



SECRETARY

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

September 8, 2017

COMMISSION VOTING RECORD

DECISION ITEM: SECY-16-0106

TITLE: FINAL RULE: LOW-LEVEL RADIOACTIVE WASTE DISPOSAL
(10 CFR PART 61) (RIN 3150-AI92)

The Commission acted on the subject paper as recorded in the Staff Requirements Memorandum (SRM) of September 8, 2017.

This Record contains a summary of voting on this matter together with the individual vote sheets, views and comments of the Commission.

A handwritten signature in black ink, appearing to read "Annette L. Vietti-Cook".

Annette L. Vietti-Cook
Secretary of the Commission

Enclosures:

1. Voting Summary
2. Commissioner Vote Sheets

cc: Chairman Svinicki
Commissioner Baran
Commissioner Burns
OGC
EDO
PDR

VOTING SUMMARY – SECY-16-0106

RECORDED VOTES

	<u>APPROVED</u>	<u>DISAPPROVED</u>	<u>ABSTAIN</u>	<u>NOT PARTICIPATING</u>	<u>COMMENTS</u>	<u>DATE</u>
Chrm. Svinicki	X	X			X	08/15/17
Cmr. Baran	X				X	02/01/17
Cmr. Burns	X	X			X	06/26/17

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary
FROM: CHAIRMAN SVINICKI
SUBJECT: SECY-16-0106: FINAL RULE: LOW-LEVEL
RADIOACTIVE WASTE DISPOSAL (10 CFR PART 61)
(RIN 3150-AI92)

Approved XX In part Disapproved XX In part Abstain _____
Not Participating _____

COMMENTS: Below _____ Attached XX None _____



SIGNATURE

08/15/17

DATE

Entered on "STARS" Yes No _____

Chairman Svinicki's Comments on SECY-16-0106
Final Rule: Low-Level Radioactive Waste Disposal (10 CFR Part 61)

I approve, in part, the draft final rule, subject to the following substantive revisions to the draft final rule and its subsequent publication as a supplemental proposed rule for a 90-day public comment period. The associated guidance documents should also be revised and should be made publicly available, concurrent with the comment period on the supplemental proposed rule. In light of the migration by the staff of significant technical detail regarding means and methods of compliance from the proposed rule to the draft final guidance documents, this concurrent public availability of the text of both draft documents will be necessary to inform public comment adequately and for the general awareness of interested stakeholders.

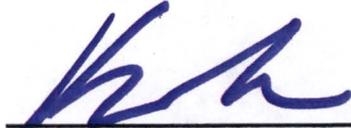
After a review of the record and while acknowledging the commendable effort the staff has put forward in adjudicating the divergent perspectives and broad range of disparate comments, I support this somewhat atypical procedural step out of concern that the integrated set of consequences and impacts to the United States' nuclear waste disposal system arising from the collection of discrete regulatory changes contained in the draft final rule is not sufficiently analyzed or completely understood. I also do not find a basis, within either the public comment record or the staff's regulatory analysis, for the proposed reversal by the staff of the Commission's previous policy direction on a number of foundational issues. The result, as noted by the Advisory Committee on Reactor Safeguards, appears to be a draft final rule that ensures consistency with agency safety goals, but does so in a way that adds "unnecessary complexity and burden."

Specifically, prior to its publication as a supplemental proposed rule, the draft final rule should be revised to incorporate the following changes:

- 1) Reinstate the use of a case-by-case basis (i.e., "grandfather provision") for applying new requirements to only those sites that plan to accept large quantities of depleted uranium for disposal;
- 2) Reinstate the 1,000 year compliance period from the proposed rule with a specific dose limit of 25 mrem/year and adopt a longer period of performance assessment (the period of which would be based on site-specific considerations and a "reasonable analysis," as defined in SRM-SECY-13-0075);
- 3) Clarify that the safety case consists of the quantitative performance assessment, as supplemented by consideration of defense-in-depth measures;
- 4) Modify the draft final rule text addressing defense-in-depth to narrow its consideration solely to providing additional assurance in mitigating the effects of large uncertainties that are identified during the performance assessment; and
- 5) Be informed by broader and more fully integrated, but reasonably foreseeable, costs and benefits to the U.S. waste disposal system resulting from the proposed rule changes, including pass-through costs to waste generators and processors.

The revised *Federal Register* notice prepared as a result of the direction in the staff requirements memorandum for this paper should be provided to the Commission for its information no later than 10 business days prior to its transmittal for publication.

I also support the proposal advanced by Commissioner Burns that the Commission modify its direction regarding the timing for the staff to prepare a regulatory basis for the disposal of Greater-than-Class C waste from the previous direction of 6 months after publication of the draft final rule to 6 months after the publication of the supplemental proposed rule.



Kristine L. Svinicki 08/15/17

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary
FROM: Commissioner Baran
SUBJECT: SECY-16-0106: FINAL RULE: LOW-LEVEL
RADIOACTIVE WASTE DISPOSAL (10 CFR PART 61)
(RIN 3150-AI92)

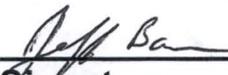
Approved Disapproved Abstain Not Participating

COMMENTS: Below Attached None

Entered in STARS

Yes

No



Signature

2/1/17

Date

**Commissioner Baran's Comments on SECY-16-0106,
"Final Rule: Low-Level Radioactive Waste Disposal (10 CFR Part 61)"**

The NRC staff has been working on a rulemaking to update the agency's Part 61 regulations on the disposal of low-level radioactive waste for nearly a decade. It is an important effort because the original rule promulgated in 1982 was based on technical assumptions that have proven inaccurate.

Thirty-five years ago, NRC did not consider the need to dispose of large volumes of depleted uranium because, at that time, private corporations were not permitted to operate the enrichment facilities that generate depleted uranium. As the staff explains, "Only very small quantities of depleted uranium were considered when the original regulatory basis was developed."¹ Yet, "all of the currently operating [low-level waste disposal] sites have disposed of thousands of metric tons of depleted uranium" and a large quantity of depleted uranium is slated for future disposal in commercial disposal facilities.² Unlike the radiological hazard posed by other Class A low-level waste, which "typically decreases relatively rapidly in the first 100 years after closure, the hazard from large quantities of concentrated depleted uranium increases for time periods far into the future."³ In fact, the peak radiological risk of depleted uranium occurs after a million years.⁴

Large-scale blending of Class B and Class C waste with Class A waste in order to produce a Class A mixture (or lower concentration of Class B or C waste) is also inconsistent with the assumptions underlying the original Part 61 rule. While the existing regulation was "developed with the assumption that only a fraction of the [low-level waste] being disposed would approach the [low-level waste] classification limit," the "result of the blending process would be to create large volumes of blended [low-level waste] that have concentrations near the [low-level waste] classification limits."⁵

Because circumstances have changed significantly over the past few decades, the existing Part 61 regulation allows for future situations in which the dose limits to protect the general public are exceeded "by a significant margin" and inadvertent intruders receive unacceptable doses of radiation from a disposal facility.⁶ The NRC staff concluded that the changes in the draft final rule are "necessary to ensure that the waste streams unanticipated when 10 CFR Part 61 was originally developed could be disposed of safely."⁷ In other words,

¹ Draft *Federal Register* Notice, Final Rule, Low-Level Radioactive Waste Disposal (Sept. 15, 2016) at 52.

² *Id.* at 37, 52.

³ *Id.* at 180. This is "because of the slow decay of uranium and the in-growth of progeny." *Id.* at 37.

⁴ Advisory Committee on Reactor Safeguards, Letter to Chairman Burns, "Review of SECY-16-0106, Proposed Final Rule 10 CFR Part 61, 'Low-Level Radioactive Waste Disposal'" (Nov. 14, 2016).

⁵ Draft *Federal Register* Notice at 16-17.

⁶ *Id.* at 16, 17, 54, 185. An "inadvertent intruder" is a "person who might occupy the disposal site after site closure and engage in normal activities, such as agriculture, dwelling construction, drilling for water and other reasonably foreseeable pursuits that might unknowingly expose the person to radiation from the waste included in or generated from a low-level radioactive waste facility." *Id.* at 255.

⁷ *Id.* at 63.

Part 61 needs to be updated in order provide the level of protection originally envisioned when the regulation was first issued in 1982.

The draft final rule would provide several additional health and safety benefits. It would enhance the protection of inadvertent intruders by requiring a site-specific inadvertent intruder assessment and establish a new inadvertent intruder dose limit of 500 millirem per year for the compliance period.⁸ The draft final rule would also require that "defense-in-depth protections be explicitly identified by the licensee to ensure that no single layer is exclusively relied upon for safety, to demonstrate that the protections are commensurate with the risks associated with the land disposal facility, and to increase confidence that the performance objectives are met."⁹ In addition, the rule would require licensees to use more up-to-date dose calculation methodologies instead of methods that date back to the 1950's.¹⁰

NRC received over 2,400 comment letters containing over 800 individual substantive comments on the proposed rule. A broad range of stakeholders, including public interest groups, Tribal governments, industry groups, licensees, and states, provided a wide array of often conflicting views. Based on these comments, the NRC staff made a number of significant changes in the draft final rule.

Many stakeholders commented that the three-tiered regulatory approach in the proposed rule was "more complicated than necessary and recommended using something simpler."¹¹ Some commenters also argued that it would be unfair to impose additional regulatory requirements on disposal facilities that did not plan to accept significant quantities of depleted uranium.

In response to these concerns, the staff developed a simpler two-tiered regulatory approach comprised of a compliance period and a performance period. Under the draft final rule, "the compliance period would be either 1,000 years or 10,000 years, depending upon the inventory and concentration of long-lived radionuclides disposed of at the land disposal facility."¹² The rule would require licensees to provide a technical rationale for using a 1,000-year compliance period and would require a performance period analysis only if a licensee uses a 10,000-year compliance period. As the draft *Federal Register* notice explains:

There is no health or safety basis to disregard waste that has been disposed to date while requiring analyses of similar waste that may be disposed in the future. However, if an existing site can demonstrate to the regulator that the amount of long-lived radionuclides that have already been disposed at the site is not significant, then the licensee would only be required to use a compliance period of 1,000 years.¹³

This balanced approach directly addresses the concerns raised by the commenters and avoids the need to require potentially costly additional measures in the site closure plan at the time of site closure.¹⁴

⁸ *Id.* at 25-29.

⁹ *Id.* at 21.

¹⁰ *Id.* at 48.

¹¹ SECY-16-0106 at 3.

¹² *Id.* at 3-4.

¹³ Draft *Federal Register* Notice at 52.

¹⁴ See Draft Regulatory Analysis for Final Rule at 4.

Many commenters expressed concern that the proposed rule would reduce health and safety protections. In response to this concern, the draft final rule would require licensees to limit doses to 25 millirem to any member of the public during the compliance period.¹⁵ This approach aligns with the current regulations of Texas and Utah, two Agreement States that regulate disposal facilities where licensees have indicated they would like to accept large quantities of depleted uranium.¹⁶

Some stakeholders argued that the proposed compatibility Category B for a number of key provisions limited the flexibility of Agreement States and would reduce the levels of protection currently provided by Agreement States that have more stringent requirements than those in the proposed rule. In response to this concern, the NRC staff switched to compatibility Category C for several important provisions. As a result of this change, "Agreement States that currently have more stringent requirements with respect to the compliance period will have the ability to preserve their approaches" and "implement their existing programs without any real or perceived reduction in safety."¹⁷

In my view, these three major changes all improve and strengthen the rule.

I am concerned that the NRC staff's guidance on how climate change should be considered in the required technical assessments states that licensees need not consider the effects of human-induced climate change. The staff acknowledges that climate change can affect hydrology, engineered barriers, and therefore water infiltration rates and the timing of radioactive releases. But then the staff concludes that "natural climate cycling and natural climate variability [are] sufficient to assess the potential impact of long-term human activity induced changes on a waste disposal system."¹⁸ Over a period of hundreds or thousands of years, scientists expect the impacts of human-induced climate change to be very significant. Relying solely on historical climate information may limit the reliability of the technical assessments designed to protect human health and safety. The staff should update the guidance in the future to address human-induced climate change.

The compliance schedule in the draft final rule also seems unnecessarily lengthy. The rule provides licensees up to six years to submit the required technical analyses and waste acceptance criteria. Because Agreement States have up to three years to adopt compatible regulations, low-level waste disposal facilities could potentially have almost a decade to comply with the requirements. The staff has not provided a convincing rationale for this timeframe. However, there are two practical constraints on the compliance deadlines. First, the rule requires licensees to make the necessary submittals at the next license renewal or within six years, whichever comes first. The licenses for the facilities in Washington and Texas expire in 2023 and 2024, respectively, so that creates a backstop for those facilities. More broadly, the compliance deadlines are listed as compatibility Category C, which allows the Agreement States to establish more stringent deadlines than those provided in the rule. Because the rule only establishes a floor on compliance deadlines and states can adopt more aggressive implementation schedules if they choose to do so, I am not proposing changes to the deadlines in the rule.

¹⁵ SECY-16-0106 at 4.

¹⁶ *Id.*

¹⁷ Draft *Federal Register* Notice at 69, 146.

¹⁸ *Id.* at 106.

Some commenters suggested that NRC should conduct a backfit analysis of the draft final rule even though Part 61 does not include a backfit provision. I agree with the NRC staff that it is not appropriate to conduct a backfit analysis where the agency's regulations do not provide for one. However, the staff did prepare a detailed regulatory analysis to examine the costs and benefits of the rulemaking.

For these reasons, I approve issuance of the draft final rule and publication of the *Federal Register* notice, subject to the attached edits. I am offering several edits to the rule language in order to ensure that the regulatory requirements are clear and enforceable. I appreciate the feedback I received from the NRC program staff and the Office of the General Counsel on these edits. In accordance with the Regulatory Flexibility Act, I also certify that this rule will not have a significant impact on a substantial number of small entities.

expects land disposal facilities that dispose of significant quantities of depleted uranium will require a compliance period of 10,000 years rather than 1,000 years. Further, the NRC's approach to analyses timeframes is suitable for depleted uranium because, though the impacts after 10,000 years would not be part of the compliance period calculation, they would be considered in the licensing process and a licensee must demonstrate that the impacts after 10,000 years have been minimized to the extent reasonably achievable. The new requirements limit the consideration of uncertainties associated with timeframes past 10,000 years.

This final rule balances the differing views associated with how impacts over very long time periods should be evaluated by having a maximum 10,000-year compliance period, followed by additional analyses beyond 10,000 years, when sufficient quantities and concentrations of long-lived radionuclides would be disposed. If the licensee can demonstrate that there is no significant long-term radiological impact that results from its inventory of long-lived radionuclides, then the licensee is only required to complete a performance assessment to 1,000 years.

L. What are WAC?

Licensees are required to propose, for ~~Commission~~NRC⁶ approval, criteria for the acceptance of waste. The revisions include a minimum set of requirements for determining waste that is acceptable for disposal. The revisions are necessary to ensure that the type of information included in the WAC is adequate to characterize the waste and certify its acceptability for disposal.

The NRC's original WAC can be found in subpart D of 10 CFR part 61, which specifies technical requirements for land disposal facilities for commercial LLRW. The technical requirements specify the classes and characteristics of LLRW that are acceptable for

⁶ For purposes of this statement of considerations, the term "NRC" or "Commission" or "NRC" is intended to include the Agreement State regulator, as appropriate.

inventory at future times. The "long-lived radionuclide" definition is designed to take this into account.

The concept of "defense-in-depth" has been implicitly used in LLRW regulations in the past, but was not explicitly defined in 10 CFR part 61. Defense-in-depth is implicitly provided through the various regulatory requirements. For instance, while § 61.59 imposes land ownership and institutional control requirements that are intended to limit the potential for intrusion into a closed land disposal facility, licensees may not take credit for these protections beyond 100 years when assessing whether the performance objectives will be met. The NRC's defense-in-depth approach to risk management ensures that safety is not wholly dependent on any single element of the design, construction, maintenance, or operation of a regulated land disposal facility. With the potential disposal of depleted uranium and other long-lived LLRW in near-surface disposal facilities, defense-in-depth takes on additional importance and it is now being defined and explicitly used in 10 CFR part 61 to demonstrate assurance that safe disposal can be achieved in light of the significant uncertainties associated with projecting doses far into the future. Defense-in-depth for a land disposal facility includes, but is not limited to, the use of remote siting, using waste forms and radionuclide content that limit radionuclide release, appropriate design of engineered features, and beneficial natural geologic features of the disposal site.

Regarding "safety case," Licensing decisions are based on whether there is reasonable assurance that the performance objectives will be met. The technical analyses are used to demonstrate that the performance objectives can be met. These analyses, together with defense-in-depth protections and the supporting evidence and reasoning for the strength and reliability of these analyses and protections, form the "safety case" for licensing a land disposal facility. The safety case must result in a conclusion that public health and safety will be adequately protected from the disposal of LLRW (including long-lived LLRW).

As a result of additional direction from the Commission in a staff requirements memorandum (SRM), SRM-COMWDM-11-0002/COMGEA-11-0002, "Revisions to Part 61," dated January 19, 2012 (ADAMS Accession No. ML120190360), the NRC published a second version of the preliminary proposed rule language (ADAMS Accession No. ML12311A444) for public comment (77 FR 72997; December 7, 2012). The NRC also published an associated regulatory basis document, "Regulatory Basis for Proposed Revisions to Low-Level Waste Disposal Requirements (10 CFR part 61)" (ADAMS Accession no. ML12356A242) at <http://www.regulations.gov>. The comment period ended on January 7, 2013; the NRC received 24 comment letters from private individuals, public interest groups, industry, and government organizations. Since these early comment periods were outside of the formal notice-and-comment rulemaking process, the NRC did not prepare responses to the comments received on the preliminary documents. However, the NRC did consider these comments in the development of the proposed rule and some of the comments did result in modifications to the preliminary proposed rule language.

In SECY-13-0075, "Proposed Rule: Low-Level Radioactive Waste Disposal (10 CFR Part 61) (RIN3150-AI92)," dated July 18, 2013 (ADAMS Accession No. ML13128A160), the NRC staff provided the Commission with a proposed rule package to amend 10 CFR part 61. The Commission approved the proposed rule in an SRM dated February 12, 2014 (ADAMS Accession No. ML14043A371), with additional Commission-directed changes. The NRC published the proposed rule for an initial 120-day comment period in the Federal Register (80 FR 16081) on March 26, 2015. During the public comment period, the NRC held seven public meetings and webinars to provide opportunities for public discussion on the proposed rule. The public comment period for the rule closed on July 24, 2015. After receiving multiple extension requests, the staff reopened the comment period by publication in the Federal Register (80 FR 51964) on August 27, 2015, and closed it on September 21, 2015. Commenters included individual members of the public, Tribal

Response: The requirements provided for LLRW disposal represent the key aspects of performing a performance assessment (e.g., consider uncertainties, provide model support, and develop scope). The requirements provided are not "how-to guidance;" they are the fundamental elements of a performance assessment.

Since the regulations for disposal of high-level waste disposal at Yucca Mountain were developed much more recently than 10 CFR part 61, some of the requirements do resemble high-level waste (HLW) guidance. However, the requirements are not HLW guidance; rather, they represent methods and techniques that have evolved since the 1980s and are used in waste disposal applications both nationally and internationally. ~~It does not matter what type of waste the performance assessment is applied to.~~ Some of the fundamental components of the analysis are the same regardless of what type of waste the performance assessment is applied to.

Section 61.7 provides a narrative context for the requirements that follow in the regulation. However § 61.7 does not provide specific regulatory requirements and therefore is not expected to produce a regulatory burden. Text was added or modified in § 61.7 to ensure consistency of the approach for the new regulations and the original 10 CFR part 61 regulations. Some text in § 61.7(e) has been revised for clarity. In addition, §§ 61.7 and 61.13 were streamlined to reduce the amount of detail in the rule. Important examples and recommendations are contained in NUREG-2175. Further, NUREG-1854 is not a HLW guidance document. It provides guidance associated with Waste Incidental to Reprocessing determinations, which use the performance objectives for LLRW (i.e., 10 CFR part 61 Subpart C).

~~Changes were made to the rule language as a result of these comments.~~

Commented [A1]: In several cases, this sentence is redundant because it follows a more detailed description of the specific changes made to the rule.

A.5 *Comment:* A commenter stated that the rulemaking should be limited to significant quantities of depleted uranium because the expansion of the rule will create an

Although no changes were made to the rule language as a result of this comment, the noted compatibility category changes were made.

B.5 *Comment:* Some commenters stated that the designation of Compatibility Category A or B was appropriate, particularly for the final performance objectives where they are primarily dose related. One of these commenters stated that the performance objectives have always been considered the primary criteria for LLRW disposal. Commenters also recommended that the final rule maintain greater consistency between the Agreement States, the NRC, and the DOE so as to create a consistency for waste classification, waste form, and waste manifest requirements. A different commenter stated that if these compatibility levels are not maintained, Agreement States would have the latitude to ignore these important changes and that human health and safety should not vary from state to state. The commenter further argued that it is important for the regulatory framework to clearly acknowledge that there can be only one scientifically-based standard.

Response: The "Compatibility of Agreement State Regulations" section of this document provides more detail on the meanings of the various compatibility category designations. Most of the performance objectives retain a designation of Compatibility Category A or Health & Safety (H&S). However, the NRC designated the objectives related to the performance period (§§ 61.41(b) and 61.42(b)) as Compatibility Category C. This designation is unchanged from the proposed rule (although the objectives for the performance period were listed as §§ 61.41(c) and 61.42(c) in the proposed rule). This flexibility allows the Agreement States to better maintain their existing programs without reducing the level of public health and safety that their programs already incorporate.

No changes were made to the rule language as a result of this comment.

B.6 *Comment:* A commenter recommended that the NRC and host Agreement States collaborate to determine the appropriate compatibility category to minimize the potential for unintended consequences that could result from the implementation of the final rule.

Response: The NRC included host Agreement State representatives on the 10 CFR part 61 rulemaking working group and also provided a draft of the proposed and final rule to the Agreement States for early comment. The NRC specifically asked for input from the Agreement States on the compatibility category designations. In addition, the compatibility category designations are reviewed by an NRC steering group that also includes a representative from the Agreement States. The Commission is informed of the interactions with Agreement States for consideration in making final compatibility determinations. No changes were made to the rule language as a result of this comment.

B.7 *Comment:* Some commenters identified that there was no proposed compatibility category for § 61.28(a) despite it being revised in the proposed rule.

Response: This was an oversight during publication of the proposed rule. Section 61.28 is being changed to compatibility category "H&S." This has been corrected, as indicated, in the "Compatibility of Agreement State Regulations" section of this document.

~~No changes were made to the rule language as a result of this comment; however, the compatibility category was changed as indicated.~~

B.8 *Comment:* A commenter requested that there be a discussion of what happens if an Agreement State does not agree to meet the compatibility requirements.

Response: All Agreement States are required to maintain a radioactive materials program that is adequate to protect public health and safety and is compatible with NRC requirements. The NRC has the oversight responsibility to ensure that Agreement States maintain adequate and compatible programs. The NRC implements this oversight responsibility through periodic reviews of each Agreement State through IMPEP. If the Agreement State does not meet the compatibility requirements, the IMPEP review team will likely make a recommendation to the Agreement State to take action to implement the necessary compatible requirements. Before all IMPEP reports and recommendations are finalized, they are reviewed by a Management Review Board (MRB) comprised of senior NRC management and an

In 1982, when 10 CFR part 61 was issued, several LLRW facilities had been open and operating for some time. For example, Barnwell had been open and accepting waste since 1971 and Hanford had been operating since 1965. At that time, LLRW disposal was regulated primarily under the "Waste Disposal" section of 10 CFR part 20, which then contained only §§ 20.301-305 (~~these were: General requirement; Method for obtaining approval of proposed disposal procedures; Disposal by release into sanitary sewerage systems; Disposal by burial in soil; and, Treatment or disposal by incineration~~). While the promulgation of 10 CFR part 61 was largely a formalization of most industry practices at that time, as well the result of years of study and work by NRC and its Agreement State partners, the regulations established a comprehensive regulatory scheme where before only a minimal scheme existed.

The rationale for the language found in § 61.1(a) can be found in the NRC's explanation and response to comments in the supporting documents for the original rule. As discussed in the 1981 Federal Register notice for the proposed regulations, the operational approaches introduced in the proposed regulations had, for the most part, already been implemented at existing facilities. With respect to applying the new regulatory scheme at existing facilities the NRC stated, "Existing disposal facilities should have no difficulty in complying with the waste classification and characteristics, manifest requirements, and the minimum requirements dealing with design and operations, environmental monitoring, closure, postclosure observation, and institutional control. Where existing operating sites have difficulty meeting any of the criteria, the Commission will consider the matter on a case by case basis" (46 FR 38086; July 24, 1981). The NRC understood that imposition of a brand new regulatory scheme on existing facilities might pose some issue-specific challenges and, as a consequence, included language in the "Purpose and scope" section to provide a path forward for relief, where necessary.

During the public comment period on the 1981 proposed rule, the NRC received many comments on a variety of issues, including comments regarding the applicability of 10 CFR part 61 to existing facilities. One concern voiced by commenters at that time was the

prospect of enforcement for immediate violation of the new requirements. The NRC addressed this concern in the comment response portion of the original regulatory basis for 10 CFR part 61: "Applicability of the rule to existing sites is a complex issue. The application of the requirements in the rule to existing sites was intended to be a case-by-case determination. The regulation was modified to clarify the applicability to existing sites and address concerns for instant noncompliance." Since 1982, the Agreement States regulating the existing facilities have all adopted State versions of 10 CFR part 61 and imposed the regulatory scheme on existing licensees through license conditions.

Thus, in adopting the original rule, the NRC anticipated that the concepts reflected in the regulations would pose few problems for existing facilities to implement; and, if such problems arose, § 61.1(a) would adequately demonstrate the NRC's intent that the application of the new regulatory scheme should allow for consideration of site-specific operational concerns. The statement in § 61.1(a) also clarified the NRC's intent regarding instant noncompliance—namely, that facilities operating prior to December 1982 should not be unnecessarily concerned about immediate enforcement. The text in § 61.1(a) was not a "grandfather clause," rather, it was a recognition of possible complications resulting from the transition to the new regulatory scheme.

Because the purpose of the last sentence in § 61.1(a) was to ensure existing facilities transitioned into meeting Agreement State versions of the new regulatory scheme as seamlessly as possible and without unintended ramifications like enforcement for instant noncompliance, and because the Agreement States that regulate existing LLRW disposal facilities have adopted state versions of 10 CFR part 61 and imposed the regulations on those facilities, that purpose has been satisfied. While the NRC is introducing a new set of requirements with this rulemaking, these regulatory changes do not approach the breadth and scale implicated through adoption of a new, ~~whole-cloth~~ regulatory scheme. Further, application of the new requirements on a case-by-case basis would be illogical given the underlying realities at all currently operating sites; because all currently operating facilities have accepted

waste not analyzed as a part of the original rulemaking for 10 CFR part 61, all these facilities need to develop the site-specific information contemplated in the final rule to ensure they will make informed decisions for future disposal activities and site management.

Accordingly, the NRC disagrees with comments that suggest that the language in § 61.1(a) is a grandfather clause or that a grandfather clause should be included in 10 CFR part 61. To eliminate future confusion over the purpose of the text in § 61.1(a) versus the applicability of the new regulations, the NRC is deleting the sentence, "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 and implemented through terms and conditions of the license or by orders issued by the Commission" from § 61.1(a) in the final rule. However, while the new requirements in this final rule apply to all new and currently operating land disposal facilities, any challenges in applying the new requirements can be addressed on a site-specific basis using applicable licensing or exemption processes.

~~The rule language was changed as a result of some of these comments.~~

B.10 *Comment:* Several commenters stated that the regulations should allow for flexibility in application and implementation, to allow consideration of historical practices, technical and economic issues, and the effect on overall site design and should only be imposed on future disposal activities. Some commenters noted that the facilities operating at the time that 10 CFR part 61 was issued had license conditions imposed on them to apply some or all of the regulations. One commenter raised a concern with the flexibility afforded by § 61.6, "Exemptions," and stated that if the Agreement State regulator were to grant an exemption to a licensee from any part of the new regulations then that action would be subject to NRC review as a part of the IMPEP process. Additionally, the same commenter noted that the language used in § 61.1(a) implies that, "the individual requirements of 10 CFR part 61 may be applied separately, since only a single condition of a license is necessary to require compliance with 10 CFR part 61 as a whole." Some commenters stated that the new requirements should only

~~Changes were made to the rule language as a result of these comments.~~

B.12 *Comment:* Some commenters were unsure if the new compatibility designations would apply retroactively to previously closed land disposal facilities, while others stated that the new regulations should not apply at all to previously closed disposal sites or facilities. One State with a closed land disposal facility stated that, "any proposed changes in the 10 CFR part 61 revision [should] not result in any increased costs with our ongoing monitoring effort for this facility or place any undue burden onto the state." Another commenter asserted that the new regulations should not apply to closed portions of a land disposal facility because meeting the inadvertent intruder standards would be technically and economically impracticable and the commenter was concerned that excavation of disposed waste would present a radiological risk to workers.

Response: The NRC agrees in part and disagrees in part with these comments. The commenters are concerned about the language in § 61.13 that states "[l]icensees with licenses for land disposal facilities in effect on the effective date of this subpart..." This language addresses licensees with licenses to operate land disposal facilities that are in effect on the date this rule goes into effect and does not apply to a closed land disposal facility that is either no longer accepting waste for disposal at the land disposal facility (i.e., the license does not authorize disposal of additional waste now or in the future) or is in post-closure care. Thus, the new requirements and the new compatibility designations do not apply to land disposal facilities that closed before the effective date of this rule.

The NRC does not agree that the new requirements should not apply to closed portions of still operating land disposal facilities. A "disposal site" is defined in § 61.2 as a "portion of a land disposal facility which is used for disposal of waste. It consists of disposal units and a buffer zone." A disposal site is part, or a portion of, a land disposal facility. In contrast, a "land disposal facility" as defined in § 61.2 is, "the land, building, and structures, and equipment which

technical rationale supporting selection of the 1,000-year compliance period is provided in NUREG-2175.

The definition for long-lived radionuclides is necessary to determine when the requirements for consideration of impacts beyond 1,000 years are needed. Otherwise, a licensee with a site that has a very minimal quantity of long-lived radionuclides would be required to perform a longer compliance period analysis as well as the performance period analysis. Thus, removing this definition would increase regulatory burden.

The NRC disagrees with the statement that long timeframes were not considered in the development of Class A limits. Class A limits contain values for both short- and long-lived radionuclides. When the Class A limits were developed, analyses were completed to 10,000 years and longer for the radionuclides in table 1.

The NRC has concluded that table A still has utility, but due to the potential for misinterpretation, it has been relocated to the guidance document where the appropriate limitations can be discussed in greater detail. Including table A in NUREG-2175 should lead to effective and consistent decision-making with respect to the need for the extended compliance period or performance period analyses. Inclusion of alpha-emitting radionuclides that are nontransuranic will ensure that depleted uranium is treated consistently with alpha-emitting transuranic radionuclides. The table values are protective for § 61.42 because the receptor scenarios used to develop the Class A waste concentrations are generally more limiting than site-specific receptor scenarios.

~~Changes were made to the rule language as a result of these comments.~~

C.2 *Comment:* A commenter asked for the technical basis for the long-lived radionuclide definition. A commenter indicated that long-lived radionuclides should be defined as done in § 61.55, table 1, which references a half-life greater than 5 years.

Response: The long-lived radionuclide definition was developed to assist licensees in determining if they may have significant quantities of radionuclides that persist longer than the

Executive Order 12770 (56 FR 35801; July 29, 1991) and that the table should not mix volumetric and mass-based units. The commenter also identified that the use of superscripts can create challenges. Another commenter expressed the view that it would be difficult to implement table A because of difficulty determining the appropriate concentrations and suggested that table A be moved from the regulation to guidance.

Response: The proposed table A has been removed from the final regulation and moved into the guidance in NUREG-2175. The appropriate radionuclide concentrations for comparison to table A values are the concentrations in the inventory projected over the compliance period. For LLRW without significant in-growth of radioactive progeny, the sum of fractions will be highest at the time of site closure. However, for radionuclides with significant in-growth of radioactive progeny, the sum of fractions could be higher during the compliance period and should be evaluated for the duration of the compliance period. In general, only decay and ingrowth need be accounted for (i.e., transport out of the disposal site need not be considered). Guidance on determining the radionuclide concentrations to compare to the table values is provided in NUREG-2175.

Per the commenter's recommendation, the proposed table A, now found in NUREG-2175, has been updated to incorporate metric units and the table format has been modified to reduce confusion associated with the use of superscripts and differing units.

~~Changes were made to the rule language as a result of these comments.~~

D. Safety Case and Defense-in-Depth

D.1 *Comment:* Some commenters supported including the concept of the safety case in the proposed regulation, including requirements for periodic updates to the safety case. A commenter recommended eliminating the separate safety case because it is unnecessary. Commenters who supported including requirements for a safety case argued it would provide a fuller view of site and disposal system understanding, help ensure that appropriate protections

Although the NRC intended for the draft guidance presented in the draft NUREG-2175 to indicate the level of quantification that the NRC expected, the NRC is revising the regulations to further improve the clarity of the requirements. Under the final regulations, strictly quantitative analyses are not necessary for demonstrating that defense-in-depth protections are provided at a land disposal facility. To accomplish this, the NRC has deleted the proposed § 61.13(f) and added a new § 61.12(o) to address defense-in-depth. Thus, the rule allows for a description of the capabilities of barriers (e.g., length of time a cover remains intact, retardation in the saturated zone, release rates from the waste) and does not require a strict quantification of the barriers' capabilities.

~~Changes were made to the rule language as a result of these comments.~~ The guidance in NUREG-2175 has also been revised to reflect these changes.

Commented [A2]: Move to the end of the prior paragraph.

D.3 *Comment:* Some commenters advised the NRC to provide or improve the definition of defense-in-depth in the regulations. Some commenters also specifically recommended that the NRC revise the proposed definition of defense-in-depth in § 61.2 and the defense-in-depth concepts in § 61.7(d) to include a more inclusive view of the term defense-in-depth. The commenters suggest that these revisions would be more consistent with the description of defense-in-depth discussed in the background and discussion sections of the proposed regulation and the accepted use of the term in the U.S. and internationally. Other commenters recommended deleting the phrase "defense-in-depth" from § 61.51(a) because the wording suggests that a site would have multiple layers or redundant systems built into the design; the commenters are concerned that this approach is a misapplication of the concept of defense-in-depth for a disposal site.

Response: The defense-in-depth principle has been a cornerstone of the NRC's regulatory framework for nuclear reactors, and it provides an important tool for making regulatory decisions in the face of significant uncertainties. Implementation of defense-in-depth protections, in the context of a land disposal facility, is consistent with the NRC's goal of

disposal unit below the land surface, hydrologic and geochemical characteristics). Diversity in the capabilities of the components and attributes of the disposal site and its design increases the resilience of the disposal site to unanticipated failures or external challenges and compensates, in part, for uncertainties in the long-term estimation of performance of the disposal site. Describing the capabilities of the disposal site protections can be accomplished by describing the applicable conceptual models and parameters used in the performance assessment. It does not require quantitative calculations beyond those performed to demonstrate compliance with the performance objectives. Description of the capability of the disposal site's protections provides an understanding of the disposal site that can increase confidence that the performance objectives are met. Multiple layers of defense must each make a definite contribution to the isolation of the waste, so that no single layer of defense is solely relied upon to achieve the overall safety objectives over timeframes of hundreds to thousands of years. Further, site design should ensure that incompatibilities between the site design features and other defense-in-depth protections are avoided that might result in the degradation or loss of significant safety functions.

The NRC has revised proposed §§ 61.2 and 61.7(d) in the final rule to reflect ~~the~~ differences in defense-in-depth between the operational and postclosure phases of a land disposal facility ~~may not allow for redundant layers of defense after closure of the land disposal facility~~. The revisions to § 61.7(d) also better align the description of defense-in-depth with the definition of a safety case in § 61.2, which is a broader collection of information than simply defense-in-depth and the technical analyses. No changes were made to § 61.51(a) as a result of these comments.

~~Changes were made to the rule language as a result of these comments.~~

D.4 *Comment:* Some commenters raised concerns about identifying defense-in-depth protections for existing land disposal facilities. Specifically, the commenters

indicated that retrofitting current disposal sites may be extremely difficult should they be dependent upon only one or two robust barriers.

Response: The requirements in 10 CFR part 61 are consistent with the principles of defense-in-depth and have been consistent since the rule was initially promulgated in 1982. For example, the technical requirements of subpart D specify site suitability requirements, site design and facility operation criteria, limits of waste concentrations, and institutional controls to name a few. Because 10 CFR part 61 has always contained principles of defense-in-depth (albeit not explicitly stated), currently operating land disposal facilities licensed under 10 CFR part 61 have defense-in-depth protections. The final rule codifies the explicit identification of defense-in-depth protections for a land disposal facility licensed under 10 CFR part 61. The rule does not stipulate a specific number of barriers; it requires a qualitative analysis. Identifying defense-in-depth protections that are commensurate with the risks and describing their capabilities and associated technical bases enhances confidence that the performance objectives will be met in the face of uncertainties associated with complex facilities and long periods of time after site closure for which the objectives must be demonstrated. Identification of the defense-in-depth protections is also important to inform licensees' operational activities (e.g., maintenance and monitoring) and improves the efficiency and effectiveness of the regulatory review by focusing on the significant defense-in-depth protections and their capabilities. Should licensees need to retrofit current land disposal facilities to enhance defense-in-depth protections, the difficulty would be dependent upon the risk that needs to be mitigated and the type of additional protection needed to mitigate the risk. Licensees would have flexibility to propose any additional protections, such as ~~(e.g.,~~ additional inventory limits), and the NRC expects that licensees would appropriately balance the level of difficulty to retrofit defense-in-depth protections and the magnitude of the risk that needs to be mitigated. NRC has included guidance on mitigation and levels above which additional defense-in-depth protections may be warranted in NUREG-2175.

differences in the treatment of radon within different regulatory programs, the NRC can ensure that the treatment of radon is internally consistent (within 10 CFR part 61) with the treatment of other radionuclides that may cause radiation dose to a member of the public.

No changes were made to the rule language as a result of these comments.

F. Dose Methodology and Limits

F.1 *Comment:* A commenter expressed concern that the proposed rule presented an insufficient consideration of sterility, genetic damage, and the impacts to future generations from exposure to radiation. The commenter noted that sterility has been observed in animal studies.

Response: The NRC's regulations set dose limits that are protective of public health and safety. No adverse health effects (e.g., cancer, genetic effects, etc.) have been observed that can be attributed to radiation exposures of 0.25 mSv (25 mrem) per year or less, ~~as discussed~~ later.

Sterility is a deterministic effect and large doses of radiation 3-5 Gray (300 to 500 Rad), which is roughly 3-5 Sievert (300 – 500 rem) for x- and gamma-rays, are required to induce permanent sterility. The regulatory limits in 10 CFR part 61 range from less than a ten-thousandth of these values (for the general population) to a thousandth of these values (for an inadvertent intruder). Therefore, the regulatory limits in 10 CFR part 61 preclude deterministic effects and significantly reduce the risk of induction of latent effects (e.g., cancer, genetic damage). From animal experiments, it is presumed that the *likelihood* of such latent effects will be induced by ionizing radiation and the frequency with which they are observed will increase with increasing exposure. This increase, however, has not been observed in these experiments. Additional information on biological effects from radiation exposure can be found in the NRC fact sheet at: <http://www.nrc.gov/reading-rm/doc-collections/fact-sheets/bio-effects-radiation.html>.

research that may have not been used or cited by the licensee, and in some cases perform independent modeling to evaluate the licensee's results. The technical analyses undergo thorough review before they are accepted.

No changes were made to the rule language as a result of these comments.

G.3 *Comment:* Some commenters expressed concern about the impact of climate change on the FEPs pertinent to assessment of a land disposal facility. A commenter sought clarification as to whether climate change needed to be considered if it was expected to occur after the required analyses timeframes.

Response: Climate change is a consideration in the technical assessment of LLRW disposal. Climate can influence a variety of FEPs potentially important to waste disposal sites, including, but not limited to, hydrology, engineered barriers, and receptor scenarios. Guidance was developed in NUREG-2175 to facilitate the consideration of changes to climate in the assessment. The guidance ~~currently discusses~~applies to natural variability and cycling of climate, ~~but the guidance will be updated in the future to address human-induced climate change.~~ Use of historical climate information is recommended where long-term climate data are needed.

~~Currently, the impacts of human-activity induced climate change are more difficult to quantify because the effects have not been "recorded" in the historical record.~~ For long timeframes (many thousands of years) the natural climate cycle is expected to result in significant changes from present day conditions. ~~For these longer timeframes, the NRC views natural climate cycling and natural climate variability as sufficient to assess the potential impact of long-term human activity induced changes on a waste disposal system. This guidance will can be revised, if as needed, as the impact of human activity induced climate change is better understood.~~

Further, ~~these~~ these technical analyses are not predictions of the future; they are used to test the performance of the land disposal facility against reasonably foreseeable challenges.

Consideration of previous climate states is expected to provide a basis for considering reasonably foreseeable climactic challenges while information about human activity induced climate change develops.

If the greatest impacts of climate change or any FEPs were expected to occur after the required analysis timeframe, only the portion of the effects that would be expected to occur during the analysis timeframe then it would ~~not~~ need to be included in the assessment.

No changes were made to the rule language as a result of these comments.

G.4 *Comment:* A commenter inquired if the proposed performance assessment analyses or stability requirements applied to existing sites to see if they complied with the requirements. The commenter specifically wanted to know if the older sites had been analyzed.

Response: The NRC did not analyze existing sites to see if they would comply with the new requirements. The NRC did perform technical analyses that were generic in nature to look at various technical requirements being considered in the rulemaking. All existing sites are located in Agreement States and those sites had to be analyzed when the facilities were licensed. The types of analyses that have been done by the Agreement State licensees, and the requirements for the analyses, vary. Some of the changes in this rulemaking were developed to ensure greater consistency between analyses and requirements within different Agreement States. Some Agreement States did perform analyses of the facilities they regulate and proposed modifications to the NRC's proposed requirements based on the results of their analyses. This rule applies to currently operating and future land disposal facilities and does not apply to closed land disposal facilities.

No changes were made to the rule language as a result of this comment.

G.5 *Comment:* Some commenters stated that some of the proposed requirements in § 61.13 were too detailed for the regulations and would be better contained in guidance. Other commenters identified specific requirements that they recommended should be eliminated or

~~Changes were made to the rule language as a result of these comments.~~

G.6 *Comment:* A commenter identified that there is an inconsistent use of language throughout the rule and guidance when discussing the different types of technical analyses. The commenter recommended that any subsequent discussion of such analyses should use identical language as used in § 61.13.

Response: The NRC agrees with this comment. The rule language and guidance document have been modified to address any inconsistencies within this rulemaking.

~~Changes were made to the rule as a result of this comment.~~

G.7 *Comment:* Commenters were concerned that the requirement in § 61.12(j)(2) that specify licensees must submit a description of the quality assurance program for the development of the technical analyses is overly broad and ambiguous and could create confusion in its implementation. The commenters suggested revising the language to clarify that the technical analyses are those required in § 61.13.

Response: Quality assurance is an essential element to the use of technical analysis to support long-term safety analysis. The regulator must review the licensee's information to determine if it is of acceptable quality. By reviewing a description of the licensee's quality assurance program, the regulator can better determine whether that licensee's technical analyses are of acceptable quality. Paragraph 61.12(j)(2) has been revised to clarify that the paragraph is intended to apply to the technical analyses in § 61.13.

~~Changes were made as a result of this comment.~~

G.8 *Comment:* A commenter indicated that while § 61.13 does not explicitly prescribe the analytical approach (i.e., deterministic vs. probabilistic), the regulatory agency will need to approve the approach selected by the licensee or applicant. The commenter appreciated the flexibility afforded by the requirements to consider uncertainty and variability over long time periods. A different commenter indicated that the NRC does not specify which model to use.

Response: The commenters are correct in that the NRC does not specify the particular approach that must be used to develop a technical analysis. Licensees may select, and must justify, the approach that is appropriate for their site-specific analyses. Regardless of the approach chosen by the licensee, the regulator will review the analysis to ensure it meets the requirements of § 61.13. In either type of analysis (deterministic or probabilistic) the likelihood of disruptive or other unlikely events can be considered. For instance, in a deterministic analysis of a disruptive event, the magnitude of the consequence may be generated and then the result multiplied by the probability of occurrence.

No changes were made to the rule language as a result of these comments.

G.9 *Comment:* Numerous commenters provided opinions about the requirement to update the technical analyses within 5 years of closure. Some indicated that this requirement was unnecessary and burdensome and that if the inventory of a site was not significantly changed from the design inventory, the requirement is unnecessary. ~~Others stated that analyses should be updated only if the inventory changed.~~ Some commenters indicated the requirement to update was useful under any circumstances because new information may have been generated that could be reflected in the final analysis.

Response: The NRC disagrees with the comments. If nothing has changed since the original analyses were performed, then the licensee may ~~simply~~ resubmit those analyses and indicate that none of the underlying information has changed. However, the NRC expects that land disposal facility licensees that actively pursue an understanding of the land disposal facility performance over time will observe changes in the licensing information used to support the technical analyses. Information from the updated analyses can also be used to support closure activities.

The updates to the technical analyses are intended to capture changes that may have occurred during operations. The requirement to update the analyses after closure is technically sound because it ensures that the disposal site is analyzed using the actual inventory that was

disposed and accounts for changes in the disposal site and surrounding area. Operational experience has shown that an analysis that was completed decades earlier is generally much different than an analysis completed today. Decades of monitoring and observation during operations provides site-specific information that can and should be used by a licensee to support or improve the prior technical analyses of the land disposal facility. It is natural that at the time of licensing there may be some uncertainties. The operational period can and should be used to develop information that can be used to update and refine the licensing analyses, including the consideration of uncertainties in those analyses.

No changes were made to the rule language as a result of these comments.

H. *Performance Assessment*

H.1 *Comment:* A commenter stated that a performance assessment, even for several hundred years into the future, cannot be regarded as a "prediction" of future disposal system behavior. Rather, a performance assessment is a hypothetical projection of possible behavior, based on reasonably conservative assumptions and simplifications. The commenter stated that this view reflects international consensus. Further, the commenter noted that these concepts and limitations on performance assessments are acknowledged in some of the Federal Register discussions but are not reflected in the regulatory language itself.

Response: The NRC agrees that the outputs of performance assessment models are not predictions; rather, they are estimates of system performance that are used to provide input for making regulatory decisions. Irrespective of how the results are described, the results of the analyses are used to inform safety decisions about current and future generations. For regulatory clarity, this type of contextual discussion of the interpretation of performance assessment results was included in the ~~in the~~ statement of considerations in the *Federal Register* notice rather than the rule text, which focuses on regulatory requirements. ~~The regulatory criteria do not require a "prediction" of future disposal site performance. Rather, the~~ ~~The~~

criteria require an assessment of disposal system performance considering FEPs, which represent a range of phenomena with both beneficial and adverse effects on performance, accounting for their likelihood.

No changes were made to the rule language as a result of this comment.

H.2 *Comment:* A commenter suggested use of language that replicates existing definitions (e.g., National Council on Radiation Protection and Measurements Report No. 152, page 18, or IAEA Specific Safety Guide (SSG)-23 on safety assessment) rather than developing new definitions. Some commenters were concerned that the proposed regulations did not use definitions that were developed through international consensus, including participation from U.S. regulatory agencies.

Response: The NRC considered the definitions in other publications and by international programs in development of the 10 CFR part 61 amendments. While not identical, the adopted definitions are reasonably consistent, at least conceptually, with these external definitions. "Safety assessment" is described in IAEA SSG-23, but it is very broad in comparison to NRC's definition of "performance assessment." For example, the IAEA SSG-23 description of "safety assessment" includes non-radiological issues and organizational and management aspects. The NRC defines "performance assessment" more narrowly than the IAEA defines "safety assessment." In the NRC's view, the science of performance assessment does not differ substantially for different waste types, and the definition of "performance assessment" in 10 CFR part 61 is consistent with NRC's definitions in other similar regulatory programs.

No changes were made to the rule language as a result of these comments.

H.3 *Comment:* Commenters stated that no definition is provided for "any member of the public." A commenter stated that the requirement should be restricted to a representative member of the public located in the general environment (i.e., outside the boundaries of the disposal system, including the buffer zone) of the land disposal facility. They indicated such an

implementation, the radiation standards, which are developed to minimize the lifetime risk, limit the annual exposure that an individual may receive. The member of the public is not limited by regulation to be an adult, though in many cases, for practical application, ~~it~~ is an adult. The radiological dose is a product of the environmental concentrations, transfer pathways, uptake rates, exposure times, and dose conversion factors. All of these factors must be considered together when evaluating radiological doses. For a common receptor scenario, such as the resident farmer, the exposure times and uptake rates are generally higher than most other receptors.

Flexibility in the exposure scenarios is warranted because of the potential for significant variability between sites. Therefore, the NRC has not provided a specific definition for any member of the public. However, NUREG-2175 has been clarified to provide a more detailed discussion of the interpretation of any member of the public.

No changes were made to the rule language as a result of these comments. However, the guidance for the rule has been changed as a result of these comments.

H.4 *Comment:* Commenters indicated that no definition is provided for the "general environment" in § 61.41(b), and requested that a definition be added in §§ 61.41(b) or 61.2 to clarify that the general environment means the area outside the boundaries of the disposal system and its buffer zone.

Response: The NRC agrees with the commenters and has added a definition of "general environment" to § 61.2.

~~Changes were made to the rule language as a result of this comment.~~

H.5 *Comment:* A commenter stated that there are no meaningful limits on the performance assessment. The commenter asserted that the NRC is allowing the waste site operator to choose his or her own allowable dose level and that dose limits are never verified or enforced.

Response: Dose limits for the compliance period are prescribed in §§ 61.41(a) and 61.42(a). Thus, it is unclear how the revision will not lead to an operator "choosing his or her own allowable dose level" during the compliance period.

The comment may have been intended to apply only to the performance period analyses, for which no numerical standard is specified in the regulation. This period occurs more than 10,000 years after site closure, a time period for which analyses were not always completed under the original 10 CFR part 61 and accompanying guidance. While the standards of minimizing releases and exposures (for §§ 61.41(b) and 61.42(b), respectively) do not contain numerical limits, requirements for the analyses are specified in § 61.13 and ensure that a licensee must provide an adequate technical basis to support its demonstration that releases and exposures are minimized to the extent reasonably achievable. The guidance in NUREG-2175 discusses how to complete and risk-inform the performance period analyses.

No changes were made to the rule language as a result of this comment.

H.6 *Comment:* A commenter indicated that although the regulation strives to protect both the general population and any member of the public, the rule language should be clarified. While the dose to any member of the public can be assessed against the performance objective of an annual maximum of 0.25 mSv (25 mrem), the population dose must be expressed differently. The commenter indicated that the term "general population" needs to be better defined in terms of the potentially affected population and stated the term "general population" is too vague.

Response: The NRC acknowledges that a population dose limit would be expressed differently (e.g., as person-rem) than the limit provided in § 61.41(a). However, the current rule does not include a population dose limit, and addition of such a dose limit is considered beyond the scope of this rulemaking. The general population is afforded protection through application of dose limits to any member of the public. See comment response H.3 for a response regarding protection of any member of the public.

No changes were made to the rule language as a result of this comment.

H.7 *Comment:* A commenter indicated that the language associated with the proposed § 61.13(a)(7) contained a mix of contaminant transport pathways and environmental media. The commenter also expressed concern that a list could become dated or limited as new processes and pathways are understood. The commenter suggested that the language could be included in the guidance instead and, if not, that more general language should be used.

Response: The NRC agrees that the cited language could be clarified, but has concluded that it should remain in the rule text. Paragraph § 61.13(a)(4) [formerly § 61.13(a)(7) in the proposed rule] has been clarified to make a better distinction between pathways and media. The revised text provides what are likely to be the most significant media and pathways while providing flexibility to consider other media and pathways as may be necessary.

[Changes were made to the rule language as a result of this comment.](#)

H.8 *Comment:* A commenter agreed with the addition of the proposed § 61.13(a)(8), which requires accounting for uncertainties and variabilities in the projected behavior of the disposal system (e.g., land disposal facility, natural system, and environment), but suggested this implies that the performance assessment is probabilistic. The commenter recommended that language be added to account for uncertainties and variabilities in the projected demographics and behavior of human receptors. The commenter stated that because the principal performance objectives for future humans is one of dose (or risk) to any member of the public (and to the general population), uncertainties and variabilities in the human element must be considered.

Response: There are multiple methods to assess uncertainties in a performance assessment as discussed in NUREG-2175. The regulations do not require probabilistic analysis, although that is generally the most direct approach to assess the impact of uncertainties.

The NRC agrees with the commenter that uncertainties and variabilities for demographics and behaviors should be included in the rule text. Paragraph § 61.13(a)(5) [formerly § 61.13(a)(8) in the proposed rule] has been revised to include this requirement.

~~Changes were made to the rule language as a result of this comment.~~

H.9 *Comment:* A commenter stated that it was not clear what purpose is served by the requirement in the proposed § 61.13(a)(10) to “identify and differentiate between the roles performed by the natural disposal site characteristics and design features of the disposal facility.” The commenter stated that the relevant aspects of both the site and the engineered features, as well as the interactions between them, are appropriately captured by requirements to consider relevant FEPs (or safety functions). The commenter stated that requiring further analyses and differentiation would impose redundant requirements and provide no value to risk-informed decision making and licensing—but would instead add confusion, especially since it implies the possibility of sub-system requirements.

Response: Section 61.13(a)(6) [formerly § 61.13(a)(10) in the proposed rule] is intended to ensure that the licensee understands what is driving reduction in risk from the hazard of the LLRW and that the licensee includes this information in its performance assessment. Although it is most important that the hazard is reduced irrespective of what is reducing the hazard, it is also important, and consistent with NRC’s defense-in-depth philosophy, that there is redundancy and resiliency within the disposal system. Here, the term disposal system is referring to the disposal site, general environment, and surrounding environment since in some instances the dose impacts may occur at points outside the buffer zone. This requirement does not specify that performance must come equally from engineered or natural system components, it simply requires the licensee to identify the roles that the various components play in reducing risk. This sort of information is vital in risk-informing the review process as discussed further in response to item D.3 in this section.

No changes were made to the rule language as a result of this comment.

affect the performance of the disposal system and there will be other FEPs that cannot affect performance (e.g., impacts from seawater corrosion on a disposal system in the Rocky Mountains). Unlikely events or a combination of events that cannot affect performance should be eliminated from the scenario-development process. However, the FEPs must first be identified or considered before any can be eliminated.

Further discussion on FEPs identification can be found in NUREG-2175.

No changes were made to the rule language as a result of this comment.

H.13 *Comment:* A commenter agreed with explicit references to site-specific analysis of FEPs, but suggested that rather than FEPs being used to define exposure scenarios, that the scenarios be included in the analysis itself — making it an analysis of features, events, processes, and exposure scenarios (FEPSs). The commenter stated that many exposure scenarios do not naturally result from an analysis of FEPs alone and are foundational in their own right — they deserve a place in the expanded acronym, FEPS. The commenter recommended that § 61.13(a)(1) be revised to include phenomena related to human exposures, as in FEPSs.

Response: The NRC agrees with the commenter that receptor scenarios are fundamental; however, the NRC does not agree that many scenarios do not naturally result from an analysis of FEPs alone. The natural evolution of a site is assumed to occur without human interference. The NRC's position is that it is too speculative to postulate on the effects of potential [future](#) human technologies and activities on the [evolution of natural systems site](#). Allowing the information and data gathered during characterization to develop scenarios of a site's future and then evaluate what receptor activities are plausible in those scenarios adheres to the NRC's position. At the same time, it is useful to allow licensees flexibility in the methodology used to meet the performance objectives as long as they provide technical basis for their approach.

assessment that indicate the regulation, at a minimum, needed further clarification to achieve an appropriate balance in the specification of exposure scenarios for the intruder assessment.

In setting the inadvertent intruder scenario requirements, the NRC seeks to balance a need to ensure a reasonable assessment of exposures that could occur, should an inadvertent intruder occupy a closed LLRW disposal site, and to avoid excessive speculation about the types of activities that humans may engage in far into the future. Constraining exposure scenarios is necessary because: 1) there is limited information available for estimating future human actions and the types of activities that an inadvertent intruder may engage in at times long after closure of the site; and 2) although institutional controls may be durable beyond 100 years, the prudent regulatory approach is to not rely on institutional controls to prevent inadvertent intrusion after 100 years in the inadvertent intruder assessment. The NRC has revised the rule language that was published in the proposed rule in § 61.13(b)(3)(i). The revised rule language, now found in § 61.13(b)(1) in the final rule, specifies that the inadvertent intruder assessment must assume an inadvertent intruder occupies the disposal site and engages in normal activities such as dwelling construction, agriculture, and drilling for water, in addition to other reasonably foreseeable pursuits that are consistent with the activities and pursuits occurring on and around the site at the time the assessment is developed.

Definitions in § 61.2 for inadvertent intruder and inadvertent intruder assessment were also revised to be consistent with the final § 61.13(b)(1).

The revised approach provides an appropriate balance between the need to evaluate the safety of LLRW disposal sites from inadvertent intrusion and the need to limit unnecessary and unsupported speculation regarding activities and pursuits that could occur far in the future and result in exposures to LLRW. First the revised regulations specify the inadvertent intruder assessment must include normal human activities, including, for example: dwelling construction, agriculture, and water well construction; these activities are expected to occur throughout the country. Although the proposed rule identified resource exploration and

exploitation as a normal activity, the final rule clarifies that licensees instead should consider construction and use of a water well because access to water is essential to most human activities. Exposure scenarios representative of normal activities would generally result in the exposure pathways of most concern. The NRC also recognizes that the manner in which the cited examples of normal activities (i.e., dwelling construction, agriculture, and drilling for water) are carried out may vary across the country depending on local practices and site characteristics or may not be physically possible at all sites. The NRC, however, agrees with the commenter that these activities are appropriate for inclusion as examples of "normal activities." The NRC is providing guidance in NUREG-2175 on acceptable approaches for determining receptor scenarios for normal activities that consider site-specific practices and conditions.

Second, the regulation also requires the licensee to consider other reasonably foreseeable pursuits; however, the activities need to be consistent with activities and pursuits in and around the site at the time the analysis is performed. The NRC has developed guidance in NUREG-2175 that provides licensees with acceptable approaches for developing inadvertent intruder receptor scenarios at a particular disposal site based on reasonably foreseeable pursuits in and around the site at the time the assessment is performed.

This approach for the specification of the exposure scenarios for the inadvertent intruder assessment provides protection for the inadvertent intruder. This approach ensures that the activities typical of human pursuits in various times and locations that generally involve the pathways of most concern (i.e., normal activities) and other activities consistent with the specific activities and pursuits occurring in and around the site at the time the inadvertent intruder assessment is conducted (i.e., reasonably foreseeable) are considered in the assessment, as appropriate, and without unnecessary or unsupported speculation. The NRC disagrees that terrorism-related receptor scenarios should be considered for protection of an inadvertent intruder. Terrorism-related events are intentional, rather than inadvertent, in that a terrorist

intends to sabotage a facility resulting in the dispersal of radioactive material. The NRC disagrees that unmonitored children need to be specified for consideration in an inadvertent intruder analysis because the NRC expects the normal human activities specified by the regulations will typically result in greater disruption of the land disposal facility and larger potential exposures to radiation from the waste than unmonitored children who may inadvertently intrude upon a disposal site. The NRC also disagrees that major natural events, such as those cited by a commenter (e.g., climate change, flooding, glaciers, volcanoes, earthquakes, and asteroid impacts) need to be specified for consideration in an inadvertent intruder analyses since the analysis is focused on exposures from intrusion events that could result in inadvertent exposures. However, the NRC provides acceptable approaches for developing inadvertent intruder receptor scenarios in NUREG-2175, which recommends that licensees consider the evolution of site characteristics over time when developing site-specific inadvertent intruder scenarios. Also, the NRC requires consideration of FEPs, such as those cited by the commenters, in the performance assessment to demonstrate protection of members of the public, in so far as the omission of the FEPs would significantly affect meeting the performance objective specified in § 61.41.

Changes were made to the rule language as a result of these comments.

J.4 *Comment:* A commenter stated that the requirement for an inadvertent intruder assessment to consider uncertainty and variability in the proposed § 61.13(b)(3)(iii) was vague and asked for clarification of what is required to be considered.

Response: The NRC agrees and has revised the proposed § 61.13(b)(3)(iii) [§ 61.13(b)(3) in the final rule] to clarify that the intent was to account for uncertainties and variability in the projected behavior of the disposal site and general environment.

~~Changes were made to the rule language as a result of these comments.~~

J.5 *Comment:* Some commenters stated that requirements proposed for the inadvertent intruder analyses in the proposed § 61.13(b) were vague or circular and added little

value. The commenters recommended deleting the proposed requirements that specified the inadvertent intruder analyses should demonstrate that the WAC are met and that adequate barriers to intrusion are included.

Response: Proposed § 61.13(b) would have required that the inadvertent intruder analysis demonstrate that the WAC developed in accordance with § 61.58 will be met, that adequate barriers to inadvertent intrusion will be provided, and that any inadvertent intruder will not be exposed to doses that exceed the limits set forth in § 61.42. The first two proposed requirements were analogous to requirements present in the original rule. However, the NRC agrees with the commenters that the proposed requirement to demonstrate that the WAC are met adds little value because § 61.58 also requires that the WAC comply with the performance objectives, which require licensees to conduct the analyses specified in § 61.13. The NRC also agrees that the proposed requirement to include adequate barriers to inadvertent intrusion added little value because the requirements for the inadvertent intruder assessment also require licensees to identify adequate barriers to inadvertent intrusion that inhibit contact with the waste or limit exposure to radiation from the waste and provide a basis for the time period over which intruder barriers are effective. Therefore, the NRC has eliminated those proposed requirements and revised § 61.13(b) accordingly.

~~Changes were made to the rule language as a result of these comments.~~

J.6 *Comment:* One commenter proposed removing the term "adequate" to describe barriers to intrusion in the requirements for an inadvertent intrusion assessment, specified in the proposed § 61.13(b)(3)(ii) because no criteria were provided to judge the adequacy of barriers.

Response: The adequacy of inadvertent intruder barriers are demonstrated in the inadvertent intruder assessment. The barriers must either inhibit contact with the waste or limit exposure to radiation from the waste. Therefore, the NRC agrees with the comment that

"adequate" does not add value to the requirement and has deleted the term "adequate" from what was proposed in § 61.13(b)(3)(ii) [§ 61.13(b)(2) in the final rule].

~~Changes were made to the rule language as a result of this comment.~~

J.7 *Comment:* A commenter expressed reservations about the approach to demonstrating protection of inadvertent intruders and stated that the NRC should be more involved in specifying parameters.

Response: The NRC requires that technical analyses be submitted as part of a license application to demonstrate that the performance objectives will be met. Before granting a license, the regulator will conduct a thorough review of the technical analyses to determine whether the licensee has provided reasonable assurance that the performance objectives will be met. The review will involve independent evaluation of the licensee's justification for receptor scenarios and parameter values. If the regulator determines that inadequate parameters were used or not properly justified, the licensee will be required to correct them before the application is approved.

No changes were made to the rule language as a result of this comment.

J.8 *Comment:* A commenter sought clarification about the proposed § 61.7(c)(3) regarding inadvertent intruder analyses and whether the NRC's intent is to protect the inadvertent intruder from either directly contacting the waste disposed at a land disposal facility or the radiation emitting from the waste. Specifically, the commenter cites text that suggests an inadvertent intruder barrier is designed only to limit contact with the waste.

Response: The clear purpose of inadvertent intruder protection is to limit radiation exposures to an inadvertent intruder from the disposed waste should inadvertent intrusion (though considered unlikely) occur. However, the NRC agrees that the rule text can more clearly specify whether an inadvertent intruder barrier is intended to limit: 1) direct contact with the waste; 2) exposures to radiation, directly or indirectly, from the waste; or 3) both. Although the proposed § 61.7(c)(3) only references barriers limiting direct contact with the waste, the

definition of an intruder barrier includes limiting contact with the waste and exposures to radiation from the waste. Therefore, the NRC has revised the final § 61.7(c)(3) to be consistent with the definition of an intruder barrier.

~~Changes were made to the rule language as a result of this comment.~~

J.9 *Comment:* A commenter recommended removing the word "individual" from the proposed § 61.23(c) to be consistent with other uses of the term "inadvertent intruder."

Response: The NRC agrees and has deleted the word "individual" from the final § 61.23(c) because the definition of the term "inadvertent intruder" is a person and "individual" is not needed.

~~Changes were made to the rule language as a result of this comment.~~

K. *Stability*

K.1 *Comment:* A commenter stated that if a site accepts only LLRW that meets the original waste classification system, which the commenter referred to as a 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.

Response: The regulatory requirement for an inadvertent intruder barrier for 500 years does not mean that there is a 500-year safety standard applied to LLRW disposal. The timeframe over which traditional LLRW can pose a risk to a member of the public can extend well beyond 500 years depending on the radiological composition. For example, disposal of depleted uranium would be acceptable under the current waste classification system; however, a 10,000-year timeframe is appropriate to evaluate site stability for disposal of significant quantities of depleted uranium.

No changes were made to the rule language as a result of this comment.

1978, large quantities of mill tailings had been ~~relatively unmanaged or~~ not well-managed.

Because of the large quantities of mill tailings, long-term safety and stability had to be balanced with financial practicality when developing the new standards under UMTRCA. In the almost 50 years since UMTRCA, technology has advanced significantly. This is not to imply that the UMTRCA criteria are inappropriate for management of uranium mill tailings but rather that the regulatory criteria for a remediation-type or long-term institutional control management-type action may differ from those of a future disposal authorization. The NRC has developed NUREG-1623, "Design of Erosion Protection for Long-Term Stabilization," August 2002, to facilitate design of long-term erosion protection covers, including rock scoring procedures. Chapter 5 of NUREG-2175 discusses other considerations relevant to long timeframes. In addition, advances in computing power have allowed the development and application of complex geomorphological models. A detailed example is provided in NUREG-2175, Appendix E. If a facility is located in an unstable environment, then a licensee may not be able to demonstrate stability. However if a facility is located in a stable environment, then stability, especially using the performance-based approach as outlined in these regulations, can be demonstrated for the required timeframes. Long-term stability has already been demonstrated for some commercial LLRW disposal facilities in the United States.

Under the final rule, stability analyses beyond 1,000 years are only required if a site is disposing of significant quantities of long-lived radionuclides. Considering the recommended approach to site stability, the NRC disagrees that stability beyond 200 to 1,000 years cannot be demonstrated for compliance with § 61.44. Further, the NRC notes the standard for compliance with the performance objectives, given in § 61.40, is "reasonable assurance," and compliance does not have to be "proven," as suggested by the commenter. This analysis is not a prediction of future performance of the disposal site at a point thousands of years in the future, but instead is an evaluation based on the best available knowledge of the disposal site stability.

The definition of stability has been revised to emphasize that stability is evaluated in terms of being able to assess system performance and to eliminate the need for active maintenance to the extent practicable.

~~Changes were made to the rule language as a result of these comments.~~

K.3 *Comment:* Commenters referenced timeframes from § 61.7 as the basis for the idea that longer timeframes are not to be considered in 10 CFR part 61. Commenters stated that 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. Commenters stated that the concept of stability for a period of 10,000 years seems in opposition to the overall concept of near-surface disposal of LLRW given the constantly changing surface environment over time.

Response: The timeframes the commenters cite from § 61.7 are for managing the risk from short-lived radionuclides that dominate the initial hazard from traditional LLRW. The timeframes suitable for disposal of short-lived radionuclides are different than those suitable for long-lived radionuclides, such as depleted uranium.

The NRC agrees with the commenters that the surface environment can change over time, and that engineered barriers have finite lifespans. However, the NRC disagrees that these limitations justify reducing the requirements for stability. The approach based on technical analyses is designed to ensure that the land disposal facility and disposal site can safely manage the waste that is disposed. If the safety of the site cannot be demonstrated, then that site may not be suitable for the waste that is disposed or changes to the design or allowable inventory may be necessary.

No changes were made to the rule language as a result of these comments.

K.4 *Comment:* Commenters stated that predictions of site stability for 10,000 years (required in § 61.44) are subjective and filled with uncertainty. They agreed with the NRC that site stability is critical to achieving the performance objectives of § 61.41 and § 61.42. However,

performance objective (§ 61.44) contains the language "to the extent practicable." Because the regulations contain inherent flexibility, the NRC determined that the definition of site closure and stabilization, which has been unaltered from the original 10 CFR part 61, does not require revision.

No changes were made to the rule language as a result of these comments.

K.6 *Comment:* A commenter indicated that the proposed stability definition is self-referential and not particularly useful. The commenter had a variety of questions about the stability definition, including how stability and structural changes may be related to radiological safety. Further, the commenter indicated that the current definition was unclear and should be revised. Another commenter felt the stability definition should be expanded to include stability of the waste form and containers.

Response: The NRC agrees that the definition of stability in the proposed rule is self-referential and could be better clarified. The definition of stability has been revised in the final rule to address stability of the waste form and containers and relate stability to the performance objectives (radiological safety) as recommended by the commenters.

~~Changes were made to the rule language as a result of this comment.~~

K.7 *Comment:* A commenter stated that the language in the proposed § 61.7(f)(1) is confusing and contradictory. On the one hand it states that stability is a cornerstone of disposal and on the other hand it states that stability is not necessary (for some waste). The commenter noted that the language is confusing concepts associated with structural stability with concepts associated with water flow; they asserted that structural stability and water flow have little relationship and that the language belies a humid site bias for 10 CFR part 61.

Response: The NRC agrees that water infiltration is not the only relevant process related to waste stability. The concept section in the original rule explained that because of the radiological composition of normal Class A waste, there is not a separate waste form stability

requirement for this type of waste. Class A waste can be "unstable" and not pose a risk, unless it could lead to degradation of the overall performance of the land disposal facility.

Early failures of disposal facilities prior to promulgation of 10 CFR part 61 were driven by instability of the waste that led to structural deformation of the facility and increased water flow to the waste. While the increased water flow in those instances was not actual instability, it was a direct result of instability. That is why the two concepts are linked in the discussion.

Both waste activity and stability affect potential risk. Waste classification and stability are linked because if waste is unstable and the concentration of radionuclides is sufficiently high, then the instability of the waste would be a potential public health and safety concern.

The text in § 61.7(f)(1) has been modified to improve clarity.

~~Changes were made to the rule language as a result of this comment.~~

L. *Timeframes*

L.1 *Comment:* There were a diverse set of views provided on the NRC's proposed approach to analysis timeframes. The main messages in the comments associated with the timeframes were:

- 1) Most of industry, industry trade groups, and the DOE supported a 1,000 year compliance period but no longer-term analysis except for a qualitative assessment.
- 2) Most state regulators supported Compatibility Category C for timeframes expressing a desire to preserve current Agreement State approaches that are more restrictive than the NRC's proposed approach. The 1,000 year compliance period combined with Compatibility Category B was viewed as a weakening of standards for LLRW.
- 3) Some members of the public supported a 1,000-year compliance period but the majority did not. Of the members of the public that did not support 1,000 years, most recommended a minimum of 10,000 years to evaluate depleted uranium disposal.

No changes were made to the rule language as a result of this comment.

L.9 *Comment:* A number of comments associated with different aspects of the protective assurance period were received. A commenter expressed general support, while others expressed general opposition. One commenter that opposed the introduction of the protective assurance period stated that the protective assurance period would be cumbersome to implement and would not add to safety. Several commenters asked for clarification of the meaning of a "goal" or "target" value in the protective assurance period and one asked whether ALARA analyses would be expected to be used to increase or decrease the dose relative to a dose "target." Others asked for clarification of how "technical and economic considerations" should be considered relative to a dose target. Another expressed the view that expending additional resources to lower a projected dose below the target dose at long timeframes would be unethical. Some commenters expressed support for the 5 mSv (500 mrem) per year value of the dose target if the protective assurance period were to be retained, while another stated that the dose target should not be increased relative to the dose limit used in the compliance period. Others expressed concern that the requirement for "minimization" would be difficult to implement. Another commenter stated that stability requirements should not apply to the protective assurance period.

Response: As discussed in item L.1 in this section, the protective assurance period was not retained because of confusion associated with the dose target, as well as for other ~~reasons~~ ~~considerations~~. As a result, the NRC is not providing specific responses to these comments about the protective assurance period.

~~Changes were not made to the final rule language as a result of these comments.~~

L.10 *Comment:* A commenter stated that the rule must respond to the fact that LLRW containing long-lived radionuclides was not considered in the development of the LLRW classification tables. The commenter stated that this fact does not justify imposing burdensome regulatory requirements (extending beyond 1,000 years) for ordinary LLRW. The commenter

Response: The revised regulations permit licensees of near-surface disposal facilities the flexibility to develop WAC using the concentration limits in § 61.55 or the results of the technical analyses required in § 61.13. The NRC does not intend to limit a near-surface disposal facility licensee's options to one or the other of the two allowable methods. Rather, the NRC agrees that near-surface disposal facility licensees should be able to use a combination of the two methods. Therefore, the NRC has revised the proposed § 61.58(a)(1) by striking the word "either" to clarify that licensees are able to use a combination of the two methods.

Regardless of the method proposed to develop WAC, a licensee must conduct technical analyses to demonstrate that the performance objectives will be met. Reliance only on the concentration limits in § 61.55, which are designed to provide protection to an inadvertent intruder, may not be protective of the general population, depending on the waste disposed and site-specific conditions. The concentration limits were not intended to provide protection of the general population—where risk is typically affected by the total activity of certain radionuclides, which tend to be more mobile in the environment and migrate off-site. Development of additional waste concentration limits, such as the commenter advocated for an arid site, would still require licensees to perform technical analyses to demonstrate that the performance objectives would be met. However, relying on site-specific technical analyses to demonstrate the performance objectives will be met ensures that the safety decisions with respect to a current land disposal facility will be focused on the site conditions and actual inventory that is disposed at the site, rather than assumptions regarding a reference disposal site. Therefore, the NRC has not revised the rule to specify additional waste concentration limits.

~~Changes were made to the rule language as a result of some of these comments.~~

M.6 *Comment:* A commenter recommended clarifying the term "WAC" by using something like "site-specific WAC" to avoid confusion with WAC or guidelines that existing waste consignees (e.g., collectors or processors) had developed prior to promulgation of this rule.

are related to approval of the WAC and that demonstrating the WAC will meet the performance objectives is more appropriate. Accordingly, the requirement that was proposed in § 61.58(h) has been deleted.

~~Changes were made to the rule language as a result of these comments.~~

M.8 *Comment:* Some commenters commented on the process for approval of amendments to the WAC. These commenters were concerned that small changes to the WAC may result in an excessive burden on the licensee because the changes would require a license amendment and accompanying information, including technical analyses to demonstrate that the performance objectives would be met. The commenters recommended that the NRC revise the regulations to ease the potential burden on a licensee in the case where a change in the WAC would be minor.

Response: The WAC are important components of the safety case and defense-in-depth protections to demonstrate that the performance objectives will be met. Therefore, the NRC is requiring that changes to the WAC be subject to the license amendment process in 10 CFR part 61. Requiring changes to the license to account for changes to WAC ensures that the criteria receive an appropriate independent review and approval. Further, the license-amendment process ensures that changes are adequately documented to support analyses and licensing decisions over the remainder of the land disposal facility's lifecycle. To have greater flexibility, a licensee could request approval of WAC that are reasonably conservative, which would allow them to accept a variety of waste streams without further modifications to the disposal site while still demonstrating that the performance objectives can be met. The NRC expects that such an approach to develop WAC, though not required, would minimize the need for frequent or minor license amendments as a result of insignificant changes in waste streams. Alternatively, a licensee could request approval of a license condition that would permit the licensee to make minor changes to the WAC without the need for an amendment (e.g., identification of new waste streams that are essentially identical for the purposes of acceptance

to waste streams that have been specifically identified in the WAC and previously approved by the regulatory authority).

No changes were made to the rule language as a result of these comments.

M.9 *Comment:* A commenter cautioned that the proposed requirements at § 61.58(a)(2) were not likely achievable as written because, in general, waste requiring stability does not always meet the stability requirement specified in § 61.56(b), when it is shipped. Rather, a waste package may be emplaced in a concrete overpack that fulfills the stability requirement. The commenter recommended rewording § 61.58(a)(2) to recognize that stability requirements may be fulfilled completely by the actions of the disposal site or partially by the waste container (i.e., shipped package).

Response: The NRC agrees that the waste container used to ship the waste to the land disposal facility need not provide structural stability to meet the stability requirements in § 61.56(b). Rather, the disposal site may manage the waste once received such that stability is ensured upon emplacement in the disposal unit or, in some cases, at some time after emplacement. Section 61.56(b) has long recognized and acknowledged this possibility: "structural stability can be provided by the waste form itself, processing the waste to a stable form, or placing the waste in a disposal container or structure that provides stability after disposal." For cases where a licensee would ensure structural stability via processing or after disposal, the NRC would not expect the approved WAC to require waste packages to provide structural stability. To alleviate the commenter's concerns, the NRC has revised § 61.58(a)(2) to require that the WAC include any site-specific waste-form characteristics and container specifications that are necessary for waste to be accepted at a disposal site to demonstrate compliance with the performance objectives of subpart C of 10 CFR part 61, rather than requiring the waste to meet the stability requirements in § 61.56(b).

~~Changes were made as a result of this comment.~~

Currently, the definition of "waste" in § 61.2 indicates that transuranic waste is not LLRW, which would mean waste with transuranic nuclides in concentrations greater than 100 nanocuries per gram could not go to an LLRW facility without an exemption being granted by the disposal site regulator.⁸ Although the NRC did not delete "transuranic waste" from the definition of waste in § 61.2 as requested by a commenter, the Commission, in SRM-SECY-15-0094, approved the staff's recommendation to address transuranic waste in § 61.2.

No changes were made to the rule language as a result of this comment.

M.13 *Comment:* A commenter stated that giving licensees the option to choose either waste classification or WAC could create some confusion among waste generators and brokers in complying with the applicable waste classification and packaging requirements and may result in added oversight resources for monitoring incoming shipments.

Response: The disposal sites are currently able to set their own WAC; therefore, the responsible Agreement State regulators already have some experience reviewing WAC for their disposal sites. Although there are four disposal sites currently operating, the waste generators are often limited to a subset of those disposal sites by the LLRW Compacts. The NRC expects these waste generators will be able to develop effective procedures to work with this small number of available disposal sites.

No changes were made to the rule language as a result of this comment.

M.14 *Comment:* A commenter recommended requiring a licensee to prepare a report and provide the findings of the annual review requirement proposed in § 61.58(f) to the regulator so that the regulator could determine the adequacy of the licensee's implementation and determine any necessary revisions.

⁸ See Table 1 in 10 CFR 61.55, which allows waste containing transuranic nuclides in concentrations ~~less~~ greater than 100 nanocuries per gram to be disposed as LLRW.

been replaced in revised form in the final rule to maintain this idea as a guiding principle while making the requirement clearer.

~~Changes were made to the rule language as a result of this comment.~~

P.3 *Comment:* A commenter expressed concern that the proposed change from the language in the original § 61.50(a)(2) [§ 61.50(a)(1) in the proposed and this final rule] would make that requirement essentially meaningless. The original requirement was "The disposal site shall be capable of being characterized, modeled, analyzed and monitored." The commenter stated that the original requirement is a crucial requirement for an analysis-based approach. The commenter indicated that adding "To the extent practicable," to the existing requirement, weakened the requirement. Further, the commenter asserted that to qualify for a license, any LLRW disposal site should be capable of being characterized, modeled, analyzed, and monitored with the best available techniques. Sites incapable of meeting this requirement should not be eligible for land disposal of LLRW, and the requirement should not be weakened by adding the words "To the extent practicable."

Response: The NRC agrees with the position of the commenter and has removed the phrase, "To the extent practicable," from § 61.50(a)(1) in this final rule.

~~Changes were made to the rule language as a result of this comment.~~

P.4 *Comment:* A commenter expressed concern with respect to the language for consideration of site characteristics for at least a 500 year timeframe in the proposed § 61.7(a)(2). The commenter questioned how the consideration of site characteristics related to the compliance and performance period. Further, the commenter questioned the relevance of a 500-year timeframe to consider site characteristics if a performance assessment was looking 10,000 years into the future.

Response: The language in § 61.7 is part of the concepts section of the rule and indicates that the site characteristics should be evaluated "for at least a 500-year timeframe" as part of site selection. This is the minimum timeframe that a licensee must consider. Ideally, the

timeframes considered while selecting a site would be longer than the radiological hazard of the waste to be disposed. Because the different types of waste that may be disposed and the persistence of the hazard can be quite variable, the language "take into account the radiological characteristics of the waste" is appropriate.

As the commenter notes, the compliance and performance periods are longer than 500 years. As discussed in item L.12 in this section, § 61.50 distinguishes between minimum site characteristics and characteristics that are evaluated in terms of performance. Site characteristics must be considered for the compliance and performance periods, but only in the context of how they affect the ability of the site to meet the performance objectives. In contrast, the final § 61.50(a)(2) specifies certain minimum characteristics that a site must have for 500 years after site closure. The 500-year timeframe in § 61.7(a)(2) is consistent with this timeframe when considered as part of site selection.

No changes were made to the rule language as a result of this comment.

P.5 *Comment:* A commenter provided two editorial comments on the proposed § 61.50 as follows:

§ 61.50(a)(2)(ii): Change "which" to "that."

§ 61.50(a)(4)(i): Remove the superfluous phrase "Within the region or state where the facility is to be located."

Response: The NRC agrees with the comments. Both changes were completed to improve clarity and readability.

~~Changes were made to the rule language as a result of this comment.~~

P.6 *Comment:* Some commenters questioned the value of the specific requirements for site-suitability. These commenters argued that the section was unduly prescriptive and detailed for a performance-based approach. More importantly, they indicated that while such provisions were meaningful, complementary requirements to the table-based classification approach are unnecessary and are at odds with a truly risk-informed approach. These

a more comprehensive picture of both the benefits to be gained from the rule as well as the costs. A backfit evaluation would not consider costs to Agreement State regulators.

No changes were made to the rule language as a result of this comment.

R.7 *Comment:* Some commenters stated that 10 CFR part 50, "Domestic Licensing of Production and Utilization Facilities," and 10 CFR part 70, "Domestic Licensing of Special Nuclear Material," licensees should receive backfit protection from new requirements that have not been adequately justified. Another commenter stated that compliance with the requirements will be costly for disposal facilities and that such costs will be passed along to waste generators. Another commenter asserted that the NRC should have conducted a backfit analysis to quantify the impacts and safety benefits of the new waste acceptance requirements for waste generators, such as uranium enrichment facilities, as required by § 70.76, "Backfitting."

Response: The NRC disagrees with these comments. Specifically, the NRC disagrees with the assertion that the NRC should provide backfit protection to 10 CFR part 50 and 10 CFR part 70 facilities from costs that get "passed along" by land disposal facilities. The backfit rules in 10 CFR part 50 (§ 50.109, "Backfitting") and in 10 CFR part 70 (§ 70.76) apply to proposed rule changes to the regulations in those parts. Further, the changes to 10 CFR part 61 do not impose modifications of or addition to the systems, structures, components, or design of 10 CFR part 50 or 10 CFR part 70 facilities; the changes to 10 CFR part 61 do not require 10 CFR part 50 or 10 CFR part 70 licensees to modify the procedures or organization required to design, construct, or operate their facilities. Thus, the changes are not backfits. Finally, the backfit rule has never required the NRC to analyze costs to parties that may experience distributed, or "passed along," costs. The backfit rule requires the agency only to look at costs imposed on those licensees immediately affected by the rule changes.

No changes were made to the rule language as a result of these comments.

S. Other

S.1 *Comment:* A commenter indicated that certain terminology was used inconsistently in the regulation. For instance in § 61.7(a) the terms "disposal facility," "disposal site," and "disposal unit," are clearly defined, but the use of these terms throughout the remainder of 10 CFR part 61 seems to be inconsistent at times. The commenter suggested the text should be carefully reviewed to ensure consistency in the use of these terms. Similarly, commenters identified that the proposed rule language used the term "closure" inconsistently (e.g., "closure," "final closure," "site closure," "final site closure,") throughout 10 CFR part 61 and as a specific period in time, rather than a process as defined in "site closure and stabilization" in § 61.2. These commenters were not sure if these were meant to be interchangeable or were meant to identify different periods. The commenters recommended that if they were meant to identify different periods, the terms should be better explained, otherwise, consistent terminology should be used.

Response: The NRC agrees with the commenters' recommendations. The final rule language has been reviewed to verify that consistent terminology is used throughout. For other sections of 10 CFR part 61 that were not modified in this rulemaking, the NRC is deferring such word changes because of the limited scope of this rulemaking. The NRC expects that deferring additional consistency changes in other sections of 10 CFR part 61 until a later rulemaking will not impact the interpretation of the existing regulations.

[Changes were made to the rule language as a result of this comment.](#)

S.2 *Comment:* A commenter expressed concern with the 5-year timeframe stated in the proposed § 61.7(g)(3), which requires a licensee to stay at the site after closure of the site for post-closure observation and maintenance, given the much longer compliance period proposed by the rule. The commenter stated the language in the proposed § 61.7(g) is vague and the timeframe is not well defined and also questioned the nature and intent of the monitoring program in the original § 61.12(l). The commenter stated it would be better to use

content and the presence of plant species can be useful early indicators of changes in facility performance. NUREG-2175 provides additional information.

The NRC agrees that § 61.12(l) should be revised to ensure better alignment between this section and the monitoring definition and has revised § 61.12(l), accordingly.

~~Changes were made to the rule language as a result of some of these comments.~~

S.3 *Comment:* A commenter noted that the definition of "disposal unit" in § 61.2 still retained the phrase "For near-surface disposal the unit is usually a trench." This same statement was removed in the proposed rule from § 61.7(a)(2). The commenter wondered if this inconsistency was an oversight.

Response: The NRC acknowledges that the inconsistency was an oversight. The definition of "disposal unit" in § 61.2 has been modified to be consistent with the changes made to § 61.7(a)(2) by removing the phrase, "For near-surface disposal the unit is usually a trench."

~~Changes were made to the rule language as a result of this comment.~~

S.4 *Comment:* Some commenters detailed areas that they indicated should be expanded in the final NUREG-2175, such as 1) defining the range of performance variables for natural and engineered features of the land disposal facility and the range of degradation mechanisms and disruptive processes; and 2) specific guidance to assist the applicant and regulator as to what should be seen as a reasonable inadvertent intruder dose and public dose during the performance period.

Response: Section 61.13(e) specifies that licensees must assess how the disposal site limits potential long-term radiological impacts during the performance period if a 10,000-year compliance period is necessary. However, this requirement does not mandate that licensees must conduct a dose analysis during the performance period. The regulations permit licensees flexibility to assess the ability of the disposal site to limit long-term radiological impacts. NUREG-2175 discusses acceptable approaches to assess the long-term radiological impacts during the performance period. Similarly, NUREG-2175 discusses acceptable approaches for

justifying parameter values, such as parameters used to model natural and engineered features of the land disposal facility as well as the FEPs (e.g., degradation mechanisms and disruptive processes) that are included in the technical analyses. The NRC has reviewed the guidance to ensure that these areas are adequately discussed in the final NUREG-2175.

No changes were made to the rule language as a result of this comment.

S.5 *Comment:* Some commenters stated that the 10 CFR part 61 rule constitutes a major Federal action that would potentially allow significant quantities of long-lived radionuclides, including depleted uranium and GTCC waste, to be disposed of in a land disposal facility. These significant quantities of long-lived radionuclides were not included in the original regulatory basis for 10 CFR part 61. Therefore, the commenters stated it is incumbent on the NRC to prepare a supplement to the 10 CFR part 61 Environmental Impact Statement (EIS) for the proposed revision, setting forth and analyzing reasonable alternatives, as well as a no-action alternative. One commenter stated that the NRC should also consider the impact of the rulemaking on climate change, and impact to the minority populations and low-income populations (i.e., environmental justice).

Response: The NRC disagrees with these comments. No supplement to the 10 CFR part 61 EIS is necessary. An agency is only required to prepare a supplement to an EIS where new and significant information is discovered before completion of the major Federal action. Once final agency action is taken—in this instance promulgation of 10 CFR part 61—no supplement to an EIS is required.

~~_____The NRC does not need to prepare an EIS for this rulemaking. The EIS for 10 CFR part 61 was developed because the NRC deemed promulgation of the rule to be a major action significantly affecting the quality of the human environment. At that time, the NRC concluded that the most significant impact from promulgation of 10 CFR part 61 would be to the public and reasoned that, "variables and processes involved in LLW disposal are sufficiently complex that unmitigated impacts cannot be avoided," but also noted that the impacts were, "not ... caused by~~

the rule, but rather impacts which are considered beyond the capability of the rule to eliminate entirely." Given this acknowledgement—that 10 CFR part 61 did not actually cause the impacts of concern—the NRC's decision to prepare an EIS was voluntary. Imposition of a new regulatory scheme on existing licensees, including the development of technical criteria and performance objectives, could have resulted in a significant disruption to established practices used by the regulated community. Unlike promulgation of the original 10 CFR part 61, the current revisions do not impose new technical standards on LLRW disposal. Further, for this rulemaking, the NRC has developed an Environmental Assessment that resulted in a finding of no significant impact, obviating the need for an EIS.

Most NRC rulemakings are not major Federal actions that significantly affect the human environment and thus do not require the preparation of an EIS under National Environmental Policy Act (NEPA). Rulemakings do not specifically license activities. Rather an applicant for a license must meet the applicable regulations before they can receive a license. As a result, generally, it is not the NRC rulemaking that could significantly affect the human environment, but rather it is the licensing decision (e.g., issuance of a license or license amendment) under the NRC's regulations that could significantly affect the human environment. As a result, the NRC typically prepares a more detailed NEPA analysis as part of the licensing action.

The NRC conducts its NEPA analysis based on guidance from NUREG-1748, "Environmental Review Guidance for Licensing Actions Associated with NMSS Programs," (ADAMS Accession No. ML032450279). This NEPA analysis would typically address a broad spectrum of environmental impacts from the proposed action (e.g., air quality, environmental justice, etc.) on the affected environment.

No changes were made to the rule language as a result of these comments.

S.6 *Comment:* Some commenters stated that the NRC should address the chemical toxicity of uranium.

rule was published on March 26, 2015, for a 120-day public comment period that ended on July 24, 2015. On August 27, 2015, the NRC reopened the public comment period for the proposed rule and draft guidance to allow more time for members of the public to develop and submit their comments (80 FR 51964). The extended public comment period ended on September 21, 2015. The NRC received comment letters from Federal agencies, States, licensees, industry organizations, Native American representatives, public interest groups, and individuals. In addition, the NRC also held a series of public meetings to promote full understanding of the action and facilitate public participation.

No changes were made to the rule language as a result of this comment.

S.9 *Comment:* Some commenters expressed concerns regarding § 61.6, which allows the NRC to grant exemptions from the waste disposal requirements. In general, the commenters felt that exemptions should not be permitted and radioactive waste should be disposed of in a land disposal facility. Commenters also requested that the reference to § 61.6 in § 61.7(a)(1) be deleted.

Response: The NRC disagrees that exemptions should not be permitted. As stated in § 61.6, an exemption can only be granted if the regulator determines that the exemption "...is authorized by law, will not endanger life or property or the common defense and security, and is otherwise in the public interest." The commenters did not present any new information that would lead the staff to revise the regulations that allow for, on a case-by-case basis, the disposal of certain LLRW in other appropriate facilities that offer effective isolation from the public and the environment. The exemption process provides adequate protection of the public and the comments have not justified a change to this provision in the regulations.

The changes to 10 CFR part 61 do not affect § 61.6. The revision to § 61.7(a)(1) that references § 61.6 does not add a new exemption type or category, although it does make it clear that exemptions are available to be used for alternative methods of disposal. As a result,

the NRC did not remove the reference to § 61.6 in § 61.7(a)(1) as recommended by the commenter.

No changes were made to the rule language as a result of these comments.

S.10 *Comment:* A commenter recommended deleting the phrase "established on the license" in § 61.41(b) because the requirement is already in the rule.

Response: Section 61.41(b), as it was published in the in the proposed rule, was deleted in its entirety in this final rule as a result of other comments (see items L.1 and L.4 in this section); the comment is no longer applicable.

No changes were made to the rule language as a result of this comment.

S.11 *Comment:* A commenter recommended changing the term "groundwater" to "ground water" to be consistent with established NRC style.

Response: The NRC notes that the terms "ground water" and "groundwater" are used interchangeably throughout NRC's regulations. In 2009, the U.S. Geological Survey (USGS), Office of Groundwater, issued a technical memorandum (2009.03) indicating that USGS would begin using the term "groundwater." The NRC is using "groundwater" consistent with the USGS in this final rule. The NRC expects that not changing this spelling in sections of 10 CFR part 61 that are unaffected by this rulemaking will not impact the interpretation of the regulations.

~~Changes were made to the rule language as a result of this comment.~~

S.12 *Comment:* A commenter expressed concern that § 61.43 referenced the dose limit in the original § 61.41, but the NRC did not change that reference despite making changes to the structure of the proposed § 61.41. The commenter recommended that the cross-reference in § 61.43 to § 61.41 should instead directly incorporate the dose limit or cross-reference the appropriate 10 CFR part 20 regulations (e.g., §§ 20.1301 and 20.1302) because the section title of § 61.43 is "Protection of individuals during operations."

Response: As identified by the commenter, the NRC agrees that the changes to § 61.41 as written in the proposed rule introduced confusion regarding how to apply the reference to

§ 61.41 in the original § 61.43. This is in part because § 61.41 was broken into multiple items with distinct periods and limits and goals, all of which occur after operations are completed and thus would not normally apply to worker protection. Accordingly, the NRC has revised § 61.43 to directly incorporate the referenced dose limit. This revision does not change the intent of the requirements of the original § 61.43.

~~Changes were made to the rule language as a result of this comment.~~

S.13 *Comment:* A commenter asked for clarification on how the labeling requirements for waste packages, as specified in the proposed § 61.57, "Labeling," apply to waste that originates from the land disposal facility. The commenter expressed concern that labeling these packages even though they are not shipped off-site would result in unnecessary occupational exposures.

Response: Labeling the containers ensures that the containers are not mishandled and are properly emplaced in a disposal unit. NRC licensees are required to manage occupational exposures to maintain them as low as reasonably achievable. In this instance, proper packaging procedures can minimize worker exposure to radiation from the waste in the container.

No changes were made to the rule language as a result of this comment.

S.14 *Comment:* A commenter raised concerns regarding the waste generator certification statement on NRC Form 540 and in appendix G to 10 CFR part 20. The commenter recommended revisions to this statement on NRC Form 540 and appendix G to account for situations in which waste is not being shipped for disposal and to remove the waste specific language that the waste be classified to account for situations when material is not being shipped for disposal (e.g., to a waste processor).

Response: The NRC agrees with some of the commenter's concern and will revise the generator's certification statement in Section II of Appendix G to 10 CFR part 20 to specify that certification that the WAC are met is only applicable when shipping to a land disposal facility for

assessment, and performance period analyses for waste containing significant quantities of long-lived radionuclides. Additionally, paragraph (c)(5) provides conceptual information on the requirement for the use of dose methodology that is consistent with those set forth in 10 CFR part 20 and also describes the flexibility of a licensee to use the latest dose methodology to demonstrate compliance with the performance objectives.

Paragraph § 61.7(d) provides conceptual information on the role of defense-in-depth protections with respect to LLRW disposal. Paragraph 61.7(e) provides conceptual information for demonstrating compliance with the performance objectives.

Section 61.8 Information collection requirements: Office of Management and Budget (OMB) approval.

Paragraph 61.8 (b) lists sections that contain the approved information collection requirements in 10 CFR part 61.

The NRC is revising paragraph 61.8(b) to include §§ 61.41 and 61.42.

Section 61.10 Content of application.

Section 61.10 identifies the contents that an application for a land disposal facility must contain. This information includes the general information, specific technical information, institutional information, and financial information set forth in §§ 61.11, "General information," through 61.16 and an environmental report.

The NRC is dividing this section into two paragraphs, assigned as paragraphs (a) and (b). Paragraph (a) retains the current rule language. Paragraph (b) explains that the information provided in an application: 1) comprises the safety case, 2) should supports the licensee's demonstration that the land disposal facility will be constructed and operated safely, and 3) should provides reasonable assurance that the disposal site will be capable of meeting the performance objectives.

refer to an "inadvertent intruder assessment." This paragraph has also been revised to enhance its readability. If the inadvertent intruder assessment uses a 1,000 year compliance period, the licensee must also include technical rationale as to why the longer timeframes do not need to be considered.

Paragraph 61.13(d) requires a licensee to prepare analyses that demonstrates long-term stability of the disposal site during the compliance period and that there will not be a need for ongoing active maintenance after site closure. The NRC is requiring that the analyses provide reasonable assurance that long-term stability of the disposal site can be ensured.

Paragraph 61.13(e) has been added to require licensees to prepare performance period analyses that assess how the land disposal facility and site characteristics limit the potential long-term radiological impacts, consistent with available data and current scientific understanding. The performance period analyses are required when a licensee is required to use a 10,000 year compliance period. The analyses will identify and describe the features of the design and site characteristics to ensure that the performance objectives set forth in §§ 61.41(b) and 61.42(b) will be met.

Section 61.23 Standards for issuance of a license.

Section 61.23 lists standards that must be met for the Commission to issue a license for receipt, possession, and disposal of LLRW containing or contaminated with source, special nuclear, or byproduct material.

The NRC is revising §§ 61.23(b), (c), (d), and (e) to include the WAC in the list of standards for issuance of a license. In addition, the NRC is adding a new paragraph (m) to § 61.23 that identifies a safety case as one of the standards for issuance of a license.

(which may include limited available expertise to address a specific issue). ~~The CER can potentially distract licensee or entity staff from executing other primary duties that ensure safety or security.~~ The NRC specifically requested comments on the cumulative effects of this rulemaking in the proposed rule published on March 26, 2015, and asked the public the following questions:

1) In light of any current or projected cumulative effects of regulation challenges, does the proposed rule's effective date provide sufficient time to implement the new proposed requirements, including changes to programs, procedures, and the facility?

2) If current or projected cumulative effects of regulation challenges exist, what should be done to address this situation (e.g., if more time is required to implement the new requirements, what period of time would be sufficient)?

3) Do other (NRC or other agency) regulatory actions (e.g., orders, generic communications, license amendment requests, or inspection findings of a generic nature) influence the implementation of the proposed requirements?

4) Are there unintended consequences? Does the proposed rule create conditions that would be contrary to the proposed rule's purpose and objectives? If so, what are the consequences and how should they be addressed?

5) Is the cost and benefit estimate developed in the regulatory analysis sufficient?

Although some commenters did provide comments regarding the regulatory analysis, no comments were received that specifically addressed the cumulative effects of regulation during the proposed rule comment period. The comments on the regulatory basis were addressed in category R, "Regulatory Analysis and Backfitting," of the "Public Comment Analysis" section of this document.

X. Plain Writing

and did not contact any additional persons or agencies to develop this environmental assessment.

F. Finding of No Significant Impact.

The Commission has determined under the National Environmental Policy Act and the Commission's regulations in subpart A, "National Environmental Policy Act—Regulations Implementing Section 102(2)," of 10 CFR part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions," that the amendments to 10 CFR part 61 described in this document would not be a major Federal action significantly affecting the quality of the human environment, and therefore, an environmental impact statement is not be required. The amendments would require disposal facility licensees and license applicants to conduct new and updated site-specific technical analyses and safety cases to demonstrate compliance with the performance objectives in 10 CFR part 61 and develop criteria for LLRW acceptance based on the results of these analyses, which would ensure the safe disposal of LLRW. The amendments would also make additional changes to the regulations to facilitate implementation and better align the requirements with current health and safety standards. These amendments would not authorize the construction of LLRW disposal facilities and do not authorize the disposal of additional LLRW in existing facilities. Licensees and applicants would need to request and receive separate regulatory approval before construction of new disposal facilities or disposal of additional LLRW in existing facilities. Consequently, because this rulemaking will not result in any physical impacts to the environment the NRC has determined that the action ~~The amendments are procedural and administrative in nature and~~ would have no significant impact on the quality of the human environment.

The determination of this environmental assessment is that there will be no significant impacts to the public from this action.

technical analyses and the assumptions made therein. The safety case also includes a description of the safety relevant aspects of the disposal site, the design of the facility, and the managerial control measures and regulatory controls.

* * * * *

Site closure and stabilization means those actions that are taken upon completion of operations that prepare the disposal site for custodial care and that ensure that the disposal site will remain stable and will, to the extent practicable, not need ongoing active maintenance.

* * * * *

Stability means the capability of the disposal site (e.g., waste form, disposal containers, and disposal units) to maintain its shape and properties to an extent that will not prohibit the demonstration that the land disposal facility will meet the § 61.41 and § 61.42 performance objectives and will, to the extent practicable, eliminate the need for active maintenance after site closure.

* * * * *

Waste means those low-level radioactive wastes containing source, special nuclear, or byproduct material that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level radioactive waste means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material as defined in paragraphs (2), (3), and (4) of the definition of Byproduct material set forth in § 20.1003 of this chapter. Consistent with the National Defense Authorization Act for Fiscal Year 2013, low-level radioactive waste also includes radioactive material that, notwithstanding Section 2 of the Nuclear Waste Policy Act of 1982, results from the production of medical

waste form on waste, these wastes have been classified as Class A waste. Unstable Class A waste will be disposed of in separate disposal units at the disposal site. However, stable Class A waste may be disposed of with other classes of waste. Wastes that must be stable for proper disposal are classified as Class B and C waste. To the extent that it is practicable, Class B and C waste forms or containers should be designed to be stable (i.e., maintain gross physical properties and identity) over 300 years. The stability of the disposal site for the disposal of long-lived radionuclides may be more uncertain and require more robust technical evaluation of the processes that are unlikely to affect the ability of the disposal site to isolate short-lived waste. For long-lived radionuclides and certain radionuclides prone to migration, a maximum disposal site inventory based on the characteristics of the disposal site may be established to limit potential exposure and to mitigate the uncertainties associated with long-term stability of the disposal site. Some waste, depending on its radiological characteristics, may not be suitable for near-surface disposal if uncertainties cannot be adequately addressed with technical analyses.

(2) Institutional control of access to the disposal site is required for up to 100 years. This permits the disposal of most Class A and B waste without special provisions for inadvertent intrusion protection, since these wastes contain types and quantities of radionuclides that generally will decay during the 100-year period and will present an acceptable hazard to the inadvertent intruder. However, waste that is Class A under 10 CFR 61.55(a)(6) may not decay to acceptable levels in 100 years. For waste classified under 10 CFR 61.55(a)(6), safety is provided by limiting the quantities and concentrations of the material consistent with the disposal site design. Safe disposal of waste classified under 10 CFR 61.55(a)(6) is demonstrated by the technical analyses and compliance with the performance objectives. The government landowner administering the active institutional control program has flexibility in controlling site access, which may include allowing productive uses of the land provided the integrity and long-term performance of the site are not affected.

9. Revise § 61.10 to read as follows:

§ 61.10 Content of application.

(a)(1) An application to receive from others, possess and dispose of wastes containing or contaminated with source, byproduct or special nuclear material by land disposal must consist of general information, specific technical information, institutional information, and financial information as set forth in §§ 61.11 through 61.16. (2) An environmental report prepared in accordance with subpart A of part 51 of this chapter must accompany the application.

(b) The information provided in an application comprises the safety case and should supports the licensee's demonstration that the land disposal facility will be constructed and operated safely and provides reasonable assurance that the disposal site will be capable of isolating waste and limiting releases to the environment.

10. In § 61.12:

- a. Revise the introductory text and paragraphs (a), (e), (g), (i), (j), and (l); and
- b. Add paragraph (o).

The revisions and additions read as follows:

§ 61.12 Specific technical information.

The specific technical information to, which supports the safety case, must include the following to demonstrate that the performance objectives of subpart C of this part and the applicable technical requirements of subpart D of this part will be met:

(a) A description of the natural and demographic disposal site characteristics as determined by disposal site selection and characterization activities. The description must

(b) An inadvertent intruder assessment that demonstrates there is reasonable assurance that any inadvertent intruder will not be exposed to doses that exceed the limits set forth in § 61.42. The inadvertent intruder assessment shall:

(1) Assume that an inadvertent intruder occupies the disposal site and engages in normal activities (e.g., dwelling construction, agriculture, and drilling for water) and other reasonably foreseeable pursuits that are consistent with the activities and pursuits occurring in and around the site at the time of development of the inadvertent intruder assessment. Licensees shall update the inadvertent intruder assessment prior to closure, in accordance with § 61.28, to reflect any significant changes to the activities and pursuits occurring in and around the site.

(2) Identify barriers to inadvertent intrusion that inhibit contact with the waste or limit exposure to radiation from the waste, and provide a basis for the time period over which barriers are effective.

(3) Account for uncertainties and variability in the projected behavior of the disposal site and general environment.

(4) Include a compliance period. If a compliance period of 1,000 years is used, include a technical rationale for why a 10,000-year compliance period does not need to be considered in the inadvertent intruder assessment.

* * * * *

(d) Analyses of the long-term stability of the disposal site and the need for ongoing active maintenance after site closure must be based upon analyses of active natural processes such as erosion, mass wasting, slope failure, settlement of wastes and backfill, infiltration through covers over disposal areas and adjacent soils, and surface drainage of the disposal site. The analyses must provide reasonable assurance that long-term stability of the disposal

to protect the public health and safety because they provide reasonable assurance that inadvertent intruders are protected in accordance with the performance objective in § 61.42.

(d) The applicant's proposed waste acceptance criteria and land disposal facility operations (including equipment, facilities, and procedures) demonstrate that they are adequate to protect the public health and safety because they provide reasonable assurance that the standards for radiation protection set out in part 20 of this chapter will be met.

(e) The applicant's proposed disposal site, disposal site design, waste acceptance criteria, land disposal facility operations, disposal site closure, and postclosure institutional controls demonstrate that they are adequate to protect the public health and safety because they provide reasonable assurance that long-term stability of the disposed waste and the disposal site will be achieved and will eliminate to the extent practicable the need for ongoing active maintenance of the disposal site following site closure.

* * * * *

(m) The applicant's safety case is adequate to support the licensing decision.

* * * * *

13. In § 61.25, revise paragraphs (a) and (b) to read as follows:

§ 61.25 Changes.

(a) Except as provided for in specific license conditions, the licensee shall not make changes in the land disposal facility or procedures described in the license application. The license will include conditions restricting subsequent changes to the facility and the procedures authorized that are important to public health and safety. These license restrictions will fall into three categories of descending importance to public health and safety as follows:

(1) Those features and procedures that may not be changed without:

- (i) 60 days prior notice to the Commission;
- (ii) 30 days notice of opportunity for a prior hearing; and
- (iii) Prior Commission approval;

(2) Those features and procedures that may not be changed without:

- (i) 60 days prior notice to the Commission; and
- (ii) Prior Commission approval; and

(3) Those features and procedures that may not be changed without 60 days prior notice to the Commission. Features and procedures falling in this paragraph (a)(3) may not be changed without prior Commission approval if the Commission so orders, after having received the required notice.

(b) Amendments authorizing waste acceptance criteria changes, site closure, license transfer, or license termination shall be ~~included in~~covered by paragraph (a)(1) of this section.

* * * * *

14. In § 61.28, revise paragraphs (a) introductory text and (a)(2) to read as follows:

§ 61.28 Contents of application for closure.

(a) Prior to closure of the disposal site, or as otherwise directed by the Commission, the applicant shall submit an application to amend the license for site closure. This site closure application must include a final revision of the safety case and specific details of the disposal site closure plan included as part of the license application submitted under § 61.12(g) that includes each of the following:

* * * * *

(2) The results of tests, experiments, or any other analyses relating to backfill of excavated areas, closure and sealing, waste migration and interaction with emplacement media,

or any other tests, experiments, or analysis pertinent to the long-term containment of emplaced waste within the disposal site, including revised analyses for § 61.13 and updates to the identified defense-in-depth protections using the details of the submitted site closure plan and waste inventory.

* * * * *

15. Revise § 61.41 to read as follows:

§ 61.41 Protection of the general population from releases of radioactivity.

(a) Concentrations of radioactive material that may be released to the general environment in groundwater, surface water, air, soil, plants, or animals must not result in an annual dose exceeding an equivalent of 0.25 milliSievert (25 millirems) to any member of the public within the compliance period. ~~Licensees shall Reasonable effort should be made to~~ maintain releases of radioactivity in effluents to the general environment as low as is reasonably achievable during the compliance period. Compliance with this paragraph must be demonstrated through analyses that meet the requirements specified in § 61.13(a).

(b) ~~Effort Licensees shall be made to~~ minimize releases of radioactivity from a disposal site to the general environment to the extent reasonably achievable at any time during the performance period. Compliance with this paragraph must be demonstrated through analyses that meet the requirements specified in § 61.13(e).

16. Revise § 61.42 to read as follows:

§ 61.42 Protection of inadvertent intruders.

(a) Design, operation, and closure of the land disposal facility must ensure protection of any inadvertent intruder into the disposal site who occupies the site or contacts the waste at any

time after active institutional controls over the disposal site are removed. The annual dose must not exceed 5 milliSieverts (500 millirems) to any inadvertent intruder within the compliance period. Compliance with this paragraph must be demonstrated through analyses that meet the requirements specified in § 61.13(b).

(b) ~~Effort Licensees shall be made to~~ minimize exposures to any inadvertent intruder to the extent reasonably achievable at any time during the performance period. Compliance with this paragraph must be demonstrated through analyses that meet the requirements specified in § 61.13(e).

17. Revise § 61.43 to read as follows:

§ 61.43 Protection of individuals during operations.

Operations at the land disposal facility must be conducted in compliance with the standards for radiation protection set out in part 20 of this chapter, except for releases of radioactivity in effluents from the land disposal facility, which must not result in an annual dose exceeding an equivalent of 0.25 milliSievert (25 millirems) to any member of the public. ~~Every reasonable effort shall be made to~~ Licensees shall maintain radiation exposures as low as is reasonably achievable.

18. Revise § 61.44 to read as follows:

§ 61.44 Stability of the disposal site after closure.

The land disposal facility must be sited, designed, used, operated, and closed to achieve long-term stability of the disposal site for the compliance period and to eliminate to the extent practicable the need for ongoing active maintenance of the disposal site following site closure so that only surveillance, monitoring, or minor custodial care are required.

objectives of subpart C of this part being met. In no case will waste disposal be permitted in the zone of fluctuation of the water table.

(iv) The hydrogeologic unit used for disposal shall not discharge groundwater to the surface within the disposal site.

(3) After 500 years, the hydrologic characteristics specified in paragraph (2) of this section shall not significantly affect the ability of the disposal site to meet the performance objectives of subpart C of this part.

(4) Other characteristics of the site shall not significantly affect the ability of the disposal site to meet the performance objectives of subpart C of this part, or preclude defensible modeling and estimation of longer-term impacts. The characteristics include:

(i) A disposal site should be selected so that projected population growth and future developments are not likely to affect the ability of the land disposal facility to meet the performance objectives of subpart C of this part.

(ii) A disposal site must avoid aAreas ~~must be avoided~~ having known natural resources which, if exploited, would result in failure to meet the performance objectives of subpart C of this part.

(iii) A disposal site must avoid aAreas ~~must be avoided~~ where tectonic processes such as faulting, folding, seismic activity, or volcanism may occur with such frequency and extent to significantly affect the ability of the disposal site to meet the performance objectives of subpart C of this part, or may preclude defensible modeling and prediction of long-term impacts.

(iv) A disposal site must avoid aAreas ~~must be avoided~~ where surface geologic processes such as mass wasting, erosion, slumping, landsliding, or weathering occur with such frequency and extent to significantly affect the ability of the disposal site to meet the performance objectives of subpart C of this part, or may preclude defensible modeling and prediction of long-term impacts.

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

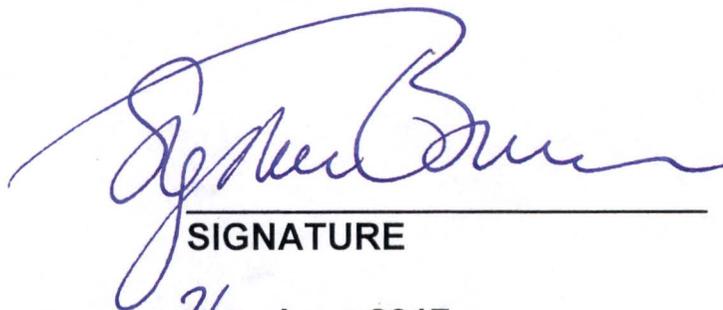
FROM: Commissioner Burns

SUBJECT: SECY-16-0106: Final Rule: Low-Level Radioactive
Waste Disposal (10 CFR PART 61) (RIN 3150-AI92)

Approved X (in part) Disapproved X (in part) Abstain Not
Participating

COMMENTS: Below Attached X None

Entered in "STARS"
Yes X No



SIGNATURE

26 June 2017

DATE

COMMISSIONER BURNS'S COMMENTS ON SECY-16-0106
FINAL RULE: LOW-LEVEL RADIOACTIVE WASTE DISPOSAL (10 CFR PART 61)

I approve the final rule except for the following discrete issues. I disapprove publishing the Part 61 final rule and associated guidance documents. Rather I approve publication of the propose final rule as a supplemental proposed rule for a 75-day comment period subject to the revisions of the rule text package and guidance document to address my comments below. I suggest the unusual step to publish a supplemental proposed rule to ensure all stakeholders have an opportunity to review the significant changes staff has made to the proposed rule.

The issue of imposing requirements necessary to safely dispose of large quantities of depleted uranium in a manner that is not injurious to the public has been the proverbial "rubber sandwich" on which stakeholders, the staff, and the Commission have chewed for many years. My position on the staff's recommendation is influenced by previous Commission direction, stakeholder comments, ACRS recommendations, and the fact that the NRC has never licensed a land disposal facility under 10 CFR Part 61. Our regulatory partners in the Agreement States have successfully licensed and regulated low-level radioactive waste (LLRW) disposal facilities using standards that are compatible to the NRC's and, as such, Agreement States should continue to be given maximum flexibility to address LLRW disposal issues within their States.

Staff did not offer a compelling safety reason for requiring current LLRW disposal sites which, as I understand it, seem to have no interest in accepting large quantities of depleted uranium, to comply with the new performance assessment requirement. The increased complexity and burden of such a requirement is not justified. Therefore, I agree with the ACRS's recommendation # 2, that staff should reinstate the case-by-case basis or so called "grandfather provision" so that new requirements only apply to those sites that plan to accept large quantities of depleted uranium.

One of the most difficult policy decisions related to this rulemaking has been the compliance period. The Commission previously directed a 1,000-year compliance period analysis, a protective assurance period of 10,000-year analysis, and a post-10,000-year performance period analysis. Although the staff suggests that stakeholder comments informed the change to a 10,000 compliance period, the wide divergent views of stakeholders was apparent when the Commission first provided its direction on the proposed rule. I did not find a compelling justification to change previous Commission direction that directed 1,000 years as a reasonably foreseeable future for a compliance period. I therefore I disapprove the use of a 10,000-year compliance period. Instead I support a two-tiered approach with a 1,000-year compliance period and a longer period of performance assessment. This longer period of performance assessment would consider the site-specific information and could be used to inform a licensing decision.

I agree with ACRS that the concept of defense-in-depth can be integrated into the performance assessment as a means to address significant uncertainties. ACRS's view that staff's proposed rule text about defense-in-depth is little more than an exposition of site attributes is accurate. Staff should revise the rule text associated with defense-in-depth as currently contained in the rule to reflect how defense-in-depth can be used to

address uncertainty in the performance assessment and provide any additional considerations in the guidance document.

Finally, staff was given direction in SRM-15-0094, in part, to prepare a regulatory basis for the disposal of GTCC and transuranic waste within 6 months of the completion of the ongoing 10 CFR Part 61 rulemaking. Staff direction on timing to begin this work should be changed to start these activities once the supplemental proposed rule is published.



Stephen G. Burns

26 June 2017