



NUCLEAR ENERGY INSTITUTE

Rod McCullum
DIRECTOR
Yucca Mountain Project

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Mr. Robert Johnson
Project Manager
Licensing and Inspection Directorate
Division of High-Level Waste Repository Safety
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20005-0001

Nuclear Energy Institute Comments on Division of High-Level Waste Repository Safety (HLWRS)-Draft Interim Staff Guidance (ISG)-02, *Preclosure Safety Analysis – Level of Information and Reliability Estimation*, 71 Federal Register 57584, September 29, 2006

Project 689

Dear Mr. Johnson:

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)-02, which supplements the Yucca Mountain Review Plan (YMRP) to provide guidance for the staff review of design and operational information and reliability estimates required for the 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Industry commends HLWRS for providing an opportunity for public comment on this draft guidance.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 the NRC provide opportunities for public input to all draft regulations and regulatory tools.

As a general matter, NEI objects to the use of ISGs as a regulatory tool for Yucca Mountain. The reasons for this objection were stated in our comments on HLWRS-ISG-01, submitted in Steven P. Kraft's July 6, 2006 letter to Mr. Mahendra Shah, and are reiterated below. However, we note that the proposed HLWRS-ISG-02, in contrast to HLWRS-ISG-01, appears to be constructed more appropriately as

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.

guidance to NRC staff and will, as such, have less of an effect of imposing specific requirements, beyond what exist in regulation, upon the licensee. While we cannot endorse this approach to the regulatory process, we do recognize the value that the substantive content of this ISG may have as staff guidance and, therefore, recommend incorporating this guidance, after considering our specific comments, directly into the YMRP.

Consistent with our prior comments on HLWRS-ISG-1, industry recommends that NRC reconstitute the staff guidance proposed in HLWRS-ISG-2 as a direct revision to the YMRP rather than further institutionalizing the ISG precedent for the following three reasons:

- In general, Interim Staff Guides are not the most effective means for NRC to clarify its regulatory intent, because they do not receive the same level of regulatory, technical, and policy review as the YMRP.
- “Interim” clarification, using a vehicle that was meant to be a form of generic communication to address emerging issues affecting multiple licensed activities, is unnecessary in a situation where there is only a single potential licensee that is not currently conducting any licensed activities and will not be conducting any such activities for a number of years. There is ample lead time before DOE’s planned license application submittal, currently scheduled for June 2008, for NRC to make a permanent change, in the form of a revision to the YMRP.
- Third, draft HLRWS ISG-2, if reconstituted as a revision to the YMRP, would receive a broader and higher level review within NRC, up to and including review and approval by the Commission, consistent with that applied to the YMRP itself. This would better facilitate the identification of cross cutting issues with respect to other sections of the YMRP and assure consistency in all aspects of NRC staff’s review commensurate with the risk significance of the subject of the review.

When incorporating the substantive content of HLWRS-ISG-2 into the Yucca Mountain review plan, NRC should consider the following specific comments:

- The discussion of uncertainty in the draft ISG should be revised to better recognize the risk-informed intent of 10 CFR Part 63.
- The discussion of event-sequence screening should be restated for consistency with the regulation.
- We endorse NRC’s recognition that published reliability values can be used even if the source of these values was not under an NRC-licensed quality assurance program.

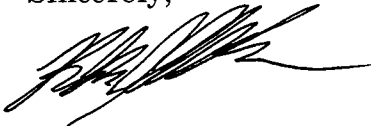
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- NRC should clarify its guidance on treatment of uncertainty, consistent with the discussion between DOE and NRC staff in the November 8, 2006, Technical Exchange on Reliability.
- We agree with the NRC's position at the November 8, 2006 Technical Exchange with DOE on Pre-closure topics that, when using probability distributions to compare accident sequence frequencies to category goals, the mean of the distribution is the appropriate basis for comparison and determination of whether or not the frequency falls above or below the category goal.

The basis for each of these general concerns and specific comments is provided in the enclosure to this letter. In conclusion, we strongly urge NRC to reconstitute this draft ISG as a direct revision to the YMRP.

Please do not hesitate to contact me at (202) 739-8082; rxm@nei.org if you wish to discuss these issues further or have any questions.

Sincerely,



Rod McCullum

Enclosure

c: Mr. Jack R. Strosnider, Director, NMSS
Dr. Margaret Federline, Deputy Director, NMSS
Mr. Lawrence Kokajko, Director, HLWRS
Mr. E. William Brach, Director, SFST
Mr. William Ruland, Deputy Director, Licensing and Inspection, SFST
Mr. Edwin Hackett, Deputy Director, Technical Review, SFST
NRC Document Control Desk

**NEI Comments on Division of High-Level Waste Repository Safety
(HLWRS) – Draft Interim Staff Guidance (ISG)-02, *Preclosure Safety
Analysis – Level of Information and Reliability Estimation*,
71 Federal Register 57584, September 29, 2006**

**Industry Basis for Recommending that NRC Directly Incorporate the
Substantive Content of Draft HLWRS-ISG-2 into the Yucca Mountain
Review Plan (YMRP)**

The nuclear industry recommends that NRC reconstitute Draft HLWRS-ISG-2 regarding Pre-closure Safety Analysis (PCSA) and the level of information required for reliability estimation as a proposed revision to the Yucca Mountain Review Plan (YMRP). We have the same general objections to the use of interim staff guidance (ISG) that were stated in prior our comments on HLWRS ISG-1 (letter Kraft to Shah dated July 6, 2006). 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 along with specific comments on the substantive content of NRC's Draft ISG-2 which should be considered in the reconstitution of this proposal.

Use of Interim Staff Guidance as a Regulatory Tool

We believe that NRC should not use of ISGs (or other forms of generic communication) to 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-2 is 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 as a response to an emerging issue that would guide NRC staff actions and ensure consistent review of ongoing licensed activities involving 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 more than 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.

If the NRC staff believes there is a need to reiterate the requirement that there be a reasonable basis for the technical inputs to the PCSA and to provide examples of acceptable methodologies for that analysis, an update or supplement to the YMRP would be a more appropriate vehicle. Such a supplement or update would also have the same NRC management and Commission approvals as was required for the current version of the YMRP.

Need for consistency in level-of-review

Draft ISG-2 recommends several changes to the YMRP. It therefore follows that such changes should go through the same approval process as the YMRP including NRC Commission approval in a public meeting. To do otherwise would be 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, such as changes to repository design or operation, that are not intended by the Commission and that may be problematic in practical application.

Notwithstanding our process objection, the substantive content of Draft ISG-2 is improved over ISG-1. In general, Draft ISG-2 is more like a section of the YMRP than was ISG-1, which appeared more like a regulatory guide in that it asserted an expectation for a specific methodology to be used in the pre-closure seismic analysis, albeit without the assurances of acceptability provided by a regulatory guide. It is clear that ISG-2 is intended as guidance to the NRC staff on how to review a Yucca Mountain license application. It is also clear from what is presented in lines 206 through 301 of this proposal that the intent for ISG-2 is to make revisions to the YMRP. Any revision to the YMRP should have the same level of review and approval as the YMRP itself.

The nuclear industry broadly agrees with the fundamental message contained in ISG-2 – that there be a reasonable technical basis for the inputs to the preclosure safety analysis. We consider it to be a positive that NRC staff has clearly recognized in the methodology examples cited: (1) that the example methodologies are not the only acceptable methods for performing such analysis, and (2) that there are reasonable sources for acceptable inputs to the preclosure safety analysis that have been developed outside of NRC quality assurance requirements. These positive attributes can most effectively be codified for use in NRC staff's review of a Yucca Mountain license application by direct incorporation into the YMRP. The broader review associated with this approach will assure that these principles are applied consistently throughout the YMRP, and hence in all aspects of the staff's review.

Specific Comments on the substantive content of Draft ISG-2

1. The paragraph beginning with line 156 specifies that the NRC staff will verify that uncertainty is addressed in the PCSA. This is reasonable as long as it is not interpreted as requiring excessive conservatism in the analysis. Applying too much conservatism in the analysis could unintentionally cause certain risks to be overstated and the application of the licensee's resources to portions of the operation or facilities with lower actual risks. Such an approach would be the opposite of the intent of risk informed regulation.

This discussion should be revised to more explicitly reflect the risk-informed nature of 10 CFR Part 63. There is no problem with instructing the staff to verify that uncertainties in the analysis are addressed as long as there is no implication that staff should expect such uncertainty to always be countered by the addition of conservatism to the analysis. Ideally, the pre-closure safety analysis calculations, under a risk informed regulation, would be best estimates of the risks involved.

In the same section of the *Statements of Consideration* in 10 CFR Part 63 referenced by the Draft ISG (as reference 6) in support of this discussion of uncertainty, NRC recognized DOE's preference for "realistic or best estimate" analysis of Category 1 Events and "suitably conservative" analysis of Category 2 events. In this reference, NRC went on to conclude "the approach in the rule is to provide DOE flexibility to select the type of analysis it believes most appropriate." The staff review of DOE's methods for addressing uncertainty should not come to rely on any expectation for conservatism that would preclude such flexibility. Specifically, NRC staff should not expect to see contingencies added to DOE's best estimate analyses that could inappropriately distort or skew the probabilistic analysis.

Applying more conservatism than necessary in the analysis could unintentionally cause certain risks to be overstated and the application of the licensee's resources to portions of the operation or facilities with lower (perhaps negligible) actual risks. This is opposite of the intent of risk informed regulation. The text of this discussion should explicitly recognize this intent.

2. The parenthetical at the end of line 127, "(e.g., $<10^{-6}$ failures/yr.)," and again in line 128 should be restated to be consistent with the regulations. The test for screening event sequences based on probability is less than one chance in ten thousand over the period of operation. NRC staff should not anticipate a particular operating concept or duration (i.e., 100 years) in creating regulatory guidance. Some structures, systems, and components (SSCs) of the repository may be necessary for less than 100

years; and there is no guarantee that the applicant may not choose to operate some SSCs for more than 100 years. Properly, the examples given later in the ISG do not arbitrarily assume a 100-year operating period (e.g., lines 450-458).

3. In line 136 NRC staff recognizes various sources of reasonable input to the PCSA including “. . . published reliability values based on industry experience and judgment.” It is important that such information does not have to be created under an NRC-licensed quality assurance program. This is apparent from the source examples cited in lines 142-148, such as the “Generic Data Base, developed by Savannah River Site” and the “Equipment Performance and Information Exchange (EPIX) System.” Such sources for reliability input are reasonable based on actual operating data and not skewed by conservatism. Even though applying conservatism is acceptable for safety analysis purposes (e.g., for analytical simplification or bounding uncertainties), doing so distorts the foundation of risk informed regulation by implying higher risks than actually exist. Again, the NRC staff is to be commended for allowing the use of real data from a variety of sources.
4. In the paragraph extending from lines 157 to 168 as well as in the proposed revision to the Yucca Mountain Review Plan presented in lines 249 to 273, staff is instructed to verify that DOE has appropriately addressed uncertainty in its reliability estimates. This guidance goes on to suggest that the staff should apply additional scrutiny or focus in its review in cases where a reliability estimate is close to a Category 1 or 2 limit. While industry agrees that this is appropriate guidance to NRC staff, it is important to note that this guidance does not imply that, in such cases, DOE is required to submit any additional analysis with its license application. This was recognized in the discussion between DOE and NRC staff in the November 8, 2006 Technical Exchange on Reliability. Therefore, consistent with this discussion, this guidance should be clarified to explicitly recognize that it is incumbent upon DOE to determine both if and when a reliability estimate is sufficiently close to a Category 1 or 2 limit to warrant additional consideration in the license application as well as the specific nature and extent of any such consideration in the application.
5. In the November 8, 2006 Technical Exchange on Pre-closure topics between NRC and DOE, Michael Frank of BSC presented the Department’s Reliability Methodology. In this presentation, Mr. Frank showed how reliability would be determined using continuous probability distributions. He addressed uncertainties in calculated accident frequencies for designs yet to be built by showing a figure (slide 6) where the probability distribution overlapped the Category 2 goal. On this

figure, Mr. Frank highlighted the mean of the distribution and the 95% confidence interval. There was some discussion of which point on the distribution should serve as the basis for comparison with the Category 2 goal. At the close of this discussion, NRC's Marissa Bailey stated NRC's position that the mean of the distribution is the appropriate basis for comparison and determination of whether or not the frequency falls above or below a category goal. Industry is in complete agreement with this position. Use of the mean in this analysis is consistent with the probabilistic framework of 10 CFR Part 63 in which mean values are, throughout the regulation, clearly intended to be the primary determinate of compliance with regulatory limits. This position should be clearly documented in the YMRP.