HUMAN FACTORS EVALUATION OF BRACHYTHERAPY USING REMOTE AFTERLOADERS

Technical and Management Proposal

Best and Final Offer

Prepared in Response to

Solicitation No. RS-RES-90-074

U. S. Nuclear Regulatory Commission

July 9, 1990

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SUMMARY OF CHANGES

This revised proposal constitutes the Best and Final Offer by Pacific Science & Engineering Group to perform work under Solicitation No. RS-RES-90-074. This revised proposal entirely supersedes the original proposal, which was submitted on April 4, 1990. It also responds to the questions posed by the NRC in a letter dated June 13, 1990. A summary of the changes from the original proposal is provided below.

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INTRODUCTION

Pacific Science & Engineering Group (PSE) is pleased to submit this proposal to provide human factors analysis support to the U.S. Nuclear Regulatory Commission (NRC) for evaluation of brachytherapy activities involving the use of automated remote afterloaders.

This proposal has been prepared with great care to ensure that it is responsive in every way to the requirements contained in the solicitation. As requested, this proposal is submitted in three parts: Solicitation Package, Cost Proposal, and Technical and Management Proposal. The Solicitation Package provides the required contractual representations and certifications. The Cost Proposal presents cost and administrative data. The Technical and Management Proposal presents a detailed plan for achieving the objectives specified in the Statement of Work. Organizational experience, personnel qualifications, program management plan, facilities, and required resources are also discussed in the Technical and Management Proposal.

Pacific Science & Engineering Group will be the Prime Contractor and will be responsible for the successful completion of all aspects of this important project. PSE provides a strong group of experienced scientists and human factors engineers who have evaluated numerous high technology human-machine systems. Joining the PSE human factors professionals will be [redacted] All team members were selected after careful study to match their capabilities and specialty areas to the requirements of this project. We believe that an ideal balance of human factors technical background and medical expertise has been achieved for all of the tasks described in the Statement of Work.

Pacific Science & Engineering Group

PSE is a small business providing technical studies and analytic services in human factors engineering, training, human performance measurement, ergonomics, safety and systems analysis. Composed of analysts and researchers with extensive experience in man-machine systems, PSE specializes in the measurement and improvement of human performance. Typical products include human-system interface specifications, training system design guidelines, human factors evaluations of military, industrial, and medical systems, basic and applied research, simulation studies, and task/function analyses.

PSE applies a unique blend of skills and knowledge to a wide variety of system engineering, ergonomic design, and training problems. Our staff is experienced with both the scientific foundations of human performance and with their applications to operational systems. From this background, we offer practical but technically sophisticated solutions to real-world problems. PSE is committed to providing responsive, high quality products that reflect solid scientific principles and the technical state of the art. We offer our clients a multi-disciplinary approach, using proven, project management techniques and technical personnel of the highest qualifications.

PSE has an established track record in applying technical and analytic methodologies to the study of operational characteristics of medical devices, their instructional materials, and their use. Human factors analyses, ergonomic evaluations, and instructional technology assessments were used to construct a comprehensive picture of the factors influencing the safe and effective use of portable blood glucose meters. And in-depth assessments of instructions for contact lens care were coupled to detailed observations of lens wearers in order to isolate and characterize critical factors in contact lens care. PSE is thus strongly and uniquely qualified to make valuable contributions to identifying errors and their likely root causes in remote afterloading brachytherapy systems.

[redacted]

Interpretations and Assumptions

PSE anticipates no major difficulties or problem areas associated with this project that have not been thoroughly examined and incorporated into the Technical Approach presented in this document. PSE likewise takes no exception to the conditions and requirements of the solicitation, and makes no reservations, interpretations, qualifications, limitations, deviations, or exceptions to the Statement of Work presented in the solicitation.

UNDERSTANDING OF THE PROBLEM

Brachytherapy (Greek, *brachy:* short) is a type of radiation treatment of cancer that uses encapsulated radioactive isotopes to irradiate tumors. Sources can be placed within a natural body cavity (intracavitary), implanted directly into a tumor (interstitial), or positioned near the body surface in custom molds. Brachytherapy contrasts with teletherapy (Greek, *tele:* far) where the radiation source is separated by several feet from the patient. Originating shortly after the discovery of radium at the turn of the century, brachytherapy has become a major cancer treatment modality. It has, however, been beset by problems of excessive radiation exposure to medical staff and of suboptimal dose distributions in patients (Goffinet, et al., 1988; Perez & Glasgow, 1987).

As identified by the NRC, this proposal focuses on issues associated with remote afterloading techniques in brachytherapy. The human factors analyses undertaken in this project will systematically identify the errors committed by human operators in these systems, determine their likelihood of occurrence, and examine their severity and consequences. Any error in a brachytherapy system is potentially very serious. The PSE Team will therefore carefully evaluate the potential importance of every error that is identified as a result of our site visits to brachytherapy facilities. This approach to analyzing human error is adopted due to the critical nature of brachytherapy technology. Efforts will also be made to discern any commonalities in the types and patterns of errors that are observed at various medical facilities.

In addition to this valuable quantitative and descriptive information, these comprehensive error analyses will contribute substantially to the objectives of this project as stated in the Request for Proposals:

- Identify factors (i.e., root causes) which contribute to errors in remote afterloading brachytherapy systems
- Evaluate the impact of these factors, both singly and in combination, on the performance of functions and tasks essential to meet system goals
- Prioritize function and task performance problems related to human errors caused by these factors in terms of their safety significance
- Identify and evaluate alternative approaches for resolving safety significant problems related to human errors with the goal of formulating viable, implementable, and cost-effective solutions.

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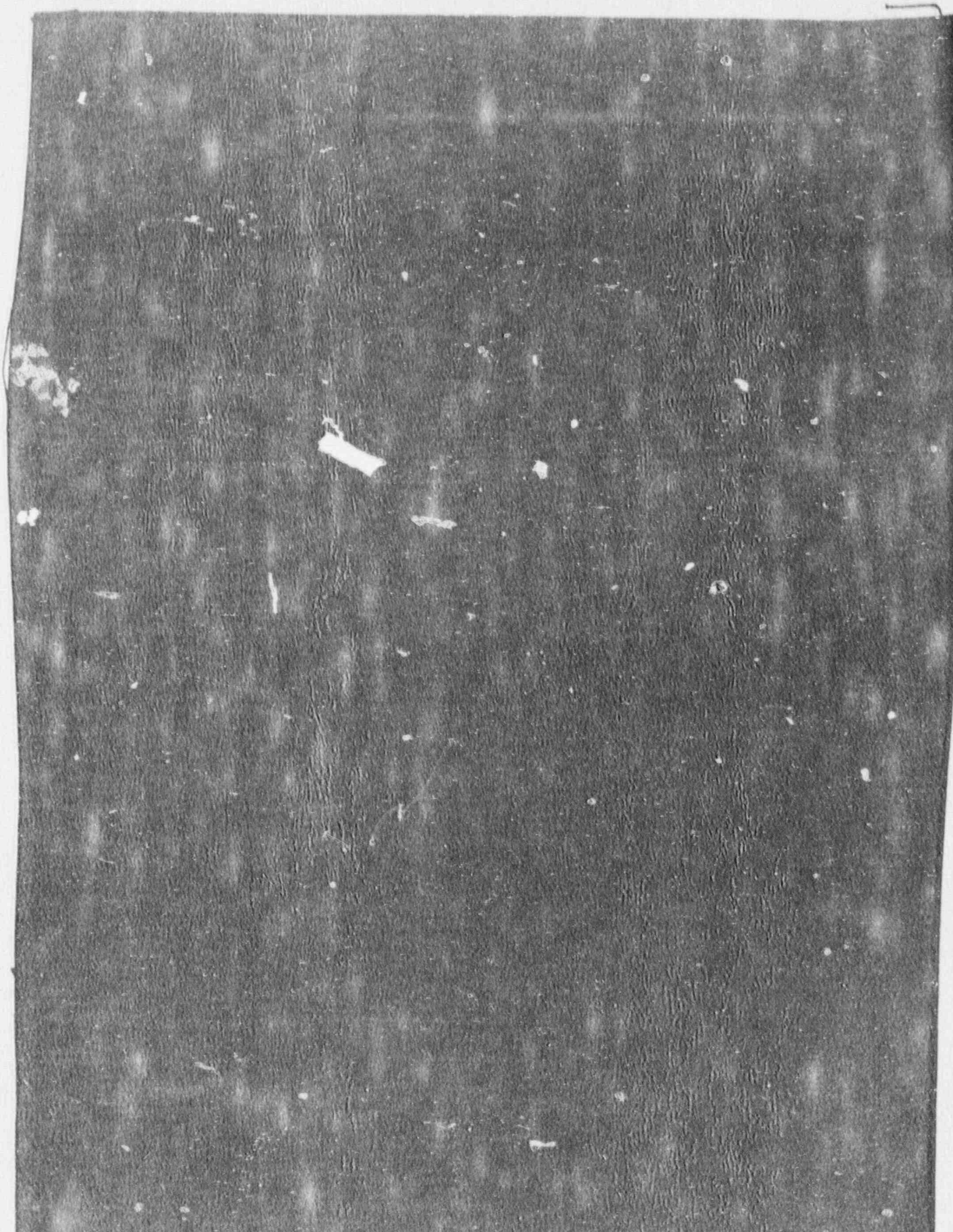

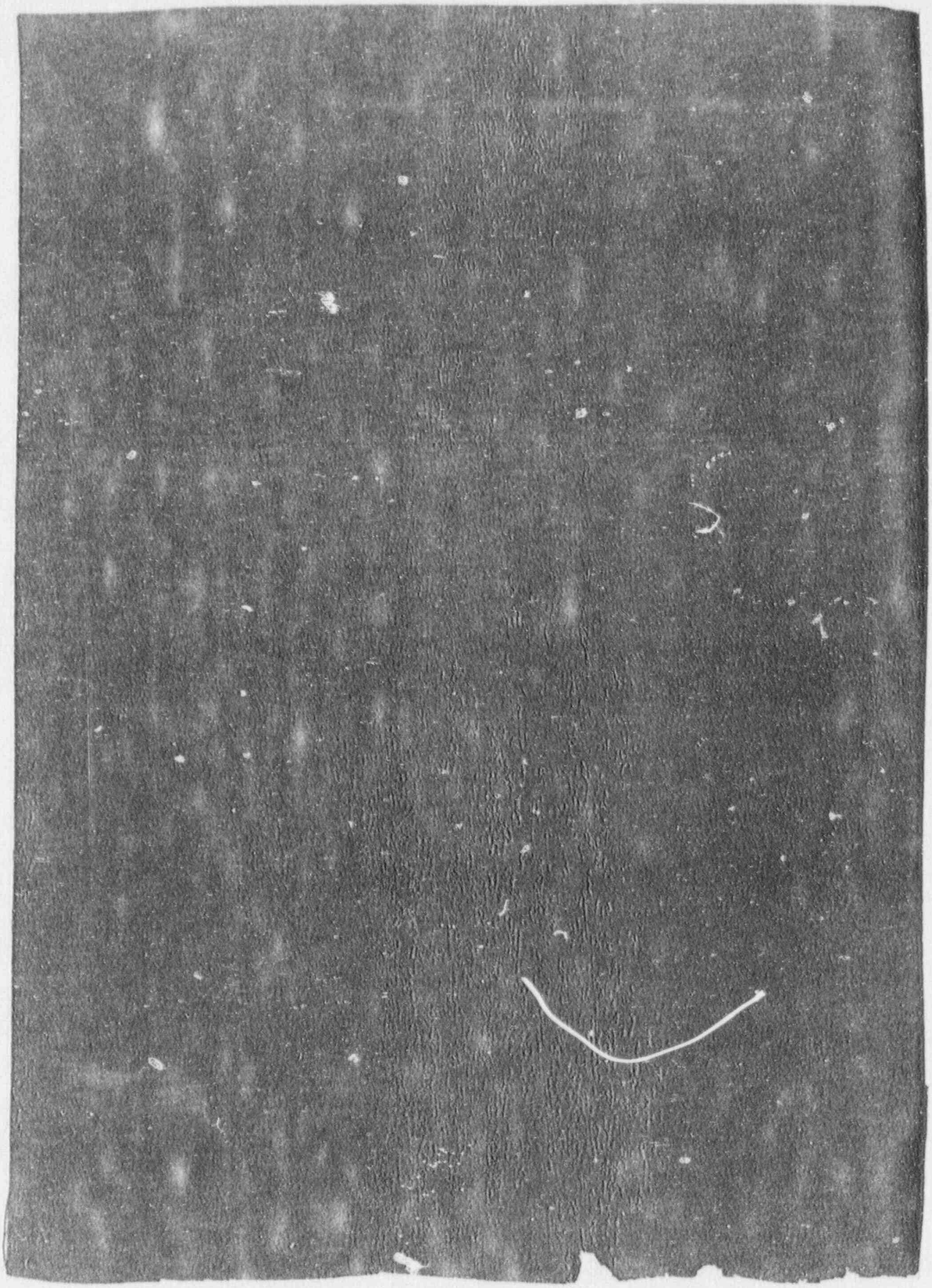

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Summary

The preceding discussion conveys the diversity among remote afterloading units. Sources can be moved mechanically or pneumatically using manual or electrical power. Low dose rate units duplicate conventional treatment regimens, whereas high dose rate systems use high activity radionuclides to shorten treatment times. Some units have single sources, others have multiple sources. Some units allow source configurations to be changed automatically for each application, while other systems are limited to preset source distributions. Some systems have been built to use existing applicators, whereas other systems use their own applicators. Prescribed three-dimensional dose distributions are achieved in several ways. Source trains (combinations of active and inactive pellets) can be held stationary during treatment. Or point-shaped sources can either oscillate or move in a step-wise manner.

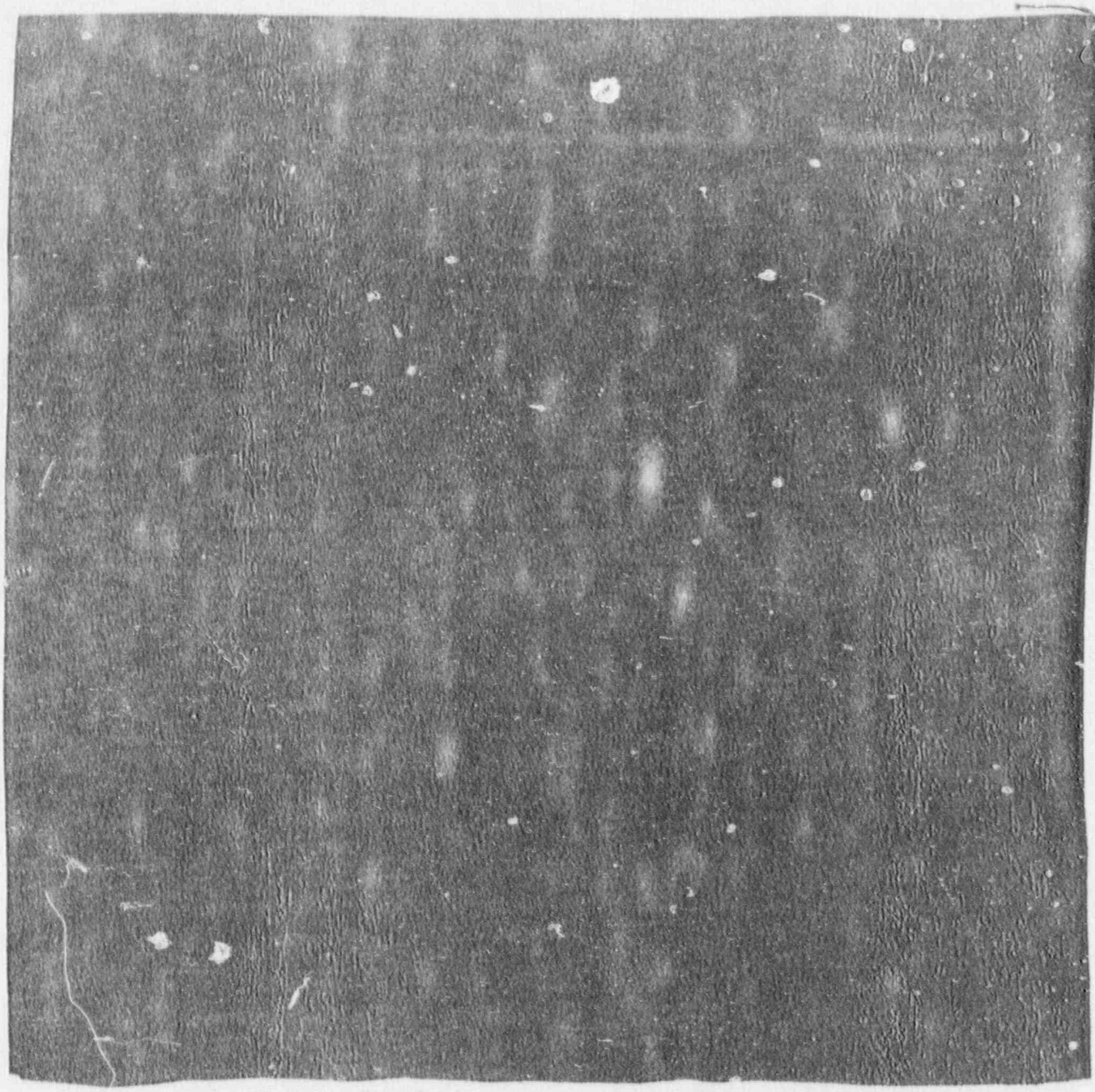
Regardless of the details of their operation, remote afterloading systems are complex and cost of errors is high, both for patients and medical staff. All possible precautions must therefore be taken to assure that these systems function properly. Failure to resolve safety significant problems can lead to excessive staff exposure to ionizing radiation as well as unsatisfactory dose delivery to the patient. We now turn to the biological bases for the action of ionizing radiation. This will increase our understanding of the dangers inherent in brachytherapy treatments, both for patient and staff.

Biological Effects of Ionizing Radiation

[redacted]

Safeguards Against Radiation Exposure

[redacted]



Brachytherapy Facility Site Visit

[redacted]

Human Errors in Brachytherapy Systems

[redacted]

[redacted]

Factors Leading to Human Error

Certain factors contributing to human errors leading to misadministrations can be identified. These include communication, function allocation, workspace organization, human-machine interfaces, inadequate corrective measures, social context of radiotherapy departments, and atypical working hours of radiotherapy personnel. Serig (1989) provided the following synopsis for each of these factors.

Communication. Communication among brachytherapy personnel is a vital, but often flawed activity. Filtering and distortion of messages and orders can occur when, as is inevitably the case, staff members possess different levels of expertise. Strong regional accents and colloquial expressions can produce discrepancies between the speaker's meaning and the recipient's understanding. The communication medium can exert unwanted effects. For example, handwritten messages and telephone conversations can easily be misinterpreted if due caution is not exercised.

Function Allocation. Brachytherapy system performance will degrade and more errors will be made if the demands placed on radiotherapy personnel exceed their physical, perceptual, or cognitive capabilities. There is a dearth of information regarding what type and how many system functions should be assigned to humans and to the machinery for optimal brachytherapy effectiveness, safety, and reliability. In addition to patient treatment procedures, maintenance and support activities demand considerable attention from brachytherapy personnel. Function allocation analyses should thus consider these elements, too.

Workspace Organization. In general, performance on complex tasks that occurs in cluttered, disorganized settings is likely to be inferior to performance in more organized work environments. Cluttered environments may make needed items hard to locate, disturb work flow, and lead to accidents. Each of these can cause task elements to be missed or performed out-of-sequence, thereby increasing occupational exposures and radiation misadministrations.

Human-Machine Interfaces. Trends toward computerization of the brachytherapy process demonstrate the importance of the interface between equipment and human operators. Deficiencies currently exist in controls, displays, labels and location aids, panel layouts, and control-display integration. Furthermore, inconsistencies in interface design standards are common and raise transfer of training issues when different radiology machines are operated by the same personnel.

Inadequate Corrective Measures. Attempts to rectify human errors in brachytherapy have been limited by an inability to identify and evaluate their root causes. Consequently, many corrective actions have had a palliative rather than a curative effect. Less reliance should be placed on idiosyncratic anecdotal reports. Instead, brachytherapy should be examined in terms of a systems framework that considers the interplay between the physical, organizational, operational, and psychological components of brachytherapy.

Social Context. Various organizational and social variables can influence the way in which messages are transmitted, decisions are made, and accountability is determined. Authority relations among staff in the brachytherapy suite can impede the timely flow of vital technical information and so increase the probability of error. Organizational practices and policies can exert vital effects on many brachytherapy activities.

Working Hours. The well-documented decrements in human performance that occur during the early morning hours (i.e., midnight to 6:00 am) pose problems for certain brachytherapy applications. Due to short expiration times of radiopharmaceuticals, it is not unusual for nuclear pharmacies to prepare and distribute radiopharmaceuticals during these hours. Care should be taken to ensure that performance of tasks in nuclear pharmacies is as simple and clear as possible. It is not uncommon for radiotherapy personnel to work split shifts, overtime, or to be on-call. Each of these conditions can produce undesirable effects on worker performance if compensatory strategies are not implemented.

Summary

Reducing errors in brachytherapy is important for staff as well as patients. Errors in brachytherapy are due to complex interactions between the characteristics of brachytherapy tasks and human skills and information-processing capabilities. To date, misadministration errors have received the most attention. This is understandable given the crucial necessity of proper patient care. It is important to note, however, that this approach has not yielded a comprehensive understanding of the root causes of errors in remote afterloading systems. One reason for this is that misadministration errors occur relatively infrequently. However, other errors of a procedural or operational nature, even though they do not result in misadministration errors, can nevertheless impact significantly on the extent of staff radiation exposure and on the quality of patient treatment. A human factors evaluation is needed that emphasizes a systems approach to brachytherapy, combined with a critical incident approach to analyzing human reliability.

This evaluation, detailed in the Technical Approach section for Task 1, will analyze in great detail the functions required to administer remote afterloading brachytherapy. It will examine the interaction between radiotherapy personnel and brachytherapy equipment in all aspects of brachytherapy. As requested in the Statement of Work, it will encompass all operational functions except for clinical evaluation, therapeutic decision making, and follow-up evaluation. Various ancillary functions necessary for safe and effective brachytherapy are also included. Communication, maintenance, record keeping, data updates, safety, and quality assurance are examples of this class of functions.

TECHNICAL APPROACH

The Statement of Work in the Request for Proposals specifies a comprehensive research program to collect and analyze data that can help to resolve safety concerns related to human error in the use of remote afterloaders for brachytherapy. This section considers the task requirements specified in the Statement of Work as interpreted by the PSE Team. No exceptions are taken to the provisions of the Statement of Work.

This project addresses the safety and effectiveness of remote afterloading brachytherapy systems from the standpoint of human error and its causes. Its major goals are to (a) identify the factors contributing to human error in these systems, (b) evaluate the impact of these factors, both singly and in combination, on the performance of tasks and functions essential to system goals, and (c) determine actual or potential root causes of human error in remote afterloading. As part of this effort, function and task performance problems will be prioritized in terms of their safety significance. Various strategies for resolving these problems will also be proposed.

Six separate Tasks have been enumerated in the Statement of Work. It is understood that all but the first task are optional, being contingent on the satisfactory completion of Task 1. Letter Reports will be prepared upon completing each Task, and Technical Reports will be submitted at the conclusion of Tasks 1 and 6.

TASK 1

Function and Task Analysis of Activities in Remote Afterloading Brachytherapy

Kick-Off Meeting

Within two weeks after contract award, the Principal Investigator and two project staff will meet with the NRC Project Officer and other appropriate individuals to discuss plans and operating procedures for performing Task 1 work. The Principal Investigator will be prepared to present a summary briefing describing the (a) overall project plans, (b) project team, (c) project management approach, and (d) the proposed approach for Task 1. Detailed discussions will then be held in order to clarify important points, to identify significant operational constraints, and to determine how the various aspects of the project fit with other NRC efforts. These valuable discussions will serve as the basis for refining the Task 1 Work Plan.

Based on these discussions at NRC, the plans for Task 1 will be modified as necessary. A detailed plan of action will then be finalized and proposed travel will be submitted to the NRC Project Officer for approval.

Develop Field Assessment Tools

[redacted]

The purpose of these guides is not to encourage rigid adherence to a pre-scripted data collection routine. Rather, they will be used as a foundation for building a thorough human factors data base for brachytherapy functions and activities. PSE analysts will be free to augment the guides with additional information that may exist uniquely at each facility. By virtue of this approach, PSE site assessments will capture all the characteristics of remote afterloading brachytherapy systems that have been identified for study by NRC.

Visits to Distributors and Medical Facilities

The site visits to the distributors and medical facilities will collect the data necessary for the task analyses and human error analyses for each of the operational and ancillary functions. These site visits comprise the majority of the work in Task 1. Accordingly, a detailed discussion of the proposed work is presented. [redacted]

Sampling Plan for Distributors

The selection of the distributors to be visited will be made in consultation with the NRC Project Officer. Our first priority will be to select distributors that handle the most widely distributed afterloaders. In this way, we could develop the greatest familiarity with the devices that are most likely to be encountered during the medical facility site visits.

As a result of our initial survey of remote afterloader distributors, we understand that two companies Nucletron (distributing Selectron devices) and Mick Radio-Nuclear Instruments (distributing GammaMed devices), dominate the market. Except for a very few facilities with other afterloader models (e.g., Curietron), nearly all brachytherapy facilities in the U. S. use one of these two remote afterloaders. Thus, we propose to visit both of these distributors. In preliminary discussions, both have indicated that they are eager to cooperate with us on this project.

Three members of the PSE Team will visit two distributors of remote afterloading brachytherapy devices. This important Task 1 activity will familiarize the PSE Team with afterloading equipment that is in current use. Besides the remote afterloading units themselves, all accessory devices and equipment that are stocked by the distributors will be thoroughly analyzed. Examples of accessory devices are treatment planning computers, dose calculating devices, quality assurance devices (for calibration and maintenance), source transport tubes and their connectors, source preparation devices, printers, nurse station displays, and alarm systems. Whenever feasible, we will conduct a hands-on evaluation of equipment configurations, both high and low dose rate, that are most commonly used in medical facilities.

[redacted]

Stratified Sampling Method for Medical Facilities

Although brachytherapy using remote afterloaders is a specialized treatment not found in all medical facilities, considerable variability may well exist between those facilities that do routinely perform this procedure. [redacted]

[redacted]

The criteria that are most relevant for Task 1 are those that most directly determine major aspects of remote afterloading activities: Geographic Region and Afterloader Model.

<u>Geographic Region</u>. One of the most important objectives of our sampling procedure is to obtain a geographically balanced sample of medical facilities which perform remote afterloading brachytherapy. Any regional differences in the types of remote afterloading equipment, and procedural, staffing, or operational practices can thereby be identified and evaluated. As one example, regional variations in the training of radiation therapy technicians could lead to differences in patient set-up and handling that impact the overall quality of brachytherapy treatment. Likewise, different state licensing requirements for radiological personnel could affect the nature of brachytherapy activities. For this Task, we will visit an equal number of facilities in the East, Central and West regions of the U.S.

<u>Afterloader Model</u>. Different afterloading systems may well impose different sets of demands on brachytherapy personnel. To systematically examine this possibility, PSE will select facilities in order to observe different afterloader brands. Two brands of afterloaders currently dominant the U.S. market: Selectron and Gamma Med II. Both are manufactured by European-based companies (Selectron is produced by Netherlands-based Nucletron; Gamma Med II by West German-based Isotopen-Technik). Other afterloaders, such as the Ralstron, Buchler, Cathetron, and Curietron, are also used, but in countries other than America for the most part.

A given manufacturer usually produces more than one model of afterloader. Often, models differ in terms of dose rate. This suggests that the relative prevalence of high and low dose rate treatments must also be considered. Low dose rate brachytherapy is done on an inpatient basis and reproduces traditional treatment schedules. High dose rate brachytherapy, on the other hand, uses much shorter treatment times (minutes as opposed to days) and can be done for both inpatients and outpatients. The fact that different hospital facilities are used in high dose rate (radiology department treatment room) and low dose rate (hospital room) brachytherapy as well as different models of afterloaders makes this an important factor to consider in conjunction with afterloader brand.

Several other factors have been found to account for differences between medical facilities using remote afterloaders for brachytherapy. While these factors are recognized as influential, they will not be used for sample selection. Nonetheless, each site will be characterized in terms of these factors, providing a comprehensive depiction of each facility. Analyses of similarities and differences on both these factors will be performed. Results can be used in conjunction with the human factors evaluations to compare numerous aspects of each facility to other facilities.

[redacted]

Sampling Plan for Medical Facilities

[redacted]

[redacted]

Once selected, each site will be contacted by phone and by formal letter inviting their participation in the project. This initial contact will explain the objectives of the visit, the type of data to be collected, and the visit schedule. Participation will be entirely voluntary; no payment or other material inducement is contemplated. Participating facilities will be assured that all data collected will be confidential and will be used for research purposes only. Logistical details of the visits will then be worked out. [redacted]

Function Analysis of Remote Afterloading Brachytherapy

For the purposes of this project, the functions and tasks performed in remote afterloading brachytherapy are partitioned into two major groupings, referred to as operational and ancillary. Operational functions are concerned most directly with the actual administration. For the most part, operational functions are independent of the specific source of the ionizing radiation. Hence, most of the analyses can be applied equally well to high and low dose rate afterloading systems. In those instances where important differences exist between high and low dose rate procedures and equipment, however, additional evaluations will be conducted to ensure a complete analysis of each brachytherapy modality. For instance, radiation exposure precautions taken by nurses who care for patients with low activity implants in hospital rooms will be assessed. This does not arise in high dose rate treatments because these are administered in the treatment rooms of the radiology department.

Operational Functions. The following operational functions will be analyzed in Task 1:

- Target Volume Localization
- Treatment Planning
- Dosimetry
- Verification of Implantation
- Treatment
- Patient Evaluation During Treatment
- Removal of Implant.

Each of these functions is vital for the safe and effective administration of brachytherapy. Target volume localization defines the geometry of the tumor volume that is to be irradiated. Traditionally, target volume determinations have been based on qualitative clinical judgment using several factors: imaging techniques; surgical staging, and knowledge of the biological behavior of various tumors. Increasingly, computers are being used to construct three-dimensional anatomical images for more precise tumor localization. Modern imaging technologies can precisely define the target volume and display the calculated three-dimensional dose distribution (e.g., Ten Haken, et al., 1988).

Target volume localization is closely related to treatment planning, which determines the degree of accuracy required to deliver a therapeutically beneficial dose of ionizing radiation. Despite its central role in brachytherapy, few published studies are available that quantify the actual accuracy of treatment planning achieved in clinical practice. Visser (1989) compared 12 computer planning systems in terms of the dose distributions calculated by each of them for five test cases. Although the algorithms were sufficiently accurate in most cases, errors in dose specification and treatment simulation were noted.

Treatment planning and target volume localization are closely related to important dosimetry considerations. Accurate dosimetry in brachytherapy is just as vital as it is in teletherapy. The suggestion has sometimes been made that dosimetry in brachytherapy is less crucial due to the enhanced tolerance when smaller target volumes are irradiated; however, rigorous empirical data to support this view are lacking. And anecdotal reports should never be given great weight in the absence of solid evidence. Dose-effect curves in radiotherapy are typically steep. As such, small changes in actual dose may result in large changes in biological effect. Indeed, one study reported clinically relevant effects for different dosages in terms of tumor control and complications (Hunter, 1986, cited in Visser, 1989).

Verification of implantation refers primarily to the treatment simulation stage of the brachytherapy process. In treatment simulation, the position of the implanted catheter relative to the isodose curves of the target volume is determined prior to source insertion. An inert dummy material is placed in the treatment position in the catheter and orthogonal X-ray images are made. Evaluation of these images may lead to a change in catheter position to facilitate optimal tumor irradiation. Once the desired position has been attained, the isodose for dose specification is chosen and source application time is determined. Errors can occur at any of these steps. For instance, localization errors can produce improper source positions. In a second sense, verification of implantation can allude to the placement of the source into the correct position in the implanted catheter. Commercial afterloaders indicate when this has been achieved. Quality assurance procedures performed regularly on the afterloader should assure that correct placement occurs.

The final three operational functions to be evaluated are treatment, patient evaluation during treatment, and removal of implant. Treatment consists of administering a specified irradiating dose to a patient. The interaction of the radiation therapy technician with the afterloader control console is the crucial factor here. Total irradiation time and source stepping size are examples of data that must be correctly calculated and entered at the console. Patient evaluation during high dose rate treatment in the radiology department is done via closed-circuit television and an intercom. For some patients, it may also be advisable to monitor vital signs. Patients undergoing low activity brachytherapy are monitored in their hospital rooms from a nursing station. Information regarding patient condition and afterloader and source status is supplied to ward personnel. Removal of implant is performed by the afterloader automatically at the end of a treatment session. In the event of an emergency, such as recognition of a dose specification error, manual override can retract the source into its storage container. Backup systems automatically retract sources in the event of a power failure at the medical facility. Most afterloaders also have a manual crank to retract sources should their primary backup systems fail.

Ancillary Functions. As requested in the Request for Proposals, ancillary functions will also be analyzed in Task 1. These include, but are not limited to:

- Communication
- Record Keeping
- Maintenance (e.g., source changes, adjustments, servicing)
- Data Updates (e.g., source strength calibration, computer program updates)
- Safety
- Quality Assurance

Ancillary functions are not directly associated with the actual administration of ionizing radiation. Nevertheless, they can exert critical and far-reaching effects on patient and staff safety and performance of operational functions. For instance, equipment maintenance and source calibration are typically performed in a less structured setting than are operational functions. The activities and locations of radiotherapy personnel both within and outside the radiotherapy room is more uncertain during these quality assurance activities. Procedural errors and miscommunication could lead to inadvertent exposures of personnel performing these functions.

Any complete human factors analysis of brachytherapy must carefully examine ancillary functions, their interdependencies, and their interactions with operational functions. It should be noted that several ancillary functions such as communication and record keeping are directly related to the factors cited by Serig (1989) leading to misadministration errors.

Functions / Procedures Assessment. It is important to obtain a thorough familiarity with the procedures used in all brachytherapy activities commonly performed. The Functions/Procedures Assessment will begin with [redacted] The different activities and operations will be considered, along with many specialized radiographic testing applications, methods, and procedures. The discussions will present a detailed overview of the most current practices in medical brachytherapy.

Additional expert consultation will be solicited during the site visits to medical facilities, including [redacted] During the site visits, PSE project personnel will observe and assess a large number of brachytherapy functions and procedures. These field observations will consist of detailed examination by means of videotape and still photography so that discrete steps of the remote afterloading brachytherapy process can be documented and presented in an illustrative format.

Task Analysis of Operational and Ancillary Functions

Task analysis is a formal methodology, derived from systems analysis, which describes and analyses the performance demands made on the human elements of a system. By concentrating on the human element in systems analysis, it can compare these task demands with known human capabilities. These analyses will identify and characterize all crucial aspects of remote afterloading brachytherapy activities including (a) the logical flow of events before, during and after radiation administration, (b) the allocation of functions and personnel workloads, (c) the likelihood and potential impact of work place distractions on task performance, (d) the distribution of work load across machines and people, (e) the coordination of events in time, and (f) the arrangement of equipment and people in space. Data for the task analysis will be collected from many sources including:

- System documentation, which includes test reports and specifications, procedural documents, operator manuals, etc;
- Interviews with incumbents, system personnel, and other subject matter experts;
- Direct observation and recording (video and audio) of the task being performed.

Every task analysis must be tailored to a certain extent for the particular type of system one is analyzing. PSE will customize these methods to analyze brachytherapy activities. Videotaping and still photography of operations will provide a documentable record as well as case history corroboration for our detailed quantitative analyses. The video tape can capture dynamic aspects of device operation as they occur over time. Still photography records various details of controls and displays, as well as the composition and relative arrangement of component parts in remote afterloading subsystems.

<u>Flow Diagrams</u> – Flow diagrams represent graphically the sequence of tasks and subtasks comprising each function. Each task step will be sequenced in the correct order. Factors to be considered in the sequencing process include delay tolerance and frequency of performance

The functional flow diagrams also depict the interrelationships of the identified tasks. They aid in function allocation and serve as an outline of tasks required for proper system performance. Environmental conditions, initiating and terminating cues, range of outputs possible, consequences of inadequate performance, equipment, human interfaces, and safety considerations can also be specified.

Of particular interest are the information exchange points in the system. Accordingly, we will describe the conditions for information exchange, the criticality of the information, the structure of the data, the source and intended target, the methods/modes of exchange, and environmental/situational variables that affect the transmission of the information. Note that the information exchange points involve both human-machine and human-human interaction.

[redacted]

[redacted]

Thus, equipment interfaces, procedure sequences, training, and organizational factors can all be represented in a common format. PSE technical staff are experienced in performing task analyses using many different approaches. [redacted] Each approach has strengths and weaknesses, and professional judgement is required to select the most suitable approach.

Information and Control Requirements - In addition to specifying the task and information flow among the people and equipment involved with brachytherapy, it is important to determine the information and control requirements of each task. We consider this to be a natural part of the task analytic process.

The control actions required of the operator will be developed from known functional and system requirements and specifications. Following, the cues that determine or modulate those actions are specified and the information sources are identified. In general, this may be done by identifying, for each action or set of actions, the initiating, ongoing, and terminating cues to the operator. Each source of information (display) that is needed to recognize that an operation is beginning, continuing normally, deviating, terminating normally, or aborting must be identified. When multiple sources of information must be integrated, matched, or compared by an operator to identify the state of system performance or to recognize a cue for a control action, such combinations and their sources must be specified.

Information sources must be identified by their location and its proximity to the primary source of control, e.g. from within or outside of the afterloader or radiotherapy spaces. The team will be required to become familiar with the institution's handling and referral processes. For example, when low dose brachytherapy is ongoing in another hospital ward, the information required for successful brachytherapy operation may be closely linked to other patient monitoring and health care functions. These information linkages must be clearly spelled out in the task analysis.

Each information item necessary for function and task accomplishment should be categorized according to the variability of its occurrence. Information items that signal a control action may be digital and binary, such as the shift of a light from red to green. Others may be provided by a therapist who reports the status of a system component in vague terms bounded by conditions.

The task analysis approach must be sufficiently comprehensive to enable the team to identify the information and control sequences for each function, task, and subtask. These analyses must proceed from all available sources, including the manufacturer's guidelines, operation and maintenance personnel interviews, full understanding of the institution's handling procedures, and careful, guided observation of the processes.

SKA Analysis – The Skills, Knowledge, and Abilities (SKA) Analysis will provide an assessment of the training needs and methods for each operational and ancillary function. This analysis identifies the skills, knowledges and abilities necessary for successful performance of each function.

The SKA analysis utilizes the individual task steps and the information regarding the consequences of error from the error likelihood analysis. For each task identified, the analyst identifies the critical performance component which is necessary for successful operator performance. The analyst also identifies the most appropriate method for acquiring the critical SKAs, subject to verification by the Brachytherapy Advisor. Methods of acquiring critical SKAs include prerequisite knowledge, job experience, on-the-job training, and formal training programs.

The SKA Analysis will also identify the degree to which procedures are unique or common across equipment configurations and brachytherapy functions/processes. During the medical facility visits, individual technicians will be requested to explain differences and similarities among equipment configurations. The resulting commonality factors will be incorporated into the flow and task analysis and will be of great importance for locating sources of error and points of negative and positive training transfer.

We recognize that most technicians are unlikely to be familiar with similarities and differences between different brachytherapy equipment configurations. Instead, we are interested in the similarities and differences between the brachytherapy equipment that they use and other similar equipment (e.g., teletherapy) that they operate intermittently. If, for example, the controls on one device, which the technician uses 4 days each week, operates one way and the controls on the brachytherapy equipment operates another, then the lack of commonality could contribute to errors.

Technicians are the personnel most closely involved in equipment use and maintenance. As such, they are highly aware of variations in equipment configurations and the implications those variations have for system performance. Additionally, by asking that technicians supply explanations of similarities and differences in equipment configurations, we can ascertain whether they correctly perceive these differences and understand how they pertain to system function.

One way to collect this information is by way of an interview. This relatively unstructured and subjective approach furnishes each person with the opportunity to freely express him- or her-self in the manner they desire. Of course, such subjective data can lead to erroneous conclusions if it is not interpreted properly. In order to avoid pitfalls of misinterpretation, we will supplement all interview data with more objective information that is generated from our task analyses, function analyses, and error analyses. When the personalized but more subjective interview data is considered in conjunction with these additional data, a more accurate, complete picture will be obtained.

Human Error Analysis

In a critical, high-hazard technology such as brachytherapy, human error carries potentially serious consequences to patients and/or medical staff. It is, therefore, important to characterize as completely as possible errors that can occur in remote afterloading. The PSE Team will accomplish this by capitalizing on the extensive task analytic work performed in

Task 1. A widely recognized technique of human error assessment, Technique for Human Error Rate Prediction (THERP; Swain, 1980; Swain & Guttman, 1980) will form the foundation for these efforts.

THERP is a major human error methodology that has been used by many federal agencies. It is a technique for predicting human error rates and for evaluating the degradation to the person-machine system likely to be caused by human error. THERP has furnished the basis for safer, more effective and more efficient operating procedures and training techniques. Human factors research on nuclear power plant control rooms and accident evaluation has successfully used THERP to identify and isolate system errors, calculate their probabilities, and ascertain their causes. THERP can deal with continuous as well as discontinuous behaviors and can account for various degrees of dependent as well as independent operations (Meister, 1984).

The THERP method entails a complete man-machine system analysis composed of several sequential steps:

1. Describe system goals and functions and situational and personnel characteristics

2. Describe the jobs and tasks performed by personnel and analyze them to identify error-likely situations

3. Estimate the likelihood of each potential error and the likelihood that each error will be undetected

4. Estimate the consequences of the undetected or uncorrected error

5. Suggest changes to the system and evaluate these.

The method relies heavily on task analysis for the description and analysis of tasks to identify error-prone situations. The system or subsystem failure that is to be evaluated is defined, after which all human operations involved in the failure and their relationship to system tasks are identified by drawing them in the form of an event-probability tree. Error rates for both correct and incorrect performance of each branch of the event tree are predicted by calling upon a variety of data sources for inputs. In this project, for instance, the task analyses and input from the Brachytherapy Advisor will form the core of these data. Human factors knowledge about the types of conditions, designs, and procedures which induce error, and the accident reports supplied by NRC upon contract award will also play prominent roles.

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To expedite our efforts to obtain the most complete and up-to-date information on problems with remote afterloading, we will review several computer-based databases that contain medically related information. The databases listed below will be the major sources of this information for Pacific Science & Engineering scientists during this project:

Diogenes. Diogenes contains documents and news releases relating to the introduction and regulation of drugs and medical devices. Its value to this project is to identify new problem areas that have been reported, but have not been published in detail in the professional literature. Problems uncovered in Diogenes may be highlighted for more detailed evaluation at the most appropriate time over the course of the project.

National Technical Information Service (NTIS). NTIS is the major resource for locating U.S. Government-sponsored research reports, studies, and materials in the medical, health, social, physical, and biological sciences as well as in engineering, business, and technology. NTIS is of particular value for scientific and technical professionals involved in Government research and contracting, and is regularly consulted by Pacific Science & Engineering for all types of R&D.

Medline. Produced by the National Library of Medicine, Medline is a comprehensive index to national and international medical literature. The database covers all aspects of biomedicine, including the allied health fields, the biological and physical sciences, delivery of health care, and chemicals and drugs. This information is, of course, somewhat more dated than MDR and PRP reports. However, it is valuable in its own right because a wider audience is likely to be reached by journals than by technical reports with limited distribution. A short Medline session conducted during the preparation of this response found two informative examples of brachytherapy system problems. A case was described in which the distal tip of a tandem fractured off in a patient's uterus during an intracavitary application of a tandem and ovoids[3], and leakage was detected from a cesium-137 needle during routine quality assurance checks[4].

IRCS. The IRCS Medical Science Database contains the full text of all articles published in IRCS medical science publications since January 1982. Publication of IRCS online is simultaneous with the printed form, providing immediate access to some of the most current medical and biomedical research data available. IRCS citations include tables, figure legends, and complete reference listings, in addition to complete textual material. IRCS is updated semi-monthly to maintain currency and is used as an adjunct to Medline.

In addition to estimating the likelihood of errors occurring during task performance, we will estimate the conditional probability that the error will be detected either by the human operator or by the equipment itself. The consequences of uncorrected errors on system safety and performance will also be determined. The severity of error consequences may be graded from least cost to most cost in terms of (a) loss of time; (b) material loss or waste; (c) equipment damage requiring repair actions; (d) minor personal injury; (e) equipment destruction and loss; (f) serious personal health or safety hazard; and (g) possible loss of life.

Computationally, THERP uses two main measures, (a) the probability that an operation will lead to an error of class i (P_i), and (b) the probability that an error or class or errors will result in system failure (F_i). P_i is based on an error rate, the frequency of error occurring

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during a defined block of time. $1 - P_i$ is the probability that an operation will be performed without error. F_iP_i is the joint probability that an error will occur in an operation that that error will lead to system failure. $1 - F_iP_i$ is the probability that an operation will be performed that does not lead to error and system failure. Other computations relating to total system performance and failure rate as a function of different classes of errors are possible (Meister, 1984).

Estimates of error likelihood derived using various observational and empirical procedures will be carefully compared. Any commonalities that exist with respect to error types and likelihoods will be further analyzed. This commonalities review enables conclusions to be drawn about whether errors are (a) highly idiosyncratic to each medical facility or (b) caused by deficiencies and problems shared by several facilities. If the latter is found to be the case, generic guidelines for reducing brachytherapy errors could be formulated.

Implications of the Function and Task Analyses for Tasks 2 - 5

The operational and ancillary functions analyzed in the Task 1 are the core of the aspects of brachytherapy using remote afterloaders to be evaluated in Tasks 2 through 5. The task analyses define how the functions need to be performed and, as such, provide a benchmark standard. This benchmark will subsequently guide evaluations and interpretations in Tasks 2 through 5. An example illustrates this point. We will consider treatment planning, one of the operational functions.

The goal of treatment planning is to administer radiation so that the dose absorbed in the target volume is within 5% of the prescribed dose, while simultaneously minimizing the dose to the surrounding healthy tissue. Treatment planning should extend beyond the target volume to calculate radiation doses to other organs and tissues for estimating the probability of complications (ICRP, 1984). And discrepancies between prescribed and actual dose distributions must be carefully analyzed to minimize their occurrence (Burgers, Awwad, & van der Laarse, 1988). To perform a comprehensive analysis of treatment planning, each of the four factors cited above should be considered.

The human-system interface is a major determinant of the effectiveness of treatment planning. Computers are invariably used to define and localize target volumes, and to formulate dose specifications. Operating and maintenance procedures for treatment planning hardware and software should be evaluated for their ability to be used correctly and efficiently (Sherouse, Naves, Varia, & Rosenman, 1987). The means by which radiology personnel (e.g., dosimetrists) are trained to use all treatment planning facilities are also an important aspect of successful treatment planning. Organizational practices help to determine who does the treatment planning and how a plan is double-checked for correctness prior to its implementation. Treatment planning is thus a complex operational function composed of multiple, interacting factors. These factors must occur in a coordinated fashion: otherwise, unintended interactions can produce system errors.

In Task 1, the PSE Team will examine each of the functions called out in the Statement of Work in detail. Our purpose is to develop a detailed yet generic descriptive model for each of these functions. Each model will define the tasks necessary for its performance.

Task 1 Reports

Task 1 reports will describe the operational and ancillary functions and tasks identified in the Statement of Work in terms of two major human factors analytic techniques:

(a) Task Analysis, which includes detailed functional flow diagrams, and the Skills, Knowledge, and Abilities (SKA) analysis;

(b) Human Error Estimates, embodied by THERP (Technique for Human Error Rate Prediction), a methodology for assessing potential human errors in complex, dynamic systems.

These techniques, which will be supplemented by interview data, will furnish the basis for a comprehensive picture of remote afterloading brachytherapy as it is currently practiced in U.S. medical facilities. There are two classes of functions that we will analyze: operational and ancillary. As previously stated, operational functions are more directly related to the administration of brachytherapy. Operational functions consist of (a) target volume localization, (b) treatment planning, (c) dosimetry, (d) verification of implantation, (e) treatment, (f) patient evaluation during treatment, and (g) removal of implant. Ancillary functions, on the other hand, can exert meaningful but indirect influences on the performance of operational functions. Ancillary functions include (a) communication, (b) record-keeping, (c) system maintenance, (d) data updates, (e) safety, and (f) quality assurance activities.

Because THERP is mathematical in nature, being expressed in the form of an event-probability tree, the information provided by THERP will be presented in as clear and understandable a manner as possible. We will clarify it by employing diagrams with descriptive labels for the events represented by each node. Description examples of the correct and incorrect actions represented by the branches also will help to make the THERP analysis understandable.

Relationship of Task 1 Reports to Tasks 2 through 5 Reports

To facilitate understanding and integrating the findings in the reports of Tasks 2 through 5 to the Task 1 report, it will view them in terms of a matrix that relates a brachytherapy system function to the task variables. The functions, which constitute one dimension of the matrix, will consist of the operational and ancillary functions that were identified in the Statement of Work and analyzed during Task 1. The task variables, which comprise the second dimension of the matrix, were presented in the discussion of each Task as important analytic criteria of their respective Task.

To illustrate this approach, consider Task 2, the human factors evaluation of human-system interfaces involved in remote afterloading brachytherapy. Several task variables were identified as critical to understanding interface design and use. They include: (a) ergonomic factors, (b) cognitive and perceptual demands, (c) environmental variables, and (d) displays and controls. In terms of the function-task variable matrix, each of the operational and ancillary functions cited in Task 1 will be analyzed. Obviously, some functions will be more strongly affected by some of these variables than will other functions.

This approach will systematically determine how various task variables influence each of the operational and ancillary functions. The relative impact of each set of task variables on each function can thus be ascertained. This level of analysis is more detailed and exhaustive than has heretofore been attempted in the analysis of radiotherapy systems. It holds much promise for supplying a fuller description of brachytherapy tasks and functions.

Furthermore, as successive Tasks are completed, an increasingly comprehensive picture of the relative importance of different sets of task variables on the operational and ancillary functions will be constructed. This will prove especially valuable in establishing the interactions among task variables and brachytherapy functions. For instance, certain sets of task variables may exert a greater impact on certain functions than on other functions. This type of information could be used to suggest possible root causes of performance problems and deficiencies. Also, specifying the nature of the interactions among different classes of task variables is a unique contribution to improved understanding of remote afterloading system functions.

Task 1 Milestone Schedule

Task 1 research efforts will proceed during the six months following contract award. A timetable of Task 1 activities is presented in Figure 2. The figure indicates the major task activities, estimated start-up and time to completion for each activity, task products, and projected project travel periods.

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TASK 2 (OPTIONAL)

Human Factors Evaluation of Human-System Interfaces Involved in Remote Afterloading Brachytherapy

Upon receiving approval to proceed from the NRC Project Officer, Task 2 will commence. The major activity in Task 2 is a detailed evaluation of the human-system interfaces in remote afterloading systems. Besides the primary interface in this system, that between the afterloader control console and the human operator, other interfaces must also be considered. These include treatment planning computers, dose calculating devices, source preparation devices, data output devices, various treatment machines and devices, nurse station display, intercom, and alarms and other safeguards. Task 2 evaluates the strengths and weaknesses of these interfaces, and develops recommendations for design improvements.

The human error model formulated in Task 1 will supply major direction to these efforts. It will serve as a basis for extending our knowledge of the role of human-system interfaces in producing or preventing performance errors in remote afterloading systems. Identification of interface features that are particularly crucial in this regard will be made.

Features include controls and displays, performance requirements, intervening environmental and situational variables, etc. The manner in which these features interact to determine overall human performance levels in remote afterloading will also be determined. Specific differences among interfaces in terms of error rates and certain features will be elucidated.

The interface between radiological personnel and the afterloader unit is a vital link in the safe, accurate, and reliable delivery of radiation to the patient. In remote afterloading brachytherapy, the interface of a remote afterloader consists of a microprocessor-based control console located outside the treatment room. Specific features of consoles differ from one afterloader brand and model to another. However, all consoles enable operation of the unit, placement of the source materials within the applicators, adjustment of dose distribution during treatment, and retraction of sources from the applicators back into their containers. Displays on the console control panel show the exact position of all sources from the time they leave the container until they re-enter it. Interlock circuitry protects patient and staff from inadvertent radiation exposure. Physical adjustments concerned with machine calibration and quality control can be made without entering the treatment room.

A series of spot checks at several medical facilities performed by Serig (1989) revealed that the human-system interfaces in many radiology departments could be improved. When compared against accepted human-machine interface guidelines (U.S. Nuclear Regulatory Commission, 1981), numerous shortcomings were found in workspace, communications, controls, visual displays, labels, location aids, panel layouts, and control-display integration. Also, little attention has been paid to the way that hardware and software are integrated. This area is especially deserving of study given the trend toward computerization of many brachytherapy activities, including dose distribution determinations, treatment delivery, data transfer, and record keeping.

Inconsistency in interface design is a particularly thorny problem. Different manufacturers use different human-machine design guidelines. Indeed, even the same manufacturer seems to employ different guidelines on different pieces of equipment (Serig, 1989). Such inconsistencies can lead to problems such as negative transfer of training that increase human errors and cause unreliable equipment operation.

In basic outline, the sequence of events in Task 2 will parallel those of Task 1. Various field assessment tools will be prepared, medical facilities will be chosen for site visits using a stratified sampling method, and comprehensive, systematic data collection will take place on-site. However, the focus will be restricted to human-system interfaces, and our efforts will be guided by the task analyses and human error probability predictions completed in Task 1.

Prepare Field Assessment Tools

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[redacted]

Selected standards data will be included, abstracted, or referenced. Sources such as military standards / specifications, the American National Standards Institute, the International Standards Organization, medical equipment manufacturers, and other human factors literature will be available. Abstracts, copies, and summaries of the manufacturer's instructions for installation, preliminary training, and maintenance will be included, as well as with any other guidance that may be available such as hospital accreditation standards and guidelines that pertain to brachytherapy.

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The guide will provide directions for preliminary analysis on-site. For example, the team may need to quickly assess their observations and data in sufficient detail to review and verify findings before departure. Thus, there will be sufficient time to reinvestigate and collect additional data if a finding is questioned or further detail is required.

Visits to Medical Facilities

Sampling Plan

In Tasks 2 - 5, 16 trips to 16 different medical facilities are proposed (four trips in each of the four tasks). A stratified random sampling method, previously discussed in Task 1, will be employed. Geographic region and afterloader model will form the sampling criteria. in each of the four tasks, one facility will be selected randomly from each of four strata of comparable size.[5] The order in which these four facilities will be visited will also be

[5] Estimates of the number of facilities in each stratum are: (Stratum 1) GammaMed (national) = 23; (Stratum 2) Selectron - East = 32; (Stratum 3) Selectron - Central = 30; (Stratum 4) Selectron - West = 31.

randomized. Upon approval by the NRC Project Officer, arrangements for the visits will be made.

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Analytic Approach and Methods

The extensive task analyses conducted during Task 1 will enable all interfaces in remote afterloading brachytherapy to be identified. The human error probability analysis (THERP), by virtue of its close connection with the task analyses, will also prove indispensable in understanding the relative strengths and weaknesses of the interfaces examined in Task 2. In addition to these two analytic schemes, established human engineering guidelines and standards will be consulted throughout the course of this Task to further evaluate the numerous interfaces to be examined.

Armed with these sources of information, the PSE Team will carefully evaluate all the human-machine and human-human interfaces that were identified for all operational and ancillary functions studied in Task 1. The major thrust of these efforts will be to ascertain how different interface properties and design characteristics mediate the probability of human error in remote afterloading functions and tasks. More specifically, we will use the task analyses constructed for each function to identify all interfaces that an operator encounters during the course of performing that function. The relative effectiveness of each interface can be judged in terms of the probability of committing an error when interacting with it. In all cases, the ergonomic, perceptual, and psychomotor requirements to interact with it in a safe, effective, and error-free manner will be determined. Video tape and 35 mm slides will be used extensively to document the interfaces examined during our site visits. A detailed description of the human-system interfaces in remote afterloading will be developed for each function.

Ergonomic Factors. PSE has extensive experience performing quantitative ergonomic analyses. Interfaces will be evaluated in light of dynamic measures of human body dimensions such as functional reach envelopes, muscle strength, and range of movement. Ergonomic standards for system design have been developed for both males and females, and will be applied to brachytherapy activities as required. Ergonometric and physical handling requirements will be evaluated in terms of biomechanics and accepted safe handling practices. The ergonomic data may be extrapolated to special populations; for example operators with arthritis, tenosynovitis, neuritis, or other disorders which limit strength and dexterity. This extensive examination of the ergonomic aspects of brachytherapy functions will make it possible to develop practical system design recommendations

Cognitive and Perceptual Demands. A survey of the cognitive and perceptual demands imposed on the radiotherapy personnel will be performed using the data from the prior analyses. PSE will examine visual, auditory, and tactile requirements of the interfaces previously identified. Decision making and problem-solving activities will be enumerated and classified. Operator cognitive and perceptual demands will be specified for each brachytherapy task identified in the Task 1, and the results will be compared to standard human-operator capabilities.

Environmental Variables. Human-system interface issues will be considered in light of different environmental conditions that could impact operator performance and contribute to human error. Examples of common environmental factors include confined workspace, low levels of ambient light, high ambient noise, temperature fluctuations, personal protective equipment, etc.

Displays and Controls. As one example, illumination conditions are important for accurately distinguishing system displays. Natural and artificial sources of illumination need to be evaluated in conjunction with the degree of reflection from adjacent surfaces to the brachytherapy equipment. Electronic displays like LEDs and LCDs may be considered, but while saving space and allowing for compact instrumentation, may present a legibility problem for some users.

Any audible signals generated as part of the operating sequence, and especially safety alerts (for example, auditory safety alarms) will be evaluated for effectiveness. Signals need to be audible--that is, discriminable above ambient noise. Differential signals should be discriminable from each other by 1 to 2 octaves, or 2 to 4 times the frequency. This could pose a problem when high levels of ambient noise are present.

Task 2 Letter Report

The Task 2 report will begin by describing the scope and details of task performance, then detail the data collection and analytical methodologies used in the Task 2 site visits. The role and importance of the human-system interface for each of the operational and ancillary functions will then be presented. Emphasis will be placed on characterizing the relative strengths and weaknesses of the different types of interfaces. Problematic aspects of brachytherapy interfaces will next be presented.

The discussion will center around the four task variables that received major analytic focus during the site visits: (a) ergonomic aspects of interface design and operation, (b) cognitive and perceptual demands placed on human operators by the interfaces, (c) environmental variables that affect how safely and effectively the interfaces can be used, and (d) display and control considerations such as stimulus-response compatibility and visual and auditory feedback concerning system status.

Throughout, emphasis will be placed on identifying and characterizing factors that facilitate successful performance as well as those that lead to errors in the conduct of the specific operational and ancillary functions that were called out in the Statement of Work. Of course, any additional and unexpected findings will also be noted. A summary of progress as compared with planned activities will be given along with a description of costs and hours expended.

Task 2 Milestone Schedule

Subject to NRC authorization, Task 2 research efforts will proceed during the five months following Task 1. A timetable of Task 2 activities is presented in Figure 3. The figure indicates the major task activities, estimated start-up and time to completion for each subtask, and projected travel periods.

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Task 3 (Optional)

Human Factors Evaluation of Operating, Emergency, and Maintenance Procedures and Practices in Remote Afterloading Brachytherapy

Task 3 entails detailed human factors evaluations of operating, emergency, and maintenance procedures and practices for each function examined in Task 1. These evaluations will be based on the task and error likelihood analyses performed in Task 1. Established guidelines and standards for addressing the preparation, presentation, verification, and validation of the procedures and practices for these functions will be emphasized.

Prepare Field Assessment Tools

[redacted]

Visits to Medical Facilities

Sampling Plan

As discussed in the Task 2 section, four medical facilities will be sampled as part of the Task 3 evaluation. One of these facilities will be selected randomly from those using the GammaMed device, and three will be selected randomly from those using Selectron devices (stratified by geographic region). Other important characteristics of the medical facilities will be recorded as part of the data collected during the visits.

Since Tasks 2 and 3 will be conducted concurrently, this provides the opportunity to evaluate the procedures at eight facilities. Two human factors analysts will be used to collect Task 3 data. Their travel will be scheduled so that each visits four medical facilities.

Analytic Approach and Methods

Operating procedures and practices should include all the requisite actions for routinely using all equipment and devices in the intended fashion. As such, they are a core aspect of all operational and ancillary functions. Emergency procedures and practices are especially vital to the safety of radiotherapy staff and patients alike. Due to the fact that emergencies are associated with hazardous, time-critical events, it is important that they be comprehensible and easily followed. Maintenance procedures and practices are similar to operating procedures and practices in that they are a normal part of brachytherapy activities and are not linked to high-hazard circumstances, as are emergency procedures. However, maintenance procedures and practices are similar to emergency procedures and practices in that they are not performed in every brachytherapy session.

The different characteristics of these three classes of procedures have significant implications for how they should be prepared, presented, validated, and verified. Our analyses will take these characteristics into account when evaluating their relative strengths and weaknesses, and the types of hardware and software that are employed.

The preparation and presentation of procedures should be keyed toward who will use them and how they will be used. From the standpoint of content, procedures should contain all the information necessary for proper execution of the function. The task analysis in Task 1 will define what this information is for each function, supplemented by consultation with the Brachytherapy Advisor. In terms of format, procedures should be organized in a manner that facilitates learning and retention. From previous research on medical device instructional materials, PSE has identified a set of criteria that are important in this regard. These include legibility, reading difficulty, comprehensibility, use of illustrations, organization, and user aids (e.g., color coding). Once this has been achieved, we will evaluate how well the radiotherapy staff perform various procedures. Performance deficiencies will be related to our analyses of the procedural demands for each function.

Because emergency and maintenance procedures are not performed during every remote afterloading session, there is a greater likelihood for operators to forget or neglect various aspects of them, relative to operating procedures. To counteract this tendency, written versions of all emergency and maintenance procedures should be available at all times to all brachytherapy personnel. All such procedures should also be included in periodic refresher training. We will be particularly cognizant of the fact that performance deficits can occur during emergency and maintenance practices due to their lower frequency of occurrence.

To determine the validity of procedures, content sufficiency must be examined. Content sufficiency refers to how completely procedures specify all necessary actions that must be followed to successfully perform a given function. It encompasses the overall required sequence of actions as well as the procedural description for each action. A procedure can be considered valid if a function can be executed successfully and in the intended manner by adhering to the steps specified by that procedure. Interactions among procedures for a given function should also be to ensure that the execution of one does not interfere with another.

Verification of procedures will be addressed in terms of the Task 1 task analytic framework and human error analyses. The procedures for each function will be scrutinized for their appropriateness for directing the sequence of events that must be performed. The error rate analyses can isolate points in the procedures that are prone to error. Once these are identified, we can investigate the possibility that errors are due partly to loosely specified or structured procedures.

The approach to evaluating procedures described above will enable us to ascertain the relative strengths and weakness of the procedures and practices for each function called out in Task 1. It will also let us address issues in using different types of hardware and software, such as the relative merits of a menu-based versus a command language-driven computer interface, and keyboard input versus mouse input .

Task 3 Letter Report

The Task 3 report will begin by describing the scope and details of task performance, then detail the data collection and analytical methodologies used during the Task 3 site visits. The role and importance of operating, emergency, and maintenance procedures for each of the operational and ancillary functions will then be presented. Each of the three types of procedures will be characterized with respect to the unique requirements associated with its use. Efforts will be placed on describing how activities are actually performed in the field.

The discussion will center around the four task variables that received major analytic focus during the site visits: (a) content sufficiency of procedural information, (b) format in which the information is presented and whether it encourages learning and retention of procedural information, (c) the validity of the procedures, and (d) verification that the procedures are appropriate for the event sequence to be performed for each function.

Throughout, emphasis will be placed on identifying and characterizing factors that facilitate successful performance as well as those that lead to errors in the conduct of the operational and ancillary functions that were called out in the Statement of Work. Of course, any additional and unexpected findings will also be noted. Points for implementing error reduction strategies will be noted. A summary of progress as compared with planned activities will be given along with a description of costs and hours expended.

Task 3 Milestone Schedule

Task 3 research efforts will proceed concurrently with Task 2 during the five months following Task 1. A timetable of Task 3 activities is presented in Figure 4. The figure indicates the major task activities, estimated start-up and time to completion for each activity, task products, and projected travel periods.

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TASK 4 (OPTIONAL)

Human Factors Evaluation of Training and Qualifications Related to Remote Afterloading Brachytherapy Administration

Task 4 involves the human factors evaluation of training and qualifications related to remote afterloading activities. The task analyses and human error reliability evaluations from Task 1 will serve as the basis for assessing specific strengths and weaknesses of training and qualifications of all brachytherapy personnel. Differences training and negative transfer of training will be analyzed in terms of the scientific theory of learning, document design guidelines, and state-of-the-art principles of training technology. Our efforts will be supplemented by established human factors and educational psychology guidelines and standards for training. The accident reports supplied by NRC will be reviewed to determine the role of training and qualifications in remote afterloading accidents and injuries.

Remote afterloading brachytherapy requires well-trained technical personnel who are familiar with radiotherapeutic procedures as well as specific aspects of the commercially available afterloaders. Staff composition varies from one brachytherapy department to another; however, the following may be taken as prototypical:

- Radiation Oncologists
- Radiological Physicists
- Dosimetrists
- Radiation Therapy Technologists
- Radiation Oncology Nurses
- Support Personnel (secretaries, clerks, etc.).

These personnel must be able to cope with emergencies arising from any aspect of system malfunction. Training and education are thus vital aspects of remote afterloading brachytherapy. They contribute to the proper care of the implanted patient, occupational safety of radiotherapy personnel, appropriate responses to emergency situations, and correct management of visitors (Hilaris, Nori, & Anderson, 1988).

A survey study (Lemley, Hedl, & Griffin, 1987) found that more than 80% of both large and small hospitals desired to receive educational materials about radiation safety. This need was perceived by hospital administrators as well as radiology staff. Besides radiological technologists, other hospital personnel expressed interest in radiation safety materials. This suggests that most hospital staff feel that they are inadequately educated about ionizing radiation and its attendant health hazards. A seminar program for in-house nursing staff increased their understanding of diagnostic and therapeutic radiology, which in turn aided them in preparing patients for brachytherapy procedures and in caring for low dose rate patients.

Problems may be encountered in this regard, however. Previous studies indicate that improved radiation protection and radiation safety training do not lessen the fear of radiation among hospital staff. In fact, such measures have resulted in refusals to care adequately for brachytherapy patients (Almond, 1983). Educational efforts must emphasize the precautions and safeguards built into modern brachytherapy systems. Otherwise, increased awareness of radiation hazards may not result in safer and more reliable system function.

Prepare Field Assessment Tools

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Visits to Medical Facilities

Sampling Plan

As discussed in the Task 2 section, four medical facilities will be sampled as part of the Task 4 evaluation. One of these facilities will be selected randomly from those using the GammaMed device, and three will be selected randomly from those using Selectron devices (stratified by geographic region). Other important characteristics of the medical facilities will be recorded as part of the data collected during the visits.

Since Tasks 4 and 5 will be conducted concurrently, this provides the opportunity to evaluate the training at eight facilities. Two human factors analysts will be used to collect Task 4 data. Their travel will be scheduled so that each visits four medical facilities.

Analytic Approach and Methods

PSE analysts will examine training at each step in the remote afterloading process with special emphasis on the actual and potential sources of operator error. It is likely that deficiencies will be found. Serig (1989), for example, found that space and time for training activities may not meet the need, and that equipment manuals are not always well written and organized.

All training materials gathered during the Task 1 distributor and medical facility site visits will be analyzed in terms of the format and content. The training materials reviewed will include not only curriculum materials (books, manuals, tests, etc.) but also videotape, computer software, and other media training applications, job aids used in the field, and sources of in-service / continuing education. The assessment technique described below outlines how this will be accomplished.

Instructional L[illegible]a. Brachytherapy training materials, documentation, and technical instructions need to be evaluated from the standpoints of comprehensibility, and legibility. Readability will be assessed with a recognized reading level measure (e.g., Kincaid). The discrimination, interpretation, and recall skills required of the learner, and the environmental conditions under which they receive the information will also be evaluated.

Comprehensibility encompasses the purpose and intended meaning of the material. Language must be geared to the educational level of the intended user. Readers should be able to understand the necessary information on the first reading. Grammar is also important; active (rather than passive) and affirmative (rather than negative) clauses are preferred. Legibility affects the students' ability to recognize or discriminate among letters and numbers. Legibility is affected by the typeface shape, size, contrast, color, and reproduction quality. Typefaces should be simple, taking into account height and stroke width. Any graphics, illustrations, figures, or tables should clearly communicate the intended message.

The review will identify absent or deficient instructions. As part of the evaluation process, the instructional materials will be assessed for compliance with established requirements. Differences between equipment and processes will necessitate some flexibility in making comparisons. However, each set of materials will be assessed against the established requirements and learning objectives. This will permit deficient and missing material to be readily identified and corrective recommendations formulated.

Instructional Media. To determine the effectiveness of different media, PSE will create a matrix of the qualities and limitations of each type of media. Media traits such as sound, color, motion, text, photographs, charts, graphs will be reviewed in terms of the learning objectives of the material. Final determination of the acceptability of the media will depend upon how accurately and clearly information is presented. The compatibility of the media to the tasks being taught is also important. For example, an audio tape is of marginal value for teaching physical dexterity events.

PSE intends to determine the most appropriate media and delivery means for each task and learning objective derived from the task analysis. In addition, other criteria will be applied to determine the best media, or media mix recommendations. These include considerations such as the requirements for motion, sound, color, interaction, simulation, use of equipment, testing procedure and textual materials.

Operating Instructions. PSE is uniquely qualified to evaluate medical equipment operating instructions having successfully designed and conducted evaluations for the Food and Drug Administration on several medical devices. All instructional materials for remote afterloading brachytherapy equipment and devices will be assessed to determine their content sufficiency for ensuring effective training and accurate operator performance. Criteria for the content analysis will be derived from the task and function analyses and verified by consultation with the Brachytherapy Advisor, in interviews of radiation therapy technicians, and by performance observation.

User Performance Aiding. User Performance Aiding (UPA) will be included in the assessments. UPA need not impart learning but only ensure a prescribed (required) level of performance. Further, it has been shown to be at least 25% more cost effective to aid performance than to train performance. In many cases, of course, formalized training is desirable and necessary, but those instances occur much less frequently than usually thought. A companion device to UPA is the self teaching package that uses current knowledge of self-teaching techniques, formats, and delivery methods to impart certain forms and levels of instruction by self study without the need for formalized instruction.

Transfer of Training. Transfer of training is inferred when performance on a task is influenced by a previously learned task. It can be positive (enhancing), negative (degrading), or zero (having no effect). Positive transfer of training is inferred when an individual who has learned some previous task performs better on a new task than another individual who has no experience with the previous task. Well designed training programs will capitalize on positive transfer whenever possible to facilitate learning efficiency and performance. Negative transfer, on the other hand, occurs when experience with one task interferes with the performance of a subsequent task. It can be a significant source of human error and must therefore be controlled. Transfer of training will be investigated in remote afterloading systems. The goal is to minimize negative transfer effects while at the same time facilitating positive transfer wherever possible. The task analyses and error likelihood predictions from Task 1 provide the means for achieving these effects. The task analyses will reveal both how procedures and operations in remote afterloading differ and how they are similar. High error rates associated with certain procedural steps may turn out to be due to negative transfer effects.

Differences Training. Differences training refers to teaching someone how to perform a certain operation by stressing how it differs from a previously learned operation. Differences training is most effective when the operations are essentially similar to each other and when the trainee is very experienced. This allows the overall behavior pattern established for one operation to be applied to the new operation, with only minor modifications. Differences training emphasizes that different responses are required to similar stimuli.

Our intent in performing the training evaluation is to develop a comprehensive picture of training procedures and requirements for brachytherapy clinical and support personnel. This will allow us to identify any deficiencies that may exist in current training at the sites that we will visit. Given this information, we can then determine the nature of the impact these deficiencies exert on the safe and effective delivery of remote afterloading brachytherapy. We will compare the results of our training evaluation with the human error rate prediction analyses from each Task to determine the role that training procedures play in the root causes of error in remote afterloading.

In order to achieve this goal, we will focus on the following job positions:

- **Radiation Therapy Technician**
  This position is centrally involved in the actual delivery of radiation to the patient. Activities include entering correct treatment dose data into the system console, connecting source transport tubes to patient applicators, monitoring the system and patient during radiation administration, and interacting effectively with other brachytherapy personnel. The required training is usually attained by completing a one or two year technical education program; certification is required.

- **Medical Physicist**
  The medical physicist can be involved in a wide range of brachytherapy functions. These can include treatment planning, dosimetric determinations, treatment simulations, and quality assurance activities. Expertise is required in a number of key areas in order to ensure the successful performance of these various functions. Board certification is required.

- **Dosimetrist**
  The dosimetrist is responsible for determining the correct dosage and treatment geometry for each brachytherapy session. As such, most of the dosimetrist's functions occur during the treatment planning phase of the remote afterloading brachytherapy process.

- **Radiological Engineer and/or Maintenance Technician**
  Proper maintenance of brachytherapy systems is crucial to the safety of patients and medical personnel alike. The radiological engineer and/or maintenance technician are responsible for routine, periodic maintenance procedures, detecting anomalies in any aspect of remote afterloading systems, and responding to inquiries by other brachytherapy personnel regarding ongoing system function.

- **Radiation Safety Officer**
  The radiation safety officer is responsible for overseeing the implementation of and adherence to radiation safety standards by all personnel involved in radiation therapy. As such, considerable accountability to this individual must be assumed by brachytherapy personnel.

- **Brachytherapy Nursing Staff**
  Low dose rate brachytherapy requires that treatment sessions occur on an inpatient basis, often for several days at a time. The nursing personnel who attend these patients should receive thorough training in radiation safety procedures and how to care for patients who have radioactive implants. Failure to do so can result in inadvertent exposure to nursing staff and visitors, as well as jeopardize the well-being of the patient.

Task 4 Letter Report

The Task 4 report will begin by describing the scope and details of task performance, then detail the data collection and analytical methodologies used during the Task 4 site visits. For each of the operational and ancillary functions, information about brachytherapy personnel training and qualifications will provide valuable input about training needs for different classes of personnel, and identify areas currently receiving insufficient or improper emphasis. Results from all training and qualifications evaluations will be provided, and points where error reduction strategies can be implemented in training will be identified.

[redacted]

Throughout the report, effort will be made to identify and characterize factors that facilitate successful performance as well as those that lead to errors in the performance of operational and ancillary functions. Of course, any additional and unexpected findings will also be noted. A summary of progress as compared with planned activities will be given along with a description of costs and hours expended.

Task 4 Milestone Schedule

Subject to NRC authorization, Task 4 will proceed concurrently with Task 5 during the five months following Tasks 2 and 3. A timetable of Task 4 activities is presented in Figure 5. The figure indicates the major task activities, estimated start-up and time to completion for each activity, task products, and projected travel periods.

[redacted]

Task 5 (Optional)

Human Factors Evaluation of Organizational Policies and Practices Related to Remote Afterloading Brachytherapy

In Task 5, the PSE Team will evaluate each operational and ancillary function analyzed in Task 1 with respect to organizational practices and policies. These practices and policies encompass a wide range of factors, including shift schedules, staffing, supervision, lines of authority, and accountabilities. Other factors will also be included in this effort as they emerge from our task analyses. Based on our knowledge of sound organizational principles, specific strengths and weaknesses of different organizational structures will be characterized.

As with all medical services, remote afterloading brachytherapy should be conducted only where there is a sound infrastructure of all professional personnel. The activities of medical personnel (radiation oncologists, nurses, physicists, dosimetrists, radiation technologists) and support personnel (secretaries, clerks) should be coordinated to ensure an effective and smoothly functioning brachytherapy department. As one example of the importance of coordinated activities, supervision of technicians' performance by medical staff has been shown to enhance the quality of their work (Kinnunen, Göthlin, & Hopfner-Hallikainen, 1988).

Predictably, views differ on what type of organizational structure is best. Evens (1989), for example, favors an organization based on an "organ system" model because it easily adapts to the way that clinical care is most often managed. In contrast, Levin (1989) advocates a structure that integrates organ systems and various radiology technologies, arguing that this confers considerable flexibility and adaptability. Regardless of its specific form, an organizational structure should support the mission of the department. The statement of mission and a list of well-defined goals and objectives can help to define extant organizational structure. This information will be obtained during the Task 5 site visits.

The vital role of radiation safety programs in the daily operations of radiology departments underlines the importance of sound organizational policies and practices. Typically, radiation safety programs are overseen by a Radiation Safety Officer. These programs affect the well-being of all persons involved in radiotherapy. They encompass a wide range of activities including (a) conducting facility radiation surveys, (b) establishing radiation safety committees, (c) training department staff in safety procedures, (d) evaluating staff radiation exposure levels, and (e) assessing ongoing practices in handling radioactive sources. Given the crucial nature of these activities, close cooperation between facility management, the radiation safety committee, and the Radiation Safety Officer is essential.

Prepare Field Assessment Tools

[redacted]

Visits to Medical Facilities

Sampling Plan

As discussed in the Task 2 section, four medical facilities will be sampled as part of the Task 5 evaluation. One of these facilities will be selected randomly from those using the GammaMed device, and three will be selected randomly from those using Selectron devices (stratified by geographic region). Other important characteristics of the medical facilities will be recorded as part of the data collected during the visits.

Since Tasks 4 and 5 will be conducted concurrently, this provides the opportunity to evaluate the organizational practices and policies at eight facilities. Two human factors analysts will be used to collect Task 5 data. Their travel will be scheduled so that each visits four medical facilities.

Analytic Approach and Methods

In order to thoroughly address organizational issues in remote afterloading, several key factors must be investigated. These include safety provisions, patterns of communications and decision making, and personnel management practices.

<u>Safety</u>. The first step in a sound organizational safety policy is to establish a written organizational policy statement on the importance of safety. This should be followed up with written procedures to implement the policy. Such a formalized structure is the foundation on which all safety activities in the company are built. It provides the legitimate basis for undertaking safety-related actions and curtails the frequent arguments among various levels of management about what constitutes

acceptable activities. The organizations observed will be assessed based on the level of management commitment to safety issues.

Because physical conditions are among the most obvious safety hazards, it is important that they be dealt with quickly to demonstrate management commitment. Relations with local, state, and federal safety agencies also reflect on management commitment to safety. Health institutions with written safety policies and guidelines that have adequate follow-through but that are constantly at odds with government safety officials may be sending confusing messages to their employees. A positive public image will enhance positive employee attitudes and send consistent messages to employees about the importance of safety.

Communication and Decision Making. Organizations must ensure an adequate flow of information in the organization. The flow must be both vertical and horizontal within the organizational hierarchy. One approach for dealing with safety communications is to establish communication networks. These are formal structures to ensure that information gets to the people who need to know the messages. These networks are designed to control the amount of information flow, guarding against information overload, misinformation, or a lack of needed information. Such networks are tailored to the specific needs of the organization. They are vital for eating hazard awareness and disseminating general safety information. It is ssary that information regarding a hazardous event be passed on from one shift to the next, which allows all workers potentially affected to be alerted to its presence. Witho t a communication network, vital information may not get to all affected employees and an otherwise avoidable accident might occur.

Organizational decision making is an important motivational tool for enhancing employee safety performance. Decisions about task organization, methods, and assignments should be delegated to the lowest level in the the organization at which they can be logically made; they should be made at the point of action. This level in the organization has the greatest knowledge of the work processes and operations and of their associated hazards. Such knowledge can lead to better decisions about hazard control. Diverse input to decision making for all organizational level makes for better decisions because there is more input to work with. Also, this spreading of responsibility through input to decision-making promotes worker and first-line supervisor participation. This type of participation gives workers greater control over their work tasks and a greater acceptance of the decisions about hazard control because of the shared responsibility (Smith & Beringer, 1987). Decisions that impact worker safety should be made as quickly as possible to reduce risk exposures and communicate management goodwill to the workers.

Personnel Management. Organizations have an obligation to increase company effectiveness by using modern personnel practices. These include appropriate selection and placement approaches, skills training, promotion practices, compensation practices, and employee assistance programs. For safety purposes the matching of worker skills and needs to job task requirements is an important consideration. It is inappropriate to place employees at job tasks or which they lack the proper skills. This will increase injury risk and job stress.

Selection procedures must be established to obtain a properly skilled work force. When a skilled worker is not available then training must be undertaken to get skill levels increased before a task is undertaken. This assumes that an employer has carried out a job task analysis and knows the skills required. It also assumes that the employer has devised a way to test for the required skills. Once these two conditions have been met, the employer can optimize the fit between employee skills and job task requirement through selection, placement, and training. Many union contracts require that workers with seniority be given first consideration for promotions. Such consideration is in keeping with this approach as long as the worker has the appropriate skills to do the job task, or the aptitude to be trained to attain the necessary skills.

The way in which work tasks are organized into organization-wide activities, the style of employee supervision the motivational climate, the amount of socialization and interaction among employees, the amount of support employees receive, and management attitude toward safety can all have an influence brachytherapy safety and effectiveness. Management attitude has often been cited as the most critical element in a successful safety program (Cohen, 1977). If the individuals that run the organization have a disregard for safety considerations, then the management atmosphere will not be one that fosters employee motivation to work safely. Conversely, if the management attitude is one in which safety considerations are paramount (even more important than production goals), then employees will show due respect for safety and safety performance will reflect this respect (Smith & Beringer, 1987).

There are other organizational considerations that are important in safety performance and related to management atmosphere and attitudes. For instance, a management structure that provides for frequent employee interaction with their supervisor and with other employees, as well as frequent social support, will instill an organizational climate that is conducive to cooperative efforts in hazard recognition and control. Such a structure encourages the motivational climate necessary for appropriate safety behavior (Smith & Beringer, 1987).

Task 5 Letter Report

The Task 5 report will begin by describing the scope and details of task performance, then detail the data collection and analytical methodologies used during the Task 5 site visits. For each of the operational and ancillary functions, the evaluations of organizational policies and practices will aid in identifying areas currently receiving insufficient emphasis. Results from all training and qualifications evaluations will be provided, and points where misadministration and accident reduction/prevention strategies strategies can be implemented will be identified.

The Task 5 discussion will center around the four task variables that received major focus during the site visits: (a) safety provisions, (b) patterns of communication, (c) patterns of decision making, and (d) personnel management practices and policies. When considered together, these four factors will generate a comprehensive picture of the types of organizational practices brachytherapy activities are currently embedded as well as suggest sources of errors that are linked to organizational factors.

Throughout the report, effort will be made to identify and characterize factors that facilitate successful performance as well as those that lead to errors in the performance of operational and ancillary functions. Of course, any additional and unexpected findings will also be noted. A summary of progress as compared with planned activities will be given along with a description of costs and hours expended.

Task 5 Milestone Schedule

Subject to NRC authorization, Task 5 will proceed concurrently with Task 4 during the five months following Tasks 2 and 3. A timetable of Task 4 activities is presented in Figure 6.

The figure indicates the major task activities, estimated start-up and time to completion for each activity, task products, and projected travel periods.

TASK 6 (OPTIONAL)

Identify and Prioritize Areas for Recommended NRC and Industry Attention

Task 6 will take an integrated look at the findings from Tasks 1 through 5. Based on this, specific factors causing human errors will be identified, and the impact of these human errors on safe system performance will be determined. Specific alternative approaches for addressing significant safety problems will then be made.

PSE is experienced in translating the results of its studies into approaches for resolving human factors problems that are directly usable by Government agencies. We understand that in order for the approaches to be most useful, they must be understood clearly, offer specific, executable, and if possible, quantitative guidelines; they should also suggest feasible alternatives for implementation. Alternatives will be presented in terms of their potential value for increasing the safe and effective delivery of brachytherapy using remote afterloaders.

Identify Factors Contributing to Human Error

The results of Tasks 1 through 5 will reveal the interface, procedural, training, and organizational factors that contribute to human errors in the process of brachytherapy using remote afterloaders. Because of the detailed way in which these data will have been collected and analyzed, it will be possible to identify precisely which factors caused (or are likely to cause) specific human errors. Thus, we will be able to define the relationships between human errors and various factors influencing the remote afterloading process.

Task 1 will establish the structure of the functions and tasks comprising the remote afterloading process. This structure also identifies the types of human error that are possible and the locations in the process where they could occur. Initial estimates of the likelihood of these errors were made based on (a) available published data, (b) general human factors data on error, and (c) expert judgements. Tasks 2 through 5 extended this model of human error in remote afterloading to include specific influences from human - system interface, procedural, training, and organizational factors. In particular, these Tasks examined how variations in these factors impacted the likelihood of human errors in each of the functions and tasks in the remote afterloading process.

Task 6 brings these data together in an integrated manner. For each factor, we will identify specific instances and conditions that have been found to affect human error likelihood. We will also indicate the magnitude of the effect of these factors on error likelihood.

Evaluate the Impact of these Factors on Performance

We will then apply these detailed and specific relationships between factors and errors to the remote afterloading function and task structure that we developed in Task 1. This will permit us to determine the impact of these factors on critical outcome measures of remote afterloading system effectiveness, namely patient misadministrations and radiation hazards. Essentially, this effort examines the causal linkage between factors, errors, performance of remote afterloading functions and tasks, and system effectiveness.

[redacted]

Prioritize Problems Associated with Human Error

[redacted]

Identify and Evaluate Alternative Approaches

The Principal Investigator, together with the Senior Human Factors Engineer and the Brachytherapy Advisor, will work together jointly to develop and evaluate alternative approaches for resolving significant safety problems in brachytherapy using remote afterloaders. This will be accomplished in a two-part session. In order to stimulate and to focus the discussion, the Principal Investigator will have first generated several "straw man" alternatives for reducing the incidence of performance problems. These "straw man" alternatives will be based on the lessons learned from the human factors analyses and field evaluations in Tasks 1 through 5. Advantages and disadvantages of each will be listed.

[redacted]

[redacted]

Present Findings

It is important that the overall findings from this project be presented to the NRC and to other interested parties as soon as possible. Thus, both briefings and a comprehensive technical report are planned at the conclusion of this project.

We understand that two technical briefings will be scheduled near the end of the project in order to present the findings and to discuss their implications. The first presentation is a Review Group Meeting, estimated to be held approximately 17 months after contract award. The other technical presentation will be held at NRC Headquarters during the final month of the contract. These presentations will enable NRC staff and other interested parties to obtain a "quick look" at the results before the final technical report is delivered and to interact directly with the researchers responsible for conducting the project.

Task 6 Technical Report

The Task 6 report will synthesize and integrate the findings from Tasks 1 through 5. The goal of this report is to provide a comprehensive picture of remote afterloading brachytherapy as it is currently practiced in the United States, with particular emphasis on system errors and their root causes .

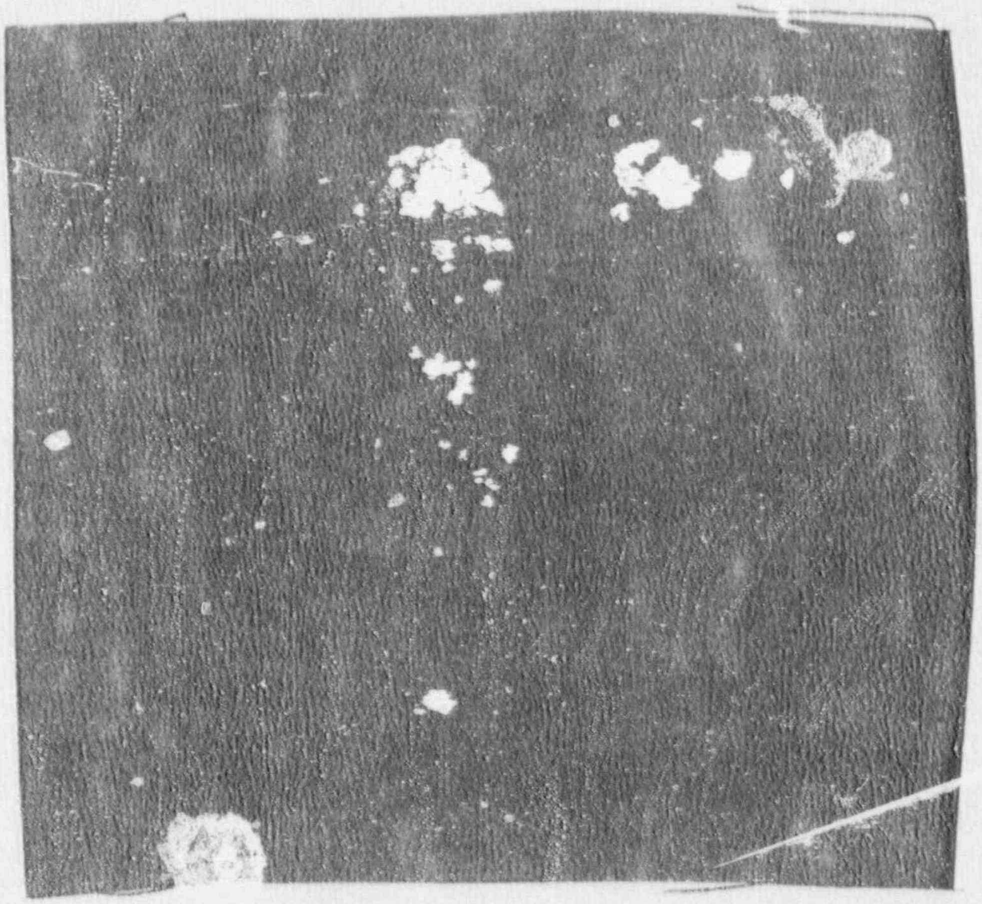
A thorough description of the specific factors contributing to actual and potential errors in remote afterloading will be given. For each factor, we will identify (a) the specific operational and ancillary function affected, (b) the specific conditions under which each factor exerts its greatest effect, and (c) means by which these factors can be minimized such that successful system performance can be achieved.

These detailed, specific relationships between factors and brachytherapy system functions will be carefully linked to the task and human error analyses developed in Task 1. And the magnitude of each factor on error likelihood will be discussed. All additional and unexpected findings encountered during the project will also be noted, and their relationship to other findings will be discussed.

As specified in the Request for Proposals, the Task 6 report will be prepared in accordance with the guidelines in NUREG-0650. A draft copy of this report will be submitted to the NRC Project Officer for review and evaluation. Comments and corrections received from the NRC Project Officer will be fully addressed, and two copies of the the revised NUREG/CR will be submitted as specified in the contract.

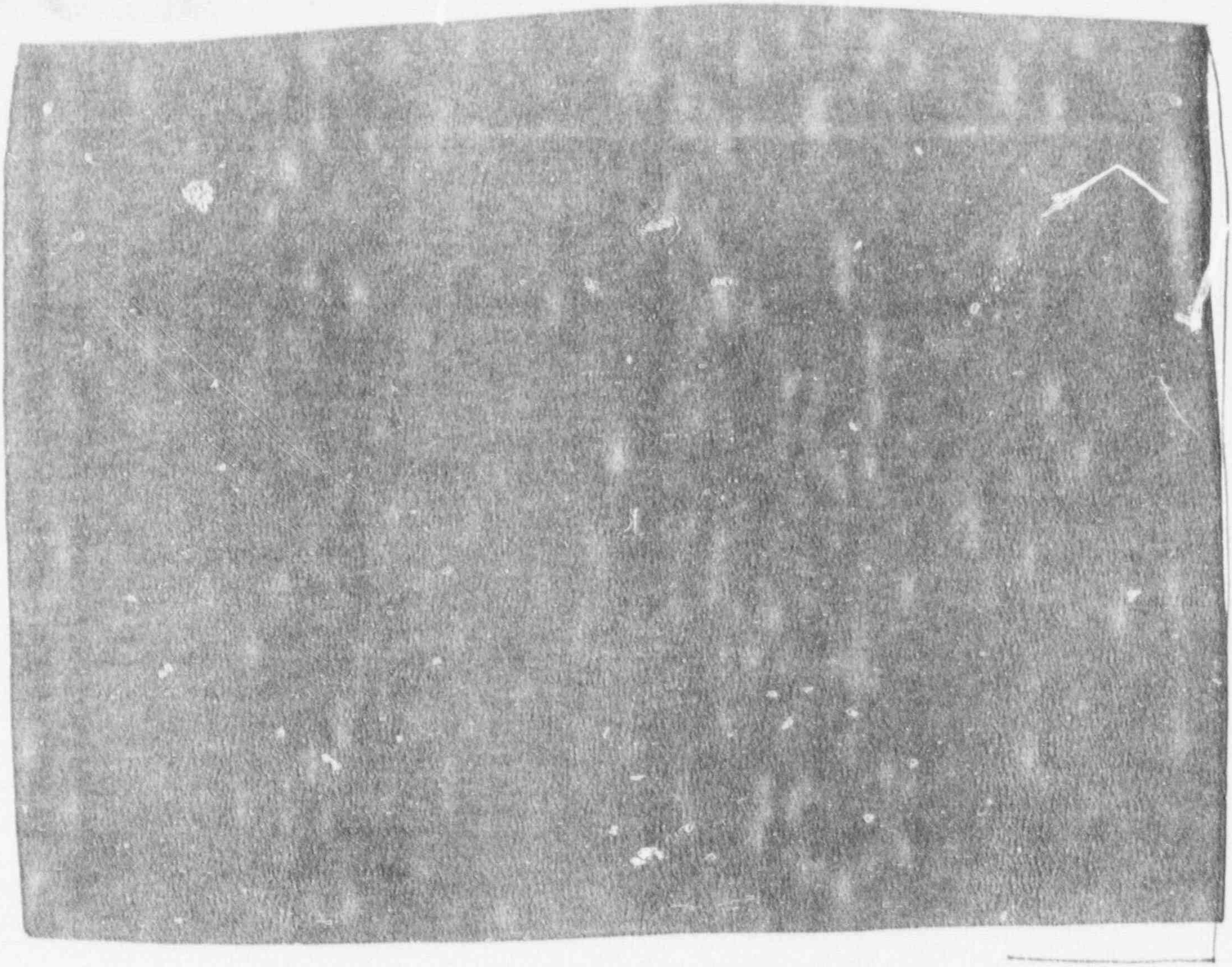
Task 6 Milestone Schedule

Figure 7 presents the plan of action and milestones for Task 6. Each of the project staff is expected to make a significant contribution to this Task, which involves integrating all of the findings and examining alternative approaches to human error / performance problems.



Relevant Human Factors Guidelines, Protocols, and Standards

Although there are few human factors guidebooks and technical sources that directly relate to the issues addressed by this project, we believe that much of the information in other human factors publications can be successfully adapted. Some of these human factors guidelines, protocols, and standards are listed below [redacted]



Potential Problem Areas and Solutions

Several potential problem areas exist in this project. These are listed below along with proposed solutions and contingency plans. None of these problems are severe enough to prevent the successful completion of this project. Furthermore, an awareness of them at the outset can help them be avoided altogether.

1. Misadministration errors may not be observed. Although accident reports involving brachytherapy misadministration errors have been filed with NRC it is highly unlikely that any misadministration errors will be observed during our site visits. Serig (1989), for example, lists a total of three such errors during 1987. In a complex system such as remote afterloading, numerous operational and procedural errors can occur that do not lead to a catastrophic outcome. However, they do impair the overall safety and effectiveness of the brachytherapy process. They should therefore be identified and the manner in which they interact with each other determined. Interactions among such errors are important because the combined effect of particular combinations of them can be different than the sum of their separate effects.

[redacted]

3. Lack of understanding of the brachytherapy remote afterloading process. Significant knowledge is needed to evaluate the existing equipment, operations, training, and organizational policies. [redacted]

4. Reluctance of medical facilities to cooperate during site visits. Another potential risk involves gaining access to the brachytherapy distributors and medical facilities in a timely manner during Tasks 1 through 5. If these distributors and medical facilities prove reluctant to grant access, then performance of this project would be severely impacted. This risk has been reduced somewhat by preliminary contacts with several medical facilities, who have been informed of this project and have indicated a willingness to cooperate. Administrative assistance by the NRC Project Officer will further reduce this potential risk.

5. Human factors analytic techniques tend to adopt a narrow perceptive. Human factors techniques are often very detailed and analytic. They provide highly specific, fine-level, descriptions of the human-machine system to which they are applied. In this light, they have been criticized as failing to construct an overall, global view of the system under study. This shortcoming, if not addressed through careful planning and design, can complicate the assessment of interactions among system components and the identification of contributory factors to human error. It can lead to a failure to see the forest for the trees.

[redacted]

[redacted]

6. Traditional approaches to task analyses tend to neglect cognitive processes. Task analysis is a primary human factors technique used in this project. It is a formal methodology, derived from systems analysis, which describes and analyzes the performance demands made on the persons who interact with a system. By focusing on the human element in the system, task analysis can compare task demands with known human capabilities. Traditional task analyses place a heavy emphasis on perceptual factors, procedural behaviors, and motor output, with a corresponding deemphasis on cognitive activities.

[redacted]

7. Human error analyses may not properly reflect the true magnitude of errors. Human error analysis is another major human factors technique that will be employed in this project. It is useful for specifying error probabilities associated with each step of a function that has been previously characterized by task analysis. Error analysis does have certain limitations, however. Most importantly, it tends to over-estimate error probabilities. It treats errors as though they are independent of each other; usually they are not. Furthermore, analyzing this interdependence of errors is often a key to thoroughly understanding system function.

[redacted]

8. There is likely to be a lack of adequate error data. System errors during brachytherapy using remote afterloading are extremely rare. Thus, it is unlikely that any will be observed during the site visits and that any will have been recorded in to medical facilities' records. Moreover, even if data on such low frequency errors are encountered, it is doubtful that sufficient information will have been recorded to permit an adequate evaluation of the contributing interface, procedural, training, and organizational factors.

[redacted]

[redacted]

9. Methods are needed to determine informal practices and policies. Informal practices and policies are especially sensitive indicators of the adequacy of existing system performance. If they are widely used, this indicates that the persons who interact with the system have felt the need to introduce their own modifications in order to simplify their tasks and make the system safer and more effective. Invariably, these remediations are not systematically reviewed in terms of their positive or negative impact on system performance. The methods described below have been selected especially for their ability to detect how informal measures influence human-system interfaces, use of procedures, and training program effectiveness.

[redacted]

QUALIFICATIONS AND EXPERIENCE

Personnel Qualifications

PSE has assembled an exceptionally well qualified technical staff in order to meet the requirements of this project. This project requires professionals who not only are qualified in human factors analysis and evaluation techniques but who also have had direct, real-world experience in applying these techniques. PSE has successfully assembled such a team.

Human Factors Engineers

The key personnel for this project are James R. Callan, PhD and Frederick A. Muckler, PhD. Dr. Callan is the Principal Investigator for this project. He has over 17 years experience in human factors research and development efforts, resulting in numerous technical publications that continue to be cited as important contributions in their fields. Most recently, Dr. Callan has been one of the principal scientists on two human factors evaluations of medical devices. An assessment of blood glucose meters included evaluations of equipment, educational practices, and instructional materials. An ongoing study of contact lens care has focused on improving the instructional materials supplied by manufacturers of soft contact lenses. In both studies, task and function analyses were performed on the procedures involved. Dr. Callan has a recognized reputation for successfully managing complex technical projects. He has over 12 years of experience in supervising and directing teams of scientists and analysts working on diverse applied scientific programs. Dr. Callan's technical background and project management skills make him the ideal choice as Principal Investigator.

Dr. Muckler is an internationally recognized leader in the human factors field with more than 30 years experience in human factors research. He is a Fellow and Past President of the Human Factors Society. Dr. Muckler has been an active contributor to several PSE projects, and his skills and experience will be a valuable asset to this project. As the Senior Human Factors Engineer, Dr. Muckler will work with the Principal Investigator to define and direct the technical work in this project. Other members of the project team will include Dr. John Gwynne and Dr. Richard Kelly. Both of these senior scientists have worked on directly relevant projects in human factors evaluation of medical devices and in function / task analysis of complex systems. Drs. Gwynne and Kelly will assist in accomplishing this project.

All these individuals have cooperated in performing comprehensive human factors studies that evaluated the role of human error and its root causes in complex man-machine systems. They have demonstrated their ability to work together effectively as a team by producing high quality human factors and analytic studies on-time and within budget for Government agencies. If needed, PSE also has staff qualified in ergonomics, occupational health and safety, computer science, industrial / organizational psychology, and instructional technology. The full range of administrative and secretarial support is also available at no additional cost to this project.

Brachytherapy Advisors

William Saunders PhD, MD will also play a key role in the successful accomplishment of this project. He has exceptional research and clinical expertise in brachytherapy, teletherapy, radiation safety, medical physics, and other directly related topics. Dr. Saunders' research includes computer-controlled radiation therapy and charged particle radiotherapy. He will be able to resolve many methodological problems and make specific recommendations throughout the ongoing project. Accordingly, he will provide direction and expert advice to the efforts carried out by the human factors staff.

Dr. Saunders is Professor of Radiology and Chief, Division of Radiation Oncology at the University of California Medical Center, San Diego, California. He has had extensive training and practice in brachytherapy as a part of his specialty training in radiation oncology. Periods of extensive brachytherapy training and experience include:

Professor of Radiology
Chief, Division of Radiation Oncology
Department of Radiology
University of California Medical Center
San Diego, California
July 1988 to Present – continuous.

Assistant Professor of Radiation Oncology
Harvard Medical School
and Chief of Radiation Therapy
New England Deaconess Hospital
Cambridge, Massachusetts
July 1985 to July 1988 – continuous.

Assistant Professor of Radiation Oncology
University of California Medical Center
San Francisco, California
July 1980 to July 1985 – continuous.

Resident in Radiation Therapy
Department of Radiation Therapy
Stanford Medical Center
Stanford, California
July 1974 to June 1978 – continuous.

Dr. Saunders currently manages approximately 25 patients daily for teletherapy and 1-2 per week for brachytherapy; he supervises 2 medical physicists (1-PhD and 1-MS), 1 dosimetrist, and 6 radiation technologists. His Department at the University of California at San Diego is equipped with a Gamma Med II-i system using GE / Minivax-based treatment planning. He also has access to a Selectron system, which is available at a nearby clinic. Dr. Saunders has a long and pioneering experience in remote afterloading brachytherapy, from basic radiation and radiotherapy research to daily operation and clinical application.

During the years that he was at the Harvard Joint Center for Radiation Therapy, Dr. Saunders was the Principal Investigator for a project to develop, implement, and evaluate a technique called "Computer Controlled Radiotherapy," or CCRT. This project was an effort to optimize the distribution of radiation dose within patients receiving teletherapy treatments, by using a computer to modulate many of the parameters of the treatment in "real time" during a treatment. In conventional radiotherapy, most of these factors (other than the angular position of the gantry in a subset of patients) are held constant. It was hoped that by simultaneously varying parameters such as dose rate, beam size, gantry angle, collimator angle, and patient couch position, optimized dose distributions could be achieved. Because of the complexity of these treatments, there were many patient safety issues that had to be resolved.

In addition to Dr. Saunders' experience in radiation therapy, other staff of the Radiation Oncology Division of UCSD Medical Center will be included as subject matter experts in brachytherapy. Provisions have been made for including a medical physicist, a dosimetrist, and a radiation therapy technician.

Roger Rice, Ph.D., Chief of Radiation Oncology Physics, UCSD Medical Center

Dr. Rice received his doctorate in Atomic Physics from North Texas State University in 1981. He was an Associate Scientist at the Fermi National Lab, then was a Research Fellow at the Harvard Joint Center before going on staff there in 1987-1988. He was then recruited by Dr. Saunders to come to UCSD. He has published extensively in the field of medical physics.

Richard Lepage, Medical Physicist, Radiation Oncology Physics, UCSD Medical Center

Mr. Lepage received a B.S. in 1980 from the Massachusetts College of Pharmacy, and worked as a Radiopharmacist at Harvard Medical School until 1982. He then joined the Balboa Naval

Hospital, San Diego, in the same role. Due to the s' ing needs of the Navy, in the ensuing years he trained in medical physics while fulfilling his duties as a Nuclear Pharmacist. In 1989, he received an M.S. in medical physics from San Diego State University. He is now working full-time as a medical physicist in the UCSD Radiation Oncology Division.

Elain Chin, Dosimetrist and Chief Technologist, Radiation Oncology, UCSD Medical Center

Ms. Chin received her B.S. in Biology from the University of California at San Francisco (UCSF) in 1979 and completed training in radiotherapy technology in the City College of San Francisco/UCSF program in 1981. She began working at UCSD in 1982, rose quickly to become Chief Technologist, and developed special expertise in dosimetry.

The addition of others, such as a radiological engineer or maintenance technician, may be appropriate and could further enhance evaluations of the various maintenance, calibration, and quality assurance activities that occur in remote afterloading brachytherapy.

Dr. Saunders and his staff are enthusiastic about participating in this project for the NRC. As clinical professionals in brachytherapy, they are eager to improve treatment quality and safety. They are also keenly aware of the significant role of human factors.

Whereas we expect that Dr. Saunders will make substantial contributions to all tasks in this project, the anticipated roles for the others are somewhat more specialized. This specialization is intended to bring those who have the most directly relevant experience to each project task.

The UCSD brachytherapy advisors will participate in the 3-person site visits to medical facilities in Tasks 1 – 5 of this project. This will help to assure that important technical issues are evaluated thoroughly. Throughout the project, the UCSD brachytherapy advisors will also contribute detailed technical information within their specialty areas, help interpret the site visit findings, and provide quality assurance review of the project's technical reports.

Summary of Related Experience

Table 1 summarizes the number of years of experience that each team member has relative to their roles and responsibilities in this project. It is apparent that this team is exceptionally well qualified to perform this project for the NRC. Each of the areas of responsibility are thoroughly covered by the team selected to perform this project.

The site visits to the equipment distributors and medical facilities are of critical importance to the successful completion of this project. We expect that, as is common in field data collection, many unique and unanticipated situations will arise that require immediate professional judgment. Thus, we considered it essential that some of our most experienced professional staff be directly involved in this project.

In addition to the team members proposed for this project, PSE has many other professionals who can be called upon as necessary for support and technical advice. These staff include specialists in ergonomics, occupational safety, software development, training systems, industrial / organizational psychology, system engineering, and operations research / analysis. Various technicians and administrative staff are also available, and their services are provided to the project automatically (as indirect overhead).

Table 1

Experience Summary of Project Team Members (Years)

Task	Role / Responsibility	Callan	Muckler	Gwynne	Kelly	Saunders	Rice	Lepage	Chin
1	Task & error analyses	6	30	4	15	-	-	-	-
	Brachytherapy activities	-	-	.5	-	14	8	5	6
2	Human-system interfaces	14	30	4	15	-	-	-	-
	Brachytherapy systems	-	-	.5	-	14	8	5	6
3	Procedural evaluations	20	30	5	15	-	-	-	-
	Brachytherapy procedures	-	-	-	-	14	8	5	6
4	Training evaluations	20	20	5	15	-	-	-	-
	Brachytherapy trng/quals	-	-	-	-	14	6	5	6
5	Organizational assessment	9	10	1	8	-	-	-	-
	Brachytherapy org policies	-	-	-	-	14	6	5	5
6	Ident problems/eval alterns	20	30	4	15	20	12	7	8

Resumes

Resumes are provided on the following pages for Drs. Callan, Muckler, Gwynne, Kelly, and Saunders.

JAMES R. CALLAN

Availability 40% **Status** Current Employee

Education

PhD	Biological Psychology, 1976	University of Oklahoma
MS	Biological Psychology, 1973	University of Oklahoma
BA	English Literature, 1957	University of Oklahoma

Employment History

1984 - Present	President Pacific Science & Engineering Group, Inc., San Diego, CA
1983 - 1984	Head, Human Performance Division Navy Personnel Research and Development Center, San Diego, CA
1982 - 1983	Head, Human Engineering Branch Naval Ocean Systems Center, San Diego, CA
1977 - 1982	Engineering Psychologist Navy Personnel Research and Development Center, San Diego, CA
1970 - 1977	Research Associate University of Oklahoma Health Sciences Center and Veterans Administration Hospital, Oklahoma City, OK
1958 - 1970	United States Navy

Professional Experience

Human Factors Engineering in System Development

Provided human factors and human engineering expertise for the design of displays and controls. Analyzed combat center arrangements using mockups,and models. Reviewed design specifications and requirements with respect to human engineering guidelines for ease of use and operability. Assessed methods for improvement of the operational performance of ship systems and the improvement of habitability and safety for maritime personnel.

Provided extensive human factors engineering support to the program manager and design engineers for the Submarine Advanced Combat System (SubACS) program. This included a detailed review of the layout of the Weapons Launch Console, an evaluation of displays for the Wide Aperture Array sonar system, development of human engineering design standards regarding the use of color in CRT displays, assessment of combat center arrangements using mockups, and review of design specifications and requirements with respect to human engineering considerations.

Developed methods for improvement of the operational performance of ship systems and the improvement of habitability and safety for ship's personnel. Supervised the human engineering program for the Advanced Combat Direction System, including display and control design. Participated in design reviews.

Analyzed requirements for Army Helicopter Pilot Training Programs. Developed a new, computer, data-base of flight performance and aptitude measures for pilots transitioning into a new attack helicopter. Created user interfaces to enable the system to be operated by instructor pilots having no experience with data-bases, little or no computer knowledge and low keyboard skills. Developed performance tests of data-base entry, and data access as performed by instructor pilots and Army Training Managers.

Human Factors / Training Research and Development

Consulted with training system designers to provide guidance for operability and training effectiveness. Served as industry consultant to the National Security Industrial Association on Anti-Submarine Warfare training.

Designed a system to evaluate submarine attack officer performance in submarine vs. submarine operations. Designed desktop computer system to train submarine officers in elementary tactical concepts. Designed and developed training and performance evaluation systems for Navy tactical combat systems, and command and control systems. Designed microcomputer programs to teach officers decision making, sonar search, and sonar employment.

Conducted field and laboratory research measuring human performance, information processing accuracy, and reaction time on operational system controls and displays. Participated in the observation and analysis of inport READIEX AAW exercises, conducted in San Diego in preparation for Battle Group deployment. Observed the Aegis system as Command and Control Center for the Battle Group AAWC.

Designed research programs and experiments for the NOSC RESA facility to test the cognitive performance of Naval personnel operating as Anti-Air Warfare Commander (AAWC) of a Carrier Battle Group in the 1990s. Analyzed measures of effectiveness and performance of the AAWC during the Outer Air Battle defense of the BG against massive Orange air strikes. Assisted NOSC personnel in preparing briefing materials and in briefing ONT and ONR sponsors on results of the experiments.

Experimental Neuropsychology and Cognitive Psychology Research

Performed basic research and analysis in the following areas: Interhemispheric information processing and laterality of attention processes in humans under cognitive stress. Performance measurement on chronic and acute alcoholics, and normal individuals under acute alcohol influence. Basic research in perception, attention, sensation, and cognitive processes. Administered test batteries for measuring memory deficit and other cognitive impairment in patients in Neurology and Psychiatry wards, University and VA Hospitals. Analyzed and measured Navy operational job performance. Correlated with aptitude test results on the Armed Services Vocational Aptitude Battery.

Management and Planning

Within the Navy Laboratories in San Diego, supervised teams of researchers in human performance evaluation and measurement. Identified and planned future research and development programs involving personnel, training, and human factors.

At the Naval Ocean Systems Center, managed teams of specialists in Advanced Combat Directions System display and control design, communications system training, human factors for shipboard habitability, and shore-based command and control equipment integration and evaluation. Member, Navy Laboratory Warfare Advisory Group (NWAG) and Director of Navy Laboratories (DNL) Long Range Planning Team. Responsible for identifying and planning future research and development programs involving personnel, training, and human factors for the Naval Ocean Systems Center and the Navy Personnel R&D Center.

Managed teams of specialists in communications system training for submarines, human factors for shipboard habitability, electronic warfare equipment design, and shore-based command and control equipment integration and evaluation. Established and managed R&D programs for federal laboratories and regulatory agencies. Created several successful proposals for nationally competed grants and contracts.

Professional Affiliations

Human Factors Society   Sigma Xi   Submarine League   Navy League

Licensure

Licensed Research Psychologist. California Board of Medical Quality Assurance

Selected Publications and Technical Reports

Kelly, R. T., Callan, J. R., Kozlowski, T. A., Jenkins, J. A., and Meringola, E. D. (September, 1989). User performance with blood glucose meters. San Diego, CA: Pacific Science & Engineering Group, Inc.

Callan, J. R., Kelly, R. T., and Conway, E. J. (September, 1989). Human factors assessment of diabetes educational materials. San Diego, CA: Pacific Science & Engineering Group, Inc.

Callan, J. R., Kelly, R. T., Kozlowski, T. A., and Mathews, W. D. (August, 1989). Effects of improper maintenance and operation procedures on blood glucose meter readings. San Diego, CA: Pacific Science & Engineering Group, Inc.

Kelly, R.T., Callan, J.R., Kozlowski, T.A. and Conway, E. J. (September 1988). Human factors analysis of blood glucose monitoring. San Diego, CA: Pacific Science & Engineering Group, Inc.

Callan, J. R., and Scott, J. F. (May 1987). Selective Aptitude and Performance Assessment of Navy Operations Specialists. San Diego, CA: Pacific Science & Engineering Group.

McTighe, R. P., Wright, C. L., Callan, J. R., Kelly, R. T., & Barten, K. (January 1986). Task analysis information requirements analysis for battle group personnel. San Diego, CA: Essex Corporation. (Confidential)

Callan, J. R., Curran, L. E., and Lane, J. S. (May 1977). Visual search times for navy tactical information displays. (NPRDC TR 77-32), San Diego, CA: Navy Personnel Research and Development Center. (NTIS No. AD-A040 543).

Bertera, J. H., Callan, J. R., Parsons, O. A., and Pishkin, V. (1975). Lateral stimulus-response compatibility effects in the oculomotor system. Acta Psychologica, 39, 175-181.

Callan, J. R., Klisz, D., and Parsons, O. A. (1974). Strength of auditory stimulus-response compatibility as a function of task complexity. Journal of Experimental Psychology, 102, 6, 1039-1045.

FREDERICK A. MUCKLER

Availability 50% **Status** Part-Time Employee

Education

Ph.D.	Psychology, 1961	University of Illinois
M.A.	Psychology, 1953	University of Illinois

Employment:

1988 - Present	Senior Human Factors Engineer Pacific Science & Engineering Group, Inc. San Diego, CA
1982 - 1988	Chief Scientist Essex Corporation. San Diego, CA
1979 - 1982	Chief Scientist Canyon Research Group Westlake Village, CA
1974 - 1979	Director, Human Factors Program Navy Personnel R&D Center San Diego, CA
1967 - 1974	President Manned Systems Sci- -ces, Inc.
1964 - 1967	Staff Scientist Bunker-Ramo Corporation Los Angeles, CA
1956 - 1964	Senior Scientist Martin-Marietta Corporation Los Angeles, CA
1951 - 1956	Graduate Research Assistant University of Illinois, Aviation Psychology Laboratory

Professional Experience

Dr. Muckler has over 30 years experience in human factors engineering research. He is a Fellow of the American Psychological Association, a Fellow of the Human Factors Society and a Fellow of the American Association for the Advancement of Science. He has taught human factors and psychology courses at California State University, Northridge, CA, the University of California at Los Angeles, California State University, Los Angeles, and the University of Southern California. Dr. Muckler has served as President of the Human Factors Society, President of the Society of Engineering Psychologists, Editor of the Human Factors Journal, and filled various national positions in human factors professional organizations. He has served as a consultant to government and industry, and as an expert in human factors research and training system design. He has carried out responsibility for the conduct of programs of research in man-machine system design, productivity, performance appraisal, cost-effectiveness analysis and manpower and personnel problems in systems.

Professional Affiliations

Past President and Fellow, The Human Factors Society,
Past President, Division 21, American Psychological Association
Fellow, American Psychological Association
Fellow, American Association for the Advancement of Science

Selected Publications and Technical Reports

Babbitt, B.A., Muckler, F.A., and Seven, S.A. (February, 1988) Training and Human Factors Research in Military Systems: A Final Report. Essex Corporation, Westlake Village, CA

F. A. Muckler, Ed. Human Factors Review; 1984. The Human Factors Society, Santa Monica, CA

Introduction to Psychopathology. (1985) Second Edition, Prentice Hall, New York (with L. I. O'Kelly).

Standards for the design of controls - a case history. Applied Ergonomics, 1984, (15.3), 175-178.

The future of human factors. Human Factors Society Bulletin, February, 1984, 27(2), 1-2.

New technology for training: An evaluation of the air controller exercise (ACE). Proceedings of the 26th Annual Meeting of the Human Factors Society, October, 1982, 758-762 (with M. E. McCauley and R. W. Root).

Evaluating productivity. In M.D. Dunnette and E.A. Fleishman (Eds.) Human performance and productivity, Volume 1: Human capability assessment. Hillsdale, New Jersey: Lawrence Erlbaum Associates, 1982, p 13-47.

JOHN W. GWYNNE III

Availability 60% **Status** Current Employee

Education

PhD	Experimental Psychology, 1988	University of New Mexico
MS	Experimental Psychology, 1984	University of New Mexico
BA	Biology, 1978	University of California at San Diego

Employment History

1988 - Present Research Scientist
Pacific Science and Engineering Group, San Diego, California

1984 - 1987 Graduate Research Assistant
University of New Mexico, Albuquerque, NM

1985 - 1985 Graduate Student Intern
Navy Personnel Research and Development Center, San Diego, CA

Professional Experience

Eight years progressive experience in designing, conducting, analyzing, and interpreting behavioral science experiments in the areas of human factors and human performance. Focus has been placed on identifying and evaluating cognitive, motivational, and perceptual factors that influence task performance and probability of human error in complex man-machine systems. In almost all cases, extensive first-hand observation of individuals and the systems with which they interact have been undertaken.

<u>Medically Oriented Human Factors Research</u>

Currently evaluating factors that determine the effectiveness of instructional and educational materials for a medical device (contact lenses). Cognitive and motivational factors that determine whether contact lens wearers properly clean and disinfect their lenses will be characterized. Improved instructional materials will be produced to increase adherence to necessary lens care tasks and procedures, and to decrease the likelihood of errors.

Analyzed human factors data on the use of portable blood glucose meters by diabetics. Evaluated cognitive and motivational factors affecting the extent to which people both comprehend and comply with prescribed monitoring procedures. When deviations were observed, analyses identified their potential root causes. Suggestions were made for redesign of equipment and system features to make blood sugar monitoring safer and more reliable.

<u>Human Performance Studies in Advanced Technology Systems</u>

Investigated factors affecting decision making in Naval warfare environments. Described information fusion and utilization, identified and characterized cognitive factors involved in strategic decision making, and performed experimental validation of new cognitive performance models. Analytic tools used include spatial and network scaling techniques. Spatial models provide global descriptions of psychological variables whereas networks define relationships among closely related concepts. Verbal protocol analysis was also used to examine information utilization, tactical approaches, and cognitive factors in decision making.

Professional Experience (continued)

Assisted on a computer-based Naval training project to formulate principles of decision making in combat systems with geographically distributed decision nodes. A technical paper described organizational architectures in Naval battle groups and their interaction with cognitive variables implicated in strategic decision making.

Theoretical Research in Human Information Processing Abilities

Participated in studies of a continuous flow model of human information processing and decision making that incorporated perceptual as well as cognitive processes. Published papers on the interference and facilitation produced by irrelevant information in visual displays and the effects of repeating information when people must do more than one task at the same time.

Examined cognitive attributes of human-system interfaces in automated computerized systems. Investigated the effect of different display formats and control-display configurations on task performance.

Professional Affiliations

Human Factors Society

Computer Skills

Experienced with DOS, UNIX, and Macintosh operating environments; performing statistical analyses with various commercially available statistical packages (e.g., Statview, Systat, SPSS-X); writing experimental control and statistical analysis programs in Pascal and APL; and applying various database management techniques to human factors and behavioral science data.

Selected Publications and Technical Reports

Gwynne, J.W., Kelly, R.T., Callan, J.R., & Meringola, E.D. (1989). *Perceptual Sensitivity to Blood Glucose by Self-Monitoring Diabetics*. San Diego: Pacific Science and Engineering Group.

Grice, G. R., & Gwynne, J. W. (1987). Dependence of target redundancy effects on noise conditions and number of targets. *Perception and Psychophysics, 42*, 29-36.

Grice, G. R., & Gwynne, J. W. (1985). Temporal characteristics of noise conditions producing facilitation and interference. *Perception and Psychophysics, 37*, 495-501.

Grice, G. R., Canham, L., & Gwynne, J. W. (1984). Absence of a redundant-signals effect in a reaction time task with divided attention. *Perception and Psychophysics, 36*, 565-570.

RICHARD T. KELLY

Availability 40% **Status** Current Employee

Education

PhD	Engineering Psychology, 1976	New Mexico State University
MA	Experimental Psychology, 1973	New Mexico State University
BA	Psychology, 1971	Hanover College

Employment History

1985 - Present Principal Scientist
Pacific Science & Engineering Group, Inc., San Diego, CA

1976 - 1985 Research Psychologist; Leader, Combat Systems Group
Navy Personnel Research and Development Center, Human Factors and Organizational Systems Laboratory, San Diego, CA

1976 - 1976 Engineering Psychologist
U. S. Army TRADOC Systems Analysis Activity, Training Analysis Branch, White Sands Missile Range, NM

Professional Experience

Human Performance Research and Development

Directed and conducted a large-scale human factors assessment of blood glucose meters, used by diabetics for self-monitoring. The project involved analyses of the meter designs (including detailed task analyses), instructional material, and training process as well as empirical observations of user performance with the meters.

Designed, conducted, and analyzed several experiments in order to examine the decision making behavior of naval warfare commanders in a realistic tactical wargaming simulator. In particular, the effects of communications degradation were studied. Extended the measures and analysis techniques from these experiments to shipboard battle group exercises.

Performed statistical analyses on data from field tests and simulators to assess human operator job proficiency involving complex cognitive, perceptual, and psychomotor tasks. Related the observed performance data to vocational aptitude test scores.

Compiled multidisciplinary research addressing command, control, and communications theory and measurement paradigms. Designed and developed an interactive database system to provide researchers with rapid and easy-to-use access to technical publications. Consulted with the tri-service, Joint Directors of Laboratories Basic Research Group on behavioral issues in command and control.

Analyzed information processing and decision making tasks in shipboard combat direction centers. Devised procedures for gathering data during field tests, simulation exercises, and mockup reviews. Developed innovative approaches for measuring decision making and organizational factors in the command, control, and communications environment using data from field exercises.

Planned, conducted, and reported empirical studies of user performance with advanced and with operational command and control systems involving query systems, interactive displays, and user aids. Developed software to collect and analyze human performance data in complex simulators intended for training and for system design.

Conducted research to determine human information processing limits and to identify factors contributing to information overload. Developed microcomputer-based job aids to facilitate tactical planning and decision making.

Prepared test plans for evaluating various Army training devices and programs. These include missile systems (TOW, Dragon, Redeye) and wargaming (MILES, CATTS). Used a force-level wargaming simulator to perform sensitivity analyses of human performance with respect to mission effectiveness. Analyzed operator performance and training system effectiveness. Provided human factors technical support to the scientific and engineering staff.

Human Factors Engineering in System Design and Development

Performed task and information requirements analyses of Navy battle group commanders. Used these analyses to develop specifications for a commander's workstation and decision support system.

Participated on the system design team as the Human Factors Engineer for several ships and major ship systems. These include the AN/BSY-1 submarine combat system, Submarine Advanced Combat System (SubACS), Advanced Combat Direction System (ACDS), Aegis Combat System for the DDG-51 class destroyer, MCM-1 mine countermeasures ship, AN/SQS-53C hull-mounted sonar, and Navy Tactical Data System (NTDS).

Reviewed system design specifications, drawings, and other documentation with regard to human engineering standards and considerations. Provided quantitative guidelines and design alternatives where appropriate. Consulted with military personnel and project engineers on man-machine interface design and other human factors engineering issues.

Planned and conducted system analysis studies for critical subsystem human interface issues using field data, computer models, and man-in-the-loop simulations. Analyzed and reported data rapidly so as to support system design decisions.

Management and Planning

Served as Principal Investigator on a several substantial human factors studies. Responsible for all aspects of problem oriented research and development on diverse scientific and military issues -- primarily in areas related to C3. Supervised and directed the activities of several research scientists and support staff leading to numerous technical reports, journal articles, and presentations at conferences.

Developed comprehensive program plans for human performance in command and control systems. This included operational problem analyses, detailed technical and management plans, appropriate sponsorship, and resource requirements.

Established and maintained liaison with Navy commands, Department of Defense agencies, and research and development centers involved in related efforts. Delivered project reviews and technical briefings to sponsors and consumers.

Professional Affiliations

Human Factors Society
Sigma Xi
IEEE Systems, Man, and Cybernetics Society
American Assoc. for the Advancement of Science

Selected Publications and Technical Reports

Dr. Kelly has authored over 35 technical reports and journal articles over the past 15 years. In addition, he has presented more than 20 research papers at professional meetings. His research has concentrated on the analysis and evaluation of human performance in complex systems, and he is an acknowledged expert in task / function analysis and human factors evaluation techniques.

Kelly, R. T., Callan, J. R., Kozlowski, T. A., & Conway, E. J. (September 1988). Human factors analysis of blood glucose monitoring. San Diego, CA: Pacific Science & Engineering Group, Inc.

Kelly, R. T., Callan, J. R., Kozlowski, T. A., & Rogitz, J. (September 1988). Outer-air battle decision performance with degraded tactical information. San Diego, CA: Pacific Science & Engineering Group, Inc. (Confidential)

Kelly, R. T. (March 1986). An approach to measuring cross-warfare coordination during battle group exercises. (Technical Report 560-9-4). San Diego, CA: Pacific Science & Engineering Group, Inc.

McTighe, R. P., Wright, C. L., Callan, J. R., & Kelly, R. T. (March 1986). Task and information requirements analysis for the Composite Warfare Commander. San Diego, CA: Essex Corporation. (Confidential)

McTighe, R. P., Wright, C. L., Callan, J. R., & Kelly, R. T. (February 1986). Summary of tasks and information requirements for battle group personnel. San Diego, CA: Essex Corporation. (Confidential)

McTighe, R. P., Wright, C. L., Callan, J. R., Kelly, R. T., & Barten, K. (January 1986). Task analysis/information requirements analysis for battle group personnel. San Diego, CA: Essex Corporation. (Confidential)

Greitzer, F. L., Kelly, R. T., & Hershman, R. L. (August 1983). Interactive simulation of mine countermeasures operations. (NPRDC SR 83-49). San Diego, CA: Navy Personnel Research and Development Center.

Kelly, R. T. & Greitzer, F. L. (January 1982). Effects of task loading on decision performance in simulated command and control operations. (NPRDC TR 82-21). San Diego, CA: Navy Personnel Research and Development Center.

Greitzer, F. L., Hershman, R. L., & Kelly, R. T. (1981). The Air Defense Game: A microcomputer program for research in human performance. Behavior Research Methods & Instrumentation, 57-59.

Callan, J. R., Kelly, R. T., & Nicotra, A. (January 1978). Measuring submarine approach officer performance on the 21A40 trainer: Instrumentation and preliminary results. (NPRDC TR 78-9). San Diego, CA: Navy Personnel Research and Development Center.

WILLIAM M. SAUNDERS

Availability 10% **Status** Current Employee of Subcontractor

Education

MD	Medicine, 1974	University of Alberta, Edmonton, Alberta, Canada
PhD	Nuclear Physics, 1971	University of Alberta, Edmonton, Alberta, Canada
MS	Solid State Science, 1967	Syracuse University, Syracuse, New York
BSc	Metallurgy, 1965	University of Alberta, Edmonton, Alberta, Canada

Present Position

Professor of Radiology
Chief, Division of Radiation Oncology
Department of Radiology
University of California, San Diego Medical Center

Internship

Straight Internship in Internal Medicine
University of Alberta Hospital
Edmonton, Alberta, Canada
July 1974 to June 1975

Residency

Resident in Radiation Therapy
Department of Radiation Therapy
Stanford Medical Center
Stanford, California
July 1975 to June 1978

Fellowship

Fellow in Experimental Radiation Oncology
Departments of Radiation Oncology and Radiation Biology
University of Alberta
Cross Cancer Institute
Edmonton, Alberta, Canada
July 1978 to April 1979

Honors and Awards

Province of Alberta Matriculation Scholarship
University of Alberta, 1961

Province of Alberta Undergraduate Scholarship
University of Alberta, 1962

American Society for Metals Foundation Scholarship in Metallurgy
University of Alberta, 1964

American Society for Testing and Materials Prize
University of Alberta, 1964

D. Farghar Johnston Bursary
University of Alberta, 1964

Honors and Awards (continued)	Province of Alberta Undergraduate Scholarship University of Alberta, 1964	
	Graduate Research Assistantship Syracuse University, 1965-1967	
	National Research Council Bursary University of Alberta, 1968	
	Percy H. Sprague Prize in Internal Medicine University of Alberta, 1974	
Licensure	Licentiate of the Medical Council of Canada	1975
	State of California	1976
	Province of Alberta	1978
	State of Massachusetts	1985
Board Certification	Fellow of the Royal College of Physicians and Surgeons of Canada (Radiation Oncology)	1978
	American Board of Radiology (Radiation Oncology)	1978

Academic and Hospital Appointments

University of Alberta and Cross Cancer Institute, Edmonton, Alberta

Assistant Professor of Radiation Oncology
April 1979 to June 1980

University of California, San Francisco

Assistant Professor of Radiation Oncology in Residence, II
July 1980 to July 1982

Assistant Professor of Radiation Oncology in Residence, III
July 1982 to July 1984

Assistant Professor of Radiation Oncology in Residence, IV
July 1984 to July 1985

Associate Professor of Radiation Oncology in Residence, I
July 1985

Lawrence Berkeley Laboratory

Visiting Student
July 1980 to July 1985

Harvard Medical School

Assistant Professor of Radiation Oncology
July 1985 to July 1988

Academic and Hospital Appointments (continued)

New England Deaconess Hospital

Acting Chief of Radiation Therapy
March 1987 to April 1987

Chief of Radiation Therapy
December 1987 to July 1988

Joint Center for Radiation Therapy

Assistant Director of Clinical Physics
January 1986 to July 1988

Acting Section Chief, Deaconess Division
March 1987 to April 1987

Section Chief, Deaconess Division
December 1987 to July 1988

Hospital Privileges Held at:

University of California, San Diego Medical Center
VA Medical Center, La Jolla, California

Service to Patients

Management of approximately 25 patients daily for radiotherapy treatment

Frequent telephone consultations for physicians in other cities nationwide for advice in management of arteriovenous malformations

Teaching

1-2 hours per year teaching refresher courses at national radiotherapy or medical oncology meetings

Research Activities

Harvard Medical School

Computer controlled radiation therapy

Stereotactic radiosurgery for Arteriovenous Malformations (AVMs) using a small x-ray beam from a modified linac

Research Activities (continued)

Lawrence Berkeley Laboratory

Collaborator in NCI project for clinical trials in charged particle radiotherapy; project director of helium ion radiotherapy section of that project, J. Castro, PI

Project director for NCI-funded project to design a heavy ion accelerator for biomedical research, E. Alpen, PI

Collaborator in NCI "HIRRO" project, C. Tobias, PI
Under HIRRO collaborated with T. Budinger investigating the late effects of heavy ion beams on the CNS using a dog model. (This project continues under T. Budinger and K. Brennan.)

University of California, San Diego Medical School

Stereotactic radiosurgery for Arteriovenous Malformations (AVMs) using a small x-ray beam from a modified linac

Proton radiotherapy

National Service

Referee for American Society for Therapeutic Radiology and Oncology

Referee for International Journal for Radiology Oncology, Biology, and Physics

Referee for Journal of Clinical Oncology

Member of NCI Site Visit Committee for proposal from Massachusetts General Hospital and Harvard Department of Physics in Spring 1984

Professional Affiliations

American Radium Society
American Society of Therapeutic Radiologists
American Association of Physicists in Medicine
American Society for Clinical Oncology
Radiation Research Society

Selected Publications

Dr. Saunders has over 50 published papers in radiation oncology, clinical radiology, medical physics, and nuclear physics. Some representative recent publications are listed on the next page.

Saunders, W.M., Winston, K.R., Siddon, R.L., Svensson, G.H., Kijewski, P.K., Rice, R.K., Hansen, J.L., & Barth, N.H. (1988). Radiosurgery for arteriovenous malformations of the brain using a standard linear accelerator: Rational and technique. International Journal of Radiation Oncology Biology and Physics, 15 (2), 441-447.

Saunders, W.M. (1987). Plans for clinical evaluation of dynamic computer-controlled radiation at the Joint Center for Radiation Therapy. In J.M. Vaith & J. Meyer (Eds.), Treatment Planning in the Radiation Therapy of Cancer (pp. 56-67). Basel, Switzerland: Karger Publishers.

Saunders, W.M., & Chin, L.M. (1986). Innovative techniques: Dynamic therapy and utilization of noncoplanar beams. In B.R. Paliwal & M.L. Greim (Eds.), Radiation Therapy Treatment Planning (pp. 123-128). Oak Brook Radiological Society of North America Publishers.

Saunders, W.M., Castro, J.R., Chen, G.T.Y., Gutin, P.H., Collier, J.M., Zink, S.R., Phillips, T.L., & Gauger, G.E. (1986). Ion beam radiation therapy for sacral chordoma: Early results. A Northern California Oncology Group Study. Journal of Neurosurgery, 64, 243-247.

Saunders, W.M., Castro, J.R., Chen, G.T.Y., Collier, J.M., Zink, S.R., Pitluck, S., Phillips, T.L., Char, D., Gutin, P., Gauger, G., Tobias, C.A., & Alpen, E.L. (1985). Helium ion radiation therapy at the Lawrence Berkeley Laboratory: Recent results of a Northern California Oncology Group clinical trial. Rad Res, 104 (8): S227-S224.

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Related Organizational Experience

PSE was established five years ago to perform scientific studies and consulting services on challenging problems concerning human performance in complex systems. This includes efforts in human factors engineering, ergonomics, systems analysis, safety, organizational systems, and training for industry and government. Our staff of experienced analysts applies sound scientific and engineering principles to military and industrial systems and processes. Typical products include human-system interface design and prototyping, simulation and modeling, human reliability and error analyses, man-in-the-loop testing, training effectiveness analyses, field testing, and systems evaluation research. From this background, we offer practical but technically sophisticated solutions to real-world problems.

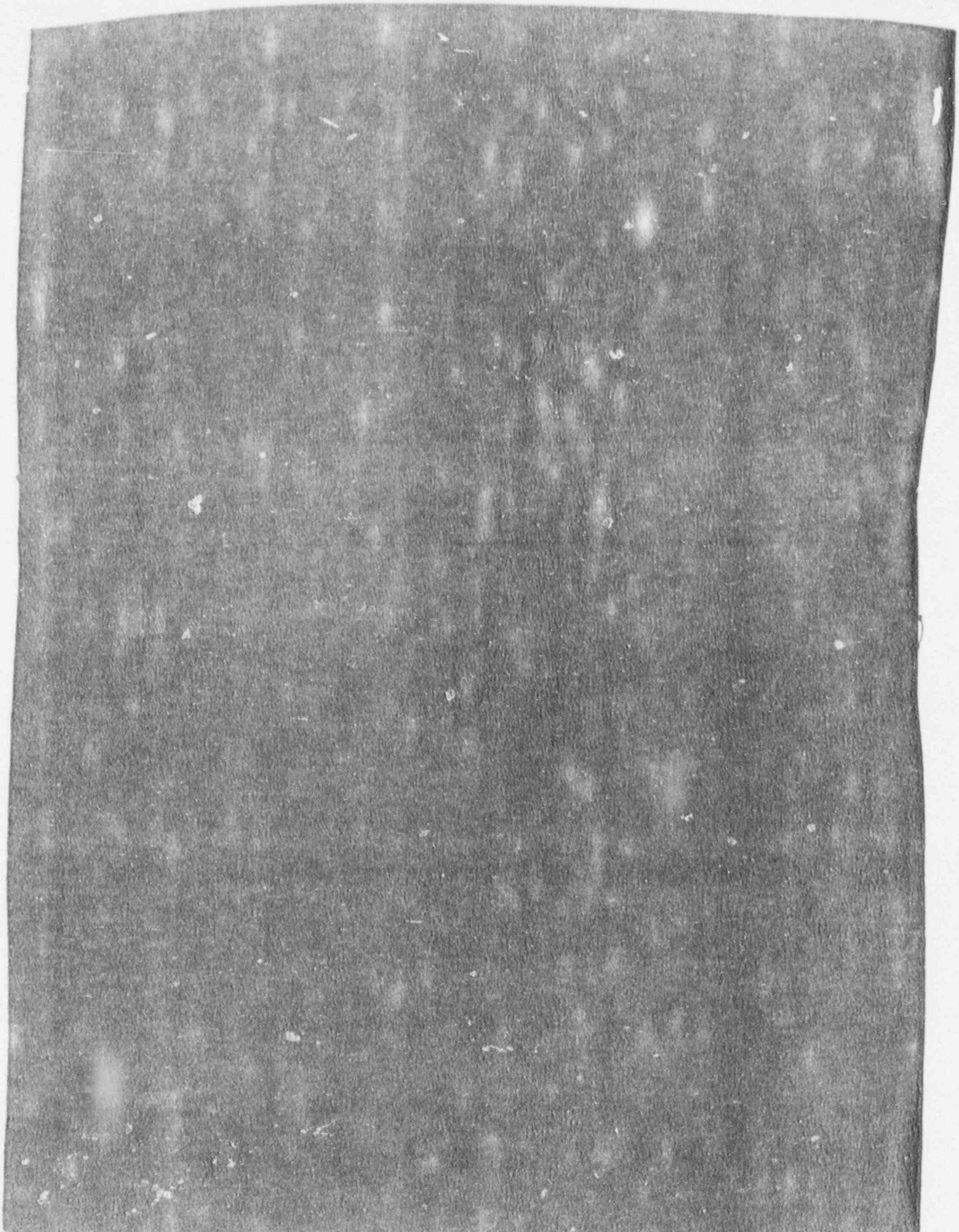
[redacted]

PSE has had considerable experience in performing function / task analyses, interface evaluations, procedural evaluations, training system analyses, and organizational assessments. In fact, most of the projects that have been undertaken by the company have involved these techniques. Moreover, PSE's projects often conclude by integrating findings from diverse sources to identify specific root causes of human errors, by prioritizing system problems resulting from human error, and by evaluating alternate approaches to resolve system problems.

Table 2 summarizes several of our recent projects that involved technical activities similar to those required for this project. The check marks indicate that the technical activity was a significant part of that project. Because of PSE's broad experience with human factors evaluations and analytic techniques, we are confident of our ability to satisfy NRC's technical needs for this project – and to do it on time and within budget.

In addition, technical personnel from PSE have played a significant role in a variety of other procedural evaluations and organizational evaluations including:

[redacted]



[redacted]

Synopses of Relevant Previous Projects

Relevant contract experience has been listed below. NRC reviewers are encouraged to contact the Project Officers and/or Contact Officers for these efforts in order to get an independent assessment of PSE's performance.

Neither the company, the project personnel, nor the subcontractor proposed for this contract have any commitments with other organizations to perform the same or similar work. Thus, there is no opportunity for conflicts of interest.

[redacted]

[redacted]

Title: Human Factors R&D Support: System and Equipment Design

[redacted]

Title: Human Factors R&D Support: System and Equipment Design

[redacted]

Title: Human Factors Evaluation of Contact Lens Labeling for Wearers of Soft Contact Lenses

[redacted]

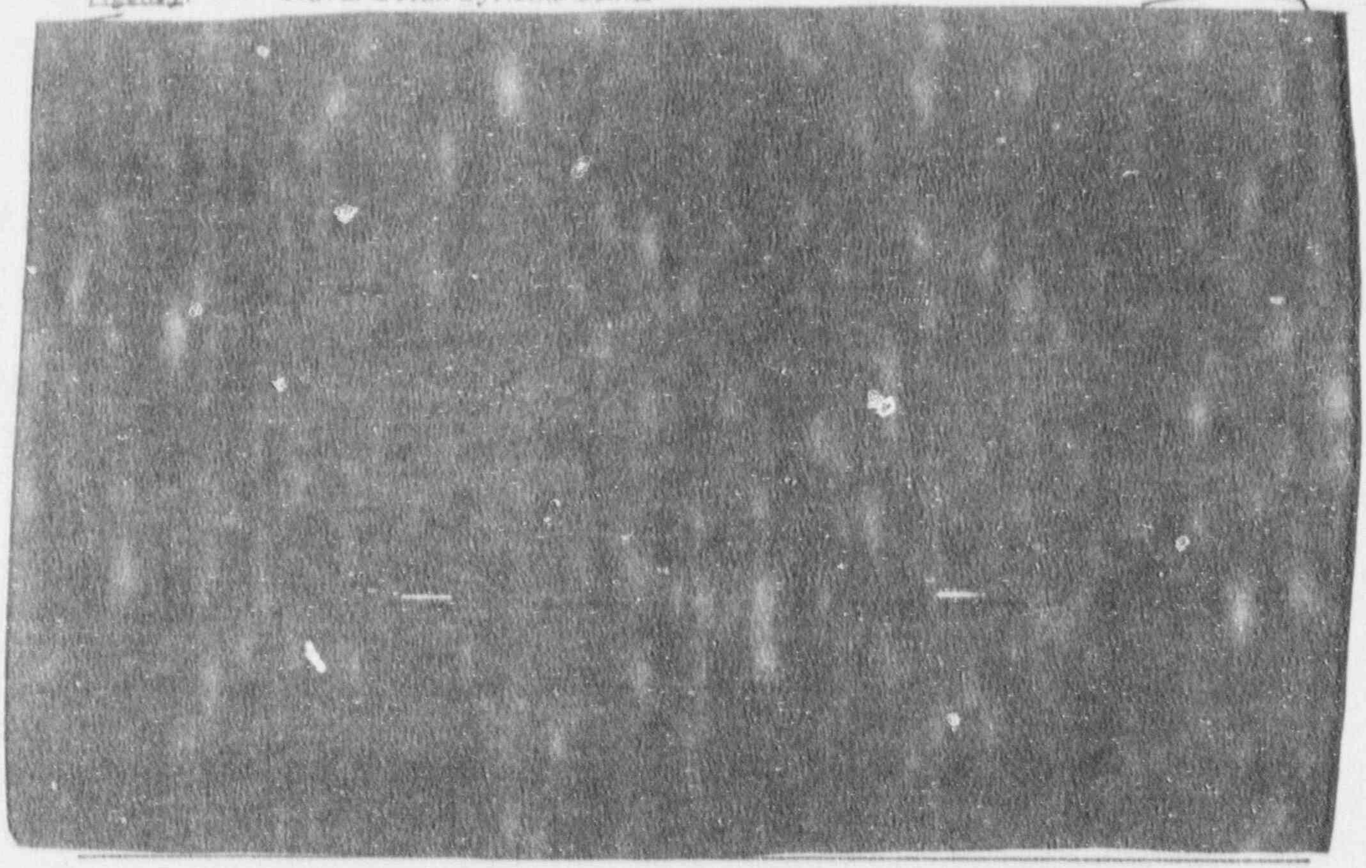
Title: Battle Force Command Simulation Experiments, Phase 2

Agency: Naval Ocean Systems Center
San Diego, California 92152-5000

[redacted]

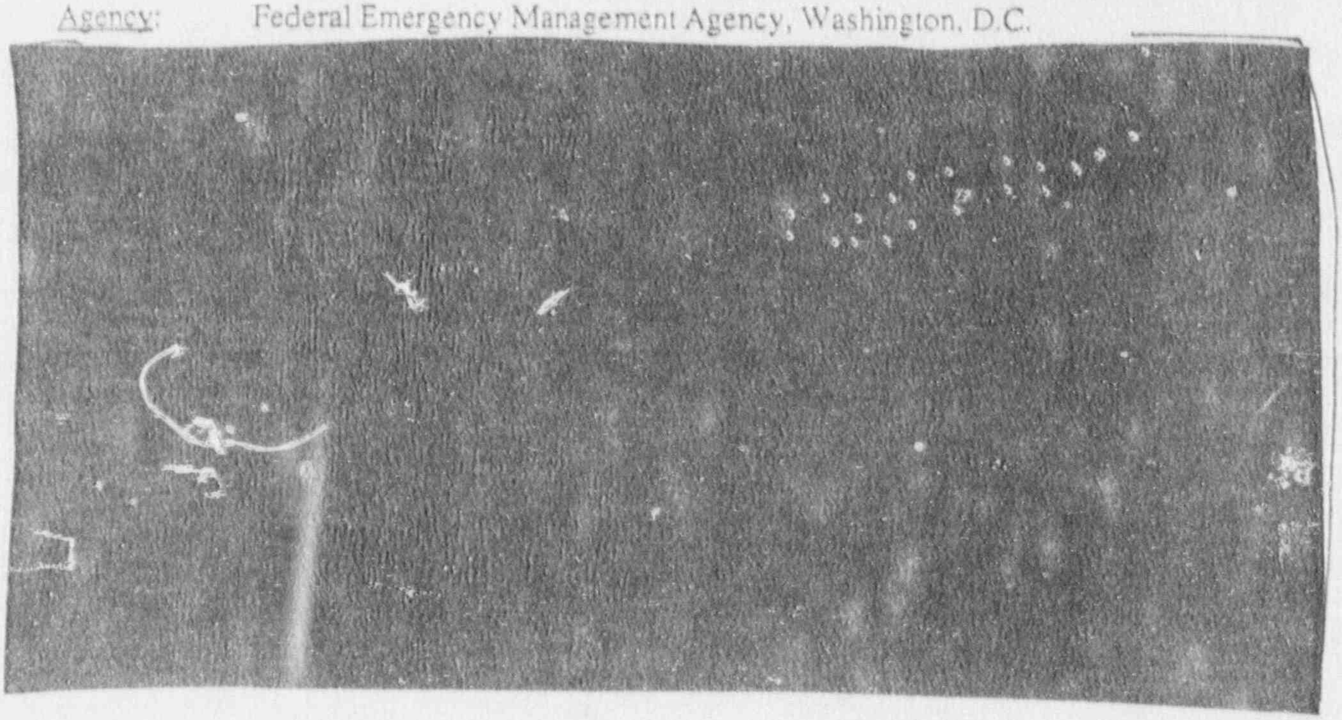
Title: Battle Force Command Simulation Experiments

Agency: Naval Ocean Systems Center



Title: Field Index Guide for Arson and Fire Investigators

Agency: Federal Emergency Management Agency, Washington, D.C.



Title: Human Factors Regarding the Use of Glucose Monitoring Equipment

Agency: Food and Drug Administration, Center for Devices & Radiological Health, Office of Training and Assistance, Rockville, MD

[redacted]

Title: C^3 / Data Fusion Research Validation

Agency: [redacted] Naval Ocean Systems Center / JDL

[redacted]

Title: Handbook for C^3 Theory

Agency: [redacted] Naval Ocean Systems Center / JDL

[redacted]

Title: Command, Control, and Communications Research

Agency: U.S. Army Research Office [redacted]

[redacted]

Title: The Army Application of the Automated Performance Assessment and Readiness Training System (APARTS)

Agency: Naval Training Systems Center, Orlando, FL 32813

[redacted]

Title: Information Requirements Analysis for the Naval Battle Group

Agency: Navy Personnel Research & Development Center, Arlington, VA

[redacted]

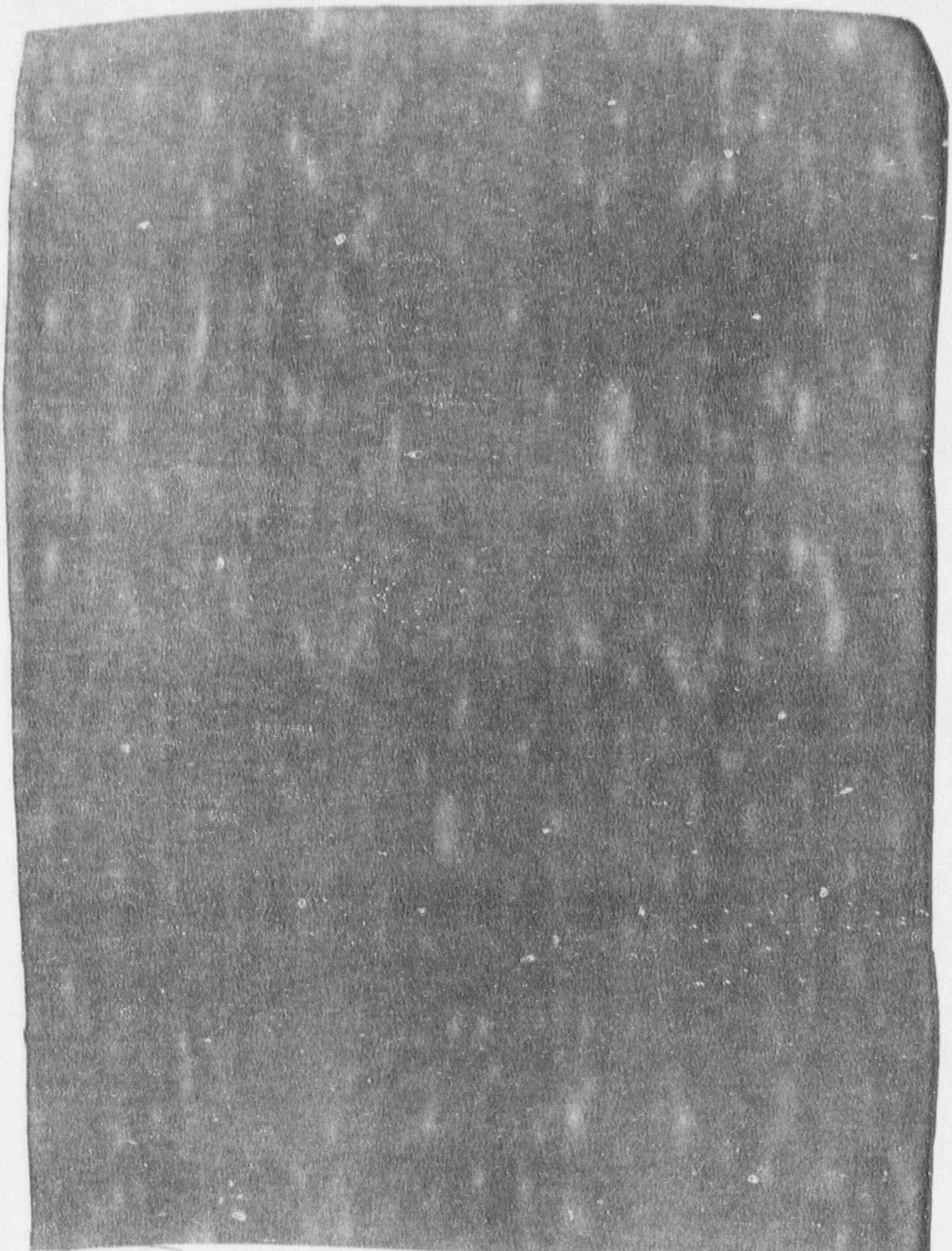
[redacted]

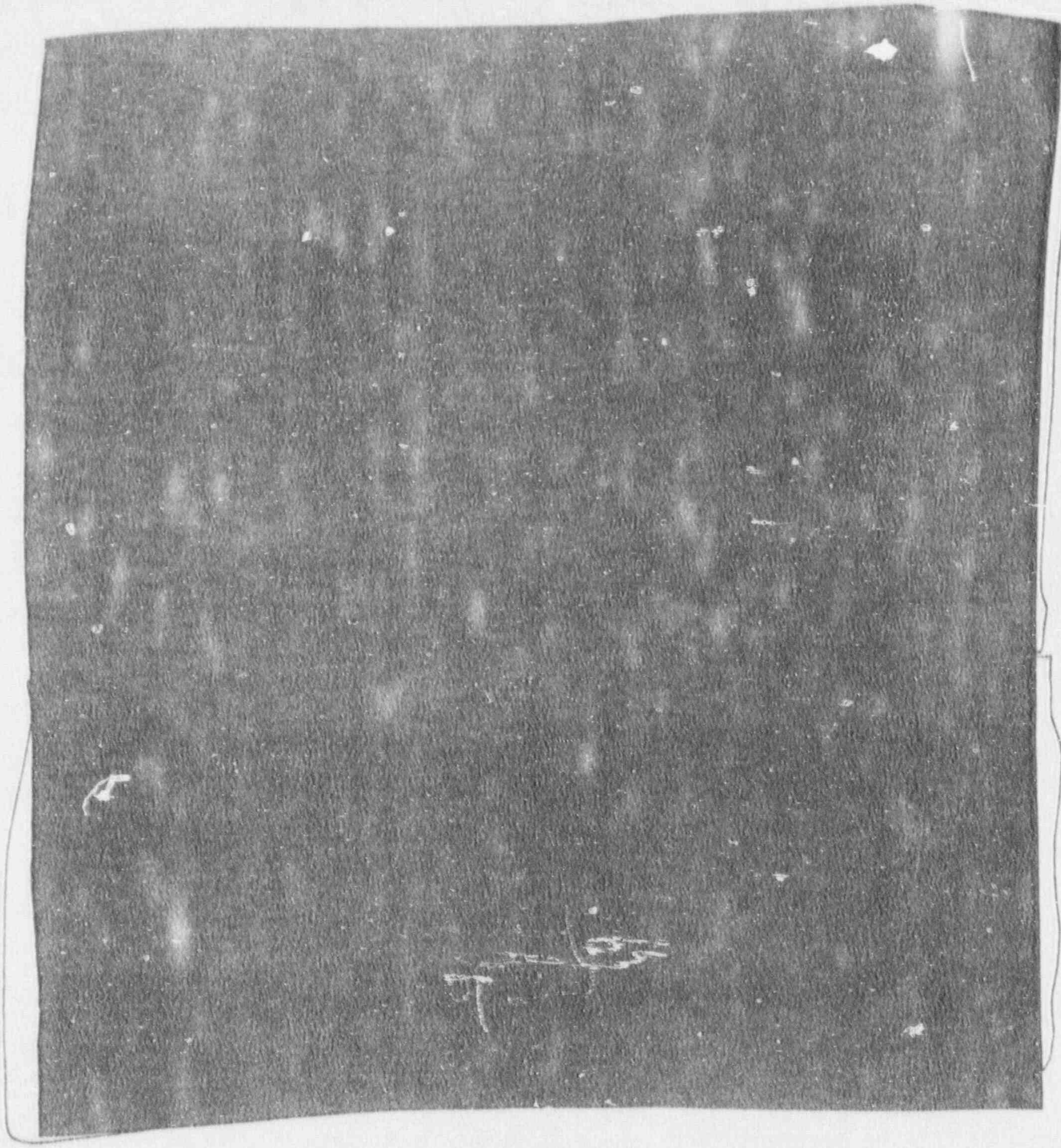
Title: Human Factors Analysis and Statistical Consulting Services

[redacted]

Facilities and Equipment

[redacted]





PROJECT MANAGEMENT

This section discusses the plans for performing this project. This discussion includes the project staff organization, the milestone schedule, and the estimated resource requirements. Project management controls and other related considerations are also presented.

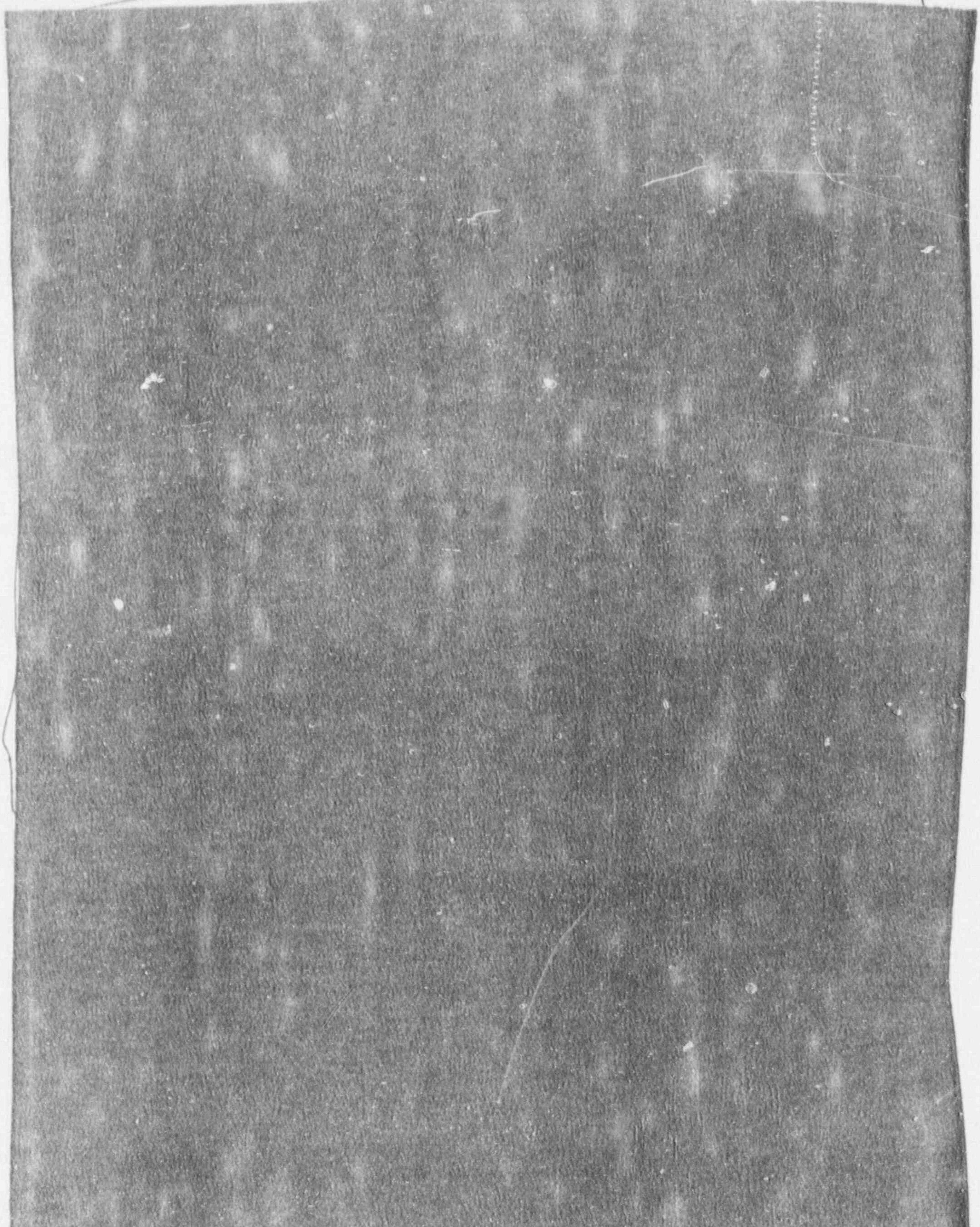
Throughout this project, PSE will exercise full responsibility as the prime contractor and will provide the major portion of the work effort. [redacted] Controls are in place to assure program responsiveness and quality of the work, analysis, and products.

Corporate Background

PSE's organizational and managerial strengths reside in the experience of its personnel and the commitment of the corporation. PSE is dedicated to quality research, development and engineering support and its principals have selected employees who share that dedication. [redacted]

Project Organization

[redacted]



[redacted]

Table 3 presents a summary of the roles and responsibilities proposed for each of the team members across the tasks in this project. PSE human factors engineers will maintain the close working relationship that has already been established [redacted]

[redacted]

Milestone Schedule

The overall milestone schedule for the project is shown in Figure 9. More detailed breakdowns of the activities in each task are presented in the Technical Approach section. The performance periods are shown as dark bars; transition periods are indicated by cross-hatched bars. Transition periods are intended to permit task reports to be completed and revised before proceeding with subsequent tasks.

[redacted]

Resource Requirements

This section provides a summary of the resources necessary to complete this project as it has been proposed. Resource information has been provided for direct labor, subcontract labor, travel, and other direct costs.

Direct and Subcontract Labor

Professional labor requirements have been developed for each task across the period of performance for the contract. The estimated direct labor hours are shown in Table 4, along with those for the subcontractor.

[redacted]

Subcontractor

[redacted]

[redacted]

Travel

The following describes the expected travel for this project, as specified in Section C.1.4 of the Request for Proposals. The locations proposed for travel to observe brachytherapy activities at various medical facilities are based on a geographic distribution, as detailed in the sampling plan. Discussions with the NRC Project Officer following contract award will help to determine the exact sites for travel.

[redacted]

[redacted]

Materials

[redacted]

During the proposed visits to the brachytherapy equipment manufacturer and the brachytherapy activities at medical facilities, we plan to conduct detailed human factors analyses, using state-of-the-art human performance measurement techniques. We have employed these techniques with great success on other projects requiring direct observation of operator performance in field settings. [redacted]

Table 5

Summary of Estimated Expendable Items

[redacted]

PSE does not propose that any equipment be acquired under this contract. The equipment owned by PSE, which is described in the Facilities section, is considered to be fully adequate for the tasks proposed. This includes cameras and other human performance measurement equipment, specialized software to support the human factors analyses, and desktop publishing and graphics production facilities.

Management Controls

Principal Investigator

The Principal Investigator is responsible for the successful management and administration of this program. The Principal Investigator will develop the overall program plans, the work plan, milestones, and resource expenditure budget. He will also maintain a timely record of resource and project expenditures against these plans and provide for a monthly Corporate review. This assignment of responsibility carries with it full authority to execute the plan. [redacted] designated officers. The Principal Investigator is responsible for subcontractor performance, work assignments, and deliverables. The Principal Investigator must approve payment of subcontractor vouchers. For this procurement, the efforts of the subcontractor are integrated into the overall work plan. We anticipate that their contributions will augment our efforts to create a totally integrated effort. PSE will retain full responsibility for all deliverables.

Technical Quality Assurance

Quality control will focus on technical progress reports, budget control, publication quality, and timeliness. Quality control of technical methods, procedures, and analyses for each Task will be the responsibility of the Principal Investigator.

Technical Reports and Publications Quality Assurance. As specified in the Request for Proposals, technical letter reports will be prepared upon completion of each of the first five Tasks. Technical reports will be submitted at the conclusion of Tasks 1 and 6. (Monthly progress reports also will be provided throughout the project.)

All letter and technical reports will belong to the NUREG/CR series and will be prepared accordingly. In preparing each report, we will adhere to the guidelines specified in Chapter NRC-3202, Publication of Technical Reports Prepared by NRC Contractors, Including Reports Prepared Under or Pursuant to Interagency Agreements.

The quality of any research contractor's efforts is reflected in the technical reports delivered to the customer for review and implementation. PSE has developed an outstanding record of report deliveries. In addition to technical reports, our personnel have participated in many informal and formal presentations of research results to customers, customer-referred visitors, professional organizations, industry, and the public. [redacted]

Technical reports and publications quality assurance addresses the content and format of each deliverable publication and ensures it meets the requirements of the contract. Reviews occur at the outline, draft, and final stages of the publication preparation. The review process is designed to determine whether the publication (a) fulfills the content and format requirements, (b) is consistent in its use of terminology, symbology and abbreviations, (c) is free of typographical errors, misspelled words and omissions, (d) is collated properly, and (e) is technically accurate.

[redacted]

[redacted]

Management Controls. Any program can go awry if there are no sound procedures to measure technical progress. Common problems are: failing to staff the program according to plan; failure to ensure action begins when the schedule indicates; failure to keep an accurate status of progress; and failure to initiate corrective action in a timely manner. PSE has management controls in place to alert management to each of these conditions. The other necessary aspect of effective control is a management team capable and willing to act on the information provided them. [redacted] He delivers quality products on time and within budget. Similarly, the project team is experienced and can be depended upon to properly assess the program status and offer constructive advice on solving problems.

Get Well Plans. As discussed above, there should be little or no reason to expect major problems on this program. However, certain events would trigger the implementation of an alternate or "get well" plan. Get Well Plans are most often required when the performing contractor has either failed to adequately scope the work or has failed to realize that performance is not progressing on schedule. Understanding the risk in a program permits management to prepare contingency plans to overcome setbacks when they occur. The PSE management team has a great deal of experience in dealing with high intensity programs. PSE will maintain direct management involvement to ensure the program develops as scheduled.

NRC Liaison

Although PSE's main offices are not in the Washington, DC area, we anticipate no difficulties in maintaining close coordination with NRC. [redacted]

Organizational Conflicts of Interest

[redacted]

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