Descriptions of Functions and Features of HRA-Informed for Byproduct Materials (Gamma Knife Applications)

This description has been developed for readers to understand the content and intended functions of the HRA-Informed Job Aid for Byproduct Materials (Gamma Knife Applications). This description is intended to help potential Job Aid users (e.g., NRC inspector, NRC staff performing reviews of license amendment requests) access human factors information that is relevant and risk-important to Gamma Knife applications (as a test-bed).

This job aid was developed in 2008 as a browser-based help system and will not necessarily function with today's browsers. Consequently, a pdf file of the content is provided as a companion document to this description. The supplied pdf file emulates some of the basic content-linking features of the job aid; it does not demonstrate many of the more useful features that are mentioned in this description (such as navigation, index, search, and glossary).

Because the format chosen for the job aid is similar to the 'Help' features in most commonly-used office software, a brief familiarization with the resources available in the job aid should allow most users to quickly start using the job aid.

The job aid's overview page content is displayed in a large (resizable) area, bounded on the left by a set of vertical tabs that provide access to the system's basic features and at the top by a button bar, which provides the basic functions and other display and navigation options. In Figure 1, the table of contents (TOC) has been selected from the vertical tabs; the TOC tab is highlighted, and 'TOC' appears at the head of the vertical tabs (in the top bar). Clicking one of the other vertical tabs changes the area above the tabs to a display appropriate for the selected function. (This style of interaction will be familiar to users of Outlook, which uses a similar design).

The icon buttons on the top bar remain the same regardless of what function is selected (or what content is displayed). Moving from left to right, the first icon button, which resembles a window, is used to hide (and restore) the function tabs and related display; it is used to expand the content area to the full width of the screen and then to redisplay the tabs when needed. The left- and right-facing double green arrows allow the user to move backward and forward (respectively) through the pages that have been displayed (i.e., to 'retrace' their steps). The printer icon is used to send create a hardcopy of the current topic. The next three icon buttons access the functions on the vertical tabs, i.e., from left to right, the table of contents, index, and search. The text box (and the magnifying glass icon to its right) represent the 'quick search' feature. This is used to find instances of a word on the current page. The next button allows the user to toggle highlighting (e.g., of search terms) on and off. The icon that resembles a folder brings up the favorites the next button (which includes a star) causes the displayed topic to be added to the 'Favorites.' Finally, the single right-facing arrow causes the browse sequence panel to be displayed. Clicking the question mark icon causes information about the job aid to be displayed.

In Figure 2, the 'Error Discussions' section of the table of contents had been opened (by clicking on the book icon or the section title), and one of the discussions ('Incorrect shot coordinates') has been selected. Links are provided to related human performance topics. The result of clicking

on one of these topics ('Checking') is shown in Figure 3. The topic is displayed, the 'Human Performance Topics' section of the table of contents has automatically expanded, and the title of the selected page is highlighted. This is referred to as 'auto-synchronization' of the table of contents. It serves to keep users aware of 'where they are' within the information structure, and of the availability of similar types of information that may be relevant. There is also an option for displaying a "trail of breadcrumbs" at the top of each displayed page to help the user see how the present page is related to the rest of the information. For the page shown in Figure 3, the breadcrumb line might read, You are here: Human Performance Topics > Reliability of Independent Verification. In addition to serving to orient the user, the names of higher levels of the hierarchy (in this case '…Topics') are links that can be used to navigate upward to those levels of information structure. This feature is not used in the current draft of the job aid, but could easily be added (for example, if the information structure becomes 'deeper' as development of the job aid proceeds).

As stated earlier, an index and a search function are useful when users are seeking specific information. For example, if after viewing the verification topic the user wanted more specific information, he or she could click the 'Index' tab, and then select the word 'checking'. As shown in Figure 4, this yields in a listing of five NMED event narratives pertaining to checking along with the 'verification' topic shown previously; the first event has been selected. To continue with the example, if the user specifically wished to view events in which coordinates were transposed (and not those involving use of the wrong treatment plan), he or she could click the 'Search' tab and type the word 'transposed' into the text box; the result is shown in Figure 5. The search function displays a list of pages containing the search term, ranked according to how often the search term appears in the page. The ranking is usually preferable to an alphabetical listing according to the title of the item. However, alphabetical ordering can be selected (by clicking on the label in the 'Title' column). This would be useful if, for example, the user wanted to group all of the event narratives (items beginning with NMED) in the search results list. By default, each occurrence of the search term is highlighted; the highlighting can be toggled on and off, as mentioned above. Search terms can be saved to a 'favorites' list by clicking on the icon to the right of the 'Search' button. To access to list of saved pages (or saved search terms), the user clicks the 'Favorites' tab; the resulting display is shown in Figure 6.

The tool used to create the job aid helps developers create and maintain a glossary for the information system. Figure 7 shows a 'pop-up' definition of a glossary term. The definition is displayed when the user clicks the small symbol immediately to the right of any instance of the term; the pop-up is closed when the user clicks again. The developer establishes the glossary by simply entering terms and definitions. When the content is 'built' or compiled, instances of all of the glossary terms are automatically found and tagged. At this point, only a few term and definitions (taken from the glossary of the Human Performance Evaluation Process, NUREG/CR-6751) have been added.

Examples of the displays associated with the user feedback functions are not shown because their use requires the job aid to be implemented on a server. (This is way in which the job aid will be deployed once it is finalized.) Users can be given the option to rate individual topics (i.e., pages) and to send comments to those responsible for maintaining and improving the job aid's content. There is also a feature that allows users to provide comments that are visible to other users. This may serve as a means for users of the job aid to share information and experiences related to their tasks.

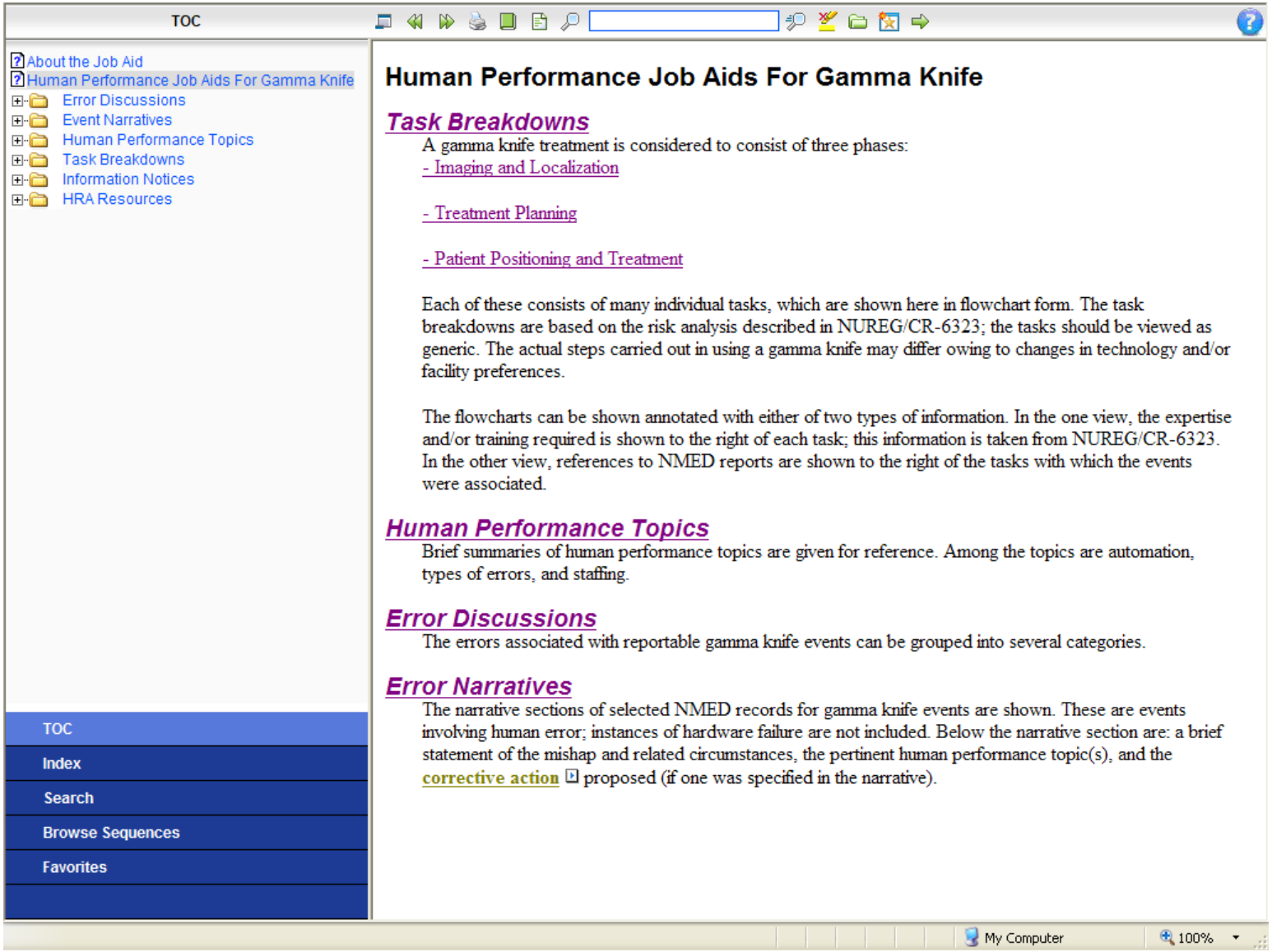


Figure 1. Overview page with table of contents

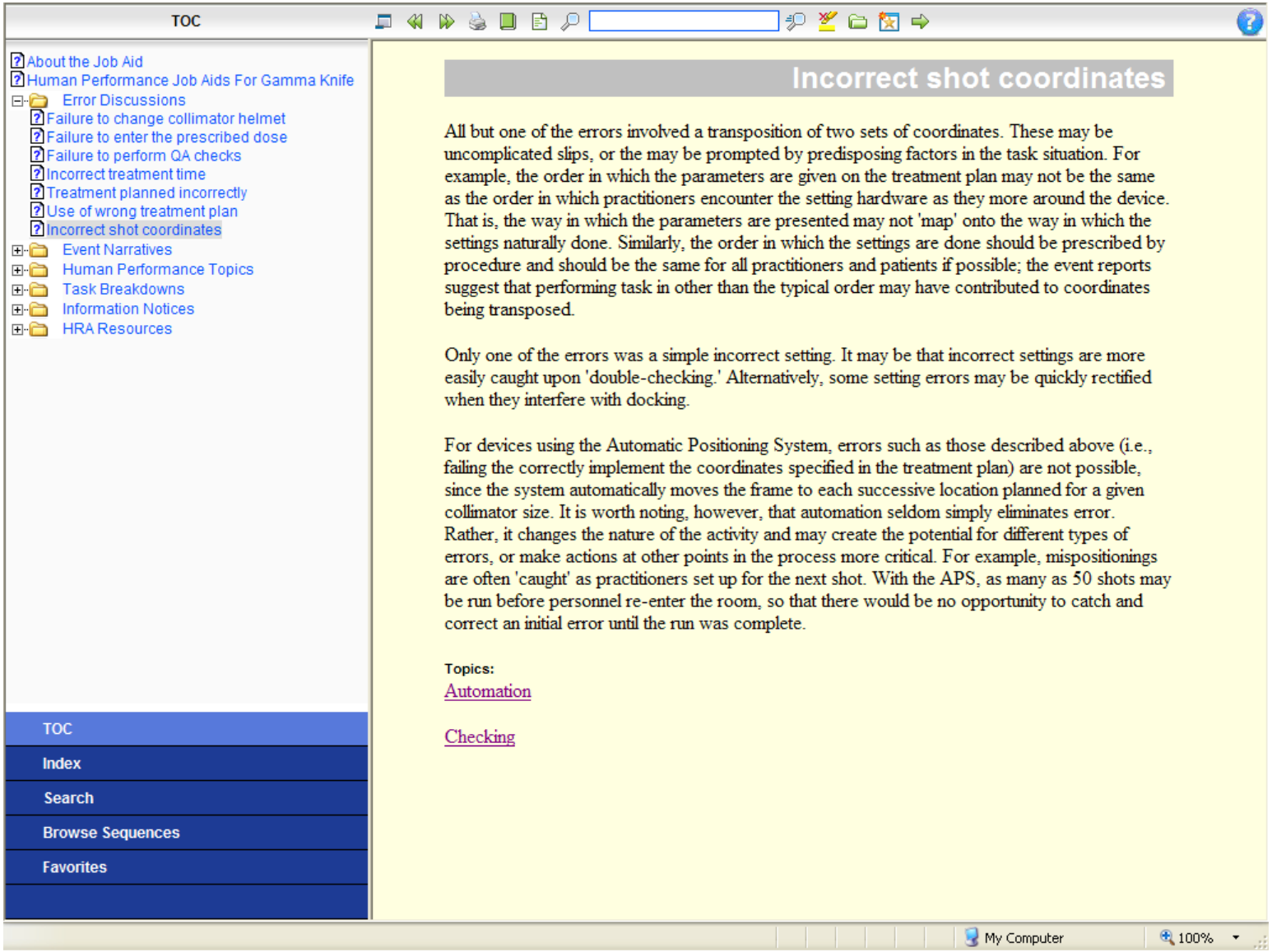


Figure 2. Error discussion page showing expanded table of contents.

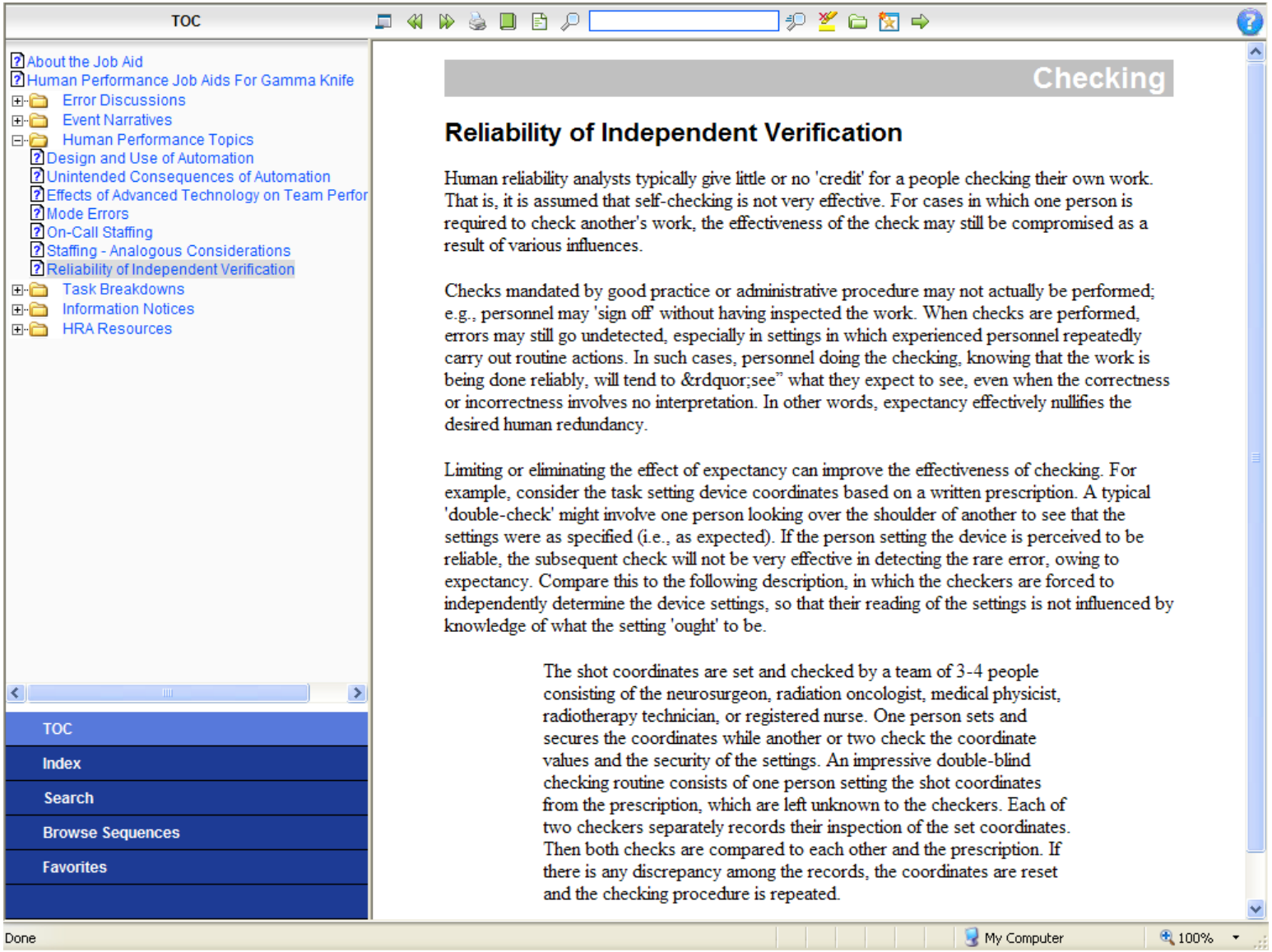


Figure 3. Display of human performance topic and synchronized table of contents.

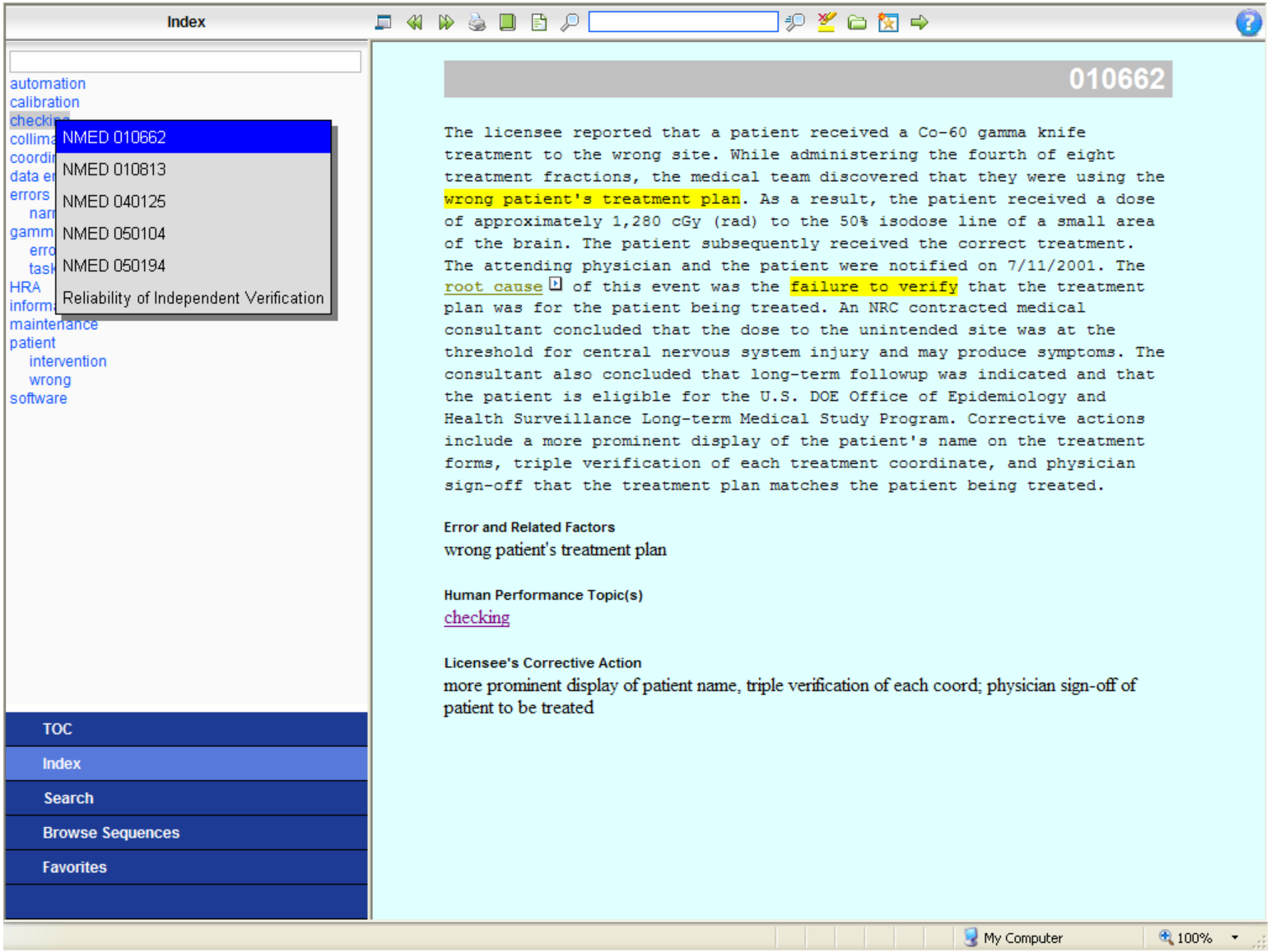


Figure 4. Job aid screen showing index function

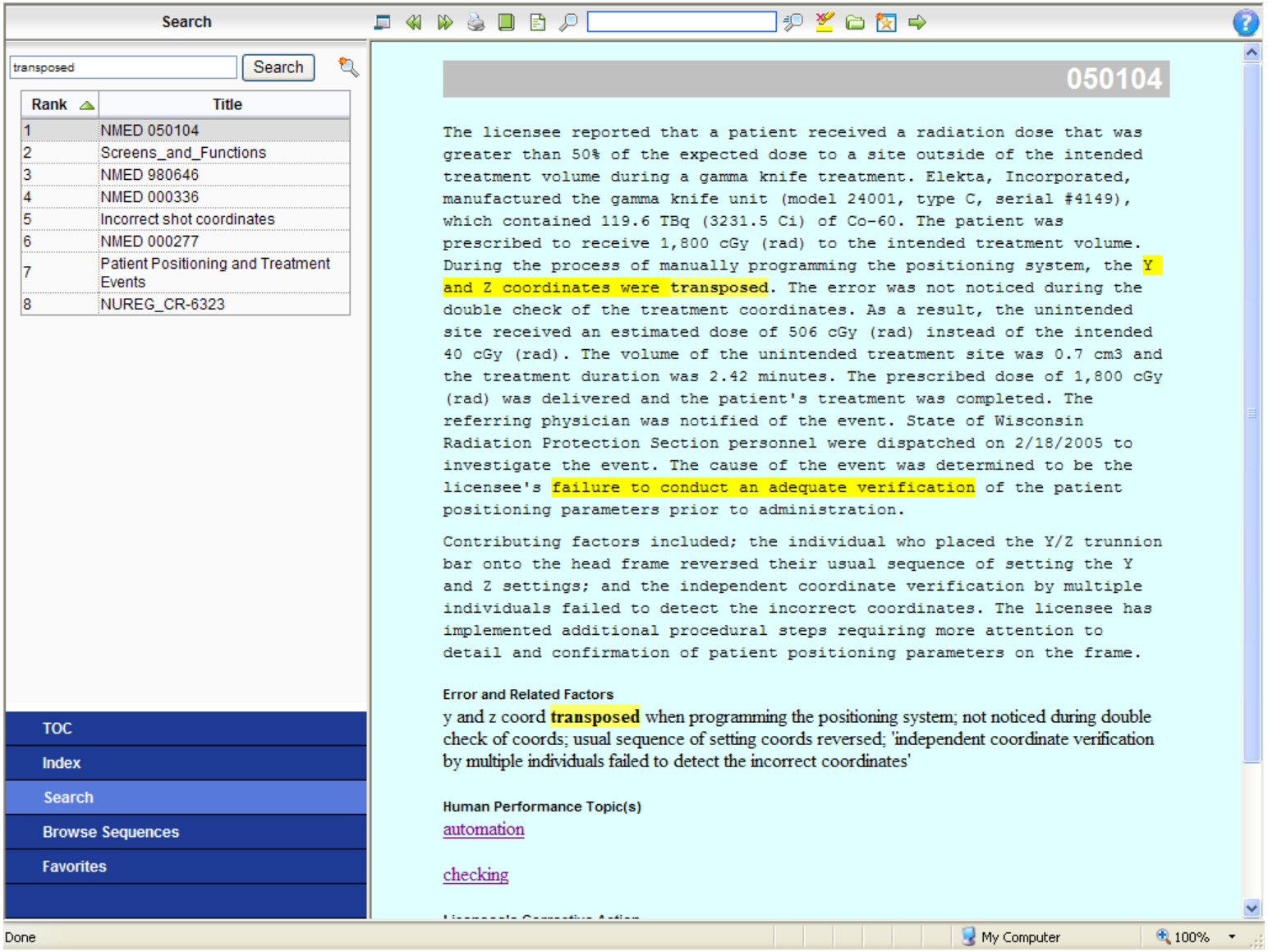


Figure 5. Job aid screen showing search function

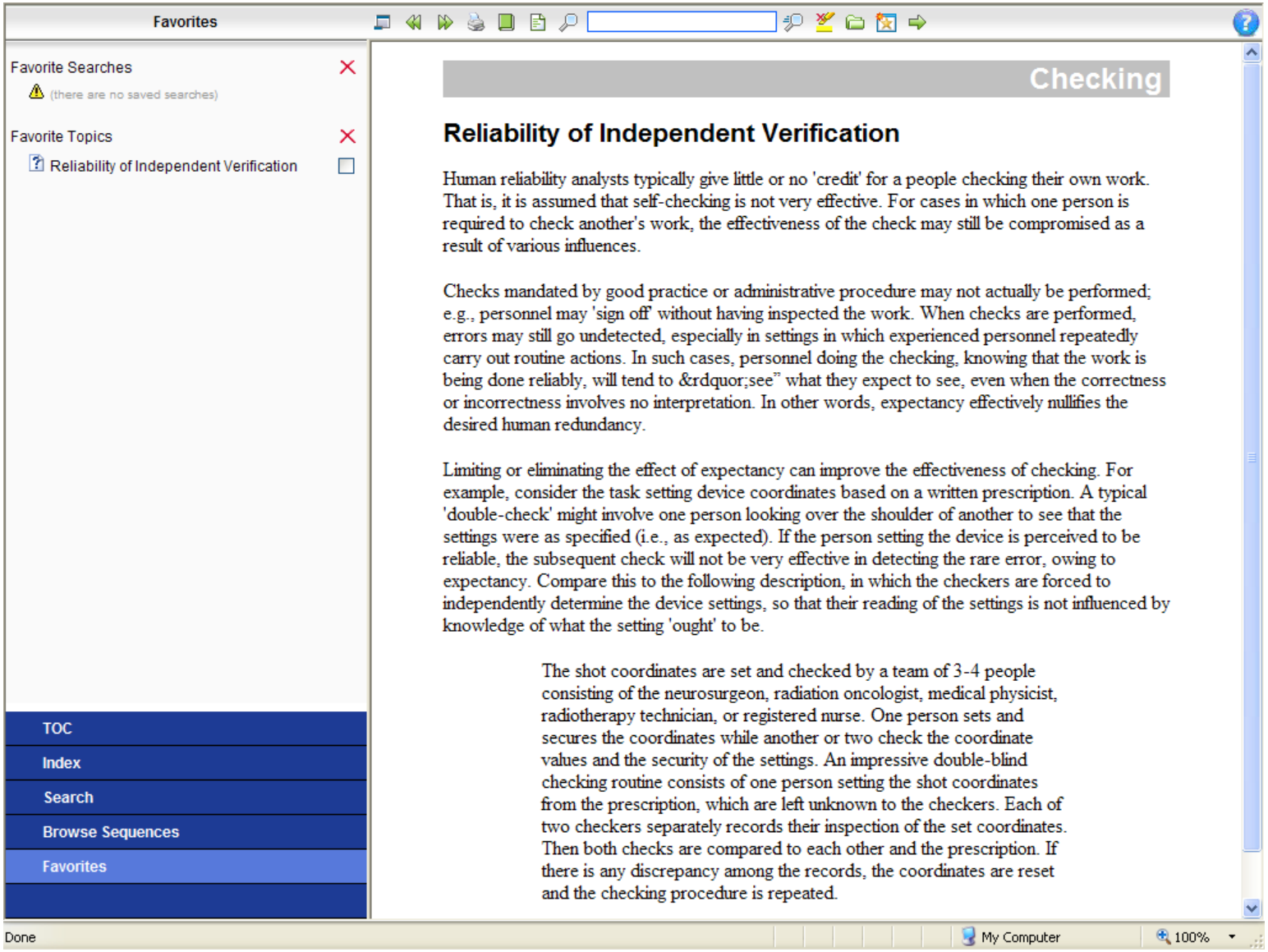


Figure 6. Job Aid screen showing favorites panel

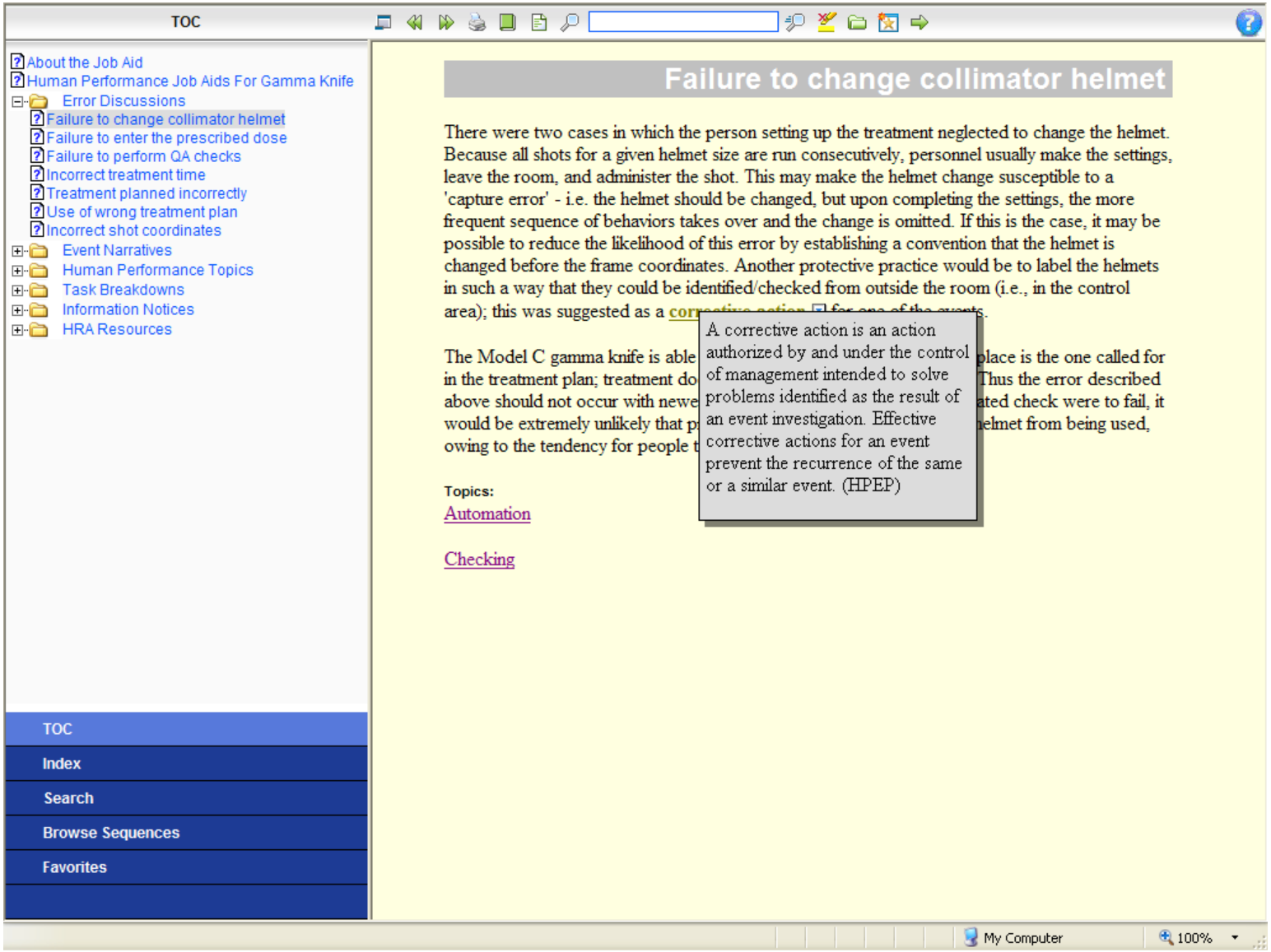


Figure 7. Job aid screen showing expanded glossary entry.

Human Performance Job Aids For Gamma Knife

Task Breakdowns

A gamma knife treatment is considered to consist of three phases:
- Imaging and Localization

- Treatment Planning

- Patient Positioning and Treatment

Each of these consists of many individual tasks, which are shown here in flowchart form. The task breakdowns are based on the risk analysis described in NUREG/CR-6323; the tasks should be viewed as generic. The actual steps carried out in using a gamma knife may differ owing to changes in technology and/or facility preferences.

The flowcharts can be shown annotated with either of two types of information. In the one view, the expertise and/or training required is shown to the right of each task; this information is taken from NUREG/CR-6323. In the other view, references to NMED reports are shown to the right of the tasks with which the events were associated.

Human Performance Topics

Brief summaries of human performance topics are given for reference. Among the topics are automation, types of errors, and staffing.

Error Discussions

The errors associated with reportable gamma knife events can be grouped into several categories.

Error Narratives

The narrative sections of selected NMED records for gamma knife events are shown. These are events involving human error; instances of hardware failure are not included. Below the narrative section are: a brief statement of the mishap and related circumstances, the pertinent human performance topic(s), and the corrective action proposed (if one was specified in the narrative).

Error Discussions

The errors associated with reportable gamma knife events can be grouped into several categories.

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

Failure to enter the prescribed dose

The value may not have been entered for various reasons:

- 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.
- The 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

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 show 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

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 errors 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 errors 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.

Errors 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

Use of wrong treatment plan

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 might have been distracted.

Topics:

Staffing

Handoffs

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

Event Narratives

The narrative sections of selected NMED records for gamma knife events are shown. These are events involving human error; instances of hardware failure are not included. Below the narrative section are: a brief statement of the mishap and related circumstances, the pertinent human performance topic(s), and the **corrective action** proposed (if one was specified in the narrative).

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)

automation

data entry

Licensee's Corrective Action

closer attention to detail

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)

checking

Proposed Corrective Action

add'l procedure 'requires more attention and better confirmation'

 See Also

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)

verification procedures

Licensee's Corrective Action

initial identifier on each page of treatment plan

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)

checking

Licensee's Corrective Action

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

See Also

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)

Licensee's Corrective Action

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)

Licensee's Corrective Action

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)

checking

Licensee's 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)

checking

Licensee's 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)

checking

Licensee's 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)

data entry

independent verification

Licensee's Corrective Action

improve verification process

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)

verification procedures

Licensee's 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 noncritical 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)

independent verification

Licensee's 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 verification by multiple individuals failed to detect the incorrect coordinates'

Human Performance Topic(s)

automation

checking

Licensee's Corrective Action

'procedural steps requiring more attention to detail and confirmation of patient positioning parameters on the frame'

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)

Licensee's Corrective Action

stop and reexamine setup if patient moves

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 (Elekta 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)

Licensee's Corrective Action

add'l education in treatment planning and 'reinforcement of the necessity of communication between personnel'.

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)

Licensee's Corrective Action

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)

automation

teamwork

Licensee's 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)

automation ...

checking ...

data entry

Licensee's Corrective Action

manufacturer to modify software to notify user when default value is being used

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

Human Performance Topic(s)

checking ...

Licensee's Corrective Action

NS and MP 'verbally verify and repeat the coordinates'

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)

checking

Licensee's Corrective Action

verification by the neurosurgeon, the radiation oncologist, and the medical physicist; two of the three to verify that coordinates are correctly set; either the neurosurgeon or the radiation oncologist to verify the treatment site after the patient is positioned; the neurosurgeon and either the radiation physicist or the radiation oncologist be physically present during the treatment; the radiation oncologist to examine the patient before the treatment and verify the treatment site

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

Human Performance Topic(s)

staffing

Licensee's Corrective Action

each set one side only

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)

checking

Licensee's 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)

automation

data entry

Licensee's Corrective Action

treatment date to be triple checked before commencing treatment; warning on computer monitor that states "Treatment date differs from system date" made more distinctive than the other information boxes that appear on the screen

Human Performance Topics

Brief summaries of human performance topics are given for reference. Among the topics are automation, types of errors, and staffing.

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.

Overreliance on automation. Operators may rely on automation too much unless factors favoring overreliance 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 lead to overreliance.

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.

See Also

Reliability of Independent Verification

Human reliability analysts typically give little or no 'credit' for a people checking their own work. That is, it is assumed that self-checking is not very effective. For cases in which one person is required to check another's work, the effectiveness of the check may still be compromised as a result of various influences.

Checks mandated by good practice or administrative procedure may not actually be performed; e.g., personnel may 'sign off' without having inspected the work. When checks are performed, errors may still go undetected, especially in settings in which experienced personnel repeatedly carry out routine actions. In such cases, personnel doing the checking, knowing that the work is being done reliably, will tend to ”see” what they expect to see, even when the correctness or incorrectness involves no interpretation. In other words, expectancy effectively nullifies the desired human redundancy.

Limiting or eliminating the effect of expectancy can improve the effectiveness of checking. For example, consider the task setting device coordinates based on a written prescription. A typical 'double-check' might involve one person looking over the shoulder of another to see that the settings were as specified (i.e., as expected). If the person setting the device is perceived to be reliable, the subsequent check will not be very effective in detecting the rare error, owing to expectancy. Compare this to the following description, in which the checkers are forced to independently determine the device settings, so that their reading of the settings is not influenced by knowledge of what the setting 'ought' to be.

> The shot coordinates are set and checked by a team of 3-4 people consisting of the neurosurgeon, radiation oncologist, medical physicist, radiotherapy technician, or registered nurse. One person sets and secures the coordinates while another or two check the coordinate values and the security of the settings. An impressive double-blind checking routine consists of one person setting the shot coordinates from the prescription, which are left unknown to the checkers. Each of two checkers separately records their inspection of the set coordinates. Then both checks are compared to each other and the prescription. If there is any discrepancy among the records, the coordinates are reset and the checking procedure is repeated.
>
> - from NUREG/CR-6323, p. 42

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. 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 how to assume control without "fighting" the system.

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

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 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.

- 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.

Unintended Consequences of Automation

System designers may automate of part or all of an activity for a variety of reasons, e.g., to reduce workload and training requirements, to eliminate human error, or simply because it is technologically feasible to do so (i.e., because they can). When automation is introduced there may be an implicit assumption that complex activities can be decomposed into a series of independent actions and that machine actions can be substituted for human actions in an uncomplicated, one-for-one fashion. Lessons learned in a variety of domains demonstrate that automation can have unanticipated consequences.

Redistributed workload. It has been observed that the workload associated with tasks is not necessarily eliminated by the introduction of automation; it may just be redistributed. That is, while automation may eliminate the need to take certain action (e.g., it may free people from having to make frequent control inputs), it may require people extend added effort on other activities (e.g., more carefully monitoring processes that are affected by the automated actions to insure that the automation is performing properly).

New knowledge requirements. People must understand something about how automation works in order to use it appropriately and to monitor its actions. For all but the simplest forms of automation, this will require some training. It is particularly important that people understand the limitations of automation so that they will be alert to the possibility that it may fail to perform as expected.

Complacency/distance. It is common for people to 'trust' automated systems, so that users will usually not question the appropriateness of their actions or the correctness of information they supply. Related to this is the tendency for automation to reduce people's involvement with parts of a process. The lessening of hands-on interactions can reduce the likelihood of recovery from errors.

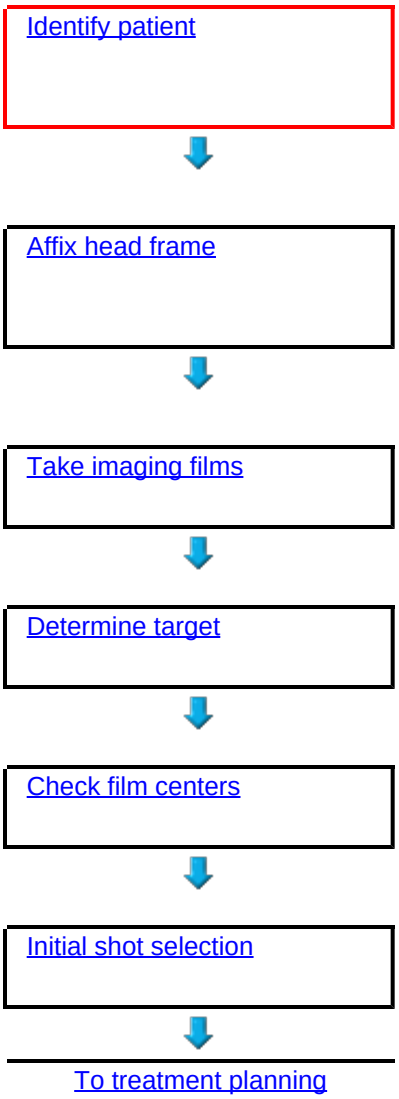
New kinds of errors. At the same time as it eliminates the opportunity for some human errors, automation can leave the door open to other types of failures. Mishaps can occur when people are not aware of the status of the automated system, owing either to it complexity or the lack of status indications; often the result is a mode error.

Task Breakdowns

Individual tasks that comprise gamma knife treatment were identified in NUREG/CR-6323. The treatment is divided into three phases: imaging and localization, treatment planning, and patient positioning and treatment. Links to events associated with each task (if any) are shown to the right of the tasks.

Tasks

Events



Tasks	Events
Perform QA checks	990097: incorrect system date 021005: system date reset during maintenance
Identify patient	000336: substituted other patient's treatment plan 010662: substituted other patient's treatment plan
Choose collimator helmet	951266: failed to change helmet 040125: neglected to change helmet
Set plug pattern	
Set shot coordinates	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
Perform final checks	
Ready treatment room	
Set treatment time	000686: entered time for previous fraction 010813: incorrect entry of treatment time
Monitor treatment	050194: patient moved vigorously 050597: patient coughed

End of Treatment

Tasks

Events

Simulate treatment without patient

Start a computerized treatment plan

Create a patient data file

Skull measurements

Enter skull data into computer

Enter gamma angle

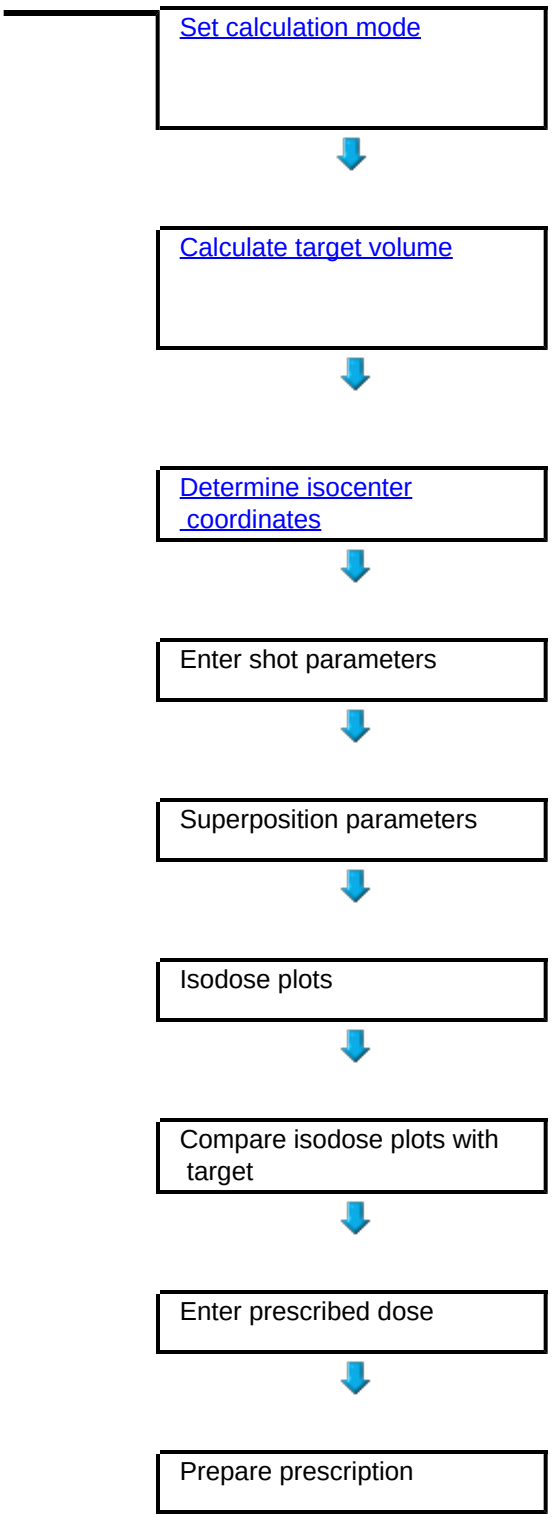
Film measurements

Enter dose matrix parameters

Set an absolute dose

continued

Tasks **Events**



NUREG_CR-6323, Section 4

The Gamma Knife and its treatment process are reviewed in Section 3.0. The subsections below summarize information gathered regarding steps in the Gamma Knife treatment planning process. The included information is germane to the preliminary selection by the project team of risk-pertinent tasks and equipment failure modes. The preliminary list of treatment tasks is provided in Table 4-1, and task data is contained in Appendix A. A list of the selected abnormal operating modes is contained in Table 4-2.

4.1.1 Patient Identification

The Gamma Knife patient must be correctly identified at least four times during the treatment process: before the stereotactic frame is affixed to the patient's head; before treatment planning to ensure the correct imaging films are used; before skull measurements are taken from the patient; and to confirm the correct prescription or treatment plan for the patient before positioning the patient for treatment. Members of the Gamma Knife team use at least two methods to identify the patient, and those methods are facility specific. The correct identification of the patient is enhanced by the fact that the patient is a constant companion to the treatment process, which is normally completed in less than a day. Though sometimes two patients are treated in one day, it is common for only one patient to be treated per day. Thus, the Gamma Knife team is very aware of the patient and the patient's records. If two patients are treated in the same day, there may be parallel activities, and some of the records and data can be confused. For instance, both patients could have their lesions imaged in the morning, and both sets of films are sent to the Gamma Knife suite. A member of the team might begin treatment planning using the data for one patient while the other is scheduled to be treated first.

4.1.2 Stereotactic Head Frame

The stereotactic frame consists of a base ring with four vertical posts, two frontal and two occipital. The base ring is engraved with scales used for setting coordinates and making measurements from CT, MRI, and angiography images. The frame's design is coordinated with the collimator helmet design so that the patient can be positioned in the Gamma Knife unit by attaching the frame to the helmet. The frame is affixed to the patient by four pins inserted through the vertical posts and screwed into the patient's skull. The affixed frame defines the Gamma Knife reference coordinate system used throughout the operative procedure: once the frame is properly attached, it is not removed until the treatment is completed. The orthogonal coordinate system consists of the patient's right-left coordinate (x), posterior-anterior coordinate (y), and cephalad-caudad or axial coordinate (z). The origin of the coordinate system is at the patient's back, upper, right. The stereotactic frame is attached to center the lesion, as much as is possible, within the frame coordinate system. This helps to position the patient later within the Gamma Knife unit and reduce the chance of errors associated with extreme coordinate values. However, medical considerations of the neurosurgeon override such mechanical concerns, and how the frame is affixed is a medical judgment. To ensure that the coordinate system is orthogonal, the integrity or "squareness" of the frame should be verified, e.g., by properly tightening screws holding together the machined pieces of the frame. Since the coordinates determined by the fixation of the frame must remain constant throughout imaging, treatment planning, and treatment, the frame is checked for movement during the operative procedure. If the frame is seen to shift, or comes off, then the frame must be re-affixed and the treatment process begun again. Such major shifts are possible since the patient has the frame on for several hours, and in some cases overnight if the treatment is extended from one day to the next.

4.1.3 CT, MRI, and Angiography Imaging

Once the stereotactic head frame is attached to the skull, the Gamma Knife team must locate the lesion to be treated within the frame's coordinate system. The Gamma Knife comes with CT, MRI, and angiography localizer or indicator boxes that attach to the stereotactic head frame and provide reference fiducials for localization of images. Angiography is used for AVMs, while CT and MRI are used for tumors and other lesions. (CT and MRI images of AVMs are sometimes made to provide complementary information to angiography.)

The indicator box fiducials are used to determine the lesion position within the Gamma Knife coordinate system. Thus, the indicator boxes must be orthogonal when attached to the stereotactic frame. This is accomplished by adjusting screws on the box adapter. Also, in setting up for imaging, the patient must be correctly aligned with respect to the

imager. The axial coordinate should be parallel to the imager base with the patient level, not angled. The patient's head movement has to be restricted so as not to disturb the alignment with the imager.

No document or checklist for these set-up procedures was observed. CT and MRI image slices are taken in the sagittal, coronal, or axial planes. Preliminary scans for gross localization of the lesion are usually at 5 mrn slice resolution; for imaging the lesion itself, 1.5 mm resolution is common. The magnification factor of the CT or MRI imager is machine specific and is provided by the computerized display. Lateral and frontal angiography images are used to locate AVMs. The geometry of the angiography set-up determines the magnification factor of the images. The films obtained for treatment planning are labeled with all pertinent information. This includes patient identification, film orientations (coordinate plane), fiducials, CTMRI and angiography coordinates, and magnification factors. The CT and MRI computerized display systems can provide this information directly on the films, but it should be checked. Labeling of the angiography films is mostly manual and is very important with respect to distinguishing frontal from lateral views as well as patient's left from right. The older Gamma Knife X-ray indicator boxes have an extra fiducial to distinguish left from right. The newer boxes do not have such a fiducial but can only be attached to the head frame in one way. It is also important to record the geometry of the angiography set-up so that the magnification factor can be properly calculated.

The reliability of the computerized imager systems was not investigated. Computer and software reliability and safety is an involved issue and was beyond the scope of this project.

4.1.4 Determine Lesion

Once acceptable imaging films are obtained, the neurosurgeon, neuroradiologist, or radiation oncologist determine and mark (with a lead or wax pencil) the outline of the lesion on orthogonal images. This is based on medical judgment. Subsequent treatment planning involves determining how to deliver a dose to this selected volume.

4.1.5 CT, MRI Film Center

The computerized CT and MRI imaging systems can be used to deposit a mark in the center of the CTMRI image. The CT/MRI coordinates of this center mark are also provided. This center serves as a convenient reference point from which to measure the lesion position, especially if the lesion has been placed near the center of the stereotactic frame. The center CT/MRI coordinates are transformed into Gamma Knife coordinates, and hence any measurements from that center position are expressed in Gamma Knife coordinates. Thus, the use of a center mark greatly reduces the number of coordinate transformation calculations and, subsequently, chances for error.

On the other hand, if a mistake is made in determining the center coordinates, the error can propagate to subsequent measurements made relative to that center. Thus, the medical physicist checks the center deposited by the CTMRI computerized system by drawing lines connecting diagonal fiducials or by manually measuring fiducial distances. This serves as a check on the orthogonality of the indicators and any computer-based distortions. There are some inherent sources of uncertainty in performing this center check. The center may shift infinitesimally from image slice to slice. The fiducial distances may not be even exact from image to image. The checker might use the wrong fiducial in cases where an extra left-right fiducial is provided. Also, the checker may not always be consistent in using the center of the fiducial images from which lines are drawn or measurements are taken. Center marks on angiography films are determined manually by using fiducials and images of the engraved scales from the X-ray indicator box system. These determinations are subject to the same mistakes as for CTIMRI.

4.1.6 Initial Selection of Shots

Before beginning the treatment planning process, the neurosurgeon, radiation oncologist, or medical physicist will mark some initial shot positions on the films, based on experience and medical judgment. This will enable the initiation of the iterative treatment planning process.

4.1.7 Treatment Simulation

Sometimes the patient, with affixed stereotactic frame, is taken to the Gamma Knife treatment facility to simulate a

treatment before treatment planning is completed. This is done especially if the lesion is in a position that may require some extreme coordinate settings. The patient is placed on the sliding couch with the head and frame inside the collimating helmet. The potential range of lesion coordinates is checked for accessibility. It is determined whether the patient can be treated in the prone or supine position. The supine position is preferred, but if the lesion is in the direction of the lower back of the head, it may be best to treat with the patient in the prone position. Approximately 15% of treatments are in the prone position. The best gamma angle (see 4.1.1 1) is selected for shot accessibility and patient comfort. Also, the possible transmission of radiation into the patient's eyes or lenses is checked, by passing a flashlight over the outside of the helmet while the patient is fixed inside. Any offending collimators can be removed and replaced with collimator plugs. If there are more than a few (5-10) plugs used to protect the lenses, the Gamma Knife team may perform manual or computer calculations to reckon the effects of the plugs (each collimator corresponds to 0.5% of the total transmitted radiation).

4.1.8 Treatment Planning Equipment

The treatment planning equipment consists of a dose planning computer and software called Kula, a plotter for printing isodose plots, and film digitizing equipment. Some sites also have separate and supplementary software to perform target volume calculations (see 4.1.14). (Elekta instruments has recently introduced a new three-dimensional, computerized treatment planning system called GamrnaPlan, a registered trademark of Elekta Instruments, Inc. Facilities visited during the study were not using GammaPlan, so no consideration of this treatment planning system was made.)

Treatment day checks of the planning equipment are made by the medical physicist or radiotherapy technician or both. A computer point dose calculation is made to check the current dose rate from the computer with a table generated manually using yearly and monthly calibration data and the decay law. The plotter integrity is checked (given that the computer dose calculation is accurate) by plotting a simple computer isodose curve calculation and comparing it to a standard profile of the same calculation. The digitizer accuracy and linearity is evaluated by making some simple geometric determinations from imaging films using the digitizer and comparing the results to manual determination of the same geometric measures. There should be independent verification of each of these checks.

4.1.9 Treatment Planning Software

The Gamma Knife comes with a custom treatment planning computer program named Kula. (Elekta now also supplies a treatment planning code, called GammaPlan, which can use computer based, three-dimensional images. This system was not in use during the data collection activities.) Kula runs on a dedicated VAX computer, i.e., the computer is only used to run Kula and no other software. The treatment planning system is kept in the Gamma Knife suite. Access to the code is controlled by use of a password, and the correct date must be entered to initiate the program. The correct date is required to ensure the use of the current dose rate of the Cobalt-60 sources. Also, if the correct date is entered and the program doesn't respond positively, there may be a problem with the computer clock or the program.

A patient data file must be created to perform treatment planning. The patient data file will eventually contain all pertinent information required to generate a treatment plan or prescription. This information includes patient name, patient identification number, skull measurements, gamma angle, dose matrix parameters and calculation mode, and shot parameters (coordinates, time weightings, collimators, plug patterns, and total dose). Only one patient file can be open at a time. If a patient file is closed, it can only be opened by typing the exact name in the data file. If there is more than one file for that exact patient name, then the latest created file will be opened by default. So, to have more than one file accessible for each patient requires a different patient name for that patient on each file. This practice may lead to confusion about which file to use for the prescription generation. Kula has a menu that allows the user to check any contents of the data file at any time during treatment planning. This provides an opportunity to verify data and inputs and recover from any errors. Typical checks on the program, as mentioned in 4.1.8, are to run dose calculations that can be checked manually against standards. Kula has two modes for calculating dose profiles. The cutand- modify method is an approximation algorithm which interpolates between intervals in the dose matrix. The exact calculation mode runs slower than the cut-and modify mode. There can be a difference in the dose calculation between the two modes by as much as 7%, depending on the size of the dose matrix. The dose algorithm in Kula has an idiosyncrasy that can cause a calculational blow-up for lesions near the skull boundary. This blow-up prevents the completion of the dose calculation.

It can be avoided by re-defining the dose matrix near the skull boundary.

Software reliability is a significant issue in dose calculation: software errors can have very serious consequences to patients. This project was not scoped to analyze the software reliability of Kula. The Kula software, as part of the Gamma Knife medical device, is approved for sale by the FDA. The FDA has review guidelines for computer software used with medical devices.

4.1.10 Skull Measurements

The skull geometry, in Gamma Knife coordinates, needs to be assessed for the Kula dose calculation to properly account for attenuation of radiation between the skull and the target. There is an attenuation of about 5% per centimeter of brain tissue.

The Gamma Knife system includes a Plexiglas hemisphere or 'bubble" which attaches to the stereotactic frame. The attached hemisphere provides a reference surface, in Gamma Knife coordinates, to determine a set of distances between the bubble exterior and the outside of the skull. This set of distances defines the dimensions of the skull geometry for purposes of calculating the attenuation of radiation between the skull and the target lesion. The bubble is attached to the affixed stereotactic frame of the correctly identified patient. The bubble must be attached correctly, flush with the stereotactic frame. The bubble fits only one way on the frame and assumes a supine treatment position. Thus, the skull data taken with this bubble needs to be transformed (manually) if the patient is to be treated in the prone position, so as not to have an incorrect orientation of the skull relative to the gamma sources.

The bubble contains 24 holes through which a scaled measuring stick ("dip-stick") is inserted to determine the set of distances between the bubble exterior and the outside of the skull. There appears to be a natural variance of plus or minus 3-4 mm in the bubble measurements. Errors can occur due to a mis-read of the measurement scale or by not holding the measuring stick orthogonal to the skull. The data are collected on a paper form. The data are usually verified by a second person.

For entering the skull data into Kula, the program, when requested, presents a template, similar to the paper data form, on the computer screen. The data are then entered manually using the keyboard, usually by the medical physicist. The person entering the data often does a self-check of the entered data, although some teams require an independent check. This information on the skull geometry becomes a part of the patient data file. Given this data, Kula can generate a skull profile to allow a check on the reasonableness of the measurements. If a measurement is grossly wrong or there has been a transposition of data, the skull profile will look odd and the data will be re-examined.

4.1.11 The Gamma Angle

The gamma angle is the angle at which the positive y-axis (posterior-anterior) of the stereotactic frame meets with the central axis beam of the Gamma Knife. It is selected for patient comfort and fit, depending on the location of the lesion, prior to treatment planning. The gamma angle is not a significant source of potential error compared to the isocenter coordinate settings, but it is usually double-checked. The gamma angle influences the position of the isodose lines at the target, and hence, to first order, the dose at a point, and secondly, the volume treated. The influence of the gamma angle is inversely proportional to the number of shots in a treatment session. Sometimes the gamma angle is changed during a treatment session-which can have multiple shots-to accommodate a patient's needs. In such cases, the treatment plan should be recalculated, with adjustments made for shots already administered.

4.1.12 Geometric Determinations From Films

Kula requires shot or isocenter positions to be in Gamma Knife x-, y-, and z-coordinates for treatment planning (see 4.1.16). This in turn requires geometric information from the imaging films to ensure that measurements in the localization indicator's coordinate system are properly translated to Gamma Knife coordinates. Of primary importance is that the films are not reversed or the right and left are not confused. Also, the magnification factor depends on the imaging system arrangement and must be consistent with the film orientations. The CT and MRI computerized systems can provide a distinguishing mark on the films, but if this was neglected, the orientation should be verified. Some hospitals use more than one angiography set-up for taking images for the Gamma Knife. The left-right orientation of

the camera or the magnification factor may differ among angiography, CT, and MRI systems. The films are marked to indicate film orientation and setup geometry. Older Gamma Knife X-ray indicator boxes have a left-right distinguishing fiducial, but the newer boxes do not. The CT and MRI computerized systems provide the user with the magnification factor and can be marked on the image. The magnification factor of the angiography images is determined by means of a calculation requiring parameter values from the imaging set up and measurements of the imaged indicator scales. Errors associated with such determinations include manual or digitizer measuring errors, misreading of film markings, using the wrong fiducial, and not consistently using the fiducial centers. CT/MRI image slices used for treatment planning are usually taken in one plane (e.g., the x-y plane) so that the value of the coordinate in the direction perpendicular or axial to the imaging plane (e.g., the z-coordinate) is determined from the slice resolution value. The translation of the CT/MRI image axial coordinate into the corresponding Gamma Knife coordinate requires the proper use of the magnification factor and a coordinate system origin transfer factor (since the origin of the CT/MRI coordinate system is not the origin of the Gamma Knife coordinate system). For determination of image centers, see section 4.1.5.

4.1.13 Computerized Dose Calculations

To perform a dose calculation with Kula, the user needs to specify a dose matrix, in which the dose calculation is made, about the lesion of interest. This specification includes correctly entering the Gamma Knife coordinates of the center of the square matrix (as marked on the imaging film) and its dimension. The user can also specify a reference absolute dose or, as is common, use Kula's default value. The value of the absolute dose does not matter for calculating the geometry of the isodose lines. The treatment dose is usually selected after an acceptable isodose configuration is developed in the treatment planning process. But Kula requires some dose value to generate isodose curves. As mentioned in 4.1.9, Kula has two modes for calculating dose profiles. The dose calculation algorithm divides the dose matrix into 3 1 x3 1 x3 1 bins, regardless of the matrix dimension, and interpolates between bins. The algorithm thus is less accurate the larger the dose matrix. The cut-and-modify mode is an approximation algorithm that interpolates between every third bin. The exact calculation mode interpolates between every bin and runs much slower than the cut-and-modify mode. Most treatment planners use the cut-and-modify mode to speed the treatment planning process along. The exact method is usually utilized to produce the final treatment plan. There can be a difference in the dose calculation between the two modes by as much as 7%, depending on the size of the dose matrix. The users can make a comparison by performing a point dose calculation within the dose matrix using both modes. A rule of thumb is that if these point calculations differ by 5% or more, use the exact mode. In Kula, the user selects the dose calculation mode by changing a parameter value in the Kula initialization file. There is no indication to the user of which calculational mode Kula is in except by checking the parameter in the initialization file. Since this is an initialization parameter, it does not return to a default value when the program is terminated. Thus, the user may think Kula is in the exact mode, because that is what was used last time, but the parameter may have been changed in the interim. The user also must not get confused about which parameter value (1 or 0) corresponds to which mode. The Kula initialization file is an ASCII file that contains all the Kula program parameters. If the user, in selecting a calculation mode, changes one character of the initialization file incorrectly, then the file is corrupted and the consequences of all subsequent calculations could be severe. This is an unfortunate arrangement. GammaPlan obviates these difficulties by always using the exact mode algorithm with a faster processor.

4.1.14 Target Volume

Some treatment planners use separate and supplementary software to make target volume calculations based on measurements (digital or manual) of the lesion boundaries from the imaging films. The target volumes help the physicians determine the prescribed dose, based on considerations of dose-volume formulae or histograms.

4.1.15 Isocenter Determinations

The treatment planners mark shot positions or isocenters on the imaging films in iterative attempts to select the best combination of isocenters to treat the lesion. (The shot locations are usually marked with a lead pencil.) The Gamma Knife coordinates of these isocenters have to be determined from the films and entered into Kula to perform isodose calculations. Errors in this process include making measurement errors and switching coordinates. The possibility of transposing coordinates is enhanced if orthogonal films are used to determine the coordinates; you have to ensure that

you are extracting the correct coordinate from the correct planar image. The coordinate determinations are independently checked, especially before the final prescription is generated.

4.1.16 Shot Parameters

Kula shot parameter values needed to make isodose curve calculations are the isocenter coordinates (Gamma Knife x, y, and z), gamma angle, collimator sizes, collimator plugging patterns, and the shot superposition and weighting factors. The isocenter coordinates are discussed in 4.1.15. For each shot, the collimator size or helmet (4 mm, 8 mm, 14 mm, or 18 mm) must be specified. Also, any plug pattern for each shot is designated. Kula has a utility that allows the user to design or enter a plug pattern and give that pattern a label. This pattern is then specified by designating its label. Kula permits the treatment planner to make dose calculations from a subset of shots in a treatment plan. This is often helpful to the treatment planners: it allows sensitivity studies of the plan. The subset selection is made by changing the weighting factors for the shots. Kula gives each shot a default weighting factor of one. If a shot is to be excluded from the shot superposition pattern, its weighting factor can be set to zero, or another plan can be established using only the subset of shots. The weighting factors for each shot can be varied (from 0 to 1) to change the contribution of each shot to the overall dose profile. The weighting factors are reflected in the time for each shot in the treatment plan. All these parameters should be carefully checked upon entry into Kula, especially before the final treatment plan is generated.

4.1.17 Plot Isodose Curves

Kula can plot, on screen and using the plotter, the isodose lines resulting from a dose profile calculation. Plots using the plotter are made on acetate so the isodose curves can be overlaid on the imaging films for comparison to the lesion. To make such isodose plots, the user must specify the coordinate plane intersecting the dose profile; the isodose (dose percent) lines to be plotted; and the scaling factor of the plot. The scaling factor should conform to the magnification factor of the images relative to the standard Gamma Knife coordinate frame size. If the scaling-factor and magnification factors don't conform, an incorrect dose profile may be delivered to the patient. The planner can also select the degree of labeling information on the plot. If the de minimus labeling option is selected, the chance of confusing overlays with images is enhanced.

4.1.18 Verification of Treatment Plan

Treatment plans are evaluated and verified by overlaying acetate isodose plots on the film images. It is obviously important to superimpose the correct plot over the correct image. The coordinate plane of the plot must match that of the image and the axial coordinates must be the same. Also, the isodose plots for the current shot selection must be used, as well as the correct imaging film, i.e., CT versus MRI. This last statement may seem trivial, but it reflects the fact that the treatment planning process usually requires several iterative steps of trial and error. In this process, many images are utilized and several more plots are generated. The treatment planners do not always manage all this information in a systematic way (they can be messy) and it isn't too difficult to get confused about which plot goes where. Assuming the correct plot is used for the correct image, the plot must be overlaid correctly on the image. This involves superimposing the center mark of the dose matrix, printed on the plot, with the mark of the center of the dose matrix on the imaging film. The center mark of the dose matrix on the imaging film can be confused with shot position marks, resulting in a gross misalignment of the dose profile. A minor misalignment of the dose profile can occur, if the superposition of the two dose matrix center marks is correct but one is not careful to properly match the marks (which are usually a + sign).

The overlays must be constantly checked as correct, especially for a plan that is accepted for treatment.

4.1.19 Prescription Preparation

Once a treatment plan is accepted, the treatment data or prescription is generated by Kula. The final treatment plan should be the last plan in the patient's data file, and all its parameter values should be correct. The physicians choose a dose for the treatment, and this must be correctly entered into the prescription template on the computer. The user can also select the mode in which the prescription is presented: either by shot number or by collimator size, with more than one shot for a collimator ordered by treatment time.

Kula produces a printout of the prescription which should be checked in all its particulars. The prescription contains the patient name, patient identification number, dose, gamma angle, shot number, x, y, and z shot coordinates, shot time, collimator size, and plug pattern, if any (about 90% of treatments are unplugged). If the patient is to be treated in the prone position, the default supine shot coordinates have to be transformed outside of Kula and rewritten on the prescription form. This requires a correct calculation, a correct transposition of coordinates, and a correct transcription.

Once the prescription is deemed verified, it is signed by at least two authorized users.

4.1.20 Treatment Svstem Oualitv Assurance Checks

On the day of and before a treatment, the Gamma Knife systems within the treatment facility are checked by the medical physicist, radiotherapy technician, or both. These daily checks augment monthly, semi-annual, and annual quality assurance activities (which are described in a separate report on the quality assurance for Gamma Knives). Typical daily quality assurance activities consist of:

1. 1. A visual inspection of the hydraulic room, console area, and treatment room. These are to ensure all necessary equipment is present. Hydraulic fluid on the floor may indicate a leak that can lead to underpressurization of the gamma unit.
2. 2. The gamma unit power is turned on as are the video monitors.
3. 3. With an active survey meter in hand, a radiation check source is taken into the treatment room and placed on the radiation monitors to verify in-room flashing. While in the room the unit is inspected and verified all right for treatment. The shielding cover at the rear of the helmet is opened, thereby breaking a safety interlock and simulating a condition for no treatment.
4. 4. The treatment room is exited and it is verified no one is in the treatment room. Then at the control console several checks are made. These include verification of the alarm of the remote radiation monitor; setting and re-setting of counters; lamp tests; verification of "cover open" light and an attempt at treatment start which should fail, since a safety interlock was interrupted in step 3.
5. 5. The treatment room is re-entered to close the rear helmet shielding cover (connecting a safety interlock) and to remove the radiation check source.
6. 6. The treatment room is exited and verified empty of personnel. The counters are set (usually to a minute) and the treatment cycle initiated. With the treatment couch in motion, the emergency interrupt button is pushed to verify that the couch freezes in place until the interrupt is released and the treatment cycle is continued. When the unit is in the treatment position, the "treatment yes" light should be on. The treatment stop button then is tested to verify that the treatment terminates and the couch is withdrawn to a safe position.
7. 7. The treatment door interlock system is tested by opening the door and trying to initiate treatment.
8. 8. Finally, the counters are set for a short treatment and a proper treatment cycle and completion (without intemption) is verified.
9. 9. The proper functions of the communication and visual systems are verified.
10. 10. Also the daily quality assurance protocol for the computerized treatment planning system Kula is run and verified (see 4.1.8 and 4.1.9).

4.1.21 Collimator Helmets

The interchangeable four-collimator helmets are heavy and require a specially designed, manually pneumatic hoist to move them from the gamma unit to their holding table and vice versa. The hoist lifts or lowers the helmets and moves on the floor. The treatment room floor is constructed as flat as possible to not hinder movement of the helmet hoist. The earlier hoist models, loaded with a helmet, are top heavy and require at least two people to stop toppling of the hoist. The newer models are easier for one person to handle. Before a retrofit, the older hoist helmet fixtures had a tendency to break off electrical connections at the back of the treatment couch helmet support when a helmet was lowered onto the support with the hoist. Treatment can not begin if those electrical connections are not sound. Each helmet has two microswitches, one on each side of the helmet, to verify the proper mating of the helmet with the internal collimator in the treatment position. The microswitches have to be adjusted within a 0.1 mm tolerance of a perfect mating. If this tolerance is not met, the switches aren't activated during mating of the collimators, and the treatment couch is automatically withdrawn from the radiation unit. The Gamma Knife comes with a special tool to adjust the

microswitches. If a switch is adjusted too low, it won't be activated at mating. If a switch is adjusted too high, it may be broken off during mating. A helmet is selected, according to the prescription, and properly placed on the gamma unit before a patient can be positioned inside the helmet for a treatment shot. Each helmet is identified by an imprinted mark and by the size of the collimators. Practitioners usually try to minimize the number of helmet handlings, so they arrange the order of shots by collimator size. There can be confusion of helmets with shots if the prescription is not simply ordered. Also, one may mis-identify a helmet. If a particular shot includes a plugging pattern, the pattern has to be formed on the appropriate helmet by replacing the removable tungsten collimators with tungsten plugs. The pattern is usually provided by a printout from the Kula utility for designing pluggings. The pattern is made before the patient is positioned and should be carefully and independently checked. All the plugs should also be checked to ensure they are properly seated; if not, they can become dislodged or broken while entering the radiation unit.

4.1.22 Patient Positioning for Treatment

For a treatment shot, the patient, with affixed stereotactic frame, is placed on the treatment couch and inside the appropriate collimating helmet on the gamma unit. The head frame is affixed to the collimating helmet at the proper shot coordinates by means of pillars and trunnions. Usually the y-coordinate is set first, by sliding a trunnion support pillars along the y-coordinate scale on each side of the head frame and tightening their screws with a hexagonal wrench. The z-coordinate is adjusted by sliding the central parts of the same pillars along their engraved z-coordinate scale and tightening them in place with screws. Errors in setting the y- or z-coordinates on one side of the stereotactic frame of more that 20 or 50 mm, respectively, will absolutely prevent fixation of the trunnions used to hold the stereotactic frame within the collimator helmet and to set the x-coordinate. If the x-coordinate is properly set on one side of the patient's head, the maximum errors possible in the x-coordinate setting on the opposite side are -1 mm or + 6.5 mm. Errors separating the trunnions by more than 6.5 mm will not allow support of the stereotactic frame in the helmet. The normal tight fit of the trunnions against the pillars attached to the frame, when the x-coordinate is correctly set on both sides, allows less than 1 mm error due to the mechanical rigidity of the frame. The gamma angle is set by rotating the trunnions after they are set into the pillars attached to the stereotactic frame.

The shot coordinates are set and checked by a team of 3-4 people consisting of the neurosurgeon, radiation oncologist, medical physicist, radiotherapy technician, or registered nurse. One person sets and secures the coordinates while another or two check the coordinate values and the security of the settings. An impressive double-blind checking routine consists of one person setting the shot coordinates from the prescription, which are left unknown to the checkers. Each of two checkers separately records their inspection of the set coordinates. Then both checks are compared to each other and the prescription. If there is any discrepancy among all three records, the coordinates are reset and the checking procedure is repeated. Mistakes in coordinate settings can occur due to using coordinates from the wrong shot, misreadings of the scales, or transposition of coordinates. The z-coordinate is the hardest to set and secure, because it holds up the weight of the patient's head. The x-trunnions are precisely machined and can be damaged if people do not follow procedures correctly or do not keep the trunnions clean. Their scales can become obscured or stuck in the helmets.

After data collection was completed, a study was published (Flickinger et al. 1993) on the potential errors and their magnitudes in setting Gamma Knife stereotactic coordinates. Final checks are performed before leaving the patient in the treatment room. The collimator size and plug pattern are verified once more. A final check is made of the potential radiation exposure of the patient's eyes or lenses (see 4.1.7). A TLD may be placed on the lens or thyroid to measure exposure. The couch should be cleared of all unnecessary items. The helmet rear shielding plate is closed and the microswitches' electrical connections are secured. A microphone is attached to hear the patient speak and breathe. Sufficient light is made available to view the patient's face with the remote cameras and monitors. Side guards are attached to the couch. Finally, the room is cleared of all personnel, and the interlock door is closed.

4.1.23 Treatment Timing

Two digital counters or timers on the control console are set before starting the treatment shot. One counter is set for the shot time to count up, while the other is set to count down to zero. One could incorrectly set the counter or use a time from another shot, by, for instance, mis-reading the prescription. Thus, the counter settings are verified. The two counters are on the same power supply, so are not independently redundant. However, one counter keeps the elapsed

time if the other counter fails. This has happened due to a faulty microchip in some of the counters. The counters will display the elapsed shot time if the emergency interrupt or treatment stop function is invoked. If the treatment is interrupted for any reason, it's important to have the elapsed time to adjust or re-calculate the overall treatment plan. The timer reset button will reset the counters to the last set time, even during a treatment shot. A backup battery keeps the counters ticking in the event of an electrical failure.

p.42,43 Process 1.0: Imaging and Localization 1.1 Identify correct patient 1.2 Affix stereotactic frame 1.2.1 Verify integrity of head frame 1.2.2 Center lesion in stereotactic frame 1.2.3 Ensure frame is immovable on patient's head 1.3 Set up CT, MR, Angiography 1.3.1 Verify attachment and alignment of CT, MR, or X-ray indicators 1.3.2 Ensure correct alignment (orthogonality) with respect to imager 1.3.3 Label films: patient id.; film orientation; fiducials; 1eftJright; etc. 1.3.4 Select image slice resolution (CT, MR) 1.4 Determine outline of lesion 1.5 Center correctly deposited on CT, MR films 1.6 Determine initial isocenter locations/coordinates Process 2.0: Treatment Planning 2.1 Identify correct patient with planning data (e.g., films) 2.2 Simulate treatment 2.2.1 Check range of lesion coordinates 2.2.2 Check supine vs. prone 2.2.3 Check gamma angle 2.2.4 Check lenses - need for collimator blocking 2.3 Check treatment planning equipment 2.3.1 Computer software calculations (e.g., today's dose rate) 2.3.2 Plotter integrity 2.3.3 Digitizer accuracy and linearity 2.4 Start up of treatment planning software 2.5 Create patient data files 2.6 Take skull measurements for supine or prone position 2.6.1 Verify identity of patient 2.6.2 Attach measuring bubble correctly 2.6.3 Use measuring stick 2.6.4 Enter scale readings on data form 2.6.5 Verify skull data 2.7 Enter skull data into patient's computer file 2.7.1 Verify computer skull data (skull profile)

Information Notices

NRC Information Notices relevant to medical uses of radioactive material are collected in this section.

NRC INFORMATION NOTICE 2003-09: SOURCE POSITIONING ERRORS AND SYSTEM MALFUNCTIONS DURING ADMINISTRATION OF INTRAVASCULAR BRACHYTHERAPY POSITIONING ERRORS AND SYSTEM MALFUNCTIONS DURING ADMINISTRATION OF INTRAVASCULAR BRACHYTHERAPY

Addressees:
All medical licensees.

Purpose:
The U.S. Nuclear Regulatory Commission (NRC) is issuing this information notice (IN) to inform addressees of four recently reported medical events, with two separate device types, that have occurred during the conduct of intravascular brachytherapy (IVB) procedures. These medical events involved errors in positioning the IVB sources or system malfunctions, resulting in administration of the dose to the wrong treatment site. Two events involved inadequate understanding of source positioning details for the most recent device being employed. The third event involved catheter malfunction and inadequate visualization of the active source and the fourth event involved system malfunction.

It is expected that recipients will review this information for applicability to their licensed operations and consider actions, as appropriate, to avoid similar problems. However, suggestions contained in this IN are not new NRC requirements; therefore, no specific action nor written response is required.

Description of Circumstances:
NRC has received four recent medical event reports involving administration of IVB doses to the wrong treatment sites. The events are summarized below.

In the first event, the licensee had been using a Guidant Galileo IVB system and had recently received an upgraded software system, the Guidant Galileo III. The old system was updated, in part, to allow delivery of the dose in two parts to the distal and proximal ends of the lesion. The new system automatically sends out an inactive wire with a marker that should align with a marker on the catheter placed in the patient. To reach exact alignment, the user may need to manually "fine tune" the positioning. With the old system, the positioning is accomplished essentially the same way. On the day of the first use of the upgraded system, the vendor's representative arrived on site to provide training. However, the first patient had already been prepped to undergo the treatment and the formal training for the new version was not delivered prior to the treatment. During the initial use of the upgraded system, the source delivery unit sent out the inactive wire to a point where its distal marker stopped in the approximate area of the catheter's distal marker. Since the users had not received formal training, nor had they reviewed the training manual, they questioned whether they had to manually fine tune the positioning of the inactive wire to align it with the distal end of the catheter. The vendor's representative had not used the upgraded system often and did not fully understand the importance of the marker alignment, and therefore, assured the users that the position of the inactive wire was acceptable and that the system would advance the active wire to cover the desired area without any "fine tuning". As a result, when the source delivery unit sent out the active wire, the wire traveled 3 to 6 millimeters short of its intended location. The users retracted the source, were again assured by the vendor's representative that the active wire would go to the desired position, and attempted to treat again. The active source wire was run out a second time and again did not reach the desired treatment position. Subsequently, the inactive wire was run out and this time the users manually adjusted it to align with the catheter's distal marker, and the treatment was administered.

In the second event, the licensee had been using the Novoste Beta-Cath 5 French IVB system

and had recently received the 3.5 French system. One of the differences between the two units is the method for locating positional markers. The vendor's representative was present for the procedure and had provided training to the licensee's staff prior to staff performing a patient treatment with the new unit. However, both the vendor's representative and the Authorized User were in the room but not in a position to see the source train positioning in the new catheter which was inserted by the interventional cardiologist. Following insertion of the active source train, the interventional cardiologist determined, via fluoroscopy, that the source train was incorrectly positioned and did not cover the desired treatment site. The source train was withdrawn after 60 seconds of treatment. The catheter was then correctly positioned and treatment was given to the proper area of the vessel.

In the third event, during a treatment with a Novoste Beta-Cath 3.5 French IVB system, the source train did not travel the entire way to the treatment site and was 40 millimeters proximal to the treatment site. The immediate cause of the event was a small kink in the delivery catheter which kept the source train from traveling to the correct site, even though the kink was not substantial enough to affect the flow of the sterile water used to send/retrieve the sources. The error was identified the next day during the medical physics quality assurance checks of the films taken during the treatment. The review revealed that the proximal end of the source train was hidden inside the guiding catheter and was not properly visualized by fluoroscopy during source placement. The licensee also noted that the proximal and distal markers of the source train are the same size and shape and are not distinguishable from each other. Therefore, the distal end of the source train was mistaken as the proximal end and the entire dose was delivered to an area 40 millimeters proximal to the intended treatment site. During on-site review of the event, NRC inspectors observed the licensee conducting a treatment with the 3.5 French IVB system. Again, the licensee had to remove the catheter from the patient, due to kinking of the catheter. As in the earlier treatment, the kinking was not substantial enough to affect the flow of the sterile water. However, the source train remained stuck in the catheter, requiring removal of the catheter containing the source train from the patient. The manufacturer is evaluating the system.

In the fourth event, there was a malfunction of the drive mechanism with a Guidant Galileo III IVB system. A vendor's representative was present for the treatment. During the treatment the inactive source successfully reached the proper position (confirmed visually via fluoroscopy) and returned. The active source was then advanced into the catheter. The licensee noted that the source movement light continued to blink well after the anticipated transit time. The licensee attempted to locate the source position via fluoroscopy; however, the source was not viewed. The licensee performed surveys that confirmed that the source stopped inside the patient. The licensee assumed a machine malfunction had occurred and initiated emergency procedures. The indicator light on the console continued to indicate the source was in transit even after the licensee confirmed the source was in the patient and not at the treatment site. While attempting to return the source to the shielded position, the licensee was unable to retract the source using the machine interrupt, the system stop button, or the manual hand-wheel. Therefore, the licensee manually removed the catheter and source from the patient. After the power cord was removed from the wall receptacle, the source was retracted back to its shielded position. The device is being evaluated for proper operation by the manufacturer. In addition, the licensee did not contact the State regulatory authority, as required.

Discussion:

In two of the four cases, the licensees received new designs for systems they had been using, and did not fully appreciate any differences in the methods used by the new designs for positioning the active source trains. In addition, a vendor's representative was present in both cases, but in one case, the representative did not fully understand the source positional differences between systems, and in the other case, the representative could not adequately view the treatment to verify whether correct positional methods were used.

In another case, two issues resulted in the wrong area being treated. First, the catheter kinked, restricting the source train from traveling to the intended treatment site. Second, the proximal

and distal markers for the source train are the same size and shape. During fluoroscopy of the treatment area for source placement verification, the licensee's staff believed that both the proximal and distal markers had been visualized. However, only the distal marker had been visualized.

In the last case, there was complete failure in safety systems when emergency procedures were implemented. The system appears to have malfunctioned both in its ability to recognize the location of the active source and its ability to retract the active source wire with emergency features. Although investigation of this reported event is ongoing, presently available information suggests that the console touch screen used to control the treatment "froze" and did not display the touch screen interrupt button. In addition, the licensee did not notify the regulatory authority of this event. Prompt notification of regulatory authorities is essential for these types of events to ensure that immediate actions are taken to prevent recurrences of such medical events by this and other device users.

Licensees performing IVB are expected to review this IN and:

- Assure that vendor training has been provided to all users prior to their actual use of new devices or re-designs of devices;
- Encourage device users to review all of the vendors training documentation and clarify any concerns with the vendors regarding particular devices prior to using the devices for patient treatments. If direction provided by the on-site vendor's representatives is believed to be in error, licensees are expected to clarify any discrepancies with the manufacturers prior to use.
- Report all system malfunctions to the vendors; and if required, to the licensing authorities expeditiously; and
- Consider performing quality assurance checks of the films taken during the treatment to identify whether correct placements of active sources were achieved.

ML031830015

NRC INFORMATION NOTICE 2003-12: PROBLEMS INVOLVED IN MONITORING DOSE TO THE HANDS RESULTING FROM THE HANDLING OF RADIOPHARMACEUTICALS

Addressees:

All holders of 10 CFR Parts 32, 33, and 35 licenses.

Purpose:

The U.S. Nuclear Regulatory Commission (NRC) is issuing this information notice (IN) to alert licensees of potential difficulties that may be encountered when monitoring doses to the hands of workers involved in handling radiopharmaceuticals. This IN describes some of these difficulties, the work that is being conducted to resolve them, and interim guidance that NRC will adopt pending completion of this work. It is expected that recipients will review the information for applicability to their facilities and consider actions, as appropriate, to avoid similar problems. However, suggestions contained in the IN are not NRC requirements; therefore, no specific action nor written response is required.

Background:

Handling of radiopharmaceuticals contained in syringes, vials, and other vessels exposes the workers' hands to radiation doses that may, in the course of a year, approach a significant fraction of the regulatory limit on the shallow dose equivalent (SDE), which is the limit that normally applies to such exposures. The practice has been, for many years, to monitor these doses using ring dosimeters worn on one or more fingers of one or both hands, depending on the details of the activity that produces the exposure. The highest ring dosimeter reading is normally considered to provide a measure of the SDE received, and is used to show compliance with the applicable dose limit.

During the past year or so, NRC inspectors have focused attention on this practice, and have concluded that, at least in some cases, the dosimeters may be underestimating the doses they are supposed to be measuring. This conclusion was reached because the dose that must be assessed for the worker is the dose at the location of the highest exposure on the extremity. When handling radiopharmaceuticals, it may happen that the location of the highest exposure is not the same as the location of the ring dosimeter, in which case the dosimeter will underestimate that dose. This is particularly true when handling radioactive materials with the fingertips, thus creating a sharp dose gradient between the location of highest exposure, which is likely to be at the fingertip, and the location of the dosimeter, which is normally at the base of the finger. Under these conditions, the dosimeter may not provide a sufficiently accurate measure of the SDE for purposes of showing compliance, and a correction factor may be warranted, in such cases, to adjust the dosimeter reading.

In response to these findings, some licensees have undertaken some measurements in an attempt to estimate the value of such a correction factor. It is clear that this factor will vary depending on the details of the handling activities, and this has been confirmed by the measurements. The results obtained by the licensees, as well as those published in the professional literature, showed factors ranging from very close to 1 up to 2, or in some cases, higher values, with an average of roughly 1.2 - 1.4. These factors were estimated using the ratio of the dose measured at the fingertip to that measured by the ring badge. Based on these results and other considerations, some licensees have concluded that their activities are such that their dose measurements do not require a correction factor or, in effect, that the appropriate factor for them is 1.

This situation has been complicated by the change in the SDE limit, which became effective in June 2002. The SDE limit has remained numerically the same, namely 0.5 Sv (50 rem) per year to the extremities. However, whereas the old rule required that the dose be averaged over an area of 1 cm^2 of skin, the new rule requires that the dose be averaged over a skin area of

10 cm under the old rule is most likely to be closer to 1 under the revised rule. turn means that any correction factor that may have been applied to the ring badge reading under the old rule, the extent of the reduction depending on the details of the exposure. This in the new rule results in an assessed dose that may be lower than would have been assessed high dose gradients, which is the case when handling radioactive materials with the fingertips, uniform, exposures, over the extremity, the effect is negligible. However, for situations involving (10 CFR 20.1201(c)). The effect of this change has been two-fold. For uniform, or nearly

The second effect of the rule change is that it now defines the limit in terms of a quantity that is not directly measurable, without specialized measurement techniques, under conditions of high dose gradients. Under the old rule, measuring the dose at the point of highest exposure, such as at the fingertips, by placing a dosimeter at that location, provided a fairly good approximation of the dose averaged over an area of 1 cm^2 , even in the presence of a high dose gradient. However, such a measurement does not provide a good estimate of the dose averaged over an area of 10 cm^2. The required dose must now be measured using special measurement techniques, or calculated. Such measurements or calculations enable estimation of any correction factors that should be used with finger ring dosimeters, to permit reasonably accurate estimation of the required SDE. It should be noted that this is not an unusual situation in applied dosimetry, but only one that is made somewhat more than usually difficult because of the relatively large area over which the dose must be averaged.

Discussion:

NRC and the radiopharmaceutical industry are currently conducting studies and measurements designed to provide estimates of the appropriate correction factors that should be used with ring dosimeters to enable accurate assessment of the SDE. It is expected, as a result of the revised SDE limit, that these correction factors will be close to unity, but may be sufficiently different to warrant their routine use in assessing the SDE. Until this work is completed, and licensees are notified of its results and conclusions, NRC will accept the reading of the finger ring dosimeter, without application of a geometry correction factor, as being sufficiently accurate to provide a direct indication of the SDE received by the worker provided the ring dosimeter is worn on the finger that is expected to receive the highest dose. NRC will reconsider this approach, and licensees will be notified of the new guidance, when the ongoing work to resolve this matter is completed. In the interim, licensees are reminded of the regulatory requirement to keep doses As Low As is Reasonably Achievable (ALARA) to ensure that, even if the appropriate correction factor is found to be higher than 1, the worker will nevertheless be adequately protected, and the SDE limit will not be exceeded.

ML032320470

NRC INFORMATION NOTICE 2003-21: HIGH-DOSE-RATE-REMOTE-AFTERLOADER EQUIPMENT FAILURE

Addressees:
All medical licensees.

Purpose:
The U.S. Nuclear Regulatory Commission (NRC) is issuing this information notice (IN) to inform addressees of a recently reported medical event that occurred during the conduct of a high-dose-rate-remote-afterloader (HDR) brachytherapy procedure. The medical event involved error in selection of ancillary equipment--transfer tube--required for use of the HDR unit, resulting in failure of the sealed source to reach its intended position for treatment, and failure of the sealed source to retract on completion of the procedure.

It is expected that recipients will review this information for applicability to their licensed operations and consider actions, as appropriate, to avoid similar problems. However, suggestions contained in this IN are not new NRC requirements; therefore, no specific action nor written response is required.

Description of Circumstances:
An Agreement State licensee reported that a 170.2 gigabecquerel (4.6 curie) iridium-192 sealed source contained in a Nucletron MicroSelectron HDR afterloader device--Model Number 31324--failed to retract on completion of a patient treatment. The physicist entered the treatment room and attempted to manually retract the sealed source, which was stuck in the transfer tube, the source conveyor device between the HDR unit and the applicator used for the procedure. Manual retraction of the sealed source failed. The physician entered the treatment room, disconnected the apparatus from the patient, and dropped the transfer tube into a lead container. Both the physicist and physician then moved the patient out of the room. The physicist observed that 2 minutes had elapsed since he entered the treatment room. The physicist surveyed the patient with a radiation detection instrument to confirm that the source had been removed. The physicist then re-entered the room to perform a radiation survey. He confirmed that the source was within the transfer tube and that it was shielded by the lead container. The physicist measured 0.1 millisievert (mSv)/hr at 0.91 meters [10 millirem (mrem)/hr at 3 feet] from the shielded container. The room was locked and posted until the manufacturer's representative arrived. The manufacturer's representative also was unable to retract the source from the transfer tube into the HDR unit. He then disconnected the transfer tube from the HDR unit, placed the transfer tube, containing the sealed source, into a shipping container, and arranged for returned of the transfer tube to the manufacturer, for further investigation.

Doses to the patient, physicist, and physician (as originally reported) were estimated as follows:

(1) patient's skin dose, at 10 centimeters (cm) [3.9 inches (in.)] from the sealed source, was 0.61 sieverts (Sv) (61 rem); (2) physicist's whole-body dose (deep-dose equivalent), for the 2-minute exposure, was 0.45 mSv (45 mrem); (3) physician's whole-body dose (deep-dose equivalent) was 1.25 mSv (125 mrem), and extremity dose was 0.15 Sv (15 rem).

The Agreement State and NRC are continuing to investigate this event. Because of the importance to licensees of the information contained in this IN, it is being issued before completion of the investigation of this event.

Discussion:
Although the transfer tube used was manufactured by Nucletron for use with the Nucletron MicroSelectron HDR afterloader device, it was a rigid gynecological-type tube, not designed for use with the Proxima Therapeutics Mammosite applicator being used by the licensee for the procedure being performed. Nucletron indicated that the licensee should have used its flexible transfer tube, approved for use for non-gynecological-type treatments, which is

designed to accommodate the Mammosite applicator.

As a result of the incorrect choice of transfer tube (i.e., an incorrect transfer tube being used with the Mammosite applicator) during the procedure, the sealed source was inadvertently positioned inside the transfer tube at a distance of 10-14 cm (3.9-5.5 in.) from the patient's breast, not in the breast, as planned. That is, the source of the radiation never arrived at the intended treatment site within the patient's body. Also, the use of the incorrect Nucletron transfer tube for the Mammosite applicator apparently caused the subsequent failure of the source to retract.

Licensees performing HDR brachytherapy procedures are expected to review this IN and:

- Assure that ancillary devices to be used with an HDR brachytherapy unit for a therapeutic procedure are designed for use with, or are known to be compatible with, both the HDR afterloader unit and with any applicator(s) to be used during the procedure;
- Assure that all HDR afterloader brachytherapy unit users are familiar with the operating procedures and applicable usage restrictions of all equipment to be employed in a procedure before actual use of such devices and ancillary equipment;
- Encourage device and equipment users to review all of the vendors' pertinent documentation and to clarify any concerns with the vendors, regarding particular devices, before using the devices for patient treatments. If, based on prior review of a vendor's documentation, and possibly discussion with a vendor, a user considers that directions provided by an on-site vendor's representative may perhaps be in error, licensees are expected to clarify any such discrepancies with the manufacturer before use of the device(s); and
- Promptly report all system malfunctions to the vendors, and if required, to the licensing authorities.

ML033250492

NRC INFORMATION NOTICE 2003-22: HEIGHTENED AWARENESS FOR PATIENTS CONTAINING DETECTABLE AMOUNTS OF RADIATION FROM MEDICAL ADMINISTRATIONS

Addressees:

All medical licensees and NRC Master Materials License medical use permittees.

Purpose:

The U.S. Nuclear Regulatory Commission (NRC) is issuing this Information Notice (IN) to alert addressees of an event where a radiation detector, installed as part of heightened homeland security measures, alarmed when a recently released radiopharmaceutical patient passed by it. In reviewing this notice, licensees are also reminded to emphasize to those patients still containing detectable amounts of radiation from medical administrations and released with written instructions in accordance with 10 CFR 35.75, the importance of following those instructions. This is essential for maintaining doses to other individuals as low as is reasonable achievable and, presently, to reduce the occurrence of patients triggering with radiation monitors, installed at public locations for increasing public security in the United States.

It is expected that recipients will review this information for applicability to their licensed operations and consider actions, as appropriate, to avoid similar problems. However, suggestions contained in this IN are not new NRC requirements; therefore, no specific action nor written response is required.

Description of Circumstances:

On March 20, 2003, a bus traveling from New York to Atlantic City set off a radiation alarm in a tunnel, as it passed by a radiation detector. When the State Police pulled over the bus, it was discovered that one of the passengers had received a 370 Megabecquerel (10 millicurie) dose of iodine-131 earlier that day from a medical procedure. Although the medical licensee provided the patient with written safety instructions, which included not using public transportation for 2 days, the patient failed to follow the instructions. This resulted in the activation of the radiation detector in the tunnel. Subsequent discussions with the patient's physician indicated that the patient's actions in taking the trip would have no safety significance to the members of the public on or near the bus. However, the event resulted in unnecessary concern and inconvenience to the patient and members of the public, as well as to law enforcement authorities and other public officials.

Discussion:

Heightened security measures are now in effect throughout the United States. These include, but are not limited to, installation of radiation surveillance equipment at critical infrastructures and mass congregation events. Therefore, types of incidents such as the one described within this IN are likely to increase for released patients that still contain detectable amounts of radiation from medical administrations of radiopharmaceuticals and brachytherapy sources. These incidents may not be limited to those patients who are required to be provided written instructions, when released in accordance with 10 CFR 35.75, but could also include patients administered diagnostic dosages or low-level therapeutic dosages of radiopharmaceuticals. In the example above, if the patient had been administered less than 259 Megabecquerel (7 millicurie) of iodine-131, NRC regulations would not have required that the licensee provide the patient with written instructions, but the patient might still have set off a radiation detection alarm.

When licensees are required to provide written directions to patients released in accordance with 10 CFR 35.75, the licensees are expected to, among other things, review with authorized users the expectation that written instructions provided to patients will be followed. Accordingly, authorized users are expected to evaluate the patient's capability to follow

recommended written instructions before release, to determine if release at that time is advisable, and **stress** the importance to the patient of following the written instructions.

In view of the event described and its potential for becoming more common, licensees should consider the following voluntary actions for all patients who still contain detectable amounts of radiation after receiving diagnostic or therapeutic quantities of radiopharmaceuticals or brachytherapy implants:

1. Released patients who are administered diagnostic or therapeutic quantities of radiopharmaceuticals or brachytherapy implants should be aware that their treatment may have additional implications, because of heightened security measures. Accordingly, provide all patients that still contain delectable amounts of radiation with an appropriate explanation about the potential of alarming radiation monitoring equipment.
2. To assist the patient and avoid unnecessary concern by law enforcement authorities and other public officials, consider providing the patient with the licensee's business card and written information for law enforcement use, stating that the radiation received by the patient poses no danger to the public and that it is allowed by NRC medical use regulations.

ML033390164

NRC INFORMATION NOTICE 2004-02: STRONTIUM-90 EYE APPLICATORS: NEW CALIBRATION VALUES AND USE

Addressees:

All U.S. Nuclear Regulatory Commission (NRC) medical-use licensees and NRC master materials license medical-use permittees.

Purpose:

NRC is issuing this Information Notice (IN) to inform all medical-use licensees and permittees of information regarding the use of newly calibrated strontium-90 (Sr-90) eye applicators. It is expected that recipients will review this information for applicability to their facilities and consider actions, as appropriate, to avoid similar problems. However, suggestions contained in this IN are not new NRC requirements; therefore, no specific action nor written response is required.

Description of Circumstances:

This notice alerts medical-use licensees and permittees to discrepancies associated with new and older calibration values for Sr-90 eye applicators and effects this may have on their use under the regulatory requirements in 10 CFR Part 35, “Medical Use of Byproduct Material.”

Discussion:

NRC issued an IN, in 1994, on the calibration and use of Sr-90 eye applicators (IN 94-17, March 11, 1994) that, among other things, informed licensees that: (1) researchers at the National Institute of Standards and Technology (NIST) recognized large discrepancies among calibrated outputs assigned to Sr-90 eye applicators; (2) original manufacturer calibrations were expressed in older (traditional) units, which differed from the System Internationale (SI) units; (3) calibration values were not comparable for units from different manufacturers; and (4) discrepancies larger than 10 percent could exist when comparing output measurements between competent measurement laboratories using state-of-the-art techniques.

At that time, the Advisory Committee on the Medical Uses of Isotopes (ACMUI) advised the staff that calibration was not a critical factor in the use of Sr-90 eye applicators for treating pterygium because licensees treated for response rather than to tolerance. Members of the ACMUI recommended that the Sr-90 eye applicator licensees continue to treat patients as they had using the original manufacturer's Sr-90 activity values and treatment times derived from decay correction charts. The ACMUI further recommended cautioning licensees that if they were to use an applicator other than the one currently in their possession, or if they were to buy a new one, their current technique might not be applicable to another device because of variances in stated and actual exposure rates for the different applicators.

In 1991, NIST implemented major revisions to its method for performing these calibrations. The major changes involved using a collecting electrode smaller than the source being calibrated and restricting measurements to air gaps less than 0.2 millimeter (mm). These changes yielded current-versus-air-gap data that are linear and which extrapolate unambiguously at distances down to zero air gap. NIST reviewed additional changes in the recombination corrections, stopping-power averages, and corrections for electrode backscatter. NIST continues to review and refine its calibration calculations and techniques for Sr-90 eye applicators.

Before October 2002, if a medical-use licensee or permittee had a calibration certificate for its eye applicator, the licensee or permittee was not required to re-calibrate its eye applicators. Effective October 24, 2002, NRC amended its regulations at 10 CFR 35.432, “Calibration measurements of brachytherapy sources.” This section of the regulations requires, among other things, that brachytherapy sources be calibrated before first medical use on or after the effective date of the rule. The effect of this requirement on Sr-90 eye applicator licensees and permittees was that they all had to have their applicators calibrated using the new techniques that more accurately measure the actual exposure rate for the eye applicator and provide the

calibration results in SI units. Thus, the calibration values and units may be significantly different from those provided in the original manufacturer's calibrations or more recent calibrations.

NRC expects each Sr-90 eye applicator licensee and permittee to carefully review the results of the new calibration with its authorized medical physicist to assure proper interpretation of the calibration results. This review should include discussion of appropriate changes to the written directives so that the patient treatments are based on the new calibration information. As described below, the authorized user has several options and should select the best option, based on his/her medical judgment, for his/her practice. It is important for the licensee or permittee to keep in mind that, although the units and calibration values may be different, the actual amount of radioactive material (corrected for decreases from radioactive decay) contained in each applicator and its distribution in the applicator remains the same.

The written directive regulations for eye applicator procedures require that the licensee (or permittee) include the following information in the written directive:

- prior to implantation: treatment site, radionuclide, and dose;
- after implantation, but prior to completion of procedure: treatment site, radionuclide, number of sources, and total source strength and exposure time (or total dose).

Maintaining the same treatment regimen - revising total dose in the written directive.

If the licensee's or permittee's medical experience with its Sr-90 treatment regimen before the October 2002 required recalibration indicated that the treatments provided appropriate medical results, the authorized user may elect to administer the same amount of radiation to the treatment site and provide the same medical results after recalibration, as before. Even though the units and calibration values may be different from those of an earlier calibration, the actual exposure rate (corrected for decreases from radioactive decay) remains the same.

Therefore, to administer the same amount of radiation from a specific eye applicator, the authorized user should keep the treatment time the same and adjust the total dose to a new value, based on the new calibration exposure rate.

For example, based on the original manufacturer's calibration data, the authorized user believes that the exposure rate is 0.42 gray per second (Gy/sec), but the exposure rate based on the new calibration certificate is really 0.55 Gy/sec, a value 31 percent higher. The authorized user's medical experience is that the treatment times used in the past provided good medical results. To achieve the same medical results, the authorized user would keep the administration time the same and increase the value of the total dose documented in the written directive by 31 percent. The treatment times will change with time, because of the normal radioactive decay of the Sr-90.

Changing the treatment regimen - retaining the same written directive total dose value.

Although the authorized user's medical experience with his/her Sr-90 treatment regimen before the October 2002 required calibration indicated that the treatments provided appropriate medical results, the authorized user decides he/she wants to keep the value of the total dose the same in future written directives. In this case, the authorized user will adjust the treatment time so that the total dose value recorded in the written directive does not change. Because the treatment regimen is changed, the authorized user should monitor his/her patients to see if the expected medical results stay the same or change.

For example, based on the original manufacturer's calibration data, the authorized user believes that the exposure rate is 0.42 Gy/sec, but the exposure rate based on the new calibration certificate is really 0.55 Gy/sec, a value 31 percent higher. In this example, the authorized user decides to keep the total dose value the same in the written directive. To achieve the same value for the total dose, the authorized user would have to reduce the administration time by 31 percent.

ML040330279

NRC INFORMATION NOTICE 2004-003: RADIATION EXPOSURES TO MEMBERS OF THE PUBLIC IN EXCESS OF REGULATORY LIMITS CAUSED BY FAILURES TO PERFORM APPROPRIATE RADIATION SURVEYS DURING WELL-LOGGING OPERATIONS

Addressees:
All well-logging licensees.

Purpose:
The U.S. Nuclear Regulatory Commission (NRC) is issuing this Information Notice (IN) to alert addressees to several events, some of which resulted in oilfield workers receiving radiation doses in excess of 1.0 millisievert (mSv) [100 millirem (mrem)] per year, NRC's dose limit for members of the public. It is expected that recipients will review the information for applicability to their facilities and consider actions, as appropriate, to avoid similar problems. However, suggestions contained in this IN are not new NRC requirements; therefore, no specific action nor written response is required.

Description of Circumstances:
During May 2002, NRC conducted a reactive inspection to review an event involving the loss of control of a cesium-137 (Cs-137) well-logging source and the unintended radiation exposure to several members of the public (rig workers). During the course of the inspection, NRC performed interviews with several individuals from various well logging licensees and equipment manufacturers. Based on these interviews and by observation of source-handling techniques employed by multiple well-logging licensees, the inspection team determined that well-logging sources do, periodically, fall off the handling tools during source transfers. However, compared to the overall number of well-logging operations, these incidents are infrequent and when they do occur, the logging crews usually identify the fact that the source has become detached, and recovery of the source is accomplished quickly and safely.

Although the number of incidents where loss of control occurs may be small in comparison to the total number of successful source transfers accomplished each day by well-logging licensees, the potential for unnecessary exposures, and of exposures exceeding NRC's dose limit to members of the public, is high whenever such an event occurs. The inspection disclosed that the licensee had experienced several additional instances similar to the May 2002 event, in which logging personnel failed to identify when sources were improperly transferred to their shielded containers and loss of control occurred. In at least two of the instances, oil/gas rig workers were inadvertently exposed to radiation. In each instance a contributing cause regarding the loss of control and exposure events was the failure of licensee personnel to perform an adequate survey of source shields (transport containers) and/or the source transfer area, before leaving the site.

Examples of events the licensee experienced during the past 15 years in NRC and Agreement State jurisdictions are described below. A contributing cause in each of these events was the failure of the logging crew to perform a radiation survey of the source container or well area before leaving the site.

- The May 2002 event involved the loss of control of a nominal 48-gigabecquerel (GBq) [1.3-curie (-Ci)] Cs-137, source which was left unshielded on the rig floor. This incident resulted in 31 members of the public (drilling-rig workers) receiving unnecessary radiation exposures, 13 of whom received doses in excess of 1.0 mSv (100 mrem). The licensee's review of the incident determined that the logging engineer accidently pulled the source back out of the shield at the conclusion of the source-transfer procedure.
- In 2001, an event occurred involving the loss of control of a nominal 63 GBq (1.7 Ci) Cs-137 source which was left unshielded on the rig floor. This incident resulted in 16

members of the public (drilling-rig workers) receiving unnecessary radiation exposures, seven of whom received doses in excess of 1.0 mSv (100 mrem). The licensee's review of the incident determined that the logging engineer accidently pulled the source back out of the shield at the conclusion of the source-transfer procedure.

- In 1987, control of a nominal 592 GBq (16 Ci) americium-241 neutron source was lost when, after removing the source from the logging tool, the engineer placed the handling tool, with the source still attached, on the catwalk section of the drill rig and left the site. The source remained on the job site, unshielded, for approximately 1 day.

Discussion:

Although 10 CFR Part 39, "Licenses and Radiation Safety Requirements for Well Logging," does not specifically require that a licensee perform a radiation survey of source containers before leaving a temporary job site, 10 CFR 39.63 (c) does require licensees to develop and follow written operating procedures involving methods and occasions for conducting radiation surveys. Section 20.1302 of 10 CFR Part 20, "Standards for Protection Against Radiation," requires that a licensee perform adequate surveys to ensure compliance with the radiation dose limits for individual members of the public. In this regard, the inspection team noted that each well-logging licensee interviewed during the inspection did in fact have standard operating procedures in place requiring logging personnel to perform some type of confirmatory radiation survey, before leaving the well site, to confirm the proper transfer of sealed sources to their shielded containers. The inspection team also concluded that, for each of the events described above, if a radiation survey had been properly conducted, the logging crews would have been alerted to the fact that the sources were not properly shielded, thereby avoiding unnecessary exposures to members of the public (rig workers).

The regulations in 10 CFR 20.1802 require that licensees "... control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and not in storage." NRC considers a licensee's failure to secure or constantly maintain surveillance of licensed material a significant safety issue. Implementation of adequate oversight and control practices is intended, in part, to prevent: (1) inadvertent exposure of workers and members of the public to radioactive material; and (2) the loss or theft of licensed material. Because of NRC's concern over licensee failure to maintain control and constant surveillance of licensed material, such violations have normally been categorized in accordance with the "General Statement of Policy and Procedure for Enforcement Actions" (Enforcement Policy), NUREG-1600, at Severity Level III. Issuance of escalated enforcement for such actions may also subject licensees to a civil penalty and increased inspection effort.

Direct, Contributing, and Root Causes

In summary, the direct, contributing, and root causes for the May 2002 event are:

The direct cause of the event was the failure of a logging engineer to properly transfer the Cs-137 source to its storage container immediately after removal of the source from the logging tool. This led directly to the loss of control event, without any additional intervening actions.

Contributing causes of the event included: (1) the failure to perform appropriate radiation surveys; (2) a false indication by the source shield plug assembly; and (3) the failure to include a design specification for the cable attachment for the plug assembly.

It appears that the investigation of the similar events did not focus sufficient attention on why improper source transfers continue to happen, and why logging engineers failed to conduct proper radiation surveys.

The **root cause** of the event was the licensee's failure to investigate precursor events adequately, focusing primarily on the direct cause of events and not on factors that made recurrent events more probable. Consequently, the licensee's limited review of precursor events failed to prevent similar incidents from happening.

Although individual licensees are not required to take any specific action, they should consider

reviewing the contents of this IN with those responsible for well-logging source transfers, to reinforce the need and importance of confirming the proper transfer of sources from logging tools to their respective shielded transport containers, before leaving the well site.

ML040500336

NRC INFORMATION NOTICE 2005-27: LOW-DOSE-RATE MANUAL BRACHYTHERAPY-- EQUIPMENT-RELATED MEDICAL EVENTS

ADDRESSEES

All medical licensees.

PURPOSE

The U.S. Nuclear Regulatory Commission (NRC) is issuing this information notice (IN) to inform addressees of recently reported medical events that occurred during an NRC licensee's implementation of low-dose-rate (LDR) manual brachytherapy procedures. It is expected that recipients will review this information for applicability to their licensed operations and consider actions, as appropriate, to avoid similar problems. However, the information contained in this IN does not constitute new NRC requirements; therefore, no specific action nor written response is required.

DESCRIPTION OF CIRCUMSTANCES

On March 28, 2005, an NRC licensee reported to NRC its identification of two medical events involving radiation doses to unintended treatment sites of two patients. The licensee had administered LDR manual brachytherapy treatments to the patients in February and March 2004 and, during a subsequent review, licensee staff determined that the treatments had resulted in medical events, as defined in NRC's regulations. During a special NRC inspection conducted on March 30, 2005, to review the circumstances of the two medical events reported by the licensee, the inspector identified three additional patients who had treatments similar to those that resulted in the reported medical events. One of those additional patients exhibited observable side effects, as did the two patients involved in the medical events reported by the licensee. As a result, NRC upgraded the special inspection to an Augmented Inspection Team (AIT) on March 31, 2005. The purpose of the AIT was to examine the conditions and circumstances surrounding the medical events to determine the probable causes and contributing factors of the events.

The AIT concluded that five LDR manual brachytherapy treatments had resulted in medical events, as defined in Title 10 of the Code of Federal Regulations (CFR) Part 35. Three of the patients developed skin lesions on the upper thighs from radiation doses to the skin of the upper thighs, an unintended treatment site. The nature of the lesions indicated that the doses were greater than 1100 centigray (cGy) (1100 rads). The other two patients did not exhibit any unintended radiation effects. Therefore, those two patients received unintended doses to the thighs that were below the threshold for observable radiation effects. The AIT also determined that the **root cause** of these medical events was the licensee staff use of radioactive sources with smaller diameters than that specified in the instructions distributed with the brachytherapy applicator employed in all five cases. This error allowed the sources to move from their intended position within the applicator to a position that resulted in the unintended doses to the skin of the five patients.

The applicator involved in the five medical events was a Mick Radio-Nuclear Instruments, Inc. Wang Front-Loading Vaginal Applicator, Model 8524 (applicator), intended for use with cesium-137 sources, to treat patients. See the attached diagram of the Wang applicator. The instructions provided with the applicator specified the use of sources manufactured by the 3M Company (3M), and the applicator was marked with the appropriate source dimensions.

The applicator design allowed the sources to be inserted into the applicator after the applicator had been positioned in the patient for treatment (i.e., "afterloaded"), thereby reducing the radiation dose to brachytherapy staff. After the applicator was positioned within the patient, one of the sources was placed into a hinged insert, referred to as a "bucket," and subsequently positioned within the applicator, perpendicular to two sources to be positioned in the tandem portion of the applicator. The tandem sources were loaded into a closable flexible carrier tube, and a coil spring was inserted into the tube, to hold the sources in position. Once the loaded flexible carrier tube was closed, the tube was placed into the applicator.

During each of the first five brachytherapy treatments performed by the licensee with the Wang applicator, that resulted in medical events, licensee staff selected G.E. Healthcare (formerly known as Amersham; hereafter referred to as Amersham) sources for use in the tandem portion of the applicator. The Amersham sources were different in a critical dimension from the 3M sources specified in the instructions - they were too small in diameter, being 2.6 millimeter (mm) (0.10 inch) in diameter, when 3.1 mm (0.12 inch) diameter sources were specified. As a result, the tandem sources slid down to the opposite end of the applicator's flexible carrier tube whenever the applicator was tilted more than 20 degrees off-level (i.e., the tandem sources moved out of their intended position whenever a patient moved more than 20 degrees off-level (e.g., sat up) during treatment), resulting in irradiation of the skin on the patient's thighs. The Amersham sources moved through the center of the applicator's carrier tube spring because the diameter of the sources was smaller than the inner diameter of the coil spring.

The licensee became aware of the error in April 2004, after the authorized user observed effects during examinations of the three patients who exhibited skin injury. The authorized user requested that licensee staff investigate the possible cause of the injuries. During this investigation, licensee staff reviewed the instructions that came with the applicator, noticed that the instructions specified the use of 3M sources, recognized that the sources that had been used were Amersham sources, not 3M sources, and discovered the mobility of Amersham sources when used in the applicator's tandem source holder.

In April 2004, immediately after the licensee identified that the Amersham sources could change position in the Wang applicator's tandem source carrier tube during brachytherapy treatments, the licensee initiated actions to prevent similar unintended patient exposures. The licensee modified the applicator by using different hardware to keep the radioactive sources in proper position during brachytherapy treatments. The licensee's modification of the applicator was effective.1 However, the licensee misinterpreted the medical event reporting requirements in 10 CFR 35.3045(a)(3) and failed to promptly identify, in April 2004, that multiple medical events had occurred. Reporting of medical events (2) to NRC was delayed until March 2005, when, following patient reexaminations, the licensee determined that treatment side effects for two patients were more severe than previously observed.

DISCUSSION

NRC staff reviewed the instructions associated with use of the Wang applicator and identified several issues of generic concern that staff believes may result in improper use of the device. For example:

- Instructions explaining the use of alternate sources were not clear. Portions of the instructions provided with the applicator indicated that only 3M sources should be used with the applicator. However, other portions of the instructions indicated that the tandem portion of the applicator may be loaded with sources manufactured by other suppliers, and it referenced an attachment with source comparisons. The attachment was not clear regarding what other sources could be used (e.g., it did not indicate the source manufacturers' names or the technical limitations on source physical dimensions).
- Instructions explaining the proper configuration of sources were not clear. The instructions indicated that the applicator used three sources in a "T" configuration (e.g., one in the bucket and two in the tandem portion of the applicator). However, another section stated that up to four sources could be used in the tandem portion of the applicator.
- Instructions did not clearly alert the user to proper action that must be taken if the spring in the tandem portion of the applicator required shortening. The distal end of the applicator coil spring was designed with an inward bend, to prevent source movement down the center of the spring. The instructions stated that the applicator spring could be shortened. This would be necessary if more than two sources

were used in the tandem portion of the applicator. The instructions did not provide a warning to the user not to cut the distal end of the spring with the inward bend, if shortening of the spring was necessary. Such an action could result in source movement down the center of the spring.

The licensee had not used more than two sources in the tandem portion of the applicator for any of the five similar brachytherapy treatments completed. Therefore, the licensee did not cut the applicator spring. However, the spring supplied with the licensee's applicator did not include the inward bend at the distal end, which increased the potential for source movement under certain circumstances. The Amersham sources could, and did, for the five patients involved in medical events, move down the center of the spring to the opposite end of the tandem portion of the applicator when the patients undergoing treatment raised up from horizontal positions.

NRC referred the generic-concern issues of the applicator instructions and this licensee's experience with the applicator spring to the FDA for its review and evaluation. Presently, FDA's review and evaluation of these issues is in progress and has not been completed.

The medical events involved errors in selection of ancillary equipment--sealed radioactive sources--required for use of the afterloader applicator employed in the treatments, resulting in failure of the sealed sources to remain in their intended positions throughout the specified treatment times. Licensees performing LDR manual brachytherapy procedures are expected to review this IN and:

- Assure that radioactive sources and any other ancillary devices to be used with an LDR manual brachytherapy applicator for a therapeutic procedure are designed for use with, or are known to be compatible with, the LDR applicator to be used during the procedure;
- Assure that all LDR manual brachytherapy applicator users are familiar with the operating procedures and applicable usage restrictions of all equipment to be employed in a therapeutic procedure, before actual use of such devices, associated radioactive sources, and any other ancillary equipment;
- Encourage device and equipment users to review all vendors' pertinent documentation and clarify any concerns with the vendors, regarding particular devices, sources, or equipment, before the devices, sources, or equipment are used for patient treatments. Licensees are expected to clarify any uncertainties, discrepancies, or potential errors in usage directions provided in vendor-supplied documentation and/or through verbal discussion with a vendor or on-site vendor representative before use of the device(s), sources, or equipment; and
- Promptly report: 1) any and all medical events, to NRC; and 2) all equipment malfunctions or problems, to the vendors and, if required, to the licensing authorities.

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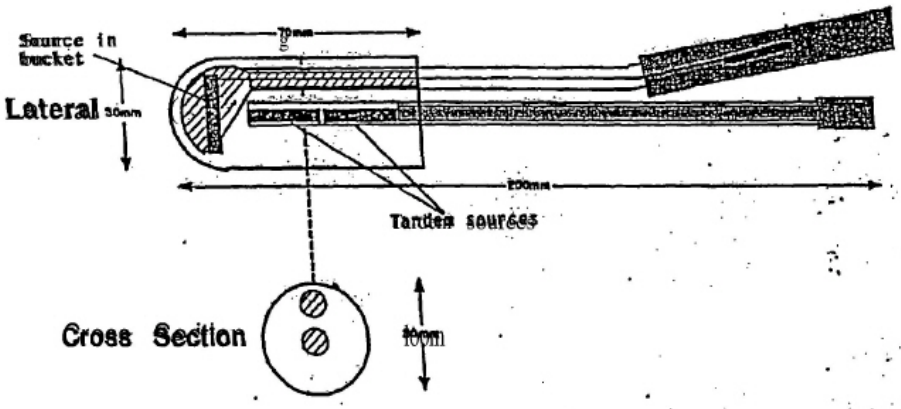

Attachment 1
IN 2005-27
Page 1 of 1

NRC INFORMATION NOTICE 2005-17: MANUAL BRACHYTHERAPY SOURCE JAMMING

ADDRESSEES

All medical licensees authorized to possess a Mick applicator.

PURPOSE

The U.S. Nuclear Regulatory Commission (NRC) is issuing this information notice (IN) to alert addressees to recently reported medical events with ruptured seeds that have occurred at different facilities during manual brachytherapy as a result of seed jamming. It is expected that recipients will review the information for applicability to their facilities and consider actions, as appropriate, to avoid similar problems. However, suggestions contained in this IN are not new NRC requirements; therefore, no specific action or written response is required.

DESCRIPTION OF CIRCUMSTANCES

NRC has received ten medical event reports in the last five years, two of them recently, involving the rupture of a jammed brachytherapy seed source while used in a Mick Radio-Nuclear Instruments, Inc. Model Mick Applicator. However, there may be more events with seeds containing accelerator-produced radioactive material that are not required to be reported to the NRC. In one of the ten incidents reported, during the prostate brachytherapy procedure, the cartridge containing seeds jammed in a Mick Applicator. When the licensee attempted to dislodge the seed from the applicator, the seed ruptured. This caused radioactive contamination to spread onto the applicator and surrounding surfaces. The applicator was placed in a plastic bag and stored behind lead shielding in the hot laboratory. This description is representative of all ten incidents.

Licensees' corrective actions included procedure modifications, such as changes in handling of the applicator and cartridge after the occurrence of a cartridge jam, and personnel training.

DISCUSSION

In the ten events over the past five years, the cause of the seed rupture was excessive force applied by the operator to the seed cartridge when trying to dislodge the jammed seed. The force of pulling the cartridge out with the seed jammed is large enough to shear the seed and cause contamination. The manufacturer, Mick Radio-Nuclear Instruments, Inc., is aware that seed jamming may occur and provides instructions in the User Manual to follow when attempting to dislodge the jammed seed. It is not apparent if the licensees involved in these events followed the recommended procedure for dislodging jammed seeds. Attempting to force the seed cartridge out of the applicator is contrary to the manufacturer's instructions. Mick Radio-Nuclear Instruments, Inc. recommends the following techniques to dislodge jammed seeds:

- Partially unscrew the head of the magazine (no more than one turn), thereby relieving the downward pressure on the seeds. Please note that the magazine head and the cartridge are NOT designed or intended to be taken apart. This is only done to relieve the spring pressure on the seeds. Carefully attempt to remove the magazine from the applicator.

- Flush the jammed seed out of the applicator using a light pressure water flush. This must be done over a collection pan situated such that all seeds are collected and accounted for.

    If the seeds cannot be removed safely, place the applicator in quarantine. The applicator must be surveyed (for radiation) to determine if the broken seed has contaminated the applicator.

    If contaminated, the applicator must remain in quarantine for a minimum

of 10 half-lives.

If clean, it is recommended that the applicator be returned to the manufacturer for evaluation and repair/adjustment.

(Source: Mick 200–TPV Applicator Instruction Manual, Pg.15A, Form #:405-06; Rev. E; 4/15/05)

The State of Wisconsin has also identified the recent seed ruptures and has issued an IN on the issue dated June 9, 2005. The Wisconsin IN is attached for your reference.

ML051780232

Enclosure 2

Discussion of Gamma Stereotactic Surgery Events 1 and 2

In Event 1, the licensee believed that the change in z-bar position was caused by two factors: (1) the large stature of the patient (mass); and (2) the "vigorous" movement of the patient's legs and torso (force-of-movement). However, historical evidence from the device manufacturer has shown that z-bar movement has only been observed when the associated screws were not properly tightened, or there was a lubricant on the z-bar. Although the patient movement in this case may have contributed to the medical event, the purpose of the head frame design and function is to keep the head from moving in spite of patient movement. The head frame essentially immobilizes the patient's head, limiting the patient's degree of upper body movement. For movement of a properly secured z-bar to occur, the patient would have to exert an extreme force on the head frame. Since the pins that secure the head frame to the patient's head are screwed directly into the patient's skull, the extreme amount of force that must be exerted to move the z-bar would be expected to also cause one or more of the pins to move. There was no indication that these pins moved during the "vigorous" movement. Also, 7 cm (2.8 inches) of z-bar slippage at one time would be expected to result in an observable reorientation of the patient, which should have prompted the licensee to stop the treatment and recheck the coordinates before continuing treatment. As stated earlier, the treatment was not interrupted, and the licensee claimed that there was no observable reorientation of the patient after the "vigorous" movement. The licensee's not noting observable patient reorientation, after the "vigorous"movement, is inconsistent with the licensee's belief that the patient's "vigorous" movement caused the 7-cm (2.8-inch) change in the z-axis coordinate.

This administration of radiation resulted in an unintended dose of 35 Sv (3500 rem), in an area of the brain that was 7 cm (2.8 inches) away from the intended treatment site, and the patient was expected to receive negligible dose in this area, which is distant from the treatment site. Therefore, NRC staff has concluded that the licensee should have reported this event, under §35.3045(a)(3).

At NRC's request, the licensee subsequently returned the z-bars to the manufacturer for testing. The manufacturer determined that the z-bars failed (slipped) at 50 percent of their designed locking force specification. After dismantling and thoroughly cleaning the z-bars, lubricating the locking screw and nut, and then reassembling the component, the z-bars functioned at 100 percent of their design specification. The manufacturer concluded that the slippage was caused by the reduced locking force of the z-bars, which was corrected by the manufacturer's dismantling, cleaning, and lubricating process. The licensee indicated that it "cleaned" the z-bars before sending them to the manufacturer. But the licensee's routine cleaning, which involves soaking the intact components, is not as rigorous as the "cleaning" performed by the manufacturer. The manufacturer revised its cleaning and lubricating instructions, but those instructions do not include the dismantling and rigorous cleaning performed by the manufacturer.

In Event 2, the licensee believed that the patient's cough caused the movement of the left anterior pin. An article from the 2002 Journal of Neurosurgery that the licensee provided to NRC, confirms that the three-pin technique the licensee used does not provide the same level of immobility as the four-pin procedure. The manufacturer of the Gamma Knife offers a number of different size screws and posts to permit repositioning of the patient's head within the head frame, if it appears a collision will occur. The manufacturer has also designed a front piece, specifically for a three-pin technique, that more evenly spaces the attachment pins and distributes the forces on the pins around the skull. Further, historical evidence from the manufacturer has shown that the attachment pins will move when the screws are not properly tightened into the table of the skull. Movement of improperly tightened screws is also more likely to happen in certain screw positions (e.g., when the screws are not positioned almost perpendicularly to the tangential skull plane). Additionally, a loose screw may not be apparent until the patient has gone through a number of preparation steps, such as pre-treatment imaging or other movements that put dynamic stresses on the pin-skull interface. The movement is usually detected by the presence of blood, caused as the sharp pin moves from its initial location. The licensee's failure to retighten the three remaining screws may have contributed to the pin slippage; the angle of the screws and positioning of the head frame medially, to accommodate the patient's head size, may have also contributed to the slippage.

The licensee in this medical use occurrence did not provide sufficient evidence to justify the claim of "patient intervention." Specifically, the licensee did not provide sufficient evidence to exclude improper tightening of the left anterior pin once the right anterior pin was removed or to demonstrate that the three-pin technique used would provide the same immobilization provided by either use of the fourth pin or equipment designed by the manufacturer specifically for a three-pin head frame attachment. As noted previously, §35.3045 (a)(3) requires a license to report any event (except for an event that results from patient intervention) where the administration of byproduct material, or radiation from byproduct material, results in a dose to the skin, or an organ or tissue other than the treatment site, that exceeds by 0.5 Sv (50 rem) or more, and 50 percent or more, the dose to the skin, or organ or tissue other than the treatment site, that was expected from the administration

defined in the written directive. Based on the licensee's initial assessment, this administration resulted in an unintended dose of 7.6 Sv (760 rem) in an area of the brain that was 6 mm (0.24 inches) away from the intended treatment site and was expected to receive approximately 2.6 Sv (260 rem). Therefore, at the time of the licensee's initial assessment, the licensee should have reported this event under §35.3045(a)(3).

Subsequent to NRC's determination that the administration was a reportable medical event, the licensee provided additional information that corrected errors in earlier information, concerning the location of the unintended site and the dose to that site. The new information more accurately set the time of the head frame slippage to halfway through the 11th exposure. This reduced the estimated dose to the unintended site to 2.5 Sv (250 rem). The licensee also corrected the location of the unintended site to the 30 percent isodose line, and not the 10 percent isodose line, as previously reported. The result of these corrections is that the event is no longer considered a reportable medical event, under §35.3045(a)(3), because the additional dose to the unintended site was 32 percent of the dose to that site (7.8 Sv, or 780 rem) expected from the administration defined in the written directive, which is less than the 50 percent threshold for reporting a medical event under this criterion. However, the event is included in the IN because the additional information the licensee subsequently provided did not change NRC's conclusion that the event was not the result of patient intervention.

NRC INFORMATION NOTICE 2006-11: APPLICABILITY OF PATIENT INTERVENTION IN DETERMINING MEDICAL EVENTS FOR GAMMA STEREOTACTIC RADIOSURGERY AND OTHER THERAPY PROCEDURES

ADDRESSEES

All medical licensees.

PURPOSE

The U.S. Nuclear Regulatory Commission (NRC) is issuing this information notice (IN) to inform addressees of an NRC concern that has arisen, regarding licensees assessing the contribution of patient activities to errors, in medical administrations, when determining whether the events constitute reportable medical events under 10 CFR 35.3045, "Report and notification of a medical event." It is expected that recipients will review this information for general applicability to all their licensed medical use operations and consider actions, as appropriate, to avoid similar problems. The information contained in this IN does not constitute new NRC requirements; therefore, no specific action or written response is required.

DESCRIPTION OF CIRCUMSTANCES

Event 1

During a routine inspection of an NRC medical use licensee, NRC inspectors discovered records of a medical administration involving the licensee's gamma stereotactic radiosurgery (Gamma KnifeÂ®) unit that should have been reported as a medical event under §35.3045. Specifically, following a Gamma Knife treatment, the licensee noted that the z-axis (up and down) coordinate of the head frame had been displaced 7 centimeters (cm) (2.8 inches) during the course of treatment. The x- and y-coordinates, however, had remained unchanged. The licensee believed the misalignment occurred when the patient moved "vigorously" more than half way through the procedure. The misalignment of the z-axis coordinate of the head frame resulted in an estimated absorbed dose of 35 Gray (Gy) (3500 rads) [or 35 Sievert (Sv) (3500 rem) dose equivalent] to an unintended site--a dose that was greater than 50 percent of the dose expected to that unintended site from the administration defined in the written directive.

The patient had complained of discomfort and back pain and had asked attending staff if he could move his legs to a more comfortable position. Permission was granted to move "a little," but the licensee noted that the patient moved "vigorously." This occurred approximately 30 minutes into a 51-minute treatment. Although the patient moved "vigorously," treatment continued until completion of the procedure. The licensee stated that there had been no observable reorientation of the patient in the Gamma Knife after the movement and that no permanent functional damage to the patient had occurred from the dose delivered to the wrong site, after the movement of the z-axis coordinate. The latter conclusion was based on the licensee's analysis of subsequent magnetic resonance images.

The licensee inspected the head frame and stated that there was no observable damage to the z-bar, which controls the positioning of the z-axis coordinate. As a **corrective action**, the licensee replaced the z-bars for that particular head frame. Although the z-bars were removed from service, the licensee did not return them to the manufacturer for component failure evaluation. Other corrective actions taken or planned included: (1) upgrading to the Model C head frame with Automatic Positioning System; (2) instructing patients not to move; and (3) increasing monitoring of patients during treatments that last 30 minutes or longer.

The licensee believed that the 7-cm (2.8-inch) change in the z-axis coordinate was caused by the patient's "vigorous" movement. Accordingly, the licensee believed that the patient's movement qualified as "patient intervention." Since the licensee also determined that the dose delivered to the wrong site had not resulted in permanent functional damage, the licensee concluded that the criteria for reporting an event, in §35.3045(b), had not been met, so the

event was not reported to NRC. NRC, however, concluded that this occurrence should have been reported under §35.3045.

Event 2

During a routine inspection of another NRC medical use licensee, NRC inspectors discovered records of a medical administration, involving the licensee's Gamma Knife unit, that also should have been reported as a medical event, under §35.3045. Specifically, after an 11-exposure Gamma Knife treatment, the licensee noted that the left anterior pin attaching the head frame to the patient's head had been displaced laterally, resulting in a shifting of the isocenter an estimated 6 millimeters (mm) (0.24 inches) during the course of the treatment. The licensee initially believed that the movement of the head frame occurred when the patient coughed at the start of the 11th exposure. The movement of the head frame resulted in a licensee initially estimated additional absorbed dose of approximately 5 Gy (500 rads), or an additional dose equivalent of approximately 5 Sv (500 rem), to an unintended site. This movement resulted in a licensee initially estimated total absorbed dose of approximately 7.6 Gy (760 rads), or a dose equivalent of approximately 7.6 Sv (760 rem), to an unintended site, which was greater than 50 percent above the approximately 2.6 Gray (260 rads) absorbed dose [or 2.6 Sv (260 rem) dose equivalent] expected to that unintended site from the administration defined in the written directive.

In a standard Gamma Knife procedure, the head frame is secured to the patient's head using four sharp pins screwed in place and tightened sufficiently to embed the point of the pin into the table of the patient's skull. During patient preparation, the neurosurgical team performed physical tests and measurements to determine if there would be collisions between either the patient's head or frame and the collimator helmet. In this specific case, there would have been a collision with the right anterior pin, and the licensee made a decision to remove this pin and proceed with the Gamma Knife procedure, using only three pins (three-pin technique). The licensee indicated that after the other three pins were tightened, the right anterior pin was removed.

The procedure then continued without event until the final 11th exposure, when the patient coughed, initially reported as occurring at the beginning of the exposure. It was not until after the treatment was completed and the patient was removed from the unit that the staff noted the patient was bleeding because the left anterior pin had moved from its original position.

The licensee determined the shift of the head frame from the movement of the pin from its original position on the skull. From this observation, the licensee estimated the isocenter shifted laterally by 6 mm (0.24 inches) and reviewed earlier magnetic resonance images to approximate the location of the new isocenter and the wrong treatment site. Based on this analysis, the licensee believed the location of the isocenter for the misdirected final exposure was inside the auditory canal.

As corrective action, the licensee initially prohibited use of the three-pin technique for Gamma Knife treatments. No other corrective actions were initially taken or planned. In later discussion with NRC staff, the licensee indicated it was reevaluating its prohibition of the three-pin technique.

The licensee believed that the movement of the left anterior pin was caused by the patient's cough, and that the patient's coughing movement constituted "patient intervention." The licensee's staff concluded that there was "...no harm" to the patient, since the patient received almost the complete dose to the treatment site, and the wrong treatment site for the one exposure was in the auditory canal, which did not result in permanent functional damage. The licensee therefore believed that the criteria for reporting an event, in §35.3045(b), had not been met, so the event was not reported to NRC. NRC, however, concluded that this occurrence should have been reported, under §35.3045.

DISCUSSION

In each of the two events discussed, the licensee asserted that the patient's movement

constituted "patient intervention." Each licensee also decided that each event was not reportable, because §35.3045(b) only requires reporting of an event resulting from intervention of a patient "...in which the administration of byproduct material or radiation from byproduct material results or will result in unintended permanent functional damage to an organ or physiological system, as determined by a physician," and this condition did not occur. However, NRC concluded that neither licensee provided sufficient evidence to exclude equipment setup as the cause of its medical event, rather than patient movement. Therefore, NRC concluded that these occurrences should have been reported to NRC as medical events, under §35.3045(a)(3). This, in part, requires that the licensee report any event (except for an event that results from patient intervention) in which the administration of byproduct material, or radiation from byproduct material, results in a dose to the skin, or to an organ or tissue other than the treatment site, that exceeds by 0.5 Sv (50 rem) or more, and 50 percent or more, of the dose to the skin, or organ or tissue other than the treatment site, that was expected from the administration defined in the written directive. See Enclosure 1 for discussion of these two Gamma Knife events.

For each of these events, the licensee's corrective actions are silent about stopping treatments when a patient moves, in order to ensure that the movement did not result in patient position changes that could result in a medical event. In fact, the licensee for Event 1, through one of its corrective measures, implies that it is unnecessary for it to increase patient monitoring during treatments that last less than 30 minutes.

As a measure for prevention of patient movement during Gamma Knife treatment, a licensee could respond to a patient's expression of discomfort by: (1) halting the treatment; (2) assisting the patient in moving to become comfortable; (3) checking the head frame for correct positioning; and (4) then resuming the treatment. We also believe that, as a potentially corrective measure, regardless of the treatment time, a licensee authorized for Gamma Knife treatments, or other high dose-rate treatments, should monitor the patient and stop the treatment when a patient moves, in order to ensure that the movement did not result in a patient position change that could result in a medical event.

The licensees believed that both of these Gamma Knife events resulted from patient intervention. However, NRC views these as resulting primarily from patient equipment setup. Similarly, incorrect decisions as to causes of events when patient actions are involved have also been made by medical use licensees employing other treatment modalities, such as temporary implant brachytherapy. Medical use licensees employing any treatment modality in which patient actions may potentially interfere with licensees properly implementing physicians' intentions, as expressed in prescribed doses or dosages, should be aware that patient movement or other involvement in an occurrence or event alone is not sufficient to rule out the need to report the occurrence as a medical event. NRC's position is that a medical event has occurred, even when the occurrence had patient movement or other involvement, if the licensee has not followed appropriate preventative and corrective procedures for usage, and if the criteria specified in §35.3045(a) or (b) are met.

Medical use licensees should review this IN and consider whether their procedures for use are in accordance with the following recommended actions:

- Monitor patient and/or source placement at reasonable frequencies;
- Correctly identify patient and/or source displacement during monitoring;
- Take prompt and appropriate actions should patient and/or source displacement occur;
- Have trained personnel present or available to prevent or mitigate patient actions during usage procedures that may impact treatment;
- Promptly report all medical events to NRC; and
- Promptly report all equipment malfunctions or problems to the vendors and, if required, to NRC (under 10 CFR 21.21 or Â§30.50(b)(2)) and the device licensing authorities (NRC or Agreement States).

NRC INFORMATION NOTICE 2007-03: REPORTABLE MEDICAL EVENTS INVOLVING PATIENTS RECEIVING DOSAGES OF SODIUM IODIDE IODINE-131 LESS THAN THE PRESCRIBED DOSAGE BECAUSE OF CAPSULES REMAINING IN VIALS AFTER ADMINISTRATION

ADDRESSEES

All U.S. Nuclear Regulatory Commission (NRC) medical use licensees and NRC Master Materials Licensees. All Agreement State Radiation Control Program Directors and State Liaison Officers.

PURPOSE

NRC is issuing this information notice (IN) to alert addressees about events in which patients were administered dosages of sodium iodide, iodine-131 (I-131) that were less than the prescribed dosages, because of sodium iodide I-131 capsules that remained in vials, containing multiple capsules, after administration. These occurrences resulted in medical events because the patients did not receive the prescribed dosages. It is expected that recipients will review the information for applicability to their facilities and consider actions, as appropriate, to avoid similar problems. However, suggestions contained in this IN are not new NRC requirements; therefore, no specific action or written response is required. NRC is providing this IN to the Agreement States for their information and for distribution to their medical licensees as appropriate.

DESCRIPTION OF CIRCUMSTANCES

In September 2006, one licensee performed administrations incorrectly on two separate occasions. In each case, only one sodium iodide I-131 capsule was administered to the patient, rather than the two capsules containing the total dose. Consequently, the patients did not receive the dosages prescribed in the written directives. Before these events, the licensee had received the total prescribed dose of I-131 in a single capsule. In the case of these two events, instead of the expected single capsule, the commercial radiopharmacy dispensed two capsules containing the prescribed dose. The licensee measured the radioactivity in each vial containing capsules, before administration, to ensure the proper dosage amount. When the content of each of the vials was emptied, for administration, one of the two capsules remained in the vial. Each vial was placed back into its shipping container and returned to the pharmacy. Each of the two patients was released, having received only a portion of the prescribed dosage.

Over the last 10 years, there have been 12 reported events of this type (i.e., events in which patients were administered dosages of sodium iodide I-131 that were less than the prescribed dosages, because capsules remained in vials after administration). In some of these cases, the patients were administered one of multiple capsules contained in a single vial. In other cases, patients were administered two of three capsules, where two capsules were placed in one vial by the commercial pharmacy, and the third capsule was placed in a separate vial.

There were a few instances where the errors were discovered shortly after the patients had been released, and the patients returned to the licensees to receive the remaining portions of the prescribed dosages. Notwithstanding that in these cases the patients returned to receive the remaining portions of the prescribed dosages, NRC concludes that the total dose, for purposes of determining whether the medical event reporting criteria had been met, is the dose received by the patients at the time when they were released from the licensee's control (i.e., following administration of the first capsule). Since, at the time of the patients' release, the delivered dosages differed from the prescribed dosages by more than 20 percent and the thyroid dose reductions resulting from the reduced dosages exceeded the 0.5 sieverts

(50 rem) to an organ, the events required reporting as medical events under 10 CFR 35.3045(a)(1)(ii).

DISCUSSION

NRC regulations, in 10 CFR 35.63, do not require licensees to perform a direct measurement of a unit dosage in a dose calibrator before administration, if the unit dosage is corrected for decay based on the activity determined by an appropriately licensed manufacturer, preparer or licensee (e.g., commercial pharmacy). However, as a measure for prevention of these types of medical events, a licensee could assay the vial containing I-131 capsules, after administration of the dosage, to assure that no capsules remain in the vial. To keep occupational doses as low as reasonably achievable, assay measurement of the vial post-administration is preferred over visual verification of the content of the vial.

Precautions can also be taken before administration, and include reviewing the packing slip before administration, to verify the number of capsules shipped by the pharmacy. Further, assaying the activity before administration could identify that the total dose was not in the vial and that missing capsule(s) may, for example, have been placed in another vial of the shipment.

Besides resulting in a medical event, another negative consequence of a capsule remaining in a vial is that the licensee may incorrectly mark and label the vial for transport back to the commercial radiopharmacy. For example, the vial may be placed back into the original container and shipped back to the commercial pharmacy with the marking and labeling of a package that is assumed to be empty, when in fact, it is not. This could result in a violation of the requirements in 10 CFR 71.5, “Transportation of Licensed Material.” Another example of an adverse consequence of a capsule remaining in the vial is that this might result in the inadvertent disposal of the vial containing I-131 in “non-radioactive” waste. This could lead to a violation of the requirements for waste disposal, or the requirements for storage and control of licensed material in 10 CFR Part 20, “Standards for Protection Against Radiation.”

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NRC INFORMATION NOTICE 2007-10: YTTRIUM-90 THERASPHERES AND SIRSPHERES IMPURITIES

ADDRESSEES

All U.S. Nuclear Regulatory Commission (NRC) Medical Licensees and NRC Master Materials Licensees. All Agreement State Radiation Control Program Directors and State Liaison Officers.

PURPOSE

The NRC is issuing this Information Notice (IN) to alert addressees to the presence ofradioactive contaminants in two variations of commercially available Yttrium-90 (Y-90) labeled microspheres, SIRSpheres® and "TheraSpheres®," manufactured by Sirtex Medical, Inc. and MDS Nordion, respectively and the possible problems with their disposal in accordance with 10 CFR 35.92. Recipients should review the information, contained in this IN, for applicability to their facilities, and consider actions, as appropriate. However, recommendations contained in this IN are not new NRC requirements; therefore, no specific action nor written response is required.

NRC is providing this IN to the Agreement States for their information, and for distribution to their medical use licensees, as appropriate.

BACKGROUND

TheraSpheres® and SIRSpheres® are therapeutic devices that deliver radiation directly to tumors in the liver, using glass or resin microspheres. Y-90 is either integrated into the glass matrix or attached to the resin beads with diameters from 15 to 35 microns (μ). Millions of these microspheres are injected into the hepatic artery, the liver's main blood vessel, in a manner that preferentially traps them in the capillary bed feeding the tumor, and not the larger blood vessels feeding healthy tissues. The SIRSpheres® and TheraSpheres® are designed to deliver radiation directly to tumors, while sparing healthy tissues.

DESCRIPTION OF CIRCUMSTANCES

On March 20, 2006, the staff at the Vanderbilt University, Department of Radiology and Radiological Science, informed NRC's Operation Center of its discovery of the presence of radioactive contaminants in SIRSpheres® and TheraSpheres®. As a follow-up, on March 21, 2006, Vanderbilt University staff, in a letter to the Radiological Devices Branch of the U.S. Food and Drug Administration (FDA), explained that they detected contaminants in the samples by using a high-purity germanium detector.

The Y-90 SIRSpheres® sample contained detectable amounts of Yttrium-88 (Y-88), with a half-life of 106.6 days and the TheraSpheres® sample had measurable amounts of the following radionuclides: Y-88; Europium-154 (half-life 8.8 years); Europium-152 (half-life 13.6 years); Cobalt-57 (half-life 270.9 days); and Cobalt-60 (half-life 5.27 years). It is important to note that only one sample from each device was analyzed. Further characterization of radioactive levels in more samples may yield more accurate results.

DISCUSSION

The main reason the Vanderbilt University, Department of Radiology and Radiological Science reported this issue, to both NRC and FDA, was because the samples of TheraSpheres®, held for decay-in-storage, appeared to be radioactive for much longer than would have been expected, because of the presence of Y-88 and other contaminants.

The staff at the Vanderbilt University, Department of Radiology and Radiological Science performed a preliminary evaluation of the radiation dose that might be delivered to the liver of an adult, assuming 100 percent of the activity of the microspheres containing contaminants was distributed uniformly in the liver and was removed only by physical decay. Based on this evaluation, the dose to the liver from the contaminants did not exceed the medical event limit,

i.e., the dose delivered did not differ from the prescribed dose by 20 percent or more, and did not differ from the prescribed dose by more than 0.5 Sv (50 rem) to an organ. However, licensees should be concerned with disposal of microspheres. Depending on the contaminants, licensees may need to: (1) hold the remaining microspheres longer in decay-in-storage, in accordance with 10 FR 35.92; (2) return the microspheres to the manufacturer; or (3) transfer to an authorized recipient according to 10 CFR 20.2006.

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NRC INFORMATION NOTICE 2007-35: VARIAN MEDICAL SYSTEMS VARISOURCE HDR EVENTS: IRIDIUM-192 SOURCE PULLED FROM SHIELDED POSITION

ADDRESSEES

All U.S. Nuclear Regulatory Commission (NRC) medical use licensees and NRC Master Materials Licensees authorized to possess or use a Varian Medical Systems VariSource High Dose Rate Remote Afterloader (VariSource HDR). All Agreement State Radiation Control Program Directors and State Liaison Officers.

PURPOSE

The NRC is issuing this information notice (IN) to alert addressees to recently reported events where the use of the emergency manual retract hand wheel on the VariSource HDR has caused the active iridium-192 (Ir-192) source to be pulled out of the shielded position. It is expected that recipients will review the information for applicability to their facilities and consider actions, as appropriate, to avoid similar problems. However, suggestions contained in this IN are not new NRC requirements; therefore, no specific action or written response is required.

NRC is providing this IN to the Agreement States for their information, and for distribution to their medical use licensees, as appropriate.

DESCRIPTION OF CIRCUMSTANCES

NRC has received four event reports in the last three years, two of them recently, involving the VariSource HDR Ir-192 source having been pulled out of the shielded position, while using the manual retract hand wheel. The four events occurred in a range of different situations, two occurred during clinical use of the afterloader, one occurred during routine QA/QC checks, and the other occurred during student training. In one of the four incidents reported, while the patient treatment was being planned, the wire containing the dummy (non-radioactive) source did not return during pre-treatment preparations. The manual retract hand wheel, which is intended only for the wire containing the radioactive source and not for the dummy source, was used by the physicist in an attempt to retract the dummy source. However, when the physicist turned the hand wheel, the active source was pulled out of the tungsten safe. Two of the events occurred when the operator of the VariSource HDR attempted to retract a "stuck" dummy source with the manual retract hand wheel. Their attempt to manually retract the dummy source caused the active Ir-192 source to be pulled out of the tungsten safe. The remaining event occurred during a training exercise when an instructor asked four students to simulate using the manual retract hand wheel, however, two of the students actually turned the hand wheel and caused the active Ir-192 source to be pulled out of the tungsten safe.

DISCUSSION

Three of the four events occurred because the operators used the manual retract hand wheel in an attempt to retract the dummy source back into the VariSource HDR unit. The fourth event occurred during a training session. The warning label on the manual retract hand wheel reads "Warning – Active Source Wire Emergency Retract only. Turn the hand wheel for a maximum of 12 turns or until the radiation alarm ceases. Contact Varian Service." Varian filed an initial notification dated September 17, 2007, with NRC in accordance with 10 CFR 21.21, following the latest event on July 15, 2007. The report delineated the event and the design characteristics of the VariSource HDR unit for safe use.

While potential long-term solutions are being considered, licensees should be aware that consequences of the active Ir-192 source being pulled out of the tungsten safe would result in the following:

1. The source would be contained within the unit, but would be unshielded and could not be returned to the shielded position.
2. The exposure rate for a 10 Curie Ir-192 source that has been pulled out of the tungsten

safe would have an exposure rate of 18 R/hr at 50 cm.

3. A recovery operation would be needed to retrieve and secure the source.
4. Treatments could not resume until a new source wire is installed.

This IN serves as a reminder that the manual retract hand wheel on the VariSource HDR units is intended only for the wire containing the Ir-192 source. The manual retract hand wheel does not retract the dummy source. In the event that the dummy source is stuck in the out position, the console displays Error Code 88. The operators should consult the operator's manual provided by Varian Medical Systems and contact Varian Service. Licensees should also read Varian's Customer Technical Bulletin (CTB) VS-366A, "Clarification on the Use of the Emergency Retract Hand Wheel to Prevent Accidental Exposure". The CTB is available at the following website:

www.varian.com/shared/oncy/pdf/CTB-VS-366a.pdf

In addition, in the event of an emergency where an operator needs to use the manual retract hand wheel to return the active Ir-192 source to the shielded position, operators should be aware that the number of turns necessary to return the source to the tungsten safe may vary. The number of turns may vary depending on how extended the source is initially and on any potential for slippage between the pinch rollers and the source wire, especially with a freshly lubricated source wire. The VariSource HDR units are designed in such a manner that the operator only knows if the source has returned to the shielded position when the audible radiation alarms and red light indicator turn off. Operators should be aware that if the manual retract hand wheel is turned too many times the active Ir-192 source can be pulled out of the tungsten safe. The unit was not designed to have a positive lock to prevent the source from being pulled out of the tungsten safe or to indicate that the source is in the shielded position.

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NRC INFORMATION NOTICE 2007-38: ENSURING COMPLETE AND ACCURATE INFORMATION IN THE DOCUMENTATION OF TRAINING AND EXPERIENCE FOR INDIVIDUALS SEEKING APPROVAL AS MEDICAL AUTHORIZED USERS

ADDRESSEES

All U.S. Nuclear Regulatory Commission (NRC) medical use licensees and NRC master materials licensees. All Agreement State Radiation Control Program Directors and State Liaison Officers.

PURPOSE

The NRC is issuing this information notice (IN) to inform addressees of the importance of verifying the completeness and accuracy of information provided by individuals seeking authorization for medical use from the NRC under the alternate pathway. Approval under the alternate pathway is based on an evaluation of an individual's training and experience against the requirements specified in Title 10 of the Code of Federal Regulations Part 35, "Medical Use of Byproduct Material," (10 CFR Part 35) for the particular authorization being sought.

Recipients should review the information for applicability to their facilities and consider actions, as appropriate, to ensure the completeness and accuracy of the information provided in support of individuals seeking authorization under the alternate pathway. However, suggestions contained in this IN are not new NRC requirements; therefore, no specific action or written response is required. The NRC is providing this IN to the Agreement States for their information and for distribution to their medical licensees as appropriate.

DESCRIPTION OF CIRCUMSTANCES

Recently, NRC has identified several instances where licensees have provided documentation of training and experience for proposed authorized individuals (i.e., physician authorized users (AUs) or authorized medical physicists (AMPs)) that contained false or inaccurate information. In each case, the proposed authorized individuals sought authorization by the alternate pathway.

In the first case, a licensee submitted an amendment request to add a number of medical physicists to its license as AMPs and included a preceptor statement for a Junior Medical Physicist who was seeking authorization under the alternate pathway. An AMP who was listed on the licensee's license completed the Junior Physicist's preceptor statement. Based on an investigation by the NRC Office of Investigations (OI), the NRC determined that the preceptor statement was inaccurate in that it documented dates of clinical training that exceeded the dates of actual training received by the Junior Medical Physicist. The NRC concluded that the actions of the preceptor AMP were deliberate, in that he knew that the preceptor statement was inaccurate at the time it was submitted to the licensee and then subsequently to the NRC. The licensee is responsible for the acts and omissions of its employees and contractors and their employees, and thus the agency determined that the submission of the inaccurate information by the licensee to the NRC was a deliberate violation of 10 CFR 30.9(a). This section of the regulations requires, in part, that information provided to the Commission by a licensee or an applicant for a license shall be complete and accurate in all material respects. As a result, the NRC cited the licensee for a Severity Level III violation of 10 CFR 30.9(a) and levied a civil penalty of $3,250.00. Severity Level III violations are causes for significant regulatory concern. Furthermore, the NRC determined that the AMP, who was a contractor or employee of the licensee, deliberately provided inaccurate information to the licensee that caused the licensee to violate NRC regulations. Therefore, the agency issued the AMP a Severity Level III Notice of Violation for violation of 10 CFR 30.10, Deliberate misconduct. This regulation requires, in part, that an employee, contractor (including a consultant or supplier), or subcontractor of a licensee or applicant for a license may not engage in deliberate misconduct

that causes a licensee or applicant for a license to violate any requirement, and may not deliberately submit to the NRC, the licensee, or the license applicant, information that the person submitting the information knows to be incomplete or inaccurate in some respect material to the NRC.

In the second case, involving the same AMP and Junior Medical Physicist and the same inaccurate preceptor statement, a different licensee submitted an amendment request to add the Junior Medical Physicist to its license. However, in this case, before submitting the amendment request to the NRC, the licensee's Radiation Safety Officer (RSO) conducted interviews with the AMP and the Junior Medical Physicist in an attempt to verify the accuracy of the information contained in the preceptor statement. Both the AMP and the Junior Medical Physicist informed the RSO that the information in the preceptor statement was accurate. The licensee subsequently submitted the amendment request with the inaccurate preceptor statement. As in the first case, the NRC concluded that the actions of the AMP and the Junior Medical Physicist were deliberate. However, because the licensee's RSO did attempt to verify the accuracy of the information contained in the preceptor statement by interviewing both individuals, before submitting it to the NRC, the agency classified the violation of 10 CFR 30.9(a) as a Severity Level IV violation and did not propose a civil penalty. Severity Level IV violations are less significant than Severity Level III violations. The NRC determined that the AMP and the Junior Medical Physicist, who were both contractors or employees of a licensee, deliberately provided materially inaccurate information to the licensee and caused the licensee to violate 10 CFR 30.9(a). The AMP and the Junior Physicist both received Severity Level III Notices of Violation for violation of 10 CFR 30.10.

In the third case, a diagnostic nuclear medicine licensee provided a proposed AU with a copy of a sample preceptor letter that contained blank spaces to be completed by the proposed AU and a preceptor AU. The blank spaces were for the documentation of the number of hours of supervised clinical and work experience in diagnostic nuclear medicine received by the proposed AU and for the signature of the supervising preceptor AU. The blank spaces of the preceptor letter were filled in, the letter was signed by the preceptor AU and the proposed AU, and the letter was returned to the licensee. The licensee did not question the authenticity or accuracy of the number of hours of supervised clinical and work experience identified in the preceptor letter. The licensee submitted a license amendment application to add the proposed AU to its license and included the preceptor letter as supporting documentation. The NRC approved the amendment and added the physician to the license as an AU. However, based on an OI investigation, the NRC determined that the preceptor letter was materially inaccurate. Specifically, the preceptor admitted to signing the letter without reading the details and acknowledged that the number of hours of supervised clinical work experience was inaccurate. As a result, the AU was subsequently removed from the license. The NRC issued separate Severity Level III Notices of Violation to the licensee and proposed AU for having violated 10 CFR 30.9(a).

DISCUSSION

In the first and third cases described above, the licensees did not fulfill their responsibility to take reasonable steps to verify that the proposed AU or AMP had actually received the training and experience claimed before submitting their license amendment applications to the NRC. NRC regulations in 10 CFR 30.9(a) require, in part, that information provided to the Commission by a licensee or applicant for a license shall be complete and accurate in all material respects. It is the licensee's and applicant's responsibility to ensure the completeness and accuracy of all information it provides to the NRC. Licensees and applicants for a license should consider contacting preceptors as well as training program directors and continuing medical education providers to verify that the training and experience submitted by proposed individuals (i.e., AUs, AMPs, authorized nuclear pharmacists and radiation safety officers) is accurate and commensurate with the training and experience required by the applicable sections of 10 CFR Part 35.

Whether or not a licensee is aware of the incompleteness or inaccuracy of the information it

submits to the NRC, a violation of 10 CFR 30.9, A Completeness and accuracy of information, @ occurs when inaccurate or incomplete information is submitted because licensees are responsible for the completeness and accuracy of the information they submit to the NRC. In addition, if the licensee willfully submits inaccurate or incomplete information to the NRC, or if inaccurate or incomplete information submitted to the NRC is determined to have been willfully supplied to the licensee by an employee, contractor, consultant, supplier, or subcontractor of the licensee, the licensee's violation of 10 CFR 30.9 may also be considered willful as the licensee is responsible for the conduct of its agents. Such violations will result in the consideration of escalated enforcement action against the licensee, including possible civil penalties. In addition, individuals who deliberately provide materially incomplete or inaccurate information to licensees or applicants for a license in connection with a submission to the NRC may be subject to NRC enforcement action under 10 CFR 30.10 and to criminal prosecution.

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HRA Resources

This section is under development.

CHAPTER 2 . EXPLANATION OF SOME BASIC TERMS

Overview

Although the glossary defines all the specialized terms used in the Handbook. this chapter elaborates on some that require additional discussion and presents the point of view taken by the authors in assessing the reliability of human performance in nuclear power plant (NPP) operations. The order of presentation of the terms in this chapter was chosen to facilitate their development:

- Human Factors Engineering, Human Engineering, Human Factors, And Ergonomics
- Man-Machine System and Interfaces
- NPP Personnel Addressed in the Handbook
- Displays, Manual Controls, and Written Materials
- Human Reliability
- Human Reliability Analysis
- Human Performance Models
- Performance Shaping Factors
- Stressors and Stress (Physiological and Psychological)
- Populational Stereotypes
- Dependence, Independence, and Coupling
- Human Error
- Consequences of Human Errors and Recovery Factors
- Types of NPP Operating Conditions Considered in HRA
- Unavailability Because of Human Error
- Types of NPP Tasks and Task Behaviors Addressed in HRA
- Task Taxonomy
- Task Analysis
- Error-Likely Situations and People
- Accident-Prone Situations and People
- Categories of Incorrect Human Outputs Related to HRA
- Human Error Probability
- Basic, Conditional, and Joint Probabilities
- Distribution of HEPs

Human Factors Engineering, Human Engineering, Human Factors, and Ergonomics

All of the above terms describe a discipline concerned with designing machines, operations, and work environments so that they match human capacities and limitations (Chapanis, 1965, p. 8). The first three terms are used most widely in the United States. The term "human engineering" is now falling into disuse by human factors practitioners since some persons have used it in the Procrustean sense of engineering humans, i.e., making people fit the environment--the antithesis of **human factors engineering**

. The last term, ergonomics, is used most frequently in other countries but is now becoming popular in the United States as well.

People working in the human factors area are often called human factors specialists, engineering psychologists, or ergonomists. The latter term is more common outside the United States. In the Handbook, these terms are interchangeable.

Man-Machine System and Interfaces

The term man-machine system denotes a system in which people have a monitoring and/or control function. The term man is used in the generic sense. The term man-machine interface refers to points of interaction between people and the system. Thus, a display, a control, written materials, or any other item a person observes or uses is a man-machine interface. Man-man interfaces refer specifically to person-to-person communication or other interaction; in the Handbook, the term man-machine interfaces includes man-man interfaces.

NPP Personnel Addressed in the Handbook

The Handbook emphasizes tasks performed by control room personnel, both licensed reactor operators and auxiliary reactor operators, and the shift technical advisor. This emphasis is dictated by the recognition that they represent the most important "man" aspect of the man-machine interfaces in NPPs of interest to probabilistic risk assessment (PRA). These personnel have many opportunities to commit errors that can result in an abnormal event, and their performance after the occurrence of such an event can either reduce or increase the consequences of the event. The Handbook also addresses errors in tasks performed by technicians who calibrate and test safety-related systems and components. Less emphasis is placed on tasks performed by maintenance personnel and by management personnel (except for shift supervisors, who are also reactor operators). Chapter 18 includes a discussion of the interaction of these personnel and their influence on tasks important for PRA.

In some chapters in the Handbook, the term operator is used to designate anyone who performs tasks that must be evaluated by the user of the Handbook. This generic use of the term "operator" is a conventional one in the human factors field.

Displays, Manual Controls, and Written Materials

A display is any instrument or device that presents information to any sense organ (visual, auditory, or other). In NPPs, displays are annunciated or unannunciated. Annunciated displays usually

consist of panels of legend indicators (often called tiles) that have auditory signals associated with them. Unannunciated displays in NPPs include meters, digital readouts, chart recorders, graphs, indicator lights, computer printouts, and video presentations.

Manual controls are those components with which the human enters his inputs to a system. Types of controls in NPPs include switches (rotary, toggle, and other), pushbuttons, levers, knobs, cranks, connectors, and tools. Manual controls may be continuous (e.g., a synchronization control or a potentiometer) or discrete, e.g., a two-position switch for a motor operated valve.

Three types of written materials are addressed in the Handbook: formal written procedures that may be used many times, ad hoc written procedures that are one-of-a-kind, informally prepared procedures for some special purpose, and written notes prepared in response to oral instructions. Since written materials direct the performance of people in a man-machine system, they are part of the man-machine interfaces in a system.

Human Reliability

Evans (1976) notes that the popular definitions of reliability and availability are as follows:

Reliability is the probability of successful performance of a mission.*

Availability is the probability that the system or component is available for use when needed.

Meister (1966) defines human reliability as "the probability that a job or task will successfully be completed by personnel at any required stage in system operation within a required minimum time (if the time requirement exists)." We borrow from Evans and Meister to define human reliability as the probability that a person (1) correctly performs some system-required activity in a required time period (if time is a limiting factor) and (2) performs no extraneous activity that can degrade the system.**

In the Handbook we use the term "reliability" in the above sense of "accuracy" rather than the conventional use by psychologists who use the term to indicate the consistency (repeatability) of some measure of human performance (English and English, 1958).

In other applications, other measures of human performance (e.g., interval or ordinal numbers) can be used to define human reliability, but in the Handbook, we use probabilities only.

Human Reliability Analysis

Human reliability analysis (HRA) is a method by which human reliability is estimated. In carrying out an HRA, it is necessary to identify those human actions that can have an effect on system reliability or availability. The most common application of HRA is the evaluation of human acts required in a system context. The consideration of extraneous actions is also important. The person in a system may not only fail to do what he is supposed to do, or fail to do it correctly, but he may also do something extraneous that could degrade the system. The latter is the weak link in HRA. It is not possible to anticipate all undesirable extraneous human actions. The best anyone can do is to identify those actions having the greatest potential for degrading system reliability and availability. The assignment of probability estimates to extraneous actions is difficult and uncertain. Often the best one can do is to estimate very broad ranges of probabilities of human errors that one believes include the true probability. Fortunately, the probabilities of extraneous actions are usually very low.

The method commonly used in solving practical human reliability problems is the one described in Chapter 5, known as THERP - Technique for Human Error Rate Prediction. Other HRA methods are described and compared in a series of reviews by Meister (1964, 1971, 1973, 1983a, b), Embrey (1976), Pew et al. (1977), and Swain (1964b). The HRA methodology in the Handbook is the THERP method. The estimates of probabilities of human errors and the modeling of human performance in the Handbook are amenable to any HRA technique.

Probabilistic Risk Assessment

In the Handbook, HRA is described in the context of a probabilistic risk assessment (PRA). As defined in the Zion Probabilistic Safety Study (1981, Vol. 1), a PRA is "a rigorous and systematic identification of the levels of damage that could conceivably result from NPP operation and a quantitative assessment of the likelihood of such occurrences." In HRA, we assess the effects of human errors in the assessments of risk in a PRA.

Human Performance Models

A model of a system is an abstraction that reproduces symbolically (simulates) the way in which the system functions operationally (Chapanis, 1961). In the Handbook, the term ' human performance model denotes a schematic representation or abstraction of human behavior in a system context. Our goal in modeling human performance for PRA is to develop descriptive models to predict (within wide limits) how well people will perform what they are

supposed to do in normal and abnormal situations in NPPs. For this limited purpose of modeling, it is sufficient to represent only a few of the limitless combinations of human and system characteristics. Estimated probabilities of human error are assigned to certain of these combinations in the human performance models in Part III of the Handbook.

Performance Shaping Factors

In modeling human performance for PRA, it is necessary to consider those factors that have the most effect on performance. Many factors affect human performance in such a complex man-machine system as an NPP. Some of these performance shaping factors (PSFs) are external to the person and some are internal. The external PSFs include the entire work environment, especially the equipment design and the written procedures or oral instructions. The internal PSFs represent the individual characteristics of the person--his skills, motivations, and the expectations that influence his performance. Psychological and physiological stresses result from a work environment in which the demands placed on the operator by the system do not conform to his capabilities and limitations.

To perform an HRA, an analyst must identify those PSFs that are most relevant and influential in the jobs studied. Chapter 3 discusses several of the PSFs that influence the reliability of NPP personnel. Chapter 4 presents a method to analyze required tasks to identify those PSFs relevant to HRA.

Sressors and Stress (Physiological and Psychological)

One of the most influential PSFs is **stress**. Montaigne, a French essayist of the late 1500s, noted, "Men under stress are fools, and fool themselves." This quotation reflects a commonly held view that stress is undesirable. In the Handbook, we consider stress to be the human response to a stressor, and note that the relationship between human performance and stress is curvilinear--too little stress and too much stress both lead to less-than-optimum performance. Some in-between level of stress is necessary to provide sufficient arousal to perform reliably.

The stressors are classified as psychological stressors and physiological stressors. The distinction is often arbitrary. Psychological stressors include task speed, distractions, monotonous work, threats from supervisors, and emergency situations. Physiological stressors include fatigue, discomfort, constriction of movement, and high temperature. Chapters 3 and 17 present discussions of stress and stressors, including the facilitative and disruptive aspects of stress.

For modeling of human performance, we represent the stress variable with four levels: very low (insufficient arousal to keep alert), optimum (the facilitative level), and two levels of high stress: moderately high (moderately disruptive), and extremely high (very disruptive). The first three levels are designated as task stress, which results from a very low task load, an optimum task load, or a heavy task load. The highest level represents threat stress and implies emotional reactions to the task situation.

Populational Stereotypes

Another strong PSF is the expectancy that certain groups of people have for certain modes of control activation, or modes of display presentation, outcomes, or meanings. Such expectancies are called populational stereotypes. For example, we strongly expect that when we turn a valve counterclockwise, water will begin to flow, and that flow will increase as the valve is turned further counterclockwise. On the other hand, when we rotate a volume control on a radio counterclockwise, we expect the volume to decrease. A populational stereotype that differs between cultures is related to the common two-position light switch. In the U.S., we expect the "UP" position of a light switch to turn the lights on. In Europe, the opposite populational stereotype holds. Cultural differences also exist for direction-of-reading stereotypes.

Any design that violates a strong populational stereotype means that the user must learn to inhibit his expectancies. Even with extensive training, it is difficult to change a populational stereotype completely. Under high stress levels, we tend to revert to our populational stereotypes despite training to the contrary.

Dependence, Independence, and Coupling

Dependence is another important PSF. Dependence between two tasks refers to the situation in which the probability of failure on one task is influenced by whether a success or failure occurred on the other task. The dependence may exist between two tasks performed by one person, or between the tasks performed by different persons. In WASH-1400, the term coupling was used and is still used by some PRA specialists. In the Handbook, we use the term dependence.

Complete dependence between two tasks means that if failure occurs on one, failure will occur on the other with certainty. Similarly, if success occurs on one task, success will occur on the other. The dependence may be negative, but for the usual situations, it will be positive.

Zero dependence (or independence) between two tasks means that the probability of failure or success on one task is the same regardless of failure or success on the other. In HRA, zero dependence is often assumed for situations in which the analysis is not materially affected by an assumption that may not be valid.

Between complete dependence and zero dependence there is a continuum of possible levels of dependence. We have developed a dependence model in which the infinite possible levels of dependence are represented by the following five levels: zero dependence (ZD), low dependence (LD), moderate dependence (MD), high dependence (HD), and complete dependence (CD). This model and other methods of assessing dependence are discussed in detail in Chapter 10.

Human Error

We define human error as any member of a set of human actions that exceeds some limit of acceptability (Rigby, 1970). Thus, an error is merely an out-of-tolerance action, where the limits of tolerable performance are defined by the system. In an objective assessment of human error, there is no connotation of blame or fault. If an error is made, the underlying causes of the error are identified so that the probability of recurrence of that error is reduced or eliminated. We regard errors as the natural outgrowth of some unfavorable combination of people and the work situation (Swain, 1969c, 1980a, b). Either the person making an error does not have sufficient skill or motivation for consistently acceptable performance, and/or aspects of his work situation are not in accord with what he can do reliably. Insufficient skill in performance may arise from some combination of inadequate training, poor provisions for practicing infrequently performed tasks, poor motivation, or any number of characteristics that directly affect the capability of the performer. The significant aspects of the work situation include the design of the equipment, the written procedures, and the general environment, as mentioned in the definition of performance shaping factors.

By convention, the definition of human error excludes malevolent behavior. Such behavior is not due to error; it is deliberate behavior calculated to produce a harmful effect. PRAs of NPP operations characteristically do not include malevolent acts and their possible consequences. However, it is possible to estimate probabilities of human error in the defense against, and recovery from, malevolent acts. Many of the estimates of probabilities in the Handbook could be used in such a study, but it does not specifically address this topic.

Human errors include intentional errors and unintentional errors.

The former occur when the operator intends to perform some act that is incorrect but believes it to be correct or to represent a superior method of performance. In everyday language, he has good intentions, but the effect on the system of his performance may be undesirable. An erroneous belief in the correctness of a method of operation often results from misinterpretation of written materials or failure to understand an oral instruction. The operator's belief that his way is better than the prescribed way can result in a deliberate violation of standard operating rules. Examples of such errors include (1) not using written procedures in the intended manner, (2) deliberately loosening some equipment tolerances (setpoints) to avoid shutting down a reactor when it may not be absolutely necessary, and (3) venting low-radioactive containment pressure to the atmosphere because the operator is not willing to wait for the automatic safety features to respond to the increasing containment pressure.

Most errors are unintentional--the error just happens; it was not intended. Another term used for this type of error is an action slip (Norman, 1981a). Examples of unintentional errors or slips include (1) inadvertent tripping of the reactor because an operator sat on the edge of the control panel, (2) activating an incorrect control because the intended control is located nearby and the labels for the two controls are similar in appearance, and (3) inadvertently skipping a step in a written procedure. (The latter type of unintentional error is the most frequent and is important in HRA.)

Consequences of Human Errors and Recovery Factors

In HRA, we are concerned with potential errors and potential consequences* of these errors to system reliability or availability. We want to estimate the probabilities of various kinds of errors that could adversely affect the system. A large number of potential errors may never have occurred, yet in HRA, we must treat the possibility of each error that has potential system consequences that should be avoided. Often we must consider errors whose probabilities of occurrence are very low__10-4 or lower on each occasion where such an error is possible. Despite low probabilities of occurrence, errors can be very important if their occurrence could lead to highly unfavorable system consequences.

Knowledge of the consequences of error can act as a PSF for the performer. This knowledge can lower or raise his probability of error, depending on the circumstances. For example, an operator may be reluctant to trip the reactor because of fear that the trip may prove to be unnecessary and that he will be blamed for the associated economic loss. Thus, the operator's knowledge of the consequences of a reactor trip could be an important PSF. The analyst may have to take this into account when estimating the time it will take for the operator to trip the reactor.

In NPP operations, few human errors cause damage or lower the availability of individual systems because the potentially adverse effect of the errors is prevented or compensated for by other components or systems or by other human actions. We call these preventive or compensatory factors recovery factors. The error that did not result in some undesirable consequence to the system is a recovered error, or a no-cost error. If an error is not recovered, and it results in some undesirable consequence, it is called an unrecovered error. Many of the recovery factors in an NPP result from someone checking someone else's performance. We use the term human redundancy to designate this type of recovery factor, and several of the models in Part III address this factor.

In PRA, one estimates the probabilities for potential errors, potential recovery factors, and potential consequences separately. In making these estimates, one considers any dependence among them. For example, in most cases, the probabilities of errors for a checker of someone else's work will be much higher than the probabilities of errors for the original performer. This is because the checker usually does not expect to find many errors when he is evaluating someone else's performance--a special case of dependence.

As mentioned, knowledge of the potential consequences of an error can affect one's behavior. A mistake made by some analysts is to assume that an operator will be more careful when he knows that the consequences of an error are serious and that the analyst should assess lower probabilities of error in such cases. Records of human performance in many complex systems do not provide support for such an assumption.

Types of NPP Operating Conditions Considered in HRA

For HRA, it is convenient to divide NPP operating conditions into normal and abnormal. Normal operating conditions include startup, planned shutdown, power level control, and refueling. Abnormal operating conditions result from events that disrupt the normal conditions in a plant. In a PRA, only certain specified abnormal events are generally considered. These events are called initiating events, i.e., events that require the plant to trip. Initiating events are classified as external events (such as a fire, flood, earthquake) or internal events. The latter are divided into loss-of-(primary-)coolant accidents (LOCAs) and transients. A transient is a condition other than a LOCA that causes a requirement for reactor shutdown. For PRA purposes, a loss of secondary coolant is classified as a transient, not a LOCA. There are some internal events that are not usually considered in PRAs, such as a leak in the spent fuel pool.

PRAs include consequence analysis (the analysis of health and

financial effects resulting from a release of radioactive material that resulted from some initiating event or events) and emergency response, e.g., the evacuation of personnel who could be affected by the release of radioactive material. To date, HRAs performed as parts of PRAs have been applied only to internal initiating events (LOCAs and transients), and the Handbook specifically addresses only the response to internal initiating events. However, some of the models and estimated probabilities of human errors could be applied to tasks in other areas of abnormal operating conditions.

Unavailability Because of Human Error

Availability is defined as the probability that a system is available for use when needed. Its converse, unavailability, is 1 minus availability. In NPPs, any errors of operation, maintenance, or calibration can result in the unavailability of some safety-related system or component for some period of time. This unavailability continues until someone discovers that the system or component is not operative, or until its condition causes other changes to the plant that lead to the discovery. In addition, other system events can cause some component to be unavailable, and this unavailability may be displayed on some meter or result in some other visible change in the plant. Plant personnel then have the opportunity to note this change and take steps to restore the component to its normal operating condition.

The role of human performance in the unavailability of safety-related systems and components is discussed in Chapter 9, "Unavailability."

Types of NPP Tasks and Task Behaviors Addressed in HRA

A task is a level of job behavior that describes the performance of a meaningful job function. It is any unit of behavior that contributes to the accomplishment of some system goal or function. Task behavior refers to the human activities involved in carrying out a task. The distinction between a task and task behavior is often blurred.

Tasks are often divided into subtasks and/or into steps. Different analysts may designate the same set of task behaviors as a task, subtask, or step; the distinction is arbitrary.

We think of a step as consisting of the following:

(1) Some type of information to the task performer from his work situation (e.g., he reads a display or a written procedure, or he receives an oral instruction)

(2) Some degree of processing of the information

(3)Some type of response (e.g., activating a switch or deciding that no action is required)

There are many ways to classify NPP tasks and task behaviors. The classifications employed in the Handbook are those we have found to be useful for HRA.

NPP tasks may be performed under normal or abnormal operating conditions. Under normal conditions, several tasks are of special interest because of their potential effect on the availability of engineering safety features (ESFs). These tasks are the following:

1. Routine control room tasks, e.g., scanning of panels to note if any display indications are not normal
2. Preventive and corrective maintenance tasks, e.g., replacing a defective part in a pump in a safety system
3. Calibration tasks, e.g., ensuring that setpoints for bistable amplifiers for detection of unacceptable conditions in the reactor are within tolerance
4. Postmaintenance or postcalibration tests, e.g., a test to see that a repaired pump works properly after maintenance
5. Change and restoration tasks, in which the normal states of valves, circuit breakers, pumps, or other components are changed to permit maintenance, calibration, or tests and then are restored to their normal states after completion of the work
6. Recovery tasks - those involving the use of recovery factors to detect deviant conditions, e.g., checking someone's work (human redundancy), noticing annunciations of out-of-tolerance conditions, active inspections (in which a person is directed to inspect specific items of equipment, usually via written procedures), and passive inspections (in which the search for deviant conditions is more casual, as in the basic walk-around inspection)

Calibration and restoration tasks are of special interest in an HRA because of the possibility that human errors may cause several redundant safety systems or components to be inoperable or unavailable. In this case, the human error becomes a common-cause event (also called common-cause failure or common-mode failure) because a single event (a human error) has the potential to fail more than one safety function or device.

The task behaviors involved in carrying out tasks under normal operating conditions usually involve little, if any, diagnosis or decision-making. What is to be done is usually prescribed either by plant policy or in written procedures and schedules for performing certain routine tasks. A useful breakdown of tasks behaviors is to designate them as skill-based, rule-based, or knowledge-based (Rasmussen, 1981). (This classification can also be applied to tasks carried out under abnormal operating conditions.) Skill-based behavior consists of the performance of

more or less subconscious routines governed by stored patterns of behavior, e.g., use of a hand tool by one experienced with the tool. Rule-based behavior requires a more conscious effort in following stored (or written) rules, e.g., calibrating an instrument or using a checklist to restore locally operated valves to their normal operating status after maintenance. Knowledge-based behavior pertains to cases in which the task situation is, to some extent, unfamiliar--where considerably more cognition is involved in deciding what to do. As in most attempts at task behavior classification, there is some overlapping between terms, and the distinction between skill- and rule-based behavior and between rule- and knowledge-based behavior may not be well-defined. Most of the models and estimates of human error probabilities in the Handbook pertain to rule-based behavior.

In NPP operations, the term skill-of-the-craft is sometimes used to denote a level of expertise in skill- and rule-based activities such that the task performer works without the aid of written materials. In HRA, it is important to determine when skill-of-the-craft is being relied on by task performers, since errors of omission are a significant factor in HRA.

Under abnormal operating conditions, the three basic classes of tasks are those involved in recognizing that there is an abnormal situation, in diagnosing the problem and deciding what to do about it, and in carrying out the actions required to mitigate the effects of the event and to control the abnormal situation.

The task behaviors in coping with unusual conditions ranging from deviant displays to abnormal events and that are of primary interest in HRA fall into several overlapping categories:

(1) Perception - noting that some abnormal condition exists, e.g., noticing that some alarms are sounding and blinking

(2) Discrimination - distinguishing the characteristics of a signal (or set of signals), e.g., noting the level of coolant in a tank

(3) Interpretation - assigning a meaning to the signal that was discriminated, e.g., realizing that a low level of coolant in a tank means that there is a leak somewhere

(4) Diagnosis - determining the most likely cause(s) of the abnormal event

(5) Decision-making - choosing between alternative diagnoses and deciding which actions to carry out

(6) Action - carrying out the activities indicated by the diagnosis, operating rules, or written procedures

(These terms are explained in more detail in Table 12-1.)

In our general model of the human component in a man-machine system (Figure 3-1), the perception and discrimination tasks are internal inputs to the human processor, interpretation and decision-making tasks are cognitive activities, and the actions carried out are the response. This classification, which also applies to routine tasks, is discussed fully in Chapter 3.

Some other terms for types of tasks are useful in HRA. We distinguish between dynamic and step-by-step tasks as one measure of different levels of task complexity. A dynamic task is one that requires a higher degree of man-machine interaction than is required by routine, procedurally guided tasks. Dynamic tasks may require decision-making, keeping track of several functions, controlling several functions, or any combination of these. These requirements are the distinction between dynamic tasks, such as may be involved in coping with an abnormal event, and step-by-step tasks, such as restoring valves after maintenance.

Related to the above two terms are some terms associated with manual control tasks and used in the human factors community. Manual control tasks may be either continuous or discontinuous (i.e., discrete). Continuous tasks are a subset of dynamic tasks in which a person performs some sort of tracking activity, i.e., he watches a frequently changing display and makes control adjustments to maintain the display indication within limits. An everyday example is that of steering an automobile, in which the display is the view through the windshield. Rod control is a continuous task in some NPPs in which an operator manipulates the controls in response to one or more displays on the control board. Most manual control tasks in an NPP are discrete in that each task element is a discrete step. For example, in a calibration procedure, many discrete switching actions are carried out.

In the Handbook, we generally use the terms dynamic and step-by-step tasks in preference to continuous and discrete tasks.

Task Taxonomy

There have been several attempts to develop a task taxonomy (or task classification). Some of the taxonomies (Chambers, 1969; Fleishman et al., 1968, 1970) were useful for psychological research but not very useful for HRA because they referred primarily to human variables. Other taxonomies brought in equipment variables and are more useful for HRA (Swain, 1956, 1971; Munger et al., 1962; Payne and Altman, 1962; Smith and Payne, 1962; Berliner et al., 1964; Irwin et al., 1964a, b; Blanchard et al., 1966; Meister, 1967; Rigby, 1967). More recent attempts to develop a taxonomy have been specifically directed at HRA as a part of a PRA of NPP operations (Rasmussen, 1981; Rasmussen et al., 1981; Topmiller et al., 1982, 1983; Comer et

al., 1983; and the draft and present versions of the Handbook).

The recent efforts to develop a task taxonomy useful for HRA categorize data on human behavior in terms of combinations of equipment and task variables. Chapter 20 in the Handbook represents our approach in this area. Figure 20-1, a search scheme for using the Chapter 20 data tables, directs the user to specific tables, based on type of operation (abnormal or normal), type of task (diagnosis or rule-based behavior), type of man-machine interface (written materials, displays, valves), and type of error (omissions or commissions). This search scheme and data tables constitute a brief and very specialized task taxonomy, designed specifically for use by HRA specialists participating in a PRA. Obviously, the search scheme and tables can be used in other applications, but they are less general than the elaborate taxonomies intended for collection and display of data (e.g., the Comer reference cited).

Task Analysis

Chapter 4 presents an analytical procedure called task analysis. This technique is used to identify the relevant human elements in tasks and to identify the potential for human error. The task analysis provides the necessary raw material for the type of HRA described in the Handbook. The level of detail in a task analysis for HRA is determined by the needs of the PRA.

Task analysis is an analytical process for determining the specific behaviors required of the human components in a man-machine system. It involves determining the detailed performance required of people and equipment, and the effects on them of environmental conditions, malfunctions, and other unexpected events. Within each task, behavioral steps are analyzed for the perceptions, decisions, memory storage, and motor outputs required, as well as for expected errors.

The data from a task analysis can be used to establish equipment design criteria, operating sequences, written procedures, and requirements for selection and training of personnel. Task analysis is the most commonly used tool. of the human factors specialist for both qualitative and quantitative applications.

Task analysis may be employed during any stage in the development or use of a system. Different methods of task analysis may be used for different stages. For example, link analysis is used to depict the pathways that are generated by people walking about and communicating with each other within a system. This technique is employed in later phases of development when mockups are available or during the use phase. Talk-throughs or walkthroughs are used when there are personnel available who can demonstrate how they would operate in a system.

Error-Likely Situations and People

In performing a task analysis to identify the potential for error, the analyst identifies work situations that are error-likely in the sense that the ergonomics are so poor that errors are likely to occur; hence, errorlikely situations (ELSs). ELSs involve demands on humans that are not compatible with their capabilities and limitations. For example, any design that violates a populational stereotype must be considered error-likely. A design that forces an operator to keep several display indications in mind, and to figure out the meaning of the combination of indications, is more error-likely than a design that displays directly the information the operator needs, without forcing him to go through an interpretation process. In general, designs that are not in accord with accepted ergonomics principles are error-likely. Accepted ergonomics principles are described in human factors reference works such as MIL-STD-1472C (1981), NUREG-0700 (1981), Van Cott and Kinkade (1972), or Woodson (1981).

Sometimes a person is characterized as error-likely. In an NPP, a truly error-likely person would soon be recognized and would be retrained, reassigned, or discharged. Although chronic error-likeliness in people qualified, trained, and experienced in a job is not common, we are all error-likely from time to time. Anyone emotionally upset is usually more likely to make errors. If one is fatigued from unusually long hours or work or has not had enough sleep, certain types of errors are relatively likely. Error-likeliness in people who have had adequate training in a job is usually temporary.

Accident-Prone Situations and People

Accident-proneness is a special case of error-likeliness. The accident-prone situation (APS) is one that fosters human errors likely to result in injury to people or damage to equipment and facilities. An accident-prone person is one who has statistically "more than his share" of accidents when compared with others having the same degree of exposure to opportunities for the same types of accidents.

A recently publicized example of an APS is that of an airliner that made a forced landing because some 0-rings had been omitted from the oil seal stems. Investigation revealed that the stems were usually issued to the mechanics with the 0-rings in place on the stems but that occasionally they were issued without the 0-rings, in which case the mechanics were required to obtain the rings at a different location and position them on the stems before threading the stems into the engines. Because the 0-rings usually were on the stems, the mechanics had a high expectancy for the stems to be complete. On several occasions, the mechanics

had failed to notice that the stems did not have the 0-rings in place. Since the forced landing, it has been made company policy that all stems be issued with the 0-rings in place, thus relieving the mechanics of the requirement to check the stems. This policy change should materially reduce the probability of future unsafe incidents of this type, provided that there is a reliable method to ensure that the 0-rings are indeed positioned on the stems before the mechanics use them.

Accident-proneness in individuals is not a very useful concept. At times, it has been used to justify negligent safety practices by blaming the person who was involved in an accident and classifying him as accident-prone. Although there are groups who seem to be accident-prone (for example, the class of male drivers in the United States under 25 years of age), studies of work situations show that chronically accident-prone people in industry are rare. Carefully controlled studies show that accident-proneness in people is usually due to temporary conditions such as illness or emotional disturbances.

In the early 1900s, the concept of the accident-prone individual in industry arose in part because faulty statistical analyses were used that did not incorporate concepts of statistical significance. Subsequent analyses of these early data showed that certain individuals were stigmatized as accident-prone when the number of accidents they experienced was not significantly greater than the number expected due to chance alone (Mintz and Blum, 1961). Even when chance can be ruled out, it may be found that people seeming to have "more than their expected share" of accidents are those who have the greatest exposure to the risk of accidents.

Taking all of the above factors into consideration, most modern industrial safety specialists conclude that it is more cost-effective to look for APSs than to look for accident-prone people. The emphasis in the Handbook is on techniques for identifying APSs and ELSs and for estimating their potential effect on the availability of ESFs.

Categories of Incorrect Human Outputs Related to HRA

As illustrated earlier, there are several ways of classifying human error. In HRA, we are interested primarily in those human errors that constitute incorrect inputs to the system. A person can make an error if he does something incorrectly, fails to do something he should, or fails to do something in time. It is convenient to categorize incorrect human outputs into errors of omission and errors of commission, with finer breakdowns as follows:

Errors of Omission

Omits entire task

Omits a step in a task

Errors of Commission

Selection error:

Selects wrong control

Mispositions control (includes reversal errors, improperly made connections, etc.)

Issues wrong command or information (via voice or writing)

Error of sequence

Time error:

Too early Too late

Qualitative error:

Too little Too much

Any of these incorrect human outputs may be the result of other human errors: an error in interpretation of a pattern of signals, a misreading of a display, a misprint in an emergency operating procedure, etc. In an HRA, the incorrect human outputs and human errors leading to these incorrect outputs must be analyzed.

From a systems point of view, any of the above incorrect human outputs and other human errors is considered to be an error only when it reduces or has the potential for reducing system reliability, system safety, or the likelihood that some other system success criterion will be met. Obviously, a person in a system performs many extraneous acts, e.g., smoking a cigarette, scratching his nose, and the like. In a system context, these behaviors are not considered errors unless they have potential for degrading the system in some manner. Sometimes an incorrect human output can result in an undesirable system consequence (an unrecovered error), but generally, because of recovery factors in a well-designed system, no serious loss to the system will occur (the error was a recovered error).

Human Error Probability

In the Handbook, the basic index of human performance is the human error probability (HEP). The HEP is the probability that when a given task is performed, an error will occur. There are many ways to estimate the HEP; some are statistical and some are judgmental. We use the term "human error probability" to represent any estimate. The HEPs listed in the Handbook are

nominal HEPS, that is, plant-specific and situation-specific PSFs have not been taken into account.

Ideally, HEPs would be determined from actuarial data consisting of error relative frequencies in which the known number of errors of a given type are divided by the number of opportunities for that error to occur. Unfortunately, very little of this type of data exists for NPP tasks. Data on the number of errors of a given type have been recorded in the Nuclear Regulatory Commission's (NRC's) Licensee Event Reporting (LER) system, a measure of the numerator of the error relative frequency. However, the number of unrecovered errors that occur is grossly underestimated, and there is no record in the LER system of the number of opportunities for each type of error, the denominator of the error relative frequency (Speaker et al. 1982). The serious problem of the scarcity of actuarial data for HRA is discussed in Chapter 6.

In our earlier reports, including Section 6.1 of WASH-1400, we used the term human error rate (HER) interchangeably with human error probability. Since the term "rate" is often used in the sense of frequency per unit of time, it is not used in the Handbook, to avoid confusion.

Because most of our estimates of HEPs are based on some combination of data and judgment, we call them derived HEPs to differentiate them from HEPs that would be calculated from error relative frequencies for NPP tasks. In developing our derived HEPs for NPP tasks, we often use data and information from other types of tasks that are similar to NPP tasks. Similarity is judged in terms of the correspondence of behavioral variables. Two physically dissimilar items of equipment might be similar in terms of the human behaviors involved in their operation, calibration, or maintenance. Therefore, an observed HEP for one of these items of equipment can be used as the estimate of the HEP for the same task on other items of equipment.

The probabilities most often used in HRA can be classified as demand probabilities; that is, the probabilities that given human actions will be performed correctly when required. If time limitations are imposed on the performance of a task, one probability of interest is the probability that the task will be completed correctly within the allotted time. If required, the HEP per hour can be obtained. For most calculations, the interest is in the probability of at least one error (for a given task) per hour. In availability estimates, the HEP per hour is estimated even though

the task may be performed with a frequency of much less than once per hour. Some sample calculations are presented in Chapter 9.

The reliability of a task (the probability of its successful

performance) is generally expressed as 1 minus HEP. Thus, when we speak of the reliability of performance of a human task, we are speaking of the probability of successful performance per demand. When we speak of the error probability, we mean the probability of unsuccessful performance per demand, or task unreliability, which is 1 minus task reliability. The terms, human error probability, human failure probability, or task failure probability are often used interchangeably with human unreliability. (Similarly, human success probability, task success probability, and human reliability are used interchangeably.)

Basic, Conditional, and Joint Probabilities

Three types of probability are important in performing an HRA. These are the basic human error probability (BHEP), the conditional human error probability (CHEP), and the joint human error probability (JHEP).

The BHEP is the probability of a human error on a task that is considered as an isolated entity, unaffected by any other task. If the task is the first in a series of tasks, there is no ambiguity in this definition. It the task is not the first task and its outcome may be dependent upon the outcome of other tasks, the BHEP would be that probability conjectured to exist if no other tasks were involved.

The CHEP is the probability of human error on a specific task, given failure, or success, on some other task. Two tasks are independent if the CHEP is the same regardless of whether success or failure occurred on the other task; otherwise, they are dependent.

The JHEP is the probability of human error on all tasks that must be performed correctly to achieve some end result. This is the probability of most interest in reliability work and is determined by using both BHEPs and CHEPs.

Distributions of HEPs

The nominal HEPs listed in the Handbook represent our best estimates of the HEPs for the tasks or activities described. For reasons discussed in Chapter 7, we assume that if sufficient actuarial data could be obtained an a large number of tasks performers, the HEPs for each task would be distributed lognormally, or approximately so. Our nominal HEPs are designated as the medians of the lognormal distributions, that is, 50% of the true HEPs should be above and 50% below our nominal HEPs.

For HRA/PRA, we express the amount of variation in estimated HEPs

in the form of uncertainty bounds (UCBs) or error factors (EFs). The estimated variation reflects the uncertainty in our estimates. This uncertainty arises from three main sources. One source is associated with variability due to people and conditions. A second is the uncertainty in our assessment of the HEPs. A third source is modeling uncertainty--how well one can model human performance in an HRA application.

We express the overall uncertainty as a lower and an upper UCB, where the lower UCB represents the 5th percentile of HEPs on a hypothesized lognormal distribution of HEPs for a task, and the upper UCB represents the 95th percentile. Thus, the expression .003 (.001 to .01) means that our nominal HEP is .003 and that we believe it unlikely that the true HEP would be lower than .001 in more than 5% of the cases, nor would it be higher than .01 in more than 5% of the cases. Most of the estimated UCBs in the Handbook are symmetrical about the median HEP, and those that are can be represented by a convenient shorthand term, the EF. In the above example, the expression may be restated as .003 (EF = 3). The lower UCB is calculated by dividing the nominal HEP by the EF. In the example, the actual upper UCB of .003 x 3 = .009 is rounded upward to .01 to preserve a range ratio of 10 between the upper and lower UCBS.

The spread between the lower and upper UCBs in the Handbook varies according to task conditions. In general, the spread increases with very small HEPs (<.001) and large HEPs (>.Ol). EFs range from 3 to 10. To express greater uncertainty, the analyst may assume the UCBs to encompass a smaller percentage of cases than the range defined by our nominal percentages of 5% and 95%, e.g., he may assume the UCBs to encompass the range of percentages from 10% and 90%, or any other values that seem to be reasonable for the situation.

The UCBs in the Handbook are based on judgment and should not be confused with statistical confidence limits, which are based on observed frequencies of occurrence. The assignment of UCBs to our nominal HEPs is to permit certain types of sampling and propagation techniques characteristic of PRAs, beginning with WASH-1400 (see Chapter 12 in NUREG/CR-2300).

TABLE 5-7. Data on Human Failure Rates for General Tasks (Williams 1989)

Task Type	5th Percentile Value	Nominal HEP	95th Percentile Value
Detect deviation from standard	2.0×10^{-2}	7.0×10^{-2}	1.7×10^{-2}
Calculation	2.0×10^{-2}	4.0×10^{-2}	1.1×10^{-1}
Alpha input	4.0×10^{-3}	8.0×10^{-3}	5.0×10^{-2}
Alphanumeric input	2.0×10^{-3}	5.0×10^{-3}	7.0×10^{-3}
Numeric input	1.0×10^{-3}	3.0×10^{-3}	8.0×10^{-3}
Control/demand	4.0×10^{-4}	1.0×10^{-3}	3.0×10^{-3}
Assembly task element	3.0×10^{-5}	7.0×10^{-5}	4.0×10^{-3}
Initial diagnosis	9.0×10^{-2}	2.0×10^{-1}	6.0×10^{-1}

ID	Description	Value
1	Unfamiliarity with a situation which is potentially important but which only occurs infrequently or which is novel.	17
2	A shortage of time available for error detection and correction.	11
3	A low signal to noise ratio.	10
4	A means of suppressing or over-riding information or features which is too easily accessible.	9
5	No means of conveying spatial and functional information to operators in a form which they can readily assimilate.	8
6	A mismatch between an operator's model of the world and that imagined by a designer.	8
7	No obvious means of reversing an unintended action.	8
8	A channel capacity overload, particularly one caused by simultaneous presentation of non redundant information.	6
9	A need to unlearn a technique and apply one which requires the application of an opposing philosophy.	6
10	The need to transfer specific knowledge from task to task without loss.	5.5
11	Ambiguity in the required performance standards.	5
12	A mismatch between perceived and real risk.	4
13	Poor, ambiguous or ill-matched system feedback.	4
14	No clear, direct and timely confirmation of an intended action from the portion of the system over which control is to be exerted.	4
15	Operator inexperience (e.g. a newly qualified tradesman but not an expert).	3
16	An impoverished quality of information conveyed by procedures and person/person interaction.	3
17	Little or no independent checking or testing of output.	3
18	A conflict between immediate and long-term objectives.	2.5
19	No diversity of information input for veracity checks.	2.5
20	A mismatch between the educational achievement level of an individual and the requirements of the task.	2
21	An incentive to use other more dangerous procedures.	2
22	Little opportunity to exercise mind and body outside the immediate confines of a job.	1.8
23	Unreliable instrumentation (enough that it is noticed).	1.6
24	A need for absolute judgements which are beyond the consistent capabilities of an operator.	1.6
25	Unclear Allocation of function and responsibility.	1.6
26	No obvious way to keep track of progress during an activity.	1.4
27	A danger that finite physical capabilities will be exceeded.	1.4
28	Little or no intrinsic meaning in a task.	1.4
29	High level of emotional **stress**.	1.3
30	Evidence of ill-health amongst operatives, especially fever.	1.2
31	Low workforce morale.	1.2
32	Inconsistency of meaning of displays and procedures.	1.2
33	A poor or hostile environment (below 75% of health or life-threatening severity).	1.15
34	Prolonged inactivity or highly repetitious cycling of half hour low mental workloads.	1.1
35	Disruption of normal work-sleep cycles.	1.1
36	Task pacing caused by the intervention of others.	1.06
37	Additional team members over and above those necessary to perform task normally and satisfactorily.	1.03
38	Age of personnel performing perceptual tasks.	1.02

Probabilities for Errors While Performing Tasks

The following tables indicate possible values for the probabilities of errors occurring during different activities. While it is not expected that the users of these tables will perform human reliability analyses using these data, they provides a perspective on what are some of the more error-likely kinds of tasks, and what could therefore be the focus of additional scrutiny during inspections or the reviews of events.

The reviewer should consider the range and types of tasks (such as by examining the task structure described for the gamma knife [link to task analysis]) to see where the number of times each kind of task is called for in performing the job. If there is a high number of times that a type of task with a high likelihood of errors must be performed, then there is a high likelihood of the task failing, which may then impact patient or worker safety.

Hand calculations: The first table, Table 5-7 from Gertman & Blackman (1994), shows data taken from industrial experience with tasks like data entry, performing hand calculations and the like. As far as hand calculations go, one error is likely for every time about 400 calculations are performed—that is, separate steps each of which involves some kind of arithmetic processing. Thus, if a task requires extensive hand calculations, there should be opportunities for checking and other job aids (such as limits to what are reasonable values to identify when gross errors occur).

Data entry: As far as data entry tasks are concerned, Table 5-7 shows that entering numeric values is a little more reliable that entering alphabetic characters, by about a factor of 2 to 3. Any task that involves entering large amounts of alphabetic characters should be considered as a potential source of harm unless there is some means of independent checking of data, such as confirming patient names against those already in a database. As seen with cross checking between people [link to cross checking data], the improvements from getting inter-personal checking is limited.

Oral instructions: Many times in healthcare, orders for treatment are given orally. For small numbers of items, this is an efficient way of transferring information. However, when more than about 4 or 5 items are included in an instruction, the reliability of the communication can decrease significantly. Table 5-15 (Gertman & Blackman 1994) indicates the significant likelihood of failing to recall a particular item or all the items as the number increases. What comprises an "item" is not well defined—it is sometimes called a perceptual unit. What this means is an item that makes sense as a unit of information for the recipient. Thus a telephone number may be a single item, and order for a particular step in a procedure is a single item. On the other hand, a series of 3 independent measurements would be three separate items.

References

Gertman, D. I. and H. S. Blackman (1994). Human Reliability and Safety Analysis Data Handbook. New York, John Wiley and Sons, Inc.

Performing Actions		
Questions	**Consequences**	**Examples & design questions**
A1. Is there physical or mental difficulty in executing the actions?	Difficult, complex, or fiddly actions are prone to being carried out incorrectly.	
A2. Are some actions made unavailable at certain times?		
A3. Is the correct action dependent on the current mode?	Creates a demand on the user to know what the current mode is, and how actions' effects differ between modes. Problems with this knowledge can manifest themselves as a **substitution** of one logical action for another.	
A4. Are additional actions required to make the right controls and information available at the right time?	The additional goals may be lost (resulting in **omissions**) and users will be unable to carry out the main goals. The overall effect may be to cause **confusion** and disorientation for the user.	

Goals, Triggering, and Initiation		
Questions	**Consequences**	**Examples & design questions**
G1. Are items triggered by stimuli in the interface, environment, or task?	If not, goals (and the tasks that achieve them) may be lost, forgotten, or not activated, resulting in **omission** errors.	Are triggers clear and meaningful? Does the user need to remember all the goals?
G2. Does the user interface "evoke" or "suggest" goals?	If not, goals may not be activated, resulting in **omission** errors. If the interface does "suggest" goals, they may not always be the right ones, resulting in the **wrong goal** being addressed.	E.g.: the display page supporting a particular function might list the constituent tasks and show current progress.
G3. Do goals come into conflict?	If so additional cognitive work (and possibly errors) may result from resolving the conflict. If the conflict is unresolvable, one or more goals may be lost, abandoned, or only partially completed.	Can attempt to design out conflicts or give participants the resources to resolve them.
G4. Can a goal be achieved without all its "sub-goals" being correctly achieved?	The sub-goals may be lost (resulting in **omissions**).	E.g.: the display page supporting a particular function might remain active until all constituent tasks are initiated or acknowledged.

Perception, Interpretation and Evaluation		
Questions	**Consequences**	**Examples & design questions**
I1. Are changes (resulting either from user action or autonomous system behavior) perceivable?	If changes are not perceivable, the user must retain a mental model of the system state. Particularly problematic if changes happen autonomously.	
I2. Are the effects of actions perceivable immediately?	If there's no feedback that an action has been taken, the user may **repeat** actions.	
I3. Does the item involve monitoring, vigilance, or continuous attention?	The user's attention can easily be diverted away from monitoring tasks, meaning that changes that confirm goals achievement (leading to **repetition** of actions or carrying out actions **too late**) or that trigger new goals may be missed (resulting in omission of the associated actions).	
I4. Can the user determine relevant information about the state of the system?	If not, the user will have to remember the information they require, thus making it prone to being lost or recalled **incorrectly**.	
I5. Is the relation of information to the plans and goals obvious?	If the relationship to plans isn't clear, then a source of feedback about correct execution of the plan, and therefore a factor that mitigates against error, is lost. If the relationship to goals is unclear, then the user may be unaware of when a goal is achieved, leading to termination of a sub-task **too early** or **too late**.	
I6. Is complex reasoning, calculation or decision making involved?	If cognitive tasks are complex, they may be prone to being carried out **incorrectly**, to being the cause of other tasks carried out **too late**, or to being **omitted** altogether.	
I7. Is the correct interpretation dependent on the current mode?	Creates a demand on the user to know what the current mode is, and to how the appropriate interpretation of information differs between modes. Problems with this knowledge can manifest themselves as a **substitution** of one logical information item for another.	

Plans		
Questions	**Consequences**	**Examples & design questions**
P1. Are there well-practiced and predetermined plans?	If a plan isn't well known or practiced then it may be prone to being forgotten or remembered incorrectly. If plans aren't pre-determined, and must be constructed by the user, then their success depends heavily on the user possessing enough knowledge about their goals and the interface to construct a plan. If pre-determined plans to exist and are familiar, then they might be followed inappropriately, not taking account of the peculiarities of the current context.	
P2. Can actions be selected in-situ, or is pre-planning required?	If the correct action can only be taken by planning in advance, then the cognitive work may be harder. However, when possible, planning ahead often leads to less error-prone behavior and fewer blind alleys.	
P3. Are there plans or actions that are similar to one another? Are some used more often than others?	A more common but similar plan may be confused for the intended one, resulting in the substitution of an entire task or sub-task.	

SYSTEM 13

3.13 Medical (Teletherapy—Gamma Stereotactic Surgery)

3.13.1 Overview

Gamma stereotactic surgery (or stereotactic radiosurgery) involves the use of external radiation, in conjunction with a stereotactic guidance device, to precisely deliver a prescribed dose to intracranial anomalies (NRC, 1995e). The Gamma Knife™ (a registered trademark of Elekta) is one such device designed to perform stereotactic surgery. It consists of a radiation unit, four interchangeable helmets, a patient treatment table, an electromechanical or hydraulic system, a control console, and a computer system. The actual gamma unit comprises 201 Co-60 sources arranged in a large, heavily shielded sphere. Radiation from each of the sources is collimated into narrow beams that focus at the center of the sphere (NRC, 1995e).

During treatment, the patient's head is held in place by the stereotactic head frame using four pins which are attached to the patient's outer skull. The frame will ensure that the patient's head is held in a precise position so that the beams of radiation can be focused at the intracranial target volume.

The treatment is a one-time process. It consists of a series of "shots" of radiation to the target volume. The time of treatment can vary based on factors such as the size and location of the abnormality and the age of the Gamma Knife™ sources. Once the treatment is completed, the patient can be released, typically that day.

The Gamma Knife™ is a large, stationary (fixed) device. A suite of rooms is typically dedicated for this device and procedure. The actual Gamma Knife™ is located in a separate room (referred to as the treatment room) which is sufficiently shielded so that exposure rates in adjacent rooms or areas are below 2 mrem/hour. The control console is located in another room or area (referred to as the control room), directly outside the treatment room. Access to the treatment room is required to be controlled by an electrical interlock system [10 CFR 35.615]. These controls are also required to prevent exposure of the primary beam if the door is not locked. Extensive controls are required for Gamma Knife™ units, the remainder of which are enumerated in 10 CFR 35.615. The patient is prepped in a separate room that is still part of the suite.

Use of sealed sources for teletherapy is regulated by 10 CFR 35.600. Licensees authorized to perform this type of procedure have specific licenses granted under 10 CFR 35.18. Licensees are required to use the sources in accordance with manufacturer's radiation safety and handling instructions. The sources used for the Gamma Knife™ are required to be obtained from a licensed manufacturer [10 CFR 35.49]. Manufacturers of these sources are licensed in accordance with 10 CFR 32.74.

There are currently 49 Gamma Knife™ units in use in the United States that utilize the 201 Co-60 sources. It is estimated that approximately 10,000 people undergo surgery with a Gamma Knife™ annually in the United States.

3.13.2 Hazard

The radiological hazards of concern are the gamma rays produced by the beams of radiation from the Co-60 sources. Two gammas with energies of 1.17 and 1.33 MeV are emitted by Co-60, which has a half-life of 5.271 years. The total activity of the 201 sources of Co-60 is approximately 6,600 Ci. One individual source has an activity of 36 Ci or less.

3.13.3 Tasks, Barriers, and Receptors

Stereotactic surgery involves the following exposure tasks:

- Source Receipt/Source Installation (Task 13-1)
- QA and Patient Preparation (Task 13-2)
- Treatment (Task 13-3)
- Maintenance/Leak Testing (Task 13-4)
- Source Change (Task 13-5)

- System Not in Use/Standby (Task 13-6)
- Disposal/Return of Source to Vendor (Task 13-7)

The receptors of concern during stereotactic surgery are the members of a dedicated team which typically consists of a neurosurgeon, a radiation oncologist, a medical physicist, and a technician or nurse. The entire team is typically present in the control room during the actual treatment. However, various members will enter the treatment room before and after the treatment to perform quality assurance checks and assist the patient. The authorized user (physician) is required to be certified and have the required training in accordance with 10 CFR 35.960. Each licensee is required to develop and implement a written radiation protection program [10 CFR 35.20, 10 CFR 20.1101]. Additionally, each licensee is required to appoint an RSO who is responsible for implementing the radiation safety program [10 CFR 35.21]. Medical institutions are required to establish a Radiation Safety Committee to oversee the use of byproduct material [10 CFR 35.22].

The treatment room should be configured and equipped with appropriate instrumentation to facilitate the required monitoring and observation. Safety instructions are required to be posted on the console which inform the operator of procedures to be followed before startup of the unit, and if a malfunction occurs [10 CFR 35.610]. The entrances to the treatment room are required to be equipped with electrical interlocks and indicators lights [10 CFR 35.615(b)]. The treatment room is required to have a permanently installed radiation monitor [10 CFR 35.615]. Continuous observation of the patient during irradiation from the console unit is required [10 CFR 35.615]. The treatment room should be provided with sufficient shielding to limit the doses to workers as well as to the public [good practice/tie-down]. Exposure to the public is restricted by the limits set forth in 10 CFR 20.1301. The licensee is required to show compliance with the limits by ensuring the dose from external exposure will not exceed 2 mrem in an hour (in unrestricted areas) [10 CFR 20.1302].

The receptor of concern during maintenance is the authorized maintenance/repair individual. A licensed individual is required to perform any maintenance or adjustments on, or install, relocate, or remove the source from, a teletherapy unit [10 CFR 35.605].

The receptor of concern during leak testing is the worker who performs the test. Leak tests are required to be performed every 6 months or other interval permitted by the NRC or Agreement State [10 CFR 35.59]. The leak tests are required to be performed when the teletherapy unit is in the “off” position [10 CFR 35.59]. During this period of time, the source is not exposed; therefore, exposure should be at a minimum.

3.13.3.1 Task 13-1: Source Receipt/Source Installation

When the Gamma Knife™ is first installed, the sources are not yet present. They are manually loaded in a “hot cell” or comparable facility. 10 CFR 35.605(b) requires that only a person who is specifically licensed to do so may install, relocate, or remove a teletherapy sealed source or a teletherapy unit that contains a sealed source. Currently, only one manufacturer has sold any gamma stereotactic units in the United States. A second manufacturer has had its design approved by the Food and Drug Administration, but none of its devices have been sold in the United States yet.

The sources are loaded using remote handling tools and shielding [good practice/tie-down]. Each source is required to be leak tested prior to loading [10 CFR 35.59], so it is unlikely that a source will be leaking during loading.

The Gamma Knife™ contains 201 sealed sources of Co-60. Each source contains approximately 36 Ci of activity. The Co-60 is in the form of metal pellets, 1 millimeter in diameter by 1 millimeter in length. The pellets are doubly encapsulated in stainless steel. The nominal dimensions of the source are 0.31 inch in diameter by 1.07 inches. The manufacturer of the source calculated the external radiation level for one 30 Ci source to be 33 Roentgen per hour, or approximately 33 rem/hour at 1 meter.

The receptor of concern during installation of the sources are the person(s) licensed to install the sources, a representative from the manufacturer (present at all initial installations and source changeouts), and any member of the radiosurgery team who might be present to observe the procedure. Since this process takes place in a “hot cell,” which is typically controlled as a restricted area, it is assumed that no members of the public will be present in the “hot cell” at the time of loading. In some facilities, the treatment room acts as the “hot cell,” and thus the dose rate at the exterior of

the walls of the treatment room are likely to be less than 2 mrem/hour. Therefore, a member of the public who might be present outside the suite is not likely to receive a notable dose of radiation.

The primary accident of concern during installation is the handling of a leaking source. This could occur if a source was damaged during shipping and not leak tested prior to installation in the unit. However, it is assumed that the shipping container will be surveyed prior to removing any sources for installation. Another potential accident would be the dropping of a source. However, it is not expected that the source would sustain any damage due to a drop. The sources are subjected to the tests described in ANSI Standard N542. For an impact test, the gamma teletherapy sources are subjected to the dropping of a 5 kg mass onto the source from 1 meter above.

Since this task is performed by the vendor or its contractor, and the frequency is much less than other tasks, the risk from this task is not analyzed.

3.13.3.2 Task 13-2: Quality Assurance and Patient Preparation

Prior to the actual treatment process, the patient must be prepped. This includes attaching a stereotactic head frame to the patient's outer skull, imaging, and dose planning. All of these tasks take place within the Gamma Knife™ suite but not in the treatment room. The dose rates in these various areas of the suite when the shielding door of the unit is closed are negligible.

Prior to treatment of the patient, a series of quality assurance checks are performed by the team members. Of interest are those that take place in the treatment room. It is during this period of time that member(s) of the team receive a very minor dose from exposure to any radiation coming through the heavily shielded gamma unit. Period spot checks are required to be performed once per calendar year [10 CFR 35.634]. However, most facilities typically perform similar, if not the same, checks prior to each treatment. These checks involve ensuring that the unit, the safety features, and the radiation detector will all function.

Once the patient has been imaged, the treatment plan has been developed, and quality assurance checks have been performed, the patient is then ready for the actual treatment. A member of the team will position the patient on the couch. The stereotactic head frame that has been affixed to the patient's head will then be placed inside a collimating helmet and attached to the helmet via trunnions and pillars. Any adjustments to the plugging pattern are made so that the lenses of the patient's eyes are not directly exposed to beams of radiation. After all of the final checks are made, all personnel leave the treatment room.

The exposure receptors of concern are the team members who perform the quality assurance checks in the treatment room. During these checks, the shielding door is closed, with the exception of a check to ensure that the door light on the console is functioning. However, the members only open a rear shield door and vacate the room while the check is performed. According to the manufacturer, the dose rate at the shielding door when closed is approximately 8 mrem/hour. Therefore, the exposure to a worker under normal conditions is expected to be minimal. Family members are not allowed in the suite during any part of the treatment. However, it would not be inconceivable if a parent of a young child was allowed to be present in the control room area or patient prep area.

The accident of concern is an inadvertent opening of the shielding door during the quality assurance checks, or patient preparation in the treatment room. In order for this to occur, a series of interlocks would have to fail or a series of human errors would have to occur.

3.13.3.3 Task 13-3: Treatment

The treatment process involves several steps, most of which occur outside the actual treatment room. The only portion of the treatment process considered by this task is that which takes place in the treatment room where the Gamma Knife™ is located.

After the patient has been positioned, and it is verified that the room is clear, the treatment process begins. The treatment process at this point is computerized. Treatment time will vary based on the location and severity of the abnormality and the age of the Co-60 sources. For newer sources, the treatment time will be less. The shielding door

will open, and the patient couch will insert into the radiation unit. After the prescribed treatment time, the couch will retract, and the shielding door will shut. When all processes are complete and the shielding door has been verified to be closed (console light indicator, visual check via camera), the team will enter the treatment room, detach the patient, and escort the patient out of the room.

The exposure receptors of concern are the radiosurgery team members. Typically, the dose rate in the control room while the shielding door is open is less than 2 mrem/hour, according to the manufacturer, and as required by regulation. Therefore, the expected dose will not be significant for one treatment. Family members are not allowed in the suite during any part of the treatment. However, it would not be inconceivable if a parent of a young child was allowed to be present in the control room area or patient prep area. However, the expected dose to this member of the public is a fraction of the dose that would be acquired by a non-worker who occupied an office in the vicinity of the suite. The exposure to this member of the public is what is considered by this risk analysis.

The accident of concern is the failure of the Gamma Knife™ unit during treatment, in particular the failure of the patient couch to retract after treatment. This could occur if any of the associated interlocks fail, the hydraulic or electromechanical system fails, or there is a power outage. A majority of the facilities do have emergency backup power, so the third scenario is not considered. An event that was the subject of Information Notice 95-25 occurred in which the patient couch failed to fully retract from the radiation unit and the patient had to be removed manually. All facilities have emergency procedures which, depending upon the event, take from 2 to 5 minutes to implement. In extreme cases, the time could be longer.

3.13.3.4 Task 13-4: Maintenance/Leak Testing

Maintenance is performed on a periodic basis as suggested by the manufacturer. However, 10 CFR 35.647 requires that the unit be fully inspected and serviced during source replacement or at intervals not to exceed 5 years, whichever comes first. The maintenance and inspection activities can be performed only by persons specifically licensed to do so by the NRC or an Agreement State [10 CFR 35.605(b), 35.647(b)]. Currently, there are only two licensees that perform the inspection and maintenance tasks–the manufacturer of the Gamma Knife™, Elekta, and its contractor.

Leak testing is required to be performed at 6-month intervals, or at intervals approved by the NRC or Agreement State [10 CFR 35.59(b)(2)]. The leak testing should be performed in accordance with the label or brochure (or manufacturer’s instructions) that accompany the source/device [10 CFR 35.59(b)(2)].

Any repairs that may be required throughout the life of the Gamma Knife™ are typically performed by the manufacturer. As with maintenance, only a person specifically licensed may perform repairs on the unit [10 CFR 35.605(b)].

The potential receptors of concern are those licensed to perform maintenance and repairs. The exposure times will vary depending upon the required service. However, it is assumed that shielding will be used when necessary. All repairs, maintenance and leak testing will take place in the treatment room or in a “hot cell.” The Gamma Knife™ is a large, heavy fixed unit, and most likely will remain in its location until the end of its life. Since these processes take place in the treatment room, which is typically controlled as a restricted area, it is assumed that no members of the public will be present while the events take place. As explained previously, the dose rate at the exterior of the walls of the treatment room should be such that a person will not get a dose greater than 2 mrem in an hour (in an unrestricted area). Therefore, a member of the public who might be present outside the suite is not likely to receive a notable dose of radiation.

The potential accident of concern is an inadvertent exposure to the beams caused by malfunction of the unit during repair or maintenance. Since specifically licensed persons are the only ones authorized to maintain or repair these units, it is expected that these individuals will be highly familiar with these units, with the likely malfunctions, and with the procedures to be implemented in the event the beams are exposed. Currently, only the manufacturer and its contractor are licensed to perform these activities.

Since this task is performed by the vendor or its contractor, the risk from these tasks are not analyzed in this system.

3.13.3.5 Task 13-5: Source Change

Sources are typically changed every 5 to 8 years, and definitely should be changed at least every 7 to 10 years. According to the information in the sealed source and device registration certificate, the unit has a useful life of 10 to 15 years, so it is anticipated that each unit will undergo at least once source change during its life.

10 CFR 35.605(b) requires that only a person who is specifically licensed to do so may install, relocate or remove a teletherapy sealed source or a teletherapy unit that contains a sealed source. As stated previously, only two licensees in the United States currently are authorized to install and remove sources.

The sources are handled using remote handling tools and shielding [good practice/tie-down]. The sources are required to be leak tested prior to their first use unless the licensee has been provided with a certificate stating that it was tested by the manufacturer within the 6 months prior to installation [10 CFR 35.59]. After a source is replaced, full calibration measurements are required to be performed on the unit [10 CFR 35.632(a)(2)(ii)].

The receptors of concern during changeout of the sources are the person(s) licensed to install and remove the sources, a representative from the manufacturer (typically present at all initial installations and source changeouts), and any member of the radiosurgery team who might be present to observe the procedure. Since this process takes place in a "hot cell," which is typically controlled as a restricted area, it is assumed that no members of the public will be present in the "hot cell" at the time of loading. In some facilities, the treatment room acts as the "hot cell," and thus the dose rate at the exterior of the walls of the treatment room should be such that a person will not get a dose greater than 2 mrem in an hour. Therefore, a member of the public who might be present outside the suite is not likely to receive a notable dose of radiation.

The primary accident of concern during source changeout is the handling of a leaking source. This could occur if a source was damaged during shipping and not leak tested prior to installation in the unit. However, it is assumed that the shipping container will be surveyed prior to the removal of any sources for installation. Additionally, both the new and old sources are leak tested prior to removal/installation [good practice, 10 CFR 35.59]. Another potential accident would be the dropping of a source. However, it is not expected that the source would sustain any damage from a drop. The sources are subjected to the tests described in ANSI Standard N542. For an impact test, the gamma teletherapy sources are subjected to the dropping of a 5 kg mass onto the source from 1 meter above.

Since this task is performed by the vendor or its contractor, and the frequency is much less than other tasks, the risk from this task is not analyzed.

3.13.3.6 Task 13-6: System Not in Use/Standby

When patients are not being treated, the Gamma Knife™ will be in an "off" or "standby" condition. That is to say, the shielding door will be closed, the beams will be turned off, and the suite will be secured. Since a procedure is estimated to take a total of four hours, and 200 procedures are estimated to take place per year per facility, it is assumed that the unit will be in "standby" the remaining 7,960 hours per year.

When the Gamma Knife™ is not operating, the dose rate at the exterior surface of the wall is required to be 2 mrem/hour or less to comply with regulations [10 CFR 20.1302]. Therefore, doses to any members of the public or workers will be negligible.

The potential accident of concern is damage sustained by the unit due to a severe phenomenon. However, the manufacturer states in the device registration certificate that the unit weighs between 16 and 18 metric tons (depending on the model), is made of cast iron and cast steel, and should withstand any accident caused by ramming, collapse of the building structure, or fire without loss or exposure of the Co-60. It is noted that the melting points of the cast iron, cast steel, and Co-60 are approximately 2100°F, 2760°F, and 2700°F, respectively. Additionally, the cast-steel structure itself is a massive heat sink. Therefore, it is unlikely that a fire of sufficient size and heat to damage the unit would occur. In the event of an earthquake, the massive structure is likely to withstand the impact of a roof collapse, based on its composition and design.

3.13.3.7 Task 13-7: Disposal/Return of Source to Vendor

At the end of the useful life of the Gamma Knife™, the unit will be dismantled. The 201 Co-60 sources will be removed and returned to the manufacturer. Regulations require that only a licensed person remove the sources [10 CFR 35.605(b)]. Removal of the sources is performed using remote handling and shielding [good practice/tie-down]. Once the sources have been removed, they are placed in an appropriate shipping container. The manufacturer will take possession of the sources until their ultimate disposition. In this case, the sources will be recycled for other uses if possible.

The receptors of concern during source removal are the person(s) licensed to install and remove the sources, a representative from the manufacturer, and any member of the radiosurgery team who might be present to observe the procedure. Since this process takes place in a "hot cell," which is typically controlled as a restricted area, it is assumed that no members of the public will be present in the "hot cell" at the time of removal. In some facilities, the treatment room acts as the "hot cell," and thus the dose rate at the exterior of the walls of the treatment room should be such that a person will not get a dose greater than 2 mrem in an hour (in an unrestricted area).

The primary accident of concern during source removal is the handling of a leaking source. This could occur due to the age and embrittlement of the source. However, it is assumed that surveys will be taken prior to performing this task, and a leak test will be performed as well. Thus, it would be known if there is a potential leaking source, and the person would take appropriate precautions. Another potential accident is the dropping of a source. However, it is not expected that the source would sustain any damage due to a drop. The sources are subjected to the tests described in ANSI Standard N542. For an impact test, the gamma teletherapy sources are subjected to the dropping of a 5 kg mass onto the source from 1 meter above. One accident of particular concern is a source that ends up in the public domain. This could occur if the device is abandoned, or taken out of service and later removed from the facility, without the source having been removed. There are 201 sources that are approximately 1 inch in length. However, removal of the sources is performed in a controlled environment by one or two people while others may observe. In addition, the sources are handled remotely and placed directly in a shipping container.

The generic lost source methodology has been used to estimate the risk from this situation. Since the devices are very large ("fixed") and weigh many tons, the frequency of the devices entering the public domain is taken to be somewhat less than that for fixed gauges and significantly less than that for portable gauges.

3.13.4 Risk Analysis

A risk analysis was performed for a typical procedure using a Leksell Gamma Knife™. The system level inputs for this system are shown in Table 3.13-1.

The annual facility risks for the worker and the public are shown in Figure 3.13-1. The risk associated with normal operations is greater than that for off-normal or accident conditions. For the worker, the total annual risk associated with normal operations is almost one-tenth the occupational dose limit of 5 rem. There are two contributors to this risk. The first is due to exposure during patient preparation in the treatment room. The exposure occurs during performance of the quality assurance checks prior to treatment. The second contributor is exposure during treatment while observing from the control room.

For the public, the total annual risk associated with normal operations is small. For this system, the member of the public is a collocated worker who occupies an office down the hall from the gamma stereotactic surgical suite. It is noted that some uncertainty exists, primarily because treatment times vary based on the age of the Co-60 sources, and preparation times vary from patient to patient.

The total risk for both the worker and public due to accidents is small. The total risk for the public due to an accident is slightly greater than that for a worker. The increased risk is due primarily to an abandoned device that ends up in the public domain, with the shielding no longer intact or available. While the likelihood of this event is very small, the consequences can be very significant.

The worker accident risk is driven by the failure of the patient couch to fully retract after treatment, thereby requiring

the team members to manually extract the patient. Several such events have occurred and have been reported. The emergency procedures are designed such that the time the workers are exposed to scattered radiation is minimal. It should be noted that accident risks have large uncertainty associated with them.

3.13.5 Regulatory Options Analysis

Step 1: Sequence Binning

Table 3.13-2a bins the sequences emerging from the risk analysis according to the methodology summarized in Section 2.6.

In this system, the dose rates in normal operational sequences are such that normal dose over a year can accumulate to a level that would be considered significant if it occurred in a single off-normal episode. However, as discussed in Section 2.6.1.3, the dose guidelines are interpreted as applying to individual episodes; therefore, essentially normal sequences are not included in the set to be prevented, even if their total annual doses would trigger attention if incurred in single episodes.

Steps 2 and 3: Application of Dose Guidance and Formulation of Regulatory Priorities

The implications of the risk results are discussed below, and the results are summarized in Table 3.13-2b. The table includes estimates of the system's costs and benefits, which influence the risk results. The summary tables below are based on the dose guidelines discussed in Section 2.6.

Table 3.13-2b addresses each major consequence category, placing "high" for public next to "high" for workers, recognizing that the actual doses are different. Based on the conclusions from the table, the following must be achieved:

- very high assurance that source will not end up in public domain
- moderate assurance that interlocks will not fail

This system assesses risk associated with gamma stereotactic surgery using a Gamma Knife™. The source used is Co-60. For the "public," it is not likely that a source (within a device) will find its way into the public domain. However, if it does and the shielding is removed, the consequences could be such that significant adverse health effects would be expected. Although this event has not occurred in the United States, it is possible, based on an event involving a similar device that occurred in South America. Therefore, very high assurance is needed for source accountability. Only moderate assurance is required for interlock failure. Since the units are shielded by 80 cm of cast steel and iron, and housed in hot cells with sufficiently thick concrete walls, the choice to ensure interlock failure is made. The dose at the exterior of the wall cannot exceed 2 mrem in an hour (assuming the area is an uncontrolled area). This must be achieved at a time when the unit is in operation. This is comparable to when an interlock fails and the shield door fails open. Therefore, any dose that is received by a worker or member of the public when not in the treatment room is insignificant. The dose is significant only in cases when the worker has to enter the room and the shield door is not in place.

Steps 4 and 5: Development of the Diamond Tree and Identify Key Performance Nodes

Figure 3.13-2, Sheets 1 through 3, shows elements of a diamond tree for Teletherapy-Gamma Stereotactic Surgery.

Sheet 1 reflects the regulatory priorities inferred above: very high assurance is needed for control of sources and moderate assurance is needed for prevention of interlock failures.

Sheet 2 addresses source accountability. The main accident of concern is a loss of control of the teletherapy source (device). A teletherapy source has high activity. If it is not disposed of properly (or returned to the vendor) or abandoned, it has the potential to enter the public domain. If the shielding is subsequently compromised, the consequences can be extreme. Therefore, very high assurance is needed that these sources will not enter the public domain at any time during their life. This assurance can be obtained by maintaining a thorough source accountability program coupled with strict access controls and removal only by authorized persons. If a device is no longer to be used,

it should be kept behind locked doors or returned to the vendor at that time for source disposition.

Sheet 3 addresses a loss of the shield door due to interlock failure. The interlock failure can be caused by equipment malfunction or fire. Equipment malfunction cannot be prevented but can be reduced by periodic performance checks. Because of the design of the Gamma Knife™, for most interlock failures the unit will fail closed. In cases where a patient is being treated and the couch fails to retract (interlock failure), the members of the team will implement emergency procedures to extract the patient and close the shield door. Human error may play a role in an inadvertent opening of the shield door, but this would have to be compounded by one or more interlock failures. As such, it is covered by equipment malfunction.

Accurate and reliable equipment performance is dependent upon maintenance, periodic service, and quality control checks that are typically performed prior to each treatment. Maintenance and service are required to be performed by a licensed person–in this case, the manufacturer or its contractor. The quality control checks are performed by the licensee. These checks include visual observance of the unit as well as computer system checks. All interlocks are typically tested prior to each treatment. All of these performance nodes together provide necessary assurance that the unit will function as designed, and interlock failure will be less likely.

One aspect of equipment function is the inherent design. Currently, there are two different systems for manipulation of the patient couch in use. One is a hydraulic system, and the newer one is an electro-mechanical system. Each is susceptible to some type of failure. However, these are characteristics that are not within the purview of the System 13 licensee.

Part of the Step 5 process is to assess the impact of the system's value and other costs, when considering the appropriate barriers and related requirements. Referring to Table 3.13-2b, three items support a regulatory option that would reduce the regulatory requirements and streamline the safety assurance process. First, the current regulatory burden for System 13 is considered high. Second, the value to society is considered high, further supporting maintaining the viability of this cancer treatment option. Finally, the contamination from normal operations is low and the contamination risk from accidents is also considered low, minimizing the problems associated with contamination of the environment.

Step 6: Regulatory Approach

Table 3.13-2c lists the regulatory options that are considered to be attainable and promising. Incorporation of these regulatory options is likely to ensure that worker and public dose limits are not exceeded.

Table 3.13-2d shows how particular current specific requirements support the above tabulated general priorities. For each barrier listed in the left-hand column, the right-hand column indicates the correspondence between that barrier and the pertinent entry in the General Regulatory Approach Summary (Table 3.13-2c). If the right-hand column is blank for a particular barrier, then it supports a function that has not emerged from the risk analysis as being particularly significant. This does not automatically imply that the barrier is not warranted, but it does raise a question.

Table 3.13-1 System Level Input for Risk Analysis

Radioisotope	Unit Activity	Physical Form	Number of Procedures
Co-60	6,600 Ci per device	Sealed source, metal pellets	200 per device per year

Estimated number of licensees: Currently, there are 49 Gamma Knife™ units in operation.

	Sequences To Be Prevented With High Assurance			Sequences To Be Prevented With Moderate Assurance		
Public	Isotope	Task	Sequences	Isotope	Task	Sequences
	Co-60	13-7 (disposal)	2-A1S*, 3-A1SC*, 5-A2S*, 6-A2SC*, 8-A3S*, 9-A3SC*, 10-A4SCA*	Co-60	13-7 (disposal)	1-A1, 7-A3
Worker	Isotope	Task	Sequences	Isotope	Task	Sequences
	None			Co-60	13-2 (prep in treatment room)	6-SA
					13-3 (treatment)	5-S, 6-SA
					13-6 (standby)	5-S, 6-SA

* Indicates sequences that require very high assurance.

Costs and Benefits	Financial Risk	Lost Source Risk 3265	Regulatory Burden	Contamination Cost	Non-Radiological Health Risk	System Value	Perceived Risk
Ranking[1]	M[2,3]	M†	H[4]	L[5,6]	L††	H[7,8]	M[B]

	Functions Requiring High Assurance			Functions Requiring Moderate Assurance		
Public	Isotope	Function	Comments	Isotope	Function	Comments
	Co-60	S or [A1 and A2 and A3 and A4] during disposal	Very high assurance is needed that shielding will not fail in the event that a teletherapy source makes its way into the public domain, or that the teletheraphy source never makes it into the public domain.	Co-60	A1 and A3 during disposal	A1 and A3 represent a pathway for a source to enter into the public domain
Worker	Isotope	Function	Comments	Isotope	Function	Comments
	None			Co-60	S during preparation, treatment and standby	The S represents some type of interlock failure which causes the shield to fail open or the couch to fail to retract. In the case of standby, a fire causes the interlock failure.

[1] L = low; M = moderate; H = high

[2] NUREG/CR-4825 (NRC, 1987)

[3] NUREG/CR-5381 (NRC, 1990a)

[4] NUREG/CR-6330 (NRC, 1995b)

[5] NUREG/CR-1754 (NRC, 1981)

[6] NUREG/CR-1754 (NRC, 1989)

[7] Nuclear News, 1999a

[8] Clarion Health, 1999

† Non-citable reference

†† Insufficient data [B] See Appendix B - B.2.7

Table 3.13-2c General Regulatory Approach Summary, System 13

Area	**Requirement Type**	**Character of Regulatory Oversight**
Source accountability	Inventory, access controls, and removal only by licensed persons as controlled by procedures through radiation safety programs	Verify that radiation safety program (including provision for source accountability) is sufficient at time of licensing, periodically review
Prevent equipment malfunction/interlock failure	Periodic maintenance and service, and QC checks performed as controlled by procedures through radiation safety program	Verify that radiation safety program is sufficient at time of licensing, periodically review
Design/manufacture shielding of source	Prescriptive requirements on design characteristics (shielding performance, foolproof interlocks…), some attention to quality assurance. Device certificate must specify the device attributes that must be protected/ maintained by System 13 licensees.	Vendor licensing, certification of device. (Note: This is not a requirement on the System13 licensee, except that the System 13 licensee is required to use only certified devices.)
Design/construction shielding of treatment area*	Prescriptive requirements on the design and construction of the treatment room shielding	Certification of meeting specifications and thereafter audits

*The risk analysis was predicated on the design and construction of the shielding of the treatment area. Consequences of operation were assessed conditional on room shielding effectiveness consistent with current regulatory requirements. Shielding of the treatment area is therefore a priority.

Barrier Code	Barrier Description	Basis for Current Requirement	Role in Regulatory Approach
C-7	Sources and devices are required to be registered	30.32(g) and 32.210	Subsumed in manufacturing
B-8 C-1	Access to material is controlled	20.1801, 1802 unrestricted areas, good practice/tie-down	Part of source accountability
C-1 to 10	Radiation safety programs	20.1101	Associated with source accountability and prevention of equipment malfunction
C-7	Purchased from authorized supplier	35.49(a)	
B-10	Beam condition indicator light (visual indicator)	Tie-down	Related to interlock function
B-18	Maximize distance from sources	Good practice/tie-down	Part of design of treatment area
B-21	Limit time in vicinity of sources	Good practice/tie-down	
B-8 C-1	Public access to source and radiation is limited	20.1801, 1802 unrestricted areas, good practice/tie-down	Part of source accountability
C-4	Shielding is checked for leaks	Good practice	
C-5	Leak-testing of sources	35.59	
C-8	Training and instructions	19.12 if likely > 100 mrem/yr 35.21: personnel 35.25: supervised individuals tie-down: patient care givers 35.900/901: RSO tie-down: authorized users	Part of radiation safety program
C-10	Emergency plans and procedures	Good practice/tie-down	Related to interlock function
B-7	Sources are shielded when not in use	Good practice/tie-down (Manufacturer’s design)	Related to source accountability
C-4	A) package receipt surveys B) installation survey	A) 35.21 and 20.1906 B) Tie-down	
C-7	Source shield and storage configuration provide protection	Good practice/tie-down (manufacturer’s design)	Part of design of treatment area

B-7	Shielded when not used (storage, transport)	Good practice/tie-down	
C-3	Source accountability	30.51, 35.21, 35.59, license condition, good practice	Basis for source accountability
C-5	Surveillance of equipment for proper operation	Tie-down	Part of interlock function
C-9	Labeling of container	20.1904	
C-4	Periodic surveys	20.1501 and good practice/tie-down	
C-5	Surveillance to prevent unauthorized use	Good practice/tie-down	Part of interlock function
B-7	Shielding of treatment room	Good practice/tie-down	Part of design of treatment area
C-9	Posting of instructions at operator's console	Tie-down	Part of interlock function (human error aspect)
C-5	Maintenance and repair only by licensed persons	Tie-down	Part of interlock function
C-4	Survey instruments are calibrated	Tie-down	
N/A	Records, reports, etc	19.12, 19.13, 20.2101 through 20.2110, 20.2201 through 20.2206, 21.21, 30.35, 30.50, 30.51, 35.14, 35.22(a)(4), 35.23, 35.31(b), 35.33, 35.51(d), 35.53(c), 35.59(d), 35.70(h), 35.75(d), 35.92(b), license conditions	As needed for inspections
C-1 to 10	Radiation safety programs	20.1101	Part of public access control
B-8 C-1	Access to material is controlled	20.1801, 1802 Unrestricted areas, good practice/tie-down	Part of public access control