[7590-01P]

NUCLEAR REGULATORY COMMISSION

HLWRS-ISG-02
PRECLOSURE SAFETY ANALYSIS - LEVEL OF INFORMATION AND RELIABILITY ESTIMATION; 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-02, “Preclosure Safety Analysis - Level of Information and Reliability Estimation,’’ and NRC responses to the public comments received on that document. The ISG clarifies or refines the guidance provided in the Yucca Mountain Review Plan (YMRP) (NUREG-1804, Revision 2, July 2003). The YMRP provides guidance to NRC staff to evaluate a potential license application for a high-level radioactive waste geologic repository constructed or operated at Yucca Mountain (YM), Nevada.

ADDRESSES: The document HLWRS-ISG-02 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-02 is ML070260204. 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.

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-02: In preparing final HLWRS-ISG-02, "Preclosure Safety Analysis - Level of Information and Reliability Estimation," ADAMS ML070260204, the NRC staff reviewed and considered 23 comments, including two editorial comments, received from two organizations during the public comment period. Two of the comments were identical; three comments were related to the ISG process; one comment endorsed NRC's recognition of the use of the published reliability values for structures, systems, and components (SSCs); and the remaining comments included recommendations on specific clarifying changes to the ISG. Three comments on the ISG process were consistent with the comments made earlier on HLWRS-ISG-01, and were addressed in responses to public comment on HLWRS-ISG-01 [see 71 FR 57582, Comments 13 (a) and (b)].

The following discussion indicates how the comments were addressed, and the changes, if any, made to ISG-02 as a result of the comments. Line numbers in the following comments refer to

the draft HLWRS–ISG–02, ADAMS ML062360241, which was made available for public comment on September 29, 2006 (71 FR 57584).

Comment 1. One commenter was concerned that the changes in the YMRP, recommended in ISG lines 59 - 66, 222 - 224, and 271 - 273, appear to suggest that information regarding "design bases and design criteria" for non-important to safety (non-ITS) SSCs be similar to those for ITS SSCs. Since non-ITS SSCs have been determined not to be necessary to assure compliance with 10 CFR Part 63 preclosure performance objectives, the commenter states that subsection 63.21(c)(3) does not appear to support inclusion of information related to design bases and design criteria for non-ITS SSCs. The commenter recommends specific changes to ISG lines 62, 222, 239, 254, 258, 263, 266, and 272, to clarify its position.

Response. NRC agrees that information required for non-ITS SSCs would be less than for ITS SSCs. Subsection 63.21(c)(3) requires a description and discussion of the design of the YM geologic repository operations area, that is sufficient to permit an evaluation of the preclosure safety analysis (PCSA). DOE will have to provide sufficient information to discuss how the proposed design would function. This also includes the general arrangements of SSCs, capacities of SSCs, and levels at which the SSCs are operated. Staff agrees with the commenter that 10 CRF Part 63 requires the design bases and design criteria for ITS SSCs, and not for non-ITS SSCs.

ISG lines 62, 222, 254, and 272 have been revised to state that design bases and design criteria refer to SSCs that have been designated as ITS. ISG lines 239, 258, 263, and 266 have not been revised, because these lines refer to estimating the reliability of SSCs sufficient for performing the PCSA and identifying ITS SSCs, as per 63.112.

Comment 2. The commenter stated that, in lines 57-259, it would be more appropriate to use “accept,” instead of “recognize,” because it is unclear. The same commenter also noted that lines 276-284 do not include an acceptance criterion element related to “acceptability of codes and standards,” as proposed in lines 258-259, and supplemented in lines 121-124.

Response. NRC disagrees that the word "recognize" is unclear in the context of the sentence in lines 257-259. Staff believes that the use of the word “accept” would be inappropriate here, because the codes and standards do not provide explicit reliability values requiring acceptance. Staff also disagrees with the commenter’s recommendation on the addition of a new acceptance criterion item (7), regarding the use of codes and standards to obtain a probability of unacceptable performance. Staff believes that, as stated in ISG lines 121-124, the application of the codes and standards, to the design and operation of an ITS SSC, is an accepted engineering practice, and is addressed as new item (2), of “Acceptance Criterion 2,” in ISG lines 276-277.

No changes to the ISG were made as a result of this comment.

Comment 3. The commenter states that the phrases "risk-significant" or "risk-significance" have a multiplicity of meanings. For example, in nuclear power plant probabilistic risk assessment applications, the terms refer to a metric of risk that is a function of both probability (or frequency) of occurrence, and consequences. However, in the context of Part 63, event sequence categorization is performed on the basis of probability, only. The consequences of interest (public and worker doses) are deterministic in nature. The commenter recommended that the terms "risk-significant" or “risk-significance” be avoided or defined specifically in the context of this ISG.

Response. NRC agrees that use of the terms "risk-significant" or "risk-significance" in the ISG requires clarification where reference is to the consequences only and not to the "risk," which includes both the probability and the consequences. Changes to lines 41 and 162 were made to either clarify or remove redundancy of the "risk" term. Specific changes to the ISG, suggested by the commenter on lines 210, 268, 289, 382, and 574, are not made, because these lines refer to the "risk" consistent with the traditional definition (U.S. Nuclear Regulatory Commission, *White Paper on Risk-informed and Performance-based Regulation*, SECY-98-144, June 22, 1998, as revised by the Staff Requirements Memorandum, March 1, 1998).

The ISG has been revised as follows:
Line 41: Change "risk-significant" to "significant."
Line 162: Delete "risk-significance or ..."

Comment 4. The commenter suggested that the lines 86 and 240 of the ISG be revised to state that "Explicit quantitative reliability estimates of software failure modes during event sequences are beyond the state-of-the-art and are not expected for the PCSA. It is acceptable to use reliability estimates of digital control units, which would implicitly include hardware and software effects."

Response. NRC disagrees that revisions to lines 86 and 240 are needed. For SSCs where the reliability estimates include hardware and software effects, it is acceptable to use the reliability estimates, without explicit consideration of software failures. However, for SSCs where such data are not available, an estimate for reliability needs to include consideration of hardware and software failures. NRC believes that ISG lines 86 and 240 do not need to be revised because these statements allow the U.S. Department of Energy (DOE) the flexibility to consider

hardware and software failures with appropriate technical bases.

No changes to the ISG were made as a result of this comment.

Comment 5. The commenter states that the sentence starting at line 89 be revised by replacing “event” with “event sequences.”

Response. NRC agrees with the suggested change.

ISG line 89 has been revised to change “events” to “event sequences.”

Comment 6. The commenter recommends that a definition of the mean value of a probability distribution be included after line 90 of the ISG.

Response. NRC disagrees that the mean value of a probability distribution needs to be defined in the ISG. The mean of a distribution is a clear and unambiguous statistical term.

No changes to the ISG were made as a result of this comment.

Comment 7. The commenter states that items 2 and 3, in lines 129-132 of the ISG, “... appear to contradict the indication that a quantitative reliability estimate is needed,” and recommends revising the ISG to clarify that quantitative reliability estimates are needed.

Response. NRC disagrees that the changes recommended by the commenter are necessary. As stated in the ISG, items 1, 2, and 3 are given as examples of methods that may be used, in

combination with a code and standard, to obtain quantitative reliability estimates, and do not contradict the need for the quantitative reliability estimates.

No changes to the ISG were made as a result of this comment.

Comment 8. The commenter states that the use of the term “procedure,” in ISG line 229, does not recognize that many of the actions associated with repository operations, such as crane and trolley operations, will also be skill-based. The commenter recommends that the ISG line 229 be revised to clarify that the review will be of "procedures and activities," related to the controls and the human interactions associated with each SSC.

Response. NRC agrees with the commenter.

ISG line 229 has been revised to add “and activities" after "procedures.”

Comment 9. The commenter states that, in Appendix A of the ISG, the probability of dropping a heavy load is estimated with empirical data, then multiplied by the number of times that heavy loads are lifted, to arrive at a number that is characterized as the "expected number of drops." The use of the word "expected" is misleading, because it implies expected value, which is often used as a synonym for the mean value. The product of these two point estimates cannot be construed as a mean or expected value of the number of drops, because the underlying probability distributions were not developed for them. The commenter recommends that the phrase "expected number of drops" in ISG line 451 should be changed to "point estimate number of drops."

Response. NRC disagrees with the change recommended by the commenter. However, the ISG has been revised to clarify the staff's approach. Whereas the staff agrees that the use of the phrase "expected number of drops" may be misleading, the staff disagrees with the reason given in the comment. The ISG calculation uses a classical statistical approach. With this approach, the number of drops in L lifts has a binomial distribution which is typically approximated by a Poisson distribution. The expected value of the Poisson distribution is the product of the drop probability and the presumed number of lifts that may occur in the preclosure facility. Since the drop probability is estimated in this case, the expected number of drops is also estimated.

The ISG has been revised to add the above approach after line 449. ISG line 451 has been revised to change "expected" to "estimated". Also, ISG lines 432 and 489 have been similarly changed.

Comment 10. Two commenters stated that scientific and technical precedent point to the use of the mean value of a frequency distribution as the appropriate metric for event sequence categorization. One commenter adds that, contrary to this, ISG lines 465-472 appear to point to the use of a fraction of a confidence interval, on which to base a conclusion about categorization of an event sequence. The commenter recommends deleting the sentence, beginning on line 467, and changing lines 470-472 to read as, "The number of expected drops, in this example, would be the mean value of a joint probability distribution of both the conditional drop probability and the number of lifts."

Response. In Appendix A of ISG-02, empirical data were used to derive a point estimate for the probability of dropping a cask. To address uncertainty in this point estimate, staff chose a

standard statistical approach of the confidence interval method, to determine the confidence level in categorization of the event sequence for the example.

NRC does not agree that the sentence beginning on line 467 should be deleted, because it provides an example of a method to illustrate consideration of uncertainty. The 48-percent level of confidence is analogous to reporting the descriptive level of significance, which is often used in reporting the results of a test of a hypothesis.

According to the "Statement of Considerations" for Part 63, November 2, 2001 (66 FR 55742), the approach in the rule is to provide DOE with the flexibility to select the type of analysis it believes most appropriate for the license application. Whatever approach DOE uses will need to be supported, taking into account uncertainties. Therefore, analyses relying on point values (e.g., best-estimate values) will need to discuss how uncertainties are taken into account.

NRC agrees that DOE can use the mean value of an event sequence frequency distribution to categorize an event sequence. However, DOE should consider the uncertainty in any mean value used to categorize event sequences. In particular, DOE should provide the technical bases for developing the event sequence frequency distribution, including consideration of uncertainties in performance of individual SSCs, the choice of distribution type, and the values of the parameters.

ISG lines 470 - 472 have been deleted, because these lines refer to the estimated conditional drop probability for a specific confidence level, which is not discussed in the ISG.

Comment 11. The commenter states that ISG line 592 be revised to clarify that the design

bases are associated with SSCs and not with an event sequence category, as stated in the ISG.

Response. NRC agrees with the comment.

ISG line 592 has been revised to read as follows: “Design bases (e.g., loadings on SSCs associated with Category 1 and Category 2 event sequences, such as a canister drop event); and ....”

Comment 12. The commenter states that the definition of “S = C/D,” in line 617, appears to be inconsistent with the definition in Figure B-2 of the ISG. The commenter recommends that either the definition of “S,” in line 617, be revised, or that Figure B-2 be revised.

Response. NRC disagrees with the commenter that definition of "S" in ISG line 617, and Figure B-2 are inconsistent. Figure B-2 is consistent with the commonly used definition of the limit state function in the form of S = C/D, as shown in line 617, where C and D are the capacity and demand, respectively. Staff, however, recognizes that Y-axis labeling in Figure B-2, and description of the ISG lines 680-681, may have resulted in an appearance of inconsistency. As stated in ISG line 676, Figure B-2 shows the cumulative distribution function of S, with the probability of failure defined as the probability that S is less than or equal to 1. The curve, shown in Figure B-2, is for the constant demand D = 497 mega pascals (MPa) [72 kips per square inch (ksi)]. Similar curves are derived for two other values of demand values, listed in Appendix B, using a log-normal distribution of the capacity, C, divided by a constant demand, D (see Ref. B.3), and are included in the revised Figure B-2 in the ISG. Probability of failure values for three different demand values, along with their corresponding ratios of American

Society of Mechanical Engineers (ASME) code allowable stress to demand, are shown in Table B-3. The results show, as expected, that the probability of failure decreases as the demand decreases. The ISG has been revised as follows:

- Figure B-2 has been revised to include plots for all three demand values shown in Table B-3, and the caption has been revised to include "for three demand values";
- Label for the ordinate axis has been changed from "Probability of Failure (x 10^{-5})" to "Cumulative Probability," and is replotted in the log-scale;
- Line 622: The phrase, " ... which is traditionally defined as the limit state function" is added at the end of the sentence.
- Line 680: A new sentence, "Failure probabilities for various values of demand are shown in Figure B-2." has been added;
- Lines 680-681: sentence has been revised to "Failure probabilities for various values of ratios of ASME allowable stress to these corresponding demand values are given in Table B-3."

Comment 13. The commenter stated that the paragraph beginning with line 156 of the ISG specifies that the NRC staff will verify that uncertainty is addressed in the PCSA. The commenter is concerned that this may be interpreted as requiring excessive conservatism in the analysis, and that such an approach would be the opposite of the intent of risk-informed regulation. The commenter recommends that text of the discussion on uncertainty be revised to explicitly recognize this intent.

Response. NRC agrees that excessive conservatism should be avoided in considering uncertainty. DOE has the flexibility to choose the method to demonstrate that the performance objectives are met. For example, DOE could perform a bounding calculation. As stated in the

“Statement of Considerations," for Part 63, “... whatever approach DOE uses will need to be supported, taking into account uncertainties." For example, if DOE is to portray its PCSA results as best estimates, this term will need to be defined because it has no statistical meaning (see “A Review of Staff Uses of Probabilistic Risk Assessment,” NUREG-1489, March 1994). Staff believes that the paragraph on uncertainty, beginning with ISG line 156, is sufficiently clear, and that no changes are required.

No changes to the ISG were made as a result of this comment.

Comment 14. The commenter stated that the screening criteria in ISG lines 127-128 presume a preclosure period of 100 years by specifying that the lower bound of Category 2 event sequence frequency is 10^{-6} failures/yr. Instead, the staff should be consistent with Part 63 in referring to the lower bound of Category 2 event sequence frequency as the one chance in 10,000 during the period of operation.

Response. NRC agrees with the comment. Unless there is a reason to state otherwise, the staff will refer to the terminology, used in Part 63, for Category 2 event sequence frequency as having at least one chance in 10,000 of occurring during the preclosure period. The quantitative frequency limit of a Category 2 event sequence is determined by the duration of the preclosure period.

ISG line 127 has been revised to change “(e.g., $\leq 10^{-6}$ failures/year)” to “(e.g., $\leq$ one chance in 10,000 of occurring during the preclosure period).”

ISG line 128 has been revised to delete “(e.g., $\leq 10^{-6}$ failures/year).”

Comment 15. The commenter stated that, in ISG line 136, the NRC staff recognizes various sources of reasonable input to the PCSA. It is important that such information does not have to be created under an NRC-licensed quality assurance program. The sources cited in the ISG [e.g., "Generic Data Base, developed by Savannah River Site," and the Equipment Performance and Information Exchange (EPIX) System], 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.

Response. NRC agrees that DOE can use reliability information from published references. However, DOE must provide the technical basis to demonstrate that any reliability information is applicable to the proposed design of the GROA.

No changes to the ISG were made as a result of this comment.

Comment 16. The commenter stated that, in ISG lines 157-168, 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. The ISG should not be taken to imply that DOE is required to submit any additional analysis with its license application. The guidance should be clarified to explicitly recognize that it is incumbent on 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.

Response. NRC has not specified criteria for determining when a sequence frequency is close enough to a category limit to warrant additional scrutiny. DOE is expected to provide NRC with enough information to demonstrate that sequences have been correctly categorized.

No changes to the ISG were made as a result of this comment.

Comment 17. The commenter stated that the demand in ISG lines 636-638 is a function of several parameters (e.g., modulus of elasticity, dimension, thermal expansion," ....). The commenter adds that these parameters would affect the material capacity, not the demands placed on the material, and recommends that this sentence be revised by deleting the words "modulus of elasticity, dimensions, thermal expansion."

Response. NRC agrees with the comment. Demand on an SSC because of an event, such as a drop or a natural event, would not depend on the modulus of elasticity, dimension, and thermal expansion.

ISG lines 636-637 have been revised to delete “modulus of elasticity, dimensions, thermal expansion.”

Comment 18. One commenter suggested the following editorial changes:
Lines 587-588: Revise “... including major components of canister structure, internals” to read “... including major components of canister structure, and its internals;”

Line 622: Revise “function can developed” to read “function can be developed.”

Response. NRC agrees with the comment. The ISG has been revised to reflect the suggested changes.

In addition to the changes described above, the ISG has also been revised, as follows, for clarification:

Line 91: the sentence “DOE should identify the key SSCs in an event sequence.” was deleted because “key” SSCs is not formally defined; a new sentence to replace the deleted sentence has been added;

Line 446: the definition of λ (now $\hat{p}$) was reworded for clarity;

Lines 445 through 453: λ was changed to $\hat{p}$, to distinguish this quantity from λ, which often is used to indicate a rate in the Poisson distribution, and that the quantity is an estimate;

Line 622: clarifying words were added.

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Dated at Rockville, Maryland this 8 day of March 2007.

For the Nuclear Regulatory Commission.

/RA/

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Dated at Rockville, Maryland this 8 day of March 2007.

For the Nuclear Regulatory Commission.

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