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Department of Energy
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Secretary
U.S. Nuclear Regulatory Commission
Washington, DC 20555
ATTN: Rulemakings and Adjudications Staff
Docket ID NRC-2011-0012

The enclosed document constitutes the Department of Energy (DOE) comments on the Nuclear Regulatory Commission's November 2012, preliminary proposed rule language and regulatory analysis for the proposed revision of 10 CFR Part 61, *Site-Specific Analyses for Demonstrating Compliance with Subpart C Performance Objectives* from DOE, Office of Environmental Management.

Sincerely,

Frank Marcinowski
Deputy Assistant Secretary for
Waste Management

Enclosure

SECY-067

DS-10

U.S. Department of Energy Office of Environmental Management Comments on the U.S. Nuclear Regulatory Commission's Preliminary Proposed Rule Language and Regulatory Analysis for Proposed Revisions to the Low-Level Waste Disposal Requirements, 10 CFR Part 61, November 29, 2012

The U.S. Department of Energy's (DOE) Office of Environmental Management welcomes the opportunity to provide comments on the U.S. Nuclear Regulatory Commission's (NRC) *November 2012 Preliminary Proposed Rule Language for Proposed Revisions to Low-Level Waste Disposal Requirements (10 CFR Part 61)* [NRC-2011-0012].

On June 21, 2011, DOE commented extensively on NRC's May 2011 preliminary rule language and associated regulatory analysis.[1] DOE incorporates those comments herein and asks NRC to reconsider those comments in addition to the comments herein. The revised preliminary proposed rule language incorporated some of DOE's suggestions from June 2011, and we believe the inclusion of these suggestions will facilitate the establishment of a risk-informed approach for the disposal of low-level waste (LLW). For example, DOE is encouraged to see that the current draft recommends an approach of allowing the use of disposal facility performance assessments and waste acceptance criteria.

In considering stakeholder comments and moving forward on its 10 CFR Part 61 revisions, DOE recommends that NRC consider the following high level comments. DOE recommends that NRC adopt a two-tier regulatory approach for low-level waste disposal that <u>requires (1) radioactive releases from a disposal facility not result in an annual dose to a member of the public in excess of 25 mrem during the 1,000 years compliance period after closure of the disposal facility; and (2) reasonable efforts be made to minimize releases of radiation from a disposal facility to the general environment to the extent practical during the performance period</u>. In addition, NRC should continue to require adequate protection for inadvertent intruders but should not require compliance with an explicit dose limit for a wide range of potential intruder scenarios. Further NRC should define "performance assessment" broadly as an iterative process involving site-specific, prospective modeling evaluations of near-surface disposal systems for low-level waste after facility closure with two primary objectives: to determine whether reasonable assurance of compliance with performance objectives can be demonstrated; and to identify critical data, facility design, and model development needs for defensible and cost-effective licensing decisions and to develop and maintain operating limits (i.e., waste acceptance criteria).

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[1] Letter from Frank Marcinowski, Deputy Assistant Secretary for Technical and Regulatory Support, Office of Environmental Management, U.S. DOE, to Secretary, U.S. Nuclear Regulatory Commission, Docket ID NRC-2011-0012, dated June 21, 2011.

DOE Comments on Preliminary Proposed Rule Language

§61.2 Definitions

Compliance Period. The proposed definition would establish a compliance period of 10,000 years after closure of the disposal facility. DOE recommends that the compliance period be defined as 1,000 years for the following reasons.

i. There is no reason to change the current practice of using a 1,000 years compliance period with respect to LLW.

Explicit dose limits already exist in the performance objectives for LLW in 10 CFR Part 61 for 1,000 years after facility closure. This 1,000-year approach is consistent with, for example, 10 CFR Section 20.1401(decommissioning) and DOE Manual 435.1-1, Chapter IV-P.(2) (DOE LLW disposal facilities directive that addresses disposal of LLW), both of which use a 1,000 year compliance period. Likewise, the State of Idaho has established a 1,000 year compliance period for the Grand View waste disposal facility. This 1,000 year compliance period is used for evaluations for disposal (at that facility) of depleted uranium (DU) and other radioactive materials generated at NRC licensed facilities. The NRC has also specified a time frame of 1,000 years for near-surface disposal of by-product materials (10 CFR Part 40, Appendix A, criterion 6).

ii. The degree of uncertainty in a model increases as time period increases, which decreases the usefulness of models as a tool to evaluate compliance with an explicit dose limit.

ICRP 81, Radiation Protection recommendations for the disposal of long-lived solid radioactive waste, provides that:

> *"The objective of protecting future generations to at least the same level as current generations implies the use as indicators of the current quantitative dose and risk constraints derived from considering the associated health detriment. Doses and risks, as measures of health detriment, cannot be forecast with any certainty for periods beyond around several hundreds of years into the future (ICRP, 1997b). Instead, estimates of doses or risks for longer time periods can be made and compared with appropriate criteria (Section 4.4) in a test to give an indication of whether the repository is acceptable given current understanding of the disposal system. Such estimates must not be regarded as predictions of future health detriment."*

iii. Concerns about long-lived radionuclides are better addressed in the context of a two-tier approach that includes: (1) a quantitative analysis of compliance with an explicit dose limit during the compliance period, and (2) a qualitative analysis of reasonable efforts to minimize the effects of radioactive releases during the performance period after the compliance period.

The primary radionuclides of concern in the vast majority of waste intended for near-surface disposal in a low-level waste facility are short-lived and will have decayed to harmless levels after 300-500 years.[2] A 1,000 year compliance period will be sufficient to ensure these radionuclides are subject to a quantitative analysis to demonstrate compliance with a 25 mrem dose limit. For LLW with longer-lived radionuclides, a two-tier approach will provide adequate protection by requiring a qualitatative analysis for the performance period after 1,000 years to demonstrate that reasonable efforts will be taken to ensure the disposal facility will operate in a manner that mitigates releases of radioactivity to the extent practical through the period when peak impact is expected to occur with respect to the longer-lived radionuclides.

In general, quantitative analyses focus on compliance with an explicit dose limit and rely on models to predict expected doses, while qualitative analyses focus on what elements are important to minimizing radioactive releases and use models to gain insight as to how a disposal facility is likely to perform over a long period of time. Qualitative analyses resemble the ALARA process but do not attempt to demonstrate what particular dose is likely to result from mitigation efforts.[3] Both quantitative and qualitative analyses are subject to appropriate technical and quality assurance measures.

As described in DOE's June 21, 2011 comments, DOE implements the two-tier approach to LLW disposal through a defense-in-depth approach that utilizes geologic barriers, engineered barriers, numerous required passive and active institutional controls, and prospective analysis to guide decision-making. The multi-faceted DOE approach for assuring protection of the public health, safety, and the environment at LLW disposal facilities utilizes:

- Site characteristics which provide geologic and hydrologic barriers to radionuclide transport
- Facility design
- Waste acceptance requirements tailored to each specific site
- A rigorous waste generator certification program
- Barriers to intrusion

[2] See e.g., Energy Solutions' prior comments which explain that a 1,000 year period: "Is more than sufficient to analyze site performance; over 95% of the activity disposed (other than uranium decay products) will have decayed away after 500 years. The uranium decay products generated by in-growth are accounted for in the second tier, the period of performance, as explained below. Thus, there is no discernable advantage served by a compliance period greater than 1,000 years." Comments from Energy Solutions, July 31, 2012, at p. 4 [ML12216A228], citing *Options for Improved Low Level Waste Disposal Using 10 CFR 61.58*, Electric Power Research Institute, Report No. 1021098, 2010.

[3] DOE recommends that NRC not use the ALARA concept with respect to the performance period, after the compliance period ends. If NRC does use ALARA, then the regulations should be clear that the ALARA performance objective does not require a demonstration that the dose to the hypothetical member of the public will not exceed 25 mrem after the compliance period ends. In this regard, DOE also suggests that NRC consider using the term "to the extent practical" or a similar term with respect to the qualitative analysis after the compliance period rather than ALARA, to avoid confusion with the ALARA concept and ALARA process to protect workers and the public during operations. (See, for example, DOE regulations at 10 CFR Part 835 concerning the ALARA process during operations.)

- Analyses projecting hypothetical performance of the facility performance assessment and composite analyses
- Siting and design to minimize requirements for future maintenance
- Continued monitoring of facility performance
- Permanent maintenance of records
- Results of the Cementitious Barriers Partnership (an international modeling consortium including technical experts from NRC, DOE, and the National Institutes of Standards and Technology) modeling engineered barrier stability over long time periods

The two-tiered approach, as implemented by DOE, also takes into account the National Academy of Public Administration "Chain of Obligation Principle" (NAPA 1997), which recommends that beyond a few hundred years, decisions be assessed qualitatively to ensure actions do not cause catastrophic irreversible impacts.

Performance Period. The preliminary proposed rule language does not provide any specification of the performance period. The definition references §§ 61.41(b) and 61.42(b), but these merely refer, without elaboration, to "the performance period" as if it were already measurable. §61.42 (a) states:

> *"Reasonable effort should be made to maintain releases of radioactivity from a disposal facility to the general environment as low as reasonably achievable at any time during the performance period."*

§ 61.42 (b) provides:

> *"Reasonable effort should be made to maintain exposures to any inadvertent intruder as low as reasonably achievable at any time during the performance period."*

Licensees are thus led in a circle. They are confronted with an undefined, indefinite, and potentially infinite period over which they are required by §61.13 to "demonstrate that the performance objectives set forth in §§ 61.41(b) and 61.42(b) will be met."
DOE recommends that rather than specifying a specific time period for a performance period, the performance period be defined as the time period out to the time when peak impact is expected to occur with respect to a particular facility taking into account the characteristics of the site, the facility, and the waste.

Although nothing in NRC's Federal Register Notice so states, the preliminary proposed rule language is apparently based on an approach "similar" to Option 6. But it is not clear how the Regulatory Analysis Option 6 discussion would apply to the proposed rule language, which includes two long term performance objectives, one for protection of the public and the other for inadvertent intruders.

As described in NRC's Regulatory Analysis, Option 6 would involve two steps: (1) a screening process to identify if long term analyses are necessary based on conservative assumptions, including peak in-growth of daughter isotopes assuming no retardation during transport; and (2) if this analysis fails to show achievement of performance objectives, a "long term, site-specific analysis to peak dose (limited to one million years)." It is quite unclear how either step would work. The Regulatory Analysis mentions that the analysis must be performed to "demonstrate the public health and safety will be protected" and, in the case of a second tier analysis, that arrangement would "maintain doses to the public ALARA." NRC's proposed regulations include, however, a requirement to demonstrate protection of inadvertent intruders as well as the public. How this would be accomplished in the context of a performance period of some undefined period is not addressed.

However these questions are resolved, the Regulatory Analysis makes clear that a long term analysis of performance in protecting the public and inadvertent intruders over a period of up to a million years may be required, based on peak dose. Such an exercise goes well beyond what is implied in ICRP, IAEA, and NAPA recommendations, especially related to near-surface disposal. Equally important, tying the performance period (or compliance oriented comparison with a performance objective) to peak dose is not sound, risk-informed regulatory policy. In analyses that extend far into the future, dose is not an appropriate metric for health detriment. In its January 2012 direction to staff, SRM COMWDM-11-0002/COMGEA-11-0002, (Jan 19, 2012), the Commission directed the staff to consider:

> *"A two tiered approach that establishes a compliance period that covers the reasonably foreseeable future and a longer period of performance that is not a priori and is established to evaluate the performance of the site over longer timeframes. The period of performance is developed based on the candidate site characteristics (waste package, waste form, disposal technology, cover technology and geo-hydrology) and the peak dose to a designated receptor."*

The Regulatory Analysis discussion of the long term performance period in the context of Option 6 fails to mention peak impact[4] to a designated receptor, or how the receptor would be defined.

<u>Inadvertent Intruder</u>. NRC should not change to the existing 10 CFR Part 61 definition of inadvertent intruder. It is not clear why a change is needed in the regulation, especially when such a change could call the basis for the waste classification tables into question. The well-drilling intruder scenario has previously been used in association with a homesteader searching for drinking water, and there is no precedence for a resource exploitation well-driller scenario. NRC's proposed definition is a new scenario that has not been fully vetted or analyzed in any of the documents associated with stakeholder comments on Part 61.

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[4] DOE uses the peak "impact" rather than "dose" when comparing disposal alternatives because the total effective dose may not be an appropriate metric far into the future. Other metrics such as releases to the environment or total releases may be more appropriate measures of detriment to future generations.

Long-Lived Waste. DOE does not agree with the proposed definition for "long-lived waste". The need for a specific definition of long-lived waste is not clear and it has the potential to do harm in a broader context with minimal benefit. As written, the recommended definition could include mill tailings, oil and gas waste, phosphogypsum and other TENORM waste, mixed waste, and NRC authorized disposal of DU waste at the Grand View Idaho hazardous waste disposal facility. These types of wastes currently are disposed of in the near-surface, so the definition as written could have potential far reaching implications on the authorized disposal practices for these wastes.

Performance Assessment. NRC should consider using a definition based on existing references rather than creating a new definition. We suggest that NRC use the definition from NCRP Report 152, which states:

> *"Performance assessment is an iterative process involving site-specific, prospective modeling evaluations of the post closure time phase of near-surface disposal systems for low-level waste with two primary objectives: to determine whether reasonable assurance of compliance with quantitative performance objectives can be demonstrated; and to identify critical data, facility design, and model development needs for defensible and cost-effective licensing decisions and to develop and maintain operating limits (i.e., waste acceptance criteria)."*

We believe NRC's proposed definition would place unnecessary focus on the concept of features, events, and processes (FEPs), which is inconsistent with other definitions that have been widely used. Performance assessment serves more roles than simply identifying, examining, and estimating dose from all FEPs. NCRP's definition appropriately emphasizes that a performance assessment should, among other things, identify critical data, facility design, and model developments needed to make defensible and cost-effective licensing decisions in conjunction with developing and maintaining waste acceptance criteria/operating limits, and does not simply identify, examine, and estimate dose releases from all FEPs. While FEPs are clearly an important consideration in performance assessments, over-reliance on FEPs alone, would effectively require a single methodology approach that may neglect important, unique aspects of a conceptual model for a specific site. By using the term FEPs in the proposed definition, NRC would also appear to be inconsistent with recent positions from the international community (e.g., EC 2009, OECD/NEA 2012, and IAEA 2012).

Conceptual and mathematical models are used in performance assessments to provide decision makers with insights as to which factors are most important to performance, and these are not necessarily limited to FEPs. Such insights play an important role in defining waste acceptance criteria and facilitating design optimization.

§61.7 Concepts

§61.7(c)(1): The phrase "over the long term" is not clear. Does this term refer to dose assessments or risk of impact to the potential receptor? Is the "long term" considered in the time of compliance or is it a reference to the period of performance? This discussion only addresses the role of performance assessment in comparison with performance objectives, but does not address how a performance assessment is used in a risk-informed context to use sensitivity and uncertainty analyses to support decision-making. In practice, performance assessments are used in a more holistic manner to support making a risk-informed decision. The current discussion does a disservice to the process by implying that a performance assessment is only used to develop a dose estimate to compare against a performance objective.

§61.7(c)(4): This section should clarify that the hypothetical inadvertent homesteader is only assumed to intrude for approximately a one year period.

§61.7(e)(1): No technical analysis has been provided to justify the assertion that low activity waste would be unstable and become a problem when mixed with higher activity waste. Additional study and information should be provided to stakeholders prior to this being inserted into the regulation.

§61.7(e)(4): Recommend deletion of "…more robust intruder barriers (such as burial below 30 meters)" and insert "engineered barriers". This is globally acceptable and could refer to intruder protection, water infiltration barrier or another type of barrier without specifying which one would be appropriate for that situation.

§61.13 Technical analyses

§61.13(a): See previous comments on performance assessment.

§61.13(b): The use of the words "any inadvertent intruder…" could easily be misinterpreted. To be consistent with more recent ICRP recommended terminology associated with the use of new dosimetry and dose coefficients, a representative person context should be incorporated into this language. The use of "any" opens up the discussion to excessive speculation of intrusion. The ICRP refers to the use of a limited number of "stylized scenarios" rather than implying a need to consider a wide variety of potential events. This language would appear to be a departure from international recommendations. The definition of the intruder assessment also includes the resource exploration and exploitation scenario which was not described or otherwise analyzed in any of the public comment documents. Also, see additional comments on inadvertent intruders above.

§ 61.41 Protection of the general population from releases of radioactivity

DOE suggests modifications to the proposed text for §61.41 (a): "… must not result in an annual dose exceeding an equivalent of 0.25 milliSievert (25 mrem), excluding radon, to a representative person...". Consistent with other rules involving radon exposures, radon should be addressed using an additional performance objective specific to radon flux from the surface of the facility similar to what has been promulgated in existing rules (e.g., 10 CFR Part 40, Appendix A, criterion 6). The rationale for this is that the modification reflects two significant changes. One is a change from "any member of the public" to "a representative person". The ICRP more recently has been using the term "representative person" to reflect the receptor that is considered in a dose assessment when using the updated dosimetry and dose coefficients. A change to the representative person terminology is consistent with the use of updated dosimetry. DOE suggests that the ICRP recommendation be considered for the language used for the performance objective, because the ICRP provides a framework to help with interpretation of what is meant by a representative person rather than leaving the term 'any member of the public' open for interpretation. This is especially important considering that, it is difficult to define or constrain, what is meant by any member of the public when considering very long time frames. The second change is to add "excluding radon" from the total dose and adding an objective for radon flux. This is consistent with precedents in other promulgated rules that address situations that can lead to significant radon exposures [e.g., 40 CFR Section190.10, 40 CFR Part 61 (subpart H), 40 CFR Section 61.192 (subpart Q), 10 CFR Part 40 (Appendix A, criterion 6)]. It is also consistent with not specifically considering the actual dose or risk from radon relative to the 100 mrem/yr radiation protection standard, when addressing the need for mitigation of radon in homes.

§ 61.42 Protection of inadvertent intruders

The proposed addition of a specific dose limit is a change from the NRC accepted practice for the last 30 years and is neither needed nor more protective for the following reasons. In its 1981 Part 61 Draft Environmental Impact Statement (EIS), NRC had proposed to adopt a 500 mrem inadvertent intruder standard. The EPA, however, advised NRC that it was not feasible to implement this standard as a regulatory requirement, and NRC dropped the proposal and provided the justification in the Final EIS. In addition, the ICRP refers to the inadvertent intruder differently than a performance objective for protection for all pathways (e.g., Section 61.41). It is recommended that wording other than "performance objective" be considered here, such as language consistent with the views of the ICRP. Finally, the ACRS found that the proposed requirement to provide reasonable assurances of intruder doses not exceeding 500 mrem/year over incredibly long time frames was impractical.

Certain erroneous statements in the Regulatory Analysis should be corrected, as indicated below.

a. *Section 5.1.2.2, Other Domestic Regulatory Agencies, Page 22, Table 1*.

   i. The entry for Part 20 under the column "ACTION" should be revised to "remediate/dispose at commercial hazardous waste disposal facility". This reflects the fact that Part 20 is also used to justify exemptions for disposal of long-lived radioactive materials at commercial hazardous waste disposal facilities.

   ii. In the column "BASIS," NRC staff did not consider the DOE Technical Basis. DOE provided the web link to the DOE Technical Basis in its June 2011 comment document (https://www.directives.doe.gov/directives/current-directives/435.1-EGuide-1-ZappA/view). The DOE Technical Basis demonstrates that DOE built on the original technical basis for the development of NRC's 10 CFR Part 61. The technical standards (performance objectives) used by DOE are essentially the same, except that DOE added an additional performance objective to protect the public from air contamination and incorporated the concepts of intergenerational equity into the Technical Basis.

iii. The statement that the 10 CFR Part 20 regulations are only used for remediation should be corrected because 10 CFR Part 20 exemptions have been used for disposal at the Grand View facility in Idaho, among others. The waste regulated by 10 CFR Part 20 may be remediation waste in origin, but the required facilities are fully functioning disposal facilities.

iv. The description of uranium mill tailing regulations should be revised to note that they use engineering considerations and not purely calculational performance assessment methodology to control risk.

b. *Section 5.1.7, Options Considered, Pages 40-43:*

i. Page 42, Table 2, Option 8: For accuracy, the NRC staff should revise the description for Item 8 from "DOE approach" to "NRC approach for disposal under 10 CFR Part 20" and change the description for item 9 to "COM and DOE approach". The descriptive text should also be revised to address the approach used by the NRC to authorize exemptions for disposal of long-lived materials under 10 CFR Part 20 (1,000 year cutoff).

ii. Page 42, Table 2, Option10: The statement that this is the "international approach" should be modified because as described in the Regulatory Analysis, there is no single international approach as every country implements the regulations differently.

c. *Section 5.2.2, Other Regulatory Approaches, Page 46:* The statement that "all operating near-surface disposal facilities in the U.S. are regulated by Agreement States" is only true for licensed facilities not owned by DOE.

d. *Section 5.2.3, Technical Considerations, Page 47:* Using the assumption that cover material is only at a 1 meter depth does not reflect current practices. DOE varies the cover depth depending upon the radionuclides present and weathering for that location.

References

1. USDOE, 2001, *Radioactive Waste Management Manual*, DOE M 435.1-1, U.S. Department of Energy, Washington, DC.
2. IAEA, 2012, The Safety Case and Safety Assessment for the Disposal of Radioactive Waste, Specific Safety Guide No. SSG-23, International Atomic Energy Agency, Vienna, Austria.
3. OECD/NEA, 2012, Methods for Safety Assessment of Geological Disposal Facilities for Radioactive Waste, Outcomes of the MeSA Initiative, ISBN 978-92-64-99190-3, Organization for Economic Cooperation and Development/Nuclear Energy Agency, Paris, France.
4. ICRP, 2000, Radiation protection recommendations as a applied to the disposal of long-lived solid radioactive waste, ICRP Publication 81, International Commission on Radiological Protection, Elsevier Publishing.
5. IAEA, 2004, Safety Assessment Methodologies for Near-Surface Disposal Facilities, International Atomic Energy Agency, Vienna, Austria.
6. OECD/NEA, 2000, Scenario Development Methods and Practice, Organization for Economic Cooperation and Development/Nuclear Energy Agency, Paris, France.
7. NAPA, 1997 document *Deciding for the Future: Balancing Risks, Costs, and Benefits Fairly Across the Generations*, Washington, DC.