

**NUCLEAR REGULATORY COMMISSION**

**HLWRS-ISG-03  
PRECLOSURE SAFETY ANALYSIS - DOSE PERFORMANCE OBJECTIVES AND  
RADIATION PROTECTION PROGRAM; 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-03 Preclosure Safety Analysis - Dose Performance Objectives and Radiation Protection Program," and NRC responses to the public comments received on this 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 for a high-level radioactive waste geologic repository constructed or operated at Yucca Mountain, Nevada.

**ADDRESSES:** HLWRS-ISG-03 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-03 is ML071240112. 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.

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**NRC RESPONSES TO PUBLIC COMMENTS ON HLWRS-ISG-03:** In preparing final "HLWRS-ISG-03 Preclosure Safety Analysis - Dose Performance Objectives and Radiation Protection Program," ADAMS ML071240112, the NRC staff reviewed and considered 18 comments, including one editorial comment, received from two organizations during the public comment period. Three comments were related to the ISG process; and the remaining comments included recommendations on specific clarifying changes to the ISG. The three comments on the ISG process were consistent with the comments made earlier on HLWRS-ISG-01, and were addressed in responses to public comments 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-03 as a result of the comments. Line numbers in the following comments refer to draft HLWRS-ISG-03, ADAMS ML070230090, which was made available for public comment on February 20, 2007 (72 FR 7778).

Comment 1. One commenter recommended that the reference to 10 CFR 63.111 on line 14 be revised to 10 CFR 63.111(a), so that the reference was explicit to Category 1 event sequences. The commenter stated that the entire 10 CFR 63.111 does not apply to preclosure.

*Response.* NRC disagrees that the entire 10 CFR 63.111 does not apply to preclosure. This section of 10 CFR Part 63 provides the regulatory requirements for performance objectives for the geologic repository operations area (GROA) through permanent closure, which is the preclosure period. However, NRC agrees that, in the context of the sentence (ISG lines 12-14), the reference is to 10 CFR 63.111(a). Therefore, the reference needs to be revised.

ISG line 14 has been revised to change "10 CFR 63.111" to "10 CFR 63.111(a)."

*Comment 2.* The commenter recommended specific revisions to footnote 1 (below line 38), to define an off-normal condition. The proposed revision could be interpreted to mean that certain deviations from procedures or equipment failures, that involve important to safety (ITS) structure, system, and component (SSC) failures during the preclosure period, may be classified as off-normal, not Category 1 events.

*Response.* NRC disagrees with the commenter that footnote 1 should be revised. As defined in 10 CFR 63.2, SSCs are designated as ITS, if they are relied on to satisfy the preclosure performance objectives for Category 1 or Category 2 event sequences. In contrast, the SSCs that are relied on for normal operations are not designated as ITS SSCs. Therefore, as stated in footnote 1, equipment failures that do not involve ITS SSCs and do not lead to significantly elevated exposures are considered as off-normal, and not Category 1 event sequences.

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

*Comment 3.* The commenter recommended deleting the last part of footnote 2 (below

line 74), which reads “if the GROA is licensed,” because, if the GROA is not licensed, then there would be no radiation protection program implementation to inspect.

*Response.* NRC agrees with the commenter that the last part of the footnote is not needed because implementation of the radiation protection program can only be inspected if NRC has already licensed the geologic repository at Yucca Mountain.

The ISG has been revised to delete “if the GROA is licensed,” in footnote 2.

*Comment 4.* The commenter recommended specific revisions to ISG lines 67-70, which state that NRC should focus on those event sequences that lead to the most significant exposure fields and locations of representative persons who may receive the greatest exposure. The commenter stated that ISG lines 67-70 are inconsistent with the discussion of “representative exposure locations,” in ISG line 114, and “potential high-exposure locations may be eliminated from consideration,” in ISG lines 118-119.

*Response.* NRC disagrees that ISG lines 67-70 are inconsistent with ISG lines 114, 118, and 119. ISG lines 67-70 refer to the Radiation Protection Program; whereas ISG lines 114 and 118-119 refer to the Estimation of Doses. It is appropriate to focus on those persons who may receive the greatest exposure, when NRC reviews the adequacy of a Radiation Protection Program, and establishment of restricted areas and access controls; whereas for dose estimates, potential high-exposure locations may be eliminated from consideration because of access controls and personnel monitoring.

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

*Comment 5.* The commenter recommended revising lines 85 through 87, and lines 92 through 94, by deleting the word “back,” since this implies that recovery actions are needed to achieve compliance with Part 63.

*Response.* NRC agrees with the suggested change.

ISG lines 85-87, and 92-94, have been revised to delete the word “back.”

*Comment 6.* The commenter stated that the method for aggregating annual doses in the ISG cannot, in all cases, be used to demonstrate compliance with the requirements of 10 CFR 63.111, and that it is not consistent with the performance objectives of Part 63. The commenter stated that the approach in the ISG does not allow consideration of the frequency of a Category 1 event sequence in aggregating the dose. The commenter recommended a specific definition of aggregate annual dose that is based on a statistical approach, where all doses from all Category 1 event sequences are frequency-weighted.

*Response.* NRC disagrees that the method in the ISG for aggregating annual doses cannot, in all cases, be used to demonstrate compliance with the requirements of 10 CFR 63.111, and that it is not consistent with the performance objectives of Part 63. The method proposed in the ISG consists of summing the doses from normal operational doses, all occurrences of Category 1 event sequences occurring one or more times per year, and the maximum Category 1 event sequence expected to occur less than once per year. This is consistent with Part 63's approach of using the frequency of event sequences to categorize them in broad frequency bins of Category 1 and Category 2 event sequences. This approach is a reasonable way to estimate annual doses during the design review, because it does not

require exactly determining frequencies for each and every event sequence, which would be necessary if all Category 1 event sequences were frequency-weighted to determine the aggregate annual dose.

There are many ways to aggregate doses and this method is one simple and direct approach to determine whether the applicant has demonstrated compliance with the performance objectives of Part 63. The applicant may propose another method in a license application, which NRC will review. According to the “Statement of Considerations” for Part 63, November 2, 2001 (66 Federal Register Notice 55742), the approach in the rule is to provide the U.S. Department of Energy (DOE) with the flexibility to select the type of analysis it believes most appropriate for the license application.

Regardless of the approach used to demonstrate compliance, NRC will inspect for, and enforce compliance with, the preclosure dose limits during operations. If during actual operations, operational releases or events (e.g., multiple Category 1 event sequences in a single year) call into question the basis of NRC’s safety decision, NRC would reevaluate the licensing basis, to determine the safety significance and take appropriate regulatory action.

*Comment 7.* The commenter stated that Table 1, “Part 63 Performance Objectives,” could be interpreted to mean that there are separate performance objectives for normal operations and Category 1 Event Sequences because the Total Effective Dose Equivalent values for these are in separate columns.

*Response.* NRC agrees that, in Table 1, lines 150-163, there should only be one column for the aggregated annual dose from normal operations and Category 1 Event

Sequences.

ISG lines 150 through 163 have been revised to combine the columns for normal operations and Category 1 Event Sequences.

*Comment 8.* The commenter suggested deleting the word “expected” before “Category 1 event sequences,” in ISG lines 309 and 333, and adding the word “types of” before “Category 1 event sequences,” in ISG line 333, to provide consistency in wording between the new Review Method 4 and Acceptance Criterion 4.

*Response.* NRC agrees with the commenter. ISG lines 309 and 333 have been revised to delete “expected,” and ISG line 333 has been revised to add “types of,” before “Category 1 event sequences.”

*Comment 9.* The commenter suggests revising ISG lines 319-321 because the commenter interpreted the word "confirm" in the ISG text as implying “...an inspection activity to determine if a facility has been built as required.”

*Response.* NRC disagrees with the revision suggested by the commenter. The intent of the ISG is clearly stated in ISG lines 1-9; namely, the review of a license application. The word "confirm," as used in the ISG, refers to the review of the "descriptions" of the Radiation Protection Program, and not to an inspection activity to determine if a facility has been built as required.

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

*Comment 10.* The commenter stated that the definition of Occupational Dose in ISG line 390 is incomplete, and should be revised to be the same as in 10 CFR 20.1003.

*Response.* NRC agrees with the commenter.

The ISG has been revised to add the following at the end of the sentence on ISG line 390: "Occupational dose does not include doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released under 10 CFR 35.75, from voluntary participation in medical research programs, or as a member of the public."

*Comment 11.* The commenter suggested the following editorial changes:

Line 178: Replace the word "does" with "do."

Line 269: Add "The analysis required in the paragraph must include, but not necessarily be limited to, consideration of," at the beginning of the sentence.

Line 330: Revise "Page 2.1-80" to "Page 2.1-81."

*Response.* NRC agrees with the commenter. The ISG has been revised to reflect these suggested changes.

*Comment 12.* The commenter stated that "NRC appears to be communicating an expectation for a greater level of detail in the Yucca Mountain license application recovery action plan than is appropriate." The commenter stated that "... the planning and monitoring of recovery actions should be done within the radiation protection program framework of the draft ISG, and that there is no need for more detail until a time nearer to planned operations." The



commenter added that "... the ISG should delineate expectations before construction authorization is granted, and additional expectations before a license to receive and possess radiological material is granted."

*Response.* NRC disagrees with the commenter because the license application must identify those Category 1 event sequences that are expected to occur during the lifetime of the facility. As a part of the license application review, NRC will verify that the applicant has planned for recovery from these events, and that they will be monitored under the Radiation Protection Program.

The ISG recommends that the reviewer determine that the applicant has described key elements of the recovery action plans. A plan should provide enough detail to determine that the corrective actions taken will assure adequate access to vital areas, and protection of safety equipment. It should describe the basic steps taken to recover from an event and the radiation exposure levels that may be present.

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

*Comment 13.* The commenter commended NRC on "applying the risk-informed principles in an exemplary manner," in ISG lines 59-66, and 143-147. However, the commenter added that the section on "Estimation of Doses in the PCSA" (ISG lines 102-147) was "... not consistent with the risk-informed principles," and the draft ISG "... removes the flexibility intended by the regulation," in the area of the aggregate annual dose for normal operations and Category 1 event sequences.

*Response.* NRC disagrees with the commenter. The ISG provides DOE with sufficient flexibility to estimate dose for selected representative radiation workers or classes, on-site persons, and off-site members of the public, with no summation of doses from different classes or to perform single-bounding dose estimations for radiation workers or classes, on-site persons, and off-site members of the public.

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

*Comment 14.* The commenter stated that the method in the ISG, to calculate an aggregate annual dose, does not allow the applicant to sum only those doses for an individual or class of workers, but instead requires the aggregate dose to include doses to all workers. Also the commenter stated that the summation of doses should not be interpreted to remove the licensee's flexibility to apply the planned special exposure provisions of 10 CFR 20.1206 in the mitigation of Category 1 event sequences.

*Response.* NRC disagrees with the commenter. There are many ways to aggregate doses and the method in the ISG is one acceptable way to demonstrate whether the applicant has demonstrated compliance with the performance objectives of Part 63. The applicant has the flexibility to propose another method in a license application, which NRC will review as long as it is supported by technical bases.

Planned special exposures (PSEs), defined in 10 CFR Part 20, are infrequent exposures to radiation, separate from, and in addition to, annual dose limits. PSEs are for exceptional situations, whereas the estimation of annual dose in the ISG includes only those doses from normal operations and Category 1 event sequences. Since Category 1 event sequences are

those that are expected to occur one or more times during the life of the facility, these events are not an exceptional situation and are not precluded when determining the annual dose.

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

*Comment 15.* The commenter suggested that the ISG clarify terminology used in two different instances. The commenter stated that the first term requiring clarification is “controlled area site boundary,” introduced in ISG line 21. ISG lines 36 and 37 define the “site boundary” as analogous to the “controlled area site boundary” defined in Part 20. The commenter stated that NRC should not assume that the “Yucca Mountain Repository site boundary” and the “controlled area for preclosure purposes,” are necessarily the same. DOE should be able to define the controlled area so long as it is outside the restricted area, but inside the site boundary, as long as the requisite safety and radiation protection requirements are met. The commenter also suggests the use of a different term, such as “preclosure controlled area,” so that limitations are not placed on the applicant. The second term for which the commenter suggested clarification is in ISG line 102, “... doses from those Category 1 event sequences that are expected to occur one or more times per year.” The commenter states that, “it is not clear why an acceptable design and operational concept would include planning for SSC failures, more often than once per year, that resulted in a radiation dose,” and these should be considered “as part of normal operations as opposed to as a Category 1 event sequence.”

*Response.* The Part 63 definition of “controlled area” is found in Subpart L - “Postclosure Public Health and Environmental Standards,” in section 63.302, and not in Subpart K - “Preclosure Public Health and Environmental Standards.” Since 10 CFR 63.111(a) requires

the GROA to meet the requirements of Part 20, the Part 20 definitions are to be applied within the context of Part 63. The site boundary is analogous to the controlled area, defined in Part 20, because the preclosure limits are based on the boundary of the site, defined for preclosure, as that area, surrounding the GROA, for which DOE exercises authority over its use, in accordance with the provisions of Part 63. DOE should clearly identify the controlled site boundary in its demonstration of compliance with Part 20 requirements. However, NRC agrees that the use of the term "controlled area site boundary" may be confusing, and thus is deleting that term from the ISG.

The second term, "doses from those Category 1 event sequences that are expected to occur one or more times per year" is used in the ISG method to aggregate doses. Although NRC agrees with the commenter that ITS SSCs should be designed and maintained in such a manner to prevent or avoid frequent failure, this term does not imply that a design that plans for frequent occurrences of ITS SSCs will be acceptable to NRC. Rather, this term is used to ensure that if the applicant submits an application with a Category 1 event sequence that occurs more than once per year, then the reviewer will include all occurrences of that event, when determining if the estimated annual dose meets the performance objectives of Part 63.

ISG line 21 has been revised by changing "controlled site boundary" to "controlled area."

ISG lines 36 and 37 have been revised by deleting the sentence, "The site boundary . . . Part 20."

ISG lines 55 and 56 have been revised by changing "controlled area site boundaries" to "the boundaries of the controlled area."

ISG line 136 has been revised by changing "controlled area site boundary" to "boundary of the site."

ISG line 144 has been revised by changing "controlled area site boundary" to "boundary of the site."

ISG lines 169 and 177 have been revised by changing "controlled-area boundary" to "controlled area."

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Dated at Rockville, Maryland this 22 day of May, 2007.

For the Nuclear Regulatory Commission.

IRA

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ISG line 144 has been revised by changing "controlled area site boundary" to "boundary of the site."

ISG lines 169 and 177 have been revised by changing "controlled-area boundary" to "controlled area."

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Dated at Rockville, Maryland this 22 day of May, 2007.

For the Nuclear Regulatory Commission.

    /RA/    

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