NUCLEAR REGULATORY COMMISSION

10 CFR Parts 20 and 61

[NRC–2011–0012; NRC–2015–0003]

RIN 3150–AI92

Low-Level Radioactive Waste Disposal

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend 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, to facilitate implementation, and to better align the requirements with current health and safety standards. This proposed rule would affect LLRW disposal licensees or license applicants that are regulated by the NRC or the Agreement States.

DATES: Submit comments on the proposed rule by July 24, 2015. Submit comments specific to the information collection aspects of this proposed rule by May 26, 2015. Comments received after these dates will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before these dates.

ADDRESSES: You may submit comments by any of the following methods (unless this document describes a different method for submitting comments on a specific subject):

- *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: 301–492–3668; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact one of the individuals listed in the **FOR FURTHER INFORMATON CONTACT** section of this document.
- *Email comments to: Rulemaking.Comments@nrc.gov.* If you do not receive an automatic email reply confirming receipt, then contact us at 301–415–1677.
- *Fax comments to:* Secretary, U.S. Nuclear Regulatory Commission at 301–415–1101.
- *Mail comments to:* Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Rulemakings and Adjudications Staff.
- *Hand deliver comments to:* 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. (Eastern Time) Federal workdays; telephone: 301–415–1677.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Gary Comfort, telephone: 301–415–8106, email: *Gary.Comfort@nrc.gov*; or Andrew Carrera, telephone: 301–415–1078, email: *Andrew.Carrera@nrc.gov.* Both of the Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

Excutive Summary

A. Need for the Regulatory Action

The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend its regulations that govern low-level radioactive waste (LLRW) disposal facilities to require new and revised site-specific technical analyses and to permit the development of criteria for LLRW acceptance based on the results of these analyses. These amendments would ensure that LLRW streams that are significantly different from those considered during the development of the current 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 would 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. This proposed rule would affect LLRW disposal licensees or license applicants that are regulated by the NRC or the Agreement States.

B. Major Provisions

Major provisions of the proposed rule include changes to:

- Revise the existing technical analysis for protection of the general population to include a 1,000-year compliance period;
- Add a new site-specific technical analysis for the protection of inadvertent intruders that would include a 1,000-year compliance period and a dose limit;
- Add new analyses that would include a 10,000-year protective assurance period and annual dose minimization target;
- Add a new analysis for certain long-lived LLRW that would include a post-10,000-year performance period;
- Add new analyses that would identify and describe the features of the design and site characteristics that provide defense-in-depth protections;
- Add a new requirement to update the technical analyses at closure; and
- Add a new requirement to develop site-specific criteria for the future acceptance of LLRW for disposal based on either the results of these technical analyses or the existing LLRW classification requirements.

C. Costs and Benefits

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

- Cost to the Industry. The proposed rule would result in an average implementation cost per licensee of $1,000,000, followed by an estimated annual cost of $4,000. Overall, the industry will incur an estimated implementation cost of $4 million, followed by an estimated annual cost of $16,000.
- Cost to the Agreement States. The proposed rule would result in additional costs to the Agreement States with all costs resulting from implementation. On average, each Agreement State would incur an estimated implementation cost of $525,000. Overall, the Agreement States will incur an estimated implementation cost of $2.1 million.
- Cost to the NRC. The NRC would incur an implementation cost for drafting and implementing a final rulemaking based on the proposed rule. This cost is estimated to be $333,000. Because the NRC does not have any LLRW disposal licensees, no annual NRC cost is expected. The NRC would also incur an estimated implementation cost of $216,000 for drafting a final guidance document based on the final rule.

The regulatory analysis also considered, in a qualitative fashion, direct benefits that would accrue and the indirect benefits from risks that could be avoided if the NRC adopted the rule. The principal qualitative benefits of the proposed action would include: (1) Ensuring that LLRW streams that are significantly different from those considered during the development of the current 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.

The draft regulatory analysis concludes that the proposed rule should be adopted because the proposed regulatory initiatives enhance public health and safety by ensuring the safe disposal of LLRW that was not analyzed in the regulatory basis for the original part 61 of Title 10 of the *Code of Federal Regulations* (*e.g.,* large quantities of depleted uranium). For more information, please see the draft regulatory analysis (Accession No. ML14289A158 in the NRC's Agencywide Documents Access and Management System).

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I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2011–0012 when contacting the U.S. Nuclear Regualtory Commission (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.
- *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, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in the **SUPPLEMENTARY INFORMATION** section.
- *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.

B. Submitting Comments

Please include Docket ID NRC–2011–0012 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *http://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

A. Existing Regulatory Framework

The NRC's licensing requirements for the disposal of commercial low-level radioactive waste (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 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 current 10 CFR part 61 into their corresponding regulations and as license conditions.

The current 10 CFR part 61 emphasizes an integrated systems approach to the disposal of commercial LLRW, including site selection, disposal facility design and operation, LLRW characteristics, and disposal facility closure. To reduce reliance on institutional controls, the current 10 CFR part 61 emphasizes passive (*e.g.,* site stability) rather than active systems to limit and retard the releases of LLRW to the environment. This integrated systems approach is similar to the defense-in-depth concept that has been well known for some time for the NRC's nuclear reactor safety design and licensing activities. However, defense-in-depth is not explicitly discussed in the existing 10 CFR part 61 regulations. Currently, the defense-in-depth concept is implicitly contained in the 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 that presents a larger hazard and should be stable for proper disposal; imposing requirements on wasteform and packaging characteristics; and requiring the use of barriers to intrusion for wastes that will not decay to levels which present an acceptable hazard to an intruder within 100 years).

Subparts of the existing 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, 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 10 CFR 61.7, ''Concepts.''

The following are key provisions in current 10 CFR part 61:

- Standards for: (1) Protection of the general population in 10 CFR 61.41, ''Protection of the general population from the releases of radioactivity;'' (2) protection of an inadvertent intruder in 10 CFR 61.42, ''Protection of individuals from inadvertent intrusion;'' (3) protection of individuals during facility operations in 10 CFR 61.43, ''Protection of individuals during operations;'' and (4) site stability in 10 CFR 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 and geomorphic characteristics for an acceptable near-surface LLRW disposal site in 10 CFR 61.50, ''Disposal site suitability requirements for land disposal.''
- A LLRW classification system (LLRW being categorized as Class A, Class B, Class C, or greater-than-Class C) for commercial LLRW in 10 CFR 61.55, ''Waste classification,'' based on the concentration of certain radionuclides.
- Specification of the LLRW characteristics in 10 CFR 61.56, ''Waste characteristics,'' that commercial LLRW forms must meet to be acceptable for disposal.
- Requirements for caretaker oversight in the form of institutional controls of LLRW disposal facilities in 10 CFR 61.59, ''Institutional requirements,'' for a period of 100 years following facility closure.

Currently, to grant a license, the NRC must conclude that there is reasonable assurance that the performance objectives will be met. To demonstrate that a license applicant will meet these performance objectives, 10 CFR part 61 license applicants need to prepare the analyses required by 10 CFR 61.13, ''Technical analyses.''

To demonstrate that the general population is protected from releases of radioactivity, license applicants are required to prepare an analysis of exposure pathways leading to potential radiological doses to the general population. The current 10 CFR part 61 does not impose a specific performance timeframe for use in the analysis to protect the general population, and there are currently differences among Agreement States regarding the analysis timeframe. For example, some Agreement States have required licensees to analyze the disposal facility for only 500 years, while others have required analyses to the peak dose. For certain long-lived LLRW, a shorter timeframe for the analysis could result in a situation where the long-term impacts from the disposal of long-lived LLRW are not adequately identified in a licensee's analysis. Conversely, the increasing uncertainties associated with very long timeframes could diminish the value of the information generated with technical analyses for applicants, regulators, and other stakeholders. The NRC has drafted this proposed rule to balance the consideration of the risks from disposal of long-lived LLRW with significant uncertainties that may be associated with long-term analyses.

License applicants must also demonstrate that potential inadvertent intruders into the LLRW disposal facility will be protected. Inadvertent intruders might occupy the site at any time after institutional controls over the LLRW disposal facility are no longer effective and may not be aware of the radiation hazard from the LLRW. Under the current regulations, protection of inadvertent intruders is demonstrated by compliance with the LLRW classification (10 CFR 61.55) and segregation requirements (10 CFR 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 are not currently provided in 10 CFR part 61 because an intruder dose assessment is not required, but the LLRW classification concentration limits for radionuclides, in tables 1 and 2 of 10 CFR 61.55, were based on a dose of 5 milliSieverts per year (mSv/yr) (500 millirem per year (mrem/yr)) to an inadvertent intruder. The LLRW classification tables were developed assuming that only a fraction of the LLRW being disposed would approach the LLRW classification limits (note that the dose to an intruder exposed to a large volume of disposed LLRW at the classification limits could exceed 5 mSv/yr (500 mrem/yr)). By complying with the LLRW classification and segregation requirements, an inadvertent intruder will be protected if the underlying assumptions are not violated.

In the existing 10 CFR part 61 regulations, 10 CFR 61.13(a) through (d) require the technical analyses needed to demonstrate that the performance objectives are met. The regulations in 10 CFR part 61 are risk-informed and performance-based, and ensure public health and safety are protected in the operation of any commercial LLRW disposal facility. Applicants can demonstrate how their proposals meet the respective performance objectives for the specific near-surface disposal method selected (47 FR 57446). The NRC is proposing to modify the current regulations to ensure that LLRW streams that are significantly different than those considered in the development of the existing 10 CFR part 61 are adequately considered during the licensing of LLRW disposal facilities, to require licensees to explicitly identify how disposal site characteristics and design provide defense-in-depth, and to ensure that the 10 CFR part 61 performance objectives will be met for disposal of those LLRW streams.

B. Low-Level Radioactive Waste Classification System

The NRC developed current 10 CFR part 61 based on assumptions regarding the types of LLRW likely to go into a commercial disposal facility. These were based on a survey of LLRW generators and the results were published in 1982 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 10 CFR 61.55 that establish 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. As the LLRW class increases in hazard, greater controls (*e.g.,* protection for a longer period of time or greater burial depth) are required in order to reduce the risk from disposal of the LLRW. 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. 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. Low-level radioactive waste 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 initial 10 CFR part 61 rulemaking, the NRC considered inadvertent intrusion scenarios and the physical stability and isotopic concentration of the LLRW when it developed the 10 CFR part 61 LLRW classification system. 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 potential disposal methods likely to be used.

In the Statement of Considerations for the final rule (47 FR 57457), the Commission noted the following:

> [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 wasteform, minimizes the potential for radionuclide migration in groundwater. Stability also plays an important role in protecting an inadvertent intruder, since the stable wasteform 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, wasteforms 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 land disposal facility, the LLRW classification system is also integral to determining Federal and State responsibilities for LLRW and requirements for transfers of LLRW intended for disposal. The Low-Level Radioactive Waste Policy Act of 1980 (as amended in 1985) defines Federal and State responsibilities for the disposal of LLRW based on 10 CFR 61.55, as in effect on January 26, 1983. Specifically, the Act assigns responsibility for disposal of Class A, Class B, and Class C commercial LLRW to the States and responsibility for disposal of commercial LLRW with concentrations that exceed the limits for Class C LLRW to the Federal Government.

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

C. Previous Public Interactions

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) for public comment. The NRC staff conducted a public meeting on May 18, 2011, in Rockville, Maryland, 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, and the NRC received 15 comment letters from public interest groups, industry, and government organizations.

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

The NRC staff also briefed the Advisory Committee on Reactor Safeguards (ACRS), Radiation Protection and Nuclear Materials Subcommittee, on June 23 and August 17, 2011, and the full committee on July 13 and September 8, 2011. The NRC staff again briefed the ACRS, Radiation Protection and Nuclear Materials Subcommittee, on April 9, 2013, and the full committee on July 10, 2013. Summaries and transcripts of these meetings can be found at the ACRS' Web site, *http://www.nrc.gov/about-nrc/organization/acrsfuncdesc.html*.

Based on early comments and interactions with the ACRS, the NRC staff revised the preliminary proposed rule language.

III. Discussion

A. What action is the NRC taking?

The NRC is proposing to amend 10 CFR part 61 to require LLRW disposal licensees or license applicants to prepare a safety case that includes a defense-in-depth analysis and new and revised site-specific technical analyses to ensure that LLRW streams that are significantly different from the LLRW streams considered in the current 10 CFR part 61 regulatory basis can be disposed of safely and meet the performance objectives in subpart C of 10 CFR part 61. These new and revised analyses would also more easily identify any additional measures that would be prudent to implement for continued disposal of radioactive LLRW at a particular facility.

The NRC is also proposing to amend 10 CFR part 61 to require LLRW disposal facility licensees or license applicants to develop site-specific criteria for the acceptability of LLRW for disposal. These amendments maintain

the existing LLRW classification system, but permit disposal facility licensees or license applicants to account for facility design, disposal practices, and site characteristics to determine criteria for accepting future shipments of LLRW for disposal at their site. Because licensees or license applicants are required to develop site-specific criteria for the acceptability of LLRW for disposal, the NRC is also proposing to amend appendix G of 10 CFR part 20, ''Standards for Protection Against Radiation,'' to conform to the proposed requirements for LLRW acceptance. The NRC is also proposing additional amendments to the regulations to facilitate implementation and better align the requirements with current health and safety standards.

Table 1 compares the proposed new and revised technical analyses to the current 10 CFR part 61 requirements. The inadvertent intruder assessment would be a new requirement under 10 CFR 61.13 to demonstrate compliance with the performance objective to protect inadvertent intruders at 10 CFR 61.42. The inadvertent intruder assessment would have to demonstrate that the annual dose would not exceed a proposed 5 mSv (500 mrem) limit over a newly defined 1,000-year compliance period. A performance assessment would also be required for the protection of the general population from releases of radioactivity. This analysis would update the current exposure-pathway analysis to use a more modern performance-assessment methodology that would better align 10 CFR part 61 with the Commission's policy regarding the use of probabilistic risk assessment methods in nuclear regulatory analysis (60 FR 42622; August 16 1995). The performance assessment would also use a newly defined 1,000-year compliance period. The performance assessment would retain the current 0.25 mSv (25 mrem) annual dose limit and the as low as reasonably achievable (ALARA) concept, but the dose methodology would be consistent with the dose methodology specified in the standards for radiation protection set forth in the current 10 CFR part 20.

Given the significant uncertainties inherent in demonstrating compliance with the performance objectives over a long timeframe, a protective assurance period analysis would be required to demonstrate that the annual dose would be minimized below 5 mSv (500 mrem) or a level that is supported as reasonably achievable based on technological and economic considerations from the end of the compliance period through 10,000 years. Further, this analysis would need to consider new site features and processes occurring at the site that are different than what is considered during the compliance period.

Finally, a qualitative analysis covering a performance period of 10,000 years or more after site closure will also be required in 10 CFR 61.13 for those sites disposing of long-lived waste or if necessitated by site-specific conditions. This analysis would be required to assess how the disposal facility and site characteristics limit the potential long-term radiological impacts, consistent with available data and current scientific understanding, for the protection of the general population and the inadvertent intruder.

Defense-in-depth is an integral part of the safety case presented by the disposal applicant or licensee. Therefore, the defense-in-depth analyses are required in each one of the periods that are analyzed, as noted in Table 1.

TABLE 1—COMPARISON TABLE OF CURRENT AND PROPOSED 10 CFR PART 61 REGULATIONS

	Protection of the general population from releases of radioactivity (10 CFR 61.41)	Protection of individual from inadvertent intrusion (10 CFR 61.42)	Stability of the disposal site after closure Long-term analyses (10 CFR 61.44)	Defense-in-depth
Current 10 CFR Part 61 regulations.	—Pathway analysis ..... —Undefined period of performance. —0.25 mSv (25 mrem) annual whole body dose limit for the protection of the general population from releases of radioactivity. —ALARA concept.	—Comply with 10 CFR 61.55 LLRW classification and segregation requirements. —Provide adequate barriers to inadvertent intrusion. —Undefined period of performance. —No annual dose limit.	Analyses of active natural processes that demonstrate that there will not be a need for ongoing active maintenance of the disposal site following closure.	Implicit in Subpart D technical requirements.
Proposed 10 CFR Part 61 regulations.	Within 1,000 Years Following Closure of Disposal Facility (Compliance Period).			
	—Performance assessment that estimates peak annual dose that occurs within 1,000 years following closure of disposal facility. —0.25 mSv (25 mrem) annual dose limit for the protection of the general population from the releases of radioactivity that occurs within 1,000 years following closure of disposal facility. —ALARA concept.	—Comply with LLRW acceptance criteria. —Provide adequate barriers to inadvertent intrusion. —Intruder assessment that estimates peak annual dose that occurs within 1,000 years following closure of disposal facility. —5 mSv (500 mrem) annual dose limit.	Analyses of active natural processes that demonstrate that long-term stability of the site can be ensured and that there will not be a need for ongoing active maintenance of the disposal site following closure.	Analyses that demonstrate the proposed disposal system includes defense-in-depth protections.
	Between 1,000 and 10,000 Years Following Closure of Disposal Facility (Protective Assurance Period).			

TABLE 1—COMPARISON TABLE OF CURRENT AND PROPOSED 10 CFR PART 61 REGULATIONS—Continued

	Protection of the general population from releases of radioactivity (10 CFR 61.41)	Protection of individual from inadvertent intrusion (10 CFR 61.42)	Stability of the disposal site after closure Long-term analyses (10 CFR 61.44)	Defense-in-depth
	—Performance assessment that estimates peak annual dose that occurs between 1,000 and 10,000 years following closure of disposal facility. —Annual dose shall 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 from releases of radioactivity that may occur between 1,000 and 10,000 years following closure of disposal facility.	—Intruder assessment that estimates peak annual dose that occurs between 1,000 and 10,000 years following closure of disposal facility. —Annual dose shall be below 5 mSv (500 mrem) or a level that is reasonably achievable based on technological and economic considerations for the protection of the inadvertent intruders from exposures that may occur between 1,000 and 10,000 years following closure of disposal facility.	—Analyses of active natural processes that demonstrate that long-term stability of the site can be ensured and that there will not be a need for ongoing active maintenance of the disposal site following closure.	—Analyses that demonstrate the proposed disposal system includes defense-in-depth protections.
	After 10,000 Years Following Closure of Disposal Facility (Performance Period).			
	—Analyses for 10,000 or more years following closure of disposal facility that demonstrates releases will be minimized to the extent reasonably achievable for the protection of the general population. —Analyses only apply for disposal sites containing long-lived radionuclides exceeding concentrations listed in table A of 10 CFR 61.13(e), or if necessitated by site-specific conditions. —Analyses that demonstrate how the facility has been designed to limit long-term releases.	—Analyses for 10,000 or more years following closure of disposal facility that demonstrates exposures will be minimized to the extent reasonably achievable for the protection of inadvertent intruders. —Analyses only apply for disposal sites containing long-lived radionuclides exceeding concentrations listed in table A of 10 CFR 61.13(e), or if necessitated by site-specific conditions. —Analyses that demonstrate how the facility has been designed to limit long-term exposures to an inadvertent intruder.	.....	—Analyses that demonstrate the proposed disposal system includes defense-in-depth protections.

B. Who would this action affect?

This proposed rule would affect 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?

Recently, the industry and the NRC have identified new LLRW streams that were not envisioned during the development of 10 CFR part 61. These LLRW streams include depleted uranium (DU) 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 not previously evaluated during the development of the current 10 CFR part 61 regulations.

The renewed interest in licensing new uranium enrichment facilities in the United States has brought disposal of DU LLRW to the forefront of commercial LLRW disposal issues. In the regulatory basis supporting the development of current 10 CFR part 61, the NRC did not consider the relatively high concentrations and large quantities of DU LLRW that are generated by enrichment facilities. Additionally, the NRC did not anticipate that the DOE would dispose of large quantities of DU LLRW or any other defense-related LLRW in commercial disposal facilities. With the existing DOE DU stockpile at the Paducah and Portsmouth Gaseous Diffusion Plants, and the recent licensing of the Louisiana Energy Services National Enrichment Facility and the United States Enrichment Corporation American Centrifuge Plant, the DOE and the industry might need to dispose of more than 10^9 kilograms (1 million metric tons) of DU LLRW.

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 large quantities of DU, the NRC staff identified conditions that would likely not meet the current performance objectives in 10 CFR 61.41 and 10 CFR 61.42, if large quantities of DU were disposed under those conditions (*e.g.,* shallow disposal, such as that commonly associated with Class A LLRW, or disposal at humid sites with a potable ground water supply). The NRC staff determined that the disposal of large quantities of DU as Class A LLRW, with no additional restrictions, could result in inadvertent intruders receiving a dose greater than 5 mSv/yr (500 mrem/yr) for both acute and

chronic exposure scenarios. The estimated dose would result from pathways such as inadvertent ingestion of uranium-contaminated soil and inhalation of radon gas (a member of the uranium decay chain). These results are consistent with those found in an earlier analysis of possible DU disposal in an LLRW 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 10 CFR 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. The NRC did not evaluate the disposal of large volumes of LLRW with concentrations near the LLRW classification limits in the final regulatory basis for the current 10 CFR part 61. The LLRW concentration values published in the draft regulatory basis for the current 10 CFR part 61 were based on the assumption that all LLRW would be disposed at the LLRW classification limit. However, the final LLRW classification tables 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/yr (500 mrem/yr) (*i.e.,* the dose limit used in developing the current LLRW classification in 10 CFR 61.55(a)).

Other unanticipated LLRW streams may also 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 regulatory basis for the current 10 CFR part 61 considered only a small quantity of radium-226 bearing LLRW in the development of the 10 CFR part 61 LLRW classification system.[1] More recently, consistent with the National Defense Authorization Act for Fiscal Year 2013,[2] 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 at a LLRW disposal facility have expanded over time, the NRC has concluded that rulemaking is necessary to better ensure that a broad spectrum of LLRW types and volumes are disposed of in a manner that is protective of public health and safety and the surrounding 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 Commission 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. The NRC concluded that amending the regulations to permit licensees or license applicants to develop criteria for LLRW acceptance from the results of the site-specific technical analyses as an alternative to the LLRW classification requirements allows for increased use of site-specific information to develop risk insights to support the safe disposal of LLRW. The new amendments also provide flexibility to determine how licensees can best meet the performance objectives for the specific design and operational practices of their disposal facility, as well as the specific environmental characteristics of their site.

Finally, the concept of ''defense-in-depth'' is currently not explicit in 10 CFR part 61. On February 11, 2011 (ADAMS Accession No. ML110680621), the NRC Chairman, Gregory B. Jaczko, 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. 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 should 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 proposed rule would add a defense-in-depth requirement in 10 CFR part 61 to address the LLRW recommendations in NUREG–2150.

When would this rule become effective?

For the NRC licensees and license applicants, the rule would become effective 1 year after the final rule is published in the **Federal Register**. The Agreement States will have 3 years from the published date of the **Federal Register** notice for the final rule to adopt compatible regulations.

D. What LLRW streams are affected by this proposed rule?

The NRC considered a number of options in developing this proposed rule. The agency decided that requiring a safety case comprised of a collection of information that demonstrates the safety of a land disposal facility and includes site-specific technical analyses and defense-in-depth protections for all LLRW inventories would be the most comprehensive approach. This approach would ensure that as LLRW streams are generated, analyses would be performed to determine if the performance objectives would be met for disposal of all isotopic concentrations and volumes of LLRW. Under the proposed rule, all sites would be required to complete performance assessments and intruder assessments for the compliance period and the protective assurance period. In addition, land disposal sites with long-lived LLRW, or land disposal sites with site-specific conditions that would necessitate it, would be required to complete performance period analyses for the performance period.

[1] For example, the equivalent of 0.5 nanocuries/gram of radium-226 contained in about 68 kg (about 150 pounds) of natural uranium ore (at equilibrium with its daughter products) was considered for the purposes of designating Class A LLRW (47 FR 57453–57454).

[2] National Defense Authorization Act for Fiscal Year 2013. Subtitle F, Sec. 3173. Improving the reliability of Domestic Isotope Supply. H.R. 4310 (112th).

E. What are site-specific technical analyses?

This rulemaking would require licensees and license applicants to prepare a performance assessment, a new intruder assessment, and new defense-in-depth analyses to demonstrate that its disposal site and design meet the performance objectives. Licensees and license applicants under 10 CFR part 61 would be required to prepare the following as part of their site-specific technical analyses: (a) A revised analysis, called a performance assessment, to demonstrate the protection of the general population from releases of radioactivity (10 CFR 61.41); (b) a new analysis, called an intruder assessment, to demonstrate the protection of inadvertent intruders (10 CFR 61.42); (c) performance period analyses to evaluate how the disposal system may mitigate the long-term risk from disposal of long-lived LLRW (10 CFR 61.13(e)); and (d) new analyses that demonstrate the disposal site includes defense-in-depth protections. The site-specific technical analyses would be required to be updated at facility closure, to provide assurance of compliance with the performance objectives for the disposal of LLRW streams that were not analyzed in the original 10 CFR part 61 regulatory basis.

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, would continue to be demonstrated with a technical analysis that would be revised and renamed in 10 CFR 61.13 as a ''performance assessment.'' [3] A performance assessment, as described in NUREG–1636, ''Regulatory Perspectives on Model Validation in High-Level Radioactive Waste Management Programs: A Joint NRC/SKI White Paper'' (ADAMS Accession No. ML012260054), would be 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 LLRW disposal site are the same as the essential elements of a performance assessment for a HLW 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 LLRW disposal site are: (a) A description of the site and engineered system, (b) an understanding of events likely to affect long-term 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 can influence the ability of a LLRW disposal facility to limit releases of radioactivity to the environment. Disposal system behavior is influenced by the LLRW 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 system and the uncertainties in the projected performance of the system. The performance assessment identifies the specific characteristics of the disposal site (*e.g.,* hydrology, meteorology, geochemistry, biology, geomorphology); degradation, deterioration, or alteration processes of the engineered barriers (including the wasteform and container) and natural system; and interactions between the disposal site characteristics and engineered barriers that might affect the performance of the LLRW disposal system. The performance assessment examines the effects of these processes and interactions on the ability of the LLRW disposal system to limit LLRW releases, and calculates the annual dose to a member of the public for comparison with the appropriate performance objective.

Currently, the descriptions of the technical information, technical analysis, and requirement to demonstrate compliance with the protection of the general population from releases of radioactivity can be found in 10 CFR 61.12, ''Specific technical information,'' 10 CFR 61.13(a), and 10 CFR 61.41, respectively, although these analyses are not called a ''performance assessment.'' In addition, these technical analyses do not have a prescribed compliance period. The original guidance documents associated with these requirements can be found in NUREG–1300, ''Environmental Standard Review Plan for the Review of a License Application for a Low-Level Radioactive Waste Disposal Facility'' (ADAMS Accession No. ML053010347); NUREG–1199, Revision 2, ''Standard Format and Content of a License Application for a Low-Level Radioactive Waste Disposal Facility'' (ADAMS Accession No. ML022550605); and NUREG–1200, Revision 3, ''Standard Review Plan for the Review of a License Application for a Low-Level Radioactive Waste Disposal Facility'' (ADAMS Accession No. ML061370484).

Proposed 10 CFR 61.41 would require licensees or license applicants to complete a performance assessment to estimate peak dose within the compliance period following closure of the disposal facility. The proposed compliance period is defined as 1,000 years following closure of the facility.

After the compliance period, licensees or license applicants would be required to provide analyses of the disposal facility performance from the end of the compliance period to 10,000 years. This period of time is referred to the protective assurance period. The analysis for the protective assurance period is an extension of the performance assessment to the timeframe following the compliance period. From a technical standpoint, the analysis for the protective assurance period is likely to be very similar to the compliance period performance assessment, but, given the uncertainty in projecting the performance of the disposal site over long time periods, uses a different metric (*i.e.,* minimize releases and keep annual doses below 5 mSv/yr (500 mrem/yr) or to a level that is supported as reasonably achievable based on technological and economic considerations). The metric for the protective assurance analyses is different from the dose limits provided for the compliance period. The protective assurance analyses are being proposed as a minimization process (*i.e.,* optimization) with guidance provided on the goals to use in the minimization process. The NRC is seeking feedback on the proposed approach.

The definition of compliance and protective assurance periods would add important technical parameters to the current technical analyses. Appropriate time periods are important for the evaluation of LLRW streams that were not considered in the original 10 CFR part 61 rulemaking as well as for evaluation of long-lived LLRW that were considered in the original rulemaking. The NRC believes that the results of a performance assessment would assist in demonstrating that the protection of the general population from releases of radioactivity can be achieved. The proposed 10 CFR 61.41, new definitions, technical analyses requirements, and concepts are risk-informed and flexible. Proposed 10 CFR 61.41 uses a risk-informed regulatory

[3] The current 10 CFR part 61 refers to a ''technical analysis.''

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 believes that the proposed approach is warranted because of the site-specific nature of LLRW disposal, which can rely on different designs operating at different sites.

The proposed amendments formally introduce the concept of features, events, and processes (FEPs), which ensure appropriate comprehensiveness of any site-specific technical analysis. For the protective assurance period, the performance assessment would need to reflect new FEPs different from the compliance period that address significant uncertainties inherent in the long timeframes only if scientific information compelling such changes is available. The NRC staff has developed a draft guidance document, NUREG–2175, ''Guidance for Conducting Technical Analyses for 10 CFR part 61,'' to facilitate the development of information and analyses that will support licensees or license applicants in addressing the regulatory requirements. This draft guidance document is being made available for public comment concurrent with this proposed rule. (See Docket ID NRC–2015–0003 in the Proposed Rules section of this issue of the **Federal Register**.)

2. 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 pursuits 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. Currently, 10 CFR part 61 does not require a site-specific analysis to demonstrate the protection of an inadvertent intruder. Instead, the safety of an inadvertent intruder is 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 10 CFR 61.55. The regulatory basis for the current 10 CFR part 61, published in NUREG–0945, contains an analysis of a reference disposal facility that evaluates the impacts of LLRW disposal on an inadvertent intruder. This analysis supported the concentration-based LLRW classification tables developed for 10 CFR 61.55.

Consistent with the development of the LLRW classification system, the technical analysis requirements currently found in 10 CFR 61.13(b) specify 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 will be met and that adequate barriers to inadvertent intrusion will be provided. The regulations 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 are presently written, the regulations do 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 10 CFR 61.55 can result in varying doses with respect to the protection of an inadvertent intruder. Therefore, the new proposed regulatory provisions require licensees and license applicants to conduct an analysis of inadvertent intruder doses.

The proposed revisions would add a requirement for licensees and license applicants to conduct a site-specific intruder assessment to demonstrate compliance with 10 CFR 61.42. The proposed intruder assessment would quantitatively estimate the radiological exposure of an inadvertent intruder at an LLRW disposal facility following an assumed loss of institutional controls at the end of the active institutional control period. The results of the intruder assessment would then be compared to the performance objective in 10 CFR 61.42. The intruder assessment would 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 proposed intruder assessment, licensees would be expected to employ a methodology similar to that used for a performance assessment, but the intruder assessment would assume that an inadvertent intruder occupies the LLRW disposal site after closure, engages in normal activities, and is unknowingly exposed to radiation from the LLRW.

With the intruder assessment requirement, the NRC is proposing to specify an intruder dose limit for the compliance period and protective assurance period as described in the original 10 CFR part 61 analysis to develop the LLRW classification tables. The regulatory basis for 10 CFR part 61 assumed that inadvertent intrusion occurred following a cessation of a caretaker or active institutional control period. Institutional control of the site was expected to occur beyond the active institutional control period, although it could not be assured because of the long timeframes involved. Therefore, an intruder was assumed to occupy the LLRW disposal facility and engage in normal activities, such as agriculture or dwelling construction. The analysis assumed that the 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 10 CFR 61.55 on radionuclide concentrations that would yield a 5 mSv/yr (500 mrem/yr) dose.

The dose limit used to develop the current LLRW classification tables was selected from a range of values that were consistent with exposure guidelines of different orders of magnitude: 0.25 mSv/yr (25 mrem/yr), 5 mSv/yr (500 mrem/yr), and 50 mSv/yr (5,000 mrem/yr). In NUREG–0945, the NRC selected the 5 mSv/yr (500 mrem/yr) dose based primarily on safety as reflected in the effective dose limit in 10 CFR part 20 at that time and public opinion gained through the four regional workshops held on the preliminary draft of 10 CFR part 61. The NRC continues to believe that this dose limit provides an acceptable level of protection to an inadvertent intruder. The NRC is proposing to add an annual intruder dose limit to 10 CFR 61.42 to ensure protection of any inadvertent intruder who occupies the disposal site or contacts the LLRW at any time after active institutional controls are removed.

Given the uncertainty in projecting performance of disposal sites over long time periods such as those beyond the compliance period, the amendments proposed in 10 CFR 61.42 would require that annual doses be minimized, as estimated by an intruder assessment, for the protective assurance period. The minimization target is for annual doses to be below 5 mSv/yr (500 mrem/yr) or a level that is supported as reasonably achievable based on technological and economic considerations. The NRC is seeking feedback on the proposed

approach, especially with regard to whether a 5 milliSievert (500 mrem) annual dose target is appropriate for the protective assurance period and whether it is appropriate to require licensees or license applicants to consider alternative levels to minimize exposures to an inadvertent intruder.

Given the uncertainty in predicting human behavior into the distant future and to limit associated speculation, the NRC is proposing to change the definition of the inadvertent intruder to limit the scenarios to reasonably foreseeable activities that are realistic and consistent with activities in and around the disposal site at the time of closure.

As discussed in Section M of this document, the NRC has prepared a draft guidance document that describes acceptable approaches for determining reasonably foreseeable intruder activities that are consistent with activities in and around the disposal site at the time of closure to be assessed in the intruder assessment. The draft guidance describes how licensees or license applicants can take credit for physical characteristics (*e.g.,* water quality) and societal information (*e.g.,* land use patterns) related to the disposal facility to limit speculation about the types of activities in which an inadvertent intruder might engage.

The proposed approach, consistent with the current approach, is to assume that the active institutional controls will fail after the end of the active institutional control period. The NRC does not believe that controls will fail, but rather that the durability of the controls cannot be assured. In addition, the NRC is not assuming the probability is 100 percent that contact with the LLRW by an intruder will occur. As in the current regulation, engineered barriers and disposal practices, such as greater disposal depth, are to be considered in the intruder assessment. For example, with a protective cover of at least 5 m (16 feet) thickness, consideration of a scenario in which a dwelling foundation is excavated in a disposal unit would not be reasonable. A 5 mSv (500 mrem) dose limit for the intruder, compared to a 0.25 mSv (25 mrem) annual dose limit for the public during the compliance period in 10 CFR 61.41, demonstrates the NRC expectation that the intruder scenario is unlikely. As previously stated, the NRC is making available the draft guidance document (see Docket ID NRC–2015–0003) for public comment concurrent with the publication of this proposed rule and is seeking comments on whether the approaches described in the guidance are adequate or if further specification for inadvertent intruder scenarios in the proposed rule is necessary.

As previously indicated, the current 10 CFR part 61 provides LLRW classification and segregation requirements. The NRC considered, based on comments received on the preliminary proposed rule language (76 FR 24831), whether additional requirements such as minimum depth of disposal were needed for large quantities of long-lived LLRW (*e.g.,* DU). The NRC proposes that a more risk-informed approach would be to require an intruder assessment that would allow the actual disposal depth and form of LLRW to be considered in the analysis.

3. Performance Period Analyses

The current 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 necessary under 10 CFR part 61, as originally written, because the NRC developed LLRW classification limits for long-lived radionuclides. The regulatory system was designed to ensure the short- and long-term impacts were limited by regulatory requirements such as the LLRW classification system. The NRC is now proposing additional analyses to ensure that LLRW streams that are significantly different from those considered in the original 10 CFR part 61 regulatory basis (*e.g.,* large quantities of DU) can be disposed of safely and that the performance objectives will be met or LLRW disposal will be prohibited. The use of a three-tiered analyses system with different performance metrics for each tier should allow licensees or applicants to perform risk-informed assessments of the land disposal of LLRW for the protection of public health and safety. The analyses-based approach to regulation is more risk-informed than the concentration-based approach used in the current 10 CFR part 61 regulations. The concentration-based approach cannot be easily adjusted to differing site conditions because concentration limits were derived based on conservative assumptions.

The long-term analyses, termed ''performance period analyses'' as set forth in 10 CFR 61.13(e), would require licensees or license applicants to prepare long-term analyses (*i.e.,* after the compliance and protective assurance periods) that assess how the disposal facility and site characteristics limit the potential long-term radiological impacts, consistent with available data and current scientific understanding. The proposed performance period analyses will only be required for land disposal sites with long-lived LLRW that contains radionuclides with average concentrations exceeding the values listed in the proposed table A of 10 CFR 61.13(e), ''Average Concentrations of Long-lived Radionuclides Requiring Performance Period Analyses,'' or if necessitated by site-specific conditions. The average concentrations, as explained in greater detail in the associated draft guidance document, are disposal site-averaged concentrations. Disposal site-averaged concentrations can include the volume of the LLRW, uncontaminated materials used to stabilize LLRW or reduce void space within LLRW packages, the volume of uncontaminated materials placed within the disposal units, and the volume of engineered or natural materials used to construct the disposal units. For the purpose of determining if performance period analyses are necessary, the disposal site-averaged concentrations should be based on the total volume of LLRW averaged over the total volume of all disposal units. For radionuclides where the concentrations are based on mass and not volume, the average density of the different materials within the disposal units can be used. The averaging calculations are explained in further detail in the draft guidance document.

The metric for the performance period analyses would be to minimize releases to the public to the extent reasonably achievable. The NRC considered a variety of approaches for metrics to evaluate the performance period analyses. The aforementioned metric was selected because it would allow 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. Whereas the calculated dose in a numerical model may be precise, the significance of that dose to a future generation is unknowable in the present. Although a dose limit is not prescribed, it is recommended that doses or concentrations and fluxes of radionuclides in the environment are calculated as they are appropriate to use to compare alternatives using a common metric. The NRC believes the value of information an applicant would provide to describe its actions to mitigate long-

term impacts to future generations is higher than the value of long-term dose estimates. The minimization of releases and barrier analyses for the performance period can demonstrate how an applicant is proposing to limit impacts to future generations. The draft guidance document discusses in more detail an acceptable approach to performing the analyses for the performance period.

The proposed 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 10 CFR 61.41(c) and 10 CFR 61.42(c) will be met. These analyses would 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 long-lived LLRW with average concentrations exceeding the values listed in the proposed table A of 10 CFR 61.13(e), or if necessitated by site-specific conditions, and to determine whether limitations on the disposal of some LLRW streams at certain sites may be needed to properly manage the disposal of LLRW.

An ending time for the performance period analyses is not specified in the proposed regulation. 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 this time is unnecessary. Because long-term impacts are going to be driven by site-specific characteristics and the particular LLRW that is disposed, the timing of peak impacts may differ substantially from site to site. A licensee or license applicant must demonstrate that impacts are minimized to the extent reasonably achievable, ensuring that facilities and disposal cells 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. The proposed approach is based on the position that there are many uncertainties in the risks imposed on future generations, especially from processes or events other than LLRW disposal. In addition, 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. The proposed approach focuses on a demonstration of how the natural and engineered barriers of the disposal system could limit releases of material rather than the radiological impact to an individual or group. The NRC is seeking feedback on the proposed approach, especially with regard to whether a dose limit is needed for the long-term analyses or whether the proposed metric combined with barrier analyses is more appropriate.

4. Defense-In-Depth Analyses

The defense-in-depth principle has served as a cornerstone of the NRC's deterministic 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 also has applied the concept of defense-in-depth elsewhere in its regulations to ensure safety of licensed facilities through requirements for multiple, independent layers, 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 LLRW land disposal facility is appropriate and reasonable. Therefore, the NRC is now proposing additional analyses to ensure that the land disposal facility includes defense-in-depth protections.

However, implementation of defense-in-depth protections, in the context of a LLRW land disposal facility, should be consistent with the NRC's goal of achieving a regulatory program and associated requirements that are risk-informed and performance-based. While waste is being disposed, and before a LLRW land disposal facility is closed, defense-in-depth protections would typically be comparable to other operating nuclear fuel cycle facilities licensed by the NRC. Application of defense-in-depth principles for regulation of disposal facility performance for long time periods following 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. 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. Although it is relatively easy to identify multiple, independent and redundant layers that comprise the engineered features and site characteristics, the capabilities of any of these design features and site characteristics may not be either independent or totally redundant. The NRC continues to believe that multiple layers of defense must each make a definite contribution to the isolation of the waste, so that the NRC may find, with reasonable assurance, that no single layer of defense will be exclusively relied upon to achieve the overall safety objectives over timeframes of hundreds to thousands of years. Disposal of LLRW is also predicated on the expectation that a portion of the 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 the long timeframes are subject to interpretation and include many uncertainties. These uncertainties can be quantified generally and are addressed by requiring the use of a multiple layers. 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 a few archaeologic analogues, there is no experience base for the performance of complex, engineered structures over periods longer than a few hundred years. Therefore, the NRC expects that licensees will rely on both the characteristics and the engineered features, in combination, to provide reasonable assurance that the overall performance of the disposal site will be adequate over long time periods.

5. Site Stability Analyses

Currently, 10 CFR 61.50, which is also being revised in this rulemaking, requires that LLRW disposal sites not be susceptible to erosion, flooding, seismicity, 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. Currently, 10 CFR 61.44 also includes a performance objective for stability at the disposal site after closure. It states that the 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 areasonable assurance

that the 10 CFR 61.44 performance objective will be met, licensees must conduct site stability analyses.

Site stability analyses focus on stability of the wasteform, stability of the engineered disposal facility, and geologic/geomorphic stability of the disposal site. For disposal of traditional LLRW (*i.e.,* range and type of LLRW that was analyzed in the current 10 CFR part 61), site stability analyses will likely focus on the former two areas. For disposal of large quantities of long-lived waste, the focus will likely be on the latter two areas. The extent of the site stability analyses will be strongly influenced by the type of waste to be disposed. Stability of wasteforms, disposal units, engineered barriers (such as cover systems), disposal site, disposal facility, and disposal system may all be within the scope of the stability assessment. However, the current 10 CFR 61.44 performance objective does 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.

The NRC proposes to revise 10 CFR 61.44 to specify that stability of the disposal site must be demonstrated for the compliance and protective assurance periods. This change was necessary to clarify that the post-closure site stability requirements apply to the compliance and protective assurance periods created in this proposed rule.

F. Updated Safety Case and Technical Analyses for Closure

Currently, 10 CFR 61.28, ''Contents of application for closure,'' requires licensees to submit an application to amend the license for closure. This application must include (1) a final revision and specific details of the disposal site closure plan, and (2) an environmental report or a supplement to an environmental report. Currently, 10 CFR 61.28 does not require licensees to prepare updated site-specific technical analyses. The proposed rule would require licensees to include updated safety case and technical analyses in their applications to amend their licenses for closure, to provide greater assurance of compliance with the performance objectives that ensure the safe disposal of LLRW streams significantly different from those considered in the original 10 CFR part 61 regulatory basis (*i.e.,* large quantities of depleted uranium). In particular, 10 CFR 61.28 would be revised to require licensees to also prepare updated performance period analyses required by proposed 10 CFR 61.13, 10 CFR 61.41, and 10 CFR 61.42. The NRC believes that this change, coupled with current 10 CFR 61.28(c) which is not being amended by this rulemaking, may require licensees to take additional action prior to closure to ensure that the LLRW that has been disposed of will meet the performance objectives.

G. What options were considered for selecting approach and timeframes and what is the NRC's preferred option?

1. Considerations Made in Developing Options

Currently, 10 CFR 61.7 discusses a number of timeframes that licensees or license applicants should consider in selecting a site, designing stable wasteforms or containers, controlling access to the site, and developing intruder barriers. The timeframes discussed are provided within the context of a LLRW management system that attempts to ensure that LLRW decays to innocuous levels prior to public exposure to radiation. The concentrations and quantities of long-lived LLRW for disposal would be limited thereby limiting potential exposures. For instance, 10 CFR 61.7(a)(2) indicates 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, 10 CFR part 61 does not provide a value for the time period [4] to demonstrate compliance with the performance objectives. The existing regulatory basis for 10 CFR part 61 in NUREG–0945 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), recognize 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. Both technical factors (*e.g.,* the characteristics and persistence of the radiological hazard attributed to the LLRW) and socioeconomic factors (*e.g.,* transgenerational equity) should be considered.[5] The purpose of completing a performance assessment of a LLRW disposal facility is to ensure that public health and safety are protected with an acceptable degree of confidence.

The NRC evaluated what other countries and international agencies use to manage the radiological risks from the disposal of long-lived LLRW. Some organizations impose a requirement to identify impacts from the disposal of long-lived LLRW using technical analyses. Results of the analyses are used to impose appropriate restrictions on LLRW disposal, if necessary. Almost every country that the NRC looked at places restrictions on how much LLRW can be disposed of in the near surface or does not allow near-surface disposal of long-lived LLRW. Most countries place explicit numerical limits on concentrations of long-lived alpha-emitting LLRW. These concentration limits are set by regulators based on generic technical analyses or policy decisions. The concentration limits are not developed based on the results of site-specific technical analyses. Site-specific 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 10 CFR part 61. The current requirements in 10 CFR part 61 supplement technical analyses with LLRW concentration limits and other disposal requirements, such as minimum disposal depth for certain types of LLRW. The development of concentrations limits by generic analysis or policy works well for countries that only have one disposal site. However, if numerous sites are regulated in this manner the concentration limits must be based on the most limiting conditions in order to assure that public health and safety is protected.

In general, different international programs have used regulatory approaches that vary considerably in 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, and/or long-term analyses). Performance assessments are used to understand how a system (*e.g.,* a disposal facility and

[4] Different terminology has historically been used to refer to the timeframe assessed for regulatory compliance or other analyses, including ''performance period,'' ''time of compliance,'' ''compliance period,'' and other variants.

[5] International Commission on Radiological Protection (ICRP), ''Radiation Protection Recommendations as Applied to the Disposal of Long-lived Solid Radioactive Waste,'' ICRP Publication 81, Annals of the ICRP, Vol. 28, No. 4, ICRP Publication 81, 2000.

natural environment) may perform. They are used to understand the potential impacts of uncertainties on public health and safety decisions that decision makers need to consider. The many sources of uncertainty associated with projecting the future risks from disposal of LLRW include, but are not limited to, natural, engineering, and societal sources. The selection of analyses timeframes or an approach to selection of analyses timeframes for the evaluation of the disposal of LLRW should consider the different sources of uncertainty and how the uncertainties may impact projected future radiological risk. The uncertainties influence how the projected future radiological risks are interpreted by decision makers. The staff evaluated these uncertainties and their impact on intergenerational decision making through review of the work by the National Academy of Public Administration, the Organization for Economic Co-Operation and Development, and others.

2. Options Considered

The NRC has considered a variety of options for selection of the analysis timeframe for the assessment of LLRW disposal.[6] These options were based on two different approaches to waste management:

- Analyses-based approach to safety, and
- Design- and control-based approach to safety.

These two approaches are not mutually-exclusive and each can contain elements of the other approach. Traditionally, for the disposal of LLRW, analyses-based approaches projecting performance of the disposal facility into the future have been used. Disposal of municipal and industrial waste that is non-radioactive have used the design- and control-based approach to safety. The primary decision is what specific regulatory requirements are needed to ensure that public health and safety will be protected.

Analyses-based approach: A variety of different options were considered with respect to the analyses-based approaches. A key consideration of these approaches is the obligation of the current generation to protect future generations from the disposal of LLRW. Though this section discusses the NRC's options for analyses timeframes, the technical analyses should be considered in context with all the requirements of the regulation. The primary decision variables with respect to analyses timeframes considered by the NRC were:

- How many tiers should be used for the analyses?
- What should be the duration of the tiers?
- What limits should be prescribed to each tier?

Table 2 provides a summary of the analyses-based approaches considered by the NRC. A more in-depth discussion of the advantages and disadvantages of each approach can be found in the NRC's ''Technical Analysis Supporting Definition of Period of Performance for Low-level Waste Disposal,'' and ''Regulatory Basis for Proposed Revisions to Low-Level Waste Disposal Requirements (10 CFR part 61)''.

TABLE 2—SUMMARY OF TIMEFRAMES CONSIDERED FOR ANALYSES-BASED APPROACHES

Tiers	Approach	Duration	Limits
Single	Current—no change	Variable, from 500 years to peak dose as currently implemented by Agreement States.	25 mrem/yr.
Single	Peak dose approach	Determined by specific waste and site characteristics.	25 mrem/yr.
Single	Concentration limits	A few thousand	25 mrem/yr, Concentration limits.
Single	Limited duration	1,000 years or less	25 mrem/yr.
Two	Risk-informed analysis	Tier 1: up to 10,000 years	Tier 1: 25 mrem/yr.
		Tier 2: undefined	Tier 2: minimize releases to the extent reasonably achievable.
Two	Risk-informed analysis with long-term dose limit.	Tier 1: 10,000 years	Tier 1: 25 mrem/yr.
		Tier 2: undefined	Tier 2: 100 mrem/yr.
Two	Site specific	Tier 1: a few hundred to 10,000 years	Tier 1: 25 mrem/yr.
		Tier 2: site-specific	Tier 2: site-specific.
Three	Uncertainty limitation	Tier 1: 1,000 years	Tier 1: 25 mrem/yr.
		Tier 2: 10,000 years	Tier 2: minimize releases using a target of keeping doses below 500 mrem/yr.
		Tier 3: undefined	Tier 3: minimize releases to the extent reasonably achievable.
Three	Uncertainty informed	Durations not defined but examples are provided in ''Technical Analysis Supporting Definition of Period of Performance for Low-level Waste Disposal''.	Limits not defined but examples are provided in ''Technical Analysis Supporting Definition of Period of Performance for Low-level Waste Disposal''.

Single Tier Options: The regulatory requirements for a single-tier approach would involve specifying the timeframe of the analyses as well as an associated metric to be met during the timeframe. Variants of the single tier approach considered by the NRC included the following:

(a) Current—no change approach: In this approach, a compliance period is not specified for the assessment of the performance objectives. All four currently operating commercial low-level waste disposal facilities are located in Agreement States, and they all have different requirements for the compliance period. No additional action would be required by the NRC to maintain the current approach.

[6] The NRC developed a position paper on the analyses timeframe for LLRW disposal and a revised regulatory basis that provides more detail than the summary provided here. For more information, refer to the NRC's ''Technical Analysis Supporting Definition of Period of Performance for Low-level Waste Disposal,'' issued in April 2011, and ''Regulatory Basis for Proposed Revisions to Low-Level Waste Disposal Requirements (10 CFR part 61),'' issued in December 2012.

(b) Peak dose approach: This approach would require the calculation of peak dose for the compliance determination regardless of when the peak occurs (which could be greater than 10,000 years if large amounts of DU are disposed at the site). If regulatory limits are met, this approach ensures that all future generations would be provided with the same level of protection as the current generation. It would also ensure that the burden from the disposal of LLRW by the present generation is not deferred to any future generations, no matter how distant in the future.

(c) Regulator-derived concentration limits approach: This approach would involve using a single tier for the analyses of up to a few thousand years, complemented with regulator-derived concentration and quantity limits for long-lived isotopes. This approach is used by some other countries. The NRC believes this approach can be effective at mitigating the impact of long-term uncertainties while avoiding unnecessary speculation and ensuring protection of public health and safety for present and future generations. The challenge of using this approach is that it would be difficult to take into account different site, disposal facility, and other characteristics when determining regulator-derived concentration and quantity limits for long-lived isotopes. The NRC believes that this approach could work well for a single LLRW disposal site (which is most common in foreign nations), but would be difficult to implement in a risk-informed manner for numerous disposal sites. To ensure protection of public health and safety, the limits that would be derived using this approach may need to be set at values derived for the most limiting conditions (*e.g.,* site and design) and may be inappropriately restrictive for some sites.

(d) Limited duration approach: This approach would assign a 1,000-year compliance period to the analysis using a single tier. No limits would be prescribed for impacts that would occur after this period. Proposed guidance would indicate that it may be useful to evaluate longer-term impacts and consider modifications to the disposal system, if practical. A challenge with this approach is that, without limits on the disposal of long-lived isotopes, the dose estimated in a 1,000-year analysis timeframe may not be close in magnitude to the peak dose even for disposal of traditional LLRW. Another shortcoming of this approach is that a performance assessment could demonstrate that the performance objectives would be met within the first 1,000 years but then be exceeded by a large margin afterwards. In fact, this result would be expected, especially for the disposal of DU where the maximum dose achieved within 1,000 years is only about 1/1000th of the peak dose. Because Agreement States have selected different compliance periods, staff anticipates that the lack of a standard approach with respect to long-term impacts (after 1,000 years) will likely result in differences in interpretation among Agreement States. The approach would also create ambiguity with respect to the Commission's objectives for the management of long-term impacts. The decisions for additional action under this approach will be subjective, with case-by-case decisions being made by different regulators using different metrics.

Two Tier Options: The regulatory requirements for a two-tier approach would involve specification of a duration for the analyses for each tier as well as an associated metric to be met for each tier. Variants of the two-tier approach considered by the NRC included the following:

(a) Risk-informed analyses approach: This approach sets standards for the analyses timeframes to ensure consistency, but then affords flexibility to licensees with respect to the technical analyses used to demonstrate compliance with the subpart C performance objectives. To ensure the long-term protection of public health and safety from the disposal of LLRW, the risk-informed analyses approach would be characterized by:

- A compliance period of up to 10,000 years.
- A second tier (*i.e.,* performance period) that would only be applicable when facility-averaged LLRW concentrations exceed certain values, or if necessitated by site-specific conditions. The concentrations would be developed by the NRC.

The analyses for the second tier would include: (1) A screening process to identify if performance period analyses are necessary, and (2) performance period analyses, if applicable. The performance requirement for the performance period analyses would be to minimize releases to the extent reasonably achievable. The analyses that could be used for the second tier would be described in guidance. The regulations would describe the analyses at a high-level.

Under this two-tiered approach, licensees or license applicants of LLRW disposal facilities that dispose of short-lived LLRW or limited quantities of long-lived LLRW would perform their compliance analyses, and no additional analyses would be required. If LLRW has average concentrations exceeding the values developed by the NRC, or if necessitated by site-specific conditions, then the licensees or license applicants would have to perform analyses for the second tier. Guidance would describe the use of a conservative screening analysis or, if desired, a site-specific technical analysis for the second tier. The screening analysis would be based on a conservative approach (*e.g.,* peak in-growth of progeny, no retardation during transport, defined scenarios) to manage long-term uncertainties and ensure that public health and safety is protected. If the screening analysis results showed the performance objectives would not be met, then inventory limits would be established based on the screening analysis or quantitative performance period analyses could be performed to demonstrate that public health and safety will be protected. Using this framework, the analyses would be risk-informed.

(b) Risk-informed analysis with long-term dose limits approach: This approach is conceptually similar to the previous two-tiered approach but differs in that a dose limit for the second tier (*i.e.,* post 10,000 years) of the analysis would be specified in the regulation (*e.g.,*1 mSv (100 mrem)) to align the requirement with regulatory precedent in similar programs (*e.g.,* high-level waste disposal at Yucca Mountain, LLRW disposal staff guidance).

(c) Site-specific approach: A final option using a two-tiered approach would be described as involving a compliance period of somewhere between a few hundred to 1,000 years, which would cover what the NRC believes is a reasonably foreseeable period for estimating future human activities. If uncertainty associated with the societal component of the problem is managed by specifying reasonably conservative scenarios, then the compliance period could be as long as 10,000 years. The time period for the second tier of this approach would not be defined in the regulation, instead it would be determined on a site-specific basis. Under this option a dose limit could be established for the second tier or an alternative metric could be used.

Three Tier Options:

a) Uncertainty limitation approach: This three-tiered approach involves a compliance period, a protective assurance period, and a performance period.

The *compliance period* would be defined as 1,000 years following closure of the disposal facility. The period of 1,000 years was selected to cover the

reasonably foreseeable future during which there would be a high degree of confidence that the requirements could be realistically met. Further, the compliance period would limit speculation on future human activities, as well as waste- and site-performance. The NRC would limit the impact of uncertainty on the compliance period decision making by limiting the duration of the compliance period.

The NRC recognizes that there is merit in considering timeframes longer than 1,000 years for some types of waste. Therefore, this approach would also establish a *protective assurance period* which would ensure that the disposal of LLRW would not present an unacceptable risk to future generations by minimizing radiation doses from the end of the compliance period until 10,000 years. The minimization process would be designed to ensure that radiological doses are maintained below 5 millisieverts (500 mrem) per year, or to a level that is reasonably achievable based on technological and economic considerations. The use of a protective assurance period with a minimization target rather than a dose limit would recognize the uncertainty in estimating future social patterns, living conditions, and environmental conditions in and around a disposal facility. The standard for the second tier is more similar to ALARA or optimization than a strict dose limit. The types of questions a licensee, license applicant, or regulator may consider when applying this approach would include but are not limited to:

- What are the projected doses?
- What other technologies are available to reduce those projected doses (*e.g.* different wasteforms, engineered covers)?
- If the doses are projected to be above 5 mSv/yr (500 mrem/yr), can they be reduced using technology in an economically justifiable manner?
- Could the waste stream be disposed at a different site? Is this site not suitable for this waste (*i.e.,* excess instability)?

The third tier of the approach is the *performance period.* The performance period would be used to evaluate the performance of the site after the protective assurance period and ensure that disposal system's ability to mitigate long-term risks associated with the disposal of long-lived LLRW is evaluated. The performance period would only apply if a facility is projected to contain sufficient long-lived radioactivity that could pose an unacceptable risk beyond 10,000 years.

(b) Uncertainty informed approach: This approach would provide decision points and regulatory limits that would consider major sources of uncertainty associated with the projection of radiological risk from the disposal of LLRW. This approach would be divided into three timeframes—compliance period, assessment period, and performance period—and is referred to as the Compliance, Assessment, and Performance approach (CAP).

The *compliance period* would be defined as the period of time when the disposal facility performance could be estimated quantitatively with relative confidence. Societal uncertainties, though large, would not prevent the performance calculations from providing meaningful information.

The *assessment period* would be the period of time after the compliance period where performance of the disposal facility would be assessed quantitatively and the results would be interpreted semi-quantitatively considering the increasing uncertainties in natural and engineered system components. The assessment period would be used to evaluate the relative performance of natural and engineered barriers.

The *performance period* would be the period of time after the assessment period where performance of the disposal facility would be evaluated qualitatively or quantitatively, as appropriate, because numerous and significant sources of uncertainty could significantly influence the results.

The objective of the CAP approach is to balance the need to consider radiological risks to future generations, even over long periods of time, with the uncertainties that could impact the interpretation of the results of the performance calculations. For LLRW inventories with long-lived radionuclides and with in-growth of more mobile progeny, the CAP approach is one way to ensure that the long-term risks would be incorporated into decision making. This three-tiered approach would ensure that the potential long-term radiological risks are communicated to decision makers while properly reflecting the uncertainties associated with the calculations. In the NRC's ''Technical Analysis Supporting Definition of Period of Performance for Low-level Waste Disposal,'' examples were given for defining the tiers and providing associated dose limits, however, specific values for each variable were not selected.

Design- and control-based approach: The NRC considered an approach to managing long-lived LLRW that requires periodic review and reassessment (*e.g.,* perpetual institutional control, monitoring, and maintenance), as is done with facilities that dispose of industrial metals. Currently, 10 CFR part 61 contemplates that involvement of a disposal site operator will follow a well-defined timeline. The more open-ended process associated with the disposal of industrial metals is viewed as a disadvantage to adoption of this type of approach.

Under current 10 CFR part 61, after satisfactory disposal site closure, licenses are transferred to the State or Federal Government, one of which is required to own the disposal site. A 5-year period during which the licensee would remain at the disposal site to ensure that the site is stable and ready for institutional control is required, though the Commission would be able to prescribe longer periods of time to demonstrate that the disposal site is stable, if warranted.[7] The disposal site is transferred to the State or Federal Government after this period.

3. NRC Proposed Option

The NRC proposed option is an approach to analyses timeframes that is based on a three-tiered conceptual framework. The proposed option includes a compliance period of 1,000 years applicable to both a performance assessment used to demonstrate compliance with 10 CFR 61.41 and to an intruder assessment used to demonstrate compliance with 10 CFR 61.42.

The second tier of the proposed option includes a 10,000 year protective assurance period, during which doses, as estimated by technical analyses, would be minimized. The objective of the minimization process would be to keep doses below 500 mrem/yr or to a level that is reasonably achievable based on technological and economic considerations. Should doses exceed the minimzation target, changes to the disposal site design, inventory limits, or alternative methods of disposal would be needed to ensure doses are minimized to avoid unacceptable consequences unless those changes can be shown to not be technically or economically practical. Given the significant uncertainties inherent in these long timeframes, the performance assessment should reflect changes in features, events, and processes of the natural environment such as climatology, geology, and geomorphology only if scientific information compelling such changes from the compliance period is available. The NRC is not proposing that features, events, and processes that are dynamic be arbitrarily fixed as static. Rather that

[7] 10 CFR 61.29.

the scope of the features, events, and processes considered does not need to be expanded unless information is available to do so.

The third tier of the proposed option includes a performance period of undefined duration during which a licensee must demonstrate that effort has been made to minimize releases to the extent reasonably achievable. This metric for the third tier would afford the flexibility for consideration of long-term radiological doses, cost-benefit type of analyses, and concentration and fluxes of radionuclides in the environment. The duration is undefined to allow for consideration of site- and waste-specific factors as well as different methods to demonstrate that the requirements have been met. This approach was informed by the views expressed by various members of the public about the consideration of long-term uncertainties. Conditions have been established to determine when the performance period analyses should be performed, therefore risk-informing the approach. In order to determine if performance period analyses are necessary, it is proposed that a licensee or license applicant compare LLRW disposal site-averaged concentrations of long-lived radionuclides to values provided in the proposed table A of 10 CFR 61.13(e). This requirement would ensure that the analyses are performed only when dictated by the radiological characteristics of the LLRW or if necessitated by site-specific conditions. The concentration values are primarily, but not solely, based on the Class A LLRW concentration values from table 1 of 10 CFR 61.55. Unlike the existing table 1, the proposed table A includes non-transuranic long-lived isotopes, as well as transuranic long-lived isotopes. It is appropriate to include the non-transuranic isotopes in the performance period analyses if they could potentially be disposed of in significant concentrations and quantities. The radiological risk is estimated using the dose conversion factors of individual isotopes at the concentration provided (10 nanoCuries per gram (nCi/g)). The dose conversion factors for all isotopes have variability; there are different values of dose conversion factors for different solubility classes of an isotope as well as different values of dose conversion factors for different isotopes. When deriving the 10 nCi/g concentration value for transuranic isotopes in Class A LLRW, the NRC applied the same conversion of concentration to dose for all of these isotopes. The dose conversion factors for non-transuranic isotopes are generally comparable to the transuranic isotopes, and the NRC believes it is appropriate to simplify the variability similar to what was done in the original rulemaking. This simplification results in a single concentration value for all long-lived alpha emitting radionuclides rather than a table of values for different isotopes. The concentrations provided in the proposed table A of 10 CFR 61.13(e) are only used to determine if performance period analyses are necessary. As explained in detail in the draft guidance document, the complexity of the analyses would be driven by the projected impacts. The results of the performance period analyses would determine if any resultant actions are necessary (*e.g.,* establish inventory limits).

The specification of certain LLRW for which the performance period calculations apply to eliminates the need for all licensees or license applicants to develop performance period analyses. However, the language ''or if necessitated by site-specific conditions'' is needed because it is difficult to determine an absolute threshold for all sites below which the projected radiological risk, especially for 10 CFR 61.41, would be acceptably low. The risk to the public from the land disposal of LLRW can be driven by many variables, including but not limited to, concentration of LLRW, quantity of LLRW, disposal facility design, hydrogeology, release pathways, and receptor location and behavior. It is technically challenging to reduce this multi-dimension problem into one-dimension (*i.e.,* concentrations) in a risk-informed manner. The approach proposed in this rule attempts to address this issue by providing disposal site-averaged concentrations for which the long-term radiological risk is expected to be suitably low for most facilities, but would afford flexibility for additional analyses if warranted by site-specific conditions. The draft guidance document describes the types of conditions that may warrant performance period analyses even with the disposal of low concentrations of long-lived LLRW.

The reasons for selecting this option are:

- The tiered analysis that is required allows for tailoring of the analysis to the problem.
- The 1,000 year compliance period, appropriate for the disposal of short-lived LLRW, would ensure consistency among Agreement State regulators.
- By providing a 1,000-year compliance period, it would limit speculation and limit the impact of uncertainties on the compliance period decision making.
- By providing a protective assurance period, it would ensure that radiological impacts are minimized up to 10,000 years after closure. The miminization process would strive to maintain doses below 5 mSv/yr (500 mrem/yr) thereby providing protection to the public from the disposal of long-lived LLRW.
- By providing a goal rather than a limit for the second tier (*i.e.,* between 1,000 and 10,000 years), it would recognize the uncertainty about future society and environmental characteristics and allow consideration of economic and technological arguments to justify that doses are minimized to a level that is reasonably achievable. It may be economically and technically justifiable to reduce doses well below the target.
- Selective constraints are provided while affording regulatory flexibility, where warranted.

H. Why are the 1,000-year compliance period and 10,000-year protective assurance period appropriate?

The NRC's perspective is that impacts should be reliably calculated for the compliance period. The NRC is proposing to manage the increasing uncertainties associated with long timeframes by limiting the timeframe of the analyses and the scope of the analyses. Licensing decisions should be based on information that is reasonable, reliable, and knowable based on current understanding. The proposed approach limits the consideration of uncertainties associated with long timeframes.

One of the factors underlying the proposed approach was the DU LLRW stream. The DU radiological characteristics are somewhat unique in that DU is very long-lived and there is potentially a large quantity of DU that needs to be disposed. In addition, the hazard of DU 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. The recommended approach is suitable for depleted uranium because though the impacts after 1,000 years would not be part of a compliance decision, they would be considered in the licensing process and a licensee must demonstrate that the impacts have been minimized after 1,000 years.

Performing analyses that ensure public health and safety are protected

when disposing of long-lived LLRW, and considering the information from the analyses in the decision-making process, is a risk-informed approach. However, it is not a risk-informed approach to disregard potential long-term impacts in the decision-making process because of large uncertainties without applying other regulatory requirements to ensure public health and safety will be protected. It would also not be a risk-informed approach to apply expensive and burdensome requirements on the present generation to offset hypothetical and unknown risks to generations long into the future. The proposed three-tiered approach balances these competing influences by having a 1,000-year compliance period, followed by site-specific technical analyses (minimization) for the period up to 10,000 years, and additional analyses beyond 10,000 years, when sufficient quantities and concentrations of long-lived LLRW would be disposed of. In the analyses performed in 2008 as part of the development of SECY–08–0147, the NRC staff estimated that concentrated, long-lived LLRW (*e.g.,* DU) could be disposed of in the near-surface but only in either limited quantities or under certain conditions. Without specifying regulatory requirements to either identify when the conditions for disposal are appropriate or to prevent disposal under inappropriate conditions, there may be instances when the performance objectives will not be met. Most other concentrated, long-lived LLRW in significant quantities may need some type of restrictions for near surface disposal. The proposed approach is to use site-specific technical analyses to identify what restrictions are necessary. Because waste disposal is a proposed future action, when all else fails or is too uncertain, inventory limits can be used to mitigate future risks.

I. Why is a 5 milliSievert per year (500 mrem per year) target appropriate for dose minimization during the protective assurance period?

Given the significant uncertainties inherent in demonstrating compliance with the performance objectives over a very long timeframe and to ensure a reasonable analysis, the analyses would be required to demonstrate that the annual dose should be minimized below 5 mSv (500 mrem) or a level that is supported as reasonably achievable based on technological and economic considerations from the end of the compliance period through 10,000 years. This 500 mrem/yr minimization target was chosen to limit releases to values that have been previously established by the NRC in 10 CFR part 20. For example, paragraph (e) in 10 CFR 20.1403, ''Criteria for license termination under restricted conditions,'' and paragraph (d) in 10 CFR 20.1301, ''Dose limits for individual members of the public,'' require annual dose limits of 5 milliSievert (500 mrem) in limited cases. This approach is designed to provide a target for minimization that takes into account the significant uncertainties over these long periods of time. As discussed in the guidance document, the minimization process most likely will result in projected impacts that are significantly lower then this mimization target. The NRC is seeking feedback on the proposed approach, especially with regard to whether a 5 milliSievert (500 mrem) annual dose goal is appropriate for the protective assurance period and whether it is appropriate to consider alternative, higher levels based on technological and economic considerations.

J. What are waste acceptance criteria (WAC)?

The NRC's current 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 near-surface disposal, as well as other requirements. Currently, 10 CFR 61.55 provides the primary criteria related to LLRW acceptance and identifies the classes of LLRW acceptable for near-surface disposal (*i.e.,* the LLRW classification system). Section 61.56 identifies 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, 10 CFR 61.52(a) specifies requirements for near-surface LLRW disposal facility operation, including segregation and intruder barrier requirements for various classes of LLRW. Section 61.58 currently allows for other provisions for the classification and characteristics of LLRW on a case-by-case basis if, after evaluation, the Commission finds reasonable assurance of compliance with the performance objectives.

The LLRW classification system is well integrated with the requirements for LLRW characteristics and 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.

In addition to reviewing other regulatory approaches, the NRC also considered the original regulatory basis for 10 CFR part 61 in the development of the proposed revisions to 10 CFR 61.58. The principle basis used for setting the current 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 facility. Other considerations, such as long-term environmental impacts, LLRW disposal facility 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 an analysis performed in 1981 of a representative LLRW disposal facility that was operated consistent with then-current practices and considered a projected set of 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 wasteform, the methods of emplacement, and to some extent, the site characteristics. These factors influenced the concentration of radionuclides transferred from the disposed LLRW to the access points for the intruder scenarios. These factors are dependent upon the LLRW disposed, methods of emplacement, engineering design, and site characteristics, which can vary from facility to facility.

For example, one of the factors the NRC considered is site characteristics, which plays a role in the movement of radionuclides between environmental media (*e.g.,* soil to air). The movement of radionuclides depend on the environmental conditions at the location of the LLRW disposal facility. The reference LLRW disposal facility used in the original regulatory basis was not intended to represent any particular location, but rather, it was used to reflect the typical environmental conditions within its region. The NRC chose the southeastern region because, at the time, most of the LLRW was produced in the eastern portion of the nation and was projected to be disposed regionally. Today, only one of the four operating LLRW disposal sites is located in the eastern United States; the other three are located in the arid or semi-arid western United States. The Southeastern region was selected for the reference facility location because the environmental characteristics of the reference LLRW disposal facility were

expected to be conservative compared to more arid site locations.

Regardless of whether the assumptions regarding the LLRW, operational practices, facility design, or site characteristics of the reference LLRW disposal facility are consistent with current facilities, the NRC believes that the 10 CFR part 61 LLRW classification system remains protective of public health and safety for the LLRW streams that were analyzed in the development of the regulations because of the reasonably conservative nature of the analysis used to develop the LLRW classification system. However, inconsistency between actual site conditions and practices at an LLRW 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 LLRW disposal facility are overly permissive based on actual site characteristics, facility design, and operational practices, the LLRW classification system alone may not adequately ensure the protection of public health and safety. If the Commission found that the LLRW classification requirements were overly permissive at a particular disposal facility, it could impose additional requirements to ensure that the 10 CFR part 61 performance objectives would be met. Therefore, it's the 10 CFR part 61 performance objectives that ultimately ensure protection of public health and safety. However, the inconsistency between the generic assumptions and current practices highlights the need for flexibility to develop site-specific WAC. The site-specific WAC would provide assurance that public health and safety can be protected, while offering the possibility for the relief of unnecessary regulatory burdens for facilities with superior site characteristics, design, and operational practices. The specifics of WAC background information, other regulatory approaches regarding LLRW acceptance practices, technical considerations, and public comments are discussed further in Section 5.2, ''Flexibility for Site-Specific Waste Acceptance Criteria,'' of the regulatory basis document issued in December 2012.

In addition to considering the original regulatory basis for 10 CFR part 61, the NRC also performed a review of other regulatory approaches, domestic and international, regarding LLRW acceptance practices to develop the proposed revisions to 10 CFR 61.58. In general, practices vary but are constrained between specification of criteria by the regulatory agency and development of site-specific WAC by LLRW disposal facility operators. In all cases, the regulatory authority maintains oversight of disposal, including approval of the LLRW acceptance requirements.

1. Options Considered

The NRC considered three options for revising the regulatory framework associated with waste acceptance criteria for the near-surface disposal of LLRW. In the first option, the NRC considered maintaining the current approach for determining LLRW acceptability, namely the generic LLRW classification system. The NRC staff also considered a second option, in which the current LLRW classification system is replaced with criteria allowing flexibility for licensees or license applicants to determine site-specific WAC. Finally, the NRC considered a third option that would add flexibility to establish site-specific WAC to the existing LLRW classification system. These options are summarized as follows:

Option 1. *No change from current approach.* The regulations in 10 CFR part 61 currently provide general criteria for LLRW acceptability for near surface disposal through the classification and LLRW characteristics requirements set forth in 10 CFR 61.55 and 10 CFR 61.56. Because of the conservative nature of the assumptions used in the original 10 CFR part 61 regulatory basis to develop the LLRW classification, the LLRW classification system is expected to be protective of public health and safety as long as LLRW disposal facilities operate within the regulatory basis of the original 10 CFR part 61 regulations.

However, new practices that differ from the assumptions of the original analyses create uncertainty regarding the protectiveness of the LLRW classification system. For instance, new LLRW streams that were not considered during the development of 10 CFR part 61 are being considered for disposal (*e.g.,* large quantities of concentrated DU and LLRW resulting from the production of medical isotopes). Also, current LLRW disposal facility design and operational practices can differ from the generic assumptions employed in the development of the LLRW classification system (*e.g.,* disposal of LLRW containers in concrete vaults).

Currently, 10 CFR part 61 allows for alternative provisions for LLRW acceptability (*i.e.,* LLRW classification and characterization) on a case-by-case basis through 10 CFR 61.58. Section 61.58 allows the Commission, either upon request or upon its own initiative, to authorize alternate provisions for classification or characteristics of LLRW. The requirements for LLRW classification and characteristics are found in 10 CFR 61.55 and 10 CFR 61.56, respectively. Such alternative provisions could be authorized after an evaluation showing that the specific LLRW disposal facility, and disposal method being proposed, would provide reasonable assurance of compliance with the performance objectives. Agreement States that regulate LLRW facilities would apply their own regulatory provisions in these situations.

At present, only one of the four Agreement States that has an operating near-surface LLRW disposal facility has adopted a corresponding regulation to 10 CFR 61.58. Currently, Agreement States are not required to adopt 10 CFR 61.58, therefore, the Agreement State compatibility designation for 10 CFR 61.58 must be changed in order to require Agreement States to adopt an alternative provision for LLRW classification and characteristics. Agreement State compatibility designation for 10 CFR 61.58 is discussed further in Section VI, ''Agreement State Compatibility,'' of this notice.

Option 2. *Site-specific waste acceptance approach.* Another possible approach to provide flexibility for licensees or license applicants to determine site-specific WAC would be for the NRC to abandon the existing LLRW classification system and replace it with requirements for developing site-specific WAC from the results of the site-specific technical analyses. This approach would require LLRW disposal facilities to define the acceptability of LLRW. In defining LLRW streams with acceptable radionuclide concentrations or activities and wasteforms, LLRW disposal facilities would be required to use the results of the site-specific technical analyses set forth in the proposed 10 CFR 61.13. Under the site-specific LLRW acceptance approach, licensees and license applicants would also need to develop strategies for characterizing LLRW and methods to certify that LLRW meets acceptance criteria that are commensurate with the

analyses used to derive the site-specific WAC.

Removal of the current LLRW classification system from 10 CFR part 61 would present challenges because the LLRW classification requirements are well integrated with other requirements of 10 CFR part 61. For instance, license requirements for the operation of a LLRW disposal facility may reference the LLRW classes of 10 CFR 61.55. Therefore, complete replacement of the LLRW classification system would likely expand the effect of the rule revisions beyond the intended scope of this rulemaking.

Further, removal of the LLRW classification system from 10 CFR part 61 would not result in total abandonment of the system because the classification of LLRW is referenced in the Low-Level Radioactive Waste Policy Act of 1980 (as amended in 1985). The Low-Level Radioactive Waste Policy Act of 1980 (as amended in 1985) establishes Federal and State responsibilities for the disposal of LLRW based on the LLRW classification system in 10 CFR part 61 as it existed on January 26, 1983. Specifically, Section 3 of the Low-Level Radioactive Waste Policy Act of 1980 (as amended in 1985) states that the responsibilities of each State shall include the disposal of LLRW generated within the State (other than by the Federal Government) that consists of, or contains, Class A, Class B, or Class C LLRW, as defined by 10 CFR 61.55, in effect on January 26, 1983. Likewise, the Low-Level Radioactive Waste Policy Act of 1980 (as amended in 1985) states that the Federal Government responsibilities shall include LLRW with concentrations of radionuclides that exceed the Class C limits established in 10 CFR 61.55 in effect on January 26, 1983.

Because the Low-Level Radioactive Waste Policy Act of 1980 (as amended in 1985) relies on 10 CFR part 61 as it existed in 1983, removing the LLRW classification system from 10 CFR part 61 would not change the assignment of responsibilities for the disposal of commercial LLRW to the States and Federal Government. Therefore, the existing LLRW classification system would remain relevant to assigning responsibilities to the States and Federal Government, regardless of its presence in 10 CFR part 61.

Removal of the LLRW classification system from 10 CFR part 61, however, may create confusion among stakeholders about how responsibility is assigned. One possible approach to avoid confusion would be to maintain a version of the LLRW classification system in an appendix to 10 CFR part 61, for the sole purpose of aiding in the determination of Federal and State responsibilities for the disposal of LLRW. Alternatively, the LLRW classification requirements could be included in appendix G to 10 CFR part 20, where LLRW is manifested for shipment. The purpose of appendix G to 10 CFR part 20 is to address the various regulatory information needs for the transfer and disposal of LLRW. These informational needs, which were identified in the Statement of Consideration that accompanies the final rule (60 FR 15664) include, among others, access to information needed for assessments to demonstrate compliance with the performance objectives in 10 CFR part 61. This includes information necessary for the States and Compacts to carry out their responsibilities. Therefore, preserving the LLRW classification requirements in appendix G to 10 CFR part 20 would minimize confusion for shippers to provide accurate information that allows the States and Compacts to carry out their responsibilities.

The NRC is assuming that changes to the Low-Level Radioactive Waste Policy Act of 1980 (as amended in 1985) will not be made to accommodate any revisions to the 10 CFR part 61 regulations. Instead, as previously noted, the NRC has developed a proposal that would implement this option without requiring changes to the Low-Level Radioactive Waste Policy Act of 1980 (as amended in 1985).

Option 3. *Hybrid waste acceptance approach.* A third approach that the NRC considered would be to allow licensees or license applicants to develop site-specific WAC from the results of the technical analyses or from the requirements of the existing LLRW classification system. This proposed approach would still require licensees or license applicants to determine the acceptability of LLRW. In defining LLRW streams with acceptable radionuclide concentrations or activities and wasteforms, licensees or license applicants would be allowed to use either the results of the site-specific technical analyses set forth in 10 CFR 61.13, or the LLRW classification requirements in 10 CFR 61.55. Beyond the radionuclide limits and acceptable LLRW characteristics, licensees or license applicants would, as discussed previously in the site-specific waste acceptance approach, need to develop strategies for characterizing LLRW and methods to certify that LLRW meets acceptance criteria.

For licensees that choose to develop WAC based on the LLRW classification system in 10 CFR 61.55, this approach would not result in a significant additional burden to their current operating practices since they are currently using acceptance practices with essentially the same type of criteria. Licensees typically develop these site-specific WAC from the existing 10 CFR part 61 requirements and the NRC guidance.[8] These licensees would still be required to demonstrate through the technical analyses set forth in 10 CFR 61.13 that they will meet the performance objectives. The required analyses may demonstrate that additional mitigation should be performed for certain LLRW streams, particularly those that were not considered in the development of the LLRW classification system.

Because the hybrid waste acceptance approach would not alter the LLRW classification requirements in 10 CFR part 61, the approach also would maintain consistency between the LLRW classification requirements in 10 CFR part 61 and the assignment of Federal and State responsibilities in the Low-Level Radioactive Waste Policy Act of 1980 (as amended in 1985), for the disposal of commercial LLRW. For instance, States may choose to permit the acceptance of LLRW designated as a Federal responsibility (*e.g.,* greater-than-Class-C LLRW) under the Low-Level Radioactive Waste Policy Act of 1980 (as amended in 1985), if the results of the site-specific technical analyses demonstrate that greater-than-Class-C LLRW would be acceptable for disposal at a specific disposal facility. Further, under the existing 10 CFR part 61 regulations, though States are responsible for disposal of LLRW with concentrations less than the upper limits for Class C, some States have exercised flexibility to further limit disposal of certain LLRW for which they are responsible at specific LLRW disposal facilities. The NRC proposes not to alter this flexibility under this proposed approach. In all cases, the regulatory authority maintains oversight of disposal, including approval of the LLRW acceptance requirements.

The NRC also considered whether licensees and license applicants should have the flexibility to consider alternative active institutional control periods to derive site-specific WAC, under both the site-specific waste acceptance and hybrid waste acceptance approaches. To allow this flexibility when developing site-specific WAC, the NRC would need to revise 10 CFR 61.59 to permit licensees or license applicants

[8] NRC, ''Branch Technical Position on Concentration Averaging and Encapsulation'', January 17, 1995, Division of Waste Management.

to develop site-specific WAC for periods beyond 100 years.

During the original development of 10 CFR part 61, in NUREG–0782, ''Draft Environmental Impact Statement (EIS) on 10 CFR part 61 'Licensing Requirements for Land Disposal of Radioactive Waste' '' (ADAMS Accession No. ML052590348), the NRC considered a range of time periods for active institutional controls but decided that 100 years is an appropriate period for determining how long the government would be able to ensure custodial care for a near-surface disposal facility. When the public commented that longer times would be appropriate, the NRC determined that, while the longevity of government may reasonably be assumed to extend beyond 100 years, the limit is tied to the possibility of bureaucratic error, which is more difficult to assess. For example, the government could, at some future date, unintentionally permit activities on the site as a result of an incomplete records search. The NRC indicated that it saw no compelling reason to abandon a 100-year institutional control period. Further, the institutional control period is a regulatory component of defense-in-depth by limiting the period of time over which oversight would need to be effective. Federal regulations for disposal of a variety of waste, including municipal and hazardous wastes, allow for a wide range of institutional control periods. International approaches for LLRW disposal vary for the period over which institutional controls are assumed to function, but generally they are limited to 300 years or less. Therefore, allowing unlimited flexibility would appear to be inconsistent with current international practice regarding the longevity of institutional controls.

Since the 100-year time duration is an integral assumption in the analyses that originally derived the radionuclide concentration limits set forth in 10 CFR 61.55, the hybrid waste acceptance approach would also need to maintain the current 100-year limit for licensees or license applicants that continue to use the LLRW classification system. The NRC maintains its earlier assessment and sees no new compelling reason to consider a revision to 10 CFR 61.59. Therefore, the NRC proposes to maintain the 100-year limit set out in 10 CFR 61.59.

2. NRC Proposed Option

In the proposed rule, the NRC is proposing the hybrid waste acceptance approach (Option 3) as the regulatory LLRW acceptance framework for the near-surface disposal of LLRW. The hybrid waste acceptance approach provides a framework for the use of either the generic LLRW classification system specified in 10 CFR 61.55 or the results of the technical analyses required in 10 CFR 61.13. Either approach, when combined with the other revisions recommended for this rulemaking, would provide reasonable assurance that public health and safety would be protected. The hybrid waste acceptance approach would provide a framework for determining LLRW acceptability at a disposal facility while achieving the following:

- Providing flexibility to develop site-specific WAC;
- minimizing revisions to 10 CFR part 61;
- maintaining consistency with the Low-Level Radioactive Waste Policy Act of 1980 (as amended in 1985);
- limiting additional regulatory burden on licensees and license applicants;
- providing States flexibility to exercise their regulatory authority within a national framework; and
- maintaining consistency with the range of domestic and international practices for the disposal of LLRW.

The implementation of the hybrid waste acceptance approach would require revisions to 10 CFR part 61 that allow land disposal facilities flexibility to establish site-specific WAC based either on the LLRW classification system specified in 10 CFR 61.55 or the results of the analyses required in 10 CFR 61.13 for any land disposal facility. The use of the LLRW classification system would be limited to a near surface disposal facility because the LLRW classification requirements were originally developed as technical requirements for disposal in a near-surface LLRW disposal facility. The revisions would specify the minimum content of the WAC and the proposed 10 CFR 61.52(a)(12) would limit the disposal facility to disposing only LLRW that meet the WAC.

The revisions would also require licensees or license applicants to develop approaches and methods for generators to characterize LLRW, to certify that LLRW meets acceptance criteria in order to demonstrate compliance with the WAC, and to annually review the content and implementation of the LLRW acceptance program. Requiring licensees and license applicants to specify acceptable methods to characterize LLRW, ensures that generators appropriately characterize the LLRW and that the data are sufficient to demonstrate that the disposal facility's WAC are met. Certification requirements ensure an appropriate administrative process developed by the licensees or license applicants is used by generators to demonstrate that the WAC are met, that necessary records are maintained, and that certified LLRW is managed to maintain its certification. Resource burdens associated with administrative and recordkeeping processes used to demonstrate compliance with disposal facility's WAC requirements are further discussed in Section X, ''Paperwork Reduction Act Statement,'' of this document and the accompanying draft regulatory analysis.

Additionally, implementation of the hybrid waste acceptance approach requires revisions to specific manifesting requirements specified in sections I, II, and III of appendix G to 10 CFR part 20 and the related guidance in NUREG/BR–0204, ''Instructions for Completing NRC's Uniform Low-Level Radioactive Waste Manifest'' (ADAMS Accession No. ML071870172), that provide information considered important for demonstrating compliance with the performance objectives and for States and Compacts to carry out their responsibilities under the Low-Level Radioactive Waste Policy Act of 1980 (as amended in 1985). The proposed revisions to appendix G to 10 CFR part 20 ensure that specific manifesting requirements, which were previously linked directly to the LLRW classification requirements, are revised to maintain consistency with the proposed requirements for LLRW acceptance in 10 CFR part 61. The proposed revisions to appendix G to 10 CFR part 20 also ensure that information important for States and Compacts to carry out their responsibilities under the Low-Level Radioactive Waste Policy Act of 1980 (as amended in 1985) will continue to be reported.

K. What other changes are proposed?

The NRC is proposing additional changes to the 10 CFR part 61 regulations to facilitate implementation and better align the requirements with current health and safety standards. These changes would include: (1) Adding new definitions to 10 CFR 61.2, ''Definitions,'' and updating concepts in 10 CFR 61.7; (2) implementing changes to appendix G to 10 CFR part 20, to conform to proposed LLRW acceptance requirements; (3) modifying site suitability requirements in 10 CFR 61.50, to be consistent with the proposed analyses framework; and (4) Updating the dose calculation system used in 10 CFR part 61.

1. Adding New Definitions to 10 CFR 61.2 and Updating Concepts in 10 CFR 61.7

Currently, 10 CFR 61.2 defines common terms used in 10 CFR part 61 and 10 CFR 61.7 provides conceptual information for the disposal facility LLRW classification and near-surface disposal, and licensing process for LLRW disposal facilities. These concepts include descriptions of: (a) The parameters for near-surface disposal in engineered facilities and the layout of land and buildings necessary to carry out the disposal; (b) the safety objectives for near-surface LLRW disposal, which emphasize the stability of the wasteforms and disposal sites; and (c) the licensing processes that the licensees or license applicants go through during the preoperational, operational, and site closure periods.

The NRC proposes to add definitions and concepts to 10 CFR 61.2 and 10 CFR 61.7, respectively, to support the site-specific technical analyses and LLRW acceptance requirements. These terms and concepts are needed to provide consistency and facilitate implementation of the proposed 10 CFR part 61 regulations.

The NRC is proposing to add definitions for ''compliance period,'' ''defense-in-depth,'' ''intruder assessment,'' ''long-lived waste,'' ''performance assessment,'' ''performance period,'' ''protective assurance period,'' and ''safety case'' to facilitate implementation of the proposed requirements for site-specific analyses. The definitions for the various analyses and time periods are necessary to support the requirements for the performance objectives and technical analyses. Three specific definitions deserve to be discussed in greater detail are ''long-lived waste'' because the proposed performance period analyses are only necessary for the disposal of long-lived LLRW, ''defense-in-depth'' because licensees will be required to demonstrate how the disposal facility relies upon multiple independent and redundant layers, and ''safety case'' because the requirements are central to demonstrating that public health and safety will be adequately protected at present and in the foreseeable future.

The performance period analyses are designed to be completed if a facility will be disposing of long-lived LLRW. The proposed ''long-lived waste'' definition contains three components. The first component is a radionuclide that does not decay sufficiently over the compliance period. The reason the NRC is expressing this as a percentage of initial activity of a radionuclide that remains after 10,000 years, instead of a half-life value such as 3,000 years as suggested by some members of the public, is 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, for instance, in a different country, a half-life of 3,000 years 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 the curium decay series or the isotope Am-241 which produces Np-237, a long-lived radionuclide that can be fairly mobile in the environment. The inventory of LLRW at the time of disposal can differ considerably from the inventory at future times. The ''long-lived waste'' 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 it has not previously been explicitly defined in 10 CFR part 61. Defense-in-depth is implicitly provided through the various regulatory requirements. For instance, while 10 CFR 61.59 imposes land ownership and institutional control requirements that are intended to limit the potential for intrusion into a closed 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 facility. With the potential disposal of DU and other long-lived LLRW in shallow land disposal facilities, defense-in-depth takes on additional importance and it is now being defined and explicitly used in this proposed revision to 10 CFR part 61 to provide 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, consideration of waste forms and radionuclide content, engineered features, and natural geologic features of the disposal site.

Regarding the proposed definition for ''safety case,'' licensing decisions are based on whether there is reasonable assurance that the performance objectives can 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 LLRW facility. The safety case must make a convincing conclusion that public health and safety will be adequately protected from the disposal of LLRW (including long-lived LLRW). A clear case for the safety of a disposal facility would also enhance communication among stakeholders.

2. Implementing Changes to Appendix G to 10 CFR Part 20 to Conform to Proposed 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, which were identified in the Statement of Consideration accompanying the current regulations (60 FR 15664), include access to information needed for the analyses to demonstrate compliance with the performance objectives and that the States and Compacts believe is necessary to carry out their responsibilities. In particular, manifests for LLRW shipments must identify the LLRW classification and certify that the LLRW is ''. . . properly classified, described, packaged, marked, and labeled . . . .'' Therefore, the NRC is proposing changes to these requirements to conform to the proposed addition of the LLRW acceptance requirements in 10 CFR 61.58.

To meet these needs, the requirements in appendix G to 10 CFR part 20 require shippers to properly classify, describe, package, mark, and label LLRW that will be transferred and is intended for disposal. Further, shippers must certify that these actions have been completed in accordance with the applicable requirements, including those in 10 CFR part 61 for LLRW classification (*i.e.,* 10 CFR 61.55), characteristics (*i.e.,* 10 CFR 61.56), and labeling (*i.e.,* 10 CFR 61.57). Therefore, the NRC is also proposing to amend the regulations at appendix G to 10 CFR part 20 to conform to the flexibility afforded by the proposal to determine site-specific WAC.

Specifically, sections I.C.12 and I.D.4 of appendix G to 10 CFR part 20 currently require the shipper of LLRW consigned to a LLRW disposal facility to identify the LLRW classification per 10 CFR 61.55 and to state if it meets the structural stability requirements of 10 CFR 61.56(b) on the uniform manifest. Because the proposed revisions to 10 CFR 61.58 allow a licensee or license applicant to use the classification system to develop site-specific WAC, shipping manifest requirements related to LLRW classification will be retained so that States and Compacts continue to receive information allowing them to carry out their responsibilities as defined by the Low-Level Radioactive Waste Policy Act of 1980 (as amended in 1985).

Information on LLRW acceptability at a disposal facility is essential to demonstrate compliance with the performance objectives. Therefore, the NRC proposes adding a requirement to section II of appendix G to 10 CFR part 20 to specify in the uniform manifest whether the LLRW being shipped to a disposal facility conforms to the facility's WAC. The addition of this requirement would also require a revision of NRC Form 541, ''Uniform Low-Level Radioactive Waste Manifest–Container and Waste Description,'' to conform to this new requirement and the accompanying guidance NUREG/BR–0204, Revision 2.

Further, the proposed requirements for LLRW acceptance would require revisions to the certification requirements of section II of appendix G to 10 CFR part 20. Section II requires LLRW generators, processors, or collectors to certify that the transported LLRW is properly classified. Since the proposed 10 CFR part 61 requirements would require licensees and license applicants to develop criteria for LLRW acceptability using either the existing LLRW classification system or the results of site-specific analyses, this certification requirement would be updated so that shippers are certifying that LLRW consigned to a disposal facility meets the facility's waste acceptance criteria for LLRW acceptability.

The proposed 10 CFR part 61 requirements for LLRW acceptability would also require 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 disposal facility. Specifically, current sections III.A.1 through 3 and III.C.3 through 5 require the LLRW to be classified according to 10 CFR 61.55 and meet the LLRW characteristics requirements in 10 CFR 61.56. The container must be labeled with the appropriate LLRW class, and the licensee who transfers the LLRW must implement a quality assurance program to assure compliance with 10 CFR 61.55 and 10 CFR 61.56. Since the proposed 10 CFR part 61 requirements would require licensees or license applicants to develop criteria for LLRW acceptability using either the existing LLRW classification system or the results of site-specific technical analyses, these requirements would be revised so that shippers are preparing, labeling, and providing quality assurance in accordance with the disposal facility operator's criteria for LLRW acceptability.

3. Modifying the Site Suitability Requirements in 10 CFR 61.50 To Be Consistent With the Proposed Analyses Framework

The site suitability requirements in 10 CFR 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 of this part are met, as opposed to short-term convenience or benefits. The concept of site characteristics is explained in 10 CFR 61.7. Site characteristics should be considered in terms of the indefinite future, 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 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 low concentrations of long-lived radionuclides. The NRC developed the LLRW classification framework around this concept. However, the regulation at 10 CFR 61.55(a)(6) allows long-lived LLRW not currently listed in table 1 or 2 of 10 CFR 61.55 to be disposed in the near surface as Class A LLRW.

In the proposed revision, it is recognized that not all LLRW may decay to relatively innocuous levels within 500 years and so a technical analysis would be required to determine if site-specific restriction of disposal of LLRW is necessary. The regulation at 10 CFR 61.50 would be revised to clarify the interpretation of site characteristics. The site suitability characteristics 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 any technical analyses. 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, flooding) in the next 500 years is unlikely to be defensibly characterized and 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 can 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 or applicant to meet the 10 CFR part 61 subpart C performance objectives. Historically, the other characteristics have not been associated to a significant degree 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 compared to the hydrological characteristics. The proposed revisions to 10 CFR 61.50 clarify the requirements for site suitability. Stability is a cornerstone of waste disposal. 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. Future instability of a disposal facility may prohibit accurate characterization and performance assessment modeling.

4. Updating the Dose Calculation System Used in 10 CFR Part 61

Currently, 10 CFR 61.41 requires 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.'' The objective of modeling in a performance assessment that would be

used to evaluate compliance with 10 CFR 61.41 is described in NUREG–1573, and provides estimates of doses to humans from radioactive releases from an LLRW disposal facility after it has been closed.

Currently, 10 CFR part 20 provides for the use of current NRC health physics practices for NRC licensees. In May 1991, the NRC updated 10 CFR part 20 based on a dosimetric modeling and effective dose equivalent approach described in the International Commission on Radiological Protection (ICRP) Publications 26 and 30.[9] 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 others within the regulations, stem from a method of calculating and limiting doses that date back to the late 1950s and were based on recommendations in ICRP Publication 2.[10] The NRC proposes to revise the 10 CFR part 61 regulations to require licensee to use the dose calculation methodology found in ICRP Publication 26 and allow the use of more up-to-date ICRP recommendations for dosimetry modeling purposes.

The topic of using updated dosimetry has been raised before. In the matter of the NRC's site-specific regulations for a geologic repository for high-level radioactive waste at Yucca Mountain, for example, the Commission was aware of the potential for future updates to the ICRP's recommendations that might be available following promulgation of its regulations in 10 CFR part 63, ''Disposal of High-Level Radioactive Wastes in a Geologic Repository at Yucca Mountain, Nevada.'' As a consequence, rather than index the site-specific regulations to a particular version of the ICRP, the Commission alternatively allowed the DOE to use ''. . . the most current and appropriate . . .'' dosimetry in its performance assessment calculations, without specifying which particular version or edition of that guidance to employ. Any updated radiation and organ or tissue weighting factors, however, would need to have been incorporated by the U.S. Environmental Protection Agency (EPA) into Federal radiation protection guidance. The Commission also stated that, ''Additionally, as scientific models and methodologies for estimating doses are updated, the DOE may use the most current and appropriate (*e.g.,* those accepted by the ICRP) scientific models and methodologies to calculate the TEDE. The weighting factors used in the calculation of the TEDE must be consistent with the methodology used to perform the calculation'' (74 FR 10828; March 13, 2009). The specific language in current 10 CFR 63.102(o), ''Concepts,'' reads, in part, as follows:

> After the effective date of this regulation, the Commission may allow [a licensee] to use updated factors, which have been issued by consensus scientific organizations and incorporated by EPA [U.S. Environmental Protection Agency] into Federal radiation guidance. Additionally, as scientific models and methodologies for estimating doses are updated, [a licensee] may use the most current and appropriate (*e.g.,* those accepted by the International Commission on Radiological Protection) scientific models and methodologies to calculate the TEDE. The weighting factors used in the calculation of TEDE must be consistent with the methodology used to perform the calculation.

The topic of using updated methodology and terminology was also addressed by the Commission in SRM–SECY–12–0064, ''Recommendations for Policy and Technical Direction to Revise Radiation Protection Regulations and Guidance,'' dated December 17, 2012 (ADAMS Accession No. ML12352A133). The Commission approved the staff's development of the regulatory basis for a revision to 10 CFR part 20 to align with the most recent methodology and terminology for dose assessment. The Commission further directed that appropriate steps should be undertaken to assure that conforming changes are made as soon as practical to make these methods consistent throughout all NRC regulations.

During the development of the regulatory basis that supports this rulemaking, the majority of the public commenters supported the proposal to allow licensees or license applicants the flexibility to use the latest ICRP dose methodologies in a site-specific performance assessment. However, some people questioned the value and the safety significance in removing critical organ dose limits in updating the dose limits in 10 CFR 61.41.

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, whether the worker or member of the public is exposed from external radiation, inhalation, ingestion, or some combination of these. Because an effective dose methodology compares, and more importantly, sums the doses from different organs, exposure routes, and radionuclides, an overall risk is evaluated. This was not possible with the critical organ system provided by the ICRP Publication 2. When the ICRP Publication 2 was developed, organ weighting factors were unknown. The doses to different organs, in the critical organ system, do not account for the radiosensitivity of the organ, nor did the system use the wider range of organs and tissues evaluated with modern approaches. A holistic approach provides a large benefit in LLRW disposal dose assessment because of the range of radionuclides that co-mingled within the LLRW. Each radionuclide has its own predominant exposure pathway and dose rate, depending on the manner in which a member of the public may get exposed. Without a holistic method that sums the total exposures across exposure pathways and radionuclides, a risk-informed, performance-based decision is harder to make, as the doses between scenarios or situations would not be comparable especially when one is trying to optimize the resources to provide maximum protection within the disposal system.

The critical organ dose approach was developed to limit doses from the intake of radioactive materials. In the critical organ dose approach, doses to a limited number of individual organ systems were calculated based on models of the movement of elements within the human body. For example, iodine collects mainly in the thyroid, ingested uranium provides doses largely to the bones and kidneys, ingested cesium provides doses to multiple organ systems with total body or liver being the critical organ.[11] However, the potential result of a dose to a specific organ was not well-known at the time. Without this radiosensitivity information, doses could not be added together to evaluate the overall risk to the individual from radionuclides present in multiple organs. In addition, any external dose was only added to the ''whole body'' critical organ (which is not directly comparable to the TEDE in the ICRP Publication 26 or later

[9] ICRP, ''Recommendations of the International Commission on Radiological Protection,'' Annals of the ICRP, Vol. 1, No. 3, 1977, (ICRP Publication 26); ICRP, ''Limits for Intakes of Radionuclides by Workers,'' Annals of the ICRP (Part 1), Vol. 2, Nos. 3–4, 1979, (ICRP Publication 30).

[10] ICRP, ''Report of ICRP Committee II on Permissible Dose for Internal Radiation (1959), with Bibliography for Biological, Mathematical and Physical Data,'' Health Physics, Vol. 3, [1959], (Reprinted in 1975 as ICRP Publication 2).

[11] Battelle Pacific Northwest Laboratories, ''Age-Specific Radiation Dose Commitment Factors for a One-Year Chronic Intake,'' NUREG–0172, NRC, November 1977 (Adams Accession No. ML14083A242).

publications). Because of the uncertainty, limits for the public were developed that gave each of the organs equal weighting, except the thyroid (for which some data was available). In the final rule for 10 CFR part 20 (56 FR 23360), the NRC responded to comments about proposed appendix B as follows:

> The former ICRP–2 ''critical organ'' concept based the limiting intake upon controlling the dose rate to the organ receiving the highest dose rate (the ''critical organ''). The doses to organs other than the critical organ did not have to be evaluated, even if these doeses [sic] were close to the estimated dose to the critical organ.

The TEDE approach, recommended in ICRP Publication 26, and subsequently updated by ICRP Publication 60 and ICRP Publication 103, uses a different approach to limiting the risk from radiation. Because more information on the risk associated with dose to specific organs exists, it is possible to calculate the overall increased risk of stochastic effects (*e.g.,* cancer) to an individual. Each of the major organ or tissue systems and the six remaining highest organs or tissues were assigned weighting factors based on the age and gender averaged risk for each organ or tissue. The internal dose to each organ system from an intake of a radionuclide, or mixture of radionuclides, is calculated, multiplied by the appropriate weighting factor, and then the results are summed to give a risk-weighted ''effective dose.'' To calculate the TEDE, the external dose is added to the risk-weighted effective dose. This radiation protection system therefore reflects the doses to all principal organs or tissues that are irradiated, not just the one organ that receives the highest dose, as was done in 10 CFR part 20 before 1991.

In the TEDE approach, the dose to individual organs also needs to be considered to ensure that deterministic effects do not occur. For this reason, an organ limit of 0.5 Sv (50 rem) is applied in addition to the TEDE dose limit for workers of 50 mSv (5 rem). Because the dose limit in 10 CFR part 20 for a member of the public is 50 times less than the occupational limit, the same concern for deterministic effects in organs does not occur. As noted in appendix B to 10 CFR part 20, ''Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage,'' consideration of nonstochastic effects is unnecessary at the dose levels established for members of the public because the organ dose can never reach the organ limit for the nonstochastic effects of 0.5 Sv/year (50 rem/year), without the TEDE dose being greater than the public dose limit (or any fraction of the public dose limit stated in 10 CFR 61.41(a)). Therefore, in modifying a dose limit such as 10 CFR 61.41(a) to be consistent with 10 CFR part 20, organ dose limits are unnecessary. The TEDE approach protects all the organ systems and provides adequate protection to members of the public, from both individual radionuclides, as well as multiple radionuclides through all exposure routes (*i.e.,* external, inhalation, and ingestion). In addition, the proposed regulations in 10 CFR 61.41(b) and 10 CFR 61.42(b) do provide a pathway for a licensee to exceed the proposed minimization target of 5 milliSieverts per year (500 millirems per year) by demonstrating a level that is supported as reasonably achievable based on technological and economic considerations. However, the NRC does not anticipate that technological and economic considerations could justify a target that would necessitate the consideration of nonstochastic effects.

The NRC considered the following three options to revise the 10 CFR part 61 regulations to allow the use of more up-to-date ICRP recommendations for dosimetry modeling purposes:

Option 1. *No change from current approach.* The NRC considered allowing the rule to remain silent on this matter and address the issue in the accompanying LLRW performance assessment guidance.

Option 2. *Edition-specific approach.* The NRC considered requiring a dose calculation approach found in ICRP Publication 26 and specifying in the regulations which version of the ICRP the licensees or license applicants should implement in any 10 CFR part 61 license application.

Option 3. *Edition-neutral approach.* The NRC considered requiring a dose calculation approach found in ICRP Publication 26 and adopting an edition-neutral approach, to allow the use of more up-to-date ICRP recommendations, for dosimetry modeling purposes.

The NRC is proposing to adopt option 3, the edition-neutral approach, for the revision of the 10 CFR part 61 regulations, to allow the use of more up-to-date ICRP recommendations for dosimetry modeling purposes. The NRC favors this approach because it has already approved and implemented this particular type of regulatory approach in its 10 CFR part 63 regulations. As the ICRP's recommendations have historically been updated more frequently than the Commission's LLRW regulations, adopting an edition-neutral approach in the regulations would obviate the need for updating 10 CFR part 61 at some future date in response to some comparable update to Federal radiation protection guidance and the associated ICRP recommendations provided that the guidance and the ICRP recommendation continue to ensure the Agency's approach to adequate protection. Licensees would need to use the dose calculation method required in 10 CFR part 20 (currently based on ICRP Publication 26). Since 10 CFR part 61 would not refer to a specific dose calculation method, the general radiation protection regulations of 10 CFR part 20 would apply.

5. Implementing the Safety Case in 10 CFR Part 61

Licensees are responsible for demonstrating that their land disposal facilties are constructed, operated, and closed safely. To this end, 10 CFR part 61 establishes requirements that licensees must meet to demonstrate that a land disposal facility will be constructed, operated, and closed so as to provide reasonable assurance that public health and safety and the environment will be protected. While the NRC believes that the existing requirements specified in 10 CFR 61.10 through 10 CFR 61.16, 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 regulations do not explicitly establish requirements for the development of a safety case.

The safety case concept in the context of radioactive waste disposal, which has been developed internationally, is generally regarded as a collection of arguments and evidence to demonstrate the safety and performance of a 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 of the safety related work associated with the 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 site, the design of the facility, and the managerial control measures and regulatory controls to inform the decision whether to grant a license for the disposal of LLRW and provide the public assurance that the facility will be

designed, constructed, operated, and closed safely.[12]

The NRC believes that the current 10 CFR part 61 implicitly includes components of the safety case concept. For instance, an important component of the international safety case concept is the safety assessment, which consists of the assessment of radiological impacts as well as an analysis of site and engineering aspects and operational safety. Currently, the NRC's regulations at 10 CFR 61.13 require analyses that achieve the intent of a safety assessment.

The safety case, as specified in the proposed requirements, would include the same type of information currently required to be submitted as part of a license application. To explicitly ensure that a robust safety case is made for each disposal facility, the NRC is proposing requirements that licensees prepare a safety case that demonstrates the assessment of the safety of a land disposal facility. In explicitly specifying a requirement for a safety case, the NRC is proposing to require the incorporation of the safety assessment and defense-in-depth components into the safety case.

The revised regulations would incorporate the 10 CFR 61.13 analyses into the licensee's safety case. Further, the proposed regulations also would require new defense-in-depth analyses in 10 CFR 61.13 which would add an explicit assessment of defense-in-depth provisions to the proposed safety case. Finally, the NRC envisions that the safety case for a land disposal facility would evolve over time as new information is gained during the various phases of the facility's development and operation. Therefore, the NRC expects that the safety case will be updated as new information that could significantly impact safety of the facility is learned and is proposing that the application for closure of a licensed land disposal facility must include a final revision to the safety case.

L. What guidance document will be available?

As previously noted, the NRC is making available for public comment a draft guidance document, ''Guidance for Conducting Technical Analyses for 10 CFR part 61'' (Docket ID NRC–2015–0003), concurrent with this proposed rule. The draft guidance document is intended to supplement existing guidance on performance assessment (*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 would be added to 10 CFR part 61 by this rulemaking. The draft guidance covers performance assessment topics such as source term, radionuclide transport, consideration of uncertainty, and model support. It also represents detailed guidance on conducting technical analyses, such as intruder assessment, analysis of site stability after closure of the disposal site, a performance period analysis for the disposal site beyond the compliance period, and an analysis demonstrating the disposal facility includes defense-in-depth protections. Additionally, the document 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. The document also contains guidance on conducting risk-informed, performance-based analyses; general technical analysis considerations, such as the incorporation of features, events, and processes into performance assessments; as well as other considerations, such as setting inventory limits, mitigation techniques, and demonstration of defense-in-depth.

M. Are there any cumulative effects of regulation associated with this proposed rule?

In the SRM to SECY–11–0032, ''Consideration of the Cumulative Effects of Regulation in the Rulemaking Process'' (ADAMS Accession No. ML112840466), dated October 11, 2011, the Commission provided direction to the staff on issues related to the implementation of the cumulative effects of regulation process enhancements. The concept of cumulative effects of regulation describes the challenges that licensees, or other impacted entities (such as State partners) face while implementing new regulatory positions, programs, and requirements (*e.g.,* rules, generic letters, backfits, or inspections). Cumulative effects of regulation is an organizational effectiveness challenge that results from a licensee or impacted entity implementing a number of complex positions, programs or requirements within a limited implementation period and with available resources (which may include limited available expertise to address a specific issue). Cumulative effects of regulation can potentially distract licensees from executing other primary duties that ensure safety or security. The NRC is specifically requesting comment on the cumulative effects of this rulemaking. In developing comments on cumulative effects of regulation, consider 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?

N. Request for Additional Public Comments

The NRC is requesting public comment on the following questions:

- Is the proposed three-tiered approach (a compliance period, followed by a protective assurance period, followed by a performance period, if applicable) appropriate?
- Is 500 mrem/yr an appropriate analytical threshold for the protective assurance period?
- Should there be a quantitative goal or dose limit associated with the performance period analysis, and if so, what should that goal or dose limit be?
- Is Compatibility Category B appropriate for the compliance period, protective assurance period, and the waste acceptance criteria?

P. What should I consider as I prepare my comments to submit to the NRC?

When submitting your comments, remember to:

[12] IAEA Safety Standards Series No. SSG–23. The Safety Case And Safety Assessment For The Disposal Of Radioactive Waste Specific Safety Guide International Atomic Energy Agency Vienna, 2012.

• Identify the rulemaking with the Regulation Identifier Number (RIN 3150–AI92) and NRC Docket ID (NRC–2011–0012).
• Explain why you agree or disagree with the proposed revisions, and suggest alternatives and substitute language to the proposed changes.
• Describe any assumptions and provide any technical information or data that support your comments.
• If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
• Provide specific examples to illustrate your concerns, and suggest alternatives.
• Explain your views as clearly as possible.
• Make sure to submit your comments by the comment period deadline.
• The NRC is particularly interested in your comments concerning the issues raised in Section Ill, Discussion, of this notice. In addition, the NRC is requesting comment on the information in the following sections of this document: (1) Section VI, Agreement State Compatibility; (2) Section VII, Plain Writing; (3) Section IX, Draft Environmental Assessment and Draft Finding of No Significant Environmental Impact; (4) Section X, Paperwork Reduction Act Statement; (5) Section XI, Regulatory Analysis; and (6) Section XII, Regulatory Flexibility Certification.

IV. Discussion of Proposed Amendments by Section

Section 20.1003 Definitions

Section 20.1003 defines common terms used in 10 CFR part 20. The NRC is proposing to revise 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

Currently, 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. Since 10 CFR 61.58 would require licensees to develop criteria for LLRW acceptability, using either the existing LLRW classification system or the results of site-specific technical analyses, the NRC proposes to revise the requirements in section II so that shippers are certifying that LLRW consigned to a disposal facility meets the facility's criteria for LLRW acceptability. Section II would also be revised to enhance its readability.

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

Currently, section III of appendix G to 10 CFR part 20 places requirements on the control and tracking of LLRW transferred to a disposal facility. Currently, sections III.A and III.C only require the LLRW to be classified according to 10 CFR 61.55 and meet the LLRW characteristic requirements in 10 CFR 61.56, and does not provide requirements for compliance with the WAC of the proposed 10 CFR 61.58. Since the amended rule would require site-specific technical analyses, and then have LLRW disposal licensees develop criteria for LLRW acceptability using either the existing LLRW classification system or the results of site-specific technical analyses, the NRC proposes to revise 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 disposal facility operator's criteria for LLRW acceptability, if applicable.

Section 61.2 Definitions

Section 61.2 defines common terms used in 10 CFR part 61. The NRC is proposing to make the following revisions: (1) Revise the definitions of ''site closure and stabilization'' and ''stability'' to correct misspellings; (2) revise the definition of ''inadvertent intruder'' to include the phrase ''reasonably foreseeable'' to limit speculation of the analyses; and (3) revise 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. The NRC is also proposing to add definitions for ''compliance period,'' ''defense-in-depth,'' ''intruder assessment,'' ''long-lived waste,'' ''performance assessment,'' ''performance period,'' ''protective assurance period,'' and ''safety case'' to facilitate implementation of the proposed requirements for site-specific analyses. For more information on ''compliance period,'' ''defense-in-depth,'' ''intruder assessment,'' ''long-lived waste,'' ''performance assessment,'' ''protective assurance analysis,'' ''protective assurance period,'' and ''safety case,'' see Section III, Discussion, of this document.

Section 61.7 Concepts

Currently, 10 CFR 61.7 provides conceptual information for the licensing of a 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 wasteforms and disposal sites. Paragraph 61.7(c) describes the licensing processes that the applicant and licensee must complete during the preoperational, operational, and site closure periods.

The NRC proposes to revise 10 CFR 61.7(a)(1) and 10 CFR 61.7(a)(2) to enhance readability. An additional sentence would be added to clarify that the additional technical criteria may be developed on a case-by-case basis for land disposal techniques that are not explicitly considered in 10 CFR part 61.

The NRC proposes to redesignate paragraphs (b)(1), (b)(2) through (b)(5), and (c) as paragraphs (b), (f), and (g), respectively. The NRC proposes to revise redesignated paragraphs (b), (f), and (g) to enhance the readability of these paragraphs. Additionally, paragraph (b) would be revised to describe the performance objectives of the 10 CFR part 61 regulations. Paragraph (f)(1) would be 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. Paragraph (f)(2) would be revised to clarify that the effective life of these intruder barriers should be at least 500 years and an additional sentence would be 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 10 CFR 61.13. Paragraph (f)(3) would be revised to clarify that waste that will not decay to levels which present an acceptable hazard to an intruder within 100 years is typically designated as Class C waste. Also paragraph (f) would provide conceptual

information on the requirement for enhanced controls or limitations at a particular LLRW disposal facility to provide reasonable assurance that the LLRW will not present an unacceptable risk over the compliance period. Paragraph (g) would be revised to include the concept of a safety case in the licensing process.

The NRC proposes to add new paragraphs (b), (c), (d), and (e) to 10 CFR 61.7. Proposed 10 CFR 61.7(c) would provide conceptual information for demonstrating compliance with the performance objectives of the technical analyses, which include a performance assessment and an intruder assessment, and performance period analyses for waste containing significant concentrations and quantities of long-lived radionuclides. Additionally, proposed paragraph (c)(5) would provide conceptual information on the requirement for the use of dose methodology that is consistent with those set forth in 10 CFR part 20 and would also describe the flexibility of the licensees' ability to consistently use the latest dose methodology to demonstrate compliance with the performance objectives.

Proposed 10 CFR 61.7(d) would provide conceptual information on the role of defense-in-depth protections with respect to LLRW disposal. Proposed 10 CFR 61.7(e) would provide conceptual information for demonstrating compliance with the performance objectives through a determination of criteria for the acceptance of LLRW.

Section 61.8 Information Collection Requirements: OMB Approval

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

The NRC proposes to revise 10 CFR 61.8(b) to include 10 CFR 61.41 and 61.42.

Section 61.10 Content of Application

Currently, 10 CFR 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 10 CFR 61.11 through 61.16 and an environmental report.

The NRC is proposing to divide this section into two paragraphs, assigned as paragraphs (a) and (b). Paragraph (a) would retain the current rule language. Paragraph (b) would be added to convey that the information provided in an application comprises the safety case, supports the licensee's demonstration that the disposal facility will be constructed and operated safely, and provides reasonable assurance that the disposal site will be capable of meeting the performance objectives.

Section 61.12 Specific Technical Information

Currently, 10 CFR 61.12 lists specific technical information that must be included in an application for a 10 CFR part 61 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, ''Technical requirements for land disposal facilities,'' would 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 proposes to revise the introductory text of this section to enhance its readability and identify that the specific technical information supports the safety case. The NRC also proposes to revise 10 CFR 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 transportation of long-lived radionuclides and the long-term erosion of the disposal site, respectively. Paragraphs 61.12(e) and (g) would be revised to enhance the readability of these sections. Proposed 10 CFR 61.12(i) would require applicants to include the criteria for acceptance of LLRW for disposal, and 10 CFR 61.12(j) would require applicants to include the development of technical analyses to the description of the quality assurance program.

Section 61.13 Technical Analyses

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

Currently, 10 CFR 61.13 does not specify the safety case and does not indicate how existing licensees would be captured in the requirements to conduct the 10 CFR 61.13 site-specific technical analyses. The NRC proposes to revise the introductory text of 10 CFR 61.13 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 10 CFR 61.13 to demonstrate that the performance objectives of subpart C will be met. Licensees with licenses for land disposal facilities in effect on the effective date of this subpart must submit these analyses at the next license renewal or within 5 years of the effective date of this subpart, whichever comes first.

Currently, 10 CFR 61.13(a) does not require considerations of features, events, and processes that can influence the ability of the LLRW disposal facility to limit the releases of radioactivity to the environment; these features, events, and processes are important elements of a performance assessment. The NRC proposes to revise 10 CFR 61.13(a) to require a licensee or applicant prepare a performance assessment to demonstrate compliance with the proposed dose limit in 10 CFR 61.41(a) during the compliance period and a dose goal in 10 CFR 61.41(b) during the protective assurance period. The performance assessment would be required to consider features, events, and processes which can influence the ability of the disposal facility to meet the performance objectives, evaluate environmental pathways, account for uncertainty, consider alternative conceptual models, and identify and differentiate the roles performed by site characteristics and design features of the disposal facility. Further, the proposed revisions to 10 CFR 61.13(a) would require that the performance assessment used to demonstrate compliance with a new 10 CFR 61.41(b) during the protective assurance period reflect new features, events, and processes different from those in the compliance period only if scientific information compelling such changes is available.

In addition, the NRC proposes a new subparagraph 10 CFR 61.13(a)(4) to further clarify that the performance assessment must reflect new features, events, and processes different from the compliance period that address significant uncertainties inherent in the long timeframes associated with demonstrating compliance with § 61.41(b) only if scientific information compelling such changes is available.

Currently, 10 CFR 61.13(b) requires an applicant to prepare analyses that demonstrate there is reasonable assurance an applicant will meet the LLRW classification and segregation requirements and that it will provide adequate barriers to inadvertent intrusion. The NRC proposes to revise 10 CFR 61.13(b) to require a site-specific intruder assessment to demonstrate the protection of inadvertent intruders. The

intruder assessment would be required to assume an intruder occupies the site and engages in normal activities that are consistent with activities in and around the site at the time of closure, identify adequate intruder barriers and provide a basis for the time period that they are effective, and account for uncertainty and variability. The NRC also proposes to revise the term ''analyses of the protection of individuals from inadvertent intrusion'' to ''inadvertent intruder analyses.'' This paragraph would also be revised to enhance its readability.

Currently, 10 CFR 61.13(d) requires an applicant to prepare analyses that demonstrate long-term stability of the site and the need for ongoing active maintenance after closure. However, the analyses are not currently required to provide reasonable assurance that long-term stability of the disposal site can be ensured. The NRC is proposing to require that the analyses also provide reasonable assurance that long-term stability of the disposal site can be ensured.

The NRC proposes to add a new paragraph (e) to 10 CFR 61.13 to require licensees and applicants to prepare performance period analyses that assess how the disposal facility and site characteristics limit the potential long-term radiological impacts, consistent with available data and current scientific understanding. The analyses would be required for LLRW disposal facilities with long-lived LLRW that contains radionuclides with average concentrations exceeding the values listed in proposed table A of 10 CFR 61.13(e), or if necessitated by site-specific conditions. The analyses would identify and describe the features of the design and site characteristics that will demonstrate that the performance objectives set forth in 10 CFR 61.41(b) and 10 CFR 61.42(b) will be met. The NRC also proposes to include table A in this paragraph to facilitate the implementation of this requirement.

Finally, the NRC proposes to add a new paragraph (f) to 10 CFR 61.13 to require licensees and applicants to prepare analyses that demonstrate the land disposal facility includes defense-in-depth protections. The analyses would identify and describe the features of the design and site characteristics that provide multiple independent and redundant layers of defense so that no single layer, no matter how robust, is exclusively relied upon during operations of the facility and after closure during the compliance period, protective assurance period, or performance period.

Section 61.23 Standards for Issuance of a License

Currently, 10 CFR 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 proposes to revise 10 CFR 61.23(b), (c), (d), and (e) to include the proposed WAC in the list of standards for issuance of a license. In addition, the NRC proposes to add a new paragraph (m) to 10 CFR 61.23 that adds a safety case as one of the standards for issuance of a license.

Section 61.25 Changes

Currently, 10 CFR 61.25 provides restrictions on the licensee to make changes in the LLRW disposal facility procedures described in the license application.

The NRC proposes to revise 10 CFR 61.25(a) to correct a misspelling, and 10 CFR 61.25(b) to include a provision restricting changes to the WAC.

Section 61.28 Contents of Application for Closure

Currently, 10 CFR 61.28 lists items that must be included in an application for 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.

Proposed revisions to 10 CFR 61.28(a) would add a requirement to submit a final revision to the safety case, which would be required in the proposed revisions in 10 CFR 61.10, and require licensees to provide updated site-specific technical analyses, which would be required in the proposed revisions in 10 CFR 61.13, using the details of the final closure plan and LLRW inventory as would be required in the proposed revisions in 10 CFR 61.13. Under current 10 CFR 61.28(c), which is not being amended by this rulemaking, the NRC can only authorize closure of the LLRW disposal facility if there is reasonable assurance that the long-term performance objectives of subpart C will be met. As a result of the proposed revision to 10 CFR 61.28(a), licensees may be required to take additional action prior to closure to ensure that the LLRW that has already been disposed, including large quantities of depleted uranium 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

Currently, 10 CFR 61.41 specifies a dose limit (organ and whole body equivalent) 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 proposes to revise 10 CFR 61.41 by adding paragraphs (a), (b), and (c). Proposed 10 CFR 61.41(a) would retain the dose limits and the ALARA concept during the compliance period, and would be updated to use a dose methodology that is consistent with the dose methodology used in 10 CFR part 20. Compliance with the proposed 10 CFR 61.41(a) would be demonstrated through analyses that meet the requirements specified in the proposed 10 CFR 61.13(a).

Proposed 10 CFR 61.41(b) would require that the licensee minimize releases of radioactivity from a disposal facility to the general environment during the protective assurance period. Proposed 10 CFR 61.41(b) would specify that an annual dose, established on the license, shall be below 5 milliSieverts (500 millirems) or a level that is supported as reasonably achievable based on technological and economic considerations in the information submitted for review and approval by the Commission. Compliance with this paragraph must be demonstrated through analyses that meet the requirements specified in 10 CFR 61.13(a).

Proposed 10 CFR 61.41(c) would require that the licensee make an effort to minimize releases of radioactivity from a disposal facility to the general environment to the extent reasonably achievable at any time during the performance period. Compliance with the proposed 10 CFR 61.41(c) would be demonstrated through analyses that meet the requirements specified in the proposed 10 CFR 61.13(e).

Section 61.42 Protection of Inadvertent Intruders

Currently, 10 CFR 61.42 requires the facility to be designed, operated, and closed to ensure the protection of any inadvertent intruder after the lifting of institutional controls.

The NRC proposes to revise 10 CFR 61.42 by adding new paragraphs (a), (b), and (c). Proposed 10 CFR 61.42(a) would retain the current regulatory language and would be updated to add an annual dose limit of 5 mSv/yr (500 mrem/yr) for the intruder assessment during the compliance period.

Compliance with the proposed 10 CFR 61.42(a) paragraph would be demonstrated through analyses that meet the requirements specified in the proposed 10 CFR 61.13(b).

Proposed 10 CFR 61.42(b) would require that the licensee minimize exposures to any inadvertent intruder during the protective assurance period. Proposed 10 CFR 61.42(b) would also specify that an annual dose, established on the license, shall be below 5 milliSieverts (500 millirems) or a level that is supported as reasonably achievable based on technological and economic considerations in the information submitted for review and approval by the Commission. Compliance with this paragraph must be demonstrated through analyses that meet the requirements specified in 10 CFR 61.13(b).

Proposed 10 CFR 61.42(c) would require that the licensee make an effort to minimize exposures to any inadvertent intruder to the extent reasonably achievable at any time during the performance period. Compliance with the proposed 10 CFR 61.42(c) would be demonstrated through analyses that meet the requirements specified in the proposed 10 CFR 61.13(e).

Section 61.44 Stability of the Disposal Site After Closure

Currently, 10 CFR 61.44 requires the 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 closure so that only surveillance, monitoring, or minor custodial care are required.

The NRC proposes to revise 10 CFR 61.44 to specify that stability of the disposal site must be demonstrated for the compliance and protective assurance periods.

Section 61.50 Disposal Site Suitability Requirements for Land Disposal

Currently, 10 CFR 61.50 specifies site suitability requirements for the minimum characteristics a disposal site must possess to be acceptable for use as a near-surface LLRW disposal facility. Site suitability requirements play an integral role in ensuring that the site is appropriate for the type of LLRW proposed for disposal.

The NRC proposes to revise 10 CFR 61.50 to clarify the interpretation of site characteristics. The technical content of the site suitability characteristics would not be changed. However, the site suitability characteristics would be reorganized to distinguish the hydrological site characteristics from other characteristics.

Section 61.51 Disposal Site Design for Land Disposal

Currently, 10 CFR 61.51 specifies disposal design requirements for a near-surface LLRW disposal facility. Site design requirements play an integral role in ensuring that the site is appropriate for the type of LLRW proposed for disposal.

The NRC proposes to revise 10 CFR 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 continuing active maintenance after site closure.

Section 61.52 Land Disposal Facility Operation and Disposal Site Closure

Currently, 10 CFR 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 proposes to revise 10 CFR 61.52(a)(3) and (a)(8) to enhance its readability and to conform to the proposed new requirements in 10 CFR 61.52(a)(12) and (a)(13).

The NRC proposes to add new paragraphs (a)(12) and (a)(13). Proposed 10 CFR 61.52(a)(12) would only allow the disposal of LLRW meeting the disposal facility's LLRW acceptance criteria, and proposed 10 CFR 61.52(a)(13) would require licensees to prepare updated site-specific analyses using the details of the final closure plan and LLRW inventory.

Section 61.55 Waste Classification

The NRC proposes to revise 10 CFR 61.55(a)(6) to enhance its readability. The change would not alter the meaning or intent of this regulation.

Section 61.56 Waste Characteristics

Currently, 10 CFR 61.56(a) lists minimum requirements for all classes of LLRW, intended to facilitate handling at the disposal site and provide protection of health and safety of personnel at the disposal site.

The NRC proposes to revise 10 CFR 61.56(a) to replace the phrase ''all classes of wastes'' with the phrase ''all waste'' which includes all classes of LLRW and WAC.

Section 61.57 Labeling

Currently, 10 CFR 61.57 requires the listing of LLRW class in accordance with 10 CFR 61.55 and does not reference the proposed WAC.

The NRC proposes to revise 10 CFR 61.57 to include any information required by the land disposal facility's criteria for LLRW acceptance developed according to 10 CFR 61.58.

Section 61.58 Waste Acceptance

Currently, 10 CFR 61.58 grants exemptions for the classification and characterization of LLRW, on a case-by-case basis, if the Commission finds reasonable assurance of compliance with the performance objectives. In the proposed rule, the alternative requirements in 10 CFR 61.58 would be replaced by the proposed LLRW acceptance requirements.

The NRC proposes to retitle and revise 10 CFR 61.58 to specify the minimum content of the WAC and require disposal facility licensees to develop approaches for generators to characterize LLRW and methods for generators to certify that such LLRW meets the acceptance criteria for demonstration compliance with the site-specific WAC. Proposed 10 CFR 61.58 would also require licensees to annually review their LLRW acceptance plan and to comply with 10 CFR 61.20 when modifying their approved WAC. Additionally, the new regulatory language would indicate that the NRC would incorporate, where consistent with State and Federal law, the WAC into existing licenses.

Section 61.80 Maintenance of Records, Reports, and Transfers

Currently, 10 CFR 61.80 requires the licensee to keep records on the LLRW received for disposal, to provide annual reports of site 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 proposes to restructure 10 CFR 61.80(i)(2) to meet codification requirements of the Office of the Federal Register. In 10 CFR 61.80(i)(1), the erroneous reference to 10 CFR 60.4 would be corrected to reference 10 CFR 61.4.

The NRC also proposes to add a new paragraph (m) to 10 CFR 61.80. This addition would require licensees and license applicants to maintain their provisions for LLRW acceptance and audits and other reviews of program content and implementation.

V. Criminal Penalties

For the purpose of Section 223 of the AEA, the NRC is proposing to amend 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.

VI. Agreement State Compatibility

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** (62 FR 46517; September 3, 1997), this proposed rule would be a matter of compatibility between the NRC and the Agreement States, which would ensure consistency between the Agreement State requirements and the NRC requirements. The NRC staff analyzed the proposed rule in accordance with the procedure established in Part III, ''Categorization Process for NRC Program Elements,'' of the Handbook for Management Directive 5.9, ''Adequacy and Compatibility of Agreement State Programs'' (*see http://www.nrc.gov/reading-rm/doc-collections/management-directives/*).

The NRC program elements (including regulations) are placed into four compatibility categories (see the proposed compatibility table in this section). In addition, the NRC program elements can be identified as having particular health and safety significance or as being reserved solely to the NRC. Compatibility Category A applies to 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 should adopt Compatibility Category A program elements in an essentially identical manner to provide uniformity in the regulation of agreement material on a nationwide basis. Compatibility Category B includes those program elements that apply to activities that have direct and significant effects in multiple jurisdictions. An Agreement State should adopt Compatibility Category B program elements in an essentially identical manner. Compatibility Category C includes those program elements that do not meet the criteria of Compatibility Categories A or B, but reflect essential objectives that 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 nationwide basis. An Agreement State should adopt the essential objectives of the Compatibility Category C program elements. Compatibility Category D applies to those program elements that do not meet any of the criteria of Compatibility Categories A, B, or C and, therefore, do not need to be adopted by Agreement States for compatibility.

Health and Safety (H&S) program elements are elements that are not required for compatibility, but are identified as having a particular health and safety role (*i.e.,* adequacy) in the regulation of agreement material within the State. Although not required for compatibility, the State should adopt program elements in this H&S category based on those elements that embody the essential objectives of the NRC program elements because of particular health and safety considerations. Compatibility Category NRC contains those program elements that address areas of regulation that cannot be relinquished to Agreement States under the Atomic Energy Act or 10 CFR. These program elements are not adopted by Agreement States.

Proposed definition ''compliance period'' in 10 CFR 61.2 would be assigned to Compatibility Category B. The NRC believes the program elements of this definition need to be adopted to ensure a consistent regulatory approach across the Nation and inconsistent definitions of this term would have direct and significant transboundary implications. Proposed definition ''defense-in-depth'' in 10 CFR 61.2 would be assigned to Compatibility Category H&S. The NRC believes the essential objectives of this definition need to be adopted to ensure consistent application of 10 CFR 61.41 and 10 CFR 61.42. Proposed definition of ''intruder assessment'' in 10 CFR 61.2 would be assigned to Compatibility Category H&S. The NRC believes that the H&S compatibility designation of this definition is appropriate to support paragraphs 61.13(a) and 61.13(b). Proposed definition of ''long-lived waste'' in 10 CFR 61.2 would be assigned to Compatibility Category B because inconsistent definitions of this term could have direct and significant effects in multiple jurisdictions. Proposed definition ''performance period'' in 10 CFR 61.2 would be assigned to Compatibility Category C. The NRC believes the essential objectives of this definition need to be adopted to ensure consistent application of 10 CFR 61.41 and 10 CFR 61.42. Proposed definition of ''performance assessment'' in 10 CFR 61.2 would be assigned to Compatibility Category H&S. The NRC believes that the H&S compatibility designation of this definition is appropriate to support paragraphs 61.13(a) and 61.13(b). Proposed definition ''protective assurance period'' in 10 CFR 61.2 would be assigned to Compatibility Category B. The NRC believes the program elements of this definition need to be adopted to ensure a consistent regulatory approach across the Nation and inconsistent definitions of this term would have direct and significant transboundary implications. Proposed definition ''safety case'' in 10 CFR 61.2 would be assigned to Compatibility Category H&S. The NRC believes the essential objectives of this definition need to be adopted to ensure consistent application of 10 CFR 61.40. The compatibility category of other amended definitions in 10 CFR 61.2 would remain unchanged.

Paragraphs 61.7(c)(1), (c)(2), (c)(4), (c)(5), (c)(6)(d), (e), and (f)(4) would be assigned to Compatibility Category H&S to be consistent with the designation of the rest of 10 CFR 61.7. The compatibility category of other amended paragraphs in 10 CFR 61.7 would remain unchanged.

The NRC is proposing to retain the existing Compatibility Category D for paragraph 61.10(a) because this paragraph provides a list of contents of an application that would not be applicable for all Agreement States (*i.e.,* an environmental report). Paragraph 61.10(b) would be assigned to Compatibility Category H&S. The NRC believes the safety case information of this paragraph needs to be included in the application for operating license for the protection of health and safety but is not required for compatibility with the national program.

Section 61.12 in its entirety would be reassigned from Compatibility Category D to Compatibility Category H&S. The NRC believes that all the requirements in 10 CFR 61.12 should be designated as Compatibility Category H&S to support the demonstration of the subpart C performance objectives. The NRC believes that the absence of these provisions could create a situation that could result in individual exposures that exceed the basic radiation protection standards of the subpart C performance objectives.

Section 61.13, in its entirety, would be reassigned from Compatibility Category H&S to Compatibility Category C. The NRC believes the essential objectives of this section need to be adopted to ensure consistent application of 10 CFR 61.40.

Proposed paragraph 61.23(m) would be assigned to Compatibility Category H&S. The compatibility category of other amended paragraphs in 10 CFR 61.23 would remain unchanged.

Section 61.28 in its entirety would also be reassigned from Compatibility Category D to Compatibility Category H&S. The NRC believes that all the information in this paragraph has to be included in the application for closure. The NRC believes that the presence of

these provisions are necessary for the Commission to make a final decision on the amendment authorizing a disposal site closure, based on protection of health and safety but is not required for compatibility with the national program.

The NRC is proposing to retain the existing Compatibility Category A for paragraph 61.41(a) because this paragraph provides a basic radiation protection standard. Paragraph 61.41(b) would be assigned to Compatibility Category B. The NRC believes the program elements of this paragraph need to be adopted to ensure a consistent regulatory approach across the Nation and inconsistent application of this paragraph would have direct and significant transboundary implications. Paragraph 61.41(c) would be assigned to Compatibility Category C because the NRC believes that the Agreement States need to adopt the essential objectives of this paragraph.

Similarly, the NRC is proposing to designate paragraph 61.42(a) as Compatibility Category A (instead of Compatibility Category H&S, which is the current compatibility level for 10 CFR 61.42) because of the prescribed annual dose limit of 5 mSv (500 mrem) for the protection of an inadvertent intruder. Paragraph 61.42(b) would be assigned to Compatibility Category B. The NRC believes the program elements of this paragraph need to be adopted to ensure a consistent regulatory approach across the Nation and inconsistent application of this paragraph would have direct and significant transboundary implications. Paragraph 61.42(c) would be assigned to Compatibility Category C because the NRC also believes that the essential objectives of this paragraph need to be adopted by the Agreement States.

Paragraphs 61.52(a)(12) and (a)(13) would be assigned to Compatibility Category H&S. The compatibility categories of 10 CFR 61.52(a)(3) and (a)(8) would remain unchanged.

At present, only one of the four Agreement States that has an operating near-surface LLRW disposal facility has adopted a corresponding regulation to 10 CFR 61.58. Currently, Agreement States are not required to adopt 10 CFR 61.58, therefore, the compatibility designation for this section must be changed in order to require Agreement States to adopt an alternative provision for LLRW classification and characteristics. Therefore, the NRC is retitling, revising and reclassifying the compatibility for 10 CFR 61.58. Section 61.58 would be assigned to Compatibility Category B because the NRC believes the program elements of this section need to be adopted to ensure a consistent regulatory approach across the Nation and inconsistent application of this section would have direct and significant transboundary implications.

Paragraph 61.80(m) would be assigned to Compatibility Category C. The compatibility category of 10 CFR 61.80(i)(1) and (i)(2) would remain unchanged.

The compatibility categories of the remaining sections (10 CFR 20.1003; appendix G to 10 CFR part 20, sections II and III; and 10 CFR 61.8, 61.25, 61.44, 61.50, 61.51, 61.55, 61.56, and 61.57) would remain unchanged.

The NRC invites comment on the compatibility category designations in this proposed rule and suggests that commenters refer to the Handbook for NRC Management Directive 5.9 for more information. Comments on the proposed compatibility categories need to be received by the end of the public comment period.

The following table lists the parts and sections that would be revised and their corresponding categorization under the ''Policy Statement on Adequacy and Compatibility of Agreement State Programs.''

PROPOSED COMPATIBILITY TABLE FOR 10 CFR PART 20, APPENDIX G

10 CFR Part 20, Appendix G proposed 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

PROPOSED COMPATIBILITY TABLE FOR 10 CFR PART 61

10 CFR Part 61 proposed rule section	Change	Subject	Compatibility	
			Existing	New
61.2	New	Definition-Compliance period		B
61.2	New	Definition-Defense-in-depth		H&S
61.2	Amend	Definition-Inadvertent intruder	C	C
61.2	New	Definition-Intruder assessment		H&S
61.2	New	Definition-Long-lived waste		B
61.2	New	Definition-Performance assessment		H&S
61.2	New	Definition-Performance period		C
61.2	New	Definition-Protective assurance period		B
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

PROPOSED COMPATIBILITY TABLE FOR 10 CFR PART 61—Continued

10 CFR Part 61 proposed rule section	Change	Subject	Compatibility	
			Existing	New
61.7(c)(6)	New	Concepts		H&S
61.7(d)	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)	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
61.13(a)	Amend/Revised Compatibility Category.	Technical analyses	H&S	C
61.13(b)	Amend/Revised Compatibility Category.	Technical analyses	H&S	C
61.13(c)	Amend/Revised Compatibility Category.	Technical analyses	H&S	C
61.13(d)	Amend/Revised Compatibility Category.	Technical analyses	H&S	C
61.13(e)	New	Technical analyses		C
61.13(f)	New	Technical analyses		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	Changes	D	D
61.25(b)	Amend	Changes	D	D
61.28(a)(2)	Amend	Contents of application closure	D	D
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.		B
61.41(c)	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		B
61.42(c)	New	Protection of individuals from inadvertent intrusion		C

PROPOSED COMPATIBILITY TABLE FOR 10 CFR PART 61—Continued

10 CFR Part 61 proposed rule section	Change	Subject	Compatibility	
			Existing	New
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 Compatibility Category.	Waste acceptance (Previously titled Alternative requirements for waste classification and characteristics).	D	B
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

VII. 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). The NRC requests comment on the proposed rule with respect to the clarity and effectiveness of the language used.

VIII. 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 proposed rule, the NRC is proposing to amend its regulations that govern LLRW disposal facilities to require new and revised site-specific technical analyses and to permit the development of criteria for LLRW acceptance based on the results of these analyses. These amendments would ensure that LLRW streams that are significantly different from those considered in the regulatory basis for the current 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. Additionally, the NRC is also proposing amendments to facilitate implementation and better align the requirements with current health and safety standards. The NRC is not aware of any voluntary consensus standards that address the proposed subject matter of this proposed rule. The NRC will consider using a voluntary consensus standard if an appropriate standard is identified. If a voluntary consensus standard is identified for consideration, the submittal should explain why the standard should be used.

IX. Draft Environmental Assessment and Draft Finding of No Significant Environmental Impact

A. The Proposed Action and the Need for the Proposed Action

The proposed action is to add new, and amend some of the existing, requirements in 10 CFR part 61. The NRC is proposing to amend 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 current 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 compliance period; add a new site-specific technical analysis for the protection of inadvertent intruders (*i.e.,* intruder assessment) that would include a 1,000-year compliance period and a dose limit; add new analyses (*i.e.,* performance assessment and intruder assessment) that would include a 10,000-year protective assurance period and dose minimization target; new analyses that demonstrate the disposal site includes defense-in-depth protections for the compliance period, protective assurance period, and performance period; add a new analysis for certain long-lived LLRW (*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 either the results of these technical analyses or the existing LLRW classification requirements. Additionally, the NRC is proposing amendments to facilitate implementation and better align the requirements with current health and safety standards.

B. Environmental Impact of the Proposed Action

The proposed action is to add new, and amend some of the existing, requirements in 10 CFR part 61. The proposed 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 proposed action would result in no significant environmental impacts.

C. Alternatives to the Proposed Action

As an alternative to the proposed 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 and no protective assurance period would be specified, no intruder assessment would be required, and development of 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. Not taking the proposed action would not provide the 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 publish the proposed rule for public comment.

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 this proposed rule containing this draft environmental assessment and the proposed rule to all State Liaison Officers and requested their comments on the 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. Draft Finding of No Significant Impact

The Commission has preliminarily 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 proposed 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 would not be required. The amendments would require LLRW disposal facility licensees and license applicants to conduct new and updated site-specific technical analyses and safety case 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 would be primarily procedural and administrative in nature and would have no significant impact on the quality of the human environment.

The preliminary determination of this draft environmental assessment is that there would be no significant impact to the quality of the human environment from this proposed action. The NRC is, however, seeking public comment on this draft environmental assessment and draft finding of no significant impact. Comments on the draft environmental assessment and draft finding of no significant impact may be submitted to the NRC by any of the methods provided in the **ADDRESSES** section of this document.

X. Paperwork Reduction Act Statement

This proposed rule contains new or amended collections of information subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq). This proposed rule has been submitted to the Office of Management and Budget (OMB) for review and approval of the information collections.

Type of submission, new or revision: Revision.

The title of the information collection: 10 CFR parts 20 and 61, ''Low Level Radioactive Waste Disposal.''

The form number if applicable: NRC Forms 540 and 541.

How often the collection is required or requested: On occasion.

Who will be required or asked to respond: Current and future LLRW disposal facilities that are regulated by the NRC or an Agreement State.

An estimate of the number of annual responses: 0.

The estimated number of annual respondents: 0.

An estimate of the total number of hours needed annually to comply with the information requirement or request: New applicants and current LLRW disposal facility licensees seeking to amend their licenses to address the requirements in these amendments will incur a reporting burden to submit performance period analyses, compliance period analyses, and LLRW acceptance plans beginning approximately 4 years from publication of the final rule. The estimated one-time reporting burden per licensee to perform these analyses is 22,200 hours. 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 OMB information collection period of 3 years following publication of the final rule, and no current licensees are anticipated to amend their licenses within the information collection period; therefore, there is no estimated annual burden (0 hours) for the next 3 years.

Abstract: The NRC is proposing to amend its regulations to require LLRW disposal facilities to conduct site-specific technical analyses to demonstrate compliance with the performance objectives of 10 CFR part 61. The intent of the rule is to ensure performance objectives are met at disposal sites for safe disposal of LLRW that was not analyzed in the original 10 CFR part 61 regulatory basis (*i.e.,* large quantities of depleted uranium). The site-specific technical analyses would

include compliance period analyses with both a performance assessment and an intruder assessment, analyses for the protective assurance period that include both a performance assessment and an intruder assessment, performance period analyses to evaluate how the disposal system could mitigate the risk from long-lived LLRW, new analyses that demonstrate the disposal site includes defense-in-depth protections, and an LLRW acceptance plan identifying the WAC for the disposal facility. In addition, licensees must review their LLRW acceptance plan annually and update the safety case and analyses as part of the application for closure.

The NRC Forms 540 and 541 would be updated to allow licensees to indicate the use of LLRW acceptance criteria.

The U.S. Nuclear Regulatory Commission is seeking public comment on the potential impact of the information collections contained in this proposed rule and on the following issues:

1. Is the proposed information collection necessary for the proper performance of the functions of the NRC, including whether the information will have practical utility?

2. Is the estimate of the burden of the proposed information collection accurate?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the proposed information collection on respondents be minimized, including the use of automated collection techniques or other forms of information technology?

A copy of the OMB clearance package and proposed rule is available in ADAMS under Accession No. ML14289A143 or may be viewed free of charge at the NRC's PDR, One White Flint North, 11555 Rockville Pike, Room O–1 F21, Rockville, Maryland, 20852. You may obtain information and comment submissions related to the OMB clearance package by searching on *http://www.regulations.gov* under Docket ID NRC–2011–0012.

You may submit comments on any aspect of these proposed information collections, including suggestions for reducing the burden and on the previously stated issues, 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 Information Services, 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, 3150–0164, and 3150–0166), NEOB–10202, Office of Management and Budget, Washington, DC 20503; telephone: 202–395–1741, email: *vladik.dorjets@omb.eop.gov.*

Submit comments by May 26, 2015. Comments received after this date will be considered if it is practical to do so, but the NRC staff is able to ensure consideration only for comments received on or before this date.

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.

XI. Regulatory Analysis

The Commission has prepared a draft regulatory analysis on this proposed regulation, and it is available in ADAMS under Accession No. ML14289A158. The draft regulatory analysis examines the costs and benefits of the alternatives considered by the Commission.

The Commission requests public comment on the draft regulatory analysis. Comments on the draft analysis may be submitted to the NRC by any of the methods provided in the **ADDRESSES** section of this document.

XII. Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), the Commission certifies that this rule would not, if adopted, have a significant economic impact on a substantial number of small entities. The LLRW licensees and license applicants impacted by this rule do not fall within the scope of the definition of ''small entities'' given in the Regulatory Flexibility Act or the standards established by the NRC in 10 CFR 2.810, ''NRC size standard.''

The NRC is seeking public comment on the potential impact of the proposed rule on small entities. The NRC particularly desires comments from licensees who qualify as small businesses, specifically as to how the proposed rule would affect them and how the rule may be tiered or otherwise modified to impose less stringent requirements on small entities while still adequately protecting the public health and safety and common defense and security. Comments on how the rule could be modified to take into account the differing needs of small entities should specifically discuss:

(a) The size of the business and how the proposed rule would result in a significant economic burden upon it as compared to a larger organization in the same business community;

(b) How the proposed rule could be modified to take into account the business's differing needs or capabilities;

(c) The benefits that would accrue, or the detriments that would be avoided, if the NRC adopts the commenter's suggestion;

(d) How the proposed rule, as modified, would more closely equalize the impact of NRC regulations as opposed to providing special advantages to any individuals or groups; and

(e) How the proposed rule, as modified, would still adequately protect the public health and safety and common defense and security.

Comments should be submitted by any of the methods provided in the **ADDRESSES** section of this document.

XIII. Backfitting

A backfit analysis is not required for this rule. The NRC's backfit 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 proposed rule do not involve any provisions that would impose backfits on nuclear power plant licensees as defined in 10 CFR part 50, ''Domestic Licensing of Production and Utilization Facilities,'' or in 10 CFR part 52, ''Licenses, Certifications, and Approvals for Nuclear Power Plants,'' or 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,'' and 10 CFR part 76, ''Certification of Gaseous Diffusion Plants.''

List of Subjects

10 CFR Part 20

Byproduct material, Criminal penalties, Licensed material, Nuclear materials, Nuclear power plants and reactors, Occupational safety and health, Packaging and containers, Radiation protection, Reporting and recordkeeping requirements, Source material, Special nuclear material, Waste treatment and disposal.

10 CFR Part 61

Criminal penalties, Low-level waste, Nuclear materials, Reporting and recordkeeping requirements, Waste treatment and disposal.

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 proposing to adopt 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 secs. 53, 63, 65, 81, 103, 104, 161, 182, 186, 223, 234 1701 (42 U.S.C. 2073, 2093, 2095, 2111, 2133, 2134, 2201, 2232, 2236, 2273, 2282, 2297f), Energy Reorganization Act secs. 201, 202, 206 (42 U.S.C. 5841, 5842, 5846); Government Paperwork Elimination Act sec. 1704 (44 U.S.C. 3504 note); Energy Policy Act of 2005 sec. 651(e), Pub. L. 109–58, 119 Stat. 549 (2005) (42 U.S.C. 2014, 2021, 2021b, 2111).

■ 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 meet the waste acceptance criteria for disposal for a specific site; 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. 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 assure 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 assure 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 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 secs. 201, 202, 206 (42 U.S.C. 5841, 5842, 5846), sec. 211, Pub. L. 95–601, sec. 10, as amended by Pub. L. 102–486, sec. 2902 (42 U.S.C. 5851). Pub. L. 95–601, sec. 10, 14, 92 Stat. 2951, 2953 (42 U.S.C. 2021a, 5851); Government Paperwork Elimination Act sec. 1704 (44 U.S.C. 3504 note); Energy Policy Act of 2005, sec. 651(e), Pub. L. 109–58, 119 Stat. 806–810 (42 U.S.C. 2014, 2021, 2021b, 2111).

■ 5. In § 61.2:

■ a. Add the definitions of ''Compliance period'' and ''Defense-in-depth'';

■ b. Revise the definition of ''Inadvertent intruder'';

■ c. Add the definitions of ''Intruder assessment,'' ''Long-lived waste,'' ''Performance assessment,'' ''Performance period,'' ''Protective assurance period,'' and ''Safety case''; and

■ d. Revise the definitions of ''Site closure and stabilization,'' ''Stability,'' and ''Waste.''

The revisions and additions read as follows:

§ 61.2 Definitions.

* * * * *

Compliance period is the time out to 1,000 years after closure of the disposal facility.

* * * * *

Defense-in-depth means the use of multiple independent and 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.

* * * * *

Inadvertent intruder means a person who might occupy the disposal site after closure and engage in normal activities, such as agriculture, dwelling construction, resource exploration or exploitation (*e.g.,* well drilling) or 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.

* * * * *

Intruder assessment is an analysis that:

(1) Assumes an inadvertent intruder occupies the site and engages in normal activities or other reasonably foreseeable pursuits that are realistic and consistent with expected activities in and around the disposal site at the time of site closure and that might unknowingly expose the person to radiation from the waste;

(2) examines the capabilities of intruder barriers to inhibit an inadvertent intruder's contact with the waste or to limit the inadvertent intruder's exposure to radiation; and

(3) estimates an inadvertent intruder's potential annual dose, considering associated uncertainties.

* * * * *

Long-lived waste means waste containing radionuclides:

(1) Where more than 10 percent of the initial activity of a radionuclide remains after 10,000 years (*e.g.,* long-lived parent),

(2) Where the peak activity from progeny occurs after 10,000 years (*e.g.,* long-lived parent—short-lived progeny), or

(3) Where more than 10 percent of the peak activity of a radionuclide (including progeny) within 10,000 years remains after 10,000 years (*e.g.,* short-lived parent—long-lived progeny).

* * * * *

Performance assessment is an analysis that

(1) Identifies the features, events, and processes that might affect the disposal system;

(2) Examines the effects of these features, events, and processes on the performance of the disposal system; and

(3) Estimates the annual dose to any member of the public caused by all significant features, events, and processes.

* * * * *

Performance period is the timeframe established for considering waste and site characteristics to evaluate the performance of the site after the protective assurance period.

* * * * *

Protective assurance period is the period from the end of the compliance period through 10,000 years following closure of the site.

* * * * *

Safety case is a collection of information that demonstrates the assessment of the safety of a waste disposal facility. This includes technical analyses, such as the performance assessment and 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 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 assure that the disposal site will remain stable and will not need ongoing active maintenance.

* * * * *

Stability means structural stability.

* * * * *

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.

* * * * *

■ 6. Revise § 61.7 to read as follows:

§ 61.7 Concepts.

(a) *The 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, which 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 environment surrounding the land disposal facility, 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 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 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 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 over the site after operations by the site owner to ensure that no such occupation or improper use of the site occurs; or, designating which waste could present an unacceptable dose to an 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. These regulations incorporate both types of protective controls.

(4) The 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 after closure. The 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 intruder assessment are compared with the appropriate performance objective of subpart C of this part. An intruder assessment can employ a similar methodology to that used for a performance assessment, but the 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 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. Performance period analyses are used to evaluate the suitability of this waste for disposal on a case-by-case basis. In general, for disposal facilities with limited quantities of long-lived waste, performance period analyses are not necessary to demonstrate protection of the general population from releases of radioactivity and protection of inadvertent intruders. However, there may be site-specific conditions that require licensees to assess disposal facilities beyond the compliance period even when long-lived waste is limited. These conditions should be evaluated on a case-by-case basis to determine whether analyses beyond the compliance period would be required.

(d) *Defense-in-depth.* With respect to waste disposal, defense-in-depth is the use of multiple independent and redundant layers of defense to compensate for uncertainties in the estimation of long-term performance. Defense-in-depth protections, commensurate with the risks, are intended to ensure that no single layer, no matter how robust, is exclusively relied upon by the disposal system to provide protection of the public and environment from radiation that may be released from the facility to the environment. Defense-in-depth protections, such as siting, wasteforms, radiological source-term, engineered features, and natural system features of the disposal site, combined with technical analyses and scientific judgment form the safety case for licensing a low-level waste disposal facility. The insights derived from technical analyses include supporting evidence and reasoning on the strength and reliability of the layers of defense relied upon in the safety case. These insights provide input for making regulatory decisions.

(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 both the waste and disposal site, which minimizes the access of water to waste that has been emplaced and covered. Limiting the access of water to the waste minimizes the migration of radionuclides, which may avoid the need for long-term active maintenance and reduces the potential for release of radioactivity into the environment. While stability is desirable, it is not necessary from a health and safety standpoint for most waste because the waste does not contain sufficient radioactivity to be of concern. This lower-activity waste (*e.g.,* ordinary trash-type waste) tends to be unstable. If unstable waste is disposed with the waste requiring stability, the deterioration of unstable waste could lead to the failure of the system. The failure of the system could permit water to penetrate the disposal unit, which may cause problems with the waste that requires stability. Therefore, to avoid placing requirements for a stable waste form on relatively innocuous 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 waste may be more uncertain and require more robust technical evaluation of the processes that are unlikely to affect the ability of the disposal system to isolate short-lived waste. 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.

(2) Institutional control of access to the site is required for up to 100 years. This permits the disposal of Class A and B waste without special provisions for 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 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 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 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 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 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 final 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 assure that the disposal site is stable and ready for institutional control. The period of postclosure observation and maintenance is used to ensure that the final 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 assure 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.

■ 7. 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.

* * * * *

■ 8. Revise § 61.10 to read as follows:

§ 61.10 Content of application.

(a) 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. 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 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.

■ 9. In § 61.12, revise the introductory text and paragraphs (a), (e), (g), (i), and (j) to 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; and

(3) Quality assurance during the design, construction, operation, and closure of the land disposal facility and the receipt, handling, and emplacement of waste.

* * * * *

■ 10. In § 61.13:

■ a. Revise the introductory text and paragraphs (a), (b), and (d); and

■ b. Add paragraphs (e) and (f).

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 the effective date of this subpart must submit these analyses at the next license renewal or within 5 years of the effective date of this subpart, whichever comes first.

(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. A 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) Evaluate specific features, events, and processes in detail if their omission would significantly affect meeting the performance objective specified in § 61.41.

(3) Consider the likelihood of disruptive or other unlikely features, events, or processes for comparison with the limits set forth in § 61.41.

(4) Reflect new features, events, and processes different from the compliance period that address significant uncertainties inherent in the long timeframes associated with demonstrating compliance with § 61.41(b) only if scientific information compelling such changes is available.

(5) Provide a technical basis for either inclusion or exclusion of degradation, deterioration, or alteration processes (*e.g.,* of the engineered barriers, waste form, site characteristics) and interactions between the disposal facility and site characteristics that might affect the facility's ability to meet the performance objective in § 61.41.

(6) Provide a technical basis for models used in the performance assessment such as comparisons made with outputs of detailed process-level models or empirical observations (*e.g.,* laboratory testing, field investigations, and natural analogs).

(7) Evaluate pathways including air, soil, groundwater, surface water, plant uptake, and exhumation by burrowing animals.

(8) Account for uncertainties and variability in the projected behavior of the disposal system (*e.g.,* disposal facility, natural system, and environment).

(9) Consider alternative conceptual models of features and processes that are consistent with available data and current scientific understanding, and evaluate the effects that alternative conceptual models have on the understanding of the performance of the disposal facility.

(10) Identify and differentiate between the roles performed by the natural disposal site characteristics and design features of the disposal facility in limiting releases of radioactivity to the general population.

(b) Inadvertent intruder analyses that demonstrate there is reasonable assurance that:

(1) the waste acceptance criteria developed in accordance with § 61.58 will be met,

(2) adequate barriers to inadvertent intrusion will be provided, and

(3) any inadvertent intruder will not be exposed to doses that exceed the limits set forth in § 61.42 as part of the intruder assessment. An intruder assessment shall:

(i) Assume that an inadvertent intruder occupies the disposal site at any time after the period of institutional controls ends, and engages in normal activities including agriculture, dwelling construction, resource exploration or exploitation (*e.g.,* well drilling), or other reasonably foreseeable pursuits that are consistent with activities in and around the site at the time of closure and that unknowingly expose the intruder to radiation from the waste.

(ii) 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 barriers are effective.

(iii) Account for uncertainties and variability.

* * * * *

(d) Analyses of the long-term stability of the disposal site and the need for ongoing active maintenance after 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 and that there will not be a need for ongoing active maintenance of the disposal site following closure.

(e) Analyses that assess how the disposal site limits the potential long-

term radiological impacts, consistent with available data and current scientific understanding. The analyses shall be required for disposal sites with waste that contains radionuclides with average concentrations exceeding the values listed in table A of this paragraph, or if necessitated by site-specific conditions. For wastes containing mixtures of radionuclides found in table A, the total concentration shall be determined by the sum of fractions rule described in paragraph 61.55(a)(7). The 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(c) and 61.42(c) will be met.

TABLE A—AVERAGE CONCENTRATIONS OF LONG-LIVED RADIONUCLIDES REQUIRING PERFORMANCE PERIOD ANALYSES

Radionuclide	Concentration (Ci/m[3]) [1]
C–14	0.8
C–14 in activated metal	8
Ni-59 in activated metal	22
Nb-94 in activated metal	0.02
Tc-99	0.3
I–129	0.008
Long-lived alpha-emitting nuclides [2]	[3] 10
Pu–241	[3] 350
Cm–242	[3] 2,000

[1] Values derived from § 61.55 Class A limits.
[2] Includes alpha-emitting transuranic nuclides as well as other long-lived alpha-emitting nuclides.
[3] Units are nanocuries per gram.

(f) Analyses that demonstrate the proposed disposal facility includes defense-in-depth protections.

■ 11. In § 61.23:

■ a. Revise paragraphs (b), (c), (d), and (e); and

■ b. Add paragraph (m).

The revisions and addition read as follows:

§ 61.23 Standards for issuance of a license.

* * * * *

(b) The applicant's proposed disposal site, disposal design, waste acceptance criteria, land disposal facility operations (including equipment, facilities, and procedures), disposal site closure, and postclosure institutional control 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 control demonstrate that they are adequate to protect the public health and safety because they provide reasonable assurance that individual 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 control 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 closure.

* * * * *

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

* * * * *

■ 12. 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.

* * * * *

■ 13. 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 final closure of the disposal site, or as otherwise directed by the Commission, the applicant shall submit an application to amend the license for closure. This 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 using the details of the final closure plan and waste inventory.

* * * * *

■ 14. 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 ground water, 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) Concentrations of radioactive material that may be released to the general environment in ground water, surface water, air, soil, plants, or animals shall be minimized during the protective assurance period. The annual dose, established on the license, shall be below 5 milliSieverts (500 millirems) or a level that is supported as reasonably achievable based on technological and economic considerations in the information submitted for review and approval by the Commission. Compliance with this paragraph must be demonstrated through analyses that meet the requirements specified in § 61.13(a).

(c) Effort shall be made to minimize releases of radioactivity from a disposal facility 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).

■ 15. 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) Design, operation, and closure of the land disposal facility shall minimize exposures to any inadvertent intruder into the disposal site at any time during the protective assurance period. The annual dose, established on the license, shall be below 5 milliSieverts (500 millirems) or a level that is supported as reasonably achievable based on technological and economic considerations in the information submitted for review and approval by the Commission. Compliance with this paragraph must be demonstrated through analyses that meet the requirements specified in § 61.13(b).

(c) 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).

■ 16. Revise § 61.44 to read as follows:

§ 61.44 Stability of the disposal site after closure.

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

■ 17. 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.

(1) To the extent practicable, the disposal site shall be capable of being characterized, modeled, analyzed, and monitored.

(2) The hydrologic characteristics that a 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 which could erode or inundate waste disposal units.

(iii) The disposal site must provide sufficient depth to the water table that ground water 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 ground water 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) Within the region or state where the facility is to be located, a disposal site should be selected so that projected population growth and future developments are not likely to affect the ability of the 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) *Disposal site suitability requirements for land disposal other than near-surface (reserved).*[Reserved]

■ 18. 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 for continuing active maintenance after site closure.

* * * * *

■ 19. 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.

* * * * *

■ 20. 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.

* * * * *

■ 21. 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.

* * * * *

■ 22. 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 whether it is Class A waste, Class B waste, or Class C waste, in accordance with § 61.55.

■ 23. 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 either § 61.13 for any land disposal facility or the waste classification requirements set forth in § 61.55 for a near-surface disposal facility.

(2) Acceptable wasteform 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 the requirements in § 61.56(b) for waste that requires stability 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 disposal facility. The certification program shall:

(1) Designate authority to certify and receive waste for disposal at the 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 the effective date of this subpart shall comply with the requirements of paragraphs (a), (b), and (c) of this section at the next license renewal or within 5 years of the effective date of this subpart, 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 the effective date of this subpart, 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.

(h) In determining whether waste acceptance criteria will be approved, the Commission will apply the criteria set forth in § 61.23.

■ 24. 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 16th day of March, 2015.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,

Secretary of the Commission.

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