.

Since simulation is currently a time-consuming task, simulations are rarely performed to detect errors after treatment planning is completed. The alternative of re-simulating just prior to treatment is a viable, albeit time-consuming, option whenever movement or measurement errors are suspected. The value of this alternative is diminished when the patient must be transported back to the treatment area after simulation, since further movement of the applicator or targets may occur during transport.

X-rays of the actual sources during LDR treatments can be used to corroborate planned treatment distances and to correct treatment plans for any applicator movement.

5.3 Critical Task 3: Target Volume Localization

This task involves identification of radiation targets and specification of target positions so that distances between the applicators and the targets can be measured. Radiation targets include structures (e.g., tumors, tissue volumes, etc.) for which a radiation dose is specified as well as structures (e.g., organs, tissue etc.) to which the dose must be limited. Errors in this task involve failure to identify radiation targets or failure to localize the position of those targets relative to the applicators. (Table A.7 in Appendix A considers these errors in more detail.)

5.3.1 Evaluation of Current Techniques

Target volume localization involves merging target information from several different sources (e.g., placement observations, CAT scans, prior clinical evaluations, x-rays) and transferring position information on the targets and the applicators into a single coordinate system so that the target's distance from the applicators can be measured.

Two procedures for target volume localization were observed. In the first, the distance between the target and the applicators is measured during applicator placement. The targets' positions are then defined using the applicators as a reference. This procedure requires accurate measurement of all target locations during placement and assumes that the distances measured between the applicators and the targets will remain within prescription tolerances during the rest of the treatment process. In the second procedure, images of the applicators are projected onto film during simulation after which target positions from other sources are transferred to the film by locating known anatomical points in the simulation view and then drawing an outline of the target, scaled to the magnification and view angle of the simulation, onto the simulation view.

Each procedure is susceptible to different errors and requires different error detection and correction methods. Reference of the dose to the image of a target drawn on simulation views is sensitive to differences between the magnifications and view angles of the simulation and target images. Reference of the dose to a volume around the applicator can be accomplished without simulation images, but depends on accurate measurement of target and applicator positions to define the target volume. Both procedures are sensitive to any changes in the distance between the applicator and the targets that occur prior to treatment. Use of distance measurements from placement without simulation renders target volume localization insensitive to simulation and transformation errors at the expense of making applicator placement errors undetectable. Applicator movement errors may be detected without simulation by noting changes in an applicator's position relative to external anatomical reference points. The consequences of movement cannot be addressed unless the target-applicator distances can be re-measured.

Target localization using simulation images can detect and compensate for placement errors and applicator movement, but enables errors in translating the target locations to the scale and view angle of the simulation images.

Neither procedure protects against applicator movement between simulation and treatment, although the second provides a baseline against which subsequent simulations could be compared to detect such movement. Interfaces for performing this translation are often quite primitive with no provision for performance feedback or detection of translation errors. Some sites addressed these problems by placing radio-opaque markers in the targets to make them visible on the simulation images.

5.3.2 Alternatives to Current Techniques

Accurate projection of a three dimensional object onto two dimensional surfaces is a difficult human task. Target images drawn on simulation views require staff physicians to perform these projections mentally by translating images from target representations into their projections on the simulation views. These difficulties can be addressed by improving equipment, software, job performance aids, procedures, and training.

Equipment and Software Modifications

An alternative for reducing the chance of errors in this task would be to provide a way to transfer images of the targets and applicators to the same coordinate system without requiring a staff member to perform the mental calculations needed to translate and combine different sources of information.

Job Performance Aids

Visualization and calculation aids would help staff translate the different scales and magnifications used in treatment planning into a set of standard parameters prior to performing this task.

Checklists or worksheets would also indicate which translations were required and provide a record of whether those translations had been performed.

Procedures

Methods for recording and specifying magnifications and view angles would standardize each site so that image relationships learned during the course of many treatments would apply without translation to all subsequent treatments.

Simulation images would be used for target localization in all cases in which applicator or target movement is possible after applicators have been placed.

A method that detects applicator movement would allow relative position changes between applicators and targets to be detected without simulation prior to treatment. Corresponding marks on the patient and applicators were used at some sites to detect potential changes in the relative position of the target and applicator at some sites.

Training

A training program designed to improve mental imagery skills would teach image translation and visualization procedures so that staff could evaluate and improve their performance in this difficult task.

5.3.3 Evaluation of the Alternatives

Target volume localization requires that target positions be specified in the same coordinate system as the applicators and dwell positions so that distance can be measured between a source at a dwell position and the radiation target. It is a difficult task since the target information often comes from x-rays or clinical measurements that are not included in the simulation views that define the coordinate system of the source dwell points.

Decreasing the Likelihood of Human Error

Providing target and applicator position information in the same magnifications and view angles would help prevent scaling errors when targets were added to simulation views. Since target information often comes from equipment that is not under control of the RAB staff or the RAB equipment manufacturers (e.g., CAT scanners) this alternative would require either a high degree of coordination between different medical equipment providers or a method for translating diverse images and information into a single coordinate system to be developed. Until equipment and software is designed to perform these translations, task performers will continue to need local methods to translate information from different coordinate systems into a single image.

Visualization aids would help provide a mental image of the target and the applicators, and would be particularly helpful in translating images from different view angles into a geometrically accurate image of the targets. Although an accurate mental image of the geometrical relationship between the applicator and targets is required for the current method of having the task performer draw the target on simulation views, there is currently little feedback provided for the person performing this task to determine whether his mental image is spatially accurate.

Checklists and worksheets would help to standardize procedures and to indicate which translation is appropriate for each information source. Without verification of the translation process, however, they also introduce the opportunity for translations to be applied inappropriately. A training program that provided instruction in translation techniques and feedback on their performance in translating target information into geometrically accurate drawings on simulation images could be used to address this problem.

Marking the target so that it was imaged in the simulation views would eliminate the root cause of many human errors in this task since it would eliminate the need for humans to perform the calculations required to project a target image onto the simulation views. Marking a single point in the target would allow distances between the applicator and that point to be calculated. The entire target volume would have to be marked to preserve the detailed target information that is currently available from other sources (e.g., CAT scans or clinical measurements).

Calibration of target images so that they would be projected automatically onto the simulation views would also reduce

the burden on treatment planners in performing these projections. Marking the target combined with projection of a calibrated target image would provide the redundant information needed to verify target localization.

Increasing the Detectability of Human Error

The problem of target positions changing relative to the applicators after target localization would remain until the distance between the applicators and the target can be measured easily after the initial target localization. Target marking would allow this task to be verified by re-simulation after movement was suspected, but would require clinical judgment on the effect of the markers on the patient.

Limiting the Consequences of Human Error

Errors in target volume localization may result in incorrectly measured distances between the source dwell positions and the radiation targets. Since the treatment plan is based on those distances, the dose delivered during treatment may differ from that in the treatment directive. These consequences are currently undetectable since no method is available to measure the dose delivered to the target during treatment. Redundant information on the target volume and its relation to the dwell positions is needed to correct localization errors and must be preserved after localization to allow verification of the localization task.

5.4 Critical Task 4: Dwell Position Localization

This task involves identification, specification and communication of the positions that sources will occupy in the applicator during treatment. Errors in performing this task involve incorrect identification, specification, or transfer of information on the source positions. (Table A.8 in Appendix A considers these errors in more detail.)

5.4.1 Evaluation of Current Techniques

Potential dwell positions are often identified by radio opaque dummy source strings inserted into the applicators during simulation. They can also be chosen at measured distances from a known reference point (e.g., the distal end) on an applicator. Actual dwell positions are then chosen from the set of potential dwell positions by measuring or recalling distances between the potential positions and the radiation targets. Interfaces involve simulation images or other representations of the applicator and targets. Target localization was considered separately as Critical Task 3.

When strings of dummy sources were used to identify dwell positions, additional interface problems were observed that provided increased opportunity for human error. Different spacing patterns for the dummy sources were used to distinguish between applicators in simulation images. These patterns were often similar and could be repeated if more than a few applicators were used. Labels on these strings were difficult to read due to their size and poor contrast, making identification of individual strings and matching them with applicators a very difficult operation.

Procedures for measuring distances within the applicators involve either identification of dwell positions on simulation images or measurement of offset distances from the reference point on the applicator. Measurement of distances within an applicator using these images usually involve the assumption that the sources in the dummy source strings are separated by fixed distances. Distances within the applicators can then be measured from the simulation images by counting the number of dummy sources between two points. This method is independent of the magnification of the simulation images and the view angles at which they are made. It can fail if dummy source strings that have unexpected source spacings are used or if spacings are not maintained between the dummy sources after insertion.

Feedback on the stabilization of dummy strings in the applicators was not provided. This made errors in which the strings were moved during simulation difficult to detect.

Local practices often addressed these interface problems. They usually involved the application of tape to each dummy string to keep it fixed in place within its applicator during simulation. This practice helped to keep the dummy within the applicator but usually did not ensure that it was fully seated and could not move. Since the tape kept the dummy string in its applicator after simulation, it allowed the correspondence between a particular dummy string and its applicator to be checked during treatment planning to determine which applicators should be connected to each treatment channel. These taping practices sometimes masked the original labels on the strings.

Another method for defining dwell positions within the applicator used distances measured either from the applicator reference point or from simulation images. Distance measurements taken from simulation images are not independent of the magnification and view angle at which those images are made.

Determination of the reference point for dwell position measurements differs depending on the afterloading equipment used. In some models of afterloader, the reference is on the afterloader head at the connection

between the afterloader and the first source guide tube (SGT). In those systems the user must measure the length of all the connecting tubes carefully so that the distance from the afterloader to applicator can be specified for each treatment channel. This distance is then added to the dwell position offsets measured within each applicator to produce the treatment distances. In other afterloaders SGTs are chosen to produce a fixed distance from the afterloader to the end of each applicator. Dwell positions are then measured referenced to the far end of the applicator as the source is pulled back toward the afterloader. Identification of the end of the applicator is required in treatment planning so that these distances can be measured. In some of those systems, a check cable is moved to the end of the applicator prior to treatment to verify that the end of the applicator is at the expected distance from the afterloader.

These procedural differences result in different error possibilities for the two systems. Detection and correction procedures must address errors in measuring the distance between the afterloader and the applicator in one system and errors in identification of the end of the applicator and preservation of the fixed applicator-SGT length in the other. Each system requires verification that dummy source strings have been fully inserted into the applicators so that measurements using the dummy sources can be referenced to the appropriate applicator reference point.

5.4.2 Alternatives to Current Techniques

Primary problems in this task involve the specification of a reference point in the applicator, the measurement of distances within the applicator (the dwell positions), and the translation of these into positioning directives to the afterloader that will cause a source to be placed at each chosen dwell position within the applicator during treatment.

Equipment and Software Modifications

When dummy source strings are used to define dwell positions, performance of this task depends on the placement and measurement of dummy positions within the applicators. The possibility that measured and actual dwell positions might differ could be limited if dummy source strings were easier to place in the applicators, and were less likely to move during patient positioning for simulation. Since it is currently possible to insert a dummy string incompletely, some radio-opaque marking that would allow the insertion distance to be measured after placement would be desirable. This could be achieved by placing radio-opaque marks on the applicators so that the position of the dummy sources in the applicator could be measured after simulation.

Alternatively, calibrated radio-opaque markings could be placed on the applicators themselves during manufacture. If those marks were spaced at regular intervals, they would identify potential source positions within the applicators and could be used instead of dummy sources to identify source dwell positions.

Afterloader units could be modified to detect a fixed point within each applicator during the check cable run. Dwell positions could be referenced to that point if the point could also be identified by treatment planners. This would allow the afterloader to verify that the chosen dwell positions were within the applicator and would allow the position of the source during treatment to be determined and compared to the planned position as a verification of system performance.

Dwell positions are currently transmitted to the afterloader control unit as linear distances from a fixed location (either the afterloader head or the end of the applicator). They are entered into the treatment planning units as either coordinates measured from simulation images or as fixed distances measured within the applicator. There is ample opportunity for error in measuring, translating, and communicating these values so that verification of the communication linkages is essential. Equipment receiving dwell position information could be modified to provide graphic feedback so that the spatial orientation of the entered dwell positions could be visualized and compared with their expected orientations. Many units provide part of the feedback needed for this verification in either their planning or treatment control units.

Job Performance Aids

Since there was often confusion about the correspondence between applicators and their images on simulation films, an alternative method of identifying individual applicators in simulation images would be desirable. This could be accomplished by choosing dummy strings with spacings or patterns that are easy to distinguish in simulation images and then manually placing a label on the portion of the string that is visible after the string has been inserted into an applicator.

Tape or other restraining methods can limit dummy movement within an applicator during simulation.

Procedures

Procedures for stabilizing dummy strings to prevent their movement during simulation could be designed for each applicator.

Requiring users to translate distances measured within the applicator into linear distances from the afterloader enables an error opportunity which can result in the treatment taking place outside the applicator. This task showed some evidence of sub-optimal allocation of tasks between people and equipment since users were often asked to measure linear distances that could be measured by the equipment as the cable was moved along the guide tubes. Since dwell positions are always located within the applicator, it would be more reasonable for users to specify dwell positions using an applicator reference point and not the linear distance to the applicator from the afterloader.

This task involves the choice of dwell positions within an applicator and the communication of those positions to treatment planners. Errors in identification and transfer of dwell positions could be reduced by local standardization of the choice of dwell positions so that most treatments used the same set of dwell positions or the same spacing between dwell positions.

QA procedures could also be designed to verify that the applicator reference point had been properly identified so that the resulting treatment plan would place the source at the expected dwell positions.

Training

The existence of two different dwell point localization systems places a burden on the selection and training of personnel. At one site a staff member was interviewed who had previously worked at a facility with a different brand of afterloading equipment. This individual was already performing dwell position localization tasks at the new site but was not aware of the differences between the hardware systems and did not realize that the reference point for distance measurements was different in the two systems. A training program could be designed to allow staff to develop accurate mental models of the localization process.

5.4.3 Evaluation of the Alternatives

Although the objective of RAB is to place a source at a specified distance from a target, the afterloader cannot detect the target for the radiation. Dwell positions for the source are therefore chosen within an applicator and at the linear distance that the source must be moved along source guide tubes to reach that position. Errors are possible in the identification of individual applicators, in location of dwell positions within the applicators, and in specification of the distance from a reference to each dwell position.

Decreasing the Likelihood of Human Error

In multi-channel RAB, dwell positions must be matched to afterloader treatment channels. Labeling and identifying applicators remains a problem in multi-channel treatments. The two dimensional projections of the applicators onto simulation films make it difficult for treatment planners to calculate the distance between the applicators and the radiation targets.

Labels that are visible outside the body for use during source guide tube attachment may not appear in simulation images. This can make it difficult for staff to discriminate between applicators and match them to afterloader treatment channels. Applicators labeled with both visual tags and radio-opaque marks visible in simulation images would help to eliminate this problem. These labels and marks could either be placed on applicators during manufacture or attached to the applicators during RAB. Use of two different labels (one visible in simulation views and the other visible outside the body as a guide tube connection reference) introduces the possibility for labeling conflicts. Permanently attached labels and marks would reduce the opportunity for mis-labeling errors and would also prevent labels from being lost or damaged during the treatment process.

The alternative of leaving dummy strings in the applicators after simulation to mark the applicators could be used without requiring applicators to be modified. This would require the dummy strings to have labels that could be used to identify applicators when source guide tubes were connected, and would require QA procedures and training to insure that the strings were not removed or substituted in the interval between simulation and treatment setup. Taping the strings to the applicators could serve as a visual and tactile aid to warn staff that strings should not be removed and replaced prior to treatment setup. QA procedures would be required to verify that permanent labels were consistent and that approved manual labeling procedures had also been followed.

Errors in identification of dwell positions can be limited by local standardization of dwell position distances. Standardization allows staff to become familiar with the expected positions and makes it easier to recognize a deviation from an expected value. A disadvantage of standardization is that it limits the positions that can be used to adapt the treatment plan to individual patient needs. Standardization also increases the chance that a well known standard will be substituted for a non-standard position or non-standard positions when values different from the standard are used in special circumstances.

A positioning reference based on distances within the applicator instead of the linear distance to the afterloader

would correspond better to the data (simulation x-rays or direct measurements) used to choose the dwell positions. This alternative would reduce the opportunity for human error in measuring these distances by shifting part of the measurement task to the equipment, but would require some afterloading equipment modifications.

If staff are trained on one type of equipment and then move to a facility using different equipment, there is a possibility that dwell position localization procedures learned for performing this task will be inappropriate. A training program that recognized equipment and procedural differences could test the mental models used by the trainees to determine whether they were appropriate for the local RAB process. Such a training program might require the reasons for localization procedures to be communicated as well as the steps needed to perform them. In particular, each facility might emphasize in its training that the dwell positions defined from simulation images are offsets from a particular reference point. The method of determining that reference point and translating measured distances to afterloader commands could then be trained, tested and certified locally at each treatment site.

Increasing the Detectability of Human Error

If hardware could sense the applicator reference while moving the source during treatment, an applicator reference would also allow automatic verification that the chosen dwell position was within the applicator. This would detect distance specification errors in which the source was positioned outside the applicator. Unfortunately, it might also enable new errors in misidentifying the applicator reference point. Since a common dwell position reference point would still be required, additional QA procedures would be required to verify that the equipment and treatment planners were using the same positioning reference within the applicator.

Limiting the Consequences of Human Error

Current systems insure that dwell position specification errors will be attributable to human error (since the afterloader need only place the source at the specified linear distance regardless of where that is in relation to the targets). This makes verification of dwell position selections difficult since neither the afterloader nor the task performer can easily match them with the radiation targets. As a consequence, dwell position localization errors can result in undetected consequences to the patient that cannot be corrected. Sensing a reference point in the applicator would require additional afterloader sophistication, but would also allow the position to be displayed during treatment to provide information (i.e., linear distance plus position within the applicator) that could be used to monitor and verify the RAB process during treatment. Such a feedback system would allow the consequences of an error to be detected so that steps could be taken, either during treatment or afterward to deal with the consequences of error to the patient.

5.5 Critical Task 5: Dosimetry

This task involves calculation of the dose distribution from sources placed at specified dwell positions for specified times. Errors in dosimetry involve failure to calculate or describe the dose that will be received by each target. Dose calculation requires accurate specification of the target locations, source activity, source dwell positions, and the time that the source will be allowed to dwell at each position. Dose description involves presentation of dosimetry results so that the calculated dose distribution can be appreciated. (Table A.8 in Appendix A presents these dosimetry errors in more detail.)

5.5.1 Evaluation of Current Techniques

This task is currently performed by interaction between staff and computerized measurement and calculation equipment. Staff commonly use a digitizing device to enter data on dwell positions and targets from simulation images or other two dimensional media into a computerized planning system. These values are used by the system to reconstruct the positions of the sources and targets in space and measure the distances between them. The measured distances, and the characteristics of the sources, are used by the planning system to calculate the radiation dose distribution around each applicator and the dosages to specific targets. The resulting distributions are displayed to the staff in either two-dimensional isodose plots or numbers representing the dose to a reference point on each target. Interfaces include the simulation images, the digitizing equipment, the interface with the calculation software, and the displays in which digitization results, user feedback and calculation results are presented. Problems were observed in all of these interfaces during the site visits.

Dosimetry Procedures

Dosimetry involves the calculation of a dose distribution based on a set of specified source positions and dwell times. It may also involve calculation of the dose to particular targets within that distribution. Dosimetric calculations in RAB were always performed by computer software at the sites visited for this study. Procedural descriptions of these calculations were embodied in the algorithms used to control the computers. These algorithms were not usually accessible to either RAB staff or the site visit team.

Although proprietary software was used to calculate dose distributions it was not used to identify the source positions and target locations. Staff perform these identifications visually and use various interfaces to translate the visual identifications into parameters that can be used by the calculation software. Dosimetry procedures for RAB staff, therefore, consist of steps used to define a coordinate system and measure the positions of simulation images in that coordinate system followed by steps used to enter those measurements into the computer programs that perform the dosimetric calculations. These procedures are often complicated by the need to measure three dimensional positions from two dimensional projections of the imaged objects. They are aided by computerized digitizing equipment and software that can combine digitizations from two different planar projections of an object to reconstruct and measure the three dimensional position of an object.

Data entry procedures using this equipment require a common coordinate system to be established for two different planar images and a corresponding point to be digitized from each image to define a particular source position or target. Task performance procedures involve specification of the digitization technique required by the software interface and the commands used to direct the software to calculate and display the resulting dose distribution. Although the human operations performed during digitization are simple, the immediate feedback between the software and the user was not adequate to allow the user to detect errors in either the digitization process or in the sequencing of image pairs.

Treatment planning manuals and planning software did not always address local treatment procedures in linear sequence. Staff often were required to re-enter complicated command strings or select choices from multiple menus to tailor general purpose software to their specific needs..

Simulation Images and Target Identifications

Multiple applicators are particularly difficult to identify on the simulation images. This difficulty increases with the number of applicators to be differentiated in each view. It can be difficult to determine whether the entire string of dummy sources has been imaged to select matching dwell positions for digitization in each image. Treatment area reconstructions from targets drawn on the simulation images assume that the drawing has been placed accurately with respect to the other structures seen in the images and drawn to the same scale as the simulation images. No feedback or method for checking that these criteria were met is provided in most cases.

Digitizing Equipment

Digitizing equipment is used to enter coordinate information as well as to define the positions of applicators and targets. In most cases these interfaces worked adequately, although error possibilities existed in some digitization units due to parallax and ambiguous entry button arrangements. The primary problem with these units is that they require far too many user entries to transfer information from the user to the computer. Each entry provides an opportunity for error. Digitization is susceptible to movement of the simulation image which can produce a shift in coordinate axes each time an entry is made. Since the numbers produced by the digitization cannot easily be compared with the original images, users often find it difficult to determine whether digitizations have been performed correctly. Hence, this digitization method is an inappropriate division of labor between humans and machines.

Software Interfaces

Data entry and determination of dose distributions are hybrid man-machine tasks in which information and direction is provided by the staff and calculation and display are performed by computer software. To avoid error, staff must know what entry is currently expected by the software and the format, content and syntax of possible entry alternatives. Since user entry errors are possible, immediate feedback is needed to inform the staff which entry has been received by the software, what actions are taking place as a result of the recent entries and what must be done to correct and recover from any entry errors. None of these requirements are currently met by most of the systems being used for RAB treatment planning although some of the interfaces provide valuable internal consistency checks on user entries.

During digitization users were often too far from the display terminals to see whether the system had responded to their digitization efforts. Audible feedback from the digitizing equipment partially compensated for this weakness by prompting users after each entry was received by the computer.

Errors are possible in both the choice of image points to digitize and on specification of the coordinate system used when digitizing different simulation views. Some systems displayed entries graphically after digitization of all points had been completed. These displays allowed users to detect some digitization errors. When errors were detected, RAB staff often found it easier to re-digitize an entire image rather than to attempt to correct individual errors. They could not determine which points had been digitized incorrectly and were not confident that attempts to correct

individual points would be interpreted correctly by the software. Similar problems were encountered during dose optimization. When the software was asked to calculate dwell times required to produce a prescribed dose distribution, users reported difficulty determining what commands they should enter, and difficulty understanding what had occurred as a result of their commands. Some users reported that they preferred to turn off the computer and restart the program rather than to attempt to correct an entry error.

Isodose plots, printouts, and treatment plans are used to transmit dosimetry results and to verify task and equipment performance. Since many of the steps in dosimetry are performed by hardware and software, these interfaces provide the only means by which the performance of the equipment can be verified by the staff.

Isodose plots served the function of translating the source characteristics, dwell times and dwell positions in the treatment plan into a picture of the applicators and the dose distribution produced around the applicator by those treatment parameters. They were a sub-optimal verification aid in that they were often plotted to a different scale than the simulation images, rarely if ever included the radiation targets, and required mental calculation to translate into three dimensions.

Printouts and treatment plan media were the physical means used to transfer dosimetry results to the treatment plan approval and treatment plan entry tasks. The printouts varied in their utility. Some printouts had to be translated before their values could be entered into the treatment control unit. Others used units which differed from those in the treatment directive. Use of different media for plan verification and plan entry provided an additional error opportunity. Different media made it possible to enter a different treatment plan from the one which had been verified. This potential for media substitution existed to a lesser extent with all dosimetry media. Multiple treatment plans and x-rays were often found in the dosimetry workspace. Identification labels on these documents were often difficult to locate and read so that detection of substitution errors required complicated identification procedures.

5.5.2 Alternatives to Current Techniques

Dosimetry was rated by treatment planners as the most demanding task in RAB. Poor HSI interfaces, distractions, and extreme time pressure add to this burden. Alternatives that address these three problems can help to prevent human error in this task. More fundamental changes may be needed to address the root causes of error in this task, since many dosimetry problems relate to the steps that staff are asked to perform rather than to the environment in which the task is accomplished.

Equipment and Software Modifications

Digitization errors could be reduced if an entire simulation view could be digitally scanned into the computer and then re-displayed prior to selection of reference points. Parallax could then be eliminated by having the selection cursor displayed directly on the scanned image. Scanning would also guarantee that all entries would be made using the same coordinate system, since the image axes used for digitization would be fixed and could not be changed accidentally during digitization. After digitization, selected points could be displayed directly on the images to provide feedback to the user. Adjustments in the density of the original simulation images might be needed to allow adequate information to be preserved in the scanning process.

Since the actions performed by the hardware in this task involve complicated mathematical transformations, it is often quite difficult for users to identify the consequences of input errors by examining the isodose plots produced in dosimetry. Scanning might allow currently undigitized information from simulation negatives to be included on isodose plots as a dose visualization reference.

Staff might find it easier to verify their own performance in entering target and dwell position coordinates if the treatment planning systems provided graphical representations of the reconstructed applicators and targets as feedback to the users. These could be presented in the planes of the original entries to facilitate comparison with the original images and then rotated in space after reconstruction to facilitate comparison with the expected characteristics and orientations of the applicators.

The consequences of some digitization errors could be detected by digitizing target positions so that the distances between the sources and those targets could be reconstructed by the software and compared to expected distances as a verification of the accuracy of the reconstruction.

The software interfaces provided for dosimetry could be improved. An interface redesign might include a method for standardizing user input of units, view angles and magnifications, provision for feedback on the history and current state of the interaction process, and methods for recording user entries to facilitate reviewing and correcting potential entry errors.

Since most sites practiced only a few types of RAB treatments, a method of simplifying the commands required

to get planning software to perform the steps in this complicated process for each local type of treatment would be desirable.

Job Performance Aids

Substitution of x-rays or other planning documents would be less likely, and easier to detect, if each document used in treatment planning were tagged with a visually striking label identifying the patient and the treatment fraction for which it was produced.

Procedures

Specific dosimetry procedures could be developed that are designed to prevent or detect the errors possible with the equipment and software in use at each site. If potential errors were identified at each site, they could form the basis for a QA program to certify that the digitization and treatment planning software and hardware reproduce the dose distribution from known arrangements of sources. This certification could be performed at intervals or before each planning session to detect any damage that might have occurred to equipment or software since its last use.

The demands of this task on dosimetrists are inconsistent with the working conditions during dosimetry at many sites. Organizational interventions might help to reduce the time pressure on staff performing dosimetry and remove the distractions that currently add to the demands on dosimetry staff.

Training

Staff could be prepared to deal with these complicated dosimetry interfaces by a training program designed to familiarize them with the software and prepare them to recognize and correct interaction failures.

Quality assurance procedures could be developed to assess the performance of both human and equipment aspects of the treatment planning system. For example, a QA procedure could be devised that uses a defined source distribution. The treatment plan generated in response to this source distribution could then be compared to an optimum treatment plan. Any marked discrepancies between these two plans would signify a deficiency in the treatment planning system. In instances where this deficiency is traced to inadequate staff performance, training programs could be instituted to improve task performance. This procedure could also detect hardware and software problems in the treatment planning system.

5.5.3 Evaluation of the Alternatives

Because the dosimetry task is performed interactively by people and equipment, alternatives for reducing error must address this interaction. The current interfaces can be improved by standardizing and clarifying the entry procedures, removing the burden placed on staff to digitize simulation views, and by providing the feedback needed by staff to correct and improve their performance of this task.

Decreasing the Likelihood of Human Error

Hardware can scan entire sheets at a time. Scanning would reduce the number of user entries needed to define the coordinate system and would allow the system to display user selected points directly on the scanned images. Image quality might be limited by the ability of current scanners to deal with dense x-ray films. Density correction algorithms or special simulation images might be required to allow scanned images to be used. Use of a computer screen rather than a digitization tablet would also require precise calibration and periodic testing of the display screen to insure that any geometric distortions introduced in the display were eliminated or compensated for in the planning software.

Scanning would eliminate some of the problems in this task but would not eliminate errors in either selecting dwell points or in projecting target images onto the simulation films. Since many targets are not visible in the simulation views, some method of marking targets so that they could be scanned along with the simulation images would improve performance of this task.

Since dosimetry depends on distance between objects reconstructed in space, accurate measurements of the magnifications and view angles used to make the simulation images are critical. Local standardization on specific view angles and magnifications can eliminate some of these problems, but can also mask errors in which the standards are not followed by all task performers. Information must be provided to enable these errors to be detected. Information on view angle and magnification can be added manually to simulation images. However, this enables another potential human error of incorrectly transcribing the view and magnification information. The best combination might be to have the information placed in the views automatically, by simulators or by positioning frames and magnification rings. Any images which were different from the standard or which lacked this information might require special identifying marks.

Since simulation views from other treatment fractions may be used as a reference during treatment planning, careful labeling is required to prevent substitution of these

documents during dosimetry. Many simulation views can be identified by the date on which they were produced, but these dates can be difficult to read and are often easy to ignore. Colored tags or some other easily compared method of identifying the patient and the current treatment fraction might help to prevent these substitution errors.

Removing distractions during dosimetry might help staff to focus their attention on dosimetry procedures, but it would not make those procedures simpler or less complicated. Until the interfaces and automated error checking procedures can be improved, training in use of the complicated interfaces and vigilance regarding interface failures will be needed to reduce the incidence of error in this task.

Increasing the Detectability of Human Error

QA procedures can help insure that the interfaces between the people and equipment have not failed. Verification of dosimetry in RAB involves detection of errors in the entry of planar coordinates, source characteristics, and source dwell times, errors in the spatial reconstruction of objects based on those coordinates, and errors in the calculation, display and interpretation of the dose distributions resulting from that reconstruction.

Verification of digitization entries would be facilitated by displaying the selected points directly on the scanned images so that the spatial relationships between the images and the points could be visualized. Reconstructing and rotating the points to show their locations in space could help identify differences between digitizations from different simulation views.

Reducing the time pressure placed on staff during this task might allow more time to perform these verifications, but might also lengthen the treatment process. Use of a dose atlas, or other forms of pre-treatment planning can reduce time pressure and shorten the treatment process, since the patient does not need to wait for a new plan to be generated. Unfortunately, pre-treatment planning also precludes many verifications since the measurements of target and applicator positions that occur long before the treatment session, cannot be used to detect potential target or applicator position changes during the treatment session.

Treatment planning systems perform some verifications by requiring duplicate parameters measured for the same point in different views to reconstruct (within some accuracy) the same measured object in space. This method can, at best, identify only a few of the possible digitization errors. The following example shows that only three out of the five points digitized on each simulation view to define a source position or a target can be verified automatically.

Redundant information may be available from other sources that would allow the program to detect more digitization errors. If the source spacing is known, the program can calculate the distances between sequential reconstructed sources and compare those differences to the known spacing. Several systems provided this as an additional form of software error identification.

Limiting the Consequences of Human Error

Any modification to the treatment planning computer's hardware or software, including use of the computer to run other programs, may unintentionally alter the treatment planning system. An effective alternative after such modification may be to re-certify the operation of the planning system prior to using it for RAB. An alternative to the development of local certification procedures would be for users and manufacturers to work together to define appropriate tests of system integrity that could make certification rapid enough to be performed prior to each planning session.

5.6 Critical Task 6: Treatment Set-up

Treatment set-up involves positioning the patient, connecting afterloader treatment channels to applicators in the patient, and verifying that the afterloading system is in good working order. Errors in this task include swapping two or more treatment channels so that treatment planned for one applicator will be delivered through another, connection of improper guide tubes so that the actual treatment distance does not correspond to the planned distance, and modification of the spatial relationship between the applicator and the targets so that the dose distribution does not hit its planned targets. (Table A.9 in Appendix A presents these set-up errors in more detail.)

5.6.1 Evaluation of Current Techniques

The user needs three pieces of information for each treatment channel to perform treatment set-up:

(1) The treatment channel must be specified.

(2) The applicator to which the channel should be connected must be specified.

(3) The source guide tube used to connect the two must be specified.

The user interfaces include the task performer's source of connection information, the labels or distinguishing marks used to identify each piece of equipment, and the feedback from connectors as each connection is made.

Procedures for performing and verifying connections often protected against only one of several error opportunities. The treatment planner connected the applicators to the afterloader at several sites. This reduced the potential for differences between the plan and the channel connections due to communication problems, but did not address the possibility that connection errors might be made or that the treatment plan might specify different connections than were expected by the person who wrote the treatment directive. The physician who prescribed the dose was responsible for connecting the applicators to the afterloader at some sites. This reduced the likelihood that afterloader channels specified (or assumed) in the treatment directive would be connected to the wrong applicators. It did not prevent those treatment channels from being different from the ones used in the treatment plan.

At several sites, the staff member responsible for connecting the channels did so from memory without any verification from the physician or the treatment plan.

Applicators were usually labeled with small, low contrast markings that were extremely difficult to discriminate. Some were not labeled at all.

Labeling on afterloader treatment channels is provided by each manufacturer. These labels were difficult to see at a distance for verification of the connections. The connecting tubes on some channels blocked lines of vision to the channel labels making them difficult to read after source guide tubes were connected. Channel connections on LDR treatment units were particularly difficult to verify due to the large number of channels used and the close spacing of adjacent channels. The need for connections to be verifiable with minimum effort was not met for most of these devices.

Standardized hook-up procedures were often used to limit the number of possible hook-ups and thereby reduce the possibility of error. These standards can produce false security and lead to additional errors when they are not explicitly documented and communicated to all task performers.

In some systems the burden for verifying connections has been partially shifted to hardware by placing mechanical interlocks in the channels. These interlocks can be sensed by the afterloader to identify channels for which a treatment plan has been entered but which have no connecting tubes attached. By using such interlocks, the hardware can detect unattached channels but it cannot detect swapped channels.

Some connectors, used for applicators requiring multiple guide tubes, were designed so that each tube would connect only to its specified treatment channel. Treatment channels for those applicators could not be swapped. At a few sites, lack of training on the differences between these specially designed applicators and others, which were not designed to prevent improper connections, led some staff to believe that the afterloader would always prevent them from making the wrong channel connections.

Staff at one site performed multiple channel treatments using a single afterloader channel that was sequentially connected to the different applicators. Although this eliminated the channel swapping error (only one channel was connected) and the possible errors in interpreting or planning the treatment (all treatments were planned for the same channel), it introduced a new error possibility of connecting the applicators in the wrong sequence. Several sites prevented treatment channel connection errors by not performing multiple channel treatments.

5.6.2 Alternatives to Current Techniques

Current procedures often fail to insure that adequate information is provided to staff performing Treatment Set-up. This makes task performance difficult and limits the opportunity to detect and correct task performance errors. Communication procedures, performance procedures, and task allocation procedures can help to address these problems so that human error is less likely and easier to correct prior to treatment.

Equipment and Software Modifications

Keyed applicators and source guide tubes can prevent errors by forcing specific afterloader channel connections. Keyed connections are currently available only for some applicators. Keyed connections for more types of applicators would enable planners to know exactly which afterloader channel would be connected to each applicator.

Job Performance Aids

Connection specifications in the treatment plan are often ambiguous or difficult to locate. A map of the specified applicator-channel connections would provide an unambiguous reference both for staff planning RAB treatments and those connecting applicators to afterloader treatment channels. The format of the map might differ from site to site depending on the format of the treatment directive and treatment plan.

Since treatment set-up often occurs immediately before treatment there may be limited time to detect and address the consequences of an error in this task. Most current connection labels are either too small or too indistinct to facilitate rapid error detection. Improving the labeling mechanism, so that anyone within range of the labels could identify an improper connection, would increase the chance

that connection errors would be detected prior to treatment delivery.

If, for example, the source guide tube (SGT)-applicator-channel combinations specified in the treatment directive were color coded so that each approved combination was a different contrasting color, any connection error could be detected by glancing at the connection.

Procedures

The number of potential connection errors can be reduced by standardizing on a single SGT length and removing SGTs that are different from the standard from the treatment area. Special SGTs that differ from the standard could be tagged or keyed so that they are difficult to substitute by mistake for the standard SGT during treatment set-up.

Connection procedures and applicator labels could also be designed so that proper connections were obvious (e.g., place a color coded label on each applicator and SGT so that all connections meant for a specific afterloader channel would be the same color).

The information path between treatment planners and the staff who perform the afterloader channel connections could be simplified and protected. An applicator-channel map for all multiple channel treatments could be used to ensure that the same connection information was used by all RAB staff. A new map could be provided for each treatment session specifying the patient, the treatment fraction, the SGT, and the afterloader channel connection for each applicator.

Connection errors could be detected after treatment if the connections were recorded so that the connections specified in the treatment directive could be compared with the physical connections used for treatment delivery.

Training

Training in local labeling procedures, connection procedures, and information transfer procedures could have prevented some of the problems observed in this task. Since several of those problems involved faulty perceptions regarding the allocation of connection tasks between hardware and staff and in the information that should be used when connections were made, a training program could be designed to insure that each task performer understood the correct connection procedure for each type of equipment and the information that should be transmitted and received during the setup task.

5.6.3 Evaluation of the Alternatives

Correct treatment set-up is indispensable to administering the prescribed radiation dosage to the patient. Efforts should be concentrated on rendering it impossible to establish improper connections between the afterloader treatment channels and the applicators. Improved hardware interfaces and supporting documentation such as checklists for applicator-channel mappings, offer considerable promise in helping to minimize human error in this vital task.

Decreasing the Likelihood of Human Error

Some hardware interfaces have been designed to prevent treatment set-up errors by sensing and preventing improper connections. These hardware lock-outs, although effective, appear in some instances to have encouraged adoption of faulty mental models of system performance. Training could be used to improve staff ability to avoid those errors by improving their understanding of system performance. This would decrease the likelihood of error, but would not limit the opportunity for error. Standardization on a small number of possible connections would reduce the number of possible hook-up errors but would not eliminate the possibility of communication and connection errors.

An applicator-channel map would be an effective alternative even in simple cases. A map could be used to formalize applicator connection procedures and would allow both the task performer and other staff to verify that afterloader channel connections were properly performed.

An expanded map could be used as a worksheet to specify the prescribed dose for each applicator, the treatment parameters for that applicator, and the treatment channel to which the applicator should be attached. Such a map would allow a planner who was not present during the radiation prescription to determine which channel was to receive each dose. An applicator-channel map could also be used to standardize channel nomenclature between tasks.

Although a map would improve the chances that connections were transmitted accurately, it would not make it any easier to identify which connections had been made. Improved labels would help to distinguish between applicators and match them to the afterloader channels so that the map could be followed during Treatment set-up. Color coding or other marks used to match applicator connections could be preserved throughout the RAB process so that they provided redundant matching clues for instructions in the treatment directive, images of applicators in simulation views, and channel specifications in the treatment plan.

Color coding has been suggested for use in distinguishing both the patient's treatment fraction and for matching applicators to source guide tubes and afterloader channels. Some sites already use color coding to distinguish between different physicians or to identify worksheets used for different treatment procedures. The value of a color coding system will depend on whether the various codes are unambiguous so that proper connections or document mismatches can be easily distinguished and identified. A single color used to identify the treatment directive for an applicator, it's image in simulation views, its source dwell positions and times in the treatment plan, its source guide tube, and its afterloader channel would an unambiguous and easily matched reference. Use of color codes to identify treatment fractions or other differences unrelated to afterloader connections might compromise that simplicity. Shades of a single color, or other distinguishing marks could be used to identify treatment fractions to prevent the color codes from being misinterpreted.

Increasing the Detectability of Human Error

Poor labeling and poor communication procedures often constrain detection of set-up errors to the time at which the connections are made. Equipment tags that could be seen easily from a distance and which identify and distinguish the appropriate connectors for each hook-up configuration would allow any staff who could see the tags to detect a connection error whenever they looked at the connections. Manually placed equipment tags would introduce the opportunity for tagging errors and require additional QA to ensure that all SGTs, applicators, and afterloader channels had been properly tagged.

Recording procedures which preserved both the desired and the actual connection sequence would allow connections to be compared to the treatment directive prior to treatment and would also permit connection errors to be identified when treatment data was reviewed after treatment was completed.

Limiting the Consequences of Human Error

Detection of connection or communication errors prior to treatment would allow the treatment to be stopped before a dose of radiation was delivered to the wrong targets. This would delay treatment until the correct connections could be established. Two different errors are possible:

(1) The connection order may not match the order specified in the treatment directive.

(2) The connections may match the order specified in the treatment directive but may not correspond to the connections used to produce the treatment plan.

An applicator-channel map which carried both the prescribed and planned connections would allow staff to distinguish between these errors so that the appropriate steps (re-connection or re-planning) could be taken.

Recording the applicator actually connected to each channel after treatment would allow a dose delivered through improperly connected applicators to be calculated after treatment. This would allow a dose delivered through the wrong applicators to be calculated after treatment so that the consequences of the dose to the patient could be determined and addressed.

5.7 Critical Task 7: Treatment Plan Entry

Treatment plan entry involves transfer of treatment parameters from the treatment plan to the afterloader control unit. Errors in treatment plan entry involve either the use of different values from those contained in the treatment plan or entry of treatment plan values from the wrong treatment plan for the intended treatment. (Table A.10 in Appendix A presents treatment plan entry errors in more detail.)

5.7.1 Evaluation of Current Techniques

Three different interface methods are used for this task. In the first method, numbers that a technologist reads from a treatment plan are entered into the treatment control unit by hand. In the second method, a magnetic storage medium (a card or disk) created by the planning system is carried to and inserted into a reader attached to the treatment control unit. In the third method, the specified treatment plan was stored in the memory of the treatment control unit and recalled from the unit's memory prior to treating the patient. Each method was subject to a different set of errors. Manual entries were particularly difficult to perform without error in some systems. Those systems required staff to perform additional calculations to adjust for source decay, dwell position offsets, and differences between the measurement units used in treatment planning and those accepted by the afterloading equipment.

Staff at most sites chose a single method for most of their entries and rarely, if ever, used the other methods. Magnetic cards or disks were the primary entry mode at all sites in which such interfaces were available. .

Manual Entry

Manual entry was used at all sites at which cards or disks were unavailable. A few of these sites also stored and recalled plans from the afterloader control unit memory.

Manual entry entails a potential key press error each time a digit or code is entered. Although the entry sequences are often complicated, trained users experienced little difficulty in performing and verifying these key press entries manually.

One HDR system required that planning parameters be entered for treatment based on a fixed (10 curie) source activity. These parameters were then automatically adjusted prior to treatment to compensate for any activity difference between the 10 curie source in the treatment plan and the source that was present in the afterloader. This entry method had the advantage that a single treatment plan would be generated for a treatment irrespective of the actual source activity. This allowed parameters from a treatment atlas to be entered without any user adjustment of the parameters for source decay.

Some manual entries are translated after entry into formats that are difficult for staff to verify. For example, one system automatically adjusted the entered values to compensate for source decay. The user was required to enter the treatment date into the treatment control unit so that the decay could be calculated. This provided an opportunity for the date to be entered incorrectly. This error opportunity was compounded by requiring the user to enter the date in "European" format [day-month-year] rather than the [month-day-year] format commonly used in the United States. Since the resulting (decayed source) dwell times were different from those specified in the treatment plan, neither entry errors nor decay errors could be detected by comparing the entered values to the resulting treatment parameters.

Card or Disk Entries

Card or disk entries completely eliminate key press errors in transferring treatment parameters to the afterloader control unit, but enable "card swap" errors in which a card or disk for the wrong treatment fraction is inserted.

Since each card stores only a single planned treatment, selection of the correct card was the only point at which a substitution error could occur with these systems. The opportunity for error was increased by the practice of placing cards containing old treatment parameters in a stack at the treatment planning station. This ensured that a supply of cards with valid, but inappropriate, treatment parameters would be available at the planning station to be substituted for newly generated cards.

One system which used floppy disks for data entry allowed parameters for many different treatments to be stored on the same disk. Selection of parameters for the wrong treatment was possible with this system even after the appropriate disk had been chosen and inserted into the afterloader control unit.

Different algorithms were used to calculate source decays in some planning and treatment control units. These also made detection of entry errors difficult, since users were conditioned to expect differences between the treatment plan and the final treatment parameters. Detection of an error at those sites required a judgment on the significance of a difference and not just the recognition of a difference. Comparison of the treatment parameters to the treatment directive was often difficult when the directive specified a dose and the parameters specified source dwell positions.

Detection of errors in entering the date was performed at some sites by generating a table of expected treatment source intensities to compare to the decayed activity calculated by the afterloader control unit. These comparison procedures were time consuming and added substantially to the burden placed on users to verify the accuracy of their data entries.

5.7.2 Alternatives to Current Techniques

Since treatment plan entry is accomplished through an interface between people and equipment, many of the potential problems in data entry can be addressed by improving the interfaces between the users and the system and by providing users with the information, procedures, and training needed to detect and correct their entry errors.

Equipment and Software Modifications

The allocation of duties between humans and equipment appears to contribute significantly to the probability of error in these systems. Human entry errors can be reduced substantially by using magnetic media or direct electronic transmission to transfer treatment plans to the treatment control unit. It would also be desirable for the equipment to track the number of days which have elapsed since source exchange to hardware instead of requiring users to enter the treatment date.

Treatment control units could be modified to provide the feedback needed to verify that data has been entered correctly. Automated checklists for verification would help standardize verification practices. Some way for the dose distribution that is about to be delivered to be calculated quickly from the treatment parameters after entry would be desirable and would be more meaningful to staff than a check of afterloader positioning parameters.

Job Performance Aids

Some systems use entries based on a standard source activity and then adjust the values after they have been entered to adjust them for the activity of the source in the afterloader. Error in those systems is possible in either the entry of the treatment parameters or in the entry of the treatment date used by the system to calculate the decayed activity of the source since it was last calibrated. Detection of plan entry errors in those systems could be facilitated by calculating the expected adjusted dwell time prior to entry so that it could be compared with the value calculated by the afterloader control unit.

Procedures

Substitution of cards carrying treatment plans could be prevented if all magnetic media used to transfer treatment plans were erased after each treatment session.

All treatment control units which used magnetic media for data entry provided displays of the entered items, although the treatment fraction was often identifiable only by the date on which the treatment plan was generated. Substitution and entry errors could be detected if the patient's name, treatment fraction, and treatment parameters were verified after each plan was entered.

Standardization of treatment plans so that staff become familiar with correct entries could increase the chance that entry errors which deviated from the standard would be recognized.

Training

The complexity of the required entry and verification procedures suggests that appropriate training be provided to increase the likelihood that the procedures are understood and will be followed.

An organizational alternative for dealing with entry problems would be to provide staff with the redundant information needed to detect errors, provide the time and facilities to use that information, and provide training in procedures designed to detect and limit the consequences of the errors.

5.7.3 Evaluation of the Alternatives

Treatment plan entry and verification are the last tasks performed prior to starting treatment. They provide the last opportunity to either make or detect errors before treatment occurs. They are also, in many cases, some of the more error-prone tasks in the treatment delivery process. These two factors suggest that particular care must be taken by RAB management to provide staff with data entry procedures that reduce the likelihood of error and with detection procedures to identify those errors.

Decreasing the Likelihood of Human Error

Magnetic media or direct electronic transmission of treatment plans to the treatment control unit would eliminate some entry errors. However, they might introduce error opportunities for substitution of magnetic media and for direct electronic transfer of inappropriate parameters. Erasing or overwriting magnetic media after each use would help eliminate any media with old treatment parameters that might be substituted for newly generated media, but erasing the media would also prevent it from being used to record or repeat the treatment.

A method for marking a card which had been used in a treatment so that it could be identified by staff or equipment would help to prevent substitution errors while still allowing the used cards to be archived as a record of the treatment.

Some possibility of error would still exist if multiple treatment plans are generated prior to treatment. Multiple plans provide access to both a printout and a card that can be swapped with those intended for a different patient or treatment fraction. Prominent tags and verification procedures for the transfer and use of treatment plans might help address these sources of error.

Removal of the requirement that some control units place on the staff to enter the date so that the source activity can be estimated would reduce the number of entry error possibilities from one per treatment to one each time the source was replaced (about twice a year in high dose systems). Some possibility of error would still remain, but it would be transferred to a well-defined point at which careful verification of data entries could be performed. For this alternative to be effective, the date entry format should be unambiguous and consistent with current practice in the country in which each unit is installed.

Increasing the Detectability of Human Error

Since treatment often occurs immediately after the treatment plan is entered, this is also the last point at which most errors can be corrected before the dose is delivered to the patient. This makes the period between entry of the treatment plan and treatment delivery the appropriate time to verify the entry and the other tasks and linkages in the RAB process.

Manual entry errors can be detected if the entered parameters are compared with the original treatment plan. Most sites performed some verification of manually entered parameters.

Tagging of the patient, the treatment plan, and the transport media so that they can be compared could help detect substitution errors and could also be used to verify that any plan, whether transmitted or manually entered, was for the proper patient and appropriate treatment fraction.

Errors in which parameters are entered correctly but do not match the channels connected to the afterloader during the setup task are more difficult to detect, since the entered values specify but do not determine the channel connections.

A effective verification procedure for the entire RAB process might check both that the entered parameters corresponded to the treatment plan and also that the dose produced by those parameters corresponded to the dose prescribed in the treatment directive. No current system allows the dose that will be delivered to the targets by entered parameters to be compared with the dosage prescribed in the treatment directive. This would be a desirable verification, but would require a method for relating the entered dwell positions to the spatial orientation of the source during treatment. The verification would also require a way to measure the distance between the entered dwell positions and the targets.

One method for providing an estimate of the spatial arrangements of the dwell positions might be for the control unit to detect the applicator during a check cable run and then display or calculate the distance into the applicator that each entered parameter would place the source. This would allow the dose delivered by an applicator of known geometry to surrounding tissue to be calculated just prior to treatment delivery. It might not provide an accurate dose estimate for flexible applicators or multiple applicators unless the actual spatial orientation of the applicators or source positions could also be determined.

Sensing the spatial location of the end of the check cable as it is placed at each dwell position is not currently possible, since only the linear distance to the positions is measured and not their spatial relationship. If the measurement could be performed, the dose distribution due to a source at those positions could be compared to the treatment directive immediately prior to initiating treatment. This would enable connection as well as entry errors to be detected, but would require significant modifications to existing equipment. It would also not guarantee that the dose would be delivered to the targets, although use of an applicator reference for the dose would allow identification of entry errors that would deliver a dose to the wrong place within the applicator.

Until the dose produced by the entered parameters can be calculated, a QA program including verification of all entries and incorporating careful tagging of documents to allow substitutions to be identified can help increase the likelihood of detecting errors in treatment plan entry. Equipment and labeling modifications by manufacturers would make these verifications less time consuming. Machine reading of identification tags would provide a redundant and independent verification that the entered treatment plan was intended for the patient connected to the afterloader. Manual tagging of documents, the use of checklists, standardization of entry procedures, and training in QA procedures can also help staff to perform these verifications.

Verification in systems which adjust parameters after entry would be easier to perform if treatment plans also included dwell times for decayed sources that could be compared with the adjusted treatment values displayed after entry. This would enable another error in which the set of values intended for comparison was entered instead of the values for treatment. Verification and training procedures could be designed to anticipate and correct these potential substitution errors.

Limiting the Consequences of Human Error

Most undesirable consequences of errors in treatment plan entry can be prevented by detection and correction of entry errors prior to treatment. Until the dose from the entered plan can be calculated, prevention of the consequences of error in this task will require careful verification of each entered parameter. Since the linear distance from the afterloader to the target is used to position the source, while the treatment plan is often based on distances within the applicators, particular care must be taken to insure that the positioning parameters bring the source to the expected distance from the targets.

Since there is often a strong psychological imperative to proceed with treatment once the patient has been connected and the plan has been entered, the ease with which post entry verifications can be performed is critical. The likelihood that verifications might be skipped could be reduced by providing verification checklists or worksheets and training in verification procedures.

Damage control after identification of an error in this task involves determination and re-entry of the correct parameters. If the parameters are written clearly and correspond to those displayed by the treatment control unit

after entry, this verification can be relatively straightforward.

5.8 Critical Task 8: Quality Assurance and Maintenance

QA in RAB involves testing equipment and procedures to identify malfunctions or potential problems before they adversely affect treatment planning, treatment delivery or patient or staff safety. Maintenance involves changes to equipment or procedures designed to prevent or eliminate either potential or actual problems. Errors in QA and maintenance involve either failures to address problems in equipment, procedures, and treatment delivery mechanisms, or the creation of new problems in those areas during the performance of the QA or maintenance procedures. (Tables A12, A13 and A14 in the Appendix present QA errors in greater detail.)

QA procedures should be designed to both identify problems and to record and communicate the QA findings so that problems, changes, or their absence can be brought to the attention of RAB task performers. Maintenance procedures must be designed to correct potential or actual problems and to perform or initiate testing to certify that the changes have produced their intended effects. QA procedures to prevent and detect errors and equipment failures should be designed to verify the performance of each RAB task, whether performed by humans or equipment, and to protect and verify the linkages between those tasks and task performers.

5.8.1 Evaluation of Current Techniques

There are two categories of interface for QA and maintenance. The first comprises the equipment or procedures that are tested or maintained in the QA program and the second comprises the special interfaces designed to perform QA and maintenance tasks. During QA, staff must deal with both interfaces, using the latter to test that the former are in good working order.

The ideal QA interface would permit one to rapidly identify or predict potential equipment or procedural problems. Interfaces were judged adequate on most of the RAB equipment for standard QA procedures. Lights on afterloaders and their control units could often be illuminated to check for burned out bulbs, QA settings were provided to operate and test the equipment without performing complete treatments, and indicators were provided to transfer information on the results of internal hardware QA checks on system performance.

Software and procedural QA and maintenance interfaces were less well developed and were notably absent from many QA programs. Checklists were used at most sites for identifying and recording compliance with the local QA procedures. Although adequate as a means of directing which QA checks were to be performed for some portion of the treatment delivery system, none of these checklists provided enough information to certify that all parts of the system were operating correctly.

5.8.2 Alternatives to Current Techniques

Alternatives for other critical tasks involve the prevention and detection of error in individual tasks and task linkages. Alternatives to QA tasks address the methods used to maintain, monitor, and certify the operation of the RAB system.

Equipment and Software Modifications

Some QA checks are performed by hardware and software used during RAB. Each check performed by equipment and software removes a burden on staff for performing that verification. Unfortunately, these equipment and software checks are difficult to integrate into a QA program since many are hidden from staff. An integrated QA program requires that records be kept of which verifications have been performed (and which have not). Many of the hardware modifications suggested for other critical tasks would improve feedback needed for QA-related verifications and transfer some responsibility for those verifications from staff to equipment. Hardware and software QA checks could be improved and integrated with manual QA procedures whether or not those modifications were made. It would be particularly useful if performance data on the afterloader and planning systems could be collected automatically so that potential interfacing or hardware degradation problems could be identified.

Job Performance Aids

Checklists could be used more extensively as guides to QA performance. Any logging scheme used to mark these checklists could be designed to preserve high visual contrast between passed, failed or omitted QA procedures.

Procedures

Comprehensive QA procedures are needed to certify the operation of all RAB hardware and software at regular intervals and to re-certify RAB system integrity immediately after any maintenance or updates are performed. These procedures should include, but should not be limited to, tests of all warning devices, panel lights, and hardware interlocks as well as certification of the accuracy

of all positioning, calculating, measurement and data entry mechanisms.

QA in RAB is performed by hardware, software, and human task performers. A procedural description could be provided for each QA check/test performed so that there is no doubt as to exactly what has been tested by each procedure and what performance can be expected after either passage or failure of each QA check.

A QA checklist could be used to direct the order and content of QA task performance. Procedures for using the checklist could be designed so that QA procedures can be logged in the order of performance on the checklist. Equipment whose proper operation depends on the performance of other equipment could be tested in the order of that dependence. In that way maintenance performed to allow passage of a QA test would not require previously logged tests to be repeated. Interdependencies between equipment could be noted so that QA can be repeated on interdependent items after a failure of one of the related components.

A tiered QA system for performing QA could be used in which

(1) Potential errors are identified.

(2) Modifications that would prevent those errors are determined and scheduled for implementation.

(3) Training is provided to reduce the incidence of any errors which have not yet been prevented.

(4) QA procedures are designed and carried out to identify the errors which still occur.

Whether or not a tiered QA program is developed, the safe operation of all hardware and software should be certified at regular intervals and verified immediately after any maintenance or updates have been performed. Since equipment and procedures can change so that new certifications are required, or old ones become irrelevant, one item on the QA checklist could be used by staff to verify that the QA procedures were still applicable to the item being tested.

Training

QA in a partially automated system like RAB must consider all the system elements that might fail. This requirement makes initial and refresher training for staff at least as important a QA issue as equipment maintenance and error detection. A QA program could be integrated with the staff training program at each site so that the time spent performing QA assessments would also serve to test and refresh staff understanding of RAB and their proficiency in performing RAB procedures.

Emergency procedures are good candidates for this type of refresher training since they are performed infrequently and are sometimes counter-intuitive to those used in normal patient care. This training could include practice in using cable cutters, tongs, and containment devices as well as practical testing to ensure that all staff who might be called upon to use those tools were able to use them rapidly and efficiently. It would be useful to practice the procedures for handling several "worst case" problems such as a cable that was stuck in an applicator attached to the patient.

5.8.3 Evaluation of the Alternatives

Errors in QA involve failures to identify equipment or interface problems or failure to take appropriate action to deal with problems that have been identified. The analysis team was concerned about economies of scale and trade-offs between error prevention and error detection during QA in RAB. To prevent QA from dominating the system the number of potential errors should be reduced by RAB management. Implementing the human factors interventions described in this report and continuing to automate error-prone tasks are obvious ways to accomplish this reduction. Another complementary alternative would be to use a tiered approach to QA so that the number of potential errors is reduced early in the RAB process so that attention can be focused on those that remain.

Decreasing the Likelihood of Human Error

Automatic logging of interfacing errors would insure that those errors were brought to the attention of QA staff so that methods for addressing them could be incorporated into the QA system. Manual error logging could substitute for automatic logging at the expense of increasing the bookkeeping burden on staff and prolonging the interface process. In either case there is a need to develop comprehensive procedures for directing human performance of QA so that the appropriate tests and monitoring will be performed and appropriate steps to deal with potential problems will be available. Training can help prepare staff to follow approved QA procedures, but does not usually provide feedback on performance outside the classroom. Checklists can be used to help focus attention on QA procedures that must be performed and to allow staff to log the QA procedures that they have performed for each treatment.

To be of maximum benefit, a checklist must be comprehensive enough to allow current system integrity to be assessed at a glance for all components of the treatment planning and delivery system. One suggested method for

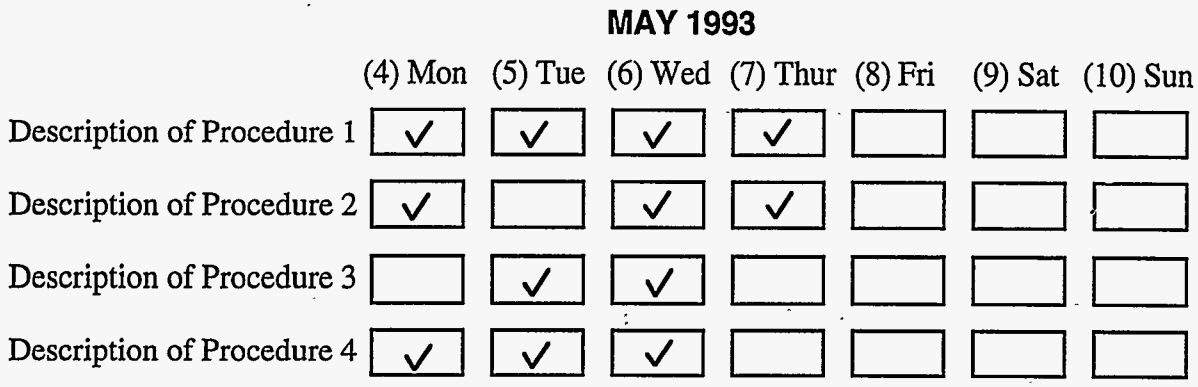


Figure 18. A QA checklist with daily QA procedures arranged in a single column.

accomplishing this goal would be to arrange the QA checklist in a way that draws attention to failed or omitted QA tests. Figure 18 shows a checklist arranged to allow rapid identification of tests passed (denoted by a check mark) and omitted or failed QA procedures (denoted by an open box). Note that a solid column of check marks indicates passage of the QA tests while any deviation from a solid column allows rapid visual identification of potential problems or omitted tests. A daily QA log is shown in this figure, although the format would be equally appropriate for QA performed prior to each treatment session. In such a case, a column might represent a treatment session rather than a day. The transposition of this checklist so that individual tests appear in the columns with one row used for each date or session can be equally visually striking. The intent of such a QA interface is to help direct the QA task performer in performance of the QA tasks and to provide a record of QA task performance that allows performance omissions and QA problems to be identified at a glance prior to each treatment.

Increasing the Detectability of Human Error

Some protection against errors in logging can be obtained by ordered execution of QA procedures. If QA procedures are executed in order, checklist gaps can provide immediate feedback on unperformed or mis-logged tests. Task performer initials can be substituted for check marks to provide a record of the staff that performed each test.

Temporal ordering of checklist entries can help draw attention to logging errors (blank boxes should not occur. If QA problems can be resolved sequentially, re-testing for related components can be eliminated. A checklist or similarly structured document should be followed for each treatment so that all equipment, verification and communication procedures needed for safe practice of RAB can be verified with minimum effort at the treatment site immediately prior to each treatment session.

Items which are tested, verified or maintained on different schedules from the treatment can be brought to this session QA log after inspection of the individual treatment logs. For example, "Daily QA performed successfully" might be included as one item on the treatment session QA log. This item would indicate that daily QA had been performed prior to treating the patient without requiring those procedures to be repeated for each treatment. Worksheets currently in use provide some of the features of this treatment session QA log in that they indicate many of the procedures that have been performed. These worksheets could be modified to provide their information in the above checklist format so that a glance prior to treatment would be sufficient to detect any omitted or compromised procedures.

Limiting the Consequences of Human Error

Errors can be resolved by either preventing them or by identifying and blocking the propagation of their consequences. In a tiered QA system, some errors can be detected and corrected within each task before their consequences can propagate through the progression of tasks in the RAB process. Since some errors may not be detected, enough information must then be brought to the other tasks to allow their consequences to be identified. Since communication errors are always possible, it is best to delay QA until just before treatment so that a single verification can be used to identify the consequences of both task performance and communication errors. This method requires that the initial error frequency be low enough so that time lost due to late correction of error consequences does not place a substantial burden on the system. In many cases this may involve limiting, rather than eliminating the consequences of QA errors. Regular

QA (e.g., daily checks) can limit the consequences of problems to a fixed number of treatments. A record of the steps taken in producing a treatment plan might help identify steps that were omitted, repeated, or performed slowly. Such a record would help identify user interfacing errors or training requirements. A record of corrections made during treatment plan entry and verification prior to treatment delivery might provide similar information for afterloader control unit interfaces.

QA based on estimates of error likelihood (e.g., certification of equipment after modifications) can block the consequences of high probability errors. Hardware verifications of system performance just prior to treatment would reduce the burden on staff and increase the number of errors which could be identified and addressed for each treatment.

Checklists could allow a final check on system performance to be made just prior to treatment by carrying the results of prior QA checks for evaluation. In either case it would be advantageous for QA information to be displayed to the person controlling treatment delivery in a way that would make the consequences of both RAB and QA errors obvious and addressable prior to treatment.

5.9 Critical Task 9: Source Exchange

Source exchange entails manipulation of radioactive sources. Errors in source exchange can result in inadvertent exposure of staff to the source during the exchange procedure, or produce changes in afterloading equipment that can cause problems in source positioning accuracy, equipment integrity, or treatment delivery. (Table A.13 in Appendix A presents source exchange errors in more detail.)

5.9.1 Evaluation of Current Techniques

Source exchange interfaces involve the containers used to hold the old and replacement sources, the mechanisms and software used to transfer the sources, the equipment used to connect the sources to the afterloaders, and the emergency equipment used to deal with problems during replacement. The equipment used to contain an exposed source during source exchange is often the same as that used to deal with an exposed source in a treatment emergency. The potential for error with that emergency equipment was particularly high. Emergency cranks for retracting cables were sometimes difficult to locate or confusing to operate. Although survey meters and radiation detectors were used during source exchanges, they provided only part of the information required by the staff. They could detect an exposed source, but did not allow staff to detect the presence or absence of a source in the safe used to hold the source or in the container used to transport it.

If an emergency occurs during scheduled source exchanges for HDR afterloaders, staff can remain outside the room while deciding how to contain the exposed source. During LDR source exchanges or in treatment emergencies staff or patients may be in the room when the source is exposed so that a more rapid and accurate response would be required. On-line help was available by telephone from the manufacturers for both source exchanges and emergencies. Descriptions of emergency procedures found at the sites were considered adequate for scheduled source exchanges but were not sufficient for emergency situations in which immediate action might be required to limit the exposure to patients or staff in the room with an exposed source.

Source exchange in HDR afterloaders is performed only a few times a year. Emergencies involving exposed sources should also occur infrequently. Because of the time lapse in performance of these tasks, training and detailed procedural descriptions would be useful during task performance.

Training was required and provided on site by the manufacturer before local RAB staff performed source exchanges. Manuals from the manufacturer also described some source exchange procedures. Checklists were sometimes used to guide performance and to document performance of the procedural steps. Some training in procedures dealing with treatment emergencies was also provided at many sites.

For example, one afterloader model had two emergency crank handles that rotated in opposite directions. The differences between these handles were judged to be confusing, so that manual retraction of a source might be prolonged due to staff uncertainty regarding which crank to grab and in what direction it should be turned. Another model also has two handles, but the source retraction handle is gold in color while the other similar handle is black. Staff trained in emergency procedures at several sites reported that they would "go for the gold" in an emergency.

All sites performed extensive tests of positioning accuracy and timing after source exchange to detect the consequences of errors in this task.

5.9.2 Alternatives to Current Techniques

At many sites, source exchanges are performed by a manufacturer's representative. These representatives performed many source exchanges per year and were familiar with source exchange and emergency procedures. They were not necessarily familiar with the local equipment for dealing with an exposed source. Alternatives to current

techniques must address emergency procedures as well as ways in which errors during source exchange can be detected and methods for limiting the consequence of those errors.

Equipment and Software Modifications

Neither LDR nor HDR sources could be counted or inventoried while they were in their safes. An exposed source was easy to detect during source exchange by using radiation monitors and survey meters. A lost source was much harder to detect. Current procedures assume that a source which is not detected in the room, is stored in its safe. A hardware method for detecting the presence of the source, rather than its absence, would be preferable.

Job Performance Aids

A method by which a source could be detached from its cable quickly if the cable should become stuck might be desirable since rapid removal of a trapped source would limit exposure of staff attempting to free the cable. To assist staff in dealing with exposed or trapped sources, transfer tongs, cable cutters, and shielded containers for loose sources could be provided in each treatment room.

Simple checklists for emergency situations in which the source must be contained or transferred could help reduce error and uncertainty in this task.

Procedures

Since source exchanges are performed infrequently, extensive documentation of the procedures to follow during this task would be useful. Having a vendor or an outside agent perform all source exchanges could help standardize performance of this task.

Errors affecting the integrity of the connection between the source and the positioning unit may be difficult to detect since the error may not be apparent until its consequences cause degradation or failure of the positioning mechanism. Test procedures could be designed to identify and document these and other hidden consequences of source positioning and connection problems. Until test information from automated equipment checks is available, staff could log any changes in positioning accuracy during QA and monitor them for trends that might indicate gradual degradation of the positioning or attachment mechanisms.

Training

Sites which perform their own source exchanges should consider providing training to all staff on the procedures and special characteristics of the workspaces and equipment used in this task.

5.9.3 Evaluation of the Alternatives

Any attempt to limit human error during source exchange must take into account the physical problems inherent in manipulating radioactive sources. The likelihood that manufacturers' representatives, who do many of the source exchanges, will not be familiar with local emergency procedures and equipment is an additional complication that alternative techniques should take into account. Checklists that specify the location of emergency equipment and emergency procedures are valuable in this regard.

Decreasing the Likelihood of Human Error

Shielded safes with entry diameters more than twice the diameter of a source trapped inside its source holder would be desirable to facilitate task performance during times of stress, when manual dexterity might be compromised. Most sites had lead containers near the afterloader unit for storing a source if it should become detached during treatment or source exchange. Only a few sites had tongs for transferring the source to the container or clippers for cutting the (HDR) source cable should it become jammed. The lead containers at many sites had an opening that was only slightly larger than the source itself so that transfer of a source to the container might prove to be quite difficult in an emergency situation.

A vendor that specializes in source exchange could limit source exchanges to a small number of trained and experienced individuals. This might prevent poor source exchange practices from being recognized and amended since feedback on the consequences of the exchange might not be recognized by RAB staff who were unfamiliar with source exchange procedures. Collaboration between people who were experienced with the local environment and the equipment used during the source exchange might be more effective.

A checklist would allow whoever performed the source exchange to locate and become familiar with the local emergency equipment and procedures before the source exchange took place. Refresher training in those procedures might be desirable immediately prior to source exchange This training could be extended to require certification of specific additional training from the manufacturer before performing this task.

Increasing the Detectability of Human Error

Equipment improvements could help staff detect the position of the source in its safe so that lost sources would be immediately obvious. Until feedback is provided from the hardware, it would be possible, although time consuming, to verify the presence of the sources in the treatment room after a treatment session by performing a radiograph with the sources positioned in a test applicator. Neither of these methods would detect whether part of a source had broken and become separated from the positioning device. Automatic source calibration before and after each treatment session would allow broken sources to be identified and may be the best alternative for identifying lost or misplaced sources. Until automated calibrators are developed, surveys of the patient and all removed applicators after treatment appear to be the only way in which these problems can be detected.

It would be desirable to follow each source exchange with periodic local evaluation of afterloader performance so that the consequences of errors (e.g., cables binding, position accuracy changes, positioning speed changes) could also be detected.

Limiting the Consequences of Human Error

Source exchange errors involving an exposed source have consequences similar to some treatment emergencies. During treatment and source exchange, inadvertent exposure of a source may require rapid action to limit exposure to the resulting radiation.

Rapid detachment and containment of a source which had become stuck in its applicator or source guide tube would not correct the error that exposed the source, but could limit radiation exposure by reducing the time that the source was exposed.

Rapid detachment may be desirable in an emergency, but would be quite undesirable if it should occur during a normal treatment. Cable cutters found at a few sites provided this quick-detach mechanism without requiring a redesign or weakening of the current source attachment methods. Since it was not clear at most sites whether staff knew what to do with these tools, or whether the tools could be used effectively by all staff for their intended purposes, a training program that provided the opportunity for staff to test the tools and their own abilities during simulated emergencies would be advantageous. Some sites used special teams to deal with emergencies. This would limit the training required for all staff, but would require careful scheduling to ensure that the emergency team was on site and able to respond to an emergency rapidly.

Any damage or misadjustment to afterloading equipment during source exchange can have serious consequences to patients if the accuracy of source placement is compromised. The consequences of damage to positioning equipment can be limited by early detection of the damage so that equipment can be repaired before it is used in RAB. Many of the tests required to detect damage to the equipment may already be incorporated in the hardware self-checks, although the results of these checks are not currently reported to users until they fail, and therefore cannot be used during QA to detect developing problems. Cooperation with manufacturers would be required to incorporate these tests into the local RAB QA program.

5.10 Critical Task 10: Source Calibration

Source calibration involves the measurement of the characteristics of a radioactive source and the transfer of that information to the RAB task in which those characteristics are needed. Source calibration errors involve either a failure to measure the activity of a radioactive source accurately or the failure to transmit the correct calibration information. (Table A.13 in the Appendix A presents source calibration errors in more detail.).

5.10.1 Evaluation of Current Techniques

RAB sources are ordered with specified intensities and are shipped with documents describing their activity as measured by the supplier. All sites perform their own calibrations of the sources after they are received and compare their calibrations to the values reported by the supplier. The activity of the source or calibrated activity was then entered into the treatment planning equipment and the afterloader control unit. Between calibrations, source activity was estimated by software that adjusted the calibrated activity using the known decay characteristics of each source. This introduced the opportunity for either entering the wrong calibration for the source or entering the wrong calibration date.

Interfaces for source calibration include activity measuring apparatus, placement and positioning equipment to hold the measuring apparatus near the source and material placed between the source and the measuring equipment during calibration. The source calibration equipment observed during the site visits required careful positioning and often needed non-intuitive manipulations to preserve stability. In particular, many of the calibration racks required accurate measurement of the distance between the source and the calibration sensor, but provided no feedback on possible movement of the sensor during the calibration and were subject to errors during measurement of that distance. These devices were adequate for calibration in spite of

these problems because the people using them were familiar with their idiosyncrasies and quite meticulous about compensating for them.

Two things were lacking in most of these interfaces:

(1) adequate feedback to allow users to detect calibration errors

(2) consensus on standard calibration procedures

5.10.2 Alternatives to Current Techniques

The likelihood of human error in source calibration can be reduced by the provision of equipment and procedures better designed to support the calibration task and the staff who perform it.

Equipment and Software Modifications

Calibration equipment and interfaces are currently undergoing investigation for standardization by several professional organizations. Those standards should address potential positioning errors by requiring that sensing apparatus be rigidly mounted to the source holder and that feedback be provided on the distance between the source and the sensor so that any damage to the rigid mounting can be detected.

No direct measurement of activity was possible for the iridium sources used in HDR RAB since chambers calibrated to measure radiation from that radionuclide were not available commercially. The calculations and adjustment procedures needed to adapt other chambers to RAB are time consuming and effectively prevent frequent spot checks of source activity on those devices due to the time and special equipment needed for the calibration.

Cost of measuring and positioning apparatus, and uncertainties about different measurement techniques have led many sites to design their own calibration equipment. These differences in equipment and measuring techniques make the interpretation of differences between the activity specified by the manufacturer and the activity measured locally difficult.

An alternative approach would be to develop a standard chamber for measuring the activity of each RAB radionuclide and a standard procedure that could be used by both the vendor and the RAB staff for measuring that activity.

Job Performance Aids

Positioning apparatus for holding the source near the calibration device was not standardized. The locally built apparatus often presented numerous opportunities for positioning errors that could lead to erroneous calibrations. A standardized positioning device which placed the source at a fixed distance from the calibration counter and which was not subject to misadjustment would help limit the opportunity for error in this task.

Procedures

The presence of unexpected isotopes in a new source could be detected if some way were found to measure the isotopes in the source during calibration. This might entail an analysis of the energies of the decay products. The consequences of source contamination could be limited if each site performed at least two calibrations of each source separated by a long enough interval to determine whether the radionuclide in the source is following its expected decay sequence. If the initial calibration is accurate, the source could be used in the interval between these calibrations. This alternative would be valuable at all sites for which the decay is significant in treatment (e.g., high dose sites or low dose sites which store or re-use radionuclides).

Source calibration could also be performed on a regular basis as part of a QA program designed to reduce the number of treatments that are affected by a calibration error.

To detect a procedural or equipment error during calibration, some way of certifying the calibration procedure and equipment performance must be provided. Most sites did not have a formal procedure for this certification and relied instead on the physicists to maintain and trouble shoot their own equipment and calibration procedures.

An alternative approach might be to institute a QA program that included certification of the calibration equipment and procedure by using it to calibrate a known source prior to each new source calibration. For HDR sites this could involve performing a calibration on the old source prior to its replacement to verify that the calibration yielded the expected (decayed) old source activity. The new source could then be calibrated using the same procedure and equipment which had just been tested on the old source.

To detect the consequences of a calibration error, some redundant information on the source activity and decay characteristics must be compared with the calibration results. Vendors supply this information with each source

from calibrations performed prior to shipping sources to RAB sites. Staff at most sites indicated that before using the sources they compare their calibrations with the values supplied by the vendor and then re-calibrate or contact the supplier for advice if these values differed by more that five to ten percent (after adjustment for decay). Calibration discrepancies of 5 percent were common and 10-15 percent were not unusual.

An alternative would be to also perform multiple calibrations of the source using different equipment, positions, and procedures and compare them.

Training

The fragility of the measuring equipment and the difficulty of the positioning and measuring steps in this task need to be balanced by expertise and dedication on the part of the task performers if this task is to be performed safely with existing equipment. Although staff performing calibrations at all sites met these requirements, there was little evidence of organized training on site for these tasks.

An alternative approach would be for either individual sites or professional associations to provide training and certification for staff performing source calibrations.

5.10.3 Evaluation of the Alternatives

Until automatic calibration becomes feasible, the potential for human error in calibration, and the serious consequences of such an error, will continue to require special QA procedures for this task. Standardization of calibration equipment and procedures would go far in helping to minimize human error. Establishing a source calibration protocol involving multiple calibrations would aid in the detection and correction of procedural errors.

Decreasing the Likelihood of Human Error

Automatic calibration would remove most sources of human error for this task. A standard chamber for measuring the activity of each RAB radionuclide would facilitate automatic or staff calibration by reducing the number of mathematical calculations required to translate calibration results into the activity units used by planning and treatment delivery systems. The most attractive use of such a chamber might be to incorporate it into the source safe so that a calibration could be performed automatically whenever the source was in its stored position. This might also reduce the chance for positioning errors during calibration since the source could be returned to a fixed position within the safe by the afterloader prior to calibration.

Calibration equipment and interfaces are currently undergoing investigation for standardization by several professional organizations. Those standards should address potential positioning errors by requiring that sensing apparatus be rigidly mounted to the source holder and that feedback be provided on the distance between the source and the sensor so that any damage to the rigid mounting can be detected.

Increasing the Detectability of Human Error

Multiple calibrations currently provide the only way to detect calibration errors. Performing multiple calibrations would be more attractive if calibrations took less time, did not interfere with patient treatment, and included fewer human error opportunities. Direct measurement would eliminate many potential sources of error in adapting calibration equipment for RAB use.

Calibrations after each treatment could be compared to increase the likelihood of detecting and correcting calibration errors. A method for determining the source activity quickly prior to each treatment would serve the same purpose and would be more desirable as a final check that the source activity specified in the treatment directive or treatment plan was the same as the one about to be used in the afterloader.

Limiting the Consequences of Human Error

Calibration errors are systemic in that a single error in this task will produce consequences in all the subsequent treatments using that calibration. These consequences can be eliminated if calibration errors are detected and corrected prior to treatment.

The alternative of performing multiple calibrations after the initial source exchange and at least one other calibration separated from the initial one by an interval long enough to identify the decay characteristics of the radionuclide could provide the basis for correcting the consequences of a calibration error.

All sites reported that they would compare calibration results with vendor values prior to using the calibration. This method of detecting a calibration error prior to treating a patient would prevent the consequences of a single calibration error (either in the vendor's or the local calibration) from propagating to a place (e.g., the treatment planning or treatment delivery systems) where it could cause damage to patients..

The consequences of another possible error were not so well limited. After calibration, many sites assumed that a single radionuclide was present in the source and that the

activity of that source at a later date could be calculated using the known half-life of that radionuclide. Since a single calibration can determine the source activity but not the actual radionuclide, a shipping or manufacturing error in which the source might contain or be contaminated with other radionuclides would not be detected by this procedure. In such a situation, although the initial calibration might be completely accurate, the activity after decay would drift away from the expected value.

An alternative that might allow source contamination to be detected would be to analyze the energies of the decay products. Such an analysis might be easier to perform by the source vendor prior to encapsulation of the source. A method for analyzing photon energies might be developed to help identify source contamination after the source was delivered to the RAB site.

The ultimate consequence of a calibration error is the delivery of a different dose of radiation to a patient than was specified in the treatment directive. In some cases in which the directed dose is delivered in multiple treatment fractions, these consequences can be limited by adjusting the dose delivered in subsequent fractions to compensate for the dosage errors in previous fractions. This form of damage control requires that the error be detected (before the total dose exceeds that on the treatment directive), that the actual source activity at the time of treatment be determined, and that careful records of dwell positions, dwell times, and target locations be preserved so that the previous target dosages can be recalculated after the calibration error is corrected.

Alternatives which allowed the actual dose to a target to be measured would help detect the consequences of a calibration error and might eliminate the need for recalculation and the possibility of additional error during the recalculation process.

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6 Summary and Conclusions

This project consisted of an extensive human factors evaluation of remote afterloading brachytherapy. It involved three stages of data collection at 23 RAB facilities that were selected to represent different treatment types (high dose rate vs. low dose rate), patient populations, geographic regions, and institutional affiliations.

6.1 Summary

Analysis of the data from these visits was performed in six phases.

Phase 1 provided a function and task analysis of RAB. This analysis characterized RAB as a process in which patient preparation, treatment planning, treatment, and quality assurance and maintenance functions were carried out by staff who performed specific RAB operational tasks.

Phase 2 evaluated the human-system interfaces used by RAB staff to perform the operational RAB functions and tasks.

Phase 3 evaluated the procedures and practices used to perform the RAB operational tasks. This analysis also identified the methods used to link the tasks together and the communications procedures used to pass information and material between the tasks.

Phase 4 evaluated the training that the RAB staff had received in those procedures and practices.

Phase 5 evaluated the organizational support provided for RAB at each site including the definition of goals, design of procedures, communications, monitoring, and goal direction.

Phase 6 used the information from the prior five phases to identify opportunities for human error in an RAB treatment planning and treatment delivery system. Alternative approaches for addressing these error opportunities were identified and evaluated.

As a result of those evaluations, ten critical tasks were identified. A task was considered to be critical if failure to accomplish it in accordance with RAB system requirements would impair system reliability, effectiveness, safety, or cost. The effects of human error on patient and staff safety were emphasized in making these determinations. The ten critical tasks and their associated errors were

Critical Task 1: Patient Scheduling, Identification, and Tracking

This task involves the initial identification of the patient and any re-identification that is required as the patient and the patient's records are moved through the RAB system. Errors in these tasks involve scheduling the patient for the wrong treatment, bringing the patient to the wrong treatment area, or delivery of treatment to the wrong patient due to misidentification of the patient or patient's records at some point during the treatment procedure.

Critical Task 2: Applicator Placement and Stabilization

This task requires that applicators be selected, placed near a target in the body, and secured to prevent movement after placement. Information on the characteristics of the applicator (e.g., diameter, length) and applicator placement must be transmitted to the treatment planners and to the staff performing applicator connections. Errors in these tasks involve failure to place the applicator so that the desired dose can be delivered to the targets, failure to stabilize the applicator after placement, or failure to transfer accurate information on placement distances and applicator characteristics to other tasks.

Critical Task 3: Target Volume Localization

This task involves identification and specification in some coordinate system of the volume that is to be irradiated during treatment. Errors in this task involve failure to identify targets, or failure to specify an accurate position and volume for each target that will be irradiated during treatment.

Critical Task 4: Dwell Position Localization

This task involves identification, specification and communication of the positions that sources will occupy in the applicator during treatment. Errors in performing this task involve incorrect identification, specification, or transfer of information on the source positions.

Critical Task 5: Dosimetry

This task involves calculation of the dose distribution due to sources placed at specified dwell positions for specified times. Errors in dosimetry involve failure to calculate the dose accurately or failure to describe the dose that will be received by each target from sources placed at the dwell positions. Errors in the specification of the target locations or dwell positions, in the strength of the source, in the specification of the dwell times at the dwell positions, in the calculation of the dose distribution due to the source placements, or in matching the dose distribution to the targets may also occur.

Critical Task 6: Treatment Set-Up

This task involves connection of the patient to the afterloader. Errors in treatment set-up involve swapping two or more treatment channels so that treatment planned for one applicator will be delivered through another, connection of improper guide tubes so that the planned treatment distance does not correspond to the planned dwell positions, or modification of the spatial relationship between the applicator and the targets so that the dose distribution does not hit its planned targets.

Critical Task 7: Treatment Plan Entry

This task involves transfer of treatment parameters from the treatment plan to the afterloader control unit. Errors in treatment plan entry involve either the use of different values from those contained in the treatment plan or entry of treatment plan values from the wrong treatment plan for the intended treatment.

Critical Task 8: Quality Assurance and Maintenance

Quality assurance in RAB involves testing equipment and procedures to identify malfunctions or potential problems before they adversely affect treatment planning, treatment delivery or patient or staff safety. Maintenance involves changes to equipment or procedures designed to prevent or eliminate either potential or actual problems. Errors in QA and maintenance involve either failures to detect, deal with, or communicate problems in equipment, procedures, and treatment delivery mechanisms or the creation of problems in these areas during the performance of the QA or maintenance procedures.

Critical Task 9: Source Exchange

Source exchange involves the scheduled replacement of radioactive sources. Errors in source exchange can result in inadvertent exposure of staff to the source during the exchange procedure, or produce changes in afterloading equipment that can cause problems in source positioning accuracy, equipment integrity, or treatment delivery.

Critical Task 10: Source Calibration

Source calibration involves the measurement of the characteristics of a radioactive source and the transfer of that information to the RAB task in which those characteristics are used. Source calibration errors involve either a failure to measure the activity of a radioactive source accurately or the failure to transmit the appropriate calibration information.

6.2 Conclusions

Phases 1 through 5 identified factors (root causes) which can contribute to human error in RAB and determined the characteristics of well-designed RAB systems. RAB human-system interfaces should clearly indicate system status and provide RAB staff with a reliable means of interacting with the RAB system. RAB procedures should direct the flow of materials and information through the RAB system. Errors should be easy to detect and correct. Training and job performance aids should impart task-relevant knowledge and skills to minimize human error. Organizational support of RAB helps to ensure that needed workspaces, resources, equipment, and training are made available, and that procedures have been designed to perform tasks, link them together, and verify that they have been performed.

In light of these findings, Phase 6 evaluated ten critical RAB tasks for current task performance techniques. These ten tasks were chosen on the basis of their vital role in determining the safety of RAB patients and staff. Where appropriate, alternative procedures for performing these tasks were proposed and evaluated.

The results of Phase 6 indicated that certain modifications to the RAB system could be performed to

(1) reduce the likelihood of human error

(2) increase the opportunities for detecting and correcting human error

(3) limit the undesirable consequences of human error

6.2.1 Human-System Interface and Equipment Modifications

Equipment modifications require additional support from equipment manufacturers, software vendors, and the research community to improve some of the interfaces between humans and the RAB equipment. Some possible alternatives include

- tag readers for patient identification tags
- automatic comparison of patient and treatment plan identifications
- permanent labels on applicators that might be misidentified
- applicator stabilization aids
- digitization aids (e.g., scanners and target superimposition aids)
- improved feedback and visualization aids for treatment planners

- unambiguous data entry formats
- dwell positions referenced to the applicator instead of the afterloader
- pre-treatment dose estimation based on treatment plan parameters
- direct calibration chambers for RAB sources
- improved access to emergency source containment safes.
- automatic calibration while the source is in its stored position
- source position sensors (minimum would detect a source in the safe)
- measurement of dose delivered (to some reference volume) during treatment
- performance certification packages for software and hardware

6.2.2 Job Performance Aids

- highly visible identification tags that can be attached to the patient and all his documents
- radio-opaque identification labels that can be attached to applicators
- an applicator-channel map
- QA checklists that highlight failed or omitted checks
- visualization aids for treatment planning

6.2.3 Procedure Modifications

- tagging procedures for the patient and patient documents
- use of an applicator-channel map for treatment planning and treatment setup
- standardization of dosage units
- target marking in simulation views (when applicable)
- minimization of patient movement between simulation and treatment
- erasure of magnetic media used to transfer treatment plans.
- multiple source calibrations

6.2.4 Training Modifications

- integration of QA with refresher training in emergency and planning procedures
- training in local task performance and linkage procedures
- training in error detection and allocation of error detection duties

6.2.5 Organizational Support Modifications

- a multi-tiered quality assurance program stressing early error detection
- identification of error opportunities
- display of information needed for error detection to all staff
- communication procedures that pass redundant information needed for error correction
- verification of task linkages prior to treatment
- certification of all RAB equipment and software after maintenance
- monitoring the efficacy of procedures and training in preventing errors
- monitoring the efficacy of RAB error detection and correction

Taken together, alternative approaches to HSI, job performance aids, procedures, and training could reduce the likelihood of errors in all of the critical tasks. The hardware modifications would also reduce the burden on staff by automatically performing some of the currently difficult procedures, automating error-prone linkages, and providing needed feedback to staff on their performance and on system integrity. The remaining organizational alternatives would improve quality assurance and increase the opportunity for detecting and correcting human errors. These alternatives would eliminate many existing opportunities for human error. They would also improve quality assurance and safety by making errors easier to detect, and by providing staff with the information they need to identify and address the consequences of error in the RAB process.

Although the alternative approaches provide some direction to solve problems in the critical tasks, they do not include the level of detail that would be required for implementation. In many cases, more than one alternative has been suggested for a single problem to allow for interim improvements until more technically challenging but potentially better solutions can be achieved.

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7 References

American National Standards Institute/Human Factors Society, "American National Standard for Human Factors Engineering of Visual Display Terminal Workstations," ANSI/HFS 100-1988, Santa Monica, CA, 1988.

Association for the Advancement of Medical Instrumentation, "Human Factors Engineering Guidelines and Preferred Practices for the Design of Medical Devices," ANSI/AAMI HE48—1993, Arlington, VA, 1993.

Callan, J.R., J.W. Gwynne, D. Sawyer, and M.T. Tolbert, *Principles of Medical Device Labeling*, NTIS PB 94-126851, 1993.

Cochran, W.G., *Sampling Techniques* (3rd ed.), Wiley, New York, 1977.

Fleishman, E.A., and M.D. Mountford, "Individual Attributes and Training Performance," In I.L. Goldstein, et al., eds., *Training and Development in Organizations*, Jossey-Bass, San Francisco, CA, 1989.

Fleishman, E.A., and M.K. Quaintence, *Taxonomies of Human Performance: The Description of Human Tasks*, Academic Press, Orlando, FL, 1984.

Gagne, R.M., L.J. Briggs, and W.W. Wager, *Principles of Instructional System Design* (3rd ed.), Holt, Rinehart, & Winston, Fort Worth, 1988.

Kish, L., *Survey Sampling*, Wiley, New York, 1965.

Mallamud, S.M., J.M. Levine, and E.A. Fleishman, "Identifying Ability Requirements by Decision Flow Diagrams," *Human Factors*, 22, 57–68, Human Factors Society, Santa Monica, CA, 1980.

National Aeronautics and Space Administration, NASA-STD-3000, "Man-System Integration Standards," Lyndon B. Johnson Space Center, Houston, TX, March 1987.

Reid, G.B., C.A. Shingledecker, and F.T. Eggemeier, "Application of Conjoint Measurement to Workload Scale Development," *Proceedings of the Human Factors Society 25th Annual Meeting*, (pp. 522–526), Human Factors Society, Santa Monica, CA, 1981.

Seven, S.A., A. Akman, F.A. Muckler, B.G. Knapp, and D. Bernstein, "Development and Application of Military Intelligence (MI) Job Comparison and Analysis Tool (JCAT)," Research Note 91-41, U.S. Army Research Institute, Alexandria, VA, 1991.

U.S. Department of Defense, "Anthropometry of U.S. Military Personnel (metric)," DOD-HDBK-743A, Washington, D.C., October 3, 1980.

U.S. Department of Defense, "Human Engineering Guidelines for Management Information Systems," MIL-HDBK-761A, Washington, D.C., September 30, 1989.

U.S. Department of Defense, "Human Factors Engineering Design for Army Materiel (metric)," MIL-HDBK-759B (MI), Washington, D.C., June 30, 1992.

U.S. Department of Defense, "Manuals, Technical: General Style and Format Requirements," MIL-M-38784B, Washington, D.C., April 16, 1983.

U.S. Department of Defense, MIL-STD-1472D, "Human Engineering Design Criteria for Military Systems, Equipment, and Facilities," Washington, D.C., March 1989.

U.S. Food and Drug Administration, "Medical Device Problem Reporting Program, Final Rule," 21 CFR Part 803, FDA Center for Devices and Radiological Health, December 13, 1984.

U.S. Food and Drug Administration, "Medical Devices Bulletin," FDA Center for Devices and Radiological Health, August 1989–June 1991.

U.S. Food and Drug Administration, "Radiological Health Bulletin," FDA Center for Devices and Radiological Health, August 1989–June 1991.

U.S. Nuclear Regulatory Commission, "Analysis and Evaluation of Operational Data, Annual Report," NUREG-1272, 1981–1992.

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

References

U.S. Nuclear Regulatory Commission, "Guidelines for the Preparation of Emergency Operating Procedures," NUREG-0899, August 1982.

U.S. Nuclear Regulatory Commission, "Medical Use of Byproduct Material (10 CFR Part 35, Subpart A, Section 35.2)," Code of Federal Regulations, January 1, 1994.

Appendix A: Error Tables

Tables A.1 to A.14 show the 76 human errors which were identified in the RAB conceptual model as likely to propagate through a RAB system and cause danger or injury to patients or staff. The data in each table are arranged by RAB function and task into 14 columns.

Column	Description
1	Identifies the task in which the error occurred.
2	Specifies the task step in which the error originated.
3	Describes the human error.
4	Shows whether the error is one of task performance or task linkage.
5	Describes the immediate effect of each error on the RAB system.
6, 7, 8	Describe the consequences predicted by the conceptual model of allowing an uncorrected error to propagate through the RAB system on other RAB tasks (6), the patient (7), and the RAB staff (8).
9	Specifies the information needed to detect an error or its consequences.
10	Describes a procedure for using information in Column 9 to determine that an error has been made.
11	Specifies what additional information is needed to recover from the error.
12	Provides an error recovery procedure that could be used if the information specified in Column 11 was available. (In some cases, the information was judged unlikely to have been preserved and transmitted to the point of detection so that the only recovery procedure specified is to repeat the task in which the error was made.)
13	Identifies possible adverse consequences to the patient or RAB system caused by the recovery procedure described in Column 12.
14	Suggests procedures that could be used to minimize or prevent the occurrence of the original error.

Individual tables are arranged in approximate sequential order of steps in RAB functions and tasks:

Table	Contains errors dealing with
A.1	Scheduling and patient preparation
A.2	Applicator selection, placement, and stabilization
A.3	Record keeping and transport after applicator placement
A.4	Simulation set-up
A.5	Simulation
A.6	Simulation record-keeping
A.7	Dose prescription communication
A.8	Treatment planning
A.9	Treatment set-up
A.10	Treatment delivery
A.11	Post-treatment
A.12	Routine quality assurance
A.13	Maintenance
A.14	Equipment and software updates

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Table A.1. Scheduling and Patient Preparation Errors

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Task	Step	Human ERROR	Type of error	Immediate effect of error	Effects on other RAB tasks	Danger to patient	Danger to staff	Information needed to detect error or its effects	Detection procedure	Additional information needed to recover from error	Recovery procedure	Recovery sequelae	Prevention procedure
Patient scheduling and tracking	Patient scheduling	Data entry error	Task performance	Wrong treatment scheduled	Unintended RAB procedures may be performed	Unintended dosage or physical trauma	None	Expected treatment from treatment directive or prior history	Compare scheduled treatment with expected treatment	Treatment prescribed for patient	Re-schedule prescribed treatment	Delay	Minimize entries and use automated cross-checking of information
	Patient tracking	Patient identification error	Task linkage	RAB procedures intended for a different patient may be performed	Records for this treatment may be used later for treating the other patient	Unintended dosage or physical trauma	None	Second method to identify patients and their records	Check that both ID methods yield the same results	A unique and correct ID for the patient	Use correct ID	Delay	Maximize ease and frequency of identification
		Patient routing error	Task linkage	Patient sent to wrong treatment area	Delay	Unintended dosage or physical trauma	None	Method to identify the expected patient at each work area	Compare the incoming patient with the expected patient	Correct destination for the mis-routed patient	Re-route patient to proper area	Delay	Minimize patient transfers between staff
Patient instruction		Failure to prepare patient for treatment	Task performance	Patient unable to perform tasks expected of him during treatment	Patient may interfere with treatment	Possible injury or overdose	Possible injury or unintended dose	Assessments of patient understanding and the understanding required for his assigned tasks	Compare patient understanding with required understanding	Reason for failure	Re-instruct patient or modify requirements	Delay	Minimize understanding required of patient
Life support attachment		Attachment error	Task performance	Life support equipment may malfunction	Life support equipment may interfere with simulation or treatment	Possible injury or death	Possible injury	1. Indicators of correct attachment. 2. Life support monitoring equipment.	1. Verify attachments. 2. Monitor life support performance.	1. Patient status indicators. 2. Equipment status indicators.	1. Re-attach. 2. Obtain expert assistance to assess and treat life support problems.	Patient must be stabilized physio-logically before proceeding	Allocate life support duties to experts familiar with the equipment

Table A.2. Applicator Selection, Placement, and Stabilization Errors

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Task	**Step**	**Human ERROR**	**Type of error**	**Immediate effect of error**	**Effects on other RAB tasks**	**Danger to patient**	**Danger to staff**	**Information needed to detect error or its effects**	**Detection procedure**	**Additional information needed to recover from error**	**Recovery procedure**	**Recovery sequelae**	**Prevention procedure**
Applicator Placement	Locate tumor	**Tumor location in body misidentified**	Task performance	Applicator not placed near tumor	Radiation target may not contain the tumor	Target dose may miss tumor and hit unintended part of body	None	Location of tumor in relation to applicator	Compare applicator position with tumor location	Location of tumor in body	Re-place applicator or adjust target	1. Possible trauma due to re-placement. 2. Adjusted treatment volume may not be optimal.	Verify tumor position after placement of applicator.
	Select applicator	**Inappropriate applicator selected**	Task performance	Characteristics of placed applicator are inappropriate for the intended target	Shaping dose distribution to cover the target may be difficult	High doses may occur at undesirable places when desired dose is delivered to the target	None	1.Characteristics of selected applicator. 2. Characteristics of the appropriate applicator.	Compare characteristics of selected applicator with those of appropriate applicator	Dose adjustment methods	Re-place applicator or adjust dose	1. Possible trauma due to re-placement. 2. Adjusted treatment volume may not be optimal	Standardize applicators. Verify choice after placement.
	Place Applicator near the tumor	**Applicator not placed near tumor**	Task performance	Applicator not placed near tumor	Dose distribution based on applicator position may not hit tumor	Target dose may miss tumor and hit unintended part of body	None	Location of tumor in relation to applicator	Compare applicator position with tumor location	Location of tumor in body	Re-place applicator or adjust dose	1. Possible trauma to patient during replacement. 2. Dose adjustment may require irradiation of normal tissue.	Verify tumor location and applicator placement before securing applicator
	Secure applicator after placement	**Applicator inadequately secured**	Task performance	Applicator-tumor geometry can change after placement	1. Dose based on the applicator position may miss targets. 2. Source travel may be blocked if applicator is bent.	Delivered dose distribution and intensity may differ from treatment directive specifications	Unintended dose possible if a trapped source must be removed manually	Indicator of applicator movement since placement	Measure amount of movement that has occurred	1. Original position of applicator. 2. Current position of applicator.	1. Re-place applicator and re-do treatment plan. 2. Re-secure at the original position.	1. Delay. 2. Movement of patient. 3. Possible trauma to patient during replacement.	Test and verify that applicator has been secured.
	Affix channel connector to applicator (catheters only)	**Connector incompletely mated to catheter**	Task performance	Connector will not mate with afterloader until reseated	1. Reseating changes length of catheter. 2. Simulated dwell positions will not match treatment positions.	Dose distribution positioned (0.1 to 1 cm.) "short" of target in space	None	Observable differences between properly and improperly inserted connections	Note tactile and visual feedback from connector during simulation. Connector will not mate at hook-up	1. Proper connection procedure. 2. Whether simulation has been performed.	(Pre-sim) re-seat connector. (Post-sim) re-seat, repeat simulation, Rx, and plan.	1. [pre-sim] None 2. [hookup] Delay and patient movement to redo simulation and plan	Check and re-seat prior to simulation

Table A.3. Patient Preparation Errors– Record-keeping and Transport after Applicator Placement

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Task	**Step**	**Human ERROR**	**Type of error**	**Immediate effect of error**	**Effects on other RAB tasks**	**Danger to patient**	**Danger to staff**	**Information needed to detect error or its effects**	**Detection procedure**	**Additional information needed to recover from error**	**Recovery procedure**	**Recovery sequelae**	**Prevention procedure**
Record keeping after placement	Label applicators (when multiple applicators used)	**Applicator mislabeled**	Task linkage	The relationship between the physical placement of applicators and their labels is lost	Channel connections using labels may not match plan based on applicator positions	Dose prescribed for one applicator may be delivered through another	None	Second method (other than labels) for identifying each applicator	Compare the two identifications for each applicator	Method [applicator-channel map] to match each applicator with a treatment channel specified in the treatment directive	Determine which applicator corresponds to each treatment channel and make the proper connections at hook-up	None	Make an applicator-channel map and verify that labels conform to it.
	Record applicator diameters	**Applicator size recorded incorrectly**	Task linkage	Wrong applicator characteristics sent to treatment planning task	Treatment directive or plan based on wrong applicator specifications	Dose intensity to tissue touching applicator may be incorrect	None	An independent method for identifying applicator diameter	Compare the two identifications for each applicator	The actual diameter used	1. [pre-plan] Record actual diameter or 2. [post-plan] Re-plan using actual diameter	Delay if a new treatment plan must be generated	Standardize on a single diameter for most cases and use self-documenting (radio-opaque) diameter codes.
	Record applicator lengths	**Applicator size recorded incorrectly**	Task linkage	Wrong applicator length sent to treatment planning task	Treatment directive or plan based on wrong distance	Dose may hit unintended target.	None	An independent method for identifying applicator length	Compare the two identifications for each applicator	The actual length used	1. [pre-plan] Record actual length. 2. [post-plan] Re-plan using actual length.	Delay if a new treatment plan must be generated	Use self-documenting (radio-opaque) applicator length codes.
	Transport patient to next area (Simulation or Treatment)	**Applicator moved during transport**	Task linkage	Applicator-body geometry changed	Dose distribution based on applicator position may not hit tumor	Target dose may miss tumor and hit unintended part of body.	None	Applicator movement indicator	Check indicator	1. Original position of applicator 2. Current position of applicator	Re-position applicator or re-plan treatment using current applicator position.	1. Delay. 2. Possible trauma to patient during repositioning.	Minimize transport. Secure applicator prior to transport.

Table A.4. Simulation Set-up Errors

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Task	**Step**	**Human ERROR**	**Type of error**	**Immediate effect of error**	**Effects on other RAB tasks**	**Danger to patient**	**Danger to staff**	**Information needed to detect error or its effects**	**Detection procedure**	**Additional information needed to recover from error**	**Recovery procedure**	**Recovery sequelae**	**Prevention procedure**
Simulation	Insert dummy sources into applicator	**Dummy string forced into applicator**	Task performance	Dummy source string may bend and change source spacing	Source spacing in plan may not match the spacing during treatment	Dose may be higher than intended at some parts of distribution	None	1. Original spacing of dummy sources. 2. Spacing from simulation.	Compare original and reconstructed spacing	Index of accuracy of reconstructed spacing	Re-do simulation or base treatment plan on reconstructed spacing	Treatment plan spacing may not correspond to standard	Use stiff dummy strings that do not bunch up in the applicator
		Dummy string not completely inserted into applicator	Task performance	First dummy source not at expected distance from end of applicator	Treatment plan may misidentify treatment distances	Dose may hit wrong target.	None	Reconstructed and expected positions of most distal dummy source	Compare reconstructed dummy distance with expected value	[post sim] Distance reference for treatment dose	Shift dose distribution from simulated to treatment distance.	Errors may occur during correction calculation	Verify dummy distance during simulation
		Short dummy string inserted	Task performance	Dummies do not reach end of applicator	Same as above	Same as above	None	Same as above	Same as above	Same as above	Same as above	Same as above	Standardize on one length of string
	Secure dummy string after insertion	**Dummy string not secured after placement**	Task performance	Dummy source string can move	Dwell positions from simulation may not match treatment positions	Dose may hit wrong target	None	Stability indicator for dummy string	Check indicator	Correct placement indicator	Place in correct position and re-secure	Simulation must be repeated after correction	Verify stability prior to exposing simulation images
	Record which dummy string was placed in each applicator	**Correspondence between dummy codes and applicator labels recorded incorrectly**	Task linkage	Dummy strings used in treatment planning will identify different applicators from labels used during hook-up.	A dose prescribed for one channel may be delivered to another	Dose may hit wrong target	None	Second method for determining which dummy should be in each applicator	Compare record with second method	Correspond-ence between dummy images, the treatment directive, applicators, and afterloader channels	Verify that the doses in the treatment directive will be delivered to the appropriate applicators. Re-plan if necessary.	Corrected treatment plan must specify which applicator is to be connected to each treatment channel	1. Base plan on channels identified by dummy images. 2. Leave dummies in applicators until hook-up.
	Record original dummy spacing	**Dummy spacing misidentified**	Task linkage	Recorded spacing does not match spacing in simulation images	Treatment plan may not match treatment locations	Dose may be too high at some parts of distribution	None	Second measurement of dummy spacing	Compare record with second method	Actual dummy spacing	Re-plan with actual dummy spacing	Error may be made while correcting information	Use a single dummy source spacing.

Table A.5. Simulation Errors

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Task	Step	Human ERROR	Type of error	Immediate effect of error	Effects on other RAB tasks	Danger to patient	Danger to staff	Information needed to detect error or its effects	Detection procedure	Additional information needed to recover from error	Recovery procedure	Recovery sequelae	Prevention procedure
Simulation	Position patient for simulation view	Patient positioned incorrectly	Task performance	View may not contain all information needed	Treatment distances based on images may be incorrect	Treatment doses may not hit intended targets	None	1. Information needed. 2. Information present in simulation.	Compare information needed with information in simulation	Source other than simulation images for excluded information	Add missing information to simulation view	Additional human error may be made while adding information	Check information content of simulation view before image is made
		Applicator moved	Task performance	Applicator-body geometry changed	Treatment dose based on original positions may miss target	Dose may hit wrong target	None	Applicator movement indicator	Check indicator	1. Original position of applicator. 2. Current position of applicator.	Re-position applicator and/or repeat simulation	1. Delay. 2. Possible trauma to patient during repositioning.	Secure applicator and minimize patient movement
		Dummy source moved	Task performance	Dummy source positions in applicator changed	Images of dummy sources not at treatment positions	Treatment doses may not hit intended targets	None	Dummy source movement indicator	Check indicator	Correct position for dummy source	Re-position dummy string and repeat simulation	Simulation and planning must be repeated if error is detected after they have occurred	Secure dummy source to prevent movement.
	Expose simulation image	Image exposed incorrectly	Task performance	Images difficult to see on film	Structure or dummy source position misidentified	Treatment doses may not hit intended targets	None	1. Information needed. 2. Information present on simulation images.	Compare information needed with information present in negative	None	Re-do simulation	Delay	Training in simulation exposure procedures
	Transport patient to treatment area	Applicator moved	Task linkage	Applicator-body geometry changed	Distances previously measured between applicators and targets will not match treatment distances.	Doses will not be delivered to their planned locations in body	None	Applicator movement indicator	Check indicator	1. Original position of applicator. 2. Current position of applicator.	Re-position applicator and/or repeat simulation and treatment plan	1. Delay. 2. Possible trauma to patient during replacement.	Secure applicator and minimize patient movement

Table A.6. Simulation Recording-keeping Errors

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Task	Step	Human ERROR	Type of error	Immediate effect of error	Effects on other RAB tasks	Danger to patient	Danger to staff	Information needed to detect error or its effects	Detection procedure	Additional information needed to recover from error	Recovery procedure	Recovery sequelae	Prevention procedure
Simulation	Record view angle and magnification for image	Magnification or view angle recorded incorrectly	Task linkage	Incorrect magnification and view angle of simulation images sent to planning task	Reconstruction of dummy source positions in space may be in error	Dose distribution may not cover intended target	None	Second method to identify view angle and magnification	Verify that both ID methods yield the same result	Independent method to identify view angle and magnification from simulation images	Determine correct view angle and magnification	Calculations using incorrect values must be repeated	Standardized values and procedures to ensure their use
	Label simulation images	Patient misidentified	Task linkage	Images labelled with ID of wrong patient	1. ID for this patient will not match image ID. 2. Images may be used for other patient's treatment.	[this patient] image ID check may cause false substitution of other images	None	Second method to match patient to images	Verify that both ID methods yield the same result	Independent method to identify patient from simulation images	Locate or reproduce images for this patient and treatment fraction	Treatment plan and directive may have to be re-produced	Training in and utilization of patient and image ID verification procedures
		Treatment fraction misidentified	Task linkage	Images labelled with wrong treatment fraction	Images may not be located when required	Images may be used in error for later treatment fraction	None	Second method for indicating treatment fraction for which images were produced	Compare label with treatment fraction	Actual treatment fraction for which negatives were produced	Replace label with correct one	Treatment plan based on label may need to be re-calculated	Training in an utilization of treatment fraction ID procedures
		AP and lateral views mislabeled	Task linkage	None	Images recognized by their positions in a view may be misidentified	None	None	Information in image to identify view angle	Compare label with information in image	None	Not needed	None	Not needed
	Transport simulation results to next planning station	Wrong images transferred	Task linkage	Images used for treatment directive or plan not those from simulation for this treatment fraction	Treatment directive or treatment plan may be based on incorrect images	Doses may not hit their intended targets	None	Identification of patient, treatment directive, and images	Compare image ID with patient, date and treatment directive	Method to identify correct images for this treatment fraction	Locate or reproduce images for this patient and treatment fraction	Treatment plan and directive may have to be re-produced	Training in and utilization of patient and image ID verification procedures

Table A.7. Dose Prescription Communication Errors

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Task	**Step**	**Human ERROR**	**Type of error**	**Immediate effect of error**	**Effects on other RAB tasks**	**Danger to patient**	**Danger to staff**	**Information needed to detect error or its effects**	**Detection procedure**	**Additional information needed to recover from error**	**Recovery procedure**	**Recovery sequelae**	**Prevention procedure**
Target volume localization	Identify radiation targets	**Target misidentified**	Task performance	Target's location misidentified	Calculated doses based on distances between source and target will be incorrect	Dose delivered to wrong targets	None	Expected target position from some other measurement	Reconstruct target location from localization and compare with expected position	Measurements of actual target position	Re-localize using correct measurements	Dose prescription and plan may need to be re-evaluated	Provide guidelines and training for target localization
Dose prescription	Specify radiation dose for each target	**Target doses miscalculated**	Task performance	Inappropriate dose specified for a target	Dose distribution used to deliver doses to other targets depends on all doses delivered	Incorrect dose	None	1. Target dose from another prescription. 2. Expected dose distribution.	1. Compare doses. 2. Calculate dose distribution and compare with expected distribution.	Dose specification criteria	Recalculate dose	Dose prescription and plan may need to be re-evaluated	Provide guidelines and training for dose specification
	Transfer treatment directive to planner	**Communication error**	Task linkage	Treatment planner gets wrong dose prescription	Treatment plan will not match original treatment directive	Incorrect dose to wrong target	None	Parameters from transmitted and received treatment directives	Convert transmitted and received parameters to standard nomenclature (if they differ) and compare	Original treatment directive	Convert original directive to format expected by receiver and retransmit	The same directive should be retransmitted to other stations at which it is used	1. Use standardized format, symbols and nomenclature 2. Minimize the number and range of different directives used.

Table A.8. Treatment Planning Errors

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Task	**Step**	**Human ERROR**	**Type of error**	**Immediate effect of error**	**Effects on other RAB tasks**	**Danger to patient**	**Danger to staff**	**Information needed to detect error or its effects**	**Detection procedure**	**Additional information needed to recover from error**	**Recovery procedure**	**Recovery sequelae**	**Prevention procedure**
Dwell position localization	Identify dwell positions	Dwell positions mis-identified	Task performance	Source dwell position misidentified	Calculated doses to targets from dwell position will be incorrect	Incorrect dose	None	Second measure that defines dwell position	Compare dwell positions	Actual positions at which source will dwell during treatment	Replace incorrect position with corrected one	Dosimetry and treatment plan selection must be repeated	Use standardized treatment distances and geometries
Dwell time selection	Choose dwell times designed to deliver prescribed doses to the targets from the chosen dwell positions	Inappropriate dwell time chosen	Task performance	Chosen dwell time does not deliver appropriate fraction of the desired dose to nearby target(s).	Prescribed dose distribution cannot be delivered to target(s).	Incorrect dose	None	Doses that would be delivered to target if dwell times were used	Compare doses and dose distribution with those specified in the treatment directive	Method for choosing more appropriate dwell times	Repeat dwell time selection until doses and dose distributions match treatment directive specifications	Dosimetry and treatment plan selection must be repeated	Automate selection criteria so that dosimetry and detection always occur prior to selection
Dosimetry	Calculate doses delivered to targets by treatment plan(s).	Doses calculated incorrectly	Task performance	Calculated doses to targets different from those produced by planned treatment	Inappropriate dwell times or positions may be selected based on dosimetry	Incorrect dose	None	Expected doses to known targets from the plan.	Compare the calculated doses to known targets with their expected values	Method to identify and correct calculation algorithm errors	Repeat dosimetry with corrected algorithm.	Dwell time and treatment plan selections based on dosimetry must be repeated	1. Automate calculation algorithm. 2. Verify entries whenever input errors are possible.
Treatment plan selection	Select a plan to be used in treatment.	Inappropriate plan selected	Task performance	Selected plan does not deliver prescribed doses to targets	None	Incorrect dose or wrong targets	None	Dose distribution calculated for treatment plan and dose prescription from treatment directive.	Compare dose distribution produced by treatment plan with the treatment directive	Method to generate a new treatment plan	Generate a new plan that satisfies the treatment directive	Steps must be taken to insure that only a single, corrected plan is transmitted.	Automate selection criteria so that dosimetry and error detection always occur prior to final selection
Treatment plan transport	Transfer treatment plan to afterloader control unit	Wrong plan transferred	Task linkage	Plan at afterloader control unit is not the plan selected for this treatment	None	Incorrect dose or wrong targets	None	Expected plan for this treatment	Compare plan (patient ID, treatment fraction, treatment date, dosages) with expected values	Correct treatment plan	Replace incorrect plan with correct plan	Incorrect plan must be restored to its proper location	Minimize the number of plans and transfer steps used

Table A.9. Treatment Set-up Errors

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Task	**Step**	**Human ERROR**	**Type of error**	**Immediate effect of error**	**Effects on other RAB tasks**	**Danger to patient**	**Danger to staff**	**Information needed to detect error or its effects**	**Detection procedure**	**Additional information needed to recover from error**	**Recovery procedure**	**Recovery sequelae**	**Prevention procedure**
Treatment set-up	Position patient for treatment	Applicator moved	Task performance	Applicator-body geometry changed	Distances measured between applicators and targets may change.	Doses will not be delivered to their planned locations in body	None	Applicator movement indicator	Check indicator	1. Original position of applicator. 2. Current position of applicator.	1. Re-position applicator. 2. Repeat simulation. 3. Re-plan treatment.	1. Delay. 2. Possible trauma to patient during replacement.	1. Secure applicator. 2. Minimize patient movement
		Patient uncomfortable or insecurely supported	Task performance	Patient movement changes applicator-body geometry	Distances measured between applicators and targets may change.	Doses will not be delivered to their planned locations in body	Possible unintended dose if source is trapped during treatment	1. Applicator movement indicator. 2. Patient movement indicator.	Check indicators	Indicator of patient comfort, stability, and support	Adjust patient supports until patient is comfortable, stable, and well supported	1. Adjustment may cause delay. 2. Comfort may decrease with time.	Anesthetize patient and utilize support devices
	Connect applicators to afterloader	Applicator moved	Task performance	Applicator-body geometry changed	Distances measured between applicators and targets may change.	Doses will not be delivered to their planned locations in body	None	Applicator movement indicator	Check indicator	1. Original position of applicator. 2. Current position of applicator.	Re-position applicator and/or repeat simulation and plan	1. Delay. 2. Possible trauma to patient during replacement.	1. Secure applicator. 2. Minimize patient movement.
		Applicator connected to incorrect treatment channel	Task linkage	None	Dose planned for one applicator delivered through another	Doses will not be delivered to their planned locations in body	None	Applicator-channel maps from treatment directive and treatment plan	Compare connections with maps	Whether the treatment directive and the treatment plan specify the same connections	1. Re-connect according to specifications 2. Re-plan if directive and plan channels differ.	Delay if plan must be re-generated	Use keyed connectors that prevent improper connection
		Applicator connected with wrong guide tube	Task performance	Treatment distance different from planned distance	Dose not delivered to planned target	Dose delivered to wrong part of body	None	Planned and actual linear treatment distances	Compare actual distance with planned distance	Characteristics of correct source guide tube	Replace incorrect tube with one of required characteristics	None	1. Label applicator-SGT pairs. 2. Use one length SGT for all unlabeled connections.
		Applicator not connected properly	Task performance	None	Possible disconnect or improper source placement during treatment	1. Dose delivered to wrong part of body. 2. Dose too high if source is trapped.	Possible unintended dose if trapped source must be removed	Indicator of proper connection	Compare indicator with connection specs.	Method to produce proper connection	Re-connect in proper manner	None	Training in proper connection techniques

Table A.10. Treatment Delivery Errors

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Task	**Step**	**Human ERROR**	**Type of error**	**Immediate effect of error**	**Effects on other RAB tasks**	**Danger to patient**	**Danger to staff**	**Information needed to detect error or its effects**	**Detection procedure**	**Additional information needed to recover from error**	**Recovery procedure**	**Recovery sequelae**	**Prevention procedure**
Treatment plan entry	Enter treatment plan	**Entry error**	Task linkage	Treatment delivered differs from treatment planned	Planned dose not delivered to target	Dose increased or delivered to wrong target.	None	Parameters of planned and entered treatments	Verification of plan after entry	None	Re-enter correct parameters	Delay	Automated entry
Treatment session monitoring & control	Start treatment	**Treatment started before preparations completed**	Task linkage	Source in room before hook-up completed	Mis-administration	Dose delivered to unintended target	Unintended dose	Checklist of treatment requirements	Verify checklist items	Dose given to patient and staff	Re-plan treatment to compensate for unintended dose	Dose to unintended targets (staff or patient) cannot be recovered	Verification of preparation prior to treatment
		Failure to clear room prior to treatment	Task performance	Staff in room at time of treatment	Emergency termination reduces planned exposure for patient	None	Unintended dose	Warning from radiation detector in room	1. Recognize radiation warning. 2. Note staff in treatment room.	Not recoverable	None	Staff exposure must be calculated and treated	1. Verify clearance prior to treatment. 2. Monitor during treatment.
	Monitor treatment session	**Failure to detect system failure**	Task performance	Treatment not interrupted when system fails	Dose delivered may deviate from planned dose	Physical injury or unintended dose	Physical injury or unintended dose	Record of detected and undetected system failures	Compare failure record with detection record	Effect of failure on patient and staff	Re-plan treatment to compensate for unintended dose	Dose to unintended targets (staff or patient) cannot be recovered	Training and automated failure detection
		Failure to take appropriate action after detection of system failure	Task performance	Treatment not interrupted when system fails	Dose delivered may deviate from planned dose	Physical injury or unintended dose	Physical injury or unintended dose	1. List of approved actions. 2. Record of actions taken.	Compare actions taken with approved actions	Effect of failure on patient and staff	Re-plan treatment to compensate for unintended dose	Dose to unintended targets (staff or patient) cannot be recovered	Training and automation of actions that take place after a failure is detected
	Interrupt treatment	**Treatment interrupted unnecessarily**	Task performance	Dose delivered is lower than planned dose	Treatment may be repeated rather than resumed	Interrupted dose may be added to planned dose if treatment is repeated	None	1. List of reasons to interrupt. 2. Record of reason for interruption.	Compare interrupt circumstances to list	Dose given to targets prior to interruption	Adjust dose for next treatment fraction	Delay before treatment can be continued	Training in interrupt procedures
	Conclude treatment	**Entry into treatment room while source is exposed**	Task performance	Unintended dose to staff	Treatment may be curtailed by entry	Dose delivered may not match prescription	Unintended dose	Record of entries while source was exposed	1. Notice radiation warnings. 2. Consult treatment log.	Dose given to targets prior to interruption	Adjust dose for next treatment fraction	Delay before treatment can be continued	Rapid automatic retraction of source on entry

Table A.11. Post-Treatment Errors

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Task	**Step**	**Human ERROR**	**Type of error**	**Immediate effect of error**	**Effects on other RAB tasks**	**Danger to patient**	**Danger to staff**	**Information needed to detect error or its effects**	**Detection procedure**	**Additional information needed to recover from error**	**Recovery procedure**	**Recovery sequelae**	**Prevention procedure**
Disconnect source guide tubes		**Failure to follow entry procedures**	Task performance	Entry into treatment area while source is exposed	Prescribed dosage may not be delivered	Interrupted dose may be added to planned dose if treatment is repeated	Unintended dose	Record of entries while source was exposed	1. Notice radiation warnings. 2. Consult record of entries	Dose given to targets prior to interruption	Adjust next treatment to compensate for interrupted dose	Substantial delays may occur before treatment can be continued	Rapid automatic retraction of source on entry
		Failure to notice evidence of applicator movement	Task performance	None	Problems due to movement cannot be corrected	Cumulative dosage errors cannot be corrected	None	Indicator of applicator movement	Check for movement using indicator	Amount of movement that occurred	Adjust dose on subsequent treatments to compensate for movement	Retraining required to prevent recurrence	Training and design of job performance aids
Patient transport		**Damage to applicator**	Task performance	Movement during treatment can no longer be detected	Applicator may malfunction if re-used	Possible physical trauma	None	Characteristics of undamaged applicator	Inspect or test applicator for damage	Repair criteria	Repair or replace applicator	Applicators should be tested before use	Training in transport procedures
Remove applicators		**Damage to applicator**	Task performance	Movement during treatment can no longer be detected	Applicator may malfunction if re-used	Possible physical trauma	None	Characteristics of undamaged applicator	Inspect or test applicator for damage	Repair criteria	Repair or replace applicator	Applicators should be tested before use	Minimize re-use of applicators
Record-keeping		**Treatment not recorded for this patient**	Task linkage	None	Treatment may be repeated	Overdosage	None	Second method to determine that treatment has occurred	Verify record using second method	Treatment parameters for this treatment	Record treatment parameters	Retraining required to prevent recurrence	Automated recording
		Treatment fraction recorded incorrectly	Task linkage	None	Treatment fraction may be repeated or skipped	Overdosage	None	Second method to identify treatment fraction	Verify record using second method	Correct treatment fraction for this treatment	Replace incorrect record with correct data	Retraining required to prevent recurrence	Automated recording
		Treatment recorded for wrong patient	Task linkage	None	Treatment may be repeated. Other patient's treatment may not be delivered.	Overdosage	None	Independent method to match patient to his treatment records	Compare patient ID with treatment record	Location of records for both patients	Replace incorrect records with correct records for each patient	Retraining required to prevent recurrence	Automated recording
		Treatment records lost or not kept	Task linkage	None	Treatment errors cannot be detected or corrected.	Treatment fraction may be repeated or skipped	None	Treatment log and expected storage location for records	Compare treatment log with found records	Alternative source of record information	Locate or replace missing records	Care must be taken to prevent differences in copies	Storage procedures and duplication of records

Table A.12. Routine Quality Assurance Errors

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Task	Step	Human ERROR	Type of error	Immediate effect of error	Effects on other RAB tasks	Danger to patient	Danger to staff	Information needed to detect error or its effects	Detection procedure	Additional information needed to recover from error	Recovery procedure	Recovery sequelae	Prevention procedure
Routine QA	Equipment and safety checks	Failure to perform QA procedure	Task performance	Faulty equipment not identified	Equipment malfunctions during use	Possible unintended dose if equipment malfunctions	Possible unintended dose if equipment malfunctions	Record of QA performance	Check record to determine whether QA has been performed	None, if detected before equipment is used	Perform QA before using equipment	1. Delay. 2. Treatment may be cancelled after applicator is placed	Task performance verification
		Failure to recognize QA problem	Task performance	Faulty equipment not identified	Equipment malfunctions during use	Possible unintended dose if equipment malfunctions	Possible unintended dose if equipment malfunctions	QA test results and performance standards	Compare test results with performance standards	Same as above	Perform QA before using equipment	Same as above	Training in QA problem recognition
		Failure to record QA problem	Task linkage	No record made of QA problem	Equipment malfunctions during use	Possible unintended dose if equipment malfunctions	Possible unintended dose if equipment malfunctions	QA test results and performance standards	Compare test results with performance standards	Same as above	Record and report QA problem	Same as above	1. Training in recording procedures. 2. Performance verification.
		Failure to report QA problem	Task linkage	Users not informed of QA problem	Equipment malfunctions during use	Possible unintended dose if equipment malfunctions	Possible unintended dose if equipment malfunctions	QA problem log	User independently checks log	Same as above	Report QA problem	Same as above	1. Training in reporting procedures. 2. Performance verification.
		QA certification error	Task linkage	QA reported but not performed	Equipment malfunctions during use	Possible unintended dose if equipment malfunctions	Possible unintended dose if equipment malfunctions	QA test results	Check that results were obtained	Same as above	Perform QA before using equipment	Same as above	1. Training in certification procedures. 2. Performance verification.
		Failure to record performance of QA test	Task linkage	QA performed but not recorded	Delay while QA is repeated	None	None	QA test results	Check whether results were obtained	Performance standards	Compare test results with performance standards	Same as above	1. Training in recording procedures. 2. Performance verification.
		Source exposed for QA during hook-up	Task performance	Source in room before hook-up completed	Total dose to patient is increased	Dose delivered to unintended target	Unintended dose	Warning from radiation detector in room	Staff notes radiation warning during hook-up	Not recoverable	None	Staff and patient exposure must be calculated and treated	Disable treatment unit during hook-up

Table A.13. Maintenance Errors

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Task	**Step**	**Human ERROR**	**Type of error**	**Immediate effect of error**	**Effects on other RAB tasks**	**Danger to patient**	**Danger to staff**	**Information needed to detect error or its effects**	**Detection procedure**	**Additional information needed to recover from error**	**Recovery procedure**	**Recovery sequelae**	**Prevention procedure**
Maintenance	Hardware maintenance	**Maintenance performance error**	Task performance	Faulty equipment returned to use	Equipment may fail when used	Possible injury or dosage error	Possible injury or unintended dose	QA log of maintenance and performance tests conducted	Check QA logs before using equipment	Maintenance and performance certification procedures	Perform required maintenance and re-test	Determine cause of error	Certify performance of all equipment after maintenance
	Hardware modification or replacement	**Hardware modification not tested**	Task performance	Equipment returned to use without adequate performance testing	Equipment may fail when used	Possible injury or dosage error	Possible injury or unintended dose	Log of modifications and performance tests performed	Check test log before using modified equipment	Performance test procedure	Perform performance tests prior to using equipment	Determine reason for lack of testing (modification may not be completed)	Disable equipment until performance tests have been completed.
		User interface changed without notice	Task linkage	Staff not aware of changes in user interface	Expected actions may have unexpected results	Possible injury or dosage error	Possible injury or unintended dose	Specifications of old and new user interface	Compare interface specifications before and after changes	Assessment of staff proficiency with new interface	Re-train staff to use new interface	Staff may return to old habits in times of stress	1. Minimize interface changes. 2. Retrain after changes.
Source exchange		**Source released or improperly secured**	Task performance	Staff must retrieve source by hand	Source may not retreat during treatment	Unintended dose	Unintended dose	Radiation monitor	Note reading on monitor	Location of source and a storage container	1. Wear shielded clothing. 2. Transfer source from patient to safe.	1. Treat injuries. 2. Survey radiation. 3. Certify equipment.	1. Training for staff. 2. Test procedures to verify that source is secured.
		Incorrect radionuclide inserted	Task performance	Minimal since source strength is measured immediately after source exchange	Calculated source activity will not match source	Dosage error	None	Decay characteristics of inserted source	Second calibration after decay has occurred	Not recoverable	Adjust subsequent treatments to actual source activity	Systemic error! Prior treatments must be checked!	Frequent calibrations to identify decay curve
Source calibration	Measure source activity	**Measurement or calculation error**	Task performance	Source strength measured incorrectly	Source activity does not match treatment plan	Delivered doses different from planned doses	None	Current and expected source activity	Compare current and expected activities	None	Re-plan using correct activity	Systemic error! Prior treatments must be checked!	Multiple calibrations
	Enter calibration into treatment and planning units	**Entry error**	Task linkage	Source strength entered incorrectly	Source activity does not match treatment plan	Delivered doses different from planned doses	None	Current and expected source activity	Compare current and expected activities	None	Re-plan using correct activity	Systemic error! Prior treatments must be checked!	Verify activities prior to treatment

Table A.14. Equipment and Software Update Errors

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Task	**Step**	**Human ERROR**	**Type of error**	**Immediate effect of error**	**Effects on other RAB tasks**	**Danger to patient**	**Danger to staff**	**Information needed to detect error or its effects**	**Detection procedure**	**Additional information needed to recover from error**	**Recovery procedure**	**Recovery sequelae**	**Prevention procedure**
Program and instruction updates		**Software error introduced during update**	Task performance	Software may malfunction	Treatment plan or treatment may not correspond to treatment directive	Possible injury or dosage error	Possible injury or unintended dose	Certification tests for software performance	Perform tests and compare results to expected values	Error identification and removal methods	Re-update with corrected software	Return to old software until error is resolved	Always certify software operation after update
		Differences in new software not specified	Task linkage	Software will perform differently from previous version	Familiar requests may give different results	Possible injury or dosage error	None	Certification tests for software performance	Perform tests and compare results to expected values	List of differences between old and new software	Retrain staff to understand new procedures	Staff may return to old habits in times of stress	Always certify software operation and retrain staff after updates
		User interface changed during update	Task linkage	User actions may have unexpected results	Familiar actions may have unexpected results	Possible injury or dosage error	None	Specifications of old and new user interface	Compare interface specifications before and after changes	Assessment of staff proficiency with new interface	Retrain staff to use new interface	Staff may return to old habits in times of stress	Minimize user interface changes. Always retrain if changes occur.

Appendix B: Literature Review

Human Factors in Brachytherapy

Appendix B

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1 Introduction

This literature review examined the brachytherapy and human factors literature for information related to problems and errors in remote afterloading brachytherapy (RAB) and the human factors that influence RAB task performance. RAB problems and errors were obtained from three sources: (1) human factors analyses performed in Phases 1 and 6 of this project, (2) government problem reports, and (3) brachytherapy literature.

1.1 Overview of Brachytherapy

Brachytherapy (Greek *brachy*, short) is a radiation treatment that uses encapsulated radioactive isotopes to retard or destroy tumors with ionizing radiation. Radioisotopes are placed on or near the body surface, within a natural body cavity (intracavitary or intraluminal) or directly into a tumor (interstitial). Brachytherapy contrasts with teletherapy (Greek *tele*, far off) which uses a focused beam of ionizing radiation to irradiate cancerous tissue. Brachytherapy can be used singly or in conjunction with teletherapy, surgery, and chemotherapy as part of a comprehensive cancer treatment regimen.

Brachytherapy originated shortly after Marie and Pierre Curie discovered radium in 1898. By 1901, radium was being used therapeutically in the form of tubes that were placed directly into tumors. Its dramatic cytotoxic effects showed that radiation therapy held much promise for cancer treatment.

For those early treatments, radium tubes were inserted into tumors for prescribed time periods. The high activity of radium made handling the radium tubes hazardous for medical staff, however, and the long half-life of radium (1,620 years) made its storage an ongoing concern.

Consequently, alternative versions of brachytherapy were developed that used other radioactive isotopes with more desirable properties. For example, one version used radon gas by collecting it in small vials and placing it in tumors. The much shorter half-life of radon gas compared to radium permitted the vials to be left in place indefinitely, thus eliminating exposure of medical staff during removal of radioactive implants.

Over the next several decades, brachytherapy became an important aspect of both palliative and curative treatment regimens. Various systems were developed to determine the appropriate radiation dosages to be administered to tumors, most notably by Patterson and Parker in Great Britain and by Quimby in the U.S. Radium and radon were the only sources used in brachytherapy until artificial isotopes were developed after World War II. These artificial radioisotopes, which included iodine-125, gold-198, iridium-192, and cesium-137, broadened brachytherapy treatment options. Over time, these sources have come to replace the more hazardous radium and radon.

In the early years of brachytherapy, the radioactive sources, encapsulated in small metal vials or hollow needles, were placed directly into tumors by surgical means. They were either removed at a later time or, in the case of radioisotopes with short half-lives, left in place indefinitely. A drawback of this type of brachytherapy was that it exposed the surgical team to ionizing radiation during source implantation.

In the 1950s, Henschke pioneered a more refined form of brachytherapy in which an applicator was first surgically placed in close proximity to a tumor. The surgical team then left the operating room and the oncologist inserted the radioactive source into the applicator. This technique, termed manual afterloading, represented a significant improvement over non-afterloading brachytherapy because of reduced radiation exposure to the medical staff.

The advent of external beam radiation therapy during the 1950s and 1960s heralded a decline for brachytherapy. Cobalt-60 machines and linear accelerators became the *de facto* treatment tools in radiation oncology because they delivered powerful and focused radiation dosages while permitting medical staff to avoid radiation exposure. Starting in the late 1970s, however, brachytherapy was recognized for its value in supplementing external beam treatments and in reaching anatomic sites that were inaccessible by external beam techniques. The development of computerized treatment planning systems encouraged the use of brachytherapy because precise dose distributions could be specified for the small target volumes typically treated by brachytherapy.

Another factor that helped to revive brachytherapy was the introduction of RAB in the U.S. in the late 1970s. RAB had been developed in Europe during the 1960s. It is similar to manual afterloading in that it also utilizes pre-positioned applicators to place the source in proximity to a tumor. Instead of manually placing the source, however, RAB features a remotely controlled device to insert and withdraw the source.

Approximately 50,000 patients annually undergo some form of brachytherapy in the U.S. While manual brachytherapy is still the predominant form of brachytherapy, RAB is becoming increasingly widely used. Many of the same types of treatments can be done with RAB and manual brachytherapy. However, automated source placement confers three advantages on RAB: (1) staff radiation exposure is minimized except possibly during emergencies, because RAB devices are controlled from outside the treatment room; (2) dose distributions can be customized for each patient more easily; and (3) the

source can be positioned in the applicator more precisely, usually to within 1 millimeter of the desired dwell position, resulting in superior source configuration and dose distribution. Largely because of these advantages, RAB became increasingly common during the 1980s.

Two types of RAB are currently practiced in the U.S., high dose rate and low dose rate (see Orton, 1991, for a comparative discussion). High dose rate treatments are often outpatient procedures due to the short treatment times (on the order of minutes) afforded by the high intensity source, which is usually iridium-192. This short session duration decreases the likelihood of inadvertent source movement during treatment. High dose rate treatments usually consist of multiple sessions, called fractions. The most common types of cancer treated by high dose rate RAB are gynecologic, lung, and soft tissue.

Low dose rate treatments are single session, inpatient procedures that duplicate manual brachytherapy treatment times (on the order of several days) using a lower intensity source such as cesium-137. As such, low dose rate treatments conform to radiobiologic principles that have been established over 90 years of manual brachytherapy with lower activity sources and dose rates. Low dose rate RAB is most often used to treat gynecologic cancers.

1.2 Summary of the Project

This project consisted of six phases, each of which contributed to an improved human factors understanding of RAB. Human factors is an applied science that seeks to understand and improve human performance. It does so by evaluating human capabilities in relation to the cognitive, perceptual, and physical demands of work-related tasks. Human factors has been used to enhance the safety and reliability of many types of systems, including aircraft, air traffic control, automobiles, nuclear power plants, and medical devices. The systems-level approach typically used in human factors is particularly appropriate for RAB since the effectiveness of RAB depends on the coordinated execution of several sequentially dependent functions and tasks. In order to furnish a context for the ensuing discussion, the six project phases are summarized below.

1.2.1 Phase 1: Function and Task Analysis

Phase 1 consisted of a function and task analysis of RAB. Table 1 shows that a total of five functions encompassing 26 tasks are required to perform RAB. In addition to the function and task analysis, Phase 1 also included a skills assessment which identified the skills required of RAB staff to perform each task; and an error analysis which provided a preliminary indication of which tasks are the most error prone. The function and task analysis, skills assessment, and error analysis identified many of the human factors variables that should be considered when evaluating task performance or suggesting RAB system design alternatives.

Table 1. RAB Functions and Tasks

Patient Preparation
Patient identification, scheduling, and tracking
Patient instructions
Life support monitoring
Applicator placement and stabilization
Patient transportation
Treatment Planning
Simulation with dummy sources
Target volume localization
Radiation prescription
Dwell position localization
Dosimetry
Treatment plan selection and approval
Treatment Delivery
Treatment set-up
Treatment plan entry
Verify treatment data prior to treatment
Treatment session monitoring
Treatment session control
Post-Treatment
Source guide tube disconnection
Applicator removal
Patient transportation
Treatment verification
Record-keeping
Quality Assurance and Maintenance
Source exchange
Source calibration
Equipment and software updates
Troubleshooting
Routine quality assurance

1.2.2 Phase 2: Human-System Interface Evaluation

Phase 2 evaluated four classes of human-system interfaces used by RAB staff to perform the 26 tasks identified by the function and task analysis: equipment, software, documents, and workspaces. Deficiencies were found for each of these interface classes. In particular, the means by which information was presented to RAB staff and then propagated through the RAB system was often problematic. Additionally, certain equipment and software interfaces were hard to use due to poor design of controls and displays and inadequate feedback regarding system status.

1.2.3 Phase 3: RAB Procedures and Practices Evaluation

In Phase 3, the procedures and practices used to perform RAB tasks were evaluated according to human factors principles, guidelines, and standards. Procedures that were linked to the operating requirements of a certain device were by necessity performed in similar ways at all sites that used that device. By contrast, procedures that were not device-bound varied considerably among sites and constituted a major source of task performance variability and human error. In this connection, two additional factors that affect task performance were identified: task linkages and task verifications. Task linkages are the means by which information and materials move from one task to another. Task verifications determine whether certain actions have occurred at the correct time and place in the RAB process. Both task linkages and task verifications tended to be overlooked, poorly organized, or sporadically used.

1.2.4 Phase 4: Training Evaluation

The Phase 4 training evaluation found that formal training programs are uncommon for RAB. Informal on-the-job training was the primary means by which RAB staff learned their jobs, and there was no follow-up or refresher training. It should not be inferred, however, that RAB staff are poorly trained. Rather, the absence of formal training programs made it difficult to assess their training. The human factors implications of this type of training procedure will be examined in terms of how it could influence RAB staff performance.

1.2.5 Phase 5: Organizational Practices and Policies Evaluation

Phase 5 examined organizational practices and policies that supported RAB. RAB is organized within a medical facility in terms of production, service, and treatment goals which in turn depend on local requirements, pre-existing staffing, workspace availability, and organizational structures. As was the case with training, there were few formally stated organizational practices, procedures, or tasks, and little documentation for organizational practices. For example, task linkage and verification information often was not transmitted through the RAB system, making it difficult to determine whether certain RAB tasks had been performed correctly.

1.2.6 Phase 6: Identification and Prioritization of Human Error in RAB

Phase 6 culminated project efforts by identifying and evaluating critical tasks—those that must be performed correctly in order for RAB to be safe, effective, and reliable. As judged by a panel of experts, errors in critical tasks are likely to result in serious consequences, such as patient misadministrations or staff radiation exposures. Alternative approaches for performing problematic aspects of the critical tasks were proposed that can reduce the likelihood of human error and lessen the consequences of errors when they do occur.

1.3 Organization of the Literature Review

The next section describes the methods that were used to identify human factors literature, medical journal articles, and government problem reports that served as sources of information for this literature review. Section 3 presents RAB problems and errors that have appeared in government problem reports, and the actual or potential problems that have appeared in medical journals. Section 4 discusses RAB problems and errors in terms of the human factors literature, showing how human factors knowledge can be used to evaluate alternative approaches to RAB task performance. Section 5 contains a complete bibliographic listing of the sources for this literature review, organized according to human factors and brachytherapy subtopics.

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2 Method

The sources of the brachytherapy and human factors literature, the search strategies employed, and the way that individual items (reports, articles, monographs, conference proceedings, etc.) were selected for inclusion in the literature review are presented in this section.

2.1 Brachytherapy Literature

Government problem reports and the medical research literature were reviewed to identify brachytherapy problems and errors that are related to inadequate attention to human factors. The government literature consisted of NRC problem reports on misadministrations, abnormal occurrences, and recordable events. The medical research literature included journal articles, textbooks, monographs, and conference proceedings on brachytherapy topics.

2.1.1 NRC Publications

NRC recognizes three categories of problems in brachytherapy: misadministrations, abnormal occurrences, and recordable events. These categories represent incidents of varying severity where either (1) the delivery of a therapy dose of ionizing radiation failed to conform to NRC regulations, or (2) conditions in some aspect of the brachytherapy system posed a threat to human health and safety.

Reports of misadministrations and recordable events are published annually by the NRC Office of Analysis and Evaluation of Operational Data (AEOD) as the NUREG-1272 report series, *Report to the U.S. Nuclear Regulatory Commission on Analysis and Evaluation of Operational Data*. AEOD was established in 1979 as one of the NRC's earliest attempts at using licensee operating experience to identify and resolve safety-related problems. These reports summarize the events and concerns during the preceding calendar year associated with the use of byproduct material, and include personnel overexposures and medical misadministrations. Specific instances where U.S. medical facilities experienced problems during brachytherapy treatment sessions are described. Safety-significant events, their causes, and the trends indicated by these events are typically discussed in these reports. NUREG-1272 reports for the years 1981 through 1991 were examined in this literature review.

NUREG-1272 reports are based on reports filed by NRC licensees. Since 1981, NRC licensees have been required to notify NRC of all misadministration events. Many states have entered into agreements with NRC to manage the use of byproduct materials used in medical applications. These states are known as Agreement States and oversee the programs conducted by their own licensees. Medical facilities in Agreement States are not required to file reports of misadministrations or recordable events with the NRC, although they are encouraged to do so.

Abnormal occurrences are reported in the quarterly *Report to Congress on Abnormal Occurrences* (NUREG-0090 series). Section 208 of the Energy Reorganization Act of 1974 defines an abnormal occurrence as an unscheduled incident or event that NRC determines to be particularly significant from the standpoint of public health or safety. Both NRC licensees and Agreement States are covered by these reports. NUREG-0090 reports for the years 1977 through 1992 were examined in this literature review.

2.1.2 Medical Research Literature

The medical research literature was examined for discussions of brachytherapy problems and errors. In contrast to the NRC problem reports, the medical research literature focuses on technical and clinical topics such as source calibration and treatment outcomes rather than task performance and human error. However, it does contain information that pertains to human factors issues, although careful reading and interpretation are usually required in order to derive it.

Three computerized bibliographic medical databases—MEDLINE, CANCERLIT, and EMBASE—were searched for discussions of technical issues, human error, operational problems, procedural variations, and other topics related to human factors in brachytherapy.

MEDLINE is the online database of MEDLARS, the computerized bibliographic Medical Literature Analysis and Retrieval System of the National Library of Medicine. MEDLINE contains citations to about 6.6 million articles from approximately 3,600 biomedical journals published in the U.S. and abroad. It includes all the citations published in the *Index Medicus* print index, as well as citations published in the *Index to Dental Literature* and *International Nursing Index*. MEDLINE was used to examine brachytherapy citations extending from 1966, the year that MEDLINE began, to the most current 1992 entries.

CANCERLIT contains over 600,000 bibliographic citations on all aspects of experimental and clinical cancer therapy. In existence since 1974, CANCERLIT includes citations drawn from more than 3,400 journals. It is sponsored by the International Cancer Research Data Bank program of the National Cancer Institute in cooperation with the National Library of Medicine. Citations include journal articles, government reports, monographs, letters, theses, and meeting abstracts and papers. CANCERLIT also contains abstracts which appeared in *Carcinogenesis Abstracts* from 1963-1980 and in *Cancer Therapy Abstracts* from 1967-1980.

EMBASE (Excerpta Medica) provides a comprehensive index in all fields of human medicine and related disciplines. Its more than 3 million records consist of abstracts and citations of articles from 4,000 medical journals published in the U.S. and abroad. EMBASE has an additional 100,000 records that do not appear in printed journals.

2.1.2.1 Search Strategy

The search strategy for each database started with the MeSH heading "brachytherapy" and moved to successively more specific terms related to brachytherapy functions and tasks. (MeSH, Medical Subject Headings, is the controlled vocabulary used to index and catalog biomedical information at the National Library of Medicine.) Particular attention was paid to functions and tasks that were involved in NRC reports of misadministrations, recordable events, and abnormal occurrences. A preliminary set of articles was obtained by this approach. As these articles were reviewed, additional human factors issues became apparent. The databases were then re-searched using key words related to these issues. This iterative approach yielded a set of medical publications that were related to human factors issues in brachytherapy. Table 2 tallies the overall results of this search effort for each database. It should be noted that citations in MEDLINE, EMBASE, and CANCERLIT were partially redundant with each other.

Approximately 800 articles were surveyed during the review of the medical literature. Based upon a careful reading of the abstract or the full document, a subset of 102 articles was selected for content specifically related to human factors in brachytherapy. The reference lists of these papers were then scrutinized and an additional 41 articles were identified, yielding a grand total of 143 brachytherapy citations.

2.1.2.2 Annual Distribution of Brachytherapy Literature

As mentioned in the introduction, brachytherapy experienced renewed interest in the U.S. during the 1980s, a fact reflected by the steadily increasing number of brachytherapy citations in MEDLINE over that decade. Figure 1 shows that few brachytherapy articles were published in U.S. medical journals during the 1960s and 1970s. Beginning in the early 1980s, however, the number of brachytherapy articles grew to several hundred per year. This period coincided with the introduction of RAB into the U.S. and its subsequent acceptance as a supplement to teletherapy and chemotherapy and as an alternative to certain types of manual brachytherapy. As might be expected, many of the articles published during the 1980s dealt with RAB.

2.2 Human Factors Literature

The human factors literature was reviewed to identify information that could be used to evaluate alternative approaches to reducing RAB problems and errors. Numerous topic areas were found that contained information that met this criterion, including human-system interfaces, equipment, workspace environment, documentation, job performance aids, training and assessment, and mental workload.

The selected journal articles, monographs, textbooks, and chapters were organized according to topic in the bibliography. Whenever possible, an article or book that is a seminal contribution in its area was included. This effort yielded a compendium of current human factors information that can be used to further evaluate alternative approaches for improving RAB task performance.

Table 2. Count of Brachytherapy Articles Found in Computerized Bibliographic Medical Databases According to Search Term

Database	Search Term	Article Count
MEDLINE (1967–1992)	Brachytherapy	3330
	Brachytherapy and Remote Afterloading	110
CANCERLIT (1974–1992)	Brachytherapy	4072
	Brachytherapy and Remote Afterloading	83
EMBASE (1982–1992)	Brachytherapy	943
	Brachytherapy and Remote Afterloading	24

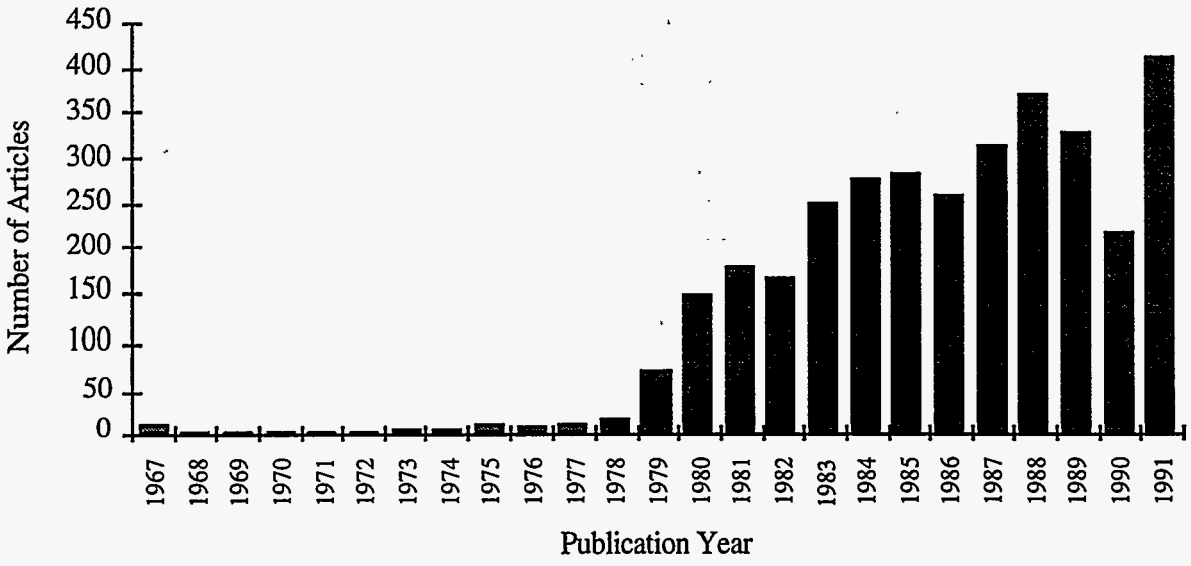

Figure 1. Annual count of brachytherapy articles listed in MEDLINE from 1967-1991

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3 Brachytherapy Problems and Errors Literature

This section summarizes published accounts of brachytherapy administration problem and errors that have appeared in government problem reports. These problems are mapped onto the brachytherapy function and task analysis in order to link RAB problem and errors to specific tasks. Finally, actual or potential problems that have been reported in the brachytherapy literature are considered in relation to the government problem reports and RAB tasks.

3.1 Categories of Brachytherapy Administration Problems

NRC recognizes three categories of administration problems in brachytherapy: misadministrations, abnormal occurrences, and recordable events. These problems are distinguished by the degree of safety hazard that they pose for patients and RAB staff.

3.1.1 Misadministration

A misadministration is the most serious type of administration problem in brachytherapy. It can imperil the health and well-being of persons involved in a brachytherapy procedure, including medical staff and non-medical personnel as well as patients. A brachytherapy misadministration means the administration of a brachytherapy radiation dose

(1) involving the wrong patient, wrong radioisotope, or wrong treatment site (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site),

(2) involving a sealed source that is leaking,

(3) when, for a temporary implant, one or more sealed sources are not removed upon completion of the procedure, or

(4) when the calculated administered dose differs from the prescribed dose by more than 20 percent of the prescribed dose (U.S. Nuclear Regulatory Commission, January 1994).

3.1.2 Abnormal Occurrence

An abnormal occurrence consists of events that NRC considers to have a moderate or severe impact on public health or safety. An abnormal occurrence may be a single incident, a series of incidents, a recurring event, or a generic concern. Procedures have been established for the Agreement States to screen abnormal occurrences using the same criteria as NRC and to report them to NRC for inclusion in NRC publications.

In terms of brachytherapy, an abnormal occurrence could include but need not be limited to

(1) moderate exposure to, or release of, radioactive material licensed by or otherwise regulated by the NRC

(2) major degradation of essential safety-related equipment

(3) major deficiencies in design, construction, use of, or management controls for licensed facilities or material (NUREG-0090, Vol. 14, No. 4, Appendix A)

The following examples are the types of events that are evaluated according to abnormal occurrence criteria:

(1) Exposure of the whole body of any individual to 25 rem or more of radiation; exposure of the skin of the whole body of any individual to 150 rem or more of radiation; or exposure of the feet, ankles, hands or forearms of any individual to 375 rem or more of radiation [10 CFR 20.403 (a) (1)], or equivalent exposures from internal sources.

(2) An exposure to an individual in an unrestricted area such that the whole body dose received exceeds 0.5 rem in one calendar year [10 CFR 20.105 (a)].

(3) The release of radioactive materials to an unrestricted area in concentrations which, if averaged over a period of 24 hours, exceed 500 times the regulatory limit of Appendix B, Table II, 10 CFR Part 20 [CFR 20.403 (b) (2)].

(4) Radiation or contamination levels in excess of design values on packages, or loss of confinement of radioactive material such as (a) a radiation dose rate of 1000 mrem per hour three feet from the surface of a package containing the radioactive material, or (b) release of radioactive material from a package in amounts greater than the regulatory limit.

(5) Any loss of licensed material in such quantities and under such circumstances that substantial hazard may result to persons in unrestricted areas.

(6) A substantiated case of actual or attempted theft or diversion of licensed material or sabotage of a facility.

(7) Any substantiated loss of special nuclear material or any substantiated inventory discrepancy that is judged to be significant relative to normally expected performance and that is judged to be caused by theft or diversion or by substantial breakdown of the accountability system.

(8) Any substantial breakdown of physical security or material control (i.e., access control, containment, or accountability systems) that significantly weakens the protection against theft, diversion, or sabotage.

(9) An accidental criticality [10 CFR 70.52 (a)].

(10) A major deficiency in design, construction, or operation having safety implications requiring immediate remedial action.

(11) Serious deficiency in management or procedural controls in major areas.

(12) Series of events (where individual events are not of major importance), recurring incidents, and incidents with implications for similar facilities (generic incidents) that create major safety concern (NUREG-0090, Vol. 14, No. 4, Appendix A).

3.1.3 Recordable Event

Recordable events are, in general, not considered to be as severe as misadministrations and abnormal occurrences. Nonetheless, they pose a significant threat to the integrity of brachytherapy systems and to the safety of patients, staff, and other persons who interact with those systems. A recordable event means the administration of

(1) radiation without a written directive where a written directive[1] is required

(2) radiation where a written directive is required without daily recording of each administered radiation dose in the appropriate record

(6) a brachytherapy radiation dose when the calculated administered dose differs from the prescribed dose by more than 10 percent of the prescribed dose (10 CFR Part 35.2)

No recordable events were found that pertained to brachytherapy, limiting the following discussion to misadministrations and abnormal occurrences.

[1]Written directive (10 CFR 35.2) means an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of radiation, except as specified in paragraph (6) of this definition, containing the following information:

(5) For high-dose-rate remote afterloading brachytherapy: the radioisotope, treatment site, and total dose; or

(6) For all other brachytherapy:

(i) Prior to implantation: the radioisotope, number of sources, and source strengths; and

(ii) After implantation but prior to completion of the procedure: the radioisotope, treatment site, and total source strength and exposure time (or, equivalently, the total dose).

3.2 Misadministration Reports

This section discusses the misadministration reports published by NRC. It shows how neglect of human factors has led to an increased likelihood of misadministrations. Starting in 1981, facilities licensed by NRC to use radioisotopes in nuclear medicine and radiotherapy have been required to report misadministrations. Brachytherapy misadministrations reported by NRC licensees are published in the NUREG-1272 annual report series, *Report to the U.S. Nuclear Regulatory Commission on Analysis and Evaluation of Operational Data*.

Currently, approximately 2,400 NRC medical licensees are authorized to administer byproduct materials or radiation from these materials to persons for medical diagnosis or therapy. Over all forms of radiation therapy, NRC licensees report a total of about 400 misadministrations annually, or about 16 events per 100 licensees. In terms of brachytherapy, NRC estimates that about 184,000 procedures were performed by NRC licensees from 1981 through 1990. Thirty brachytherapy misadministrations were reported over that same nine-year period, yielding a misadministration rate per treatment of 0.02 percent. Thus, approximately 0.02 percent of RAB treatments resulted in reported misadministrations during each of those nine years.

This low misadministration rate indicates that most NRC licensees perform brachytherapy in a way that minimizes misadministrations. A distinction must be maintained between misadministrations and human error, however. Errors can and do occur that fail to cause a misadministration. System safeguards have been built into many systems to detect and correct errors and prevent the consequences of those errors from propagating through the RAB system. Unfortunately, these safeguards are not fail-safe, making it possible for one error or an accumulation of errors to lead to a misadministration.

Several possibilities can be proposed that can account for discrepancies between estimated error rates and reported misadministrations:

- Some errors may be detected and corrected before a misadministration occurs.
- Some errors may not produce enough difference from the prescribed dose for a treatment to be labeled a misadministration.
- Some errors may produce dosages which exceed the misadministration criteria for a single treatment but do not exceed the total dose prescribed for a series of treatment fractions. Under reporting rules in place at the time of the site visits, a dosage error on one

fraction that could be compensated for in subsequent fractions need not be reported.

- Each error which has not yet resulted in a misadministration might do so in the future under slightly different RAB system conditions. If so, the underlying errors must be addressed regardless of whether any particular occurrence led to a misadministration.

Error checking and correction by RAB staff were observed at each medical facility visited during this project. In addition, each of these facilities reported that errors were routinely detected and corrected by RAB staff. These findings indicate that the error rate per site may be substantially higher than the reported misadministration rate. An appreciable error rate is therefore not inconsistent with the low misadministration rates that have been reported.

3.2.1 Types of Errors Reported

Table 3 summarizes the 54 brachytherapy misadministrations reported by NRC licensees from 1981 through 1992 and published in NUREG-1272 reports. Over this period of time, there is an increasing trend of brachytherapy misadministrations. This trend is probably due to several factors, including the increase of brachytherapy procedures in general as well as the greater role of the more technologically complex RAB systems.

Most of the reported misadministrations occurred in manual brachytherapy, a finding largely attributable to the fact that manual procedures are performed more frequently than RAB procedures. This has led to a bias in the types of errors that have been reported because certain errors, such as source loading, occur predominantly in manual brachytherapy. As expected, errors that occur in tasks performed in both manual and remote afterloading, such as failing to approve a treatment plan prior to treatment delivery, are more evenly distributed over the two types of brachytherapy.

The most common cause of misadministrations was loading the wrong sources in manual afterloading brachytherapy. This error was caused by inadequacies in several areas, including source inventory control, written procedures, compliance with established procedures, and training. To illustrate a specific root cause of a source loading error, consider the color coding of source capsules. White is sometimes used to code source capsules of a specified activity. Unfortunately, the inactive spacer pellets used to separate source capsules in the applicator are often also white, a situation which has led to source loading errors. In addition, many source capsules are colored only on their ends, making it impossible to verify that the correct sources

Table 3. Brachytherapy Misadministration Reports Submitted by NRC Licensees, 1981–1992

1981–1985 (Total = 7)
Various incidents. NUREG-1272 reports could not be located for these years.
1986 (Total = 2)
Wrong activity sources loaded
Dose calculation error
1987 (Total = 3)
Wrong activity sources loaded
Wrong number of sources loaded
Leaking iodine-125 seed
1988 (Total = 5)
Wrong activity sources loaded (2)
Sources loaded incorrectly (2)
Dose calculation error
1989 (Total = 5)
Wrong activity sources loaded (2)
Wrong number of sources loaded
Wrong radioisotope loaded
Wrong decay factor used
1990 (Total = 8)
Wrong treatment site (3)
Patient removed applicator
Failure to detect dislodged source
Wrong treatment plan
Wrong data entered into afterloader control unit (2)
1991 (Total = 11)
Dose calculation error (3)
Wrong treatment site (2)
Inadequate training of staff
Inadequate or no review of patient chart
Wrong activity sources loaded
Sources placed outside target volume
Inadequate patient restraint
Treatment session (in 1987) was too long
1992 (Total = 13)
Failure to use correct source or verify sources strength (4)
Sources placed outside target volume (3)
Wrong data entered into planning computer (2)
Dose calculation error
Failure to perform radiation surveys and/or weak safety program (2)
Inadequate training of staff

have been loaded into an applicator. One institution has remedied this problem by painting additional color on the sides of the source capsules, permitting source loading to be verified by direct visual inspection. Otherwise, source loading can be checked only by indirect means, such as determining which sources are not in their storage locations. This indirect method requires flawless source inventory control, a dubious premise given that inventory control errors have been reported.

In addition to source loading, inadequate source inventory procedures have been a recurring problem, not only in manual brachytherapy but in RAB as well. Source loading and source inventory errors can sometimes share a common cause. Inadequate source identification makes it hard to keep track of source location and to load sources into applicators in conformance with the radiation prescription. This is especially true for facilities with heavy case loads where a sizable number of individual sources can be in use at any given time.

Several source inventory problems have been linked to inadequate record-keeping and failure to perform radiation surveys at the conclusion of a treatment session. A cesium-137 source capsule was lost for several weeks before the brachytherapy staff realized it was missing. It was not until a subsequent brachytherapy treatment that required the same source that it was determined to be missing. A high dose rate RAB source capsule was left inside a patient when the weld attaching it to the drive cable fractured. Inadequate radiation survey procedures (including failing to heed an alarm signal) caused this event to go undetected, and the source was left in the patient for several days before the situation was discovered. The patient later died of complications associated with acute radiation poisoning.

The second most common cause of misadministrations was dose calculation errors. This error can be attributed to either an absence of procedures for verifying treatment plan parameters or to a failure to use those procedures. Failure to verify plan parameters before a treatment session prevents the detection of dose calculation errors. Independent verification of plan values should be performed by a person who has not performed the tasks that generated the treatment plan parameters. Usually this verification consists of manually computing selected values to verify the correctness of the plan.

Misadministrations can occur in other ways besides source loading and dose calculation errors. For example, the correct source capsules can be placed in the wrong position within applicators or held in the correct position for either too long or short a time. A source can be held in the wrong position in RAB by entering incorrect values into the afterloader control unit; this error can occur in manual brachytherapy by using source ribbons that are different lengths.

Improved quality assurance procedures would significantly reduce the likelihood of many misadministration problems, especially those related to errors in dose calculation and source loading. Developing better procedures for independently verifying dose calculations and source activity before they are used in treatments should be a principal goal of RAB departments.

3.3 Abnormal Occurrence Reports

In addition to the annual NUREG-1272 misadministration reports, NRC publishes a quarterly report series, *Report to Congress on Abnormal Occurrences* (NUREG-0090) which provides meaningful feedback to licensees, Government agencies, and the interested public about radiation-related incidents that are significant from the standpoint of public health and safety. A total of 29 brachytherapy abnormal occurrences were found in NUREG-0090 reports from 1977 through 1992. These abnormal occurrences took place in all five brachytherapy functions in a total of 12 tasks, most of them in the treatment planning or the treatment delivery functions. (Several of these occurrences were also reported in the misadministration reports of the NUREG-1272 series.) Table 4 describes these abnormal occurrences, identifies the task(s) involved, and provides a brief human factors evaluation based on the description of each incident.

3.4 Abnormal Occurrences and Misadministrations in Relation to Brachytherapy Functions and Tasks

This section discusses abnormal occurrences and misadministrations in relation to the function and task analysis conducted in Phase 1 of this project (NUREG/CR-6125, Vol. 2). Understanding how problems and errors are distributed across brachytherapy tasks enables tasks that are especially error prone to be identified. Mismatches between task demands and human capabilities can then be evaluated in terms of the skills, abilities, equipment, and information needed to perform the tasks properly.

Table 5 shows that treatment planning and treatment delivery are associated with most of the problems. Caution is advised when interpreting these findings, however. It is likely that errors occur in more tasks than these data indicate. Those tasks that are not directly related to treatment planning and treatment delivery may not be as closely scrutinized for errors. Additionally, brachytherapy personnel may not be aware that errors in earlier tasks can increase the likelihood of errors in subsequent tasks. It is possible that errors are detected but not reported because

Table 4. Description and Human Factors Evaluation of Abnormal Occurrences

Year (Vol:No.)	Description	Failed Task(s)	Human Factors Evaluation
1980 (4:3)	Wrong dose conversion factor transformed output of treatment planning computer (in rads per hour) to wrong brachytherapy dose (in total rads).	Dosimetry	Inadequate written procedures for treatment planning and record-keeping contributed to this incident. Personnel training and management oversight also were lacking.
1982 (5:4)	Wrong cesium-137 sources were loaded despite color coding of sources. Patient received 12,000 rads instead of prescribed 4,000 rads.	Treatment session monitoring	Loading procedures lacked verifications needed to ensure that correct sources are used. Record forms lacked spaces for approval signatures.
1983 (7:1)	A plastic template and needles thought to be empty were partially loaded with iridium-192 seeds. This device was loaned by one facility to another. About 50 persons were exposed when this device transited between facilities.	Routine QA; Applicator removal; Record-keeping	Procedures for handling potentially radioactive materials were inadequate at both facilities. Procedures for handling and tracking a loaned device were lacking. Records of post-treatment radiation surveys were inadequate.
1985 (8:2)	Patient received 14,000 rads instead of prescribed 5,000 rads. Treatment period was not calculated by physicist. Discrepancies were noted between physician (who stated that physicist proposed a 50-hour treatment) and physicist (who denied making this recommendation).	Dosimetry	No procedures existed to verify treatment plan accuracy. Communication problems, perhaps related to organizational factors, contributed to the reporting discrepancy.
1985 (8:4)	Wrong area of one eye was irradiated with a strontium-90 applicator. This area contained scar tissue which the attending physician interpreted as the intended treatment area. No written treatment instructions were provided.	Treatment set-up	Inadequate communication of the definition of the target area and the accompanying treatment plan.
1984 (9:3)	A leaking iodine-125 source caused an unintended radiation exposure to a patient's thyroid.	Routine QA	Inadequate radiation surveys were performed in the source preparation area; inadequate procedures used to remove iodine-125 seeds from applicators.
1986 (9:3)	A bronchial applicator and iridium-192 seeds inside it were inadvertently removed by a sedated patient sometime between nurse checks of patient, which occurred about every 1 hour and 40 minutes.	Treatment session monitoring	Infrequent patient monitoring intervals, inadequate patient restraint.
1988 (11:4)	Treatment plan was generated using wrong reference table in a manual, resulting in 1,800 rads being delivered to endobronchial tumor instead of the prescribed 750 rads.	Dosimetry	Failure to independently verify treatment plan parameters prior to treatment delivery; Inadequate training on treatment planning equipment and procedures.

Table 4 (continued)

Year (Vol:No.)	Description	Failed Task(s)	Human Factors Evaluation
1990 (13:1)	During a low dose rate remote afterloading uterine cancer treatment, a source guide tube connector came loose from the patient applicator. This caused a cesium-137 source to rest against one of the patient's legs for an undetermined period of time.	Treatment session monitoring	Faulty material in the connector or inadequate design rather than operator error caused this problem. Quality control procedures for assessing the condition of the connector may be inadequate.
1990 (13:1)	A kink developed in a bronchial applicator which prevented a ribbon of iridium-192 seeds from reaching the intended treatment area. This kink was not detected until treatment session was completed.	Applicator placement and stabilization	Procedures for visualizing applicator condition and source position are inadequate. Additional visual information is required in order to determine the spatial relationship between the applicator and the source.
1990 (13:1)	Incorrect treatment plan values were entered into the afterloader control unit, resulting in the delivery of a non-prescribed treatment. This error occurred on two separate occasions.	Treatment plan entry	Inadequate task verification procedures for treatment plan parameters, especially when parameters are entered manually.
1990 (13:1)	A ribbon of iridium-192 seeds came loose from its endobronchial applicator and was erroneously taped to the face of the patient by a nurse. It remained in this position for about 3 hours when another nurse discovered it and notified the radiation safety officer.	Treatment session monitoring	Deficient nurse training was the primary cause of error. Nurse training should be reviewed for content adequacy. Organizational factors can influence whether needed information is communicated to all nurses caring for a patient.
1990 (13:2)	Allegations were made that treatment plans were not reviewed prior to treatment delivery and that some patients did not receive prescribed dosages. Inadequate treatment planning and treatment delivery records did not permit determination of whether treatments had been administered as prescribed.	Record-keeping; Routine QA	Inadequate record-keeping and procedural failures indicate quality assurance problems. Detailed documentation is a necessity for all treatment plans and treatment delivery events.
1990 (13:3)	Five iridium-192 seeds were stripped from a ribbon as it was removed from its trochar. Seeds remained within a cavity of a uterine tumor.	Treatment session monitoring	The treatment ribbons were not of a standardized length, and the trochar material could be bent by a hardened tumor. No provision was made for assaying the amount of radioactivity in the recovered ribbon or that which might have been left in the patient.
1990 (13:4)	A permanent implant of 86 iodine-125 seeds was intended for the prostate. Subsequent review showed that most of the seeds were implanted outside the prostate. The prostate received little radiation while deeper tissues received about 15,000 rads.	Treatment session monitoring	Inadequate training in the ultrasonic imaging technique that was used to position the implant. Inadequate means for assessing the location of the implanted seeds.

Table 4 (continued)

Year (Vol:No.)	Description	Failed Task(s)	Human Factors Evaluation
1991 (14:1)	A design modification of a custom eye plaque was not accompanied by corresponding changes in treatment plan parameters	Dosimetry	Failure to independently verify dose calculations prior to treatment delivery. Lack of written procedures also played a role.
1991 (14:4)	Pt misidentification resulted in eye being treated instead of simulation procedure for teletherapy.	Patient scheduling, identification, and tracking	Failure to follow established procedure of reviewing Pt chart for prescription prior to treatment. No Pt chart in treatment room, language barrier existed between Pt and physician.
1991 (14:4)	An incorrect treatment plan was used for a high dose rate RAB treatment. A physicist mistakenly assumed that the patient chart in the treatment control area was for the patient who was present and did not verify patient identity.	Treatment plan selection and approval; Treatment plan entry	Procedures for verifying patient identity, including photographs or other means of identification, were either absent or not followed.
1989 (14:4)	Cesium-137 source capsules were left in an applicator after a treatment session and were returned to the source storage room. This applicator was subsequently transported to another facility where it was discovered to still contain sources.	Applicator removal; Routine QA (radiation survey)	Refresher training is needed on source handling and storage procedures. The sources were not detected at the first facility because there was no radiation monitor in the source storage room.
1990 (14:4)	During transport of cesium-137 sources from a medical facility to the source supplier, package containing sources opened and its contents spilled out. Mail handlers replaced contents and shipped package to supplier, where sources were found to be missing. Sources were found at mail facility.	Source exchange	Package was most likely improperly sealed prior to leaving the medical facility. Inadequate procedures for packaging radioactive materials for shipment and for verifying that procedures had been followed.
1990 (15:2)	Wrong end of one Ir-192 ribbon was inserted into applicator; excess ribbon (containing Ir-192 seeds) was cut off and put in trash can in open area after being held in physicist's hand for several minutes. Error discovered upon inventory of ribbons removed from Pt.	Treatment set-up; Treatment verification	No survey of ribbons before implanting them into Pt. Failure to inventory ribbons promptly upon removal from Pt. Failure to follow established procedures involving removal of temporary implants in that RSO was not present during removal.
1992 (15:2)	Incorrect sources Cs-137 were loaded which then slipped from the prescribed position within applicator and irradiated normal tissue.	Routine QA	Inadequate training of personnel; Inadequate QA program; Failure to develop and maintain QA procedures; Failure to properly label storage vault for sources.
1992 (15:2)	Placement of 58 I-125 seeds in the prostate was guided by ultrasound imagery. 21 seeds were implanted in surrounding tissue rather than the prostate. Underdosage of prostate resulted.	Dwell position localization	Difficulties inherent in using ultrasound techniques to guide placement in soft tissue organs. Ultrasound image is hard to interpret in placing seeds with implanting needles.

Table 4 (continued)

Year (Vol:No.)	Description	Failed Task(s)	Human Factors Evaluation
1992 (15:3)	Five misadministrations manually afterloaded Ir-192 seeds were discovered during review of Pt charts. Net result was 12% underdosage of patients.	Dosimetry	Incorrect entry into treatment planning computer; due to using wrong units for source calibration factor. Computer was set for metric (SI) units, but factor was entered in non-SI units.
1992 (15:4)	Ir-192 ribbon supplied had higher dosage than was requested. Different units of measurement being used: 0.79 mCi requested versus 0.79 mg Ra equiv. supplied. Unit discrepancy not noted until review of shipping documents after treatment.	Source calibration	Failure to perform independent verification of source strength prior to implantation. Dosimetrist failed to notice discrepancy in units of measurement. Miscommunication between licensee and vendor was a contributing factor.
1992 (15:4)	Both Ir-192 ribbons became displaced during a treatment session, probably due to repeated dressing changes. Nurse noticed ribbons laying on patient's chest and taped them to patient's abdomen, not realizing they were source ribbons.	Treatment session monitoring	Radiation Safety Officer failed to provide oversight for procedure; inadequate training of nursing staff to recognize brachytherapy sources and how to deal with radiological emergencies.
1992 (15:4)	Incorrect offset distance entered into a HDR remote afterloader control unit (7 mm was entered instead of the correct 7 cm). Normal tissues were irradiated and tumor was underdosed.	Verify treatment data prior to treatment	Established procedures did not include verifying data entries on afterloader control unit prior to treatment.
1992 (15:4)	Loss of Ir-192 source from remote afterloader. Source capsule broke off in an applicator and was left in Pt, who received about 3 orders of magnitude over dosage. Pt death attributed to acute radiation exposure and consequences thereof.	Applicator removal; Routine QA	Weaknesses in radiation safety program for HDR brachytherapy; inadequate staff training in radiation safety; Defective design and testing of source capsule and its connection to drive cable.
1992 (15:4)	Source was lost before or during a LDR treatment session and was inadvertently disposed of in bed linen. Source was subsequently recovered.	Treatment session monitoring; Routine QA	Failure to visually confirm that sources are properly loaded. Failure to perform a radiation survey on disposable bed linens before they were removed from Pt's room.

brachytherapy personnel fail to realize that the consequences of errors can propagate through the system to influence subsequent tasks.

Treatment delivery is the function in which the most errors have been detected. This finding does not necessarily mean that treatment delivery is the most error prone function; it is likely that brachytherapy personnel monitor the system most closely while radiation is being administered to a patient. This increased vigilance leads to a higher level of error detection. Additionally, the consequences of errors committed in previous functions may not become evident until treatment delivery. Indeed, the error analysis traced the occurrence of some errors detected during treatment delivery to patient preparation or treatment planning.

The majority of treatment delivery errors occurred in manual brachytherapy and involved loading sources of the wrong activity. Source loading problems can be linked to several human factors issues, including inadequate color

Table 5. Distribution of Abnormal Occurrences and Misadministrations in Relation to Brachytherapy Functions and Tasks

Function/Task	Abnormal Occurrences RAB	Manual	Misadmin	Total	Example
I. Patient Preparation					
1. Patient scheduling, ident, and tracking	0	1	0	1	Misidentify patient
2. Patient instruction	0	0	0	0	
3. Life support monitoring	0	0	0	0	
4. Applicator placement and stabilization	0	0	0	0	
5. Patient transportation	0	0	0	0	
II. Treatment Planning					
1. Simulation with dummy sources	0	0	0	0	
2. Target volume localization	0	1	0	1	Wrong site treated
3. Radiation prescription	0	0	0	0	
4. Dwell position localization	0	2	0	2	Imaging analysis inaccurate
5. Dosimetry	1	3	10	14	Dose calculation error Wrong dose conversion Wrong decay factor
6. Treatment plan selection and approval	0	1	0	1	Fail to verify calculations
III. Treatment Delivery					
1. Treatment set-up	0	4	25	29	Wrong activity sources Wrong treatment site Sources loaded incorrectly
2. Treatment plan entry	4	0	3	7	Wrong plan values used Mismatch plan and patient
3. Verify treatment data prior to treatment	0	1	0	1	Fail to verify plan values
4. Treatment session monitoring	1	3	4	8	Fail to detect dislodged source
5. Treatment session control	0	0	0	0	
IV. Post-Treatment					
1. Source guide tube disconnection	0	0	0	0	
2. Applicator removal	0	0	0	0	
3. Patient transportation	0	0	0	0	
4. Treatment verification	0	0	0	0	
5. Record-keeping	1	3	0	4	Fail to account for sources Inadequate treatment records
V. Quality Assurance and Maintenance					
1. Source exchange	0	1	0	1	Improper packaging of source
2. Source calibration	0	1	0	1	Calibration units different
3. Equipment and software updates	0	0	0	0	
4. Troubleshooting	0	0	0	0	
5. Routine quality assurance	0	1	5	6	No radiation survey
TOTALS	7	22	47*	76	

* Full reports for seven incidents in Table 3 could not be located, preventing them from being categorized according to function and task.

coding schemes for source capsules, faulty source inventory control, and poor communication of revised treatment plans among brachytherapy staff.

In contrast to manual brachytherapy, source loading errors are almost unknown in remote afterloading brachytherapy. All high dose rate systems and one low dose rate system use sources contained within the afterloader, making it impossible for other sources to be substituted for them during routine operation. Another low dose rate system uses a separate source storage container, requiring that the correct subset of the 45 source ribbons in the storage container be transferred to the remote afterloader. Transferring sources from their storage container to the remote afterloader safe requires an accurate one-to-one mapping between afterloader treatment channels and storage container channels. The console of the remote afterloader is then programmed to transfer the source ribbons to be used in a certain treatment session from the storage container to the afterloader. Source transfer therefore depends on correctly programming the afterloader console. To date, no source loading errors using this system have been reported to NRC.

Treatment delivery errors also occurred in the verification of plan values prior to treatment and in treatment session monitoring. Inadequate treatment session monitoring was slightly more of a problem; misadministrations occurred when situations requiring intervention were not perceived as such, experienced slow response times, or when staff responded incorrectly.

Most of the reported treatment planning errors have occurred in manual brachytherapy. This finding is almost certainly due to the fact that manual brachytherapy is much more frequently practiced than remote afterloading brachytherapy. No factor was uncovered during the literature review indicating that manual brachytherapy treatment planning was inherently more prone to errors than remote afterloading treatment planning. Indeed, treatment planning errors would seem to be most likely to occur in high dose rate remote afterloading where time pressures under which brachytherapy staff are often asked to work increase error likelihood. For example, it is not unusual for staff to be asked to generate a plan for a patient who is under a short-lived local anesthetic or analgesic and who has an applicator placed in an irritating location, such as the bronchus. Errors in reviewing treatment plans also were found that resulted in the use of the incorrect treatment plan parameters because of a failure to verify them prior to treatment delivery.

The most important error to fall under this heading is the failure to account for all sources. Several serious situations have developed as a consequence of not establishing that the sources assumed to be used during treatment are present after treatment is done. Sources have been left in patients or applicators for extended periods before they were determined to be missing from their proper storage locations. Record-keeping errors also occur during post-treatment and include mis-recording patient treatment data, failing to document anomalous events during treatment delivery, and mis-recording source inventory data. These errors can result in several problems such as faulty patient records, misadministrations in subsequent fractions, and lost sources.

Quality assurance and maintenance errors are relatively infrequent. This is partly due to the fact that certain tasks, such as software updates and troubleshooting, are seldom performed. Source exchange errors have been reported; the radiation hazard associated with this error makes it especially important to perform this task according to established procedures.

3.5 Brachytherapy Literature

In addition to government problem reports, the brachytherapy literature was also reviewed for information pertaining to problems and errors in brachytherapy task performance. Unlike government problem reports, few brachytherapy papers specifically discuss the role of human error in brachytherapy. There are, however, numerous papers on topics related to brachytherapy functions and tasks. In particular, articles related to three brachytherapy functions frequently appear: treatment planning, treatment delivery, and quality assurance and maintenance. Perusal of these articles revealed worthwhile information about actual and potential brachytherapy problems and errors that are due, in part, to a lack of attention to human factors aspects of brachytherapy systems.

3.5.1 Treatment Planning

The voluminous treatment planning literature attests its central role in brachytherapy as well as to numerous opportunities for human error during the performance of its six tasks. Many treatment planning articles discuss the relative merits of various aspects of treatment planning tasks, such as how to optimize dose distributions (e.g., Anderson, 1985; Hilaris, Nori, and Anderson, 1987b; Ling et al., 1988; Niroomand-Rad, Thomadsen, and Vainio, 1987; Purdy, 1984; Suit and du Bois, 1991). One issue that underlies much of the treatment planning literature is the extent to which the target volume is actually irradiated (e.g., Dutreix, 1988; Krishnan et al., 1990; Meertens, 1989; Meigooni, Meli, and Nath, 1988; Paul, Koch, and Philip, 1988; Siwek, O'Brien, and Leung, 1991; Spearman, 1988). This concern encompasses all treatment planning tasks, but focuses especially on target volume localization, simulation with dummy sources, and dosimetry.

Target volume localization is the process of defining the volume to be exposed to prescribed levels of ionizing radiation. In turn, it is dependent on ascertaining the location of the applicator relative to the tumor. Simulation x-rays with dummy sources is the means used to visualize this relationship. Simulation x-rays are usually taken with some magnification factor. This magnification factor must be taken into account when determining the desired dwell positions for the source(s). Failure to do so can produce a difference between the prescribed dose distribution and the actual dose distribution large enough to produce a misadministration.

Visser (1989) confirmed that operator accuracy and precision are crucial factors in dosimetry. Poor accuracy and precision result in localization errors and inaccurate source position values. Digitization errors of no more than 5 mm often result in a 10 percent error in dose rate. Chow, Lane, and Rosen (1990) conducted a controlled experimental study of uncertainty in dose estimation. They found that uncertainty was due to imprecision in localizing sources and points of interest on simulation x-rays. Operators committed digitization errors and experienced problems in identifying source location. It was concluded that standard definitions and locations for points of calculation are needed to reduce operator errors. Additionally, a consistent dose specification method is needed to reduce uncertainty and improve accuracy of source localization.

Many articles discuss the software that is used in treatment planning (e.g., Plott, 1990; Roy et al., 1991; Ten Haken et al., 1988; Tolbert and Reed, 1981; Visser, 1989). Tolbert and Reed (1981) recommend that QA procedures be used for computerized treatment planning systems that are routinely used in dose calculations. Caution must be exercised to maintain a close match between the dose distribution specified by the treatment plan and that actually delivered to minimize the possibility of a geographic miss (Burgers, Awwad, and van der Laarse, 1988).

3.5.2 Treatment Delivery

For the most part, the many articles on treatment delivery describe studies of brachytherapy techniques and clinical outcomes without making mention of the problems and errors that can accompany the performance of treatment delivery tasks. There are some interesting exceptions to this general situation, however.

One of the major problems with low dose rate RAB is movement of intracavitary applicators during a lengthy treatment session. Ljunggren et al. (1987, cited in Roman, 1991) evaluated applicator motion in eight randomly selected patients undergoing low dose rate remote afterloading brachytherapy for gynecologic cancers. Significant motion, defined in terms of movement relative to the pelvis or bladder, was observed in seven of the eight patients.

High dose rate treatments, because of their much shorter durations, would seem to be less likely to experience applicator motion. However, the validity of this assumption likely varies with treatment site and patient condition. For example, gynecologic applicators can be anchored more securely than endobronchial or nasopharyngeal applicators. Anchoring endobronchial or nasopharyngeal applicators in place is recognized as a problem even for the short duration of a high dose rate treatment (Denham, 1988). To complicate matters, the presence of the applicator may cause the patient to cough repeatedly, which can displace the applicator from its intended position.

Documentation, such as manuals, worksheets, and checklists, that supports the performance of various tasks, has been cited as a factor in treatment delivery errors (Flynn, 1990). Slessinger (1990) describes a treatment prescription form that was developed for low dose rate remote afterloading treatments. It facilitates the specification of active source positions and the total time for each treatment channel. Providing a graphical representation of the source configurations helps greatly when entering source dwell positions and dwell times into the afterloader control unit.

The patient chart also has been linked to brachytherapy misadministrations. A well-organized and complete patient chart facilitates patient identification and provides a record of patient treatment sessions (Byrum and McMurry, 1989). Keefer (1991) recommends that a patient chart should include prescriptions, final dose levels and distributions, documented calculations, date of prescription, date implant was inserted, date implant was removed, and whether or not final dose conformed to NRC regulations for a prescribed administration.

3.5.3 Quality Assurance and Maintenance

The medical literature comes closest to dealing with human error in brachytherapy in articles related to quality assurance. Source calibration, source exchange, and routine quality assurance tasks are discussed in terms of the undesirable consequences that can arise from failure to perform them adequately (Baltas, 1991; Grigsby et al., 1991; Hudson, 1990; Jordan and Mantravadi, 1991; Lajon, 1984; Morton, 1984; Nettles, 1986; Randall, Drake, and Sewchand, 1987; Suntharalingam and Johansson, 1988).

Source calibration has received much attention from medical physicists and the medical literature contains many discussions about its technical aspects (Flynn and

Workman, 1991; Goetsch et al., 1991; Kohn, Gooch, and Zajac, 1991; Meertens, 1990; Wu et al., 1990). Problems have been reported that have implicated inaccurate supplier source calibration data. Ashby et al. (1989) reports a sharp rise in treatment failures when a facility's source supplier was changed; underdosage due to manufacturer calibration error was suspected, but not substantiated due to poor source calibration records. Inadequate source calibration capabilities also result in undue reliance on the value provided by the source supplier. Several cases have been reported where patients exhibited symptoms associated with higher than prescribed radiation dosages. Source calibration by an independent agency found the source supplier's value to understate the actual source activity (Last, Cardew, and Hunt, 1986).

Standardization is an important issue in source strength specification. Historically, the strength of radioactive sources used in brachytherapy has been described by many physical quantities. Recently, the American Association of Physicists in Medicine (AAPM) Task Group 32 has recommended that these quantities be replaced by a single quantity, air kerma strength. Adopting this quantity will require the correct use of source strength conversion factors. Many of these factors depend upon vendor choices of physical constants and exposure rate constants. Care must therefore be taken to review vendor source strength specification practices in order to make the appropriate conversions (Williamson and Nath, 1991).

A QA program should ensure that brachytherapy administrations are performed according to NRC or state regulations concerning the medical use of byproduct material. Various QA procedures should be performed on a daily, weekly, or monthly basis, as appropriate to maintain a safe and properly functioning brachytherapy facility, with annual system audits to ensure the integrity of the QA program (Grigsby, 1989).

The medical literature indicates that there is a need for certain QA procedures that are not yet widely practiced. For example, Leung (1983) demonstrated the desirability of periodically checking the integrity of the cesium-137 source pellets in low dose rate remote afterloaders. Source pellets have been damaged by steel spacers during simulated repeated transit from the afterloader to the treatment position. The radiation pattern of the damaged pellets is altered relative to undamaged pellets, making it likely that the dose distribution generated by damaged pellets will not match the calculated dose distribution. Despite its advisability, none of the medical facilities visited during the project performed this procedure.

Medical literature contains few references to equipment quality assurance issues such as source capsule leakage (Clarkson, 1989). One study investigated an unshielded source preparation station that was used to prepare iridium-192 wires (van't Riet, Kramer, and Elders, 1991). Over a five-year period, the annual mean radiation dose to the fingertips of personnel using this device increased with increasing numbers of applications. Upon acquiring a shielded source preparation station, a three-fold reduction in annual mean finger dose was observed (25 mSv decreased to 8 mSv). A new policy of source reuse also contributed to this reduction according to which source wires were cut to several standardized lengths.

3.5.4 Lessons Learned from Teletherapy

The teletherapy literature contains findings that also apply to brachytherapy. Treatment set-up errors, such as incorrectly specifying field size and gantry angle parameters, occur approximately 2–3 percent of the time (Hendrickson, 1978). Other teletherapy problems include arithmetic mistakes and the misreading of graphs and charts (Cunningham, 1984). Byhardt et al. (1978) found that tumor localization techniques varied from one institution to another, terminology is used inconsistently, and that many locally developed procedures are practiced that have not received formal organizational approval. These topics are relevant to brachytherapy because brachytherapy staff also work with numerical information and local procedures.

Research suggests that numerical errors in teletherapy are related to overall work load. When two trained technologists worked together, error rates were greatly reduced. These reductions were not due to each technologist double-checking the other's work, as might be expected. Rather, each technologist performed fewer tasks and worked more carefully as a result (Hendrickson, 1978). This example emphasizes the importance of evaluating cognitive variables when analyzing human error in radiation therapy.

4 Human Factors Literature

This section discusses the human factors literature that pertains to brachytherapy problems and errors obtained from government problem reports, medical research literature, and the critical tasks described in Phase 6 of this project. Although this review focuses on RAB, problems and errors in manual brachytherapy are also considered if they involve tasks that are also performed in RAB.

Table 5 summarizes the problems and errors identified by the government problem reports and medical research literature in terms of RAB functions and tasks; Table 6 does likewise for the critical tasks identified in Phase 6. Table 6 also lists the alternative approaches that were proposed to reduce the likelihood of problems and errors in the critical tasks. There is considerable overlap between the problems and errors presented in Tables 5 and 6, a finding that demonstrates the validity of the Phase 6 effort while also revealing the constancy of many RAB problems and errors.

The section is organized into several sections that relate RAB problems and errors to major topic areas in the human factors literature. This organization facilitates the presentation of human factors principles and findings that are pertinent to RAB:

Human-Systems Interfaces

- Equipment
- Data Entry
- Environment
- Mental Workload

Procedures

- Documentation
- Job Performance Aids

Training and Organization

Representative examples of the problems and errors that arise from human factors deficiencies in RAB are presented for each area. Alternative approaches for reducing these problems and errors are then discussed in terms of the human factors literature.

4.1 Human-System Interfaces

Human-system interfaces are important determinants of task performance, a fact attested to by the large body of human factors literature on user-interface interactions (Brown, 1988; Carroll, Mack, and Kellogg, 1988; Christie and Gardiner, 1990; Downton, 1991; Helander, 1988; Rubin, 1988). Interface characteristics influence the ease, effectiveness, and safety with which system hardware, software, and supporting equipment can be used.

Human factors has traditionally focused on equipment design, task characteristics, and environmental factors in assessing human performance in complex systems. More recently, however, information processing models have been developed that can evaluate the cognitive demands that a system places on its users (Card, Moran, and Newell, 1983; Carroll, Mack, and Kellogg, 1988; Karat, 1988; Williges, Williges, and Elkerton, 1987). Both types of factors are considered in this section. Equipment, data entry, and environment represent the traditional approach; mental workload represents the cognitive perspective.

The Phase 6 analysis of critical RAB tasks and the review of the government problem reports and brachytherapy literature identified problems and errors that are attributable in part to inadequate human-system interfaces. From Tables 5 and 6, these problems and errors include:

- misidentification of patients
- failure to place and stabilize applicators so that the prescribed dose can be delivered
- failure to specify the exact locations of targets and critical anatomic structures
- faulty identification, specification, or transfer of information about source positions from the treatment planning system to the treatment delivery system
- failure to calculate the radiation dose accurately
- failure to describe the radiation dose to be received by each target
- failure to use correct dose conversion or decay factor
- mismatching of applicator treatment channels with afterloader source guide tubes
- entering the treatment plan for another patient into the afterloader control unit
- mis-entering values from the correct treatment plan
- failure to accurately calibrate source activity

The alternative approaches that were proposed to overcome these problems and errors by improving RAB human-systems interfaces included:

- use tag readers for patient identification
- develop applicator stabilization aids
- improve system feedback and visualization aids
- pre-treatment dose estimation based on plan values
- use digitization aids
- place prominent labels on applicators
- reference dwell positions to applicators, not channels
- automatically compare patient and plan identifications

Table 6. Summary of Alternative Approaches to Problems and Errors in Critical Tasks

Critical Task/Problems and Errors	Alternative Approaches*
Patient Scheduling, Identification, and Tracking	
Schedule patients for wrong treatment	
Bring patients to wrong area	
Substitute one patient for another	Tag readers for patient identification (HSI)
Substitute records of one patient for those of another	Tagging procedures for patients and documents (P)
	Visible ID tags on patients and all documents (JPA)
Applicator Placement and Stabilization	
Fail to place applicator for prescribed dose	Improved feedback and visualization aids (HSI)
Fail to stabilize applicator after placement	Applicator stabilization aids (HSI)
Fail to transmit accurate placement information to other tasks	Verification of task linkages before treatment (TO)
Target Volume Localization	
Fail to identify all radiation targets	Target marking in simulation views (P)
Fail to specify exact locations of targets	Visual aids for treatment planning (JPA)
	Improved feedback and visualization aids (HSI)
Dwell Position Localization	
Faulty identification, specification, or transfer of information about source positions to treatment delivery system	Visual aids for treatment planning (JPA) Improved feedback and visualization aids (HSI)
Dosimetry	
Fail to calculate dose accurately	Pre-treatment dose estimation based on plan values (HSI)
	Standardization of dosage units (P)
Fail to describe dose to be received by each target	Digitization aids (HSI)
Treatment Set-up	
Swap two or more treatment channels	Prominent labels on applicators (HSI)
Mismatch source guide tubes to treatment channels	Reference dwell positions to applicator, not channels (HSI)
	Use of an applicator-channel map (P)
	Applicator-channel map (JPA)
	Applicator identification labels (JPA)
Modify applicator-target spatial relationship	Minimize patient movement between simulation and set-up(P)
Treatment Plan Entry	
Mis-enter values from treatment plan	Unambiguous data entry formats (HSI)
Enter treatment plan for another patient	Automatic comparison of patient and plan IDs (HSI)
	Measurement of delivered dose during treatment (HSI)
	Erasure of magnetic media used to transfer plan (P)

* Key for codes in parentheses: HSI: Human-Systems Interface and Equipment Modifications; P: Procedure Modifications; JPA: Job Performance Aids; TO: Training and Organization Modifications

Table 6 (continued)

Critical Task/Problems and Errors	Alternative Approaches*
Quality Assurance and Maintenance	
Fail to detect and correct hardware and software problems or to communicate them to the appropriate authority	Performance certification packages for software and hardware (HSI) Certification of all RAB software and hardware after maintenance (TO) Checklists highlighting failed or omitted items (JPA) Integrate QA with refresher training in emergency procedures (TO)
Source Exchange	
Exposure of staff to radioactivity	Source position sensors (HSI) Improved access to emergency source containers (JPA)
Introduce inadvertent modifications to equipment that degrades its accuracy and reliability	
Source Calibration	
Fail to accurately calibrate source activity	Direct calibration chambers for RAB sources (HSI) Automatic calibration while source is stored (HSI) Multiple source calibrations (TO)
Fail to accurately transmit calibration data	

* Key for codes in parentheses: HSI: Human-Systems Interface and Equipment Modifications; P: Procedure Modifications; JPA: Job Performance Aids; TO: Training and Organization Modifications

- use unambiguous data entry formats
- measure dose being delivered during treatment
- automatically calibrate source while it is stored

These alternative approaches are discussed below in relation to four subtopics of human-system interfaces: equipment, data entry, environment, and mental workload.

4.1.1 Equipment

Equipment modifications are a potentially powerful means for improving RAB. The operational requirements of a given piece of equipment constrains the range of acceptable actions by a task performer. Device-bound actions nearly always result in less performance variability and hence a lower likelihood for error than do actions that are not constrained by device operability requirements.

Some of the problems mentioned above are due to inadequate constraints being placed on certain operator actions during task performance. Several new devices—tag readers, applicator stabilization aids, and digitization aids—are proposed as alternative approaches to current human-system interface deficiencies in RAB. In each case, these devices would place greater limits on operator actions, decreasing the likelihood of human error. Of course, to achieve this goal, each new device must be designed, evaluated, and constructed according to strict standards.

Other alternative approaches listed above would furnish the user with more feedback from various RAB equipment and devices than is currently provided. Improved feedback regarding applicator placement, determining exact target locations, and specifying the dose being delivered during treatment are examples of enhanced feedback that could reduce RAB misadministrations.

An important human factors principle regarding feedback is that system users must be supplied with specific information regarding the effects of their actions on the system in order to understand the state of the system. Given this information, users can then take any necessary actions to bring the system within normal operating limits

(Bullinger, Kern, and Muntzinger, 1987; Grandjean, 1987; Stammerjohn, Smith, and Cohen, 1981). When the system does not provide this feedback information, users find it difficult to make correct and timely responses, especially when anomalous conditions arise.

Human factors engineering guidelines exist for the design of equipment in general (van Cott and Kincaide, 1972) as well as for medical devices in particular(Association for the Advancement of Medical Instrumentation, 1993). The human factors literature also contains a large amount of information about equipment characteristics that determine how safely and effectively a piece of equipment can be used (e.g., Maddock, 1987; Meertens, Bartelink, and Minderhoud, 1988; Thomadsen et al., 1991).

Because numerous RAB tasks involve computer use, the human-computer interface has a significant role in determining the approaches that are developed to minimize RAB problems and errors. Control of treatment delivery and feedback on system status and operator actions are important aspects of RAB systems that require well designed human-computer interfaces.

The human-computer interface should be evaluated in terms of how it influences RAB task performance. The human factors literature examines this topic primarily in terms of how information is presented to the user: (1) the type of interface metaphor (e.g., desktop, document) (Carroll and Olson, 1988; Tullis, 1983), (2) whether to use menus or command names to input commands to the computer (Christie and Gardiner, 1990); (3) if menus are chosen, the best way to design them (Paap and Roske-Hofstrand, 1988); (4) if commands names are chosen the types of names that should be used (Williges and Williges, 1984); (5) the type of feedback that should be provided (e.g., error messages); (6) the form and timing of that feedback; (7) the type of online help, if any, that will best assist the operator (Duffy, Palmer, and Mehlenbacher, 1992); and (8) the overall system image that the interface projects to the user about how the system operates and responds to user input (Downton, 1991; Harrison and Thimbley, 1990).

4.1.2 Data Entry

Analysis of the critical tasks in Phase 6 found that data entry errors can occur during the entry of treatment plan values into the afterloader control unit. This determination was corroborated by government problem reports that documented several instances where this error had led to a misadministration. Data entry errors occur as a result of two failed actions: the initial entry of incorrect data and the failure to detect this error.

Data entry errors can be reduced through the use of unambiguous data entry formats that restrict the range of acceptable values (Greenstein and Arnaut, 1987). This feature prevents the system from accepting values that deviate from a defined range of values. RAB treatment plan parameters typically fall within a relatively constant range of values, making this approach a viable intervention.

The detection of data entry errors can be increased by improving system feedback and error checking capabilities. Requiring a separate confirmation action immediately following each data entry increases accuracy (Greenstein and Arnaut, 1988). The time needed to complete data entry is greater when confirmation actions are required, but the importance of accuracy in RAB data entry tasks makes this tradeoff acceptable.

The keyboard and mouse are the primary data entry devices currently used in RAB tasks. Other data entry devices could be investigated for their appropriateness for RAB tasks, including touch screens, light pens, and track balls. Human factors principles can be used to determine the suitability of these devices for specific RAB data entry tasks and to suggest implementation alternatives.

Several factors should be considered when evaluating or selecting an input device for a specific application. The characteristics of the task, users, environment, and existing hardware and software should be determined. Insofar as possible, future contingencies as well as current demands should be included in this determination. Next, the properties of the input devices should be compared with these characteristics to narrow the set of acceptable alternatives. Relevant properties include the ability to attend to the display while entering data, freedom from parallax problems, input resolution, amount of eye-hand coordination required, flexibility of placement within a workspace, and user preferences. A set of candidate input devices can then be tested in an actual or simulated RAB work setting using RAB staff members. The results of this test amd evaluation procedure can be used to optimize the device for RAB tasks (Greenstein and Arnaut, 1987).

4.1.3 Environment

Hospital and clinics provide the settings in which the vast majority of RAB is performed. The environments of these medical facilities possess characteristics, such as physical layout, noise, and illumination, that often affect task performance. These characteristics were not identified explicitly by government problem reports as contributors to RAB human-system interface problems and errors. However, given their documented ability to influence human performance, inadequate environmental characteristics are likely potentiating factors for human

error in RAB (Bennett, 1977; Eastman-Kodak, 1986; Harrigan, 1987; Pheasant, 1990). The role of three environmental variables common to all RAB systems—physical layout, noise, and illumination—is considered in relation to RAB task performance.

4.1.3.1 Physical Layout

The effect of physical layout on brachytherapy task performance has not been thoroughly investigated. However, based on recurring failures to transmit information from one task to another, physical layout appears to be a contributing factor to certain problems and errors. To illustrate, the settings for certain brachytherapy functions and tasks are often physically separated; however, information such as patient charts and treatment plans must move through the brachytherapy system with the patient. There have been documented instances where patient charts and treatment plans have been misplaced, causing patients to be misidentified or administered the wrong treatment plan.

An evaluation of the effects of physical layout on RAB task performance must consider both the relationships between different work areas as well as the characteristics of individual work areas. Turning first to the interrelationship of different work areas, human factors techniques, such as path analysis (Kantowitz and Sorkin, 1983), can be used to analyze the patterns of activity and information that flow from one work area to another. Findings from this analysis could be used as a basis for suggesting alternative physical layouts to improve the effectiveness of brachytherapy.

The potential value of this type of analysis is most apparent in cases where the proximity of different work areas can influence brachytherapy errors. For example, it is vital that the applicator, once placed, does not move until treatment delivery is completed. However, if treatment simulation and treatment delivery occur in physically separated areas, transporting a patient from one area to the other can cause the applicator to shift position. If its position is not rechecked upon arrival at the treatment delivery area (as it almost always is not), the patient may receive a misadministration. On the other hand, if simulation and treatment delivery are located in the same work area (as they are at some facilities), this problem is less likely to occur.

Turning now to individual work areas, human factors guidelines exist for designing and evaluating individual work areas in accordance with human performance limitations (e.g., National Aeronautics and Space Administration, 1978, 1987; Pheasant, 1987). Anthropometric data are available that specify a range of acceptable values for work surface heights and clearances, reach envelopes, and related physical aspects of work areas. Anthropometric and biomechanical aspects of the work environment have not been explicitly identified as contributors to human error in brachytherapy. However, human factors research has established that the failure to take these factors into account can lead to increased operator fatigue, stress, and tendency for error (Chaffin, 1987; Kantowitz and Sorkin, 1983).

4.1.3.2 Noise

The effects of noise, defined as unwanted sound, on human performance have been extensively documented by human factors researchers (Davies and Jones, 1984; Jones and Chapman, 1984; Kryter, 1985; Loeb, 1986). In the most basic sense, noise can affect performance in one of two ways, both of which can occur during brachytherapy task performance:

- Noise can mask an auditory signal that is important to task performance.
- Noise can influence an individual's mental and physical state (Kantowitz and Sorkin, 1983).

The first case occurs whenever noise impairs an individual's ability to perceive accurately another person's verbal communication. In settings where brachytherapy tasks are performed, it is not unusual for personnel who are not directly involved in task performance to be present during task performance. Other sources of noise, such as public address systems and telephones, can also mask communications. Not surprisingly, noise is associated with errors, accidents, and decreased productivity (Webster, 1984). Other devices may be in the vicinity of brachytherapy workspaces. The steady-state noise generated by these devices should not exceed 50 decibels when measured at the location of the RAB task performer (Association for the Advancement of Medical Instrumentation, 1993).

Human factors research has documented the effects of interfering sounds on the ability to detect auditory signals like those produced by computers and other equipment used in brachytherapy (Davies and Jones, 1984; Fisher, 1973; Haselgrave, 1990). Noise can mask speech to a remarkable degree, requiring extra care when conversing in noisy environments. A finding with particular relevance to brachytherapy is that background speech, even at relatively low levels, can disrupt memory for visually presented items (Jones and Broadbent, 1987). Thus, an operator of a treatment planning computer or an afterloader control unit in a noisy setting may not remember transient visual information that appeared on the displays of those devices.

4.1.3.3 Illumination

Illumination is a measure of the amount of light from ambient and local sources that falls on a surface (Cushman and Crist, 1987). Because vision provides people with more information than all of the other senses combined, establishing environmental conditions that optimize visual information processing is of great importance (Hopkinson and Collins, 1970; Howarth, 1990). The ability to perform most tasks depends on the quantity and quality of light that illuminates the area in which the task occurs. Illumination is a major determinant of the ease with which information presented by computer monitors and written documentation, can be perceived (Boyce, 1981; Hopkinson and Collins, 1970; Kaufman and Haynes, 1987).

Inadequate lighting conditions, ranging from low levels of illumination to glare, can interfere with tasks that involve visually intensive activities (Cushman, 1983). Poor illumination or glare from overhead fluorescent lighting may be partly responsible for the failure to detect data entry errors during treatment planning and treatment plan entry into the afterloader control unit. For example, glare can reduce visibility by producing a reflection that veils part of the display. Its effects can be minimized by using light sources and workspace arrangements that limit the amount of light reflected toward the operator's eyes. Light sources should be mounted above and away from the normal lines of sight, and the amount of light reflected toward the eyes should be minimized (Kantowitz and Sorkin, 1983; Kaufman and Haynes, 1981).

4.1.4 Mental Workload

Mental workload refers to the cognitive demands placed on system users during task performance. As with environmental factors, mental workload was not identified explicitly as a factor in RAB problems and errors. Given the cognitively demanding and time pressured nature of several RAB tasks, however, mental workload is a likely contributor to RAB task performance errors. Identifying the specific problems and errors caused by excessive mental workload requires additional study. However, knowledge of the basic features of mental workload permits a preliminary determination of the sorts of tasks in which errors due to high workload demands are most likely.

Human factors has accumulated an extensive body of theoretical and empirical findings describing how mental workload can be allocated among tasks and task performers to maximize system performance and decrease the likelihood of human error (e.g., Moray, 1979). The function and task analysis conducted in Phase 1 showed that mental workload was an important determinant of brachytherapy task performance, especially when complex cognitive operations and sustained concentration were involved, such as during treatment planning.

Mental workload is a complex construct that has been intensively researched by cognitive psychologists and human factors scientists (Moray, 1979, 1982). Mental workload can be viewed as composed of three interrelated variables: the cognitive effort needed to perform a task, the time available to complete a task, and task complexity. When these factors singly or in combination exceed an individual's information processing capacity, task performance is degraded. Human factors techniques can be used to redesign tasks to decrease mental workload. Conducting mental workload analyses of treatment planning tasks could lead to the restructuring of single tasks or groups of highly inter-related tasks in order to decrease workload demands.

Tasks that require complex information processing activities and skilled performance, especially under time pressure, are most likely to produce these demands. Several critical tasks in treatment planning—target volume localization, dwell position localization, and dosimetry—possess high mental workload demands according to these criteria. Errors in these tasks are therefore likely to be due at least in part to excessive mental workload demands. Given the importance of treatment planning to RAB, the need to propose alternative approaches that can reduce workload demands becomes evident.

4.2 Procedures

Procedures are ordered sequences of tasks or steps that have been designed and approved in order to assist workers in the performance of tasks. Even highly skilled workers can profit from the use of procedures, especially if it is performed relatively infrequently, such as source exchange in a high dose rate remote afterloader, or if it has a high safety significance (Wieringa, Moore, and Barnes, 1993). RAB procedures should be designed to minimize errors in all tasks, but especially so in those most directly concerned with radiation administration, such as treatment planning and treatment delivery tasks.

The Phase 6 analysis of critical brachytherapy tasks and the review of the government problem reports and the brachytherapy literature identified problems and errors that occur as a consequence of inadequate procedures. From Tables 5 and 6, these problems and errors include:

- misidentification of patient
- substitution of the records of one patient for those of another
- failure to identify all radiation targets
- failure to calculate the radiation dose accurately

- failure to use the correct source decay factor
- mismatching of applicator treatment channels with afterloader source guide tubes
- mis-entering values from the treatment plan into the afterloader control unit
- entering treatment plan for another patient into the afterloader control unit

The alternative approaches that were proposed to overcome these problems and errors by procedural means included:

- tagging procedures for patients and documents
- target marking in simulation views
- standardization of radiation dosage units
- using a map of the relationship between source guide tubes and treatment channels
- erasure of the magnetic media that is used to enter the plan into the afterloader control unit

These approaches require that new procedures be generated, tested, revised, and approved. The human factors literature provides guidelines for each of these stages of procedure development (e.g., Swezey, 1987, Wieringa, Moore, and Barnes, 1993). One of the most crucial aspects of procedures is that they be used consistently in the intended manner. The best way to ensure that this requirement is met is to make it clear that the procedure is designed to assist workers in the performance of tasks that can have significant health and safety consequences for both themselves and others if those tasks are done incorrectly.

Procedures are most effective when they are organized in a hierarchical, logical, consistent manner. Hierarchical procedures are easier to understand and remember (Dixon, 1987). The hierarchical organization of a procedure should be explicitly shown through the use of headings, subheadings, and highlighting techniques such as bolding and white space. Heading names should reflect their content, and related steps should be grouped into sections and subsections (Hartley and Jonassen, 1985). There is no one correct format for headings (Brusaw, Alred, and Oliu, 1987). The important factor is that headings stand out from surrounding text and that the hierarchical structure of the procedure be readily apparent.

Step numbers should be formatted so that they uniquely identify steps and provide information regarding the position of a step in a procedural hierarchy (Mackh and Rew, 1991). Unique identification of steps permits users to focus on actual task steps and to refer to supporting information only when it is needed to clarify a task step. Hierarchical step numbering provides useful information regarding the relationship of a step to an overall procedure (Wieringa, Moore, and Barnes, 1993).

4.2.1 Documentation

Documentation consists of textual and graphical material, both hard copy and on-line, that is available to aid system users in performing task procedures (Simpson and Casey, 1988; Sheppard, 1987). Documentation should supply users with information they need to perform tasks while minimizing problems and errors. Well designed documentation can facilitate task performance by conveying system objectives, required procedures, and system limitations (Wright, 1988). RAB documentation includes manufacturers' and distributors' operating manuals and on-line help systems, as well as locally developed task checklists, worksheets, and job performance aids.

Human factors research has formulated document format and content guidelines that can significantly increase the ability of users to read and understand document contents, and to follow instructions for performing tasks (Duffy and Waller, 1985; Gong and Elkerton, 1990). Format characteristics significantly influence comprehensibility and include highlighting, use of illustrations and graphics, information organization, language, legibility, physical characteristics, and readability (Hartley, 1978, 1980; Wright, 1988). Content characteristics pertain to the informational requirements for performing a task and include background information about the purpose of the task and it relationship with other tasks; procedural information to direct the operator to perform the correct sequence of task steps; and risk communication information that discusses hazards that could arise should task procedures not be performed correctly (Callan, Gwynne, Sawyer, and Tolbert, 1993).

4.2.2 Job Performance Aids

A job performance aid (JPA) is a device or document containing information that is needed to perform a task. JPAs are intended to be used during task performance rather than during the initial learning of a task. Most often, they reduce the cognitive demands of a task by decreasing memory load or the amount of decision making necessary to perform a task (Swezey, 1987).

The Phase 6 analysis of critical brachytherapy tasks and the review of the government problem reports and the brachytherapy literature identified problems and errors that occur because of inadequate job performance aids. These problems and errors include:

- substitution of the records of one patient for those of another
- failure to specify the exact location of targets
- treatment of the wrong site
- faulty identification, specification, or transfer of information about source positions to treatment delivery system
- mismatching of source guide tubes to treatment channels
- loading of the wrong sources
- failure to detect and correct hardware and software problems or to communicate them to the appropriate authority
- exposure of staff to radiation during source exchange

The alternative approaches that were proposed to overcome these problems by means of improved job performance aids included:

- improved patient identification methods such as placing visible identification tags on patients and patient documents
- enhanced visual aids for treatment planning
- map of the relationship between source guide tubes and treatment channels
- applicator identification labels
- checklists that are constructed to highlight failed or omitted items
- improved access to emergency source containers

JPAs are most suitable for tasks that involve following a set of procedures, although they can serve other purposes including cueing, aids to association, analogs, and examples. JPAs that serve a procedural role should provide step-by-step instructions for performing a task, whereas JPAs whose purpose is to provide performance cues should be designed to provide signals for executing some action without step-by-step directions (Swezey, 1987). For example, checklists typically provide cues to experienced system users who already are familiar with the tasks involved in system operation. The checklist only serves to remind them of task performance details and the order in which tasks should be done (Geis, 1984). JPAs serving a cueing role should include highlighting, such as bolding, underlining, and arrows, that draws attention to the most important aspects of a task (Swezey, 1987).

JPAs also should possess certain content characteristics in order to be effective. They should be based directly on an analysis of what the intended user must do in performing a task. They should convey their message in a procedural manner, telling the user what to do, and when and how to do it. They should present information in small, discrete amounts, thereby alleviating problems involving the retention of lengthy procedures in short-term memory (Swezey and Pearlstein, 1974, cited in Swezey, 1987).

4.3 Training and Organization

Training is the process of imparting task-specific information and skills in either a group or individual setting. The purpose of training insofar as RAB is concerned is to achieve a high level of task performance. A variety of means can be used to train RAB staff members, including classroom instruction, individual instruction, on-the-job training, and independent study. Organizational factors influence the type of training that is used and its effectiveness.

The Phase 6 analysis of critical brachytherapy tasks and the review of the government problem reports and the brachytherapy literature identified problems and errors that occur as a consequence of inadequate training and organization. From Tables 5 and 6, these problems and errors include:

- failure to transmit accurate placement information to other tasks
- failure to detect dislodged source during or after a treatment session
- failure to detect and correct hardware and software problems or to communicate them to the appropriate authority
- failure to conduct post-treatment radiation survey
- failure to accurately calibrate source activity

The alternative approaches that were proposed to overcome these problems and errors by training and organizational means included:

- verification of task linkages before starting treatment delivery
- training in local task performance and linkage procedures
- certification of all RAB software and hardware after maintenance
- integration of QA with refresher training in emergency procedures
- performance of multiple source calibrations

4.3.1 Training

A theoretical framework for training, referred to as instructional system design or the systems approach to training, has been developed during the past three decades

by researchers in human factors and related fields (Gagne, Briggs, and Wager, 1988; Kaufman, Corrigan, and Nunnelly, 1966). Instructional system design incorporates the necessary components for designing, evaluating, and modifying many types of complex systems. Instructional system design emphasizes the specification of training objectives based on needs assessment, the use of controlled learning procedures to achieve these objectives, the establishment of performance criteria, and the assessment of training effectiveness (Goldstein, 1987).

Instructional system design can be implemented by the following five functions which, taken together, facilitate the establishment of an effective, reliable, and valid training system:

- define training needs
- establish training objectives
- specify management and delivery plan
- develop courses or some other means of imparting instruction
- implement management and delivery plan

Each of these functions is comprised of several sequentially executed tasks. The end product of these functions, which can range from information to a training device, serve as input to the first task in the next function. The final product of this process is a program for training specific tasks. Instructional system design enables the knowledge and skills required for each RAB task to be identified, training materials for imparting needed information and skills to be designed, and assessment methods developed to determine whether training objectives have been satisfied.

The RAB function and task analysis (NUREG/CR-6125, Vol. 2) aided in the analysis of job tasks and establishing required capabilities, which are tasks associated with defining training needs. Likewise, the function and task analysis helped to identify knowledge and skill requirements, which is information needed to establish training objectives.

Current training in brachytherapy usually consists of relatively unstructured on-the-job instruction of less experienced individuals by more experienced staff members. Little standardized or formalized training, such as classroom instruction, occurs at any stage of brachytherapy training. The effectiveness of any form of training is seldom tested by formal means. The absence of formal assessment procedures complicates determining the contributions of various forms of training and the extent to which inadequate training methods contributes to brachytherapy problems and errors.

This situation has resulted in training system that has not addressed all pertinent aspects of RAB task performance. Task linkages and task verification procedures are perhaps the most obviously overlooked activities in this regard, as several of the alternative approaches indicate.

Human factors research indicates that verbal methods are not the most effective way to teach complex, skilled tasks such as those performed in RAB. Verbal sequences contain large amounts of information and place large capacity demands on human memory. Verbal training methods are best limited to the early stages of training that precede on-the-job training when the initial orientation to RAB is provided (Holding, 1987).

Human factors studies have established that behavior modeling is appropriate for higher-level training programs of the sort used in brachytherapy (Holding, 1987). As training progresses to learning how to perform the specific sequences of actions required by RAB tasks, some form of behavior modeling should be used. Showing the learner what to do can take the form of visual demonstration or of guiding performance with various degrees of constraint (Holding, 1987).

Demonstration training is an effective means of teaching an action sequence for RAB task performance. This demonstration training is should consist of first person, on-the-job training, although alternative media such as videos can also play a role. The use of video, however, precludes active learner participation with RAB equipment and prevents the learner from asking questions regarding specific aspects of task performance. Training materials and procedures should be keyed to each person's role in the RAB process. The function and task analysis is an excellent guide for determining the skills, abilities, and knowledge required to perform each brachytherapy task.

4.3.2 Organizational Factors

Human factors approaches to designing, evaluating, and modifying organizations also use a systems-level analysis (Hendrick, 1984, 1987). An organization may be defined as "the planned coordination of two or more people who, functioning on a relatively continuous basis and through division of labor and a hierarchy of authority, seek to achieve a common goal or set of goals" (Robbins, 1983, cited in Hendrick, 1987).

For the most part, organizational factors were not directly responsible for the problems and errors cited in government reports and the critical tasks. However, deficiencies in any organizational function can increase the likelihood of RAB problems and errors. Human factors research on the

influence of organizational factors on task performance has established several findings that pertain to RAB systems.

As in training, organizational functions are defined in terms of the overall goals of the RAB process. These functions include defining RAB production, service, and safety objectives; assigning tasks to RAB staff, machines, or some combination thereof; acquiring the resources needed to perform RAB tasks, including personnel, equipment, and supplies; designing procedures for performing RAB tasks; allocating tasks, workspaces, and resources; communicating goals and procedures to RAB staff; monitoring system progress toward achieving RAB goals; and directing progress toward those goals by intervening at the appropriate time and place in the RAB process.

Human factors typically takes a microergonomic approach to systems intervention, which focuses on the design of specific tasks and human-systems interfaces. Although applied within the context of a systems analysis, most human factors activities are oriented to the individual or subsystem levels. Organizational analysis, in contrast, requires a macroergonomic approach that takes into consideration the entire organization in which the activity of interest occurs. This approach involves evaluating organizational effectiveness criteria and the dimensions of organizational structure, determining what sociotechnical system components moderate organization design, and choosing the correct structural form for the organization in which RAB is occurring (Hendrick, 1987; Robbins, 1983).

4.4 Conclusion

This literature review has demonstrated that human factors issues are relevant to the performance of many RAB functions and tasks. The human factors literature also constitutes an important source for understanding human error in RAB. This understanding can be used in subsequent efforts to develop and implement improvements in RAB systems.

This literature review informs the research effort of the entire project by demonstrating how human factors concepts bear directly on major RAB problems and errors. In so doing, this review shows that human factors offers important lessons for investigators who would make RAB safer, more effective, and more reliable.

5 Bibliography

5.1 Human Factors

5.1.1 General Background

Bailey, R.W., *Human Performance Engineering: A Guide for System Designers* (2nd ed.), Prentice Hall, Englewood Cliffs, New Jersey, 1989.

Boff, K.R. and J.E. Lincoln, *Engineering Data Compendium: Human Perception and Performance*, Harry G. Armstrong Aerospace Medical Research Laboratory, Wright-Patterson Air Force Base, Ohio, 1988.

Cochran, W.G., *Sampling Techniques* (3rd ed.), Wiley, New York, 1977.

Drury, C.G., B. Paramore, H.P. van Cott, S.M. Grey, and E.N. Corlett, "Task Analysis," In G. Salvendy, ed., *Handbook of Human Factors* (Ch. 3.4), Wiley, New York, 1987.

Fleishman, E.A., and M.K. Quaintence, *Taxonomies of Human Performance: The Description of Human Tasks*, Academic Press, Orlando, FL, 1984.

Grandjean, E., *Fitting the Task to the Man: An Ergonomic Approach*, Taylor & Francis, Ltd., London, 1982.

Kantowitz, B.H., and R.D. Sorkin, *Human Factors: Understanding People-System Relationships*, Wiley, New York, 1983.

Kinger, A., ed., *Human-Machine Interactive Systems*, Plenum, New York, 1991.

Kish, L., *Survey Sampling*, Wiley, New York, 1965.

Mallamud, S.M., J.M. Levine, and E.A. Fleishman, "Identifying Ability Requirements by Decision Flow Diagrams," *Human Factors*, 22, 57–68, Human Factors Society, Santa Monica, CA, 1980.

McCormick, E.J. *Human Factors Engineering*, McGraw-Hill, New York, 1970.

Myers, L.B., Tijerina, L., and Geddie, J.C., "Proposed Military Standard for Task Analysis," Technical Memorandum 13-87, U.S. Army Human Engineering Laboratory, Aberdeen Proving Ground, MD, July, 1987.

National Aeronautics and Space Administration, NASA Reference Publication 1024," Anthropometric Source Book," Lyndon B. Johnson Space Center, Houston, TX (July 1978).

Salvendy, G., *Handbook of Human Factors*, Wiley, New York, 1987.

Sanders, M.S., and E.J. McCormick, *Human Factors in Engineering and Design* (6th ed.), McGraw-Hill, New York, 1987.

Woodsen, W.E., *Human Factors Design Handbook*, McGraw-Hill, New York, 1981.

5.1.1.1 Human Error and Reliability

Bailey, R.W., *Human Error in Computer Systems*, Prentice Hall, Englewood Cliffs, New Jersey, 1983.

Bogner, M.S., ed., *Human Error in Medicine*, Erlbaum, Hillsdale, NJ, 1994.

Kirwan, B. "Human Reliability Assessment," In J.R. Wilson and E.N. Corlett, eds., *Evaluation of Human Work: A Practical Ergonomics Methodology* (pp. 706–754), Taylor & Francis, London, 1990.

Meister, D., "Human Reliability," In F.A. Muckler, ed., *Human Factors Review '84*, Human Factors Society, Santa Monica, CA, 1984.

Meister, D., *Behavior Analysis and Measurement Methods*, Wiley, New York, 1985.

Miller, D.M., and A.D. Swain, "Human Error and Reliability," In G. Salvendy, ed., *Handbook of Human Factors* (Ch. 2.8), Wiley, New York, 1987.

Rasmussen, J., "Human Error and the Problem of Causality in Analysis of Accidents;" *Philosophical Transactions of the Royal Society of London, Series B: Biological Sciences*, 327: 449–462 (1990).

Reason, J., "The Contribution of Latent Human Failures to the Breakdown of Complex Systems," *Philosophical Transactions of the Royal Society of London, Series B: Biological Sciences*, 327: 475–484 (1990).

Senders, J.W., and N.P. Moray, *Human Error: Cause, Prediction, and Reduction*, Erlbaum, Hillsdale, NJ, 1991.

Seven, S.A., Akman, A., Muckler, F.A., Knapp, B.G., and Bernstein, D. "Development and Application of Military Intelligence (MI) Job Comparison and Analysis Tool (JCAT)," Research Note 91-41, U.S. Army Research Institute, Alexandria, VA, 1991.

Swain, A.D., and H.E. Guttman, "Handbook of Human Reliability Analysis with Emphasis on Nuclear Power Plant Applications," (NUREG/CR-1278, SAND80-0200, RX, AN), Sandia National Laboratories, Albuquerque, NM, 1983.

5.1.2 Human-System Interfaces

Brown, C.M., *Human-Computer Interface Design Guidelines*, Ablex, Norwood, NJ, 1988.

Card, S.K., T.P. Moran, and A. Newell, *The Psychology of Human-Computer Interaction*, Erlbaum, Hillsdale, NJ, 1983.

Carroll, J.M., and J.R. Olson, "Mental Models in Human-Computer Interaction," In M. Helander, ed., *Handbook of Human-Computer Interaction* (pp. 45–65), North Holland, Amsterdam, 1988.

Carroll, J.M., R.L. Mack, and W.A. Kellogg, "Interface Metaphors and User Interface Design," In M. Helander, ed., *Handbook of Human-Computer Interaction* (pp. 67–85), North Holland, Amsterdam, 1988.

Christie, B., and M.M. Gardiner, "Evaluation of the Human-Computer Interface," In J.R. Wilson and E.N. Corlett, eds., *Evaluation of Human Work: A Practical Ergonomics Methodology* (pp. 271–320), Taylor & Francis, London, 1990.

Downton, A. ed., *Engineering the Human-Computer Interface*, McGraw-Hill, New York, 1991.

Duffy, T.M., J.E. Palmer, and B. Mehlenbacher, *On Line Help: Design and Evaluation,* Ablex, Norwood, NJ, 1992.

Harrison, M., and H. Thimbleby, eds., *Formal Methods in Human-Computer Interaction*, Cambridge University Press, Cambridge, England, 1990.

Karat, J., "Software Evaluation Methodologies," In M. Helander, ed., *Handbook of Human-Computer Interaction* (pp. 891–903), North Holland, Amsterdam, 1988.

M. Helander, ed., *Handbook of Human-Computer Interaction*, North Holland, Amsterdam, 1988.

Paap, K.R., and R.J. Roske-Hofstrand, "Design of Menus," In M. Helander, ed., *Handbook of Human-Computer Interaction* (pp. 203–235), North Holland, Amsterdam, 1988.

Rivlin, C., R. Lewis, and R. Davies-Cooper, eds., *Guidelines for Screen Design*, Blackwell Scientific Publications, Boston, 1990.

Rubin, T., *User Interface Design for Computer Systems*, Wiley, New York, 1988.

Tullis, T.S., "Screen Design," In M. Helander, ed., *Handbook of Human-Computer Interaction* (pp. 377–411), North Holland, Amsterdam, 1988.

Tullis, T.S., "The Formatting of Alphanumeric Displays: A Review and Analysis," *Human Factors*, 25: 657–682 (1983).

U.S. Department of Defense, "Human Engineering Guidelines for Management Information Systems," MIL-HDBK-761A, Washington, D.C., September 30, 1989.

Williges, B.H., and R.C. Williges, "Dialogue Design Considerations for Interactive Computer Systems," In F.A. Muckler, ed., *Human Factors Review: 1984*, Human Factors Society, Santa Monica, CA, 1984.

Williges, R.C., B.H. Williges, and J. Elkerton, "Software Interface Design," In G. Salvendy, ed., *Handbook of Human Factors* (Ch. 11.3), Wiley, New York, 1987.

5.1.2.1 Equipment

American National Standards Institute/Human Factors Society, ANSI/HFS 100-1988, "American National Standard for Human Factors Engineering of Visual Display Terminal Workstations," Santa Monica, CA.

Association for the Advancement of Medical Instrumentation, "Human Factors Engineering Guidelines and Preferred Practices for the Design of Medical Devices," Arlington, VA (1993)

Bullinger, H-J, P. Kern, and W.F. Muntzinger, "Design of Controls," In G. Salvendy, ed., *Handbook of Human Factors* (Ch. 5.3), Wiley, New York, 1987.

Enoch, J.M., "Effect of the Size of a Complex Display Upon Visual Search," *Journal of the Optical Society of America*, 49: 280–286 (1959).

Grandjean, E. "Design of VDT Workstations," In G. Salvendy, ed., *Handbook of Human Factors* (Ch. 11.1), Wiley, New York, 1987.

Hammer, C.H., and S. Ringel, "Information Assimilation from Updated Alphanumeric Displays," *Journal of Applied Psychology*, 50: 383–387 (1966).

Helander, M.G., "Design of Visual Displays," In G. Salvendy, ed., *Handbook of Human Factors* (Ch. 5.1), Wiley, New York, 1987.

Helander, M.G., P.A. Billingsley, and J.M. Schurick, "An Evaluation of Human Factors Research on Visual Display Terminals in the Workplace," *Human Factors Review*, 55–130, 1984.

Horii, S.C., H.N. Horii, S.K. Mun, H.R. Benson, and R.K. Zeman, "Environmental Designs for Reading from Imaging Work Stations: Ergonomic and Architectural Features," *Journal of Digital Imaging*, 2: 156–162 (1989).

International Business Machines Corporation, *Human Factors of Workstations with Visual Displays*, San Jose, CA, 1984

National Research Council, *Visual Displays, Work, and Vision*, National Academy Press, Washington, D.C., 1983.

Senders, J.W., J.E. Elkind, M.C. Grignetti, and R.P. Smallwood, "An Investigation of the Visual Sampling Behavior of Human Observers," (NASA-CR-434), Bolt, Beranek, & Newman, Inc., Cambridge, MA, 1964.

Stammerjohn, L.W., M.J. Smith, and B.G.F. Cohen, "Evaluation of Workstation Design Factors in VDT Operations," *Human Factors*, 23: 401–412 (1981).

U.S. Department of Defense, "Anthropometry of U.S. Military Personnel (metric)," DOD-HDBK-743A, Washington, D.C., October 3, 1980.

U.S. Department of Defense, "Human Engineering Design Criteria for Military Systems, Equipment, and Facilities," MIL-STD-1472D, Washington, D.C., March 14, 1989.

U.S. Department of Defense, "Human Factors Engineering Design for Army Materiel (metric)," MIL-HDBK-759B(MI), Washington, D.C., June 30, 1992.

U.S. Food and Drug Administration, "Reviewer Guidance for Computer Controlled Medical Devices Undergoing 510(K) Review," Center for Devices and Radiological Health, Rockville, MD (1 February 1991 Draft).

van Cott, H.P., and R.G. Kincaide, eds., *Human Engineering Guide to Equipment Design*, U.S. Superintendent of Documents, Washington, D.C., 1972.

5.1.2.2 Data Entry

Alden, D.G., R.W. Daniels, and A.F. Kanarick, "Keyboard Design and Operation: A Review of the Major Issues," *Human Factors*, 14: 275–293 (1972).

American National Standards Institute, *American National Standard for Office Machines and Supplies—Alphanumeric Machines—Alternative Keyboard Arrangement*, ANSI X4.22-1983, ANSI, New York, 1983.

American National Standards Institute, *American National Standard for Office Machines and Supplies—Alphanumeric Machines—Keyboard Arrangement*, ANSI X4.23-1982, ANSI, New York, 1982.

Beringer, D.B., and J.G. Peterson, "Underlying Behavioral Parameters of the Operation of Touch-Input Devices: Biases, Models and Feedback," *Human Factors*, 27: 445–458 (1985).

Chapanis, A., and R.G. Kinkade, "Design of Controls," In H.P. Van Cott and R.G. Kinkade, eds., *Human Engineering Guide to Equipment Design* (rev. ed.) (pp. 345–379), U.S. Government Printing Office, 1972.

Greenstein, J.S., and L.Y. Arnaut, "Input Devices," In M. Helander, ed., *Handbook of Human-Computer Interaction* (pp. 495–519), North Holland, Amsterdam, 1988.

Pollard, D., and M.B. Cooper, "The Effects of Feedback on Keying Performance," *Applied Ergonomics*, 10: 194–200, 1979.

Rouse, W.B., "Design of Man-Computer Interfaces for On-Line Interactive Systems," *Proceedings of the IEEE*, 63: 847–857, 1975.

Seibel, R., "Data Entry Devices and Procedures," In H.P. Van Cott and R.G. Kinkade, eds., *Human Engineering Guide to Equipment Design* (rev. ed.) (pp. 311–344), U.S. Government Printing Office, 1972.

5.1.2.3 Environment

Physical Layout

Bennett, C., *Spaces for People: Human Factors in Design*, Prentice-Hall, Englewood Cliffs, NJ, 1977.

Eastman-Kodak Company, *Ergonomic Design for People at Work*, Vol. 2, Van Nostrand Reinhold Company, New York, 1986.

Harrigan, J.E., "Architecture and Interior Design," In G. Salvendy, ed., *Handbook of Human Factors* (Ch. 6.7), Wiley, New York, 1987.

National Aeronautics and Space Administration, NASA-STD-3000, "Man-System Integration Standards," Lyndon B. Johnson Space Center, Houston, TX (March 1987).

Pheasant, S.T., "Anthropometry and the Design of Workspaces," In J.R. Wilson and E.N. Corlett, eds., *Evaluation of Human Work: A Practical Ergonomics Methodology* (pp. 455–471), Taylor & Francis, London, 1990.

—, NUREG-0700, "Guidelines for Control Room Design Reviews," September 1981.

Noise

Broadbent, D.E., and M. Gregory, "Effects of Noise and Signal Rate Upon Vigilance Analysed by Means of Decision Theory," *Human Factors*, 7: 155–162 (1965).

Davies, D.R., and D.M. Jones, "Effects of Noise on Performance," In W. Tempest, ed., *The Noise Handbook*, Academic, London, 1984.

Fisher, S., "The 'Distraction Effect' and Information Processing Complexity," *Perception*, 2: 78–89, (1973).

Haslegrave, C.M., "Auditory Environment and Noise Assessment," In J.R. Wilson and E.N. Corlett, eds., *Evaluation of Human Work: A Practical Ergonomics Methodology* (pp. 406–439), Taylor & Francis, London, 1990.

Jones, D.M., and D.E. Broadbent, "Noise," In G. Salvendy, ed., *Handbook of Human Factors* (Ch. 6.1), Wiley, New York, 1987.

Kryter, K.D., *The Effects of Noise on Man* (2nd ed.), Academic Press, London, 1985.

Loeb, M., *Noise and Human Efficiency*, Wiley, New York, 1986.

Patterson, R.D., "Auditory Warning Sounds in the Work Environment," *Philosophical Transactions of the Royal Society of London, Series B: Biological Sciences*, 327: 485–492 (1990).

Webster, J.C., "Noise and Communication," In D.M. Jones and A.J. Chapman, eds., *Noise and Society*, Wiley, Chichester, Great Britain, 1984.

Illumination

Boyce, P.R., *Human Factors in Lighting*, Macmillan, New York, 1981.

Cushman, W.H., "Lighting for Workplaces with Visual Display Terminals," In *Health and Ergonomic Considerations of Visual Display Units—Symposium Proceedings*, American Industrial Hygiene Association, Akron, OH, pp. 73–85, 1983.

Cushman, W.H., and B. Crist, "Illumination," In G. Salvendy, ed., *Handbook of Human Factors* (Ch. 6.3), Wiley, New York, 1987.

Grether, W.F., and C.A. Baker, "Visual Presentation of Information," In H.P. van Cott and R.G. Kincaide, eds., *Human Engineering Guide to Equipment Design*, U.S. Superintendent of Documents, Washington, D.C., 1972.

Hopkinson, R.G. and J.B. Collins, *The Ergonomics of Lighting*, MacDonald, London, 1970.

Howarth, P.A., "Assessment of the Visual Environment," In J.R. Wilson and E.N. Corlett, eds., *Evaluation of Human Work: A Practical Ergonomics Methodology* (pp. 351–386), Taylor & Francis, London, 1990.

Kaufman, J.E., and H. Haynes, eds., *IES Lighting Handbook* , application volume, Illuminating Engineering Society of North America, New York, 1987.

Kaufman, J.E., and H. Haynes, eds., *IES Lighting Handbook* , reference volume, Illuminating Engineering Society of North America, New York, 1981.

5.1.2.4 Mental Workload

Crossman, E.R.F.W., J.E. Cooke, and R.J. Beishon, "Visual Attention and Sampling of Displayed Information in Process Control," In E. Edwards and F.P. Lees, eds., *The Human Operator in Process Control*," (pp. 25–50), Taylor & Francis, London, 1974.

Eggemeier, F.T., "Properties of Workload Assessment Techniques," In M. Venturino, ed., *Selected Readings in Human Factors* (pp. 227–248), Human Factors Society, Santa Monica, CA, 1990.

Meshkati, N., P.A. Hancock, and M. Rahimi, "Techniques in Mental Workload Assessment," In J.R. Wilson and E.N. Corlett, eds., *Evaluation of Human Work: A Practical Ergonomics Methodology* (pp. 605–627), Taylor & Francis, London, 1990.

Moray, N., ed., *Mental Workload: Theory and Measurement*, Plenum Press, New York, 1979.

Moray, N., "Monitoring Behavior and Supervisory Control," In K.R. Boff, L. Kaufman, and J.P. Thomas, eds., *Handbook of Perception and Performance: Vol. II, Cognitive Processes and Performance*, Wiley, New York, 1986.

Moray, N., "Subjective Mental Workload," *Human Factors*, 24: 25–40 (1982).

Moray, N., "The Role of Attention in the Detection of Errors and the Diagnosis of Failures in Man-Machine Systems," In J. Rasmussen and W.B. Rouse, eds., *Human Detection and Diagnosis of System Failures*, Plenum Press, New York, 1981.

Norman, D.A., "The 'Problem' with Automation: Inappropriate Feedback and Interaction, Not 'Overautomation'," *Philosophical Transactions of the Royal Society of London, Series B: Biological Sciences*, 327: 585–593 (1990).

Reid, G.B., C.A. Shingledecker, and F.T. Eggemeier, "Application of Conjoint Measurement to Workload Scale Development," *Proceedings of the Human Factors Society 25th Annual Meeting*, (pp. 522–526), Human Factors Society, Santa Monica, CA (1981).

Wickens, C., and C. Kessel, "Failure Detection in Dynamic Systems," In J. Rasmussen and W.B. Rouse, eds., *Human Detection and Diagnosis of System Failures*, Plenum Press, New York, 1981.

Wickens, C., and C. Kessel, "The Effects of Participatory Mode and Task Workloads on the Detection of Dynamic Systems Failures," *IEEE Transactions on Systems, Man, and Cybernetics*, 9: 24–34 (1979).

5.1.3 Procedures

Brusaw, C.T., G.J. Alred, and W.E. Oliu, *Handbook of Technical Writing*, Martin's Press, New York, 1987).

Dixon, P., "Actions and Procedural Directions," *Coherence and Grounding in Discourse*, (pp. 70–89), John Benjamins, Philadelphis, 1987.

Hartley, J., and D.H. Jonassen, "The Role of Headings in Printed and Electronic Text, " In D.H. Jonassen, ed., *The Technology of Text: Volume Two*," (pp. 237–263), Educational Technology Publications, 1985.

Mackh, G.E., and L.J. Rew, "Using Access Aids to Boost Information Retrieval," *Technical Communication*, 38: 210–219, 1991.

Swezey, R.W., "Design of Job Aids and Procedure Writing," In G. Salvendy, ed., *Handbook of Human Factors* (Ch. 8.6), Wiley, New York, 1987.

U.S. Nuclear Regulatory Commission, "Guidelines for the Preparation of Emergency Operating Procedures," NUREG-0899, August 1982.

Wieringa, D., C. Moore, and V. Barnes, *Procedure Writing: Principles and Practices*, Battelle, Columbus, OH, 1993.

Zimmerman, C.M., and J.J. Campbell, *Fundamentals of Procedure Writing* (2nd ed.), GP Publishing, Columbia, MD, 1988.

5.1.3.1 Documentation

Adams, K.A., and I.M. Halasz, "25 Ways to Improve your Software User Manuals," Technology Training Systems, Worthington, OH, 1983.

Callan, J.R., J.W. Gwynne, D. Sawyer, and M.T. Tolbert, *Principles of Medical Device Labeling*, NTIS PB 94–126851, Pacific Science & Engineering Group, Inc., San Diego, 1993.

Carroll, J.M., P.L. Smith-Kerker, J.R. Ford, and S.A. Mazur-Rimetz, "The Minimal Manual," *Human-Computer Interaction*, 3: 123–153 (1987–1988).

Coke, E. U., "Reading rate, Readability, and Variations in Task-Induced Processing," *Journal of Educational Psychology*, 68:167-173 (1976).

Coleman, E.B., "Imptoving Comprehensibility by Shortening Sentences," *Journal of Applied Psychology*, 46: 131–134 (1962).

U.S. Department of Defense, "Manuals, Technical: General Style and Format Requirements," MIL-M-38784B, Washington, D.C. , April 16, 1983.

Dillon, A., *Designing Usable Electronic Text: Ergonomic Aspects of Human Information Usage*, Taylor & Francis, London, 1994.

Duffy, T.M. and R. Waller, eds., *Designing Usable Texts*, Academic Press, New York, 1985.

Fleming, M.I., "Perceptual Principles for the Design of Instructional Materials," *Viewpoints*, 46 (1970).

Gong, R., and J. Elkerton, "Designing Minimal Documentation Using a GOMS Model: A Usability Evaluation of an Engineering Approach," In Proceedings *of CHI '90: Human Factors in Computing Systems* (pp. 99–106), Association for Computing Machinery, New York (1990).

Hartley, J., ed., *The Psychology of Written Communication*, Kogan Page, London, 1980.

Hartley, J., "Is This Chapter Any Use? Methods for Evaluating Text," In J.R. Wilson and E.N. Corlett, eds., *Evaluation of Human Work: A Practical Ergonomics Methodology* (pp. 248–270), Taylor & Francis, London, 1990.

Hartley, J., *Designing Instructional Text*, Kogan Page, London, 1978.

Hartley, J., S. Fraser, and P. Burnhill, "A Selected Bibliography of Typographical Research Relevant to the Production of Instructional Materials," *Audio Visual Communication Review.*, 22:181-190 (1974).

Monteith, M.K., "How Well Does the Average American Read? Some Facts, Figures, and Opinions," *Journal of Reading*, ERIC/RCS, 460-464 (February, 1980).

Payne, D.E., "Readability of Typewritten Material: Proportional versus Standard Spacing," *Journal of Typographic Research*, 1:125 (1967).

Poulton, E.C., "A Note on Printing to Make Comprehension Easier," *Ergonomics*, 3: 245–248 (1960).

Poulton, E.C., "Size, Style, and Vertical Spacing in the Legibility of Small Typefaces," Journal of Applied Psychology, 56: 156–161 (1972).

Ralph, J.B., "A Geriatric Visual Concern: The Need for Publishing Guidelines," *Journal of the American Optometric Association*, 53:43-50 (1982).

Robinson, D.O., M. Abbamonte, and S.H. Evans, "Why Serifs are Important: The Perception of Small Print," *Visible Language*, 5: 353–359 (1971).

Sheppard, S.B., "Documentation for Software Systems," In G. Salvendy, ed., *Handbook of Human Factors* (Ch. 11.7), Wiley, New York, 1987.

Simpson, H., and S.M. Casey, *Developing Effective User Documentation: A Human Factors Approach*, McGraw-Hill, New York, 1988.

Twyman, M., "Using Pictorial Language: A Discussion of the Dimensions of the Problem." In T.M. Duffy and R.Waller, eds., *Designing Usable Texts*, 245-312, Academic Press, New York, 1985.

U. S. Department of Health and Human Services, Public Health Service, National Institutes of Health, Pretesting in health communications: Methods, examples, and resources for improving health messages and materials, NIH Publication No. 84-1493. Appendix C, pp. 46-47 (1984).

Weiss, E.H., *How To Write a Usable User Manual*, ISI Press, Philadelphia, 1985.

Wiggins, R.H., "Effects of Three Typographical Variables on Speed of Reading," *Journal of Typographic Research*. 1:5-18 (1967)

Wright, P., "Issues of Content and Presentation in Document Design," In M. Helander, ed., *Handbook of Human-Computer Interaction* (pp. 629–652), North Holland, Amsterdam, 1988.

5.1.3.2 Job Performance Aids

Berry, E., "How to Get Users to Follow Procedures," *IEEE Transactions on Professional Communications*, 25: 22–25 (1982).

Blaiwes, A.S., "Formats for Presenting Procedural Instructions," *Journal of Applied Psychology*, 59: 683–686, 1974.

Geis, G.L., "Checklisting," *Journal of Instructional Development*, 7: 2–9 (1984).

Swezey, R.W., "Design of Job Aids and Procedure Writing," In G. Salvendy, ed., *Handbook of Human Factors* (Ch. 8.6), Wiley, New York, 1987.

Swezy, R.W., and R.B. Pearlstein, "Performance Aids—Key to faster learning?," *Training: The Magazine of Manpower and Management Development*, 8: 30–33 (1974).

Color Coding

Carter, E.C., and R.C. Carter, "Color and Conspicuousness," *Journal of the Optical Society of America*, 71: 723–729 (1981).

Christ, R.E., "Review and Analysis of Color Coding Research for Visual Displays," *Human Factors*, 17: 542–570 (1975).

Green, B.F., and L.K. Anderson, "Color Coding in a Visual Search Task," *Journal of Experimental Psychology*, 51: 19–24 (1956).

Judd, D.B., and G. Wyszecki, *Color in Business, Science, and Industry*, Wiley, New York, 1975.

Smith, S.L., "Color Coding and Visual Search," *Journal of Experimental Psychology*, 64: 434–440 (1962).

Wagner, D.W., "Color Coding—An Annotated Bibliography," (NWC-TP-5922), China Lake, CA: Naval Weapons Center (March 1977) (DTIC No. ADA041061).

5.1.4 Training and Organization

Duncan, K.D., "Training for Fault Diagnosis in Industrial Process Plants," In J. Rasmussen and W.B. Rouse, eds., *Human Detection and Diagnosis of System Failures*, Plenum Press, New York, 1981.

Fleishman, E.A., and M.D. Mountford, "Individual Attributes and Training Performance," In I.L. Goldstein, et al., eds., *Training and Development in Organizations*, Jossey-Bass, San Francisco, CA, 1989.

Gagne, R.M., L.J. Briggs, and W.W. Wager, *Principles of Instructional System Design* (3rd ed.), Holt, Rinehart, and Winston, Fort Worth, TX, 1988.

Glaser, R., and M. Bassok, "Learning Theory and the Study of Instruction," *Annual Review of Psychology*, 40, 631–666 (1989).

Goldstein, I.L., "The Relationship of Training Goals and Training Systems," In G. Salvendy, ed., *Handbook of Human Factors* (Ch. 8.3), Wiley, New York, 1987.

Hendrick, H.W., "Wagging the Tail with the Dog: Organizational Design Considerations in Ergonomics," *Proceedings of the Human Factors Society 28th Annual Meeting*, Human Factors Society, Santa Monica, CA (1984).

Hendrick, H.W., and O. Brown, Jr., eds., *Human Factors in Organizational Design and Management*, North-Holland, Amsterdam, 1984.

Holding, D.H., "Concepts of Training," In G. Salvendy, ed., *Handbook of Human Factors* (Ch. 8.2), Wiley, New York, 1987.

Kaufman, R.A., R.E. Corrigan, and C.L. Nunnelly, "The Instructional System Approach to Training," *Human Factors*, 8: 157–162 (1966).

Phillips, J.J., *Handbook of Training Evaluation and Measurements Methods*, University Associates, San Diego, CA, 1983.

Robbins, S.R., *Organizational Theory: The Structure and Design of Organizations*, Prentice-Hall, Englewood Cliffs, NJ, 1983.

Schneider, W., "Training High-Performance Skills: Fallacies and Guidelines, In M. Venturino, ed., *Selected Readings in Human Factors* (pp. 297–312), Human Factors Society, Santa Monica, CA, 1990.

Wrightman, D.C., and G. Lintern, "Part-Task Training for Tracking and Manual Control," In M. Venturino, ed., *Selected Readings in Human Factors* (pp. 313–329), Human Factors Society, Santa Monica, CA, 1990.

5.2 Brachytherapy

5.2.1 General Background

Gerber, R.L., "Manpower Requirements in Training and Certification of Technologists and Dosimetrists," *International Journal of Radiation Oncology, Biology, Physics*, 10, Sup. 1: 127–130 (1984).

Glasgow, G.P., and C.A. Perez, "Physics of Brachytherapy," In C.A. Perez and L.W. Brady, eds., *Principles and Practice of Radiation Oncology*, Chap. 10, Lippincott, Philadelphia, 1987.

Godden, T.J., "Physical Aspects of Brachytherapy," *Medical Physics Handbook 19*, Adam Hilger, Bristol, England, 1988.

Goffinet, D.R., R.S. Cox, D.H. Clarke, K.K. Fu, B. Hilaris, and C.C. Ling, "Brachytherapy," American *Journal of Clinical Oncology*, 11: 342–354 (1988).

Hilaris, B.S., D. Nori, and L.L. Anderson, "New Approaches to Brachytherapy," *Important Advances in Oncology* (pp. 237–261) (1987a).

Hilaris, B.S., D. Nori, and L.L. Anderson, *An Atlas of Brachytherapy*, Macmillan, New York, 1988.

Interstitial Collaborative Working Group, *Interstitial Brachytherapy: Physical, Biological, and Clinical Considerations*, Raven Press, New York, 1990.

Martinez, A.A., C.G. Orton, and R.F. Mould, eds., *Brachytherapy: HDR and LDR*, Nucletron Corporation, Columbia, MD, 1990.

Nath, R., and J. Meli, "Brachytherapy," In J.G. Webster, ed., *Encyclopedia of Medical Devices and Instrumentation*, Vol. 1, pp. 525–535, Wiley, New York, 1988.

Orton, C.G. "High and Low Dose Rate Remote Afterloading: A Critical Comparison," In R. Sauer, ed., *Interventional Radiation Therapy: Techniques-Brachytherapy*, Springer-Verlag, Berlin, 1991.

Orton, C.G., "HDR: Forget Not "Time" and "Distance"," *International Journal of Radiation Oncology, Biology, Physics*, 20: 1131–1132 (1991).

Paine, C.H., and D.V. Ash, "Interstitial Brachytherapy: Past-Present-Future," *International Journal of Radiation Oncology, Biology, Physics*, 21: 1479–1483 (1991).

Pierquin, B., J.F. Wilson, and D. Chassagne, *Modern Brachytherapy*, Masson Publishing, New York, 1987.

Radiation Oncology in Integrated Cancer Management. Report of the Inter-Society Council for Radiation Oncology (November 1991), Blue Book.

Rotte, K., and J Kiffer, eds., *Changes in Brachytherapy*, Wachholz, Nurnberg, 1989.

Sauer, R., *Interventional Radiation Therapy*, Springer-Verlag, Berlin, 1991.

Speiser, B., "Advantages of High Dose Rate Remote Afterloading Systems: Physics or Biology," *International Journal of Radiation Oncology, Biology, Physics*, 20: 1133–1135 (1991).

Trott, N.G., ed., *Radionuclides in Brachytherapy: Radium and After*, British Institute of Radiology, Sup. 21, London, 1987.

U.S. Nuclear Regulatory Commission, "Medical Use of Byproduct Material (10 CFR Part 35, Subpart A, Section 35.2)," Code of Federal Regulations, January 1, 1994.

U.S. Nuclear Regulatory Commission, "Specific Domestic Licenses of Broad Scope for Byproduct Material," Federal Register (10 CFR Part 33), 436-441, Washington, D.C., January 1, 1991.

5.2.2 Problems and Errors

Blanco, S., M.A. Lopez-Bote, and M. Desco, "Quality Assurance in Radiation Therapy: Systematic Evaluation of Errors During the Treatment Execution," *Radiotherapy and Oncology*, 8: 253–261 (1987).

Karzmark, C.J., "Procedural and Operator Error Aspects of Radiation Accidents in Radiotherapy," *International Journal of Radiation Oncology, Biology, Physics*, 13: 1599–1602 (1987).

Muller-Runkel, R., and S.S. Watkins, "Introducing a Computerized Record and Verify System: Its Impact on the Reduction of Treatment Errors," *Medical Dosimetry*, 16: 19–22 (1991).

Serig, D., "Human Factors and the Medical Use of Nuclear Byproduct Material," Proceedings of the Human Factors Society 33rd Annual Meeting (pp. 1014-1018), Human Factors Society, Santa Monica, CA, 1989.

Serig, D.I., "Radiopharmaceutical Misadministrations: What's Wrong?," In M.S. Bogner, ed., *Human Error in Medicine* (Ch. 10), Erlbaum, Hillsdale, NJ, 1994.

Thomadsen, B., S. Shahabi, D. Buchler, M. Mchla, and B. Paliwal, "Anatomy of Two High Dose-Rate Misadministrations," *Medical Physics*, 18: 645 (1991).

U.S. Food and Drug Administration, "Medical Device Problem Reporting Program, Final Rule," 21 CFR Part 803, FDA Center for Devices and Radiological Health, December 13, 1984.

U.S. Food and Drug Administration, "Medical Devices Bulletin," FDA Center for Devices and Radiological Health, August 1989–June 1991.

U.S. Food and Drug Administration, "Radiological Health Bulletin," FDA Center for Devices and Radiological Health, August 1989–June 1991.

—, NUREG-0090, "Report to Congress on Abnormal Occurrences," Vols. 1–15, 1978–1992.

—, NUREG-1272, "Analysis and Evaluation of Operational Data, Annual Report, Nonreactors" 1981–1992.

—, NUREG/CR-6125, Vol. 1, "Human Factors Evaluation of Remote Afterloading Brachytherapy: Human Error and Critical Tasks in Remote Afterloading Brachytherapy and Approaches for Improved System Performance," February 1995.

—, NUREG/CR-6125, Vol. 2, "Human Factors Evaluation of Remote Afterloading Brachytherapy: Function and Task Analysis," February 1995.

—, NUREG/CR-6125, "Human Factors Evaluation of Remote Afterloading Brachytherapy: Vol. 3, Section A: Human-System Interfaces in Remote Afterloading Brachytherapy; Section B: Procedures and Practices in Remote Afterloading Brachytherapy; Section C: Training and Organizational Policies and Practices in Remote Afterloading Brachytherapy," February, 1995.

5.2.3 Treatment Planning

Amlos, H.I., and M. Martel, "Determination of the Relative Angle Between Orthogonal Film for Radioactive Implants," *Medical Physics*, 15: 773–775 (1988).

Anderson, L.L., "Physical Optimization of Afterloading Techniques," *Strahlentherapie*, 161: 264–269 (1985).

Burgers, J.M.V., H.K. Awwad, and R. van der Laarse, "Discrepancies in Dose and Dose Specification in Interstitial Implants," *Radiotherapy and Oncology*, 11: 327–336 (1988).

Chow, H., R.G. Lane, and I.I. Rosen, "Uncertainty in Dose Estimation for Gynecological Implants," *International Journal of Radiation Oncology, Biology, Physics*, 19: 1555–1559 (1990).

Coltart, R.S., A.B. Nethersell, S. Thomas, and A.K. Dixon, "A CT Based Dosimetry System for Intracavitary Therapy in Carcinoma of the Cervix," *Radiotherapy and Oncology*, 10: 295–305 (1987).

Cunningham, J.R., "Quality Assurance in Dosimetry and Treatment Planning," *International Journal of Radiation Oncology, Biology, Physics*, 10, Sup. 1: 105–109 (1984).

Dutreix, A., "Can We Compare Systems for Interstitial Therapy?," *Radiotherapy and Oncology*, 13: 127–135 (1988).

Hanna, S.L., M.A. Lemmi, J.W. Langston, J. Fontanesi, H.L. Brooks, Jr., and S. Gronemeyer, "Treatment of Choroidal Melanoma: MR Imaging in the Assessment of Radioactive Plaque Position," *Radiology*, 176: 851–853 (1990).

Hilaris, B.S., D. Nori, and L.L. Anderson, "Brachytherapy Treatment Planning," *Frontiers in Radiation Therapy and Oncology*, 21: 94–106 (1987b).

Hoetzinger, H., and G. Ries, "New Possibilities for Individualization of HDR-Afterloading of Endometrial Cancer," *Proceedings of the Second International High Dose Rate Remote Afterloading Symposium*, 107–114 (1987).

Houdek, P.V., J.G. Schwade, A.J. Medina, C.A. Poole, K.R. Olsen, D.H. Nicholson, S. Byrne, R. Quencer;, R.S. Hinks, and V. Pisciotta, "MR Technique for Localization and Verification Procedures in Episcleral Brachytherapy," *International Journal of Radiation Oncology, Biology, Physics*, 17: 1111–1114 (1989).

Krishnan, L., E.P. Cytacki, C.D. Wolf, E.K. Reddy, L.S. Gemer, P.G.S. Giri, S.R. Smalley, and R.G. Evans, "Dosimetric Analysis in Brachytherapy of Carcinoma of the Cervix," *International Journal of Radiation Oncology, Biology, Physics*, 18: 965–970 (1990).

LaVigne, M.L., S.L. Schoeppel, and D.L. McShan, "The Use of CT-Based 3-D Anatomical Modeling in the Design of Customized Perineal Templates for Interstitial Gynecologic Implants," *Medical Dosimetry*, 16: 187–192 (1991).

Ling, C.C., D.Y. Huang, C. Barnett, D. Goffinet, M. Mariscal, L.W.B. Roberts, K.K. Fu, and T. Phillips, "Improved Dose Distribution with Customized I-125 Source Loading in Temporary Interstitial Implants," *International Journal of Radiation Oncology, Biology, Physics*, 15: 769–774 (1988).

Meertens, H., "A Comparison of Dose Calculations at Points Around an Intracavitary Cervix Applicator," *Radiotherapy and Oncology*, 15: 199–206 (1989).

Meigooni, A.S., J.A. Meli, and R. Nath, "Influence of the Variation of Energy Spectra with Depth in the Dosimetry of ^{192}Ir Using LiF TLD," *Physics in Medicine and Biology*, 33: 1159–1170 (1988).

Niroomand-Rad, A., B.R. Thomadsen, and P. Vainio, "Evaluation of the Reconstruction of Brachytherapy Implants in Three-Dimensions from Stereo Radiographs," *Radiotherapy and Oncology*, 8: 337–342 (1987).

Paul, J.M., R.F. Koch, and P.C. Philip, "Uniform Analysis of Dose Distribution in Interstitial Brachytherapy Dosimetry Systems," *Radiotherapy and Oncology*, 13: 105–125 (1988).

Plott, G., "Radiation Treatment Planning for GammaMed Using GammaDot," *Proceedings of the Fifth International High Dose Rate Remote Afterloading Symposium*, 9–16 (1990).

Potish, R.A., and B.J. Gerbi, "Cervical Cancer: Intracavitary Dose Specification and Prescription," Radiology, 165: 555–560 (1987).

Purdy, J.A., "Dosimetry and Treatment Planning," *International Journal of Radiation Oncology, Biology, Physics*, 10, Sup. 1: 139–141 (1984).

Rasovská, O., O. Ott, V. Strnad, and T. Tacev, "Calculation of Radiation Doses in Critical Organs Compared with in vivo Dosimetry During Brachytherapy of Carcinoma of the Uterine Cervix," *Neoplasma*, 37: 205–211 (1990).

Rosenow, U.F., "Tumor Localization and Dose Standardization in High Dose Rate Remote Afterloading," *Proceedings of the Second Annual International High Dose Rate Remote Afterloading Symposium*, 165–167 (May 1987).

Roy, J.N., K.E. Wallner, S-T Chiu-Tsao, L.L. Anderson, and C.C. Ling, "CT-Based Optimized Planning for Transperineal Prostate Implant with Customized Template," *International Journal of Radiation Oncology, Biology, Physics*, 21: 483–489 (1991).

Sherouse, G.W., J. Rosenman, H.L. McMurry, S.M. Pizer, and E.L. Chaney, "Automatic Digital Contrast Enhancement of Radiotherapy Films," *International Journal of Radiation Oncology, Biology, Physics*, 13: 801–806 (1987).

Sherouse, G.W., J.L. Naves, M.A. Varia, and J. Rosenman, "A Spreadsheet Program for Brachytherapy Planning," *International Journal of Radiation Oncology, Biology, Physics*, 13: 639–646 (1987).

Siwek, R.A., P.F. O'Brien, and P.M.K. Leung, "Shielding Effects of Selectron Applicator and Pellets on Isodose Distributions," *Radiotherapy and Oncology*, 20: 132–138 (1991).

Suit, H., and W. du Bois, "The Importance of Optimal Treatment Planning in Radiation Therapy," *International Journal of Radiation Oncology, Biology, Physics*, 21: 1471–1478 (1991).

Ten Haken, R.K., R.F. Diaz, D.L. McShan, B.A. Fraass, J.A. Taren, and T.W. Hood, "From Manual to 3-D Computerized Treatment Planning for 125-I Stereotactic Brain Implants," *International Journal of Radiation Oncology, Biology, Physics*, 15: 467–480 (1988).

Tolbert, D.D., and S.A. Reed, "An Examination of the Consistency and Accuracy of Computerized Brachytherapy Dose Predictions," *International Journal of Radiation Oncology, Biology, Physics*, 7: 675–682 (1981).

Visser, A.G., "An Intercomparison of the Accuracy of Computer Planning Systems for Brachytherapy," *Radiotherapy and Oncology*, 15: 245–258 (1989).

Wallner, K., S.T. Chiu-Tsao, J. Roy, M. Rosenstein, H. Smith, and Z. Fuks, "A New Device to Stabilize Templates for Transperineal I-125 Implants," *International Journal of Radiation Oncology, Biology, Physics*, 20: 1075–1077 (1991).

Williams, D.F., W.F. Mieler, M. Lewandowski, and M. Greenberg, "Echographic Verification of Radioactive Plaque Position in the Treatment of Melanomas, *Archives of Ophthalmology*, 106: 1623–1624 (1988).

5.2.4 Treatment Delivery

Ashby, M.A., J.A. Pacella, R. de Groot and J. Ainslie, "Use of a Radon Mould Technique for Skin Cancer: Results from the Peter MacCallum Cancer Institute (1975–1984)," *The British Journal of Radiology*, 62: 608–612 (1989).

Denham, J.W., A.C. Baldacchino, J. Gutte, and R.L. Nicholls, "Remote Afterloading Techniques for the Treatment of Nasophyaryngeal and Endometrial Cancer," *International Journal of Radiation Oncology, Biology, Physics*, 14: 191–195 (1988).

Jordan, L.N., and R.V.P. Mantravadi, "Nursing Care of the Patient Receiving High Dose Rate Brachytherapy," *Oncology Nursing Forum*, 18: 1167–1171 (1991).

Joslin, C.A.F., "High-Activity Source Afterloading in Gynecologic Cancer and its Future Prospects," *Endocurie, Hyperthermia, Oncology*, 5: 69–81 (1989).

Krell, W.S., "An Overview of Endobronchial Brachytherapy," *Activity: Selectron Brachytherapy Journal*, Sup. 1: 33–37 (1990).

Maddock, P.G., "Brachytherapy Sources and Applicators," *Seminars in Oncology Nursing*, 3: 15–22 (1987).

Meertens, H., H. Bartelink, and T. Minderhoud, "First Clinical Experience with a Remote Afterloading System for Low Dose Rate Interstitial Breast Implants," *Radiotherapy and Oncology*, 11: 387–393 (1988).

Mount, A.M., "Endobronchial Brachytherapy Applicators," *Activity: Selectron Brachytherapy Journal*, Sup. 1: 40–44 (1990).

Nettles, B., "Nursing Considerations in the Use of Gamma Med," *Proceedings of the First International Meeting of GammaMed Users*, 55–58 (1986).

Orton, C.G., "Remote Afterloading for Cervix Cancer: The Physicist's Point of View," *Activity: Selectron Brachytherapy Journal*, Sup. 2: 53–55 (1991).

Perez, C.A., and G.P. Glasgow, "Clinical Applications of Brachytherapy," In C.A. Perez and L.W. Brady, eds., *Principles and Practice of Radiation Oncology*, Lippincott, Philadelphia, 1987.

Porter, A.T., J.W. Scrimger, and J.S. Pocha, "Remote Interstitial Afterloading in Cancer of the Prostate: Preliminary Experience with the Micro Selectron," *International Journal of Radiation Oncology, Biology, Physics*, 14: 571–575 (1988).

Roach, M. III, E.M. Leidholdt Jr., B.S. Tatera, and J. Joseph, "Endobronchial Radiation Therapy (EBRT) in the Management of Lung Cancer," *International Journal of Radiation Oncology, Biology, Physics*, 18: 1449–1454 (1990).

Roman, T.N., L. Souhami, C.R. Freeman, C. Pla, M.D.C. Evans, E.B. Podgorsak, and K. Mendelew, "High Dose Rate Afterloading Intracavitary Therapy in Carcinoma of the Cervix," *International Journal of Radiation Oncology, Biology, Physics*, 20: 921–926 (1991).

Shiu, M.H., B.S. Hilaris, L.B. Harrison, and M.F. Brennan, "Brachytherapy and Function-Saving Resection of Soft Tissue Sarcoma Arising in the Limb," *International Journal of Radiation Oncology, Biology, Physics*, 21: 1485–1492 (1991).

Sipila, P., and A. Kauppila, "Intracavitary Irradiation of Endometrial Carcinoma Using a High-Intensity ^{60}Co Afterloading Method," *Acta Oncologica*, 28: 601–605 (1989).

Streeter, O.E., A.L. Goldson, C. Chevallier, and J. Rao Nibhanupudy, "High Dose Rate ^{60}Co Remote Afterloading Irradiation in Cancer of the Cervix in Haiti, 1977–1984," *International Journal of Radiation Oncology, Biology, Physics*, 14: 1159–1163 (1988).

Utley, J.F., C.F. von Essen, R.A. Horn, and J.H. Moeller, "High-Dose-Rate Afterloading Brachytherapy in Carcinoma of the Uterine Cervix," *International Journal of Radiation Oncology, Biology, Physics*, 10: 2259–2263 (1984).

Yamashita, H., "Problems and Results of Remote Controlled Afterloading Therapy with High Dose Rate 252-Cf in Uterine Cancer," *Sonderbande zur Strahlentherapie und Onkologie*, 82: 180–186 (1988).

5.2.5 Quality Assurance and Maintenance

5.2.5.1 General Background

Baltas, D., "Quality Assurance in HDR Brachytherapy," *Activity: Selectron Brachytherapy Journal*, 5: 149–153 (1991).

Chaffey, J.T., "Quality Assurance in Radiation Therapy: Clinical Considerations," *International Journal of Radiation Oncology, Biology, Physics*, 10, Sup. 1: 15–17 (1984).

Clarkson, D.G., "Leakage from a Cesium-137 Needle," *The British Journal of Radiology*, 62: 94 (1989).

Earley, L., J. Prows, and D.D. Leavitt, "Documentation of Ovoid Cap Size," *Medical Dosimetry*, 16: 255–260 (1991).

Goldson, A.L., and J.R. Nibhanupudy, "Guidelines for Comprehensive Quality Assurance in Brachytherapy," *International Journal of Radiation Oncology, Biology, Physics*, 10 (Sup. 1): 111–114 (1984).

Hanks, G.E., "Quality Assurance in Radiation Oncology in the United States 1988," *Cancer*, 54: 223–225 (1989).

Heilman, R.S., "Radiology Quality Assurance: Is There a Silver Lining?," *American Journal of Roentgenology*, 151: 1054 (1988).

Horiot, J.C., K.A. Johansson, D.G. Gonzalez, E. van der Schueren, W. van den Bogaret, and G. Notter, "Quality Assurance Control in the EORTC Cooperative Group of Radiotherapy. 1. Assessment of Radiotherapy Staff and Equipment," *Radiotherapy and Oncology*, 6: 275–284 (1986).

Human Resource Task Force of the Technologist Section, The Society of Nuclear Medicine, "Human Resources Survey of Nuclear Medicine Technologists—1984," *Journal of Nuclear Medicine Technology*, 13 (September, 1985).

Keefer, B.S., "Closing in on Brachytherapy Regulations," *R.T. Image*, Vol. 4, No. 43, p. 1, 4–6, October 28, 1991.

Kramer, S., G.E. Hanks, and J.J. Diamond, "Summary Results from the Fourth Facilities Master List Survey Conducted by the Patterns of Care Study," *International Journal of Radiation Oncology, Biology, Physics*, 9: 1881–1883 (1983).

Laughlin, J.S, "Development of Quality Assurance in Radiation Therapy in North America," *International Journal of Radiation Oncology, Biology, Physics*, 10, Sup. 1: 9–13 (1984).

Nelson, T.J., W.J. Spanos, and R.D. Lindberg, "GYN Implant Orthogonal Film Holder," *Medical Dosimetry*, 15: 169–171 (1990).

Perez, C.A., B. Gillespie, T. Pajak, N.B. Hornback, B. Emami, and P. Rubin, "Quality Assurance Problems in Clinical Hyperthermia and their Impact on Therapeutic Outcome: A Report by the Radiation Therapy Oncology Group," *International Journal of Radiation Oncology, Biology, Physics*, 16: 551–558 (1989).

Rossiter, M.J., "The Traceability of Brachytherapy Sources Supplied by Amersham International," *British Journal of Radiology*, 63: 663 (1990).

Slessinger, E., P.W. Grigsby, and J. Williams, "Improvements in Brachytherapy Quality Assurance," *International Journal of Radiation Oncology, Biology, Physics*, 16: 497–500 (1989).

Suntharalingam, N., and K-A Johansson, "Quality Assurance/Physics/Dosimetry," *International Journal of Radiation Oncology, Biology, Physics*, 14: S21–S24 (1988).

Svensson, G.K., "Quality Assurance in Radiation Therapy: Physics Efforts", *International Journal of Radiation Oncology, Biology, Physics*, 10, Sup. 1: 23–29 (1984).

U.S. Nuclear Regulatory Commission, "Quality Management Program and Misadministrations (10 CFR Parts 2, 19, 20, and 35)," *Federal Register*, Vol. 56, No. 143, Washington, D.C., July 25, 1991.

Williamson, J.F., and R. Nath, "Clinical Implementation of AAPM Task Group 32 Recommendations on Brachytherapy Source Strength Specification," *Medical Physics*, 18: 439–448 (1991).

Wu, R.K., N.D. Liu, A.G. Kasenter, W-J Wang, and A.M. El-Mahdi, "Uncertainties Associated with HDR Calibration and the Clinical Significance," *Proceedings of the Fifth International High Dose Rate Remote Afterloading Symposium*, 24–33 (1990).

5.2.5.2 Remote Afterloading

Flynn, A., "Quality Assurance Checks on a MicroSelectron-HDR," *Activity: Selectron Brachytherapy Journal*, 4: 112–115 (1990).

Flynn, A., and G. Workman, "Calibration of a Microselectron HDR Iridium 192 Source," *The British Journal of Radiology*, 64: 734–739 (1991).

Goetsch, S.J., F.H. Attix, D.W. Pearson, and B.R. Thomadsen, "Calibration of ^{192}Ir High-Dose-Rate Afterloading Systems," *Medical Physics*, 18: 462–467 (1991).

Grigsby, P.W., "Quality Assurance for Remote Afterloading Equipment at The Mallinckrodt Institute of Radiology," *Activity: The Selectron User's Newsletter*, 1: 15 (1989).

Kohn, M.L., A.W. Gooch Jr., and A.J. Zajac, "Nucletron MicroSelectron Calibration and Radiation Survey," *International Journal of Radiation Oncology, Biology, Physics*, 21: 1057–1061 (1991).

Last, V., P. Cardew, and P. Hunt, "Practical Consideration in the Use of GammaMed II Remote Afterloading System," *Proceedings of the First International Meeting of GammaMed Users*, 185–198 (1986).

Leung, P.M.K., "Mechanical Damage to Small Spherical ^{137}Cs Sources in a Pneumatically Operated Remote Afterloading Brachytherapy Unit," *Physics in Medicine and Biology*, 28: 185–188 (1983).

Meertens, H., "In-Phantom Calibration of Selectron-LDR Sources," *Radiotherapy and Oncology*, 17: 369–378 (1990).

Slessinger, E.D., "Selectron-LDR Quality Assurance," *Activity: Selectron Brachytherapy Journal*, 4: 36–40 (1990).

Spearman, D., "In-Vivo-Dosimetry: Applications with High Dose Rate Remote Afterloading," *Proceedings of the Third International High Dose Rate Remote Afterloading Symposium*, 91–95 (1988).

5.2.6 Radiation Protection

5.2.6.1 General Background

Committee on the Biological Effects of Ionizing Radiation, *Health Effects of Exposure to Low Levels of Ionizing Radiation. BEIR V*," National Academy Press, Washington, D.C., 1990.

Early, P.J., "Radiation Safety and Handling of Therapeutic Radionuclides," *International Journal of Radiation Applications and Instrumentation, Part B, Nuclear Medicine and Biology*, 14: 263–267 (1987).

Harrison, R.M., "The Role of the Physicist in Radiation Protection in Medical Practice," *Journal of Radiological Protection*, 9: 19–28 (1989).

Huda, W., J. Bews, and A.M. Sourkes, "Occupational Doses in Radiation Oncology in Manitoba—1980 to 1986," *Health Physics*, 57: 521–527 (1989).

Hudson, F.R, "Radiation Protection Surveys in Brachytherapy," *Activity: Selectron Brachytherapy Journal*, 4: 60–64 (1990).

International Commission on Radiological Protection, *1990 Recommendations of the International Commission on Radiological Protection.* ICRP Publication 60, Pergamon, Oxford, 1991.

International Commission on Radiological Protection, *Protection of the Patient in Radiation Therapy*. ICRP Publication 44, Pergamon, Oxford, 1984.

Lajon, R., "Suggested Guidelines for Radiation Protection," *International Journal of Radiation Oncology, Biology, Physics*, 10, Sup. 1: 145–146 (1984).

Morton, R.J., "Radiation Protection," *International Journal of Radiation Oncology, Biology, Physics*, 10, Sup. 1: 115–118 (1984).

National Council on Radiation Protection and Measurements, "*Protection Against Radiation from Brachytherapy Sources*," NCRP Publications, Washington, D.C., 1972.

Smathers, J.B., "Uses of Ionizing Radiation and Medical-Care-Related Problems," *Health Physics*, 55: 165–167 (1988).

5.2.6.2 Staff Exposure

Black, R.E., and K.J. Stehlik, "Reducing Radiation from Brachytherapy Patients with a Cost-Effective Bedshield," *Health Physics*, 56: 939–941 (1989).

Datta, R., and S. Datta, "Nursing Personnel Taking Care of Brachytherapy Patients: To Be or Not To Be Classified as Radiation Workers?," *Health Physics*, 57: 199–201 (1989).

Forsberg, B., P. Spanne, and S. Hertzman, "Radiation Exposure to Personnel in Departments of Gynaecologic Oncology in Sweden," *Acta Oncologica*, 26: 113–123 (1987).

Gifford, D., T.J. Godden, and D. Kear, "An Analysis of Personnel Dose Records which Justifies the Application of Cost-Benefit Techniques in the Design of an Afterloading Facility and the Use of Controlled Areas and Systems of Work Within Suite to Control Occupational Exposure," *The British Journal of Radiology*, 63: 214–218 (1990).

Grigsby, P.W., C.A. Perez, J. Eichling, J. Purdy, and E. Slessinger, "Reduction in Radiation Exposure to Nursing Personnel with the Use of Remote Afterloading Brachytherapy Devices," *International Journal of Radiation Oncology, Biology, Physics*, 20: 627–629 (1991).

Lemly, A.A., J.J. Hedl Jr., and E.E. Griffin, "A Study of Radiation Safety Education Practices in Acute Care Texas Hospitals," *Radiologic Technology*, 58: 323–331 (1987).

Nelson, C.E., "Comment on 'Reducing Radiation from Brachytherapy Patients with a Cost-effective Bedshield'," *Health Physics*, 58: 219–220 (1990).

Papin, P.J., M.J. Ramsey, R.L. LaFontaine, and R.P. LePage, "Effect of Bedside Shielding on Air-Kerma Rates Around Gynecologic Intracavitary Brachytherapy Patients Containing ^{226}Ra or ^{137}Cs," *Health Physics*, 58: 405–410 (1990).

Randall, T.M., D.K. Drake, and W. Sewchand, "Neuro-Oncology Update: Radiation Safety and Nursing Care During Interstitial Brachytherapy," *Journal of Neuroscience Nursing*, 19: 315–320 (1987).

Sewchand, W., R.E. Drzymala, P.P. Amin, M. Salcman, and O.M. Salazar, "Radiation Control in the Intensive Care Unit for High Intensity Iridium-192 Brain Implants," *Neurosurgery*, 20: 584–588 (1987).

van't Riet, A., G.D. Kramer, and L.H. Elders, "Radiation Exposure to Personnel Preparing Iridium-192 Wire Sources," *Activity: Selectron Brachytherapy Journal*, 5: 160–161 (1991).

5.2.7 Radiation Therapy Other Than Brachytherapy

Byhardt, R.W., J.D. Cox, A. Hornburg, and G. Liermann, "Weekly Localization Films and Detection of Field Placement Errors," *International Journal of Radiation Oncology, Biology, Physics*, 4: 881–887 (1978).

Hendrickson, F.R., "The Four P's of Human Error in Treatment Delivery," *International Journal of Radiation Oncology, Biology, Physics*, 4: 913–914 (1978).

Rassow, J., "Quality Control of Radiation Therapy Equipment," *Radiotherapy and Oncology*, 12: 45–55 (1988).

Svensson, G.K., "Quality Assurance in External Beam Radiation Therapy," *Radiographics*, 9: 169–182 (1989).

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11. ABSTRACT *(200 words or less)*

Remote Afterloading Brachytherapy (RAB) is a medical process used in the treatment of cancer. RAB uses a computer-controlled device to remotely insert and remove radioactive sources close to a target (or tumor) in the body. Some RAB problems affecting the radiation dose to the patient have been reported and attributed to human error. To determine the root cause of human error in the RAB system, a human factors team visited 23 RAB treatment sites in the U.S. The team observed RAB treatment planning and delivery, interviewed RAB personnel, and performed walk-throughs, during which staff demonstrated the procedures and practices used in performing RAB tasks. Factors leading to human error in the RAB system were identified. The impact of those factors on the performance of RAB was then evaluated and prioritized in terms of safety significance. Finally, the project identified and evaluated alternative approaches for resolving the safety significant problems related to human error.

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