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A HUMAN RELIABILITY-CENTERED APPROACH TO THE DEVELOPMENT OF JOB AIDS FOR REVIEWERS OF MEDICAL DEVICES THAT USE RADIOLOGICAL BYPRODUCT MATERIALS

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SUMMARY/ABSTRACT

The U.S. Nuclear Regulatory Commission (NRC) is engaged in an initiative to risk-inform the regulation of byproduct materials. Operating experience indicates that human actions play a dominant role in most of the activities involving byproduct materials, which are radioactive materials other than those used in nuclear power plants or in weapons production, primarily for medical or industrial purposes. The overall risk of these activities is strongly influenced by human performance. Hence, an improved understanding of human error, its causes and contexts, and human reliability analysis (HRA) is important in risk-informing the regulation of these activities. The development of the human performance job aids was undertaken by stages, with frequent interaction with the prospective users. First, potentially risk significant human actions were identified based on reviews of available risk studies for byproduct material applications and of descriptions of events for byproduct materials applications that involved potentially significant human actions. Applications from the medical and the industrial domains were sampled. Next, the specific needs of the expected users of the human performance-related capabilities were determined. To do this, NRC headquarters and region staff were interviewed to identify the types of activities (e.g., license reviews, inspections, event assessments) that need HRA support and the form in which such support might best be offered. Because the range of byproduct uses regulated by NRC is so broad, it was decided that initial development of knowledge and tools would be undertaken in the context of a specific use of byproduct material, which was selected in consultation with NRC staff. Based on needs of NRC staff and the human performance related characteristics of the context chosen, knowledge resources were then compiled to support consideration of human performance issues related to the regulation of byproduct materials. Finally, with information sources and an application context identified, a set of strawman job aids was developed, which was then presented to prospective users for critique and comment. Work is currently under way to develop training materials and refine the job aids in preparation for a pilot evaluation.

INTRODUCTION

The U.S. Nuclear Regulatory Commission (NRC) is risk-informing its regulatory activity related to the use of byproduct materials [1], which are radioactive materials other than those used in nuclear power plants or in weapons production, primarily for medical or industrial purposes. Operating experience indicates that human actions play a dominant role in most of the activities regulated by NRC; the overall risk of these activities is strongly influenced by human performance. Hence, an improved understanding of human error can provide better risk insights to risk-inform the regulation of byproduct materials. During early risk-inform initiatives undertaken by NRC, important gaps in the methods, data, and tools available to perform risk analyses for byproduct material uses were identified. In particular, it was noted that NRC staff lacked methods for taking human reliability in to account when considering the wide range activities performed by licensees.

While many human reliability analysis (HRA) methods and models have been developed for nuclear power plants, they may not be well suited for application to byproduct materials. For example, HRA for nuclear power plants is focused on quantification and representation of human errors within the framework of probabilistic risk assessment (PRA) models. For most byproduct materials applications on the other hand, PRA and quantitative HRA may not be required nor desirable. Consequently, many byproduct materials applications may simply require qualitative tools that incorporate the essential knowledge and understanding of both qualitative and quantitative HRA methods, models, and approaches.

Also, the cognitive models that are the basis for nuclear power plant HRA may not be relevant to byproduct materials applications. In power plant HRA, the analysis often focuses on complicated human-system interactions, often associated with diagnosing failures within the reactor plant and the many safety systems associated with it. In contrast, for most NRC-regulated uses of byproduct materials, the hardware and systems involved are much simpler than those in nuclear plants. Consequently, while the same basic HRA process may be applicable to the broad range of byproduct materials uses, HRA methods, models, and data sets developed for nuclear plants are not generally directly applicable to byproduct applications.

However, to address human performance in NRC-regulated byproduct activities, the necessary disciplines (e.g., human factors, cognitive science, engineering) must be integrated with the risk basis provided by HRA. The term “HRA” used here refers to both qualitative and quantitative HRA methods and models, although the qualitative aspects or insights from HRA are likely to be of most use for many byproduct applications.

APPROACH

The development of the human performance job aids was undertaken by stages, with frequent interaction with the prospective users. First, potentially risk significant human actions were identified based on reviews of available risk studies for byproduct material applications and of descriptions of events for byproduct materials applications that involved potentially significant human actions. Applications from the medical and the industrial domains were sampled. Next, the specific needs of the expected users of the human performance-related capabilities were determined. To do this, NRC headquarters and region staff were interviewed to identify the types of activities (e.g., license reviews, inspections, event assessments) that need HRA support, and the form in which such support might best be offered. Because the range of byproduct uses regulated by NRC is so broad, it was decided that initial development of knowledge and tools would be undertaken in the context of a specific use of byproduct material, which was selected in consultation with NRC staff. Based on needs of NRC staff and the human performance related characteristics of the context chosen, knowledge resources were then compiled to support consideration of human performance issues related to the regulation of byproduct materials. Finally, with information sources and an application context identified, a set of strawman job aids was developed, which was then presented to prospective users for critique and comment. Each of these activities is described in more detail in the sections below.

IDENTIFICATION OF RISK-SIGNIFICANT HUMAN ACTIONS

A number of byproduct materials applications were identified prior to the start of the project as being of particular concern. Among these were various medical (therapeutic) applications (including intravenous brachytherapy, gamma knife, teletherapy, brachytherapy), field radiography, irradiators, and well-logging. The common characteristic is the potential for acute damage to be done in a relatively short time. Risk studies and event reports were reviewed for each of the systems.

The basic reference for studies of risk in byproduct activities is Schmidt et al [2]. The document provides, for each of forty ‘systems,’ descriptions of the use of byproduct materials and a barrier analysis for the application. The descriptions provide background information about the types of tasks performed (with an orientation of evaluating risk). The document is particularly valuable in the present context because it treats very varied systems

systematically, so that the similarities among them are more readily recognized, and it explicitly identify barriers to undesired events, which serves as a starting point for considering those barriers that depend on human action. However, the risk treatments in Schmidt et al are not a sufficient basis by themselves for developing HRA methods and tools. They do not consider in detail the individual human actions on which a node may depend, and, importantly, they do not consider risks of exposures to patients in association with medical systems; i.e., the risk analysis considers 'worker' and 'public' exposures.

The Nuclear Material Events Database (NMED), which is maintained for the U.S. Nuclear Regulatory Commission at the Idaho National Laboratory, was a principal source of information about events related to byproducts materials. The database is made available both online or as a Microsoft® Access file. The review of medical events used the Access-based version of the database, so that the search was not limited by the coding used for event causes or contributors in NMED. The review of other types of events (involving applications of byproducts materials in non-medical, primarily industrial settings) was done using the online version of the database. The online database allows records to be selected by predefined systems, components, causes and keywords. It is also possible to filter the records according to the event classification, so that, for example, lists limited to abnormal occurrences could be generated. However, the circumstances under which the actions took place are rarely described (e.g., time pressure, conflicting instructions).

Based on the sampling of the specific byproduct material systems described above, general characteristics that can lead to unintended events (i.e., misadministrations, overexposure of workers, or exposure of members of the public) were identified. Some of these are:

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

This last general characteristic cross-cuts many of the others and is involved in one way or another in large numbers of the events reviewed. Despite the different byproduct materials activities and the purposes for which they are carried out and environments in which they are conducted, they have some common features. For example, some potentially hazardous operations are carried out very frequently; often enough that they become routine, in what might be termed a 'production' environment. Mishaps are rare, and in many event descriptions an unusual circumstance can be identified that occasions a failure. Such events reveal that participants have been 'running risks;' that is, required activities that should have allowed an error or failure to be discovered and recovered were not effective (e.g., checks being omitted or done in a perfunctory way). Put another way, in many incidents, in very different systems, 'routine circumventions' (frequent breaking of a rule or standard practice) are revealed by unique conditions. Overall, the risk studies and events review underscore the need to focus on the effectiveness of barriers that depend on human performance.

IDENTIFICATION OF USERS' REQUIREMENTS

Several NRC personnel were selected to represent the range expected users of HRA-related capabilities for byproduct materials. They included NRC headquarters experts in medical and industrial uses, risk analysts, and reviewers/inspectors from NRC regional offices. Each was interviewed separately; the principal aim of the

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

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

SELECTION OF CONTEXT FOR INITIAL DEVELOPMENT

It had been decided that a pilot application of the HRA-informed training and tools would be carried out early in the development process. To do this, it was necessary to narrow the scope of the initial effort. In consultation with NRC, various applications of byproduct materials were prioritized and characterized with the aim of specifically identifying the context for the initial development of job aids and supporting information.

Identification of High Priority Modalities

Potential users of the job aid (specifically, staff at NRC headquarters) were asked to identify several important medical treatment modalities. An exercise was then conducted during which each of the modalities was ranked or rated on a number of dimensions:

- frequency – how often the treatment is used
- potential for harm – the consequences of error
- failures – rate of failures during use
- timescale – is the need for an aid continuing, or likely to be temporary
- scope – broad rather than narrow applicability
- need for guidance – lack of guidance, or recognized deficiencies

The aim was to identify which of the selected modalities would be appropriate contexts in which to develop initial job aids (i.e., those that tended to have higher ranks and ratings are candidates for use as a test bed). The frequency of use for the gamma knife and 'microspheres' was estimated to be high compared to other modalities; furthermore, use of both of these modalities is increasing. In addition, the potential for harm in the event of error is great in both cases. Gamma knife was thought to have a relatively low rate of failures, but it was noted that, with rapid expansion of the use of this treatment (both in terms of the numbers of centers and the treatments for which it is being used), the operating environment is changing. Increasingly there is more than one unit at a site, and they are being located in less sophisticated facilities. Also, whereas to date errors have tended to involve the reversal of x and y coordinates in location settings, other mechanisms, such as shifting of the device on the head, are beginning to appear.

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

Human Performance Characterization of Modalities

In order to further focus the development effort, the human performance characteristics of each of the modalities were considered. The aim was to insure that the modality or modalities selected to provide the context for initial development of human performance guidance and job aids would allow a range of human performance characteristics to be sampled. The same subject matter experts that participated in the above prioritization exercise were asked, for each of the treatment modalities, whether or not each of several aspects of human performance had a bearing on the use the modality. The human performance characteristics were among those identified earlier as being relevant to medical uses of byproduct material; they included communication, labeling, staffing and qualifications, checking, automation, human-system interfaces, testing and maintenance, and training.

In general, modalities involving remote and/or computer-controlled actions tend to have multiple issues (e.g., human system interfaces and automation) in common, whereas more manual processes have other specific issues.

Thus, the gamma knife was seen as having a wider range of human performance considerations than microspheres (the other high-priority modality).

Overall Conclusions

The ratings and characterizations described above were sufficient to narrow the scope of the initial development of job aids and supporting technical information. Based on priority ranking and human performance characteristics, and the availability of a track record of operation and incidents, it was decided to develop the initial aids from the perspective of the gamma knife. Because the aim is to develop guidance that is generic in nature, the human performance characteristics considered initially will be selected from among those that apply to multiple modalities. Based on the analysis described above, human-system interfaces, staffing, testing and maintenance, checking and training were considered. The choice of this focus was is in accord with NRC's requirement that the initial development should address day-to-day needs while attending to the need for guidance pertaining to emerging technologies, and appears narrow enough to meet the need to develop and evaluate a tool within a short time frame.

COMPILATION OF KNOWLEDGE SOURCES

In order to support the development of training on human performance and HRA-informed job aids, it was necessary to assemble a knowledge base that reflected human reliability issues relevant to applications byproduct materials. The types of information sources reviewed included work relevant to the selected topics that has been done in the context of nuclear power, literature on medical errors and patient safety, general treatments of human error, and descriptions of human performance analysis methods. The knowledge base will be added to as training materials are developed and the scope is expanded to other byproduct materials contexts. At present, it concentrates on human performance topics associated with the selected development context, the gamma knife; these topics are automation, staffing, checking, and human-system interfaces.

Automation

There is a growing literature on the role of automation in complex systems and its effects on human performance. Much of the work concerns the use of sophisticated automated systems in aviation, but process control (such nuclear power) applications are also represented. Current thinking, however, tends to concentrate on applications in which the automation operates in a more independent fashion than is typical in radiotherapy. Thus, for the present purpose, the treatment of automation will concentrate on relatively simple forms of automation, the human performance effects of which of which are well documented [3, 4].

Staffing

The treatment of staffing in the context of nuclear power generation is considerably more structured and prescriptive than in radiotherapy (or any other byproduct application). Nevertheless, some of the factors that are identified as relevant in evaluating power plant staffing issues may also be apply to personnel requirements in byproduct applications. The technical basis for assessing requests for exemption from the required staffing levels in nuclear power plants is provided by Plott et al [5]. Staffing and qualification (in the context of power plants) is also addressed in Element 6 of the Human Factors Engineering Program Review Model [6] and in Section 13 of the Human Performance Evaluation Process [7]. Patterson and Woods [8] specifically address the issue of on-call staffing strategies.

Checking

Patterson and her co-workers [9, 10] studied communication, and cross-checking in medical settings.

Human-System Interfaces

Tools and training will have to address the types of error made with computer mediated data entry and control. Human engineering review guidelines for various aspects of computer-based interfaces are found in the Human-System Interface Design Review Guidelines [11]. Specific topics that may be applicable to radiotherapy devices include computer-mediated controls, menu-driven interaction, and computer input (e.g., pointing devices, touch screens). While NRC staff will not review interfaces per se, the review guidelines can be used as specific examples of good design practices for any human-system interaction topic to be treated in the training and job aids. In addition the guideline items, the document contains, for each broad subject area, an overview describing the area from the point of view of human performance; these characterization may be adapted to familiarize staff with human engineering consideration for various topics. Furthermore, many of these characterizations were developed from documents (e.g., O'Hara et al [12] and Stubler et al [13]) that detail, for the more advanced human-system

interaction technologies, the technical basis for the associated guidelines. These documents will allow training content for some topics to be developed efficiently, since the pertinent literature has already been digested.

PROPOSED JOB AIDS

Development of the job aids needs to be seen within the context of the overall development effort. Training will be developed on general human performance considerations to provide staff with grounding in factors that influence human reliability. In addition, there will be training that applies to specific applications of byproduct material. The purpose of the job aids described below is to help NRC staff apply the HRA-informed knowledge provided in the training. Various candidate methods have been created for connecting human performance considerations to the specific activities or circumstances that are to be reviewed. These are briefly described below.

Formats

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

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

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

As shown in Fig. 1, task breakdowns play a central role organizing information about specific uses of byproduct material (e.g., medical treatment modalities) and the associated specific human actions and errors. As indicated above, overall task breakdowns for the current strawman development were available from an earlier risk analysis of gamma knife use [14]. Among the task data collected for the analysis was the training and knowledge required to perform each task. Because dealing with staffing-related exemption requests was identified as an activity this effort set out to support, one of the strawman tools is simply a block diagram of the task breakdown (as given in the risk analysis), showing the knowledge or training required for each task. This provides an example of how one might begin to evaluate a request involving staffing by considering whether the proposed staffing provided equivalent knowledge and skills as the current rules require.

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

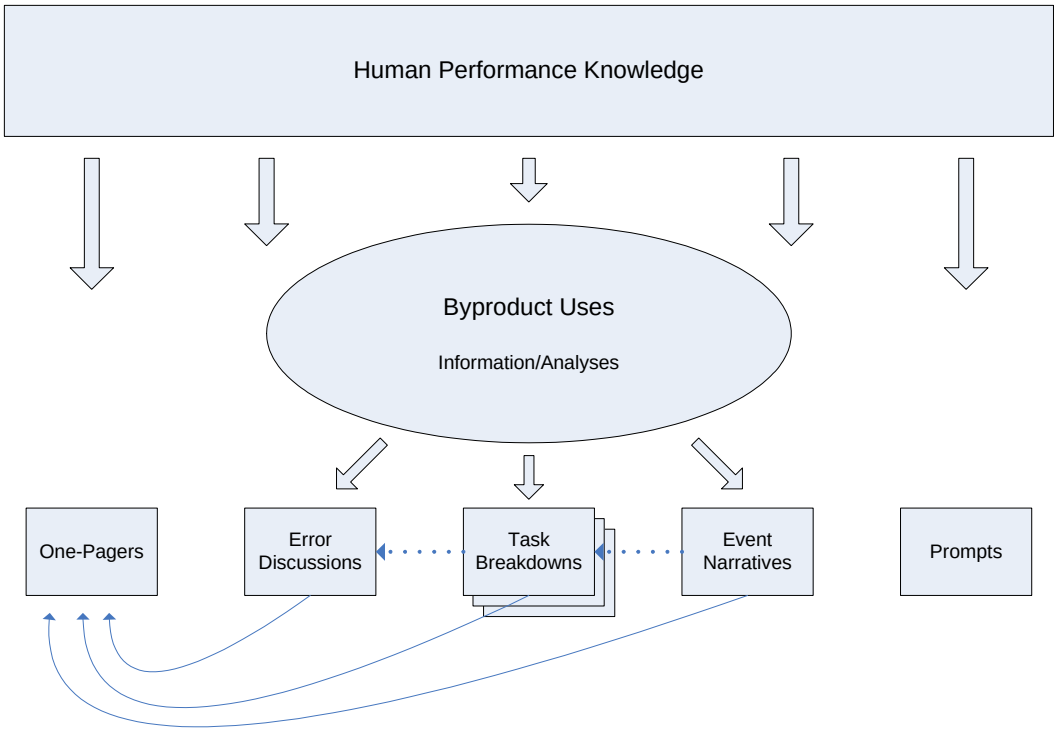

Figure 1. Job Aid Formats and Their Relationship to Human Performance Knowledge

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

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

Expected Use of Job Aids Formats

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

In the case of a licensee requesting an exemption, such as to staffing requirements, the reviewer can identify the different specific activities that would be affected by the proposed exemption using the format that shows the links from the relevant steps in the process description would identify the particular knowledge, skills, and abilities (KSAs) and performance standards (e.g., the need for double checking), and in turn would point to the relevant ‘one pagers’ in the human factors topics. In addition, the reviewer could use the format in which the process steps are annotated with NMED event numbers to consider the type of errors that have been associated with the affected steps in the past. The event narratives also point to the relevant one-page human performance summaries.

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

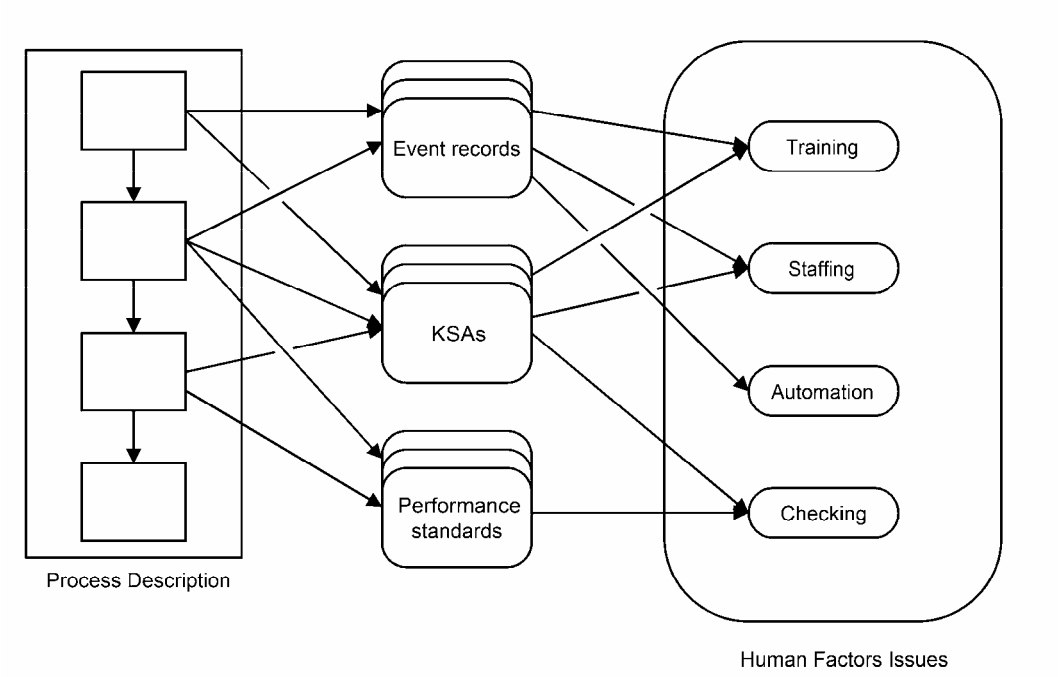

Figure 2. Illustration of Accessing Human Performance Topics via Job Aid Formats

These are intended as examples of how the different formats could be used. Such uses would need to be tested in trail applications, but the feedback received from prospective users suggests that these sorts of applications would be consistent with their needs.

Feedback from Users

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

FURTHER DEVELOPMENTS

Preparation of the strawman job aid formats has clarified the types of information that will have to be developed in the course of gathering the material that will form the basis for training on human performance topics. Once training material for these topics is developed, both the training and the job aids will be evaluated in a pilot application, which will help to identify any changes needed prior to going forward.

Some additional activities are required to support its further development. First, the currently available process descriptions are outdated (at least for the Type C devices), and more detail regarding the individual steps will allow a better specification of the task performance standards and personnel knowledge/skills required. Second, work is required to associate events with the steps in a more detailed process description. In principle, the linkages could be achieved using the NMED database. However, the current NMED database does not provide any explicit breakout of human factors issues. This could be an on-going task performed by trained NRC staff. One way to help staff develop the necessary perspective might be to add human performance related annotations and links to existing event narratives from the NMED database that are included as part of the job aid. Users could then learn, as they used the job aid, how to “read between the lines” to identify potential human performance issues.

Discussion with NRC staff clearly indicated that the usefulness of the various formats derived from the fact that they were related to each other and to human performance topics; i.e., their value was is their interconnections. The information formats described above were all produced in hardcopy form. It is apparent from the description of how

they are expected to be used that they could also be developed as a hypertext document or system, as suggested above. This would allow more extensive linkages and make the information more accessible to the users. For instance, starting with one step in the task breakdown, a link could bring up the relevant NMED record that has, in turn, links to the relevant "one pagers." Similarly where particular KSAs are identified as important in a step in the task breakdown, they could be linked to one pagers for relevant guidance on how to assess whether alternative staffing proposed by licensees are to be considered equivalent. As a trial, a preliminary demonstration hypertext tool has been developed that provides the kinds of links discussed, using common document processing tools. Work is currently under way to develop training materials and refine the job aids in preparation for a pilot evaluation.

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