[7590-01-P]

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 20 and 61

NRC-2011-0012

RIN 3150-AI92

Low-Level Radioactive Waste Disposal

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is amending its regulations that govern low-level radioactive waste (LLRW) disposal facilities to require new and revised site-specific technical analyses, to permit the development of site-specific criteria for LLRW acceptance based on the results of these analyses, and to facilitate implementation and better align the requirements with current health and safety standards. This rule affects LLRW disposal licensees or license applicants that are regulated by the NRC or the Agreement States.

DATES: This final rule is effective on **[INSERT DATE 1 YEAR AFTER THE DATE OF PUBLICATION].**

ADDRESSES: Please refer to Docket ID NRC-2011-0012 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- **Federal Rulemaking Web Site:** Go to http://www.regulations.gov and search for

Docket ID NRC-2011-0012. Address questions about NRC dockets to Carol Gallagher; telephone: (301) 415-3463; e-mail: Carol.Gallagher@nrc.gov. For technical questions, contact the individuals listed in the FOR FURTHER INFORMATION CONTACT section of this document.

- **NRC's Agencywide Documents Access and Management System (ADAMS):** You may obtain publicly-available documents online in the ADAMS Public Documents collection at http://www.nrc.gov/reading-rm/adams.html. To begin the search, select "ADAMS Public Documents" and then select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209 or (301) 415-4737 or by e-mail to pdr.resource@nrc.gov. For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in the "Availability of Documents" section of this document.
- **NRC's PDR:** You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Gary Comfort, Office of Nuclear Material Safety and Safeguards, telephone: (301) 415-8106, e-mail: Gary.Comfort@nrc.gov; or Stephen Dembek, Office of Nuclear Material Safety and Safeguards, telephone: (301) 415-2342, e-mail: Stephen.Dembek@nrc.gov. Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

SUPPLEMENTARY INFORMATION:

EXECUTIVE SUMMARY:

A. Need for the Regulatory Action

The U.S. Nuclear Regulatory Commission (NRC) is amending its regulations in part 61 of title 10 of the *Code of Federal Regulations* (10 CFR) that govern low-level radioactive waste (LLRW) land disposal facilities to require new and revised site-specific technical analyses and to permit the development of site-specific criteria for LLRW acceptance based on the results of these analyses. These amendments ensure that LLRW streams that are significantly different from those considered during the development of the original regulations (i.e., depleted uranium and other unanalyzed waste streams) can be disposed of safely and meet the performance objectives for land disposal of LLRW. These amendments also increase the use of site-specific information to ensure performance objectives are met that are designed to provide protection of public health and safety. The NRC has developed a guidance document, NUREG-2175, "Guidance for Conducting Technical Analyses for 10 CFR part 61" (ADAMS Accession No. ML16218A504) to facilitate the development of information and analyses that will support licensees or license applicants in addressing the regulatory requirements. This rule affects LLRW disposal licensees or license applicants that are regulated by the NRC or the Agreement States. The NRC is also making conforming changes to certain regulations in 10 CFR part 20.

B. Major Provisions

Major provisions of the final rule:

- Specifies time periods for the existing technical analyses for protection of the general population (none was previously stated in 10 CFR part 61) as a 1,000-year compliance period if there are no significant quantities of long-lived radionuclides in the LLRW that necessitate a

longer compliance period; or a 10,000-year compliance period for disposal sites that contain or plan to accept significant quantities of long-lived radionuclides;

- Adds a new technical analysis for the protection of inadvertent intruders;
- Adds a new analysis for certain long-lived LLRW that would include a post-10,000-year performance period if a 10,000-year compliance period is required;
- Adds a new requirement to identify and describe the features of the design and site characteristics that provide defense-in-depth protections;
- Adds a new requirement to update the technical analyses at site closure; and
- Adds a new requirement to develop site-specific criteria for the future acceptance of LLRW for disposal based on the results of these technical analyses, the existing LLRW classification requirements, or a combination of both.

C. Costs and Benefits

The NRC prepared a regulatory analysis to determine the expected quantitative costs and benefits of the final rule, as well as qualitative factors to be considered in the NRC's rulemaking decision. The analysis concluded that the final rule will result in net costs to the industry and the Agreement State regulators. The key findings of the analysis are as follows:

- Cost to the Industry. The final rule will result in an average undiscounted implementation cost per licensee of an estimated $1.13 million, followed by an estimated undiscounted average ongoing operations cost of $1.33 million over the regulatory analysis period for each licensee (i.e., the time period starting at the present day and continuing through the lifetime of each current licensee). Overall, the industry (i.e., all licensees licensed under 10 CFR part 61) will incur an estimated undiscounted implementation total cost of $4.5 million, followed by an estimated undiscounted ongoing operations cost of $5.3 million over the regulatory analysis period;

- Cost to the Agreement States. On average, an Agreement State with an operating land disposal facility licensed by the Agreement State will incur an estimated undiscounted implementation cost of $0.74 million, followed by an estimated undiscounted average ongoing operations cost of $1.0 million over the regulatory analysis period. Overall, the Agreement States will incur an estimated undiscounted implementation total cost of $2.9 million followed by an estimated undiscounted ongoing cost of $4.0 million over the regulatory analysis period;
- Cost to the NRC. Because the NRC does not currently have any LLRW disposal licensees, and does not expect any in the near future, no annual NRC cost is expected.

The regulatory analysis also included a qualitative analysis of the direct and indirect benefits from risks that could be avoided if the NRC adopted the rule. The principal qualitative benefits of the final rule include: 1) ensuring that LLRW streams that are significantly different from those considered during the development of the original regulations can be disposed of safely and meet the performance objectives for land disposal of LLRW; 2) facilitating the use of site-specific information and up-to-date dosimetry methodology in site-specific technical analyses to ensure public health and safety is protected; and 3) promoting a risk-informed regulatory framework that specifies what requirements need to be met and provides flexibility to a licensee or applicant with regard to what information or approach they use to satisfy those requirements.

Based upon the regulatory analysis, the NRC concludes that the final rule should be adopted because the revised regulations enhance public health and safety by ensuring the safe disposal of LLRW that was not analyzed in the regulatory basis for the original 10 CFR part 61 (e.g., large quantities of depleted uranium). For more information, please see the regulatory analysis (ADAMS Accession No. ML16189A050).

TABLE OF CONTENTS:

I. Background

A. Existing Regulatory Framework

The NRC's licensing requirements for the disposal of commercial LLRW in near-surface disposal facilities can be found in part 61 of title 10 of the *Code of Federal Regulations* (10 CFR), "Licensing Requirements for Land Disposal of Radioactive Waste." The NRC originally adopted 10 CFR part 61 on December 27, 1982 (47 FR 57446). The existing LLRW

disposal facilities are located in and licensed by Agreement States, and those Agreement States have incorporated many of the requirements in 10 CFR part 61 into their corresponding regulations and as license conditions.

The LLRW disposal regulations emphasize an integrated systems approach to the disposal of commercial LLRW, including site selection, land disposal facility design and operation, LLRW characteristics, and site closure. To limit reliance on institutional controls, 10 CFR part 61 emphasizes passive (e.g., site stability) rather than active systems to limit and retard releases of LLRW to the environment. This integrated systems approach is similar to the defense-in-depth concept that has been used for some time for the NRC's nuclear reactor safety design and licensing regulations. However, defense-in-depth was not explicitly discussed in the original 10 CFR part 61 regulations. Instead, the defense-in-depth concept was implicitly contained in the original 10 CFR part 61 regulations (e.g., requiring that the disposal site design complement and improve upon the ability of the site's natural characteristics to ensure the performance objectives will be met; imposing concentration limits on waste that presents a higher hazard through the waste classification requirements; requiring the segregation of unstable waste from waste presenting a larger hazard that should be stable for proper disposal; imposing requirements on waste form and packaging characteristics; and requiring the use of intrusion barriers for wastes that will not decay to levels that present an acceptable hazard to an inadvertent intruder within 100 years).

Subparts of 10 CFR part 61 cover general provisions and procedural licensing matters; performance objectives; technical requirements for near-surface disposal; financial assurance; State and Tribal participation; and records, reports, tests, and inspections. The regulations cover all phases of near-surface commercial LLRW disposal from site selection through facility design, licensing, operations, site closure, postclosure stabilization, and the end of active institutional controls. The overall philosophy that underlies the regulatory requirements of 10 CFR part 61 is provided in § 61.7, "Concepts."

The following are key provisions in 10 CFR part 61:

- Standards for: 1) protection of the general population in § 61.41, "Protection of the general population from the releases of radioactivity;" 2) protection of an inadvertent intruder in § 61.42, "Protection of individuals from inadvertent intrusion;" 3) protection of individuals during land disposal facility operations in § 61.43, "Protection of individuals during operations;" and 4) site stability in § 61.44, "Stability of disposal site after closure." These standards are collectively known as the "Performance Objectives" in subpart C of 10 CFR part 61.

- Specification of the minimum geologic, hydrologic, and geomorphic characteristics for an acceptable near-surface LLRW disposal site in § 61.50, "Disposal site suitability requirements for land disposal."

- An LLRW classification system (LLRW being categorized as Class A, Class B, Class C, and greater-than-Class C) for commercial LLRW in § 61.55, "Waste classification," based on the concentrations of certain radionuclides.

- Specification of the LLRW characteristics, in § 61.56, "Waste characteristics," that commercial LLRW must meet to be acceptable for disposal.

- Requirements for disposal site land owner or custodial agents oversight in the form of institutional controls of LLRW disposal facilities, in § 61.59, "Institutional requirements," for a period following site closure.

To grant a license, the NRC must conclude that there is reasonable assurance that the performance objectives will be met. To demonstrate that a licensee[1] will meet these performance objectives, 10 CFR part 61 licensees need to prepare the analyses required by § 61.13, "Technical analyses."

To demonstrate that the general population is protected from releases of radioactivity, licensees are required to prepare an analysis of exposure pathways leading to potential

[1] The term "licensee" includes "license applicant," when appropriate.

radiological doses to the general population. The original 10 CFR part 61 did not impose a specific performance timeframe for use in the analysis to protect the general population, and there are differences among Agreement States, which currently regulate the existing land disposal facilities, regarding the analysis timeframe. For example, one Agreement State has required licensees to analyze the land disposal facility for 500 years, while another has required analyses to the peak dose.

Licensees also must demonstrate that potential inadvertent intruders into the LLRW disposal site will be protected. Inadvertent intruders might occupy the disposal site at any time after closure of the land disposal facility and may not be aware of the radiation hazard from the LLRW. Disposal site land owners or custodial agents are required to carry out an institutional control program that ensures that no such occupation or improper use of the site occurs. However, the NRC recognizes that institutional controls may not be effective and only permits licensees to take credit for institutional controls in their technical analyses for up to 100 years following closure, even if a longer institutional control program is required by the regulator. Under the original regulations, protection of inadvertent intruders was demonstrated by compliance with the LLRW classification (§ 61.55) and segregation requirements (§ 61.52, "Land disposal facility operation and disposal site closure"), and by providing adequate barriers to inadvertent intrusion. The NRC developed the LLRW classification requirements as part of the original 10 CFR part 61 rulemaking. Explicit dose limits for an inadvertent intruder were not provided in the original 10 CFR part 61 because an inadvertent intruder dose assessment was not required, but the LLRW classification concentration limits for radionuclides, in tables 1 and 2 of § 61.55, were based on a dose of 5 milliSieverts (mSv) (500 millirem (mrem)) per year to a hypothetical inadvertent intruder. The LLRW classification tables were developed assuming that only a fraction of the LLRW being disposed would approach the LLRW classification limits. If an inadvertent intruder is exposed to a large volume of disposed LLRW near or at the classification limits, the dose could exceed 5 mSv (500 mrem) per year. By complying with the

LLRW classification and segregation requirements, protection of an inadvertent intruder is only assured if the underlying assumptions that were used to develop the classification requirements are met.

B. Low-Level Radioactive Waste Classification System

The NRC developed the original 10 CFR part 61 based on assumptions regarding the types of LLRW likely to go into a commercial land disposal facility at the time the original rule was promulgated in 1982. These assumptions were based on a survey of LLRW generators, the results of which were published in NUREG-0945, "Final Environmental Impact Statement on 10 CFR Part 61, 'Licensing Requirements for Land Disposal of Radioactive Waste'" (ADAMS Accession Nos. ML052590184, ML052920727, and ML052590187). The results of this survey ultimately formed the regulatory basis for the source terms used in the analysis to define the allowable isotopic concentration limits in tables 1 and 2 of § 61.55, which established four classes of LLRW (Class A, Class B, Class C, and greater-than-Class-C). Table 1 provides limiting concentrations for long-lived radionuclides and table 2 provides limiting concentrations for short-lived radionuclides. Class A LLRW is the least hazardous to the inadvertent intruder and requires the fewest controls, while Class C LLRW is more hazardous and requires additional controls. As the LLRW class increases in hazard, greater controls (e.g., protection for a longer period of time or greater burial depth) are required to reduce the risk from disposal of the LLRW. For example, Class C LLRW may require either greater burial depth or an engineered barrier that will prevent inadvertent intrusion for 500 years. The additional controls for Class C LLRW reduce the radiological risk from the greater hazard when compared to Class A or B LLRW. LLRW with greater-than-Class-C concentrations of radionuclides is generally not suitable for near-surface disposal because of the radiological risk that can result from disposal of this LLRW without adequate barriers or other protective measures.

As part of the original 10 CFR part 61 rulemaking, the NRC considered inadvertent

intrusion receptor scenarios and the physical stability and isotopic concentration of the LLRW. These isotopic concentration limits were based on the NRC's understanding of the characteristics and volumes of commercial LLRW reasonably expected for commercial disposal through the year 2000, as well as the disposal methods likely to be used.

In the statement of considerations (47 FR 57457) for the final rule for the original 10 CFR part 61, the Commission noted:

> [W]aste that is stable for a long period helps to ensure the long-term stability of the site, eliminating the need for active maintenance after the site is closed. This stability requirement helps to assure against water infiltration caused by failure of the disposal covers and, with the improved leaching properties implicit in a stable waste form, minimizes the potential for radionuclide migration in groundwater. Stability also plays an important role in protecting an inadvertent intruder, since the stable waste form is recognizable for a long period of time and minimizes any effects from dispersion of the waste upon intrusion.

The Commission also noted that "to the extent practicable, waste forms or containers should be designed to maintain gross physical properties and identity over 300 years, approximately the time required for Class B waste to decay to innocuous levels..." (47 FR 57457).

In addition to determining the acceptability of LLRW for disposal in a near-surface disposal facility, the LLRW classification system also is integral to determining Federal and State responsibilities for LLRW and requirements for transfers of LLRW intended for disposal. The Low-Level Radioactive Waste Policy Amendments Act of 1985 defines Federal and State responsibilities for the disposal of LLRW based on § 61.55, as in effect on January 26, 1983.

Finally, appendix G, "Requirements for Transfers of Low-Level Radioactive Waste Intended for Disposal at Licensed Land Disposal Facilities and Manifests" (60 FR 15664; March 27, 1995), to 10 CFR part 20, "Standards for Protection Against Radiation," imposes manifest requirements on shipments of LLRW consigned for disposal. Manifests for LLRW shipments must identify the LLRW classification and provide a certification that the LLRW is properly classified, described, packaged, marked, and labeled.

II. Discussion

A. What action is the NRC taking?

The NRC is amending 10 CFR parts 20 and 61 to require new and revised site-specific technical analyses and other requirements that will permit the development of site-specific waste acceptance criteria (WAC) based on the results of these analyses. These amendments also better align the requirements with current health and safety standards (i.e., 10 CFR part 20). The new requirements will help identify any additional measures that would be prudent to implement for continued disposal of radioactive LLRW at a particular land disposal facility. In summary, this action specifies requirements for:

- Technical analyses for demonstrating compliance with the public dose limits
- Technical analyses for demonstrating compliance with dose limits for protection of inadvertent intruders
- Identification and description of defense-in-depth protections that, taken together with the technical analyses, constitute the safety case
- Development of site-specific WAC
- Implementation of current dosimetry in the technical analyses.

Technical Analyses (Public Dose Limits)

The revised regulations specify that a performance assessment is necessary to demonstrate compliance with the public dose limit of 0.25 mSv (25 mrem). The dose limit applies to a compliance period of 1,000 years after closure, or 10,000 years after closure if there are significant quantities of long-lived radionuclides in the LLRW that has been or will be disposed. The licensee is required to provide a technical rationale to support the decision to use a 1,000-year compliance period. Should a 10,000-year compliance period be necessary,

the licensee is also required to conduct a technical analysis beyond 10,000 years (designated the performance period) to demonstrate that releases from the disposal site are minimized to the extent reasonably achievable. Guidance is provided in NUREG-2175 to help determine what should be considered to be a significant quantity of long-lived radionuclides.

Technical Analyses (Inadvertent Intruder)

The new regulations specify that licensees must conduct an inadvertent intruder assessment to demonstrate compliance with the inadvertent intruder dose limit of 5 mSv (500 mrem). The dose limit applies to a compliance period of 1,000 years after closure or 10,000 years after closure if there are significant quantities of long-lived radionuclides in the LLRW that has been or will be disposed. The licensee is required to provide a technical rationale to support the decision to use a 1,000-year compliance period. Should a 10,000-year compliance period be necessary, the licensee would then also be required to conduct a technical analysis beyond 10,000 years to demonstrate that inadvertent intruder exposures are minimized to the extent reasonably achievable. Additionally, the regulations specify certain receptor characteristics that must be used in the inadvertent intruder receptor scenario.

Safety Case and Defense-in-Depth

The safety of LLRW disposal is demonstrated through technical analyses and the information supporting the technical analyses, including the identification and description of the defense-in-depth protections of the land disposal facility. The analyses and supporting information taken together constitute the safety case. One aspect of the safety case is that the licensee is required to identify and describe the defense-in-depth protections. Diversity in the capabilities of the components and attributes of the disposal site and design increases the resilience of the land disposal facility and improves the land disposal facility's ability to contend with unanticipated failures or external challenges. This diversity in capabilities also

compensates, in part, for uncertainties in the long-term estimation of the performance of the disposal site.

Site-Specific WAC

The NRC is amending 10 CFR part 61 to require land disposal facility licensees to develop site-specific criteria for the acceptability of LLRW for disposal. These amendments allow licensees to 1) develop WAC using the existing LLRW classification system (§ 61.55) or 2) account for facility design, disposal practices, and site characteristics to determine site-specific criteria for accepting future shipments of LLRW for disposal. Because licensees are required to develop site-specific criteria for the acceptability of LLRW for disposal, the NRC also is amending appendix G of 10 CFR part 20 to conform to the new requirements for LLRW acceptance.

Current Dosimetry

The NRC is amending its regulations to facilitate implementation and better align the requirements with current health and safety standards (i.e., 10 CFR part 20 requirements). The regulations specify that licensees use the dose calculation methodology in International Commission on Radiological Protection (ICRP) Publication 26, but also allow for the use of more up-to-date ICRP recommendations for dosimetry modeling purposes.

B. Who would this action affect?

This rule applies to existing and future LLRW disposal facilities that are regulated by the NRC or an Agreement State.

C. Why do the regulatory requirements need to be revised?

The industry and the NRC have identified new LLRW streams that were not considered during the original development of 10 CFR part 61. These LLRW streams include depleted uranium from enrichment facilities, LLRW from the U.S. Department of Energy (DOE) operations, and blended LLRW streams in quantities greater than previously expected. In addition, new technologies might result in the generation of different LLRW streams that have not previously been considered.

The licensing of new uranium enrichment facilities in the United States has brought disposal of depleted uranium LLRW to the forefront of commercial LLRW disposal issues. In the original regulatory basis[2] supporting the development of 10 CFR part 61, the NRC did not consider the relatively high uranium concentrations and large quantities of LLRW that are generated by enrichment facilities because, at the time, these facilities were operated only by the DOE. It was not until 1996 that private corporations were permitted to operate enrichment facilities (USEC Privatization Act, 42 U.S.C. § 2011 (1996)). Additionally, the NRC did not anticipate that the DOE would dispose of large quantities of depleted uranium LLRW or any other defense-related LLRW in commercial disposal facilities. With the existing DOE depleted uranium stockpile at the Paducah and Portsmouth Gaseous Diffusion Plants, and the licensing of the Louisiana Energy Services National Enrichment Facility and the United States Enrichment Corporation (now Centrus Energy) American Centrifuge Plant, the DOE and industry may consider disposing more than 10^9 kilograms (1 million metric tons) of depleted uranium LLRW in commercial disposal facilities.

In a 2008 analysis, provided in SECY-08-0147, "Response to Commission Order CLI-05-20 Regarding Depleted Uranium," dated October 7, 2008 (ADAMS Accession No. ML081820762), involving a land disposal scenario for significant quantities of depleted

[2] Although the 1982 promulgation of 10 CFR part 61 did not include a formal regulatory basis, the term "original regulatory basis" refers to NUREG-0945, "Final Environmental Impact Statement on 10 CFR part 61, 'Licensing Requirements for Land Disposal of Radioactive Waste" (ADAMS Accession Nos. ML052590184, ML052920727, and ML052590187).

uranium, the NRC identified conditions that would likely result in the land disposal facility not meeting the original performance objectives in §§ 61.41 and 61.42. The conditions included, but were not limited to, shallow disposal of significant quantities of depleted uranium or disposal of depleted uranium at humid sites with a potable ground water supply. The NRC determined that the disposal of large quantities of depleted uranium as Class A LLRW, with no additional restrictions, could result in inadvertent intruders receiving a dose greater than 5 mSv (500 mrem) per year for both acute and chronic exposure scenarios. The estimated dose could result from pathways such as inadvertent ingestion of uranium-contaminated soil and inhalation of radon gas (part of the uranium decay chain). These results are consistent with those found in an earlier analysis of possible depleted uranium disposal in a land disposal facility discussed in a Sandia National Laboratories report titled, "Performance Assessment of the Proposed Disposal of Depleted Uranium as Class A Low-Level Waste" (ADAMS Accession No. ML101890179).

The blending of different classes of LLRW could also result in LLRW streams with concentrations that are inconsistent with the assumptions used to develop tables 1 and 2 of § 61.55. Blending of LLRW would enable some materials that would otherwise have been disposed of as a higher class (e.g., Class B or Class C LLRW) to be blended with a lower class (e.g., Class A LLRW) or lower concentration LLRW of the same class. The result of the blending process would be to create large volumes of blended LLRW that have concentrations near the LLRW classification limits, which were not evaluated in the final regulatory basis for the original 10 CFR part 61. Although the draft original regulatory basis for the original 10 CFR part 61 (NUREG-0782, "Draft Environmental Impact Statement on 10 CFR Part 61, Licensing Requirements for Land Disposal of Radioactive Waste," (ADAMS Accession Nos. ML052590347, ML052590350, ML052590353,and ML052590354) included calculations for LLRW concentration limits based on the assumption that all LLRW would be disposed at the LLRW classification limit, LLRW classification tables in the final original regulatory basis were

developed with the assumption that only a fraction of the LLRW being disposed would approach the LLRW classification limit. In SECY-10-0043, "Blending of Low-Level Radioactive Waste," dated April 7, 2010 (ADAMS Accession No. ML090410246), the NRC staff noted that large-scale blending of Class B and Class C concentrations of LLRW with Class A to produce a Class A mixture could result in a dose to an inadvertent intruder that is above 5 mSv (500 mrem) per year (i.e., the dose limit used in developing the current LLRW classification in § 61.55(a)).

Other unanticipated LLRW streams also may need to be considered for future disposal at LLRW disposal facilities. For example, the Energy Policy Act of 2005 expanded the NRC's regulatory authority under the Atomic Energy Act of 1954, as amended (AEA), to include discrete sources of naturally occurring radioactive material (including radium-226) that might be produced, extracted, or converted as a byproduct material. The original regulatory basis for 10 CFR part 61 considered the disposal of only small quantities of radium-226 bearing LLRW in the development of the 10 CFR part 61 LLRW classification system. More recently, consistent with the National Defense Authorization Act for Fiscal Year 2013, LLRW also includes radioactive material that, notwithstanding Section 2 of the Nuclear Waste Policy Act of 1982, results from the production of medical isotopes that have been permanently removed from a reactor or subcritical assembly, for which there is no further use, and the disposal of which can meet the performance objectives in 10 CFR part 61. Because the types of LLRW streams requiring disposal have expanded over time, the NRC has concluded that this final rule is necessary to ensure that this LLRW is disposed of in a manner that is protective of public health and safety and the environment.

Further, as part of its regulatory effectiveness strategy described in NUREG-1614, Volume 6, "Strategic Plan Fiscal Years 2014-2018" (ADAMS Accession No. ML14246A439), the NRC strives, through its regulatory processes, to use risk-informed and performance-based approaches, where appropriate, to enhance the effectiveness and efficiency of the regulatory

framework. This rule allows licensees, using the results of the technical analyses, to develop risk insights to support the safe disposal of LLRW (e.g., site-specific WAC). The new amendments also provide licensees flexibility in determining how they can best meet the performance objectives in § 61.42 for the specific design and operational practices of their land disposal facility based on the specific environmental characteristics of their site.

Finally, the concept of "defense-in-depth" was not explicitly discussed in the original 10 CFR part 61. On February 11, 2011, the NRC Chairman created a Risk Management Task Force (RMTF), to develop a strategic vision and options for adopting a more comprehensive and holistic risk-informed, performance-based regulatory approach for reactors, materials, waste, fuel cycle, and transportation that would continue to ensure the safe and secure use of nuclear material (ADAMS Accession No. ML110680621). The RMTF issued NUREG-2150, "A Proposed Risk Management Regulatory Framework," dated April 30, 2012 (ADAMS Accession No. ML12109A277). Three recommendations for LLRW were proposed in NUREG-2150. One of these recommendations was that the NRC develop an explicit characterization of how defense-in-depth, within the proposed risk management framework, applies to the LLRW program and build this into current and future staff guidance documents and into training and development activities for the staff. This final rule adds a new requirement to identify and describe defense-in-depth protections relied on to maintain safety at the land disposal facility. This new requirement enhances understanding of the performance of the land disposal facility and improves the efficiency and effectiveness of regulatory reviews consistent with the LLRW recommendations in NUREG-2150.

D. When does this rule become effective?

For NRC licensees, this final rule is effective 1 year after publication in the Federal Register. NRC licensees will, however, have until their next renewal or up to 5 years, whichever is earlier, after the effective date of this rule to update and submit their technical analyses

required by § 61.13 and WAC required by § 61.58. The Agreement States will have 3 years from the date this final rule is published in the Federal Register to adopt compatible regulations.

E. How does this final rule differ from the proposed rule?

The following is a list of the significant changes that the NRC made as a result of public comments. The rationale for these changes is found in the "Discussion" and "Public Comment Analysis" sections of this document.

1. Revised the approach for analyses timeframes, which included a compliance period, a protective assurance period, and a performance period to be either 1) a compliance period of 1,000 years for sites without significant quantities of long-lived radionuclides, or 2) a compliance period of 10,000 years followed by a performance period for sites with significant quantities of long-lived radionuclides. Licensees are required to provide a technical rationale for using the 1,000-year compliance period.

2. Removed the requirement for defense-in-depth analysis from proposed § 61.13(f) and instead require identification of defense-in-depth protections in a new paragraph (o) in § 61.12, "Specific technical information."

3. Eliminated many of the detailed requirements for the technical analyses from the proposed § 61.13; instead, the concepts behind the originally proposed requirements are addressed in the guidance document, NUREG-2715, "Guidance for Conducting Technical Analyses for 10 CFR Part 61" (ADAMS Package Accession No. ML16218A504).

4. Revised the Agreement State compatibility categories from the proposed Category B to Category C for the definition of "compliance period" in § 61.2, the requirements for the performance period in §§ 61.41 and 61.42, and the requirements in § 61.58, "Waste acceptance,"[3] to allow the Agreement States greater flexibility to continue their existing

[3] Section 61.58 was titled "Alternative requirements for waste classification and characteristics" in the original 10 CFR part 61 rule.

programs. See the "Compatibility of Agreement State Regulations" section in this document for more information on compatibility categories.

5. Implemented numerous conforming edits and clarifications throughout the rule.

F. What is the safety case in 10 CFR part 61?

Licensees are responsible for demonstrating that their land disposal facilities are constructed, operated, and closed safely. To this end, 10 CFR part 61 establishes requirements that licensees must meet to operate a land disposal facility. While the NRC concluded that the requirements specified in § 61.10, "Content of applications," through § 61.16, "Other information," together with the performance objectives of subpart C and the technical requirements of subpart D, ensure that a licensee demonstrates the safety of a land disposal facility, the former regulations did not explicitly establish requirements for the development of a safety case.

The safety case concept in the context of radioactive waste disposal is generally regarded as a collection of arguments and evidence to demonstrate the safety and performance of a land disposal facility. A safety case for a land disposal facility covers the suitability of the site and the design, construction and operation of the facility, as well as the assessment of radiation risks and assurance of the adequacy and quality of all the safety related work associated with the land disposal facility. The purpose of a safety case is to provide a sufficient level of detail regarding the description of all safety relevant aspects of the disposal site, the design of the facility, and the managerial control measures and regulatory controls to inform the decision whether to grant a license for a land disposal facility and provide assurance that the land disposal facility will be designed, constructed, operated, and closed safely. The safety case includes the same type of information that the original 10 CFR part 61 required to be submitted as part of a license application.

The revised regulations incorporate the § 61.13 analyses into the licensee's safety case. Further, the regulations also require the identification of defense-in-depth protections in § 61.12, which will add an explicit statement of defense-in-depth provisions to the proposed safety case. Finally, the NRC envisions that the safety case for a land disposal facility will evolve over time as new information is gained during the various phases of the facility's development and operation (e.g., site-specific information on types, forms, and activities of LLRW disposed at the site; hydrology; geography). Therefore, the NRC expects that the safety case will be updated at renewal if new information that could significantly impact safety of the facility is acquired. The NRC also is requiring that the application for site closure of a licensed land disposal facility include a final revision to the safety case.

G. What is defense-in-depth?

The defense-in-depth principle has served as a cornerstone of the NRC's regulatory framework for nuclear reactors, and it provides an important tool for making regulatory decisions, with regard to complex facilities, in the face of significant uncertainties. The NRC has applied the concept of defense-in-depth throughout its regulations to ensure the safety of licensed facilities through requirements for multiple, independent layers of defense, and, where possible, redundant safety systems. Traditionally, the reliance on independence and redundancy of barriers has been used to provide assurance of safety when reliable, quantitative assessments of barrier reliability are unavailable. The NRC maintains, as it has in other regulations for disposal (such as for high-level radioactive waste), that the application of the defense-in-depth concept to a land disposal facility is appropriate and reasonable. Therefore, the NRC is now requiring 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.

Application of defense-in-depth protections for land disposal facilities needs to recognize differences between operating facilities and closed land disposal facilities. While waste is being disposed, and before a land disposal facility is closed, defense-in-depth protections, as with other operating nuclear facilities, provide for active and passive safety systems commensurate with the hazard and complexity of the activities. Application of defense-in-depth principles for regulation of land disposal facility performance for long time periods following site closure, however, must account for the difference between an operating land disposal facility with active safety systems and the potential for active control and intervention (i.e., taking action to address) and a closed land disposal facility, which largely relies upon passive barriers. A disposal site is essentially a passive system, and assessment of its safety over long timeframes is best evaluated through consideration of the relative likelihood of threats to its integrity and performance. With respect to the long-term performance of the disposal site, defense-in-depth is provided through the diversity and capabilities of the components and attributes of the disposal site (e.g., waste form, container, engineered features, depth of the 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 contend with unanticipated failures or external challenges. This diversity also compensates, in part, for uncertainties in the long-term estimation of performance of the disposal site. The NRC continues to hold that each layer of defense must make a definite contribution to the isolation of the waste, so that the NRC can find with reasonable assurance that no single layer of defense will be relied upon exclusively to achieve the overall safety objectives over timeframes of hundreds to thousands of years. Disposal of LLRW is predicated on the expectation that attributes of the disposal site, in combination with engineered features, will minimize the migration of radionuclides away from the disposal site. However, the capabilities of site characteristics and engineered features over long timeframes are subject to interpretation and many uncertainties. These uncertainties can be quantified generally and are

addressed by requiring the use of multiple layers of defense. Similarly, although the composition and configuration of engineered features, as well as their capacity to limit releases or function as intruder barriers, may be defined with a degree of precision in the near term that may not be possible for site characteristics, it is recognized that except for archaeologic analogues, there is no experience base for the performance of complex, engineered structures used for waste disposal over periods longer than a few hundred years. Therefore, the NRC expects that licensees will rely on both the natural site characteristics and the engineered features, in combination, to provide reasonable assurance that the overall performance of the disposal site will be adequate over long time periods.

H. What are technical analyses?

This final rule requires each licensee to prepare a performance assessment and a new inadvertent intruder assessment to demonstrate that its land disposal facility and design meet the performance objectives. Licensees are now required to prepare the following as part of their technical analyses: a) a revised analysis, called a performance assessment, to demonstrate the protection of the general population from releases of radioactivity (§ 61.41); b) a new analysis, called an inadvertent intruder assessment, to demonstrate the protection of inadvertent intruders (§ 61.42); c) a performance period analysis to evaluate how the disposal system may mitigate the long-term risk from disposal of long-lived radionuclides, if present in significant quantities, in the LLRW inventory; and d) a site stability analysis to demonstrate the stability of the site for the compliance period. The technical analyses are required to be updated prior to site closure to provide assurance of compliance with the performance objectives and continued demonstration of the safety case. The NRC has developed guidance in NUREG-2175 to facilitate the development of information and analyses that will support licensees in addressing the regulatory requirements.

1. Performance assessment

The first performance objective of subpart C of 10 CFR part 61, which provides protection of the general population from releases of radioactivity, continues to be demonstrated with a technical analysis that has been renamed in § 61.13 as a "performance assessment." A performance assessment, as described in NUREG-1636, "Regulatory Perspectives on Model Validation in High-Level Radioactive Waste Management Programs: A Joint NRC/SKI[4] White Paper" (ADAMS Accession No. ML012260054), is a systematic analysis that addresses what can happen, how likely it is to happen, what the resulting impacts are, and how these impacts compare to regulatory standards. The essential elements of a performance assessment for a land disposal facility are the same as the essential elements of a performance assessment for a high-level radioactive waste repository described in "Risk Assessment: A Survey of Characteristics, Applications, and Methods Used by Federal Agencies for Engineered Systems" (ADAMS Accession No. ML040090236). The essential elements of a performance assessment for a land disposal facility are: a) a description of the features of the site and engineered system; b) an understanding of events likely to affect long-term land disposal facility performance; c) a description of processes controlling the movement of radionuclides from LLRW disposal units to the general environment; d) a computation of doses to members of the general population; and e) an evaluation of uncertainties in the computational results.

Many features, events, and processes (FEP) can influence the ability of a land disposal facility to limit releases of radioactivity to the environment. Behavior of the disposal site is influenced by the land disposal facility design, the characteristics of the LLRW, and the geologic and environmental characteristics of the disposal site. A performance assessment evaluates the projected behavior of an LLRW disposal site and the uncertainties in its projected behavior. The performance assessment includes the specific characteristics of the disposal site (e.g.,

[4] Swedish Nuclear Power Inspectorate.

hydrology, meteorology, geochemistry, biology, and geomorphology) and degradation, deterioration, or alteration processes of the engineered barriers (including the waste form and container) and natural system. The performance assessment also identifies interactions between the disposal site characteristics and engineered barriers that might affect the performance of the LLRW disposal site. The performance assessment examines the effects of these processes and interactions on the ability of the LLRW disposal site to limit LLRW releases and calculates the projected annual dose to a member of the public for comparison with the appropriate performance objective.

Section 61.13 requires licensees to complete a performance assessment to estimate peak dose within the compliance period following closure of the disposal site. The results of a performance assessment will assist in demonstrating that the general population is adequately protected from releases of radioactivity. The revised § 61.41, new definitions, revised technical analyses requirements, and revised concepts are risk-informed and flexible. The revised § 61.41 uses a risk-informed regulatory framework that specifies what requirements need to be met and provides flexibility to a licensee with regard to what information or approach it uses to satisfy those requirements. This approach is warranted because of the site-specific nature of LLRW disposal.

The amendments also formally introduce the concept of FEPs, which ensure that a technical analysis is comprehensive.

2. Inadvertent intruder assessment

In 10 CFR part 61, the NRC recognizes that it is possible, though unlikely, that an inadvertent intruder might occupy a disposal site in the future and engage in normal activities without knowing that they are receiving radiation exposure. Therefore, the second performance objective in subpart C of 10 CFR part 61 is the protection of inadvertent intruders. Prior to this rulemaking, 10 CFR part 61 did not require a site-specific analysis to demonstrate the protection

of an inadvertent intruder. Instead, the safety of an inadvertent intruder was demonstrated by compliance with the LLRW classification system and the disposal requirements imposed for each class of LLRW. The connection between the LLRW classification system and protection of an inadvertent intruder is reflected in the LLRW classification tables in § 61.55. The original regulatory basis for 10 CFR part 61 contains an analysis of a reference land disposal facility that evaluates the impacts of LLRW disposal on an inadvertent intruder. This analysis supported the concentration-based LLRW classification tables developed for § 61.55.

Consistent with the development of the LLRW classification system, the technical analysis requirements previously found in § 61.13(b) specified that the analyses of the protection of inadvertent intruders must include a demonstration that there is reasonable assurance that the LLRW classification and segregation requirements would be met and that adequate barriers to inadvertent intrusion would be provided. The requirements previously found in § 61.13(b) were intended to ensure the safety of the inadvertent intruder through the LLRW classification system and the LLRW disposal requirements imposed for each class of LLRW. However, as they were written, the regulations did not explicitly require an analysis of inadvertent intruder doses. Differences between LLRW disposal inventories, disposal practices, and the underlying assumptions used to develop the LLRW classification tables in § 61.55 could result in varying doses with respect to the protection of an inadvertent intruder.

This final rule adds a requirement for licensees to conduct a site-specific inadvertent intruder assessment to demonstrate compliance with § 61.42. The inadvertent intruder assessment will quantitatively estimate the radiological exposure of an inadvertent intruder at an LLRW disposal site following an assumed loss of institutional controls after the end of the active institutional control period. The results of the inadvertent intruder assessment then will be compared to the performance objective in § 61.42. The inadvertent intruder assessment will identify the intruder barriers, examine the capability of the barriers, and address the effects of uncertainty on the performance of the barriers. The capabilities of the barriers to inhibit contact

with the disposed LLRW or limit the radiological exposure of an inadvertent intruder, and the time period over which the capability persists, must be demonstrated and a technical basis must be provided. In performing the inadvertent intruder assessment, licensees are expected to employ a methodology similar to that used for a performance assessment, but the inadvertent intruder assessment will assume that an inadvertent intruder occupies the LLRW disposal site after the end of the active institutional control period, engages in normal activities, and is unknowingly exposed to radiation from the LLRW.

Along with this new inadvertent intruder assessment requirement, the NRC is implementing a new inadvertent intruder dose limit of 5 mSv (500 mrem) per year for the compliance period consistent with the dose limit used to develop the LLRW classification tables in the original 10 CFR part 61. The original regulatory basis for 10 CFR part 61 assumed that inadvertent intrusion occurred following a cessation of an active institutional control period administered by the land owner or custodial agent. Institutional control of the disposal site was expected to occur beyond the active institutional control period; however, control becomes increasingly difficult to assure for longer periods of time and thus it is not relied upon to ensure safety. Therefore, an inadvertent intruder was assumed to occupy the LLRW disposal site and engage in normal activities, such as agriculture or dwelling construction. The analysis assumed that the inadvertent intruder directly contacted the disposed LLRW, and was exposed to radionuclides through inhalation of contaminated soil and air, direct radiation, and ingestion of contaminated food and water. The NRC based the LLRW classification tables in § 61.55 on radionuclide concentrations that would yield a 5 mSv (500 mrem) per year dose and adjustments to those values based on expectations about the composition of waste streams, among other factors.

The dose limit used to develop the LLRW classification tables was selected from a range of values that were consistent with exposure guidelines of different orders of magnitude that were applicable at that time: 0.25 mSv (25 mrem) per year, 5 mSv (500 mrem) per year, and

50 mSv (5,000 mrem) per year. In NUREG-0945, the NRC selected the 5 mSv (500 mrem) per year dose considering safety, costs, disposal efficiency, and the potential for increased disposal of waste containing long-lived radionuclides that could increase the hazard for long time periods. The NRC reaffirmed its selection in its denial of a petition for rulemaking PRM-61-2, "New England Coalition on Nuclear Pollution, Inc.; Denial of Petition for Rulemaking, dated March 29, 1994 (ADAMS Accession No. ML093490607), and continues to believe that this dose limit provides an acceptable level of protection to an inadvertent intruder.

Given the uncertainty in predicting human behavior into the distant future and to limit associated speculation, the NRC has changed the definition of the inadvertent intruder to limit the receptor scenarios to reasonably foreseeable activities that are realistic and consistent with activities in and around the land disposal facility at the time the inadvertent intruder assessment is developed. The NRC has prepared guidance in NUREG-2175 for the inadvertent intruder assessment that describes acceptable approaches for determining reasonably foreseeable inadvertent intruder activities that are consistent with activities in and around the land disposal facility at the time of closure. The guidance also describes how licensees can take credit for physical characteristics (e.g., water quality) and societal information (e.g., land use patterns) related to the land disposal facility to limit speculation about the types of activities in which an inadvertent intruder might engage.

Consistent with the original approach used in developing the LLRW classification tables, the licensee is required to assume that the institutional controls will cease to be effective after the end of the active institutional control period, but no later than 100 years after site closure. The NRC does not expect that controls will fail, but has concluded that the durability of the controls cannot be assured. In addition, the NRC does not assume that contact with the LLRW by an inadvertent intruder is certain to occur. A 5 mSv (500 mrem) dose limit for the inadvertent intruder, compared to a 0.25 mSv (25 mrem) annual dose limit for the public during the compliance period in § 61.41, provides a dose limit that considers both the health risk to the

inadvertent intruder and the likelihood of the inadvertent intruder receptor scenario. Furthermore, as in the original regulation, engineered barriers and disposal practices, such as greater disposal depth, are allowed to be considered in the inadvertent intruder assessment. For example, if the disposal site implements a protective cover of at least 5 meters (16 feet) thickness, it would not be reasonable to consider a receptor scenario in which a dwelling foundation is excavated below 5 meters (16 feet) and waste is exhumed from a disposal unit if it is not normal to construct foundations in the surrounding area to that depth.

3. Performance period analyses

The regulations in 10 CFR part 61 limit radiological risks from land disposal of LLRW regardless of the half-life of the LLRW. To ensure protection of public health and safety, 10 CFR part 61 includes regulations regarding analyses, LLRW classification, site-selection, LLRW characteristics, and other requirements. A long-term analysis (e.g., longer than 10,000 years) was not considered necessary under 10 CFR part 61, as originally written. The original regulatory system was designed to ensure that the short- and long-term impacts were limited by regulatory requirements such as the LLRW classification system and based upon waste inventories expected to be disposed of at that time. Because the land disposal facilities are now disposing of or considering the disposal of waste inventories (e.g., large quantities of depleted uranium) that are different than those originally projected for disposal, the NRC is now requiring additional analyses to ensure that LLRW streams that are significantly different from those considered in the original regulatory basis for 10 CFR part 61 can be disposed of safely and that the performance objectives will be met. If the performance objectives cannot be met, then LLRW disposal will be prohibited. This analyses-based approach to regulation is more risk informed than the concentration-based approach used in the original 10 CFR part 61 regulations. The original concentration-based approach, by itself, cannot be easily adjusted to

differing site conditions because concentration limits were derived based on specific assumptions.

As set forth in the new § 61.13(e), licensees that have disposed of, or plan to dispose of, LLRW containing significant quantities of long-lived radionuclides are required to prepare long-term analyses, termed “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 will be required only for technical analyses where a compliance period of 10,000 years is used by the licensee.

The metric for the performance period analyses is to minimize releases to the public to the extent reasonably achievable. The NRC considered a variety of approaches for metrics to evaluate these analyses. The aforementioned metric was selected because it allows socioeconomic information to be considered in a risk-informed manner. Considering the timeframes involved, uncertainties may be considerable and therefore the precision typically assigned to a dose limit is not warranted. Although a dose limit is not prescribed, it is recommended that doses or concentrations and fluxes of radionuclides in the environment be calculated, as they are an appropriate common metric for use in comparing alternative approaches. Acceptable approaches to performing the analyses for the performance period are described in NUREG-2175.

The performance period analyses must identify and describe the features of the design and site characteristics that will demonstrate that the performance objectives set forth in §§ 61.41(b) and 61.42(b) will be met with reasonable assurance. These analyses will also help determine whether any additional measures are needed at a disposal site to ensure the protection of the general population and the inadvertent intruder from disposal of LLRW containing long-lived radionuclides. The performance period analyses will determine whether

new or additional limitations are needed for the disposal of some LLRW streams at certain land disposal facilities.

No ending time for the performance period analyses is specified in this final rule. A number of factors influenced this decision. First, the analyses may demonstrate the time when the peak impact is likely to occur such that further calculation beyond when peak dose occurs is unnecessary. Because long-term impacts are driven by site-specific characteristics and the particular LLRW that is disposed, the timing of peak impacts may differ substantially at each land disposal facility. A licensee must demonstrate that impacts are minimized to the extent reasonably achievable, ensuring that facilities and disposal units are not under-designed. Second, the analyses that are developed for the performance period may differ from traditional projections of long-term radiological doses. Performance period analyses may demonstrate that the performance period metrics have been satisfied irrespective of peak radiological impacts. There is uncertainty in the projected radiological risk to future populations from LLRW disposal, which may be based on a number of assumptions about the behavior and characteristics of future society. Because of this uncertainty, this rule focuses on a demonstration of how the natural and engineered barriers of the disposal system could limit future releases of material rather than the exact radiological impact to an individual or group.

4. Site stability analyses

The regulations in § 61.50 require that LLRW disposal sites not be susceptible to erosion, flooding, seismic activity, or other disruptive events or processes to such a degree or frequency that compliance with the 10 CFR part 61 performance objectives cannot be demonstrated with reasonable assurance. The regulations in § 61.44, “Stability of the disposal site after closure,” also include a performance objective for stability at the disposal site after closure. Section 61.44 states that the land disposal facility must be sited, designed, used, operated, and closed to achieve long-term stability of the disposal site and to eliminate, to the

extent practicable, the need for ongoing active maintenance of the disposal site following closure. To demonstrate with reasonable assurance that the § 61.44 performance objective will be met, licensees must conduct site-stability analyses. The original § 61.44 performance objective did not specify an analysis timeframe for the site-stability analyses. Without an analysis timeframe, the applicability of the stability requirement would be subject to different interpretations. Therefore, the NRC has revised the performance objective to specify that stability must be demonstrated during the compliance period.

Site-stability analyses focus on stability of the waste form, stability of the engineered land disposal facility, and geomorphic stability of the disposal site. For disposal of traditional LLRW (i.e., range and type of LLRW that was analyzed in the original 10 CFR part 61), site stability analyses will likely focus on the waste form and engineered features. For disposal of LLRW containing significant quantities of long-lived radionuclides, the focus will likely be on the engineered land disposal facility and geomorphic stability of the disposal site. The extent of the site-stability analyses will be strongly influenced by the radiological characteristics of waste to be disposed. Stability of waste forms, disposal units, engineered barriers (such as cover systems), disposal site, land disposal facility, and the general environment may all be within the scope of the stability assessment.

I. Updated safety case and technical analyses for site closure

The regulations in § 61.28, “Contents of application for closure,” require licensees to submit an application to amend the license for site closure. This application must include 1) a final revision and specific details of the site closure plan, and 2) an environmental report or a supplement to an environmental report. Although the original § 61.28 did not require licensees to prepare updated technical analyses (though it did require licensees to include in its final revision data pertinent to long term containment, such as geologic and hydrologic data), the revisions made in this final rule require licensees to include an updated safety case and

technical analyses in their applications to amend their licenses for site closure. This new requirement will provide greater assurance of compliance with the performance objectives that ensure the safe disposal of LLRW streams that are significantly different from those considered in the original regulatory basis for 10 CFR part 61. In particular, the revised § 61.28 requires a licensee to prepare updated performance period analyses required by §§ 61.13, 61.41, and 61.42 if the licensee has disposed of LLRW containing significant quantities of long-lived radionuclides. This change, coupled with § 61.28(c), which is not being amended in this final rule, will require licensees to take additional action prior to site closure to ensure that the LLRW that has been disposed will meet the performance objectives.

J. What is the compliance period and how was it chosen?

In the original 10 CFR part 61, § 61.7 discussed a number of timeframes that a licensee should consider when selecting a site, designing stable waste forms or containers, controlling access to the land disposal facility, and developing intruder barriers. The timeframes discussed were provided within the context of an LLRW management system that attempts to ensure that LLRW decays to safe levels prior to public exposure to radiation. The quantities of LLRW containing long-lived radionuclides intended to be disposed at a land disposal facility were expected to be limited, thereby limiting potential exposures. For instance, the original § 61.7(a)(2) indicated that in choosing a disposal site, site characteristics should be considered for the indefinite future and evaluated for at least a 500-year timeframe. However, the original 10 CFR part 61 did not provide a value for the time period to demonstrate compliance with the performance objectives. The original regulatory basis for 10 CFR part 61 and the related guidance in NUREG-1573, “A Performance Assessment Methodology for Low-Level Radioactive Waste Disposal Facilities: Recommendations of NRC's Performance Assessment Working Group” (ADAMS Accession No. ML003770778), recognized the need to use an analysis timeframe commensurate with the persistence of the hazard of the source. In selecting

an analysis timeframe, the general practice is to consider the characteristics of the LLRW, the analysis framework (e.g., assumed scenarios, receptors, and pathways), societal uncertainties, and uncertainty in predicting the behavior of natural systems over time. Typically, both technical factors (e.g., the characteristics and persistence of the radiological hazard attributed to the LLRW) and socioeconomic factors (e.g., transgenerational equity) are considered. The purpose of analyzing a land disposal facility is to ensure that public health and safety are protected with an acceptable degree of confidence.

The NRC evaluated approaches used by other countries and international agencies for managing the radiological risks from the disposal of LLRW containing long-lived radionuclides. Some organizations impose a requirement to identify impacts from the disposal of LLRW containing long-lived radionuclides using technical analyses. Results of the analyses are used to impose appropriate restrictions on LLRW disposal, if necessary. Almost every country that the NRC considered places restrictions on how much LLRW can be disposed of in the near-surface environment or does not allow near-surface disposal of LLRW containing long-lived radionuclides. Most countries place explicit numerical limits on concentrations of LLRW containing long-lived alpha-emitting radionuclides. These concentration limits are set by regulators based on generic technical analyses or policy decisions rather than on the results of site-specific technical analyses. Technical analyses are performed, but only for LLRW that satisfies the generic limits. This approach is very similar to what was done for the initial development of the original 10 CFR part 61. The original requirements in 10 CFR part 61 supplemented technical analyses with LLRW concentration limits and other disposal requirements, such as minimum disposal depth for certain types of LLRW. However, regulating multiple land disposal facilities using generic technical analyses means that the concentration limits must be based on the most limiting conditions across the various sites to ensure protection of public health and safety.

Other countries have used regulatory approaches that vary considerably in the methodology used to achieve protection of future generations from the disposal of LLRW. However, countries and international safety organizations consistently apply limiting conditions on the near-surface disposal of LLRW (e.g., prohibit disposal, or impose concentration limits, disposal depth requirements, flux limits, or requiring development of long-term analyses).

Technical analyses are used to understand how a land disposal facility, together with the general environment, may perform and include the potential impacts of uncertainties on public health and safety. The many sources of uncertainty associated with projecting the future radiological risks from disposal of LLRW include, but are not limited to, natural, engineered, and societal sources. The NRC's selection of analyses timeframes for the evaluation of the disposal of LLRW considered the different sources of uncertainty and how the uncertainties may impact projected future radiological risk. The NRC evaluated these uncertainties and their impact on intergenerational review of decision-making through the work by the National Academy of Public Administration, the Organization for Economic Co-Operation and Development, and others.

The NRC discussed the options that were considered in developing its approach and timeframes in Section III, Discussion, Item G, "What options were considered for selecting approach and timeframes and what is the NRC's preferred option," of the proposed rule (80 FR 16082). In the proposed rule, the NRC proposed moving forward with an approach consisting of: 1) a compliance period of 1,000 years with a 0.25 mSv (25 mrem) annual dose limit for the protection of the general population; 2) a protective assurance period that extended from 1,000 years to 10,000 years and had a goal that the annual dose be below 5 mSv (500 mrem) or a level that is reasonably achievable based on technological and economic considerations for the protection of the general population; and 3) a performance period that extended past 10,000 years for sites with long-lived radionuclides. The NRC received very few comments supporting this specific approach; many comments stated that the proposed approach was too

complex and unclear. Other commenters felt that the protective assurance period's dose goal significantly relaxed standards for this period.

In response to the public comments (see also the "Public Comment Analysis" section of this document), the NRC is instead implementing simpler, more straightforward requirements:

1) For land disposal facilities that have disposed of insignificant quantities of long-lived radionuclides and do not plan to accept wastes containing such material in the future, licensees will have to complete a performance assessment using a compliance period of 1,000 years and use a 0.25 mSv (25 mrem) annual dose limit for the protection of the general population. Similarly, licensees are required to complete an inadvertent intruder assessment with a 5 mSv (500 mrem) annual dose limit and a site stability analysis for the 1,000 year period. These licensees are not required to complete any performance period analyses. As such, the revisions to the regulations are expected to have minimal impact on these sites.

2) For land disposal sites that plan to dispose of or have disposed of LLRW with significant quantities of long-lived radionuclides, licensees will need to complete performance assessments using a compliance period of 10,000 years and an annual dose limit of 0.25 mSv (25 mrem) for the protection of the general population. Similarly, they are required to complete an inadvertent intruder assessment with an annual dose limit of 5 mSv (500 mrem) and a site stability analysis for the 10,000 year period. These licensees would also have to complete performance period analyses to understand and minimize, to the extent reasonably achievable, future doses resulting from the disposal of the long-lived radionuclides.

The NRC has concluded that this approach ensures that public health and safety are protected and only imposes a regulatory burden upon licensees when it is necessary due to the risks associated with the LLRW that is accepted for disposal. In addition, the NRC has removed proposed table A, "Average concentrations of long-lived radionuclides requiring performance

period analyses," from § 61.13 and instead has inserted the table in NUREG-2175.[5] Instead of using the proposed Table A for determining if significant quantities of long-lived radionuclides are present in the LLRW, the licensee will have to provide a technical rationale as to why the presence of long-lived radionuclides should not be considered significant enough to require a longer compliance period. A simple evaluation of the inventory can be used to demonstrate that the performance objectives would not be exceeded. Licensees may still use the guidance in the NUREG-2175 table as part of their rationale, but must demonstrate that the selected concentrations provide adequate protection for their site or they may develop other concentration limits or quantity limits using site-specific factors. The development of the technical rationale is not expected to be burdensome and if it becomes overly complex, the licensee should consider using the longer compliance period. Acceptable approaches for determining the duration of the compliance period are discussed in greater detail in NUREG-2175.

K. Why is a 10,000-year compliance period appropriate for long-lived radionuclides?

One of the factors underlying this rulemaking is the unique radiological characteristics of depleted uranium when compared to traditional LLRW. Depleted uranium is very long-lived and there is a large quantity of depleted uranium that is being considered for disposal in commercial land disposal facilities. In addition, the hazard of depleted uranium increases over very long periods of time because of the slow decay of uranium and the in-growth of progeny. The time at which the concentration of radionuclides in the LLRW is within one order of magnitude of the peak concentration is sensitive to the assumed isotopic mass fractions in the initial LLRW. For depleted uranium this time is approximately 10,000 years or longer. Therefore, the NRC

[5] This table was removed from § 61.13 because the identified concentrations in the table may not always be protective of public health and safety as required by § 61.41. These values continue to remain useful with respect to § 61.42 and therefore have been retained in the guidance document.

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[6] 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 "Commission" or "NRC" is intended to include the Agreement State regulator, as appropriate.

near-surface disposal, as well as other requirements. Section 61.55 defines the classes of LLRW acceptable for near-surface disposal (i.e., the LLRW classification system). Section 61.56 defines the minimum characteristics for all classes of LLRW and characteristics intended to provide stability of certain LLRW (i.e., Class B and Class C LLRW). Additionally, § 61.52(a) specifies requirements for near-surface disposal facility operation, including segregation and intruder barrier requirements for various classes of LLRW. In the original regulations, § 61.58 allowed the NRC to authorize other provisions for the classification and characteristics of waste. The new waste acceptance requirements replace the requirements permitting alternative classification and characteristics in the original § CFR 61.58. Requests for alternative classification and characteristics can still be made through § 61.6, "Exemptions."

The LLRW classification system is integrated with the requirements for LLRW characteristics and land disposal facility operation. This integration stemmed from the generic nature of the original regulatory basis for 10 CFR part 61. The integrated requirements are intended to ensure that the performance objectives are met.

The principle basis used for setting the original 10 CFR part 61 classification limits, LLRW characteristic requirements, and operational requirements was limiting exposures to a potential inadvertent intruder at a reference LLRW disposal site. Other considerations, such as long-term environmental impacts, LLRW disposal site stability, institutional control costs, and financial impacts to small entities, were also considered. The NRC developed the LLRW classification system in 10 CFR part 61 from a 1981 analysis of a representative land disposal facility. The facility was assumed to operate consistent with then-current practices, and the analyses considered projected LLRW streams (46 FR 38081; July 24, 1981). Specifically, the LLRW class limits were derived from an analysis that considered a combination of factors including radionuclide characteristics and concentrations, the waste form, the methods of emplacement, and to some extent, the disposal site characteristics. These factors influenced the concentration of radionuclides projected to move from the disposed LLRW to the access

points for the inadvertent intruder receptor scenarios. The factors are dependent upon the LLRW disposed, methods of emplacement, engineering design, and site characteristics, which can vary from facility to facility.

One of the factors the NRC considered is site characteristics; this factor plays a role in the movement of radionuclides between environmental media (e.g., soil to air). The movement of radionuclides depends on the environmental conditions at the location of the land disposal facility. The reference land disposal facility used in the original regulatory basis was not intended to represent any particular location; it was used to reflect the typical environmental conditions within the southeast United States. This region was selected for the reference land disposal facility location because the environmental characteristics were expected to be conservative compared to more arid locations. Further, at the time, most of the LLRW was produced in the eastern United States, and was projected to be disposed at a nearby regional disposal site. Today, only one of the four operating land disposal facilities is located in the eastern United States; the other three are located in the arid or semi-arid western United States.

Regardless of whether the assumptions regarding the LLRW, operational practices, facility design, or site characteristics of the reference land disposal facility are consistent with current facilities, the NRC holds that the 10 CFR part 61 LLRW classification system remains protective of inadvertent intruders for the LLRW streams that were analyzed in the development of the regulations because of the reasonably conservative nature of the analysis used to develop the LLRW classification system. However, inconsistency between actual site conditions and practices at land disposal facilities and the generic assumptions used to develop the LLRW classification system may cause the radionuclide concentration limits to be either overly restrictive or permissive. If radionuclide concentration limits are overly restrictive based on actual site characteristics, facility design, and operational practices, the LLRW classification system would ensure the safe disposal of LLRW, but it would impose unnecessary regulatory burdens on licensees and LLRW generators. Whereas, if the generic concentration limits at a

land disposal facility are overly permissive based on actual site characteristics, facility design, and operational practices, then the LLRW classification system alone may not adequately ensure the protection of inadvertent intruders. In circumstances where the limits were too permissive, the Commission could impose additional requirements to ensure that the 10 CFR part 61 performance objectives would be met. The site-specific WAC will provide assurance that public health and safety will be protected, while offering the possibility for the relief of unnecessary regulatory burdens for facilities with strong site characteristics, design, and operational practices. The specifics of WAC background information, other regulatory approaches regarding LLRW acceptance practices, and technical considerations are discussed further in Section 5.2, "Flexibility for Site-Specific Waste Acceptance Criteria," of "Regulatory Basis for Proposed Revisions to Low-Level Waste Disposal Requirements (10 CFR part 61)" (ADAMS Accession No. ML12356A242), issued in December 2012.

In addition to considering the original regulatory basis for 10 CFR part 61, the NRC also reviewed other regulatory approaches (domestic and international) for LLRW acceptance practices during development of the waste acceptance requirements in this final rule. The NRC found that practices vary but, in general, follow one of two approaches: specification of criteria by the regulatory agency; or development of site-specific WAC by land disposal facility licensees. In all cases, the regulatory authority maintains oversight of disposal, including approval of the LLRW acceptance requirements.

M. What other changes were made in the rule?

The NRC made additional changes to the 10 CFR part 61 regulations to facilitate implementation of this final rule and to align the requirements with current health and safety standards. These changes include: 1) adding new definitions to § 61.2, "Definitions," 2) implementing changes to appendix G to 10 CFR part 20 to conform to the new LLRW

acceptance requirements; 3) modifying site suitability requirements in § 61.50 to be consistent with the analyses timeframes; and 4) updating the dose methodology used in 10 CFR part 61.

1. Adding and revising definitions to § 61.2

Common terms used in 10 CFR are defined in § 61.2. The NRC is adding new definitions to § 61.2 for "compliance period," "defense-in-depth," "general environment," "inadvertent intruder assessment," "long-lived radionuclide," "performance assessment," "performance period," and "safety case" to facilitate implementation of the requirements for site-specific analyses. The NRC also revised the definitions of "disposal unit," "inadvertent intruder," "site closure and stabilization," "stability," and "waste."

The performance period analyses are required if a land disposal facility has been, or will be, disposing of significant quantities of long-lived radionuclides. The "long-lived radionuclide" definition contains three components. The first component is a radionuclide that does not decay sufficiently over the compliance period. The NRC is expressing this as a percentage of initial activity of a radionuclide that remains after 1,000 years to ensure that stakeholders understand that the "long-lived waste" definition is conditional on the analyses framework. If the analysis framework were to be changed in the future or if a different framework was used, a specific half-life value may or may not be appropriate. The second component is a long-lived radionuclide parent that produces short-lived radionuclide progeny. The second component is designed to ensure that the analysis includes radionuclide progeny, such as those resulting from the uranium decay series. The third component is a short-lived radionuclide parent that results in long-lived radionuclide progeny. Examples would include some curium decay series in which a short-lived curium isotope decays to a long-lived radionuclide (e.g., shorter-lived curium-244 decays to longer-lived plutonium-240, shorter lived curium-243 decays to longer-lived plutonium-239). The inventory of LLRW at the time of disposal can differ considerably from the

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).

2. Implementing changes to appendix G to 10 CFR part 20 to conform to the LLRW acceptance requirements

Appendix G to 10 CFR part 20 imposes manifest requirements on shipments of LLRW consigned for disposal. The purpose of the requirements in appendix G to 10 CFR part 20 is to address various regulatory information needs for the transfer of LLRW. These information needs were identified in the statement of considerations accompanying the original regulations (60 FR 15664) and include providing access to information for analyses used to demonstrate compliance with the performance objectives and providing the States and Compacts the information they determine is necessary to carry out their responsibilities.

Because the NRC is revising § 61.58, the NRC is also amending appendix G to 10 CFR part 20 to conform to the flexibility afforded by the option to determine site-specific WAC.

The requirements in this final rule for LLRW acceptance require revisions to the certification requirements of section II of appendix G to 10 CFR part 20. The revised regulations in 10 CFR part 61 require licensees to develop WAC using the existing LLRW classification system, the results of site-specific analyses, or a combination of both. The revisions also require that the certification requirement be updated so that shippers are certifying that LLRW consigned to a land disposal facility for disposal meets the land disposal facility's WAC. In the background information for the proposed rule (80 FR 16802), the NRC stated that the revision of § 61.58 would also require a revision of NRC Form 541, ''Uniform Low-Level Radioactive Waste Manifest–Container and Waste Description,'' and the accompanying guidance, "Instructions for Completing NRC's Uniform Low-Level Radioactive Waste Manifest (NUREG/BR-0204, Revision 2)," (ADAMS Accession No. ML071870172) to conform to the new waste acceptance requirements. The Uniform Waste Manifest (NRC Forms 540, 541, and 542) includes a certification that the materials have been classified, packaged, marked, and labeled and are in proper condition for transportation and disposal in accordance with the applicable requirements

of 10 CFR parts 20 and 61. Certifying that waste is in proper condition for disposal in accordance with 10 CFR parts 20 and 61 requires that the waste be acceptable for disposal prior to shipment to a land disposal facility; thus, a separate acknowledgement from the certification statement that the waste meets the WAC would be redundant and unnecessary. Therefore, NRC is making no change to the Uniform Waste Manifest.

The revised 10 CFR part 61 requirements for LLRW acceptance also required revisions to section III of appendix G to 10 CFR part 20. Section III of appendix G to 10 CFR part 20 imposes requirements on the control and tracking of LLRW transferred to a land disposal facility for disposal. Because the revised 10 CFR part 61 requires that licensees develop WAC using the existing LLRW classification system, the results of technical analyses, or a combination of both, sections III.A.1 through 3 and III.C.3 through 5 in appendix G to 10 CFR part 20 have been revised. Shippers to either a land disposal facility or to a licensed waste collector who will not repackage the waste or transfer to a licensed waste processor are required to prepare, label, and provide quality assurance in accordance with the land disposal facility's WAC. Waste processors who treat or repackage the waste also are required to prepare, label, and provide quality assurance in accordance with the land disposal facility's WAC.

The NRC did not make any revisions to sections I.C.12 and I.D.4 of appendix G to 10 CFR part 20 based on the revisions to 10 CFR part 61. Sections I.C.12 and I.D.4 require the shipper of LLRW consigned to a land disposal facility to identify the LLRW classification per § 61.55 and to state if it meets the structural stability requirements of § CFR 61.56(b) on the uniform manifest. Although the revised § 61.58 allows a licensee to develop site-specific WAC, shippers must continue to identify the classification of a LLRW shipment using the requirements in § 61.55 so that States and Compacts will continue to receive information allowing them to carry out their responsibilities as defined by the Low-Level Radioactive Waste Policy Amendments Act of 1985.

3. Modifying the site suitability requirements in § 61.50 to be consistent with the new analyses framework

The site suitability requirements in § 61.50 specify the minimum characteristics a disposal site must possess to be acceptable for use as a near-surface disposal facility. The primary factors considered for disposal site suitability are isolation of LLRW—which is dependent on the radiological characteristics of the LLRW—and disposal site features that ensure that the long-term performance objectives of subpart C in 10 CFR part 61 will be met, as opposed to short-term convenience or benefits. The concept of site characteristics is explained in § 61.7. Site characteristics should be considered in terms of the indefinite future (see NUREG-2175), take into account the radiological characteristics of the LLRW, and be evaluated for at least a 500-year timeframe. Site characteristics and site suitability requirements play an integral role in ensuring that the disposal site is appropriate for the type of LLRW proposed for disposal. When the site suitability requirements were originally developed, it was envisioned that LLRW would primarily contain short-lived radionuclides with only small quantities and concentrations of long-lived radionuclides. The NRC developed the LLRW classification framework around this concept. However, the regulation at § 61.55(a)(6) allows long-lived LLRW not currently listed in table 1 or 2 of § 61.55 to be disposed in the near surface as Class A LLRW.

In this final rule, it is recognized that not all LLRW may decay to relatively innocuous levels within 500 years and therefore a technical analysis is required to determine if site-specific restriction of disposal of LLRW is necessary. The regulation at § 61.50 has been revised to conform to these changes. The site suitability characteristics themselves have not been changed, but have been reorganized to distinguish the hydrological site characteristics from other characteristics. The hydrological site characteristics have been separated to clarify that for 500 years the hydrological site characteristics must be met regardless of the results of technical analyses designed to show that the 10 CFR part 61 subpart C performance objectives

will be met. Historically, most of the problems encountered in LLRW disposal resulted from water impacting the LLRW disposal system. A site that is unlikely to satisfy the hydrological site characteristics (e.g., disposal of LLRW in the zone of water table fluctuation or flooding) in the next 500 years is unlikely to be defensibly modeled. If the site cannot be defensibly characterized and modeled, the radiological risk from the disposal of LLRW cannot be reliably projected. The short-lived radionuclides that are disposed of may result in significant impacts if they are improperly managed. Therefore, the hydrological site characteristics are treated differently than the other site characteristics. After 500 years for hydrological characteristics and for all timeframes for other characteristics, it is appropriate to consider if the characteristics will limit the ability of the licensee to meet the 10 CFR part 61 subpart C performance objectives. Historically, the other characteristics have not been associated with problems encountered in LLRW disposal. Therefore it is anticipated that it is less likely that the other characteristics will be associated with performance issues within 500 years compared to the hydrological characteristics.

Stability is a cornerstone of waste disposal. Future instability of a land disposal facility may prohibit accurate characterization and performance assessment modeling. Future instability of a waste disposal site may provide the basis to limit or prohibit disposal of certain types of waste if the stability of the disposal site cannot be ensured.

4. Updating the dose methodology used in 10 CFR part 61

The original regulations in § 61.41 required that concentrations of radioactive material released to the general environment “not result in an annual dose exceeding an equivalent of 0.25 mSv (25 mrem) to the whole body, 0.75 mSv (75 mrem) to the thyroid, and 0.25 mSv (25 mrem) to any other organ of any member of the public.” NUREG-1573 describes the performance assessment objectives that would be used to evaluate compliance with § 61.41.

Further, this guidance provides estimates of doses to humans from radioactive releases from a land disposal facility after it has been closed.

The regulations in 10 CFR part 20 allow the use of current NRC health physics practices for NRC licensees. In 1991, the 10 CFR part 20 standards were updated to the total effective dose equivalent (TEDE) approach, consistent with the Federal radiation protection guidance signed by the President on January 20, 1987 (56 FR 23360), for occupational exposure to implement the ICRP recommendations found in Publication 26. The current 10 CFR part 61 dose limits, and several other dose limits within the regulations, stem from a method for calculating and limiting doses that dates back to the late 1950s and was based on recommendations in ICRP Publication 2. The NRC has updated the 10 CFR part 61 regulations to require licensees to use the dose calculation methodology found in ICRP Publication 26 or to use more up-to-date ICRP recommendations for dosimetry modeling purposes.

N. What guidance will be available?

As previously noted, the NRC is issuing NUREG-2175, “Guidance for Conducting Technical Analyses for 10 CFR Part 61” (Docket ID NRC-2015-0003), concurrent with this final rule. This guidance document is intended to supplement existing guidance on non-high-level waste performance assessments (e.g., NUREG-1573, “A Performance Assessment Methodology for Low-Level Radioactive Waste Disposal Facilities—Recommendations of NRC's Performance Assessment Working Group,” issued in October 2000; and NUREG-1854, “NRC Staff Guidance for Activities Related to U.S. Department of Energy Waste Determinations—Draft Report for Interim Use,” issued in August 2007) and to provide additional guidance on the new requirements that are added to 10 CFR part 61 by this rulemaking. The guidance in NUREG-2175 covers performance assessment topics such as source term, radionuclide transport, consideration of uncertainty, and model support. It provides detailed guidance on conducting technical analyses, such as an inadvertent intruder assessment, analysis of site

stability after closure of the disposal site, and a performance period analysis for the disposal site beyond the compliance period. The document also includes information on how to identify and describe defense-in-depth protections and how to select compliance periods. Additionally, NUREG-2175 contains guidance on acceptable approaches for determining WAC based on the results of the site-specific analyses, establishing LLRW characterization methods, and implementing a certification program. Further, NUREG-2175 provides guidance on developing the scope of the analyses, including the identification and assessment of uncertainties and the identification of analytical boundaries. Finally, the document contains guidance on conducting risk-informed, performance-based analyses; general technical analysis considerations, such as the incorporation of FEPs into performance assessments; and other considerations, such as setting inventory limits, and mitigation techniques.

III. Opportunities for Public Participation

On May 3, 2011, the NRC published preliminary proposed rule language (76 FR 24831) and an associated regulatory basis document, "Technical Analysis Supporting Definition of Period of Performance for Low-level Waste Disposal," (ADAMS Accession No. ML111030586) at http://www.regulations.gov for public comment. The staff held a public meeting on May 18, 2011, in Rockville, MD, to discuss the preliminary proposed rule language and its associated regulatory basis document. A summary and transcript of this meeting can be found in ADAMS under Accession No. ML111570329. The comment period ended on June 18, 2011; the NRC received 15 comment letters from private individuals, public interest groups, industry, and government organizations. Although these comments were considered during the rulemaking process, the NRC did not develop specific responses to the comments received during that stage of the rulemaking.

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 members of the public, Tribal representatives,

nongovernmental organizations, the nuclear industry, and State and Federal Government agencies.

IV. Public Comment Analysis

The NRC received 90 letters from commenters, representing 51 individuals, 7 environmental groups (in some cases multiple environmental groups signed a single letter), 9 industry members or industry groups, 4 groups related to educational institutions, 2 native American Tribal organizations, 9 State organizations, and 1 Federal agency. In addition, the NRC received oral comments from 36 organizations and individuals that in many cases also submitted written comments. Oral commenters included 17 individuals, 5 environmental groups, 9 industry members or industry groups, 4 State organizations, and 1 Federal agency. Finally, the NRC received over 2300 form letters. Copies of the public comments can be accessed using any of the methods provided in the ADDRESSES section of this document and referencing Docket ID NRC-2011-0012. In general, most individuals and environmental groups opposed many of the new provisions of the proposed rule. Other groups provided mixed support by agreeing with some parts of the rule and opposing other parts. A few commenters recommended withdrawal of the rule. The comments received on the proposed rule and NRC's responses to those comments have been grouped into the following areas: a) Overall Approach to the Rulemaking; b) Agreement State and Site-Specific Issues; c) Waste Containing Long-lived Radionuclides and Table A; d) Safety Case and Defense-in-Depth; e) Performance Objectives; f) Dose Methodology; g) Technical Analyses; h) Performance Assessment; i) Protection of the Inadvertent Intruder; j) Inadvertent Intruder Assessment; k) Stability; l) Timeframes; m) Waste Acceptance; n) Waste Classification; o) Waste Characteristics; p) Site Suitability and Site Characteristics; q) Institutional Controls and Ownership; r) Regulatory Analysis and Backfitting; s) Other; and t) Out of Scope. To the extent possible, all of the

comments on a particular subject are grouped together. A discussion of the comments and the NRC's responses follow:

A. *Overall Approach to the Rulemaking*

A.1 *Comment:* Commenters indicated that the proposed regulatory requirements should apply only to new waste streams (i.e., wastes different from those considered in the original regulatory basis) or sites desiring to take new waste streams such as large quantities of depleted uranium. Some commenters stated that a new section (e.g., § 61.60) should be added to the regulation to specifically address the new requirements for waste containing significant quantities of long-lived radionuclides. Other commenters argued that the rule should be abandoned completely.

Response: A "new waste" approach was rejected because of the operating history of all of the existing sites (other than the Waste Control Specialists site in Texas that has more recently begun operations). According to information supplied to the NRC by the Agreement State regulators, all of the currently operating sites have disposed of thousands of metric tons of depleted uranium. Only very small quantities of depleted uranium were considered when the original regulatory basis was developed. Therefore, all of the existing sites have already disposed of "new waste." There is no health and 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 of at the site is not significant, then the licensee would only be required to use a compliance period of 1,000 years.

The new requirements also address waste streams such as blended waste. Significant quantities of blended waste near the class limit may pose a risk to an inadvertent intruder based on short-lived isotopes. Therefore, limiting the requirement to sites that will only accept wastes with long-lived radionuclides could address some, but not all, waste streams.

Risk is a result of the concentrations and quantities of the radionuclides that are disposed. A licensee or regulator would need to compare a proposed inventory (both concentrations and quantities) to the inventory in the original regulatory basis to determine if a waste stream was significantly different from the waste streams considered in the original regulatory basis. Invariably there would be differences in the radionuclides that may have been considered in the original regulatory basis analysis compared to a modern inventory comprising different waste streams. It would not be productive or efficient to focus resources on the differences between a hypothetical inventory generated over 30 years ago and a current inventory. It could also be misleading to conclude that because there are differences in the inventories that safety is compromised. The NRC's approach 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.

There is likely to be a difference in risk resulting from disposal of thousands of metric tons and hundreds of thousands of metric tons of depleted uranium because of the differences in radionuclide quantities and concentrations. However, the risk implications for disposal of certain quantities of depleted uranium at a particular site can only accurately be determined by a site-specific analysis. Technical analyses completed by the licensees for this regulation should be able to verify the historical safe disposal of this waste (thousands of metric tons of depleted uranium) at the currently operating sites. In the event that the analysis cannot demonstrate the criteria are met with respect to historical waste disposals at a site, it is incumbent upon the licensee to propose measures to be able to meet those dose limits or seek an appropriately justified exemption under § 61.6 or an Agreement State equivalent. There are several approaches that may be used to demonstrate protection of public health and safety under these circumstances.

As discussed further in item L.1 in this section, the definition of the compliance period has been changed so that the compliance period takes into account the hazard of the waste.

Land disposal facility licensees that only accept wastes with low concentrations of long-lived radionuclides will not be subject to a 10,000-year analysis, whereas those licensees accepting waste streams with significant quantities of long-lived radionuclides will. Licensees that accept waste streams with significant quantities of long-lived radionuclides are also subject to the performance period requirements.

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

A.2 *Comment:* A commenter stated that land disposal facilities operating under the original 10 CFR part 61 regulations should not need to demonstrate protection of the general population from releases of radioactivity and protection of inadvertent intruders using the 1,000-year compliance period analysis because the current waste classification system already ensures protection at 500 years. The commenter asked why, if using the waste classification system ensures protection at 500 years, the NRC is requiring proof at 1,000 years for sites that are not going to accept non-traditional waste streams. The commenter stated that the proposed rulemaking is unnecessary and burdensome, especially when one considers that the NRC has already determined that public health and safety and the protection of an inadvertent intruder are adequately addressed by the current language found in 10 CFR part 61, as long as the waste classification system is followed.

Response: The radionuclide concentrations that define waste classes in the current waste classification system were based only on consideration of inadvertent intrusion. Protection of the general population from releases of radioactivity (§ 61.41) has been and will continue to be provided by technical analyses covering the likely duration of environmental transport. As indicated in item L.1 in this section, the dose from waste that has concentrations of long-lived radionuclides at or below the Class A limits may, in certain circumstances, exceed the dose limit in § 61.41 by a significant margin. Technical analyses are required to demonstrate compliance with the performance objectives. The compliance period is now specified in the rule to prevent misunderstanding and misinterpretation of the role of the waste

classification system and inadvertent intruder protection with respect to the performance objective in § 61.41.

If wastes are significantly different from the wastes considered in development of the original 10 CFR part 61, then the waste classification system may not ensure protection for wastes that are classified using § 61.55(a)(6); for example, if significant quantities of any long-lived waste are disposed, a longer inadvertent intruder analysis may be needed. As already discussed in the response to item A.1 in this section, the NRC evaluated the possibility of designing requirements that could be applied only to "new waste" and determined that approach would not be practical or technically justified.

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

A.3 *Comment:* A commenter noted that one of the reasons provided for why new requirements are needed relates to new waste streams not envisioned during the development of the original 10 CFR part 61. The commenter stated that these waste streams include, but are not limited to, depleted uranium from enrichment facilities, LLRW from DOE operations, blended LLRW streams in quantities greater than previously expected, and the generation of different LLRW streams that may result from new technologies. The concerns related to the disposal of these waste streams are not entirely applicable to all existing facilities. For example, only two of the existing facilities are candidates for the disposal of depleted uranium from commercial enrichment facilities or from the DOE. The commenter stated that one of the disposal facilities disposes of all waste with inadvertent intruder barriers so the "large scale blending of Class B and C concentrations of LLRW with Class A to produce a Class A mixture that could result in a dose to an inadvertent intruder that is above [5 mSv] 500 mrem" would not be relevant. The commenter stated that since the waste streams described will be considered for future disposal, the associated new requirements should only affect those facilities that pursue these waste streams in the future.

Response: As already discussed in item A.1 in this section, the NRC evaluated the possibility of designing requirements that could be applied only to "new waste" and determined that approach would not be practical or technically justified. The NRC disagrees that disposal of waste with an inadvertent intruder barrier makes concerns about large scale blending irrelevant. As described in item Q.1 in this section, the development of the waste classification system included subjective factors like the adjustment of the Class C limits for long-lived radionuclides and the adjustment of the Class A and B cesium-137 limits. These adjustments were based on assumptions about the composition of typical waste streams not just consideration of inadvertent intruder barriers. While the presence of an inadvertent intruder barrier is likely a good defense-in-depth measure for these wastes, a site-specific analysis would be needed for demonstrating the safety of disposal of significant quantities of blended waste. However, the addition of a requirement to complete a performance assessment provides disposal facilities with the flexibility to account for site-specific conditions and engineering barriers in establishing WAC.

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

A.4 *Comment:* Commenters stated that the NRC, in its goal to develop new requirements governing the disposal of large quantities and concentrations of long-lived radionuclides in a near-surface disposal facility, proposed a framework of requirements largely based on high-level radioactive waste guidance documents. One commenter referenced NUREG-1854 as a high-level waste guidance document. They expressed the opinion that the "how to guidance" in the rule language, was both unnecessary and overly restrictive, and that the discussion was not concise and was ambiguous. Several commenters stated, in general, that many of the revisions made to the rule language were too detailed and should be removed from the rule and placed into guidance (e.g., NUREG-2175). They were particularly concerned with §§ 61.7 and 61.13.

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.

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.

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 unnecessary regulatory burden. The commenter noted that the revision to the rule originated from consideration of disposal of significant quantities of depleted uranium.

Response: The commenter is correct in noting that the revision to the rule originated from consideration of significant quantities of depleted uranium. However, the concerns addressed in this rulemaking apply to any waste containing radionuclide inventories or concentrations that are significantly different from those evaluated in the analyses supporting the original regulatory basis. For example, waste that is classified for disposal using § 61.55(a)(6) may represent an unanalyzed waste stream. It would be inefficient to apply the requirements only to depleted uranium when the issue being addressed in this rulemaking is generic in nature and not limited to significant quantities of depleted uranium. This was discussed in item A.1 in this section.

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

A.6 *Comment:* A commenter questioned how verification of future performance would be completed with the long compliance period. Another commenter noted that they had conducted an independent review that addressed future land uses of the Central Plateau at the Hanford site after the 1,000-year compliance period, when all institutional controls, inadvertent intruder barriers, and other precautions have failed. The future land use was based on the Yakama Nation's vision of fully exercising their treaty rights that include hunting, gathering, cattle grazing, sweat lodge use, Tribal ceremonies, and the development of a small community. Because the future community is not aware of the buried radioactive material, a community could be built over the site resulting in cancer deaths to the inhabitants.

Response: The 10,000-year compliance period was determined to be necessary to protect the public health and safety if a near-surface disposal site elects to dispose of significant quantities of long-lived radionuclides. The NRC's approach to disposal is based on an upfront analysis of potential impacts and design of the facility to ensure public health and safety will be protected. The final rule includes requirements to develop technical analyses, using scenarios that are consistent with activities ongoing at or near the site at the time of the analysis, that show that the performance limits with be met through the compliance period (up to 10,000 years

for land disposal facilities that have disposed, or will dispose of, wastes containing significant quantities of long-lived radionuclides) followed by a performance period review, if required. After operations have ended, there will be an active institutional control period where the land disposal facility will be monitored and access controlled. The monitoring program during the active institutional control period is designed to provide further confirmation that the disposal site is performing as expected. The combination of the upfront assessment, a final reassessment at the time of site closure, and disposal site monitoring during the institutional control period (normally this will be a 100-year period) will provide reasonable assurance that the disposal site will perform as designed and thus be protective of future generations without imposing a requirement for continuous verification for thousands of years in the future.

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

A.7 *Comment:* A commenter stated the best disposal action for long-lived radionuclides is disposal in a deep geologic repository like the DOE Waste Isolate Pilot Project in New Mexico. Deep geological disposal is the only method that can protect human health and the environment over the long term.

Response: In general, the NRC agrees that deep disposal of long-lived radionuclides, such as in a deep geologic repository, is more protective (if all other factors are equal) compared to near-surface disposal. However, not all long-lived radionuclides are high risk. Radiological dose is driven by both quantity and concentration. The NRC regulations allow disposal of long-lived radionuclides in the near surface if it can be demonstrated that the safety requirements can be met. Under these regulations, licensees are required to prepare technical analyses to determine where the boundaries are for different types and quantities of waste to ensure that the disposal protects public health and safety. Not all waste will be suitable for near-surface disposal. Licensees should use technical analyses to develop inventory limits or to identify waste types and quantities that are not suitable for near-surface disposal. Certain wastes may only be suitable for disposal with specialized designs or favorable sites.

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

A.8 *Comment:* Commenters stated that NUREG-2175 should be issued again for public comment after the final rule is issued.

Response: The NRC generally tries to issue a draft guidance document concurrently with the proposed rule and a final guidance document concurrently with the final rule. To ensure proper implementation of the rule, the guidance needs to be available when the rule is issued. Although comments will not be specifically solicited on the final NUREG-2175, any comments received on the final guidance document will be considered if the guidance is revised in the future.

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

A.9 *Comment:* One commenter stated that the three current 10 CFR part 61 related activities (this rulemaking and potential rulemakings related to waste classification and greater-than-Class-C (GTCC) waste) could have significant impacts, including adverse financial impacts, on the disposal of depleted uranium from the commercially operating enrichment facility. The commenter recommended that the NRC pursue the 10 CFR part 61 related activities in a coordinated manner and determine the most appropriate prioritization of the rulemaking activities as they move forward.

Response: During the licensing of a commercial enrichment facility, the Commission directed the NRC staff to determine if depleted uranium could be safely disposed of in a land disposal facility because this was an option for disposal considered by the operator of the enrichment facility. The staff determined that depleted uranium could be safely disposed of in such a facility if a site-specific assessment demonstrates the safety of the disposal at the LLRW site. The NRC acknowledges there are financial consequences to this rulemaking as discussed in the regulatory analysis. However, the financial impacts are not expected to be a significant concern for at least two of the existing land disposal facilities. Those facilities that are already considering accepting significant quantities of depleted uranium have either already performed

or are in the process of completing site-specific analyses to justify to their respective Agreement State regulators that this material can be safely disposed at these sites; thus the expenditure of financial resources for at least two facilities, to a certain extent, has already occurred. Also, as discussed in the regulatory analysis for this final rule, the safety concerns resulting from disposing of significant quantities of depleted uranium in a shallow land disposal facility without adequate analysis justify the costs associated with this rulemaking. For additional information see SECY-08-147.

The other rulemakings cited by the commenter will be commenced after this rulemaking is completed, as already prioritized by the Commission. The NRC will solicit comments on the need for revising the waste classification tables in § 61.55 after this rulemaking is completed. Additionally, the NRC will prepare a regulatory basis for the disposal of GTCC and transuranic waste within 6 months of the completion of this 10 CFR part 61 rulemaking. These rulemakings will be coordinated to avoid unnecessary cumulative effects of regulation.

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

A.10 *Comment:* A commenter noted that commercial reprocessing is not being done in the U.S. at this time and the NRC should not change its rules to accommodate reprocessing.

Response: This rulemaking was not promulgated to accommodate reprocessing, although the disposal of waste streams resulting from reprocessing could be addressed through the revisions introduced in this final rule. This final rule ensures that LLRW streams that are significantly different (i.e., depleted uranium and other unanalyzed waste streams) from those considered during the development of the original regulatory basis can be disposed of safely and meet the performance objectives for land disposal of LLRW. The amendments also increase the use of site-specific information to ensure performance objectives that are designed to provide for protection of public health and safety are met. Although this rulemaking was originally intended to address only the disposal of large quantities of depleted uranium in commercial disposal sites, these rule changes are also intended to allow for any future waste

stream to be properly analyzed before disposal at a land disposal facility, so that additional rulemakings for specific LLRW streams may not be necessary in the future.

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

A.11 *Comment:* One commenter stated that the new requirements undermined the regulatory scheme set forth in the Low-Level Radioactive Waste Policy Amendments Act of 1985 (LLRWPAA) because the new requirements apply to depleted uranium waste, which "is not even a state or interstate compact responsibility," and, thus, in the commenter's view, is inequitable.

Response: The NRC disagrees with this comment. The LLRWPAA does not address individual waste streams. Instead, the LLRWPAA addresses classes of waste (i.e., Class A, B, C, and GTCC) and assigns responsibility for disposal of LLRW to the States and the Federal Government. As set forth in Section 3 of the LLRWPAA, States are responsible for disposal of Class A, B, and C waste generated within the State, except such waste that is owned or generated by the U.S. Navy or the DOE or waste that results from research, development, testing, or production of atomic weapons. The definition of LLRW in the LLRWPAA permits the NRC to classify material as low-level radioactive waste and, further, under § 61.55(a)(6) depleted uranium waste is classified as Class A waste. Under section 3113(c) of the AEA, however, States are not liable for the treatment, storage, or disposal of LLRW resulting from the operation, decontamination, and decommissioning of any uranium enrichment facility.

The requirements promulgated in this rule do not alter the assignment of responsibility for disposal of LLRW as provided in the LLRWPAA. Under the LLRWPAA, disposal of depleted uranium generated within a State, other than depleted uranium resulting from uranium enrichment facilities, is the responsibility of that State.

No changes were made as a result of this comment.

A.12 *Comment:* Commenters indicated that the proposed rule did not fully implement a risk-informed and performance-based approach. The commenters were concerned that the

proposed regulations added numerous new requirements for site-specific analyses. One of these commenters stated that the proposed regulations would not allow these analyses to form the basis on which compliance is evaluated. Instead, that commenter indicated that the proposed rule retained vestiges of a mandatory, non-site-specific approach, which preserves and, in fact, adds to technology-based and generic (i.e., non-site-specific) requirements related to engineered components, stability, determination of analytical timeframes and siting criteria, among others. The commenters stated that such criteria are unnecessary and at odds with a truly risk-informed approach to regulation.

Response: The rulemaking is limited in scope and the changes made to the regulation were necessary to ensure that the waste streams unanticipated when 10 CFR part 61 was originally developed could be disposed of safely. The criteria in 10 CFR part 61 have been used effectively for over 40 years. However, the NRC notes that § 61.13 has been revised from the proposed rule to eliminate specific requirements that are already covered by other requirements. Instead, acceptable approaches for meeting the requirements in § 61.13 are described in NUREG-2175. In addition, the rule's requirement for a site-specific analysis provides the flexibility necessary to account for site-specific information, and results in an increase in how risk-informed the rule is.

Licensing decisions under this part are based on the set of safety-related information and understanding of system performance, not just the dose numbers generated by a performance assessment model. The requirements ensure that the dose assessments are of proper quality and have an adequate basis. The performance assessment models require appropriate scope, consideration of uncertainties and variability, technical basis and model support.

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

A.13 *Comment:* A commenter asked how the quality of the review would be ensured under the new requirements because each applicant or licensee will choose their own model

and their own inputs, making it difficult for the States and the NRC to thoroughly review the accuracy and validity of the results.

Response: The standard for quality of the review by the regulator is independent of the substance of the requirements. The NRC uses the reasonable assurance standard to inform regulatory decision making. The NRC evaluates the implementation of each Agreement State's regulatory program through the Integrated Materials Performance Evaluation Program (IMPEP). This program ensures adequacy of the review quality across different regulatory agencies using a non-common set of performance criteria through the sampling of specific licensing and inspection actions taken by the Agreement State. The IMPEP generally evaluates an Agreement State's LLRW Disposal Program every 4 years, or more frequently if required.

To facilitate review of the new requirements, the NRC developed NUREG-2175. This document provides detailed guidance on a variety of topics. In addition, upon completion of this rulemaking and if resources are available, the staff may develop a training course to facilitate use of NUREG-2175. The training materials would be made publicly available.

Additional details of how an applicant's or licensee's technical analyses will be reviewed can be found in section G, "Technical Analyses," in this document.

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

A.14 *Comment:* Some commenters expressed concerns about the proposed rule, stating that the rule constitutes a relaxation of exposure standards for members of the public. Some commenters stated that the rule does not require greater isolation of the waste but enables increased amounts to be disposed and allows for unlimited doses in the future from nuclear waste generated and buried today. Some commenters also stated that the relaxation of the rule increases "acceptable" exposure limits approximately twenty fold from the previous standard and potentially prohibits the full, safe utilization of natural resources by Tribal members and the general public during that time period.

Other commenters expressed general support for the proposed rule. Some commenters stated that they support the proposed requirement for development of WAC based on site-specific analysis. They further expressed support for conducting an inadvertent intruder analysis and identification and evaluation of FEPs. Some commenters supported the flexibility of the proposed approach to tailor regulatory requirements to the characteristics of particular wastes and disposal sites in the context of risk management. Some commenters suggested that a public dose limit of 0.25 mSv (25 mrem/year) and a 5 mSv (500 mrem/year) inadvertent intruder dose limit are appropriate for adequate protection.

Response: The NRC disagrees that the revised rule results in a relaxation of the radiation protection standard in 10 CFR part 61. The original 10 CFR part 61 did not contain requirements for conducting performance period analyses, no period of compliance was specified, no inadvertent intruder assessment was required, and development of a waste acceptance plan was not required.

In contrast, the final rule establishes requirements for new and revised site-specific technical analyses to demonstrate compliance with the subpart C performance objectives. The rule also establishes requirements for developing the WAC for LLRW acceptance that would ensure the safe disposal of LLRW, and would provide assurance that LLRW streams not considered in the original regulatory basis comply with the 10 CFR part 61, subpart C performance objectives. Further, the technical analyses are expected to help identify any additional measures that would be prudent to implement. These amendments also improve the efficiency of the regulations by making changes to facilitate implementation and to better align the requirements with current health and safety standards. Taken together, the new and amended requirements in the final rule will further enhance the protection of public health and safety.

Some commenters referenced a “twenty fold” dose limit increase from a dose limit of 0.25 mSv (25 mrem)/year for the compliance period to a 5 mSv (500 mrem)/year goal for the

protective assurance period as a "relaxation of the rule." As discussed in items L.1 and L.4 in this section, the NRC has removed the protective assurance period from the final rule as a result of other comments. As a result, the commenters' concerns are not applicable to the final rule language.

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

B. Agreement State and Site-Specific Issues

B.1 *Comment:* A commenter expressed technical concerns with the Clive site in Utah, including flooding, water-table fluctuation, erosion, geologic concerns, and seismicity.

Response: Utah is an Agreement State. Regulatory authority for the disposal of LLRW at the Clive, UT, facility is under the Utah Division of Waste Management and Radiation Control (DWMRC). Therefore, specific technical concerns about the Clive site should be directed to the Utah DWMRC.

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

B.2 *Comment*: A commenter expressed concern that the use of technical analyses combined with WAC could result in manipulation of the calculations to achieve a desired outcome.

Response: If a licensee, contractor, subcontractor, or consultant were to deliberately misrepresent, distort, or falsify information, that action would be considered deliberate misconduct under § 61.9(b) and would be subject to enforcement actions in accordance with the procedures in 10 CFR part 2, subpart B, or Agreement State equivalent regulations. Safety concerns should be reported to the Agreement State or the NRC. To report a safety concern to the NRC see: http://www.nrc.gov/about-nrc/regulatory/allegations/safety-concern.html.

A more likely situation is human bias affecting the outcome of analyses, which is well established phenomenon in technical literature. A licensee or consultant may unknowingly misinterpret uncertain information because they have a personal stake in the outcome. The

regulator serves as an independent, objective technical reviewer of the information who ensures that the licensing decisions are based on defensible technical bases. In addition, the licensing process is intended to be transparent and publicly accessible so that other stakeholders have the opportunity to review the technical bases for licensing decisions.

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

B.3 *Comment:* A commenter stated that implementation of the proposed rule would place an undue burden on Agreement States and expressed the view that the Agreement States do not currently have the resources or capabilities needed to review the performance assessment requirements set forth in the guidance document. The commenter also expressed concern that there are a limited number of experts who can effectively perform these analyses. The commenter stated that, while the NRC alluded to the fact that the NRC can provide technical expertise to States for their reviews, historically, these resources have not been made available to assist Agreement States even when requested. For example, when the State of Utah requested support from the NRC to review EnergySolutions's Clive depleted uranium performance assessment, NRC did not provide this support on the basis that they cannot act on behalf of an Agreement State unless the Agreement State relinquishes its authority to them. The commenter proposed that NRC explicitly clarify in the rule the availability of its resources to assist in the review of licensee submittals.

Response: The NRC has consistently advocated for simple, conservative models or analyses if that type of analysis is sufficient to support the regulatory decision. However, the NRC does recognize that some licensing decisions may need to rely on complex models because the disposal of certain wastes is inherently complex. In those cases, the burden for Agreement State regulators and other stakeholders will be increased. However, it is the complexity of proposed waste disposal that drives the burden and not the regulatory requirements themselves. The additional burden is warranted, particularly for the disposal of

large quantities of long-lived radionuclides, to ensure the continued protection of public health and safety.

The Agreement States will be required to have adequate and compatible programs to implement all the requirements requiring compatibility in the revised 10 CFR part 61. Generally, Agreement States have three years from the effective date to adopt NRC requirements, such as 10 CFR part 61. The NRC will evaluate each Agreement State's program to ensure its adequacy and compatibility through IMPEP. Criteria used as part of the IMPEP to evaluate a State's performance would require the Agreement State to have the necessary resources to implement the revised 10 CFR part 61.

One of the tools available to the Agreement States to supplement their ability to implement a revised 10 CFR part 61 is to request technical assistance from the NRC in accordance with Management Directive 5.7, "Technical Assistance to Agreement States." For example, this directive provides a mechanism for an Agreement State to request technical assistance to evaluate their licensee's proposed plan to meet the performance assessment requirements in 10 CFR part 61. The Agreement States are well aware of this agency policy and have taken advantage of it. One such example was provided by the commenter regarding the State of Utah requesting support from the NRC to review EnergySolutions's Clive depleted uranium performance assessment. Contrary to the commenter's assertion that the NRC refused to provide this support, the NRC staff did discuss options with the State of Utah for supporting the review. However, after careful consideration of the advantages and disadvantages of the individual options, the State of Utah elected to seek contractor support for the review. The NRC has also provided technical assistance on a number of other issues to Agreement States with LLRW disposal facilities. As a result, the NRC does not see a need to specifically identify the availability of resources to provide assistance in the 10 CFR part 61 regulations.

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

B.4 *Comment:* Several commenters noted that the proposed rule recommended Compatibility Category A or B for many of the revised sections. In those areas where such a designation is made, the Agreement State regulators would be required to implement program elements that are essentially identical to those implemented by the NRC. Some of these commenters stated that they failed to see what transboundary issues would arise from those proposed revisions that were designated as Compatibility Category B. Those commenters argued that such a designation usually applies to the movement of goods and services under reciprocity between NRC and Agreement States and not simply the transport of radioactive material from one location to another. Other commenters stated that the Agreement States should be allowed to have flexibility to implement more restrictive requirements for most of the proposed revisions because the NRC's proposed approach would result in a reduction in safety already provided by the Agreement State. These commenters requested that the NRC designate these revisions as Compatibility Category C. Some of these commenters were also concerned that the designated compatibility levels would require already completed technical analyses to be redone at significant cost and would reduce public confidence because of the apparent reduction in standards from what the Agreement States were already implementing.

Response: The NRC has reviewed the compatibility designations that were provided in the proposed rule and agrees that in some cases a designation of Compatibility Category B is not appropriate. As such, the NRC has assigned Compatibility Category C to the definition of "compliance period" in § 61.2. This change should allow the individual Agreement States to implement their existing programs without any real or perceived reduction in safety that the formerly proposed compatibility designation may have had. Similarly, the NRC has reassigned Compatibility Category C to § 61.58.

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 Agreement State liaison. Once the MRB completes the findings and recommendation(s), a letter is sent to Agreement State management from the Chair of the MRB. Any

recommendation in the report must be addressed by the State, and the matter is covered at the time of the next IMPEP review. If ineffective or no action is taken, the NRC has a series of progressively stronger oversight tools that can be used, including heighted oversight of the Agreement State program as well as suspension or termination of the agreement. This process is well understood by the NRC and Agreement State staffs.

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

B.9 *Comment:* Some commenters asked if there was a grandfather provision, or expressed a desire that the NRC add a grandfather provision to 10 CFR part 61 (i.e., any statutory or regulatory clause exempting a class of people or transactions because of circumstances existing before the clause takes effect). Many commenters suggested that the approach found in the last sentence of § 61.1(a) (i.e., allowance for a case-by case application of regulations), was in fact a grandfather provision. Some commenters expressed the opinion that the approach in § 61.1(a) should be followed for the new requirements.

Response: The requirements in 10 CFR part 61 do not contain a "grandfather provision" and the addition of such a provision would not further the NRC's public health and safety purpose in amending 10 CFR part 61. The sentence found in § 61.1(a), "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," that some members of the public have labeled as a "grandfather provision," is not a grandfather provision. Instead this provision was included in 10 CFR part 61 to recognize that facilities operating at the time the original rule was adopted in 1982 might encounter issues when adopting, wholesale, a brand new regulatory scheme. The provision was never intended to absolve any operating facility from ultimately coming into compliance with Part 61.

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

apply to facilities that have, “identified new unexpected conditions” and should not be imposed on waste that has already been disposed.

Response: The NRC agrees in part and disagrees in part with these comments. Regarding applicability of the new regulatory provisions, they apply to existing and future land disposal facilities, (i.e., any land disposal facility with an operating license in effect on the effective day of this rule as well as future land disposal facilities). All land disposal facilities in operation today have disposed of depleted uranium and other long-lived waste streams that could impact the long-term performance of the disposal site. Consequently, all currently operating land disposal facilities must undertake the analyses required by this rule to ensure they have the site-specific information necessary to make risk-informed decisions regarding future disposal activities and site management or provide technical rationale as to why the longer timeframes should not apply to them. The analyses do not evaluate individual disposal actions, rather, they evaluate site characteristics and the disposal site as a whole to ensure the performance objectives in 10 CFR part 61 can be met during operation and after site closure. Thus, applying these provisions solely to future disposal activities (i.e., individual disposal actions) or to land disposal facilities that have identified new unexpected conditions would not further the goal of this rulemaking, which is to ensure that waste streams not analyzed during the development of the original 10 CFR part 61 can be safely disposed and that sites that have disposed of such waste streams develop the necessary site-specific information to demonstrate that the site can meet the performance objectives.

The NRC agrees with commenters that there needs to be flexibility in the LLRW disposal regulatory scheme. The NRC is not changing the regulation at § 61.6. The exemption process allows the NRC or Agreement State to grant relief from any requirement in 10 CFR part 61 so long as such relief will not be detrimental to life or property or the common defense and security, is authorized by law, and is in the public interest. Where a requirement would be unnecessary or contrary to effective site management, a licensee can pursue the exemption process with

their regulator. In addition, the new requirements implicitly contain flexibility. For example, licensees or license applicants can develop criteria for LLRW acceptance from the results of the site-specific technical analyses, the LLRW classification requirements, or a combination of both. Flexibility is also afforded in how licensees conduct and consider analyses in the performance period by allowing consideration of long-term radiological doses and concentration and fluxes of radionuclides in the environment.

The NRC agrees that an Agreement State's LLRW program will be evaluated as part of an IMPEP review, including the effects of any exemptions on the Agreement State's LLRW program. The NRC expects that any action taken by an Agreement State regulator will have a well-founded technical basis. The NRC further agrees that the original text in § 61.1(a) permitting a case-by-case application of the requirements in 10 CFR part 61 could have been carried out as multiple license conditions or one license condition imposing all of 10 CFR part 61, or the comparable State regulations, on a licensee with an operating license in existence on December 22, 1982.

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

B.11 *Comment:* Many commenters expressed confusion over the apparent conflict between the existing language in § 61.1(a) and the language in the proposed § 61.13. Some commenters disagreed that the language in § 61.1(a) was intended to apply only to facilities operating at the time of the initial introduction of 10 CFR part 61. Several commenters asked the NRC to explain why the rule language in § 61.13 applied to all facilities when the text in § 61.1(a) suggested that the requirements in 10 CFR part 61 would be imposed only on a case-by-case basis, noting that licensees licensed under the original regulations have operated in good faith with those regulations.

Response: The NRC agrees in part and disagrees in part with these comments. The NRC disagrees with the comments that state that the case-by-case regulatory application noted in § 61.1(a) was intended to apply to all land disposal facilities, rather than applying only to

facilities operating at the time of the initial issuance of 10 CFR part 61 in 1982. According to the plain language used in § 61.1(a), the case-by-case application was a process available to facilities with licenses in effect at the time of the rule's (i.e., 10 CFR part 61) promulgation in 1982. Low-level radioactive waste land disposal facilities licensed after 1982 would not have needed any special accommodation and thus would not have been able to argue that the requirements included in the original rule should be applied to them on a case-by-case basis.

The NRC agrees that the last sentence in § 61.1(a) can be read to pose a conflict with the new language in § 61.13. As evidenced by the comments received on the proposed rule, the text in § 61.1(a) led some readers to incorrectly conclude that a case-by-case application of the requirements in 10 CFR part 61, including the new requirements, should be the general approach for all facilities.

The original purpose of this rulemaking was to revise 10 CFR part 61 to adequately address the disposal of significant quantities of depleted uranium, a waste stream that had not been analyzed as a part of the original regulatory basis for 10 CFR part 61. Over time, this rulemaking has evolved in scope to address not just disposal of depleted uranium, but also disposal of any waste stream not originally analyzed in the original regulatory basis. In SRM-SECY-08-0147, which provided the instruction for initiation of this rulemaking, the Commission stated, "In revising 10 CFR 61.55(a)(6)…the Commission is not proposing to alter the waste classification of depleted uranium. Eventual changes to waste classification designations in the regulations must be analyzed in light of the total amount of depleted uranium being disposed of at any given site. However, the Commission is stating that for waste streams consisting of significant amounts of depleted uranium, there may be a need to place additional restrictions on the disposal of the depleted uranium at a specific site or deny such disposal based on unique site characteristics and those restrictions should be determined by a site-specific analysis which satisfies the requirements of the new § 61.55(a)(9)" (ADAMS Accession No. ML090770988). In order to establish whatever additional restrictions may be

necessary for disposal of both unique waste streams as well as those waste streams originally analyzed in the original regulatory basis, a licensee needs to understand how the disposal site functions. This is the ultimate purpose of the analyses required under § 61.13.

All currently existing land disposal facilities have disposed of depleted uranium and other long-lived waste streams that could impact the long-term performance of the site. The new requirements will ensure that all licensees take the necessary measures to properly evaluate their site characteristics and develop key information to assist in determining future waste disposal activities and further enhance disposal site management. Since its inception, the regulatory scheme in 10 CFR part 61 has included qualitative concepts, in the form of performance objectives, that provide the necessary reasonable assurance that a land disposal facility is protective of the general population, inadvertent intruders, and the environment (§ 61.40, "General Requirement," through § 61.44), as well as quantitative measures to increase assurance that a site meets the performance objectives, such as a final revision to the site closure plan addressing data and analyses pertinent to long-term containment of waste (§ 61.28). The new requirements complement this approach by requiring development of site-specific information, allowing use of that site-specific information in the development of WAC, and recognizing the fundamental role that defense in depth plays in disposal site management.

The sentence at the end of § 61.1(a) is no longer necessary. The original purpose of this text was to offer relief to licensed land disposal facilities operating in 1982 from any unintended consequences resulting from the adoption of 10 CFR part 61. These facilities are now operating under Agreement State regulations that are compatible with 10 CFR part 61, so the relief contemplated in § 61.1(a) is no longer needed. Further, the text has caused confusion for members of the public and is in conflict with the applicability of the new requirements. For these reasons, and as a result of comments received, and as discussed in item B.9 in this section, the NRC is deleting the last sentence of the text in § 61.1(a).

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

are intended to be used for the disposal of radioactive wastes" (i.e., the entirety of the LLRW disposal facility).

The purpose of this rulemaking is to ensure that waste streams not analyzed in the original regulatory basis can be safely disposed and to allow increased use of site-specific information to demonstrate that the performance objectives, which are designed to provide protection of public health and safety, can be met. The analyses resulting from these regulatory revisions would allow identification of any additional measures that may be prudent to implement for continued disposal of radioactive LLRW at a particular facility. Any operating land disposal facility licensee accepting LLRW for disposal must have an idea of its current inventory to ensure it will meet the performance objectives both during operation and after site closure. Consequently, the requirements apply to a land disposal facility as a whole, and not to individual disposal units. If a land disposal facility has closed disposal units or sites, but maintains a license that does not prohibit future waste disposal, then the requirements still apply to that land disposal facility. The NRC conducted a cost-benefit analysis for these requirements and determined that the rulemaking offered numerous benefits, including:

- ensuring that LLRW streams that are significantly different from those considered during the development of the original regulations can be disposed of safely and meet the performance objectives for land disposal of LLRW;

- increasing the use of site-specific information and up-to-date dosimetry methodology in site-specific technical analyses to better ensure public health and safety is protected; and

- promoting a risk-informed regulatory framework that specifies what requirements need to be met and provides flexibility to a licensee or applicant with regard to what information or approach they use to satisfy those requirements.

The NRC concluded that the rule is cost justified because the requirements enhance public health and safety by ensuring the safe disposal of LLRW that was not analyzed in the original regulatory basis.

With respect to the concern about digging up disposed waste, nothing in the new regulations would require a licensee to excavate emplaced waste. If a licensee were to determine that its disposal site may not be able to meet the annual dose limits during the compliance period (0.25 mSv (25 mrem) annual dose limit for members of the general public or the 5 mSv (500 mrem) annual dose limit for inadvertent intruders), it would be incumbent upon the licensee to propose measures to meet those dose limits or seek an appropriately justified exemption under §61.6 or an Agreement State equivalent. Excavation of emplaced waste may be a method, though it may not be the only, or best method, a licensee could use to demonstrate protection of worker and public health and safety.

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

C. *Waste Containing Long-Lived Radionuclides and Table A*

C.1 *Comment:* Commenters had a variety of comments regarding table A as found in the proposed rule for this rulemaking. Some commenters sought clarification on language associated with table A and asked what average was being referenced and how it should be calculated. Other commenters noted that table A should be removed from the regulation and placed in guidance, because the site-specific conditions associated with the table made the table not useful. Others recommended that because a site-specific analysis was required, the long-lived radionuclide definition and table A were unnecessary and lacked technical basis. One commenter indicated that long timeframes were not considered in development of the Class A limits. Commenters stated that the performance assessment could be used to define when performance period analyses were necessary. Some indicated that table A had too much detail to include in the regulation and that it would be difficult to interpret. However, others

stated that table A was a useful requirement and that the Class A values were appropriate to use as a trigger to determine when performance period analyses should be required.

Response: The proposed table A has been removed from the final regulation and moved into the guidance in NUREG-2175. The radiological doses that result from LLRW that is at or below the Class A concentrations found in § 61.55 may exceed the dose limit found in § 61.41(a) by a significant margin for sites with unfavorable hydrology. Alternatively, the radiological doses may be under the limit by a significant margin for sites with favorable hydrology. The NRC considered whether concentration or inventory limits could be developed that would be useful with respect to defining significant quantities of long-lived radionuclides with respect to § 61.41 and determined that the site-specific variability was too large to allow for determination of concentration or inventory limits on a generic basis, however assessment on a site-specific basis should be relatively straightforward (e.g., limited variability for site designs and characteristics versus many generic designs and characteristics).

The approach implemented in this final rule requires that if a compliance period of 1,000 years is used, the licensee must provide a technical rationale explaining why longer time periods do not need to be considered in the technical analyses. Licensees are required to determine the significance of quantities of long-lived radionuclides with respect to radiological dose. The technical rationale is not intended to be a full performance and inadvertent intruder assessment. The results of the performance assessment for the 1,000-year timeframe are not, by themselves, sufficient to identify if analyses covering longer timeframes are necessary. The inventory as well as the site-specific release and transport phenomena drive the timing and magnitude of future doses. In addition, the NRC acknowledges that the table 1 and 2 values cannot ensure protection of inadvertent intruders for receptor scenarios and assumptions different from those assumed in the analysis used to develop the table 1 and 2 values in the original 10 CFR part 61. Additional guidance about what could be discussed as part of the

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

radioactivity of traditional LLRW. The definition is intended to reduce the analysis burden if a disposal site only has limited amounts of long-lived radionuclides.

In table 1 of § 61.55, the NRC addressed long-lived radionuclides, whereas table 2 addressed short-lived radionuclides. The new definition of long-lived radionuclides that includes radionuclides for which more than 10 percent of its initial radioactivity remains after 10,000 years ensures consistency between the new regulatory requirements and the pre-existing tables. For instance, carbon-14 would be considered long-lived using this definition and is considered long-lived in the existing regulation (i.e., it is in table 1 of § 61.55). The other parts of the new definition ensure further consistency, such as capturing plutonium-241 and curium-242, both of which are listed in table 1 because of the in-growth of long-lived daughter radionuclides. The concentrations in the § 61.55 tables were originally based on inadvertent intruder analyses using a 5 mSv (500 mrem) dose limit, with additional adjustments.

The inclusion of transuranic radionuclides with a half-life greater than 5 years was made to capture the in-growth of long-lived progeny and not because the NRC determined that 5 years was an appropriate cut-off to assign a division between long- and short-lived radionuclides.

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

C.3 *Comment:* A commenter posed various questions associated with the interpretation and content of the proposed table A. The commenter requested clarification for the use of the term “waste” in the phrase “waste that contains radionuclides with average concentrations exceeding the values listed in table A of this paragraph.” Specifically, the commenter asked if the concentrations referred to were the radionuclide concentrations in the waste as it was originally disposed accounting for 10,000 years of decay and ingrowth, or if it referred to only the radionuclides remaining in the original disposal volume after 10,000 years, or if another meaning was intended. The commenter also expressed concern with the formatting of table A and recommended that table A should use metric units consistent with

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

to enhance public health and safety are provided to account for the risks posed by wastes containing significant quantities of long-lived radionuclides, and provide a means to document and address the nonquantitative factors that can enhance confidence in safety. Some of these and other commenters requested the NRC provide additional clarity about the definition of the safety case in the regulations. The commenters sought clarity on the NRC's expectations for a safety case. In particular they asked whether the radioactive material licensing and environmental review processes that the Agreement States have are consistent with the NRC's concept of the safety case (the combination of a performance assessment and defense-in-depth). Some commenters also recommended moving the description of the safety case to guidance. Another commenter recommended that the NRC add a definition for "safety case" in the regulations. Other commenters recommended that the NRC adhere more closely to the international concept of safety case as defined by the International Atomic Energy Agency (IAEA).

Response: Safety case for a land disposal facility is defined in § 61.2 and is intended to be a collection of information that demonstrates the assessment of the safety of a land disposal facility. A safety case would include technical analyses, such as the performance assessment and inadvertent intruder assessment, as well as information on defense-in-depth and supporting evidence and reasoning on the strength and reliability of the technical analyses and the assumptions made therein. The safety case also includes a description of the safety relevant aspects of the site, the design of the facility, and the managerial control measures and regulatory controls such as those specified in § 61.10. Guidance on what should be considered in a safety case can be found in NUREG-2175.

The NRC disagrees with one commenter's assertion that the collection and presentation of information in a cohesive framework is unnecessary. The NRC expects that the type of information included in a safety case will form the basis of licensing decisions. Further, the NRC does not expect the development of a safety case to be burdensome because the

information that will be included in the safety case should already be generated as part of the licensing basis for disposal.

The NRC's safety-case concept for a land disposal facility is consistent with the international concept of the safety case as defined by the IAEA in its guidance. For example, in Specific Safety Guide No. SSG-23, "The Safety Case and Safety Assessment for the Disposal of Radioactive Waste," the IAEA defines the safety case as "the collection of scientific, technical, administrative and managerial arguments and evidence in support of the safety of a disposal facility, covering the suitability of the site and the design, construction and operation of the facility, the assessment of radiation risks and assurance of the adequacy and quality of all of the safety related work associated with the disposal facility." The elements of NRC's safety case for a land disposal facility are consistent with the elements of IAEA's safety case. Therefore, additions to the safety case definition would not contribute further to the safety of disposal sites.

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

D.2 *Comment:* Some commenters were supportive of requiring licensees to explicitly identify and describe how a land disposal facility provides defense-in-depth protections. Other commenters raised issues with requirements to provide an analysis of defense-in-depth protections. Some of these latter commenters were concerned that an analysis would require a quantitative evaluation, which, they argued, is not always possible for some protections relied upon for defense-in-depth.

Response: In proposing the defense-in-depth analysis, the NRC did not intend to require a solely quantitative evaluation of defense-in-depth protections because the NRC agrees that some defense-in-depth protections may not be amenable to strictly quantifying the contribution the barrier makes to compliance (e.g., percentage reduction of the dose due to the barrier). For example, procedures or the actions of personnel are not always quantifiable in terms of their impact on dose reduction.

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.

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

achieving a regulatory program and associated requirements that are risk-informed and performance-based.

With respect to operational activities (e.g., waste handling), while waste is being disposed, and before a land disposal facility is closed, defense-in-depth protections are comparable to other operating nuclear facilities licensed by the NRC. Operating facilities typically include both active safety systems (e.g., equipment, procedures, and controls) and passive safety systems (e.g., physical barriers) for defense-in-depth protection. Application of the concept of defense-in-depth at operating facilities is used to ensure safety of licensed facilities through requirements for multiple, independent barriers, and, where possible, redundant safety systems and barriers. Traditionally, the reliance on independence and redundancy of barriers has been used to provide assurance of safety. Thus, application of defense-in-depth principles for operational activities at a land disposal facility, as with other operating nuclear facilities, would provide active and passive safety systems commensurate with the hazard and complexity of the regulated activities.

Application of defense-in-depth principles to the regulation of land disposal facility performance for long time periods following site closure, however, must account for the difference between a closed land disposal facility and an operating facility with active safety systems and the potential for active control and intervention. Additionally, many of the components of the disposal site, both natural and designed (e.g., the saturated zone hydrology, the waste container) are expected to behave continuously, rather than work or fail in a binary fashion in contrast to many safety systems of operating facilities (e.g., cranes, pumps, valves). A closed land disposal facility is essentially a passive system, and assessment of its safety over long timeframes is best evaluated through consideration of the relative likelihood of threats to its integrity and performance. With respect to the long-term performance of the disposal site, defense-in-depth is provided through the diversity and capabilities of the components and attributes of the disposal site (e.g., waste form, container, engineered features, depth of the

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 that 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 (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.

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

E. *Performance Objectives*

E.1 *Comment:* A commenter suggested the term "minimize," as used in the proposed §§ 61.41(c) and 61.42(c), does not properly reflect the multi-faceted optimization process, which entails consideration of numerous factors; indeed, "minimize" as used in the proposed regulatory language can be interpreted as being more stringent than the “as low as reasonably achievable” (ALARA) requirement applied to the compliance period, since it does not clearly allow for consideration of what is feasible or reasonable. The commenter suggested that the language be revised to read, "Effort shall be made to reduce releases of radioactivity…" A different commenter indicated that analyses after the compliance period should use an ALARA approach. Another commenter indicated that “minimize” should be changed to “reduce.” Other commenters recommended dropping the proposed minimization concept from the final rule because of the practical difficulties that will be created for implementing these subjective requirements over thousands of years. Instead, a different commenter recommended that the NRC rely on the specific dose limits set forth in proposed §§ 61.41 and 61.42, which would provide objective criteria for licensees, generators, and Agreement States.

Response: The requirements proposed in §§ 61.41(c) and 61.42(c) [§§ 61.41(b) and 61.42(b) in the final rule] provide for minimization to the extent reasonably achievable, which makes minimization, in this context, analogous to the ALARA requirement. It is not intended to be more restrictive. NUREG-2175 provides guidance on risk-informing the performance period analyses. The performance period analyses are focused on the potential long-term performance of the system.

For the compliance period, including the 10,000-year value used for significant quantities of long-lived radionuclides, a specific dose limit is prescribed. After the compliance period, analysis of the performance period may be necessary depending on the concentrations and

quantities of specific radionuclides. The standard for minimization to the extent reasonably achievable has been retained for the performance period in the final rule. It provides more flexibility to demonstrate how the land disposal facility is limiting long-term impacts in the post-10,000-year timeframe than a strict comparison to a prescriptive dose limit.

The standard for the performance period is like ALARA, but the ALARA standard was not used because ALARA is applicable only if a dose limit is provided and the performance period has no dose limit. The minimization requirements for the protective assurance period have been eliminated with the elimination of the protective assurance period. The requirements for minimization of releases of radioactivity (for § 61.41(b) [§ 61.41(c) in the proposed rule]) and exposure to inadvertent intruders (for § 61.42(b) [§ 61.42(c) in the proposed rule]) to the extent reasonably achievable have been retained for the performance period. The requirements provide the same level of detail as the ALARA requirement in § 61.41(a) that has been used effectively in licensing decisions. The requirement is intended to be analogous to the ALARA requirement, without the dose limit. NUREG-2175 provides extensive guidance on how to implement the minimization requirement.

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

E.2 Comment: A commenter questioned whether the minimization approach for the performance period would apply to engineered measures alone or if it would also apply to site selection.

Response: The minimization approach would emphasize evaluation of engineered measures, but could also include consideration of natural features. In general this minimization approach would be performed on a site that has already been selected for waste disposal. Therefore alternate sites may not be considered. However, if a licensee operated multiple land disposal facilities, the licensee could consider different land disposal facilities for the waste as part of their minimization evaluation. The licensee could also consider how use of inventory limits might limit releases from the land disposal facility.

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

E.3 *Comment:* A commenter inquired if the performance objectives developed in this rulemaking would apply to Waste Incidental to Reprocessing (WIR) or if the older performance objectives would apply.

Response: The new performance objectives apply to WIR determinations. A review of the legislative history found in House Report 108-767 indicates specific Congressional intent that modifications to the 10 CFR part 61 performance objectives shall apply to WIR determinations. The NRC will evaluate the need to update NUREG-1854 in the future.

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

E.4 *Comment:* Some commenters submitted similar comments that stated that radon should be excluded from the dose-based performance objectives. The commenters asserted that the inclusion of radon is inconsistent with expectations applied to other U.S. Environmental Protection Agency (EPA), NRC, and DOE regulations that address management of uranium-containing materials (e.g., 40 CFR 190.10, 40 CFR part 61 (subpart H), 40 CFR 61.192 (subpart Q), 10 CFR part 40 (appendix A, criterion 6), 10 CFR 20.1101(d), DOE Order 435.1). The commenters indicated the proposed performance objectives in 10 CFR part 61 should be updated to be more consistent with other national requirements related to radon for wastes containing uranium and recommended that the NRC add a performance objective for radon flux, consistent with the approaches in other promulgated rules. One of the commenters stated that the NRC should exclude uranium from the all-pathways dose objective.

Response: The amendments to 10 CFR part 61 ensure that LLRW streams that are significantly different from those considered during the development of the original regulations (e.g., depleted uranium and other unanalyzed waste streams) can be disposed of safely and meet the performance objectives for land disposal of LLRW. Thus, the amendments require analyses that evaluate the ability of the site's natural characteristics and the disposal site design to meet the performance objectives for the radionuclides to be disposed and their progeny. The

benefit of these analyses would be diminished if specific radionuclides were excluded from the analyses. The primary reason radon was not included in the original 10 CFR part 61 analyses was because significant amounts of radon generating waste were not anticipated to be disposed as LLRW and not because the NRC determined that radon should be treated differently from a human-exposure standpoint.

The NRC is aware that different radon flux rates have been specified in different regulations; however, the purpose of the analyses required by 10 CFR part 61 (i.e., evaluation of the site and design to ensure protection of the public and a potential inadvertent intruder) dictates that the entire inventory of the disposal site be considered. A flux-limit approach is problematic for LLRW disposal using protection of public health and safety performance objectives because, unlike regulations that use a flux-limit approach, 10 CFR part 61 does not require continual control. Additional reasons for the differences between 10 CFR part 61 and the regulations relevant to uranium mill tailings are discussed in items K.2 and Q.1 in this section. Further, to ensure protection of public health and safety after active institutional controls are no longer effective, the NRC requires an inadvertent intruder assessment. The dose that may result from a given flux will be strongly dependent on the characteristics of the receptor. For example, a given flux into the atmosphere will produce a much lower dose than the same flux into a basement of a home. The dose values resulting from radon being released into the environment will be a better measure of public health and safety than a flux limit. Because the NRC is not adopting a flux value for this regulation, the NRC has concluded that there is a technical justification for not removing radon from the dose calculations. Similarly, the NRC has not identified a technical justification for removing uranium from the dose calculation because a radon flux limit would not ensure protection of the public from the potential doses from uranium itself and other progeny (e.g., radium) in this situation.

It is not feasible, within this rulemaking, for the NRC to resolve the different approaches to the treatment of radon in different regulations. While the NRC cannot resolve all the

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.

Failure to observe radiation induced health effects in offspring was also confirmed by the ICRP in their publication 103; however the ICRP continues to conservatively include the potential risk of heritable effects in its analyses. The ICRP notes that: "There continues to be no direct evidence that exposure of parents to radiation leads to excess heritable disease in offspring. However, the [ICRP] judges that there is compelling evidence that radiation causes heritable effects in experimental animals. Therefore, the [ICRP] prudently continues to include the risk of heritable effects in its system of radiological protection."

More recently, the lack of observable health effects in children born to survivors of the atomic bombings in Japan was reaffirmed in an October 2015 article from *The Lancet Oncology*[7] entitled "Risk of death among children of atomic bomb survivors after 62 years of follow-up: a cohort study."

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

F.2 *Comment:* A commenter indicated the proposed dose thresholds in § 61.42 are not risk-informed when the same numerical values are used for 0 to 1,000 years and 1,000 to 10,000 years given the increases in uncertainty that occur as time elapses.

Response: Uncertainty in whether a protective standard can be achieved is fundamentally different from the permissible level of radiation a member of the public can be exposed to under current practices and understanding. To sufficiently address uncertainty, the regulator must first establish an appropriate radiation safety standard. Next an assessment is done to determine if the standard can be satisfied; and the results of the assessment will have uncertainties. It is then up to the decision-makers to use qualitative judgements derived from the quantitative results to determine whether 1) the uncertainties are acceptable and 2) protection of public health and safety can be demonstrated. When making these qualitative

[7] Risk of death among children of atomic bomb survivors after 62 years of follow up: a cohort study. The Lancet Oncology. (Volume 16, Issue 13). October 2015: 1316–1323. See http://www.thelancet.com/pdfs/journals/lanonc/PIIS1470-2045(15)00209-0.pdf for purchasing options.

judgements based on quantitative results, the NRC determines whether there is reasonable assurance that public health and safety will be protected.

Setting dose limits for long time periods such as 1,000 years, 10,000 years, and potentially much longer time periods (e.g., 100,000s of years) involves a number of challenging considerations (e.g., uncertainty in long-term estimates of performance, protection of future generations, time period for quantitative analyses, dose or risk limits). The NRC and international bodies continue to evaluate the application of requirements for disposal of long-lived radionuclides over long time periods (e.g., "Regulating the Long-Term Safety of Geological Disposal," NEA No. 6182, Nuclear Energy Agency (NEA), 2007; "Radiation Protection Recommendations as Applied to the Disposal of Long-Lived Solid Waste," ICRP Publication 81, International Commission on Radiation Protection, 2000; EPA Public Health and Environmental Radiation Protection Standards for Yucca Mountain, Nevada, Final Rule (73 FR 61256; October 15, 2008)). Generally, there is no clear consensus for a "single" approach (e.g., time period of analysis; dose or risk limits) for regulating the disposal of long-lived radionuclides; however, there have been no significant consequences in terms of radiological impact identified due to the diversity of criteria that exist among different countries' requirements (NEA No. 6182, page 7).

Nationally and internationally there is support for application of quantitative requirements for time periods on the order of 10,000 years. The ICRP stated in ICRP 81 that: "To evaluate the performance of waste disposal systems over long time scales, one approach is the consideration of quantitative estimates of dose or risk on the order of 1,000 to 10,000 years. This approach focuses on that period when the calculation of doses most directly relates to health detriment and also recognizes the possibility that over longer timeframes the risks associated with cataclysmic geologic changes such as glaciation and tectonic movements may obscure risks associated with the waste disposal system." Thus, the NRC considers a 10,000-year time period with a single dose limit to be an appropriate requirement for disposal of

significant quantities of long-lived radionuclides that will allow for a reasonable evaluation of disposal unit designs and site characteristics, including uncertainties. The information from these evaluations can be used to identify important defense-in-depth protections and to risk-inform such activities as engineering design, site characterization, maintenance activities, and closure plans. Increasing the dose limit beyond a certain time (e.g., 1,000 years), as suggested by the commenter, could result in a more limited evaluation of the land disposal facility site, design, and potential defense-in-depth protections. The purpose of evaluating a dose at long time periods is not to predict a specific dose that will be received, but to evaluate the safety of the system.

Although there is no clear single dose limit and time period for analyses that has consensus support, the NRC decided that the current approach (i.e., a single dose limit applied for 1,000 or 10,000 years) provides a reasonable balance between the limitations of long-term evaluations, protection of future generations, and providing information for risk informing disposal of radioactive wastes.

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

F.3 *Comment:* A commenter provided specific recommendations for changes to dose limits based in part on ICRP publication 103. When referring to waste disposal, ICRP 103 (2007) states: "[D]ose estimates should not be regarded as measures of health detriment beyond times of several hundred years into the future. Rather they represent indicators of the protection afforded by the disposal system. The [ICRP] has given specific guidance for disposal of long lived solid radioactive waste in publication 81 and this guidance remains valid." The commenter stated that the dose thresholds in the proposed rule should align with the latest ICRP guidance to be consistent with international standards; the commenter provided the following recommendations:

- The dose values in §§ 61.41(a), 61.41(b), 61.42(a), and 61.42(b) should state that the units are presented as effective dose equivalents (EDE) to be consistent with latest dose assessment science and terminology.

- The value in the proposed § 61.41(a) for doses to the public during the compliance period (0 to 1,000 years) should be changed from 0.25 mSv (25 mrem) per year to 0.3 mSv (30 mrem) per year for consistency with ICRP 103 and ICRP 81.

- The value in the proposed § 61.41(b) for doses to the public during the protective assurance period (1,000 to 10,000 years) should be changed from 5 mSv (500 mrem) per year to 10 mSv (1 rem) per year. This is consistent with ICRP 81 recommendations for doses below which interventions are likely not justified.

- The value in the proposed § 61.42(a) for doses to the inadvertent intruder during the compliance period (0 to 1,000 years) should be changed from 5 mSv (500 mrem) per year to 10 mSv (1 rem) per year. This is consistent with ICRP 81 recommendations for doses below which interventions are likely not justified.

- The value in the proposed § 61.42(b) for doses to the inadvertent intruder during the protective assurance period (1,000 to 10,000 years) should be changed from 5 mSv (500 mrem) per year to 100 mSv (10 rem) per year. This is consistent with ICRP 81 recommendations for doses above which interventions are almost always justified.

Response: The NRC disagrees that it would be beneficial to specify that the dose values provided are expressed as EDE. As stated in the statement of considerations, the NRC's intention, as specified in § 61.7(e), is to allow the licensees to use the most current scientific models and methodologies (e.g., those accepted by the ICRP) appropriate for site-specific circumstances to calculate the dose, whether it be "EDE" or the most current "effective dose" methodology.

In ICRP 103 and ICRP 81, the ICRP recommended a dose limit of *up to* 0.3 mSv (30 mrem) per year. The value chosen by the NRC is within the range of the recommendation, and 0.25 mSv (25 mrem) per year has been used effectively in the United States LLRW disposal community for over 30 years. The NRC considers the recommendations from a large variety of groups, such as the ICRP, when establishing dose limits.

The value in § 61.42(a) of 5 mSv (500 mrem) per year is consistent with the dose limit that the NRC used when developing tables 1 and 2 of § 61.55. The NRC has not modified the waste classification tables in this rulemaking. Therefore, to ensure consistency, the 5 mSv (500 mrem) per year value is maintained. Please see item I.1 in this section for more information.

The analysis timeframes have been simplified and the final rule no longer includes target thresholds that were proposed in §§ 61.41(b) or 61.42(b). Therefore, the recommendations to change the §§ 61.41(b) and 61.42(b) optimization targets no longer apply. Although optimization targets are no longer included in §§ 61.41(b) and 61.42(b), the NRC notes that a comparison to ICRP guidelines for interventions is not appropriate for planning waste disposal. A waste disposal action is fundamentally different from mitigating a hazard that already exists. Further, the NRC notes that the commenter's recommendation to use the ICRP's intervention limit of 100 mSv (10 rem) per year is not protective as a general public health and safety limit; this is double NRC's occupational dose limit and is 100 times NRC's public dose limit.

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

F.4 *Comment:* Commenters stated that the annual dose limit should be set to 0 mSv (0 mrem).

Response: The NRC's annual radiation dose limit of 0.25 mSv (25 mrem) is a small fraction of the annual radiation dose the average member of the public in the U.S. receives from all sources. Public health and safety is protected by this stringent dose standard and the NRC does not see a reason to lower it further at this time.

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

F.5 *Comment:* Commenters expressed a variety of views on the use of updated dose methodologies. One commenter expressed support for use of more recent ICRP publications (compared to ICRP 2) containing dose conversion factors for assessments. Other commenters expressed concerns regarding the value and safety significance of removing critical organ dose limits in the updated dose limits in § 61.41. Some of these commenters asserted that the updated dose methodology (i.e., effective dose methodology) would increase allowable radioactive releases, or projected doses to people, during or after the operational period.

Response: The NRC disagrees with the assertion that revisions to the dose methodology in 10 CFR part 61 increase allowable radioactive releases or projected doses to people. As stated in the proposed rule, the benefit of updating the dose limit to an effective dose, whether it is the TEDE or a more current effective dose methodology, is that it provides a holistic and consistent evaluation of the risks of radiation, regardless of the source of exposure. A holistic approach provides a large benefit in LLRW disposal dose assessment because of the range of radionuclides that are comingled within the LLRW. Each radionuclide has its own predominant exposure pathway and dose rate. Without a holistic method that sums the total exposures across exposure pathways and radionuclides, a risk-informed, performance-based decision is harder to make because the doses between receptor scenarios or situations would not be comparable.

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

F.6 *Comment:* Commenters asserted that the NRC did not evaluate the unique vulnerability of children, “which is required under the Executive Order on the Protection of Children from Environmental Health Risks and Safety Risks, signed on April 21, 1977.”

Response: The NRC considers the annual dose limit of 0.25 mSv (25 mrem) for LLRW disposal protective of all age groups and genders based the potential health risks from such an

exposure over an individual's lifetime. The international community and Federal agencies (including the EPA) follow ICRP's current guidelines that the overall annual dose to members of the public from all sources should not exceed 1 mSv (100 mrem), to be protective of all individuals and the environment. The purpose of the public dose limit is to limit the lifetime risk from radiation to a member of the general public. Variation of the sensitivity to radiation with age and gender is built into the standards, which are based on a lifetime exposure. A lifetime exposure includes all stages of life, from birth to old age. For ease of implementation, the radiation standards, which are developed to minimize the lifetime risk, limit the annual exposure that an individual may receive.

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

G. *Technical Analyses*

G.1 *Comment:* Some commenters expressed concern that the use of site-specific technical analyses, which would likely involve complex computer models to develop site-specific WAC, reduces transparency. The commenters indicated that it is more difficult for the public to understand complex models and assumptions, and the public may be less accepting of future waste sites.

Response: Communication, transparency, and clarity are essential to engage the public in licensing decisions. The NRC understands that the use of complex models has the potential to be a challenge to public involvement; however, steps can be taken to alleviate this burden. Regulatory decisions should be as transparent as possible and documented with a clear description of the process and basis for the decisions. Considering modern information technology, most information should be able to be made publicly available. The requirement to develop a safety case should help ensure that a plain-language description of the basis for the safety decision is available to the public.

The issue of communication and transparency has been added to NUREG-2175.

No changes were made to the rule language as a result of these comments. However, changes were made to the guidance document.

G.2 *Comment:* Some commenters expressed concern with the development of technical bases that support site-specific analyses. In particular, they were concerned that the decisions would rely on information developed by licensees or their contractors — the people financially benefiting from the decisions. The commenters stated that studies need to be vigorous, thorough, replicable, and peer reviewed. Other commenters voiced support for the use of site-specific analyses.

Response: The NRC agrees that scientific studies must have acceptable technical bases and quality to support the licensing basis for waste disposal decisions. In most cases the site-specific studies will be performed by the licensees or contractors hired by the licensees. Other information may be obtained from scientific literature. It is important that the responsible regulator reviews the technical basis for the licensing decision to ensure that it is of adequate quality and it is unbiased. Some of the requirements in § 61.13 (e.g., § 61.13(a)(3)) were added to ensure that proper basis and support for the models are provided to justify the licensing decision.

In the development of these analyses, the responsible regulator is an independent technical reviewer with the primary objective of ensuring that public health and safety are protected. Licensees may propose analyses developed by their contractors but those analyses must be approved by the regulator. In some cases, the regulatory agency may use independent measurements or sampling to verify information supplied by a licensee. The NRC does not require independent scientific studies, but does require an independent technical review of information developed by licensees be performed by the regulator.

Detailed guidance has been developed in NUREG-2175 to facilitate the review of the technical analyses. When the NRC performs a technical review of a performance assessment, the NRC will commonly evaluate and run the licensee's models, review references, evaluate

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 applies to natural variability and cycling of climate. 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 can be revised, if needed, as the impact of human activity-induced climate change is better understood.

Further, 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 impacts of climate change or any FEPs were expected to occur after the required 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 moved to guidance. Some commenters supported the specific requirements in the proposed regulations.

Response: The NRC agrees with some of these concerns. The proposed regulation provided 10 requirements for the performance assessment in § 61.13(a). Some of the requirements have been deleted while others have been retained.

The proposed § 61.13(a)(9) was deleted because it was deemed to be duplicative with the proposed § 61.13(a)(6). Model support is critical to performance assessments (§ 61.13(a)(6)). Consideration of alternative conceptual models of features and processes is an important technique to address the inevitable situation for complex waste disposal problems where model uncertainty cannot be effectively reduced (§ 61.13(a)(9)). However, additional information about alternative conceptual models of features and processes is provided in in NUREG-2175. The NRC agrees that groundwater monitoring data can be an important source of model support (or refute a model) for a performance assessment. The NRC also agrees that a separate requirement, as proposed in § 61.13(a)(5), regarding degradation or alteration processes, was unnecessary. The proposed § 61.13(a)(5) has been deleted because it was deemed to be duplicative with §§ 61.13(a)(1) and 61.13(a)(3). Further discussion of degradation or alteration processes is now discussed in NUREG-2175.

The requirements for consideration of FEPs have been simplified and the separate requirement for consideration of degradation or alteration processes has been deleted. The requirement in the proposed § 61.13(a)(10) plays an important role related to understanding the significance of the major components of the disposal system in mitigating or reducing risk. This information is valuable in risk-informing the review of disposal system performance. Therefore, the paragraph has been retained as § 61.13(a)(6) in the final rule. Consideration of FEPs and description of how the integrated system of FEPs is functioning are two different concepts. The requirement does not provide sub-system requirements, but rather it provides for a description of the contributions of the natural and engineered systems to overall performance.

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

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 develop 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

approach is consistent with the application of updated dosimetry methods that would be allowed by the proposed changes and that more recent ICRP guidance discusses the applicability of limits and constraints to a “representative person” (ICRP 103. Section 5.4.2). A commenter indicated that protection of the general population and protection of any member of the public are different concepts. A commenter stated the definition of any member of the public should explicitly include people of all ages, including infants and children, and include males as well as females. Annual dose compliance should be assessed to the member of the public who is estimated to get the largest dose according to this definition.

Response: Historically, with 10 CFR part 61, the term “any member of the public” is used to refer to the receptor for which the dose calculation is performed. For example, see page B-111 in NUREG-1573. The NRC recommends the use of the average member of the critical group as the receptor in performance assessments to demonstrate compliance with dose criteria. The critical group is that subset of the population most likely to be exposed to radiation. For example, in the case of atmospheric releases, the critical group would be individuals living at the point of highest concentrations downwind from the release point. The average member of the maximally exposed group is then compared to the radiological dose limits. “Any member of the public” is not the hypothetical maximally exposed individual within the population subset. The variability in doses between the critical group and the members of public not exposed to radiation is in general much larger than the variability in doses within the critical group. Considering the unknown characteristics of the future exposure group, this simplification is reasonable and warranted. This approach ensures protection of the general population.

The purpose of the public dose limit is to limit the lifetime risk from radiation to a member of the general public. The conversion factor used to equate dose into risk is based on data from various populations exposed to very high doses of radiation, such as the atomic bomb survivors, which included individuals of all ages. Therefore, variation of the sensitivity to radiation with age and gender is built into the standards, which are based on a lifetime exposure. For ease of

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 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.

H.10. *Comment:* Commenters recommended that a definition or discussion be added for the term “reasonable assurance.” They stated that this term could have very different implications when applied to the timeframes of hundreds or thousands of years, as proposed in the rule, than its application as applied by the NRC in other contexts (e.g., operation of a fuel cycle facility). A commenter suggested that the concept adhere to NRC’s interpretation, as used in the context of geological disposal, to be consistent with EPA’s term “reasonable expectation,” as applied to analyses to or beyond 10,000 years. In addition, commenters stated that the term “ensure,” should not be used with respect to the regulatory requirements because it is not consistent with reasonable assurance.

Response: The NRC disagrees that “ensure” is inconsistent with the reasonable assurance standard. The regulator must ensure that the regulatory requirements are met. The degree of proof applied to the requirements is reasonable assurance; these concepts are not inconsistent. Reasonable assurance is not a different standard whether applied to a long-term analysis of a land disposal facility or to the licensing of a facility using medical isotopes.

With respect to the term “reasonable expectation,” that term was used by the EPA with respect to the postclosure performance objectives for the proposed high-level waste repository at Yucca Mountain. The term “reasonable expectation” is not relevant to LLRW disposal or this rulemaking. The NRC has addressed “reasonable assurance” and “reasonable expectation” in great detail in the context of development and implementation of 10 CFR part 63 (May 18, 2007 letter from Cyr to Malsch, “Nevada’s Request for a Binding Opinion on ‘Reasonable Expectation’ in 10 CFR Part 63” (ADAMS Accession No. ML071520180)), but the “reasonable expectation” standard does not apply to land disposal facilities for LLRW.

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

H.11 *Comment:* One commenter stated that the proposed definition of "performance assessment" places unnecessary focus on the FEPs approach and is inconsistent with other widely-used definitions (e.g., from ICRP, IAEA, and Nuclear Energy Agency (NEA)). The

commenter stated that the proposed rule appears to require a single methodology to achieve a conceptual site model, and suggested that the NRC use a definition of performance assessment from the international community (e.g., the IAEA Safety Guide No SSG-23 on safety assessment and the 2012 NEA, “Methods for Safety Assessment of Geological Disposal facilities: Outcomes of the MeSA Initiative”). Commenters also characterized developing scenarios based on safety functions as a more current approach for scenario development and recommended that the rule place more emphasis on the use of safety functions.

Response: Although the definition of performance assessment has been modified as a result of other comments, FEPs continue to be part of the definition of performance assessment because they are an integral part of performance assessment methodology. Although safety functions can be used in developing scenarios, safety functions rely on components of the disposal system to contribute to safety. These components are either features or processes and degradation of the safety functions will be caused by FEPs. Thus, the FEPs approach is comprehensive and flexible enough to provide the information needed to identify safety functions. At this time either approach (FEPs or safety functions) is considered appropriate for performance assessment because both approaches would need to consider FEPs and safety functions in the analysis.

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

H.12 *Comment:* A commenter stated that the consideration of all FEPs is too broad and could entail consideration of highly unlikely or fantastic events or combinations of events. The commenter suggested that consideration should be limited to "reasonably foreseeable and significant" FEPs or factors that are relevant to performance.

Response: The term “consider” as used in § 61.13 refers to identification and categorization of FEPs. Identification of FEPs can occur after information and documentation pertaining to the characterization and description of the site has been evaluated. If a previously compiled generic FEPs list is used to identify relevant FEPs, there will be some FEPs that may

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 human technologies and activities on the evolution of natural systems. 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 positon. 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.

Current regional land use and other local conditions in place at the time of the analysis will strongly influence the identification of exposure pathways from disposal sites with relatively

short-lived radionuclides. That is, not much emphasis is placed on the potential evolution of the disposal site. For the time periods associated with the decay of short-lived radionuclides, fixed receptor or exposure scenarios may be developed once an understanding is obtained of how a disposal system functions. In this relatively static environment, it is conceivable that exposure scenarios could be included in the analysis itself as suggested by the commenter. However, for LLRW disposal sites that will contain significant quantities of long-lived radionuclides and even for some site locations containing relatively short-lived radionuclides, performance may need to be assessed at a disposal site that is changing or evolving with time (e.g., colder, wetter, more eroded). Conditions can change during these timeframes such that exposure pathways and receptor activities, and subsequently the exposure scenarios, may also change. In such cases, the future evolution of the disposal site will determine where exposure pathways could exist and the activities of onsite and offsite receptors. The scenario development process will identify the future scenarios that need to be analyzed. Only after this process is complete, can exposure scenarios be selected that fit with the altered disposal site.

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

H.14 *Comment:* A commenter expressed concern that it is difficult to provide technical bases for inclusion or exclusion for some FEPs, either because studying the FEP is very expensive, or the very nature of the FEP is difficult to observe under real conditions or has an extreme element of uncertainty (e.g., impact of long term climate change on various man-made materials that have not yet existed for a long period of time). Requiring a technical justification for every FEP may be an unrealistic expectation. The commenter suggested that rather than requiring a technical basis or justification for inclusion or exclusion of every FEP, it may be more feasible to require a documented justification instead. A documented justification does not have to be technical but still requires the applicant to put an appropriate level of thought into each FEP.

Response: The NRC agrees with the commenter that it may be difficult to provide technical bases for inclusion or exclusion for some FEPs due to the lack of information at present and obtaining reliable information about specific characteristics in the future. NUREG-2175 discusses this issue and states that expert judgment will constitute a key element of the screening process. The term "technical basis" in § 61.13(a)(1) was not intended to imply that the uncertainties associated with the specific FEPs are supposed to be reduced to zero, but that FEPs should be screened using the best scientific and technical information available.

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

H.15 *Comment:* A commenter pointed out that the proposed § 61.13(a)(4) discusses the potential for other FEPs if compelling scientific information exists. The commenter recommended that the regulation should have clearer wording.

Response: Paragraph § 61.13(a)(4) was included in the proposed rule to address a timeframe ("protective assurance period") that has been eliminated in the final rule, thus making the requirement proposed in § 61.13(a)(4) no longer necessary. As a result, the proposed § 61.13(a)(4) was deleted in its entirety and so additional clarification is no longer necessary.

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

H.16 *Comment:* A commenter recommended that the word "demographic" be added to the list of site characteristics that need to be described in the second sentence of § 61.12(a). The commenter also suggested adding the following statement to the end of § 61.12(a): "These features, events, processes, and exposure scenarios (FEPSs) must be related to their respective roles in both migration of and human exposure to radionuclides originating in the disposed waste."

Response: Section 61.12(a) is a requirement to describe the current natural characteristics of the disposal site and the current demographic characteristics of the area around the disposal site. Describing demographic characteristics entails describing the size, growth, density, and distribution of the human population in the area; however, describing

natural characteristics can include a great range of characteristics and are therefore specified in more detail in § 61.12(a). Therefore, "demographic" was not added to the list in § 61.12(a).

The commenter's proposal to constrain the description to those FEPs and receptor scenarios to their respective roles in both migration of and human exposure to radionuclides originating in the disposed waste has similarities to the language in § 61.12, which states that the technical information must include information needed for demonstration that subpart C of 10 CFR part 61 will be met. However, the commenter's proposed addition would be too constraining for demonstrating that subpart D of 10 CFR part 61 would be met. Much of the information needed for subpart D is not directly tied to the FEPs associated with exposure pathways, but rather it is tied to the suitability of the land disposal facility. A description of the site characteristics, as determined by the characterization activities, should include sufficient information for the reviewer to develop an understanding of the safety attributes of the disposal site. The description includes those features and processes that were considered significant for performance, FEPs that were excluded from the assessment, and the rationale for their exclusion. More detailed information on this topic can be found in NUREG-2175.

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

I. *Protection of the Inadvertent Intruder*

I.1 *Comment:* The NRC received several comments about the dose standard for protection of inadvertent intruders. Some commenters supported an explicit dose limit to ensure protection of inadvertent intruders, while others rejected the use of an explicit dose limit. Some commenters supporting an explicit dose limit also supported an explicit dose limit of 5 mSv (500 mrem) per year. Other commenters who supported an explicit dose limit preferred a limit consistent with the limit for protection of the general population (i.e., 0.25 mSv (25 mrem) per year), or the public dose limit specified in 10 CFR part 20 (i.e., 1 mSv (100 mrem) per year). Commenters advocating a dose limit for protection of inadvertent intruders similar to the limit

used for protection of the general population or the public dose limit stated that a future inadvertent intruder should be afforded the same level of protection as a member of the public because they would also be unknowingly exposed to the radioactivity, while another commenter was concerned that higher limits would simply allow more radioactivity to be disposed.

Commenters rejecting the use of an explicit dose limit for protection of the inadvertent intruder cited inconsistency with the DOE's approach and international recommendations for protection of inadvertent intruders, the Advisory Committee on Reactor Safety's stated opposition to using the results of long-term assessments for strict adherence to dose limits rather than the avoidance of catastrophic results, and the NRC's previous justification for removing a proposed 5 mSv (500 mrem) annual limit from the original 10 CFR part 61. Many of these commenters advocated for recasting the limit as a goal or guideline to optimize facility design or develop WAC. One commenter specifically recommended that ALARA be used with 5 mSv (500 mrem) per year as a guideline.

Response: The NRC understands the commenters' concerns with setting a dose limit involving a stylized scenario for an inadvertent intruder. As discussed later, the NRC is specifying an explicit dose limit of 5 mSv (500 mrem) per year for the inadvertent intruder because such an approach: 1) provides a level of protection consistent with the initial development of 10 CFR part 61; 2) is generally consistent with the ICRP recommendations for such calculations; and 3) provides a reasonable limit for licensees to consider additional measures, which would further reduce the likelihood of an intrusion or limit the consequences should an intrusion occur.

(1) Consistent with Initial Development of 10 CFR Part 61

During the initial promulgation of the original 10 CFR part 61, the NRC considered three candidate values of different orders of magnitude; 0.25 mSv (25 mrem) per year, 5 mSv (500 mrem) per year, and 50 mSv (5 rem) per year. Selection of the 0.25 mSv (25 mrem) per

year value would likely have resulted in considerably higher costs, required more changes in existing practices, and resulted in less disposal efficiency than the other two candidates. The NRC thought this was important considering the hypothetical nature of the intrusion event. The NRC concluded that the 50 mSv (5 rem) per year alternative involved approximately the same costs and impacts as the 5 mSv (500 mrem) per year alternative. The NRC was concerned that the higher value could result in allowing the disposal of larger quantities of long-lived radionuclides, which could result in moderately higher inadvertent intruder hazards for long time periods. Therefore, the NRC selected 5 mSv (500 mrem) per year as a general dose rate limitation guideline for the inadvertent intruder and used that guideline to develop the concentration limits in § 61.55. The NRC reaffirmed the adequacy of 5 mSv (500 mrem) per year for protection of an inadvertent intruder in its denial of a petition for rulemaking (PRM-61-2) that requested the concentration limits be reevaluated considering a limit of 1 mSv (100 mrem) per year. Specifying a dose limit of 5 mSv (500 mrem) per year affords a consistent level of protection for the inadvertent intruder regardless of whether a licensee develops WAC using the concentration limits specified in § 61.55 or the results of the technical analyses.

Further, the NRC rejects the notion that promulgating a 5 mSv (500 mrem) per year dose limit is inappropriate because it is inconsistent with its prior rationale for excluding a dose limit for protection of an inadvertent intruder. In the initial promulgation of 10 CFR part 61, the NRC concluded that the 5 mSv (500 mrem) per year dose limit could reasonably be used as the basis for deriving waste classification tables, but its use as a regulatory limit was not justified or practical. The NRC reached this conclusion in response to comments from the EPA that the licensee would not be able to monitor or demonstrate compliance with a specific dose limit that applies to an event that might occur hundreds of years from now. In promulgating the revised 10 CFR part 61, the NRC concluded that an inadvertent intruder assessment is necessary to ensure that LLRW not analyzed as a part of the initial development of part 61 is disposed safely and that the inadvertent intruder assessment will be used to demonstrate compliance with the

inadvertent intruder dose limit. The approach promulgated in this rulemaking does not require the licensee to monitor or demonstrate compliance with the inadvertent intruder performance objective beyond the closure of the facility obviating the concern raised previously by EPA. The NRC concluded that the use of the inadvertent intruder assessment represents a practical method to ensure protection of the inadvertent intruder far into the future.

(2) Consistent with ICRP Recommendations

The NRC considers the performance objective for the inadvertent intruder to be consistent with international recommendations for the protection of inadvertent intruders through constrained optimization, contrary to the commenters' assertion. The ICRP recommends a system of limits and constraints be used to ensure protection from beneficial uses of radioactive materials, including any waste associated with their use. The ICRP differentiates between limits, which ensure protection of all regulated sources in planned exposure situations, and constraints, which ensure protection from a single regulated source. Therefore, the NRC has designated a dose limit to members of the public from all sources of 1 mSv (100 mrem) per year in 10 CFR part 20. In the context of land disposal of radioactive waste, the NRC has also established performance objectives in 10 CFR part 61 to constrain the exposures from a land disposal source of exposure below the public dose limit specified in 10 CFR part 20 because a member of the public could receive exposures from multiple licensed radioactive sources. In the case of the performance objective for protection of the general population, the NRC relies upon a dose constraint, specified in § 61.41, to determine the acceptability of exposures from natural processes.

The ICRP recommends that the use of the dose constraint *for members of the public* [emphasis added] is not appropriate for human intrusion because, by definition, intrusion will have bypassed the barriers that were considered in the optimization of protection for the land disposal facility. However, the ICRP recognizes that a measure of the significance of human

intrusion for protection is necessary and, in circumstances where intrusion may lead to sufficiently high doses to those living around the site, intervention based on current criteria would be justified. In these circumstances, the ICRP recommends that reasonable efforts should be made to reduce the probability of human intrusion or to limit its consequences. Therefore, the NRC has specified a separate dose level of 5 mSv (500 mrem) per year in § 61.42(a) for the inadvertent intruder, which is different than the dose constraint established for a member of the public. The NRC concluded this is appropriate, given the unlikely and stylized nature of the inadvertent intruder scenarios that need to be considered in the intruder assessment. (See comment response in Section J for further details on the inadvertent intruder assessment.)

(3) Reasonable Limit for Consideration of Additional Safety Measures

The NRC considers a dose constraint of 5 mSv (500 mrem) per year a reasonable level for the consideration of additional measures to further reduce the likelihood of an intrusion or limit the consequences should an intrusion occur. Projected doses to an inadvertent intruder below this level would likely not require additional protection measures when designing, operating, and closing a land disposal facility. Although this level of protection is lower than the level recommended by the ICRP (i.e., levels that would necessitate intervention), the NRC determined that the level is protective and enhances the defense-in-depth protections of a land disposal facility without being unduly burdensome.

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

I.2 *Comment:* A commenter recommended different approaches for dose limits to protect the inadvertent intruder over different timeframes. The commenter argued that a single dose limit is not risk informed when the same numerical values are used for 0 to 1,000 years and 1,000 to 10,000 years, given the increases in uncertainty that occur as time elapses. The commenter recommended that the NRC designate a dose limit of 10 mSv (1 rem) per year for

the first 1,000 years and 100 mSv (10 rem) per year for the period from 1,000 years to 10,000 years because these values would be consistent with recommendations in ICRP Publication 81.

Response: Uncertainty in whether a protective standard can be achieved is fundamentally different from the permissible level of radiation a member of the public can be exposed to under current practices and understanding. The process for providing protection from radiation generally involves establishment of a radiation safety standard followed by assessment to determine if the standard can be satisfied. The results of the assessment will have uncertainty and it is up to the decision-makers to use qualitative judgments derived from the quantitative results to determine whether 1) the uncertainties are acceptable, and 2) protection of public health and safety can be demonstrated.

The NRC acknowledges that there is uncertainty in the level of protectiveness of a current dose standard far into the future. A dose standard deemed protective of public health and safety today could, in the future, be deemed overly or inadequately protective. Nonetheless, the NRC considers the current dose standards to be protective today and appropriate for comparison with the results of assessments conducted for land disposal facilities. See response to item F.2 in this section for further discussion on applying dose limits over different timeframes.

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

I.3 *Comment:* A commenter raised a concern that the proposed wording of the inadvertent intruder performance objective at § 61.42(a) could imply “any inadvertent intruder” is the maximally exposed individual or other such exposure context, which is not consistent with evaluating exposures based on typical regional human behaviors and consumption rates. The commenter recommended that the NRC revise “any inadvertent intruder” to “an inadvertent intruder” in the aforementioned paragraph.

Response: NRC disagrees that the wording of § 61.42(a) requires the consideration of a maximally exposed individual or other such exposure context that is not consistent with typical

regional human behaviors and consumption rates. The definition of an inadvertent intruder in § 61.2 and the requirements for inadvertent intruder assessment in § 61.13(b) constrain excessive speculation on the behavior of the inadvertent intruder while ensuring a reasonable assessment of exposures based on knowledge of human activities and behaviors.

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

J. *Inadvertent Intruder Assessment*

J.1 *Comment:* Comments were received on the need to protect inadvertent intruders separate from the general population and the need to conduct a site-specific inadvertent intruder analyses. A commenter stated the disposal of depleted uranium justified the need for site-specific inadvertent intruder analyses. Some commenters questioned the need for protection of an inadvertent intruder. A commenter argued that 10 CFR part 61's requirements for institutional controls would protect potential inadvertent intruders and eliminate the need to evaluate exposures. Other commenters recommended that the distinction between protection of an inadvertent intruder and a member of the public be abandoned because the distinction is blurry. One commenter provided a supporting example in which an initial inadvertent intruder disturbs the site, which results in a release of radioactivity, to which another individual is later exposed. The commenter recommended that protection of an inadvertent intruder be folded into protection of the general population and assessed in a performance assessment that evaluates risks to populations that are expected to occur at any given site rather than undertaking a distinct inadvertent intruder assessment.

Response: While, in principle, the significance of human intrusion might be ideally assessed using a risk-based approach that considers both the probability of intrusion and the associated consequences, any projections of the magnitude of intrusion are by necessity dependent on assumptions that are made about future human behavior. Since no scientific basis exists for predicting the probability of future human actions, it is not appropriate to include

the probabilities of such events in a quantitative performance assessment that is to be compared with the dose constraint for protection of the general population. Rather, consideration of a reasonable set of receptor scenarios against a separate dose limit—which recognizes that an inadvertent intrusion is unlikely, but possible—affords a reasonable level of protection, should an inadvertent intrusion occur.

The NRC does not expect an inadvertent intruder to occupy the site, but has established regulations to ensure that, should the institutional controls fail, an inadvertent intruder who might occupy the site would be protected. The NRC is relying on the common understanding of the word "occupy"—to hold or take possession of the disposal site for some period of time—when specifying inadvertent intruder receptor scenarios. Therefore, the NRC does not require licensees to evaluate the impact to someone traversing the area around the site as part of the inadvertent intruder assessment. Rather, the performance objective for the protection of the general population would ensure that individuals traversing around the site were protected from releases of radioactive material from the disposal site.

The requirements do not specify that an inadvertent intruder must contact the waste, as one of the commenters indicates, only that the inadvertent intruder occupy the site and is unknowingly exposed to radiation from the waste. While the NRC acknowledges that an inadvertent intruder could cause a disturbance that then results in releases from the land disposal facility as the commenter postulates, the exposures due to potential inadvertent intrusion would naturally be expected to be largest for the person directly contacting the disposed waste onsite. This is consistent with the comparison of results from NRC's analysis for a reference land disposal facility in the original regulatory basis for 10 CFR part 61. The NRC has provided guidance in Chapter 4 of NUREG-2175 that discusses acceptable methods licensees can use to demonstrate that releases that may result from an inadvertent intrusion event are considered appropriately.

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

J.2 *Comment:* A commenter recommended specifying that the inadvertent intruder was a human rather than a plant or other animal.

Response: The definition of "inadvertent intruder" in § 61.2 clearly states that the intruder is a person.

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

J.3 *Comment:* Commenters expressed various views on the proposed requirements for the types of inadvertent intrusion receptor scenarios to be considered in an inadvertent intrusion assessment. Some commenters were supportive of the proposal to require consideration of receptor scenarios that are consistent with expected activities around the site at the time of site closure because it would limit speculation and regulatory burden regarding potential receptor scenarios. Other commenters requested further clarification regarding the inadvertent intruder receptor scenarios. Some of these commenters requested additional limitations while others considered the rule language unduly restrictive.

Several commenters supported requiring consideration of a wider range of inadvertent intruder receptor scenarios than normal activities and provided a range of potential scenarios to be considered (e.g., terrorism, unmonitored children, and major events such as climate change, flooding, glaciers, volcanoes, earthquakes, and asteroid impacts). A commenter recommended citing agriculture, dwelling construction, and resource development as examples rather than specifying them as normal activities. Another commenter advocated abandoning the proposed separate analysis of inadvertent intrusion and, rather, considering likely future receptor scenarios as part of the performance assessment.

Some commenters that supported limiting the range of scenarios recommended that the inadvertent intruder assessment focus on considering the types of receptor scenarios used to develop the original waste classification tables and asked the NRC to remove resource exploration and exploitation receptor scenarios from consideration. The commenters were concerned that the resource exploration and exploitation scenarios were vague and could

include activities, which they stated have not been traditionally considered in the context of LLRW disposal, such as mining. They also expressed confidence that the resulting impact from resource exploration and exploitation activities would likely be bounded by receptor scenarios that were used to develop the waste classification tables, such as dwelling construction, agriculture, and well drilling, which already account for the possibility of waste being encountered directly.

Response: The NRC is requiring licensees to assess exposures to an inadvertent intruder who occupies the site. The intent of the proposed rule language was to require licensees and applicants to develop exposure scenarios based on reasonable assumptions and characteristics of the site and not to require unsupported or excessive speculation regarding future human activities and behaviors. Given the uncertainty in estimating human behavior into the distant future, the proposed rule language provided that a licensee may evaluate exposure to an inadvertent intruder via a set of stylized scenarios based on normal activities including dwelling construction, agriculture, and resource exploration or exploitation that are typical of human activities when occupying land in different timeframes and in varying locations, or based on reasonably foreseeable activities that are known to occur in or around the site at the time of closure of the land disposal facility. Commenters provided a range of views regarding concerns and uncertainties in selecting specific exposure scenarios to be used in the inadvertent intruder 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 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.

K.2 *Comment:* Commenters indicated that requiring stability for 10,000 years is unreasonable and there is no technical basis for the proposed stability period. They stated that no other regulatory agency has a comparable requirement for LLRW disposal, and no Agreement State or licensee would be able to demonstrate stability for 10,000 years because the data to assess engineered features over this time period simply do not exist. A commenter specifically suggested changing the phrase "following closure" in the proposed § 61.44 to "during the institutional control period." Another commenter stated that the NRC, the EPA, and Congress (e.g., Uranium Mill Tailings Remediation Control Act legislation (UMTRCA)) have recognized that requiring stability beyond 200 to 1,000 years cannot be proven and that current stability requirements for 10 CFR part 61 disposal sites are largely met.

Response: The NRC developed an approach to site stability that has three primary components: 1) ensure site stability for short-lived wastes; 2) allow for the demonstration of stability for the longer term by considering the implications of instability with respect to § 61.41 and § 61.42; and 3) allow for the regulator to deny or limit disposal if projected instability prohibits modeling of the site. NUREG-2175 discusses the recommended approach to demonstrating site stability in Chapter 5.

The original requirement for stability is highlighted as being a cornerstone of disposal. The original regulation is silent on the duration of the stability requirement and could be interpreted to mean that stability needs to be ensured for as long as the waste remains hazardous. In this rulemaking, the NRC clarified the requirements to ensure consistency. The performance objective in final § 61.44 has been revised from the proposed rule because the protective assurance period has been eliminated. The stability requirement in § 61.44 now applies only to the compliance period, which is 1,000 years for sites that do not contain significant quantities of long-lived radionuclides and 10,000 years otherwise.

In 1978, UMTRCA was enacted and the agencies mentioned by the commenter developed stability criteria associated with the management of uranium mill tailings. Prior to 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, they did not see why the site-stability performance objective (§ 61.44) needed to stand alone. They indicated that the proposed compliance period of 1,000 years and the site stability period of 10,000 years were inconsistent.

Response: A separate performance objective is provided for site stability because, as identified in the original regulation, stability is a cornerstone of disposal. In addition, stability can influence whether compliance with § 61.41 and § 61.42 can be demonstrated. Instability can compromise both disposal and the ability of a licensee to assess projected disposal site performance. A licensee may attempt to evaluate the radiological impacts from a system that is simply not amenable to technical assessment because it is unstable. If the system is unstable, demonstration of the ability to meet the performance objective might not be possible. The stability performance objective can be used to limit or otherwise prohibit disposal of waste under

unstable conditions. 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.

Under the final regulation, the compliance period will be 1,000 years if waste does not contain significant quantities of long-lived radionuclides and 10,000 years otherwise. The site stability performance objective has been revised accordingly to be consistent with the revised compliance period.

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

K.5 *Comment:* Commenters expressed concern that assurance of site closure and stabilization cannot be provided. They stated it is not possible to guarantee that stability will be maintained and that ongoing active maintenance will not be needed; thus, they recommended revising the definition for "site closure and stabilization."

Response: The NRC uses the standard of "reasonable assurance" when evaluating compliance with the requirements. This standard applies to determining whether the regulations regarding site closure and stabilization have been complied with. In addition, the associated 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.

4) A number of commenters expressed concern that longer-term analyses (>1,000 years) for "traditional" LLRW were not warranted because most of the waste would decay before 1,000 years.

There were also numerous comments received on the proposed protective assurance period and the three-tiered approach. A few commenters supported limited aspects of the proposal but the overwhelming majority did not support the proposal for a diverse set of reasons. Some commenters expressed support for a simpler two-tiered approach to increase efficiency and decrease regulatory burden. Some of those reasons provided in opposition to the proposal included:

- the language was unclear,
- the associated complexity was not warranted,

- the approach would not add to understanding of system performance or provide protection,
- minimization was too stringent and would create litigation risk,
- inadequate justification was provided to apply the approach to all waste, and
- the approach should only apply to wastes containing significant quantities of long-lived radionuclides.

Some commenters also indicated that the definition of the compliance period was unclear as to when the compliance period begins.

Response: As a result of the comments received, the NRC has revised the approach to analysis timeframes to provide flexibility to Agreement States to be more restrictive, if desired, while providing protection to public health and safety from the disposal of both traditional and unique waste streams. The revised approach eliminates the protective assurance period and revises the compliance period definition to ensure that the duration of the technical analyses for the compliance period takes into account the hazard of the waste. The revised approach better accommodates the considerable differences between traditional LLRW and a unique waste stream, such as one containing significant quantities of depleted uranium. Traditional waste with no significant quantities of long-lived radionuclides will not be subject to a 10,000-year analysis whereas a unique waste stream containing significant quantities of depleted uranium will. Other LLRW that poses a significant hazard after 1,000 years would also be subjected to a 10,000-year compliance period and the performance period requirements. If a licensee elects to use a 1,000-year compliance period, then they must provide a technical rationale for not considering the longer timeframe. This explanation can be an analysis of the long-lived inventory, a screening analysis showing the radiological impacts of the projected inventory, or other methods that demonstrate the performance objectives will not be exceeded. This

approach provides considerable flexibility while ensuring that the analysis will be tailored to the waste that is disposed.

Table A, which was included in the proposed rule, is no longer included in the final rule; the table has been moved to NUREG-2175. The proposed table A was useful for examining the need for a 10,000-year compliance period for § 61.42; however in some cases, the identified concentrations in the table may not always be protective of public health and safety with respect to the dose requirements in § 61.41. Depending on the site-specific hydrology or other release pathways, a land disposal facility that only disposes of waste at Class A concentrations (the basis for table A) could significantly exceed the dose limits associated with the § 61.41 performance objective.

In addition, the compatibility category for the definition of "compliance period" has been changed from the proposed B to C. Therefore, Agreement States that currently have more stringent requirements with respect to the compliance period will have the ability to preserve their approaches. This is discussed further in B.4 in this section.

The revised approach is simpler than what was originally presented in the proposed rule and does not introduce as many new features that regulators have limited experience applying. The revised approach aligns NRC's requirements with existing practice in the majority of Agreement States.

Changes were made to the rule language as a result of these comments. Conforming changes were also made to the guidance document.

L.2 *Comment:* A commenter stated that the risk from radionuclides typically present in nuclear power plant waste is primarily driven by relatively short half-life radionuclides. Longer lived radionuclides, such as the transuranic isotopes, dominate the risk after 500 years and are initially limited by concentration to ensure safety. The commenter stated that their research indicates that after 1,000 years, LLRW generated during the course of the normal operation of a nuclear plant poses little risk to the public. The commenter expressed the view that the

proposed rule recognizes the general nature of LLRW and limits the time period for the performance assessment for compliance to 1,000 years.

Response: Releases from an LLRW disposal site can result in risk to an offsite member of the public (§ 61.41). Exposure to waste also could cause risk to an inadvertent intruder who accesses the disposal site after the active institutional control period (§ 61.42). Generally, the assessment of doses for § 61.41 involves projecting releases to water and air. The statement that "the risk from radionuclides typically present in nuclear power plant waste is primarily driven by relatively short half-life radionuclides" may be correct for nuclear power plant workers but it is not correct with respect to protection of the general population from releases of radioactivity from LLRW in a land disposal facility. The *hazard* of nuclear power plant waste is dominated by the short-lived radionuclides, however the *risk* from disposal (i.e., projected dose multiplied by probability of occurrence) is dominated by the long-lived radionuclides. The management of the hazard associated with short-lived radionuclides in nuclear power plant waste at disposal sites is a testament to the design and operation of LLRW disposal facilities that effectively contain the short-lived isotopes while they decay in place.

As part of a statement of support for a 1,000-year compliance period, the commenter indicated that some longer-lived radionuclides are limited by concentration to ensure safety. The commenter appears to be referring to the § 61.55 classification tables. However, if waste acceptance is based on the results of the site-specific analysis, the concentrations of longer lived radionuclides may not be limited *a priori* and therefore safety objectives may not be achieved if a site-specific analysis beyond 1,000 years is not performed. The commenter's statement that "…research results indicated that after 1,000 years, LLRW generated during the course of the normal operation of a nuclear plant poses little risk to the public" is generally accurate with respect to an inadvertent intruder (§ 61.42) for nuclear power plant waste that is classified using tables 1 and 2 of § 61.55. However, the commenter's statement could be inaccurate with respect to the general population (§ 61.41). This concept was recognized as

early as 1982 when 10 CFR part 61 was originally developed and is reflected in the original § 61.7(b)(2), which states, “For 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.” Depending on the disposal-site hydrogeology, the risk from LLRW with concentrations below Class A limits can result in doses exceeding the limits prescribed in § 61.41(a) by a large margin.

A proper technical analysis needs to be performed to determine if projected doses are below the established limits. Most modern LLRW disposal facilities will reduce or eliminate releases of radioactivity to the environment for extended periods of time. For most arid sites, significant releases will be delayed longer than 1,000 years and the majority of sites currently operating are in arid locations. In addition, 10 CFR part 61 applies to all types of LLRW, not just LLRW resulting from nuclear power plant operations. For instance, this rulemaking was initiated, in part, to address the disposal of large quantities of depleted uranium, which presents a hazard extending well beyond 1,000 years.

No changes were made to the rule language as a result of this comment. However the approach to the analyses timeframes including the compliance period was modified as a result of other comments.

L.3 *Comment:* A commenter stated that as a result of uncertainty, the compliance period should be limited to 1,000 years. Other commenters stated that uncertainty is not an adequate basis to limit the compliance period to what is “reasonably foreseeable.” A commenter also stated that excess uncertainty is an indication that near-surface disposal is unacceptable and protection of public health and safety cannot be demonstrated. Some commenters stated that the compliance period for waste containing long-lived radionuclides, such as concentrated depleted uranium, should be a minimum of 10,000 years and ideally would consider peak activity of the waste.

Response: Based on other stakeholder comments (see item L.1 in this section), the approach to analyses timeframes has been revised. The revised approach requires a compliance period of 10,000 years if LLRW containing significant quantities of long-lived radionuclides has or will be disposed of at the land disposal facility. If a 10,000-year compliance period is necessary, the revised approach also requires a performance period analysis to be completed. The compliance period definition has been redesignated Compatibility Category C (the performance period was already designated Compatibility Category C in the proposed rule); therefore an Agreement State may adopt more restrictive requirements as further discussed in item B.4 in this section. Further discussion of uncertainties can be found in item L.16 in this section.

The combination of the compliance period with the performance period is designed to consider the activity of the waste and its persistence. However, dose standards are not applied as part of the requirements for the performance period. Rather, licensees must demonstrate that releases or exposures are minimized to the extent reasonably achievable. Over the very long timeframes associated with the performance period, the assumptions upon which the dose assessment are developed may be difficult to justify. However, it is useful to understand how the disposal site may perform and how the capabilities of the engineered and natural barriers limit risk.

Performance assessments are not predictions of a future result but rather they are designed to assess potential future performance. Current experience and knowledge associated with engineered near-surface disposal facilities is limited to a few decades, but it is anticipated that the scientific community will continue to invest in developing better understanding of the long-term performance of engineered designs. The objective of safety analyses for LLRW disposal is not to model or calculate only those things that are known precisely. Safety standards should not be weakened in the face of large uncertainties. The safety analyses must consider uncertainties including those uncertainties associated with

long-term performance. If the uncertainties are too large or cannot be defined, then the risk is unknowable and safety cannot be assured. Not all LLRW is suitable for near-surface disposal. The NRC's requirements will ensure that the viability of near-surface disposal will be determined for each LLRW stream.

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

L.4 *Comment:* Commenters indicated that the protective assurance period should only be applied to sites that pursue acceptance of large volumes of waste containing long-lived radionuclides. In addition, commenters were unclear about the interpretation of the limits for the protective assurance period.

Response: The protective assurance period has been eliminated. Changes to the compliance period (1,000 years for land disposal facilities that have only disposed of LLRW containing an insignificant quantity of long-lived radionuclides and 10,000 years otherwise) align with the concept expressed by the commenters that analysis for a 10,000 year period should only be applied to land disposal facilities that have or plan to dispose of LLRW containing a significant quantity of long-lived radionuclides. However, as discussed in the response to items A.1 and A.2 in this section, the NRC evaluated the possibility of designing requirements that could be applied only to "new waste" and determined that approach would not be practical or technically justified.

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

L.5 *Comment:* Commenters expressed support for the concept of extending performance analyses and inadvertent intruder assessments over longer periods (>10,000 years), stating that there is value in considering, qualitatively, the results of modeling beyond the time when the results can be assigned quantitative meaning with respect to potential health effects. Such an assessment can provide valuable information to guide WAC, design optimization, and defense-in-depth measures. They supported, in principle, the performance period and the approach to use analytical results only qualitatively.

Response: The performance period approach has been retained. The NRC notes that the performance period may involve quantitative calculations but that the results of those calculations will be interpreted qualitatively since no numerical standard has been provided for the performance period.

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

L.6 *Comment:* Commenters expressed concern about the messages that are implied by references to "long-term analysis" in the context of 10,000 years that were found in the statement of considerations for the proposed rule. They stated that the language choice undermines the fact that for near-surface disposal of LLRW, regulations consistently consider much longer timeframes than are considered for disposal of other wastes. The commenters stated that 500 or 1,000 years are very long timeframes and should be described as such.

Response: Analyses of 500- to 1,000-year timeframes in the future are long-term analyses in almost any context outside of radioactive waste disposal. The field of radioactive waste disposal is unusual in this respect. The terminology used, "short" or "long," with respect to the analyses timeframes was intended to describe one approach relative to another.

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

L.7 *Comment:* Commenters stated it is not appropriate to forego an ultimate end-point for the performance period. A commenter asserted that, without an endpoint (or factors to be considered) for the performance period and associated analysis, the proposed regulations would impose an arbitrary and burdensome approach and would risk generating uncertain analyses without potential usefulness for risk-informed decision making. The commenter stated that this is not justifiable and conflicts with ethical principles that assign greater weight to near-term hazards than to hypothetical long-term risks. In this regard, the commenter indicated the DOE generally conducts performance assessments for LLRW disposal to the time of peak dose or a shorter time period, as appropriate, to risk-inform decisions.

However, the commenter indicated that the DOE does not impose dose limits or performance measures during timeframes beyond 1,000 years post-closure.

Response: The NRC considered a variety of options to establish regulatory requirements for the safe disposal of low-level radioactive waste in a land disposal facility per 10 CFR part 61. In the proposed rule, the NRC described other approaches that were considered, including the approach described by the commenter, and rejected them for the evaluation of waste containing significant quantities of long-lived radionuclides because the NRC's requirements establish a clear standard that must be demonstrated, are equitable to future generations, and are consistent with other NRC waste disposal regulations and international regulatory programs, as well as principles expressed by other international organizations. In establishing the specific requirements, the NRC has concluded that for disposal of long-lived radionuclides, a performance objective to assess radiological impacts beyond 10,000 years is necessary to provide reasonable assurance that future generations will be adequately protected. The NRC disagrees with the commenter's statement that the NRC's approach is in conflict with ethical principles prioritizing near-term hazards as compared to hypothetical long-term risks. The greater weight the NRC assigns to near-term hazards is evidenced by the variety of requirements applicable to the operational and institutional control periods. However, the NRC's approach to longer timeframes does not assign zero weight to long-term hazards.

The NRC's concern with the commenter's description of their alternative is that it does not provide objective and clear standards to interpret analyses' results beyond 1,000 years. With no objective and clear standards beyond 1,000 years, licensees would lack a clear path to demonstrate that the land disposal facility will perform safely, and regulators would lack clear criteria on which to determine that the licensee has successfully demonstrated that the land disposal facility will protect public health and safety. Analyses that are truncated and are not consistent with the hazard of the waste do not provide for equitable protection of future

generations. The NRC's approach in the final rule provides a dose limit up to 10,000 years and requires exposures to be minimized to the extent reasonably achievable for the performance period. Although the NRC does not provide a dose limit for the performance period, the requirements do provide protection of public health and safety. Therefore, the final rule provides an approach for evaluating safety for a time period consistent with the hazards. The NRC's approach for the evaluation of waste containing long-lived radionuclides provides for equitable protection of future generations, is consistent with other NRC waste disposal regulations and international regulatory programs, and is in alignment with principles expressed by other international organizations.

In addition, the termination of the performance period is not amenable to specification as a single number because of the site-specific nature of system evolution over long time periods.

NUREG-2175 provides guidance on how to complete and risk-inform the performance period analyses, including the issue of end points of the performance period.

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

L.8 *Comment:* A commenter recommended that, at most, the performance period should not extend beyond peak dose (or impacts) or the period of surface geologic stability, whichever occurs first. The commenter indicated that the NRC expressed legitimate concerns with the use of surface geologic stability. However, the commenter stated that the concerns nonetheless did not justify the regulatory approach proposed in the rule and supporting guidance. The commenter agreed that it would be objectionable to provide an incentive for picking an unstable site to avoid the regulatory burden of extended analyses but stated it would be unlikely that such a site would fulfill the other significant requirements in the rule. The commenter indicated that a better approach would be to require a description and justification of when and why the performance period is truncated to give insights into the site characteristics and stability, and that it is within NRC's discretion to consider such information as part of the safety case on which the licensing process will be based.

Another commenter stated that the extension of performance analyses beyond the period of surface geologic stability is unsupportable from a technical perspective. Geologic repositories may rely on longer timeframes for analysis precisely because, being at depth, they are not likely to be significantly affected by events and processes at the surface. The timeframe for surface effects from geologic processes is notably less than that for deeper geologic stability (NEA 2009 "Timescales Report;" Figure 5.12a and pages 27-28). The commenter indicated that once processes affecting the surface at a certain magnitude and breadth occur, the analysis of the site is unreliable, even qualitatively. Thus, any results of the performance analyses are much less likely to be relevant, since populations near a site affected by, for example, a new ice age are likely to face much more significant and immediate threats to their lifestyle and survival than the potential for a localized incremental increase in cancer risk. The commenter understood that a significant motivator for the performance period is to gain information regarding long-term performance, but stated that even 1,000 years is long-term performance. The commenter recommended that analyses for longer-term performance should be conducted with the recognition of the growing speculation and uncertainty over time.

Response: The performance period analyses are designed to determine, for sites containing significant quantities of long-lived radionuclides, how the land disposal facility could mitigate long-term impacts. The "other significant requirements" referenced by the commenter are not required during the performance period.

Instability of the site can occur at any timeframe. Although a site may be stable for 100 or 1,000 years, it does not mean that stability will extend to longer timeframes. A good example would be a site that is located outside a 100-year floodplain. The site could be stable from the perspective of floods for 100 years but may be unstable from the same events on a 1,000-year timeframe. The discussion in draft NUREG-2175, regarding near-surface stability, remains valid.

The NRC sees value in analyses beyond 1,000 years. These analyses have been used for regulatory decision making for LLRW disposal for over 40 years. A licensee can provide a description of when and why the performance period is truncated, as the commenter suggests; however, that does not obviate the need for performance period analyses. The NRC agrees that analyses for longer-term performance should be conducted with the recognition of the uncertainty over time. If the approach advocated by the commenter was adopted, it could mean that a site would be evaluated until it experienced instability, which is exactly the time when risks may be highest. It is not clear, conceptually, how this approach would lead to good waste management decisions. For example, near-surface disposal of spent nuclear fuel, which is regarded internationally as not suitable for near-surface disposal, could appear to be appropriate if analyses were truncated as soon as the environment became unstable.

As discussed in item L.7 in this section, the NRC rejected a single-tiered, 1,000 year approach for evaluation of disposal of waste containing significant quantities of long-lived radionuclides primarily to ensure that the timeframe of the performance assessment is consistent with the hazard of the waste. Guidance on how to complete and risk-inform the performance period analyses is provided in NUREG-2175.

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 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 further stated that the risks posed by depleted uranium and by other such "unique wastes" that require additional analysis may, depending on circumstances, require special protective measures. These risks should be addressed through a flexible, site-specific performance-based approach rather than specifying unrealistically long periods for demonstrating conformance with regulatory standards including quantitative exposure limits for a diverse set of LLRW. The commenter stated that special issues posed by long-lived radionuclides should be resolved on a site-specific, waste-specific basis through a collaborative approach involving input from the Risk and Performance Assessment Community of Practice.

Response: The commenter incorrectly characterizes the development of the waste classification tables. The waste classification tables were developed considering both long- and

short-lived wastes, resulting in two different tables (tables 1 and 2 in § 61.55). Calculations were performed to 10,000 years and longer in the analyses supporting development of the waste classification tables. The waste classification tables were developed to ensure protection of an inadvertent intruder (§ 61.42); the waste classification tables do not ensure protection of the public under § 61.41, and protection of a member of the public under § 61.41 has always relied upon site-specific technical analyses. There appears to be a misconception that if waste is Class A it is benign and "low risk." Under some conditions, long-lived mobile radionuclides (i.e., technetium-99, iodine-129, carbon-14) at the Class A limits can result in doses that far exceed the performance objectives, such as at a humid site with unfavorable hydrogeology. As such, a proper site-specific technical analysis estimating future doses is, and always has been, required to demonstrate compliance with § 61.41.

The approach to analyses timeframes has been modified in the final rule to ensure that requirements for analyses beyond 1,000 years will not be applied to disposal sites where only LLRW without significant quantities of long-lived radionuclides has been disposed. Management of the risks from the disposal of long-lived radionuclides will rely on site-specific performance and inadvertent intruder assessments. The technical analyses requirements in § 61.13 impose minimum requirements for those analyses. Guidance on completing those analyses and the interpretation of the results is provided in NUREG-2175. As discussed further in item F.2 in this section, quantitative dose limits are appropriate for the compliance period of 1,000 years for waste that does not contain significant quantities of long-lived radionuclides and for 10,000 years otherwise.

The Risk and Performance Assessment Community of Practice is a group of professionals that meet periodically to discuss and advance the use of performance and risk assessments. Although the NRC appreciates and benefits from interaction with the Risk and Performance Assessment Community of Practice, it would not be appropriate for the NRC to develop NRC regulations in collaboration exclusively with any one group.

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

L.11 *Comment:* A commenter commended the NRC for not proposing a uniform 10,000-year Tier 1 compliance period. As the commenter explained in previous comments, which had been made in response to public comment requests on preliminary proposed rule text, reliable demonstration of compliance with exposure limits for such a long period of time into the future is not feasible and is unrealistic in the context of current scientific understanding. The commenter stated that demonstrating compliance with a regulatory limit at 1,000 years is at the limits of practicality associated with the current body of knowledge. Current experience and knowledge associated with engineered near-surface disposal facilities is limited to a few decades and only a limited number of studies have been conducted to determine whether these facilities are functioning in accordance with predictions. Consequently, the commenter stated that a shorter Tier 1 period, in the range of around 500 to 1,000 years, is appropriate and consistent with the characteristics of typical LLRW. The commenter further stated that a 1,000-year compliance assessment period has been used for LLRW at various sites by agencies such as the DOE and Agreement States. The commenter indicated that the State of Texas uses a 1,000-year period for assessing the performance of a land disposal facility and that a 1,000-year period is provided in DOE's Radioactive Waste Management Manual, DOE Manual 435.1-1.

Response: As indicated in item L.1 in this section, the approach to analyses timeframes has been modified to ensure that requirements for analyses beyond 1,000 years will not be applied to short-lived waste. The modified approach is designed to ensure that analyses for disposal sites that have or plan to dispose of LLRW containing significant quantities of long-lived radionuclides, such as depleted uranium, are protective of public health and safety. The NRC concluded that dose limits are appropriate for the compliance period of 1,000 years if the land disposal facility does not dispose of LLRW containing significant quantities of long-lived radionuclides and 10,000 years otherwise.

The NRC disagrees with the commenter's characterization of the time periods used in LLRW licensing. Licensing of commercial LLRW disposal facilities in the United States has been completed using analyses to 10,000 years and longer. In fact, all Agreement States with operating land disposal facilities currently require technical analyses beyond 1,000 years for their licensing decisions. The NRC staff acknowledges that the DOE specifies a 1,000-year compliance period in DOE Manual 435.1-1; however, none of the Agreement States, which currently regulate the four operating land disposal facilities, have exclusively used a 1,000 year compliance period in their licensing decisions. In particular for depleted uranium disposal, three of the four Agreement States that host land disposal facilities have required a compliance period of 10,000 years or longer; the other required 2,000 years. Texas's standard is 1,000 years or peak dose, whichever is longer. Therefore, in the licensing decision for the disposal site in Texas, the analysis timeframe for compliance was approximately 50,000 years (the time of peak dose in the analysis).

Please see the response to item L.3 in this section for additional information with respect to reducing safety standards as a result of lack of information or uncertainty. In summary, safety standards should not be reduced as a result of uncertainty; rather uncertainties should be quantified as part of the site-specific analyses.

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

L.12 *Comment:* A commenter indicated that the timeframes associated with the site stability and site characteristics analyses are unclear and inconsistent. The proposed § 61.44 stated that site stability must be analyzed over the compliance and protective assurance periods (i.e., to 10,000 years after closure). The proposed § 61.50(a)(2) described what characteristics the site must have over 500 years. The proposed §§ 61.50(a)(3) and (4) stated that the hydrogeological characteristics must not affect the ability to meet the performance objectives, which cover all three timeframes, including the performance period. Section 2.3.2.4 of the draft NUREG-2175 provides concentration-based criteria for determining the timeframe to evaluate

the site characteristics with three tiers: 500 years, 10,000 years, and the performance period. The commenter recommended that the required time period be clarified to allow licensees to begin their evaluations. Commenters also expressed confusion about the “at least 500 years” language in the proposed § 61.7 with respect to siting characteristics.

Response: The protective assurance period has been eliminated and the compliance period has been revised to be 1,000 years for land disposal facilities that have not disposed of LLRW containing significant quantities of long-lived radionuclides and 10,000 years otherwise. The site stability performance objective has been revised to be the same duration as the compliance period that is used.

Site hydrogeological characteristics are to be considered for as long as necessary to demonstrate that the relevant performance objectives can be met. A distinction is made in § 61.50 between minimum characteristics a site must have and those that are performance based. Certain hydrogeological characteristics listed in § 61.50(a)(2) must be true for a site for at least 500 years after closure. Sites that cannot meet these minimum requirements may not be sufficiently stable and are expected to be of higher relative risk. Small releases of short-lived, high specific-activity radionuclides can result in significant risk. Complex hydrological systems may not be amenable to accurate modeling and the risks associated may not be accurately assessed. However, at longer timeframes some of the site characteristics may change from the conditions specified in § 61.50(a)(2), as long as they do not affect compliance with the performance objectives. Therefore, in addition to requiring that performance assessment analyses be completed, the final rule specifies that the presence of certain FEPs are unacceptable within 500 years of site closure because they are indicators of potential instability and higher risk.

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

L.13 *Comment:* Commenters suggested that § 61.13(e) be revised to read, "The time period required to be considered shall be determined based on site-specific conditions

addressed in the performance assessment. Performance period calculations shall be performed if the analyses for compliance period in §§ 61.41 (a) and 61.42(a) indicate that peak doses have not been attained (i.e., doses are stable or rising) at 1,000 years, including consideration of the in-growth or progeny from the intended waste streams." The commenter made a similar recommendation with respect to the protective assurance period.

Response: The recommended changes related to the protective assurance period were not considered because the protective assurance period has not been retained as discussed in item L.1 in this section.

Modern land disposal facilities have been historically designed and operated to mitigate the risk from short-lived radionuclides. The long-lived radionuclides produce most of the dose for § 61.41(a). In NRC's experience, almost every performance assessment would show stable or rising doses for § 61.41(a) at 1,000 years; however, the magnitude of some of those doses and the continued increase may be very small. Therefore, essentially all disposal sites would be required to perform the performance period analyses if the commenters' recommendation was implemented. Likewise, even if a land disposal facility disposed of very small quantities of long-lived radionuclides, the doses could be increasing. Only those disposal sites that could pose significant long-term risk should be required to perform the 10,000-year compliance period analyses or performance period analyses.

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

L.14 *Comment*: A commenter recommended that the definition for compliance period be revised to indicate that for purposes of applying the required analyses for the performance period, the compliance period is considered to be a minimum of 10,000 years.

Response: The approach to the compliance period has been revised, as discussed in item L.1 in this section. Depending on the radiological inventory and disposal site performance, either a 1,000-year or 10,000-year compliance period will be used. The requirement for the performance period analyses was revised to indicate that performance period analyses are

required only when a 10,000-year compliance period is required. The NRC concluded that a 10,000-year compliance period was not necessary for LLRW that does not contain significant quantities of long-lived radionuclides because there would be no significant hazard present after 1,000 years due to decay of the shorter-lived isotopes.

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

L.15 *Comment:* A commenter indicated that the NRC should use a risk-based approach and timeframes similar to those used for the Comprehensive Environmental Response, Compensation, and Liability Act, and the Resource Conservation and Recovery Act (also known as Superfund).

Response: The NRC is aware of other approaches used for regulating hazardous substances (e.g., the Comprehensive Environmental Response, Compensation, and Liability Act and the Resource Conservation and Recovery Act), as well as national and international approaches for evaluating the geologic disposal of radioactive wastes. Although the various approaches have a number of similar attributes (e.g., safety limits, consideration of deleterious and beneficial attributes of the disposal systems, evaluation of environmental transport of the hazardous materials or wastes), it is typical that every approach is somewhat tailored to accommodate specific aspects of the materials and facilities, any applicable legal requirements, and, as appropriate, regulatory precedents for the implementing government agencies (e.g., timeframe of the hazardous material, significance of the hazard or risk, similarity with other regulated materials). The NRC has developed regulations for the disposal of radioactive wastes (both high-level and low-level radioactive waste) that provide for defense-in-depth protections to help ensure long-term safety, use risk information to improve the understanding of the safety attributes of the facility, and do not rely on long-term maintenance of the disposal site. The NRC's regulatory approach is an appropriate method for ensuring protection of public health and safety. The NRC determined that the other approaches, which may be substantially different from current and historical NRC regulatory programs for waste disposal, are not

practical to implement within the scope of this limited rulemaking and would not, in any substantial way, improve NRC's regulatory approach for the protection of public health and safety.

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

L.16 *Comment:* A commenter provided a detailed explanation that NRC's proposed compliance period of 1,000 years was both too short and too long. First, the commenter noted the uncertainties associated with extended timeframes make technical assessment as proposed by the NRC invalid and not scientifically sound. The commenter provided references to NRC transcripts as well as his own calculation results and stated that, without provisions for barrier effectiveness, compliance cannot be achieved beyond 500 years. The commenter also indicated that there is no scientific basis to provide less protection to future generations compared to the present generation and stated that some radionuclides present in LLRW require much more than 10,000 years for limiting doses.

In light of this position, the commenter provided an alternate proposal for the NRC to consider:

- Long-lived radionuclides should be defined as those radionuclides with more than a 10-year half-life.
- The compliance period should be set to 500 years.
- Total curie limits for radionuclides should be provided. The curie limits should be developed by assuming a hypothetical pulse release of the total inventory of long-lived radionuclides at the end of the compliance period.
- Peak inventory of radionuclides with build-up of progeny should be assumed, and released instantly at the end of the compliance period.
- With the previous conditions in place, modeling could be performed for 500 years, as envisioned in the proposed rule.

The commenter indicated that if NRC did not adopt this approach, then a compliance period should not be specified, similar to the original 10 CFR part 61.

Response: The NRC disagrees that the existence of uncertainties, even if the uncertainties are significant, results in the technical analyses being invalid and not technically and scientifically sound. A performance assessment is used to explicitly account for uncertainties and to determine if those uncertainties have a significant impact on decision making. The NRC understands that some stakeholders do not support the use of technical analyses for long timeframes. The NRC has concluded that analyses covering longer timeframes can provide important information to the decision making process.

Performance assessments have been used worldwide for over 25 years to assess the performance of waste disposal facilities. With modern computer systems, many performance assessments are probabilistic; uncertainties are explicitly represented in the calculations. A modern performance assessment will include data, model, and scenario uncertainties. The NRC agrees that if a performance assessment does not have an adequate technical basis, including model support, then the results can be invalid. The commenter provided a good example with respect to the sensitivity of dose assessment results to changes in a parameter value and showed projected doses were sensitive to erosion rates. But just because calculations can be performed to show a sensitivity, such as to erosion rate, it does not mean that an adequate technical basis has been provided for those calculations. Net erosion rates in some environments can be accreting.

New requirements were added to § 61.13 in the proposed rule to ensure adequate support is provided for the technical analyses to address the type of concern raised by the commenter.

The alternate proposal for the technical assessment provided by the commenter may be feasible in ideal situations with limited variability or in generic application but would be impractical in real world application. The commenter suggested using pulse release of the

entire inventory and deriving curie limits for a variety of release modes such that dose criteria would not be exceeded for any combination of inventory and release modes. This approach would produce unrealistic results. The FEPs that are relevant at one site may not be possible at another site. For example, a large earthquake could be the dominant release mode and would result in the most restrictive curie limit. The fact that earthquakes may occur at one location does not mean the performance of a facility at a location without earthquakes should be limited because some other site could experience an earthquake. The site-specific release modes are numerous, and many are driven by events. The NRC has been advocating the use of site-specific release modes to develop inventory limits since 1982.

Here, the commenter is suggesting that because of uncertainties in the very long timeframes, only worst case scenarios should be used (referenced as heuristic calculations) to develop the limits. The NRC believes that science and engineering that can be supported should be credited and accounted for in the safety case for a land disposal facility. For example assuming the entire inventory of waste including progeny that may take millions of years to in-grow is instantly deposited on the land surface at the end of the compliance period (particularly if chosen to be 500 years) exceeds a worst case scenario because it is not physically possible. Assuming the whole inventory is released instantaneously to an aquifer would violate geochemical and mass transfer constraints. Conservative or pessimistic analyses are useful to understand the upper bounds of dose impacts, but not to make safety decisions because the probability of the scenarios being evaluated would be zero.

Inclusion of the inadvertent intruder assessment as a component of 10 CFR part 61's safety case is unique with respect to waste disposal approaches. Neither hazardous waste disposal facilities nor municipal waste disposal facilities include this component. Although site-specific receptor scenarios may be used, NUREG-2175 encourages licensees to provide a comparison of site-specific inadvertent intruder scenarios that are used for the inadvertent intruder assessment to results using the generic receptor scenarios similar to those used for the

original development of the waste classification tables. This approach highlights the importance of the inadvertent intruder scenario while providing some degree of constraint on the types of waste suitable for near-surface disposal from direct disturbance and exposure scenarios.

The NRC considered developing inventory or other limits on a generic basis for § 61.41 that would apply to any low-level waste disposal site in the United States. As a result of site, environment, inventory, and other sources of variability, the NRC determined that generic inventory limits would be overly restrictive while not adding to safety in any meaningful way. The inventory limits applied at a site would be based on the worst site and would not be in accordance with NRC's risk-informed, performance-based regulatory philosophy. The commenter indicated that if the NRC did not adopt his approach, then a compliance period should not be specified in the regulation similar to the original regulation. The NRC is specifying a compliance period in this regulation to ensure that an adequate time period is analyzed. In addition, the compatibility category for the definition of compliance period has been changed from the originally proposed Compatibility Category B to C, which will allow Agreement States to be more restrictive.

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

M. *Waste Acceptance*

M.1 *Comment:* Some commenters were supportive of regulations permitting flexibility for the development of site-specific WAC or continuing use of the waste classification concentration limits because they stated the approach would ensure that the performance objectives are met while allowing flexibility for licensees to account for site-specific factors. Other commenters raised concerns about whether the waste acceptance requirements would protect public health and safety and whether the requirements should apply to all existing sites

as proposed or only sites that expect to accept waste streams containing higher concentrations and larger total quantities of long-lived radionuclides.

Response: The NRC agrees that the requirements for the development of WAC will continue to ensure compliance with the performance objectives while allowing flexibility for licensees to account for site-specific factors. Compliance with the performance objectives provides assurance that public health and safety are adequately protected. Regardless of the method chosen to develop WAC, licensees must demonstrate that the performance objectives will be met.

The new waste acceptance requirements apply to all operating land disposal facilities. These requirements ensure that waste acceptable for disposal provides reasonable assurance that the performance objectives will be met. In general, the use of the concentration limits specified in § 61.55 remain protective of public health and safety; however, the concentration limits in § 61.55 are designed to provide protection to an inadvertent intruder, where risk is typically bounded by the concentration of radionuclides in the waste. The limits were not intended to provide protection of the general population from releases, where risk is typically affected by the total activity of certain radionuclides that tend to be more mobile in the environment and migrate off-site. Further, all existing land disposal facilities have taken varying amounts of waste containing long-lived radionuclides. The waste concentration limits in § 61.55 may not be adequately protective for certain waste streams containing long-lived radionuclides that are classified as Class A by default because concentration limits were not developed for those long-lived radionuclides (e.g., depleted uranium). Class A waste is considered relatively innocuous because it usually contains the types and quantities of radionuclides that will decay during the first 100 years and will present an acceptable hazard to an inadvertent intruder. The new requirements to develop WAC provide reasonable assurance that the performance objectives will continue to be met for all land disposal facilities.

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

M.2 *Comment:* Some commenters were concerned that permitting the development of site-specific WAC would overwhelm the Agreement States' ability to review WAC and thereby transfer the decision making from the Agreement States to licensees and their consultants. Another commenter noted that the performance assessment analysis for depleted uranium disposal in Utah was large and complex; and the regulator did not have the staffing or expertise to review the model and therefore hired outside consultants. Some commenters recommended that the regulation be clear regarding who approves the WAC.

Response: The NRC disagrees that the decision making authority to approve the WAC could be transferred from the Agreement State to the licensee or its consultant but agrees the regulation should be clear about who approves the WAC. While the licensee must always demonstrate that the WAC will provide reasonable assurance that the performance objectives will be met, § 61.58(a) clearly specifies that the WAC are subject to NRC approval. In Agreement States, the pertinent state regulatory agency would assume the responsibility for approving the WAC proposed by a licensee per their agreement with the NRC under Section 274(b) of the Atomic Energy Act of 1954, as amended. Further, changes to approved WAC would require a license amendment subject to NRC or Agreement State approval, unless otherwise authorized by license condition.

The NRC has consistently advocated for simple, conservative models or analyses, if that type of analysis is sufficient to support the regulatory decision. However, the NRC does recognize that some licensing decisions may need to rely on complex models because the disposal of certain wastes is inherently complex. In those cases, the burden for Agreement State regulators and other stakeholders will be increased. However, it is the complexity of proposed waste disposal that drives the burden and not the regulatory requirements themselves. The NRC determined that the additional burden is warranted, particularly for the disposal of significant quantities of long-lived radionuclides. Regarding the use of consultants to review complex analyses, Agreement States and the NRC staffing levels fluctuate according to

agency needs and regulators often use independent consultants when specific expertise is needed. The NRC has developed guidance (e.g., NUREG-2175) and regulatory requirements (§ 61.13) to ensure adequate quality of the technical reviews.

The burden on Agreement States resulting from this final rule is addressed in item B.3 in this section.

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

M.3 *Comment:* Some commenters supported flexibility for Agreement States to establish stricter limits on the types of waste that would be considered acceptable at a land disposal facility.

Response: The LLRWPAA assigns responsibility for disposal of Classes A, B, and C LLRW to the States. Some States have exercised flexibility to further limit disposal of certain LLRW for which they are responsible at specific LLRW disposal facilities. The NRC, in promulgating revisions to 10 CFR part 61 that facilitate flexibility for determining WAC at a particular land disposal facility while protecting public health and safety, has maintained flexibility for the Agreement States to continue limiting disposal of certain LLRW consistent with the Federal and State laws and regulations.

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

M.4 *Comment:* Some commenters recommended that the NRC retain the original § 61.58 regarding alternative waste classification and characterization. Other commenters were critical of the level of detail included in the proposed § 61.58. These commenters recommended either that new acceptance requirements be included in a different section than § 61.58 or that the proposed § 61.58 be amended to include a set of uniform criteria for all land disposal facilities to establish alternative waste classification and characteristics.

Response: The original § 61.58 requirements allowed licensees to request alternative waste classification and characteristics requirements. With the adoption of the new waste acceptance requirements in the revised § 61.58, the previous alternative waste classification

and characteristics requirements are no longer necessary because licensees can develop site-specific WAC that would include allowable radionuclide concentrations or activities and waste form characteristics. Therefore, the objectives of the previous requirements can be accomplished using the new waste acceptance requirements.

The revised § 61.58 provides better detail for determining whether waste is acceptable for disposal. The NRC has also included guidance in NUREG-2175 that provides acceptable approaches for demonstrating that the requirements are met. The requirements at § 61.58 ensure that the information is adequate to characterize the waste and certify its acceptability for disposal.

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

M.5 *Comment:* Some commenters raised concerns about the development of WAC per § 61.58. A commenter was concerned that the proposed regulation appeared to limit a licensee's option to develop WAC to only one of the two approved methods mentioned in § 61.58(a)(1). Another commenter raised a concern with the difficulty in developing site-specific WAC. The commenter recommended that the NRC develop new waste classification tables for both a humid and arid disposal sites rather than allow the development of site-specific WAC.

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.

Response: The NRC does not expect there to be confusion between the WAC for disposal and the terms used by collectors or processors. The final rule requires all land disposal facilities to develop WAC using the results of the technical analyses, the waste classification system specified in § 61.55, or a combination of both. Land disposal facilities may choose to then establish lower acceptance limits than their approved WAC to ensure that they do not exceed their WAC. The approved WAC, regardless of whether they were developed from § 61.55 requirements or the results of site-specific technical analyses, will be incorporated into the land disposal facility's license, thereby making it clear what waste a land disposal facility is permitted to accept for disposal.

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

M.7 *Comment:* Some commenters raised concerns with § 61.58(h), which specifies that the NRC would use the standards in § 61.23 in determining whether to approve WAC. The commenters were concerned that the criteria in § 61.23 are not all directly tied to the approval of WAC and were more appropriately related to demonstrating that the performance objectives will be met.

Response: The proposed § 61.58(h) specified that the Commission would use the criteria specified in § 61.23 to determine whether to approve a licensee's WAC. The standards in § 61.23 specify the criteria the Commission would use in approving a license or an amendment. Although approval of WAC would be necessary to approve a license or a license amendment in the case of modified WAC, the NRC agrees with the commenters that not all the standards specified in § 61.23 are directly related to approval of WAC. While some of the standards specified in § 61.23 identify compliance with the performance objectives, the NRC's regulations at § 61.58 already specify that WAC must demonstrate compliance with the performance objectives of Subpart C. Further, the standards related to the performance objectives in § 61.23 specify that the WAC must also demonstrate that the performance objectives will be met. Therefore, the NRC agrees that not all the standards specified in § 61.23 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.

M.10 *Comment:* A commenter raised concerns about § 61.58(b). Specifically, the commenter cautioned against requiring submittal of waste characterization data as part of the approval of the acceptable methods for characterizing the waste for acceptance, and recommended that the NRC consider specifying additional information in § 61.58(b)(7), including lower limits of detection and uncertainty in reported characterization values used for waste certification.

Response: The regulations at § 61.58(b) specify that the acceptable methods for characterizing the waste for acceptance must be submitted for approval. The requirements also specify a minimum amount of information that the acceptable methods for characterizing the

waste must identify. However, the regulations do not require that the actual characterization data used to determine acceptance be submitted to the NRC for approval. The NRC expects that the characterization data would be maintained as part of the certification program that would be approved and periodically inspected by the NRC or Agreement State.

Likewise, § 61.58(b) specifies that the methods considered acceptable for characterizing waste for acceptance identify the parameters and acceptable uncertainties. The NRC expects that this would include limits of detection as part of characterizing the activity of radionuclides in the waste. The NRC has included a discussion of limits of detection in the context of waste characterization methods in the final NUREG-2175.

No changes were made to the rule language as a result of this comment; however, the guidance document was changed.

M.11 *Comment:* One commenter supported the NRC allowing licensees to use contemporary ICRP recommendations for the dose methodology to determine site-specific WAC. Another commenter raised concerns about the potential mismatch between site-specific WAC developed using contemporary ICRP recommendations and criteria developed from the waste classification tables in § 61.55, which were developed using historical ICRP recommendations.

Response: The NRC agrees that the use of contemporary ICRP recommendations to develop site-specific WAC could result in differences in WAC from those developed from the waste classification system, which relied on prior ICRP recommendations for some radionuclides. For some radionuclides, allowable site-specific limits developed with more recent ICRP recommendations might be higher than the limits developed from the waste classification system, which relies upon prior ICRP recommendations; for other radionuclides, the site-specific limits could be lower. However, it is appropriate to use the latest scientific information available to inform decisions and thus the NRC is allowing the use of more recent ICRP recommendations. Regardless of whether the licensee elects to develop site-specific limits

using more recent ICRP recommendations or the waste classification system, which relies upon prior ICRP recommendations, licensees will need to demonstrate that the limits will meet the performance objectives at the land disposal facility using dose methodology that is consistent with the dose methodology specified in 10 CFR part 20, including the use of updated factors recommended by the EPA in Federal radiation protection guidance or the most current scientific models and methodologies (e.g., those accepted by the ICRP) to calculate the dose. The weighting factors used in the calculation of the dose must be consistent with the methodology used to perform the calculation.

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

M.12 *Comment:* A commenter stated that GTCC and transuranics above 10 or 100 nanocuries per gram, which were not allowed to go to these facilities under the original rule, would be allowed under the proposed rule. Another commenter sought clarification about whether an applicant for a land disposal facility for GTCC waste could propose to use the waste classification tables in § 61.55 or the results of the technical analyses. Another commenter maintained that the limits establish the threshold for GTCC waste, and recommended modifications to limit the amount of long-lived alpha-emitting radionuclides, such as certain isotopes of uranium, thorium, and radium, which are not transuranic, but pose a longer-term hazard.

A separate commenter recommended that the existing definition of LLRW contained in § 61.2, "waste," be amended to conform to the statutory definition of LLRW contained in the LLRWPAA. The commenter recommended that the term "transuranic waste" be removed and instead, the definition should be taken from the LLRWPAA and should read "…radioactive material that is not high-level radioactive waste, spent nuclear fuel, or byproduct material (as defined in § 11e.(2) of the Atomic Energy Act of 1954…)." The commenter stated that updating the definition would also serve to conform the definition of waste in 10 CFR part 61 to the existing provisions in § 61.1(b) dealing with the purpose, scope, and applicability of the rule.

Another commenter also urged the NRC to expand the safety requirements to other higher classes of radioactive waste.

Response: At this time, neither the waste classification tables in § 61.55 nor the results of a site-specific analyses in 10 CFR part 61 are intended for GTCC waste. GTCC waste is not generally acceptable for near-surface disposal; therefore, waste forms and disposal methods will be different from those specified in 10 CFR part 61. GTCC waste must be disposed of in a geologic repository as defined in 10 CFR part 60 or 63, unless a proposal for disposal of such waste in a disposal site licensed pursuant to 10 CFR part 61 is approved by the Commission. In SRM-SECY-15-0094, "Historical and Current Issues Related to Disposal of Greater than Class C Low-Level Radioactive Waste," dated December 22, 2015 (ADAMS Accession No. ML15356A623), the Commission directed the NRC staff to prepare a regulatory basis to evaluate the disposal of GTCC waste through means other than deep geologic disposal, including near-surface disposal. Depending upon the results of the regulatory basis, the Commission could initiate a future rulemaking to develop generic disposal criteria to allow for disposal of GTCC waste under 10 CFR part 61. This regulatory basis will not be initiated until after this 10 CFR part 61 rulemaking has been completed.

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.

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

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.

Response: Section 61.80(m) requires licensees to maintain waste acceptance records including audits and other reviews of program content and implementation, such as the annual review required in § 61.58(f). While licensees are not required to submit the records of the annual review to the regulator, the regulator will inspect the licensee's records periodically to ensure that the reviews are completed and to evaluate the adequacy of the content and implementation of the WAC, waste characterization methods, and certification program.

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

N. *Waste Classification*

N.1 *Comment:* Some commenters expressed concerns about the waste classification requirements in § 61.55 and the need to modify them to account for waste streams

containing other long-lived radionuclides such as depleted uranium. Some of these commenters raised concerns about whether depleted uranium is properly classified as a Class A waste by default in § 61.55. Many of these commenters noted that its long half-life and increasing activity as a result of the in-growth of progeny is inconsistent with the longevity of the hazard for Class A waste as defined in § 61.55. One commenter expressed concern that the classification of depleted uranium as Class A could limit future disposal capacity because depleted uranium's current classification creates a disincentive for local communities to permit land disposal facilities. Nearly all these commenters supported the NRC identifying waste classification limits for depleted uranium in § 61.55. Some commenters supported resolving the classification of depleted uranium prior to completing or as part of this final rule**,** while another commenter supported publishing this rule prior to initiating work to classify depleted uranium. A commenter also recommended that NRC staff provide a recommendation to the Commission regarding the need for rulemaking efforts for revising the waste concentration limits specified in § 61.55.

Other commenters raised concerns about modifying the concentration limits specified in § 61.55. One of these commenters questioned what would be learned from classifying depleted uranium and whether the classification would account for the concentrations and volumes of depleted uranium that have been or will be produced. Some of these commenters raised concerns about modifying the class limits because of their integration with the other requirements in 10 CFR part 61 and the LLRWPAA. One of the commenters recommended that the NRC consider these issues in this rulemaking rather than deferring to a future rulemaking.

Some commenters indicated that the waste acceptance requirements proposed in the revised § 61.58 eliminated the need to classify depleted uranium and blended wastes. These commenters also highlighted both the superiority of site-specific analyses to account for specific

volumes of waste and associated radionuclides as well as the potential for disruption and cost to the NRC associated with ongoing rulemaking following the completion of this rulemaking.

Response: The NRC agrees that large quantities of concentrated depleted uranium do not present the same radiological hazard as other Class A waste streams over time because of the differing radioactive decay and in-growth characteristics. While the hazard from Class A waste 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. Because of the potential for disposal in the near surface of significant quantities of concentrated depleted uranium, and other long-lived radionuclides not analyzed during the original development of 10 CFR part 61, the NRC initiated this rulemaking to specify requirements for licensees to conduct site-specific technical analyses to determine what quantity of these wastes could be disposed safely at a given land disposal facility.

The NRC also agrees that careful consideration is necessary before modifying or removing the waste classification limits in § 61.55 because of implications such as those cited by the commenters. However, the NRC does not intend to expand the scope of this current rulemaking at this late stage to consider modifications to the waste concentration limits. Recognizing that the safe disposal of depleted uranium and other waste streams containing long-lived radionuclides is important, the NRC is not convinced that there is a need to consider modification of the § 61.55 limits as part of this rulemaking because this final rule requires site-specific analyses to demonstrate that the performance objectives will be met. The NRC agrees with some of the commenters that the site-specific technical analyses are well suited to demonstrate that a land disposal facility's WAC are appropriate and that the 10 CFR part 61 performance objectives will be met and provide reasonable assurance that public health and safety will be protected, regardless of the classification of a particular waste.

Further, revisiting the classification of depleted uranium would require the NRC to make assumptions about the behavior of the site that may not be realistic at all land disposal facilities.

Rather than deferring the current rulemaking and modifying the waste concentration limits in § 61.55 as part of this current rulemaking, the NRC will evaluate these comments and the need for a future rulemaking to modify the waste concentration limits after completion of this rulemaking.

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

N.2 *Comment:* A commenter raised a concern that waste concentrations specified in tables 1 and 2 in § 61.55 are inadequate to protect public health and safety because some radionuclides also require a total activity limit for a land disposal facility.

Response: The concentration limits in tables 1 and 2 of § 61.55 are designed to provide protection to an inadvertent intruder. The tables 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. Thus, 10 CFR part 61 has always required a performance assessment to demonstrate protection of the public from releases from the land disposal facility. The performance assessment can also account for site-specific conditions that may affect the risk from these radionuclides more realistically than generic inventory limits. The results of the performance assessment can then be used to identify radionuclides that may require total inventory limits and to establish those limits.

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

O. *Waste Characteristics*

O.1 *Comment:* Commenters expressed a variety of views about blending and concentration averaging. A commenter stated that “references to blended waste streams as not being analyzed should be removed” from the rule, because the NRC staff analyzed blended waste streams to develop Revision 1 of the “Concentration Averaging and Encapsulation Branch Technical Position” (CA BTP) (ADAMS Accession Nos. ML12254B065 and ML12326A611). Another commenter expressed general opposition to blending and

concentration averaging, while another expressed the view that blending complicates disposal. A commenter expressed general safety concerns about blending and made a comparison to mixing absorbent material with waste.

Response: Although Revision 1 of the CA BTP provides guidance on disposal of LLRW based on protection of an inadvertent intruder, it is not a substitute for the site-specific inadvertent intruder analyses required by § 61.42. As one commenter noted, the revised CA BTP position on blended waste is based on analysis of projected dose to an individual who inadvertently drills into a hot spot in blended LLRW. The revision to the CA BTP did not consider the projected dose to an inadvertent intruder exhuming a larger volume of waste (e.g., to excavate for a basement), as was considered during the development of the waste classification tables of § 61.55 or could be considered in a site-specific inadvertent intruder analysis under § 61.42. The technical basis of the CA BTP position on blended waste was limited in this way because the CA BTP was intended to provide guidance on managing hot spots in LLRW, not average concentrations of radionuclides over larger volumes. That is, the CA BTP replaces neither waste classification nor site-specific inadvertent intruder analyses. Further, the CA BTP cannot take the place of any revision to 10 CFR part 61 because the CA BTP is guidance.

Neither § 61.55(a)(8), which allows concentration averaging, nor the Commission position on blending in SRM-SECY-10-0043 (ADAMS Accession No. ML102861764) are affected by this rulemaking. Therefore, comments related to opinions about whether blending or concentration averaging should be allowed are out of scope.

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

O.2 *Comment:* Some commenters stated that waste that remains hazardous for more than 100 years should be prohibited from disposal and that regulations specifying time periods for analysis and corresponding dose limits do not protect the public. A few commenters objected to disposal of waste streams with long-lived radionuclides (e.g., depleted uranium and

certain reprocessing wastes) in near-surface disposal facilities because of the longevity of its radiological hazard. One of these commenters also rejected the use of analyses to determine acceptable limits for disposal of long-lived radionuclides; this commenter argued that no limit was safe for certain long-lived radionuclides, such as plutonium.

Response: The NRC agrees that disposal of significant quantities of long-lived radionuclides in the near-surface environment presents challenges because of the longevity of the radiological hazard. The near-surface environment may be very dynamic over long time periods depending on the site conditions. The NRC's LLRW regulations are designed to ensure that the risk to public health and safety can be maintained at suitably low levels. For example, the dose limit in the § 61.41(a) performance objective is 0.25 mSv (25 mrem) per year, which is a fraction of the natural background radiation in the United States.

As part of this rule, the NRC is requiring licensees to conduct site-specific technical analyses to demonstrate that the performance objectives will be met and provide a technical basis for the WAC. These technical analyses and NRC's licensing process, which includes a safety review by the NRC, are well suited to determine appropriate WAC for long-lived radionuclides by accounting for site-specific conditions that may influence the mobility of long-lived radionuclides or the potential for exposure to the radiation from these radionuclides. The technical analyses allow for stakeholders to develop an understanding of potential future system performance as well as an understanding of the impact of uncertainties. Timeframes longer than 100 years are required to be evaluated as part of the technical analyses of land disposal facility performance. These analyses can then be used to properly design the land disposal facility and to develop WAC to ensure that the waste that is disposed in a land disposal facility is appropriate for the disposal site so that doses that may occur in the future will be acceptable.

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

O.3 *Comment:* A commenter noted that the NRC did not consider depleted uranium that had been contaminated by fission products during processing and enrichment.

Response: The enrichment process increases the relative amount of uranum-235 in the enriched product. Depleted uranium, which is the waste stream from the enrichment process, contains less uranium-235 than natural uranium because the uranium-235 has been preferentially moved into the enriched product. Depleted uranium does, however, still contain some uranium-234 and uranium-235. In its analysis of depleted uranium disposal, the NRC considered depleted uranium with a mixture of uranium-234, uranium-235, and uranium-238 isotopes typical of depleted uranium waste.

Depleted uranium can also sometimes be contaminated with fission products. The NRC did not consider depleted uranium contaminated with fission products in the technical analysis for SECY-08-0147, "Response to Commission Order CLI-05-20 Regarding Depleted Uranium" (ADAMS Accession No. ML081820762). However, the conclusion of that analysis was that the NRC needed to perform a rulemaking to provide technical criteria for the evaluation of the disposal of large quantities of depleted uranium. If the NRC had considered uranium contaminated with fission products that conclusion would be the same and consideration of fission products would only increase the need for site-specific analyses. The technical requirements for a performance assessment, inadvertent intruder assessment, stability analyses, and development of WAC will ensure that all types of depleted uranium will be properly evaluated to determine if public health and safety can be protected.

The waste inventory used in the technical analyses must include all radionuclides anticipated to be present that may impact public health and safety. If the depleted uranium inventory contains radionuclides associated with reprocessing spent nuclear fuel, then those radionuclides must be included in the inventory of the performance assessment. The NRC is aware that the inventory of depleted uranium evaluated in the performance assessment for disposal in Utah did include estimates of radionuclides associated with depleted uranium contaminated with fission products.

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

O.4 *Comment:* A commenter compared depleted uranium to natural uranium to note the low risk associated with depleted uranium disposal.

Response: Depleted uranium has lower specific activity than natural uranium when they are compared by mass of uranium. However, depleted uranium concentrations per unit mass or volume of waste are expected to approach 80 percent by weight (mass uranium per mass waste) whereas natural uranium in the United States is commonly on the order of a few tenths of percent uranium by weight. Thus, in comparison to uranium as it occurs mixed with geological materials (i.e., soil and rock) in nature, depleted uranium waste is much more radioactive per unit mass.

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

O.5 *Comment:* A commenter asserted that based on the language in § 61.7(f)(3), which states that waste that will not decay to levels that present an acceptable hazard to an inadvertent intruder within 100 years is designated as Class C waste, depleted uranium should be Class C waste. Depleted uranium decays to levels that are increasingly hazardous for over 2 million years, and "decay" does not imply a reduction in hazard.

The commenter also stated it was not clear why Class C waste must be disposed at greater depth. The individual indicated that a performance assessment should be performed, no matter the waste stream, to determine if a waste stream can be disposed in a given disposal configuration or engineered system.

Response: The current classification of depleted uranium is based on § 61.55(a)(6); essentially waste containing radionuclides not in table 1 or 2 is Class A by default. This rulemaking was undertaken because waste classified using § 61.55(a)(6) could result in unacceptable impacts to the public under § 61.42. Half-life is not the only component of the classification calculations. The other component is concentration. Some long-lived radionuclides are appropriately managed, at low concentrations, as Class A waste. Large amounts (thousands of metric tons) of concentrated depleted uranium are unlikely to be Class A

waste if classified using the same approaches as were used to develop § 61.55, tables 1 and 2. The NRC has concluded that the revised regulations can ensure the safe disposal of depleted uranium even in larger concentrations than originally envisioned during the development of the original 10 CFR part 61.

Disposal depth and inadvertent intruder barriers mitigate the risk to an inadvertent intruder from short-lived radionuclides. While the NRC agrees that an inadvertent intruder assessment can be used to determine proper disposal depth, the depth requirement ensures that the risk from short-lived Class C waste will be mitigated. In almost every circumstance the risk to inadvertent intruders is driven by disturbance of the waste from above, hence the use of this approach.

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

P. *Site Suitability and Site Characteristics*

P.1 *Comment:* A commenter expressed concern with respect to how site characteristics are considered in making regulatory decisions and cited several examples of site characteristics including flooding and seismicity.

Response: Site characteristics play an important role in determining the suitability of a site for LLRW disposal. Site characteristics are evaluated with respect to their risk implications. For example, 10 CFR part 61 lists certain hydrologic characteristics that a site must have for 500 years after closure. For time periods more than 500 years after closure, those characteristics are evaluated in the context of how the FEP may influence compliance with the performance objectives. The other role that the site characteristics have is that they may be used to identify potential future instability that may make the disposal site incapable of being adequately modeled to estimate future performance. A discussion on how site characteristics can be considered is provided in NUREG-2175.

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

P.2 *Comment:* A commenter expressed concern that the language from the original § 61.50(a)(1) [§ 61.50(a) in the proposed and this final rule] would be weakened by eliminating existing language that was present in the original rule. The commenter indicated that although the deleted language is more of an interpretive statement rather than a substantive requirement, its deletion seems illustrative of some of the changes that are being proposed. The commenter recommended that the deleted language be retained and should remain a guiding principle.

Response: As the commenter noted, the rule language that was deleted from the original § 61.50(a)(1) was interpretive and did not provide a requirement. The rule language was deleted for these reasons and because it was unclear. For instance, some disposal site features are advantageous while other features may lead to negative performance. However, the NRC agrees with the commenter's intent. The rule language that was deleted has now 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 commenters stated that a sound conceptual model of the site and a comprehensive performance assessment provide the means to assess the significance of site attributes. They recommended that the detailed site-suitability criteria in the proposed § 61.50(a) be eliminated to reflect the implementation of a performance-based approach.

Response: The requirements for site-suitability have not been enhanced, only reorganized to align with the specification of analyses timeframes.

Although a full “analysis based” approach may work in some circumstances, in others it must be used cautiously—the presence of some FEPs may make modeling of a particular site intractable. In addition, the complexity of those features is not amenable to generation of specific guidance that would be needed to ensure consistency of review when implemented by different regulators. The site-suitability requirements provide constraints on adequate sites as a result of FEPs that would reasonably be expected to create significant challenges in modeling and assessment. Of course, a licensee can request an exemption from these requirements.

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

P.7 *Comment:* A commenter indicated that for near-surface disposal, the description in § 61.12(b) should include "occurrence and activity of biota."

Response: Paragraph 61.12(b) discusses design features. While the occurrence and activity of biota may impact the performance of the design, the type of information that commenter is recommending would be addressed through the requirements in § 61.13.

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

P.8 *Comment:* A commenter indicated that the language in the proposed § 61.50(2)(iii) could be interpreted as excluding humid sites as a suitable location for waste disposal due to the shallow water table. The commenter stated that this requirement should be revised or removed because, although it is reasonable to assume humid sites may require more engineered features and technical justification than arid sites, the requirement should be that the performance objectives of Subpart C of the rule must be met.

Response: Humid sites are not excluded by the language in § 61.50(2)(iii). However, this language does generally exclude disposal below the water table and does prohibit disposal in the zone of water table fluctuation. These requirements apply to any site whether humid or arid. These prohibitions are necessary because disposal below the water table or in the zone of water table fluctuation may result in increased releases to the environment, more challenging modeling, and more complex and expensive remedial actions for sites that do not meet § 61.50(2)(iii).

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

P.9 *Comment:* A commenter suggested the elimination of the proposed requirements for a new extensive stability analysis.

Response: Since 1982, § 61.44 has required stability of the disposal site after closure. The only significant change made to § 61.44 in this rulemaking is to clarify the timeframe as the compliance period.

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

Q. *Institutional Controls and Ownership*

Q.1 *Comment:* Some commenters indicated that the basis for the "100-year active institutional control period" and timing of inadvertent intrusion is unclear. One commenter felt that as part of the defense-in-depth philosophy, the NRC should allow Agreement States the flexibility to fund institutional control periods beyond the 100-year institutional control period. The commenter indicated that NRC should recognize the need for a "passive" institutional control period beyond the first 100 years and for the remainder of the life of the facility and that the timeframe for the institutional control period should be established on a state-specific basis.

Another commenter indicated that the NRC should reconsider its argument that although the longevity of government may reasonably be assumed to extend beyond 100 years, the 100-year institutional control period is also tied to the possibility of bureaucratic error. The commenter stated that such an argument is unreasonable in light of the fact that 40 CFR 192.12 requires post-closure care and maintenance in perpetuity at reclaimed uranium mill sites and that the NRC should address the inconsistency between LLRW institutional control periods and perpetual institutional control periods required at uranium mill tailings facilities. Another commenter instead expressed concern that NRC is assuming the current form of government would persist indefinitely.

A commenter stated that an active institutional control period of 300 years is more probable, provides a more accurate assessment of the risk to an inadvertent intruder, and would better align with U.S. and international practices. The commenter referenced studies conducted on behalf of the Nevada National Security Site (NNSS) and the DOE into the probability of intrusion, as well as citations from documents from other organizations. The commenter stated that their research indicates that the majority of activity in LLRW from nuclear utilities will decay to minimal levels within 300 years, and provided a graph of average concentrations (see

ADAMS Accession No. ML15204A915) of primary radionuclides from nuclear utilities. The concentration values were divided by the existing § 61.55 concentration limits as a measure of risk. For the first 300 years the commenter indicated that disposal risk is driven almost entirely by cesium-137 and nickel-63. After 500 years, only carbon-14 and transuranic waste were dominant risk contributors. The commenter noted that neither carbon-14 nor transuranic waste were ever more than about 10 percent of the Class A limits.

Response: The NRC requires institutional control of the land disposal facility after site closure. The institutional control period is used to prevent the public from contacting the short-lived waste while it decays, but also to allow the disposal site owner to conduct monitoring activities and perform active site maintenance. The institutional control period was developed in the early 1980s during development of 10 CFR part 61 based on extensive public interaction with a wide variety of groups. A variety of different approaches to site control were considered when 10 CFR part 61 was developed. The general consensus at the time was that an institutional control period of up to 100 years was appropriate. The increased financial requirement associated with an increased institutional control period was one of the main disadvantages of requiring a longer institutional control period. The NRC staff is not aware of significant changes in the potential for loss of control of a site, costs of maintaining longer institutional controls, or more recent extensive stakeholder interactions that would justify changing that position.

The NRC recognizes that while the institutional controls are expected to be durable, uncertainty over long time periods exists. As noted in § 61.59(b), "the period of institutional controls will be determined by the Commission, but institutional controls may not be relied upon for more than 100 years following transfer of control of the disposal site to the owner." This means that although a disposal site may be required to implement institutional controls for a period longer than 100 years, the licensee can only take credit in their technical analyses for a maximum of 100 years. The duration of the institutional control period is tied to more than

bureaucratic error. The duration of the institutional control period also considers loss, theft, or deterioration of monuments and markers, loss or damage of records, loss of institutional memory of the hazards involved, and release of the land for alternate uses. Error can be one source of loss, but other phenomena can also result in loss of control.

The approach to institutional controls for management of uranium mill tailings resulted in part because mill tailing management, especially resultant contaminated groundwater, represented an extensive remediation problem. Controls were needed to allow uranium concentrations in water to decrease to protect public health and safety. In addition, unlike 10 CFR part 61 sites where the performance assessment is intended to show that the performance objectives will continue to be met after institutional controls are removed, mill tailing piles are intended to have active institutional controls in perpetuity to control the ongoing potential hazards resulting from the relatively high concentrations of long-lived radionuclides. The objective for future LLRW disposal is to prevent the need for remediation and land use restrictions.

The NRC expects that some form of government is likely to exist well into the future. Because the NRC requires analyses and provides requirements for the loss of institutional controls (whether active or passive), public health and safety is protected.

The NRC interprets the NNSS study referenced by a commenter, as a site-specific analysis applicable to a deep, arid site such as one located in the Nevada desert. The NRC's regulations must apply to LLRW sites located anywhere within the United States. Therefore many of the assumptions in that study are likely not applicable to all sites, although the overall methodology may apply. The NNSS study was based on extrapolating current conditions into the distant future. The likelihood of future human intrusion is driven by dynamic changes to current conditions. The NRC disagrees that the approach in 10 CFR part 61 is inconsistent with international practices and notes that ICRP 81 states that there is no scientific basis for predicting the nature or probability of future human actions. Outside of the site-specific NNSS

study, the other references cited by the commenter appear to be policy positions or opinions of those agencies rather than scientific studies.

The NRC notes that the graph presented by a commenter is based only on waste from nuclear power plants, whereas 10 CFR part 61 applies to all LLRW. Further, the waste classification system is more complex than reflected in the graph. The concentration values shown in the graph can be divided by the waste classification table concentrations; however, the class limits are not simply translatable to projected dose. For example, the Class C concentration limits were increased by a factor of 10 between the calculations performed for the draft regulatory basis for the original 10 CFR part 61 (NUREG-0782) and the values presented in the final original regulatory basis to account for the relative inaccessibility of Class C waste, among other factors. If the land disposal facility concentrations are at these values, then the projected dose from Class C waste is not 5 mSv (500 mrem), as shown in the commenter's letter, but rather is 50 mSv (5 rem) to an inadvertent intruder. One cannot simply take the concentrations and divide them by the waste classification table concentrations to estimate relative or a percentage of risk unless all the underlying assumptions are understood and remain valid.

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

Q.2 *Comment:* A commenter indicated it is unclear when the institutional control period begins.

Response: Paragraph 61.59(b) provides that the institutional control period begins after transfer of control of the disposal site from the disposal site operator to the site owner (i.e., the Federal or State government).

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

Q.3 *Comment:* Some commenters expressed concern that if the DOE becomes the site owner, the NRC's requirements would no longer apply because the NRC does not have regulatory authority over the DOE in this area.

Response: The regulations in § 61.14, "Institutional information," require that a licensee provide a certification that the disposal site be on land owned by the Federal or State government and the government "will assume responsibility for custodial care after site closure and postclosure observation and maintenance" or that arrangements have been made for the assumption of ownership by the Federal or State government. The transfer of the disposal site license to the Federal or State government cannot take place until the provisions of § 61.30, "Transfer of license," are met. One of the findings the NRC has to make before this transfer can take place is in § 61.30(a)(5), which states: "That the Federal or State government agency which will assume responsibility for institutional control of the disposal site is prepared to assume responsibility and ensure that the institutional requirements found necessary under § 61.23(g) will be met." The commenter is correct that the NRC would not have regulatory authority over the DOE if the DOE assumes responsibility for a closed LLRW disposal site, but the NRC has reviewed the institutional control requirements in the regulations and has concluded they will adequately protect the public when the Federal or State government (e.g., DOE) takes possession of the closed disposal site.

Although the original § 61.7(c)(4), which describes this process, was redesignated as § 61.7(g), the actual language in the rule was not changed.

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

R. *Regulatory Analysis and Backfitting*

R.1 *Comment:* Some commenters were concerned that the NRC was not considering unintended consequences on future site development resulting from the potential for increased burden and regulatory uncertainty. In particular, some commenters were concerned that the proposed regulatory changes failed to identify "unquantified liabilities" and would limit the likelihood of new waste-site development or lead to premature shut down of existing sites. Some commenters were concerned that the regulatory analysis did not consider

new sites. Another commenter raised the concern that allowing site-specific WAC would make it more difficult for enrichment facilities to dispose of significant quantities of depleted uranium waste, which in turn could have operational impacts. Another commenter was concerned that the rule revision would generate extensive litigation risk for existing sites as closure plans are implemented.

Response: Although all disposal site licensees and Agreement State regulators will have additional burdens imposed by this rulemaking, the amount of effort expended by the licensees and Agreement State regulators will depend on whether or not they decide to accept significant quantities of long-lived radionuclides, such as depleted uranium. A 1,000-year compliance period will apply for those sites that have never accepted, and do not plan to accept, significant amounts of long-lived radionuclides. A 10,000-year compliance period, along with a performance period analysis, will apply to those sites that have already disposed of or plan to accept significant quantities of long-lived radionuclides. Since the burden on the licensees and Agreement States will depend on whether or not they have already disposed of or will accept significant quantities of long-lived radionuclides, and the acceptance of this waste is voluntary, the staff does not anticipate that the regulations will cause current sites to cease operating or prevent new sites from being developed. Based on the staff's experience, the following factors contribute to determining whether disposal sites either continue to open or new sites are developed: the availability of a suitable remote location; the economic need in the area; the supply of and demand for available disposal capacity; and public and political support.

The 10 CFR part 61 regulatory analysis did not evaluate any future sites because the NRC's research did not identify any parties interested in pursuing a license during the regulatory analysis period. The NRC does not expect new aspects of this final rule to have a significant impact on existing commercial enrichment facilities. Even if LLRW disposal facilities could not accept sufficient quantities of depleted uranium because of site-specific conditions, the DOE is

required to accept LLRW on a reimbursable basis from anyone licensed under the NRC to operate a uranium enrichment facility (USEC Privatization Act, 42 USC 2011).

The NRC disagrees that the rule would result in early site closure or extensive litigation risk due to any unquantified liabilities resulting from the rule. Part of the purpose of this rulemaking is to clarify potential areas in the regulations that may not be clear. The NRC established regulatory requirements at 10 CFR part 61 to ensure that disposal of LLRW in a land disposal facility is done safely and in a manner that protects public health and safety. Likewise, the NRC is revising the regulatory requirements to ensure that LLRW streams that are significantly different than those considered in the initial development of 10 CFR part 61 are disposed safely. The use of technical analyses to demonstrate the performance objectives will be met, together with defense-in-depth protections, managerial controls, and other components of the safety case as required by the final rule, provide confidence that public health and safety will be protected.

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

R.2 *Comment:* A commenter raised a concern for disposal sites with 90 percent of their inventory in place that the new requirements will force the licensees to do site-specific performance assessments, which will cost millions of dollars. Another commenter argued that the new requirements are burdensome and do not allow flexibility.

Response: The NRC has developed a cost benefit analysis in the regulatory analysis associated with this final rule. The regulatory analysis has been revised to estimate the cost impacts for each of the four active sites based upon the expected incremental costs needed to update existing performance assessments and each disposal site's expected future operating timeframe. Some of the benefits identified in the regulatory analysis include: 1) ensuring that LLRW streams that are significantly different from those considered during the development of the original regulations can be disposed of safely and meet the performance objectives for land disposal of LLRW without the need for future rulemakings to address those different streams on

a case-by-case basis; 2) facilitating the use of site-specific information and up-to-date dosimetry methodology in site-specific technical analyses to better ensure protection of public health and safety; and 3) enhancing the risk-informed regulatory framework in 10 CFR part 61 by specifying which requirements need to be met and providing flexibility to a licensee or applicant with regard to the information or approach that may be used to satisfy the 10 CFR part 61 requirements. The WAC should also allow licensees to dispose of material in a more risk efficient manner, which is likely to reduce costs. Based upon this evaluation, the NRC has concluded that the health and safety benefits outweigh the financial costs associated with this rulemaking.

The NRC disagrees that the new regulations do not allow flexibility. Licensees can still opt between using the waste classification tables, site-specific performance analyses, or a combination of both, although some site-specific analyses are, and have been, required in any case. The new site-specific WAC will also allow licensees to dispose of material in a more risk efficient way, which may reduce costs for the land disposal facility.

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

R.3 *Comment:* Some commenters were concerned that the draft regulatory analysis significantly underestimated the burden and cost of implementation for the Agreement States, operators, and generators. The commenters stated that the regulatory analysis needed to provide more details and be site specific to capture all the potential costs. A commenter was also concerned that the cost justification provided in the draft regulatory analysis was insufficient.

Response: The NRC appreciates the information provided on cost in the comments and has also obtained updated cost information from the Agreement States and operating LLRW disposal site licensees. The NRC considered this information when estimating the incremental costs in the final regulatory analysis, which increased the estimated cost of implementing the

measures, as well as the estimated ongoing cost. The final regulatory analysis was updated to provide site-specific cost breakdowns with additional details on assumptions and costs.

The cost-justification is provided in section five, “Decision Rationale,” of the regulatory analysis. The NRC concluded that the rule is cost justified because the regulations enhance public health and safety by ensuring the safe disposal of LLRW that was not analyzed in the original 10 CFR part 61 regulatory basis (e.g., significant quantities of depleted uranium).

No changes were made to the rule language as a result of these comments; however, the regulatory analysis has been revised.

R.4 *Comment:* A commenter was concerned that the draft regulatory analysis (ADAMS Accession No. ML14289A158) considered only two options. The commenter stated that the regulatory analysis did not consider stopping the rulemaking or limiting it to apply only to future disposal of depleted uranium. Further, the commenter argued that the draft regulatory analysis did not identify any benefits due to the rule.

Response: The NRC considered a wide variety of alternatives to address specific requirements (e.g., timeframes) of the rule. These alternatives were identified in the proposed rule and in the draft regulatory basis. Because these approaches all had similar components and, therefore, similar costs, the regulatory analysis did not consider these as separate options and did not break down their costs individually. The NRC concluded, after careful consideration of these alternatives for achieving the goal of addressing the disposal of waste streams not analyzed as a part of the original development of 10 CFR part 61, that there were two reasonable options: 1) no action, or 2) drafting the rule.

The commenter specifically suggested that the NRC should consider the alternative of stopping the rulemaking and instead working with the sited Agreement States with or without continuing development of guidance. The NRC concluded that these options really fall under the “no action” alternative because without implementation through regulation, although the NRC could request Agreement States to take certain actions, there would be no enforceable

regulatory requirements in place to allow the NRC or the Agreement States to compel action to address issues associated with the disposal of radionuclides that were not previously analyzed as part of the original regulatory basis. In addition, working with each Agreement State individually could result in a wide variety of waste disposal requirements that are significantly different across the Agreement States. There could also be situations where the Agreement State could not implement a necessary change without an NRC rulemaking because certain Agreement State requirements are required to be exactly the same or similar to NRC requirements because of compatibility category designations. The commenter also recommended limiting the rulemaking to the acceptance of future significant quantities of depleted uranium. The NRC considered this option during development of the proposed rule and concluded that considering this option as a separate alternative in the regulatory basis did not have merit because this approach was unlikely to result in costs or requirements significantly different than those implemented by the final rule. This issue is discussed further in item A.1 in this section.

The NRC disagrees that the regulatory analysis failed to identify benefits of the rule. As outlined in section four, “Presentation of Results,” of the final regulatory analysis (ADAMS Accession No. ML16189A050), the benefits of the rule include: 1) ensuring that LLRW streams that are significantly different from those considered during the development of the original regulations can be disposed of safely and meet the performance objectives for land disposal of LLRW without the need for future rulemakings to address those different streams on a case-by-case basis; 2) facilitating the use of site-specific information and up-to-date dosimetry methodology in site-specific technical analyses to better ensure protection of public health and safety; and 3) enhancing the risk-informed regulatory framework in 10 CFR part 61 by specifying what requirements need to be met and providing flexibility to a licensee or applicant with regard to what information or approach they use to satisfy those requirements. The WAC

should also allow licensees to dispose of material in a more risk efficient manner, which is likely to reduce costs.

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

R.5 *Comment:* Some commenters suggested that, although not required under 10 CFR part 61, the NRC should have conducted a backfit analysis for this rulemaking. Some commenters noted that a regulatory analysis is not required but the NRC conducts that analysis voluntarily and, thus, should also have voluntarily conducted a backfit analysis for these new requirements. A commenter recommended that a back fit requirement should be added to 10 CFR part 61.

Response: The NRC disagrees with these comments. Although the commenters correctly state that development of a regulatory analysis is a voluntary activity that the agency has historically undertaken, the NRC disagrees with the assertion that the NRC should also voluntarily prepare a backfit analysis for this rulemaking. As noted by some commenters, regulatory analyses are not statutorily required but the NRC has been preparing regulatory analyses since 1976. A regulatory analysis is a holistic evaluation of the various costs and benefits that may result from a regulation, whereas a backfit analysis is an evaluation that is limited to certain already licensed facilities and focuses on the degree of safety or security benefit derived from the proposed regulation.

The regulatory analysis developed for this rulemaking considered items such as increases in operational flexibility for licensees as well as benefits not easily quantified, such as reduction in exposure, which cannot be calculated to a strict number; a backfit evaluation would not consider these items. The regulatory analysis also evaluated costs to licensees and applicants, such as the costs of performing the required analyses, as well as costs to the regulators (e.g., adopting compatible regulations and reviewing licensee or applicant analyses). In this instance, due to the long-lived radionuclides, the long timeframes these new regulations are seeking to address, and the increase in operational flexibility for licensees achieved through

these regulations, the NRC concluded that the regulatory analysis provides an adequate review that is appropriate for this rulemaking.

The NRC does not see a need to add a backfit provision to 10 CFR part 61 at this time.

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

R.6 *Comment:* A commenter questioned how the regulatory analysis, instead of a backfit analysis, benefits state regulators.

Response: The draft regulatory analysis developed for the proposed rule (ADAMS Accession No. ML14289A158) included a cost benefit analysis that provides members of the public, including State regulatory authorities, with information about the expected costs for complying with these rule revisions. The cost benefit analysis evaluates costs for regulatory authorities, both State and Federal, as well as the costs to the regulated entities (i.e., licensees). The analysis also discusses the benefits, both quantitative and qualitative, that will result from compliance with the final rule. This gives both Agreement State regulators and the Commission 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 some of the concepts from the DOE and from NUREG/CR-6948, "Integrated Ground-Water Monitoring Strategy for NRC-Licensed Facilities and Sites: Logic, Strategic Approach and Discussion," (ADAMS Accession Nos. ML073310297 and ML073320395) on long-term performance assessment maintenance to provide a technical framework and basis for long-term monitoring and maintenance and stated that the monitoring program should be broadened to encompass more than evaluating radiological concentrations at the site boundary. The commenter specifically mentioned that the original § 61.12(l) should be modified to address inconsistencies with the definition of monitoring in § 61.2.

Response: The period the commenter is referencing is the 5-year period following closure when the licensee is required to remain at the site prior to transfer of the disposal site to the owner for institutional control. The specific requirement is found in § 61.29, "Post-closure observation and maintenance," and the actual time period for post-closure observation and maintenance may be shorter or longer, as approved in the licensee's site closure plan and

based on site-specific conditions. The purpose of this period is to ensure that any closure activities that have been performed have not introduced instability that will become a problem for the disposal site owner during the institutional control period. Monitoring of potential radiological releases and of the state and condition of the disposal site will occur during the 5-year observation period as well as during the institutional control period. However, monitoring of the disposal site by the licensee is not limited to this 5-year period. The requirements in § 61.53, "Environmental monitoring," specify that licensees must conduct a monitoring program both before construction and during operations of a land disposal facility.

Monitoring is defined in § 61. 2 as observing and making measurements to provide data to evaluate the performance and characteristics of the disposal site. Therefore, monitoring is not limited to measuring environmental concentrations of radioactivity. The NRC agrees with the commenter that the monitoring of other characteristics such as moisture 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.

Response: The NRC does not explicitly regulate chemical toxicity of uranium for a member of the public because that authority is not within the jurisdiction of the NRC. However, the NRC does regulate chemical toxicity of uranium for an occupational worker. To demonstrate compliance with the performance objectives in 10 CFR part 61, subpart B, the licensee or license applicant must also demonstrate compliance with the radiation protection standards in 10 CFR part 20. Section 20.1201(e) establishes the limit for the intake of soluble mixtures of uranium by an occupational worker. An intake of 8 milligrams (mg)[9] of soluble uranium per week was found to be near the threshold for mild transient effects that have no known long-term effects. The NRC's regulations permit intakes of up to 9.6 mg of soluble uranium per week for workers with the assumption of no significant adverse effects.

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

[9] Just, R. A., and V. S. Emler, "Generic Report on Health Effects for the U.S. Gaseous Diffusion Plants," DOE Report K/D-5050, Section VIII, Part 1, 1984.

S.7 *Comment:* A commenter expressed concern about the proposed table A and how it was going to achieve the fiduciary responsibilities of the regulatory agencies.

Response: All of the requirements NRC is prescribing in this rulemaking, such as the definition of analyses timeframes, are designed to protect public health and safety. Therefore NRC is performing its fiduciary duty to the public. For technical reasons, described in item C.1 in this section, table A has been moved to the guidance document.

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

S.8 *Comment:* A commenter stated that public participation improves rules and avoids mistakes.

Response: The NRC agrees that public participation is an important component of rulemaking. Throughout the proposed rule development process, the NRC sought enhanced stakeholder interactions via numerous public meetings and technical workshops, as indicated in section II.C, "Previous Public Interactions," of the proposed rule (80 FR 16081). The proposed 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, 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 disposal. The revision adds a new sentence to the requirement to certify that material meets the WAC to clarify that meeting the WAC is only applicable when shipping for disposal. The revision also aligns the certification requirement in 10 CFR part 20, Appendix G, Section II with the U.S. Department of Transportation (DOT) shipper's certification in 49 CFR 172.204.

The commenter's recommendation to remove language stating that the waste should be classified only when shipped for disposal from the waste generator certification statement in 10 CFR part 20 is out of scope for this rulemaking because the NRC only proposed adding a requirement to be consistent with the waste acceptance requirements in § 61.58. The commenter's proposal would result in an inconsistency with the DOT shipper's certification, which requires classification according to DOT regulations for all shipments. While the requirement to which the commenter refers was taken directly from DOT regulations, the NRC has always intended that the requirement to apply to both DOT and NRC regulations. Further, as stated in the certification regulation, certification is only for applicable regulations. The

regulations at 10 CFR part 20, appendix G, section I.C.12 and I.D.4 are clear that waste consigned to a land disposal facility must be classified according to §§ 61.55 and 61.56. Waste not consigned to a land disposal facility is not required to be classified according to §§ 61.55 and 61.56, therefore, classification would not be applicable when shipping other than to a land disposal facility. Therefore, the NRC will not be revising the certification requirement to remove the statement that the waste should be classified.

The NRC intends to revise the Uniform Waste Manifest (NRC Forms 540, 541, and 542) and associated guidance in NUREG/BR-0204 to clarify when shipped material must be classified according to §§ 61.55 and 61.56.

Changes were made to the rule language in appendix G to 10 CFR part 20 as a result of this comment.

S.15 *Comment:* A commenter was concerned that a licensee may stop updating their technical analyses and wanted to know if there was an opportunity for intervention or challenge if someone can show that the technical analyses was not properly updated by the licensee.

Response: The NRC has a hearing process associated with licensing decisions that allows a stakeholder to raise concerns, such as associated with the technical analyses. The Agreement States generally have processes similar to the NRC. A stakeholder can always raise a public health and safety concern by contacting the NRC (see NUREG/BR-0240, "Reporting Safety Concerns to the NRC," Rev. 6, May 2012 (ML12146A003)) or the Agreement State.

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

S.16 *Comment:* A commenter recommended changing the word “practicable” in § 61.44 to “practical.” The commenter stated that “practicable” means capable of being put into effect, while “practical” refers to something that is also sensible or worthwhile.

Response: The commenter’s summary of the terms “practicable” and “practical” is consistent with the summary provided in the NRC Style Guide (NUREG-1379, Rev. 2). The

word “practicable” is the word used in the original version of § 61.44 and the NRC finds its continued use is appropriate for § 61.44. Guidance for complying with § 61.44 is provided in NUREG-2175.

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

T. *Out of Scope*

T.1 *Comment:* A commenter expressed concern about the Emergency Access Clause, Section 6 of the LLRWPAA, which is addressed in NRC’s regulations in 10 CFR part 62, “Criteria and Procedures for Emergency Access to Non-Federal and Regional Low-level Radioactive Waste Disposal Facilities.” Specifically, the commenter argued that States should not be expected to take large amounts of waste during emergencies.

Response: As the commenter noted, the regulations for emergency access to disposal facilities are in 10 CFR part 62. The NRC can only take action to enforce emergency access if it “…is necessary because of an immediate and serious threat to the public health and safety or the common defense and security.” Further, elimination of the regulations in 10 CFR part 62 would require Congressional action on Section 6 of the LLRWPAA.

Finally, this comment is outside the scope of this rulemaking.

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

T.2 *Comment:* A commenter expressed concern that the Trans Pacific Partnership Treaty will force the U.S. disposal sites to accept LLRW from the other treaty partners.

Response: The regulations for import and export of radioactive material, including radioactive waste, are contained in 10 CFR part 110, “Export and Import of Nuclear Equipment and Material.” Because the import and export regulations are in another part of the regulations that are not addressed by this rulemaking, this comment is considered to be outside the scope of this rulemaking.

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

T.3 *Comment:* A commenter expressed concern with abandonment of a currently operating site. Another commenter was concerned about the future burden on the State or other regulatory body that is required to take ownership of the site after closure. The commenter indicated that no discussion of financial assurance was included and that the site would become a taxpayer burden.

Response: There are currently regulations in 10 CFR part 61 (see §§ 61.62, "Funding for disposal site closure and stabilization," and 61.63, "Financial assurances for institutional controls") associated with financial assurance requirements for operating a land disposal facility. These regulations are not affected by this final rule.

Additionally, in accordance with § 61.25(a), a licensee is not permitted to make changes to the facility or the facility's procedures that are important to public health and safety without prior regulatory approval. This regulatory provision may not address unanticipated abandonment of a facility, but does address situations where a licensee wishes to make material changes that may impact the site's ability to meet the performance objectives.

The NRC does not have a basis for concluding the rulemaking will make the current financial assurance requirements or license amendment review process any less effective. As these regulations are not being revised by this rule change, this comment is considered outside the scope of this rulemaking.

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

T.4 *Comment:* A commenter stated that further expansion of safety measures should be made across disposal sites for "all radioactive waste levels" to better protect against site failures caused by land subsidence, human errors, or natural disaster. The commenter expressed concerns about disposal and storage sites related to offsite releases, inadvertent intrusion, site stability, site testing, and site inspections. The commenter also recommended further action be taken in a variety of areas, including consolidating regulations for transportation and storage of waste, improving radionuclide detection devices, improving the

siting, design, and management of a high-level waste repository, and reducing the amount of radioactive waste generated. The commenter suggested these activities should build on the concepts and standards of the proposed rule.

Response: The commenter's concerns and suggestions span a range of technological and regulatory areas. While specific safety concerns should be raised to the NRC or the Agreement State regulator, the commenter did not indicate how the general concerns mentioned in the comment should be addressed in the current rulemaking. Although the commenter made a number of recommendations that span a number of NRC's regulatory programs, they are considered outside the scope of this rulemaking.

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

T.5 *Comment:* Some commenters provided general negative opinions about nuclear energy, the nuclear industry, NRC processes, depleted uranium, radioactive waste, and radiation protection that did not directly apply to the proposed rule.

Response: These comments were considered outside the scope of the rulemaking because they did not provide specific information relating to this final rule.

The NRC's mission is to protect public health and safety and common defense and security, and this mission remains the agency's sole focus. The NRC's robust regulatory framework, which includes site-specific licensing reviews and ongoing inspection and enforcement programs, ensures that NRC licensees continue to meet the NRC's safety standards.

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

T.6 *Comment:* A commenter suggested requiring licensees line the excavation area with a thin layer of clay because such a lining provides a minimum layer of protection from intrusion by animals, insects, and covert personnel action.

Response: This comment is outside the scope of this rulemaking because it discusses a specific suggestion for improving LLRW sites instead of commenting on the proposed changes to the rule language.

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

V. Discussion of Amendments by Section

Section 20.1003 Definitions.

Section 20.1003 defines common terms used in 10 CFR part 20. The NRC is revising the term "waste" to capture waste streams resulting from the production of medical isotopes that have been permanently removed from a reactor or subcritical assembly, for which there is no further use, and the disposal of which can meet the requirements of this part, consistent with the National Defense Authorization Act for Fiscal Year 2013.

10 CFR Part 20, Appendix G, Section II Certification.

Section II of appendix G to 10 CFR part 20, requires LLRW generators, processors, or collectors to certify that the transported LLRW is properly classified. Because § 61.58 would require licensees to develop WAC, using the existing LLRW classification system, the results of technical analyses, or a combination of both, the NRC is revising the requirements in section II so that shippers must certify that LLRW consigned to a land disposal facility for disposal meets the facility's WAC. Section II has also been revised to enhance its readability.

10 CFR Part 20, Appendix G, Section III Control and Tracking.

Section III of appendix G to 10 CFR part 20 places requirements on the control and tracking of LLRW transferred to a land disposal facility for disposal. Because this rule requires technical analyses and requires LLRW disposal licensees to develop WAC using the existing

LLRW classification system, the results of technical analyses, or a combination of both, the NRC is revising the requirements in sections III.A.1, III.A.2, III.A.3, III.C.3, III.C.4, and III.C.5, to ensure that shippers prepare, label, and provide quality assurance in accordance with the land disposal facility's WAC, if applicable.

Section 61.1 Purpose and Scope.

Section 61.1 provides the purpose and scope of 10 CFR part 61. The NRC is revising § 61.1 by removing the last sentence "Applicability of the requirements in this part to Commission licensees 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). The statements applicability was intended to only apply to the original promulgation on 10 CFR part 61 and is being removed to prevent confusion regarding the sentences applicability to this and future rulemakings.

Section 61.2 Definitions.

Section 61.2 defines common terms used in 10 CFR part 61. The NRC is revising the following definitions: 1) "disposal unit" to make the definition consistent with the rule language changes made to § 61.7(a)(2); 2) "inadvertent intruder" to include the phrase "reasonably foreseeable" to limit speculation of the analyses; 3) "site closure and stabilization" to correct a misspelling and add the phrase "to the extent practicable"; 4) "stability" to make the definition less self-referential and to reflect the purpose of the site stability performance objective; and, 5) "waste" to capture waste streams resulting from the production of medical isotopes that have been permanently removed from a reactor or subcritical assembly, for which there is no further use, and the disposal of which can meet the requirements of this part, consistent with the National Defense Authorization Act for Fiscal Year 2013. The NRC is also adding definitions for "compliance period," "defense-in-depth," "general environment," "inadvertent intruder

assessment," "long-lived radionuclide," "performance assessment," "performance period," and "safety case" to facilitate implementation of the requirements for site-specific analyses.

Section 61.7 Concepts.

Section 61.7 provides conceptual information for the licensing of a land disposal facility, the LLRW classification system, and near-surface disposal. Paragraph 61.7(a) describes the parameters for near-surface LLRW disposal in engineered facilities and the layout of land and buildings necessary to carry out the disposal. Paragraph 61.7(b) describes the safety objectives for near-surface LLRW disposal and emphasizes the stability of the waste forms and disposal sites. Paragraph 61.7(c) describes the licensing processes that the licensee must complete during the preoperational, operational, and site closure periods.

The NRC is revising §§ 61.7(a)(1) and 61.7(a)(2) to enhance readability. An additional sentence has been added to clarify that additional technical criteria may be developed on a case-by-case basis for alternative methods of land disposal.

The NRC is redesignating paragraphs (b)(1), (b)(2) through (b)(5), and (c) as paragraphs (b), (f), and (g) in § 61.7, respectively. The NRC revised redesignated paragraphs (b), (f), and (g) to enhance the readability of these paragraphs. Additionally, redesignated paragraph (b) has been revised to describe the performance objectives of the 10 CFR part 61 regulations. Redesignated paragraph (f)(1) has been revised to clarify that for long-lived waste 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 disposal if uncertainties cannot be adequately addressed with technical analyses. Redesignated paragraph (f)(2) has been revised to discuss materials that may not decay within 100 years. Redesignated paragraph (f)(3) has been revised to clarify that the effective life of these intruder barriers should

be at least 500 years and that waste that will not decay to levels which present an acceptable hazard to an inadvertent intruder within 100 years is typically designated as Class C waste. An additional sentence has been added to clarify that the disposal of LLRW above the Class C limit will be evaluated on a case-by-case basis with the technical analyses required in § 61.13. Paragraph (f)(4) provides conceptual information on the requirement for enhanced controls or limitations at a particular land disposal facility to provide reasonable assurance that the LLRW will not present an unacceptable risk over the compliance period. Paragraph (g) is revised to include the concept of a safety case in the licensing process.

The NRC has added new paragraphs (c), (d), and (e) to § 61.7. Paragraph 61.7(c) provides conceptual information for demonstrating compliance with the performance objectives of the technical analyses, which include a performance assessment and an inadvertent intruder 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) supports the licensee’s demonstration that the land disposal facility will be constructed and operated safely, and 3) provides reasonable assurance that the disposal site will be capable of meeting the performance objectives.

Section 61.12 Specific technical information.

Section § 61.12 lists specific technical information that must be included in an application for a 10 CFR part 61 land disposal facility license. This information is needed to demonstrate that the performance objectives of 10 CFR part 61, subpart C, and the applicable technical requirements of 10 CFR part 61, subpart D, will be met. The specific technical information includes a description of natural and demographic disposal site characteristics as determined by disposal site selection and characterization activities.

The NRC is revising the introductory text of this section to enhance its readability and identify that the specific technical information supports the safety case. The NRC is also revising § 61.12(a) to include geochemistry and geomorphology in the description of the natural and demographic disposal site characteristics. Geochemical and geomorphological characteristics need to be included in the description because they play a role in the transport of long-lived radionuclides in the environment and the long-term erosion of the disposal site, respectively. Paragraphs 61.12(e) and (g) have been revised to enhance the readability of

these sections. Paragraph 61.12(i) requires licensees to provide the criteria for acceptance of LLRW for disposal, and § 61.12(j) requires licensees to describe how the quality assurance program was applied to the technical analyses. Paragraph 61.12(l) has been revised to make the language more consistent with the language in the definition for monitoring. Paragraph 61.12(o) was added to move defense-in-depth requirements from the proposed § 61.13(f) to clarify that identification and description of the defense-in-depth protections is required but a new analysis is not required.

Section 61.13 Technical analyses.

Section 61.13 lists technical information that must be included in an application for a 10 CFR part 61 land disposal facility license to demonstrate that the performance objectives of subpart C of 10 CFR part 61 will be met.

The introductory text of § 61.13 was revised to specify the requirements for technical analyses as one element of the safety case and to clarify that licensees must conduct the analyses set forth in § 61.13 to demonstrate that the performance objectives of subpart C will be met. Licensees with operational land disposal facilities on the effective date of this rule must submit the analyses at the next license renewal or within 5 years of the effective date of publication of this rule, whichever comes first.

Paragraph 61.13(a) was revised to require a licensee to prepare a performance assessment to demonstrate compliance with the dose limit in § 61.41(a) during the compliance period. The licensee is required to consider FEPs that can influence the ability of the land disposal facility to meet the performance objectives, evaluate environmental pathways, account for uncertainty, provide model support, and identify and differentiate the roles performed by site characteristics and design features of the land disposal facility. If the performance assessment uses a 1,000 year compliance period, the licensee must also include technical rationale as to

why the longer timeframes (i.e., a 10,000 compliance period and the performance period) do not need to be considered.

Paragraph 61.13(b) has been revised to require a site-specific inadvertent intruder assessment to demonstrate the protection of inadvertent intruders. The licensee is required to assume an inadvertent intruder occupies the disposal site and engages in normal activities that are consistent with activities in and around the disposal site at the time when the inadvertent intruder assessment is developed, identify adequate intruder barriers and provide a basis for the time period that they are effective, and account for uncertainty and variability. The term "analyses of the protection of individuals from inadvertent intrusion" has also been revised to 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 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.

Section 61.25 Changes.

Section 61.25 provides restrictions on the licensee to make changes in the land disposal facility procedures described in the license application.

The NRC is revising § 61.25(a) to correct a misspelling, and § 61.25(b) to include a provision restricting changes to the WAC without prior approval by the regulator.

Section 61.28 Contents of application for closure.

Section CFR 61.28 lists items that must be included in an application for site closure. These items include 1) a requirement for a final revision and specific details of the disposal site closure plan, and 2) an environmental (or a supplemental) report.

The revised § 61.28(a) adds a requirement to submit a final revision to the safety case, which is required in § 61.10, and requires licensees to provide updated technical analyses and defense-in-depth identifications using the details of the site closure plan and LLRW inventory. Under § 61.28(c), which is not being amended by this rulemaking, the NRC can only authorize closure of the land disposal facility if there is reasonable assurance that the long-term performance objectives of subpart C will be met. As a result of the revisions to § 61.28(a), licensees are required to take additional action prior to site closure to ensure that the LLRW that has already been disposed, including significant quantities of long-lived radionuclides and other

LLRW streams that were not analyzed in the original 10 CFR part 61 regulatory basis, will meet the long-term performance objectives of subpart C.

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

Section 61.41 specifies a dose limit for protection of the general population from the releases of radioactivity and requires licensees to exercise reasonable effort to keep all doses ALARA.

The NRC is revising § 61.41 by adding paragraphs (a) and (b). Paragraph 61.41(a) requires a 0.25 mSv (25 mrem) per year dose limit and the ALARA concept for the compliance period, and specifies the use of a dose methodology that is consistent with the dose methodology used in 10 CFR part 20. Compliance with § 61.41(a) will be demonstrated through analyses that meet the requirements specified in § 61.13(a).

Paragraph 61.41(b) requires that the licensee 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 § 61.41(b) will be demonstrated through analyses that meet the requirements specified in § 61.13(e).

Section 61.42 Protection of inadvertent intruders.

Section 61.42 requires the land disposal facility be designed, operated, and closed to ensure the protection of any inadvertent intruder after the lifting of institutional controls.

The NRC is revising § 61.42 by adding new paragraphs (a) and (b). Paragraph 61.42(a) retains the original regulatory language and has been updated to add an annual dose limit of 5 mSv (500 mrem) per year for the inadvertent intruder assessment during the compliance period. Compliance with § 61.42(a) will be demonstrated through analyses that meet the requirements specified in § 61.13(b).

Paragraph 61.42(b) requires that the licensee minimize exposures to any inadvertent intruder to the extent reasonably achievable at any time during the performance period. Compliance with § 61.42(b) will be demonstrated through analyses that meet the requirements specified in § 61.13(e).

Section 61.43 Protection of individuals during operations.

Section 61.43 sets out the requirements for protection of individuals during operations. This NRC is revising § 61.43 because the reference to § 61.41 is no longer applicable. Instead, § 61.43 directly incorporates the dose limit.

Section 61.44 Stability of the disposal site after closure.

Section 61.44 requires the land disposal facility to be sited, designed, used, operated, and closed to achieve long-term stability of the disposal site 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.

The NRC is revising § 61.44 to specify that stability of the disposal site must be demonstrated for the compliance period.

Section 61.50 Disposal site suitability requirements for land disposal.

Section 61.50 specifies site suitability requirements for the minimum characteristics a disposal site must possess to be acceptable for use as a near-surface disposal facility. Site suitability requirements play an integral role in ensuring that the disposal site is appropriate for the type of LLRW proposed for disposal.

The NRC is revising § 61.50 to clarify the interpretation of disposal site characteristics. The technical content of the site suitability characteristics is not being changed. However, the

site suitability characteristics have been reorganized to distinguish the hydrological site characteristics from other characteristics.

Section 61.51 Disposal site design for land disposal.

Section 61.51 specifies disposal design requirements for a near-surface disposal facility. Site design requirements play an integral role in ensuring that the disposal site is appropriate for the type of LLRW proposed for disposal.

The NRC is revising § 61.51(a)(1) to clarify that site design features must be directed toward providing defense-in-depth protections in addition to long-term isolation and avoidance of the need to continue active maintenance after site closure.

Section 61.52 Land disposal facility operation and disposal site closure.

Section 61.52 imposes requirements to ensure the integrity of the LLRW, the proper marking of the disposal unit boundary, and the proper maintenance of the buffer zone.

The NRC is revising §§ 61.52(a)(3) and (a)(8) to enhance their readability and to conform to the new requirements in §§ 61.52(a)(12) and (a)(13).

The NRC is adding new paragraphs (a)(12) and (a)(13). Paragraph 61.52(a)(12) only allows the disposal of LLRW meeting the land disposal facility's WAC, and § 61.52(a)(13) requires licensees to prepare updated site-specific analyses using the details of the site closure plan and LLRW inventory.

Section 61.55 Waste classification.

The NRC is revising § 61.55(a)(6) to enhance its readability. The change does not alter the meaning or intent of this regulation.

Section 61.56 Waste characteristics.

Section 61.56(a) lists minimum requirements for all classes of LLRW, intended to facilitate handling at the land disposal facility and provide protection of health and safety of personnel at the land disposal facility.

The NRC is revising § 61.56(a) to replace the phrase “all classes of wastes” with the phrase “all waste” which includes all classes of LLRW and WAC. Waste may be determined to be suitable for disposal using § 61.58 (i.e., site-specific WAC or Table 1 and 2 in § 61.55).

Section 61.57 Labeling.

The NRC is revising § 61.57 to include any information required by the land disposal facility’s criteria for LLRW acceptance developed in accordance with § 61.58.

Section 61.58 Waste acceptance.

The NRC is retitling and revising § 61.58 to specify the minimum content of the WAC, to ensure that LLRW is adequately characterized, and that methods are developed to certify that such LLRW meets the acceptance criteria for demonstration of compliance with the site-specific WAC. Section 61.58 also requires licensees to annually review their WAC, characterization methods, and certification program and to comply with § 61.20 when modifying their approved WAC. Additionally, the new regulatory language identifies that the NRC will incorporate, where consistent with State and Federal law, the WAC into existing licenses.

Section 61.80 Maintenance of records, reports, and transfers.

Section 61.80 requires the licensee to keep records on the LLRW received for disposal, to provide annual reports of land disposal facility and financial activities, and to comply with

specified provisions of 10 CFR parts 30, 40, and 70 for any transfer by the licensee of byproduct, source, or special nuclear material.

The NRC is restructuring § 61.80(i)(2) to meet codification requirements of the Office of the Federal Register. In § 61.80(i)(1), the erroneous reference to § 60.4 is corrected to reference § 61.4.

The NRC is also adding a new paragraph (m) to § 61.80. This addition requires licensees to maintain their provisions for LLRW acceptance and audits and other reviews of program content and implementation.

VI. Regulatory Flexibility Certification

Under the Regulatory Flexibility Act (5 U.S.C. 605(b)), the NRC certifies that this rule does not have a significant economic impact on a substantial number of small entities. The LLRW licensees impacted by this rule do not fall within the scope of the definition of "small entities" set forth in the Regulatory Flexibility Act or the size standards established by the NRC (10 CFR 2.810).

The NRC requested comment on the proposed rule and accompanying regulatory analysis on the impact of the proposed rule on small entities. The NRC received no comment submissions from an identified small entity.

VII. Regulatory Analysis

The NRC has prepared a final regulatory analysis on this regulation. The analysis examines the costs and benefits of the alternatives considered by the NRC. The regulatory analysis is available as indicated in the "Availability of Documents" section of this document. When the draft regulatory analysis for the proposed rule was issued for public comment, the

NRC received feedback from industry and the Agreement State regulators that the estimates in the draft regulatory analysis were off by significant amounts. In preparing this regulatory analysis, the NRC has taken measures to ensure it does not deliberately or systematically underestimate the costs of compliance by regulated entities, and is using the best available cost data, or realistic estimates of costs. After receiving comments on the draft regulatory analysis, the NRC met with industry representatives, Agreement State regulators, and other interested stakeholders in public meetings to understand the cost drivers and to collect actual costs and industry estimates associated with implementing new rule provisions.

VIII. Backfitting and Issue Finality

A backfit analysis is not required for this rule. The NRC's backfit or issue finality provisions appear in the regulations at 10 CFR 50.109, 52.39, 52.63, 52.83, 52.98, 52.145, 52.171, 70.76, 72.62, and 76.76. The requirements in this final rule do not involve any provisions that would impose either backfitting on nuclear power plant licensees as defined in 10 CFR part 50, "Domestic Licensing of Production and Utilization Facilities," or violations of issue finality under 10 CFR part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants;" backfitting on licensees under 10 CFR part 70, "Domestic Licensing of Special Nuclear Material," 10 CFR part 72, "Licensing Requirements for the Independent Storage of Spent Nuclear Fuel and High-Level Radioactive Waste, and Reactor-Related Greater Than Class C Waste;" or backfitting on certificate of compliance holders under 10 CFR part 76, "Certification of Gaseous Diffusion Plants."

IX. Cumulative Effects of Regulation

Cumulative effects of regulation (CER) describes the challenges that licensees,

certificate holders, States, or other entities may encounter while implementing new regulatory requirements (e.g., rules, generic letters, orders, backfits, inspection findings). The CER is an organizational effectiveness challenge that results from a licensee or impacted entity implementing a significant number of new and complex regulatory actions stemming from multiple regulatory actions, within a limited implementation period and with available resources (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

The Plain Writing Act of 2010 (Pub. L. 111-274) requires Federal agencies to write documents in a clear, concise, and well-organized manner. The NRC has written this document to be consistent with the Plain Writing Act as well as the Presidential Memorandum, “Plain Language in Government Writing,” published June 10, 1998 (63 FR 31883).

XI. Environmental Assessment and Final Finding of No Significant Environmental Impact

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission’s regulations in subpart A of 10 CFR Part 51, that this rule, if adopted, would not be a major Federal action significantly affecting the quality of the human environment and, therefore, an environmental impact statement is not required. The basis of this determination reads as follows:

A. The Action and the Need for the Action.

The action is to add new, and amend some of the existing, requirements in 10 CFR part 61. The NRC is amending its regulations that apply to LLRW disposal facilities to require new and revised site-specific technical analyses, to permit the development of criteria for LLRW acceptance based on the results of these analyses, and to require the application for closure to include updates to the safety case and the technical analyses. These amendments would ensure that LLRW streams that are significantly different from those considered in the

regulatory basis for the original regulations can be disposed of safely and meet the performance objectives for land disposal of LLRW. These amendments would also increase the use of site-specific information to ensure public health and safety is protected. These amendments would revise the existing technical analysis for protection of the general population (i.e., performance assessment) to include a 1,000-year or 10,000-year compliance period, dependent upon if a significant quantity of long-lived radionuclides was disposed of or are planned to be disposed of at the disposal site; add a new site-specific technical analysis for the protection of inadvertent intruders (i.e., intruder assessment) that would include a 1,000-year or 10,000-year compliance period and a dose limit; add a new analysis for the disposal of long-lived radionuclides (i.e., performance period analysis) that would include a post-10,000 year performance period; and revise the application for closure to include updates to the safety case and the technical analyses. The NRC would also be adding a new requirement to develop criteria for the acceptance of LLRW for disposal based on the results of these technical analyses, the existing LLRW classification requirements, or a combination of both. Additionally, the amendments would facilitate implementation and better align the requirements with current health and safety standards.

B. Environmental Impact of the Action.

The action is to add new, and amend some of the existing, requirements in 10 CFR part 61. The rulemaking would modify the analyses that licensees need to perform to demonstrate compliance with the subpart C performance objectives and to permit the development of criteria for LLRW acceptance based on the results of these analyses. 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 would result in no significant environmental impacts.

C. Alternatives to the Action.

As an alternative to the action, the NRC staff considered the “no-action” alternative. Under this alternative, the NRC would not modify 10 CFR part 61, no performance period analyses would be required, no period of compliance would be specified, no intruder assessment would be required, and the development of a waste acceptance plan would not be required. However, requiring new and revised site-specific technical analyses to demonstrate compliance with the subpart C performance objectives and development of LLRW site-specific acceptance criteria for LLRW acceptance would ensure the safe disposal of waste streams not previously analyzed in the development of part 61 and would provide assurance that these waste streams comply with the subpart C performance objectives. Further, these analyses would identify any additional measures that would be prudent to implement, and these amendments would improve the efficiency of the regulations by making changes to facilitate implementation and better align the requirements with current health and safety standards. By not implementing the action, there would not be added assurance that disposal of the LLRW streams not considered in the original 10 CFR part 61 regulatory basis comply with the subpart C performance objectives. Therefore, the NRC has decided to reject the no-action alternative and finalize the rule.

D. Alternative Use of Resources.

This action would not result in any irreversible commitments of resources.

E. Agencies and Persons Contacted and Resources Used.

The NRC sent a copy of the proposed rule, which contained the draft environmental assessment, to all State Liaison Officers and requested their comments on the assessment. No comments were received from the States regarding the draft environmental assessment. Aside from those sources referenced in this notice, the NRC staff did not use any additional sources 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. 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.

XII. Paperwork Reduction Act

This final rule contains new or amended collections of information subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). The collections of information were approved by OMB approval number 3150-0135 and 3150-0164.

New applicants and current land disposal facility licensees will incur a reporting burden to update technical analyses to conform to the new requirements of this final rule beginning as early as 4 years from publication of the final rule. The estimated one-time reporting burden per licensee to perform these analyses is 7,400 hours, annualized (2,467 hours per response). An additional 80 hours of annual recordkeeping per licensee would be required once its LLRW acceptance plan has been submitted. However, the NRC does not expect to receive any license applications or license closure applications within the 3-year clearance period, and no current licensees are anticipated to amend their licenses within the clearance period; therefore, there is no estimated annual burden (0 hours) for the next 3 years. Burden estimates include the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection.

The information collection is being conducted 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 will ensure the safe disposal of LLRW. Information will be used by the NRC to ensure compliance with the performance objectives in Subpart C of 10 CFR part 61, which will ensure that LLRW streams that are significantly different from those considered during the development of the original regulations can be disposed of safely and meet the performance objectives for land disposal of LLRW. These amendments will also increase the use of site-specific information to ensure public health and safety continues to be protected. Responses to this collection of information are mandatory under 10 CFR 61.12(o),

61.13(e), 61.28, 61.41, 61.42, 61.58, and 61.80(m). Confidential and proprietary information is protected in accordance with NRC regulations at 10 CFR 9.17(a) and 10 CFR 2.390(b). However, no confidential or proprietary information will be requested.

You may submit comments on any aspect of the information collection(s), including suggestions for reducing the burden, by the following methods:

- **Federal rulemaking Web Site:** Go to http://www.regulations.gov and search for Docket ID NRC-2011-0012.
- **Mail comments to:** FOIA, Privacy, and Information Collections Branch, Office of the Chief Information Officer, Mail Stop: T-5 F53, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001 or to Vlad Dorjets, Desk Officer, Office of Information and Regulatory Affairs (3150-0135 and 3150-0164), NEOB-10202, Office of Management and Budget, Washington, DC 20503; telephone: 202-395-1741, e-mail: oira_submission@omb.eop.gov.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the document requesting or requiring the collection displays a currently valid OMB control number.

XIII. Congressional Review Act

This final rule is a rule as defined in the Congressional Review Act (5 U.S.C. §§ 801-808). However, the OMB has not found it to be a major rule as defined in the Congressional Review Act.

XIV. Criminal Penalties

For the purposes of Section 223 of the Atomic Energy Act of 1954, as amended (AEA), the NRC is issuing this rule that amends 10 CFR part 61 under one or more of Sections 161b, 161i, or 161o of the AEA. Willful violations of the rule would be subject to criminal enforcement. Criminal penalties as they apply to regulations in 10 CFR part 61 are discussed in § 61.84, "Criminal penalties."

XV. Coordination with Agreement States

The NRC has coordinated with the Agreement States throughout the development of this final rule. Agreement State representatives have served on the rulemaking working group that developed the proposed and final amendments to 10 CFR part 61. Agreement State representatives have also participated on the steering committee for the proposed rule.

Through All Agreement State Letters, the Agreement States were notified of the availability of the regulatory basis, early preliminary rule text, and the proposed rule for review and comment. In addition, on September 28, 2011, the NRC provided a pre-decisional copy of the draft proposed rule and draft implementation guidance document to the Agreement States for review and comment. Subsequently, on March 13, 2013, after receiving additional Commission direction in the January 2012 SRM-COMWDM-11-0002/COMGEA-11-0002, the NRC provided a revised pre-decisional copy of the draft proposed rule and draft implementation guidance document to the Agreement States for review and comment. The Agreement State comments are summarized in SECY-13-0075, enclosure 3, "Summary of Public and Advisory Committee on Reactor Safeguards (ACRS) Interactions and Comments Received in Response to Preliminary Documents for Low-Level Radioactive Waste Disposal (10 CFR Part 61) Rulemaking."

The Agreement States also had an opportunity to comment on the draft final rule. In preparing both the proposed rule and the final rule, the rulemaking working group considered the comments provided by the Agreement States.

XVI. Compatibility of Agreement State Regulations

Under the "Policy Statement on Adequacy and Compatibility of Agreement State Programs" approved by the Commission on June 30, 1997, and published in the Federal Register on September 3, 1997 (62 FR 46517), NRC program elements (including regulations) are placed into compatibility categories A, B, C, D, NRC or adequacy category Health and Safety (H&S). Compatibility Category A are those program elements that are basic radiation protection standards and scientific terms and definitions that are necessary to understand radiation protection concepts. An Agreement State must adopt Category A program elements in an essentially identical manner in order to provide uniformity in the regulation of agreement material on a nationwide basis. Compatibility Category B are those program elements that apply to activities that have direct and significant effects in multiple jurisdictions. An Agreement State must adopt Category B program elements in an essentially identical manner. Compatibility Category C are those program elements that do not meet the criteria of Category A or B, but the essential objectives of which an Agreement State should adopt to avoid conflict, duplication, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a national basis. An Agreement State must adopt the essential objectives of the Category C program elements. Compatibility Category D are those program elements that do not meet any of the criteria of Compatibility Categories A, B, or C, and, thus, do not need to be adopted by Agreement States for purposes of compatibility. Compatibility Category NRC are those program elements that address areas of regulation that cannot be relinquished to the Agreement States under the Atomic Energy Act of 1954, as amended, or

provisions of title 10 of the Code of Federal Regulations. These program elements should not be adopted by the Agreement States. H&S are program elements that are required because of a particular health and safety role in the regulation of agreement material within the State and should be adopted in a manner that embodies the essential objectives of the NRC program.

The final rule is a matter of compatibility between the NRC and the Agreement States, thereby providing consistency among Agreement State and NRC requirements. The compatibility categories are designated in the following table:

Compatibility Table for 10 CFR Part 20, Appendix G

10 CFR Part 20, Appendix G Final Rule Section	Change	Subject	Compatibility	
			Existing	New
20.1003	Amend	Definition Waste.	B	B
II	Amend	Certification.	D	D
III.A	Amend	Control and Tracking.	D	D
III.C	Amend	Control and Tracking.	D	D

Compatibility Table for 10 CFR Part 61

10 CFR Part 61 Final Rule Section	Change	Subject	Compatibility	
			Existing	New
61.1	Amend	Purpose and scope.	D	D
61.2	New	Definition-Compliance period.	-	C
61.2	New	Definition-Defense-in-depth.	-	H&S
61.2	Amend	Definition-Disposal unit.	D	D
61.2	New	Definition-General environment.	-	D
61.2	Amend	Definition-Inadvertent intruder.	C	C
61.2	New	Definition-Inadvertent intruder assessment.	-	H&S
61.2	New	Definition-Long-lived radionuclide.	-	B
61.2	New	Definition-Performance assessment.	-	H&S
61.2	New	Definition-Performance period.	-	C
61.2	New	Definition-Safety case.	-	H&S
61.2	Amend	Definition-Site closure and stabilization.	D	D
61.2	Amend	Definition-Stability.	D	D
61.2	Amend	Definition-Waste.	B	B
61.7(a)(1)	Amend	Concepts.	H&S	H&S
61.7(a)(2)	Amend	Concepts.	H&S	H&S
61.7(b)	Amend	Concepts. (Previously 61.7(b)(1))	H&S	H&S
61.7(c)(1)	New	Concepts.	-	H&S
61.7(c)(2)	New	Concepts.	-	H&S
61.7(c)(3)	Amend	Concepts. (Previously 61.7(b)(3))	H&S	H&S
61.7(c)(4)	New	Concepts.	-	H&S
61.7(c)(5)	New	Concepts.	-	H&S
61.7(c)(6)	New	Concepts.	-	H&S

61.7(d)(1)	New	Concepts.	-	H&S
61.7(d)(2)	New	Concepts.	-	H&S
61.7(e)	New	Concepts.	-	H&S
61.7(f)(1)	Amend	Concepts. (Previously 61.7(b)(2))	H&S	H&S
61.7(f)(2)	Amend	Concepts. (Previously 61.7(b)(4))	H&S	H&S
61.7(f)(3)	Amend	Concepts. (Previously 61.7(b)(5))	H&S	H&S
61.7(f)(4)	New	Concepts.	-	H&S
61.7(g)(1)	Amend	Concepts. (Previously 61.7(c)(1))	H&S	H&S
61.7(g)(2)	Amend	Concepts. (Previously 61.7(c)(2))	H&S	H&S
61.7(g)(3)	Amend	Concepts. (Previously 61.7(c)(3))	H&S	H&S
61.7(g)(4)	Amend	Concepts. (Previously 61.7(c)(4))	H&S	H&S
61.8	Amend	Information collection requirements: Office of Management and Budget approval.	D	D
61.10(a)(1)	Amend/ Revised Compatibility Category	Content of application.	D	H&S
61.10(a)(2)	Amend	Content of application.	D	D
61.10(b)	New	Content of application.	-	H&S
61.12(a)	Amend/ Revised Compatibility Category	Specific technical information.	D	H&S
61.12(b)	Revised Compatibility Category	Specific technical information.	D	H&S
61.12(c)	Revised Compatibility Category	Specific technical information.	D	H&S
61.12(d)	Revised Compatibility Category	Specific technical information.	D	H&S
61.12(e)	Amend/Revised Compatibility Category	Specific technical information.	D	H&S
61.12(f)	Revised Compatibility Category	Specific technical information.	D	H&S
61.12(g)	Amend/Revised Compatibility Category	Specific technical information.	D	H&S
61.12(h)	Revised Compatibility Category	Specific technical information.	D	H&S
61.12(i)	Amend/Revised Compatibility Category	Specific technical information.	D	H&S
61.12(j)	Amend/Revised Compatibility Category	Specific technical information.	D	H&S
61.12(k)	Revised Compatibility Category	Specific technical information.	D	H&S
61.12(l)	Revised Compatibility Category	Specific technical information.	D	H&S

61.12(m)	Revised Compatibility Category	Specific technical information.	D	H&S
61.12(n)	Revised Compatibility Category	Specific technical information.	D	H&S
61.12(o)	New	Specific technical information.	-	H&S
61.13	Amend/ Revised Compatibility Category	Technical analyses.	H&S	C
61.23(b)	Amend	Standards for issuance of a license.	H&S	H&S
61.23(c)	Amend	Standards for issuance of a license.	H&S	H&S
61.23(d)	Amend	Standards for issuance of a license.	H&S	H&S
61.23(e)	Amend	Standards for issuance of a license.	H&S	H&S
61.23(m)	New	Standards for issuance of a license.	-	H&S
61.25(a)	Amend/ Revised Compatibility Category	Changes.	D	H&S
61.25(b)	Amend/ Revised Compatibility Category	Changes.	D	H&S
61.28(a)	Amend/ Revised Compatibility Category	Contents of application for closure.	D	H&S
61.41(a)	Amend	Protection of the general population from releases of radioactivity.	A	A
61.41(b)	New	Protection of the general population from releases of radioactivity.	-	C
61.42(a)	Amend	Protection of individuals from inadvertent intrusion.	H&S	A
61.42(b)	New	Protection of individuals from inadvertent intrusion.	-	C
61.43	Amend	Protection of individuals during operations.	H&S	H&S
61.44	Amend	Stability of the disposal site after closure.	H&S	H&S
61.50	Amend	Disposal site suitability requirements for land disposal.	H&S	H&S
61.51(a)	Amend	Disposal site design for land disposal.	H&S	H&S
61.52(a)(3)	Amend	Land disposal facility operation and disposal site closure.	H&S	H&S
61.52(a)(8)	Amend	Land disposal facility operation and disposal site closure.	H&S	H&S
61.52(a)(12)	New	Land disposal facility operation and disposal site closure.	-	H&S
61.52(a)(13)	New	Land disposal facility operation and disposal site closure.	-	H&S
61.55(a)(6)	Amend	Waste classification.	B	B
61.56(a)	Amend	Waste characteristics.	H&S	H&S
61.57	Amend	Labeling.	H&S	H&S
61.58	Retitled, revised and Revised	Waste acceptance (Previously titled Alternative requirements for waste classification and characteristics)	D	C

	Compatibility Category			
61.80(i)(1)	Amend	Maintenance of records, reports, and transfers.	C	C
61.80(i)(2)	Amend	Maintenance of records, reports, and transfers.	C	C
61.80(m)	New	Maintenance of records, reports, and transfers.	-	C

XVII. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995, Pub. L. 104-113, requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this final rule, the NRC has revised the regulations that govern LLRW disposal facilities to require new and revised technical analyses and to permit the development of criteria for LLRW acceptance based on the results of these analyses. These amendments ensure that LLRW streams that are significantly different from those considered in the regulatory basis for the original regulations can be disposed of safely and meet the performance objectives for land disposal of LLRW. These amendments also increase the use of site-specific information to ensure public health and safety is protected. Additionally, the amendments will better align the requirements in 10 CFR part 61 with current health and safety standards. This action does not constitute the establishment of a standard that contains generally applicable requirements.

XVIII. Availability of Guidance

The NRC is issuing new guidance, NUREG-2175, “Guidance for Conducting Technical Analyses for 10 CFR Part 61,” for the implementation of the requirements in this rulemaking. The guidance is available in an ADAMS package under Accession No. ML16218A504. You

may access information and comment submissions related to the guidance by searching on http://www.regulations.gov under Docket ID NRC-2015-0003.

In NUREG-2175, the NRC provides guidance on conducting technical analyses (i.e., performance assessment, inadvertent intruder assessment, assessment of the stability of an LLRW disposal site, and performance period analyses) to demonstrate compliance with the performance objectives in 10 CFR part 61. This guidance should facilitate licensees' implementation of the amendments in this final rule as well as assist regulatory authorities in reviewing the technical analyses. This guidance applies to all waste streams disposed of at a 10 CFR part 61 land disposal facility, including large quantities of depleted uranium and blended waste.

In addition, NUREG-2175 provides detailed guidance in new areas, such as the inadvertent intruder analysis, and for analysis timeframe (compliance period and performance period). This guidance discusses the use of a graded level of effort needed to risk-inform the analyses for the compliance period (1,000 years after disposal site closure or 10,000 years after disposal site closure if significant quantities of long-lived waste are present), and also covers the performance period analyses that should be performed for analysis of long-lived waste beyond 10,000 years. Additional topics covered in this document include: 1) demonstration that radiation doses are minimized to the extent reasonably achievable; 2) identification and screening of the FEPs to develop scenarios for technical analyses; 3) use of the waste classification tables or the results of the technical analyses to develop site-specific WAC; and 4) use of performance confirmation to evaluate and verify the accuracy of information used to demonstrate compliance prior to site closure.

XIX. Availability of Documents

The documents identified in the following table are available to interested persons

through one or more of the following methods, as indicated.

DOCUMENT	ADAMS ACCESSION NO. / WEB LINK / FEDERAL REGISTER CITATION
SECY	
SECY-08-0147, "Response to Commission Order CLI-05-20 Regarding Depleted Uranium," dated October 7, 2008.	ADAMS Accession No. ML081820762
SECY-10-0043, "Blending of Low-Level Radioactive Waste," dated April 7, 2010.	ADAMS Accession No. ML090410246
SECY-13-0075, "Proposed Rule: Low-Level Radioactive Waste Disposal (10 CFR Part 61) (RIN3150-AI92)," dated July 18, 2013.	ADAMS Accession No. ML13129A268
SRM	
SRM-COMWDM-11-0002/COMGEA-11-0002, "Revisions to Part 61," dated January 19, 2012.	ADAMS Accession No. ML120190360
SRM-SECY-13-0075, "Proposed Rule: Low-Level Radioactive Waste Disposal (10 CFR Part 61) (RIN3150-AI92)," dated February 12, 2014.	ADAMS Accession No. ML14043A371
SRM-SECY-08-0147, "Response to Commission Order CLI 05 20 Regarding Depleted Uranium," dated March 18, 2009.	ADAMS Accession No. ML090770988
SRM-SECY-10-0043, "Blending of Low-Level Radioactive Waste," dated October 13, 2010.	ADAMS Accession No. ML102861764
SRM-SECY-15-0094, "Historical and Current Issues Related to Disposal of Greater than Class C Low-Level Radioactive Waste," dated December 22, 2015.	ADAMS Accession No. ML15356A623
NUREG	
NUREG-0782, "Draft Environmental Impact Statement on 10 CFR Part 61, 'Licensing Requirements for Land Disposal of Radioactive Waste,'" Issued in September 1981.	ADAMS Accession Nos. ML060930564, ML060930573, ML060930577, ML060930583
NUREG-0945, "Final Environmental Impact Statement on 10 CFR Part 61, 'Licensing Requirements for Land Disposal of Radioactive Waste,'" issued in November 1982.	ADAMS Accession Nos. ML052590184, ML052920727, and ML052590187
NUREG-1614, Volume 6, "Strategic Plan Fiscal Years 2014-2018," issued in September 2014.	ADAMS Accession No. ML14246A439
NUREG-2150, "A Proposed Risk Management Regulatory Framework," issued in April 2012.	ADAMS Accession No. ML12109A277

Draft NUREG-2175, “Draft Guidance for Conducting Technical Analyses for 10 CFR Part 61,” issued in March 2015.	ADAMS Accession No. ML15056A516
Final NUREG-2175, “Final Guidance for Conducting Technical Analyses for 10 CFR Part 61.”	ADAMS Package Accession No. ML16218A504
NUREG-1636, “Regulatory Perspectives on Model Validation in High-Level Radioactive Waste Management Programs: A Joint NRC/SKI White Paper,” issued in March 1999.	ADAMS Accession No. ML012260054
NUREG-1573, “A Performance Assessment Methodology for Low-Level Radioactive Waste Disposal Facilities: Recommendations of NRC's Performance Assessment Working Group,” issued in October 2000.	ADAMS Accession No. ML003770778
NUREG/BR-0204, “Instructions for Completing NRC's Uniform Low-Level Radioactive Waste Manifest,” Revision 2, Issued in July 1998.	ADAMS Accession No. ML071870172
NUREG-1854, “NRC Staff Guidance for Activities Related to U.S. Department of Energy Waste Determinations—Draft Report for Interim Use,” issued in August 2007.	ADAMS Accession No. ML072360184
NUREG-1623, “Design of Erosion Protection for Long-Term Stabilization—Final Report,” issued in September 2002.	ADAMS Accession No. ML022530043
NUREG/CR-6948, “Integrated Ground-Water Monitoring Strategy for NRC-Licensed Facilities and Sites: Logic, Strategic Approach and Discussion,” issued in November 2007.	ADAMS Accession No. ML073310297
NUREG-1748, “Environmental Review Guidance for Licensing Actions Associated with NMSS Programs,” Final Report, issued in August 2002.	ADAMS Accession No. ML032450279
NUREG/BR-0240, "Reporting Safety Concerns to the NRC," Rev. 6, issued in May 2012.	ADAMS Accession No. ML12146A003
NUREG-1379, “NRC Editorial Style Guide,” Rev. 2, issued in May 2009.	ADAMS Accession No. ML093280744
Regulatory Basis	
Regulatory basis, “Technical Analysis Supporting Definition of Period of Performance for Low-level Waste Disposal,” dated April 28, 2011.	ADAMS Accession No. ML111030586
Regulatory basis, “Regulatory Basis for Proposed Revisions to Low-Level Waste Disposal Requirements (10 CFR part 61),” dated December 19, 2011.	ADAMS Accession No. ML12356A242

Regulatory analysis, “Draft Regulatory Analysis for Proposed Rule: Low-Level Radioactive Waste Disposal (10 CFR Part 61),” dated February 28, 2015.	ADAMS Accession No. ML14289A158
Regulatory analysis, “Final Regulatory Analysis for Proposed Rule: Low-Level Radioactive Waste Disposal (10 CFR Part 61),” dated August 2016.	ADAMS Accession No. ML16189A050
Rule Language	
Preliminary proposed rule language, “Site-Specific Analyses for Demonstrating Compliance With Subpart C Performance Objectives,” dated May 03, 2011.	76 FR 24831
Preliminary proposed rule language, ‘‘November 2012 Preliminary Rule Language for Proposed Revisions to Low-Level Waste Disposal Requirements (10 CFR part 61),’’ dated December 7, 2012.	77 FR 72997
Final rule, U.S. Environmental Protection Agency (EPA), “Public Health and Environmental Radiation Protection Standards for Yucca Mountain, Nevada,” dated October 15, 2008.	73 FR 61256
Final rule, U.S. Environmental Protection Agency (EPA), “Public Health and Environmental Radiation Protection Standards for Yucca Mountain, Nevada,” dated October 15, 2008.	73 FR 61260
Proposed rule, “Low-Level Radioactive Waste Disposal,” dated March 26, 2015.	80 FR 16081
Meeting Transcript	
Transcript of Proceedings: 10 CFR Part 61, Site-Specific Analysis for Demonstrating Compliance with Subpart C Performance Objectives on May 18, 2011 in Rockville, MD. Pages 1-200.	ADAMS Accession No. ML111570329
Acts	
The Low-Level Radioactive Waste Policy Amendments Act of 1985	P.L. 99–240
Energy Policy Act of 2005.	P.L. 109-58
National Defense Authorization Act for Fiscal Year 2013.	H. R. 4310

National Environmental Policy Act of 1969 (as amended)	P.L. 91–190
National Technology Transfer and Advancement Act of 1995.	P.L. 104-113
Atomic Energy Act of 1954.	P.L. 83–703, P.L. 104-134
Superfund or the Comprehensive Environmental Response, Compensation, and Liability Act of 1980.	P.L. 96–510
Resource Conservation and Recovery Act of 1976.	P.L. 94–580
Uranium Mill Tailings Remediation Control Act (UMTRCA) of 1978.	P.L. 95–604
Executive Order on the Protection of Children from Environmental Health Risks and Safety Risks, dated April 21, 1977.	https://ceq.doe.gov/nepa/regs/eos/eo13045.html
Executive Order 12770, dated July 25, 1991.	56 FR 35801
Other Publications	
Sandia National Laboratories report titled, "Performance Assessment of the Proposed Disposal of Depleted Uranium as Class A Low-Level Waste," dated December 16, 1992.	ADAMS Accession No. ML101890179
Risk Management Task Force (RMTF), "Charter for Task Force for Assessment of Options for More Holistic Risk-Informed, Performance-Based Regulatory Approach," dated February 11, 2011.	ADAMS Accession No. ML110680621
NRC, "Adequacy and Compatibility of Agreement States Program," Management Directive 5.9, dated February 1998.	ADAMS Accession No. ML041770094
"Risk Assessment, A Survey of Characteristics, Applications, and Methods Used by Federal Agencies for Engineered Systems," dated November 30, 1992.	ADAMS Accession No. ML040090236
Comment (47) of Lisa Edwards, Senior Program Manager - EPRI, Regarding Low-Level Radioactive Waste Disposal, dated July 22, 2015.	ADAMS Accession No. ML15204A915
10 CFR Part 63 (May 18, 2007) letter from Cyr to Malsch, "Nevada's Request for a Binding Opinion on Reasonable Expectation in 10 CFR Part 63"	ADAMS Accession No. ML071520180
NRC fact sheet addressing biological effects from radiation exposure	http://www.nrc.gov/reading-rm/doc-collections/fact-sheets/bio-effects-radiation.html
NRC, "Technical Assistance to Agreement States," Management Directive 5.7, dated	https://scp.nrc.gov/procedures/md0507

March 28, 2013.	pdf
Concentration Averaging and Encapsulation Branch Technical Position (CA BTP), Revision 1, issued February 2015.	ADAMS Accession No. ML12254B065
Denial of petition for Rulemaking, "New England Coalition on Nuclear Pollution, Inc.," PRM-61-2, dated March 29, 1994.	ADAMS Accession No. ML093490607
NRC reopened the public comment period for the proposed rule and draft guidance	80 FR 51964
The Lancet Oncology, "Risk of death among children of atomic bomb survivors after 62 years of follow up: a cohort study." Volume 16, Issue 13, October 2015, Pages 1316–1323	http://www.thelancet.com/pdfs/journals/lanonc/PIIS1470-2045(15)00209-0.pdf
U.S. Geological Survey (USGS), Office of Groundwater, issued a technical memorandum (2009.03), dated March 2009.	http://water.usgs.gov/admin/memo/GW/gw09.03.html
IAEA Safety Standards, "The Safety Case and Safety Assessment for the Disposal of Radioactive Waste," Specific Safety Guide SSG-23, issued in 2012.	http://www-pub.iaea.org/mtcd/publications/pdf/pub1553_web.pdf
Nuclear Energy Agency, "Considering Timescales in the Post-closure Safety of Geological Disposal of Radioactive Waste," NEA# 6424, ISBN: 978-92-64-06058-6, issued in 1999.	http://www.oecd-nea.org/rwm/pubs/2009/6424-considering-timescales.pdf
USDOE, "Radioactive Waste Management Manual," Manual 435.1-1, issued in July 1999.	http://www.gtcceis.anl.gov/documents/docs/m4351_1c1.pdf
Nuclear Energy Agency, "Regulating the Long-Term Safety of Geological Disposal," NEA# 6182, ISBN: 978-92-64-99031-9, issued in 2007.	http://www.oecd-nea.org/rwm/reports/2007/nea6182-regulating.pdf
ICRP Publications	
ICRP 2	"Permissible Dose for Internal Radiation," ICRP Publication 2, International Commission on Radiation Protection, 1959.
ICRP 26	"Recommendations of the ICRP," ICRP Publication 26, Ann. ICRP 1 (3), 1977.
ICRP 60	"1990 Recommendations of the International Commission on Radiological Protection," ICRP Publication 60, Ann. ICRP 21 (1-3), 1991.
ICRP 81	"Radiation Protection Recommendations as Applied to the Disposal of Long-Lived Solid Waste," ICRP Publication 81, Ann. ICRP 28 (4), 1998.

ICRP 103	"The 2007 Recommendations of the International Commission on Radiological Protection," ICRP Publication 103, Ann. ICRP 37 (2-4), 2007.

List of Subjects

10 CFR Part 20

Byproduct material, Criminal penalties, Hazardous waste, Licensed material, Nuclear energy, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Packaging and containers, Penalties, Radiation protection, Reporting and recordkeeping requirements, Source material, Special nuclear material, Waste treatment and disposal.

10 CFR Part 61

Criminal penalties, Hazardous waste, Indians, Intergovernmental relations, Low-level waste, Nuclear energy, Nuclear materials, Penalties, Reporting and recordkeeping requirements, Waste treatment and disposal, Whistleblowing.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to 10 CFR parts 20 and 61.

PART 20 — STANDARDS FOR PROTECTION AGAINST RADIATION

1. The authority citation for 10 CFR part 20 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 11, 53, 63, 65, 81, 103, 104, 161, 170H, 182, 186, 223, 234, 274, 1701 (42 U.S.C. 2014, 2073, 2093, 2095, 2111, 2133, 2134, 2201,

2210h, 2232, 2236, 2273, 2282, 2021, 2297f); Energy Reorganization Act of 1974, secs. 201, 202 (42 U.S.C. 5841, 5842); Low-Level Radioactive Waste Policy Amendments Act of 1985, sec. 2 (42 U.S.C. 2021b); 44 U.S.C. 3504 note.

2. In § 20.1003, revise the definition of “Waste” to read as follows:

§ 20.1003 Definitions.

* * * * *

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 this section. 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 isotopes that have been permanently removed from a reactor or subcritical assembly, for which there is no further use, and the disposal of which can meet the requirements of this part.

* * * * *

3. In appendix G to part 20:

a. Revise section II; and

b. Revise paragraphs III.A.1, III.A.2, III.A.3, III.C.3, III.C.4, and III.C.5.

The revisions read as follows:

Appendix G to Part 20 — Requirements for Transfers of Low-Level Radioactive Waste Intended for Disposal at Licensed Land Disposal Facilities and Manifests

* * * * *

II. * * *

An authorized representative of the waste generator, processor, or collector shall certify by signing and dating the shipment manifest that the transported materials are properly classified, described, packaged, marked, and labeled; and are in proper condition for transportation according to the applicable regulations of the U.S. Department of Transportation and the Commission. When transporting material to a licensed land disposal facility for disposal, the authorized representative shall also certify by signing that the transported material and packaging meets the waste acceptance criteria, as applicable, for the land disposal facility. A collector who signs the certification is certifying that nothing has been done to the collected waste that would invalidate the waste generator's certification.

III. * * *

A. * * *

1. Prepare all wastes according to the land disposal facility’s criteria for waste acceptance developed in accordance with § 61.58 of this chapter;

2. Label each disposal container (or transport package if potential radiation hazards preclude labeling of the individual disposal container) of waste in accordance with § 61.57 of this chapter;

3. Conduct a quality assurance program to ensure compliance with the land disposal facility’s criteria for waste acceptance that has been developed in accordance with § 61.58 of this chapter (the program must include management evaluation of audits);

* * * * *

C. * * *

3. Prepare all wastes according to the land disposal facility's criteria for waste acceptance developed in accordance with § 61.58 of this chapter;

4. Label each package of waste in accordance with § 61.57 of this chapter;

5. Conduct a quality assurance program to ensure compliance with the land disposal facility's criteria for waste acceptance that has been developed in accordance with § 61.58 of this chapter (the program shall include management evaluation of audits);

* * * * *

PART 61 — LICENSING REQUIREMENTS FOR LAND DISPOSAL RADIOACTIVE WASTE

4. The authority citation for 10 CFR part 61 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 53, 57, 62, 63, 65, 81, 161, 181, 182, 183, 223, 234 (42 U.S.C. 2073, 2077, 2092, 2093, 2095, 2111, 2201, 2231, 2232, 2233, 2273, 2282); Energy Reorganization Act of 1974, secs. 201, 206, 211 (42 U.S.C. 5841, 5846, 5851); Low-Level Radioactive Waste Policy Amendments Act of 1985, sec. 2 (42 U.S.C. 2021b); 44 U.S.C. 3504 note.

5. In § 61.1, revise paragraph (a) as follows:

§ 61.1 Purpose and scope.

(a) The regulations in this part establish, for land disposal of radioactive waste, the procedures, criteria, and terms and conditions upon which the Commission issues licenses for

the disposal of radioactive wastes containing byproduct, source and special nuclear material received from other persons. Disposal of waste by an individual licensee is set forth in part 20 of this chapter.

* * * * *

6. In § 61.2:

a. Add the definitions of “Compliance period” and “Defense-in-depth,”

b. Revise the definition of “Disposal unit,”

c. Add the definition of “General environment,”

d. Revise the definition of “Inadvertent intruder,”

e. Add the definitions of “Inadvertent intruder assessment,” “Long-lived radionuclide,” “Performance assessment,” “Performance period,” and “Safety case,” and

f. Revise the definitions of “Site closure and stabilization,” “Stability,” and “Waste.”

The revisions and additions read as follows:

§ 61.2 Definitions.

* * * * *

Compliance period means the time from the completion of site closure to 1,000 years after site closure for disposal sites that do not contain significant quantities of long-lived radionuclides. For disposal sites that contain or plan to accept significant quantities of long-lived radionuclides, the compliance period ends at 10,000 years after closure of the disposal site.

* * * * *

Defense-in-depth means the use of multiple independent and, where possible, redundant layers of defense such that no single layer, no matter how robust, is exclusively relied

upon. Defense-in-depth for a land disposal facility includes, but is not limited to, the use of siting, waste forms and radionuclide content, engineered features, and natural geologic features of the disposal site to enhance the resiliency of the land disposal facility.

* * * * *

Disposal unit means a discrete portion of the disposal site into which waste is placed for disposal.

* * * * *

General environment means that area outside the boundaries of the disposal site.

* * * * *

Inadvertent intruder means 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.

* * * * *

Inadvertent intruder assessment is an analysis that:

(1) Assumes an inadvertent intruder occupies the disposal site and engages in normal activities and other reasonably foreseeable pursuits that are realistic and consistent with expected activities in and around the disposal site at the time of the assessment and that might unknowingly expose the person to radiation from the waste in the disposal units;

(2) Examines the capabilities of intruder barriers to inhibit an inadvertent intruder’s contact with the waste in the disposal unit or to limit the inadvertent intruder’s exposure to radiation from the disposal unit; and

(3) Estimates an inadvertent intruder's potential annual dose resulting from radiation in the disposal unit, considering uncertainties.

* * * * *

Long-lived radionuclide means radionuclides:

(1) Where more than 10 percent of the initial activity of the radionuclide remains after 1,000 years:

(2) Where the peak activity from progeny occurs after 1,000 years; or

(3) Where more than 10 percent of the peak activity of the radionuclide (including progeny) within 1,000 years remains after 1,000 years.

* * * * *

Performance assessment is an analysis used to demonstrate compliance with 10 CFR 61.41(a) and (b) that identifies the features, events, and processes that could affect the disposal site performance; and estimates the potential dose as a result of releases caused by all significant features, events, and processes including the uncertainties.

* * * * *

Performance period is the timeframe established for considering waste and disposal site characteristics to evaluate the performance of the disposal site after the compliance period.

* * * * *

Safety case is a collection of information that demonstrates the assessment of the safety of a land disposal facility. This includes technical analyses, such as the performance assessment and inadvertent intruder assessment, but also includes information on defense-in-depth and supporting evidence and reasoning on the strength and reliability of the

technical analyses and the assumptions made therein. The safety case also includes 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

isotopes that have been permanently removed from a reactor or subcritical assembly, for which there is no further use, and the disposal of which can meet the requirements of this part.

* * * * *

7. Revise § 61.7 to read as follows:

§ 61.7 Concepts.

(a) The land disposal facility. (1) Part 61 is intended to apply to land disposal of radioactive waste and not to other methods such as sea or extraterrestrial disposal. Part 61 contains procedural requirements and performance objectives applicable to any method of land disposal. It contains specific technical requirements for near-surface disposal of radioactive waste, a subset of land disposal, which involves disposal in the uppermost portion of the earth, approximately 30 meters. Near-surface disposal includes disposal in engineered facilities that may be built totally or partially above-grade provided that such facilities have protective covers. Near-surface disposal does not include disposal facilities that are partially or fully above-grade with no protective cover, which are referred to as “above-ground disposal.” Burial deeper than 30 meters may also be satisfactory. Technical requirements for alternative methods may be added in the future. Alternative methods of disposal may be approved on a case-by-case basis as needed under § 61.6.

(2) Near-surface disposal of radioactive waste takes place at a near-surface disposal facility, which includes all of the land and buildings necessary to carry out the disposal. The disposal site is that portion of the facility used for disposal of waste and consists of disposal units and a buffer zone. A disposal unit is a discrete portion of the disposal site into which waste is placed for disposal. A buffer zone is a portion of the disposal site that is controlled by the licensee and that lies under the site and between the boundary of the disposal site and any disposal unit. It provides controlled space to establish monitoring locations that are intended to

provide an early warning of radionuclide movement. An early warning allows a licensee to perform any mitigation that might be necessary. In choosing a disposal site, site characteristics should be considered in terms of the indefinite future, take into account the radiological characteristics of the waste, and be evaluated for at least a 500-year timeframe to provide assurance that the performance objectives can be met.

(b) Performance objectives. Disposal of radioactive waste in land disposal facilities has the following safety objectives: protection of the general population from releases of radioactivity, protection of inadvertent intruders, protection of individuals during operations, and ensuring stability of the site after closure. Achieving these objectives depends upon many factors including the design of the land disposal facility, operational procedures, characteristics of the general environment, and the radioactive waste acceptable for disposal.

(c) Technical analyses. (1) Demonstrating compliance with the performance objectives requires assessments of the site-specific factors including engineering design, operational practices, site characteristics, and radioactive waste acceptable for disposal. Technical analyses assess the impact of site-specific factors on the performance of the land disposal facility and the site environment both during the operational period, as in the analysis for protection of individuals during operations and, importantly for disposal of radioactive waste, over the longer term, as in the analyses for protection of the general population from releases of radioactivity, protection of inadvertent intruders, and stability of the disposal site after site closure.

(2) A performance assessment is an analysis that is required to demonstrate protection of the general population from releases of radioactivity. A performance assessment identifies the specific characteristics of the disposal site (e.g., hydrology, meteorology, geochemistry, biology, and geomorphology); degradation, deterioration, or alteration processes of the engineered barriers (including the waste form and container); and interactions between the site characteristics and engineered barriers that might affect performance of the disposal site. A

performance assessment examines the effects of these processes and interaction on the ability of the disposal site to limit waste releases and estimates the annual dose to a member of the public for comparison with the appropriate performance objective of subpart C of this part.

(3) Inadvertent intruders might occupy the disposal site in the future and engage in normal pursuits without knowing that they were receiving radiation exposure. Protection of inadvertent intruders can involve two principal controls: institutional control to ensure that no such occupation or improper use of the site occurs; or, designating which waste could present an unacceptable dose to an inadvertent intruder, and disposing of this waste in a manner that provides some form of intruder barrier that is intended to prevent contact with the waste and limit exposure to radiation from the waste. These regulations incorporate both types of protective controls.

(4) The inadvertent intruder assessment must demonstrate protection of inadvertent intruders through the assessment of potential radiological exposures should an inadvertent intruder occupy the disposal site following a loss of institutional controls. The inadvertent intruder can be exposed to radioactivity that has been released into the environment as a result of disturbance of the waste or from radiation emitted from waste that is still contained in the disposal site. The results of the inadvertent intruder assessment are compared with the appropriate performance objective of subpart C of this part. An inadvertent intruder assessment can employ a similar methodology to that used for a performance assessment, but the inadvertent intruder assessment must assume that an inadvertent intruder occupies the disposal site following a loss of institutional controls after closure, and engages in activities that unknowingly expose the inadvertent intruder to radiation from the waste.

(5) Implementation of dose methodology. The dose methodology used to demonstrate compliance with the performance objectives of this part shall be consistent with the dose methodology specified in the standards for radiation protection set forth in part 20 of this chapter. After the effective date of these regulations, applicants and licensees may use

updated factors incorporated by the U.S. Environmental Protection Agency into Federal radiation protection guidance or may use the most current scientific models and methodologies (e.g., those accepted by the International Commission on Radiological Protection) appropriate for site-specific circumstances to calculate the dose. The weighting factors used in the calculation of the dose must be consistent with the methodology used to perform the calculation.

(6) Waste with significant concentrations and quantities of long-lived radionuclides may require special processing, design, or site conditions for disposal. Demonstrating protection of the general population from releases of radioactivity and inadvertent intruders from the disposal of this waste requires an assessment of long-term impacts. Longer compliance period and performance period analyses are used to evaluate the suitability of this waste for disposal on a case-by-case basis. In general, for disposal sites with limited quantities of long-lived radionuclides, a shorter compliance period is sufficient and performance period analyses are not necessary to demonstrate protection of the general population from releases of radioactivity and protection of inadvertent intruders.

(d) Defense-in-depth.

(1) Defense-in-depth protections are important, together with the technical analyses, for ensuring safety, with regard to complex facilities, in the face of significant uncertainties. Defense-in-depth protections combined with technical analyses and scientific judgment form a fundamental part of the safety case for licensing a land disposal facility. Understanding the capabilities of the defense-in-depth protections and the basis for those capabilities ensures that no single layer is exclusively relied upon for safety, ensures that the protections are commensurate with the risks associated with the land disposal facility, and increases confidence that the performance objectives are met.

(2) Defense-in-depth protections for a land disposal facility may be different during the operational phase while the licensee is disposing of waste than after closure of the land disposal facility. While waste is being disposed, and before a land disposal facility is closed,

defense-in-depth protections, with respect to operational activities (e.g., waste handling), consist of both active safety protections (e.g., equipment, procedures, and controls) and passive safety protections (e.g., physical barriers). The active and passive safety protections used for operational activities at a land disposal facility are comparable to defense-in-depth protections at other operating nuclear facilities licensed by the NRC and are commensurate with the risk and complexity of the operational activity. Following closure of the land disposal facility, defense-in-depth protections are provided through essentially passive safety protections due to the long time periods associated with disposal of waste. Diversity in the capabilities of the passive safety protections provided by the disposal site (e.g., waste form, container, engineered features, depth of disposal unit below the land surface, hydrologic and geochemical characteristics of the disposal site) 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.

(e) Waste acceptance. Demonstrating compliance with the performance objectives also requires a determination of criteria for the acceptance of waste. The criteria can be determined from the results of the technical analyses that demonstrate compliance with the performance objectives for any land disposal facility or, for a near-surface disposal facility, the waste classification requirements of subpart D of this part.

(f) Waste classification and near-surface disposal. (1) A cornerstone of the waste classification system is stability of the disposal site. Stability helps ensure that releases of radioactivity, such as via infiltrating water, are minimized, thus avoiding the need for, to the extent practical, active maintenance. Stability is desirable from an operational and management standpoint for all wastes. However, it may not be necessary from a health and safety standpoint for some waste depending on the radiological composition. If unstable waste is disposed with waste that does require stability, the deterioration of unstable waste could lead to poor performance of the disposal site. Therefore, in order to avoid placing requirements for a stable

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 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.

(3) Waste that will not decay to levels that present an acceptable hazard to an inadvertent intruder within 100 years is typically designated as Class C waste. Class C waste must be stable and be disposed of at a greater depth than the other classes of waste so that subsequent surface activities by an inadvertent intruder will not disturb the waste. Where site conditions prevent deeper disposal, intruder barriers such as concrete covers may be used. The effective life of these intruder barriers should be at least 500 years. A maximum concentration of radionuclides is specified in tables 1 and 2 of § 61.55 so that at the end of the 500-year period, the remaining radioactivity will be at a level that does not pose an unacceptable hazard to an inadvertent intruder or to public health and safety. Waste with concentrations above these limits is generally unacceptable for near-surface disposal. There may be some instances where waste with concentrations greater than permitted for Class C would be acceptable for near-surface disposal with special processing or design. Disposal of this waste will be evaluated on a case-by-case basis with the technical analyses required in § 61.13.

(4) Regardless of the classification, some waste may require enhanced controls or limitations at a particular land disposal facility. A performance assessment and an inadvertent intruder assessment are used to identify these enhanced controls and limitations, which are site- and waste-specific. Enhanced controls or limitations could include additional limits on waste concentration or total activity, more robust intruder barriers, deeper burial depth, and waste-specific stability requirements. These enhanced controls or limitations could mitigate the uncertainty associated with the evolutionary effects of the natural environment and the land disposal facility performance over the compliance period.

(g) The licensing process. (1) During the preoperational phase, the potential applicant goes through a process of disposal site selection by selecting a region of interest, examining a number of possible disposal sites within the area of interest, and narrowing the choice to the proposed site. Through a detailed investigation of the disposal site characteristics the potential

applicant obtains data on which to base an analysis of the disposal site's suitability. The potential applicant uses these data and analyses to develop a safety case that describes the safety relevant aspects of the site, the design of the facility, and the managerial control measures and regulatory controls. The safety case demonstrates the level of protection of people and the environment and provides reasonable assurance that the performance objectives will be met. Along with these data and analyses, the applicant submits other more general information to the Commission in the form of an application for a license for land disposal. The Commission's review of the application is in accordance with administrative procedures established by rule and may involve participation by affected State governments or Indian tribes. While the proposed disposal site must be owned by a State or the Federal Government before the Commission will issue a license, it may be privately owned during the preoperational phase if suitable arrangements have been made with a State or the Federal Government to take ownership in fee of the land before the license is issued.

(2) During the operational phase, the licensee carries out disposal activities in accordance with the requirements of these regulations and any conditions on the license. Periodically, the authority to conduct the above ground operations and dispose of waste will be subject to a license renewal, at which time the operating history will be reviewed and a decision made to permit or deny continued operation. When disposal operations are to cease, the licensee applies for an amendment to the site license to permit site closure. After final review of the licensee's site closure and stabilization plan, the Commission may approve the final activities necessary to prepare the disposal site so that ongoing active maintenance of the site is not required during the period of institutional control.

(3) During the period when the disposal site closure and stabilization activities are being carried out, the licensee is in a disposal site closure phase. Following that, for a period of 5 years, the licensee must remain at the disposal site for a period of postclosure observation and maintenance to ensure that the disposal site is stable and ready for institutional control.

The period of postclosure observation and maintenance is used to ensure that the disposal site closure and stabilization activities have not resulted in unintended instability at the disposal site. The Commission may approve shorter or require longer periods if conditions warrant. At the end of this period, the licensee applies for a license transfer to the disposal site owner.

(4) After a finding of satisfactory disposal site closure, the Commission will transfer the license to the State or Federal Government that owns the disposal site. If the U.S. Department of Energy is the Federal agency administering the land on behalf of the Federal Government the license will be terminated because the Commission lacks regulatory authority over the Department for this activity. Under the conditions of the transferred license, the owner will carry out a program of monitoring to ensure continued satisfactory disposal site performance, perform physical surveillance to restrict access to the site, and carry out minor custodial activities. During this period, productive uses of the land might be permitted if those uses do not affect the stability of the site and its ability to meet the performance objectives. At the end of the prescribed period of institutional control, the license will be terminated by the Commission.

8. In § 61.8, revise paragraph (b) to read as follows:

§ 61.8 Information collection requirements: OMB approval.

* * * * *

(b) The approved information collection requirements contained in this part appear in §§ 61.3, 61.6, 61.9, 61.10, 61.11, 61.12, 61.13, 61.14, 61.15, 61.16, 61.20, 61.22, 61.24, 61.26, 61.27, 61.28, 61.30, 61.31, 61.32, 61.41, 61.42, 61.53, 61.55, 61.57, 61.58, 61.61, 61.62, 61.63, 61.72, and 61.80.

* * * * *

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 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, 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

include geologic, geotechnical, geochemical, geomorphological, hydrologic, meteorologic, climatologic, and biotic features of the disposal site and vicinity.

* * * * *

(e) A description of codes and standards that the applicant has applied to the design and that will apply to construction of the land disposal facilities.

* * * * *

(g) A description of the disposal site closure plan, including those design features that are intended to facilitate disposal site closure and eliminate the need for ongoing active maintenance.

* * * * *

(i) A description of the kind, amount, and specifications of the radioactive material proposed to be received, possessed, and disposed of at the land disposal facility, including the criteria for acceptance of waste for disposal.

(j) A description of the quality assurance program, tailored to low-level radioactive waste disposal, developed and applied by the applicant for:

(1) The determination of natural disposal site characteristics;

(2) The development of technical analyses required in § 61.13; and

(3) Quality assurance during the design, construction, operation, and site closure of the land disposal facility and the receipt, handling, and emplacement of waste.

* * * * *

(l) A description of the environmental monitoring program to provide data to evaluate disposal site performance including potential health and environmental impacts and the plan for taking corrective measures commensurate with any detected radionuclide migration.

* * * * *

(o) Identification of defense-in-depth protections, including a description of the capability of each defense-in-depth protection relied upon to maintain safety and a basis for the capability of each defense-in-depth protection.

* * * * *

11. In § 61.13:

a. Revise the introductory text and paragraphs (a), (b), and (d); and

b. Add paragraph (e).

The revisions and additions read as follows:

§ 61.13 Technical analyses.

The specific technical information must also include the following analyses needed to demonstrate that the performance objectives of subpart C of this part will be met. The technical analyses are one of the elements of the safety case. Licensees with licenses for land disposal facilities in effect on **[INSERT DATE THAT IS 1 YEAR AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER]** must submit these analyses at the next license renewal or by

[INSERT DATE THAT IS 6 YEARS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER], whichever comes first.

(a) A performance assessment that demonstrates that there is reasonable assurance that the exposure to humans from the release of radioactivity will meet the performance objective set forth in § 61.41. The performance assessment shall:

(1) Consider features, events, and processes that might affect demonstrating compliance with § 61.41. The features, events, and processes considered must represent a range of phenomena with both beneficial and adverse effects on performance, and must consider the specific technical information required in § 61.12(a) through (i). A technical basis for either inclusion or exclusion of specific features, events, and processes must be provided.

(2) Consider the likelihood of disruptive or other unlikely features, events, or processes for comparison with the limits set forth in § 61.41.

(3) Provide a technical basis for models used in the performance assessment (e.g., comparisons made with outputs of detailed process-level models or empirical observations such as laboratory testing, field investigations, or natural analogs).

(4) Evaluate contaminant transport pathways and processes in environmental media (e.g., air, soil, groundwater, surface water) including but not limited to advection, diffusion, plant uptake, and exhumation by burrowing animals.

(5) Account for uncertainties and variability in the projected behavior of the disposal site and general environment and in the demographics and behaviors of human receptors.

(6) Identify and differentiate between the roles performed by the natural disposal site characteristics and design features of the land disposal facility in limiting releases of radioactivity to the general population.

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

(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 technical rationale 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

site can be ensured for the compliance period and that there will not be a need for ongoing active maintenance of the disposal site following site closure.

(e) If a 10,000 year compliance period is used for either the performance assessment or inadvertent intruder assessment, the licensee shall assess how the disposal site limits the potential long-term radiological impacts during the performance period, consistent with available data and current scientific understanding. The analyses must identify and describe features of the design and site characteristics relied on to demonstrate compliance with the applicable performance objectives set forth in § 61.41(b) and § 61.42(b).

12. In § 61.23:

a. Revise paragraphs (b), (c), (d), and (e); and

b. Add paragraph (m).

The revisions and additions read as follows:

§ 61.23 Standards for issuance of a license.

* * * * *

(b) The applicant's proposed disposal site, disposal site design, waste acceptance criteria, land disposal facility operations (including equipment, facilities, and procedures), 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 the general population will be protected from releases of radioactivity as specified in the performance objective in § 61.41.

(c) The applicant's proposed disposal site, disposal site design, waste acceptance criteria, land disposal facility operations (including equipment, facilities, and procedures), 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 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 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. 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 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 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 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.

19. Revise § 61.50 to read as follows:

§ 61.50 Disposal site suitability requirements for land disposal.

(a) Disposal site suitability for near-surface disposal. The purpose of this section is to specify the minimum characteristics a disposal site must possess to be acceptable for the disposal of radioactive waste in the near surface. The primary emphasis of disposal site suitability requirements is to provide for favorable conditions and minimize unfavorable conditions with respect to long-term isolation of waste from the environment, rather than short-term benefits to site operation. Site suitability requirements help to ensure that the performance objectives of subpart C of this part are met.

(1) The disposal site shall be capable of being characterized, modeled, analyzed, and monitored.

(2) The hydrologic characteristics that a disposal site must have for 500 years following closure of the land disposal facility to be acceptable for the disposal of radioactive waste in the near surface include:

(i) Waste disposal shall not take place in a poorly drained site or a site subject to flooding or frequent ponding, or in a 100-year flood plain, coastal high-hazard area or wetland, as defined in Executive Order 11988, “Floodplain Management Guidelines.”

(ii) Upstream drainage areas must be minimized to decrease the amount of runoff that could erode or inundate waste disposal units.

(iii) The disposal site must provide sufficient depth to the water table that groundwater intrusion, perennial or otherwise, into the waste will not occur. The Commission will consider an exception to this requirement to allow disposal below the water table if it can be conclusively shown that disposal site characteristics will result in molecular diffusion being the predominant means of radionuclide movement and the rate of movement will result in the performance

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) Areas 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) Areas 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) Areas 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.

(v) The disposal site must not be located where nearby facilities or activities could adversely impact the ability of the site to meet the performance objectives of subpart C of this part or significantly mask the environmental monitoring program.

(b) [Reserved]

20. In § 61.51, revise paragraph (a)(1) to read as follows:

§ 61.51 Disposal site design for land disposal.

(a) * * *

(1) Site design features must be directed toward defense-in-depth, long-term isolation and avoidance of the need to continue active maintenance after site closure.

* * * * *

21. In § 61.52, revise paragraphs (a)(3) and (a)(8) and add paragraphs (a)(12) and (13) to read as follows:

§ 61.52 Land disposal facility operation and disposal site closure.

(a) * * *

(3) All wastes shall be disposed of in accordance with the requirements of paragraphs (a)(4) through (13) of this section.

* * * * *

(8) A buffer zone of land must be maintained between any buried waste and the disposal site boundary and beneath the disposed waste. The buffer zone shall be of adequate dimensions to allow a licensee to carry out environmental monitoring activities specified in § 61.53(d) of this part and take mitigative measures if needed.

* * * * *

(12) Only waste meeting the acceptance criteria shall be disposed of at the disposal site.

(13) Waste will be disposed of consistent with the description provided in § 61.12(f) and the technical analyses required by § 61.13.

* * * * *

22. In § 61.55, revise paragraph (a)(6) to read as follows:

§ 61.55 Waste classification.

(a) * * *

(6) Classification of wastes with radionuclides other than those listed in tables 1 and 2 of this section. If radioactive waste does not contain any nuclides listed in either table 1 or 2 of this section, it is Class A.

* * * * *

23. In § 61.56, revise paragraph (a) to read as follows:

§ 61.56 Waste characteristics.

(a) The following requirements are minimum requirements for all waste and are intended to facilitate handling at the disposal site and provide protection of health and safety of personnel at the disposal site.

* * * * *

24. Revise § 61.57 to read as follows:

§ 61.57 Labeling.

Each package of waste must be clearly labeled to identify any information required by the land disposal facility's criteria for waste acceptance developed according to § 61.58. Each

package of waste disposed in a land disposal facility with waste acceptance criteria developed in accordance with the waste classification requirements must indicate what Class it is, in accordance with § 61.55.

25. Revise § 61.58 to read as follows:

§ 61.58 Waste acceptance.

(a) Waste acceptance criteria. Each applicant shall provide, for approval by the Commission, criteria for the acceptance of waste for disposal that provide reasonable assurance of compliance with the performance objectives of subpart C of this part. Waste acceptance criteria shall specify, at a minimum, the following:

(1) Allowable activities and concentrations of specific radionuclides. Allowable activities and concentrations shall be developed from the technical analyses required by § 61.13 for any land disposal facility, the waste classification requirements set forth in § 61.55 for a near-surface disposal facility, or a combination of both for a near-surface disposal facility.

(2) Acceptable waste form characteristics and container specifications. The characteristics and specifications shall meet the minimum requirements for waste characteristics set forth in § 61.56(a) for all waste, and 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 this part.

(3) Restrictions or prohibitions on waste, materials, or containers that might affect the facility's ability to meet the performance objectives in subpart C of this part.

(b) Waste characterization. Each applicant shall provide, for Commission approval, acceptable methods for characterizing the waste for acceptance. The methods shall identify the

characterization parameters and acceptable uncertainty in the characterization data. The following information, at a minimum, shall be required to characterize waste:

(1) Physical and chemical characteristics;

(2) Volume, including the waste and any stabilization or absorbent media;

(3) Weight of the container and contents;

(4) Identities, activities, and concentrations;

(5) Characterization date;

(6) Generating source; and

(7) Any other information needed to characterize the waste to demonstrate that the waste acceptance criteria set forth in § 61.58(a) are met.

(c) Waste certification. Each applicant shall provide, for Commission approval, a program to certify that waste meets the acceptance criteria prior to shipment to the land disposal facility. The certification program shall:

(1) Designate authority to certify and receive waste for disposal at the land disposal facility.

(2) Provide procedures for certifying that waste meets the waste acceptance criteria.

(3) Specify documentation required for waste acceptance including waste characterization, shipment (including the requirements set forth in appendix G of 10 CFR part 20), and certification.

(4) Identify records, reports, tests, and inspections that are necessary to comply with the requirements in § 61.80.

(5) Provide approaches for managing waste that has been certified as meeting the waste acceptance criteria in a manner that maintains its certification status.

(d) Licensees with licenses for land disposal facilities in effect on **[INSERT DATE THAT IS 1 YEAR AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER]** shall comply with the requirements of paragraphs (a), (b), and (c) of this section at the next license

renewal or by **[INSERT DATE THAT IS 6 YEARS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER]**, whichever comes first.

(e) For license applicants, the waste acceptance criteria will be incorporated into the facility license. For licensees with licenses for land disposal facilities in effect on **[INSERT DATE THAT IS 1 YEAR AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER]**, upon Commission approval and if otherwise consistent with applicable State and Federal law, the NRC will issue an amendment to the license incorporating the waste acceptance criteria in to the existing license.

(f) Each licensee shall annually review the content and implementation of the waste acceptance criteria, waste characterization methods, and certification program.

(g) Applications for modification of approved waste acceptance criteria must be filed in accordance with § 61.20.

26. In § 61.80, revise paragraphs (i)(1) and (2) and add paragraph (m) to read as follows:

§ 61.80 Maintenance of records, reports, and transfers.

* * * * *

(i)(1) Each licensee authorized to dispose of waste materials received from other persons under this part shall submit annual reports to the Director, Office of Nuclear Material Safety and Safeguards, by an appropriate method listed in § 61.4, with a copy to the appropriate NRC regional office shown in appendix D to 10 CFR part 20. Reports must be submitted by the end of the first calendar quarter of each year for the preceding year.

(2) The reports shall include:

(i) Specification of the quantity of each of the principal radionuclides released to unrestricted areas in liquid and in airborne effluents during the preceding year;

(ii) The results of the environmental monitoring program;

(iii) A summary of licensee disposal unit survey and maintenance activities;

(iv) A summary of activities and quantities of radionuclides disposed of;

(v) Any instances in which observed site characteristics were significantly different from those described in the application for a license; and

(vi) Any other information the Commission may require.

(3) If the quantities of radioactive materials released during the reporting period, monitoring results, or maintenance performed are significantly different from those expected in the materials previously reviewed as part of the licensing action, the report must cover this specifically.

* * * * *

(m) Each licensee shall maintain waste acceptance records including:

(1) Provisions for waste acceptance including the waste acceptance criteria, characterization methods, and certification program.

(2) Audits and other reviews of program content and implementation. The licensee shall retain records of audits and other reviews for 3 years after the record is made.

Dated at Rockville, Maryland, this ….th day of …... 2016.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,
Secretary of the Commission.