

**NUCLEAR REGULATORY COMMISSION**

**HLWRS-ISG-04**

**PRECLOSURE SAFETY ANALYSIS - HUMAN RELIABILITY ANALYSIS; AVAILABILITY OF  
FINAL INTERIM STAFF GUIDANCE DOCUMENT**

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Notice of availability.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) is announcing the availability of the final interim staff guidance (ISG) document, "HLWRS-ISG-04 Preclosure Safety Analysis - Human Reliability Analysis," and NRC responses to the public comments received on the draft document. The ISG clarifies or refines guidance provided in the Yucca Mountain Review Plan (YMRP) (NUREG-1804, Revision 2, July 2003). The YMRP provides guidance to NRC staff for evaluating a potential license application (LA) for a high-level radioactive waste geologic repository constructed or operated at Yucca Mountain, Nevada.

**ADDRESSES:** HLWRS-ISG-04 is available electronically at NRC's Electronic Reading Room, at <http://www.nrc.gov/reading-rm.html>. From this site, a member of the public can access NRC's Agencywide Documents Access and Management System (ADAMS), which provides text and image files of NRC's public documents. The ADAMS accession number for ISG-04 is ML071910213. If an individual does not have access to ADAMS, or if there are problems in accessing the documents located in ADAMS, contact the NRC Public Document Room (PDR) Reference staff at 1-800-397-4209, or (301) 415-4737, or (by e-mail), at [pdr@nrc.gov](mailto:pdr@nrc.gov).

This document may also be viewed electronically on the public computers located at NRC's PDR, Mail Stop: O-1F21, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852. The PDR reproduction contractor will copy documents, for a fee.

**NRC RESPONSES TO PUBLIC COMMENTS ON HLWRS-ISG-04:** In preparing final NRC Division of High-Level Waste Repository Safety (HLWRS) ISG HLWRS-ISG-04, "Preclosure Safety Analysis - Human Reliability Analysis," ADAMS ML071910213, the NRC staff reviewed and considered 34 comments received from two different organizations during the public comment period. Several comments regarded questions about the regulatory basis for human reliability analysis (HRA), and perceived ambiguity in expectations. Several related comments addressed the use of empirical data and their relationship to HRA. The remaining comments included recommendations on specific changes to the ISG. Three comments on the ISG process were consistent with comments made earlier on HLWRS-ISG-01, HLWRS-ISG-02, and HLWRS-ISG-03, and were addressed in responses to public comment on HLWRS-ISG-01 [see 71 FR 57582, "Response to Comments 13 (a) and (b)"].

The following discussion indicates how the comments were addressed, and the changes, if any, made to ISG-04 as a result of the comments. Line numbers in the following comments refer to draft HLWRS-ISG-04, ADAMS ML070820387, which was made available for public comment on April 19, 2007 (72 FR 19729).

*Comment 1.* Both commenters noted that ISG lines 79-82 appear to imply that "direct manual operator actions," and "administrative and procedural safety controls" are important to safety (ITS), which is inconsistent with the definition of ITS in 10 CFR 63.2. 10 CFR 63.2 defines ITS as applying to structures, systems, and components (SSCs) that are engineered

features of the geologic repository operations area (GROA), and therefore, actions and controls would not be ITS. One commenter recommended specific revisions to ISG lines 79-82.

*Response:* NRC agrees with the commenters. However, note that 10 CFR 63.112(e), which is quoted in the “Regulatory Bases” section, in ISG lines 196-202, also states that the preclosure safety analysis (PCSA) of the GROA must include an analysis of the performance of the ITS SSCs. “This analysis identifies and describes the controls that are relied on to limit or prevent potential event sequences or mitigate their consequences. This analysis also identifies measures taken to ensure the availability of safety systems.” Therefore, the PCSA analyses for ITS SSCs also relate to controls, and measures to ensure safety system availability, and these could be tied to human actions.

The ISG has been revised to change ISG lines 79–82 to: “Examples of human actions that are risk-significant include: (1) direct manual operator actions that are related to reliability of important-to-safety (ITS) structures, systems, or components (SSCs); (2) administrative or procedure safety controls that are related to reliability of ITS SSCs and involve human actions; or (3) human actions that contribute significantly to the reliability of ITS SSCs.”

*Comment 2.* One commenter stated that there are two broad categories of methods to be considered for quantification in HRA: (1) methods based on actual surrogate human performance data from other facilities (e.g., chemical processes, interim storage, industrial operations, and nuclear power plants); and (2) generic second-generation methods in which probability distributions for human reliability are based on a qualitative assessment of context and performance factors. The commenter states that ISG-04 provides a considerable amount of guidance and cautions about the use of nuclear power plant data, but provides no explicit guidance on the use of non-nuclear data and no guidance on the use of generic second-

generation quantification methods [such as Cognitive Reliability and Error Analysis Method (CREAM) and Human Error Assessment and Reduction Technique (HEART)].

The commenter recommends adding text to:

(a) recognize human reliability data sources in addition to those associated with nuclear power plants; specifically, the commenter recommends adding a sentence at the beginning of Line 138, as follows: “Use of any quantification method, either data-driven or contextual, requires justification that it applies to Geologic Repository Operations Area (GROA) operations”;

(b) provide guidance on the use of generic second-generation methods.

*Response.* (a) NRC agrees with the commenter that data sources and approaches other than those associated with nuclear power plants may be used as part of the basis for estimating reliability, provided that there is sufficient technical justification to do so. The discussion in the ISG on the use of nuclear power plant data and approaches, and associated justification needed, applies to the use of data and approaches from other sources, as well.

ISG lines 138-139 have been revised as follows: “commercial nuclear power applications” has been changed to “applications for commercial nuclear power plants or other facilities.”

ISG line 142 has been revised as follows: “commercial nuclear-power-plant HRAs” has been changed to “HRAs for commercial nuclear-power plants or other facilities.”

The sentence in ISG lines 142-145 has been revised to “Staff should expect the use of any quantification method, either data-driven or model-driven, to be justified regarding its applicability to GROA operations.”

(b) The U.S. Department of Energy (DOE) has the flexibility to use any quantification method it chooses, including CREAM or HEART, provided there is sufficient technical basis to use the method for a particular application.

The following sentence is added after ISG line 136: “DOE has the flexibility to choose any method(s) to support the PCSA, given there is a sufficient technical basis for applying the method(s) and approach(es) to the GROA.”

*Comment 3.* One commenter noted that the term “risk-significant” is used in many ways in this ISG without a clear definition. The commenter recommended the following definition of risk-significant in the Glossary: “Risk-significant: important contributor to the probabilities or the consequences of a single event sequence.”

*Response:* NRC agrees with the suggestion to clarify the meaning of “risk-significant” in the Part 63 context, and add a definition for “risk-significant” to the Glossary. Risk-significance would be assessed according to those aspects of the LA and technical bases that bear on regulatory compliance with 10 CFR Part 63, which is based on: (a) whether an event sequence is category 1, category 2, or beyond category 2; and (b) whether the projected consequences meets the performance objective for that category. NRC expects the data and information provided to be commensurate with supporting these determinations. For example, staff expectations will be informed by: (1) the extent to which particular SSCs and controls are relied on to prevent or reduce the occurrence of event sequences; (2) the severity of the potential radiological consequences associated with these event sequences; and (3) the potential effects of uncertainty on regulatory compliance (e.g., the proximity of the associated frequency to the categorization limits for preclosure event sequences, and the proximity of the consequences to regulatory performance requirements). See also the discussion under “Uncertainty,” in HLWRS-ISG-02, p. 4, and the discussion under “Introduction,” to Appendix A, in HLWRS-ISG-02, p. 11.

The ISG has been revised as follows.

The following has been added to the end of ISG line 64:

“The goal of the review is to evaluate whether there is reasonable assurance that the performance objectives in Part 63 will be met, which in turn is determined by: (a) whether an identified event sequence is category 1, category 2, or beyond category 2, and (b) whether the projected consequences meet the performance objective for that category. NRC expects the data and information in an LA to be commensurate with supporting these determinations, rather than supporting precise quantification for all event sequences.”

The following definition has been added to the Glossary, after ISG line 379: “*Risk-significant*: Making a significant contribution to the probabilities and/or consequences of one or more event sequences that have the potential to exceed the performance objectives of Part 63 during GROA operations.”

In addition, the following sentence has been added to the beginning of the Glossary: “The definitions provided in this glossary are specific to the way the terms are used in this ISG, and may not be universally appropriate or applicable.”

*Comment 4.* One commenter stated that the term “full-blown” is not a clear term, and recommended replacing the term with “full HRA.”

*Response:* NRC agrees with the commenter.

ISG line 56 has been revised to change “full-blown HRA” to “full HRA (i.e., encompassing all elements of a complete HRA).”

*Comment 5.* One commenter recommended that ISG lines 117-119 be revised to delete the phrase, “Because recoveries are not possible for some waste-facility initiators,....” The commenter stated that the reason for reducing the frequency of occurrence of an event sequence or minimizing the probability of a hazard is not necessarily because of recovery difficulty.

*Response.* The intent of the sentence in lines 117-119 is to point out that for some waste-facility operational events or initiators (e.g., a drop event), recovery actions, such as actuation of safety systems to prevent the events-in-progress, may not be possible. Therefore, special attention to the associated human-induced initiators and the sequence of events leading up to the initiators may be of special interest in the staff review of the HRA/PCSA.

ISG lines 117-119 have been revised to change “Because....hazards)” to “For waste-facility initiators that may not have safeguards to prevent events-in-progress, once initiated (e.g., drop events).”

*Comment 6.* One commenter stated that the cited nine regulatory bases in ISG lines 173-215 do not specifically address HRA within the context of the PCSA. The commenter recommended adding the definition of an *Event Sequence*, from 10 CFR 63.2 at ISG line 173, to specifically show the regulatory basis for HRA within the context of the PCSA.

*Response:* NRC agrees with the commenter’s suggestion.

The following has been added to the beginning of item 1. at ISG line 173: “*Event sequence* means a series of actions and/or occurrences within the natural and engineered components of a geologic repository operations area that could potentially lead to exposure of individuals to radiation. An event sequence includes one or more initiating events and associated combinations of repository system component failures, including those produced by the action or inaction of operating personnel.”

*Comment 7.* One commenter stated that the term “key” is used in a variety of phrases in lines 220, 223, 446, 461, and 476; yet, the term “key” is not defined and its use in the ISG implies multiple definitions. The commenter recommends providing a definition of the term

“key,” in the Glossary, that states, “Key: relates to an important contributor to the probability or the consequence of a single event sequence.”

*Response.* The meaning of the term, “key,” in the ISG, and recommended changes to the YMRP, is the same as it is in plain language (i.e., important or fundamental). No further definition is necessary.

No change was made to ISG as a result of these comments.

*Comment 8.* One commenter recommended adding definitions to the Glossary for the following terms that are used throughout the ISG, and suggested a definition for each of these terms: (a) human-induced initiator, (b) human reliability analysis, (c) pre-initiator human failure event, and (d) post-initiator human failure event.

*Response.* NRC agrees with the commenter.

The ISG has been revised, as follows, to add the recommended terms, to the Glossary, which begins on ISG line 352, except the term “Pre-initiator Human Failure Event,” which has been defined already in ISG lines 375-379 as “Pre-initiators.” The “Pre-initiators” term has been revised to “Pre-initiator Human Failure Event (HFE).”

*Human-Induced Initiator:* An HFE that represents actions that cause or lead to an initiating event. The GROA is expected to employ various manually controlled waste-handling and transport equipment that may be subject to HFEs that could initiate an event sequence.

*Human Reliability Analysis (HRA):* HRA evaluates the potential for, and mechanisms of, human errors that may affect the safety of the GROA operations, including consideration of human reliability as it relates to design and programs such as training of personnel. The main objectives of the HRA are:

1. To ensure that human actions that could affect event sequences are systematically identified, screened, analyzed, and incorporated into the safety analysis in a traceable manner;

2. Where necessary, to quantify the probabilities of success and failure of human actions for event-sequence quantification and screening.

*Post-Initiator Human Failure Event (HFE):* Post-initiator HFEs include both operator actions and inactions that have the result of degraded plant/facility conditions. An example of such an HFE is the failure to manually actuate or manipulate systems or equipment that are required for response to an initiating event, to prevent propagation of an event sequence, or to mitigate its consequences. Post-initiator HFEs can be further divided into recovery and non-recovery events, as appropriate for a given event sequence.

*Comment 9.* One commenter stated that the definitions for error of commission and error of omission use the term “degraded plant state,” which does not apply to the GROA. The commenter recommends revising lines 354-355 and line 358 by replacing “degraded plant state” with “event sequence.”

*Response.* NRC agrees with the commenter that reference to the “degraded plant state” or “plant configuration,” in the definitions of *Error of Commission* and *Error of Omission*, in ISG lines 353-358, is not appropriate for the GROA.

ISG lines 354-355 and 357-358 have been revised as follows: “plant configuration” is changed to “facility configuration,” and “degraded plant state” is changed to “degraded facility state that may lead to an event sequence.”

*Comment 10.* One commenter stated that although the discussion in ISG lines 50-64 is useful, the reference, in footnote 3, to Regulatory Guide 1.174, is general in nature and not directly applicable to the PCSA. The commenter recommends deleting footnote 3 from the ISG.

*Response.* NRC agrees with the commenter that the reference to Regulatory Guide 1.174, in ISG footnote 3, is general in nature and not directly applicable to the Part 63 PCSA. However, as stated in footnote 3, the general discussion on the application of NRC's risk-informed regulatory principles is useful for other regulatory applications. Therefore, NRC disagrees with the commenter's suggestion to delete ISG footnote 3.

No change to the ISG was made as a result of this comment.

*Comment 11.* One commenter submitted several closely related comments, stating that the draft ISG lacks a sound regulatory basis, in that it is built on a presumption that DOE will be conducting an HRA that goes beyond what is required by Part 63. The commenter adds that the introduction section of the draft ISG on page 1 discusses HRA "...as if it were a stand-alone requirement for conducting the PCSA", when "...HRA should more appropriately be considered one of many possible elements of preclosure performance." The commenter, although recognizing that the paragraph on ISG page 2, lines 50-64, provides a more appropriate representation of how the HRA concepts should be used by the NRC staff, cites specific examples in the ISG that appear to be inconsistent with these concepts. The commenter's examples include the use of the phrase, "the HRA review," in ISG page 1; and the mention of "the HRA," the "HRA approach," or "an HRA for the GROA," in ISG lines 103, 108, 123, 154, and 168, as if a full HRA were required. The commenter also states that the ISG statement on page 2 that staff should not expect a full HRA including quantification of all human error probabilities in the PCSA, seems inconsistent with later ISG statements (lines 87-89) which suggest reviewers should verify that the HRA for risk-significant processes at the GROA was performed following a complete and technically appropriate HRA process, with follow-on discussion of "...elements of a highly quantitative HRA process."

*Response.* NRC disagrees with the commenter. Part 63 requires a PCSA, supported with adequate technical bases in risk-significant areas. Human reliability has been shown to be a key component in operations at industrial facilities similar to the GROA. The PCSA should address any aspects of human involvement, in pre-closure operations, that have a bearing on the performance criteria. The term “HRA” is used broadly to encompass any aspect of the PCSA that addresses human involvement. The HRA is not a stand-alone analysis, but rather a part of the PCSA that is required (10 CFR 63.112) to demonstrate compliance with Part 63 (10 CFR 63.111). As stated in ISG lines 2-4 and 50-64, the staff review of human reliability is in the context of the PCSA, and is not beyond what is required by Part 63. Furthermore, the ISG explicitly states (ISG lines 82-84), “Staff should tailor the scope and emphasis of its review to the approach taken in the LA, and the extent to which human actions are (or are not) relied on to meet 10 CFR Part 63 performance objectives”; and (ISG lines 55-57) that the review should be risk-informed, and staff should not expect a full HRA, including quantification of all human-error probabilities in the PCSA. Note that even for risk-significant processes at the GROA, ISG lines 89-98 explicitly state that the quantification HRA steps (c) - (e), may not be needed.

For clarification, the ISG has been revised as follows.

The following sentence has been added to the introduction, in line 7:

“In this ISG, “the HRA” refers to any consideration of human performance in the PCSA analyses, i.e., the evaluation of the potential for, and mechanisms of, human errors that may affect safety of GROA operations, including consideration of human reliability, as it relates to design and programs such as training of personnel.”

ISG line 5 has been revised to change “the HRA review” to “in the review of HRA in the PCSA.”

ISG lines 38-39 have been revised to change “The HRA supporting an LA” to “The HRA supporting the PCSA in an LA.”

The following sentence has been added to the paragraph preceding ISG line 65: “Staff should also recognize that the analysis of how human performance fits into planned operations and meeting performance goals at the GROA may appear in many different parts of the PCSA, and in varying scopes (in other words, human performance is likely to be addressed in different relevant parts of the PCSA, rather than addressed together in one place).”

The sentence in ISG lines 65-66 has been changed to the following: “The guidance in this ISG is written with the expectation that staff will seek the assistance of an HRA specialist(s) for review of risk-significant aspects of an LA affected by human performance.”

ISG line 78 has been revised to change “qualitative analyses in the HRA” to “the qualitative HRA analyses.”

ISG lines 123-124 have been revised to change “an HRA for the GROA” to “HRA in the GROA PCSA.”

*Comment 12.* One commenter stated that the ISG imposes, on the license applicant (DOE), an expectation that information be provided, in the initial LA, that would be more appropriately developed later in the licensing and repository development process – and the expectation being conveyed by this ISG not only exceeds what is required, but goes beyond what is expected to be reasonably available at the time of the initial LA. The commenter adds that the programs and processes will be developed over time, as the repository moves toward operational status, and thus need not be fully developed at the time of the initial LA.

*Response.* NRC disagrees with the commenter that the ISG imposes an expectation on DOE to provide information beyond what is required to demonstrate compliance with Part 63. For NRC staff to review the LA, DOE needs to provide sufficient information to demonstrate compliance with Part 63 – including the basis for safe operations, and where safety relies on procedural controls (and human performance), versus hardware components. The

expectations conveyed in this ISG are consistent with 10 CFR 63.21(a) that “The application must be as complete as possible in light of information that is reasonably available at the time of docketing.” The Technical Review Guidance contained in the ISG provides staff guidance on verifying that appropriate technical bases are provided in the LA for the PCSA, with respect to human reliability. The subsection, “Relationship to Programmatic Review and Licensing Specifications,” that begins on ISG line 153, specifically recognizes that certain assumptions may need to be verified later and included as probable subjects for license conditions in the LA. Note also that Part 63 requires one LA, with two regulatory decisions: whether to grant a construction authorization in accordance with 10 CFR 63.31, and whether to grant the license to receive and possess, in accordance with 10 CFR 63.41, after construction of the facility is substantially complete. NRC recognizes that additional information may become available in different stages of the licensing process, but at each stage, DOE must provide sufficient information to support that stage. See Commission’s discussion accompanying issuance of Part 63 (66 FR 55738-9; November 2, 2001).

No change to the ISG was made as a result of this comment.

*Comment 13.* One commenter submitted two closely related comments, stating that the bases, for the parenthetical material in ISG lines 36-37, and statement in ISG lines 115-116 and footnote 6, discussing differences in nuclear power plant versus nuclear materials facility operations, are unclear or speculative, since many of the fuel-handling operations at the repository will largely be a subset of the types of operations carried out at nuclear power plants. The commenter adds that there is no reason for NRC to convey additional expectations for HRA at the repository over and above what is expected at a power plant and suggests that, unless there is a basis, the parenthetical material in ISG lines 36-37 should be removed.

*Response.* NRC agrees with the commenter that the fuel-handling operations at the repository are likely to be similar to the fuel-handling operations at a nuclear power plant. The intent of the parenthetical material in ISG lines 36-37 and the statement in ISG lines 115-116 is to compare at-power nuclear power plant *power-generation* operations, where rule-based control-room tasks may dominate, versus *materials-handling* activities at nuclear materials facilities, where skill-based manual tasks may dominate the operations. The reason for these statements is to alert staff to these differences since, to date, much of the experience with HRAs, and focus of available guidance documents, are on HRAs for nuclear *power-generation* operations (*not* including *fuel-handling* activities at nuclear power plants). Furthermore, the ISG does not imply staff expectations for HRA beyond what is expected for power plants. Therefore, the staff disagrees with the commenter's suggestion that the parenthetical material in ISG lines 36-37 be removed.

The ISG, however, has been revised, as follows, to clarify the staff's intent:

In ISG line 36, "(e.g., nuclear power plant," is revised to "(e.g., at-power nuclear power-generation operations."

In ISG line 37, "nuclear materials facility" is revised to "nuclear materials facility activities."

*Comment 14.* One commenter stated that the first paragraph beginning on ISG line 69 appears internally contradictory, since it first discusses the qualitative HRA tasks that are performed as part of an overall PCSA (i.e., the conceptual understanding of human performance in the planned operations), and then identifies tasks, such as identification of HFEs and unsafe actions, as qualitative tasks. The commenter stated that: (a) It is not appropriate to describe the activities of identification of HFEs and unsafe actions "...as qualitative when they are the initial steps of a quantitative analysis"; (b) "Most reliability analysis

input for PCSA should not require explicit HRA. The reliability of most important to safety (ITS) systems, structures, and components (SSCs) should be determined by using empirical data collected from similar operations.”

*Response.* (a) NRC agrees with the commenter that the tasks encompassed by a conceptual understanding of human performance provide an important basis of, and hence could be considered a part of, and the initial steps, of a quantitative analysis. Similarly, the tasks of identification of HFES, unsafe actions, and factors that influence performance *are* qualitative tasks related to a mechanistic understanding of human performance, and can be considered as the initial steps of a quantitative analysis. (b) NRC agrees with the commenter that reliability analysis inputs based on the use of empirical data, in many cases, may not require explicit HRA. However, DOE would need to justify that the empirical data are applicable to the planned GROA operations, including any human performance aspects. (See also response to comment 15 below.)

For clarification, the ISG has been revised as follows.

ISG lines 69-74 are replaced with the following sentences: “It is important to have a conceptual understanding of how human performance fits into the planned GROA operations and safety. Although quantified reliability estimates are typically needed for categorizing event sequences, much of the HRA review should focus on the HRA tasks, that are performed as part of an overall PCSA, that explain the conceptual understanding of human performance in the planned operations. These tasks are part of the qualitative HRA analysis and would include, for example: (1) identification of HFES and unsafe actions; (2) identification of important factors influencing human performance; and (3) selection of appropriate HRA quantification method(s), if considered necessary. ”

The following entry has been added to the ISG glossary: “*Qualitative HRA Analysis:* HRA tasks that include: (1) identification of HFES and unsafe actions; (2) identification of

important factors influencing human performance; and (3) selection of appropriate HRA quantification method(s), if considered necessary.”

*Comment 15.* One commenter submitted several closely related comments about the use of empirical data and their relationship to HRA. The commenter’s statements include:

- A qualitative evaluation justifying the use of empirical data for the repository PCSA is a reasonable NRC staff expectation, but the applicant should be required to perform quantitative HRA as part of the reliability inputs only if human factors were not part of the existing data sets.
- “HRA is only one method of quantifying the human elements of risk. A preferable, and likely more accurate, method would be to use empirical reliability and event data that quantifies the total operational reliability including human influenced circumstances.”
- Regarding the crane data from NUREG-1774, “Human error is implicit in the data. If the applicant can show or commit to programs that have comparable rigor to the programs under which the data was collected, separate HRA should not be necessary.”
- ISG lines 428-431 guide NRC staff reviewers to determine whether the LA provides justification for data sources, based on relevant qualitative considerations – namely HRA activities: (a) Identification of HFES, and associated unsafe actions, to be considered in the overall PCSA; and (b) identification of important factors influencing human performance. The commenter stated that this is an inappropriate implied requirement that is more appropriate for the goal of improving human performance, but is not necessary to perform safety analysis, and is not required by Part 63 .
- “Items 4, 5, 6, and 7 on page 14 and 15 are more reasonable expectations of the NRC staff review of the repository license application than items 2 and 3 (*ISG - Appendix A*).”

*Response.* As noted on ISG lines 50-54, the applicant has flexibility in its approach to demonstrate compliance with Part 63 performance objectives. DOE may choose from a variety of approaches that, with adequate technical bases, can successfully demonstrate regulatory compliance. Relying on empirical data is one possible approach. If the applicant chooses to rely on empirical data to estimate reliability of SSCs during GROA operations, staff expects a technical-basis discussion to be provided, on why the data apply to the GROA operations.

In addition, see ISG lines 145-150, for guidance on staff review of use of empirical failure rates and their technical bases, with regard to human performance. If the LA relies on empirical data where human performance is an important contributor, the staff expects a qualitative evaluation that the relevant conditions at facilities from which the empirical data were obtained are similar to those expected at the GROA, since HFEs depend greatly on context (see ISG “Discussion” section, lines 28-39). NRC expects that, as part of this justification of “similarity,” of the operations at the empirical data facilities and the GROA, DOE would include a discussion on conditions relevant to human performance, if human performance were an important contributor. Item 6, in the Appendix beginning on ISG line 461, also clarifies the information pertinent to the data source (NUREG-1774), in the hypothetical example and potential discussion, that could be included in an LA, to address differences between the GROA and data source facilities.

No change to the ISG was made as a result of this comment.

*Comment 16.* One commenter submitted two closely related comments, stating that, “The sections titled, “Consideration of Applicability of Data Approaches,” beginning on page 4, line 137, and “Relationship to Programmatic Review and Licensing Specifications,” beginning on page 5, line 153, are more reasonable than...other parts of the Draft ISG,” with one

exception (see next sentence). The last sentence, starting at ISG line 167, in the section titled “Relationship to Programmatic Review and Licensing Specifications,” should be clarified or deleted, because: (a) the term “the HRA” incorrectly presumes a full HRA is necessary; and (b) the phrase “relevant programmatic elements of the HRA” is not clearly defined.

*Response.* (a) See response to Comment 11 above. (b) The purpose of this section is to highlight the dependency between HRA and programs such as training. Risk-significant elements of the PCSA and HRA that rely on assumptions about the adequacy of training and other programs are expected to be identified explicitly, and possibly identified as probable subjects for license specifications in the LA (requirements for future implementation, to ensure that the technical bases of the PCSA are valid).

For further clarification, ISG line 167 has been revised to change “programmatic elements of the HRA” to “programmatic elements supporting the HRA.”

*Comment 17.* One commenter was concerned that the proposed additions of “key human actions” and “human factors engineering,” to the YMRP, described in ISG lines 220, 223, 292, 296, 300, 304, 308, 312, 316, and 320, “...may imply that staff LA review should be to verify improvement of human performance, rather than to determine if regulatory requirements are met.” The commenter suggested that warnings should be placed, in the appropriate sections of the YMRP, stating that the purpose of the staff review is to determine regulatory compliance.

*Response.* NRC disagrees with the commenter. NRC believes that the staff understands clearly that the LA review is to verify compliance with Part 63, and that the change suggested by the commenter is not necessary. The proposed additions of the phrase “key human actions” to the YMRP are to alert the staff to the need to confirm that descriptions of the

GROA operations in the LA include the key actions that operators would have to perform to maintain safety. Similarly, the phrase, “human factors engineering,” was added to the YMRP, to alert the staff to verify that the quality assurance personnel, assigned by DOE to perform independent review of the plans for conduct of normal activities, including the written operating procedures, have experience and competence in the area of human engineering.

No change to the ISG was made as a result of this comment.

*Comment 18.* One commenter recommended changing lines 252 and 253 to (addition underlined): “Verify that any necessary human reliability analysis is consistent with....”

*Response.* NRC agrees with the commenter. However, the word “necessary” is not included. DOE has the flexibility to choose from a variety of approaches for different aspects of the LA. HRA may be chosen as one of multiple alternative possible approaches, rather than the only necessary approach, for a particular aspect of the LA.

The ISG has been revised as follows.

ISG line 108 has been changed from “the HRA” to “any HRA in the LA.”

ISG lines 252-253 have been changed from “Verify that the human reliability analysis is consistent with....” to “Verify that any human reliability analysis in the license application is consistent with....”

*Comment 19.* One commenter noted that on ISG lines 415-417, the concept of “important to human reliability” is introduced. (a) The commenter stated that this term is not defined in regulation and is unnecessary in the draft ISG context. (b) The commenter recommended truncating the sentence as follows, “...the data accurately reflect the

characteristics or features of the GROA,” in particular because it is not just the human reliability aspects that need to be accurately reflected in the applicant’s safety analysis.

*Response.* (a) “Important to human reliability” is not introduced as a regulatory concept, but rather used as plain language. The purpose of this phrase is to remind review staff to keep a risk-informed focus. Not every characteristic or feature of the GROA will be important to risk contribution from human reliability; the review focus should be on those characteristics and features that are significant with respect to human reliability. (b) NRC recognizes that human reliability aspects are not the totality of a PCSA. The scope of this ISG, though, is specifically to provide guidance on reviewing any human reliability aspects of a PCSA.

No change to the ISG was made as a result of this comment.

*Comment 20.* One commenter stated that the quote, from NUREG-1774, on ISG lines 422-427, that the percentage of “crane issue reports caused by poor human performance” has increased over time and averaged between 70-80 percent of the reports, should not be taken to mean that human performance is getting worse over time, and NRC should not establish any regulatory expectations based on such an assumption.

*Response.* NRC is not adding expectations based on these statistics reported in NUREG-1774. NRC recognizes there could be many factors, known and unknown, that may be driving the statistics. The intent of quoting the statistics in the ISG is to show that human performance did contribute significantly to the rate of load drops from cranes in the empirical data in this hypothetical example.

To help clarify, the ISG is revised to add the following sentence starting in line 425: “The reason for citing this statistic is not to imply that human performance is deteriorating over time,

but as an indicator that human performance *does* contribute significantly to events in the empirical data in this hypothetical example.”

*Comment 21.* One commenter stated that the statement in item 6 on ISG lines 491-493 that the NRC staff review should look for a “rigorous performance-monitoring program that might compensate for elements missing from the NUREG-1774 facilities” would not be a necessary part of the LA unless the applicant claimed better crane reliability than the empirical data in NUREG-1774.

*Response.* NRC disagrees with the commenter. The ISG does not direct NRC staff review to look for “...a rigorous performance-monitoring program that might compensate for elements missing from the NUREG-1774 facilities.” ISG lines 487-493 discuss a hypothetical scenario where there are differences, in the conditions at the facilities from which the empirical data were obtained, compared to those at the GROA. The ISG lists examples of what the LA might provide as part of the technical basis for whatever empirical rate(s) are chosen. “Rigorous performance-monitoring program to account for uncertainties” is just one example of justification the LA may provide for using a particular empirical rate (as is, or modified). This is part of the staff review of assumptions in the analysis, and checking for justifiable inputs from a human performance perspective (which the commenter recognized is a reasonable thing to do in the LA review).

No change to the ISG was made as a result of this comment.

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Dated at Rockville, Maryland this 10<sup>th</sup> day of August, 2007.

For the Nuclear Regulatory Commission.

/RA/

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