

RulemakingComments Resource

From: llwforuminc@aol.com
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To: RulemakingComments Resource
Subject: [External_Sender] Attached Please Find Comments re Proposed New 10 CFR Part 61 Rule (Docket ID NRC 2011-0012) from LLW Forum's Part 61 Working Group
Attachments: P61WG Comments re New Proposed Part 61 Rule Language - FINAL (7.22.15).pdf

To whom it may concern:

Attached please find comments from the Low-Level Radioactive Waste Forum (LLW Forum) Part 61 Working Group (P61WG) on the proposed rule to amend 10 CFR Part 61, *Licensing Requirements for Land Disposal of Radioactive Waste*, as published for public comment at 80 *Federal Register* 16,081 on March 26, 2015.

The LLW Forum is a non-profit organization of representatives appointed by Governors and compact commissions that seeks to facilitate state and compact implementation of the Low-Level Radioactive Waste Policy Act of 1980 and its 1985 amendments, as well as to promote the objectives of regional low-level radioactive waste disposal compacts.

In 2012, the LLW Forum formed the P61WG—which is comprised of representatives from the four sited-states of South Carolina, Texas, Utah and Washington, as well as a representative from the Commonwealth of Pennsylvania—to provide input from the states and compacts on the 10 CFR Part 61 rule making initiative.

Thank you in advance for your consideration.

Regards,

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P61WG Comments re NRC's Proposed Amendments to 10 CFR Part 61, Licensing Requirements for Land Disposal of Radioactive Waste, as Published for Comment at 80 *Federal Register* 16,081

The Low-Level Radioactive Waste Forum (LLW Forum) is a non-profit organization of representatives appointed by Governors and compact commissions that seeks to facilitate state and compact implementation of the Low-Level Radioactive Waste Policy Act of 1980 and its 1985 amendments, as well as to promote the objectives of regional low-level radioactive waste disposal compacts. In 2012, the LLW Forum formed the Part 61 Working Group (P61WG)—which is comprised of representatives from the four sited-states of South Carolina, Texas, Utah and Washington, as well as a representative from the Commonwealth of Pennsylvania—to provide input from the states and compacts on the 10 CFR Part 61 rulemaking initiative.

On March 26, 2015, the U.S. Nuclear Regulatory Commission (NRC) published a proposed rule to amend 10 CFR Part 61, *Licensing Requirements for Land Disposal of Radioactive Waste*, at 80 *Federal Register* 16,081 for public comment. On the same day, NRC also published a notice of availability of associated guidance, *Guidance for Conducting Technical Analyses for Low-Level Radioactive Waste Disposal*, for public comment at 80 *Federal Register* 15,930.

The P61WG developed and hereby submits for consideration by NRC the following comments in response to the Part 61 proposed rule and associated technical guidance document as published in the *Federal Register* on March 26, 2015.

SPECIFIC COMMENTS

The P61WG has identified the following areas of agreement with the proposed new rule language and offers the following comments with regard to proposed changes concerning intruder analysis, institutional control period, performance assessment, defense-in-depth, and site stability.

Areas of Agreement

The P61WG agrees with statements made by the NRC that the current 10 CFR Part 61 regulations ensure public health and safety at all the commercial low-level radioactive waste (LLRW) facilities and also supports the following *Federal Register* notice statements:

- “The regulations in 10 CFR Part 61 are risk-informed and performance-based, and ensure public health and safety are protected in the operation of any commercial LLRW disposal facility.”¹

¹ *Federal Register* notice dated March 26, 2015, “Low-Level Radioactive Waste Disposal,” (80 *Federal Register* 16,082), page 16,084.

- “Regardless of whether the assumptions regarding the LLRW, operational practices, facility design, or site characteristics of the reference LLRW disposal facility are consistent with current facilities, the NRC believes that the 10 CFR Part 61 LLRW classification system remains protective of public health and safety for the LLRW streams that were analyzed in the development of the regulations because of the reasonably conservative nature of the analysis used to develop the LLRW classification system.”²
- “Because of the conservative nature of the assumptions used in the original 10 CFR Part 61 regulatory basis to develop the LLRW classification, the LLRW classification system is expected to be protective of public health and safety as long as LLRW disposal facilities operate within the regulatory basis of the original 10 CFR Part 61 regulations.”³

In addition, the P61WG agrees with the following changes to 10 CFR Part 61 as proposed by NRC:

1. Revisions to the existing technical analysis for protection of the general population to include a 1,000 year compliance period and explicitly requiring a site specific analysis using modern dose methods.
2. Adding a new site-specific technical analysis for the protection of inadvertent intruders that would include a 500 mSv/yr dose limit.
3. Providing licensees and regulators flexibility by allowing waste acceptance criteria (WAC) to be developed using site-specific analyses for LLRW disposal of unique waste streams (based on the results of these technical analyses) or to continue using the existing LLRW classification requirements.
4. Use of the total effective dose equivalent (TEDE) in § 61.41 and the dose limit of 25 mSv/yr.
5. Allowing licensees the flexibility to use International Commission on Radiation Protection (ICRP) dose methodologies in a site-specific performance assessment.
6. The new requirement to redo performance assessments within five years of closure, provided no new additional sampling should be done (unless absolutely needed) and provided only updating:
 - the inventory; and,
 - equation values such as k_d and potential exposure scenarios appropriate to the specific location.

² *Federal Register* notice dated March 26, 2015, “Low-Level Radioactive Waste Disposal,” (80 *Federal Register* 16,082), page 16,099.

³ *Federal Register* notice dated March 26, 2015, “Low-Level Radioactive Waste Disposal,” (80 *Federal Register* 16,082), page 16,099.

Intruder Analysis

The P61WG offers the following comments and questions concerning intruder analysis considerations:

7. NRC has stated that there may be site-specific conditions that require licensees to assess disposal facilities beyond the compliance period even when long-lived waste is limited. This statement is not consistent with other NRC statements and inspection findings. NRC should state in detail what specific concerns they have with current sited state facilities that would require additional analysis beyond the currently accepted 500-year timeframe, associated with the current waste classification system, for the more traditional LLRW streams.
8. The inadvertent intruder assessment would be a new requirement under § 61.13 to demonstrate compliance with the performance objective to protect inadvertent intruders at § 61.42. The inadvertent intruder assessment would have to demonstrate that the annual dose would not exceed a proposed 500 mSv/yr limit over a newly defined 1,000-year compliance period. Current LLRW sites operating under current Part 61 regulations should not need to demonstrate protection of the general population from releases of radioactivity, and protection of inadvertent intruders using the 1000-year compliance period analysis, because the current waste classification system already ensures protection at 500 years. If use of the waste classification system ensures protection at 500 years, why is NRC requiring proof at 1,000 years for sites that are not going to accept non-traditional waste streams?

Institutional Control Period

The P61WG offers the following comments concerning the institutional control period:

9. As part of the defense-in-depth philosophy, NRC should allow Agreement States the flexibility to fund institutional control periods beyond the 100-year institutional control period. NRC should recognize the need for a “passive” institutional control period beyond the first 100 years and for the remainder of the life of the facility. The timeframe for the institutional period should be established on a state-specific basis.
10. NRC should reconsider its argument that although the longevity of government may reasonably be assumed to extend beyond 100 years, the 100-year institutional control period is also tied to the possibility of bureaucratic error. Such an argument is unreasonable in light of the fact that 40 CFR 192.12 requires post-closure care and maintenance in perpetuity at reclaimed uranium mill sites.⁴ NRC should address the inconsistency between LLRW institutional control periods and perpetual institutional control periods required at uranium mill tailings facilities.

⁴ See also Appendix A to Part 40, “Criteria Relating to the Operation of Uranium Mills and the Disposition of Tailings or Wastes Produced by the Extraction or Concentration of Source Material from Ores Processed Primarily for Their Source Material Content,” and NUREG-1620, “Standard Review Plan for the Review of a Reclamation Plan for Mill Tailings Sites Under Title II of the Uranium Mill Tailings Radiation Control Act.”

Performance Assessment

The P61WG offers the following questions and comments regarding issues concerning performance assessments:

11. The uncertainties associated with the long period of performance assessment are large enough that it is very challenging to make a credible prediction about the long-term performance of the disposal facility (10,000 years and beyond). This will complicate the licensing process for any future commercial LLRW disposal facilities and currently operating sites that elect to only accept traditional LLRW streams. Therefore, the most appropriate action for the NRC would be to develop a new stand-alone § 61.60 or a new Subpart H for sites that propose to accept large volumes of long-lived radionuclides. (See the following sections for additional information.)
12. Provide the basis for defining long-lived waste as waste that contains more than 10 percent of its initial radioactivity after 10,000 years. Does this correlate to the annual dose limit of 500 mSv for the inadvertent intruder scenario?
13. The protective assurance period should be applied only to sites that pursue acceptance of large volumes of long-lived waste streams. This makes sense and ensures that the disposal of these new or previously unanalyzed waste streams would not present an unacceptable risk to future generations by minimizing radiation doses from the end of the compliance period until 10,000 years. In addition, the assigned dose stated in § 61.41(b) and § 61.42(b) for the protective assurance period is not clear. As stated in these paragraphs, the annual dose shall be below 5 mSv or a level that is supported as reasonably achievable. Is the 5 mSv an upper limit or are higher levels allowed if supported as reasonably achievable based on technological and economic considerations?
14. Establishing a three-tiered approach is not efficient, clear or reliable. Implementation of a three-tiered approach will place a significant burden on Agreement States, facility operators and generators without providing added safety protection. A two-tiered 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 more clear, efficient and reliable. A two-tiered approach out to peak dose will close the current gap for risks that increase for long-lived radionuclides.
15. Some sited states have concerns about revisiting the site performance assessment unless they opt to take significant quantities of long-lived alpha emitters (e.g., depleted uranium). The concept of requiring all facilities to redo the performance assessment, even when a state will not accept the new waste streams, brings in to question the cost/benefit of the action.
16. Section 61.13(e) seems to state that a performance assessment is only needed if a site is going to take long-lived alpha emitters.

Defense-in-Depth

The P61WG offers the following comments related to defense-in-depth considerations:

17. The proposed rule should include a clear (explicit) statement that licensing decisions are based on defense-in-depth protections. The extensive proposed text explaining the “safety case” and describing its attributes should be removed and provided in guidance. The proposed language is not clear (understandable), efficient, and will be very difficult to implement reliably. It is understood that explicitly identifying and describing the features of the design and site characteristics that provide defense-in-depth protection should be required. However, no specific new analyses beyond identifying and describing the features of the design and site characteristics that provide defense-in-depth protection should be required.
18. The revised regulations introduce a new term called the “Safety Case.” Safety Cases (SC) are, in their simplest terms, a collection of arguments and evidence showing that a facility can be sited, designed, constructed, commissioned, operated and shutdown/closed in a safe manner. A key component of the SC is the analytical safety (performance) assessment. The NRC equates the Safety Case to a Performance Assessment + Defense-in-Depth. Sited states will also be constrained by the state laws and regulations governing safety. Currently operating sites believe their processes (radioactive materials licensing, including a performance assessment and a site environmental review (e.g., National Environmental Policy Act (NEPA) or similar state laws)) will produce as robust a safety case.
19. Defense-in-depth information (e.g., several independent barriers) should be available in pre-operational documents for each site. For current sites, retrofitting may be extremely difficult if the site is dependent on only one or two robust barriers. For example, in Washington, the site operator buries radium sources, stabilized in concrete, in state-approved packages at depth in stable trenches.

Site Stability

The P61WG offers the following comments related to site stability considerations:

20. If a site accepts only LLRW that meets the current waste classification system (500-year safety standard), that site should be exempted from the NRC’s proposal to revise § 61.44 to specify that stability of the disposal site must be demonstrated for the compliance and protective assurance periods of 10,000 years.
21. NRC states, because NRC regulations already require a site stability analysis, the NRC does not anticipate any additional cost to the licensee resulting from the changes to § 61.44. The P61WG disagrees. Revised § 61.44, requiring stability for 10,000 years, is unreasonable. The NRC, the U.S. Environmental Protection Agency (EPA) and Congress (e.g., Uranium Mill Tailings Remediation 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.
22. The “Concepts” § 61.7 refers to 100, 300 and 500-year timeframes in multiple instances, but not timeframes on the order of thousands of years. Specifically, § 61.7(a)(2) for waste characterization requires that site characteristics should take into account the radiological

characteristics of the waste and be evaluated for at least a 500-year timeframe and § 61.7(f)(3) suggests that the effective life of an intruder barrier be at least 500 years. Section 61.7(f)(1) suggests that Class B and C waste forms or containers should be designed to be stable over 300 years. However, the language proposed in § 61.44 requires long-term stability of the disposal site for the newly defined compliance (1,000 years) and protective assurance (10,000 years) periods that are much longer timeframes.

The concept of stability for a period of 10,000 years seems incommensurate with the overall concept of near-surface disposal of LLRW given the constantly changing surface environment over time. Also, ensuring stability of surface soil in 10,000 years presents an obvious challenge, yet Class C waste can be buried up to 5 meters below the ground surface of a near-surface disposal facility in accordance with § 61.52(a)(2). In addition, engineered barriers for near-surface disposal have finite lifespans.

GENERAL COMMENTS

The P61WG offers the following comments regarding applicability of the proposed new requirements and policy considerations related to the Part 61 rulemaking initiative.

Applicability of the Requirements

NRC should consider the following comments regarding the potential impact of the new proposed rule language:

23. In the section titled, “Why do the regulatory requirements need to be revised?” as contained on page 16,087 of the *Federal Register* notice, one of the reasons provided is related to new waste streams that were not envisioned during the development of 10 CFR Part 61. These waste streams include, but are not limited to, depleted uranium from enrichment facilities, LLRW from U.S. Department of Energy (DOE) operations, blended LLRW streams in quantities greater than previously expected, and the generation of different LLRW streams that may result from new technologies. The concerns related to the disposal of these waste streams are not entirely applicable to all existing facilities. For example, only two of the existing facilities are candidates for the disposal of depleted uranium from commercial enrichment facilities or from DOE. Also, one of the disposal facilities disposes of all waste with intruder barriers so the “large scale blending of Class B and C concentrations of LLRW with Class A to produce a Class A mixture that could result in a dose to an inadvertent intruder that is above 500 mrem” would not be relevant. Since the waste streams described will be considered for future disposal, the associated new requirements should only affect those facilities that pursue these waste streams in the future.
24. For those sites that continue to use the existing classification requirements, any new requirements should be determined on a case-by-case basis and implemented through terms and conditions of the license consistent with the provisions in § 61.1(a). [Note: NRC’s recent explanation of § 61.1(a) purpose and scope is problematic. Section § 61.1 states 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 facility is sited, licensed and

operated under previous requirements would not necessarily be binding on either Agreement States or operators that, in good faith, committed to, and were licensed under, specific site conditions and licensing requirements. NRC staff interprets that this only applies to the early 1980's timeframe. NRC's new interpretation is changing those commitments and licensing requirements and adding burdens on Agreement States, operators and generators by changing the criteria for long-term operation, closure and decommissioning for a specific site as a form of back-fit. Without some form of grandfathering, Agreement States will be subject to significant burdens and future litigation risks.].

25. The applicability of the original rule published in 1982 was set forth in § 61.1(a) which states in relevant part, "Applicability of the requirements in this Part in effect on the effective date of this rule will be determined on a case-by-case basis and implemented through terms and conditions of the license or by orders issued by the Commission." Many of the Part 61 requirements were eventually applied through license conditions to near-surface disposal facilities in operation on the effective date of the rule, and the applicability was determined on a case-by-case basis as stated in § 61.1(a). This language afforded regulators of licensed disposal facilities the flexibility to consider when, and if, each facility should comply with the new requirements based on practical, economical and technical considerations.
26. Language is proposed to be added in § 61.13 requiring that technical analyses shall be submitted by all "[l]icensees with licenses for land disposal facilities in effect on the effective date of this subpart...at the next license renewal or within 5 years of the effective date of this subpart, whichever comes first." The case-by-case decision-making afforded by § 61.1(a) is thereby taken away in the proposed language of § 61.13. The proposed rule language should be clarified to reflect that the case-by-case application afforded by § 61.1(a) also applies to the proposed rule.
27. During a public meeting in Columbia, South Carolina on June 2, 2015, an NRC representative indicated that the language in § 61.1(a) was only intended to apply to the initial Part 61 requirements and not to subsequent revisions to Part 61. We disagree. That interpretation is not made clear by either the current or the proposed language. If available, the NRC should identify information in documents related to the original promulgation of Part 61 that supports this interpretation. We recommend providing explicit language to allow flexibility regarding subsequent revisions to Part 61 for licensed facilities with licenses in effect on the effective date of the original rule.
28. While the use of the term "case-by-case" may have been intended to refer to a facility, the proposed changes to Part 61 are the most significant since its promulgation and warrant flexibility for each requirement. It is unclear what flexibility exists in the applicability of the original and the proposed new Part 61 requirements.
29. NRC should also consider revising the language to clearly indicate that the applicability of individual requirements of the rule would be determined on a case-by-case basis. In support of this suggestion, please note that the current and proposed language "implemented through terms and **conditions** of the license" implies that the individual requirements of Part 61 may be applied separately since only a single **condition** of a license to require compliance with Part 61 as a whole.

30. The NRC should revise the language to indicate that “case-by-case” refers to each individual licensed facility and to each individual requirement. It is understood that many of the requirements of Part 61 are related. Therefore, the regulator would have to carefully consider how to individually apply the requirements of the regulation. NRC should structure the regulation to be amenable to individual application of requirements where practical. This could be accomplished by separating the proposed new requirements for technical analyses into a separate section, an appendix or a subpart.
31. NRC should allow flexibility in determining the applicability of the proposed requirements to waste already disposed and future waste disposal, taking into consideration established precedence, technical and economic issues, and the effect on overall site design.
32. Although many Part 61 requirements were eventually applied to waste disposal facilities that had licenses in effect on the effective date of the original Part 61 rule, the requirements were typically only applied to future waste disposal operations. For example, waste already disposed was not required to be evaluated to determine whether it may have been considered Class B or Class C waste under the then-new waste classification system. Such an evaluation was not considered necessary since a decision to apply new stability and intruder protection requirements to waste already disposed would likely be disruptive to the disposal system, result in an increase in dose to workers and potentially the general population, and create an unnecessary technical and economic burden for the licensee and the regulator.
33. The proposed language in § 61.7(f)(2) states that waste classified under § 61.55(a)(6) may not decay to acceptable levels in 100 years and safety is provided by limiting quantities and concentrations of the material consistent with the disposal site design. Such limitations on quantities and concentrations can only reasonably be applied to future waste disposals.
34. Similarly, § 61.7(f)(3) states that waste that will not decay to acceptable levels in 100 years “...must be stable and be disposed at a greater depth...” and “where site conditions prevent deeper disposal, intruder barriers such as concrete covers may be used.” For waste already disposed, classified under § 61.55(a)(6), and where site conditions prevent deeper disposal, the only option would be to use intruder barriers. The incorporation of such barriers into site design as a remedial measure could have negative consequences. For example, high integrity containers (special containers designed to provide stability) within the disposal unit have structural design requirements based in part on the overburden expected in the disposal environment. In this example, adding concrete barriers on the surface would be incompatible with the overall site design and could compromise the integrity of the high integrity containers. Also, for LLRW disposal facilities, one of the major activities is typically to install a final engineered cap as an engineered barrier and to enhance site stability. For one site, the final cap has been installed for the majority of the disposal area. Once the final cap is installed and the related drainage features of the site are designed, any modification such as adding concrete barriers would compromise the overall site design.
35. It is clear that, at the time of the initial promulgation of the requirements in Part 61, NRC recognized the need to allow for flexibility in applying new regulations to existing facilities by explicitly addressing its applicability to existing facilities in § 61.1(a). The language in § 61.1(a) aligns with the philosophy that waste disposed in good faith and in accordance with applicable

standards in place at the time should not necessarily be subject to new requirements that may be technically impractical and/or financially prohibitive. The reasons to adopt such a philosophy remain valid regardless of whether disposal facilities were able to eventually comply with some of the, then-new, requirements. The NRC should continue to adhere to this philosophy.

36. This philosophy is also evident in the following examples found in EPA's regulations:

Example One

EPA's 40 CFR 191, "Environmental Radiation Protection Standards for Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Wastes - Subpart B, Environmental Standards for Disposal" originally promulgated September 19, 1985: The applicability paragraph found at 40 CFR 191.11(b)(2) states that the Subpart does not apply to "Wastes disposed of before November 18, 1985."

The explanation for the decision not to apply the new rule to wastes already disposed can be found in the document, "The US EPA's Re-Promulgation of Environmental Standards for the Management and Disposal (40 CFR Part 191) Update 1990," by Raymond Clark, *et al.* The document, which can be found at <http://www.wmsym.org/archives/1990/V1/87.pdf>, states as follows:

As it was originally promulgated, 40 CFR 191 did not apply to wastes already disposed of. The various provisions of Subpart B were to be met through a combination of steps involving disposal system design and site selection and operational techniques. The agency believed that it was appropriate that subpart B apply only to disposal occurring after promulgation so that the full range of site selection and design controls could be taken into account in complying with this rule.

It is reasonable to apply the same logic to LLRW that has already been disposed. For existing LLRW disposal facilities and waste already disposed, site selection is fixed, disposal system design is either fixed or offers limited options for changes, and operational techniques may offer more options for changes but only for future disposals. Given these limitations, actions that have been taken prior to the effective date of the rule should be subject to new standards on a case-by-case basis.

Example Two

EPA's "Amendments to the Corrective Action Management Unit Rule," which can be found at <http://www.gpo.gov/fdsys/pkg/FR-2000-08-22/pdf/00-20534.pdf>: While the entire context of this rule is not relevant to the applicability of new requirements for LLRW disposal, the concepts applied regarding "grandfathering" are of interest. In providing an explanation for the flexibility offered by "grandfathering" certain corrective action management units, the EPA states that "...good-faith work has been done ..." and the "... imposition of the new requirements would be an inefficient use of a facility's and the agency's cleanup resources." (EPA also suggests using the proposed amendments as guidance.)

This idea is relevant in terms of an existing licensed LLRW disposal facility where both the licensee and regulator may have already expended resources in the development of a closure plan and, more significantly, in performing and completing activities associated with closure of the disposal facility, such as final cap installation and the construction of site drainage features.

Policy Considerations

The P61WG encourages NRC to take note of the following policy considerations:

37. If the NRC proceeds with the proposed rulemaking approach, it will likely make future site development much more difficult and it will:
 - Considerably change the dynamics of the site development process, including the ability of states and compacts to gain public support for the development of new LLRW disposal facilities. There needs to be a significant separation in the LLRW regulations between what is considered a traditional LLRW disposal facility (using waste classification tables to ensure safety after 500 years), and those facilities that intend to pursue the disposal of large volumes of long-lived radioactive wastes, in which the peak dose will not occur for tens of thousands of years.
 - Impact one of the most important arguments for both regulators and state officials, as regulators will no longer be able to inform the public that the vast majority of activity of the LLRW disposed at a facility will decay to a safe level that is only a fraction of its original activity within 500 years (1% of the original activity)—a statement the public can relate to and accept.
 - Adversely impact current operating sites that have no intention of accepting for disposal large quantities of long-lived radionuclides, such as large volumes of depleted uranium. Such action is unnecessary and burdensome, especially when one considers that NRC has already determined that public health and safety and the protection of an inadvertent intruder is adequately addressed by the current language found in Part 61, as long as the waste classification system is followed. If NRC moves forward with the proposed revision, it is likely that any new states considering the development of a traditional LLRW site may decide against it, as they recognize that the rules can change at any time to allow extremely different waste streams than were contemplated during the original public process.
38. Where practical, NRC should avoid the “one size fits all” approach in the development of new regulations or requirements for disposal of LLRW. For example, the design of the Pennsylvania regional facility requires an above-grade construction with multiple barriers (e.g., engineered cover, over-packs and disposal modules) and shallow land burial is prohibited. The facility design and other state-specific requirements would not allow disposal of large quantities of certain types of waste (low activity - high volume waste and depleted uranium) at a future facility in the Commonwealth of Pennsylvania. The regulations in Pennsylvania, as well as the regulations in the four current sited states of South Carolina, Texas, Utah and Washington, establish a concentration limit for disposal of Ra-226 at their regional facility.

39. It is extremely important that NRC maintain the current LLRW classification system in 10 CFR Part 61 and not remove it. Removal would present many challenges because the LLRW classification requirements are well integrated with other requirements of 10 CFR Part 61 as well as with some sited states' LLRW disposal requirements and as individual licensee programs. Complete replacement of the LLRW classification system would likely expand the effect of the rule revisions beyond the intended scope of this rulemaking.
40. The Regulatory Analysis of the proposed rule is inadequate because staff has significantly underestimated the burden and cost of implementation of the complex proposal on the Agreement States, operators and generators. The estimated costs (burden) of implementation are off by a factor of two or more.
41. The NRC fails to identify un-quantified liabilities created by the proposed language. It will also likely generate extensive litigation risk for existing sites as closure plans are implemented.

The NRC staff, in its goal to develop new requirements governing the 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 guidance documents. This extensive "how to" guidance, applied to all LLRW disposal facilities, is both unnecessary and overly restrictive. The discussion is wordy, not concise, rambling and ambiguous. Certain language used in the "Concepts" section of the regulation (e.g., "insights provide input for making regulatory decisions") is undefined, broad, unclear and ambiguous and therefore not appropriate language for a regulation. This language is more suitable for regulatory guides or the statements of consideration that should accompany the rule, not for the regulation itself.

The proposed new rule could have significant unintended consequences including the following: existing sites may consider early closure to avoid litigation risks incurred by the proposed rule amendments; the proposed rule will likely be a barrier for development of new sites for LLRW disposal; and, the burdensome and unnecessary new language included in the proposed rule may deter investment in new disposal capacity. The rule should not overlie the new set of requirements on existing sites that desire to continue to use and apply the existing Part 61 requirements.

PROPOSED ALTERNATIVE APPROACH: MAINTAIN CURRENT 10 CFR PART 61 REGULATIONS AS WRITTEN FOR TRADITIONAL WASTE STREAMS AND DEVELOP A NEW STAND-ALONE § 61.60 OR A NEW SUBPART H TO ADDRESS NEW UNANTICIPATED WASTE STREAMS

The P61WG provides the following analysis in support of keeping the 10 CFR Part 61 regulations as written for traditional LLRW streams, as well as retaining the current language in § 61.58 and its intended flexibility for NRC and Agreement States. In regard to waste streams that were not previously anticipated, the P61WG recommends that NRC develop a new stand-alone § 61.60 or a new Subpart H as more fully explained below.⁵

⁵ The State of Texas, which has already authorized the disposal of large quantities of depleted uranium at the Waste Control Specialists LLC facility in Andrews County, does not concur with the approach that is described in this section as advocated by the States of South Carolina, Utah, Washington and the Commonwealth of Pennsylvania.

Reasons to Keep the Current Part 61 Regulations as Written for Traditional Waste Streams

The P61WG believes that NRC should keep the current 10 CFR Part 61 regulations as written for traditional LLRW streams and should retain the current language in § 61.58 and its intended flexibility for NRC and Agreement States for the following reasons:

42. The principle basis used for setting the current 10 CFR Part 61 classification limits, LLRW characteristic requirements, and operational requirements, focused on limiting public exposures, as well as limiting exposure to an inadvertent intruder. Other considerations at the time included long-term environmental impacts, LLRW disposal facility stability, institutional control costs, and financial impacts. NRC has stated on numerous occasions that all four operating sites have been found to be in compliance with Part 61 and protective of public health and safety. This finding illustrates how valuable the current regulations are for safe disposal of LLRW. It is very important to keep Part 61 as written for traditional LLRW streams.
43. In its *Federal Register* notice, NRC stated that regardless of whether the assumptions concerning the LLRW regulations, operational practices, facility design, or site characteristics of the referenced LLRW disposal facility are consistent with current facilities, NRC believes that the 10 CFR Part 61 LLRW classification system remains protective of public health and safety for the LLRW streams that were analyzed in the development of the regulations because of the reasonably conservative nature of the analysis used to develop the LLRW classification system.
44. NRC's contention that the proposed rule will balance the consideration of the risks from the disposal of large volumes of long-lived LLRW with significant uncertainties that may be associated with long-term analysis is not necessary for sites that continue to only take the traditional waste streams allowed under the current classification system. Traditional sites follow the current regulations, and the protection of inadvertent intruders is demonstrated by compliance with the LLRW classification language (§ 61.55) and segregation requirements (§ 61.52, "Land disposal facility operation and disposal site closure"), and by providing adequate barriers to inadvertent intrusion.
45. The statement in the *Federal Register* notice that "the development of concentration limits by generic analysis or policy works well for countries that only have one disposal site" fails to properly acknowledge that the current system has a long history of success and has worked well for the four operational sites in the United States.
46. The current classification system establishes concentration limits for all of the LLRW sites. This approach involves using an analysis that demonstrates the safe decay of waste within 500 years, with regulator-derived concentrations and quantity limits for long-lived isotopes. This approach has been used successfully in this country and has the advantage of effectively mitigating the questions of long-term performance uncertainties, and ensuring the protection of public health and safety for present and future generations.

Proposed Alternative Approach that Addresses Traditional Waste Streams and the New Unanticipated Waste Streams

The P61WG recommends the following alternative approach to address the new unanticipated waste streams:

47. A Waste Acceptance Criteria (WAC) approach should be included. However, removing the current language in § 61.58 and its intended flexibility for NRC and Agreement States is not the most preferred approach. A new stand-alone § 61.60 or a new Subpart H should be developed that addresses use of the WAC approach and incorporates the following additional changes:
 - Section 61.7, “Concepts,” has been overwhelmed by an attempt to provide unnecessary and burdensome “how to” guidance in the rule. In general, the proposal is an overreach with inclusion of excessively prescriptive language taken from high-level radioactive waste (HLW) guidance documents that is not necessary for rulemaking and should be limited to guidance.
 - Similarly, § 61.13, “Technical Analysis,” has been overwhelmed with very prescriptive “how to” guidance in the rule. Section 61.13(e) is not clear and will be very difficult to implement in a contested case. Table A is unclear and subject to interpretation, which will place an unnecessary burden on states and operators.
 - Add a subsection to § 61.7, “Concepts,” to reflect the new structure and requirements in Part 61 governing acceptance and disposal of “the newer and additional waste streams” containing higher concentrations and larger quantities of longer-lived radionuclides. This would include reference to a new stand-alone § 61.60 or a new subpart H that would apply prospectively to new long-lived waste streams. It would specify the new incremental requirements and analyses that an applicant would need to complete in order to receive and dispose of the newer waste streams. The incremental requirements would be based on the proposed revisions to § 61.13, “Technical Analyses” (Performance Assessment), § 61.42 “Protection of Individuals to Inadvertent Intrusion,” and § 61.58 “Alternative Requirements for Waste Classification and Characteristics.”
48. NRC staff indicates that a currently operating site, or a new 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.” NRC further states as follows: “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.” This distinction does not appear to be clearly delineated in the rule changes. It is not clear how the regulator and operator would implement this approach. Moving this language to a new stand-alone § 61.60 or a

new subpart H would be efficient, effective and clarify that it applies only to any new waste streams accepted after the date of the new rule.

49. The proposed language in 61.58(a)(1) states that “Allowable activities and concentrations shall be developed from the technical analyses required by either 61.13 for any land disposal facility or the waste classification requirements set forth in 61.55 for a near-surface disposal facility.” The discussion of "Option 3. Hybrid waste acceptance approach" on page 16,100 of the *Federal Register* notice uses the term hybrid but then describes an "either/or" approach. NRC should clarify whether a WAC could be approved that proposes limits for individual radionuclides from both the results of the technical analyses and the waste classification tables, a true hybrid approach. (i.e., can the licensee pick and choose limits for each specific radionuclide from the waste classification tables **and** the results of the analysis carte blanche or does the licensee have to choose one **or** the other exclusively?).
50. As currently written, the proposed changes in paragraph 61.58(h) create at least four important concerns. First, it inappropriately predetermines the outcome of a decision about the use of waste acceptance criteria by using the phrase “will be approved.” Second, with the apparent certainty in the approval of the waste acceptance criteria, it limits flexibility and undermines the ability to exercise the option proposed by the hybrid approach, which allows for the continued use of the existing waste classification system. Third, it creates regulatory confusion by implying that with the approval of waste acceptance criteria, application of the waste classification system is unnecessary or even completely moot. Fourth, the reference to applying the criteria of § 61.23 is overly broad and should at least specifically exclude paragraph (h), which addresses financial surety, and is not directly tied to a determination of the approval of waste acceptance criteria. Additionally, given the proposed language in § 61.7, “Concepts,” regarding waste acceptance, the reference to using the criteria of § 61.23 is inconsistent. As described in § 61.7, waste acceptance is based on meeting the performance objectives and is not specifically linked to the criteria of § 61.23.
51. Notwithstanding the substantive comments above, the language in 61.58(a)(1) should be grammatically revised to move the word “either” and add the word “from,” as follows: “Allowable activities and concentrations shall be developed **either** from the technical analyses required by ~~either~~ 61.13 for any land disposal facility or **from** the waste classification requirements set forth in 61.55 for a near-surface disposal facility.”

COMPATIBILITY CATEGORIES, ADMINISTRATIVE COMMENTS AND RECOMMENDATION TO PERFORM REGULATORY AND BACK-FIT ANALYSES

The P61WG offers the following comments regarding compatibility categories and administrative issues. In addition, the P61WG recommends the performance of regulatory and back-fit analyses for the proposed rulemaking.

Compatibility Categories

The P61WG provides the following comments related to compatibility categories for the proposed rulemaking:

52. NRC and the host Agreement States should collaborate to determine an appropriate compatibility category and to minimize the potential for unintended consequences that could result from the implementation of the final rule.
53. Key revisions to Part 61 are designated as Compatibility Category B. Such a designation creates a conflict with Utah's existing depleted uranium performance assessment rule. In April 2010, Utah adopted a rule specifically addressing when a performance assessment is required for depleted uranium disposal, as well as the framework and nature of the performance assessment. The use of Compatibility Category B removes the flexibility that an Agreement State, such as Utah, needs in order to address state-specific needs and circumstances. For example, the proposed compliance period of 1,000 years is inadequate for a depleted uranium performance assessment. The certainty of progeny ingrowth requires a minimum compliance period of 10,000 years in order to determine compliance with the required performance objectives. The P61WG strongly encourages the Commission to offer the needed flexibility to the Agreement States by removing the Compatibility Category B designations in the proposed rule. While the 10,000-year timeframe may be workable, the breakdown between compliance period and protective assurance period should be left to the states with a minimum compliance period of 1,000 years.

Administrative Comments

The P61WG offers the following administrative comment related to the proposed rulemaking:

54. Changes are proposed for the language in § 61.28(a); however, there is no listing for § 61.28(a) in the "Proposed Compatibility Category for 10 CFR Part 61" on page 16,112 of the *Federal Register* notice. There is, however, a listing for § 61.28(a)(2) that also has proposed changes.

Regulatory Analysis and Back-fit Analysis

The P61WG encourages NRC to consider performing a regulatory analysis and back-fit analysis for the following reasons:

55. NRC should perform a rigorous cost-benefit analysis so that it fully understands the impacts of this important rulemaking on all affected licensees.
56. The NRC voluntarily performed a regulatory analysis and published Draft Regulatory Analysis for Proposed Rule: Low-Level Radioactive Waste Disposal (10 CFR Part 61) in February 2015. The NRC did not perform a back-fit analysis as described in 10 CFR 50.109. Neither a back-fit analysis nor a regulatory analysis is required by statute or regulation for 10 CFR Part 61. However, the NRC has been voluntarily performing regulatory analyses since 1976.

57. Although this regulatory analysis does provide assumptions of the estimated costs for implementation of revisions to Part 61, the estimated implementation costs presented are generic in nature and do not include site specific considerations that could substantially increase these costs. Also, there are potential additional costs that may not have been considered. These include, but may not be limited to, costs associated with procuring regulatory technical expertise required to review and comment on the performance assessments that utilize the new complex methods proposed, and costs associated with potential remediation activities at existing sites under the current Part 61 requirements.

NRC estimates that the regulators of existing facilities will need to expend substantial resources in implementing the proposed new requirements. Many states do not have the resources or expertise to review analyses that are substantially more complex than the current required analyses and will likely need to seek assistance from the NRC staff or private companies to perform the reviews. External review assistance is more expensive than internal reviews and most states do not have funds set aside for this. License fees could potentially be increased to support the more complex reviews, but license fees are typically set in regulation and would require legislative support to increase and therefore could not be guaranteed. It is our understanding that actual costs incurred by licensees that completed similar performance analyses (to meet state requirements for depleted uranium acceptance that are already in place), and those incurred by Agreement States reviewing the analyses, substantially exceeded the NRC cost estimates published in the Regulatory Analysis document. NRC should reconsider the basis for these cost estimates and publish updated information.

58. Given the significant costs to licensees, license applicants, and regulators associated with implementing the new proposed requirements, and considering that the proposed revisions represent the most substantial changes to Part 61 since its promulgation, the NRC should consider performing an expanded regulatory analysis, including a back-fit analysis. This analysis should assess whether the proposed revisions will provide for a substantial increase in the overall protection of the public health and safety at sites that will not accept these new unanticipated waste streams and at the sites that will take them and that the associated direct and indirect costs are justified by the benefits. In performing the expanded analysis, the NRC should address the pertinent items listed in 10 CFR 50.109(c).