

RulemakingComments Resource

From: Roger Seitz <rogerseitz5@msn.com>
Sent: Friday, July 24, 2015 11:25 AM
To: RulemakingComments Resource
Subject: [External_Sender] Docket ID NRC-2011-0012
Attachments: Roger Seitz.pdf

Dear Sir/Madame

Please find attached my comments on the propose rule for 10 CFR Part 61.

Regards,
Roger Seitz

Comments from Roger Seitz

NRC's Proposed Rule: 10 CFR Part 61

Docket ID NRC-2011-0012

Published March 26, 2015

I appreciate the opportunity to review the language for the proposed rule. The effort from NRC staff to provide draft guidance along with the rule was very helpful in better understanding the intent regarding implementation of the rule. However, I do have a number of concerns related to the proposed rule. I have provided responses to the specific requests for feedback followed by comments on specific language in the rule.

Note that although the guidance was helpful, I believe that substantial revision will be necessary to accommodate the needed changes for the proposed rule, thus I request that the guidance be revised and then resubmitted for public comment after the proposed rule is updated (I have also submitted a similar comment in response to the request for comments on the guidance).

NRC requests for comment in Federal Register notice

The 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)

Comment #1: I believe that the protective assurance period should be eliminated. After reviewing the proposed rule and associated guidance, it is my opinion that the use of an intermediate “protective assurance” period (from 1000 to 10,000 years after closure) with a numerical dose target does not really enhance protectiveness with respect to long-lived radionuclides and does not appropriately acknowledge and recognize the uncertainties and limitations of modeling over very long time frames. A two-tiered approach using the 1,000 year compliance period and performance objectives followed by the more qualitative performance period more appropriately addresses uncertainties and also provides a means to address the potential for catastrophic impacts that could potentially occur. Much of the excessive complexity of the proposed rule and guidance can be attributed to trying to accommodate the added protective assurance time frame.

If the protective assurance period is retained, the use of 500 mrem as a dose target or goal seems reasonable because it reflects the uncertainty and speculative nature of calculations extending into extreme times beyond 1,000 years. 500 mrem/yr is below the average annual dose for people living in the United States today (see NCRP Report 152) and is also not inconsistent with risks considered acceptable resulting from radon exposure in residences.¹ Internationally, there is good

¹ 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, which is equivalent to doses well above 100 mrem/yr. See, *A Citizen's Guide to Radon*, U.S. Environmental Protection Agency, <http://www.epa.gov/radon/pubs/citguide.html>

acceptance that exposures on the order of natural background are reasonable reference points for very long term assessments. The IAEA suggests that “[i]n very long time frames . . . uncertainties could become much larger and calculated doses may exceed the 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.”²

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. This is inconsistent with the 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.

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 1000 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. If the protective assurance period is retained (noting that I think it should not be retained), I recommend the proposed regulatory language be changed to reflect that additional efforts need not be made to further reduce doses if the goal of 500 mrem is met for these times far in the future.

As previously stated, the 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)

Comment #2: I recommend that the definitions for intruder assessment and inadvertent intruder be clarified. Although including the text 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” is helpful, I would recommend adding further clarification in the inadvertent intruder definition to specify “reasonably foreseeable” pursuits. For full clarity, I recommend that the definition of “intruder assessment” more specifically state that consideration of the scenarios used originally in the development of Part 61 is sufficient to comply with the proposed requirements for intruder assessment, which confirms that those scenarios remain sufficient. I also believe the need for the phrase “resource exploration or exploitation” is not clear and thus I suggest it should be eliminated from the definition of “inadvertent intruder.”

² “Geological Disposal of Radioactive Waste,” DS154, IAEA, 2005, Section A.7.

The 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)

Comment #3: It is my view that a dose limit is not needed or appropriate for the extremely long timeframe addressed by the performance period. I do believe there is benefit in considering potential impacts 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. I believe it is most appropriate during the performance period and the approach to use analytical results only qualitatively. I recommend that the protective assurance period be eliminated and that the performance period, with no quantitative dose criterion, begins immediately following the compliance period, at 1000 years after closure. The results from any performance period analyses after 1000 years should be viewed recognizing the increasingly speculative and uncertain nature of the results especially as the likelihood of catastrophic natural processes becomes high (e.g., ice ages).

Due to the increasingly speculative nature of calculations over hundreds or thousands of years, a dose limit or goal for timeframes beyond 1,000 years is difficult to justify. Recommendations from a number of organizations, including the IAEA, NEA, ICRP, and ACNW tend to recognize the lack of credibility when trying to quantitatively interpreting modeling results for timeframes beyond even several hundred years. The proposed approach with no dose limit or target during the performance period is appropriate and reasonable. I also believe that it is not necessary to establish a requirement for a barrier analysis as a formal criterion. Such an analysis can help to better understand the relative roles of different components of a disposal system, but is not appropriate as a formal criterion.

The 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)

Comment #4: As stated above (see comment 1), I recommend that the protective assurance period be eliminated. I recommend that a two-tiered approach be adopted that retains the proposed 1000-year compliance period, eliminates the protective assurance period, and applies the qualitative performance period approach to modeling assessments beginning at 1000 years after closure.

However, if the protective assurance period is retained, I support the use of 500 mrem as a dose target or goal because it reflects, better than lower dose levels would, the uncertainty and speculative nature of calculations extending into extreme times 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 (see NCRP Report 152) and is not inconsistent with risks considered acceptable resulting from radon exposure in residences. See more details in Comment #1.

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)

Comment #5: It is my opinion that a three-tiered approach is not appropriate. A two-tiered approach with a compliance period of 1,000 years is preferred. See comments 1 and 4 above for additional discussion.

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

Comment #6: As described previously, I do not support a protective assurance period, but if such a period is retained, I support a 500 mrem/yr dose target or goal for the protective assurance period, recognizing the increasingly speculative nature of calculations over hundreds and thousands of years. This is also consistent with the fact that 500 mrem/yr is less than annual average exposures considered acceptable in the United States today (see NCRP Report 152).

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)

Comment #7: As described in preceding comments, no quantitative goal or dose limit should be established for the performance period.

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

Comment #8: I believe the proposed rule language needs revision to improve its clarity and effectiveness, including removal of content that is better suited for guidance. A number of the updates proposed for the regulation are unnecessarily complex and difficult to understand in places. This appears largely related to trying to define considerations related to the protective assurance period and highlights the consequences of being too prescriptive and not fully embracing a performance based approach. The prescriptive approach leads to content in multiple sections using language more appropriate for guidance. 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 proposed regulation would require new analyses while retaining (and even adding to) detailed, directive criteria on aspects that would be addressed more appropriately in site-specific PA and intruder assessment analyses.

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 the NRC’s proposed definitions signify a meaningful departure from the accepted concepts, and for what reasons. I suggest that NRC be consistent with established definitions as much as possible. See more detail below.

General Concerns (followed by specific comments)

Risk-informed approach

Comment #9: I agree with the NRC's intention for the proposed changes to reflect a risk-informed approach to regulation of low-level waste 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 appear to not embrace the use of performance based site specific analyses to form the basis on which compliance is evaluated.

The proposed rule appears to embrace a more prescriptive regulatory approach using 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 prescriptive 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." (See 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.

For a performance based approach, the emphasis should be on the use of site-specific analyses demonstrate a reasonable assurance of compliance with the dose limits or targets based on 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 that are implied in the proposed rule 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 the longevity of the hazard and site stability. I suggest that the NRC carefully review the proposed rule to eliminate extraneous prescriptive criteria and analyses that do not align with a risk-informed and performance-based approach.

Three-tiered approach to compliance over different timeframes

Comment #10: I recommend that a two-tiered approach be adopted that retains the proposed 1000-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 1000 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.

I support the 1000-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 waste disposal can reasonably be used in a quantitative manner to assess compliance.

I also support the concept of considering analyses and intruder assessments over longer periods. There is value in considering, qualitatively, potential impacts 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. I 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 the NRC; these are discussed in more detailed comments.

However, the imposition of an intermediate “protective assurance” period (from 1000 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 time frames. 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.

- The IAEA says, for example, that for engineered near-surface disposal facilities, a modeling period on the order of “a few thousand years may still be reasonable.” (IAEA Safety Guide SSG-23, 2012) The ICRP observes that doses and risk “cannot be forecast with any certainty beyond around several hundreds of years into the future.” (ICRP-81) The 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.” A 10,000-year period for quantitative assessment and comparison against a dose criterion for low-level disposal facilities goes well beyond these recommendations.
- In addition, the 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 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 1000 years, at most. (See 10 CFR Part 20.2002; 10 CFR Part 40, Appendix A; 40 CFR Part 192.) The NRC’s own 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.” (See 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.
- 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. (See “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 background radiation or routine medical exposures—for the next *forty* generations covered by a 1000-year compliance period goes well beyond averting “catastrophic consequences.” This is especially true considering that exposures from a disposal system, even in the extremely far future, would be localized and will be considered qualitatively.

I 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 1000 years after closure.

New definitions

Comment #11: The proposed regulation includes some new definitions. Among these are several that are justified (in the Federal Register 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 consensus approaches, including participation from U.S. regulatory agencies. I believe that linking the concepts to international and national guidance, as applicable, is a reasonable approach. But this would be best accomplished by adopting the documented definitions that have been established for these terms.

Uncertainty and limitations of PA over long time frames

Comment #12: The 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 time frames. (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 OECD Nuclear Energy Agency. More generally, a performance assessment, 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 concepts and limitations on PA

are acknowledged in some of the FR discussions, but are not well reflected in the regulatory language.

I suggest that additional caveats and explanation be added in the concepts section and throughout the rule to appropriately reflect the issue with meaningfulness of speculative and uncertain results in the context of decision-making. The use of terms such as “ensure” protectiveness should be avoided. The regulatory language should instead be consistent with the concept of reasonable assurance.

Reasonable assurance

Comment #13: There is a need to define or clearly explain the term “reasonable assurance” in the context of the increasingly speculative nature of calculations over hundreds or thousands of years. Given the longer time frames that are associated with the proposed rule, there is a need to better describe the concept, especially compared to the expectations for operations of nuclear facilities.

Exclusion of radon

Comment #14: I believe 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 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 Order 435.1]. 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. One of the main reasons for considering 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 should exclude uranium from the all pathways dose objective and also add a performance objective for radon flux, consistent with the approaches in other promulgated rules.

Concepts and Technical Analyses

Comment #15: These sections of the proposed rule include information that reflects a prescriptive rather than risk informed approach and is better suited for guidance. 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.

Long-term analyses

Comment #16: I am concerned about the messages that are implied by references to “long-term analysis” (e.g., 80 FR 16091) in the context of 10,000 years. This undermines the fact that for near surface disposal of radioactive waste, regulations consistently consider much longer time

frames than are considered for disposal of other wastes. Five hundred or 1,000 years are very 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 are misleading and should be avoided and greater emphasis should be placed on how robust the approach has been, and is, for assessments to support safe disposal of radioactive waste.

Closure terminology

Comment #17: 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 to review and terminology and make it consistent as much as possible; where there are differences, the reasons should be made clear by context or explanation.

Specific Comments

§ 61.2, Compliance period definition

Comment #18: 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. I suggest that the cross-reference in § 61.43 (to § 61.41) 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

Comment #19: 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. (See 80 FR 16102, col. 2.) It is suggested that the definition be revised to reflect the broader consideration that are discussed in the preamble as well as in § 61.7(d).

§ 61.2, Inadvertent intruder and intruder assessment definitions

Comment #20: I 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.” Further, I note that NRC has stated that the approach used to develop the classification tables remains protective. I agree, and thus suggest that the use of scenarios similar to those considered in the development of Part 61 is sufficient to meet inadvertent intruder protection requirements. I suggest clarifying this approach in the definitions in the proposed rule. 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.

§ 61.2, Long-lived waste definition

Comment #21: I suggest that the definition of long-lived waste be deleted. The definition appears to imply a definition of a new class of waste, which is not necessary in a true risk informed, performance based approach. The appropriate basis to determine whether longer-term analysis is needed is the site-specific performance assessment rather than arbitrary numerical criteria using the tables for Class A waste. Note that implementation of a two tier approach with a compliance time of 1,000 years would remove the need for the prescriptive definition and table. See also comments on § 61.13(e).

§ 61.2, Performance assessment definition

Comment #22: The definition should include a consideration of associated uncertainties, as is done in the definition of *intruder assessment*, especially 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 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 the ICRP, the IAEA, and the 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. (See, e.g., the IAEA Safety Guide No SSG-23 on safety assessment and the OECD 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 §§ 61.13(a)(1) through (a)(5).

§ 61.2, Performance period definition

Comment #23: 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. (See *ibid.* and 80 FR 16092, col. 1) This is, in general, an approach that is consistent with a risk-informed process. It is not appropriate to imply there is no end to the potential time frame to be considered. 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)

I recommend that, at a maximum, the performance period should not extend beyond peak dose (or impacts) or the period of near-surface geologic stability, whichever is sooner. I understand that a significant motivator for the performance period is to gain information regarding long-term performance—but 1,000 years *is* very long-term performance. Modeling beyond 1,000 years should be conducted with the recognition of the growing speculation and uncertainty. At some time beyond 1,000 years, the loss of value of the information obtained from additional modeling as a quantitative basis for decisions needs to be acknowledged. The value of quantitative results for decisions will always be limited by whether 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. As the 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.”³

The 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 performance period extends until peak dose or impacts are reached or the period of surface geologic stability, whichever is sooner. This is consistent with the approach NRC presents in its draft guidance (NUREG-2175). Note that this approach does not exclude discussing what may happen beyond a performance period, but helps to maintain proper perspective regarding the utility of such speculation.

³ NEA 2009 *Timescales Report*, p. 27.

§ 61.2, Safety case definition

Comment #24: I 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 provides a means to document and address 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. However, it is unclear why NRC staff have developed their own definition of safety case rather than using those established in international guidance (e.g., IAEA SSG-23, Paragraph 1.3). I suggest using a definition from existing publications.

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

Comment #25: 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. The IAEA 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. (See IAEA SSG-5, para. 2.15.) The 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.” The 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.” (See ICRP-81, paragraphs 63-64).

I 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 I recommend that additional clarifying discussion be provided in the concepts section to include the points mentioned above. See also comments on § 61.42(a).

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

Comment #26: In a risk-informed approach, a site-specific analysis will inherently address whether the proposed waste inventory poses longer term hazards or not and, thus, whether analyses will need to address longer time frames. 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

Comment #27: 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, “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. (See 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

Comment #28: The emphasis on details related to “long term” stability is not needed. Stability is important for the several hundred year time frame assumed for the classification system (e.g., assumptions for the classification tables), but over many hundreds or thousands of years, stability as a criterion, becomes less meaningful for assessing level of protectiveness. If the site-specific PA demonstrates that performance objectives can be met with reasonable assurance for extreme time frames (e.g., thousands of years or more), even if there are increases in infiltration or other changes in the system, then “stability” as a separate and specific criterion is not needed. In addition, 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, the performance assessment 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; if it is kept, no changes from the existing rule language in § 61.7 are necessary and, in the interest of reducing complexity and confusion, the existing language in the current rule should be retained. See also comments on §§ 61.13(d) and 61.51.

§ 61.13, Application to existing facilities

Comment #29: 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 for § 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.” I 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, it seems more appropriate

to delay 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)

Comment #30: 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 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.

If the protective assurance period is retained (which I do not support), the approach to the identification of relevant FEPs in performance assessment beyond the compliance period seems reasonable (i.e., FEPs applicable in the compliance period (up to 1000 years) be extended and that new FEPs be added only if scientific information compelling such changes is available (See 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. I suggest that the proposed § 61.13(a)(5) be deleted.

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

Comment #31: I do not understand the purpose for 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. Prescriptively requiring further analyses seems to imply redundant requirements. Further, it is not clear what value is added to risk-informed decision-making and licensing, while at the same time adding to potential confusion, especially since it implies the possibility of sub-system requirements. I suggest that this paragraph be deleted.

§ 61.13(b), Inadvertent intruder analyses

Comment #32: The description of the inadvertent intruder analyses is confusing and inconsistent with the definition proposed for an *intruder assessment* in § 61.2. The “analyses” appear to include additional requirements beyond the assessment, as described in §§ 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 and thus does not appear necessary in the proposed rule. I recommend removing this detail from the rule.

§ 61.13(d), Long-term stability

Comment #33: 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 from the original intent of the rule, when applied over timeframes of thousands to tens of thousands of years that are addressed in the proposed rule. It is not possible for extreme time frames (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 risk informed, performance based approach advocated in the new rule. In a risk-informed, performance-based approach, the site specific analysis 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 for extreme time frames (e.g., thousands of years or more), 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)

Comment #34: 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 extreme time frames based on the Class A limits, since such time frames 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 and protective assurance period 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 informed, performance-based approach using site-specific analysis.
- To establish clear expectations on the part of licensees, further explanation should be provided on what “site-specific conditions” might necessitate performance period analyses

(e.g., results of site specific 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 analysis extending into the extremely far future. I recommend that the site-specific analysis be used to determine the appropriate duration to be considered.

- As noted in my general comments, I 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 1000 years, including consideration of the in-growth of progeny from the intended waste streams.”

§ 61.13(f), Defense-in-depth

Comment #35: The basis for the need to conduct a defense in depth analysis is not clear. 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) encompass 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, the 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.” (See 66 FR 55759.)

Further quantitative assessment, as implied by the term “analyses,” of redundancy over long time frames 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

Comment #36: 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.” (See ICRP 103, Section 5.4.2.). Since one intent of the update to Part 61 is to address new dosimetry, a change to consider the concept of a representative person seems to be reasonable as well.

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

Comment #37: As noted in my general comments, I recommend that the protective assurance period be deleted, and that the performance period be designated to begin at 1000 years after closure. Accordingly, I 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 the 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 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 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 the 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

Comment #38: The treatment of radon should be consistent with that in other rules that address Uranium from the 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 Order 435.1]. A major factor in the update to Part 61 is to address DU, so consistency with other national regulations addressing uranium is appropriate. NRC should address radon using a performance objective for radon flux similar to other existing rules.

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

Comment #39: As noted in my general comments, I support the concept of a performance period, for which the potential impacts beyond 1000 years are considered qualitatively to inform site understanding and contribute to optimization of design. I recommend that the performance period begin at 1000 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 not appropriate 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

Comment #40: 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.” (See IAEA SSG-5, para. 2.15.) The 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). The 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. (See ICRP-81, paragraphs 63-64). I 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 § 61.13(b)(3) to reflect that dose-based performance objectives in § 61.42 are goals (or guidelines) and not strict dose limits. See also comments on § 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”

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

Comment #41: The treatment of radon should be consistent with that in other rules addressing Uranium from the 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)], 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

Comment #42: As noted in my general comments, I recommend that the protective assurance period be deleted, and that the performance period be designated to begin at 1000 years after closure. Accordingly, I 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 comments on § 61.41(b).) For the same reasons, it is suggested to revise the requirement to read:

Reasonable and practicable 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 § 61.13 to reflect the NRC's stated intention that the reference dose is intended as a target and not a limit. In 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 objective in § 61.42(a) (see preceding comment) and § 61.42(b) are goals (or guidelines) and not strict dose limits.

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

Comment #43: 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 (§ 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

Comment #44: 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 my general comments, I recommend that the protective assurance period be eliminated. Whether or not this is done, the extension of the existing requirements to extremely long time frames—out to ten thousand years—is unjustified and burdensome. The value in separate requirements for site stability over thousands of years is questionable. More 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 for extreme time frames (e.g., thousands of years or more), even if there are increases in infiltration, then "stability" as a separate and specific criterion or performance objective 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 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. I suggest that it could be appropriate to demonstrate stability for the period of time 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., 1000 years). The language should also be modified to require that measures "eliminate to the extent practicable 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." See also comments on §§ 61.7(f) and 61.13(d).

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

Comment #45: The value of the enhanced specific requirements for site-suitability is questionable, and this section is unduly prescriptive and detailed for a performance based approach. 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 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.” (See 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. 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 § 61.13(a)(s) be eliminated to reflect the implementation of a performance-based approach.

§ 61.58, Waste acceptance criteria exceptions

Comment #46: 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 § 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 [§ 61.58(g)].

There is no provision for considering exceptions from the WAC. Under the proposed regulation, 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 that would be reviewed by the regulator, 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 in the license.