

RulemakingComments Resource

From: Dan Shrum <dshrum@energysolutions.com>
Sent: Friday, July 24, 2015 5:16 PM
To: RulemakingComments Resource
Subject: [External_Sender] Docket ID NRC-2011-0012 and NRC-2015-0003
Attachments: EnergySolutions Docket ID NRC-2011-0012 and NRC-2015-0003.pdf

Reference: Docket ID NRC-2011-0012 and Docket ID NRC-2015-0003

Subject: Comments to Proposed Rule and Part 61 Guidance, Low-Level Radioactive Waste Disposal, 80 FR 16082 and 80 FR 15930

Dear Ms. Bladey:

Please find our attached comments in response to the *Federal Register* notices regarding the U.S. Nuclear Regulatory Commission's (NRC) proposed changes to 10 CFR Part 61, *Licensing Requirements for Land Disposal of Radioactive Waste* and Draft NUREG-2175, "Guidance for Conducting Technical Analyses for 10 CFR Part 61." We look forward to future opportunities to comment on this and other potential changes to Part 61.

Daniel B. Shrum

ENERGYSOLUTIONS

Senior VP, Regulatory Affairs

Office: 801-649-2109

Mobile: 801-580-3201

dshrum@energysolutions.com

July 24, 2015

CD15-0163

Cindy Bladey
Chief, Rules, Announcements, and Directives Branch
Office of Administration
Mail Stop: OWFN-12-H08
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Reference: Docket ID NRC-2011-0012 and Docket ID NRC-2015-0003

**Subject: Comments to Proposed Rule and Part 61 Guidance, Low-Level
Radioactive Waste Disposal, 80 FR 16082 and 80 FR 15930**

Dear Ms. Bladey:

EnergySolutions appreciates the opportunity to provide comments in response to the *Federal Register* notices regarding the U.S. Nuclear Regulatory Commission's (NRC) proposed changes to 10 CFR Part 61, *Licensing Requirements for Land Disposal of Radioactive Waste* and Draft NUREG-2175, "Guidance for Conducting Technical Analyses for 10 CFR Part 61." The proposed rulemaking and guidance affects many aspects of EnergySolutions business operations. Our detailed comments on both the rule and the associated guidance are attached.

EnergySolutions appreciates the effort that the NRC staff has invested in this proposed rule. We also appreciate the degree of openness and receptivity to stakeholder comments that have characterized this proceeding. We believe that there are positive elements to the rulemaking, most notably the revisions to §61.58 that would allow for the derivation of site-specific waste acceptance criteria that could be used in lieu of the tables in §61.55. However, we believe that rulemaking as proposed is overly complicated and simply does not constitute the limited rulemaking that was envisioned by the Commission at the onset.

In SRM-SECY-08-0147 issued in March of 2009, the Commission directed the staff to undertake a limited rulemaking to "...specify a requirement for a site-specific analysis for the disposal of large quantities of depleted uranium..." While much has happened

regarding the rule over the ensuing years, that fundamental basis has not changed. The broad and far from limited nature of the proposed changes would impose additional requirements that are not realistic and do not serve to provide added assurance in meeting performance objectives. Additionally, the proposed changes have generated confusion through inconsistent language when defining the technical analyses in both the proposed rule and the supplemental technical guidance document.

One of the most significant consequences of this increase in scope is that the rule would significantly and adversely affect the operations of LLW disposal facilities that have no desire to dispose of the waste streams that the NRC has concluded were not adequately evaluated in the promulgation of the original Part 61. EnergySolutions believes this is a regulatory overreach that is not justified, nor has the cost of this overreach been correctly assessed by the NRC. EnergySolutions recommends modification to either § 61.1 *Purpose and Scope* to include a provision for “grandfathering” active Agreement State sites, or that § 61.6 *Exemptions* be restructured to specifically exempt active sites that can demonstrate they have restricted and will continue to restrict access to their sites for the disposal of the waste streams in question.

While we do not agree with the extent of some aspects of the proposed rule, EnergySolutions applauds the adoption of an individual site-specific basis for the development of waste acceptance criteria that can be used in lieu of the tables in 10 CFR 61.55. We believe every aspect of that approach is superior to uniform use of the generically-derived classification tables and that their promulgation and use would constitute a significant advancement in protecting human health and safety and protection of the environment. We also compliment the NRC on proposing that the site-specific values be determined using contemporary guidance from the International Commission for Radiation Protection. This further enhances the technical credibility of the site-specific WAC approach. It is clear that the use of site-derived WAC is preferable over use of the classification tables no matter how well-informed their development.

Given the superiority of this approach, it is also clear that there is no value in the NRC revisiting the question of classification of any isotope, including uranium, or of restructuring the classification tables. There simply is no generic approach to defining waste streams or disposal sites that will be superior to the site-specific approach envisioned by the proposed 10 CFR 61.58. In addition to the benefits and technical

superiority of the site-specific approach, it enables a licensee or applicant to account for specific volumes of waste and associated radioactive isotopes, which is superior to the existing classification system that is concentration based. As such, there is no benefit, although there would be significant disruption and cost, to the Commission pursuing an additional Part 61 rulemaking following the completion of the ongoing proceeding.

We also appreciate the Commission's identification of defense-in-depth as constituting a safety case for the operation of a LLW disposal site. Unfortunately, the proposed rule goes far beyond the direction of the February 12, 2014 SRM that "...the proposed rule should include a **clear statement** [emphasis added] that licensing decisions are based on defense in depth (DID) protections..." and instead includes a new requirement for a defense-in-depth "analysis." The implementation of defense-in-depth strategies to improve robustness is not new in the nuclear industry; however, as articulated in the proposed rule it does represent a new requirement, one which is neither reasonable nor rationale.

By proposing the institution of a requirement for an analysis, the proposed rule suggests a quantitative assessment of multiple independent and redundant layers of defense. This concept of redundancy is misapplied in the context of a disposal site, where defense-in-depth is achieved by a reliance on the combined protection provided by proper siting, waste forms, and radionuclide content, engineered features, and natural geologic features of the disposal site (as contemplated by the SRM), such that no single layer, no matter how robust, is exclusively relied upon. In fact, the preparation of a performance assessment represents the analysis required to demonstrate the requisite level of protection and reasonable assurances that the performance objectives will be met are sufficient. No additional analysis to demonstrate defense-in-depth is necessary.

Another new requirement of the proposed rule that is not technically justified is the requirement in §61.44 to demonstrate site stability for 10,000 years. This requirement is related to the new requirement for a three-tier analysis, which in general contributes to the unreasonable complexity of the proposed rule. Previously the Commission, the Environmental Protection Agency and our federal legislators recognized in the Uranium Mill Tailings Radiation Control Act that demonstrating stability beyond 1,000-years was not achievable scientifically. There is no new evidence that would indicate that the science in this regard has changed. While there is no doubt that models can be run that

purport to demonstrate condition in deep time, the credibility of an analysis that pretends to demonstrate conditions of man-made materials over such time scales is questionable. This requirement should be eliminated from the proposed rule.

Finally, we would like to offer our comments on the proposed Agreement State Compatibility Category of B, with which we are in complete agreement. It is the responsibility and obligation of the NRC to establish credible limits for protecting human health and safety associated with the beneficial uses of atomic energy. It simply cannot be argued that having safety standards vary from state-to-state is scientifically or rationally justified. It also cannot be argued that the benefits of this rule change, a multi-year endeavor to regulate a waste stream that the NRC believes is not currently being effectively regulated, will even be realized if a lesser compatibility category is selected. Doing so would give states the latitude to ignore these important changes that have taken years even to come to the proposed rule stage.

This letter serves to highlight our concerns and most significant comments regarding the proposed rule. More detailed comments are contained in the attachments which delineate our specific comments, concerns and recommendations for your consideration.

Thank you again for this opportunity to comment. Questions regarding these comments may be directed to me at (801) 649-2109 or dshrum@energysolutions.com.

Sincerely,

Daniel B. Shrum
Senior Vice President, Regulatory Affairs

COMMENTS ON THE PROPOSED REVISIONS TO 10 CFR PART 61

EnergySolutions has reviewed the proposed rule and we are in general agreement with several of the proposed changes, principal among them:

- The proposed revision to include a 1,000 year compliance period.
- Including a specific dose limit of 500 mrem/y for the protection of inadvertent intruders.
- Adding an alternative to develop site-specific waste acceptance criteria (WAC) for use in lieu of the tables currently in §61.55. This approach clearly is superior to any generic approach that makes assumptions that will not accurately represent the disposal conditions at any given site.

The rule as proposed could have several unintended consequences, including the following:

- The NRC fails to identify or quantify potential liabilities and litigation risk for existing sites as closure plans are implemented. The NRC also fails to properly identify or quantify the potential burden the proposed rule will have on new sites.
- The staff, in its efforts to develop new requirements governing disposal of large quantities and concentrations of long lived radionuclides in a near surface disposal facility, has proposed a framework of requirements largely based on high level radioactive waste (HLW) guidance documents. Applying these prescriptive requirements, which are both unnecessary and overly restrictive, to all *low* level radioactive waste (LLW) disposal facilities is unreasonable and unnecessary. Existing sites could consider early closure to avoid litigation risks incurred by the proposed rule amendments. Furthermore, the burdensome and unnecessary new language included in the proposed rule could be a barrier for development of new sites for LLW disposal capacity. Only two sites have been developed since 10 CFR Part 61 was promulgated – the proposed rule will significantly impact future development.
- The complexity associated with the proposed rule will be to make it easier to dispose of LLW in RCRA or unregulated disposal sites using the 20.2002 exemption process, rather than at a LLW facility that is much better suited to manage radioactive waste. While this approach is acceptable for some waste streams, it is not desirable nor adequately protective of human health and safety to drive LLW into unregulated disposal sites.

Our specific comments below address these and other concerns with the proposed rule.

NRC's calculation of the average implementation cost of per licensee is incorrect. The proposed rule will be a significant burden on the Agreement States, licensees, and generators. Staff has significantly underestimated the burden and cost of implementation of the complex

proposal on the Agreement States, licensees, and generators. *EnergySolutions* is in the process of completing a performance assessment specifically designed to assess the impact of disposing of depleted uranium at its Clive site, and has already spent over \$4,000,000 on this effort. It should be noted that this cost does not include the preparation of a stand-alone DID analysis.

Recommendation – Revise the implementation burden to correctly address the financial impact to licensees and Agreement State regulators.

Implementation of the proposed rule would place an undue burden on Agreement States – Currently, the Agreement States do not have the resources or capabilities needed to review the PA requirements set forth in the guidance document. There are a limited number of experts who can effectively perform these analyses. While the NRC alludes to the fact that they can provide technical expertise to States for their reviews in the guidance document, historically, these resources have not been made available to assist Agreement States even when requested. For example, when the state of Utah requested support from the NRC to review *EnergySolutions*' Clive DU PA, NRC did not provide this support on the basis that they cannot act on behalf of an Agreement State unless the Agreement State relinquishes their authority to them.

Recommendation – *EnergySolutions* proposes that NRC explicitly clarify in the rule the availability of its PA resources to assist in the review of licensee submittals. This would not only help address the availability of necessary expertise, but it would also address the issue of the undue burden imposed on the states.

The Licensing Process as proposed is not clear and is too complex to be consistently applied. In general, the process for development of the safety case for licensees and applicants is unclear. The language throughout the proposed regulation and the technical guidance needs to be minimized and clarified. Specific comments are provided below.

We attempted to create a flowchart to fit the pieces of the proposed rule together (see Figure 1). This flowchart clearly illustrates the cumbersome nature of the process. We recommend several changes that should streamline the process, including using a two-tier system. These are discussed in further detail in the following sections.

Recommendation – We propose that the NRC include a flowchart of the process so that an applicant or licensee can understand the components, requirements, key decision points, and how they fit together.

The language used to describe the technical analyses is inconsistent throughout the rule and the technical guidance contained in NUREG-2175. In the proposed rule, the analyses are discussed in some form in sections 61.2, 61.7, and 61.13. The types and number of analyses and how they are referred to are different in each section. In addition, the guidance document uses inconsistent language when referring to the analyses. The FRN has yet another way of referring

to (and ordering) the analyses (80 FR 16089-16093). The end result is confusing and difficult for an applicant or licensee to follow. Examples of these inconsistencies include:

- The Inadvertent Intruder Assessment is referred to using several different names throughout the rule and guidance document (e.g. Intruder Assessment, Inadvertent Intrusion Assessment, Inadvertent Intrusion);
- The long-term stability analyses is referred to using different names in the rule and guidance document (Long-Term Stability in the rule, Site Stability Analyses in the guidance document)
- The Protective Assurance Analyses is only referred to in the guidance document.
- Section 16.13(e) is entitled “Long-Term Radiological Impacts” but Table A refers to the Performance Period Analysis. The guidance document also refers to the Performance Period Analysis.

Recommendation – The definitions included in §61.2 should be consistently applied throughout the rule and guidance documents.

The language regarding the inadvertent intruder should be revised to more accurately account for site-specific conditions. As written, the proposed rule requires the analysis of an intruder who occupies the site and “...engages in normal activities including agriculture, dwelling construction, resource exploration or exploitation (e.g., well drilling)...” It goes on to require consideration of “...other reasonably foreseeable pursuits that are consistent with activities in and around the site at the time of closure...” The requirement that potential activities be “consistent with activities in and around the site” should apply to all elements of the intruder analysis. One might infer that this is the intent of the proposed regulation, but the wording does not make this clear. To remove doubt and avoid confusion, the section should be revised to move the modifying language regarding site-specific activities to the beginning of the description of activities.

Recommendation – Revise this section to clarify that all aspects of the intruder analysis should account for site-specific conditions.

Remove the requirement for a protective assurance period analysis. We do not agree that a three tier approach is needed. The performance assessment and inadvertent intruder analyses are good tools for evaluating long-term risks at a site. However, as discussed in more detail in following sections, there is unnecessary confusion and complexity added to these analyses due to the three-tiered assessment timeframe. The three tiers make for a cumbersome and overly burdensome process. Establishing a three tier approach is not efficient, clear or reliable, nor is there any evidence that it would contribute meaningfully to human health and safety. Implementation of a three tier approach will be a significant burden on Agreement States, licensees, and generators without added safety protection.

Recommendation – A two tier approach with a compliance period of 1,000 years and an analysis out to peak dose as a second tier would be protective and is much clearer, more efficient and reliable. A two tier approach out to peak dose will close the current gap for risks that increase for long lived radionuclides that are not adequately addressed by the current regulations.

There is no technical basis for a stability requirement of 10,000 years, nor is it possible to credibly demonstrate compliance with such a requirement. Proposed revisions to §61.44 require a disposal site to “...achieve long-term stability ... for the compliance and protective assurance periods.” While we agree that stability is an important component to the ability of a disposal site to properly isolate waste, 10,000 years is not a reasonable stability standard for a LLW disposal site. NRC, EPA and congress (Uranium Mill tailings control act legislation) have recognized that requiring stability beyond 200 to 1,000 years cannot be proven. Current stability requirements for Part 61 sites are largely met by complying with guidance developed for uranium recovery facility sites that implement a 200 to 1,000 year standard consistent with the URMCA requirements. Requiring stability for a 10,000 year period is unworkable. No other regulatory agency has a comparable requirement for LLW disposal. No Agreement State or licensee would be able to demonstrate stability for 10,000 years because the data to assess engineered features over this time period simply do not exist.

Recommendation – Reduce the stability requirement to 1,000 years. §61.44 should be revised to delete the words “and protective assurance.”

The timeframes associated with the Site Stability and Site Characteristics analyses are unclear and inconsistent. Section 61.44 says the site stability must be analyzed over the compliance *and* protective assurance periods (10,000 years after closure); Section 61.50(a)(2) talks about characteristics the site must have over 500 years; Section 61.50(a)(3) and (4) say that the hydrogeological characteristics must not affect the ability to meet the performance objectives, which cover all three time frames including the performance period. Section 2.3.2.4 of the guidance document gives concentration based criteria for determining the timeframe to evaluate the site characteristics with three tiers: 500 years, 10,000 years, and the performance period. The required time period must be clarified in order for a licensee to even begin the process of evaluation.

Recommendation – Simplify the time period for site characteristics to either 500 or 1000 years. Make clear where the analyses of site characteristics fits into the safety case.

The requirement for a defense-in-depth “analysis” should be removed. EnergySolutions is in agreement with the direction from the Commission in SRM-SECY-13-0075 that licensing decisions be based on defense-in-depth (DID) protections such as siting, waste forms and radionuclide content, engineered features, and natural geologic features of the disposal site. We also agree that taken together with the PA, DID can help form the safety case for licensing. Where the proposed rule deviates from the Commission’s direction, however, is in the

requirement for a DID analysis. The SRM articulates no such requirement, and in fact there is no basis for a DID “analysis.” The requirement to perform an analysis suggests the need for a quantitative analysis of redundant safety systems, such as would be the case in a nuclear power plant.

The requirement to perform a DID analysis is neither appropriate nor necessary. The effect of the various elements that provide DID for a waste disposal site (siting, engineered features, etc.) is to ensure compliance with the performance objectives in Subpart C. The analysis to demonstrate compliance with the performance objectives is the PA and the intruder analysis. Staff seemingly acknowledges as much by inclusion of the following statement in NUREG-2175, the proposed guidance for implementing the rule:

Therefore, licensees should be able to draw, principally, upon the results and risk insights gained from those other analyses to identify and describe defense-in-depth protections at the land disposal facility rather than developing separate analyses for demonstrating defense-in-depth.

And yet in the very next sentence in the guidance, staff states:

In some cases, licensees may need to consider whether additional features, events, and processes or alternative scenarios might be appropriate to consider solely for demonstrating that defense-in-depth protections are included.

This is a perfect illustration of our concern that the requirement for an “analysis” will lead to additional modeling that will be time consuming and expensive without contributing meaningfully to demonstrating the suitability of a site or compliance with the performance objectives. Defense-in-depth for the sake of defense-in-depth renders the concept meaningless. Each defensive element of the disposal system contributes to the safety of the site, which is demonstrated by compliance with the performance objectives. If the value of a given element, e.g., a site feature or engineered barrier, cannot be demonstrated in the PA, then it has no merit.

Recommendation – Delete the requirement for a separate DID analysis. Revise the proposed rule to clarify that DID is an important element of the safety basis and that each applicant or licensee must address how DID has been accounted for in its technical analyses.

The requirement to update the technical analyses at closure for existing sites that have met all previous requirements to date should be deleted. This is a significant and unnecessary burden on both licensees and regulators and no basis for this new requirement has been provided. As we have discussed repeatedly in our comments and in testimony before the Commission, the technical analyses required by the rule are expensive to prepare and to review. To require them to be updated for a site that is at the end of its licensed life and has operated in accordance with the regulations and the technical analyses that provide the licensing basis for the site simply makes no sense. It is not apparent what different outcome might be expected from repeating

analyses given no change in operating conditions previously analyzed. The only reasonable rationale for such a requirement is when conditions have changed, whether they be related to site conditions or waste inventory.

Recommendation – Revise the proposed rule so that this requirement applies only to sites that have encountered new, unanalyzed conditions.

The proposed rule should be revised to grandfather existing sites that do not dispose of the unanalyzed waste streams that led to the development of the proposed changes. The rule makes clear that the new requirements apply to all currently operating sites. However, the NRC has provided no justification for revising the rules currently in effect for licensed sites unless they accept waste streams that were not sufficiently analyzed in the development of Part 61 as originally constituted. In fact, the agency has gone to great lengths to state that the current rules are sufficiently protective of human health and safety.

The intent of section §61.1 is that “Applicability of the requirements in this part to Commission licenses for waste disposal facilities in effect on the effective date of this rule will be determined on a case-by-case basis.” This language recognizes that new requirements introduced after a site is sited, licensed and operated under previous requirements would not be binding on either Agreement States or licensees that committed to specific site conditions and licensing requirements in good faith. This is a reasonable regulatory approach where there has been no demonstration of a need for a change to reflect changed conditions or the scientific understanding of a particular condition. It also is consistent with the NRC’s *Principals of Good Regulation*, which in reference to Efficiency, state:

Regulatory activities should be consistent with the degree of risk reduction they achieve. Where several effective alternatives are available, the option which minimizes the use of resources should be adopted.

Requiring additional costly analyses that provide no reduction in risk is in direct conflict with the agency’s own principals.

The NRC staff indicates that a currently operating site, or a newly proposed LLW disposal site, could choose to continue to use and apply the existing waste classification system and associated waste form and disposal requirements set out in Part 61, or could apply a new set of WAC developed through the analyses prescribed in the proposed rule changes. For example, the staff states:

In defining LLRW streams with acceptable radionuclide concentrations or activities and waste forms, licensees or license applicants would be allowed to use either the results of the site-specific technical analyses set forth in 10 CFR 61.13, or the LLRW classification requirements in 10 CFR 61.55. (80 FR 16100)

Staff goes on to state:

In the proposed rule, the NRC is proposing the hybrid waste acceptance approach (Option 3) as the regulatory LLRW acceptance framework for the near-surface disposal of LLRW. The hybrid waste acceptance approach provides a framework for the use of either the generic LLRW classification system specified in 10 CFR 61.55 or the results of the technical analyses required in 10 CFR 61.13. (80 FR 16101)

Currently operating sites already have had to conduct technical analyses as required by §61.13 to demonstrate that they will comply with the performance objectives of Subpart C when disposing of LLW that meets the concentration limits in §61.55. As written, the proposed rule would require these sites to prepare new technical analyses at the cost of millions of dollars even if they do not propose either to accept new waste streams or to derive new operating limits as would be allowed under the proposed revisions to §61.58. Thus, the rule changes, as proposed, impose an unreasonable regulatory burden on the existing operating sites and existing Agreement State regulatory agencies who desire to remain under the current regulatory regime set out in existing Part 61. These new requirements should only apply to existing sites and any new sites that accept and dispose of new waste streams containing higher concentrations and larger total quantities of long lived radionuclides.

Recommendation – Provide an exemption for sites that are currently operating under approved licenses, as discussed in detail in the following section.

EnergySolutions agrees with the NRC proposal to make significant portions of the proposed rule be Agreement State Compatibility Category B. In undertaking the rulemaking to revise Part 61 to address waste streams not previously accounted for in its regulatory scheme, NRC has recognized the importance of requiring Agreement States to implement these regulations as proposed. EnergySolutions emphatically concurs in this conclusion. This is true for two reasons:

- 1) The benefits of this proposed rule, a multi-year endeavor to regulate a waste stream that the NRC believes is not currently being effectively regulated, may not be realized if a lesser compatibility category is selected. Agreement States should not have the latitude to ignore these important changes that have taken years just to bring to the proposed rule stage.
- 2) Human health and safety standards do not vary from state-to-state. It is incumbent upon the federal regulator to ensure scientific defensibility and consistency in the establishment of standards that are important to human health and safety. It also is important for the credibility of the regulatory framework to clearly acknowledge that there can be only one scientifically-based standard.

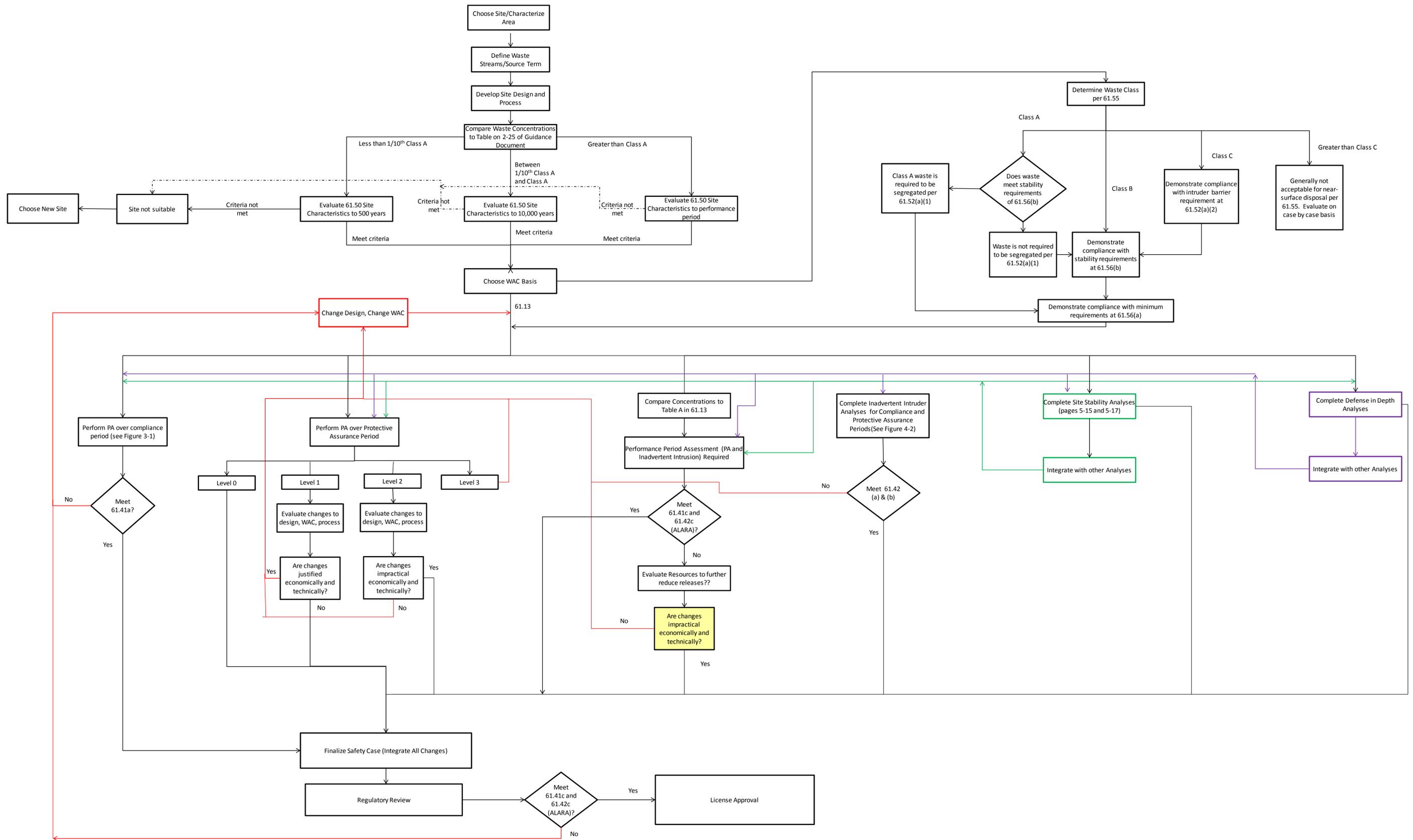
This is not a matter of flexibility for the states, it is a matter of scientific credibility, protecting human health and safety, and maintaining regulatory consistency in what is undoubtedly and indisputably a nationwide enterprise.

Recommendation – Retain the Compatibility Category B as published in the Federal Register request for comment notice.

SPECIFIC COMMENTS BY SECTION

Section	Comment	Comment Type
61.7	This section needs to be reconfigured. The flow of concepts is not logical, it is too detailed, and there is overlap with §61.13. The proposed language includes excessively prescriptive language that is not appropriate for regulation and should be removed to guidance. Specific comments are given by subsection below.	Technical
61.7€	Remove the majority of this language and replace with language to describe the new structure and requirements governing acceptance and disposal of the newer and additional waste streams containing higher concentrations of long-lived radionuclides. Provide a brief, concise summary of the technical analyses and refer to §61.13 for details.	Technical
61.7€	This is a good example of clear, concise language that then refers to a different section for details.	
61.12	In subsection (j)(2) include a reference to §61.13 after “technical analyses.”	Editorial
61.13	This section should be the one section where the technical analyses are defined. Any subsequent reference to the analyses in the rule or guidance should use the identical names used in this section. Each subsection describing an analysis should begin with the name of the analysis underlined. The details of the analyses, such as subsections (a)(1) – (a)(10) should be removed and placed in the guidance, and only minimal, concise language used in this section.	Technical
61.13	In the first paragraph of this section, delete the text: “Licensees with licenses for land disposal facilities in effect on the effective date of this subpart must submit these analyses at the next license renewal or within 5 years of the effective date of this subpart, whichever comes first.” The applicability of the new rules is addressed in §61.1, which properly notes that their applicability to existing licenses will be considered on a case-by-case basis.	
61.13(a)(9)	Delete. This requirement to consider “alternative conceptual models of features and processes” is illogical and unjustified. The applicant or licensee has the obligation to submit and justify its modeling approach, and the regulatory agency has the responsibility to confirm the technical suitability of the approach. To require a NEPA-esque alternatives approach is excessive, overly burdensome regulation that would be ripe for abuse. This requirement invites the prospect of incessant regulatory “what ifs?” that are not productive, protective, or justified.	Technical
61.13(b)(3)	Revise to read as follows: “An intruder assessment shall: (i) Assume that, at any time after the period of institutional controls ends, an inadvertent intruder engages in pursuits that are	

	consistent with activities in and around the site at the time of closure, potentially including agriculture, dwelling construction, resource exploration or exploitation (e.g., well drilling) or other reasonably foreseeable pursuits and that unknowingly expose the intruder to radiation from the waste.	
61.13(e)	This section is not clear and will be very difficult to implement. Table A is unclear and subject to interpretation, which will be a burden on states and operators. This section should be reworded and clarified so that it is clear that the Table A is to be solely used to determine whether or not a Tier II analyses is required.	Technical
61.13(f)	Revise by deleting the phrase “Analyses that demonstrate” and replacing it with “Description of how.”	Technical
61.28(a)(2)	Revise so that the revised analyses for §61.13 are only required for sites that have identified new unexpected conditions.	Technical
61.41	Delete subsection (b) to be consistent with the two-tier system.	Technical
61.42	Delete subsection (b) to be consistent with the two-tier system.	Technical
61.44	The words “and protective assurance” should be removed so that the stability analyses is only required for the compliance period.	Technical
61.51(a)	Delete the phrase “defense-in-depth.” This wording suggests that a site would have multiple layers or redundant systems built into the design. This is a misapplication of the concept of defense-in-depth for a disposal site. Defense-in-depth is provided by the additive protection arising from proper site selection and design and there should be no specific requirement for DID to be built specifically into the site design. The extent to which design features are necessary to ensure compliance with the performance objectives should be driven by the overall technical analyses, not a DID focused “analysis.”	Technical



COMMENTS ON NUREG-2175, GUIDANCE FOR CONDUCTING TECHNICAL ANALYSES FOR 10 CFR PART 61

CHAPTER 1

Summary Comment – The document introduces designations for individual technical analyses that are not cited in the proposed rule and inconsistently refers to these analyses in multiple chapters. This lack of consistent language throughout the documents would create an opportunity for the user community to misinterpret or possibly misapply the Commission’s intent when developing the safety case.

Recommendation – Align guidance document section/subsection titles with analytical designations in §61.13 and ensure they are consistently cited through its entirety.

SPECIFIC COMMENTS BY SECTION

No.	Section	Comment
1	1.0	The document would be improved by providing detailed guidance on how to prepare a technically defensible safety case and this would be best stated in Chapter 1. This section describes the approach for implementing the requirements for the technical analyses and the waste acceptance criteria to demonstrate compliance with the performance objectives, although never fully describes the underlying basis for the developing the safety case.
2	1.1	In each subsection, the titles should match the terminology in the proposed rule, and any repetitive, unnecessary content should be removed.
3	1.1.2	Because the WAC is relied upon to ensure that the performance objectives are met, the WAC should be included as part of the safety case.
4	1.1.2	Updating the safety case as part of the application for site closure is unwarranted and unnecessarily burdensome for licensees with sites having conditions that have been determined to adhere to the existing safety case. The section should be modified to discuss circumstances which an update is required, and to make an allowance for facilities with no changes to retain the existing safety case.
5	1.1.3	The placement of this subsection implies that defense in depth is a separate analysis, yet the text itself re-iterates our position that the concept of defense-in-depth should be incorporated into the other technical analyses and is not an independent analysis. This section should focus more on how the Commission would like the defense in depth protections highlighted throughout the other technical analyses.
6	1.1.4	The term “technical analyses” is redefined in this section differently than in the rule. It is technically careless to intentionally use the same term to mean different things in the context of a single regulatory application. Uniform terms and designations for technical analyses should be used throughout the rule and guidance.
7	1.1.4	To align with our comment that the rule should only contain definitions of

		the analyses and the discussion around the analyses should be relocated to the guidance, we suggest that much of the language in §61.13 of the proposed rule be removed and relocated to this section, which provides explanations of the technical analyses required.
8	1.1.4.2	The background regarding the basis for an inadvertent intrusion is helpful by citing the corresponding technical basis for the analyses. We recommend including a similar basis for each analysis referenced in this section.

CHAPTER 2

Summary Comment – The requirements outlined in this chapter are overly burdensome, and the staff did not adequately assess the time and effort for licensees to complete the technical analyses. The level of effort required to evaluate FEPs and perform technical analyses with respect to the performance objectives rivals high level waste geological repositories. The technical analyses for the Yucca Mountain Repository required over 20 years to complete. Appendix C, referenced in this chapter, provides examples of FEPs to consider for repositories, including EnergySolutions’ site in Clive, Utah. As Staff state in this section, the level of effort required to perform technical analyses should be commensurate with the risk associated with the waste. LLW, including LLW with long-lived radionuclides, still poses significantly less risk to the public and environment than HLW. Therefore, the technical analyses requirements outlined in this guidance should be reduced. Specifically, requiring a licensee to consider alternative scenarios and provide model validation and uncertainty quantification for analyses beyond 1,000 years provides little benefit to providing assurance of results, especially given the level of effort required to perform these tasks, and is not commensurate with the risk.

Recommendation – Staff should reassess the requirements for technical evaluations, eliminating overly burdensome suggestions, such that the anticipated level of effort and costs associated with the technical analyses are more appropriately aligned with the associated risk. The requirements for model validation, data adequacy review, and uncertainty quantification should be significantly reduced or eliminated.

Summary Comment – The content regarding the considerations of FEPs, scenarios, model development presented in this chapter are too prescriptive, unnecessarily conservative, and in some instances circular. The iterative processes suggested can lead to a never-ending analyses period that provide little return with respect to providing greater confidence that performance objectives are met. Such requirements include requiring the licensee to consider and run multiple models when data are sparse, to validate efforts by modeling similar sites modeled by alternative agencies, and to update FEPs when new information is found. Overall, the considerations in this chapter ask the licensee to go beyond providing “reasonable assurance” of long-term site stability and adequate protection of the public. These specific examples are expanded upon in the specific comments below.

Recommendation – The level of detail describing how to perform the technical analyses should be reduced, such that the chapter describes a clear path for performing technical analyses that allows licensees flexibility in the overall approaches used to demonstrate compliance objectives are met.

Summary Comment – Time periods for analyses and additional considerations based on waste concentration are introduced in this chapter, including for example those in §2.3.4, that are not included in the rule.

Recommendation – Revise the guidance and rule to ensure consistency throughout both documents. Analysis requirements should not be in the guidance that are not included in the rule.

Summary Comment – Accounting for uncertainty is a theme that is addressed numerous times throughout this chapter in separate subsections. In many cases, the discussions and examples for addressing uncertainty are incomplete. In other cases, redundancy and over-conservatism in the design and analyses are presented as necessary to address the uncertainties. As a result, the proposed guidance is overly prescriptive, particularly in light of there being other techniques available to address uncertainty which are considered leading practices in the nuclear power industry.

Recommendation – Instead of weaving comments and requirements around uncertainty through the text, we recommend the Staff draft a subsection to specifically address how to perform an uncertainty quantification analysis. The uncertainty quantification should be used to inform the numerical models and overall design such that the licensee and regulator have confidence that the site meets or exceeds performance objectives while minimizing the costs associated with model development and validation and overall site construction costs.

SPECIFIC COMMENTS BY SECTION

No.	Section	Comment
1	2.1	The discussion around accounting for uncertainty is overly simplistic and incomplete. Model uncertainty cannot be accounted for simply by developing and analyzing conceptual models. Accounting for model uncertainty is an iterative process that requires evaluation of the model form, parameters, and representation of parameters within the model in order to address and potentially correct bias and calibrate parameters. Because the assessment process relies upon multiple models with some model outputs being inputs of other models, uncertainty quantification becomes a computationally expensive and time consuming exercise. Researchers specializing in uncertainty quantification are only now developing defensible techniques to address uncertainty propagation through multiple models. The guidance should include a more thorough discussion on uncertainty quantification and propagation.
2	2.2.1	Parameter uncertainty is described in §2.2.2.1.3, not §2.2.2.1.2 as referenced in the text
3	2.2.2	The italicized emphasis on scenario uncertainty when describing uncertainties in the performance assessment is confusing and might lead the licensee and/or reviewer to place a greater emphasis on scenario

		uncertainty. We recommend staff provide better support for the emphasis or eliminate the use of italics.
4	2.2.2	Figure 2.2 is oversimplified does not provide an adequate representation of uncertainty analysis and the treatment of uncertainty. The figure seems to imply that the same parameter sets might be used in all models, potentially modeled using the same distributions and or discretization, and that all parameter sets will be incorporated into making a decision, which might not be appropriate. Additionally, the figure does not depict model interaction and parameter interaction which is common to model building for performance assessments. The performance assessment can be comprised of many submodels interwoven together to ultimately predict radiation release. We recommend the figure be updated to reflect the true level of effort required to account for future, model, and parameter uncertainty, or the figure should be removed the text.
5	2.2.2.1.2	The requirement that when data are sparse, multiple conceptual models should be evaluated and the most conservative model selected is overly burdensome. It is difficult to assess which model is actually the most conservative for the data considered without actually constructing and running the model. This requirement should be eliminated.
6	2.2.3	We agree with Staff that the technical analyses required by the performance assessments and site stability analyses cannot be validated. We also agree with comments that the greatest sources of uncertainties in the performance assessment are due to projecting out models calibrated with relatively brief histories across periods of time that are orders of magnitude greater than the calibration periods. Given the level of effort required to perform the technical analyses, including the iterative process of parameter characterization, model calibration and model verification, we question the validity and benefit of performing quantitative analyses beyond 1,000 years. For example, post-audit reviews of groundwater models show that the predictive capability of groundwater models is generally poor. Prediction accuracy is even poorer in models that are recalibrated to better fit historical data, even with calibration periods of 40 years.
7	2.2.3	With respect to the quantity and quality of model support being dictated by consistency with past experiences in similar conditions, the example presented using an engineered barrier is nonsensical and should be removed from the text. Little evidence (if any) is available showing the performance of an untouched engineered barrier beyond 1,000 years, as required by the performance assessment and site stability analysis for sites accepting long-lives radionuclide waste. Because no such examples exists, the example is superfluous and licensees will still have to provide a great amount of model support for engineered barriers.
8	2.2.3	The guidance suggesting that licensees might have to prepare analyses and provide comparisons of results to similar sites modeled by other organizations is not reasonable. Such a suggestion goes against the concept of site-specific analyses, and poses an unjust burden on

		licensees that have been provided the flexibility to model sites differently than other organizations in order to provide reasonable assurance of site stability and public health protection at their site. We recommend that the suggestion be removed from the text.
9	2.3.2	The guidance that licensees should perform quantitative analyses for the protective assurance period contradicts the guidance in Chapter 6.0, which states that for dose limits below 0.25 MSv/yr, qualitative or quantitative analyses can be performed. The guidance should remain consistent throughout the entire document.
10	2.3.4	The introduction of additional requirements for the assessment of site characteristics based on waste concentration adds additional confusion to an already burdensome and convoluted process. It is unclear how these time frames for analyses based on concentration limits should be incorporated into other analyses including site stability, intruder analysis and protective assurance period compliance analyses. As the requirements are not included in the rule, they should be removed from the guidance.
11	2.3.5	The table for required analyses based on site characteristics again adds confusion to the burdensome licensing process. It is unclear if the analyses required are dependent upon the waste concentration as prescribed in §2.3.4. We recommend providing additional context for the table and including guidance regarding the site characteristic requirements.
12	2.5.3.1.1.1	The iterative process for FEP identification and the consideration of additional FEPs when information is available is unnecessarily burdensome. Staff should provide guidance regarding when it is acceptable for the licensee to stop the iterations. Without such information, the FEP identification process is circular and has no clear end point.
13	2.3.5.1.2.1	The quality of the hazard maps in Appendix B related to features and phenomena that can be used to screen FEP's are of poor quality and can easily be misinterpreted by both the regulator and licensee. We recommend removing the hazard maps from the Appendix and as an alternative, providing digital map files (such as ESRI Shapefiles) that allow for viewing on a finer scale.
14	2.5.4.1	The statement that "a licensee should use scenarios to describe the scenario uncertainty associated with the system" is circular and confusing. We recommend revising the statement or removing it from the text, as it is ripe for misinterpretation by both licensees and regulators.
15	2.5.4.1	The paragraphs describing alternative scenarios is confusing and seems to be in contradiction to the descriptions of FEPS that can be excluded based on regulations. The benefit of developing and analyzing highly improbable scenarios has not been demonstrated and poses unnecessary burdens on both the licensee and reviewer. The requirement should be removed from the guidance.

CHAPTER 3

Summary Comment – The majority of this chapter is devoted to describing modeling efforts for radionuclide release and subsequent transport to receptor locations. Each subsection focuses on a specific model, and primarily referencing existing guidance or literature to consult for more in-depth specifications while providing commentary on general considerations. The focus on existing guidance is understandable and warranted, but the reader could benefit from additional context describing the referenced sources.

Recommendation – Develop a table, similar to Table 11-4, which references existing guidance or literature by model/topic and also provides a description of the source and its potential use. Given the current layout of the chapter, it would be beneficial to create two of these tables: one for source term modeling and another for transport modeling.

SPECIFIC COMMENTS BY SECTION

No.	Section	Comment
1	3.1.1, Line 14	The reference to “Step 8” should be revised and corrected to “Step 9.”

CHAPTER 4

Summary Comment – Generic scenarios do not inherently account for site-specificity, and numerous viable disposal sites across the country can be seen to demonstrate the inaccuracies in NRC staff’s claim on line 28 of page 4-11 that such generic scenarios represent “*normal activities that humans typically engage in . . .*” For example, Clive Utah’s groundwater is of extremely poor quality and very low yield. The generic inadvertent intruder scenarios not only completely misrepresent any potential inadvertent intruder exposure from Clive Utah’s groundwater, the generic scenarios also arbitrarily underestimate the sites’ ability to comply with the inadvertent intruder protection performance objective. Such arbitrary support of generic inadvertent intruder scenarios by NRC staff is also dramatically inconsistent with NRC staff’s own claim on line 38 of page 4-11 that “depending on the method used, licensees should provide justification for their selection.” Similarly, simple reliance by a licensee on the generic inadvertent intruder scenarios is also contrary to NRC’s own guidance on line 20 of page 4-7 that the inadvertent intruder analysis is an “iterative process involving site-specific, prospective modeling evaluations . . .”

Recommendation – Place greater emphasis throughout the text on the importance of considering reasonably foreseeable and site-specific scenarios at the site location. A table of lines from the text that we recommend be edited to provide such additional clarity are shown below.

Table 4.1 Lines Needing Additional Clarity

No.	Section	Page	Line
1	4.1	4-3	28

2	4.2.3	4-6	26
3	4.3	4-9	8
4	4.3.1	4-11	7
5	4.3.1	4-13	40
6	4.3.1	4-16	1
7	4.3.1	4-19	3
8	4.3.2	4-26	33
9	4.3.2	4-27	2
10	4.3.2.2	4-30	10
11	4.3.2.2	4-34	35
12	4.3.2.4	4-35	37
13	4.3.2.4	4-25	43

SPECIFIC COMMENTS BY SECTION

No.	Section	Comment
1	4.0, Line 14	Figure 4-1 is inconsistent with the text of Section 4.0. The caption in the top circle of the Figure should be revised to “ <i>Demonstrate Compliance with Waste Acceptance Requirements</i> ” to remain consistent with the text.
2	4.2	For added clarity, Section 4.2 could be adjusted to reinforce that the chapter’s focus is for protection of an inadvertent intruder.
3	4.3.1	Line 26 of page 4-11, regarding the assessment that generic receptor scenarios are reasonably conservative should be deleted.
4	4.3.1	The intent behind NRC’s justification of generic inadvertent intruder receptor scenarios provided on line 9 of page 4-13 does not automatically equate to their projection of conservatisms and bounding results without adaptation to reasonably-expected site-specific analysis and justifications suggested throughout subsection 4.3.1.2. Rather, the generic receptor scenarios provide conservative bounds for the sites that existed at the time 10 CFR 61 was first promulgated. Such qualifications should be added to the text.
5	4.3.1	We appreciate that NRC staff realizes that when drilling resistance is encountered (as part of the Intruder-Driller Receptor Scenario), a driller will typically adapt by moving the drill rig to a more suitable location. It is recommended that the guidance also note in subsection 4.3.1.1.2 that when extremely low yield or extremely poor quality groundwater is encountered, the driller will also adapt by moving sufficiently far to be located over completely different hydrogeologic conditions of higher yield and quality.
6	4.3.1	Since Staff recognizes that prior to construction and dwelling intrusion scenarios, the inadvertent intruder must first excavate a viable production groundwater well, the text should be revised to note that when failing to do so, it can be reasonably expected that neither the construction, dwelling, nor agricultural intrusion receptors will represent site-specific conservatisms.

7	4.3.1	Licenses should only be allowed to adopt generic receptor scenarios after providing justification that facility design, operations, and site are reasonably represented in the generic scenario characteristics. Line 22 should be revised to reflect this position.
8	4.3.1	Estimated exposures from generic receptor scenarios might not always be higher than site-specific scenarios. A generic scenario does not automatically equate to conservatism without appropriate consideration and analysis of reasonably expected site-specific conditions. It should be the burden of the licensee to demonstrate, and the reviewer to confirm, whether or not results produced by the application of generic-receptor-scenarios are more conservative (e.g., higher projected doses). The statement on line 17 of page 4-17 should be revised to reflect that the generic scenarios represent greater exposure estimates.
9	4.3.1.2.	The main advantage of site-specific intruder receptor scenarios is not the flexibility provided the licensee; rather, the main advantage to the licensee and the reviewer is that site-specific intruder receptor scenarios more closely reflect reality. This adds to the degree of confidence that a technically-based and reproducible assessment is achieved. Statements within this section should be edited to reflect the true advantages of site-specific analyses.
10	4.3.2.2 Page 4-30 Line 44	Because the statement regarding conservative estimates of waste inventory is given without qualification, it is easily misinterpreted by reviewers. The statement should be removed or better qualified.
11	4.3.2.2	This section (and this chapter in general) is replete with references to “conservatives;” conservative designs, scenarios, estimates, limits, assumptions, parameters – the list goes on and on. It is inappropriate to urge conservatism at every step, particularly in the case of site parameters. Staff should promote site-specific input parameters and only use (conservative) default values where the input parameters either don’t matter (based on sensitivity) or are impossible to obtain. It also is important to recognize that an input parameter that is conservative for one analysis may not be conservative for another (take, for example, staff’s own caution of using conservative releases for 61.41 compliance vis a vis 61.42 compliance). Incessantly compounding conservatisms is a reflexive and inappropriate approach to preparing an analysis with a suitable safety margin.
12	4.3.2.2	The first clarification for appropriate inadvertent intruder assessment source term on line 33 of page 4-34 should be revised to clarify that environmental contamination generated by the inadvertent intrusion is not included in demonstration of the protection of the general public.
13	4.3.2.2	Line 45 of page 4-34 describing the importance of assessing waste accessed via excavation by the intruder should be clarified so that it is clear that performance assessment demonstrating protection of the general public does not require and should not include an assessment of the transport of waste via intruder excavation.

14	4.3.2.3	The two examples cited in this section of gaseous diffusion and an intruder well inappropriately imply that these transport mechanisms are always reasonably expected. If non-potable and of extremely low yield, a site's aquifer may not be a viable target for an intruder well. It is suggested to remove the sentence beginning on line 17 of page 4-35.
15	4.3.2.3	General public exposures are not modeled for any radionuclides transported off-site due to the actions of an inadvertent intruder. Line 20 of 4-35 should be amended to include this qualification. For example, if an inadvertent intruder drills into disposed waste in preparation for a garden, the dust generated from doing so is not modeled when projecting doses to the general public nor included when comparing to regulatory limits for post-closure general public exposures.
16	4.3.2.4	The statement beginning on line 25 of page 4-35 is misleading. Any contact by anyone (whether on the site or downstream) with waste that has transported away from its original disposal placement will be the result of " <i>onsite releases from the LLW disposal facility.</i> " The reference to direct contact with waste should be removed.
17	4.3.2.4	The inadvertent intruder methodology summarized on line 30 of page 4-35 should be revised to clarify, "Dose modeling consists of converting radionuclide concentrations <u>generated in environmental media from the inadvertent intrusion onto the licensed site and/or into the waste</u> to dose through various <u>onsite</u> exposure pathways."
18	4.4	The statement made on line 10 of page 4-37 stating that licensees may assume institutional controls provide durable site protection seems to contradict the entire theme of this chapter, which is a guidance on how a licensee can demonstrate, through analyses not assumptions, reasonable assurance that performance objectives are met. This statement should be eliminated from the text.

CHAPTER 5

Summary Comment – The guidance for proving site stability is convoluted and limits the ability of an applicant or licensee to determine how to develop a site stability analyses. Adding to the confusion already considered in the guidance, Chapter 2 presents new time periods for analyses, and then this chapter introduces another time period based on waste concentration.

Recommendation – Clarify the time period for analyses. The licensee and reviewer would both greatly benefit from the addition of a table or flow diagram that outlines all analyses considerations and time frames for analyses presented in the rule in Section 61.44, Section 61.50(a)(2), Section 61.50(a)(3), and guidance in Chapter 2.3.2.4, and this chapter.

Summary Comment – Requiring quantitative analyses periods beyond 1,000 years for low-level waste is unreasonable, unprecedented, and without scientific merit. The use of natural analogues, though helpful to support the design and technical basis for engineered barriers, cannot be used to prove with confidence stability of a man-made or engineered barrier

Recommendation – Remove requirements to prove site stability past 1,000 years.

Summary Comment – The frequent shifts between the requirements and scope of “site stability analysis” and “stability analysis” is confusing and in some instances seem to be used interchangeably and in other instances “stability analyses” seems to reference a larger analysis of which “site stability analyses” are a component. This is also demonstrated in Chapter 2, which provides guidance for analyses required with respect to site characteristics.

Recommendation – Use language that is consistent throughout both the rule and the guidance.

SPECIFIC COMMENTS BY SECTION

No.	Section	Comment
1	5.1	Staff should eliminate or provide context for the requirement that licensees that choose to use site-specific scenarios over generic receptor scenarios must consider low frequency natural events in the site stability analyses. An explanation of why generic receptor scenarios “may bound the impact” from these events, and site-specific scenarios would not is missing.
2	5.1.1.3	The guidance suggests that site stability against other disruptive processes should include climate change for sites accepting waste with long-lived isotopes. The concept that climate change is a disruptive process and should be modeled as such is never referenced in the proposed rule. Furthermore, the guidance suggesting climate change should be considered within the site stability analyses seems to directly contradict guidance in §5.1.2 which states that licensees should evaluate natural climate cycling, but are not required to evaluate “anthropogenic climate change.” There are no conservative scenarios with respect to the concept of climate change, and as such any climate change projections cannot be considered reasonably foreseeable at the individual site. The suggestions around climate change should be stricken from the guidance. This also is in direct conflict with Commission direction that analyses beyond the compliance period <i>not</i> rely on such assumed conditions: “Given the significant uncertainties inherent in these long timeframes, and to ensure a reasonable analysis, this performance assessment should reflect changes in features, events, and processes of the natural environment such as climatology, geology, and geomorphology only if scientific information compelling such changes from the compliance period is available.” (SRM-SECY-13-0075)
3	5.2.2	The suggestion that refinement of a model with results showing a FEP to be significant could lead to new results showing the FEP is actually insignificant, and thus site stability is proved, should be eliminated from the text. The suggestion encourages the licensee to massage data, parameterization, boundary conditions, and model form to produce satisfactory compliance results.
4	5.3.1	If as suggested, the existing guidance for uranium mill tailings is applicable to LLW disposal sites, and as such, the limitations of the

		existing guidance should also be applicable. Comments on the uranium mill tailings analyses recognized that stability over 1,000 years cannot be proven. We reiterate our comments that the licensee should not be required to make attempts to demonstrate site stability from 1,000 to 10,000 years.
5	5.3.1	The comment that the Staff “plans to periodically assess the sufficiency” of the guidance around proving engineered barrier stability and “supplement it when necessary” is disturbing. NRC’s <i>Principles of Good Regulations</i> state that regulation should be reliable and not in a state of transition. The proposed actions to reassess the guidance goes against this principle. If Staff lack technical confidence in the actions outlined in the Guidance, then the steps should be stricken from the text.
6	5.3.1	Additional content is needed discussing how the requirement to provide a technical basis for engineered barriers are to be incorporated into the overall site stability assessment. The engineered barrier technical basis considerations are only referenced in the discussion of design based approach, yet the text in this section suggest it is a requirement, and thus, not subject to the type of analyses approach used.
7	5.3.2	The concept of defense-in-depth is implied in this section, demonstrating as we suggest that defense-in-depth is adequately woven throughout the analyses such that a separate independent analyses is not required. That said, we do not agree with the Staff that licensees should have to consider “multiple, independent, and redundant barriers” in the design of engineered barriers for long-term waste disposal. Redundancy is demonstrated in the multiple layers of defense including proper site selection, waste inventory, natural barriers and engineered barriers. The suggestion should be removed from the text.
8	5.3.3	We agree with Staff in the benefit of site monitoring and that site monitoring results can be used to assess both site performance and evaluate model predictions and performance. When monitoring results for the institutional control period support initial analyses, the technical analyses should not have to be updated upon site closure

CHAPTER 6

Summary Comment – The protective assurance analysis, as it is described in the guidance, is based on both engineering and economic theory that cannot be defended. As we discussed in Chapter 5, site stability cannot be proven with confidence past 1,000 years. Additionally, very long-term discounting has not been demonstrated beyond 1,000 years. With the uncertainties that surround economic models, calculating the net present value of an asset out to 10,000 years should not be used as a decision basis to prove that a design alternative minimizes dose exposure with respect to what is economically feasible. Furthermore, the guidance in Chapter 6 is too prescriptive with respect to methodology, and falls short with respect to providing clear examples of how to implement the detailed methodologies. Though licensees have the liberty to

perform alternative cost-benefit analyses to demonstrate protective assurance compliance, most of the chapter is dedicated to describing a singular approach that is suspect.

Recommendation – Eliminate this chapter and the entire protective assurance analysis requirement from both the rule and the guidance in favor of a two-tiered assessment, with the second tier requiring analyses out to peak dose. Alternatively, the requirement to provide comparisons out to 10,000 years can be eliminated, requiring only the comparison of peak dose of design alternatives.

SPECIFIC COMMENTS BY SECTION

No.	Section	Comment
1	6.2	Figure 6-1 should be removed from the guidance, or a detailed legend should be provided to help convey the meaning. As it is currently presented, the color gradation and gradient size can be subject to multiple inaccurate interpretations of required level of effort by both the regulator and licensee.
2	6.2.1.2	The minimization analysis as it is presented in the guidance is not optimized with respect to mathematics, nor does it provide assurance that a design to reach a true minimum dose has been reached, as suggested in the guidance. A mathematical optimization requires the evaluation of function with alternative values to find a maximum or minimum, which is potentially restricted to a domain based on variable or value constraints. The analysis presented in the guidance is a comparison of viable and reasonable alternatives, and should be renamed as such.
3	6.2.1.2	The prescribed discount rates of 1 to 7 percent for the long-term net present value analysis have no basis in economic research. Additionally, requiring licensee to perform the analysis with multiple discount rates is overly burdensome and only serves to add additional confusion to decision making. The suggested discount rates, and the requirement to perform economic discounting across very-long time periods is a misapplication of the singular research source presented to defend the suggested approach. The reference only demonstrates economic discounting out to 999 years and provides no basis for extending analyses beyond 1,000 years. These concepts should be removed from the guidance.
4	6.2.1.2	The term “prohibitively large” with respect to uncertainties is used as a metric or quantity to determine when inventory limits might be warranted. This definition for this term is not found within the rule or guidance. We recommend defining this term.
5	6.2.1.2	We believe Example 6.1 is flawed in the use of significant digits and evaluating precision in dose predictions. For example, the time periods to peak dose are calculated out to the single digit, while net present value costs are rounded to the millionth. The assumption that peak dose calculations can be computed with a precision of one digit is misguided and does not adequately address the uncertainties associated with the peak dose calculations. The rounding of net present value costs seems reasonable given the extreme uncertainties associated with long-term

		discounting. We recommend using the same conservatism with peak dosage estimates and time to peak dosages.
--	--	--

CHAPTER 7

Summary Comment – The subtitles and text in this section are inconsistent when referring to required analyses. These inconsistencies exacerbate the confusion around how licensees can adequately demonstrate compliance. The rule specifically states that a “qualitative analysis covering a performance period of 10,000 years or more” is required. Contradicting the proposed rule, the guidance requires a “quantitative risk assessment” which is never detailed, but includes a section around “quantitative analyses.” Edits to enhance the clarity and content of this chapter are suggested.

Recommendation – Develop a more detailed approach to better inform licensees in demonstrating performance period compliance when the results initial screenings necessitate additional analyses.

Summary Comment – The requirements to evaluate additional FEPs that are the result of scenarios that have “as low as a 10 percent chance of occurrence over the analysis timeframe” is in direct conflict with the direction given by the Commission in SRM-SECY-13-0075. Regarding the analyses for the Protective Assurance Period, the Commission directed the staff as follows:

Given the significant uncertainties inherent in these long timeframes, and to ensure a reasonable analysis, this performance assessment should reflect changes in features, events, and processes of the natural environment such as climatology, geology, and geomorphology only if scientific information compelling such changes from the compliance period is available.

The comments made by Staff in §7.3.1 state that the information regarding FEPs will be “limited” and “more susceptible to bias,” implying that the additional FEPs considered in this time frame would not have a scientific basis for supporting the frequency estimates. This clearly is a standard far below “compelling,” and based on the direction from the Commission, is inappropriate.

It is unclear if these less likely but plausible FEPs represent “key” FEPs as described on page 7-12, line 6. The guidance suggest that the existence of these FEPs might require the licensee to modify conceptual and numerical models, rather than extending calculations or the analyses period. Requiring the licensee to develop alternative conceptual and numerical models for scenarios that lack a defensible scientific basis is unreasonable and overly burdensome.

Recommendation – Remove the requirements for consideration of less-likely but plausible FEPs.

SPECIFIC COMMENTS BY SECTION

No.	Section	Comment
1	7.3.3	The recommendation to perform a side-by-side comparison of generic receptor scenarios to the assumed characteristics of the receptors should be limited to the performance period. If this comparison is necessary for other evaluation periods, then the suggestion should be explicitly made in the appropriate sections of the guidance and rule.
2	7.4	The site-specific conditions that warrant the performance analyses listed in Figure 7-1 should be explicitly written into the guidance.
3	7.4	The use of “quantitative risk assessment” should be removed as a quantitative risk assessment is not warranted by the proposed rule. The caption in Figure 1 should be revised to read “Qualitative Analyses.”
4	7.4	The guidance to perform additional analyses with bounding values when reasonable averages are available is not reasonable. As stated in the guidance, bounded values, especially those that span many values, can result in illogical and impossible model results. These additional analyses would add nominal value if any to the assessment.
5	7.4.1.1.1	The required evaluations for screening of potential waste streams should be limited to site-specific and reasonably foreseeable radiation exposure pathways.
6	7.4.1.12	It is unclear what additional analyses can be performed to demonstrate 10 CFR 61.41(c) and 10 CFR 61.42(c) requirements will be met when the screening analyses results are unacceptable. This section requires far more explanation and context than what is currently included.
7	7.4.1.1.2	The section title, “Quantitative Analyses” should be renamed to “Qualitative Analyses” to remain consistent with the proposed rule. The content in the section should reflect the shift in the type of analyses required.
8	7.4.1.1.2	Additional content is needed to describe how the analyses in Chapter 6.0 can be applied to the performance period analyses, when there is no dose goal available. The crux of Chapter 6 is the minimization analyses, which includes leveling scale factors based on dosage goals for 10 CFR 61.41 and 10 CFR 61.42. Without a dose context for the leveling scale factor, viability of the design cannot be evaluated using the prescribed methods.
9	7.4.1.1.3	Additional time periods for analyses are presented, including the 500 year, Class C waste intruder barrier period. The Class C waste intruder barrier period is never explicitly referenced in the proposed rule and as such should be removed from consideration.
10	7.4.1.1.3	Performing cost analyses over multiple time frames is not justified, and these suggestions should be removed the guidance. Requiring cost analyses for time periods that pre-date the performance period does not align with the scope of the performance period analyses
11	7.4.1.2	The barrier analyses again models the defense-in-depth concept, requiring that multiple, independent, redundant barriers be included in the design and consequentially analyzed. Again, we do not see the merit in requiring

		a separate, independent, defense-in-depth analysis, when it is already woven into the requirements for the compliance period analyses.
--	--	--

CHAPTER 8

Summary Comment – Much of Chapter 8 is general language about the meaning and usefulness of defense-in-depth (DID) and is appropriate for inclusion even should the Commission adopt our recommendation that the requirement for a DID “analysis” be removed. However, section 8.3 is focused on analytical elements necessary for compliance, and is in need of extensive reduction and revision, if not complete elimination. Its description of analyses necessary to prove the efficacy of DID have not been shown to provide any additional protection for health and safety beyond that provided by preparing the other analyses required by the new regulations. In fact, the guidance itself, although inconsistently, implies the acceptability of this approach (relying on the other analyses) to some extent.

Many of the concepts of DID are misapplied in this document. We highlight a few merely to illustrate the point.

Independent Layers – The individual elements that provide defense-in-depth for a LLW site are by their very nature inherently independent. For example, the location of a site is dependent upon no other aspect of the design and operation of a site in terms of the protection it provides. A site that is distant from potentially affected populations or sensitive environments is protective by virtue of this distance and isolation. Should a container fail earlier than projected, the time for its contents to reach a receptor and provide a dose to the member of the public is increased by (among other things) this distance. The extent to which this distance mitigates or eliminates the potential hazard is determined by fate and transport modeling in the performance assessment. But the extent to which this proximity-derived protection can be diminished by some other aspect of the design or operation of the site is zero. The same is true for each of the other elements of the disposal system. There is no “analysis” necessary to demonstrate independence.

Redundant Layers – The concept of redundancy is misapplied in the guidance. In a more traditional application, e.g., a nuclear power plant, redundancy is important because there are certain systems that perform a function that is vital to maintain, thus the concept of duplication. If the principal method of keeping water in the core is lost, another – redundant – method is necessary because keeping the reactor core cooled is essential. It is not acceptable to simply default to relying on the containment to retain the release of radioactivity because the consequences of its failure are potentially very high. There is no comparably important system in a LLW disposal site and certainly no comparable risk in the event of failure.

There is not now and should not be imposed a requirement for redundancy of anything at a LLW site because there is no implicit need for redundancy per se. It is understood that there are varying times for which LLW must be isolated from the environment. For waste that decays quickly, this may be a very short time period. It is the role of the performance assessment to demonstrate that any given waste stream can be isolated from the environment for an adequate period of time. The components of the waste disposal system are evaluated to assess their contribution to this task and to ensure that the overall operation of the system is acceptable. There is no element of the system that is so essential that the risk of its failure is intolerable.

This is not to say that a given applicant or licensee should not be allowed to propose and take credit for redundant systems, e.g., multiple liners, at its discretion. However, there should be no requirement for an analysis that proves that redundancy has been incorporated into the design of a LLW disposal site.

Our complaint is not that it is unreasonable to expect an applicant or licensee to demonstrate that its disposal can be expected to properly isolate waste, operate safely, and demonstrate compliance with the performance objectives. Our complaint is in the requirement that a separate analytical exercise – a DID analysis – is necessary to demonstrate safety, or that an “analysis” is necessary to demonstrate that defense-in-depth has been accounted for in the siting and design of the site. In addition, we do not believe that a DID analysis was the direction given by the Commission in SRM-SECY-13-0075. Instead, the Commission directed that the rulemaking and guidance document include, “a clear statement that licensing decisions are based on DID protections.”

In section 8.3.2, staff states that:

In some cases, layers of defense may not be amenable to representation in one of the other 10 CFR 61.13 analyses.

We reject that logic. Layers of defense that cannot be accounted for in the other analyses should not be relied upon for demonstrating compliance.

Recommendation – *EnergySolutions* submits that this section requires extensive editorial revision and as such should be revised and published again in draft form for public comment.

CHAPTER 9

Summary Comment – A clear explanation of the hybrid WAC system is not presented in this Chapter. The process for using either the generic waste classification tables in 61.55 or the results of the technical analyses in 61.13 as a basis for the WAC is unclear, and the chapter is dense with unnecessary language. As previously noted, the distinction between the application of these two approaches is unclear in the regulation, and the guidance seems to indicate that these two options are not mutually exclusive. In fact, in reviewing this section of the guidance, we are not able to conclude that there is a way for an applicant or a licensee to choose to comply with the classification tables in §61.55 in lieu of developing WAC that would be used for regulating the site. We do not believe this is the intent of the revised regulations and we are not in agreement that this is reasonable. The two options are intermingled in the chapter so that the path for using one versus the other remains unclear (as is the case with the proposed rule.)

Recommendation – Outline the waste acceptance process clearly for each approach. We suggest that Chapter 9 be split out into two chapters, one dealing with using the old classification system and the other outlining the process for developing the WAC from the technical analyses. A section should be provided at the very beginning of the chapter that discusses the applicability of the new requirements to existing or new sites which desire to accept and dispose of newer waste streams with higher concentrations and quantities of long-lived radionuclides.

Provide a clear description of the waste acceptance process for sites that do not dispose of waste containing significant quantities of long-lived radionuclides. As with our companion comments on the proposed rule, the guidance should be revised to provide current and future disposal sites that do not dispose of significant quantities of long lived isotopes with the alternative to operate under the existing regulatory regime. The guidance should be revised to include a clear discussion of the process for such sites that does not include the preparation and regulatory review of extensive new technical analyses that provide no public benefit or improvement in human health and safety.

SPECIFIC COMMENTS BY SECTION

No.	Section	Comment
1	9.1	This section does not provide a clear distinction between the technical analyses required to generate site-specific WAC and those required to demonstrate compliance with the classification tables in 61.55. As stated above, everything discussed in this section should be specifically focused on one option or the other to eliminate confusion.
2	9.1.1.1	In general, the language in this section is not clear should be simplified as much as possible.
3	9.1.1.1	This section should include a more detailed summary regarding the development of allowable limits from the technical analyses. Clear guidance is missing, while obvious information is repeated (i.e. paragraph 1 of the section). A flow chart, similar to Figure 9-4 should be created to outline the documentation process for proposed waste classification limits determined using technical analyses in order to satisfy the requirements in §61.13 of the rule.
4	9.1.1.2	The first paragraph in this section includes statements that are in direct conflict with the regulations in 10 CFR Part 61 and are not appropriate for including in guidance. Take for example the last sentence in this paragraph: “Guidance on developing limits on radionuclides not listed in the waste classification tables is also provided in this section.” Given that the regulations impose no limits on nuclides not listed in the tables, but rather designate them as Class A waste, it is not acceptable that the NRC would issue guidance that essentially imposes limits on other nuclides.
5	9.1.1.2	Another issue with the language cited in the point above is that it creates a significant unintended consequence of the rule in that it fundamentally undermines the either-or (WAC or classification tables) approach that is created in §61.58. It is anticipated that in the process of developing a WAC to comply with §61.68, an applicant or licensee would have to create a matrix of nuclides, including concentration and inventory limits, that would go beyond the isotopes listed in the tables in §61.55. However, if the result of the new regulations is to require applicants and licensees who propose only to comply with the tables in §61.55 to also calculate limits for nuclides not listed in the tables, then what is the point of the tables? In fact, there would be no circumstance where an applicant or licensee <i>could</i> comply only with the tables. This is a fundamental

		change to the status quo that extends far beyond what is suggested by the proposed rule language or has been discussed by the staff in the many public meetings on the proposed rule.
6	9.1.1.2	The statement that existing limits “are not intended to provide reasonable assurance that all of the performance objectives are met” and that technical analyses might also be required for sites that rely on the current waste classification limits negate the purpose of retaining the current classification system. It could be argued that Part 61 licensees and applicants always have had to prepare analyses (a performance assessment by any other name) in order to demonstrate compliance with §61.41 (performance objective for the protection of the general population); but compliance with §61.42 (performance objective for the protection of the inadvertent intruder) <i>was</i> demonstrated by compliance with the classification tables. The suggested requirements in this section place an unnecessary burden on facilities that intend to rely on the current classification system and not dispose of long-lived radionuclides. A process by which the facilities can simply rely on the current classification system is needed in order to have a true hybrid system, otherwise there is no use for the current classification system. These comments should be eliminated and a discussion of a streamlined process for facilities relying on the existing classification system should be added.
7	9.1.1.3	The concept of “insignificant radionuclides” introduced in this section appears arbitrarily. There is no mention of this concept in the proposed rule and the concept is only implied, but not explicitly referenced in one other place in the guidance, under the Inadvertent Intruder scenario. The sum of radionuclide contribution concept is presented in the rule and Chapter 4 of the guidance. The definition of “insignificant radionuclides” should be added to the proposed rule and discussed in further detail in Chapter 2.
8	9.1.2	The two approaches for waste classification are again intermingled in this section, specifically regarding the applicability of stability requirements, wastefrom characteristics, and wastefrom test methods. As stated previously, these approaches should be discussed separately.
9	9.1.2	The three approaches for demonstrating stability requirements should be made obvious to the reader through edits such as highlighting, bulleting or some other mechanism.
10	9.2	The format of this section is easy to follow, and could be useful to help streamline other sections that have been noted to be unclear or wordy.
11	9.2	Another new term “significant radionuclides” is introduced that is not reference anywhere else in the regulation or guidance. It is suggested that the concept be discussed in Chapter 2.
12	9.2	Page 9-16 lines 20-22 state: “For waste acceptance criteria developed from the waste classification requirements specified in 10 CFR 61.55, <i>waste characterization methods should be commensurate with the assumptions and approaches</i> employed to develop the waste classification requirements.” As mentioned previously, these “assumptions and

		approaches” need to be presented and discussed in the document, since they are so critical to the use of the waste classification system. One example is provided later in the text but additional detail is required.
13	9.2.1.1	The use of the new term “significant radionuclides” appears again in this section.
14	9.2.1.1.1 and 9.1.1.2	We commend the staff for providing a clear delineation of the processes for using each different basis for the WAC in this section.
15	9.2.1.2	The content in this section should be divided into a discussion for waste classification and separate discussion for technical analyses.
16	9.5	Mitigation is a concept that is applicable to more than just the WAC. This section should be moved to Chapter 2 and a flowchart would help clarify the process.
17	9.5	This section refers to the updated technical analyses at closure, which we do not agree with. This section should be modified to explain circumstances when this requirement applies, which as when new unexpected conditions are identified at a site.