



NUCLEAR ENERGY INSTITUTE

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June 1, 2007

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Division of High-Level Waste Repository Safety
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20005-0001

Subject: Nuclear Energy Institute Comments on Division of High-Level Waste Repository Safety (HLWRS)-Draft Interim Staff Guidance (ISG)-04, *Preclosure Safety Analysis – Human Reliability Analysis*, 72 Federal Register 19729, April 19, 2007

Project Number: 689

Dear Ms. Ghosh:

The Nuclear Energy Institute (NEI)¹, on behalf of the nuclear energy industry, is pleased to comment on the Division of High-Level Waste Repository Safety (HLWRS)-Draft Interim Staff Guidance (ISG)-04, which supplements the Yucca Mountain Review Plan (YMRP) to provide guidance concerning the staff review of the Yucca Mountain Repository Pre-closure Safety Analysis (PCSA).

Industry commends HLWRS for providing an opportunity for public comment on this draft guidance. It is important to assuring a sound and predictable regulatory process that NRC provides opportunities for public input to all draft regulations and regulatory tools. In this instance, we encourage NRC to take advantage of this opportunity to reconsider both the nature and content of the proposed guidance.

As a general matter, NEI objects to the use of ISGs as a regulatory toll for Yucca Mountain. The reasons for this objection were stated in our comments on HLWRS-ISG-01², HLWRS-ISG-2³, and HLWRS-ISG-3⁴ and are reiterated in the enclosure to this letter. Unfortunately, HLWRS-ISG-4 is a prime example of why ISGs are not effective regulatory tools. We find this guidance to be

¹ NEI is the organization responsible for establishing unified nuclear industry policy on matters affecting the nuclear energy industry. NEI's members include all utilities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect/engineering firms, fuel fabrication facilities, nuclear material licensees, and other organizations and individuals involved in the nuclear energy industry.

² Letter, Steven P. Kraft to Mahendra Shah, dated July 6, 2006

³ Letter, Rod McCullum to Robert Johnson, dated December 13, 2006

⁴ Letter, Rod McCullum to Sheena Whaley, dated April 2, 2007

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significantly flawed in two respects: 1) it lacks a sound regulatory basis in that it is built on a presumption for the conduct of a Human Reliability Analysis (HRA) that goes beyond what is required by 10 CFR Part 63, and 2) it imposes an expectation that information be provided in the initial license application that would be more appropriately developed later in the licensing and repository development process. We believe that the broader review that would be associated with the development of this guidance through a more appropriate vehicle, such as a direct revision to the YMRP, would have prevented – and could still be applied to correct – these flaws.

Accordingly, and in the interest of helping NRC meet its stated intent of providing staff guidance for the review of any HRA that might be included in DOE's pre-closure safety analysis, we offer detailed comments in the enclosure to this letter. These comments are intended to support the reconsideration of the substantive content of the proposed ISG as a more appropriate direct revision to the Yucca Mountain Review Plan. The basis for our long-standing general concern with the use of an ISG to promulgate guidance of this nature is reiterated in Section I of the enclosure and a detailed explanation of the two significant concerns mentioned above, as well as other specific comments, is provided in Section II of this enclosure.

We strongly urge NRC to give all due consideration to these comments and reconsider this draft. To facilitate a constructive dialogue toward this end, we request an opportunity to meet with you to discuss this issue further at your earliest convenience. Please do not hesitate to call me at (202) 739-8082 if you have any questions.

Sincerely,



Rod McCullum

Enclosure

c: Mr. Martin J. Virgillio, Deputy EDO, NRC
Mr. Michael F. Weber, Director, NMSS, NRC
Mr. Eric J. Leeds, Deputy Director, NMSS, NRC
Mr. Lawrence E. Kokajko, Director, HLWRS, NRC
Mr. E. William Brach, Director, SFST, NRC
Mr. Edward F. Sproat III, Director, OCRWM, DOE
Mr. Mark Williams, Director, Regulatory Authority Office, OCRWM, DOE
Mr. Michael R. Johnson, Chairman, Committee for Review of Generic Requirements, NRC
NRC Document Control Desk

**NEI Comments on Division of High-Level Waste Repository Safety
(HLWRS) – Draft Interim Staff Guidance (ISG)-04, *Preclosure Safety Analysis – Human
Reliability Analysis*, 72 Federal Register 19279,
April 19, 2007**

The nuclear industry recommends that NRC reconsider Draft HLWRS-ISG-4 regarding Preclosure Safety Analysis (PCSA) human reliability analysis. We have the same general objections to the use of interim staff guidance (ISG) that were stated in our prior comments on HLWRS ISG-1, ISG-2, and ISG-3 (letters Kraft to Shah dated July 6, 2006; McCullum to Johnson dated December 16, 2006; and McCullum to Whaley dated April 2, 2007). Those comments regarding the use of ISGs as a regulatory tool and the application of ISGs to the Yucca Mountain licensing process are reiterated below as Section I to this enclosure. More importantly, in this case, we strongly object to the substantive content of NRC's Draft ISG-4 because we find it to be significantly flawed in two respects 1) It lacks a sound regulatory basis in that it is built on a presumption for the conduct of a Human Reliability Analysis (HRA) that goes beyond what is required by 10 CFR Part 63, and 2) It imposes an expectation that information be provided in the initial license application that would be more appropriately developed later in the licensing and repository development process. Our specific comments calling for modifications to the substantive content of NRC's Draft ISG-4 are contained in Section II of this enclosure.

I. General Concern Regarding the Use of Interim Staff Guides

Use of Interim Staff Guidance as a Regulatory Tool

As a general matter, we continue to encourage NRC to limit use of ISGs and other forms of generic communication to clarifications of regulatory review guidance that do not involve new technical issues and/or compel licensees or prospective licensees to take actions beyond those required by regulation. Other, more appropriate regulatory tools, such as revision to review plans or regulations, that receive broader NRC regulatory, technical, and policy review are available to address such matters. In this case, the appropriate vehicle for what is proposed in Draft ISG-4, once the flaws discussed below are corrected, would be a revision to the YMRP.

Application of the Interim Staff Guidance Precedent to Yucca Mountain

ISGs were originally intended by NRC's Spent Fuel Project Office (now Division of Spent Fuel Storage and Transportation) as a response to an emerging issue that would guide NRC staff actions and ensure consistent reviews of ongoing licensed activities by multiple licensees and certificate holders. These documents were labeled as "interim," because they were only intended to be in place until the regulations and/or standard review plan could be revised.

This rationale does not extend to Yucca Mountain, where there is only one potential licensee and no ongoing licensed activities. Based on DOE's public statements, a license application is approximately a year away and the NRC staff review will not begin until after this application is submitted. In addition, in the case of Yucca Mountain, there is no potential for any emerging issue to affect the NRC staff's review in any way that requires "interim" guidance to be issued until the issue can be more directly addressed in the YMRP.

Also, in the case of Yucca Mountain, there has been no event, occurrence, discovery, or scientific advance that would cause NRC to need to change its Yucca Mountain review guidance in this area. If the NRC staff believes there is a need to clarify the requirements to evaluate human reliability, an update or supplement to the YMRP would be a more appropriate vehicle.

Need for consistency in level-of-review

Draft ISG-4 recommends several changes to the YMRP. It therefore follows that such changes should go through an equivalent approval process to that applied to the YMRP, ideally including NRC Commission approval in a public meeting. To do otherwise tends to usurp the authority of the Commission and constrain the extent to which interested parties to the Yucca Mountain licensing proceedings are provided the opportunity for due process. The ISG process does not have the same rigor or level of review as the YMRP. ISGs issued at the NRC staff level have the potential for creating consequences that are not intended by the Commission and that may be problematic in practical application.

II. Specific comments On the Substantive Content of Draft ISG-4

Unfortunately, Draft ISG-4 appears to be a prime example of how the process concerns described above can lead to a product that is not an effective regulatory tool. The nuclear industry believes that the content of Draft ISG-4 is flawed and should be reconsidered. We believe that the broader review that would be associated with revisiting the topic of HRA in a potential direct revision to the YMRP should be applied to facilitate such reconsideration. Specifically, our concerns fall into two specific areas:

- 1) HLWRS-ISG-4 lacks a sound regulatory basis in that it is built on a presumption for the conduct by DOE of an HRA that goes beyond what is required by 10 CFR Part 63. Specifically, 10 CFR 63.112 (a) requires a "systematic analysis of...human-induced hazards at the geologic repository operations area" while 63.112 (b) requires "The technical basis for either inclusion or exclusion of specific...human-induced hazards." This requirement for DOE to demonstrate that it has adequately evaluated the effect of human induced hazards does not equate to an expectation that the applicant has performed a complete HRA for safety significant event sequences. The proposed ISG flip-flops between this over-reaching expectation and the more appropriate expectation that the basis for inputs to the applicants safety analysis be appropriately justified, including any human factors inputs. In doing so, it's appears that the Draft ISG was prepared with these two competing expectations in mind, but instead of making a single set of expectations clear, this Draft ISG serves to confuse the matter. Specific examples of this ambiguity, and the resultant over-reaching expectations, are given in the comments on lack of regulatory basis below.
- 2) HLWRS-ISG-4 imposes on the license applicant (DOE) an expectation that information be provided in the initial license application that would be more appropriately developed later in the licensing and repository development process. Commitments to programs, processes and controls are all that is necessary at the time of the initial license application. It is up to the applicant to define the details of its programs and processes and NRC staff to verify they are implemented as defined. These programs and processes will be developed over time as the repository moves towards operational status in accordance with the commitments made at the time of the initial license application. NRC opportunities to verify the effectiveness of program implementation will arise as the programs are developed, however, sufficient detail about these programs to construct the HRA being called for in ISG-4 is not likely to be available at the time of the application. Therefore, the expectation being conveyed by this ISG not only exceeds what is required but goes beyond what is can be expected to be "reasonably available"

¹at the time of the initial license application. Specific examples of this temporal conflict are given in the comments on premature expectations below.

Comments Regarding the lack of regulatory basis for the HLWRS-ISG-4

1. The introduction section of the draft ISG on page 1 discusses HRA as if it were a stand alone requirement for conducting the preclosure safety analysis (PCSA). It discusses actions to "aid the HRA review" as if HRA was a specific requirement. HRA should more appropriately be considered one of many possible elements of preclosure performance. It is a factor that may or may not already be implicitly included in reliability statistics that are used as inputs to PCSA. The introductory discussion should focus on an adequate NRC staff review of the PCSA, including HRA to the extent reasonable, not as an "HRA review." There are later citations in the Draft ISG that say this, but how HRA is to be included within the context of PCSA is inconsistent throughout the ISG.
2. The paragraph on page 2, lines 50 – 64, is a more appropriate representation of how HRA concepts should be used in the NRC staff review of the repository license application. This paragraph recognizes the flexibility provided in 10 CFR Part 63 as a risk informed, performance-based regulation. As stated, "Staff should not construe guidance in this ISG to mean that staff should expect a full-blown HRA . . ." The use of HRA concepts in the PCSA may be appropriate when establishing inputs to the analysis that have great uncertainty because of limitations in supporting data or limitations in available state-of-the-art methods and approaches. This paragraph demonstrates a broad understanding of 10 CFR Part 63, as opposed to the narrow focus on HRA that is found in the examples cited in the following comments that do not appear to take the statements in this paragraph to heart.
3. Under the Technical Review Guidance, Level of Information section, the first paragraph beginning on line 69 appears to have contradictions within it. It first discusses a "conceptual understanding of human performance in the planned operations." It then goes on to discuss "qualitative tasks" such as identification of HFEs [human failure events]; . . . identification of factors influencing human performance; and selection of appropriate HRA quantification method(s)." It is not appropriate to describe these activities as qualitative when they are really the initial steps of a quantitative analysis.

Most reliability analysis inputs 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. It is agreed that a qualitative evaluation justifying use of such empirical data for the repository PCSA is a reasonable expectation by the NRC staff. Part of that justification should include a qualitative evaluation of the implicit nature of human factors being part of the empirical data. Only if human factors (in similar operating circumstances) were not part of the existing data sets or where there are human actions within event sequences that have not otherwise been included in the PCSA, should the applicant be required to perform quantitative HFE as part of the reliability inputs.

4. In the first full paragraph on page 3, lines 79 and 80 raise the concept of "direct manual operator actions" and "administrative or procedural safety controls" that are ITS. Neither the definition of ITS in 10 CFR Part 63, nor the same definition in this Draft ISG discuss ITS

¹ 10 CFR 63.21 (a) states "The application must be as complete as possible in light of information that is reasonably available at the time of docketing." This requirement recognizes that the Yucca Mountain licensing process is a multi-step process and that additional information will become available as the project proceeds through the steps of the process.

in terms other than ITS systems, structures, and components. It is unnecessary to extend the ITS concept beyond what is defined in the regulations and staff guidance should not attempt to do so.

5. The "Acceptable Methods and Approaches" section beginning on page 3, line 85, discusses an acceptable approach to performing HRA as if HRA were a required element of PCSA. This is despite the admonition to NRC staff in the paragraph beginning on line 50 that states, "DOE may choose from a variety of approaches which, with adequate technical bases, can successfully demonstrate regulatory compliance. . . . Staff should not construe guidance in this ISG to mean that staff should expect a full-blown HRA, including quantification of all human error probabilities in the PCSA." Lines 87 – 89 state, "Reviewers should verify that the HRA for risk-significant processes at the GROA was performed following a complete and technically appropriate HRA process." It goes on to discuss the elements of a highly quantitative HRA process.

There is no requirement to have "the HRA" for risk-significant or other processes. This section mentions "the HRA" several other times as if it were required. The requirement for PCSA is to have justifiable inputs. If empirical data is available for preclosure operations that include appropriate human factors elements, no additional HRA type analysis should be necessary. If the applicant can show (or commit to, in the initial license application) comparable or more rigorous quality assurance, maintenance, operations training, and procedures under which empirical data inputs were collected, no further HRA analysis should be necessary. A perfect example of this is the crane data from NUREG-1774 cited in this Draft ISG. As noted on page 1 of the Draft ISG, human error is not only included in the crane event data, it is the leading cause of such events. 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. The applicant then has the burden to put the appropriate controls in place and the NRC staff has the burden to verify the controls are in place before an operating license is issued.

6. The sentence on lines 99 – 102 states, ". . . if the LA demonstrates that acceptable risk is achieved through robust hardware design features that cannot be defeated by human actions (errors of omission or errors of commission), HRA activities (b) through (e) may be omitted or significantly reduced in scope." The issue isn't whether or not human error is possible, but rather to make sure the risk is quantified appropriately. 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.
7. Lines 103, 108, 123, 128, 154, and 168, among others, mention "the HRA," "the HRA approach," or "an HRA for the GROA," as if a full HRA is required. As discussed in previous comments, it is not.
8. On lines 220, 223, 292, 296, 300, 304, 308, 312, 316, and 320 review elements for key human actions and human factors engineering are proposed additions to the YMRP. Based on the wording of this Draft ISG, it is not clear that staff will understand that the LA review should be to determine if regulatory requirements are met versus an implied review to identify actions that can be implemented to improve human performance. Warnings should be placed in the appropriate sections of the YMRP that the staff review is to determine regulatory compliance. Improvement in human performance is a worthy goal, but it should not be regulated except as specifically required in regulation.

These elements are examples of the presumption that seems to exist throughout this ISG that studies and analysis that have traditionally been applied to determine areas of improvement to human performance are necessarily required to support PCSA. While improvements in human performance are a worthy goal for operations, what is required in safety analysis is a reasonable depiction of projected operations. The use of empirical data from similar operations is the most accurate method to do this. Where human performance can be shown to be implicitly included in the empirical data, no additional human performance inputs or details are necessary.

9. At lines 252 and 253 the sentence, "Verify that the human reliability analysis is consistent with . . ." should be changed to "Verify that any necessary human reliability analysis is consistent with . . ."
10. Appendix A of the Draft ISG is an example of HRA considerations for the reliability estimate of a crane. Much of this example makes sense, especially if the implicit human elements of crane reliability in the data are accepted. However, there are some issues. On lines 415 – 417 the concept of "important to human reliability" is introduced. In part it states, ". . . the data accurately reflect the characteristics or features of the GROA that would be important to human reliability." This term is not defined in regulation and is unnecessary in the Draft ISG context. The sentence should be truncated as follows, ". . . the data accurately reflect the characteristics or features of the GROA." It's not just the human reliability aspects that need to be accurately reflected in the applicants safety analysis. Human reliability is not regulated separately; it may be used as part of an integrated safety analysis and should be appropriately considered as is the case with other potential safety analysis inputs.
11. Item number 2 on page 14, lines 428-431, guides the NRC staff reviewers to determine whether the license application provides justification for data sources "based on relevant qualitative considerations, namely HRA activities (a) and (b) . . ." Activity (a) is "identification of HFES, and associated unsafe actions, to be considered in the overall PCSA." Activity (b) is "identification of important factors influencing human performance (both traditional "performance-shaping factors" and "contextual factors." This is an inappropriate implied requirement unless the applicant chooses to segment the human performance aspects of crane reliability versus overall reliability. If the applicant uses empirical crane reliability data, it is sufficient to describe how repository operations, maintenance, and quality assurance will be performed with comparable or more rigor than that under which the empirical data was collected. If the task at hand were to improve human performance beyond that in the empirical data, perhaps activities (a) and (b) would be necessary; but performance improvement is not necessary to perform safety analysis and is not required by 10 CFR Part 63.
12. Item 3 on page 14, lines 432-437, discusses the need to identify specific HFES and past unsafe human actions regarding crane operations. This is not necessary to reasonably quantify crane reliability. If the applicant shows similar crane operations under which the empirical data was collected and commits to comparable rigor of procedural, maintenance, and quality assurance controls; no additional human performance input or data should be necessary. The task of PCSA is to analyze safety versus to improve upon past performance. Improvement of human performance is a worthy goal that can utilize many of the techniques prescribed in this Draft ISG, but there is no reasonable expectation or regulatory

requirement that the repository license applicant utilize these techniques in its safety analysis.

13. 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. They basically require that the staff consider whether the applicant's safety analysis has justifiable inputs from a human performance perspective. Checking the basis of safety analysis inputs from a human performance or any other perspective is a reasonable thing for the NRC staff to do in their review of the applicant's PCSA.
14. Item 6, page 15, lines 491-493, states that the NRC staff review should look for a "rigorous performance-monitoring program that might compensate for elements missing from the NUREG-1774 facilities. This would not be a necessary part of the license application unless the applicant claimed better crane reliability than the empirical data presented in NUREG-1774. Again, it might be a reasonable element of a program to improve human performance, but is unlikely to be a necessary element of safety analysis.

Comments Regarding the premature expectation for HRA information

15. Lines 115 and 116 state, ". . . in HRAs for nuclear waste facilities, the role of human-induced initiators may be more dominant than that of post-initiator HFEs . . ." An associated footnote states, "This is in part because compared to nuclear power plants, waste-processing facilities typically involve more manual actions and may employ fewer safeguards against human-induced initiators because of lower levels of risk and complexity." The only accurate part of that statement is that a repository is a lower risk facility than a nuclear reactor. As applied to the Yucca Mountain repository, this statement is otherwise speculative and without basis. 10 CFR Part 63 requires comprehensive quality assurance and operations training programs. The fuel handling operations at the repository will largely be a subset of the types of operations carried out at nuclear power plants. Beyond that, it is up to the applicant to define the details of its programs and processes and NRC staff to verify they are implemented as defined. These programs and processes will be developed over time as the repository moves towards operational status, and need not be fully developed at the time of the initial license application. The speculative words quoted at the beginning of this comment should be deleted. Furthermore, NRC should not place any expectations for HRA on the Yucca Mountain facilities that go beyond those placed on nuclear reactors due to the lower risk associated with repository operations.
16. The sections titled, "Consideration of Applicability of Data and 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, with one exception (see next comment), other parts of the Draft ISG. The former discusses the use of empirical failure rates for implicit inclusion of human reliability considerations and lays out reasonable staff expectations. It states in regards to expectation of NRC staff reviews, "Any implicit assumptions on the existence and efficacy of administrative controls contained in the empirical data should be identified for subsequent verification." This is a much more reasonable approach than that discussed earlier in the Draft ISG where the implication was that any risk-significant activities should be the subject of a quantitative HRA.

The latter section states that "the staff should identify any assumptions that need to be verified in the program reviews . . . and assumptions that need to be verified during construction or operations." This is reasonable and recognizes an important point – that the

administrative controls instituted by the applicant can only be verified at appropriate stages of the licensing process. Commitments to those controls are all that is necessary at the time of the initial license application.

17. The last sentence of the section titled "Relationship to Programmatic Review and Licensing Specifications" beginning on page 5, line 167, does not make sense and should be clarified or deleted. It states, "As necessary, the staff should check that DOE verifies risk-significant assumptions and identifies relevant programmatic elements of the HRA as probable subjects for license specifications in the LA." As discussed in the previous section of these comments, terms like "the HRA" incorrectly presume a full blown HRA is necessary. Furthermore, it is totally unclear as to what "relative programmatic elements of the HRA" means. If it means an appropriate quality assurance program, training program, or administrative controls; these are elements of nuclear operations, not elements of "the HRA." Again, commitments to those programs are all that is necessary at the time of the initial license application. Their specific implementation, and the role that HRA plays in this implementation is something that will be developed as the repository moves to operational status.

Other Substantive Comments

18. The basis for the parenthetical on lines 36 and 37 discussing a nuclear power plant ". . . where rule-based control-room tasks may dominate, versus nuclear materials facility where skill-based manual tasks may dominate" is unclear. Many, possibly most, of the fuel handling operations at nuclear power plants are the same as projected for a repository where the same types of equipment and operator skills would be required. Accordingly, 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 – as could be inferred from this statement. Unless there is a basis for the statement, it should be removed.
19. Page 14, lines 422-427 discuss the percentage of "crane issue reports caused by poor human performance" increasing over time and the human performance caused [issue reports] averaging between 70 and 80 percent of the total. It's not clear what point is being made here. If it is that human performance is an important aspect of crane safety, the point is well taken. If the implication is meant to show that human performance is getting worse over time, thereby somehow justifying the additional HRA expectations conveyed by this Draft ISG, that conclusion is not supported by the information presented in the Draft ISG or in the NUREG cited. There are many possible reasons for such statistics. For instance, the threshold for being the subject of a "crane issue report" may have decreased over time, the types of crane activities may have become less standard over the period of the study, or other unknown factors may be driving the statistics. It should not be assumed that human performance is getting worse and NRC should not establish any regulatory expectations based on such an assumption.