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COMMENTS ON DRAFT INTERIM STAFF GUIDANCE (ISG) DOCUMENT HLWRS-ISG-03, *PRECLOSURE SAFETY ANALYSIS – DOSE PERFORMANCE OBJECTIVES AND RADIATION PROTECTION PROGRAM*

In response to the U.S. Nuclear Regulatory Commission's (NRC) request for comment published in the Federal Register Notice (72 FR 7778), dated February 20, 2007, the U.S. Department of Energy (DOE) is providing the enclosed comments on the Draft ISG, Document HLWRS-ISG-03, *Preclosure Safety Analysis – Dose Performance Objectives and Radiation Protection Program.*

The DOE appreciates the effort undertaken by the NRC staff to develop the Draft ISG which is intended to supplement the Yucca Mountain Review Plan (YMRP), for the NRC staff review of consequence estimates for the Preclosure safety analysis, and the associated radiation protection program that will be reviewed by the NRC in a license application for implementation by DOE during operation of a geologic repository operations area. The DOE appreciates the opportunity to provide comments on this Draft ISG, which will be useful in demonstrating compliance with the performance objectives of Code of Federal Regulations, Title 10, Part 63 (10 CFR Part 63) and radiation protection requirements of 10 CFR Part 20.

The staff has proposed a definition for aggregate annual dose which the DOE proposes to modify. The modification involves the inclusion of the mean annualized dose from all combinations of Category 1 event sequences calculated as the sum of frequency-weighted doses from all Category 1 event sequences, plus one standard deviation of the frequency distribution over aggregate dose of Category 1 event sequence occurrences for a single year. An additional feature of the proposed DOE methodology is to use a conservative representation of the Category 1 event sequence doses based on the use of 95th percentile input parameters. This provides additional assurance that the performance objectives in 10 CFR 63.111 are met in any year.

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The enclosure contains specific suggested changes to the proposed YMRP changes presented in Draft ISG, Document HLWRS-ISG-03.

There are no new regulatory commitments in this letter or its enclosure. Please contact Mark H. Williams at (702) 794-5567 or e-mail mark_williams@ymp.gov, or Joe C. Price at (702) 794-1441 or e-mail joe_price@ymp.gov for any additional information required.

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RAO:JCP-0827

Enclosure:
Department of Energy's Comments on
Draft Interim Staff Guidance, Document
HLWRS-ISG-03

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ENCLOSURE

DEPARTMENT OF ENERGY'S COMMENTS ON DRAFT INTERIM STAFF GUIDANCE, DOCUMENT HLWRS-ISG-03

Comment 1: Line 14

Revise the reference to 63.111 to be explicit to the Category 1 event sequences being discussed. The entire 63.111 does not apply to preclosure.

DOE recommends revising line 14 as follows:

"...specified in 10 CFR 63.111(a) will be met."

Comment 2: Footnote 1 (Below Line 38)

In order to more clearly and succinctly state what DOE believes is NRC's intended definition of off-normal, DOE recommends the following revised text of footnote 1.

DOE recommends revising footnote 1 to read as follows:

[1]Deviations from procedures or equipment failures that do not lead to significantly elevated exposures to radiation workers during preclosure operations at the GROA are considered off-normal events and are therefore evaluated as part of normal operations.

Comment 3: Footnote 2 (Below Line 74)

Delete the last part of footnote 2 which reads, "if the GROA is licensed." If the GROA was not licensed, there would not be any preclosure operation or a radiation protection program to inspect.

DOE recommends revising footnote 2 as follows:

[2]The program's implementation would be subject to NRC inspection during preclosure operations.

Comment 4: Lines 67 and 70

This ISG states, "For Category 1 event sequences that could potentially lead to on-site exposures, the staff should focus on those sequences that lead to the most significant exposure fields (e.g., direct dose rate or radionuclide concentrations in air) and the locations of representative persons who may receive the greatest exposure."

This statement discusses the locations of representative persons who may receive the greatest exposure. This is inconsistent with "representative exposure locations" in Line 114 and "potential high-exposure locations may be eliminated from consideration" in Lines 118 and 119.

DOE recommends revising Lines 67 through 70, as follows:

"For Category 1 event sequences that could potentially lead to on-site exposures, the staff should focus on representative exposure locations and those sequences that lead to the most significant exposure fields (e.g., direct dose rate or radionuclide concentrations in air)."

Comment 5: Lines 85-87, and 92-94

Lines 85-87 of the ISG state, "Recovery actions may take place to safely recover materials and/or place the facility back into a safe condition in compliance with Part 63." Lines 92-94 of the ISG state, "The recovery actions should provide reasonable confidence that recovery back to a safe condition in compliance with Part 63 is feasible without exceeding the Part 20 limits to individual radiation workers, or threatening public health and safety." These sentences infer that the facility is not in compliance with 10 CFR Part 63 after an event sequence has been terminated, and that recovery actions are needed to achieve compliance. The facility will be controlled by the license specifications, radiation protection program and other administrative programs after an event sequence has been terminated. Consider, for example, an inadvertent opening of a shield door which causes an event sequence that may expose workers to external radiation. When the shield door is closed the event sequence would be terminated. However, the event sequence will be analyzed as part of the repository licensing basis, and the repository will be in compliance with the performance standards of 10 CFR Part 63 during and after the event. There will be no period of time, before, during, or after the event sequence that the repository would not be in compliance with 10 CFR Part 63.

Recovery actions, themselves, must be conducted within the licensing basis.

DOE recommends revising lines 85-87, and 92-94 as follows:

Lines 85-87 - Delete the word "back" such that the sentence reads, "Recovery actions may take place to safely recover materials and/or place the facility into a safe condition in compliance with Part 63."

Line 92-94 - Delete the word "back" such that the sentence reads, "The recovery actions should provide reasonable confidence that recovery to a safe condition in compliance with Part 63 is feasible without exceeding the Part 20 limits to individual radiation workers, or threatening public health and safety."

Comment 6: Lines 106 to 110, 172 to 176, and 292 to 296

This ISG provides the following definition of the aggregate annual dose:

"The aggregate annual dose is the sum of: (i) doses from normal operations, involving direct radiation or airborne radioactivity, that are not associated with SSC failures; (ii) doses from those Category 1 event sequences that are expected to occur one or more times per year; and (iii) the dose, from the maximum Category 1 event sequence, that is expected to occur less than once per year."

The above definition of the aggregate annual dose cannot, in all cases, be used to demonstrate reasonable assurance that the preclosure safety analysis meets the requirements specified in 10 CFR 63.111 and is not consistent with the risk-based regulatory performance objectives of 10 CFR Part 63. DOE believes that this definition needs to be revised before it is used to demonstrate compliance with 10 CFR Part 63. There are three issues.

1) The aggregation method of Category 1 event sequences is not consistent with the risk-informed, performance-based framework of 10 CFR Part 63. 10 CFR Part 63 requires an estimate of annual total effective dose equivalent (TEDE) for Category 1 event sequences. This requires an estimate be made of the expected doses from such event sequences, which must take into consideration both the frequency and consequences of each Category 1 event sequence. Using the approach proposed in the ISG, the only way that the "aggregate annual dose" can be changed is by changing the consequences of an event sequence. For example, if the maximum Category 1 event sequence with frequency less than once per year has a frequency of 0.9/year and dose of 10 mrem, then 10 mrem is added to the aggregate dose. If DOE then improves the design such that the frequency is changed to 0.1/year, there is no effect on the aggregate dose -- 10 mrem must still be added to the aggregate dose. This is clearly inconsistent with the risk-informed, performance-based framework of 10 CFR Part 63.

2) The use of the dose from the single maximum Category 1 event sequence, which is expected to occur less than once per year, could significantly underestimate the aggregate annual dose. If more than one Category 1 event sequence has an expected value reasonably near but less than one per year, then it can be shown by use of the Poisson distribution that multiple event sequences could occur in a year. The section below entitled, "Normal Operation and Category 1 Event Sequence Dose Aggregation Methodology" provides further discussion on this topic.

3) Doses from those Category 1 event sequences that are expected to occur one or more times per year, should include the dose from each occurrence of such Category 1 event sequences. The ISG definition of the aggregate annual dose does not explicitly require adding multiple occurrences for such event sequences.

To resolve these issues, DOE proposes the following recommendation for the definition of aggregate annual dose. This recommendation is based on the fact that the frequency-weighted dose is the expected dose from all Category 1 event sequences. This is proven by using a Poisson distribution to treat each possible occurrence of a Category 1 event sequence as a discrete event. The mean annualized dose from such a Poisson analysis is exactly equal to the frequency-weighted doses from all Category 1 event sequences. Thus, the use of frequency-weighted dose inherently includes dose contributions from all combinations of Category 1 event sequences. To provide conservatism, one standard deviation of the frequency distribution over aggregate dose of Category 1 event sequence occurrences for a single year is added to the aggregate annual dose. This provides an aggregate annual dose result with a non-exceedance probability of approximately 84%.

An additional feature of the DOE methodology is to use a conservative representation of the Category 1 event sequence doses based on the use of 95th percentile input parameters. This provides additional reasonable assurance that the performance objectives in 10 CFR 63.111 are met in any year. The section below entitled, "Normal Operation and Category 1 Event Sequence Dose Aggregation Methodology" provides further discussion on this topic.

Normal Operation and Category 1 Event Sequence Dose Aggregation Methodology

For any given year of repository operation, the aggregate annual dose is calculated by summing the normal operation doses from direct radiation and airborne radioactivity with the doses from Category 1 event sequences that have occurred in that year of operation. This is expressed in the following equation:

$$D_a = D_n + \sum_{i=1}^{N} n_i \cdot D_{1i} \qquad \textbf{Equation 1}$$

Where:

D_a is the aggregate annual dose (mrem),
D_n is the annual dose from normal operations (mrem),
n_i is the number of occurrences of Category 1 event sequence i, in that year,
D_{1i} is the dose per event for Category 1 event sequence i (mrem/event), and
N is the number of Category 1 events that may occur at the repository.

Because Category 1 event sequences are independent events and occur only as discrete occurrences, e.g., not as fractions of an event, the number of occurrences in any given year for a Category 1 event sequence can be expressed as a Poisson distribution with the expected value (λ) equal to the mean frequency of occurrence per year. The Poisson distribution includes the probabilities of multiple occurrences in any given year. The Poisson distribution is applied to all of the Category 1 event sequences, N, to account for all possible combinations of event sequences that could occur in any given year. The resulting probability distribution provides the sum of doses from all combinations occurring in a single year as shown in Equation 2:

$$D_a = D_n + \sum_{i=1}^{N} Po(\lambda_i) \cdot D_{1i} \qquad \textbf{Equation 2}$$

Where:

λ_i is the mean frequency of occurrence of Category 1 event sequence *i* per year,

$Po(\lambda_i)$ is the Poisson distribution with the expected value (λ_i),

$Po(\lambda_i)$ is probability distribution over the number of occurrences of the event sequence in a single year. It can be shown using Monte Carlo simulations that the mean value of the Category 1 event sequence dose contributions using the Poisson distribution as shown in Equation 2 is exactly equal to the sum of products of mean frequency of occurrence per event times dose per event. Therefore, a mean aggregate annual dose may be represented by Equation 3:

$$\overline{D_a} = D_n + \sum_{i=1}^{N} \lambda_i \cdot D_{1i} \qquad \textbf{Equation 3}$$

Where:

$\overline{D_a}$ is the mean aggregate annual dose (mrem),

However, there may be years that the actual dose exceeds this mean aggregate annual dose. Therefore, a conservative representation of the Category 1 event sequence contributions to the aggregate annual dose, rather than a mean representation should be used. A conservative representation would recognize the inherent conservatism of estimating the doses, D_{1i}, based on the use of 95th percentile input parameters.

One reasonable method based on this conservative representation of the Category 1 event sequence to provide reasonable assurance that the aggregate annual dose meets the performance objectives in any year is the following algorithm.

1. Using Equation 2 summation term, develop a frequency distribution over aggregate dose of Category 1 event sequence occurrences for a single year.
2. From the frequency distribution, obtain two summary parameters:
   a) mean aggregate dose, $\overline{d}_a$ and
   b) standard deviation of aggregate dose, σ_{ad}.
3. Add $\overline{d}_a$ and σ_{ad} to the annual dose from normal operations.

The recommended approach for the aggregate annual dose can be summarized as Equation 4.

$$D_a = D_n + \overline{d}_a + \sigma_{ad} \qquad \textbf{Equation 4}$$

Where:

D_a is the aggregate annual dose estimated for compliance (mrem),

$\bar{d}_a$ is the mean aggregated dose, and

σ_{ad} is the standard deviation of aggregated dose estimated from the distribution $\sum_{i=1}^{N} Po(\lambda_i) \cdot D_{1i}$.

To illustrate this methodology and compare it to the NRC proposed methodology, two hypothetical examples are provided for worker dose compliance. In these examples the normal operation dose is assumed to be zero for simplicity.

The first example considers three Category 1 event sequences with frequencies slightly less than once per year:

Sequence	Frequency (Events/yr)	Dose (mrem)
1	0.98	10
2	0.98	9
3	0.98	8

Using the NRC proposed methodology in Draft HLWRS-ISG-03, because all three event sequences occur less than once per year, only the maximum dose would be added to the normal operation dose. This would result in 10 mrem added to the aggregate dose.

The second example considers four Category 1 event sequences, two with frequencies slightly less than once per year and two with frequencies greater than once per year:

Sequence	Frequency (Events/yr)	Dose (mrem)
1	0.8	20
2	0.98	5
3	3	3
4	4	2

Using the NRC proposed methodology in Draft HLWRS-ISG-03, the dose from the Category 1 event sequences added to the normal operation dose would be the sum of the doses from the Category 1 event sequences occurring more than once per year (5 mrem) plus the highest dose from the Category 1 event sequence occurring less than once per year (20 mrem), for a total aggregate annual dose of 25 mrem in a year.

The table below summarizes the aggregate annual dose using the NRC proposed ISG-3 methodology compared to the DOE proposed methodology. The DOE methodology also allows an estimate of the non-exceedance probability of the aggregated dose estimates.

	Example 1	Example 2
NRC Methodology		
Aggregate Annual Dose (mrem) in a yr	10	25
Non-exceedance Probability (Percent)	20%	30%
DOE Methodology		
Aggregate Annual Dose (mrem) in a yr	42	58
Non-exceedance Probability (Percent)	83%	85%

We observe that the non-exceedance probabilities of the DOE estimates are both near the 84th percentile. This would be expected if the aggregated annual dose from a Category 1 event sequence behaves with a Normal distribution. The process of aggregating at least three Poisson distributions per Equation 2 results in a reasonable approximation of a Normal distribution, as expected by the Central Limit Theorem. Except in unrealistic cases, therefore, the DOE algorithm is expected to result in a non-exceedance probability of approximately 84%. This is compared to non-exceedance probabilities using the proposed NRC algorithm in these examples of less than 50%.

An additional desirable feature of the DOE methodology is the conservative representation of the Category 1 event sequence doses based on the use of 95th percentile input parameters. This provides reasonable assurance, beyond the non-exceedance probability of approximately 84% level, that the aggregate annual dose meets the performance objectives in any year.

DOE recommends revising the ISG definition of aggregate annual dose in Lines 106 to 110, 172 to 176, and 292 to 296 as follows:

"The aggregate annual dose is the sum of: (i) doses from normal operations, involving direct radiation or airborne radioactivity; (ii) the mean annualized dose from all combinations of Category 1 event sequences calculated as the sum of frequency-weighted doses from all Category 1 event sequences; and (iii) one standard deviation of aggregate dose estimated from the frequency distribution over aggregate dose of Category 1 event sequence occurrences for a single year."

Comment 7: Lines 150-163 (Table 1)

The table has one column entitled "Normal Operations" and one entitled "Category 1 Event Sequence" with the same TEDE values in each column. This could be interpreted as separate performance objectives for normal operations and for Category 1 event sequences; whereas, the regulation applies these performance objectives to the combination of normal operations and Category 1 event sequences as explained in footnote d.

DOE recommends revising lines 150-163 as follows:

Delete column 2 in Table 1 and revise the heading of Column 3 to "Normal Operations and Category 1 Event Sequences."

Comment 8: Line 309 and 333

Delete the word "expected" before the mention of Category 1 event sequences in the proposed wording for the New Review Method 4 and New Acceptance Criterion 4. The recommended revisions below will ensure consistency in wording between New Review Method 4 and New Acceptance Criterion 4.

DOE recommends revising lines 309 and 333 as follows:

Line 309 – Delete the word "expected" in the sentence such that the sentence ends with, "...for the GROA and types of Category 1 event sequences."

Line 333 – Delete the word "expected" and add the word "types" for consistency with the wording in the New Review Method 4. The sentence should end with, "...for the GROA and types of Category 1 event sequences."

Comment 9: Lines 319-321

This ISG states, "Confirm the descriptions are consistent with commonly accepted programs and practices, such as the guidance in NUREG-1567 for radiation protection (U.S. Nuclear Regulatory Commission, 2000)." The word "confirm" implies an inspection activity to determine if a facility has been built as required. DOE proposes to revise the wording of this sentence to include the word "evaluate" as it implies an evaluation to determine if the proposed design is appropriate.

DOE recommends revising lines 319-321 as follows:

Commensurate with the scope of normal activities proposed for the GROA and expected types of Category 1 event sequences, evaluate the descriptions as appropriate for consistency with commonly accepted programs and practices, such as the guidance in NUREG-1567 for radiation protection (U.S. Nuclear Regulatory Commission, 2000).

Comment 10: Line 390

The definition of Occupational Dose is incomplete and should be the same as in 10 CFR 20.1003.

DOE recommends revising line 390 as follows:

Add "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 § 35.75, from voluntary participation in medical research programs, or as a member of the public." to the end of the line.

Editorial

Line 178 – Delete the word "does" in the sentence and replace it with the word "do" such that it reads, "…duties that do not involve…"

Line 269 – Add "The analysis…must include, but not necessarily be limited to, consideration of" at the beginning of the line.

Line 330 – Revise to read, "Page 2.1-81:…"