



Department of Energy
Washington, DC 20585

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

To Whom It May Concern:

The enclosed document provides comments from the U.S. Department of Energy, Office of Environmental Management, on the proposed rule (published on March 26 at 80 FR 16082) for revisions to 10 CFR Part 61, *Low-Level Radioactive Waste Disposal*.

Sincerely,

A handwritten signature in cursive script, reading "Frank Marcinowski", is positioned above the typed name.

Frank Marcinowski
Deputy Assistant Secretary for
Waste Management

Enclosure



**Department of Energy's Comments on
Nuclear Regulatory Commission's Proposed Rule: 10 CFR Part 61,
Published March 26, 2015**

Department of Energy's Comments – General Issues

Risk-informed approach

We agree with the Nuclear Regulatory Commission's (NRC) intention for the proposed changes to reflect a risk-informed approach to regulation of low-level radioactive waste (LLW) disposal (See, e.g., 80 FR 16083, col. 1; 16089, col. 3; 16091, col. 2. . .), but the proposed rule does not fully implement a risk-informed and performance-based approach. The proposed regulations would add numerous new requirements for site-specific analyses. However, the proposed regulations would not allow these analyses to form the basis on which compliance is evaluated.

Instead, the proposed rule retains vestiges of a mandatory, non-site-specific approach, which preserves—and, in fact, adds to—technology-based and generic (i.e., non-site-specific) requirements related to engineered components, stability, determination of analytical timeframes, and siting criteria, among others. Such criteria are unnecessary and at odds with a truly risk-informed approach to regulation. As the NRC has stated, “the risk-informed, performance-based approach . . . eliminates arbitrary or prescriptive siting and design criteria, as well as detailed requirements such as quantitative subsystem performance objectives” (66 FR 55737). A sound conceptual model of the site and a comprehensive performance assessment (PA) provide the means to assess the significance of site attributes, the components of the disposal system, their interactions, and their effects on performance. Again, as NRC has observed: “advances in performance assessment technology support the use of performance assessment results for estimating long-term repository performance. They also obviate, in the Commission's view, the need to prescribe arbitrary, minimum performance standards for subsystems to build confidence in the system's overall performance” (66 FR 55758). While these observations were made in the context of regulations for the Yucca Mountain repository, the conclusions were based on high-level regulatory approaches and technological evolution—not site-specific considerations—and therefore the reasoning is equally applicable to this rulemaking.

Thus, it should be sufficient that the PA and other site-specific analyses demonstrate a reasonable assurance of compliance with the dose limits or targets—considering the relevant features of the site and facility (including those that may be beneficial as well as those that may be detrimental to performance). Numerous additional requirements and separate analyses are merely burdensome without adding to protectiveness. For example, with site-specific analyses, the definition and table for “long-lived waste” are not needed and can be removed. Likewise, a separate, quantitative site stability analysis (as implied by the technical analysis mentioned in §§ 61.7(c)(1), 61.13(d) and 61.23(e) and as suggested in the Guidance) is not necessary; rather,

the focus should be on whether the PA provides reasonable assurance that the performance objectives at §§ 61.41 and 61.42 will be met, taking account of site stability. We note specific instances where requirements should be deleted, and we also suggest that NRC carefully review the proposed rule to eliminate extraneous criteria and analyses that do not align with a risk-informed and performance-based approach.

Three-tiered approach to compliance over different timeframes

We do not support the proposal for a three-tiered approach to compliance. We recommend that a two-tiered approach be adopted that retains the proposed 1,000-year compliance period (and associated dose limit), eliminates the protective assurance period (and associated reference dose), and applies the qualitative performance period approach to modeling assessments beginning at 1,000 years after closure. A two-tiered approach would provide important information about the performance implications of long-lived nuclides into the very far future, while reducing the unnecessary complexity of the proposed rule and appropriately accommodating greatly increased uncertainties at very long timeframes.

We endorse the 1,000-year timeframe and associated dose limit for the initial compliance period; the period appropriately limits speculation and reflects the limitations on how long performance assessment results for low-level radioactive waste disposal can reasonably be used in a quantitative manner to assess compliance.

We also support the concept of extending performance analyses and intruder assessments over longer periods. There is value in considering, qualitatively, the results of modeling beyond the time when the results can be assigned quantitative meaning with respect to potential health effects. Such an assessment can provide valuable information to guide waste acceptance criteria, design optimization, and defense-in-depth measures. We support, in principle, the performance period and the approach to use analytical results only qualitatively. Several changes are suggested to better align the proposed rule language with the declared intentions of NRC; these are discussed in more detailed comments.

However, the imposition of an intermediate “protective assurance” period (from 1,000 to 10,000 years after closure) with a numerical dose limit (as written) or dose target (as NRC apparently intended) does not appropriately accommodate the uncertainties and limitations of modeling over very long timeframes. It establishes *de facto* requirements over very long timeframes without adding materially to an understanding of the relevant behavior of long-lived nuclides and does not provide additional protectiveness to members of the public or to the hypothetical inadvertent intruder:

- The International Atomic Energy Agency (IAEA) says, for example, that for engineered near-surface disposal facilities, a modeling period on the order of “a few 1,000 years may still be reasonable” (IAEA Safety Guide SSG-23, 2012). The International Commission on Radiological Protection (ICRP) observes that doses and risk “cannot be forecast with any certainty beyond around several hundreds of years into the future” (ICRP-81). The Organization for Economic Cooperation and Development’s (OECD) Nuclear Energy Agency (NEA) acknowledges that, “While some hazard may remain for extremely long

times, increasing uncertainties mean that there are practical limitations as to how long anything meaningful can be said about the protection provided by any system against these hazards. These practical limitations need to be acknowledged in safety cases.” NEA further states, regarding the application of quantitative criteria at 1,000 to 10,000 years and beyond, that it is “recognized in regulations and safety cases that the actual levels of dose and risk, if any, to which future generations are exposed cannot be forecast with certainty over such time frames”.¹ A 10,000-year period for quantitative assessment and comparison against a dose criterion for low-level radioactive waste disposal facilities goes well beyond these recommendations.

- In addition, NRC’s primary justification (as described in the “Technical Analysis Supporting Definition of Period of Performance for Low-Level Waste Disposal”) for a 10,000-year “break-point” is consistency with regulatory precedents that relate solely to high-level waste and deep geologic repositories. The characteristics of the waste and the predictability of the disposal systems both differ substantially from the context of near-surface low-level radioactive waste disposal and therefore are not appropriate precedents. More relevant are existing regulations for materials and sites that are comparable to low-level waste; those regulations establish compliance periods of 1,000 years, at most. (See 10 CFR Part 20.2002; 10 CFR Part 40, Appendix A; 40 CFR Part 192.) NRC’s Advisory Committee on Nuclear Waste (ACNW) noted, regarding earlier staff proposals to impose a 10,000-year period of performance, that the timeframe was “arbitrary and lacked bases in either standards or regulations.”
- The ACNW further warned that assessments beyond an initial compliance tier should “be used to evaluate the robustness of the facility over long periods of time and should not become *de facto* regulation” (NRC Technical Analysis, pp. 1, 2). As discussed in further detail in later comments, the proposed regulations would establish dose limits rather than goals—and, in fact, with greater stringency than for the compliance period.
- Quantitative—or “semi-quantitative” (as described at 80 FR 16096, col. 2)—assessment of modeling results up to 10,000 years after closure also contributes little to protectiveness. The discussion accompanying the proposed regulations states repeatedly that disposal of depleted uranium (DU) low-level radioactive waste is a driving factor in the proposed rule revisions. However, the activity of DU low-level waste (taking account of ingrowth of progeny) is expected to be relatively constant until well beyond 10,000 years (“Technical Analysis Supporting Definition of Period of Performance,” Figure 1).
- The protective assurance period also is not necessary in view of intergenerational equity considerations to avoid “actions that pose a realistic threat of irreversible harm or catastrophic consequences” for future generations (“Technical Analysis Supporting Definition of Period of Performance,” p. 10). The proposed compliance period alone is sufficient to satisfy that ethical obligation. That is, providing reasonable assurance that doses (which will be extremely localized) will be limited to 25 mrem/yr—much less than

¹ See *Considering Timescales in the Post-Closure Safety of Geological Disposal of Radioactive Waste*, OECD Nuclear Energy Agency, 2009, pp. 8, 9.

background radiation or routine medical exposures—for the next *forty* generations covered by a 1,000-year compliance period goes well beyond averting “catastrophic consequences”.

We recommend, therefore, that the proposed requirements related to a protective assurance period be eliminated. Instead, the performance period (and the qualitative approach to further modeling) should begin at 1,000 years after closure.

New definitions

The proposed regulation would add new definitions for a number of terms. Among these are several that are justified (in the Federal Register (FR) discussions) primarily on aligning the U.S. approach with those endorsed in international guidance: specifically, defense-in-depth, performance assessment and safety case. However, the proposed regulations do not use definitions that have been developed through international consensus, including participation from U.S. regulatory agencies. No explanation is provided for the departure from accepted published definitions. We believe that linking the concepts to international and national guidance is a laudable goal, and that it will be best accomplished by adopting the documented definitions that have been established for these terms in international and national guidance and technical reports. See comments on specific definitions in § 61.2.

Uncertainty and limitations of PA over long timeframes

FR notice appropriately discusses the increasing uncertainties, and the decreasing confidence—and thus meaningfulness for quantitative decision-making—that can be placed in numerical analyses over longer timeframes (See, e.g., 80 FR 16091, col. 3.). As noted previously, such limitations on the use of PA are also well-recognized internationally by the IAEA, ICRP and NEA. (See general comment on the three-tiered compliance approach.) More generally, a PA, even for several hundred years into the future, cannot be regarded as a “prediction” of future disposal system behavior. Rather, it is a hypothetical projection of possible behavior, based on reasonably conservative assumptions and simplifications. These views reflect international consensus. NEA says: “Calculated values are to be regarded not as predictions but rather as indicators that are used to test the capability of the system. . . . Doses and risk evaluated in safety assessments are to be interpreted as illustrations of potential impact to stylized, hypothetical individuals based on agreed sets of assumptions.”² These concepts and limitations on PA are acknowledged in some of the FR discussions, but are not well reflected in the regulatory language.

We suggest that additional caveats and explanation be added in the concepts section and throughout the rule to appropriately reflect the issue and the balance to be struck (see subsequent comment). The use of terms such as “ensure” protectiveness should be avoided. The regulatory language should instead be consistent with the concept of reasonable assurance.

² NEA 2009 Timescales Report, pp. 9, 12.

Reasonable assurance

In a similar vein, a definition or discussion (in § 61.2 or § 61.7) should be added for the term “reasonable assurance.” None is provided in the proposed rule though the term is used extensively in the regulatory language. The concept, when applied to the timeframes incorporated in the proposed rule, has implications very different than its application in other contexts in which it is applied by NRC (during operation of nuclear facilities, for example) and, therefore, deserves particular attention. We suggest that the concept adhere to NRC’s interpretation as used in the context of geological disposal, which is consistent with the Environmental Protection Agency’s (EPA) term “reasonable expectation,” as applied to analyses up to or beyond 10,000 years:

Performance assessments need not provide complete assurance that the requirements . . . will be met. Because of the long time period involved and the nature of the events and processes of interest, there will inevitably be substantial uncertainties in projecting disposal system performance. Proof of the future performance of a disposal system is not to be had in the ordinary sense of the word in situations that deal with much shorter time frames. Instead, what is required is a reasonable expectation, on the basis of the record before the implementing agency, that compliance . . . will be achieved. [40 CFR 191.13(b)]

This is consistent with NRC’s explanation in the “Technical Analysis” (p. 5) that the results of compliance analysis “are not interpreted as unequivocal numerical proof of the expected behavior of a waste disposal facility”.

Exclusion of radon

It is recommended that radon be excluded from the dose-based performance objectives. The inclusion of radon is significantly inconsistent with expectations applied to other EPA, NRC and the Department of Energy’s (DOE) regulations that address management of uranium-containing materials [e.g., 40 CFR Part 190.10, 40 CFR Part 61 (subpart H), 40 CFR Part 61.192 (subpart Q), 10 CFR Part 40 (Appendix A, criterion 6), 10 CFR Part 20.1101(d), DOE Manual 435.1-1]. The proposed performance objectives in Part 61 should be updated to be more consistent with other national requirements related to radon for wastes containing uranium. A major factor in the update to Part 61 is to address DU, so modifications to the existing rule in the interest of consistency with other EPA and NRC regulations addressing uranium is appropriate. NRC might consider instead adding a performance objective for radon flux, consistent with the approaches in other promulgated rules.

Concepts and Technical Analyses

These sections of the proposed rule include information that appears overly prescriptive and is better suited for guidance. Furthermore, some of the detail is not appropriate (see specific comments below). For example, the discussions in concepts on “intruder assessment,” “waste with significant concentrations and quantities of long-lived radionuclides,” defense-in-depth, and also the discussion of stability in the waste classification discussion do not appear necessary.

The use of words such as “can,” “may,” and “should” are indicators that statements are more appropriate for guidance rather than for a rule. See specific comments on §§ 61.7 and 61.13.

Long-term analyses

The references to “long-term analysis” in the FR notice (e.g., 80 FR 16091) seem to emphasize analysis covering 10,000 years or more; however, depending on the context, analyses for 500 or 1,000 years are also long-term analyses and should be described as such. Statements that give the impression that analyses for 500 or 1,000 years are not considering long-term impacts should be avoided.

Closure terminology

The proposed regulation contains inconsistent use of the term “closure.” The definition of intruder assessment (proposed § 61.2), for example, refers to “the time of site closure.” The definition of compliance period refers to “closure of the disposal facility.” An existing definition for site closure and stabilization describes a set of actions rather than a point in time. The definition for the protective assurance period uses the terminology “following closure of the site”. There is similarly inconsistent usage throughout the rule, with various terms being used: closure, final closure, site closure, final site closure, time of site closure, site closure phase, disposal site closure, and closure of the land disposal facility. It is not clear if the terms are meant to be interchangeable or if the differences in terms carry significance. It is recommended that NRC review such terminology and make it consistent as much as possible; where there are differences, the reasons should be made clear by context or explanation.

DOE Comments – Proposed Regulatory Provisions

§ 61.2, Compliance period definition

The definition for compliance period describes when it ends, but is unclear about when it begins. This leaves some ambiguity regarding whether the provision should be applied during the operational period. It is suggested that the definition be revised to clarify that the compliance period for the purposes of § 61.41 and § 61.42 begins at the time of closure of the disposal facility. As a conforming change, the cross-reference in § 61.43 (to § 61.41) should be deleted, and either the salient requirements incorporated directly into § 61.43 or, given the existing cross-reference to Part 20, the requirements concerning effluents in § 20.1302 and § 20.1301 be used.

§ 61.2, Defense-in-depth definition

The definition of defense-in-depth does not reflect the accepted use of the term, either in the U.S. or internationally (e.g., in IAEA SSR-5 and the IAEA Safety Glossary) and is inconsistent with the preamble. As noted in the preamble, “The NRC’s defense-in-depth approach to risk management ensures that safety is not wholly dependent on any single element of the design, construction, maintenance or operation of a regulated facility. . . . Defense-in-depth for a land

disposal facility includes, but is not limited to, the use of remote siting, consideration of waste forms and radionuclide content, engineered features, and natural geologic features of the disposal site.” Other relevant features mentioned in the preamble are, for example, land ownership and institutional control requirements (80 FR 16102, col. 2). Even in operating nuclear facilities, the term is understood to encompass a range of strategies, procedures, and operational considerations that go well beyond simply redundant physical barriers. (See <https://www.iaea.org/ns/tutorials/regcontrol/assess/assess3213.htm>.) It is suggested that the definition be revised to reflect the broader consideration that are discussed in the preamble as well as in proposed § 61.7(d).

§ 61.2, Inadvertent intruder and intruder assessment definitions

We support the clarification that the intruder assessment should consider only activities that are “realistic and consistent with expected activities in and around the disposal site at the time of site closure.” NRC notes that the approach used to develop the classification tables remains protective. We agree, and note that this implies that the use of scenarios similar to those considered in the development of Part 61 is sufficient to meet the intent of the requirements. We suggest clarifying this point in the regulatory language, in the definition for either the inadvertent intruder or the intruder assessment. This is a reasonable approach to limit speculation regarding potential scenarios and emphasizes the continued protectiveness of the existing classification system. It also reduces the regulatory burden because there already exists considerable experience in implementing these scenarios.

The use of the term “resource exploration or exploitation” in the definition of inadvertent intruder is problematic. It could be interpreted to include mining, which has not been considered within the realm of inadvertent intruder analyses in the past and could be complex to model and quantify. More importantly, the inclusion of resource exploitation adds little to no value to the intruder analysis for low-level radioactive waste. For geologic disposal, such scenarios can be important because they may serve as the sole means for intruders to access waste. For near-surface disposal, however, the potential outcomes of resource exploration would be very similar to (and likely bounded by) the “standard” intruder scenarios (i.e., resident farmer, well-drilling, and basement excavation), which already account for the possibility of waste being encountered directly. It is recommended that the term resource “exploitation” be eliminated from the definition of inadvertent intruder and, as noted above, that the definition of inadvertent intruder assessment be clarified to focus on the intruder scenarios used to establish the waste classification tables.

§ 61.2, Long-lived waste definition

The definition of long-lived waste should be deleted (and if retained, technical justification should be provided). Furthermore, the definition is extraneous; after being defined, the term appears only in § 61.7, Concepts. A quantitative interpretation of the term is not needed or relevant to its single use in that context. The appropriate basis to determine whether longer-term analysis is needed is the site-specific performance assessment rather than arbitrary numerical criteria. Implementation of a two tier approach with a compliance time of 1,000 years, as we

recommend, would remove the need for the definition and table. See also comments on proposed § 61.13(e).

§ 61.2, Performance assessment definition

The definition should include a consideration of associated uncertainties, as is done in the definition of *intruder assessment*. This is especially important in view of the proposed requirement in § 61.13(a)(3), (a)(8) and (a)(9) to consider probabilities and uncertainties regarding various aspects of performance assessment including unlikely features, events and processes; variability in the disposal facility and environment; and alternative conceptual models. It is suggested to use language that is as consistent as possible with existing definitions (e.g., NCRP Report No. 152, p. 18, or IAEA SSG-23 on safety assessment) rather than developing a new definition.

The proposed definition also places unnecessary focus on the concept of features, events and processes (FEPs), which is at odds with other definitions that have been widely used (e.g., from ICRP, IAEA, and NEA). By using this terminology, the proposed rule appears to be requiring a single methodology to achieve a conceptual site model, an approach that is inconsistent with recent positions from the international community (e.g., the IAEA Safety Guide No SSG-23 on safety assessment and the NEA Methods for Safety Assessment of Geological Disposal Facilities: Outcomes of the MeSA Initiative, 2012). The use of an existing definition from one of these sources would resolve this issue as well.

Finally, the consideration of all FEPs (or whatever terminology is ultimately used)—namely, FEPs that “might affect the disposal system”—is too broad and could entail consideration of highly unlikely or fantastic events or combinations of events. Consideration should be limited to “reasonably foreseeable and significant” FEPs or factors that are relevant to performance. See also the comments on proposed § 61.13(a)(1) through (a)(5).

§ 61.2, Performance period definition

The proposed definition of the performance period specifies no end point and no criteria for establishing what period of time must be covered by analyses beyond 10,000 years. NRC makes clear that the period is left undefined in order to allow site-specific factors to be considered (80 FR 16097, col. 1). Additional discussion highlights that the time of peak dose would be a substantial consideration in determining how far into the future the modeling projections should run (*ibid.* and 80 FR 16092, col. 1). This is, in general, an approach that is consistent with a risk-informed process and that DOE supports.

However, it is not appropriate to forego any ultimate end-point for the performance period. Without an endpoint (or factors to be considered) for the performance period and associated analysis, the proposed regulations would impose an arbitrary and burdensome approach and would risk generating uncertain analyses without potential usefulness for risk-informed decision making. In this regard, NRC (in its “Technical Analysis Supporting Definition of Period of Performance”) rejects a peak dose approach with an undefined performance period, in part

because "peak dose could occur beyond the period of geologic stability, which would render quantitative values essentially meaningless" (p. 11).

An unrestrained performance period would not only extend modeling analyses beyond potential usefulness, but would also impose additional requirements. The proposed requirements in § 61.42(c), for example, require that "effort shall be made to minimize releases . . . at any time during the performance period." (See also DOE comments on minimization, in general comments and regarding proposed sections § 61.41(b) and (c); § 61.42(b) and (c).) With no end to the performance period, this means that licensees could be required to take measures now to reduce future potential releases, based on highly uncertain and limited analyses. This is not justifiable and conflicts with ethical principles that assign greater weight to near-term hazards than to hypothetical long-term risks. In this regard, DOE generally conducts performance assessments for low-level radioactive waste disposal to the time of peak dose or a shorter time period, as appropriate, to risk inform decisions. However, DOE does not impose dose limits or performance measures during time frames beyond 1,000 years post-closure.

Consistent with the above principles, we recommend that, at a maximum, the performance period should not extend beyond peak dose (or impacts) or the period of surface geologic stability, whichever is sooner.

NRC has apparently dismissed part of this approach, stating in the proposed supporting guidance (NUREG-2175) that "It would not be appropriate to constrain the analyses to the period of near-surface geologic stability, as one of the reasons for undertaking the performance period analyses is for a licensee to communicate to decision-makers the potential range of consequences from the disposal action. Near-surface geologic instability may result from a process such as fluvial erosion (e.g., driven by lake formation), which could have severe impacts at an unstable site. Near-surface geologic instability may indicate that the site is unsuitable for disposing of significant quantities of long-lived radioactive waste. A licensee should not use near-surface geologic instability as a basis for limiting the analysis. If the analysis for LLW disposal was limited to the period of near-surface geologic stability, the analysis could be truncated prematurely and the long-term risks and uncertainties may not be understood. In addition, instability could be used as a basis to select a site, which is not acceptable." (p. 2-24)

While NRC's staff express legitimate concerns, these concerns nonetheless do not justify the regulatory approach proposed in the rule and supporting guidance. We agree that it would be objectionable to provide an incentive for picking an unstable site in order to avoid the regulatory burden of extended analyses, but we find it unlikely that such a site would fulfill the other significant requirements in the rule. Furthermore, there are means to counter such an effect without extending modeling. Indeed, requiring a description and justification of when and why the performance period is truncated would give significant insights into the site characteristics and stability. It is within NRC's discretion to consider such information as part of the safety case on which the licensing process will be based.

Most important, the extension of performance analyses beyond the period of surface geologic stability is unsupportable from a technical perspective. Geologic repositories may rely on longer timeframes for analysis precisely because, being at depth, they are not likely to be significantly

affected by events and processes at the surface. The timeframe for surface effects from geologic processes is notably less than that for deeper geologic stability (NEA 2009 Timescales Report³, Figure 5.12a and pp. 27-28). Once processes affecting the surface at a certain magnitude and breadth occur, the analysis of the site is unreliable even qualitatively. Any results are, furthermore, much less likely to be relevant, since populations near a site affected by, for example, a new ice age are likely to face much more significant and immediate threats to their lifestyle and survival than the potential for a localized incremental increase in cancer risk.

NEA says, “Truncating calculations too early may run the risk losing information – for example on the possible timing and magnitude of peak consequences At sufficiently distant times, however, uncertainties call into question most of the assumptions made in evaluating radionuclide releases.” The NEA further cautions that relying on such modeling can undermine confidence in the safety case (NEA 2009 Timescales Report, p. 73). While calculations can always be extended, they add no value if they cannot be meaningfully interpreted, and to require them implies a level of confidence that is not warranted. As noted in our general comments on the three-tiered approach, doses and risk “cannot be forecast with any certainty beyond around several hundreds of years into the future” (ICRP-81), so calculations for longer time periods already test the limitations of PA. The interpretation, even qualitatively, of assessments beyond the time of relevant geologic stability is truly questionable. Even if peak impacts might occur beyond the period of surface geologic stability, the reliance on modeling at that point, with its inherent uncertainties regarding nearly every aspects of assessment⁴ is entirely insufficient as a basis for regulatory decision making and the requirement for “effort to minimize . . . to the extent reasonably achievable”. (See proposed § 61.41(c) and proposed § 61.42(c); see also DOE comments regarding minimization, in general comments and regarding proposed sections § 61.41(b) and (c); § 61.42(b) and (c).)

We understand also that a significant motivator for the performance period is to gain information regarding long-term performance—but even 1,000 years already *is* long-term performance. Analyses for longer-term performance should be conducted with the recognition of the growing speculation and uncertainty over time. As NEA aptly noted, “while some hazard may remain for extremely long times, increasing uncertainties mean that there are practical limitations as to how long anything meaningful can be said about the protection provided by any system against these hazards. . . . These practical limitations need to be acknowledged in safety cases.”⁵ Modeling should be extended further only if site-specific characteristics dictate that it might be useful *and* there is a valid scientific and technical basis on which assessment may be founded. For near-surface disposal, the second condition is fulfilled only during the period of surface geologic stability, and this is the maximum amount of time that any assessments in the regulation should cover.

NRC has already recognized, in its draft NUREG-2175 (p. 2-24) that it is necessary to establish an end point for the performance period; the essential criteria to do so belong in regulation, not in guidance. The definition of “performance period” should be revised, therefore, to clarify that the

³ *Considering Timescales in the Post-closure Safety of Geological Disposal of Radioactive Waste*, OECD Nuclear Energy Agency, 2009, p. 39. Future citations refer to this report as “NEA 2009 Timescales Report.”

⁴ See “Technical Analysis Supporting Definition of Period of Performance for Low-Level Waste Disposal, Figures 3 and 4.”

⁵ NEA 2009 *Timescales Report*, p. 27.

performance period extends until peak dose or impacts are reached or the period of surface geologic stability, whichever is sooner.

§ 61.2, Safety case definition

We support including the concept of the safety case in the proposed regulation, as it provides a fuller view of site and disposal system understanding, and the non-quantitative factors that can enhance confidence in safety. While these concepts have long been an implicit part of the licensing process, using the term *safety case* emphasizes that the U.S. approach is in concert with international approaches. It is puzzling, therefore, that NRC provides its own definition of safety case rather than using those established in international guidance. The existing international guidance is sufficient and applicable for the case of LLW disposal, thus there is no need for significant elaboration of the concept in the rule. We suggest that NRC, as much as possible, use language consistent with the safety case definition issued by IAEA. See *The Safety Case and Safety Assessment for the Disposal of Radioactive Waste*, Specific Safety Guide No. SSG-23, IAEA, 2012 (Paragraph 1.3, for example).

§ 61.7(c)(4), Intruder assessment concept

The proposed new performance objective (cross-referenced in proposed § 61.7(c)(4)) uses a dose limit during the compliance and protective assurance periods (or, for the protective assurance period only, an alternative level, if approved, that is reasonably achievable based on technical and economic considerations). The use of a strictly enforced dose limit as the performance objective for an inadvertent intruder assessment covering any period after closure is inconsistent with DOE and international positions regarding inadvertent intrusion. The general position internationally is that intruder assessments are hypothetical cases used to identify features that can help reduce the potential for and/or consequences of intrusion. That is, human intrusion analyses are used as a tool to assist in optimization of the disposal facility design. IAEA's safety standards, for example, recommend no limits regarding human intrusion, but instead offer guidelines for what doses may warrant efforts to reduce the probability or consequences of intrusion (IAEA SSG-5, para. 2.15). ICRP similarly recommends no dose constraint for human intrusion, saying that a constraint "is not applicable in evaluating the significance of human intrusion because, by definition, intrusion will have bypassed the barriers which were considered in optimization of protection for the disposal facility . . . any protective actions required should be considered during the development of the disposal facility". ICRP considered that "reasonable efforts should be made to reduce the probability of human intrusion or to limit its consequences" when doses exceed 100 mSv (ICRP-81, paragraphs 63-64).

We recommend that the dose limit for intruder protection be recast as a goal that is used to develop waste acceptance criteria and demonstrate added robustness of the disposal approach. If this is not done, then we recommend that additional clarifying discussion be provided in the concepts section to include the points mentioned above. See also comments on proposed § 61.42(a).

§ 61.7(c)(6), Waste with significant concentrations of long-lived radionuclides

The site-specific PA will inherently address whether the proposed waste inventory poses longer term hazards or not and, thus, whether analyses will need to address longer timeframes. The site-specific analyses required over the compliance period and beyond, in themselves, constitute a case-by-case evaluation that provides the basis for determining whether relevant performance aspects (such as time of peak dose) have been adequately captured. This is true regardless of what characteristics (longevity, mobility, etc.) contribute to the need for longer-term assessment. The specificity defining and categorizing "long-lived waste" is unnecessary and the concept should be deleted from the rule.

§ 61.7(d), Defense-in-depth

The discussion of defense-in-depth, while broader than the proposed definition in § 61.2, does not reflect the accepted use of the term, either in the U.S. or internationally (e.g., in IAEA SSR-5 and the IAEA Safety Glossary) and is inconsistent with the preamble. As noted in the preamble, "NRC's defense-in-depth approach to risk management ensures that safety is not wholly dependent on any single element of the design, construction, maintenance or operation of a regulated facility. . . . Defense-in-depth for a land disposal facility includes, but is not limited to, the use of remote siting, consideration of waste forms and radionuclide content, engineered features, and natural geologic features of the disposal site." Other relevant features mentioned in the preamble are, for example, land ownership and institutional control requirements (80 FR 16102, col. 2). The more inclusive view of defense-in-depth, including administrative and operational controls, should be included in the discussion of the concept.

§ 61.7(f), Waste classification and stability

The emphasis on details related to "long term" stability is not needed. Stability is important for the 500 year timeframe for the classification system (e.g., assumptions for the classification tables), but over thousands of years, stability becomes less meaningful for assessing level of protectiveness. If the site-specific PA demonstrates that performance objectives can be met with reasonable assurance, even if there are increases in infiltration or other changes in the system, then "stability" as a separate and specific criterion is not needed. Such requirements may be very difficult to meet, but at the same time may have little impact on the protection of human health (e.g., calculated dose). In a performance-based approach, PA is the appropriate means to account for the relevance of factors such as this. It is recommended that the discussion of stability in this section be deleted. See also comments on §§ 61.13(d) and 61.51.

§ 61.13, Application to existing facilities

The preamble to the proposed regulations (at page 16088) states that the proposed rule would become effective 1 year after the final rule is published for NRC licensees, and that Agreement States would have 3 years to adopt compatible provisions. In turn, the proposed regulatory language in the chapeau to § 61.13 and in § 61.58(d) would require existing licensees to conduct various additional technical analyses and apply new waste acceptance provisions at the next license renewal or within 5 years of the effective date of the proposed new requirements,

whichever comes first. In contrast to both approaches, the existing general provisions in Subpart A (§ 61.1(a))—which would not be amended by the proposed regulation—state that applicability of requirements in Part 61 to existing licensees “will be determined on a case-by-case basis.” We recommend conforming revision to § 61.1(a) and, as necessary, the final preamble to the regulations, so that the provisions are consistent with each other. Given the numerous new provisions and new analysis that would be required by the regulations, DOE also supports delaying application of the proposed regulations until a reasonable time in the future, with an emphasis on *new* waste streams and *new* operations.

§ 61.13(a)(1) to (a)(5), Technical analyses (FEPs consideration)

The focus on the term “features, events and processes” does not align well with more recent international best practice, in which approaches based on “safety functions” have emerged (see, for example, <http://www.oecd-nea.org/rwm/reports/2012/nea6923-MESA-initiative.pdf>). It is recommended that the proposed rule be revised to reinforce and place more emphasis on the more current approaches for scenario development involving the use of safety functions, either through revisions to this section or with additional discussion added in the concepts section.

Furthermore, as noted in our general comments, DOE does not support the imposition of the protective assurance period and recommends that it be eliminated. However, if the protective assurance period is retained, DOE supports the approach to the identification of relevant FEPs in performance assessment beyond the compliance period: that FEPs applicable in the compliance period (up to 1,000 years) be extended and that new FEPs be added only if scientific information compelling such changes is available (80 FR 16090, col. 1). However, the proposed regulatory language may require revision to properly reflect the stated intention. To this end, § 61.13(a)(1) should be revised to more clearly apply to the compliance period performance assessment, as in “Consider features, events and processes that might affect compliance with § 61.41(a).”

It is not clear why a separate requirement is provided [in § 61.13(a)(5)] regarding degradation or alteration processes. The requirement in § 61.13(a)(1) already requires a technical basis for inclusion or exclusion of all FEPs, so the provisions on degradation are redundant. We suggest that the proposed § 61.13(a)(5) be deleted.

§ 61.13(a)(10), Roles of natural and engineered features

It is not clear what purpose is served by the requirement to “identify and differentiate between the roles performed by the natural disposal site characteristics and design features of the disposal facility.” The relevant aspects of both the site and the engineered features, as well the interactions between them, are appropriately captured by requirements to consider relevant FEPs (or safety functions). To require further analyses and differentiation imposes redundant requirements and provides no value-added to risk-informed decision-making and licensing—but does add confusion, especially since it implies the possibility of sub-system requirements. We suggest that this paragraph be deleted.

§ 61.13(b), Inadvertent intruder analyses

The description of the inadvertent intruder analyses is confusing and inconsistent with the definition proposed for an *intruder assessment* in proposed § 61.2. The “analyses” appear to include additional requirements beyond the assessment, as described in proposed § 61.13(b)(1) to 61.13(b)(2). However, the required information is vague and adds little apparent value to risk-informed decision making:

- It is not clear how (or what type of) “human intrusion analyses” can demonstrate that the waste acceptance criteria will be met [proposed § 61.13(b)(1)]. The allowable activity levels in waste acceptance criteria (WAC) may, in fact, be based on an intruder assessment, among other analyses (see proposed § 61.58(a)(1)). To base the WAC on an intruder assessment and then to require a human intrusion analysis to confirm compliance with the WAC is circular and meaningless. On-the-ground compliance with the WAC is adequately addressed by the waste characterization and certification requirements in § 61.58. The provision at proposed § 61.13(b)(1) should be deleted.
- It is not clear how (or what type of) analyses can demonstrate that “adequate barriers to human intrusion will be provided” [proposed § 61.13(b)(2)]. In a performance-based and risk-informed approach, the means to demonstrate that barriers are adequate is to show that performance objectives can be met with the performance assessment and intruder assessment. As NRC has observed in other regulations related to radioactive waste disposal, “A complete performance assessment . . . will illustrate the effectiveness of the multiple barriers, and the implementation of the philosophy of defense in depth, such that the individual protection standard is shown to be met even when barriers are challenged. . . . The Commission is confident that evidence for the resilience, or lack of resilience, of a multiple-barrier system will be found by examining a comprehensive and properly documented performance assessment of the behavior of the overall repository system.” (66 FR 55759) The analysis at proposed § 61.13(b)(2) adds no specificity or substance and should be deleted.

Proposed paragraph 61.13(b)(3)(ii) would require “adequate” barriers to intrusion. No definition or criteria are provided to judge the adequacy of barriers. The remaining language in the paragraph appropriately describes the relevant features of a barrier that may contribute to its effectiveness and the need to provide a basis for the period of effectiveness. The term “adequacy” adds little value but raises the question of additional (but arbitrary, given that they are not specified) criteria being applied; the term should be dropped from the requirement.

§ 61.13(d), Long-term stability

The proposed rule retains an existing requirement to analyze long-term stability of the disposal site, with slight changes to the language. However, the implications of this requirement are very different when applied over timeframes of thousands to tens of thousands of years. It is not possible for such timeframes (thousands of years or more) that long-term stability of the site “can be ensured,” as the revised language now states. Furthermore, the requirement is superfluous in view of the numerous other site-specific analyses now proposed. In a performance-based approach, the performance assessment is the appropriate means to account for the relevance of factors such as this. If performance objectives can be demonstrated to be met with reasonable

assurance, even if there are increases in infiltration or other stability-related changes, then “stability” as a separate and specific criterion is not needed. A requirement on long-term stability may be very difficult to meet, and at the same time may have little impact on the protection of human health (e.g., dose calculation). It is recommended that the requirement for a separate analysis of site stability be deleted. If the provision is retained, the proposed language that stability “can be ensured” should be dropped, and the analysis should extend no longer than the compliance period. See also comments on § 61.44.

§ 61.13(e), Potential long-term radiological impacts (Table A)

The proposed provisions require analyses over the performance period (i.e., beyond 10,000 years after closure) “for disposal sites with waste that contains radionuclides with the average concentrations exceeding the values listed in Table A of this paragraph, or if necessitated by site-specific conditions”. Several changes from the proposal are suggested to enhance the technical basis and better align it with the intent to use site specific performance analyses:

- Table A should be eliminated. The technical basis described for the derivation of the concentrations is limited and unclear. The preamble states that the values are “primarily, but not solely, based on the Class A LLRW concentration values” (80 FR 16097, col. 1), but does not explain why the Class A limits are an appropriate indicator or technical basis to determine the need for analyses beyond 10,000 years. There is no justification for defining hazards over this duration based on the Class A limits, since such timeframes were not considered in developing those limits. Furthermore, Table A may be rendered moot by the clause regarding “site-specific conditions,” where the table alone will not be determinative of whether a longer-term analysis is needed. Given this, the results of site-specific analyses already required for the compliance period (and the protective assurance period, if it is retained) should be used to determine whether it is appropriate to conduct longer-term analyses. This approach is technically supportable and better aligns with the declared intent to establish a risk-based approach using site-specific PAs.
- To establish clear expectations on the part of licensees, further explanation should be provided on what “site-specific conditions” might necessitate performance period analyses. The preamble discussion on timeframes (80 FR 16093 *et seq.*) makes clear that the peak dose, including potential in-growth of progeny (from uranium, in particular) is a central consideration, and this could provide an appropriate basis for delineating the need for extending the analysis. We recommend that the site-specific analysis be used to determine the need for analyses into the far future.
- As noted in our general comments, we recommend that the protective assurance period be eliminated.

Therefore, it is suggested that § 61.13(e) be revised to read, “The time period required to be considered shall be determined based on site-specific conditions addressed in the PA. Performance period calculations shall be performed if the analyses for compliance period in §§ 61.41(a) and 61.42(a) indicate that peak doses have not been attained (i.e. doses are stable or rising) at 1,000 years, including consideration of the in-growth of progeny from the intended

waste streams.” See also DOE’s comments on § 61.2, performance period definition, for discussion of the recommended limits on the performance period.

If the protective assurance period is retained, then the language in § 61.13(e) should be revised to read: “The time period required to be considered shall be determined based on site-specific conditions addressed in the PA. Performance period calculations shall be performed if the analyses for compliance and protective assurance periods in §§ 61.41(a)-(b) and §§ 61.42(a)-(b) indicate that peak doses have not been attained (i.e. doses are stable or rising) at 10,000 years, including consideration of the in-growth of progeny from the intended waste streams.” See also DOE’s comments on § 61.2, performance period definition, for discussion of the recommended limits on the performance period.

§ 61.13(f), Defense-in-depth

It is unclear what value is provided by “analyses” to be conducted to demonstrate that defense-in-depth measures are included at a disposal facility. This effort should be focused on documenting the contributors to defense-in-depth rather than a quantitative analysis. As noted earlier, the accepted use of the term (and NRC’s own discussions of it in the preamble to, and other sections of, this proposed rule) encompasses siting and operational aspects. Furthermore, as NRC observes, “The capabilities of any of those design features and site characteristics may not be either independent or totally redundant. . . . The capabilities of site characteristics and engineered features over the long timeframes are subject to interpretation and include many uncertainties. . . . Therefore, NRC expects that licensees will rely on both the characteristics and the engineered features, in combination, to provide reasonable assurance that the overall performance of the disposal site will be adequate over long time periods.” (80 FR 16092) The function of the various engineered and natural barriers, and their interactions, is required to be accounted for in the performance assessment. As NRC has observed in other regulations related to radioactive waste disposal, “A complete performance assessment . . . will illustrate the effectiveness of the multiple barriers, and the implementation of the philosophy of defense in depth, such that the individual protection standard is shown to be met even when barriers are challenged. . . . The Commission is confident that evidence for the resilience, or lack of resilience, of a multiple-barrier system will be found by examining a comprehensive and properly documented performance assessment of the behavior of the overall repository system.” (66 FR 55759)

Further quantitative assessment, as implied by the term “analyses,” of redundancy over long timeframes is likely to be highly uncertain and difficult to interpret—and ignores many other important facets of defense-in-depth. To address these concerns, it is suggested that the language in § 61.13(f) be revised to read, “A description of defense-in-depth measures applied at the proposed disposal facility, and discussion of the means by which they provide passive safety, provide redundancy, or enhance confidence in the safety case and long-term performance.”

§ 61.41(a), Protection of the general population

No definition is provided for “any member of the public”. The requirement should be restricted to a representative member of the public located in the general environment (i.e., outside the

boundaries of the disposal system, including the buffer zone) of the disposal facility. Such an approach is also consistent with the application of updated dosimetry methods that would be allowed by the proposed changes. More recent ICRP guidance discusses the applicability of limits and constraints to a “representative person” (ICRP 103, Section 5.4.2).

§ 61.41(b), Protection of the general population during the protective assurance period

As noted in our general comments, we recommend that the protective assurance period be deleted, and that the performance period be designated to begin at 1,000 years after closure. Accordingly, we recommend that the proposed provisions of § 61.41(b) be eliminated.

If the protective assurance period and the associated analyses are retained, then several important changes and clarifications should be made to align the provision with NRC’s stated intentions.

- The requirement to “minimize” releases of radioactivity for the protective assurance period is inappropriately stringent and does not seem to reflect the intention of NRC. The preamble discussion states that “The protective assurance analyses are being proposed as a minimization process (i.e., optimization) with guidance provided on the goals to use in the minimization process.” (80 FR 16089, col. 3) The term minimize does not properly reflect the multi-faceted optimization process, which entails consideration of numerous factors; indeed, “minimize” as used in the proposed regulatory language can be interpreted as being more stringent than the As Low As Reasonably Achievable (ALARA) requirement applied to the compliance period, since it does not clearly allow for consideration of what is feasible or reasonable.
- Furthermore, proposed § 61.41(b), as written, does not set forth “goals,” but rather imposes requirements. As such, it is not consistent with the Commission’s direction in its February 12, 2014 Memorandum, which calls for a “goal of keeping doses below a 500 mrem/yr analytical threshold”. NRC expresses its intention that the dose level for the protective assurance period should function as “a goal rather than a limit” (80 FR 16097, col. 3). While this intention is reflected in the language allowing “a level that is supported as reasonably achievable,” the requirement to minimize releases adds confusion.
- No definition is provided for the “general environment”. A definition should be added, here or in § 61.2, to clarify that the general environment means that area outside the boundaries of the disposal system and its buffer zone.

In order to better align the regulatory language with the stated intentions of NRC for the protective assurance period, it is suggested that the following alternative language be used:

Efforts shall be made to reduce releases to a level that is reasonably achievable based on technical and economic considerations, *provided* that licensees shall be presumed to meet this goal if the annual dose does not exceed a dose target of 5 milliSieverts (500 millirem). Compliance with this paragraph must be demonstrated through analyses that meet the requirements specified in § 61.13(a).

§ 61.41(a)-(b), Protection of the general population

The treatment of radon should be consistent with that in other rules from NRC and other U.S. regulatory agencies. Radon should be specifically excluded from consideration in assessing compliance with the dose limits and targets in these sections. A separate radon performance objective (e.g., a flux limit) would be consistent with other NRC, EPA, and DOE rules [e.g., 40 CFR Part 190.10, 40 CFR Part 61 (subpart H), 40 CFR Part 61.192 (subpart Q), 10 CFR Part 40 (Appendix A, criterion 6), 10 CFR Part 20.1101(d), DOE Manual 435.1-1]. A major factor in the update to Part 61 is to address DU, so consistency with other national regulations addressing uranium is appropriate. NRC might consider instead adding a performance objective for radon flux.

§ 61.41(c), Protection of the general population during the performance period

As noted in our general comments, we support the concept of a performance period, for which the results of modeling analyses are considered qualitatively to inform site understanding and contribute to optimization of design. We recommend that the performance period begin at 1,000 years after closure, directly following the compliance period. Whether or not this change to the performance period timeframe is made, the use of the term “minimize” is problematic in the requirements for the performance period. The term “minimize” does not properly reflect the multi-faceted optimization process, which entails consideration of numerous factors; indeed, “minimize” as used in the proposed regulatory language can be interpreted as being more stringent than the ALARA requirement applied to the compliance period, since it does not clearly allow for consideration of what is feasible or reasonable. It is suggested that the language be revised to read, “Effort shall be made to reduce releases of radioactivity”

§ 61.42(a), Protection of inadvertent intruders during the compliance period

The application of a dose limit for an inadvertent intruder assessment covering any period after closure is inconsistent with international positions regarding inadvertent intrusion. The general position internationally is that intruder assessments are hypothetical cases used to identify features that can help reduce the potential for and/or consequences of intrusion. That is, human intrusion analyses are used as a tool to assist in optimization of the disposal facility design. The IAEA safety standards, for example, recommend no limits regarding human intrusion, but instead offer guidelines for what doses may warrant additional optimization: for annual doses in the range of 1-20 mSv (100 mrem-2 rem), “reasonable efforts are warranted at the stage of development of the facility to reduce the probability of intrusion or to limit its consequences” (IAEA SSG-5, para. 2.15). ICRP similarly declined to recommend a dose constraint for human intrusion, saying that a constraint “is not applicable in evaluating the significance of human intrusion because, by definition, intrusion will have bypassed the barriers which were considered in optimization of protection for the disposal facility. . . any protective actions required should be considered during the development of the disposal facility” (i.e., in optimization). ICRP considered that “reasonable efforts should be made to reduce the probability of human intrusion or to limit its consequences” when doses exceed 100 mSv (ICRP-81, paragraphs 63-64).

The establishment of a dose limit for intrusion is also inconsistent with NRC's approach in establishing 10 CFR Part 61 initially. While NRC originally proposed to adopt a 500 mrem inadvertent intruder standard, this approach was dropped from the final rule because (as explained in the final EIS⁶) NRC concluded that the dose level could reasonably be used as the basis for deriving waste classification tables (i.e., as a target for identifying measures to reduce potential impacts of inadvertent intrusion), but its use as a regulatory limit was not justified or practical. We recommend that the 500 mrem dose limit for intruder protection during the compliance period be recast as a goal that is used to develop waste acceptance criteria and to demonstrate added robustness of the disposal approach. Corresponding changes are also needed in proposed § 61.13(b)(3) to reflect that dose-based performance objectives in proposed § 61.42 are goals (or guidelines) and not strict dose limits. See also comments on proposed § 61.7(c)(4).

The requirement that the disposal facility must "ensure" protection is an overstatement of what can be demonstrated in performance assessment projections for even the compliance time period. The language should be revised to more accurately reflect the reasonable assurance concept (which is applied through the proposed provision at § 61.23(b)), to read, "Design, operation and closure of the land disposal facility must provide protection of an inadvertent intruder" (Suggested language changes are shown underlined.)

§ 61.42(a)-(b), Protection of inadvertent intruders during the compliance and protective assurance periods

The treatment of radon should be consistent with that in other rules from NRC and other U.S. regulatory agencies. That is, radon should be specifically excluded from consideration in assessing compliance with the dose limits and targets in these sections. Instead, NRC should develop a separate radon performance objective consistent with other NRC, EPA, and DOE rules (e.g., the flux limit). All agencies that address uranium related wastes that lead to radon generation exclude radon from all pathways and treat it separately [e.g., 40 CFR Part 190.10, 40 CFR Part 61 (subpart H), 40 CFR Part 61.192 (subpart Q), 10 CFR Part 40 (Appendix A, criterion 6) 10 CFR Part 20.1101(d), DOE Manual 435.1-1], all of which specifically exclude radon in the air/all pathways objectives]. A major factor in the update to Part 61 is to address DU, so consistency with other EPA and NRC regulations addressing uranium is appropriate.

§ 61.42(b), Protection of inadvertent intruders during the protective assurance period

As noted in our general comments, we recommend that the protective assurance period be deleted, and that the performance period be designated to begin at 1,000 years after closure. Accordingly, we recommend that the proposed provisions of § 61.42(b) be eliminated.

If the protective assurance period and the associated analyses are retained, then important changes and clarifications should be made to align the provision with NRC's stated intentions. The use of the term "minimize" is problematic in this context, as discussed regarding the requirements for protection of the general public for the protective assurance period. (See

⁶ NUREG-0945: Final Environmental Impact Statement on 10 CFR Part 61 "Licensing Requirements for Land Disposal of Radioactive Waste," Vol. 1 - Summary and Main Report, Nov. 1982, p. 5-4.

comments on proposed § 61.41(b).) For the same reasons, it is suggested to revise the requirement to read:

Reasonable and practical measures shall be taken in the design, operation and closure of the land disposal facility to control exposures to an inadvertent intruder during the protective assurance period. Efforts shall be made to reduce releases to a level that is reasonably achievable based on technical and economic considerations, *provided* that licensees shall be presumed to meet this goal if the annual dose does not exceed a dose target of 5 milliSieverts (500 millirem). Compliance with this paragraph must be demonstrated through analyses that meet the requirements specified in § 61.13(b).

Corresponding changes are also needed in proposed § 61.13 to reflect NRC's stated intention that the reference dose is intended as a target and not a limit. In proposed paragraph 61.13(b)(3), the phrase "doses that exceed the limits set forth in § 61.42" should be revised to reflect that dose-based performance objectives in § 61.42(a) (see preceding comment) and § 61.42(b) are goals (or guidelines) and not strict dose limits.

Note that we also recommend using the term "practical" rather than "practicable" in the regulatory language. See comments on proposed section § 61.44 for further explanation.

§ 61.42(c), Protection of inadvertent intruders during the performance period

The use of the term "minimize" is problematic in this context, as discussed regarding the requirements for protection of the general public for the performance period (proposed § 61.41(c)). For the same reasons, it is suggested to revise the requirement to read: "Efforts shall be made to reduce exposures to an inadvertent intruder . . ."

§ 61.44, Stability of the site after closure

The proposal retains an existing requirement regarding stability of the site after closure, with proposed wording that extends the requirement to cover the compliance period and the protective assurance period. As noted in our general comments, we recommend that the protective assurance period be eliminated. Whether or not this is done, the extension of the existing requirements out to 10,000 years is unjustified and burdensome. The value in separate requirements for site stability over thousands of years is questionable. It is also inconsistent with previous NRC evaluations of stability relevant to disposal of long-lived radionuclides. In considering disposal of DU-contaminated materials in near-surface disposal, NRC accepted that design measures and cell construction practices provided a "technical basis sufficient for demonstrating long-term site stability".⁷

Most importantly, in a performance-based approach, the performance assessment is the appropriate means to account for the relevance of factors such as this. If performance objectives can be demonstrated to be met with reasonable assurance, even if there are increases in infiltration, then "stability" as a separate and specific criterion or performance objective is not

⁷ "Safety Evaluation Report Request For Alternate Disposal Approval And Exemptions For Specific Hematite Decommissioning Project Waste At US Ecology's Idaho Facility, October 28, 2011, ADAMS ML 111441087, p. 7.

needed. A requirement on long-term stability may be very difficult to meet, and at the same time may have little impact on the protection of human health (e.g., dose calculation).

It is recommended that this performance objective be deleted. If it is retained, the language should reflect that the requirement is relevant for only a limited, reasonable period of time following closure. We suggest that it could be appropriate to demonstrate stability for the period of 300 years over which Class B and Class C wastes forms are expected to endure (as discussed in the proposed concepts in § 61.7(f)), in order to support continued use of the classification tables. Another period may be justifiable, but in no case should stability be evaluated separately beyond the compliance period (i.e., 1,000 years). We also recommend changing “practicable” to “practical” in the existing regulatory language; as commonly understood, “practicable” means capable of being put into effect, whereas “practical” refers to something that is also sensible or worthwhile.⁸ The language should also be modified to require that measures “eliminate to the extent practical the need for ongoing active maintenance of the disposal site during the institutional control period so that only surveillance, monitoring, or minor custodial care are required.” (Suggested language modification are shown underlined.) See also comments on proposed §§ 61.7(f) and 61.13(d).

§ 61.50 (a)(2), Site suitability for near-surface disposal

NRC’s proposal retains (but reorganizes) detailed site suitability requirements. In view of the numerous other site-specific analyses now proposed, the value of specific requirements for site-suitability is questionable, and this section is unduly detailed. More importantly, while such provisions were meaningful complementary requirements to the table-based classification approach, such criteria are unnecessary and at odds with a truly risk-informed approach to regulation. As NRC has stated, “the risk-informed, performance-based approach . . . eliminates arbitrary or prescriptive siting and design criteria, as well as detailed requirements such as quantitative subsystem performance objectives” (66 FR 55737). A sound conceptual model of the site and a comprehensive performance assessment provide the means to assess the significance of site attributes. In a performance-based approach, the appropriate method to evaluate the site suitability is the site-specific performance assessment. Performance-relevant site characteristics and associated disruptive events (and uncertainties) must be considered (as is required already by other parts of the proposed regulations); if the performance objectives can be shown to be met with reasonable assurance, then additional criteria are not necessary. Such restrictions may eliminate potentially viable sites without adding public protection. It is recommended that the detailed site suitability criteria in proposed § 61.13(a)(s) be eliminated.

§ 61.58, Waste acceptance criteria exceptions

NRC’s proposed approach allows that the WAC may be established based on site-specific analyses that account for the site and facility performance, or based on the pre-existing classification tables. Once the WAC is established, the provisions of proposed § 61.52(12) prohibit the disposal of any waste that does not meet the acceptance criteria. According to the proposed rule, any adjustments to the WAC would require a license modification [proposed § 61.58(g)].

⁸ See, e.g., *Webster’s II New Riverside University Dictionary*, 1984.

There is no provision for considering exceptions from WAC. Under the proposed regulation, a request for a license amendment would be required in order to accept waste with characteristics that were not addressed in the PA and WAC. However, as NRC acknowledges throughout its regulatory discussion, small amounts of waste falling outside the PA assumptions (i.e., small amounts of DU or other long-lived waste) may be accommodated in a disposal facility without affecting its protectiveness. Given this, it would be useful to provide a means for exceptions by a less onerous method than submitting a license amendment. An appropriate mechanism might be by special analyses as a supplement to the PA, which shows reasonable assurance that the performance objectives can still be met. Alternatively, NRC may consider an alternative approach that does not incorporate the WAC directly into the license.

DOE responses to NRC's specific requests for comments in the Federal Register notice

NRC is seeking feedback on the proposed approach, especially with regard to whether a 5 milliSievert (500 mrem) annual dose target is appropriate for the protective assurance period and whether it is appropriate to require licensees or license applicants to consider alternative levels to minimize exposures to an inadvertent intruder. (80 FR 16090-16091)

As discussed in our general comments (above), we recommend that the protective assurance period be eliminated. The imposition of an intermediate "protective assurance" period (from 1,000 to 10,000 years after closure) does not appropriately accommodate the uncertainties and limitations of modeling over very long timeframes. It establishes *de facto* requirements over very long timeframes without adding materially to an understanding of the relevant behavior of long-lived nuclides—depleted uranium, in particular. We recommend that a two-tiered approach be adopted that retains the proposed 1,000-year compliance period (and associated dose limit), eliminates the protective assurance period (and associated reference dose), and applies the qualitative performance period approach to modeling assessments beginning at 1,000 years after closure.

If the protective assurance period is retained, we support the use of 500 mrem as a dose goal for the hypothetical inadvertent intruder (and the hypothetical future member of the public) because it reflects, better than lower dose levels would, the uncertainty and speculative nature of calculations extending into timeframes beyond 1,000 years. A target dose of 500 mrem/yr is below the average annual dose for people living in the United States today⁹ and is on the same order as risks considered acceptable resulting from radon exposure in residences, for example.¹⁰ Internationally, there is good acceptance that exposures on the order of natural background are reasonable reference points for very long term assessments. IAEA suggests that "In very long time frames . . . uncertainties could become much larger and calculated doses may exceed the

⁹ The National Council on Radiation Protection and Measurements (NCRP) estimates that the average annual exposure in the U.S. is 620 mrem/yr. Approximately half that amount is due to natural background radiation. See NCRP Report No. 160: *Ionizing Radiation Exposure of the Population of the United States* (2009), as cited at <http://www.epa.gov/radiation/understand/perspective.html>.

¹⁰ The EPA's radon action level—the level below which the Agency does not recommend actions to further reduce radon levels—is 4 pCi/L. At that level of exposure over a lifetime, the increased risk of lung cancer is up to 62 in 1000. See *A Citizen's Guide to Radon*, U.S. Environmental Protection Agency, <http://www.epa.gov/radon/pubs/citguide.html>

dose constraint [of 100 mrem]. Comparison of the doses with doses from naturally occurring radionuclides may provide a useful indication of the significance of such cases.”¹¹

In addition, several changes to the proposed regulatory language would also be needed to align the requirements with NRC’s stated intentions if the protective assurance period is retained. Importantly, the proposed regulatory language does not set forth 500 mrem as a “goal,” but rather imposes requirements. As such, it is inconsistent with NRC’s stated intent in the preamble and with the Commission’s direction in its February 12, 2014 Memorandum, which calls for a “goal of keeping doses below a 500 mrem/yr analytical threshold”. The use of the term “minimize” is also problematic and can be interpreted to be more stringent than the dose limits applied during the compliance period. See comments on §§ 61.41(b), 61.41(c), 61.42(b), and 61.42(c).

If the 500 mrem annual dose is properly conveyed as a target, then consideration of alternative levels is inherently included; that is, a goal allows some flexibility, especially in view of appropriate qualifying terms such as “reasonably achievable”. Beyond 1,000 years after closure, measures to further reduce doses below the target level are not justifiable, because they may entail large costs for little change in modeled doses to a hypothetical future member of the public and a hypothetical future inadvertent intruder; such an approach is inconsistent with ethical principles that state that emphasis for the very long term should be on averting catastrophic consequences (NRC’s “Technical Analysis Supporting Definition of Period of Performance,” p. 10). We recommend changes to the proposed regulatory language to eliminate the protective assurance period or, in the alternative, to reflect that additional efforts need not be made to further reduce doses if the goal of 500 mrem is met.

As previously stated, NRC is making available the draft guidance document (see Docket ID NRC–2015–0003) for public comment concurrent with the publication of this proposed rule and is seeking comments on whether the approaches described in the guidance are adequate or if further specification for inadvertent intruder scenarios in the proposed rule is necessary. (80 FR 16091)

We recommend that several changes be made to the intruder assessment and inadvertent intruder definitions in the proposed regulatory language. These recommended changes provide important clarification and boundaries that should not be left to guidance. We support the clarification that the intruder assessment should consider only activities that are “realistic and consistent with expected activities in and around the disposal site at the time of site closure”. We also support clarification in the inadvertent intruder definition regarding “reasonably foreseeable” pursuits; however, we recommend that the phrase “resource exploration or exploitation (e.g., well drilling)” be eliminated from the definition of “inadvertent intruder”. We further recommend that the definition of “intruder assessment” be revised to clarify that consideration of the scenarios used originally in the development of Part 61 is sufficient to comply with the proposed requirements for intruder assessment. Refer to our comments on § 61.2, inadvertent intruder and intruder assessment definitions, for further explanation.

¹¹ “Geological Disposal of Radioactive Waste,” DS154, IAEA, 2005, Section A.7.

NRC is seeking feedback on the proposed approach, especially with regard to whether a dose limit is needed for the long-term analyses or whether the proposed metric combined with barrier analyses is more appropriate. (80 FR 16092)

No dose limit is needed or appropriate for the timeframe beyond 10,000 years addressed by the performance period. We support the concept of extending performance analysis and intruder assessments over periods beyond the compliance timeframe. There is value in considering, qualitatively, the results of modeling beyond the time when the results can be assigned quantitative meaning. Such an assessment can provide valuable information to guide waste acceptance criteria, design optimization, and defense-in-depth measures. We support, in principle, the performance period and the approach to use analytical results only qualitatively. As noted in our general comments, we recommend that the protective assurance period be eliminated and that the performance period, with no dose criteria, begins immediately following the compliance period, at 1,000 years after closure. In any case, the performance period should extend no longer than the time of peak dose or impact is reached or the period of surface geologic stability, whichever is sooner. See comments on § 61.2, performance period definition.

Regardless of whether a two-tier or three-tier approach is chosen, a dose limit or goal for timeframes encompassed by the proposed performance period would not be justified. Advisory bodies—including IAEA, NEA, ICRP, and ACNW—have cautioned strongly against quantitatively interpreting performance assessment and modeling results as health indicators for timeframes beyond even several hundred years. (Refer to our general comments, above, on the three-tiered approach for further details and citations.) To impose a limit for longer time periods is unsupportable, and no clear purpose is served by providing a reference dose for the performance period, whenever it is designated to begin. To do so would imply a degree of certainty and reliance on the quantitative modeling results that is unjustified for near-surface disposal over such timeframes. The proposed approach, with no dose limit or target during the performance period, is appropriate and reasonable.

However, no separate barrier analysis is appropriate as a complementary criterion; separate analysis of barriers constitutes sub-system performance criteria, which is widely discounted as a regulatory strategy for waste disposal, in which complex interactions between natural and engineered systems may be central to the maintenance of safety functions and the overall performance of the disposal facility. OECD NEA states, for example, “The detailed specification in regulation of requirements on system components is generally avoided; the current view is that this would unnecessarily reduce the flexibility of the implementer to adapt system components to the specific characteristics of the waste and the geological environment under consideration, and would potentially undermine the need for the implementer to take full responsibility for the safety case.”¹²

Furthermore, retaining a separate barrier analysis would be inconsistent with a site-specific, performance-based approach. As NRC itself has said, “The Commission is confident that evidence for the resilience or lack of resilience, of a multiple-barrier system will be found by examining a comprehensive and properly documented performance assessment of the behavior

¹² NEA 2009 *Timescales Report*, p. 39.

of the overall repository system.” (66 FR 55759) See comments on § 61.13(b), intruder analyses.

NRC is seeking feedback on the proposed approach, especially with regard to whether a 5 milliSievert (500 mrem) annual dose goal is appropriate for the protective assurance period and whether it is appropriate to consider alternative, higher levels based on technological and economic considerations. (80 FR 16098)

As discussed in our general comments (above), we recommend that the protective assurance period be eliminated. The imposition of an intermediate “protective assurance” period (from 1,000 to 10,000 years after closure) does not appropriately accommodate the uncertainties and limitations of modeling over very long timeframes. It establishes *de facto* requirements over very long timeframes without adding materially to an understanding of the relevant behavior of long-lived nuclides—depleted uranium, in particular. We recommend that a two-tiered approach be adopted that retains the proposed 1,000-year compliance period (and associated dose limit), eliminates the protective assurance period (and associated reference dose), and applies the qualitative performance period approach to modeling assessments beginning at 1,000 years after closure.

If the protective assurance period is retained, we support the use of 500 mrem as a dose target because it reflects, better than lower dose levels would, the uncertainty and speculative nature of calculations extending into timeframes beyond 1,000 years. A target dose of 500 mrem/yr is below the average annual dose for people living in the United States today and is on the same order as risks considered acceptable resulting from radon exposure in residences, for example.¹³

In addition, several changes to the proposed regulatory language—in both proposed § 61.41(b) and proposed § 61.42(b)—would be needed to align the proposed regulations with NRC’s stated intentions, if the protective assurance period is retained. Importantly, the proposed regulatory language does not set forth 500 mrem as a “goal,” but rather imposes requirements in both proposed § 61.41(b) and proposed § 61.42(b). As such, it is inconsistent with NRC’s stated intent in the preamble and with the Commission’s direction in its February 12, 2014 Memorandum, which calls for a “goal of keeping doses below a 500 mrem/yr threshold”. The use of the term “minimize” is also problematic and can be interpreted to be more stringent than the dose limits applied during the compliance period. See comments on §§ 61.41(b), 61.41(c), 61.42(b), and 61.42(c).

If the protective assurance period is retained, it is entirely appropriate to consider alternative, higher potential exposures that are reasonably achievable based on technological and economic considerations. Indeed, these factors are central to the concept of a target dose. If consideration of alternative, higher dose levels is excluded, the “target” becomes a *de facto* limit. Similarly, technological and economic considerations are essential components of an evaluation of what is “reasonably achievable”. Measures to further reduce doses below the target level beyond 1,000 years are not justifiable, because they may entail large costs for little change in modeled doses to a hypothetical future member of the public and a hypothetical future inadvertent intruder; such an approach is inconsistent with ethical principles that state that emphasis for the

¹³ See, as before, NCRP Report No. 160 and *A Citizen’s Guide to Radon*.

very long term should be on averting catastrophic consequences (“Technical Analysis Supporting Definition of Period of Performance,” p. 10). If the protective assurance period is retained, we recommend changes to the proposed regulatory language to reflect a goal dose level that is reasonably achievable based on technical and economic considerations, and that additional efforts need not be made to further reduce doses if a goal of 500 mrem per year is met.

Is the proposed three-tiered approach (a compliance period, followed by a protective assurance period, followed by a performance period, if applicable) appropriate? (80 FR 16106)

A three-tiered approach is not appropriate. As described in our general comments, we recommend that the protective assurance period be eliminated and that the performance period begin at 1,000 years after closure, ending once peak dose or impact is reached or the period of surface geologic stability, whichever is soonest. We further note that the proposed regulations are inconsistent with the request for comment concerning the performance period; the request for comment includes the qualifier “if applicable” for the performance period, whereas the proposed regulations are written such that “performance period” is *always* applicable, with requirements that “effort *shall* be made to minimize ... to the extent reasonably achievable” [emphasis added]. See proposed § 61.41(c) (releases to general population), § 61.42(c) (protection of inadvertent intruders).

Is 500 mrem/yr an appropriate analytical threshold for the protective assurance period? (80 FR 16106)

As described in preceding comments, we support a 500 mrem/yr analytical threshold for the protective assurance period, if that period is retained. The 500 mrem/yr threshold should function as a dose target or goal—not a limit—and changes to the proposed rule language are needed to appropriately convey that intent.

Should there be a quantitative goal or dose limit associated with the performance period analysis, and if so, what should that goal or dose limit be? (80 FR 16106)

As described in preceding comments, no quantitative goal or dose limit should be established for the performance period. A quantitative, or even semi-quantitative, interpretation of modeling results for such timeframes is unjustified, unsupported for near-surface disposal, and inconsistent with international guidance (“Technical Analysis Supporting Definition of Period of Performance,” p. 10). Refer to our general comments on the three-tiered approach for further details.

NRC requests comment on the proposed rule with respect to the clarity and effectiveness of the language used. (80 FR 16114)

The proposed rule language merits significant attention to improve its clarity and effectiveness. In our view, the proposed regulation is unnecessarily complex and difficult to understand. For example, requirements are found in multiple sections, with difficult-to-follow cross-referencing. In our view, sections such as “concepts” are excessively detailed (with much information that

would be more appropriately included in guidance) and contain some discussions that imply possible requirements; at the same time, the discussions omit clarifying details essential to bound the regulatory analyses and prevent unfettered discretion in implementation. The complexity and confusion throughout the proposed regulation are due in large part to a failure to fully implement a site-specific, performance-based approach. The proposed regulation would require new analyses while retaining (and even adding to) detailed criteria on aspects that would be addressed more appropriately by site-specific PA and intruder assessment analyses. Many of the analyses previously required to complement the table-based classification approach are unnecessary and burdensome in light of the new site-specific analyses, and should be eliminated. We note such cases in our specific comments above.

Another source of confusion is that the proposed regulation would add new definitions for several terms, which do not follow well-established, internationally accepted concepts described clearly in published documentation. This leaves open questions about whether or not NRC's proposed definitions signify a meaningful departure from the accepted concepts, and for what reasons. It is suggested that NRC be consistent with established definitions as much as possible. We note specific instances on our detailed comments regarding definitions in § 61.2.