Development of Human Reliability Analysis Capability for
Regulatory Applications Involving By-Product Materials

Letter Reports:

Task 1: Identify Potentially Risk-Significant Human Actions

Task 2: Identify Level of Detail Required for NMSS Byproduct Material Users

Task 3: Group Similar Byproduct Material Applications

Task 4: Identify NMSS Byproduct Material HRA Capability Needs

Task 5: Identify Scope of HRA-Informed Job Aid for Reviewing License Requests

Task 6: Collect Information to Provide a Knowledge-Base for an HRA-Informed Job Aid for Reviewing License Requests
Task 7: Structure and Format Relevant Knowledge-Base into HRA-Informed Job Aid

Task 10: Specification for HRA-Informed Job Aid

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Letter Report

Task 1: Identify Potentially Risk-Significant Human Actions

Prepared for
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Office of Nuclear Regulatory Research
Division of Risk Analysis and Applications

Background

NRC is engaged in an initiative to risk-inform the materials and waste safety arenas. Operating experience indicates that human actions play a dominant role in most of the NMSS regulated activities. The overall risk of these activities is strongly influenced by human performance. Hence, an improved understanding of human error, its causes and context and human reliability analysis (HRA) can provide better risk insights to risk-inform, as appropriate, NMSS regulated activities.

Objective

In order to proceed, NRC needs to establish the following:

1. An understanding of what potentially, risk-significant human actions should be addressed by NMSS.
2. An understanding of NMSS user needs regarding HRA capabilities, including HRA methods, HRA-informed tools, or other HRA needs.
3. The applicability and usefulness of existing HRA methods and tools for NMSS byproduct material applications (as required by NMSS user needs).
4. Recommendations specific to each NMSS by-product material application (or group of applications) for: (a) direct use of, (b) needed modification of, or (c) needed development of HRA methods or HRA-based tools, in order to support NMSS user needs.

The above will be the basis for future work that could include any or all of the following:

- Demonstration of the direct use of existing HRA methods or tools for NMSS byproduct material applications.
- Modification of existing HRA methods and/or tools for NMSS byproduct material applications.
- Development of new HRA methods and/or tools for NMSS byproduct material applications.

The objective of this project is to identify the HRA capability needs for NMSS byproduct material applications and to provide recommendations regarding how to meet these needs. The overall plan for meeting these objectives can be summarized as follows:

- Identify potentially risk-significant human actions (Task 1)
- Identify level of detail required for NMSS byproduct material users (Task 2)
- Group similar byproduct material applications (Task 3)
- Identify NMSS byproduct material HRA capability needs (Task 4)

This letter report describes the results of the first of these tasks - identifying potentially risk-significant human actions (Task 1 of the Statement of Work).

Approach

Potentially risk-significant human actions were identified by

- reviewing available risk studies for byproduct material applications, specifically those in which the role of human performance is non-trivial
- reviewing available of descriptions of events for byproduct materials applications that involved potentially significant human actions

Medical events associated with the following modalities of treatment have been reviewed: high-dose-rate afterloader (HDR) brachytherapy, teletherapy, gamma stereotactic radiosurgery (the "Gamma knife"), and

intravascular (IV) brachytherapy. These modalities were selected because they involve high dose-rate sources so there is very little margin for error (or opportunity for recovery) for the safety of the patient because the treatments involve short durations and very small volumes. In addition, because of the source strengths, the clinical workers, and the family or others near the patient, can be at risk. A similar approach was taken for industrial applications; i.e., the areas sampled were those in which there was a potential for harm in the event of an error. The specific systems identified were irradiators, field radiography, and well-logging. Risk studies and event reports were reviewed for each of the systems.

Sources for Risk Studies

The basic reference for studies of risk in byproduct activities is NUREG/CR-6642. The document provides, for each of forty 'systems,' descriptions of the use of byproduct materials and a barrier analysis for the application. The descriptions provide background information about the types of tasks performed (with an orientation of evaluating risk). The document is particularly valuable in the present context because it treats very varied systems systematically, so that the similarities among them are more readily recognized, and it explicitly identify barriers to undesired events, which serves as a starting point for considering those barrier that depend on human action. However, the risk treatments in NUREG/CR-6642 are not a sufficient basis by themselves for developing HRA methods and tools. They do not consider in detail the individual human actions on which a node may depend, and, importantly, they do not consider risks of exposures to patients in association with medical systems; i.e., the risk analysis considers 'worker' and 'public' exposures.

The relevant sections of the Code of Federal Regulations (e.g., 10CFR Part 34 for industrial radiography and Part 36 for irradiators) were also consulted, since they identify by implication the aspects of the activities that are important to risk. For a few NMSS applications (e..g., fixed gauges, field radiography) specific, standalone risk analyses or reports also supplemented the treatments in NUREG/CR-6642.

As the task proceeded, other possible sources for risk-related information, such as risk analyses or investigation reports prepared in association with specific applications or events, were identified. Most of these were not as readily available and therefore were not sought for in this initial information gathering. However, material associated with the question of irradiator operators being located offsite was provided and reviewed on the course of this effort.

Sources for Events

The NMED database was a principal source of information about events related to byproducts materials. The database, maintained at INEEL, is made available both online (i.e., searchable via the internet) or as a Microsoft® Access file (which can be downloaded and searched on a standalone PC). The review of medical events used the Access version of NMED, which was downloaded from INEEL (on June 25, 2003) and then analyzed using Microsoft Access. In the cases of the Gamma knife and the IV brachytherapy, all events in the database up to the date of downloading were reviewed. Because of the significantly larger number of events associated with the other two modalities, data only for events between January 1, 1995 and December 31, 2002 were reviewed. By using the Access-based version of the database, the reviewer's search was not limited by the coding used for event causes or contributors in NMED. The summaries of the events presented below are not to be considered "root causes" but simply the unsafe actions involved. The circumstances under which the actions took place are rarely described (e.g., time pressure, conflicting instructions). The review of other types of events (involving applications of byproducts materials in non-medical, primarily industrial settings), was done using the online version of the database. The online database allows records to be selected by predefined systems, components, causes and keywords. It is also possible to filter the records according to the event classification, so that (for example) lists limited to abnormal occurrences could be generated (see below).

Incidents or events having a moderate or more severe impact on public health or safety, including moderate exposure to or release of radioactive material, are described in NUREG-0090, Reports to Congress on Abnormal Occurrences. The criteria for tracking an event as an abnormal occurrence include various medical errors (e.g., deviation of 50% or more in dose; wrong site, treatment mode, radiopharmaceutical, or route of administration); criteria for reporting as an abnormal occurrence are given in an Appendix to each volume of NUREG-0090. The reports for fiscal years 2001 and 2002 (volumes 24 and 25) were available electronically. These documents had more detailed narrative descriptions of events than was typical of NMED database records generally.

Several misadministration events that occurred between 1991 and 1992 are collected and described in detail in NUREG/CR-6088.This collection is especially useful because it represents the findings of investigative teams that looked into the events described. Thus the treatments are considerably more informative than the event descriptions available from other sources. For each event, direct causes and contributing factors are identified, and corrective actions are described and critiqued.

NUREG/BR-0024 briefly describes the ways in which radiography accidents can occur
Exposure accidents associated with gamma radiography (for the period 1971 to 1980) are tabulated in Appendix F. The error(s) leading to exposure are given for each of 48 events.

At the recommendation of an NRC license reviewer, reports of radiological accidents prepared by IAEA were also looked at. These reports are detailed investigations of the causes and consequences of mishandling or misapplication of radioactive material. A number of such reports were immediately available in electronic form:

- The radiological accident in Samut Prakarn (exposure to source from disassembled teletherapy head)
- The radiological accident in Gilan (handling of a lost industrial radiography source)
- Investigation of an accidental exposure of radiotherapy patients in Panama (software error)
- Accidental exposure of radiotherapy patients in San Jose, Costa Rica (calibration error)

A review of the causes of these accidents prepared for the NRC was also made available.

Risk and Human Performance Associated with Byproduct Systems

A number of NMSS applications were identified (in information developed by NRC prior to the start of the project) as being of particular concern. Among these were various medical (therapeutic) applications (including IVB, gamma knife, teletherapy, brachytherapy), field radiography, irradiators, and well-logging. The common characteristic is the potential for acute damage to be done in a relatively short time.

HDR Brachytherapy

Risk Analysis. The risk study of HDR brachytherapy given in NUREG/CR-6642 identifies the receipt and storage of sources, loading of sources into the HDR device, equipment in standby, and connecting/disconnecting the patient as requiring greatest assurance of prevention for public safety; storage was important for workers. In particular, loss of sources was to prevented with a very high assurance. This involves human performance issues associated with source accountability and control of public access, specifically the conduct of physical inventories, limiting access to relevant rooms and materials, and the training, procedures and enforcement of these administrative controls.

The risk study of HDR brachytherapy described in NUREG/CR-5362 used discrete event simulation (DES) as a means for simulating and studying processes that have defined beginnings and ends, particularly tasks involving human actions. It differs from many other PRA and HRA methods in that it

does not incorporate performance shaping factors and only considers limited dependency mechanisms. However, it does identify scenarios where human actions are significant contributors to failure pathways. Generally the report does identify that activities associated with the use of the applicators (connecting, moving, securing and marking them) are the primary area for attention. The next most important task is associated with patient transport. (It is not clear the extent to which these activities fall under NRC review.)

Event review. Of the 39 events reviewed, all but two were identified as involving human performance issues, either alone or in combination with other problems. Many of the events involved some kinds of failures associated with data entry or use of the systems planning computers that are used to calculate the locations and dwell times of the sources to complete the prescribed treatment. Examples include NMED event # 960313, where the medical physicist entered 10mm step distances in place of 5mm; #990130 where during data entry, the sequence of key strokes unintentionally changed the step distance from 2.5mm to 10mm, and #980082 where the wrong starting point for treatment was entered. In most cases, treatment plans were created and printed out for review, but the errors were not found. It is noteworthy that in at least two cases, simple numerical transpositions (e.g., '898' for '989') occurred. Several reports mention that the software resorted to default values (particularly the step distance) after other data had been entered. An additional set of events resulted from incorrect geometry data being used in dose calculations or in the treatment planning process, such as the length of the catheter (#990178) and the diameter of the source (#970423). Typical corrective actions in these types of events were: to remind staff of the need to double check data entries (#010896), to request verification of the data entered (#960717), and to require checking by a second person (#990322).

A comparatively small number of events involved incorrect connections of the catheters (through which the radioactive sources enter the patient) to the treatment system (e.g., #980209, #010552).
A few events involved the planning program for the treatment having faulty data entered into it in more of a maintenance mode—most noticeably the source strength, such as it not being updated when a new source was used, as in #980353. One event resulted from inadvertent use of an incorrect replacement part that changed the geometrical configuration (and thus, the source insertion length) (#990389).
Of the two events not identified as involving human performance problems, one had an insufficient description (#970500), and the other involved a patient moving during treatment, causing the catheter to move (#000238).

An event was reported in the Sydney Morning Herald (June 21, 2003), whereby a technician had misaligned a flexible catheter used for the palliative treatment of esophageal tumors (through a data entry problem with the treatment computer) and the treatments to 10 patients were miss-located over a period of four years.

Based on the above reviews of events and analyses, the following potentially risk significant human actions have been identified:

- errors when using the data entry interfaces (particularly the treatment planning computers or the maintenance functions of the system) whereby keystroke entry errors or system mode changes (e.g, returns to default values) are not detected
- incorrect connections of catheters, such that sources do not enter the patient or arrive at the correct treatment site
- failures to detect errors in the treatment plans.

Teletherapy

Risk Analysis. The risk analysis in NUREG/CR-6642 for single source teletherapy systems identifies seven tasks: teletherapy unit installation, patient preparation, treatment, maintenance/leak testing, source

change, system not in use/standby, and disposal /return of source to vendor. The greatest risks to the public were assessed as being associated with loss of control of the sources, requiring very high assurance of prevention. The human performance issues in this area are associated with the conduct of physical inventories, limiting access to relevant rooms, and the training, procedures and enforcement of these administrative controls. For the workers, the greatest sources of risk were associated with loss of the source shielding during a fire or other energetic event. In this area, human performance issues are associated with operability and supervision of the fire suppression systems and the effectiveness of the fire prevention program.

Event Review. Of the 18 events in the NMED database reviewed for this task, all involved some kinds of human performance problems. No type of event was particularly dominant, as it was with the problems in setting up the software in the above HDR brachytherapy events, though a number of events did involved problems with the treatment planning computer system. Some of these seemed to result from changes in the types of computers used for planning, or in their programs (e.g., #0100500, #020100), rather than from data entry errors.

Another set of events resulted from mistaken configurations of treatment (such as laterality—e.g., treating the left side instead of the right) because of miscommunications between the groups involved, or x-rays being mislabeled (e.g., #970358, #010215). A number of events were the result of the physical configuration of the teletherapy device, with "wedges' (that attenuate the dose to the patient) either being installed when they should not have been, or vice versa (e.g., #990276, #980865). Several events resulted from failures to read or follow the prescriptions completely (#990421, #971039), including a case where a prescription was changed but the changes were not documented properly (#980014). Finally there was one case where the operator miss-centered the axis of treatment because of confusion with the prescription (#970846)—the physician appears to have miss-identified the markers used to identify the treatment site.

Based on the above reviews of events and analyses, the following potentially risk significant human actions have been identified:

- errors when using the treatment planning computers (often associated with changes in computer functioning or use of non-standard computers)
- laterality errors, whereby the treatment was given to the ‘wrong side’ because of errors in reading x-rays or other planning materials
- failures to detect errors in the treatment plans
- failures to follow the directions in the prescriptions or changes were made in the prescriptions that were not documented properly.

Gamma Knife

Risk Analysis. The same seven tasks identified for teletherapy apply here (a gamma knife is a specialized type of teletherapy, using multiple individual sources [typically over 200] to concentrate the radiation on a small focused volume of the brain).

The greatest risks to the public were assessed as being associated with loss of control of the sources, requiring very high assurance of prevention. The human performance issues in this area are associated with the conduct of physical inventories, limiting access to relevant rooms, and the training, procedures and enforcement of these administrative controls. There were no high or very high assurance scenarios identified for worker safety.

Event Review. As with the above modalities, a large fraction of events involved errors in setting up the treatments via the treatment planning software system and not being corrected during reviews of the

treatment plans. Treatment locations were mistakenly transposed (e.g., x-y-z coordinates were entered as y-x-z (#981167, #980646)), treatment times were entered incorrectly (#010813) or not updated for a second treatment (#000686), or default values were inadvertently used (#980259). In one case, the physician entered the date of treatment incorrectly (1998, not 1999) and overrode the warning that the date was not the ‘system date' (#990097), thereby using an incorrect source decay value. One planning error occurred because of confusion over the images used as the basis for the treatment plan (#940802).

In one case, source strength data used in the planning software was in error because of unrelated maintenance involving an attached printer that led to a system reset with the wrong date (#021005).
In two cases, the physical configuration of the patient in the gamma knife unit was incorrect. In one case, a laterality error occurred when the patient was aligned in the treatment cavity with treatment for the right side when it should have been the left (#981080), and in one case when the collimator helmet was not changed as planned between treatments (#951266).

Based on the above reviews of events and analyses, the following potentially risk significant human actions have been identified:

- errors when using the data entry interfaces (particularly the treatment planning computers or the maintenance functions of the system) whereby keystroke entry errors (such as confusion of coordinate values, duration of treatment, and other data) are not detected
- failures to detect errors in the treatment plans
- failures of alignment of the helmet and the treatment cavity.

It is noted that some of the above events may become less frequent as the users of gamma knife devices upgrade to the model ‘C’. This model includes direct data transfers between the treatment planning and treatment management computers (so data entry is not required for the treatment management computer) and the optional use of an automatic positioning system (APS) for the helmet during treatment (which eliminates mispositioning of the helmet [x-y-z coordinate confusion, etc.]). It has been estimated that approximately 50% of the gamma knife units in use are model ‘C’ units. (Note: the fraction of such systems that use APS is not known at the time of this report.)

IV Brachytherapy

Risk Analysis. No risk analysis for IV brachytherapy was included in NUREG/CR-6642.

Event Review. As mentioned earlier, 12 of the 29 events were either hardware failures or no specific cause of the event was presented in the summaries. Since this is an emerging procedure, this large fraction of events is considered a result of new devices being tried out ‘in the field' while still under development. The following are the results of those seemingly related to human performance, though it is recognized that some described as hardware failures may result from incorrect setup of the equipment.

Several events occurred because of dose planning problems involving the detailed estimates of the doses depending on the catheter size; several other events occurred because of the unanticipated need to use additional saline solution during the source withdrawal process, thus leaving the source in the patient for longer than anticipated (e.g., #010572, #010547).

Based on the above reviews of events and analyses, the following potentially risk significant human actions have been identified:

- errors made when calculating the dose rate for the specific source size and type
- failures in planning the treatment process, thus not anticipating the need for longer durations to remove the sources because of a lack of saline.

Brachytherapy (Low Dose Rate)

The term ‘low dose rate brachytherapy’ is used to describe several different modalities of treatment where sources are typically are left in a patient for extended periods of time (hours to days). These modalities are manual brachytherapy, manual afterloading brachytherapy, and manual implant brachytherapy. While the details of each are quite different medically, they are grouped together here because they represent typically much lower risks to workers and the public than do the high dose rate treatments, and there are strong similarities as to the kinds of human errors that occur.

Risk Analysis. The risk analysis described in NUREG/CR-6642 for manual afterloading brachytherapy assigns a high importance to maintaining close control over source material during preparation, use, etc. The discussion also emphasizes the role of area monitors and surveys in limiting accumulated dose (by alerting staff to the presence of a source that has been left unshielded). These same risk consideration apply for remote afterloading brachytherapy, since these sources are also small and portable. With afterloading, however, there are also shielding aspects (i.e., sources are intended to remain inside the afterloader while workers are in the room). Thus prevention of stuck sources and visual indication of source position are emphasized in this application.

Event Review. The NMED database was used to retrieve abnormal occurrences for three keyword searches: manual afterloader (28 events), manual implant (7 events), and remote afterloader LDR brachytherapy (3 events). The events provided instances of a variety of types of human performance failures, which are typified by

- several events in which sources either were not placed in the patient (instead becoming lost in bedding or on the floor, e.g., #921098, #941116) or were dislodged from the patient (and left in contact with the patient, e.g., #950291, #951015), often after some equipment-related difficulty in placing the sources. In at least one case, the dislodged source was discovered and handled by an untrained nurse, who taped it to the patient (#900189). In another event, the wrong end of a ribbon was inserted, and the end with the seeds was handled by an untrained worker, and then discarded, possibly exposing members of the public.
- four events in which a mechanical problem while inserting the sources (e.g., a kink in the catheter) resulted in placement at the wrong site; the errors were either discovered sometime after by radiographs (e.g., #940082), or not noticed until the treatment was completed (e.g., #921049, #900085).
- several events in which the wrong dose was administered; causes included an incorrect calibration value being entered into a computer system (#950755), an incorrect end time entered on a chart (#950842), a miscommunication between a physician and dosimetrist (#960483), and errors involving incorrect units, either in computer inputs (#920085) or by a material supplier (#920764). In some cases, a required cross-check or verification was not done.

Based on the above reviews of events and analyses, the following potentially risk significant human actions have been identified:

- errors in physically locating and retaining source seeds in the correct location
- misuse or errors while entering data when using the treatment planning programs
- failures to check source locations during treatment, or to verify treatment plans.

Field Radiography

Risk Analysis. According to NUREG/CR-6642 (p. 3-997), the important contributors to accidental exposure of radiographers are “a stuck or exposed source after a radiograph is taken, along with the failure to perform the radiation survey and failure to use the alarm ratemeter, and the violation of access

control and good ALARA practices without equipment failures." Risks to the public are associated with the exposure device becoming lost and with failure to limit access to areas where sources are being used. The following, therefore, are identified (p.3-987) as the key barriers to worker or public exposure:

- training, procedures (normal and incident)
- limiting public access
- source control
- surveys, ratemeters, dosimetry, alarms to indicate off-normal conditions

Regulations (10CFR Parts 34.47 and 34.49) aimed at preventing exposure of radiographers call for 'work practices' controls; i.e., the barriers rely on the workers' cooperation and compliance with procedures.

According to NUREG/BR-0024, sources may remain outside the shielding for a variety of reasons (operator error or inattention, movement of the camera, damage to the guide tube). The only indication to the operator that this has happened is the presence of high levels of radiation. Thus any failure that results in a source not being fully retracted is very likely to be recovered from if properly functioning radiation monitoring equipment is used, and very likely to result in exposure if it is not used (i.e, if surveys are not done or ratemeters are not working).

Event Review. In NUREG/BR-0024, for each of 48 incidents, a table shows, among other information, whether a survey had been made and what other factors may have contributed to the overexposure. In all but a few instances, a survey was either not carried out or was not done effectively. Among the other factors cited were illness, difficult environments, shift change, hurrying, poor training, poor coordination between team members, poor equipment interface, and malfunctioning radiation alarms.

Events have been recorded in which radiography source have been found and retained by untrained person (#990318, #000507, IAEA STI/PUB/1123). Although these occurred outside the U.S. the severity of the exposures that can result suggests the actions contributing to source accountability are important.

A study of source drive disconnects (NUREG-1631) concluded that failures of radiography drive cables occurred because the cables (which are not actually designed for use in the field) are subjected to impact loads, frequent bending, corrosives (chemicals or salt water) or abrasion (dirt and sand).

Based on the above risk considerations and the event descriptions available for review, the following potentially risk-significant human actions are identified:

- inspecting and maintaining source drive mechanisms - poor maintenance can make source more likely to jam outside shielding or become detached
- cranking source out/in - at least one incident where radiographer claimed to have been confused about direction of movement; impact loads are applied when source is quickly cranked in against the stop
- properly storing and transporting equipment -
- locking source in shielded position - failure to do so blamed for source moving out of shielding while camera is being transported or repositioning
- surveying camera on all sides after retracting source

Well Logging (Sealed Sources)

Risk Analysis. This application of byproduct materials is of interest principally owing to the strengths of the sources used. Accordingly, NUREG/CR-6642 emphasizes the risks associated with loss of these sources and with their being damaged or dispersed by fire. Other key barriers identified include

- robust source seals
- control of general public access
- worker access control, including practices that minimize dose in normal operations

- surveys/alarms to alert workers to off-normal events (loss of shielding, loss of confinement)

Event Review. NMED contains roughly 340 instances of well-logging sources being 'lost or stolen,' but the overwhelming majority of these seems to be cases in which the sources is abandoned in the well because it cannot be recovered. Only a few cases of overexposure are recorded in the database. As might be expected, events occur as tools are being removed from wells; while well-logging tools are actually in use (underground), they pose no hazard.

Based on the above risk considerations and the event descriptions available for review, the following potentially risk-significant human actions are identified:

- actions contributing to the physical integrity and security of sources
- actions contributing to the detection of a loss of confinement - e.g., survey of well fluids
- actions surrounding the removal of drilling equipment from the hole - sources can be unintentionally brought up possibly exposing workers and untrained personnel (#000761, #000810)
- removal of tools and storage of well-logging sources - sources can be left exposed on the platform (#020536, #020889)

Irradiators

Risk Analysis. Because of the nature of the device, the risk analysis in NUREG/CR-6642 places great emphasis on (i.e, indicates a need for very high assurance of) shielding during maintenance and use. Access is considered only moderately important to assure because for there to be serious consequences as a result of access control, there would also have to have been a failure involving shielding.

The protection to personnel afforded by shielding depends to a great extent on interlocks, which are designed to prevent access to an irradiator while it is in a state theat could result in exposure, and alarms, which warn personnel of the presence of radiation and can serve to mitigate the consequences of interlock failure. Important human actions, therefore, include maintenance and inspection of interlocks and maintenance and testing of radiation detectors and alarms.

Palmrose et al. (2000) evaluated the risk to workers associated with irradiator operator being located offsite. The risk analysis explicitly modeled the possibility that workers would enter the radiation room when confronted with a process problem. The analysis demonstrated the importance of having product doors that cannot be bypassed (for continuous irradiators) and of the proper functioning of the door interlock (for batch irradiators). It was noted that the risk changes significantly depending on assumptions about the behavior of the worker. Commenting on the sensitivity analysis, Damon (2001) noted that risk is highly dependent the probability of workers following safety procedures, and that this probability is highly uncertain because circumstances (such as production pressure and the unavailability of an operator) might predispose workers to try to correct problems themselves.

Event Review. The NMED database contains examples of a failure to restore interlocks after maintenance (#960678), interlocks intentionally bypassed during unapproved maintenance with exposure limited owing to alarms (#951144), and failures of interlocks found on inspection (#940819, #000035).

In a study of the root causes of five international irradiator incidents resulting in fatalities, Palmrose noted that 'a lack of proper administrative controls (not following accepted procedures, unwarranted safety complacency, impromptu changing of procedures, etc.)' contributed to all of the events. Other cause categories were design of equipment deficiencies, equipment failures, training/qualification deficiencies, and operation/maintenance deficiencies.

Based on the above risk considerations and the event descriptions available for review, the following potentially risk-significant human actions are identified:

- actions associated with inspecting and maintaining interlocks and radiation alarms
- activities that require personnel to access the device (e.g., to remove an obstruction)
- respect for and compliance with procedures governing entry into the radiation room

Fixed Gauges

Risk Analysis. Fixed gauges are used in industrial settings to measure, using principles of radiation absorption, the volume of various materials. Sources used in these gauges are encapsulated and shielded; a shutter exposes the source when the device is in use. There is no need for workers to manually operate fixed gauges; they are often mounted in inaccessible and/or inhospitable locations. The primary safety concern for these devices is apparently the possibility that they may enter the scrap/recycling stream (see, e.g., NUREG-1669). Such events have occurred, resulting in contamination of steel mills and exposure of workers and the public.

NUREG/CR-6642 identifies a number of potential deviations or accidents associated with tasks related to fixed gauges:

- installation - damage to source confinement; shutter stuck open
- maintenance - damage to source confinement; shutter left open during maintenance
- operation - worker or public near gauge while operating; leaking source; extreme event resulting in loss of shielding and/or encapsulation
- disposal - other than normal disposal (e.g., lost or stolen)

Owing to the nature of the sources, the risk analysis identifies shielding as being very important (i.e., very high assurance). Source accountability is evaluated as important (high assurance) but less so, because of the emphasis on shielding; i.e., loss of accountability per se does not result in high doses. However, it is noted that when a source is lost and recycled, confinement will not be maintained.

Event Review. The NMED database contained was sampled for records having the keyword ‘gauge fixed’ for the period 1/1/2000 to present; 91 records were returned. About one-third of these involved cases of gauges being lost or scrapped. About 20 records described damage to gauges, typically as a result of fire or as a result of the gauges being struck by material that was incorrectly oriented on conveyors or had ‘piled up’ (#000140, #000634). In six cases the damaged gauge had fallen from its mounting (e.g., #030359, #030565); among these was the recent event in which a fallen gauge was not recognized by the employee who discovered it, resulting in exposures.

Based on the above risk considerations and the event descriptions available for review, the following potentially risk-significant human actions are identified:

- actions associated with establishing and maintaining ownership and awareness of the device
- actions associated with installing and maintaining the device
- activities in which untrained personnel may encounter misplaced gauges

Typical circumstances associated with errors in byproduct applications

Based in the sampling of the specific NMSS systems described above, general characteristics of NMSS applications that can lead to intended events (i.e., misadministrations, overexposure of workers, or exposure of members of the public) can be identified. Some of these are:

- circumstances in which source activity may change - calibration of source intensity, either new (replaced) source or at intervals to take into account decay; incorrect level of activity assumed in treatment planning; calculation
- circumstances in which material is supplied by others - ordering radiopharmaceuticals, when there can be errors associated with unit conversion; or when misidentification (e.g., mislabeling) can occur when multiple doses are prepared and transported
- circumstances in which treatments are performed by personnel other than the prescribing physician - errors resulting in misidentification of patients by those unacquainted with them; errors associated with orders that are vague or not transmitted accurately resulting in, e.g., therapeutic doses being administered when diagnostic procedures were intended
- circumstances in which source configurations (physical dimensions, activity) can vary - incorrect selection of source configuration (e.g., seed type); error owing to lack of familiarity, mislabeling
- circumstances in which untrained personnel may encounter radioactive sources - as in brachytherapy, when sources are dropped unnoticed while being inserted or become dislodged during the treatment, or with fixed gauges, when damaged gauges may fall into restricted areas or enter the waste stream.
- circumstances in which treatment planning is computer aided or partially or fully automated - familiar keying errors when entering information into treatment planning software; poorly designed interfaces (e.g., clumsy automation, forced workarounds; unintended and unpredictable results, poorly defined error conditions)
- circumstances in which checks may become ineffective owing to repetition or production pressure

This last general characteristic cross-cuts many of the others and is involved in one way or another in large numbers of the events reviewed. Despite the different NMSS-related activities and the purposes for which they are carried out and environments in which they are conducted, they have some common features. For example, potentially hazardous operations very frequently; often enough that they become routine, performed in what might be termed a ‘production’ environment. Mishaps are rare, and in many event descriptions an unusual circumstance can be identified that occasions a failure (i.e., ‘contingent conditions’ or ‘changes and unique conditions’). Such events reveal that participants have been ‘running risks;’ required activities that should have allowed an error or failure to be discovered and recovered from were not effective (e.g., checks being omitted or done in a perfunctory way). Put another way, in many incidents, in very different systems, ‘routine circumventions’ are revealed by unique conditions.

Overall, the risk studies and events review underscore the need to focus on the effectiveness of barriers that depend on human performance.

Documents Collected

Note: the list that follows is a fairly complete list of the published material collected to date for this effort; it is a bibliography, not a reference list for the foregoing letter report. (It is expected that it will be useful to have this log of available material as the effort proceeds.)

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Development of Human Reliability Analysis Capability for Regulatory Applications Involving By-Product Materials

Letter Report

Task 2: Identify Level of Detail Required for NMSS Byproduct Material Users

Prepared for
U.S. Nuclear Regulatory Commission
Office of Nuclear Regulatory Research
Division of Risk Analysis and Applications

Background

NRC is engaged in an initiative to risk-inform the materials and waste safety arenas. Operating experience indicates that human actions play a dominant role in most of the NMSS regulated activities. The overall risk of these activities is strongly influenced by human performance. Hence, an improved understanding of human error, its causes and context and human reliability analysis (HRA) can provide better risk insights to risk-inform, as appropriate, NMSS regulated activities.

Objective

In order to proceed, NRC needs to establish the following:

1. An understanding of what potentially risk-significant human actions should be addressed by NMSS.
2. An understanding of NMSS user needs regarding HRA capabilities, including HRA methods, HRA-informed tools, or other HRA needs.
3. The applicability and usefulness of existing HRA methods and tools for NMSS byproduct material applications (as required by NMSS user needs).
4. Recommendations specific to each NMSS by-product material application (or group of applications) for: (a) direct use of, (b) needed modification of, or (c) needed development of HRA methods or HRA-based tools, in order to support NMSS user needs.

The above will be the basis for future work that could include any or all of the following:

- Demonstration of the direct use of existing HRA methods or tools for NMSS byproduct material applications.
- Modification of existing HRA methods and/or tools for NMSS byproduct material applications.
- Development of new HRA methods and/or tools for NMSS byproduct material applications.

The objective of this project is to identify the HRA capability needs for NMSS byproduct material applications and to provide recommendations regarding how to meet these needs. The overall plan for meeting these objectives can be summarized as follows:

- Identify potentially risk-significant human actions (Task 1)
- Identify level of detail required for NMSS byproduct material users (Task 2)
- Group similar byproduct material applications (Task 3)
- Identify NMSS byproduct material HRA capability needs (Task 4)

Approach

In Task 1, potentially risk significant human actions were identified based on reviews of available risk studies for byproduct material applications and of descriptions of events for byproduct materials applications that involved potentially significant human actions. Applications from the medical and the industrial domains were sampled. Risk-significant human actions in medical applications included data entry, use of planning software, miscommunications (of prescription or source orders), selection of sources, calculations of source strength and location, source handling and installation, and verification of planned actions. For industrial applications, risk-significant actions included testing, and maintenance of monitoring equipment and interlocks, surveillance and custody of sources, protecting against physical damage to devices, sources, or confinement (during use or transportation), and making required surveys to prevent unexpected exposure. Details of Task 1 are described in a separate letter report.

The present letter report describes the results of Task 2 - identifying the requirements of the expected users of the human performance-related capabilities to be developed. In this task, NMSS headquarters and region staff were interviewed to identify the types of activities (e.g., license reviews, inspections, event assessments) that need HRA support and the form in which such support might best be offered.

The NRC technical lead for this effort identified a sample of several NRC personnel that represented the range expected users of NMSS HRA-related capabilities. The following individuals were interviewed:

Reviewers (NRC Headquarters)
Bob Ayres (medical)
Donna Beth Howe (medical)
Ujagar Bhachu (industrial)

Risk Analysts (NRC Headquarters)
Jim Smith
Albert Wong

Reviewer/Inspectors (NRC Regions)
Jim Dwyer (Region I license review & inspection; primarily medical area)
Vivian Campbell (Region IV agreement state liaison, reviewer; primarily industrial)

In order to accommodate the schedules and availability of the interviewees and project staff, the interviews were done by teleconference. Interviews typically lasted about 90 minutes. A set of questions and topics was prepared to structure the interviews; some of the interviewees reviewed this in advance. The principal aim of the conversations was to discuss:

- the application domains the interviewees were concerned with
- the kinds of tasks they performed
- the areas they regarded as most important in terms of risk
- the major human performance issues they had observed in their work
- the kinds of resources available to them for dealing with such issues
- the kinds of tools, aids, etc., would help in their work

Findings

General conclusions drawn from the interviews are summarized here. Individual summaries of the interviews are given in the Appendix.

As indicated above, the interviewees represented varied subject matter concerns and orientations. They typically agreed that the applications selected to be looked at in detail in Task 1 were appropriate. However, based on comments during the interviews, two additional applications (fixed gauges and low dose rate brachytherapy) were added to the set previously examined.

The interviewees confirmed the assertion on which this effort is based, i.e., that human performance issues are a major concern in most events. However, it was noted that evaluation of human performance concerns in the course of reviews or inspections is limited; it is apparently not expected that these aspects will be addressed.

The interviewees seemed to have gained some appreciation of human performance considerations based on their own individual experiences; they claimed no systematic knowledge of human factors issues and did not cite any formal references or resources that they used in this regard.

Interviewees generally were of the opinion that some form of training in general principles of human performance would be helpful to solidifying the reviews' or inspectors' awareness of these considerations. It was expressed that the training should not be abstract, but rather should be grounded in the kinds of things the staff sees in the course of their work. It was also recommended that, where appropriate, training should be offered that addresses particular areas of concern in specific NMSS applications (e.g., automation in medical treatment systems).

Interviewees mentioned various ways in which information about human performance might be used. They saw it as a means of identifying 'deeper' causes of performance problems (i.e., for going beyond 'human error' as a root cause), which in turn would help in evaluating corrective actions proposed by licensees. They also saw a potential use in prioritizing events; i.e., being able to identify occurrences that while lacking immediate serious consequences might nevertheless signal underlying performance problems. Another use of human performance resources was in guiding the evaluation of changes in risk associated with changes in processes or procedures (e.g., "What is the impact of new administrative checks?"). There is currently little or no guidance for such considerations.

Related to the above, reviewers (especially in the medical devices area) noted that as a result of technological advances they are often faced with novel applications. In these cases, they assemble facts and expertise developed in connection with other applications that, while generally dissimilar from the one being reviewed, had some common elements. This suggests that human performance resources should not be highly tailored to existing applications, at least in areas in which novel applications are likely to be proposed.

Checklists were recommended as a means of bringing knowledge of human performance considerations to bear in reviews and event investigations. It was noted that the application-specific compliance guidance in NUREG-1556 included checklists that summarized requirements, and that it might be useful to have supplementary resources in a similar format that summarized possible human performance concerns.

APPENDIX

Notes from Interviews

Bob Ayres, 5/23/2003

In the medical area, the risks associated with high dose-rate sources are the highest priority. These would largely encompass the modalities of HDR brachytherapy, the gamma knife, some teletherapy, IV brachytherapy (IVB), and use of I_{131}. Typical issues with these modalities include:

- HDR brachytherapy: The lack of attention to monitors or alarms (as in the Indiana PA event), user problems with treatment planning software, doses to user (worker) fingers when installing new or removing old sources and in shipping.
- Gamma knife: Often involves misreading x-ray or other images and get laterality events (e.g., L vs. R), confusion of x and y measurements during entry of treatment plan data (new automation processes minimize this but automation errors tend to be less detectable), errors in treatment plan (again automation can hide this).
- Teletherapy: One common source of problems is the exchange of C_{60} sources (about every 5 years) but the treatment planning software does not get told that the source strengths have been restored to new (patients overdosed)—another was errors in calculating source decay rates (Riverside Methodist Hospital, Columbus, OH). Planning software data entry errors are also significant.
- IV Brachytherapy: This is a relatively new modality in use in cardiology that involves placing a source in a main heart blood vessel via the femoral artery to reduce the growth of occlusions that takes place after (e.g.,) balloon angioplasty is performed. These sealed sources can get loose or be placed incorrectly.
- $Iodine_{131}$: This modality can often involve both diagnostic and therapeutic procedures, and they become mixed up. This can involve not having the proper paperwork (or it not being checked), and not following procedures.

The kinds of influences that seem to play a part in these events include the following:

- Staffing: New staff, high workloads, temporary staffing and coverage for different specialties by other specialties (e.g., radiology for nuclear medicine)
- Lack of supervision
- Mixing up treatment plans: such as treatment A given to patient B.
- Mis-programming treatment equipment: especially for HDR brachytherapy—one example is when using European equipment, the date order is often reversed from the usual US convention (e.g., dd/mm/yyyy vs. mm/dd/yyyy).

Significant inadvertent doses to medical personnel are rare; occasional high doses to fingers occur if source is handled. Public may be exposed if shielding is compromised; public exposure more of a concern in industrial settings.

Finally, regulators have several tools they can use to influence safety, principally issuing guidance (e.g., raising short term awareness with information notices) and the use of new regulations. The diagram below, taken from NRC's website, summarizes the agency's overall regulatory activities. One potential use of HRA is to evaluate corrective actions proposed by licensees; when corrective actions are approved, there are typically not repeat events.

Ujagar Bhachu, 7/17/03

Ujagar reviews sealed sources & devices for medical other uses.

Reviews are carried out both at HQ and the regions: regional people issue the license to users and review procedures, etc. After approval inspector(s) would look at configuration, procedures, installation in the field. Inspection is done in the regions; the frequency of inspection is related to the risk.

HQ reviewers look more at such things as containment, and shielding. Reviewers are all trained but not all equally informed w/r to HF issues; there is no requirement for HF training for license review. To the extent that ergonomic issues are reviewed, this is at HQ. However, the review of software (user interface?) would be done by FDA or regional inspector.

HQ has a set of review guidelines in NUREG-1556, Consolidated Guidance About Materials Licenses, a 20-volume document, generally with different volumes for different types of systems. Volume 3, Applications for Sealed Source and Device Evaluation and Registration, contains a generic checklist for reviewers in Appendix C, Application and Review Checklist, which contains very little related to human-factors issues.

The focus of reviews is on safety (although recently security concerns have been emphasized as well). Accordingly, there is an interest in systems like irradiators. There have been violations in the U.S., but no fatalities. Events are associated with lack of training, willful violation of procedures. Areas of particular concern include irradiators (panoramic irradiators), and the medical systems (teletherapy, brachytherapy).

Ujagar suggested that since there is very little human-factors training for NMSS reviewers there needs to be education both at the technical and managerial levels about the issue of human factors and safety, especially as new systems are developed that add complexity to safe operations.

Regarding tools that are available, he noted that application specific regulatory documents (NUREG-1556 volumes) have checklists for each device or application, and that human performance support might be more useful if presented in the context of existing tools (e.g., the checklists)

He remarked that while applications are not as complex as nuclear power plants, the level of complexity in new technology is increasing. To deal with new devices or applications, reviewers assemble a team and draw on collective knowledge of applications with similarities to reach decisions. Therefore any HRA-related product offered intended to support review of new or advanced technology would have to be general, and not too prescriptive

Jim Smith, 7/17/03

Jim was one of the prime developers of the risk study of byproduct materials, NUREG/CR-6642, Risk Analysis And Evaluation Of Regulatory Options For Nuclear Byproduct Material Systems. (This study excluded patient safety from the dimensions of risk because, at that time, the boundaries of responsibility for patient safety between NRC and the medical community was a matter of discussion.) However, the study did include an analysis of human actions. Extending the HRA analysis in this area would allow the ranges of uncertainty to be narrowed.

Jim conducts risk studies using NUREG/CR-6642; studies done or in progress include radiography, irradiators, radiography two-man rule, portable gauge (Seaman density gauge), chemical agent. Prior to NUREG/CR-6642, the assessment of a change in risk was qualitative. Therefore, the evaluation of a proposal as to whether delta risk was acceptable might therefore be less defensible. NUREG/CR-6642 provides justification). The database companion to NUREG/CR-6642 is not user friendly but contains the information needed to evaluate risk; i.e., is useful in the hands of one familiar with its use. The typical process for using NUREG/CR-6642 in a risk evaluation is to look at relevant system treatment, go to site to 'verify parameters,' and tweak as needed.

Notwithstanding its exclusion from NUREG/CR-6642, Jim believes that patient safety is the highest priority for medical systems. Systems focused on are those in which there is a possibility of death or serious injury (vs violation of occupational limits) or there are deterministic effects (vs compliance issues), e.g., teletherapy, brachytherapy, iodine ablation.

Jim said that data to support human reliability aspects of risk assessments don't exist in a hard form. The treatment of human performance is weak, and users need a context in which to use numbers. He agreed that identifying the 'contingencies' can narrow down the range. Jim claimed that HRA-related input can help further improve the safety (as opposed to compliance) focus of inspections, the evaluation of exemptions, and the evaluation of risk-significance in enforcement action. Specific needs include a user friendly database system to support use of NUREG/CR-6642 and "something that we could reference" regarding human reliability.

Donna-Beth Howe, 7/23/03

Donna-Beth is primarily responsible for reviewing emerging technologies, particularly in the area of medical devices.

One area of current interest that involves human factors concerns is that of microspheres; Y-90 microspheres are manual brachytherapy sources used for permanent brachytherapy implantation therapy. Users are required to develop and use Quality Management Plans that include sign-offs and cover issues like patient identification processes.

Most medical events are human factors related; device failure is a design problem. Recently, Donna-Beth has observed a significant increase of medical events associated with IV brachytherapy. These seem to be associated with the user interfaces. Available sources for addressing interface design include the sealed source and device registry if the issue is related to delivery or dose; not code or physical interfaces.

The QMP was an attempt to reduce human error (in such areas as patient identity and treatment verification) by means of self-assessment.

Donna-Beth feels that for her uses, the strongest need is for reviewer guidelines that keep the human factors issues to the fore (i.e., “need to think about this…”) when reading an application, since these issues will become more important as devices become more sophisticated. New devices may be hybrids of different technologies (e.g., use of ultrasound to place radiotherapy sources). The reviewer guidelines would be in two parts: a section that explains the basic principles and concepts, and then sets of questions that apply to specific devices. The second part could, for example, be in the form of a series of checklists (supplemented by examples), since reviewers work from a mental checklist.

Jim Dwyer, 7/29/03

Jim is an inspector and license reviewer for Region I. He spent 10 weeks on rotation at NRC HQ and recently returned to the region. Jim particularly reviews medical devices and schedules inspections. Routine inspections for broad scope programs (typically large hospitals) are changing from 1 every 2 years about to 1 every 3 years, and smaller facilities, from 1 every 3 years to 1 every 5 years. This is to reduce the regulatory burden. Special inspections occur if an event occurs, or spills or losses of sources are reported, or if the facility has put in place a new modality.

Jim was of the opinion that human factors issues are important contributors to medical events but there is little in the way of systematic understanding of HF issues and no significant pressure to engage this area. For example, there is rarely any inquiry into the causes of HF-related events, nor any pressure from the organization to follow up on these events. Jim had written up a couple of event analyses that he thought were typical in terms of the human factors issues seen in the regions.

Jim thinks that the development of human factors-related review and inspection guidance with related training is a high priority need. Region I inspectors meet together about 2 times a year for a week, and several training activities take place during these weeks. This would provide an opportunity to provide such training.

Vivian Campbell, 7/31/03

Vivian is the NRC's Region IV State Agreements Officer; she had just returned from assignment at NRC HQ. In this role, she is the liaison with the agreement states, and reviews states' programs, performs periodic visits with the states' program staff, including visits to state-licensed sites, and holds technical discussions with the states' staff. NRC reviews events reported from the agreement states.

She was also a license reviewer for 12 years. In Region IV, staff do not specialize in industrial, academic or medical applications—all reviewers review all types of applications.

Typically state inspectors perform more frequent visits to licensees than do the NRC inspectors, because access is easier (closer travel, smaller area for the number of inspectors to visit).

Procedures are not reviewed as they were in the past; emphasis is more on performance. Procedures looked at only if performance is less than adequate. Performance is based on experience of potential problems.

For work with agreement states (currently 32), the framework for raising human factors issues is perhaps much more limited than within NRC. NRC currently uses a set of performance indicators to monitor state's performance (e.g., technical staffing levels and training) and can put a state program on heightened oversight, which involves increased NRC (region and HQ) involvement.

Vivian's perspective was the need to have some basis for prioritizing events and to know where attention should be focused. Right now, information is just gathered. The priorities are basically on the basis of outcomes; the criteria for an abnormal occurrence are clear. An effective tool that would help the states differentiate among the remaining events – to distinguish minor things from potentially significant 'close calls.' The significance prioritization would be useful since too many reports simply clog up the system (reported "to be safe") and potentially important information just gets lost in the volume. Vivian didn't comment on the value of familiarization with general human factors issues. However, she noted that effective root cause identification is needed but is often weak. It is perhaps too easy to label an event as a "human error" and leave it at that.

Additional Notes

(from kickoff meeting)

Bob Ayres & Donna-Beth Howe, 5/15/2003

The regulatory guidance for medical uses of byproduct materials are covered in 10CFR35, in the following subsections: below 300--radiopharmaceuticals & diagnostic materials; 400--brachytherapy; 600--HDR brachytherapy and gamma knife; 1000--new and emerging technologies. Materials inspections take place at the regions' level. NRC regulates the *users* of byproduct materials, and FDA regulates the manufacturers of equipment that incorporate byproduct materials for medical uses. Interfaces exist with other organizations involved in the medical uses area, particularly the boards that certify medical users (medical physicists, etc.). There is a current issue concerning training requirements, where some board certifications do not meet the training requirements set out in 10CFR35.

Information on the byproducts area is on the NRC website (www.nrc.gov) on the MIAU (Medical, Industrial, Academic Uses) page (http://www.nrc.gov/materials/medical.html). The Advisory Committee on the Medical Uses of Isotopes (ACMUI) advises NRC on policy and technical issues that arise in the regulation of the medical uses of radioactive material in diagnosis and therapy.

Most medical uses inspections are the result of events. Licensees are responsible for performing root cause analyses (RCAs), but NRC inspectors have RCA training. Reportable medical events occur when a dose is +/-20% or more deviation form the prescribed dose, or when the dose is to the wrong site and involves a dose >50 rem to the organ or > 5 rem to the whole body. Patient interventions can cause reportable events, for example moving a source and thus dosing the wrong site.

Industrial applications involve sealed sources and devices. Designs are reviewed by NRC engineers, and inspections are made of "manufacturers" (actually distributors) and users.

Systematic problems were identified in the events at Riverside Hospital and "Panama"—particularly associated with software issues in treatment planning systems. FDA requires ISO V&V for treatment planning software.

Memoranda of understanding (MOUs) exist with EPA and DOT for shipping.

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Development of Human Reliability Analysis Capability for Regulatory Applications Involving By-Product Materials

Letter Report

Task 3: Group Similar Byproduct Material Applications

Prepared for
U.S. Nuclear Regulatory Commission
Office of Nuclear Regulatory Research
Division of Risk Analysis and Applications

Background

NRC is engaged in an initiative to risk-inform the materials and waste safety arenas. Operating experience indicates that human actions play a dominant role in most of the NMSS regulated activities. The overall risk of these activities is strongly influenced by human performance. Hence, an improved understanding of human error, its causes and context and human reliability analysis (HRA) can provide better risk insights to risk-inform, as appropriate, NMSS regulated activities.

Objective

In order to proceed, NRC needs to establish the following:

1. An understanding of what potentially risk-significant human actions should be addressed by NMSS.
2. An understanding of NMSS user needs regarding HRA capabilities, including HRA methods, HRA-informed tools, or other HRA needs.
3. The applicability and usefulness of existing HRA methods and tools for NMSS byproduct material applications (as required by NMSS user needs).
4. Recommendations specific to each NMSS by-product material application (or group of applications) for: (a) direct use of, (b) needed modification of, or (c) needed development of HRA methods or HRA-based tools, in order to support NMSS user needs.

The above will be the basis for future work that could include any or all of the following:

- Demonstration of the direct use of existing HRA methods or tools for NMSS byproduct material applications.
- Modification of existing HRA methods and/or tools for NMSS byproduct material applications.
- Development of new HRA methods and/or tools for NMSS byproduct material applications.

The objective of this project is to identify the HRA capability needs for NMSS byproduct material applications and to provide recommendations regarding how to meet these needs. The overall plan for meeting these objectives can be summarized as follows:

- Identify potentially risk-significant human actions (Task 1)
- Identify level of detail required for NMSS byproduct material users (Task 2)
- Group similar byproduct material applications (Task 3)
- Identify NMSS byproduct material HRA capability needs (Task 4)

Approach

In Task 1, potentially risk significant human actions were identified based on reviews of available risk studies for byproduct material applications and of descriptions of events for byproduct materials applications that involved potentially significant human actions. Applications from the medical and the industrial domains were sampled. Risk-significant human actions in medical applications included data entry, use of planning software, miscommunications (of prescription or source orders), selection of sources, calculations of source strength and location, source handling and installation, and verification of planned actions. For industrial applications, risk-significant actions included testing, and maintenance of monitoring equipment and interlocks, surveillance and custody of sources, protecting against physical damage to devices, sources, or confinement (during use or transportation), and making required surveys to prevent unexpected exposure. Details of Task 1 are described in a separate letter report.

The aim of Task 2, was to identify the requirements of the expected users of the human performance-related capabilities to be developed. In this task, NMSS headquarters and region staff were interviewed to identify the types of activities (e.g., license reviews, inspections, event assessments) that need HRA support and the form in which such support might best be offered. Interviewees were of the opinion that training in human performance issues would be helpful. The training would be general enough to allow staff to deal with novel questions, but not abstract, i.e., oriented toward application. Availability of specialized training for areas of special concern was also considered important. Interviewees also commented that the information should be provided in a form that would make it easy to apply (e.g., checklists). They also saw a need for resources that would allow them to go beyond 'human error' as a root cause and to be able to identify occurrences that while lacking immediate serious consequences might nevertheless signal underlying performance problems. Another use mentioned for of human performance resources was in guiding the evaluation of changes in risk associated with changes in processes or procedures.

The goal of Task 3 was to identify, based on the results of Tasks 1 and 2, aspects that the various NMSS systems have in common, so that the human factors/HRA methods, models, data, tools, and/or guidance to be developed would apply across byproduct uses, and not be focused on specific systems. Although other categorizations are possible, for the present purpose (i.e., addressing human performance in byproduct material activities), it makes sense to group uses that involve similar human activities or those performed in similar environments.

Results

Grouping by Risk. In view of the ultimate purpose of the current effort (i.e., to support risk-informing the NMSS arena), it is reasonable to note that the NMSS applications can be grouped by the level of risk associated with them. In fact, informal judgements about the relative risks involved in various applications guided the sampling of risk studies and event reports that were reviewed in Task 1. For a more rigorous categorization, it is most useful if all of the applications are formally assessed using the same methods, as was done in NUREG/CR-6642. The categorization given in that document is shown in Table 1. The International Atomic Energy Agency has recently issued a revised categorization system for radioactive sources (IAEA, 2003). The categories are based on a ranking of sources for their potential to produce deterministic health effects. The evaluation considered both the physical properties of the sources and the ways in which they were used (e.g., "the nature of the work, the mobility of the source, experience from reported accidents, and typical vs. unique activities within an application"). As in NUREG/CR-6642, deliberate exposure for medical reasons is not considered in the categorization. This categorization is also shown in Table 1. It is encouraging to note that, despite the different methods and emphases on which the categorizations are based, there is a rough ordinal similarity between them. Inconsistencies may be attributable the differences in international practices and experience as compared with that in the U.S. For example, worldwide there have been five fatal irradiator events, but none of these events occurred in the U.S.

These risk categorizations do not offer any insight into the likelihood or the consequences of human performance problems in byproduct uses. They are given here because the depth of the analysis associated with event investigations or licensing questions will depend to a certain extent on some *a priori* judgement of the stakes involved. Therefore, being able to identify byproduct uses associated with the greatest potential for harm will be useful in determining the areas deserving special attention in the development of human performance resources for NMSS staff.

Grouping by Type of Application. It also is possible to group byproduct uses according to the general nature or the purpose of the activity. Such a grouping is provided in NUREG/CR-6642, and is shown, in part, in Table 2. This type of categorization is of more use in the present context because tasks within a

category are more likely to share types of human actions or take place in similar settings. For example, it is likely that laboratory/research uses have similar aspects that relate to human performance. However, this is not necessarily the case; there are great differences among the uses categorized as "industrial," differing, for example, with respect to the nature of the actions associated with them (e.g., well logging and irradiators). Nevertheless, these groups may be important in guiding the development of resources for those systems that were not considered in detail (i.e., those for which the risk analyses and event descriptions were not reviewed for this feasibility study).

Grouping by Human Performance Considerations. As indicated above, the most valuable way of organizing byproduct material uses for the present purpose is according to human actions and the settings in which those actions occur. Such a categorization can be made by listing characteristics of byproduct material uses (derived from the important actions and circumstances identified from the risk studies and event descriptions in Task 1) and then noting the individual uses to which they might apply. Table 3 lists characteristics of byproduct material systems. The list of categories of human performance characteristics is not intended to be complete. Rather, it is intended to help to group byproduct uses around general expressions of the principal activities identified in Task 1 of the overall feasibility study effort Table 3 also shows, for each of the principal system characteristics identified, the relevant human reliability considerations. These characteristics and associated human reliability considerations help to identify the specific knowledge areas that need to be addressed in developing HRA capability for NMSS byproduct materials applications.

Table 4 illustrates the relationship between characteristics and systems. Three things are noteworthy in the table with respect to groupings of uses. First, as might be expected, uses associated with radiotherapy modalities share some characteristics that other uses do not have. This is related to the fact that the medical uses involve intended exposure of people to radiation, whereas the other uses lack this aspect. Second, there are some aspects of industrial applications that also are characteristic of some medical uses. For example, the practice of surveying to check for misplaced sources is common to field radiography and brachytherapy. Finally, it is clear that all byproduct materials uses rely on administrative controls (e.g., policies, procedures, training). Thus, it is expected that the training materials and tools to be developed to support analysis of human performance in byproduct materials context will have at least two orientations - one general and the other focused on considerations specific to medical applications.

As indicated above, the list of characteristics is not exhaustive. It will serve as a basis for developing generally applicable human performance resources. As byproduct materials uses (or systems) are examined in greater detail (e.g., in the course of developing more specialized methods or tools), elements may be added, or uses may be placed under existing entries. Lacking any other requirements (e.g., the need to respond to a particular application) development of more detailed treatments can be prioritized by the risk associated with the byproduct use (as given, e.g., in Table 1). Alternatively, other considerations not recognized at this time may form the basis for prioritizing the Phase 2 development work.

Table 1 Risk Groupings of Byproduct Applications

Category	Nuclear Byproduct Material Systems (NUREG/CR-6642)	Common Practices (IAEA-TECDOC-1344)
High (1)	Radiography Medical (Therapeutic) Medical (Brachytherapy - Manual Afterloading) Medical (Teletherapy - Single Source) Radiography (Shield Room)	Radioisotope Generators Irradiators Teletherapy Fixed Multi-Beam Teletherapy (Gamma Knife)
Moderately High (2)	Portable Gauges (Gamma/Neutron Source) Medical (Diagnostic - Unit Doses) Irradiators (Self-Shielded) Fixed Gauges (Gamma) Nuclear Pharmacy Well Logging (Sealed Sources) Lab Use (R&D, Unsealed Synthesis Quantities) Vet (Diagnostic and Therapeutic) Medical, Diagnostic Devices (Fixed) Medical (Brachytherapy - LDR Remote)	Industrial Gamma Radiography Brachytherapy - high dose rate - medium dose rate
Moderate (3)	Medical (Teletherapy - Gamma Knife) Medical (Brachytherapy - Implanted Seeds) Well Logging (Tracers, Field Flooding) Medical (Brachytherapy - HDR Remote) Medical (Generators) Manufacturers & Distributors (Sealed Sources) Medical (Human Research Only) Lab Use (R&D, Unsealed Prepared) Measuring Systems (X-Ray Fluorescence) Animal Research Waste Disposal (Packaging)	Fixed Industrial Gauges - level gauges - dredger gauges - conveyor gauges - spinning pipe gauges Well Logging Gauges
Moderately Low (4)	Fixed Gauges (Beta) Irradiators (Pools) Other Small Sealed Sources Waste Disposal (Incineration) Manufacturers & Distributors (Unsealed Liquid Sources)	Brachytherapy - low dose rate - excl. eye plaques, implants Thickness/fill-level Gauges Portable Gauges - moisture/density gauges Bone Densitometers Static Eliminators
Low (5)	Measuring Systems (Gas Chromatograph) Waste Disposal (Compacting) Very Small Sources Lab Use (R&D, Unsealed, Other, Including Exempt Quantities) Medical (Brachytherapy - Sr-90 Eye Applicator) Measuring Systems (Other)	Sr-90 Eye Plaques Permanent Implant Sources X-Ray Fluorescence Devices Electron Capture Devices Mossbauer spectrometry Positron Emission Tomography checking

Table 2 Groupings of NMSS Systems (From NUREG/CR-6642, Table 4.1-1, p.4-3)

Medical Systems -1 (patient retains radionuclide)	
4	Medical (Generators)
5	Medical (Diagnostic - Unit Doses)
6	Medical (Therapeutic)
7	Med (Brachytherapy - Implanted Seeds)
14	Medical (Human Research Only)
15	Nuclear Pharmacy
16	Vet (Diagnostic and Therapeutic)
Medical Systems -2 (sealed, patient does not retain radionuclide)	
8	Med (Brachytherapy - Man Afterloading)
9	Med (Brachytherapy - LDR Remote Afterloading)
10	Med (Brachytherapy - HDR Remote Afterloading)
11	(Brachytherapy - Sr-90 Eye Applicator)
12	Medical (Teletherapy - Single Source)
13	Medical (Teletherapy - Gamma Knife)
39	Medical, Diagnostic Devices
Research/Laboratory Systems	
1	Lab Use (R&D, Unsealed, Synthesis Quantities)
2	Lab Use (R&D, Unsealed Prepared Compounds)
3	Lab Use (R&D, Unsealed, Others inc Exempt Quan)
16	Vet (Diagnostic and Therapeutic)
25	Animal Research
Industrial Applications	
17	Well Logging (Tracers, Field Flooding)
18	Well Logging (Sealed Sources)
19	Radiography (Shield Room)
20	Irradiators (Pools)
21	Irradiators (Self-shielded)
40	Radiography (Field)

Table 2 Groupings of NMSS Systems (continued)

Manufacturing and Distribution Systems	
15	Nuclear Pharmacy
31	Manufacturers & Distributors (Sealed Sources)
32	Manufacturers & Distributors (Unsealed Solid Sources)
33	Manufacturers & Distributors (Unsealed Liquid Sources)
34	Manufacturers & Distributors (Unsealed Gas Sources)
Measuring Systems	
22	Fixed Gauges (Gamma)
23	Fixed Gauges (Beta)
24	Portable Gauges (Gamma, Neutron Source)
26	Measuring Systems (X-Ray Fluorescence)
27	Measuring Systems (Gas Chromatograph)
28	Measuring Systems (Other)
29	(Other Small Sealed Sources)

Table 3 Characteristics of Byproduct Systems and Human Reliability Considerations

Characteristics of Systems	Human Reliability Considerations
different individuals choose, prepare/order, transport, use sources	written and verbal communications, labeling, transcription
'independent' verification of planned action required by procedure/policy	effectiveness of checking, safety culture
dose or source strength is calculated	manual calculation, transcription
computerized user interfaces or treatment planning aids	human-system interface design, data entry
automated tasks or processes	automation-assisted error, over-reliance
physical interlocks protect against exposure	testing and maintenance, restoration after maintenance
sources prepared or positioned manually	slips, detection of mechanical failures
devices/sources are transported and used in field settings	maintenance, accountability
surveying for unshielded or misplaced source	effectiveness of detection
monitors/alarms indicate unshielded or misplaced source	response to alarms, confidence in indications
policies and procedures relied upon to limit unintended exposure	effectiveness of administrative controls, safety culture

Table 4 Characteristics of Byproduct Systems

Characteristics of Systems	Medical Uses						Industrial Uses			
	High Dose Rate Brachytherapy	Teletherapy	Gamma Knife	Intravenous Brachytherapy	Low Dose Rate Brachytherapy		Field Radiography	Well Logging	Fixed Gauges	Irradiators
different individuals choose, prepare/order, transport, use sources	■	■	■	■	■					
'independent' verification of planned action required by procedure/policy	■	■	■	■	■					
dose or source strength is calculated, updated, or converted	?	?	?	?	?					
computerized user interfaces or treatment planning aids	■	■	■							■
automated tasks or processes	?									?
physical interlocks protect against exposure	■									■
sources prepared or positioned manually				■	■		■			
devices/sources are transported and used in field settings							■	■		
surveying for unshielded or misplaced source					■		■	■		■
monitors/alarms indicate unshielded or misplaced source	■						■	■		■
policies and procedures relied upon to limit unintended exposure	■	■	■	■	■		■	■	■	■

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Development of Human Reliability Analysis Capability for Regulatory Applications Involving By-Product Materials

Letter Report

Task 4: Identify NMSS Byproduct Material HRA Capability Needs

Prepared for
U.S. Nuclear Regulatory Commission
Office of Nuclear Regulatory Research
Division of Risk Analysis and Applications

Background

NRC is engaged in an initiative to risk-inform the materials and waste safety arenas. Operating experience indicates that human actions play a dominant role in most of the NMSS regulated activities. The overall risk of these activities is strongly influenced by human performance. Hence, an improved understanding of human error, its causes and context and human reliability analysis (HRA) can provide better risk insights to risk-inform, as appropriate, NMSS regulated activities.

Objective

In order to proceed, NRC needs to establish the following:

1. An understanding of what potentially risk-significant human actions should be addressed by NMSS.
2. An understanding of NMSS user needs regarding HRA capabilities, including HRA methods, HRA-informed tools, or other HRA needs.
3. The applicability and usefulness of existing HRA methods and tools for NMSS byproduct material applications (as required by NMSS user needs).
4. Recommendations specific to each NMSS by-product material application (or group of applications) for: (a) direct use of, (b) needed modification of, or (c) needed development of HRA methods or HRA-based tools, in order to support NMSS user needs.

The above will be the basis for future work that could include any or all of the following:

- Demonstration of the direct use of existing HRA methods or tools for NMSS byproduct material applications.
- Modification of existing HRA methods and/or tools for NMSS byproduct material applications.
- Development of new HRA methods and/or tools for NMSS byproduct material applications.

The objective of this project is to identify the HRA capability needs for NMSS byproduct material applications and to provide recommendations regarding how to meet these needs. The overall plan for meeting these objectives can be summarized as follows:

- Identify potentially risk-significant human actions (Task 1)
- Identify level of detail required for NMSS byproduct material users (Task 2)
- Group similar byproduct material applications (Task 3)
- Identify NMSS byproduct material HRA capability needs (Task 4)

Approach

In Task 1, potentially risk significant human actions were identified based on reviews of available risk studies for byproduct material applications and of descriptions of events for byproduct materials applications that involved potentially significant human actions. Applications from the medical and the industrial domains were sampled. Risk-significant human actions in medical applications included data entry, use of planning software, miscommunications (of prescription or source orders), selection of sources, calculations of source strength and location, source handling and installation, and verification of planned actions. For industrial applications, risk-significant actions included testing, and maintenance of monitoring equipment and interlocks, surveillance and custody of sources, protecting against physical damage to devices, sources, or confinement (during use or transportation), and making required surveys to prevent unexpected exposure. Details of Task 1 are described in a separate letter report.
The aim of Task 2, was to identify the requirements of the expected users of the human performance-related capabilities to be developed. In this task, NMSS headquarters and region staff were interviewed to

identify the types of activities (e.g., license reviews, inspections, event assessments) that need HRA support and the form in which such support might best be offered. Interviewees were of the opinion that training in human performance issues would be helpful; the training would be general enough to allow staff to deal with novel questions, but not abstract, i.e., oriented toward application. Availability of specialized training for areas of special concern was also considered important. Interviewees also commented that provided in a form that would make it easy to apply (e.g., checklists). They also saw a need for resources that would allow them to go beyond 'human error' as a root cause and to be able to identify occurrences that while lacking immediate serious consequences might nevertheless signal underlying performance problems. Another use mentioned for of human performance resources was in guiding the evaluation of changes in risk associated with changes in processes or procedures.

The goal of Task 3 was to identify, based on the results of Tasks 1 and 2, grouping of byproduct application that can be used to organize the development of human factors/HRA methods, models, data, tools, and/or guidance. The principal groups defined, based on common system characteristics, were radiotherapy modalities and industrial uses, although groupings based on risk or the general nature of the activity may also be useful.

The present report describes the results of Task 4, the aim of which was to identify, based on the results of the previous tasks, the resources needed to allow NMSS staff to address human reliability, and to suggest a plan for filling those needs. The needed human performance capabilities were defined based on interviews with NMSS staff (Task 2), and the specific resources to be developed were based on the groupings and system characteristics identified in Task 3 (which themselves were based on mainly on information developed in Task 1).

Results

As noted in the Task 2 letter report, there was general agreement on the need for resources to help better understand the factors that can cause risk important human failures in NMSS byproduct materials. NMSS staff saw a need for familiarity with principles and concepts related to human performance in the particular contexts with which they are concerned, but those with experience in radiotherapy applications cautioned that the information should be general enough to support dealing with new technology.

The resources requested by the staff were principally qualitative in nature, with two types of use. One focus could be termed prospective, and would include identifying for reviewers the kinds of human performance concerns or issues they should be aware of and providing a basis for anticipating problems and prescribing requirements, rather than waiting for incidents related to human performance to occur. The other could loosely be called retrospective. This would include providing a means of identifying potentially significant human performance related events or trends among reported incidents, and providing a basis for going beyond 'human error' as root cause (such as in assessing corrective actions).

Staff concerned with risk analysis, not surprisingly, had mentioned quantitative needs as well. They apparently did not anticipate a need to undertake HRA analyses per se. Rather the requirement was seen as something to make the assessment of risk change estimates more defensible, i.e., a basis for judgements regarding human reliability. They also expressed a need for a way to consider the context in which human performance occurs in order to 'narrow the range' in estimating human failure probabilities.

Two points emerged from discussions of the formats in which resources for better understanding human performance would be provided. First, staff who expressed an opinion favored face-to-face training over, e.g., computer-based training. An interactive element was deemed necessary to insure that the training addressed application specific issues; interactive 'case study' exercises were mentioned as useful components of the training. It was also noted that staff regularly participates in training on other topics,

which presents the opportunity to add face-to-face training without significant disruption. The second point made by staff was that the conceptual knowledge and background information on which training is provided should be supplemented with material to facilitate its practical application. Checklists were mentioned as necessary aids that would help reviewers, investigators, and analysts keep in mind the kinds of human performance considerations they should be aware of.

The needs expressed by the prospective users point to the development of the following types of resources

- training material
- aids for reviewing licensee requests
- aids for inspection
- methods for reviewing corrective actions
- a guide for reviewing risk assessments

Training Material

As indicated above, the topics addressed in training will be based on the human reliability considerations associated with characteristics of the byproduct systems, as identified in Task 3. Basic knowledge will be culled from the general human performance literature. For some topics, the basic information may be supplemented with the more practically oriented treatments associated with HRA tools (see discussion under Risk Assessment Resources). Some likely information sources for the required training content are summarized in the paragraphs below.

The effectiveness of *checking* (e.g., verification of treatment plans) can depend on a variety of factors, such as the design of the paperwork system that supports it or the circumstances under which it occurs. At an abstract level, effective checking can be seen as a vigilance problem, and the various influences can be systematically considered in terms of that conceptualization. The question of whether checking is done at all (as opposed to its effectiveness) is one of following procedures or conforming to policy (see below).

The reliability of human interactions (e.g., entering data, selecting operating options) with technology such as computerized treatment planning systems depends on *human-system interface* design. There are numerous accessible treatments of general issues associated with interface design (e.g., Norman, 1988). Detailed design guidelines and technical basis documents have been developed for NRC (e.g., NUREG-0700, Rev.2); these can be consulted for specific examples of good practices in interface design.

Issues associated with *automation* include automation-assisted error and over-reliance on computerized systems. It can be anticipated that computerized systems will increasingly be used to guard against certain classes of human error (e.g., those associated with paper-based systems). There is a large body of human factors literature on potential negative aspects of automated systems (e.g., their ability to proliferate or even induce errors, the fact that error may be less apparent to the user, users' tendency to accept system-generated data as correct). The work of Woods (e.g., 1994) is a good source in this area; he also has recently turned his attention to patient safety (e.g., Woods and Cook, 2002).

A wide variety of protective mechanisms depend on the quality of *testing and maintenance* (e.g., interlocks, alarms, area radiation monitors, radiation survey devices), and are, therefore, subject to classic 'failure to restore' considerations (e.g., procedures, environmental conditions, maintenance extending over more than one shift). Treatments based on existing HRA techniques developed for nuclear power plants are adequate in this area.

While some mispositionings of sources involve *slips* (i.e., simple manual errors such as turning an operator in the wrong direction), a greater number where related to the fact that the positioning is done

'blind' (i.e. there is no immediate positive indication of the location of the source; rather its position is inferred by the behavior of the positioning device). In such cases, the ability of the user to detect mechanical failures becomes important, and knowledge of the concept of *feedback* will be useful. However, details will differ for specific devices; i.e. information provided for this topic will not be as general as that in other areas.

Conceptually, the factors related to the effectiveness of *surveying* to verify that sources have not been misplaced are similar to those for administrative verification (i.e., checking), described above. There are system and situational aspects to the task, that can be organized within the framework of vigilance. A detailed treatment of human performance in surveying (albeit in the context of decommissioning activities) is given in NUREG/CR-6364.

The *effectiveness of alarms* in alerting personnel to the possibility of exposure can depend on a variety of factors. In some settings (e.g., where noisy equipment is nearby), effectiveness depends on the detectability of the alarm signal; there are many sources of information on such considerations (e.g., O'Hara and Brown, 1999). More commonly, proper response to alarms is influenced by factors such as confidence in indications (i.e., issues related to perceived reliability of the warning), and the perceived likelihood of the condition being signaled.

An key observation of the review of events and risk analyses was the importance to safety of procedural protections in all of the systems reviewed; the *effectiveness of administrative controls* of one kind or another widely relied upon. Instances of compliance or non-compliance with administrative policies can be understood in terms of the perceived and actual benefits and costs of one or the other course of action. Behaviorally oriented treatments of factors influencing adherence to safety policy are instructive in this area (e.g., Krause, 1995). On a more global level, effectiveness of intangible barriers can be said to depend on *safety culture*; Reason (1998) provides a comprehensive treatment of organizational factors and safety.

Review/Inspection Aids

Review and inspection related functions all involve identifying circumstances in which safety depends on the reliability of human performance. This in turn requires the ability to independently identify the types of human actions that comprise the activities being considered.

Incident investigation techniques, which are ostensibly retrospective in nature, can be used in a prospective way to help identify important human actions. Thus it is anticipated that the taxonomies and techniques that comprise processes such as the NRC's Human Performance Investigation Process (HPIP, NUREG/CR-5455) will be adapted to lead the user through a thorough consideration of the possible influences relevant to a given setting.

Another process, the Human Performance Evaluation Process (HPEP, NUREG/CR-6751), has been recently developed, and can be seen as complementing the former tool. That is, while HPIP might point to direct performance factors, HPEP is designed to take into account higher level influences. Its stated aim is to assist in evaluating licensee corrective actions (which is among the functions the current effort aims to support), but the information it provides (especially the treatment of analysis techniques, including barrier analysis) can be adapted contribute to the development of review and inspection aids needed by NMSS staff. HPEP includes modules on procedures, tools and equipment, supervision, human-system interface, task environment, communication and coordination and control. Like the former approach, its orientation is practical (i.e., it provides succinct account of factors influencing human performance and summary table that may serve as models for the 'checklist' type resources that users saw a need for).

Risk Assessment Resources

Human reliability analysis (HRA) provides a process for providing quantitative estimates of the likelihoods of failure for different kinds of human actions. In general, these methods consist of three related components:

- a process for performing HRA (including such tasks as collecting relevant information),
- a knowledge base that describes the basis for estimating error probabilities on certain factors, and
- a mathematical process for manipulating data in the knowledge base to yield an overall probability of failure.

Underlying all of these aspects of HRA is a perspective on why human errors occur. However, this perspective is not always explicitly identified in the documentation of a particular HRA method.

The process for performing HRA generally remains the same, regardless of the type of application. The process used in applying most of what are called "first generation" HRA methods is the "Systematic Human Action Reliability Procedure" (SHARP) (Hannaman & Spurgin, 1984). The "second generation" method "A Technique for Human Event Analysis," ATHEANA (NRC, 2000) provides a similar process but with expanded capabilities, including explicit collection of information related to organizational factors and how teams work together, and comprehensive search schemes for identifying human errors and their associated contexts.

The knowledge base and quantification approach for HRA methods are often related or intertwined. For example, the knowledge base of the Technique for Human Error Rate Prediction, THERP (Swain & Guttmann, 1983) provides extensive discussion of many different types of human errors (skipping steps in procedures, missing indications, etc.) and the bases for estimating the failure probabilities of such errors based on a range of performance shaping factors (PSFs) like the layout of the procedures, the location of indications, and so on. The mathematical process for THERP describes how the different types of error probabilities are combined, to allow for dependencies and redundancy of actions for example. Because different HRA methods provide guidance on different factors, both in terms of their knowledge base and their quantification processes, different methods may need to be used for different applications.

When considering the use of HRA methods for a particular application, it is important to consider whether the factors contained in knowledge base for a method matches the issues that are important in a particular application. Examples of the issues of importance found in the use of byproduct materials, and their relationship to the knowledge bases of relevant HRA methods are shown in the table below. Often the knowledge base can provide insights as to cause of errors and what are suitable remedial actions without having to complete a full quantitative assessment (though quantitative assessments are often performed to measure how good an improvement is needed, or what is expected from some kind of fix).

Many methods now in use have focused on modeling errors as if the person were the cause of random errors. That is, given a particular procedure, there is, for example, a 1-in-a-hundred chance of a person skipping a particular step. These methods have been termed the 'first generation' HRA methods. However, since the late 1980's, work has progressed in the behavioral sciences on developing a better representation of the causes of human errors–the so-called 'New Look' of human error, as exemplified by Reason (1990, 1998), Woods (1990, 1994), and Rasmussen (1990). This work has recognized that the ways in which failures come about can be much more complex than simply people making random errors, and that the situations and circumstances (often collectively called the 'context' for the actions) play a dominant role in shaping the opportunities for failure. In contrast to the '1 in a 100' chance of a random error, the view here might be expressed as 'there are 1 in a 100 contexts in which error is almost certain.'

Using the concepts of the "New Look" in human error and advances in behavioral science, several so-called 'second generation' methods have been developed. Examples include the NRC-developed A Technique for Human Event Analysis, ATHEANA (NRC, 2000), MERMOS, developed by Electricité de France (Bieder et al., 1998), the Cognitive Reliability and Error Analysis Method, CREAM (Hollnagel, 1998), and others. Compared with the earlier methods, the knowledge base associated with these methods is much richer in terms of the combinations of factors that can play a role in causing failures. Because they were developed for HRA of nuclear power plants, these "second generation" methods focus on the principal concerns of modern nuclear power plants: cognitive processes (that is, the mental analysis of events and decisionmaking processes of humans, such as when an alarm sounds that is unexpected, rather than simply the responses to alarms) and identifying different ways in which they can go wrong (particularly how the process can be misled).

Limited work has been performed to evaluate the usefulness of HRA methods for use in risk assessments of uses of byproduct materials. In 1994, NRC sponsored a workshop to discuss the use of probabilistic risk assessment (PRA) methods in the area of safety assessments of medical applications of byproduct materials; this workshop included discussions of HRA methods. As part of the workshop, several evaluations of misadministration events resulting from human actions were performed that showed that frequently there were unique or unusual conditions that made the unsafe actions (and thus the events) more likely; an example was where the work was being performed close to holidays, the normal staff were absent and temporary staff were on duty. However, no specific recommendation for using HRA methods was made for this area.

As noted above, the appropriate selection of an HRA method, for both qualitative and quantitative use, should be based on what human performance issues are of most concern to the technology being evaluated. For the purpose of NMSS byproduct materials applications, the tables in Task 3 report identify several characteristics of human behavior that have been found important in the different types of actions reviewed in Task 1. Particularly these include:

- clarity and accuracy in communications
- labeling & data errors (e.g., transcription errors)
- effectiveness of checking (treatment plans versus prescription, administrative controls, etc.)
- calculations
- human-system interfaces
- over-reliance on automation
- testing & maintenance of hardware
- slips in attention (e.g., inaccuracies in positioning sources)
- detection of failures & alarms

In addition, discussions with NMSS staff, reviews of events, and other HRA work related to, for example, medical events (Reason, 2003; Wreathall & Nemeth, in press), have revealed that human performance concerns seem to fall into two major categories:

1. Human errors that are the result of simple design problems (e.g., human-system interface problems).
2. Human errors that are "set up" by a combination of circumstances, including usually multiple failures in "barriers" designed to prevent such failures.

The first kind of human error primarily involves uncomplicated failures in skill- and ruled-based behavior. Because some of the first generation HRA methods (e.g., THERP) were developed before HRA began to address more complex behavior, the perspective and knowledge base contained in these methods can be useful in addressing this kind of human error.

The second kind of human error is the focus of second generation HRA methods and their associated "New Look" perspectives on human error. Consequently, there is a set of NMSS byproduct materials activities that would benefit from using the "New Look" perspective that is embedded in second generation HRA methods.

While no one method has been developed that provides both a knowledge base and a quantification process for all the characteristics identified above, methods have been developed that can be applied to one or more of the above behaviors. These include THERP, Human Error Rate Assessment and Reduction Technique, HEART (Williams, 1988) and its companion method associated with modeling violations of procedures (Reason, 1998), and some elements of CREAM. In addition, work by INEEL has led to the creation of a HRA method (SPAR-H) that uses data from several of these methods for application in the NRC Accident Sequence Precursor Program (ASP), used for screening operational abnormalities at nuclear power plants (Gertman et al., 2003).

Many methods that have been developed for estimating the probabilities of failure of operators to respond correctly to an abnormal condition in a nuclear power plant use parameters such as the time available for responding to control panel alarms before core damage results. Examples include first generation methods by Dougherty & Fragola (1988), the Operator Action Tree method (Hall et al., 1982), and the EPRI methods like the Human Cognitive Reliability method, HCR (Spurgin, 1990). These methods do not appear to be immediately useful in the analyses of NMSS byproduct materials applications.

Some methods have been developed to incorporate data from databases and judgment of experienced practitioners; that is, they do not provide their own knowledge base, but rely on expertise from outside the method. One of the first was the Success Likelihood Index Method (SLIM; Embrey et al., 1984) that requires the analyst to select what they consider to be the most important performance shaping factors (PSFs) and provides a basis for calculating their degree of effectiveness in setting an overall probability of failure. (In many ways, SLIM is a potential method 'of last resort' in that it provides a quantification process for applying judgement but does not provide any data for use by the analysts, unlike most other methods.) Also, while the ATHEANA HRA method provides its own knowledge base, its perspective, process and quantification approach can be used with an external data base. An example of such an analysis is that performed for the Pueblo Chemical Agent Disposal Facility (Cooper, 2003).

A recent approach provides a way for combining partially relevant data and then using judgments of experienced people to filter and scale the database data (i.e., removing data that are not relevant and then compensating for under-reported or censored data) to yield ranges of failure probabilities (Wreathall et al., in press; Wreathall et al., 2003).

The table below provides a summary of which methods have knowledge bases relevant to the behaviors of interest identified earlier. These knowledge bases can provide additional materials for use in the training activities discussed earlier.

Relevant HRA Methods for Behaviors of Interest

Behavior of interest	Relevant HRA knowledge base
Communications	HEART, THERP
Labeling errors	?
Checking	HEART (violations), THERP
Calculations	?
Human-system interfaces	THERP, HEART
Automation	?
Testing & maintenance	THERP
Attention slips	?
Detection of failures & alarms	THERP, SPAR-H

In the case of *communications* errors, the HRA methods listed provide only limited applicability in that HEART and THERP discuss a few of the causes of communications problems, such as the general effects of complexity and stress that can lead to problems in communications (complexity and stress narrow the window of attention paid to messages, for example). THERP focuses on long sequences of verbal communications as substitutes for written procedures. Neither method analyzes such issues as noisy environment or poor telephone systems.

No method is considered useful for the general area of *labeling* errors.

Generally the issues of the *checking* of one person's work by another or of *complying* with administrative procedures have been examined in the violations version of HEART, and in THERP (but primarily in nuclear plant operations where a procedure-following culture is generally well-ingrained).

Calculations are not well modeled in any HRA method.

Human-system interfaces are a classical area for HRA, with methods like THERP and HEART providing suitable data and models. However the degree to which they represent more soft system (computer) interfaces is quite limited.

The effect of *automation* is now being studied for incorporation in HRA models. The effects of changing the work modes of people (e.g., from being a hands-on performer of tasks to becoming a supervisor of equipment) and having to cope with arcane error messages from the system are generally known but not yet modeled in HRA.

Behaviors and errors in *test and maintenance* of equipment is a classical area for the application of THERP, for which it is well suited.

Slips in attention that can lead, for example, to sources being misplaced are not well modeled in HRA. Such errors often result from distractions or interruptions in work routines.

Detection of failures and alarms is a common task in nuclear power plants, but the indications are often loud, clear and compelling; this not always true of alarms or equipment faults in the systems in this study. THERP provides general ground rules for modeling the detection and recognition of different levels of alarms (such as a single indicator lamp) that are more typical of equipment alarms here. SPAR-H also provides generic guidance on detection and recognition of alarms.

Finally, where no method currently exists for an area of interest, it is possible to use methods like SLIM or ATHEANA in conjunction with a knowledge base constructed from relevant literature in the behavior sciences, such as that identified earlier for training uses, to provide a basis for making the judgments necessary to apply the method.

Conclusion

In summary, a case has been made that the resources needed by NMSS staff to deal with issues related to human performance can in large part be developed from existing information sources and by adapting existing tools and techniques.

The largest task lies in developing the appropriate information base or knowledge base from existing psychological literature and that which underlies existing HRA methods. This information or knowledge base will be used in developing all NMSS byproduct materials products: training material, reviewer and inspection aids, and formal HRA methods. Training material will be most directly related to such a knowledge base. Reviewer and inspection aids will be need to be tailored to specific user needs and, therefore, may focus on specific aspects of the overall knowledge base. Development of an HRA method that specifically applies to NMSS byproduct materials activities will be guided by, again, activity-specific needs and the overall knowledge base.

It is technically feasible to develop all of the products for NMSS byproduct materials activities that have been discussed in this report. The timing and extent of this development cannot be predicted, at present since it is not known what resources will be available for this development. Based on the results of all four tasks in the feasibility study for NMSS byproduct materials, it is evident that development of an appropriate knowledge base should be the first priority since all other products are dependent on this work. Also, since Phase 2 of this project (i.e., development of HRA capability for NMSS) is the first work of its kind, it is likely that more than one iteration of development will be required for NMSS HRA capability to be comparable to that for other technologies.

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Development of Human Reliability Analysis Capability for Regulatory Applications Involving Byproduct Materials

Letter Report

Task 5:Identify Scope of HRA-Informed Job Aid for Reviewing License Requests

Prepared for
U.S. Nuclear Regulatory Commission
Office of Nuclear Regulatory Research
Division of Risk Analysis and Applications

June 30, 2005

Background

Operating experience demonstrates that human actions play a dominant role in most NMSS regulated activities. Hence, an improved understanding of human error and human reliability analysis (HRA) can provide better risk insights to risk-inform, as appropriate, NMSS regulated activities. In 2003, research was begun on the development of human reliability analysis capability for regulatory applications involving byproduct materials. During Phase 1 of this effort, a study was conducted of the feasibility of developing HRA-related support to NMSS in the area of byproduct materials. At the conclusion of Phase 1 (which comprised the first four tasks), several recommendations were made for possible future HRA development, including development of HRA-informed guidance or job aids for NMSS reviewers of byproduct material license applications.

Objective

The objective of Phase 2 of this effort is to begin to develop such HRA-informed tools or job aids to assist IMNS/NMSS license reviewers. The context for which assistance would be developed will involve emerging or "new" technologies or modalities, since established practices are least applicable in these areas. The initial development will be narrowly focused on a subset of new technologies of concern or interest to IMNS/NMSS (as guided by NMSS input).

The purpose of the tools and related material is to help reviewers identify and evaluate potential human performance or reliability concerns and to provide a technically defensible basis for identified concerns. The technical knowledge on which the tools will be based will be derived from human engineering guidance developed in the context of nuclear power, the general human factors engineering literature, and studies of human performance and reliability in healthcare settings. The information will be presented in formats appropriate for use by non-HRA experts (NMSS/IMNS staff), and its usability by them will be confirmed in a pilot application. If it is deemed useful, the technical information and tools will be adapted to support other uses (e.g., inspection or investigation).

The specific tasks to be undertaken during Phase 2 include

- scoping the initial development of specific HRA-informed job aids (Task 5)
- compiling a technical basis for the job aids (Task 6)
- developing the job aids per se (Task 7)
- developing related training material (Task 9)
- conducting an evaluation of pilot use of the job aids (Task 10)
- refining the job aids, based on the evaluation (Task 11)
- adapting the material to other uses (e.g., inspection) (Task 12)

This letter report describes the results of the first of these tasks - identifying the scope for the initial development of specific HRA-informed job aids (Task 5 of the Statement of Work).

Approach

RES and NMSS staff and management have agreed that is necessary to work together closely during the development of the products listed above in order to best address the needs of NMSS staff. A kickoff meeting was organized to continue this interaction and to begin the Phase 2 work. Specifically, the purpose of the kickoff meeting was to provide a narrower focus for the Phase 2 development of an HRA-informed job aid. The initial assumption was that the HRA-informed job aid would be aimed at reviewers of license applications, particularly those involving new or emerging technologies (for which existing guidance is limited, and often not directly applicable).

In the kickoff meeting, representatives from NMSS and RES management and staff brainstormed the nature of the job aid and ways to further narrow this focus. For example, initial development efforts could concentrate on a particular category of treatments, or on specific human performance issues that are a current or anticipated concern. After these discussions, various treatment modalities were prioritized and characterized with the aim of specifically identifying the context for the initial development of job aids and supporting information.

Results

Stakeholder/User Perspectives

NMSS management expressed the view that development should emphasize day-in, day-out licensing and inspection activity, and tools to support the systematic examination of user performance. In the case of a prescriptive rule (e.g., 'physical presence') the resources developed should support rigorous evaluation with a technical basis. NRC currently directs its attention based on suspicious outcomes; the tool should ideally increase the effectiveness of choosing which 'strings to pull'. This will have the benefit of increasing efficiency, which is important owing to decreasing resources. While the products should fill a current need, emerging technology should not be ignored; e.g., hydraulic insertion of IV brachytherapy sources is problematic and associated with multiple events. Region I has requested assistance on gamma knife license issues. It was also mentioned that there may be an additional need for support with respect to security inspections. Security is not delegated to agreement states; therefore NRC staff are inspecting facilities they have never been to before. The requirements have been developed by security staff, so inspectors need to get up to speed quickly. It also was noted that activities affected by the effort may go beyond licensing/inspection to regulation. It was further suggested that the information developed in this effort be able to be adapted for event analysis (i.e., retrospective use), and that the tools provided should be accompanied by training.

RES recommended that the initial aim should be to develop and test limited scope products to demonstrate their value. Regarding the uses of the products of this effort, it was noted that having NRC expectations documented is useful to licensees. It was also noted that the products might support enhancements to existing review guidance.

NMSS license reviewers emphasized that users of the products of the project may be "several layers away from the device itself." License reviewers typically will not see the actual device, but review written submittals and discuss any questions with the applicant by phone. Furthermore, information about the software will not be available; reviewers will not see it used. Procedures may be "to-be-determined" (TBD) at the time of the review. Inspectors are more likely to see the device, but will principally talk to people about its use; they typically do not see procedures (except the emergency procedures). It was also noted that, while documents submitted in connection with license reviews will be captured by the ADAMS system, requests for information and discussion with applicants may occur informally. Furthermore, materials licenses per se are not longer publicly available, owing to security concerns. Thus, in order to gain an appreciation of the potential users' requirements, it may be necessary to go beyond just reviewing documentary material. Region I currently has three gamma knife reviews pending; reviewers thought that two days would be sufficient to observe a review.

Identification of High Priority Modalities

Potential users of the job aid (headquarters license reviewers) were asked to identify several important treatment modalities. An exercise was then conducted during which each of the modalities was ranked or rated on an number of dimensions:

- frequency - how often the treatment is used (5 is most frequent, 1 is the least)
- potential for harm - the consequences of error (5 is the greatest harm, 1 the least)
- failures - rate of failures during use (5 is the highest failure rate, 1 is the lowest)
- timescale - is the need for an aid continuing, or likely to be temporary (low, med, high)
- scope - broad (high) rather than narrow (low) applicability
- need for guidance - lack of guidance, or recognized deficiencies (high) or adequate (low)

The aim was to identify which of the selected modalities would be appropriate contexts in which to development initial job aids (i.e., those that tended to have higher ranks and ratings are candidates for use as a test bed). The results are summarized in Table 1.

Table 1. Rankings and Ratings of Treatment Modalities on Priority Dimensions

	Frequency	Potential for Harm	Failures	Timescale	Scope	Need for Guidance
Novoste	1	2.5	5	medium	high	medium
Manual Brachy	2	1	2.5	medium	low	high
HDR Brachy	3	2.5	2.5	medium	high	low
Gamma Knife	4	4	1	high	high	high
Micro-spheres	5	5	4	high	high	medium

The frequency of use for the gamma knife and microspheres was estimated to be high compared to other modalities; furthermore, use of both of these modalities is increasing. In addition, the potential for harm is great in both cases. The rationale for this judgment was that in the case of the gamma knife, the damage would be to the brain, while for the microspheres, the effects would be untreatable. The modality ranked highest for rate of failure was the Novoste, owing to the design of the source transport; it was noted that this aspect of the technique has been incrementally improved. Microspheres were also judged to be susceptible to failure, based on reports of medical events as their use increases. Gamma knife was thought to have a relatively low rate of failures. However, it was noted that with rapid expansion of the use of this treatment (both in terms of the numbers of centers and the treatments for which it is being used), the operating environment is changing. Increasingly there is more than one unit at a site, and they are located in less sophisticated facilities. Also, whereas, to date, errors have tended to involve x-y reversals, other mechanisms, such as shifting of the device on the head, are beginning to appear.

Perhaps because of the growing use and the possibility that failures will increase over time, both gamma knife and microspheres were judged high on both the continuing need for, and broad applicability of, guidance on human performance.

Human Performance Characterization of Modalities

In order to further focus the development effort, the human performance characteristics of each of the modalities were considered. The aim was to insure that the modality or modalities selected to provide the context for initial development of human performance guidance and job aids would allow a range of human performance characteristics to be sampled. The same subject matter experts that participated in the above prioritization exercise were asked, for each of the treatment modalities, whether or not each of several aspects of human performance had a bearing on the use the modality. The human performance characteristics (shown in the left column of Table 2) are among those identified in Phase 1 of this project as being relevant to medical uses of byproduct material.

Results are shown in Table 2. The '+' symbols or notes indicate characteristics (rows) applicable to the different modalities (columns). Possible relevance is indicated by a question mark. In cases for which a human performance characteristic was not judged to be an important factor for a given modality, the cell is left blank.

In general, modalities involving remote and/or computer-controlled actions tend to have multiple issues (e.g., human system interfaces and automation) in common, whereas more manual processes have other specific issues. Thus, the gamma knife, was seen as having a wider range of human performance considerations than microspheres (the other high-priority modality).

Overall Conclusions

The information generated during the course of the meetings was sufficient to narrow the scope of the initial development of job aids and supporting technical information. Based on priority ranking and human performance characteristics, it was decided to develop the initial aids from the perspective of the gamma knife. Because the aim is to develop guidance that is generic in nature, the human performance characteristics considered initially will be selected from among those that apply to multiple modalities. Based on the analysis described above, and the results in Table 2, human-system interfaces, staffing, testing & maintenance, checking and training were considered. Owing to its cross-cutting relevance, staffing was chosen as a specific human performance characteristic around which the development will be focused; a second human performance characteristic will be selected as development proceeds. The choice of this focus was is in accord with NMSS management's suggestion that the initial development address day-to-day needs while attending to the need for guidance pertaining to emerging technologies, and appears narrow enough to serve the intention of RES to develop and evaluate a tool within a short time frame.

It was also decided that, if the opportunity presents itself, the development team should observe the work associated with a license review to gain a better appreciation of the kinds of human performance related support that reviewers will find useful.

Table 2. Human Performance Characterizations of Treatment Modalities

	Gamma Knife	HDR Brachy	Manual Brachy	Novoste	Micro-spheres
Communication	+			+	+
Labeling		guide tubes	indication of activity level		indication of activity level
Checking	+	QC in regs	+	+	+
Calculation	+	infrequently, as a check			hand calcs
Human-System Interface	+	changes to programming	imaging	imaging	?
Automation	+	TPS to device			
Testing and Maintenance		stuck sources		poor design	
Attention Slip	info entry ?	source position			
Detection of Failures, Alarms	?	brief alarm duration		lights	
Staffing and Qualifications	+	+	+		
Instructions and Procedures	slippage issue			no mention of failures	
Training	+	+	+		“simple”

Appendix

A kickoff meeting for Phase 2 of the effort to develop of human reliability analysis support for regulatory applications involving byproduct materials was held on June 1-2 at NRC Headquarters in Rockville, MD. Members of the project team are William Brown, of Brookhaven National Laboratory, and John Wreathall of John Wreathall & Co., Inc. The NRC Project Manager is Susan Cooper, RES/DRAA/PRAB.

Participants from RES and NMSS are listed below.

RES/DRAA	NMSS
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Development of Human Reliability Analysis Capability for Regulatory Applications Involving Byproduct Materials

Letter Report

Task 6: Collect Information to Provide a Knowledge-Base for an HRA-Informed Job Aid for Reviewing License Requests

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October 28, 2005

Background

Operating experience demonstrates that human actions play a dominant role in most NMSS regulated activities. Hence, an improved understanding of human error and human reliability analysis (HRA) can provide better risk insights to risk-inform, as appropriate, NMSS regulated activities. In 2003, research was begun on the development of human reliability analysis capability for regulatory applications involving byproduct materials. During Phase 1 of this effort, a study was conducted of the feasibility of developing HRA-related support to NMSS in the area of byproduct materials. At the conclusion of Phase 1 (which comprised the first four tasks), several recommendations were made for possible future HRA development, including development of HRA-informed guidance or job aids for NMSS reviewers of byproduct material license applications.

Objective

The objective of Phase 2 of this effort is to begin to develop such HRA-informed tools or job aids to assist IMNS/NMSS license reviewers. The context for which assistance would be developed will involve emerging or "new" technologies or modalities, since established practices are least applicable in these areas. The initial development will be narrowly focused on a subset of new technologies of concern or interest to IMNS/NMSS (as guided by NMSS input).

The purpose of the tools and related material is to help reviewers identify and evaluate potential human performance or reliability concerns and to provide a technically defensible basis for identified concerns. The technical knowledge on which the tools will be based will be derived from human engineering guidance developed in the context of nuclear power, the general human factors engineering literature, and studies of human reliability in healthcare settings. The information will be presented in formats appropriate for use by non-HRA experts, and its usability by NMSS/INMS staff will be confirmed in a pilot application. If it is deemed useful, the technical information and tools will be adapted to support other uses (e.g., inspection or investigation).

The specific tasks to be undertaken during Phase 2 include

- scoping the initial development of specific HRA-informed job aids (Task 5)
- compiling a technical basis for the job aids (Task 6)
- developing the job aids per se (Task 7)
- developing related training material (Task 9)
- conducting an evaluation of pilot use of the job aids (Task 10)
- refining the job aids, based on the evaluation (Task 11)
- adapting the material to other uses (e.g., inspection) (Task 12)

This letter report describes the results of the second of these tasks - compiling a technical basis for the job aids (Task 6 of the Statement of Work).

Approach

The information generated during discussions with NMSS reviewers (see the letter report for Task 5) was used to narrow the scope of the initial development of job aids and supporting technical information. Based on priority ranking and human performance characteristics, it was decided to develop the initial aids from the perspective of the gamma knife. It was also decided that staffing and qualifications should be one of the human performance considerations included in the limited-scope initial development of a job aids. This was due at least in part due to the fact that, as gamma knife units have become more widely used, reviewers have begun to receive applications regarding physical presence requirements. Other

human performance characteristics to be addressed in the initial development were identified based on information from the first phase of the project.

In the event review for the gamma knife (described in the letter report for Task 1), it was noted that a large fraction of events involved errors in setting up the treatments via the treatment planning software system that were not corrected during reviews of the treatment plans. Accordingly, it was concluded that errors in using data entry interfaces and failures to detect errors in treatment plans were significant sources of risk. The event review also noted that gamma knife units increasingly provide for direct data transfers between the treatment planning and treatment management computers, and also allow the use of an automatic positioning system for the helmet during treatment. While the use of automation can be expected to reduce the frequency of some types of errors, the effects on human performance and reliability associated with automation per se have to be taken into account in considering overall risk.

Among the issues mentioned in the summary of interviews with NRC staff (see the letter report for Task 2) were automation in medical treatment systems and the impact of administrative checks. Specific influences on reported events listed by one interviewee (see notes in the Appendix of the letter report) included new staff, high workloads, temporary staffing and coverage for different specialties by other specialties (e.g., radiology for nuclear medicine), and lack of supervision.

Thus, in addition to staffing and qualifications, the first phase information points toward development of knowledge for two other human performance characteristics - checking and automation. Because they are interrelated, choice of these three topics should allow jobs aids to be relatively self-contained, despite being limited in scope. (For example, automating tasks can affect the time and expertise required of staff to carry out their tasks; staffing and automation can both affect the effectiveness of cross-checking.) Owing to the increasing use of computerized planning systems that automatically provide treatment data to gamma knife units, it will also be desirable to include information on selected aspects of human-system interaction.

Human Performance Characteristic	**Examples of Specific Related Topics**
Staffing and Qualifications	technical basis staffing strategies
Checking	availability of needed expertise teamwork
Automation	identified problems with automation safety-critical software
Human-System Interface	entry of data/control input via techniques such as menus and soft controls display of feedback

Contents of Knowledge Base

Types of information sources reviewed included work relevant to the selected topics that has been done in the context of nuclear power, literature on medical errors and patient safety, general treatments of human error, and descriptions of human performance analysis approach methods. Some key information sources for each of the topics to be included in the strawman development are given below. These references will form the basis of the initial brief topics summaries. In subsequent work, additional information sources will be used to prepare more complete treatments of the topics for use in the training materials that will be developed. A comprehensive listing of these sources is given in the Appendix.

Automation

There is a growing literature on the role of automation in complex systems and its effects on human performance. Much of the work concerns the use of sophisticated automated systems in aviation, but process control (such nuclear power) applications are also represented. Current thinking, however, tends to concentrate on applications in which the automation operates in a more independent fashion than is typical in radiotherapy. Thus, for the present purpose, the treatment of automation will concentrate on relatively simple forms of automation, the human performance effects of which of which are well-documented (Billings, 1997; Parasuraman & Riley,1997). Cook and Woods (1996) provide examples of automation pitfalls (clumsy automation, lack of feedback, difficulty reverting to manual control, increased complexity) in a medical context (anesthesia) that may have analogous in the area of radiotherapy.

Several studies have documented how errors in radiotherapy occur in spite of (or because of) the use of computerized 'record & verify' systems (e.g., Macklis, 1998; Patton et al., 2003; Goldwein, Podmaniczky, and Macklis, 2003; Huang et al., 2005). Although these studies involve accelerator-based therapy, and therefore address errors in activities not found in GSR (such as the placement of wedges), they demonstrate the vulnerabilities involved in programming automated systems that are designed to prevent human error. Goetsch (2002) reported a study errors observed in GSR with automatic positioning systems.

Staffing

The treatment of staffing in the context of nuclear power generation is considerably more structured and prescriptive than in radiotherapy (or any other byproduct application). Nevertheless, some of the factors that are identified as relevant in evaluating power plant staffing issues, may also be apply to personnel requirements in byproduct applications. The technical basis for assessing requests for exemption from the required staffing levels in nuclear power plants is provided in NUREG/CR-6838. Staffing and qualification (in the context of power plants) is also addressed in Element 6 of the Human Factors Engineering Program Review Model (NUREG-0711) and in Section 13 of the Human Performance Evaluation Process (NUREG/CR-6751).

Checking

Patterson and her co-workers (Patterson, Cook, Woods, and Render, 2004; Patterson, Woods, Cook, and Render, 2005) studied communication, and cross-checking in medical settings; aspects of these interactions (e.g., 'handoffs') are closely related to staffing. Patterson and Woods (2001) specifically address the issue of on-call staffing strategies.

Human-System Interfaces

Tools and training will have to address the types of error made with computer mediated data entry and control. Human engineering review guidelines for various aspects of computer-based interfaces is found in NUREG-0700, Rev.2. Specific topics that may be applicable to radiotherapy devices include computer-mediated controls, menu-driven interaction, and computer input (e.g., pointing devices, touch screens).

While NMSS staff will not review interfaces *per se*, the review guidelines can be used as specific examples of good design practices for any human-system interaction topic to be treated in the training and job aids. In addition the guideline items, NUREG-0700 contains, for each broad subject area, an overview describing the area from the point of view of human performance; these characterization may be adapted to familiarize staff with human engineering consideration for various topics. Furthermore, many of these characterizations were developed from documents (e.g., NUREG/CR-6634 and NUREG/CR-6635) that detail, for the more advanced human-system interaction technologies, the technical basis for the associated guidelines. These documents will allow training content for some topics to be developed efficiently, since the pertinent literature has already been digested.

Nunnally, Nemeth, Brunetti, and Cook (2004) provide examples of difficulties in operating computerized medical devices (infusion pumps) associated with menu-based input and multiple modes. These examples should be useful in developing training material, since radiotherapy devices may share some of the same interface characteristics.

References

Barnes, V., & Haagensen, B. (2001). *The Human Performance Evaluation Process: a resource for reviewing the identification and resolution of human performance problems* (NUREG/CR-6751). Washington, DC: U.S. Nuclear Regulatory Commission.

Billings, C. E. (1997). *Aviation automation; the search for a human-centered approach*. Mahwah, NJ: Lawrence Erlbaum Associates, Inc.

Cook, R. I., & Woods, D. D. (1996). Implication of automation surprises in aviation for the future of total intravenous anesthesia (TIVA). *Journal of Clinical Anesthesia, 8,* 29S-37S.

Nunnally, M., Nemeth, C. P., Brunetti, V., & Cook, R. I. (2004). Lost in menuspace: user interactions with complex medical devices. *IEEE Transactions on Systems, Man and Cybernetics, Part A,, 34*(6), 736-742.

Persensky, J., Szabo, A., Plott, C., Engh, T., & Barnes, V. (2005). *Guidance for assessing exemption requests from the nuclear power plant licensed operator staffinf requirements specified in 10CFR50.54(m)* (NUREG-1791). Washington, DC: U.S. Nuclear Regulatory Commission.

Plott, C., Engh, T., Barnes, V., Szabo, A., & Persensky, J. (2004). *Technical Basis for Regulatory Guidance for Assessing Exemption Requests from the Nuclear Power Plant Licensed Operator Staffing Requirements Specified in 10CFR 50.54(m)* (NUREG/CR-6838). Washington, DC: U.S. Nuclear Regulatory Commission.

APPENDIX:

BIBLIOGRPAHY

Selected Information Sources Organized by Topic

Staffing

Desaulniers, D. R. (1997, October 13-17). *Behaviors and Conditions that Challenge Teamwork: An Assessment of Operating Events at U.S. Commercial Nuclear Power Plants.* Paper presented at the OECD Specialists Meeting on Human Performance in Operational Transients, Chattanooga, TN.
Not sure how exactly this relates–its NPP experience, but should be evaluated for relevant knowledge that can be extrapolated to NMSS applications.

Patterson, E. S., Cook, R. I., Woods, D. D., & Render, M. L. (2004). Examining the complexity behind a medication error: generic patterns in communication. *IEEE Transactions on Systems, Man and Cybernetics, Part A,, 34*(6), 749-756.
Medical case study demonstrating patterns of inadequate communication among team members; discusses mechanism leading to error and failure to recover, and gives potential interventions.

Plott, C., Engh, T., Barnes, V., Szabo, A., & Persensky, J. (2004). *Technical Basis for Regulatory Guidance for Assessing Exemption Requests from the Nuclear Power Plant Licensed Operator Staffing Requirements Specified in 10CFR 50.54(m)* (NUREG/CR-6838). Washington, DC: U.S. Nuclear Regulatory Commission.
Specific to nuclear power; adaptable to corresponding NMSS issues?

Risser, D. T., Rice, M. M., Salisbury, M. L., Simon, R., Jay, G. D., & Berns, S. D. (1999). The potential for improved teamwork to reduce medical errors in the emergency department. The MedTeams Research Consortium. *Ann Emerg Med, 34*(3), 373-383.

Wreathall, J. (2004). *PRA & Patient Safety Insights for Improvements in Healthcare.* Paper presented at the Probabilistic Safety Assessment and Management PSAM 7 -- ESREL '04, Berlin, Germany.
This study examined the risks associated with heart transplants, but of relevance here, it included a task analysis to provide an examination of the effects of interactions between groups such as those involved in cross-checking data entry into computerized databases.

Automation

Billings, C. E. (1997). *Aviation automation; the search for a human-centered approach*. Mahwah, NJ: Lawrence Erlbaum Associates, Inc.
Book length treatment of automation issues as of several years ago; good treatment of problems with automation; aviation orientation doesn't detract too much from usefulness.

Christoffersen, K., & Woods, D. D. (2002). How to make automated systems team players. In E. Salas (Ed.), *Advances in human performance and cognitive engineering research* (Vol. 2, pp. 1-12). New York, NY: Elsevier Science.
All the papers by Woods (and collaborators; see below) are associated with the various ways that automation, and particularly systems that are computer-controlled, can create opportunities for failure that are unexpected and involve looking at the ways automation changes the nature of work in subtle ways.

Dekker, S. W. A., & Hollnagel, E. (Eds.). (1999). *Coping with computers in the cockpit*. Aldershot, UK: Ashgate.
Dekker is has spent much time considering how automated systems in the workplace can create new problems, particularly related to aviation. His work tends to be less abstract than the papers by Woods, et al.

Dekker, S. W. A., & Woods, D. D. (1999). Automation and its impact on human cognition. In S. W. A. Dekker & E. Hollnagel (Eds.), *Coping with computers in the cockpit*. Aldershot, UK: Ashgate.
See above.

Endsley, M. R., & Kiris, E. O. (1995). The out-of-the-loop performance problem and level of control in automation. *Human Factors, 37,* 381-394.
Mica Endsley is the leader in the area of situation awareness (knowing what is going on), and how this can be lost due to poor interface issues and automation.

Koppel, R., Metlay, J. P., Cohen, A., Abaluck, B., Localio, A. R., Kimmel, S. E., & Strom, B. L. (2005). Role of computerized physician order entry systems in facilitating medication errors. *JAMA, 293*(10), 1197-1203.

Leveson, N. G., & Turner, C. S. (1993). An investigation of the Therac-25 accidents. *Computer, 26*(7), 18-41.
Detailed treatment of software errors underlying the events.

Norman, D. A. (1990). The 'problem' of automation: Inappropriate feedback and interaction, not 'over-automation.'. *Philosophical Transactions of the Royal Society of London, B,* 327, 585-593.

Parnas, D. L., Schouwen, A. J. v., & Kwan, S. P. (1990). Evaluation of safety-critical software. *Communications of the ACM, 33*(6), 636-648.
Discussion of the unique aspects of software that make computerized control different from conventional control, especially with respect to failures and testing.

Moray, N. (2000). Are observers ever really complacent when monitoring automated systems? In *Proceedings of the IEA/HFES 2000 Congress* (Vol. 1). Santa Monica, CA: HFES.
Moray's work here is concerned with such factors as how people can come to over-rely on computer information systems, thus leading to opportunities for failure in detecting when things have gone wrong.

Moray, N., Inagaki, T., & Itoh, M. (2000). Adaptive automation, trust & self-confidence in fault management of time-critical tasks. *Journal of Experimental Psychology, Applied, 6*(1), 44-58.
See above.

Woods, D. D. (1996). Decomposing automation: apparent simplicity, real complexity. In R. Parasuraman & M. Mouloua (Eds.), *Automation and human performance: Theory and applications*. Mahwah, NJ: Erlbaum.
See Christoffersen & Woods (2002).

Woods, D. D. (2003). Discovering How Distributed Cognitive Systems Work. In E. Hollnagel (Ed.), *Handbook of Cognitive Task Design*: Erlbaum.
See Christoffersen & Woods (2002).

Woods, D. D., Johannesen, L., Cook, R. I., & Sarter, N. B. (1994). *Behind Human Error: Cognitive Systems, Computers, and Hindsight*. Dayton OH: Crew Systems Ergonomic Information and Analysis Center, WPAFB.
See Christoffersen & Woods (2002).

Woods, D. D., & Shattuck, L. G. (2000). Distance supervision--local action given the potential for surprise. *Cognition, Technology and Work, 2*, 86-96.
See Christoffersen & Woods (2002).

Woods, D. D., & Watts, J. C. (1997). How Not To Have To Navigate Through Too Many Displays. In M. G. Helander, T. K. Landauer & P. Prabhu (Eds.), *Handbook of Human-Computer Interaction*. Amsterdam: Elsevier Science.
See Christoffersen & Woods (2002).

Checking

Cacciabue, P. C. (1998). *Modelling and simulation of human behaviour in system control*. Berlin ; New York: Springer.
Cacciabue has studied team performance in simulation and process industry settings and gathered performance data from them. Its direct relevance will be explored once we have more information on the review process.

Cacciabue, P. C., & Vivalda, C. (1991). A dynamic methodology for evaluating human error probabilities. In G. Apostolakis (Ed.), *Probabilistic Safety Assessment and Management (PSAM)*. New York: Elsevier Science Publishing Co.
See above.

Gertman, D. I., & Blackman, H. S. (1994). *Human Reliability & Safety Analysis Data Handbook*. New York: John Wiley & Sons, Inc.
Gertman & Blackman have been gathering and reporting data on many sorts of tasks including checking processes–related are studies at Halden reported informally by Hallbert.

Hollnagel, E. (1993). *Human Reliability Analysis: Context and Control*. San Diego, CA: Academic Press, Inc.
Hollnagel touches on this area in his review of HRA issues; its relevance will be evaluated further in later parts fo the project once more details are obtained of the processes involved.

Swain, A. D., & Guttmann, H. E. (1983). *Handbook of Human Reliability Analysis with Emphasis on Nuclear Power Plant Applications* (NUREG/CR-1278, Rev. 1). Albuquerque, NM: Sandia National Laboratories.
THERP chapters provide much still-relevant information about checking processes and associated reliability.

Human-System Interaction

O'Hara, J. M., Brown, W. S., Lewis, P. M., & Persensky, J. J. (2002). *Human-System Interface Design Review Guidelines* (NUREG-0700, Rev. 2). Washington, DC: U.S. Nuclear Regulatory Commission.
Review guidelines are highly detailed and provide specific criteria; probably more useful in post-event activities than in license application review. However, the main sections of the document each begin with a characterization, which lays out human performance considerations for aspects of the human-system interface. These discussions could be adapted for use in a survey of human system interface considerations (e.g., menu interfaces, soft controls).

Stubler, W. F., O'Hara, J. M., & Kramer, J. (2000). *Soft controls: technical basis and human factors review guidance* (NUREG/CR-6635). Washington, DC: U.S. Nuclear Regulatory Commission.
Detailed treatment of characteristics of computer-mediated input devices; technical basis for the corresponding guidance in NUREG-0700, Rev.2.

O'Hara, J., Higgins, J. C., & Stubler, W. F. (2000). Computer-based procedure systems: technical basis and human factors review guidance (NUREG/CR-6634). Washington, DC: U.S. Nuclear Regulatory Commission.
Among the issues discussed is the potential for computer-mediated interaction to decrease team members' awareness of the others' goals and actions.

General Human Performance and Human Reliability Analysis

Arnstein, F. (1997). Catalogue of human error. *British Journal of Anaesthesia, 79*(5), 645-656.
Basic survey of human error and human factors psychology from a medical point of view.

Barnes, V., & Haagensen, B. (2001). *The Human Performance Evaluation Process: a resource for reviewing the identification and resolution of human performance problems* (NUREG/CR-6751). Washington, DC: U.S. Nuclear Regulatory Commission.
Intended to complement HPIP for programmatic issues; investigation/review oriented, but concise statements of influences on performance may be useful.

Hollnagel, E. (1993). *op. cit.*

Hollnagel, E. (2004). *Barriers and accident prevention.* Hampshire, England: Ashgate.

Paradies, M., Unger, L., Haas, P., & Terranova, M. (1993). *Development of the NRC's human performance investigation process (HPIP)* (NUREG/CR-5455). Washington, DC: U.S. Nuclear Regulatory Commission.
The structure of the investigation process and modules may be useful as a model (or strawman) for one type of job aid (i.e., a series of questions or error taxonomy linked to discussions and references to source material). Much of the content will be directly usable.

Swain, A. D., & Guttmann, H. E. (1983). *op. cit.*

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Development of Human Reliability Analysis Capability for Regulatory Applications Involving Byproduct Materials

Letter Report

Task 7: Structure and Format Relevant Knowledge-Base into HRA-Informed Job Aid

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Background

Operating experience demonstrates that human actions play a dominant role in most NMSS regulated activities. Hence, an improved understanding of human error and human reliability analysis (HRA) can provide better risk insights to risk-inform, as appropriate, NMSS regulated activities. In 2003, research was begun on the development of human reliability analysis capability for regulatory applications involving byproduct materials. During Phase 1 of this effort, a study was conducted of the feasibility of developing HRA-related support to NMSS in the area of byproduct materials. At the conclusion of Phase 1 (which comprised the first four tasks), several recommendations were made for possible future HRA development, including development of HRA-informed guidance or job aids for NMSS reviewers of byproduct material license applications.

Objective

The objective of Phase 2 of this effort is to begin to develop such HRA-informed tools or job aids to assist IMNS/NMSS staff. The context for which assistance would be developed will involve emerging or "new" technologies or modalities, since established practices are least applicable in these areas. The initial development will be narrowly focused on a subset of new technologies of concern or interest to IMNS/NMSS (as guided by NMSS input).

The purpose of the tools and related material is to help staff identify and evaluate potential human performance or reliability concerns and to provide a technically defensible basis for identified concerns. The technical knowledge on which the tools will be based will be derived from human engineering guidance developed in the context of nuclear power, the general human factors engineering literature, and studies of human reliability in healthcare settings. The information will be presented in formats appropriate for use by non-HRA experts, and its usability by NMSS/INMS staff will be confirmed in a pilot application. If it is deemed useful, the technical information and tools will be adapted to support other uses (e.g., inspection or investigation).

The specific tasks to be undertaken during Phase 2 include

- scoping the initial development of specific HRA-informed job aids (Task 5)
- compiling a technical basis for the job aids (Task 6)
- developing the job aids per se (Task 7)
- developing related training material (Task 9)
- conducting an evaluation of pilot use of the job aids (Task 10)
- refining the job aids, based on the evaluation (Task 11)
- adapting the material to other uses (e.g., inspection) (Task 12)

This letter report describes the results of the third of these tasks - structuring and formatting relevant information as an HRA-informed job aid for NMSS staff (Task 7 of the Statement of Work).

Approach

Based on discussions with NMSS reviewers, it was decided to develop the initial aids from the perspective of the gamma knife. It was also decided that staffing, automation, checking, and human-system interfaces should be the human performance considerations included in the limited-scope initial development of a job aids. The information sources identified for each of these topics are described in the letter report for Task 6.

The goal of the current task was to determine how to present human performance related information so that it will be useful to NMSS staff in carrying out their jobs. Specific aims were to adopt a format for the information and to consider the level of detail to be included in the job aid. The overall approach for accomplishing these aims was to develop some sample products representing alternative ways of structuring the available information, and then meet with NMSS staff to discuss the sample material. The strawman job aid was then finalized based on their input.

Results

The results of the development effort are described below. First, a description is given of each of the information formats that were proposed as possible job aids; examples are provided in appendices to this report. Next, the feedback provided by headquarters staff regarding these formats is summarized. Finally, the implications of the strawman effort for the longer term development of training and job aids is discussed.

Formats

As noted in the overview of this effort, development of the job aid is one part of the work and needs to be seen within the context of the overall development effort. Training will be developed on general human performance considerations relevant to NMSS to provide staff with grounding in factors that influence human reliability. In addition, there will be training that applies to specific uses of byproduct material. The purpose of the job aids described below is to help NMSS staff apply the knowledge provided in the training. Various candidate methods have been created for connecting human performance considerations to the specific activities or circumstances that are to be reviewed. These are briefly described below. Samples are contained in appendices to this report.

Prospective users interviewed early in the project mentioned that the material to be presented in the training would be more likely used if it were also subsequently available in digest form (e.g., as 'crib sheets' or checklists). Two of the strawman formats are intended to serve this purpose. The first is a set of summaries ('one-pagers') of human factors topics, intended as ready references for material presented in more detail in the training that is to be developed; these summaries represent core information that can be accessed directly by topic or arrived at via links or pointers from other job aids (see below). They will represent the general conceptual aspects of the human performance training. See Appendix A for examples of such summaries, which have been identified as important areas for gamma knife operations.

The second is comprised of sets of prompts pertaining to each of the human performance topics for which information was developed, intended to cue users to human performance considerations. In addition to pointing to human performance topics, the prompts may be accompanied by statement of the specific human performance concern for the situation in question (for example, what comprises effective double-checking of treatment plan data entries), and an example of a mitigating practice. These prompts will represent a distillation of the more practically oriented parts of the training (i.e., the examples). These will be developed in conjunction with the training in later tasks.

The remaining job aid formats depend more heavily on descriptions and analyses of the processes for the specific byproduct uses being considered. They are organized around breakdowns of the overall steps in performing byproduct-related activities, to the level of identifying who does what, where, and what is the requirement for success. (For the current strawman product, the process description was based on the existing process description in NUREG/CR-6323, but ideally this should be expanded to provide more explicit detail, and perhaps be updated for the newer types of gamma knife, such as the model C.) Two specific formats have been developed.

As shown in Figure 1, task breakdowns play a central role organizing information about specific uses of byproduct material (e.g., medical treatment modalities) and the associated specific human actions and errors. As indicated above, overall task breakdowns for the current strawman development were available from an earlier risk analysis of gamma knife use (Jones, Banks, Altenbach, and Fischer 1995). Among the task data collected for the analysis was the training and knowledge required to perform each task. Because dealing with staffing-related exemption requests was identified as an activity this effort set out to support, one of the strawman tools is simply a block diagram of the task breakdown (as given in the risk analysis), showing the knowledge or training required for each task. This provides an example of how one might begin to evaluate a request involving staffing by considering whether the proposed staffing provided equivalent knowledge and skills as the current rules require. Appendix B provides examples of this format

Another format consists of the task breakdown annotated, for the individual tasks affected, with events involving human errors from the NMED database (providing the NMED number and a brief statement of the human error(s)). This allows NRC staff to identify quickly the areas where human performance problems appear to be most frequent and the types of problems that occur. By further linking the types of problems with the human factors knowledge, it can provide NRC staff with a rapid access to the structured knowledge base. An example of this approach is presented in Appendix C.

Because the available task breakdowns do not describe the associated human actions and situational factors in detail, it is the NMED events (in particular the event narratives) that make it possible to consider specific errors and predisposing circumstances. (This is represented by the dotted arrow between the narratives and the task breakdowns.) That is, the error reports (those that contained a reasonable amount of detail) acted as a surrogate for actual observations or analyses of gamma knife operations, and allowed tasks to be linked to human performance topics (as indicated by the solid line) for this strawman. Appendix D provides samples of NMED reports, showing the kind of information contained in the narrative forms of the NMED records.

Finally, when the narratives in NMED records provide descriptions of specific errors, the circumstances or the error(s), or the actions taken to prevent similar error, that information is used to prepare a brief discussion of the error from a human performance perspective, followed by a list of the human performance topics that may have played a role in the event. Appendix E provides examples of this format.

The above formats have all been achieved using paper products–the appendices to this report. It is apparent that such linkages that are shown in the examples could also be achieved using an electronic job aid that has hypertext linkages between sections. This would allow extensive linkages that are perhaps more accessible to the users. For instance, starting with one step in the task breakdown in Appendix C, a link could bring up the relevant NMED record that has, in turn , links to the relevant ‘one pagers’ in Appendix B. Similarly where particular KSAs are identified as important in a step in Appendix B could be linked to one pagers for relevant guidance on how to assess whether alternative staffing proposed by licensees are to be considered equivalent.

As a trial, a preliminary demonstration hypertext tool has been developed. This simply provides the kinds of links discussed above using Adobe Acrobat technology. This has been provided to the NRC project manager for trial use. No feedback has yet been obtained for the use of this approach. Its development was based on the last feedback discussions with NMSS staff.

Illustration of Format Uses

Figure 2 provides an illustration of how information contained in the formats described above could be used by license reviewers and inspectors when the job aid is complete. The analysis in most cases will start with a process description, such as those presented in Appendices B and C. This is because the process description provides the breakdown of the overall human task into the particular actions for which different types of human performance information can be provided, as discussed earlier.

In the case of a licensee requesting an exemption, such as to staffing requirements, the reviewer can identify the different specific activities that would be affected by the proposed exemption using the format in Appendix B. The links from the relevant steps in the process description would identify the particular knowledge skills and abilities (KSAs) and performance standards (e.g., the need for double checking), and in turn would point to the relevant 'one pagers' in the human factors topics as illustrated in Appendix A. In addition, the reviewer could access NMED event reports related to the relevant steps in the process description using the types of links shown in Appendix C. These in turn could link to the 'one pagers' using the kinds of summaries as shown in Appendix E.

In the case of inspections or evaluations of the effectiveness of licensee responses to events, again the starting point would be the particular actions in the process description. Depending on the particular problems, the inspector could access related NMED event reports via the links shown in Appendix C to see if there is a history of similar problems and then access the human factors information to obtain guidance on the underlying issues to judge the adequacy of any proposed responses.

These are intended as examples of how the different formats could be used. Such uses would need to be tested in trail applications, but the feedback (below) suggests that these sorts of applications would be consistent with NMSS intentions. If developed further, the electronic version of the job aid would provide a simple way to use the logic of this approach.

User Feedback

Samples of the information formats being considered as job aids were shown to headquarters NMSS staff and the usefulness of each was discussed. These discussions are summarized below.

'One-Pagers'
NMSS staff responded positively to the sample one-page summaries of human performance consideration, even though they were not intended as standalone presentations (i.e., the presentations were very brief and lacked the detail and specific examples that will be part of the training).

Prompts
It was recognized that many of the prompts would only be useful in the context of an inspection or event investigation, since they pertain to specific details (e.g., aspects of the user interface); some were more widely applicable since they did not reference details of the use of the device. NMSS staff noted that while detailed review of device interfaces is not their principal concern, the prompts would be useful in that they could help bring attention to areas where there might be problems; i.e., they served the intended purpose of the effort - to prompt the user to think about human performance concerns that may apply to the activities under consideration.

Task Breakdowns Annotated with Error Reports
Users remarked on two fortuitous features of the presentation. The listing of events from the NMED database alongside the corresponding activity was considered useful in that it demonstrated graphically the parts of the process at which the consequences of error may be significant. It was also pointed out the

it is possible, by looking at the event numbers (which reflect to year in which the event occurred), to discern whether, e.g., errors associated with a particular part of the process have only recently begun to occur, or whether there is a persistent problem.

More importantly, it was pointed out the this representation could be used to identify the human performance topics that might pertain in reviewing a request; if a request involved a task for which events were listed, the topics list associated with that event would be considered. Similarly, users pointed out that it would likewise be useful to provide access to the event narratives themselves (rather than just the NMED numbers and brief descriptors). Accordingly, selected event narratives were formatted, summarized, and associated with the other information formats.

Task Breakdowns Annotated with Knowledge, Skills and Abilities

This format was seen as a key first step in considering staffing issues. In discussing it with NMSS staff, it was suggested that it might be combined with a tabular presentation, showing which of the individual proposed personnel is providing the required expertise for each of the steps. NMSS staff raised the question of personnel loading (i.e., at what points in the process might a person be required to do two things at once which demanded the same resources, for example monitoring equipment status displays and monitoring the patient). This could be addressed using a similar approach (perhaps augmented by task timelines), but would probably require a more detailed representation of the tasks (to the level of individual actions) than is currently available.

Overall

Users saw value in each of the alternative presentations, and did not favor the development of any one to the exclusion of the others. The cross-referencing (e.g., of topics by event discussions) was seen as helpful, and it was recommended that the linking of the content be augmented (e.g., by referencing and making available the full descriptions of the NMED events listed on the task breakdown). Subsequent discussion of how this might be implemented in the strawman tool pointed toward a computer application. Computerization of the knowledge base and tools had been suggested at the Phase 2 kickoff meeting, and identified as a likely longer term aim of the effort, but in light of the value placed on it may be advisable to try to develop a prototype hypertext tool as part of the current strawman. This would be a supplement to the paper-based material discussed at the meeting with NMSS staff.

It was decided that the content developed to date, while it did not address all of the human performance aspects of the gamma knife , was sufficient for purposes of evaluating strawman tools.

Further Development

It is considered based on the feedback to date that the strawman job aid is appropriate for NMSS use. However, further work is required to complete the tasks as described under Objectives. For instance, preparation of the strawman job aid formats has clarified the types of information that will have to be developed in the course of gathering the material that will form the basis for the training. Additional work is required to demonstrate how human performance considerations apply to specific actions and circumstances, such as in a new review or inspection.

If the proposed job aid is to be adopted, several activities are required to support its development in addition to the tasks listed earlier. First, the currently used process descriptions are outdated (at least for the Type C devices), and generally a further levels of detail of the individual steps would allow a better specification of the task performance standards and the levels of KSAs required.

Second, work would be required to add events to the database associated with each step in the process description. In principle, the linkages could be achieved through linking to the NMED database.

However, the current NMED database does not provide any explicit breakout of human factors issues in the type shown in Appendix E. This could be an on-going task performed by trained NMSS staff.

References

Jones, E.D., Banks, W.W., Altenbach, J.T., and Fischer, L.E. (1995). Relative Risk Analysis in Regulating the Use of Radiation-Emitting Medical Devices [NUREG/CR-6323]. Washington.DC: U.S. Nuclear Regulatory Commission.

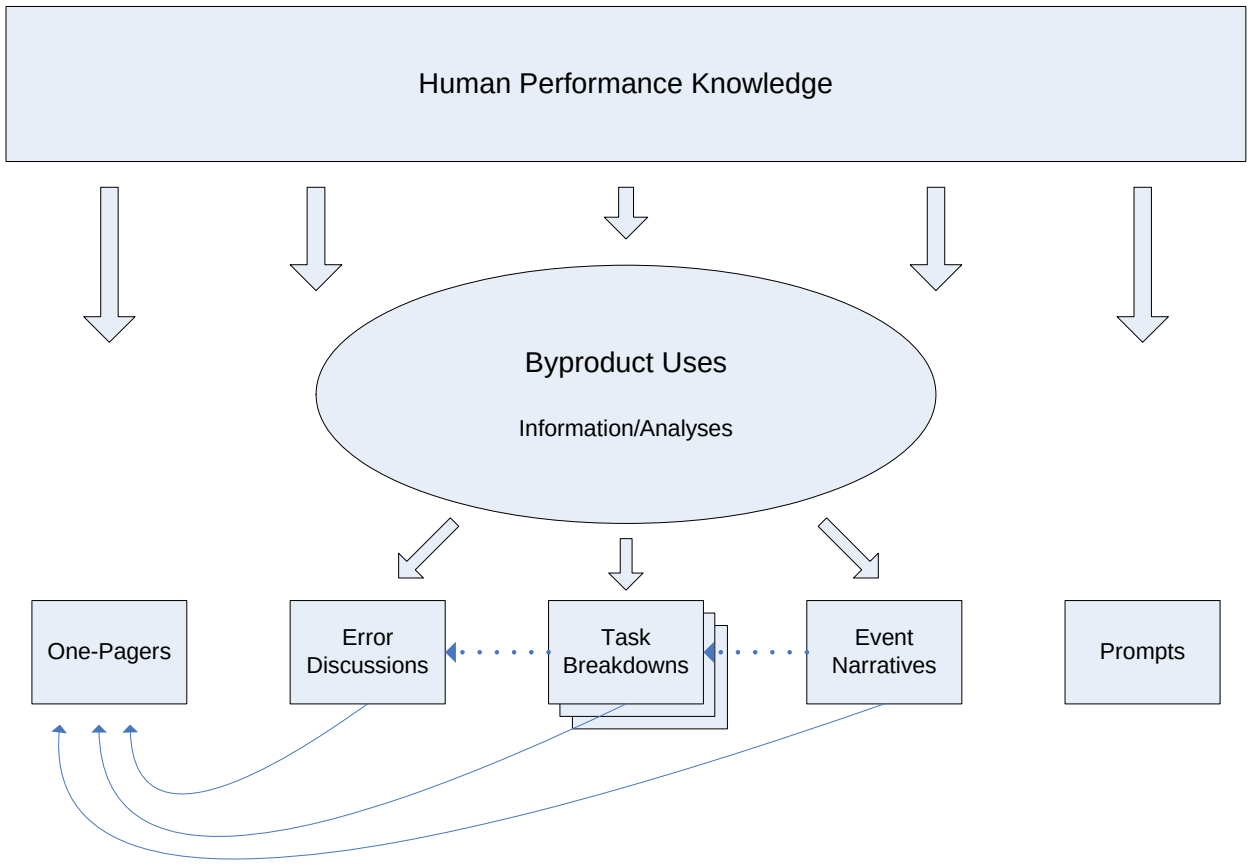


Figure 1 Structuring of Human Performance Knowledge for INMS Activities

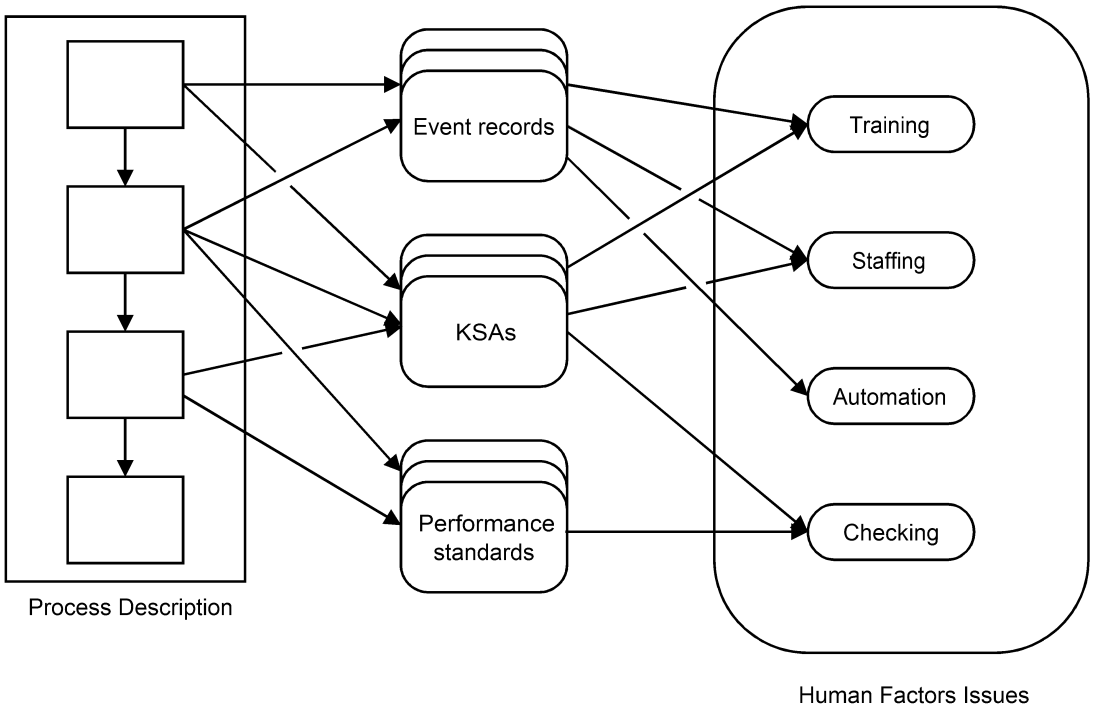


Figure 2. Illustration of How to Access Human Performance Knowledge with Strawman Job Aid

APPENDIX A:

Sample Human Performance Topics
‘One Pagers’

Design and Use of Automation

A survey of operating experience with automation identified several practical implications for designing for more effective automation; these are summarized below:

Use of automation. When operators understand the purpose and the functioning of the automation, they are able to use it more effectively. Even so, leaving the circumstance and manner of use of the automation entirely up to the individual can result in variable performance. Therefore, use of automation (and conditions under which it should not be used) should be explicitly included in procedures and operator training. The decision to use (or not to use) automation should not be influenced by effort involved in managing it; automation should not be difficult or time consuming to turn on or off.

Over-reliance on automation. Operators may rely on automation too much unless factors favoring over-reliance are countered. For example, when monitoring the performance of automation, common behavioral biases act to make operators unlikely to detect an automated process going wrong, especially when they are busy. One way to counter this is to reduce workload, especially that associated with the monitoring per se. Feedback about the automation's states, actions, and intentions can be presented so as to direct the operators' attention appropriately without imposed an undue burden. Operators may also defer to automated control if they doubt their own skills; this signals a need for further training. Similarly, in making decisions under uncertainty, operators may overvalue the data provided by the automation and fail to seek out independent information; again, training can help operators to recognize and counter decision biases that may cause to over-reliance.

Failure to use automation. Operators will not use automation if they lack confidence in it. The effects on operator confidence of the performance of automated monitoring systems (false alarm rates in particular) should be considered in their design. An excessive false alarm rate can be a consequence of an overly conservative choice of the setpoint. However, an automated alarm may also be judged to lack predictive value when the base rate of the hazardous condition to be detected is very low. Accordingly, it is worth considering graded alerts that reflect the likelihood of the condition to be detected, rather than encouraging the operator to rely on the alarm as the final authority on the existence of a dangerous condition.

Inappropriate application of automation. Application of automation should not be driven by technological feasibility; it should be designed to assist operators with tasks that may exceed their capabilities. The implementation of automation should take into account the need for operators to remain involved in the process. The notion that fully automating a process will result in greater safety or reliability is, at best, an oversimplification. For example, it is not correct to assume to a process is less susceptible to error as a result of the application of automation; operator errors can be replaced by errors in the design of the automation. In making design decision, the effects of both sources of error should be considered.

Mode Errors

Mode errors are defined as performing the operation that is appropriate for one mode when the device is in another one. They comprise a large class of errors covering many types of human-machine systems, including computer-based devices. Mode errors occur most frequently in systems and devices with inadequate feedback on their mode or the state of the system. Depending upon specific characteristics, the consequences of mode errors can range from having no effect to an extremely serious one.

Modes are created when a control or display device is used for more than one function as, for example, when a single operator's workstation accesses more than one soft control. (Note that control modes should not be confused with plant operating modes, such as startup, standby, and shutdown.) Mode errors occur when there is inadequate awareness of the device's current mode (i.e., the user believes the device is in one mode when it is in another) and, as a result, performs an inappropriate input action. Mode errors associated with computer-based control systems are receiving growing attention because (1) computer-based technologies are being used in more and more human-machine systems, (2) computer-based control and display devices may contain more modes than traditional analog instrumentation (i.e., a single device may give access to many displays and control interfaces), and (3) the digital systems using computer-based technologies often are more advanced than their analog counterparts. Four design strategies for preventing mode errors are described next: eliminating modes, making modes distinct, providing different inputs for different modes, and coordinating inputs across modes.

Eliminating Modes – Mode errors cannot occur if there is only one mode. However, multiple modes are normally eliminated by having additional dedicated control and display devices. This is not always possible for equipment where there may be insufficient space. Also, adding more devices may increase the likelihood choosing the wrong one.

Making Modes Distinct – The goal of the second strategy is to ensure that the user is aware of the currently active mode by providing distinct, salient indications of mode state.

Coordinating Inputs Across Modes – The consequences of mode errors can be reduced by insuring that a command does not have very different meanings in different modes.

A special mode error consideration relates to systems that change modes automatically. Automated systems should be designed to inform the operator of their current operating mode, mode transition points, limits on operator actions, and circumstances under which the operators need to assume control. In addition, the operator must be aware of indications from the automated system or other means, of how to assume control without "fighting" the system or causing unnecessary transients.

On-Call Staffing

'On-call' staffing approaches are used in a variety of domains to minimize personnel demands during nominal operations. Under this strategy, additional personnel are called in when a deviation from normal operations occurs. This can put personnel in a difficult position, since the 'on-call' staff are necessarily coming in with less-than complete knowledge of the situation, and those already on the job have to divert attention from the current activity to brief incoming staff on the situation and to coordinate joint activity.

In settings where continuity of operations is imperative, provisions are made to bring about a smooth handover from one shift to the next. Information is conveyed to incoming personnel that allows them to

- have a complete model of the state of the activity
- be aware of significant data or events
- be prepared to deal with impacts from previous events
- be able to anticipate events
- have the knowledge necessary to carry out relevant tasks
- continue activities that are in progress or planned
- avoid unwarranted shifts in goals, decisions, priorities, or plans

A study of the handoffs occurring in such an environment found that update briefings contained relatively few specifics about nominal events, and concentrated instead on off- normal events and on information pertinent to future activities and decisions. The implication of this is that incoming personnel have significant knowledge prior to the start of the update. If they did not (as might be the case for called-in practitioners), the update could not conducted as quickly and effectively, and could burden the staff involved as described above.

As a partial solution to this problem, it has been suggested that 'on-call' staff maintain some level of awareness of the process. This requires an investment of resources, but not to the extent that would be needed to have positions continuously staffed. It would involve establishing and maintaining 'common ground' with practitioners in duty during nominal operations. On-call staff might use various means to 'look in' on the process from their on-call location (e.g., status displays or video feeds).

Staffing - Analogous Considerations for Nuclear Power Plants

The technical basis for assessing requests for exemption from the required staffing levels in nuclear power plants is provided in NUREG/CR-6838. The analyses and documentation associated with addressing regulatory question regarding nuclear power plants are considerably more involved those associated with byproduct materials. Nevertheless, it may be useful to briefly summarize some of the factors that are identified as relevant in evaluating power plant staffing issues, since they may also be apply to personnel requirements in byproduct applications.

The aim of the NRC's review exemption requests is to "determine whether the staffing proposals will provide adequate assurance that public health and safety are maintained to a level that is comparable to compliance with the current regulations." Thus the criterion against which requests are judged is an equivalence of safety. It is noted that the specific minimum staffing levels reflects a "margin of safety" policy, requiring "a sufficient number of operators and senior operators to safely operate the plant, plus one more, in case something happens to one of them."

The staffing requirements for a single operating unit (and a single control room) are two operators and two senior operators. When two units are operated from a single control room, an additional operator is required (i.e., three operators and two senior operators). For two units operated from separate control rooms, an additional operator *and* senior operator are required (i.e., four operators and three senior operators). The prescribed levels assume one operator always at the controls for each unit, one or two additional operators per unit, and one senior operator in the control room for each unit in operation.

The purpose of NUREG/CR-6838 is primarily motivated by the need to address staffing issues in light of possible changes in the concept of operations associated with fundamentally different reactor designs. However, it also can help to address the staffing implications of less extensive technological changes, such as the introduction of automation and advanced human-system interfaces into existing control rooms. For example, the document mentions that advances in the bandwidth and reliability of telecommunication technologies (including wireless) may allow monitoring of processes from remote locations, and that it may be necessary to consider an expanded definition of "at the controls." It is noted that staffing proposals based on such technologies would make it necessary to consider "capabilities for managing and coordinating control room personnel functions among control room personnel who may be located remotely from each other."

According to NUREG/CR-6838, the following analyses and data that would be needed to review an exemption request:

- a description of the concept of operations for the control personnel
- a description of the operating conditions applicable to the exemption request
- a description of new or modified positions for control personnel, preferably in the
- form of job definitions
- operational experience
- functional requirements analysis and function allocation
- task analysis
- staffing plans
- other analyses described in NUREG-0711

Effects of Advanced Technology on Team Performance

Teams are often relied upon to support situation assessment, error detection and recovery in high-consequence activities. Coordination of the team members' work requires them to be aware of the each others activities. Successful teams actively locate errors, question improper procedures, and monitor the status of others. In carrying out tasks, personnel convey, directly and indirectly, their intentions and actions to others. Computer-mediated tasks, especially those performed at individual workstations, may isolate users, making an individual's actions less visible to others, thus reducing team effectiveness.

It has been suggested that traditional work environments with conventional technologies have characteristics that contribute to team performance: horizon of observation, openness of tools, and openness of interaction.

- *Horizon of Observation* - This refers to the portion of the team task that can be seen or heard by each individual. It results from the arrangement of the work environment (e.g., proximity of team members) and is influenced by the openness of tools and interactions. By making portions of a task more observable, team members can monitor errors of intent and implementation, and determine when assistance might be helpful.

- *Openness of Tools* - This is the degree to which an observer is able to infer information about another's ongoing tasks through observation of a tool's use. Open tools show characteristics of the problem that give an observer the context for understanding what has been done and the possible implications.

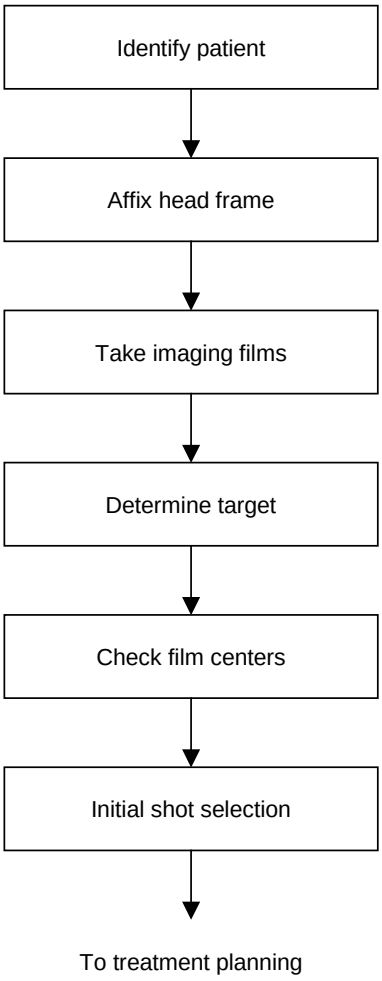
- *Openness of Interaction* - This is the degree to which the interactions between team members provide an opportunity for others with relevant information to contribute. Openness of interaction depends on the type of communication (e.g., discussing actions or decisions in the presence of others) and the style of interaction (e.g., the extent to which unsolicited input is accepted). Openness of interaction is also influenced by characteristics of the work environment (e.g., openness of tools, horizon of observation) that allow other team members to see and hear the interaction.

When computer-based technologies are introduced, these positive characteristics may be compromised. For example, using an individual computer-based workstation may reduce the horizon of observation because that view cannot be readily seen by others and may lead to less open styles of communication. Also, the openness of tools may be impaired by having methods of user-system interaction that convey less task-related information to observers.

APPENDIX B:

Task Breakdown, KSAs, and Mitigating Practices
from NUREG/CR-6323

Imaging and Localization



Academic: nursing
Training: OTJ

Academic: neurosurgery
Training: medical expertise

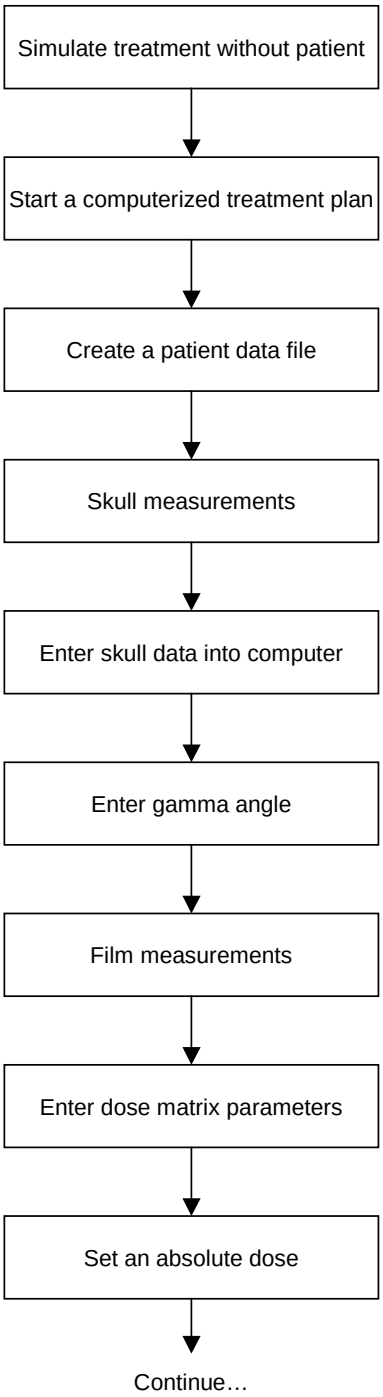
Academic: medical imaging
Training: equipment, apprentice, experience

Academic: medical

Training: equipment operation and interpretation
OTJ – apprentice training

Academic: medical
Training: gamma knife

Treatment Planning



Academic: medical
Training: experience with gamma knife

Training: treatment planning software

Training: patient record procedures
treatment planning software

Training: OTJ – apprentice training

Training: gamma knife treatment planning

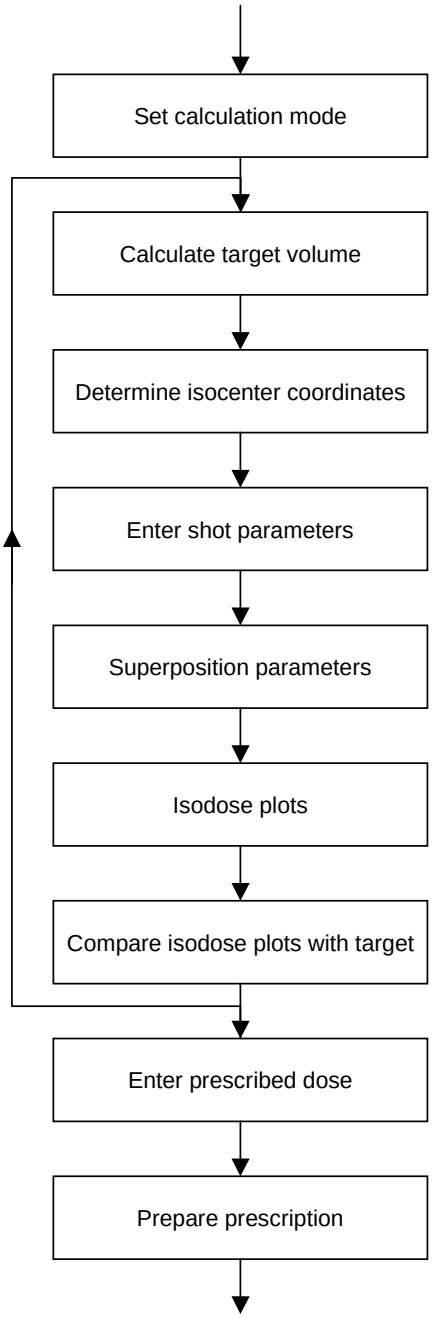
Training: treatment planning

Training: gamma knife treatment planning

Training: treatment planning
experience

Training: treatment planning

Treatment Planning (continued)



Training: treatment planning experience

Training: apprentice

Training: gamma knife apprentice

Training: treatment planning

Training: treatment planning experience

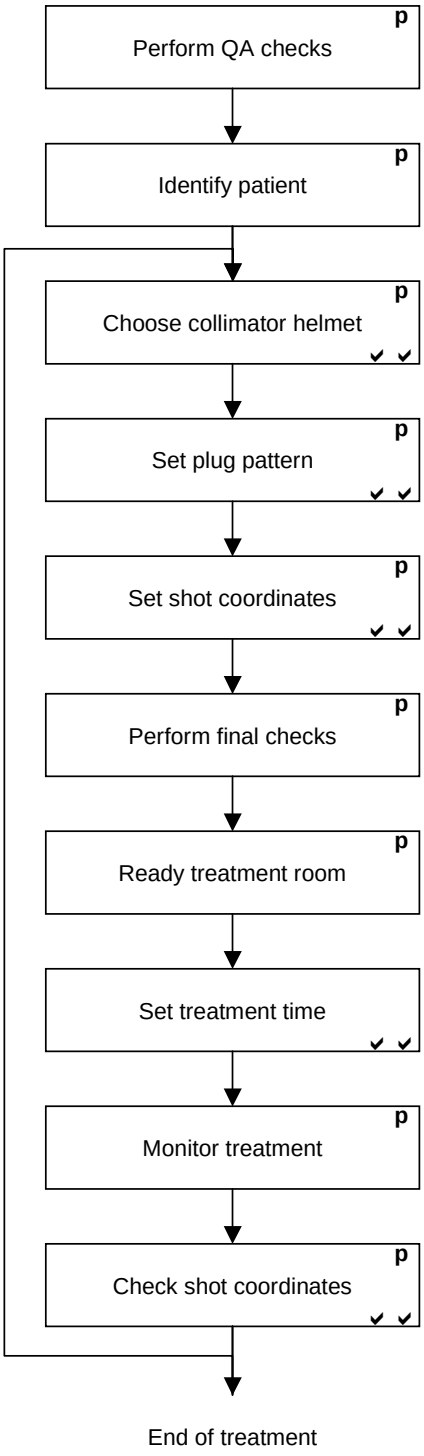
Training: treatment planning experience

Academic: medical
Training: treatment planning experience

Training: treatment planning

Academic: medical
Training: treatment planning experience

Patient Positioning and Treatment



Academic: medical physics, radiation therapy
Training: gamma knife, experience

Academic: nursing
Training: OTJ

Training: gamma knife, OTJ

Training: gamma knife, OTJ

Training: gamma knife, OTJ

Training: gamma knife, OTJ – experience

Training: radiation safety, gamma knife, OTJ

Training: gamma knife, OTJ

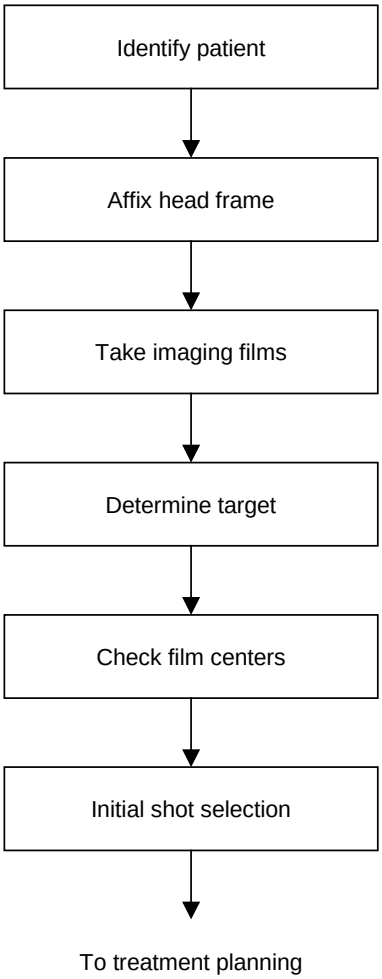
Academic: medical
Training: gamma knife, experience

Training: gamma knife, OTJ – experience

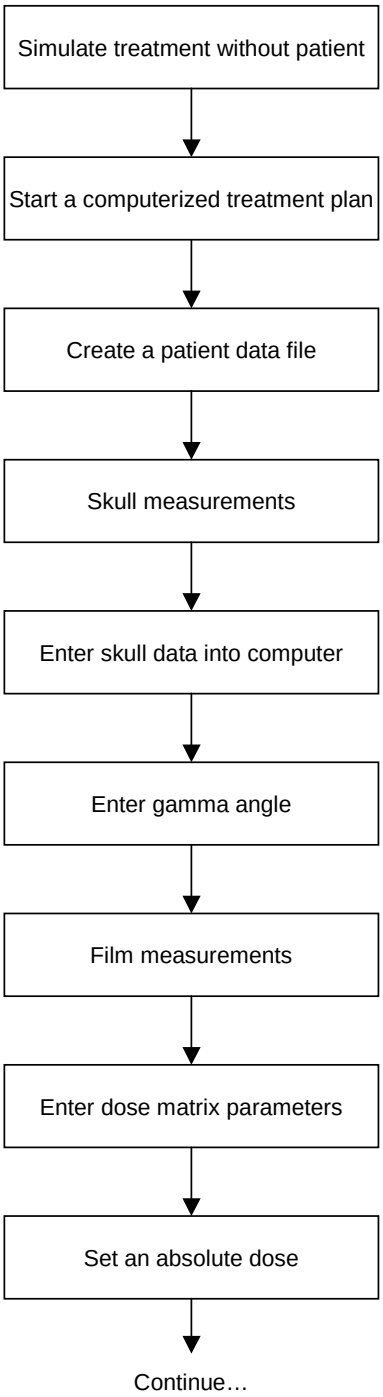
APPENDIX C:

Task Breakdown from NUREG/CR-6323
with Links to Relevant NMED Events

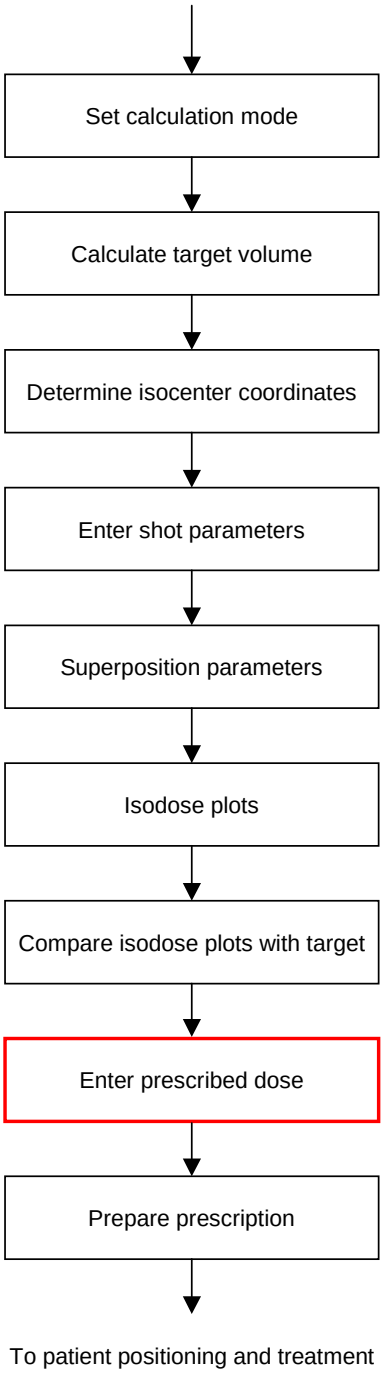
Imaging and Localization



Treatment Planning

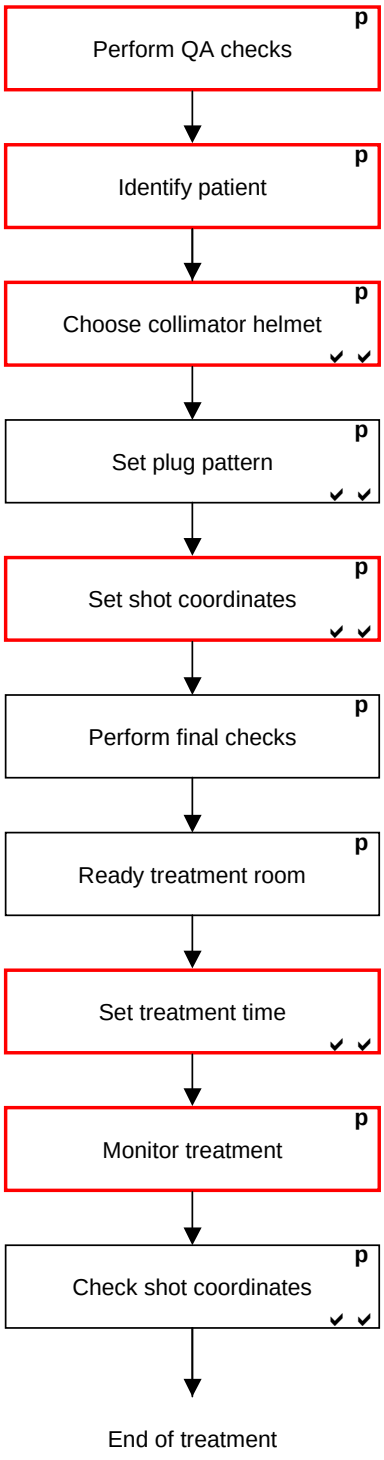


Treatment Planning (continued)



980259: failed to enter dose; default value used

Patient Positioning and Treatment



990097: incorrect system date
021005: system date reset during maintenance

000336: substituted other patient's treatment plan
010662: substituted other patient's treatment plan

951266: failed to change helmet
040125: neglected to change helmet

980646: y,z coordinates reversed
981167: y,z coordinates reversed
000615: y coordinate incorrect
000616: y,z coordinate error
000787: x coordinate entered for z
050104: y,z coordinates transposed

000686: entered time for previous fraction
010813: incorrect entry of treatment time

050194: patient moved vigorously
050597: patient coughed

Note: Symbols in the task boxes show where procedures ('P') and independent checks (double check marks) were identified in NUREG/CR-6623 as ways to reduce error/risk. Steps that have associated NMED events are highlighted.

APPENDIX D:

Selected NMED Event Narratives

940802

The licensee reported a gamma stereotactic radiosurgery (gamma knife) misadministration involving dose to the wrong site. A patient was admitted for gamma knife treatment for a long-standing arteriovenous malformation in the left posterior dura of the brain. Films were given to the physicist who optically scanned them into the computer planning system (the Leksell gamma plan or LGP). The physicist and neurosurgeon then began setting up the LGP to perform the dose planning function. Several anomalous events were occurring with the LGP during this entire process. Two critical software malfunctions were: 1. During the definition process, the screen showed a sudden "floating point error" message. 2. The definition program in the LGP refused to accept on at least two occasions, the "correct" (as viewed by the planning team) orientation of the image. Eventually, the neurosurgeon and physicist had to instruct the LGP to accept the image they knew to be intuitively correct, but which the computer recognized only as an older orientation system. Dose planning then proceeded with the lateral and p/a images entered into the system as defined. After initiating the treatment sequence for shot 8, the physicist reviewed the target points for target a (shots 1-6). He noticed that the x coordinates ranged from 67.7 to 85.5 indicating a definite right-side target. The physicist immediately terminated shot 8 with 5.45 minutes remaining. It was determined that targets 7 and 8 were right of the intended treatment areas. The physicist was unaware that a different angiography room had been used to acquire the images. QA tests had been performed in what the physicist believed to be the only angiographic suite. This room was equipped in such a way that the lateral x-ray tube could only be on the patient's right with the patient supine. The actual angiographs were performed in another room where the tube focus was on the patient's left. The physicist was performing another case during the acquisition of the angiographs and was unaware of the room change (or that another room was even available). The neurosurgeon, who was present, was not aware that the QA runs had been performed earlier in another room. As a result, the images which were "intuitively correct" to the neurosurgeon and the physicist were, in fact, perceived as incorrect to the computer software. Software was completely exonerated. The computer correctly refused to accept the image because the physicist and neurosurgeon were not aware of the reversed x-ray focus in the special procedure room which was used that day.

Error and Related Factors

users forced reversed orientation software recognized as incorrect; opposite film orientation owing to use of different room for imaging; users unaware of change from routine

Human Performance Topic(s)

Proposed Corrective Action

980259

An agreement state medical licensee reported a medical misadministration associated with a gamma knife radiation therapy. A patient received a dose 54.5 percent below that intended because the treatment physician failed to enter the prescribed dose into the treatment planning software system (Gamma Plan 3.01) of the Elekta Instruments Leksell gamma unit. This resulted in the systems default value to be used for the treatment. The prescribed dose was 22 Gy (2200 rad) and the dose received using the default value was 10 Gy (1000 rad). This oversight was missed by all three signers of the treatment plan while all quality management program procedures were being followed. The misadministration was found during a quality management program review of treatment records. Over 1200 prior treatments have been reviewed by the licensee and it was determined that this misadministration was an isolated event. The treatment planning software did not notify the user that a default dose was being used. Elekta Instruments, the software manufacturer was notified of the problem and is modifying the software so that the user is notified when the default value is being used. The patient was notified of the misadministration and was administered an additional dose to the treatment area on 10/14/97.

Error and Related Factors

user failed to enter dose resulting in default value being used; missed by three signers of the treatment plan

Human Performance Topic(s)

Proposed Corrective Action

980646
The licensee reported a misadministration where an error in treatment geometry with a gamma knife resulted in a total treatment dose differing from the prescribed dose be more than 10 percent. As the third area was being set for treatment, it was discovered that the patient's position would have to be changed from supine to prone to physically achieve the appropriate coordinates. When replanning the third area of treatment, the neurosurgeon and physicist rechecked the coordinates and realized the y and z coordinates were transposed during the second treatment. The patient was notified by the physician. All parties agreed to continue the treatment. The second treatment was recalculated and readministered. To prevent a recurrence, procedures for defining gamma knife coordinates were improved to include having both the neurosurgeon and physicist verbally verify and repeat the coordinates.
Error and Related Factors y and z coords reversed; corrective action NS and MP ‘verbally verify and repeat the coordinates’
Human Performance Topic(s)
Proposed Corrective Action

981080

The licensee reported a medical misadministration where the administered treatment was to the wrong site. A patient was prescribed a treatment of 90 Gy (9,000 rad) to the left trigeminal nerve (fifth cranial nerve) of his brain using a gamma knife. However, the treatment was actually administered to the right trigeminal nerve. The misadministration occurred because the medical physicist had prepared a treatment plan for the wrong side of the patient's head. The radiation oncologist, listed as the authorized user on the license, signed the treatment plan without properly verifying the neurosurgeon's request that identified the correct site. Also the neurosurgeon was not present during the procedure due to a surgery he was performing at the same time. The stereotactic frame was placed on the patient to correctly treat the left side. When the patient was placed in the machine's treatment cavity, the medical physicist aligned him so the right side would be treated. The dose was delivered and the error was not discovered until later. The medical physicist was training another medical physicist on how to use the facility's gamma knife equipment, which may have caused a distraction. The patient may experience increased numbness on the treated side of the face within one to eighteen months. If the numbness occurs the licensee may not be able to treat the affected side. To prevent recurrence, the licensee revised the gamma knife treatment procedure to require that (1) the treatment plan be verified before each procedure by the neurosurgeon, the radiation oncologist, and the medical physicist, (2) two of the three individuals (the neurosurgeon, the radiation oncologist, and the medical physicist) verify that the treatment program coordinates are correctly set, (3) either the neurosurgeon or the radiation oncologist verify the prescribed treatment site after the patient is positioned, and (4) the neurosurgeon and either the radiation physicist or the radiation oncologist be physically present during the treatment. Also, the radiation oncologist shall examine the patient before the treatment and verify the treatment site.

Error and Related Factors

treatment plan for wrong side; not noticed by signer; NS not present - in other surgery

Human Performance Topic(s)

Proposed Corrective Action

981167

The licensee reported a medical misadministration due to the reversal of the Y and Z coordinates when a patient was treated on the Elekta Instruments Leksell gamma knife. The plan called for three doses of radiation using the 4 mm helmet with a plug pattern. The prescribed dose to the treated volume was 1,100 cGy (rad) to the 58% isodose line. The first treatment was set up and delivered to the patient. When the coordinates for the second treatment were set, it was discovered that the Y and Z coordinates had been reversed on the first treatment. The correct coordinates were then set, and the patient was treated correctly. The remaining two treatments were also delivered to complete the treatment plan. The first treatment was simulated on the computer with the coordinates set as delivered to the patient, and the treatment site in the brain was determined. The treated site was fluid in the left ventricle of the brain. The initial calculated dose was 585 cGy (rad) to the 50% isodose volume of the 4 mm helmet, with a maximum point dose of 1,170 cGy (rad). The treated volume was small, approximately 0.96 mm3. It was determined that there would be no harmful effects to the patient. A later reconstruction utilizing the treatment planning software indicated that the dose to the ventricle wall was approximately 50 cGy (rad). The attending physician and patient's family were notified. While the root cause of this event appears to be human error during the setting of patient positioning parameters, other factors contributed to the cause of this event. Due to the patient's medical condition, variations in typical procedures as described above occurred. One variation was a reduction in the number of personnel typically involved in setting up the patient treatment from three to two individuals. Another variation was that the Z coordinate was set prior to attaching the Z bar to the stereotactic frame. For all gammaknife treatments in the future, a minimum of three individuals will be involved in setting up the patient treatment. Individuals involved in actually setting the coordinates on the stereotactic frame shall be allowed to set coordinates X, Y, and Z on one side of the patient only.

Error and Related Factors

y and z coords reversed; discovered on setup for second shot; two rather than three involved in setup; z setup procedure also not as typical; corrective: each set one side only

Human Performance Topic(s)

Proposed Corrective Action

981221
The licensee reported a misadministration involving a patient receiving gamma knife radiation therapy using an Elekta Instruments gamma knife unit (model Leksell 23016, serial #21) containing 238.72 TBq (6,452 Ci) of Co-60. As a result of this misadministration, the patient received 2,600 cGy (rad) to the first of three lesions instead of the prescribed dose of 1,600 cGy (rad). This dose has been analyzed by licensee oncologists who determined it to be within the range of acceptable prescribed doses for intra-cranial lesions. The patient and the referring physician were notified of the event. The effect to the patient is expected to be minimal. The root cause of the incident was determined to be human error by the physician. Specifically, the neurosurgeon and the oncologist did not follow procedures describing the Team Approach in treatment planning. During preparation of the treatment plan for the second treatment site, the settings for the first treatment site were unintentionally included. The neurosurgeon and the oncologist reviewed and signed the treatment plan without identifying the unintended dose. The licensee immediately implemented measures to ensure that treatment will only be carried out after planning for all treatment sites is completed. The medical physicist will participate in the entire treatment planning process and will review the treatment plan before the plan is executed. The neurosurgeon and the oncologist will collaborate at critical points in the process, such as dose selection, approval of the written plan, and initiation of the treatment. Re-training was given to all appropriate individuals and the manufacturer may be instituting software changes to assist in the prevention of a reoccurrence.
Error and Related Factors
included first site settings in second site treatment plan; signed by NS and RO
Human Performance Topic(s)
Proposed Corrective Action
treat only after planning all sites, MP involved throughout, NS and RO collaborate at critical points

990097

The licensee reported that a patient had received a therapeutic underdose of 12.3% during a Co-60 gamma stereotactic radiosurgery (gamma knife) treatment for brain cancer. While reviewing a patient's medical chart, a neurosurgeon discovered the underdose. The cause of the misadministration was an incorrect date entered on the treatment planning computer. The licensee entered 1/6/1998 into the treatment planning computer rather than 1/6/1999. This resulted in a decay error of 12.3% and corresponding reduction in treatment time. The intended treatment dose was 1,200 cGy (rad) to the isodose and because of the treatment error, the administered dose of 1,052 cGy (rad) was delivered. Contributing factors to the event include; 1) a treatment planning computer crash that occurred after successful completion of the daily treatment planning computer test, 2) failure to recognize a treatment planning computer warning that the entered treatment date differed from the system date, 3) a decision not to repeat the daily treatment planning computer test and, 4) failure to ensure that the treatment date was accurate prior to dose administration. The licensee made modifications to its Quality Management Program to prevent similar incidents. The patient and referring physician have been informed of the misadministration. Licensee corrective actions include: 1) The Gamma Knife procedures were changed to specify that the treatment date on the printed treatment setup sheet be included as one of the critical parameters that must be triple checked before commencing treatment. 2) The warning information box on the GammaPlan computer monitor that states "Treatment date differs from system date" was made more distinctive than the other information boxes that appear on the screen.

Error and Related Factors

incorrect date entered in treatment planning; early JAN; failure to re-run system test after crash; missed computer warning of date mismatch; failure to check correct date

Human Performance Topic(s)

Proposed Corrective Action

000104
The licensee reported a misadministration involving a patient being treated with a gamma knife for brain lesions. An adult patient diagnosed with metastic lung disease and up to 80 brain lesions was being treated with a gamma knife (Elekta Instruments model Leksell 23016) and was undergoing the fourth of five planned treatments when the event occurred. The event resulted in one treatment site (lesion site 16) receiving a second unintended treatment of 1200 cGy (rad) for a total dose of 2400 cGy (rad). Lesion site 47 was the intended site to receive the dose. The gamma knife was loaded with 201 rods, each containing an activity of 1.33 TBq (36 Ci) of Co-60, for a total of 267.7 TBq (7,236 Ci) of Co-60. The error was discovered by the licensee during a routine quality assurance review of the treatment. The Florida Bureau of Radiation Control conducted an on-site investigation on 2/2/2000 that included a review of the treatment plans, the written directive, physician approval procedures, and a re-enactment of the treatment plan for lesion site 47. The event was determined to be caused by human error when the wrong site was selected in the computer. Except for closer attention to detail, no corrective actions or changes in protocols were identified by the licensee or the state that would have prevented this event. There was no malfunction of the gamma knife or computer equipment. The additional dose to this site has not caused any harmful effects in the patient. The patient was notified on 1/28/2000.
Error and Related Factors duplicate treatment of one site; ‘wrong site selected in the computer’
Human Performance Topic(s)
Proposed Corrective Action

000277

The licensee reported a medical event involving a 52-year-old female patient who was scheduled to receive a six-fraction gamma knife therapy of 1800 cGy (rad) to the 50% isodose line for treatment of Pituitary Adenoma. The Elekta Instruments gamma knife (model Leksell 23016) uses 201 sealed Co-60 sources of 1.1 TBq (30 Ci) each for the radiation treatment of human patients. During the first fraction, the patient received 1,250 cGy (rad) to an unintended site with a volume of approximately 0.18 cm3 (at the base of the frontal lobe). The unintended site would have received approximately 160 cGy (rad) during the first fraction, had the first fraction been completed as prescribed. This misadministration was caused by the inaccurate positioning of the steriotactic frame on the patient's head. Specifically, the Y and Z coordinates were transposed on both sides of the frame. This error resulted in a distance of 4.2 cm between the intended and unintended sites. The treatment planning for the patient was uneventful and was prepared and reviewed by a hospital gamma knife team of a radiation oncologist, a neurosurgeon, and a medical physicist. The frame adjustment was to be checked for accuracy by a nurse and the medical physicist. Normally, the coordinates are read out in a specific order. The licensee indicated that the order might have been reversed due to a specific frame orientation problem that occurs approximately once in every 20 treatments. The error was noted when the licensee started to set up for the second fraction. The treatment plan was reevaluated to include some partial dose to the tumor from the first fraction and the treatment was completed in seven fractions instead of six. The patient and her referring physician were notified of this misadministration on the same day that the event occurred. A written notification of the event was also sent to the patient on 5/4/2000. The licensee reviewed previous medical files to ensure that the switching of coordinates had not occurred before without a misadministration being identified. A hospital management meeting was held on 4/24/2000 to include personnel from Hospital Administration, Oncology, Neurosurgery, and the Radiation Safety Office to discuss this incident. This event was investigated by Maryland Radiological Health and Protection (RHP). The root cause was determined to be a sequence of human errors made by the neurosurgeon, the oncologist, and the medical physicist during patient positioning. After the oncologist inadvertently reversed the Y and Z coordinates, the neurosurgeon and the medical physicist each signed the licensee's Gamma Knife Treatment Quality Assurance checklist indicating that they had physically checked the patient positioning coordinates for conformance with the written directive. However, they failed to conduct an adequate verification of the patient positioning parameters prior to the administration of the radiation dose. The licensee has developed and implemented an additional procedure that requires more attention and better confirmation of coordinate placement on the frame. The licensee held a management conference with radiation safety, radiation oncology, neurosurgery, patient care services, and clinical effectiveness. As a result of this meeting, the licensee implemented a written protocol regarding patient positioning.

Error and Related Factors

y and z coords reversed by RO; reading out coords in reverse order may have contributed; NS and MP signed QA checklist

Human Performance Topic(s)

Proposed Corrective Action

add’l procedure ‘requires more attention and better confirmation’

000336
The licensee reported a medical event where a gamma knife was set up incorrectly and delivered the dose to the wrong location of a patient's brain. A radiosurgery treatment was to be delivered to the left trigeminal nerve of a 51-year-old woman using the Elekta Instruments gamma knife (model Leksell 23016) containing 243.9 TBq (6592.8 Ci) (activity as of 8/1/95) of Co-60. On the same date, a 75-year-old man was admitted for the identical treatment. During the signature phase of plan approval, the dose delivery sheet of the 75-year-old man's treatment protocol was inadvertently transposed with that of the 51-year-old woman's treatment protocol. As a result, the 51-year-old woman was treated with the radiosurgery parameters that were intended for the 75-year-old man. This resulted in an 8000 cGy (rad) dose to the wrong treatment site of the patient's left trigeminal nerve. The intended dose to the treatment site was 8000 cGy (rad) at the 50% isodose line. The actual dose delivered to the intended treatment site was 20 cGy (rad) (maximum) as calculated by the licensee. A dose of 8000 cGy (rad) was delivered to an 88.6 mm3 volume inside the skull of the woman, but outside of the intended treatment site. The misadministration was discovered immediately following the delivery of the dose by the patient's radiation oncologist. A telephone report was made to the Alabama Department of Public Health, Office of Radiation Control. The patient was notified verbally within 24 hours. On 4/20/2000, the patient returned to the medical center and received treatment, without incident, to the intended treatment site. As a result of the misadministration, the licensee took immediate action to prevent the mixing of patient treatment protocol documentation. Each page of the treatment protocol contains a unique name and time stamp which will be reviewed by the Radiation Oncologist or Medical Physicist (as evidenced by initialing each page of the protocol near this stamp) prior to the delivery of the radiosurgery treatment.
Error and Related Factors substitution of treatment plan for another patient
Human Performance Topic(s)
Proposed Corrective Action initial identifier on each page of treatment plan

000615

The licensee reported a medical event involving a gamma stereotactic radiosurgery (gamma knife) treatment to an unintended area of the patient's brain. The event was discovered as a result of a licensee quality control verification of the gamma knife parameters performed after the radiation treatment. A patient with melanoma metastases was referred to the licensee's Department of Radiation Oncology for radiation treatment of two metastatic lesions located in the left thalamus and right parietal regions of the brain. Irradiation of the two lesions was performed using the licensee's gamma knife, which contains 201 sources of Co-60, nominally 1.11 TBq (30 Ci) each, arranged in a semihemispherical (helmet) configuration that allows the sources to collectively focus on small volumes of the brain. The treatment plan that was developed for the 3.0 cc lesion located in the left thalamus was a single exposure of 1600 cGy (rad), at the 60% isodose line, to a 4.7 cc treatment volume. One of seven parameter settings of the gamma knife, the "left Y" coordinate, was erroneously set at 111 mm instead of 101 mm for this exposure, resulting in a 5 mm translocation of the treatment volume. This error resulted in an under-dose of a portion of the intended treatment volume and an unintended dose of more than 1000 cGy (rad) to brain tissue outside of the prescribed treatment volume. The 5 mm translocation exceeded the licensee's accepted tolerance of 1 to 2 mm for this procedure. A treatment physician notified the patient of the medical event and the necessity of another exposure to improve tumor coverage. An additional exposure was added to the treatment plan to complete the prescribed dose to the intended treatment volume of the left thalamus and the treatment proceeded to completion uneventfully. The licensee stated that the brain volume receiving the unintended dose of 1600 cGy (rad) was approximately 3 cc, which included 0.2 cc of the thalamus tissue. The licensee stated that the patient experienced no acute side effects related to this medical event. The licensee reported that the patient died as a direct result of the metastatic melanoma condition on 3/3/1999. A medical consultant was not used by the State. On-site investigation was conducted by the State staff on 9/24/1998. This event was caused by human error that resulted in an initial erroneous coordinate setting by one member of the treatment team and the failure of the independent verification of the coordinate setting by another member of the treatment team. The licensee claimed that personnel distraction contributed to the error. Initial corrective actions by the licensee included limiting distractions to the treatment team by limiting telephone calls in the treatment control area and restricting conversations in the treatment room to only those required for the treatment of the patient. The State requested the licensee contact other gamma knife facilities to review their methods of operation. The licensee has adopted the procedure of performing two independent checks of the coordinate settings before each exposure and retaining their follow-up check of the coordinate settings after each exposure to determine if an error was made. The findings of the on-site investigation by the State staff agreed with the findings of the licensee's quality assurance review. The State was satisfied with the licensee's corrective actions. No enforcement actions were taken by the State for this medical event.

Error and Related Factors

incorrect y coord setting; independent verification failed; possible distraction

Human Performance Topic(s)

Proposed Corrective Action

limit distraction, phone calls, conversation; use two independent checks and retain post-shot check

000616
The licensee reported a misadministration involving a gamma knife treatment to an unintended area of the patient's brain. An error occurred in reading the Y and Z coordinates for placing a patient relative to the beam from the gamma knife. This resulted in an exposure of 5 Gy (500 rad) to a volume of 0.034 cm^3 that was 1-5 cm from the intended location. The neurosurgeon in attendance stated that there would be no adverse effects to the patient.
Error and Related Factors ‘error occurred in reading the Y and Z coordinates’
Human Performance Topic(s)
Proposed Corrective Action

000686
The licensee reported a misadministration involving a gamma knife radiosurgery treatment. An incorrect exposure time was set, which resulted in a dose 11% greater than intended. When the authorized user set up for the next treatment fraction on the list, the exposure time for the previous treatment fraction, which had not been performed, was used.
Error and Related Factors entered time for the previous fraction on the list
Human Performance Topic(s)
Proposed Corrective Action

000787
The licensee reported a medical event that occurred during the performance of a gamma stereotactic radiosurgery treatment for acoustic neuroma. The patient's treatment plan called for the administration of 1,200 cGy (rad) to a tumor volume in three shots. The first shot was delivered with the 8-mm collimated helmet and was to be followed by two shots with the 4-mm collimated helmet. When the coordinates of the second shot were being set, it was discovered that the z-coordinate of the first shot was 11-mm off of the target volume. It was determined that the x-coordinate was accidentally entered for the z-coordinate. The licensee determined that the positioning error resulted in the treatment of a small volume (0.58 cm3) of normal brain. The licensee stated that this area would have received some radiation exposure during the normal course of treatment, but not the 460 cGy (rad) that resulted from the positioning error. The patient and the patient's physician were immediately advised of the error. A new treatment plan was generated to account for the misplaced shot. The patient was then treated with the second and third shots (with the modified treatment times) and the physician added a fourth shot to ensure that the target area missed during the first shot was fully treated. The NRC contracted a medical consultant to review this event and the probable deterministic effects on the patient. The medical consultant concluded that this event is not expected to produce clinically identifiable adverse effects on the patient. This event was caused by the licensee's failure to follow their established Quality Management Plan (QMP) in that the licensee failed to verify that the treatment coordinates set on the patient's head-frame were the same as those established in the written treatment protocol. Corrective actions include 1) procedure modification to explicitly state that all team members must verify treatment coordinates and 2) conducting an in-service to re-familiarize the team members with the QMP and the revised procedure.
Error and Related Factors
x coord entered for z; discovered as second shot was being set up
Human Performance Topic(s)
Proposed Corrective Action
modify procedure ‘to state that all team members must verify treatment coordinates’

010072
The licensee reported that a patient received a dose to an unintended site while being treated with an elekta Instruments gamma knife (model Leksell 23004 type B). The treatment plan called for 13 treatments, each with prescribed doses of 15 Gy (1,500 rad) or 20 Gy (2,000 rad). Following the seventh treatment, the licensee identified the error. The event resulted in six unintended sites receiving doses of 15 or 20 Gy (1,500 or 2,000 rad) each. The correct sites were subsequently treated. The licensee informed the patient and the patient's physician. The licensee reported that no adverse effects were expected as a result of the medical event. The root cause of this event was human error resulting in a fiducial box being incorrectly positioned on the patient. When imaged by MRI, the box provides an X, Y, and Z coordinate system to allow for precise localization of treatment sites. Contributing factors included subtle markings on the fiducial box, an assumption that the box was assembled correctly, and an assumption that the box could not be installed incorrectly. Corrective actions include working with the fiducial box manufacturer to improve its safety features and modifying the Quality Management Plan to require independent verification of box positioning. The NRC contracted with a medical consultant to review this event. After discussion with the NRC Region III and NMSS, it was determined that this event did not constitute a reportable medical event. The event was retracted on 4/11/2001.
Error and Related Factors fiducial box incorrectly positioned; assumed that box was assembled correctly and could not be installed incorrectly
Human Performance Topic(s)
Proposed Corrective Action require independent verification of box positioning

010662
The licensee reported that a patient received a Co-60 gamma knife treatment to the wrong site. While administering the fourth of eight treatment fractions, the medical team discovered that they were using the wrong patient's treatment plan. As a result, the patient received a dose of approximately 1,280 cGy (rad) to the 50% isodose line of a small area of the brain. The patient subsequently received the correct treatment. The attending physician and the patient were notified on 7/11/2001. The root cause of this event was the failure to verify that the treatment plan was for the patient being treated. An NRC contracted medical consultant concluded that the dose to the unintended site was at the threshold for central nervous system injury and may produce symptoms. The consultant also concluded that long-term followup was indicated and that the patient is eligible for the U.S. DOE Office of Epidemiology and Health Surveillance Long-term Medical Study Program. Corrective actions include a more prominent display of the patient's name on the treatment forms, triple verification of each treatment coordinate, and physician sign-off that the treatment plan matches the patient being treated.
Error and Related Factors wrong patient's treatment plan
Human Performance Topic(s)
Proposed Corrective Action more prominent display of patient name, triple verification of each coord; physician sign-off of patient to be treated

010813
The licensee reported that a patient received a therapeutic dose 39% greater than prescribed to the inferior right parietal of the brain. The patient was to receive 2,000 cGy (rad) to the 50 percent isodose line using Co-60 gamma stereotactic radiosurgery (gamma knife), but instead received 2,780 cGy (rad). This treatment was the first in a series of five geographically distinct treatments. The treatment was terminated when it was recognized that the elapsed treatment time had exceeded the prescribed time. The resulting treatment duration was 7.18 minutes longer than prescribed. This event was caused by the incorrect entry of the treatment time into the Leksell treatment unit and the failure to identify the error during the second verification of the treatment parameters. The remaining four treatment sites were subsequently treated in accordance with the patient's treatment plan. The patient and physician were notified of the event. To prevent recurrence, the licensee modified their Quality Management Program to improve the verification process for treatment plan time entry. The NRC contracted a medical consultant to review this event. The consultant concluded that the licensee took appropriate immediate actions and performed an appropriate assessment. The consultant also agreed with the licensee that the patient should not experience any adverse effects from this event because the delivered dose falls within the normal range of standard treatment.
Error and Related Factors incorrect entry of treatment time not caught upon verification of treatment parameters
Human Performance Topic(s)
Proposed Corrective Action improve verification process

021005
The licensee reported that ten patients received radiation doses at least 60% greater than prescribed during Gamma Knife treatments. The patients were treated during the period of 8/26/2002 through 10/30/2002. The prescribed radiation doses ranged from 1,220 to 2,400 cGy (rad) to the brain. However, the delivered doses ranged between 1,920 and 3,840 cGy (rad). On 10/30/2002, the RSO discovered that the physics parameters had an incorrect calibration factor. Further investigation determined that the system had an older calibration date, which indicated that the sources had 60% less activity. The licensee stated that the manufacturer's employee changed the unit's printer on 8/26/2002, and during the process reset the calibration parameters to a different date. The instrument was removed from service and the patients and physicians involved were notified. Elekta Instruments manufactured the Gamma Knife (model Leksell 24001, type C, serial #4189C) that contained Co-60 with an activity of 211.64 TBq (5720 Ci). The Florida Bureau of Radiation Control conducted an investigation and concluded that the licensee's quality management program did not routinely verify calibration information to determine the state of the equipment. To prevent recurrence, the licensee revised their quality management program to include daily checks to verify the systems dose rate.
Error and Related Factors
overdose to ten patients; physics parameters had incorrect calibration factor; calibration parameters reset to a different date during printer maintenance; failure to routinely verify calib info
Human Performance Topic(s)
Proposed Corrective Action
'include daily checks to verify the systems dose rate.'

040125
The licensee reported that a patient received 2,700 cGy (rad) to a brain metastasis instead of the intended 1,800 cGy (rad) during gamma knife treatment. The physicist did not determine an error had occurred until the treatment was complete. The RSO determined that one of the four brain metastases received greater than the prescribed dose. The other three metastases received the prescribed dose. The tumor that received the incorrect dose was at the periphery of the brain next to the skull in a non-critical area so that much of the extra dose was delivered to the space between the brain and the skull. The cause of the incident was the use of the 14-mm collimator helmet instead of the prescribed 8-mm collimator helmet. The personnel setting up the treatment neglected to change the helmet. The referring physician was notified of the event. Corrective actions taken by the licensee included establishing a new procedure requiring the physician, physicist, and nurse to sign off on the treatment time, helmet size, and position before each shot. Also, new labels identifying the size of the helmet were attached to each of the four helmets such that the helmet size can be determined outside the room on the TV monitor at the control. The physician will verify the correct size before the control panel button is pushed to start the treatment.
Error and Related Factors neglected to change helmet
Human Performance Topic(s)
Proposed Corrective Action require physician, physicist, and nurse to sign off on the treatment time, helmet size, and position before each shot; added helmet labels visible from outside room; physician to verify helmet before pushing start button

050104
The licensee reported that a patient received a radiation dose that was greater than 50% of the expected dose to a site outside of the intended treatment volume during a gamma knife treatment. Elekta, Incorporated, manufactured the gamma knife unit (model 24001, type C, serial #4149), which contained 119.6 TBq (3231.5 Ci) of Co-60. The patient was prescribed to receive 1,800 cGy (rad) to the intended treatment volume. During the process of manually programming the positioning system, the Y and Z coordinates were transposed. The error was not noticed during the double check of the treatment coordinates. As a result, the unintended site received an estimated dose of 506 cGy (rad) instead of the intended 40 cGy (rad). The volume of the unintended treatment site was 0.7 cm3 and the treatment duration was 2.42 minutes. The prescribed dose of 1,800 cGy (rad) was delivered and the patient's treatment was completed. The referring physician was notified of the event. State of Wisconsin Radiation Protection Section personnel were dispatched on 2/18/2005 to investigate the event. The cause of the event was determined to be the licensee's failure to conduct an adequate verification of the patient positioning parameters prior to administration. Contributing factors included; the individual who placed the Y/Z trunnion bar onto the head frame reversed their usual sequence of setting the Y and Z settings; and the independent coordinate verification by multiple individuals failed to detect the incorrect coordinates. The licensee has implemented additional procedural steps requiring more attention to detail and confirmation of patient positioning parameters on the frame.
Error and Related Factors
y and z coord transposed when programming the positioning system; not noticed during double check of coords; usual sequence of setting coords reversed; 'independent coordinate verificiation by multiple individuals failed to detect the incorrect coordinates'
Human Performance Topic(s)
Proposed Corrective Action
'procedural steps requiring more attention to detail and confirmation of patient positioning parameters on the frame

050194
The licensee reported that a patient received a radiation dose to an unintended site during Co-60 gamma knife treatment. The gamma knife unit (model Leksell 23004 type B, serial #/project #4132) was manufactured by Elekta AB. There were more than 200 Co-60 sealed sources in the gamma knife unit with a total activity of 129.2 TBq (3,492 Ci). The patient was prescribed to receive a dose of 85 Gy (8,500 rad). During the treatment, the patient became uncomfortable and asked to move. He was told to move only his legs, but made a vigorous movement and shifted his body. The licensee did not suspend treatment to verify the setting coordinates after this movement. At the completion of the procedure, the licensee noted that the z-bars used to set the z-coordinate had changed position by approximately 7 cm. This resulted in the patient receiving approximately 35 to 40 Gy (3,500 to 4,000 rad) to the skin and tissue of an unintended site. Follow-up examinations of the patient identified no harm from this event and indicated that the intended treatment was effective. The licensee immediately replaced the z-bars. The NRC contracted a medical consultant to review this event. The consultant concluded that the dose delivered to the wrong treatment site is of no physiologic consequence. Corrective actions taken by the licensee included reminding individuals present during a gamma knife treatment to emphasize to patients to remain completely still, if possible; the y and z bars were replaced; personnel are to stop the procedure and reexamine the set-up should the patient move; and personnel are to confer with the patient every 15 minutes and determine if the patient needs to move. The licensee plans to upgrade the gamma knife unit to a Model C, which would automatically terminate the procedure if the patient moves.
Error and Related Factors
patient moved vigorously, positioning not checked until after treatment completed
Human Performance Topic(s)
Proposed Corrective Action
stop and reexamine setup if patient moves

050529
The licensee reported that a patient received 50% less dose than prescribed to two of seven lesions during a gamma knife treatment. The Elekta gamma knife unit (model 24001) contained several Co-60 sources (Eleckta model 43047) with a combined activity of 259 TBq (7,000 Ci). The patient was prescribed 1,500 cGy (rad) per lesion, but only received 750 cGy (rad) to two lesions. The event was discovered on 8/3/2005 during an internal audit of treatments. An investigation did not identify a problem with the gamma knife or the dose programs involved in planning. The cause of the event was determined to be personnel lack of knowledge concerning the treatment planning software and communication difficulties between the physicist and neurologist. Correction actions taken by the licensee included additional education in treatment planning and reinforcement of the necessity of communications between personnel.
Error and Related Factors error found in audit post hoc; report 'lack of knowledge concerning the treatment planning software and communication difficulties between the physicist and the neurologist'
Human Performance Topic(s)
Proposed Corrective Action add'l education in treatment planning and 'reinforcement of the necessity of communication between personnel'.

050597
The licensee reported that a patient, being treated for a brain tumor with a gamma knife, received dose to an unintended site. The patient coughed and dose was administered approximately 6 mm from the correct treatment site. The event occurred toward the end of the patient's final treatment, toward the end of the 11th stage of the treatment. The cough caused the pin used to stabilize the patient skull to become dislodged (shifted). This resulted in the patient being administered a dose not directly to the tumor. All physicians involved in the case were notified.
Error and Related Factors patient coughed, securing pin dislodged
Human Performance Topic(s)
Proposed Corrective Action

APPENDIX E:

Brief Discussions of Events from NMED Database & Their Links to Issues

The errors discussed below are among those found in a recent search of NMED for gamma knife events. The relationship to human factors and human reliability topics are added to show how links to relevant areas can be created.

Failure to enter the prescribed dose

The error may have occurred for various reasons:

- The system user may simply have forgotten to enter the value (owing, e.g., to distraction).
- There may be something in the design of the interaction mediating the entry of parameters that predisposes the user to omit the parameter (e.g., a mismatch between the way the system tabs through an entry screen and the order in which values appear on the paper that the user is working from.
- They parameter entry interface make it possible for the user to invalidate an entry after making it (e.g., by 'backing up') without giving any indication that this has occurred.

Regardless of the reason, the system clearly should not proceed without having accepted a user input for an essential parameter. The event report noted that the software was modified by the manufacturer so that users are notified if a default value is being used. There seems to be little value in having a default value at all, unless an overwhelming number of treatments use the default for this parameter – in which case there would be a small but frequent savings in time. Other event reports suggest that a system warning about the default value might be missed by the user. Ultimately, recovery from this error depends on verification procedures.

Topics:
General error
Interface design: data entry
Warnings
Checking

Failure to perform QA checks

Both instances of error involve an incorrect date setting (which affects dose calibrations). Requiring users to check values such as the system date should probably not be relied upon as the only barrier against this type of error. It has been shown in a variety of contexts that people are not good at detecting deviations that occur with a very low probability. In light of the importance of the date to the correct delivery of treatment, the system should present a very conspicuous warning of a mismatch and require explicit confirmation before the process is allowed to proceed.

Topics:
General error
Interface design: confirmation
Warnings
Checking

Use of wrong treatment plan

In both instances, another patient's treatment plan was substituted for the correct one. It is anticipated the barcode-based patient identification system will be incorporated in future gamma knife units, but the need to positively establish the identity of patients to be treated will remain.

Topics:
Staffing
Checking

Failure to change collimator helmet

There were two cases in which the person setting up the treatment neglected to change the helmet. Because all shots for a given helmet size are run consecutively, personnel usually make the settings, leave the room, and administer the shot. This may make the helmet change susceptible to a 'capture error' - i.e. the helmet should be changed, but upon completing the settings, the more frequent sequence of behaviors takes over and the change is omitted. If this is the case, it may be possible to reduce the likelihood of this error by establishing a convention that the helmet is changed before the frame coordinates. Another protective practice would be to label the helmets in such a way that they could be identified/checked from outside the room (i.e., in the control area); this was suggested as a corrective action for one of the events.

The Model C gamma knife is able to determine whether the helmet is in place is the one called for in the treatment plan; treatment does not proceed if there is a mismatch. Thus the error described above should not occur with newer gamma units. However, if the automated check were to fail, it would be extremely unlikely that practitioners would prevent the wrong helmet from being used, owing to the tendency for people to rely on automatic processes.

Topics:
Automation
Checking

Incorrect shot coordinates

All but one of the errors involved a transposition of two sets of coordinates. These may be uncomplicated slips, or the may be prompted by predisposing factors in the task situation. For example, the order in which the parameters are given on the treatment plan may not be the same as the order in which practitioners encounter the setting hardware as they more around the device. That is, the way in which the parameters are presented may not 'map' onto the way in which the settings naturally done. Similarly, the order in which the settings are done should be prescribed by procedure and should be the same for all practitioners and patients if possible; the event reports suggest that performing task in other than the typical order may have contributed to coordinates being transposed.

Only one of the error was a simple incorrect setting. It may be that incorrect settings are more easily caught upon 'double-checking.' Alternatively, some setting errors may be quickly rectified when they interfere with docking.

For devices using the Automatic Positioning System, errors such as those described above (i.e., failing the correctly implement the coordinates specified in the treatment plan) are not possible, since the system automatically moves the frame to each successive location planned for a given collimator size. It is worth noting, however, that automation seldom simply eliminates error. Rather, it changes the nature of the activity and may create the potential for different types of errors, or make actions at other points in the process more critical. For example, mispositionings are often 'caught' as practitioners set up for the next shot. With the APS, as many as 50 shots may be run before personnel re-enter the room, so that there would be no opportunity to catch and correct an initial error until the run was complete.

Topics:
Automation
Checking

Incorrect treatment time

Two instances occurred. In one, the time for the previous shot was entered by mistake. Such error are likely in the absence of checkoffs or some other aids to help users enter set of parameters correctly. The specific nature of the other error was not specified.

Error such as these are precluded by the use of more recent gamma knife systems, which allow the treatment plan to be transferred electronically to the control unit electronically. As noted above, the automation magnifies the importance of 'upstream' actions (such as the preparation of the treatment plan) and checking.

Topics:
General error
Interface design: data entry
Checking

Treatment planned incorrectly (wrong side)

There were two events in which the treatment plan was prepared for the wrong side. In one, personnel preparing the treatment plan were unaware that the usual imaging room had not been used - resulting in the film being the opposite of the typical orientation. This underscores the importance of communication among the members of multi-person teams. The treatment planning software evidently generated a warning, but its significance was not immediate recognized. In the second case, the treatment plan was generated for the wrong side and this was not caught by the signer; the neurosurgeon (who had prepared the order/patient correctly) was not present. The report suggested that the medical physicist may have been distracted.

Topics:
Staffing
Handoffs
Warnings
Checking

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Development of Human Reliability Analysis Capability for Regulatory Applications Involving By-Product Materials

Letter Report

Task 10: Specification for HRA-Informed Job Aid

Prepared for
U.S. Nuclear Regulatory Commission
Office of Nuclear Regulatory Research
Division of Risk Analysis and Applications

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Introduction

In Task 7, a prototype job aid was developed in order to illustrate how a structured knowledge base of human reliability and performance topics could be useful for staff in the byproducts materials area. The current task defines how the prototype job aid is to be extended, and modified, to become a fully functional tool for use by staff in the byproduct materials area. This reports briefly documents the development up to this point, summarizes the input received at a meeting with prospective users of the job aid, and considers the tools that are available to support further development.

Background

Operating experience demonstrates that human actions play a dominant role in most activities overseen by the Medical Safety and Event Assessment Branch (MSEAB) of the NRC's Office of Federal and State Materials and Environmental Management Programs (FSME). Hence, an improved understanding of human error and human reliability analysis (HRA) can provide better risk insights to risk-inform MSEAB regulated activities. Research has been undertaken on the development of a human performance analysis capability for regulatory applications involving byproduct materials. A study was conducted of the feasibility of developing HRA-related support to MSEAB in the area of byproduct materials and several recommendations were made for possible future development, including development of HRA-informed guidance or job aids for MSEAB reviewers of byproduct material license applications.

Development to Date

Earlier work on the project had identified a knowledge base of human performance information that was pertinent to MSEAB concerns, particularly activities associated with the gamma knife. Consultations and interviews with prospective users of such information guided the development of various ways of structuring this information. Discussions with MSEAB staff identified four information formats that were expected to be effective in supporting users' tasks. It was also recognized at that time that, to be most effective, the information in each of the formats should be cross-referenced with related material in the others, and that development and usability would likely be facilitated if a computer-based implementation of the job aid were undertaken.

Information Formats

As noted above, four types of information presentation formats were developed. A set of summaries ('one-pagers') of selected human performance topics considered pertinent to the gamma knife was prepared (see Figure 1 for an example); these were intended to present core information that could be accessed directly by topic or referred to from other information formats. While the one-pagers were considered relatively independent of the specific application (and therefore represent 're-usable' content as the job aids is expanded in scope), other job aid formats depend more heavily on descriptions and analyses of the processes for the specific byproduct uses being considered. Examples of this are formats organized around breakdowns of the overall steps in performing byproduct-related activities, to the level of identifying who does what, where, and what is the requirement for success. Two such specific formats were developed.

Task breakdowns play a central role organizing information about specific uses of byproduct material (e.g., medical treatment modalities) and the associated specific human actions and errors. Because dealing with staffing-related exemption requests was identified as an activity this effort set out to support, one of the formats is simply a block diagram of the task breakdown (as given in the risk analysis), showing the knowledge or training required for each task. Another format consists of the task breakdown annotated, for the individual tasks affected, with events involving human errors from the NMED database (providing the NMED number and a brief statement of the human error(s)). This allows NRC staff to identify quickly the areas where human performance problems appear to be most frequent and the types of problems that occur. By further associating the types of problems with the human factors knowledge, it can provide NRC staff with a rapid access to the structured knowledge base. An example of this approach is presented in Figure 2.

Because the available task breakdowns do not describe the associated human actions and situational factors in detail, it is the NMED events (in particular the event narratives) that make it possible to consider specific errors and predisposing circumstances. That is, the error reports (those that contained a reasonable amount of detail) acted as a surrogate for actual observations or analyses of gamma knife operations, and allowed tasks to be associated with human performance topics. Figure 3 is a sample of the kind of information contained in the narrative section of the NMED records.

Computer-based Prototype

Samples of each of the formats described above were prepared. The content was output as an Adobe Portable Document Format (pdf) file so that printed version of the material would appear the same as it did on screen. Pages were formatted with identifying banners at the top to facilitate use of both the hardcopy and computer-displayed material (see, e.g., Figure 1).

It was recognized early in the development of the prototype aid that it would be necessary to provide, in a readily accessible place, a description of the types of resources that the aid contained and a method for getting to them. This function was filled in the prototype by a main page containing the needed information and links. It was the first page in the job aid document, so it was easy to return to using the paging features of the pdf reader. Navigation buttons were available at the bottom of the window that could be used to page backward and forward through the document. Additional buttons were provided for moving back to the first page or forward to the last page. Users were also able to retrace their steps through the document.

Related information in the various formats (task breakdowns, human performance topics, error discussions, and error narratives) was linked to make it easier to access. A blue underline indicated words or phrases for which linked information is available. Clicking on the underlined term causes the view to moved to the page containing the related information.

Characteristics for Future Development

A meeting was held with FSME medical devices staff. The information formats and features used in the prototype were briefly reviewed, and a discussion of the desirability of these and of other possible formats/features was then undertaken. The areas explored fell into three categories: the content of the job aid, methods of navigating the information, and the results or products of using the job aid. The outcome of the discussions is summarized below.

Content

Event-related content

It had been previously agreed (in earlier meetings with MSEAB staff) that event narratives were an important part of the job aid, and that the implementation of this presentation in the prototype was useful. Participants in the recent meeting responded favorably to the inclusion in the event narrative (based on a previous recommendation) of highlighting that called attention to sections of the narratives having human performance implications. Medical devices staff had also suggested that licensee corrective actions, when they were mentioned in the narrative, be more clearly labeled as such.

Keeping gamma knife event content current (i.e., annotating and adding events as needed) is considered feasible by the staff; expansion to other modalities is also considered practical. However, staff suggested that reported events in the industrial domain might be too numerous to annotate, and would not provide the same incremental value with respect to the usefulness of the job aid. As the scope of the job aid is expanded, it may be necessary to develop methods for screening operating experience and including only items that are representative or instructive.

Task-related content

Staff anticipate using the job aid to help them consider the types of human performance problems that are associated with particular actions. One would expect therefore that the lists of human actions associated with particular byproduct uses will have to be reasonably specific; this represents another aspects of the job aid for which periodic updating will be necessary, especially in areas such as medical devices, where methods and technology change frequently. For example, in the newest gamma knife models, details of the tasks undertaken in positioning the patient (and the associated potential errors) differ from those of previous models. On the other hand, it was pointed out by staff that the overall 'mix' of older vs. newer technology for a given type of device will change relatively slowly, so that updating in this regard will probably not be burdensome.

Relevant documents and references

The 'one-page' format was considered adequate to give users of the job aid an appreciation for specific human performance topics. At the time the prototype was developed and first reviewed, it was not considered necessary to include citations of source literature in the 'one-pagers.' Similarly, the view was expressed at the specification meeting that it was probably not necessary to provide any more detail than that contained in the 'one-pagers.' However, in early discussions of the purposes the job aid could serve, it was mentioned that it could be used to supply the technical bases for judgments about, e.g., the human performance implications of changes in the manner in which devices were used, or the likely effectiveness of specific corrective actions. Accordingly, it might be advantageous to make further information available if needed, either by means of references or by actually including (or linking to) source documents. Staff recommended that citations to literature should be very selective (as contrasted with the typical practice in academic writing of citing multiple sources); whenever possible reference material would be included within the job aid and links would point directly to the pertinent material within the reference.

Relationship to training materials

The contents of the human performance training evolved (in response to the input of MSEAB staff) after the job aid prototype was prepared. Therefore, the next phase of job aid development will have to reflect the changes in the contents and aims of the training. Two principal areas were discussed with staff.

First, because it was decided that detailed information about human performance topics would be given in the job aid and not as part of the training, it may be necessary, the above discussion notwithstanding, to expand or reorient some of the 'one-pagers.' (Originally the one-pagers were described as brief refreshers on topics treated in more detail in the training; the roles of the training and job aid with respect to the topics are now reversed).

The most recent development has been directed entirely at the training; therefore, it will be necessary to realign the job aid so that it better complements the current training materials (e.g., with respect to topics referred to and terminology). Once the final form of the job aid is settled on, descriptions of its content and instructions for using its functions will be added to the training; it will also be necessary to add similar material to the job aid itself.

Navigation Requirements

Two principal types of navigation features were discussed: those that have analogous features in paper documents and those users have come to expect based on their experience with computer-based documentation. These are discussed below.

Basic Functions

As described above, a starting point for use of the job aid is essential. Therefore, something similar to the *main page* of the prototype will be retained in the job aid. MSEAB staff indicated that their use of the job aid would typically begin with looking at tasks and the errors associated with them, so the main page should conspicuously display links to this content. However, in order to orient the user and to facilitate moving through the job aid material, a more conventional hierarchical *table of contents* will also be useful. This will allow users to quickly arrive at the general types of content they wish to review.

When users have more specific aims in accessing the job aid, an *index* will be helpful; it will allow users to browse for particular topics. If users have still more specific requirements (i.e., finding a specific term or phrase), a *search* function is also useful. Both of these options will become more important as the amount of content in the job aids expands.

Page-to-page Navigation

Paging through content as one would page through a book is the simplest form of navigation. *Hypertext links* support a more purposeful drilling down or free-form exploration of related content in an information system; this type of navigation capability, as implemented in the prototype, elicited a very positive response from prospective users. In either case (but especially in the case of hypertext) it is necessary for users to be able to *retrace* their steps.

The ability to keep track of pages already visited is useful to efficiently review content and to maintain a sense of where one 'is' in the content. (For example, a convention has developed in Internet browsers for the color of *visited links* to change from blue to purple when they have been viewed.)

Prospective FSME users of the job aid were in agreement that they might require different portions of the information (or prefer to view it in different orders) depending on the task that they had to carry out. Although staff did not want to speculate about what subsets or orders would be most useful (see below), it is reasonable to assume that the ability to view subsets of pages in orders other than the sequence in which they appear in the overall structure of the job aid (i.e., *selective browsing*) will be a useful feature as the scope of the job expands.

Use and Products

Process

Prospective users of the job aid were of the opinion that it would not be possible (in advance of actually using the aid) to predict how the process of using the job aid might differ depending on the purposes for which is being used (i.e., for evaluating corrective actions, license applications, or requests for exceptions). In each case, however, staff expected that users would initially use task breakdowns as a starting point to access the information needed to carry out the evaluation; as noted earlier, the main page will provide immediate access to the task-related material). Beyond this, providing specific prescribed 'paths' through the formats to support different uses was not considered an immediate development priority, but will be reconsidered as experience is gained in the use of the job aid. Staff expected that it might be possible to incorporate checklists that would guide the user in carrying out various tasks. Another approach to adapting the job aids to specific aims might be to define subsets of information for selective browsing, as described above.

Documentation

There is nothing in the prototype job aid explicitly designed to support the preparation of products; i.e., the use of the tool per se does not produce documentation. The ways in which such a feature could be implemented were discussed at the specification meeting. The participants tended toward a 'shopping cart' analogy, i.e., a feature that allows users to save a collection of visited pages for later use. They speculated that, in the near term, the ability to easily cut-and-paste selected material would be adequate for using the knowledge base in preparing documentation. However the possibility of a function that assisted in completing specific documents or activities was also discussed; it was suggested that this could be developed as a separate application (running in parallel with the knowledge base job aid) when the requirements were better defined.

Implementation

Development Tools

Two types of programs were considered for use in developing the job aid: document processing programs and help authoring tools. Increasingly, tools for processing documents are incorporating features to facilitate the on-screen use of the information contained therein. For example, Microsoft Word supports hyperlinks both to other locations within a document, to documents stored separately, and to internet resources; there is also a browser-like retrace feature. Adobe Acrobat, the tool used to produce the prototype job aid, has similar capabilities.

Help authoring tools are specialized utilities for creating and presenting technical information. Trial versions of two well-known and comprehensive help authoring tools were looked at as part of this effort: RoboHelp 7 (Adobe) and Flare 3.0 (MadCap). RoboHelp, part of the Adobe technical communication suite of programs, was able to import the pdf-based prototype with much of the functionality intact. Because Flare is able to import RoboHelp projects, it was also possible to create a prototype job aid with the Flare tool. Operations that are expected to be required to develop the job aid were tried in both tools.

The degree to which the features mentioned earlier in the report are supported by the development tools is summarized in Table 1. Several general observations can be made. Regarding the document processing tools, they

- support linking, but lack features that would make creating links easier
- support user annotations of content (in a document review context)

The two help authoring tools have similar features; in general they:

- offer better support for creating indexes than do the document processing tools
- are not oriented toward paging through in a default order
- provide a means for easily creating conceptual links among pages

Environment

Having job aid files reside locally on users' personal computers has the advantage of being simple to implement, and this approach will probably be used early in development. Updates could be accomplished by emailing revisions to users or (if files became too large) making revised material available for download from a central location. However, the ability to update and expand the job aid continue to be seen as important characteristics, and therefore it is expected that at some point the job aid will reside at a central location and be accessed via the internet.

When the possibility was raised of the job aid incorporating links to NRC documents such as medical generic communications, it was noted that FSME is currently developing a Materials Operational Experience Gateway on the U.S. NRC website. This resource is intended to facilitate access to information such as event notifications, reports, assessments, and regulatory toolboxes. Because a variety of relevant resources have already been identified and located, it should be relatively simple to include in the job aid links to those that would be particularly useful for activities that the job aid is intended to support. It seems reasonable to expect that, when the job aid is ready for general use, it could reside in this area of the NRC website.

A job aid developed using help authoring tools introduces another potential environment – specialized server software running at a central location. Help systems use this style of implementation in order to monitor users' interactions and identify parts of the system that are visited often or that have potential problems. The server-based function can also collect users' comments about the content and pass them on either to the system authors or to the user entire community. In the context of the job aid, such a feature could be useful in involving users in keeping the content up-to-date and in sharing experiences.

Summary and Suggested Approach

The overriding factor in defining an approach to further development of the job aid is the expected expansion in the scope of the byproduct activities included, the breadth of the content, and the user tasks that the job aid will support. Although it would be possible to adequately implement a ‘one-off’ job aid by using the features of document processing tools to the utmost, the need to keep adding to the job aid argues in favor of using specialized tools that facilitate maintenance of the content. In addition, the possibility that the job aid might be used in tandem with a special purpose ‘front-end’ or document preparation function also points toward the use of help authoring tools, since help systems are designed to be run alongside an to interact with another application. Furthermore, the ability for the users to eventually have a role in the addition and vetting of content will be facilitated by use of a tool that has server-based feedback capabilities. Accordingly, it is recommended that further job aid development be done using a help authoring tool. As indicated earlier, initial implementation as a stand-alone (running locally on the user’s computer) would not preclude moving the job aid to a central host when it is finalized, or adding server-based functionality if that becomes desirable.

Staffing

Effects of Advanced Technology on Team Performance

Teams are often relied upon to support situation assessment, error detection and recovery in high-consequence activities. Coordination of the team members' work requires them to be aware of the each other's activities. Successful teams actively locate errors, question improper procedures, and monitor the status of others. In carrying out tasks, personnel convey, directly and indirectly, their intentions and actions to others. Computer-mediated tasks, especially those performed at individual workstations, may isolate users, making an individual's actions less visible to others, thus reducing team effectiveness.

It has been suggested that traditional work environments with conventional technologies have characteristics that contribute to team performance: horizon of observation, openness of tools, and openness of interaction.

- *Horizon of Observation* - This refers to the portion of the team task that can be seen or heard by each individual. It results from the arrangement of the work environment (e.g., proximity of team members) and is influenced by the openness of tools and interactions. By making portions of a task more observable, team members can monitor errors of intent and implementation, and determine when assistance might be helpful.

Figure 1 Sample human performance topic ('one-pager')

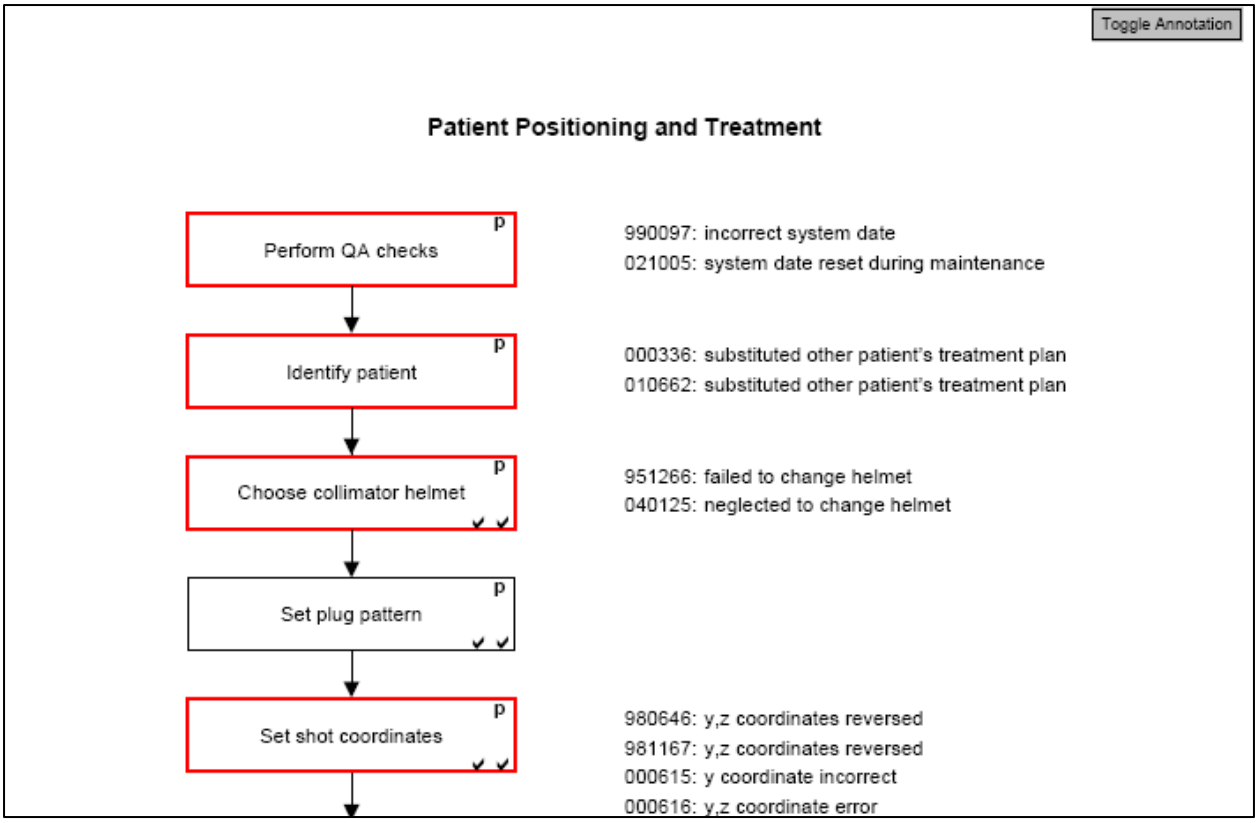

Figure 2 Sample of gamma knife task breakdown view

000787

The licensee reported a medical event that occurred during the performance of a gamma stereotactic radiosurgery treatment for acoustic neuroma. The patient's treatment plan called for the administration of 1,200 cGy (rad) to a tumor volume in three shots. The first shot was delivered with the 8-mm collimated helmet and was to be followed by two shots with the 4-mm collimated helmet. When the coordinates of the second shot were being set, it was discovered that the z-coordinate of the first shot was 11-mm off of the target volume. It was determined that the x-coordinate was accidentally entered for the z-coordinate. The licensee determined that the positioning error resulted in the treatment of a small volume (0.58 cm3) of normal brain. The licensee stated that this area would have received some radiation exposure during the normal course of treatment, but not the 460 cGy (rad) that resulted from the positioning error. The patient and the patient's physician were immediately advised of the error. A new treatment plan was generated to account for the misplaced shot. The patient was then treated with the second and third shots (with the modified treatment times) and the physician added a fourth shot to ensure that the target area missed during the first shot was fully treated. The NRC contracted a medical consultant to review this event and the probable deterministic effects on the patient. The medical consultant concluded that this event is not expected to produce clinically identifiable adverse effects on the patient. This event was caused by the licensee's failure to follow their established Quality Management Plan (QMP) in that the licensee failed to verify that the treatment coordinates set on the patient's head-frame were the same as those established in the written treatment protocol. Corrective actions include 1) procedure modification to explicitly state that all team members must verify treatment coordinates and 2) conducting an in-service to re-familiarize the team members with the QMP and the revised procedure.

Error and Related Factors

x coord entered for z; discovered as second shot was being set up

Human Performance Topic(s)

Proposed Corrective Action

modify procedure 'to state that all team members must verify treatment coordinates'

Figure 3 Sample gamma knife annotated NMED event narrative

Error Discussions

Failure to enter the prescribed dose

The system user may have failed to enter the value:

- The system user may simply have forgotten to enter the value.
- There may be something in the design of the interaction mediating the entry of parameters that predisposes the user to omit the parameter (e.g., a mismatch between the way the system tabs through an entry screen and the order in which values appear on the paper that the user is working from.
- They parameter entry interface make it possible for the user to invalidate an entry after making it (e.g., by 'backing up') without giving any indication that this has occurred.

Regardless of the reason, the system clearly should not proceed without having accepted a user input for an essential parameter. The event report noted that the software manufacturer so that users are notified if a default value is being used. There seems to be little value in having a default value at all, unless an overwhelming number of treatments use the default for this parameter – in which case there would be a small but frequent savings in time. Other event reports suggest that a system warning about the default value might be missed by the user. Ultimately, recovery from this error depends on verification procedures.

Topics:
General error
Interface design: data entry
Warnings
Checking

Figure 4 Sample gamma knife error discussion

Table 1 Support for Selected Features in Document Processing and Help Authoring Tools

Functions	Document Processing		Help Authoring	
	Word	**Acrobat**	**RoboHelp**	**Flare**
Contents	Automated based on information structure; page numbers linked	Hierarchical bookmark structure can be continuously displayed	Can be continuously displayed; indicate current page being shown	Can be continuously displayed; indicate current page being shown
Index	Automated assistance in creating; entries not linked (?)	Actually a 'search' index; terms can be added to content	Index terms can be attached to topics; automated assistance; index entries are links	Index terms can be attached to topics; automated assistance; index entries are links
Search	Conventional 'find' – i.e., move from instance to instance through the document	See above; results are displayed in context	Results list alphabetical; Boolean search available (?)	Relevance ranked results; save search terms in favorites
Paging	Browse buttons can be set to 'page' (or other landmarks)	Next, previous, first , last	From lists (contents, browse, search results) or links (e.g., related topics	From lists (contents, browse, search results) or links (e.g., related topics
Hypertext Links	Yes	Yes	Yes	Yes
Retrace	Yes	Yes	Browser-like forward and back	Browser-like forward and back
Viewed Pages	Visited links indicated per browser convention	Visited links indicated per browser convention	Visited links indicated per browser convention	Visited links indicated per browser convention; save selected pages to favorites
Selective Browsing	'Browse by' modes limited; could be created manually	Could be created manually	Order(s) other than the default can be defined; similar to an index	Order(s) other than the default can be defined; similar to an index
Related Topics Links	Would have to be defined manually	Would have to be defined manually	'See also' and 'Related Topics' links are supported; use of conceptual tags for updating	'See also' and 'Related Topics' links are supported; use of conceptual tags for updating
User input	Document review features	Various commenting options; document review oriented	Supported in server-based implementation (?)	Supported in server-based implementation (?)
Output	Paper; on-screen	Paper; on-screen	Word, pdf; HTML Help, Web Help	Word; HTML Help, Web Help