

FSME BYPRODUCT MATERIALS HRA-INFORMED PROJECT: RECENT DEVELOPMENTS AND STATUS

Briefing to
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Briefing Topics

- Overview of previous efforts to develop HRA-informed training & job aids
- Recent developments: New version of job aid
- Current status & near-term plans
- Long-term view of development plans
- Questions and/or discussion

Overview of efforts to develop HRA-informed training & job aids

- Development of HRA-informed job aid & training for medical applications (gamma knife as “test bed”)
- HRA-informed training has been developed, refined, & presented to FSME staff several times (last time – August 2007)
- Proto-type of HRA-informed job aid developed & presented to FSME staff in 2006

Current Status & Near-Term Plans

- With carryover from FY 2007, BNL:
 1. Has identified new requirements & specifications for HRA-informed job aid (November 2007)
 2. Has submitted a letter report with recommendations for re-specifying job aid
 3. Has drafted a new job aid
 4. Will present (today) the new job aid at FSME staff
- In the near term, there are additional development efforts that are needed:
 - Revisions & refinements of job aid (based on staff feedback)

Long-Term View of Development Plans

- Pilot of HRA-informed job aid & training at Region I
- Agency-wide roll-out of training & job aid for medical applications
- Expansion to address industrial applications, etc.

Excerpts from HRA-Informed Job Aid

Initial Aims and Approach

- Risk inform byproduct-related tasks
 - Apply HRA perspective to materials issues
 - Lacking models, primary qualitative
 - Provide technical basis for staff decisions
- How to provide this perspective
 - Basic information on human performance
 - Relevant resources
- Specific implementation
 - Training
 - Job Aid

Desired Features

- Consistent default starting point
- Support *ad hoc* (non-scripted) access
- Expect later development of ‘paths’
- Help find broad types of info, or specific items
- Maintain orientation w.r.t. available info
- Provide information that is task-relevant
- Show increasing levels of detail
- Allow user customization

Development Tool

- Considerations
 - Types of content
 - Desired features
- Help authoring tools (HATs)
 - Designed for creating information systems
 - Familiar interaction (software help function)
 - Support for implementing needed functions
- Draft created with *Madcap Flare*
 - Prototype material transferred
 - Limited amount of additional material

- About the Job Aid
- Human Performance Job Aids For
- Error Discussions
- Event Narratives
- Human Performance Topics
- Task Breakdowns
- Information Notices
- HRA Resources

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).



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Incorrect shot coordinates

All but one of the errors involved a transposition of two sets of coordinates. These may be uncomplicated slips, or they 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 move around the device. That is, the way in which the parameters are presented may not 'map' onto the way in which the settings are 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 tasks 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 to 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](#)

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- [-] About the Job Aid
- [-] Human Performance Job Aids For
- [-] Error Discussions
 - [-] Failure to change collimator height
 - [-] Failure to enter the prescribed
 - [-] Failure to perform QA checks
 - [-] Incorrect treatment time
 - [-] Treatment planned incorrectly
 - [-] Use of wrong treatment plan
 - [-] Incorrect shot coordinates
- [-] Event Narratives
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 - [-] Design and Use of Automator
 - [-] Unintended Consequences of
 - [-] Effects of Advanced Technolog
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- [-] Task Breakdowns
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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

[check](#)[automation](#)[calibration](#)[checking](#)**NMED 010662**

NMED 010813

NMED 040125

NMED 050104

NMED 050194

Reliability of Independent
Verification

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

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transposed

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050104

Rank ▲	Title
1	NMED 050104
2	NMED 980646
3	Incorrect shot coordinates
4	NMED 000277
5	NMED 000336

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'

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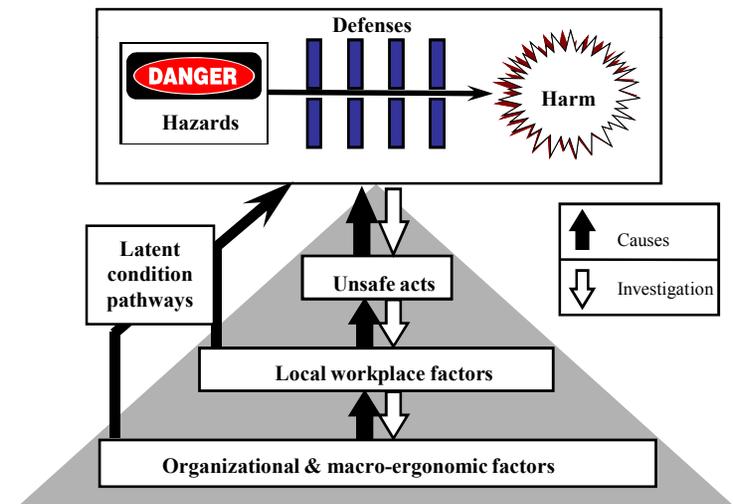
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Proposed Additional Content

- Approaches presented in training
 - Make consistent with ‘triangle’ focus for search & analysis
- HRA resources
 - Add knowledge about significance of differences
- Human-factors information
 - Expanded materials about levels in ‘triangle’ model
- NRC material

Consistency with Training

- Training reoriented to use ‘triangle’ model
- Materials to be added for levels of ‘triangle’
 - To help with analysis at different levels:
 - Individual
 - Workplace & tasks
 - Organizational



HRA Resources

- As well as being a 'mess of numbers' HRA is about making trade-offs
 - When is something 'good enough' and when will changes be worth while?
- HRA data allow these kinds of questions to be addressed
 - E.g.: Checker fails to detect mistake by another in written plan
 - $P_f = 0.1$
 - Second checker fails to detect mistake
 - $P_f = 0.5$

Questions and/or discussion?

BACKUP SLIDES

Background on Development of HRA-Informed Products for NMSS

- User Need (2003-003) from NMSS:
 - Phase 1 feasibility studies to identify NMSS needs were completed by 2005
 1. BNL performed study for byproduct materials (both medical & industrial uses)
 2. Study for high-level waste, fuel cycle, SFPO, & decommissioning was performed in-house
- Based on staff input (HQ & Regions), BNL is now focusing on development of HRA-informed products for medical applications (**gamma-knife based**) :
 - HRA-informed job aid (principally, for license reviewers)
 - HRA-informed training (both general & associated with HRA-informed job aid)
- NRC staff see this project as addressing Commission concerns about human errors in medical applications of byproduct materials, e.g.,
 - SRM issued April 30, 2007 (ML071200265)
 - Presentation & comments from Commission in May 2006