Draft Regulatory Analysis for Final Rule: Low-Level Radioactive Waste Disposal (10 CFR Part 61)

U.S. Nuclear Regulatory Commission

Office of Nuclear Material Safety and Safeguards

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Executive Summary

The U.S. Nuclear Regulatory Commission (NRC) is amending Title 10 of the *Code of Federal Regulations* (10 CFR) Part 61 to require new and revised site-specific technical analyses, to permit the development of site-specific criteria for low-level radioactive waste (LLRW) acceptance based on the results of these analyses, and to facilitate implementation and better align the requirements with current health and safety standards. These new and revised analyses also help identify any additional measures that would be prudent to implement for continued disposal of LLRW at a particular land disposal facility. In summary, the new and revised requirements specify:

1. Technical analyses for demonstrating compliance with the public dose limits
2. Technical analyses for demonstrating compliance with dose limits for protection of the inadvertent intruder
3. Requirements for development of site-specific waste acceptance criteria
4. Implementation of current dosimetry in the technical analyses
5. Requirements for the safety case including the identification and description of defense-in-depth protections

This rule will affect LLRW disposal licensees or license applicants that are regulated by the NRC or the Agreement States.

This regulatory analysis examines the benefits and costs of the new requirements. The term "regulatory analysis period" is defined, for purposes of this regulatory analysis, as the time period starting at the present day and continuing through the lifetime of the existing impacted entities (i.e., parties licensed under Part 61 and Agreement State regulatory authorities). The key findings of the analysis are as follows:

- **Cost to the Industry**. The rule will result in an average undiscounted implementation cost per licensee of an estimated $1.13 million (M), followed by an estimated undiscounted average ongoing operations cost of $1.33M over the regulatory analysis period for each licensee. Overall, the industry (i.e., all licensees licensed under Part 61) will incur an estimated undiscounted implementation total cost of $4.5M, followed by an estimated undiscounted ongoing operations cost of $5.3M over the regulatory analysis period.

- **Cost to the Agreement States**. On average, an Agreement State with an operating land disposal facility licensed by the Agreement State will incur an estimated undiscounted implementation cost of $0.74M, followed by an estimated undiscounted average ongoing operations cost of $1M over the regulatory analysis period. Overall, the Agreement States will incur an estimated undiscounted implementation total cost of $2.9M followed by an estimated undiscounted ongoing cost of $4M over the regulatory analysis period.

- **Decision Rationale**. The NRC considered two alternatives, one in which the NRC takes no rulemaking action, and the second alternative that consists of two periods of analysis. The NRC selected alternative two. Alternative two results in a net overall cost; however, the rule does have many benefits. Although the NRC could not quantify the benefits of

this rule, it did examined its benefits qualitatively. These include both the direct benefits that will accrue and the indirect benefits from risks that could be avoided.

The principal qualitative benefits of the regulatory action include: 1) ensuring 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 without the need for future actions to address those different streams on a case-by-case basis; 2) facilitating the use of site-specific information and up-to-date dosimetry methodologies in site-specific technical analyses to better ensure public health and safety is protected; and 3) enhancing the 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 waste acceptance criteria should also allow licensees to optimize disposal capacity while ensuring protection of public health and safety, which is likely to reduce costs. In addition, ensuring that LLRW streams that are significantly different from those considered during the development of the current regulations can be disposed of safely, minimizes the likelihood that future mitigation would be required as a result of disposing of such LLRW streams, thus averting potential future costs to licensees. The NRC concluded that the rule is cost-justified because the regulatory initiatives enhance public health and safety by ensuring the safe disposal of LLRW that was not analyzed in the original 10 CFR Part 61 regulatory basis (e.g., large quantities of depleted uranium).

Glossary of Terms and Acronyms

The following are abbreviations of terms used in this Regulatory Analysis.

ADAMS	Agencywide Documents Access and Management System
CFR	*Code of Federal Regulations*
BLS	Bureau of Labor Statistics
DU	Depleted Uranium
FTE	Full-time equivalent
LLRW	Low-level radioactive waste
M	million
mrem/yr	millirem per year
mSv/yr	milliSieverts per year
NRC	U.S. Nuclear Regulatory Commission
OMB	Office of Management and Budget

1. Introduction

This document presents the final regulatory analysis of the NRC's revision to 10 CFR Part 61. The regulatory action modifies regulations governing 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 will 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) will be disposed of safely and meet the performance objectives for land disposal of LLRW. These amendments will also increase the use of site-specific information to ensure performance objectives that are designed to provide protection of public health and safety are met.

1.1 Statement of the Problem and Objectives for Rulemaking

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

In order to address these new circumstances, the NRC is amending 10 CFR Part 61 to require LLRW disposal licensees and license applicants to prepare a safety case that includes identification of defense-in-depth protections and new and revised site-specific technical analyses to ensure that LLRW streams that are significantly different from the LLRW streams considered in the original 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 will help identify any additional measures that would be prudent to implement for continued disposal of LLRW at a particular land disposal facility.

The NRC is also amending 10 CFR Part 61 to require LLRW land disposal facility licensees or license applicants to develop site-specific criteria for the acceptance of LLRW for disposal. These amendments maintain the existing LLRW classification system, but permit land disposal facility licensees and 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 land disposal facility. Because licensees and license applicants are required to develop site-specific criteria for the acceptance of LLRW for disposal, the NRC is also amending appendix G of 10 CFR Part 20, "Standards for Protection Against Radiation," to conform to the new requirements for LLRW acceptance. The NRC is also amending its regulations to facilitate implementation and better align the requirements with current health and safety standards.

Table 1-1 compares the new and revised technical analyses to the former 10 CFR Part 61 requirements. The inadvertent intruder assessment is a new requirement under 10 CFR 61.13 and is used to demonstrate compliance with the performance objective to protect inadvertent intruders at § 61.42. The inadvertent intruder assessment must demonstrate that the annual dose would not exceed a proposed 5 mSv (500 mrem) limit over a newly defined compliance period. The compliance period is either 1,000 years or 10,000 years, depending on the amount of long-lived radionuclides present in the waste disposed of at the site or that will be disposed of at the site. Development of a performance assessment is also required to demonstrate the protection of the general population from releases of radioactivity. This analysis updates the

previous exposure-pathway analysis to use more modern performance-assessment methodologies that 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 also incorporates a compliance period. The performance assessment retains the current 0.25 mSv (25 mrem) annual dose limit and the as low as reasonably achievable (ALARA) concept, but the dose methodologies have been updated to be consistent with the dose methodologies specified in the standards for radiation protection set forth in the current 10 CFR Part 20.

A qualitative analysis covering a performance period beyond 10,000 years after site closure is also required in § 61.13 for those land disposal facilities disposing, or that have disposed, of significant quantities of long-lived radionuclides. This analysis requires an assessment of how the land 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.

Table 1-1- Comparison Table of Current and Proposed 10 CFR Part 61 Regulations

	Former 10 CFR Part 61 regulations	Revised 10 CFR Part 61 regulations
Protection of the general population from releases of radioactivity (10 CFR 61.41)	- 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	- Performance assessment that estimates peak annual dose that occurs within the compliance period - 0.25 mSv (25 mrem) annual dose limit for the protection of the general population from the releases of radioactivity that occurs within the compliance period - ALARA concept - Analyses that demonstrate releases will be minimized to the extent reasonably achievable for the protection of the general population beyond the compliance period - Analyses only apply for disposal sites containing significant quantities of waste with long-lived radionuclides - Analyses that demonstrate how the disposal site has been designed to limit long-term releases.
Protection of individual from inadvertent intrusion (10 CFR 61.42)	- Comply with § 61.55 LLRW classification and segregation requirements - Provide adequate barriers to inadvertent intrusion - Undefined compliance period - No annual dose limit	- Inadvertent intruder assessment that estimates peak annual dose that occurs within the compliance period - 5 mSv (500 mrem) annual dose limit - Analyses that demonstrate exposures will be minimized to the extent reasonably achievable for the protection of inadvertent intruders beyond the compliance period. - Analyses only apply for disposal sites containing significant quantities of waste with long-lived radionuclides - Analyses that demonstrate how the disposal site has been designed to limit long-term exposures to an inadvertent intruder.
Stability of the disposal site after closure Long-term analyses (10 CFR 61.44)	Analyses of active natural processes that demonstrate that there will not be a need for ongoing active maintenance of the disposal site following closure	Analyses of active natural processes that demonstrate 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 during the compliance period

1.2 Background

The NRC's licensing requirements for the disposal of commercial LLRW in near-surface disposal facilities can be found in 10 CFR Part 61, "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 as license conditions.

The LLRW disposal regulations emphasize an integrated systems approach to the disposal of commercial LLRW, including site selection, land disposal facility design and operation, LLRW characteristics, and site closure. To reduce reliance on institutional controls, 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 was not explicitly discussed in 10 CFR Part 61 regulations. Instead, the defense-in-depth concept was implicitly contained in the 10 CFR Part 61 regulations (e.g., (i) 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; (ii) imposing concentration limits on waste that presents a higher hazard through the waste classification requirements; (iii) requiring the segregation of unstable waste from waste that presents a larger hazard and should be stable for proper disposal; (iv) imposing requirements on waste form and packaging characteristics; and (v) requiring the use of barriers to intrusion for wastes that will not decay to levels which present an acceptable hazard to an inadvertent intruder within 100 years).

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

2. Identification of Alternative Approaches

The following discussion describes the two alternatives being considered in this regulatory analysis, with additional analysis presented in Section 3.

2.1 Alternative 1: No-Action

Alternative 1, the no-action alternative, will maintain the regulations as written. Under this option, the NRC will not modify 10 CFR Part 61. Depleted uranium (DU) would continue to be considered as Class A waste and would not require additional analysis for disposal at LLRW disposal sites, unless previously required by the Agreement States (3 out of 4 of the licensees have had to complete some form of analysis to comply with their Agreement State regulations). If additional analyses are not conducted to allow significant quantities of DU, and other long-lived waste streams, to be disposed, then analyses conducted in support of the application for closure of the facility could identify the need for additional measures to be included in the site closure plan. Such additional measures could potentially require more time and money to implement than if the additional measures were considered at an earlier time (e.g., prior to disposing of significant quantities of DU or other long-lived waste streams).

Further, the no action alternative would not allow for the licensees to develop waste acceptance criteria from the results of the technical analyses. Development of waste acceptance criteria from the results of the technical analyses provides licensees flexibility to better manage disposal capacity consistent with the risks of disposal of LLRW streams. This flexibility may allow for additional revenue streams for disposal facility operators than may be permitted using the waste classification limits, depending on the performance of the disposal site. The no action alternative would avoid the costs that the rule revisions would impose. This alternative maintains the status quo and serves as a baseline to measure against Alternative 2.

2.2 Alternative 2: Amending 10 CFR Part 61

Under Alternative 2, the NRC will ensure the safe disposal of LLRW streams significantly different from those considered in the original 10 CFR Part 61 regulatory basis by amending 10 CFR Part 61. The amendments will require LLRW disposal facility licensees and license applicants to develop a safety case, identify defense-in-depth protections, prepare new and updated site-specific technical analyses to demonstrate compliance with 10 CFR Part 61, Subpart C performance objectives, and determine site-specific waste acceptance criteria.

The changes introduce a compliance period that considers the longevity of the hazard of the waste being disposed. If a disposal facility disposes, or has disposed, only LLRW streams with limited quantities of long-lived radionuclides, the licensee may conduct the analyses for 1,000 years following site closure. However, if a disposal facility disposes or has disposed of significant quantities of long-lived radionuclides, the licensee must conduct the analyses for 10,000 years following site closure and demonstrate how the disposal site limits the potential long-term radiological impacts during the performance period after 10,000 years (see Figure 2-1).

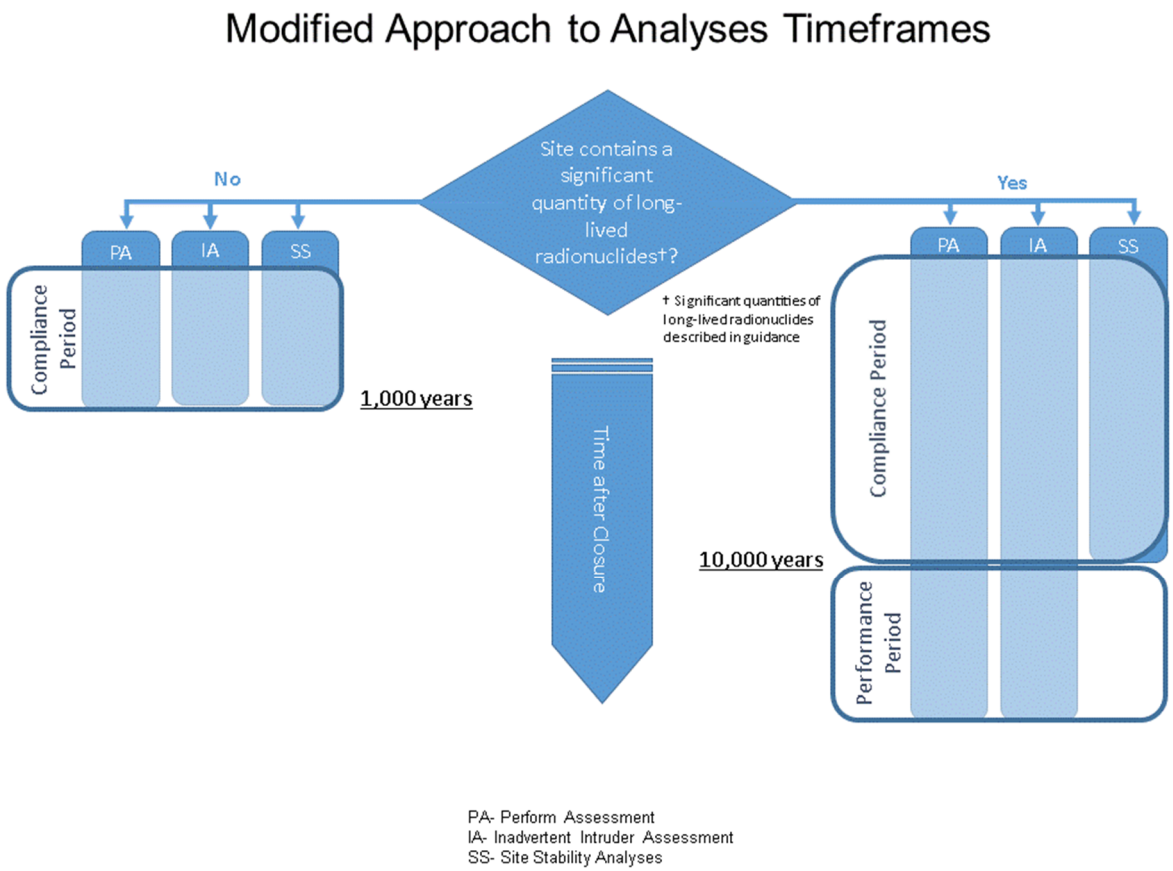

Figure 2-1 Analysis Timeframes Breakdown

The changes listed below are consistent with Alternative 2 to revise 10 CFR Part 61 and will result in an incremental increase in cost and benefit.

Note that there are other amendments in this rulemaking, but for the purpose of this regulatory analysis, only the sections that have any cost or benefit impacts are considered.

Paragraph 61.10(b) was revised to ensure that 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. This revision simply identifies the information submitted as part of a license application that comprises the safety case. The NRC expects this change will have minimal cost impacts on licensees and Agreement States during the license renewal and site closure analyses update and review, since much of the information has always been required of licensees. New requirements that differ from what was previously required as part of a license application and their associated cost impacts are described below.

Paragraph 61.12(o) was revised to require that information provided in an application identifies the defense-in-depth protections for the land disposal facility and describes both their capabilities and the associated technical bases. Defense-in-depth protections provide confidence that the performance objectives will be met in the face of significant uncertainties associated with a complex facility such as a land disposal facility and the long-time frames associated with radioactive waste. The NRC has always implicitly incorporated the defense-in-depth philosophy in the 10 CFR Part 61 regulations for land disposal of radioactive waste; however, this revision will ensure that licensees explicitly identify defense-in-depth protections used at a land disposal facility and describe the capabilities of the protections and associated technical bases. Describing the capabilities of the disposal site components and attributes can be accomplished by describing the applicable conceptual models and parameters used in the technical analyses. It does not require quantitative calculations beyond those performed to demonstrate compliance with the performance objectives. Nonetheless, the identification of the defense-in-depth protections and a description of their capabilities and associated bases will impact licensees. Likewise, Agreement State regulatory agencies will incur costs to review the identification of defense-in-depth protections and description of the capabilities of the protections, including the supporting technical bases.

Section 61.13 requires that specific technical analyses be included in a license application that demonstrates that the performance objectives of subpart C will be met. Licensees must submit these analyses at their next license renewal or within 5 years of the effective date of these new requirements, whichever comes first. Specifics for the technical analysis by section are described below.

Paragraphs 61.13(a)(1) through (6) require licensees to conduct a performance assessment to demonstrate that the general population will be protected from releases of radioactivity during the compliance period and the performance objective in § 61.41(a) will be met. The NRC has always required an analysis demonstrating protection of the general population from releases of radioactivity; however, the revisions to this section ensure that the analyses include essential elements of a more modern performance assessment methodologies to provide reasonable assurance that the performance objective will be met. Specifically, the revisions require licensees to: (1) consider features, events, and processes that might affect compliance with the performance objective in § 61.41(a) and provide a technical basis for their inclusion or exclusion; (2) consider the likelihood of disruptive or other unlikely features, events, and processes; (3) provide a technical basis for the models used in the performance assessment; (4) evaluate contaminant transport pathways and processes; (5) account for uncertainties and variability in the projected behavior of the disposal site, the general environment, and the demographics and behaviors of human receptors; and (6) identify and differentiate the roles performed by the natural characteristics of the disposal site and engineered features of the disposal facility. The NRC expects that the revisions will have varying degrees of impact on existing land disposal facility operators and Agreement State regulatory agencies depending upon the information that these operators previously submitted to their respective Agreement State to comply with the existing requirements.

Paragraph 61.13(a)(7) was added to require licensees to include a technical basis for not considering longer time periods in the performance assessment if a compliance period of 1,000 years is used to demonstrate the performance objective in § 61.41(a) will be met. The NRC expects that this revision may impact licensees and Agreement State regulatory agencies

depending upon the timeframes previously analyzed to comply with the existing requirement for this technical analysis. These timeframes have varied in each of the four Agreement States that currently have operating land disposal facilities, with three of the four Agreement States already requiring technical analyses out to 10,000 years or longer.

Paragraphs 61.13(b)(1) through (3) were added to require licensees to conduct an assessment to demonstrate that an inadvertent intruder will be protected during the compliance period and the performance objective in § 61.42(a) will be met. The requirement to conduct an inadvertent intruder assessment is new. However, licensees in some of the Agreement States with operating land disposal facilities have already conducted inadvertent intruder assessments. For licensees that have not conducted an inadvertent intruder assessment, this revision will have a cost impact. Likewise, there will be a cost impact to the Agreement State regulatory agency to review the inadvertent intruder assessment. For licensees that have previously performed an inadvertent intruder assessment, the cost impacts to both the licensee and Agreement State regulatory agency are expected to be variable depending on the type of information associated with the completed assessments. Specifically, the revisions require licensees to: (1) assume an inadvertent intruder occupies the site at any time after the period of institutional control ends and engages in normal activities or other reasonably foreseeable pursuits consistent with the site at the time of closure; (2) identify barriers to inadvertent intrusion and provide a basis for their capabilities; and (3) account for uncertainties and variability in the projected behavior of the disposal site and general environment.

Paragraph 61.13(b)(4) was added to require licensees to include a technical basis for not considering longer time periods in the inadvertent intruder assessment if a compliance period of 1,000 years is used to demonstrate the performance objective in § 61.42(a) will be met. The NRC expects that this revision may impact licensees and Agreement State regulatory agencies depending upon whether an inadvertent intruder assessment had been previously conducted and the timeframes previously analyzed in that assessment. Licensees in three of the four Agreement States with currently operating land disposal facilities have already conducted an inadvertent intruder assessment. The timeframes analyzed in each of those assessments have varied, with three of the licensees already conducting an inadvertent intruder assessment analyzing periods out to 10,000 years or longer.

Paragraph 61.13(e) was revised to require licensees to assess how the disposal site limits radiological impacts after 10,000 years when a 10,000 year compliance period is analyzed to demonstrate compliance with either § 61.41(a) or § 61.42(a). The performance period analyses must identify and describe features of the design and site characteristics that will demonstrate the applicable performance objectives will be met as set forth in § 61.41(b) and § 61.42(b). The NRC expects that this revision will impact licensees and Agreement State regulatory agencies depending upon the timeframes previously analyzed to comply with the performance objectives prior to this revision. These timeframes have varied in each of the four Agreement States that currently have operating land disposal facilities, with three of the four Agreement States already requiring technical analyses out to 10,000 years or longer. For licensees that have already conducted analyses beyond 10,000 years, the NRC does not expect a significant cost impact. However, for licensees that have not already conducted analyses beyond 10,000 years, the NRC expects these licensees to have a cost impact. The revision does not require a quantitative analyses with the same level of complexity as the analyses used to assess the

compliance period, thus the NRC expects the cost impacts to be smaller than the cost impact associated with the analyses that will be used to assess the compliance period.

Section 61.25 was revised to require licensees to provide sufficient notification to the Commission and to provide an opportunity for hearing when changes are proposed to waste acceptance criteria. Changes to waste acceptance criteria by licensees will incur a cost impact for both the licensee and Agreement State regulatory agencies. Some of the cost impacts associated with this revision (e.g., time delays) are fixed and will be similar for all disposal facilities, while others will be variable depending on the complexity and risk significance of the proposed change to the waste acceptance criteria.

Paragraph 61.28(a)(2) was revised to clarify that licensees must submit updated technical analyses as part of the application for closure of a disposal facility. Submitting these technical analyses will result in a cost impact to licensees as the land disposal facility approaches closure. Also, for Agreement States with an operating land disposal facility that had not anticipated revisiting the technical analyses as part of the licensing action to amend the license for closure of a disposal facility, this revision will result in a cost impact as the land disposal facility approaches closure.

Paragraph 61.41(a) requires licensees to demonstrate that the general population will be protected from releases of radioactivity from a land disposal facility during the compliance period using a performance assessment which meets the criteria specified in § 61.13(a). Specifically, licensees must demonstrate through the performance assessment that releases will not result in an annual dose to a member of the public that exceeds an equivalent of 0.25 milliSieverts (25 mrem). The costs to licensees to demonstrate the public will be protected, and for Agreement State regulatory agencies to review a licensee's analyses, are incurred through development of the performance assessment required in § 61.13(a).

Paragraph 61.41(b) requires licensees to minimize releases of radioactivity from a disposal site to the general environment to the extent reasonably achievable at any time during the performance period. Licensees must demonstrate compliance with this paragraph through analyses that meet the requirements specified in § 61.13(e). The costs to licensees to perform these analyses and to Agreement State regulatory agencies to review these analyses are incurred through the performance period analyses required in § 61.13(e). Licensees that do not accept waste with significant quantities of long-lived radionuclides will not be required to perform analyses for the performance period. Therefore, those licensees and Agreement States will not incur costs to perform and review the performance period analyses.

Paragraph 61.42(a) requires licensees to demonstrate that an inadvertent intruder will be protected. Specifically, licensees must demonstrate through the inadvertent intruder assessment that the annual dose to an inadvertent intruder, who might occupy the disposal site after institutional controls are removed, will not exceed 5 milliSieverts (500 mrem). The costs to licensees to develop the inadvertent intruder assessment, and to Agreement State regulatory agencies to review such an assessment, are incurred through the performance period analyses required in § 61.13(b).

Paragraph 61.42(b) requires licensees to minimize exposures to any inadvertent intruder to the extent reasonably achievable at any time during the performance period. Licensees must

demonstrate compliance with this paragraph through analyses that meet the requirements specified in § 61.13(e). The costs to licensees to perform these analyses and to Agreement State regulatory agencies to review them are incurred through development of the performance period analyses required in § 61.13(e). Licensees that do not accept waste with significant quantities of long-lived radionuclides will not be required to perform analyses for the performance period. Therefore, those licensees and Agreement States will not incur any associated costs.

Section 61.44 requires licensees to demonstrate that the disposal site will be stable and to eliminate to the extent practical the need for active maintenance during the compliance period. This revision clarifies the timeframe over which the stability must be ensured. Licensees must demonstrate compliance with § 61.44 through analyses that meet the requirements specified in § 61.13(d). The costs to licensees to perform these analyses, and to Agreement State regulatory agencies to review them, are incurred through the compliance period analyses required in § 61.13(d). The NRC expects that this revision will impact licensees and Agreement State regulatory agencies depending upon the timeframes previously analyzed to comply with the performance objectives prior to this revision. These timeframes have varied in each of the four Agreement States that currently have operating land disposal facilities.

Section 61.50 specifies the minimum characteristics a disposal site must possess to be acceptable for disposal of LLRW. The revisions to this section clarify differences in how hydrologic characteristics are to be considered during the first 500 years after closure and after the initial 500-year post-closure period. The NRC expects that these revisions will have minimal cost impact on licensees because the criteria are similar to previous criteria from the first 500 years after closure and are more flexible for the time period beyond 500 years after closure, in that licensees can assess the site's suitability in terms of impacts on the demonstration of compliance with the performance objectives. Therefore, any cost impacts incurred by licensees would likely be through the conduct of the technical analyses specified in § 61.13 that are used to demonstrate compliance with the performance objectives.

Section 61.51 was revised to ensure licensees direct site design toward defense-in-depth protections. Because defense-in-depth has been implicit in the regulations for land disposal in 10 CFR Part 61, licensees have been incorporating defense-in-depth protections, implicitly, in the site design that are commensurate with the risks. Therefore, the NRC expects the costs associated with this revision to primarily involve the explicit identification of defense-in-depth protections and the description of their capabilities and associated technical bases, which will be incurred through compliance with § 61.12(o). However, in explicitly identifying and justifying defense-in-depth protections, some land disposal facilities may recognize that additional defense-in-depth protections and physical modifications may be needed that could result in a cost impact associated with disposal site design.

Paragraph 61.52(a)(12) was added to ensure that only waste meeting the authorized waste acceptance criteria is acceptable for disposal. The NRC expects that any cost impacts associated with this modification would be incurred by licensees in demonstrating compliance with the requirements for waste acceptance specified in § 61.58 and by Agreement State regulatory agencies in reviewing a licensee's submittals.

Paragraph 61.52(a)(13) was added to ensure that waste will be disposed consistent with the technical analyses required in § 61.13 and the licensee's description of the construction and operation of the disposal site required in § 61.12(f). Licensees have generally been disposing of waste consistent with existing license conditions and specifications which have been authorized after review of a licensee's technical analyses and supporting information to demonstrate that the performance objectives will be met. Therefore, the NRC does not expect this addition to result in a significant cost impact to licensees. Likewise, Agreement State regulatory agencies have been responsible for inspecting land disposal facilities to ensure that waste is disposed of according to license conditions and specifications. Thus, the NRC does not expect a significant cost impact for the Agreement States either. However, it is possible that a licensee may recognize that disposal of certain waste streams may need to change based on the results of the new and revised technical analyses required by this rule. Should a cost impact occur because of changes to disposal facility operations and construction, Agreement State regulatory agencies would also incur a cost associated with reviewing and authorizing changes to the license.

Section 61.57 was revised to require that waste packages be labeled with any information required by a land disposal facility's waste acceptance criteria developed according to the criteria in § 61.58. The NRC expects costs associated with this revision to vary from land disposal facility to land disposal facility, and would be incurred by a waste generator depending on the requirements developed by a licensee with respect to waste acceptance.

Section 61.58 requires that licensees develop waste acceptance criteria, acceptable characterization methods, and a program to certify that waste is acceptable for disposal. Licensees must comply with these requirements at their next license renewal or within 5 years of the effective date of these new requirements, whichever comes first, per § 61.58(d). Specifics for waste acceptance by section are listed below.

Paragraph 61.58(a) was added to require licensees to develop criteria for waste acceptance that provides reasonable assurance the performance objectives will be met. The criteria require licensees to establish allowable activities and concentrations of specific radionuclides in waste, acceptable waste form characteristics and container specifications, and restrictions or prohibitions on waste, materials, or containers. Current licensees operating land disposal facilities have all previously developed waste acceptance criteria to varying degrees. The NRC expects any cost impacts associated with this revision to be function of the level of detail previously used to develop and document waste acceptance criteria. Existing licensees that have developed more detailed waste acceptance criteria are likely to incur a smaller cost than licensees whose waste acceptance criteria is less detailed. Similarly, review and authorization of the waste acceptance criteria will result in a cost for Agreement State regulatory agencies, the magnitude of which will depend upon the level of detail in previously authorized waste acceptance criteria.

Paragraph 61.58(b) was added to require licensees to specify waste characterization methods to demonstrate that waste is acceptable for disposal. The revisions require licensees to identify the characterization parameters and acceptable uncertainty in the characterization data. The revisions also require a minimum set of information necessary to characterize waste. Though waste characterization has always been necessary to accept waste at a land disposal facility, the NRC expects there will be cost impacts for land disposal facility operators to comply with the

minimum set of information needed to obtain authorization from the Agreement State regulatory agencies for these methods. The degree of the cost impact will vary depending upon the level of detail that land disposal facility licensees previously used to describe acceptable waste characterization methods, though licensees for all existing land disposal facilities will need to obtain authorization from an Agreement State regulatory agency to use the methods. Similarly, Agreement State regulators will incur costs to review and authorize acceptable waste characterization methods.

Paragraph 61.58(c) was added to require that licensees for land disposal facilities develop a program to certify that waste meets the acceptance criteria prior to shipment to a disposal facility. The revisions include criteria for the content of the certification program. Though licensees for land disposal facilities have previously required certain information in order to accept waste, the NRC expects there will be cost impacts for those licensees to comply with the minimum set of information to develop an acceptable waste certification program and obtain authorization from their Agreement State regulatory agency. Similarly, Agreement State regulators will incur costs to review and authorize waste certification programs.

Paragraph 61.58(e) requires that a waste acceptance program be incorporated into the facility license. The cost associated with this revision will be incurred by licensees and Agreement State regulatory agencies as part of the development and review of § 61.58(a), (b), and (c).

Paragraph 61.58(f) requires licensees annually review the waste acceptance criteria, waste characterization methods, and certification program. The NRC expects licensees to incur a cost to annually review their waste acceptance programs.

Paragraph 61.58(g) requires licensees to submit an application to modify approved waste acceptance criteria. The NRC expects licensees to incur costs associated with license amendments, but the costs will vary depending on the frequency and magnitude of changes proposed by a licensee.

Paragraph 61.80(i)(2) was restructured to meet codification requirements of the Office of the Federal Register and to remove a requirement to report activities and concentrations of radionuclides by waste class. Licensees are still required to report activities and quantities of radionuclides; however, not all licensees may rely on the waste classification requirements for waste acceptance. The NRC does not expect licensees to experience significant cost savings associated with this amendment.

Paragraph 61.80(m) was added to require licensees to maintain records associated with the new waste acceptance requirements. Although many licensees currently retain records of disposal site inventory, the NRC expects licensees to incur incremental costs associated with the retention of these records in order to comply with the new required information specified.

Section 6 discusses the reasons for why the NRC proposes Alternative 2, and consequently is pursuing this rule change.

3. Estimation and Evaluation of Benefits and Costs

This section describes the analysis that the NRC conducted to identify and evaluate the benefits and costs of the two regulatory alternatives. Section 3.1 describes how the benefits and costs were analyzed. Section 3.2 presents the assumptions of the analysis. Section 3.3 identifies the entities expected to be affected by the rulemaking. Section 3.4 identifies the attributes expected to be affected by the rulemaking.

3.1 Analytical Methodology

This section describes the methodology used to analyze the consequences associated with the rule. The methodology for a regulatory analysis is specified by various guidance documents. The two documents that govern the NRC's voluntary regulatory analysis process are NUREG/BR-0058, Revision 4, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," dated September 2004 (RA Guidelines), and NUREG/BR-0184, "Regulatory Analysis Technical Evaluation Handbook," dated January 1997 (RA Handbook). In addition, the methodology is in accordance with guidance from the Office of Management and Budget (OMB), Circular A-4. Based on OMB guidance, present-worth calculations are presented using both 3-percent and 7-percent real discount rates. The real discounted rates or present-worth calculation determines how much society would need to invest today to ensure that the designated dollar amount is available in a given year in the future. By using present-worth calculations, costs and benefits, regardless of time, are valued equally. The 3-percent rate approximates the real rate of return on long-term government debt which serves as a proxy for the real rate of return on savings. This rate is appropriate when the primary effect of the regulation is on private consumption. Alternatively, the 7-percent rate approximates the marginal pretax real rate of return on an average investment in the private sector, and is the appropriate discount rate whenever the main effect of a regulation is to displace or alter the use of capital in the private sector. Current trends in the marketplace have provided returns on investments well below the 3 percent and 7 percent discount rates, upon which OMB Circular No. A-4 is based. The NRC is providing a zero discount rate (e.g., undiscounted values) as a further sensitivity analysis. The NRC is reporting the undiscounted costs as part of the sensitivity analysis based on current market trends and future predictions.

The regulatory analysis identifies all attributes related to the regulatory action and analyzes them either quantitatively or qualitatively. For the quantified regulatory analysis, the NRC staff developed expected values for each cost and benefit. First for each alternative, the staff determined the cost and benefit, and then discounted the consequences in future years to the current year of the regulatory action. Finally, the NRC staff summed the costs and the benefits for each alternative and compared them.

This regulatory analysis measures the incremental costs of the final rule relative to a "baseline" that reflects anticipated behavior in the event the NRC undertakes no additional regulatory action (Alternative 1, the "no-action" alternative). As part of the regulatory baseline used in this analysis, the NRC staff assumes full licensee compliance with existing NRC regulations. This alternative is equivalent to the status quo and serves as a baseline to measure against the other alternatives. Section 4 presents the estimated incremental benefits and costs of the rule relative to this baseline.

After performing the quantitative regulatory analysis, the NRC staff addressed attributes that could only be evaluated qualitatively. The rule includes changes that affect attributes in a

positive but not easily quantifiable manner. For example, the attribute of public health (accident)[1] would be enhanced by the changes made in requirements for intruder assessment such as in § 61.42, but it is difficult to assign a number to this benefit, as the quantification would require the analysis to estimate the reduction in accident frequency and associated risk for the action and report this as person-rem avoided exposure.

The benefits include any desirable changes in the affected attributes. The costs include any undesirable changes in affected attributes.

The NRC staff used data from subject matter experts, NRC documents, stakeholder comments, knowledge gained from past rulemakings, and information gained during public meetings and from correspondence, to collect data for this analysis.

3.2 Assumptions

Assumptions used are identified throughout this document. For reader convenience, major assumptions are listed below:

3.2.1 General assumptions:

- The NRC assumes the final rule will be published in calendar year 2016 and will become effective one year later in 2017. Because all four affected licensees are Agreement States' licensees and the Agreement States are allowed up to 3 years to develop conforming regulations, the NRC is assuming that the rule will not be implemented by licensees until calendar year 2020.[2] It is assumed that the initial analyses (including development of the waste acceptance criteria) will be completed in 2020. The associated cost will be included in industry implementation and will be discounted to 2016 dollars.

- The NRC calculates benefits and costs over the entire analysis period, discounted at a 7-percent and 3-percent discount rate and expressed in 2016 dollars. The NRC is also reporting the undiscounted costs as part of the sensitivity analysis, based on current market trends and future predictions.

- As described in the OMB Circular A-76, "Performance of Commercial Activities," the number of productive hours in 1 year is 1,776. As this actual value is likely to vary from State to State and no specific data are available, the Full-time equivalent (FTE) costs for the States and licensees are based on the number of hours estimated in OMB Circular A-76.

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[1] The inadvertent intruder is not considered an accident scenario in 10 CFR Part 61, but to allow for the capture of the cost/benefit impact attribute, the NRC is using Public Health (accident).

[2] NRC, "Adequacy and Compatibility of Agreement States Program," Directive 5.9, February 1998, ADAMS Accession No. ML041770094.

- The NRC assumes that the four impacted licensees have developed modeling tools to complete their existing technical analysis. In addition, the NRC assumes that the licensees will utilize these existing modeling tools with modifications to update their technical analysis to be in compliance with the new requirements. The cost of updating these modeling tools will vary by licensee, and these costs are reflected below in the site specific assumptions. In addition, it is assumed that each impacted licensee has already performed a technical analysis to demonstrate their site meets the performance objectives. The NRC assumes that the bulk of a licensee's cost and an Agreement State's review costs will occur in connection with updating the technical analyses. The scope of the existing analyses is assumed to be similar to the updated analyses, though the importance of some features, events, and processes will differ.

- It is assumed that licensees and Agreement States will use a team to complete their technical analyses and review/approval, respectively. The teams will include attorneys, environmental scientists, and office administrative support staff along with contractors. It is assumed that attorneys will constitute approximately 5 percent of the total effort, administrative staff will constitute approximately 5 percent of the total effort, and environmental scientists will constitute approximately 30 percent of the effort, with the balance completed by contractors.

- Although a licensee is expected to update its technical analyses prior to accepting any new, previously unanalyzed waste streams, for the purposes of this regulatory analysis, the NRC assumes new waste streams are only introduced at the time of license renewal and the impacted Agreement State will complete its review during the license renewal review time period.

- The NRC conservatively assumes that all four licensees will conduct both compliance period and performance period analyses (although 3 out of 4 of the licensees have had to already complete some form of analysis to comply with their Agreement State regulations). The NRC assumes that each licensee will incur a range of 3,552 to 8,880 hours (two to five FTE) developing and updating their technical analyses for the compliance period and 1,776 hours (one FTE) developing the performance period analyses. The labor effort is dependent on a variety of factors which will be outlined in more detail in the site specific assumptions. The NRC assumes that a licensee expends 1,776 hours (one FTE) developing the initial waste acceptance criteria. In addition, it is assumed licensees will incur varying additional costs (e.g., updating modeling tools, software, contractors, etc.) associated with updating their technical analyses to comply with the new regulations. The specifics associated with the additional costs will be outlined below in the site specific assumptions.

- The NRC assumes that a licensee, when renewing its license, will expend 4,440 hours (2.5 FTE) developing its updated analyses, the lower labor cost (in relation to the cost for initially updating their analyses as a result of the rule) for updating analyses is associated with lower labor effort necessary at the time of license renewal. The NRC assumes the licensee on average will expend 1.5 FTE in

developing its site closure application. It is assumed that significant site-specific changes or the introduction of new waste streams will occur during each renewal cycle thus requiring the licensee to update its technical analyses; however, if these situations do not occur, the licensee would be expected to incur little or no additional cost during renewal as a result of this rule.

- The NRC assumes that a licensee renewing its license incurs 888 hours (0.5 FTE) developing the updated waste acceptance criteria.

- The NRC assumes that a licensee spends 80 hours to annually review the LLRW acceptance criteria and to meet additional recordkeeping requirements.

- The NRC staff determined Agreement State labor rates using National Wage Data available on the Bureau of Labor Statistics (BLS) Web site (www.bls.gov). Because exact hourly rates for each state vary from State to State, nationwide mean hourly rates are used. Also, the exact rulemaking burden varies from State to State depending, among other things, on the mix of different professional skills and administrative support required. These rates are multiplied by 1.5 to account for items such as pension, insurance, overhead, and other legally-required benefits and have been adjusted to 2016 dollars. For the review of licensee-developed site-specific technical analyses and waste acceptance criteria associated with this rulemaking, $49.26/hour is used ($32.84*1.5), which is from the BLS employer cost data set for an "Environmental Scientist" in the private sector; $29.23 is used ($19.48*1.5), which is from the BLS employer cost data set for "Administrative Staff"; and $76.08 is used ($50.72 *1.5), which is from the BLS employer cost data set for "Lawyer."

- Licensee labor rates were also obtained from Bureau of Labor Statistics National Wage Data available on the BLS Web site. The NRC selected an appropriate mean hourly labor rate depending on the listed industry and the occupation (e.g., waste management, health and safety) and multiplying by 1.5 to account for pension, insurance, and other legally-required benefits, and the rates have been adjusted to 2016 dollars. Because exact licensee hourly rates can vary significantly, the NRC used nationwide mean hourly rates. For the development of site-specific technical analyses and waste acceptance criteria associated with this rulemaking, $56.76/hour is used ($37.84*1.5), which is from the BLS employer cost data set for an "Environmental Scientist" in the private sector; $39.20 is used ($26.13*1.5), which is from the BLS employer cost data set for "Administrative Staff"; and $83.35 is used ($55.57 *1.5), which is from the BLS employer cost data set for "Lawyer."

3.2.2 Site-specific assumptions:

- EnergySolutions located in Clive, Utah was required to develop a new modeling approach to demonstrate compliance with the State of Utah rules for the disposal of DU. It is estimated that updating of the modeling tools costs an estimated $400,000 which the NRC considers a sunk cost. The NRC estimates that EnergySolutions will spend an additional $100,000 to update its modeling tools

and an additional $200,000 for contractors, software, and other associated costs to become complaint with the new rule requirements. EnergySolutions used new modeling tools to perform a technical analysis, which was for a minimum of 500 years and out to beyond 10,000 years for DU disposal to be in compliance with the State of Utah regulations. In addition, the NRC assumes that EnergySolutions will incur 3,552 hours (two FTE) developing and updating its technical analyses for the compliance period and 1,776 hours (one FTE) developing the performance period analyses. This facility is subject to a 10-year renewal period and its current license is considered to be under timely renewal (with a previous license expiration date of January 25, 2013). The NRC estimates that this renewal will be approved in 2016. It is also estimated that this licensee will renew its license in 2026 and 2036. It is estimated that this licensee will close its facility in 2045 and will complete the required site closure analysis in 2045.

- US Ecology Inc., located in Richland, Washington, has completed a technical analysis for up to 10,000 years. It is assumed that US Ecology will use its existing modeling tools with modifications and that it will cost approximately $400,000 to update the modeling tools. In addition, it is assumed that US Ecology Inc. will incur $600,000 in additional cost (e.g., updating software, hiring contractors, etc.) associated with updating technical analyses to comply with the new regulations. The NRC assumes that US Ecology Inc., will incur 8,880 hours (five FTE) developing and updating its technical analyses for the compliance period and 1,776 hours (one FTE) developing the performance period analyses. This facility is subject to a 5-year renewal period and the licensee will need to submit its license renewals in 2023, 2028, 2033, 2038, 2043, 2048, and 2053. It is estimated that this licensee will close its facility in 2056 and will complete the required site closure analysis in 2056.

- As required by Texas regulations, Waste Control Specialists LLC (WCS), located in Andrews, Texas has performed a technical analysis up to 50,000 years. It is assumed that WCS will use its existing modeling tools with modifications and that it will cost approximately $100,000 to update the modeling tools and an additional $200,000 for contractors, software, and other associated costs to comply with the new requirements. In addition, the NRC assumes that WCS will incur 3,552 hours (two FTE) developing and updating its technical analyses for the compliance period and 1,776 hours (one FTE) developing the performance period analyses. This facility is subject to 10-year renewal period and the licensee will need to renew the facility license in 2024 and 2034. It is estimated that this licensee will close its facility in 2044 and will complete the required site closure analysis in 2044.

- EnergySolutions located in Barnwell, South Carolina performed a technical analysis to 2,000 years for its license application for the Barnwell site. It is assumed that the licensee will use its existing modeling tools with modifications and that it will cost approximately $400,000. In addition, it is assumed that EnergySolutions will incur $600,000 in additional costs (e.g., updating software, hiring contractors, etc.) associated with updating its technical analyses to comply

with the new regulations. The NRC assumes that EnergySolutions will incur 8,880 hours (five FTE) developing and updating its technical analyses for the compliance period and 1,776 hours (one FTE) developing the performance period analyses. This facility is subject to 5-year renewal periods and the NRC estimates that the licensee will renew its license for this facility in 2020, 2025, 2030 and 2035. It is estimated that this licensee will close its facility in 2039 and will complete the site closure analysis in 2039.

3.2.3 Agreement State assumptions:

- The state of Utah will be required to review the analyses submitted by EnergySolutions located in Clive, Utah. Utah will need to update its modeling review approach. The NRC estimates that Utah will spend $100,000 to update its modeling review tools and an additional $300,000 for contractors, software, and other associated costs. Utah's licensing term for EnergySolutions is 10-years and EnergySolutions' current license is considered to be under timely renewal (with a previous license expiration date of January 25, 2013). The NRC estimates that this renewal will be approved in 2016. It is estimated that Utah will review license renewal analyses for EnergySolutions in 2026 and 2036. It is also assumed that this licensee will close its facility in 2045 and will complete the required site closure analysis for review in 2045. Thus it is assumed that Utah will incur costs for review of the closure application in 2045.

- The state of Washington will be required to review the analyses submitted by US Ecology Inc., located in Richland WA. Washington will need to update its modeling review approach. The NRC estimates that Washington will spend $100,000 to update its modeling review tools and an additional $300,000 for contractors, software, and other associated costs. This facility is subject to a 5-year renewal period and Washington will need to review license renewal submittals in 2023, 2028, 2033, 2038, 2043, 2048, and 2053. It is also assumed that this licensee will close its facility in 2056 and will complete the required site closure analysis for review in 2056. Thus it is assumed that Washington will incur costs for review of the closure application in 2056.

- The state of Texas will be required to review the analyses submitted by Waste Control Specialists LLC, located in Andrews, Texas. It is assumed that Texas will use its existing modeling review tools with modifications and that it will cost approximately $100,000 to update the modeling tools, as well as an additional $300,000 for contractors, software, and other associated costs. This facility is subject to a 10-year renewal period and Texas will need to review license renewal submittals in 2024 and 2034. It is estimated that this licensee will close its facility in 2044 and will complete the required site closure analysis for review in 2044. Thus it is assumed that Texas will incur costs for review of the closure application in 2044.

- The state of South Carolina will be required to review the analyses submitted by EnergySolutions located in Barnwell, SC. It is assumed that South Carolina will use its existing modeling review tools with modifications and that it will cost

approximately $100,000 to update the modeling tools and an additional $300,000 for contractors, software, and other associated costs. This facility is subject to a 5-year renewal period and the NRC estimates that South Carolina will need to review the additional analyses submitted by the licensee in 2020, 2025, 2030 and 2035. It is assumed that this licensee will close its facility in 2039 and will complete the site closure analysis for review in 2039. Thus it is assumed that South Carolina will incur costs for review of the closure application in 2039.

- The NRC assumes that an Agreement State incurs 3,552 hours (two FTE) reviewing the updated technical analyses for the compliance period and 888 hours (half FTE) reviewing the updated performance period analysis. The NRC assumes that the Agreement States will expend 1,776 hours (one FTE) reviewing the initial LLRW acceptance criteria.

- The NRC assumes that an Agreement State, when reviewing a licensee's submittal for closure or license renewal, will expend 3,552 hours (2 FTE).

- The NRC assumes that an Agreement State, when reviewing a licensee's submittal with updated LLRW acceptance criteria in connection with license renewal, incurs 888 hours (0.5 FTE).

- The NRC assumes that an Agreement State incurs 40 hours annually reviewing the updated LLRW acceptance criteria.

3.3 Affected Entities

The affected entities are those entities that could be impacted from any of the alternatives. The NRC does not anticipate any new LLRW disposal facility will be built during the next twenty years. The affected entities are four licensees located in four separate Agreement States. The affected entities (Agreement State licensees and Agreement States) are listed in Tables 3-1 and 3-2.

Table 3-1 Impacted LLRW Disposal Waste Licensees

Licensee	Location
1. EnergySolutions	Clive, Utah
2. U.S. Ecology, Inc.	Richland, Washington
3. Waste Control Specialists LLC	Andrews, Texas
4. EnergySolutions	Barnwell, South Carolina

Table 3-2 Impacted Agreement States

Agreement States Impacted
1. Utah
2. Washington
3. Texas
4. South Carolina

3.4 Identification of Affected Attributes

This section identifies the factors within the public and private sectors that the final rule is expected to affect, using the list of potential attributes in Chapter 5 of NUREG/BR 0184, "Regulatory Analysis Technical Evaluation Handbook," issued January 1997, and in Chapter 4 of NUREG/BR 0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," Revision 4, issued September 2004. This evaluation considered each attribute listed in Chapter 5 of NUREG/BR-0184. The basis for selecting those attributes is presented below.

Affected attributes include the following:

- Industry Implementation - Under the action, the industry will incur a one-time cost to implement the rule.

- Industry Operation - The changes to 10 CFR Part 61 requires licensees to meet the new and amended requirements discussed in Section 2.2.

- Other Government - The Agreement States will incur an implementation cost to issue compatible regulatory requirements and guidance as well as on-going costs to review technical analyses (at renewal and closure) and waste acceptance criteria.

- NRC Implementation - Under the regulatory action, the NRC developed proposed and final rule packages. In addition, the NRC developed the NUREG guidance document. The costs incurred to develop these documents and all rulemaking activities are considered sunk costs and are not included in this regulatory analysis.

- Other Consideration - Under the action, a licensee must analyze its LLRW disposal site to ensure that disposal of waste streams not considered during

the development of the current rule can occur safely and that the site will still meet the performance objectives in subpart C of 10 CFR Part 61. New technologies could result in future generation of different kinds of LLRW streams. The rule will allow industry to dispose of an increased variety of waste without compromising safety. The waste acceptance criteria should also allow licensees to optimize disposal capacity while ensuring protection of public health and safety, which is likely to reduce costs. In addition, ensuring that disposal of these new LLRW streams occurs safely may minimize the likelihood that future mitigation would be required, thereby limiting potential future costs to licensees.

- Public Health (Accident) - This attribute measures expected changes in radiation exposures to the public due to changes in accident frequencies or accident consequences associated with the action. The rule requires new site-specific technical analyses to ensure that an inadvertent intruder, who occupies the site and might unknowingly be exposed to radiation from disposed LLRW, will be better protected. These analyses will demonstrate there is reasonable assurance that any inadvertent intruder will not be exposed to doses that exceed the performance objectives set forth in § 61.42.

- Improvements in Knowledge - This attribute accounts for the potential value of new information. The new and revised analyses will help the licensee gather additional valuable information that would be used in the current and continued disposal of LLRW at its facility. This new information will ensure that LLRW streams that are significantly different from those considered during the development of the current regulations can be disposed of safely. Development of new waste acceptance criteria should also allow licensees to optimize disposal capacity while ensuring protection of public health and safety, which is likely to reduce a licensee's costs.

Attributes that are not affected include the following: NRC operations, public health (routine), general public, regulatory efficiency, occupational health (routine), occupational health (accident), off-site property, on-site property, environmental considerations, antitrust considerations, and safeguards and security considerations.

4. Presentation of Results

This section presents the results of the alternatives.

4.1 Alternative 1: No action

By definition, the No-Action Alternative, the baseline for the main analysis, does not result in any change of benefits or costs. The baseline assumes full compliance with current NRC requirements.[3]

4.2 Alternative 2: Rulemaking to amend 10 CFR Part 61

This section presents the quantitative results by attribute broken down by impacted entity.

4.2.1 Industry Implementation Costs:

Initial safety case forecasted to be conducted in year 2020.

> Section 61.10 requires licensees to submit a safety case. The safety case includes the technical analyses that licensees are required to conduct under § 61.13. The technical analyses include a performance assessment, an intruder assessment, and a site stability analysis to demonstrate compliance with the performance objectives in §§ 61.41, 61.42, and 61.44. For those sites that have disposed of, or plan to dispose of, significant quantities of long-lived radionuclides, a performance period analysis is also required. Additionally, § 61.58 requires licensees to develop waste acceptance criteria and § 61.12(o) requires licensees to identify defense-in-depth protections and describe the capabilities of those protections to ensure safety is maintained.
>
> The NRC estimates that the costs will vary for each licensee to update their safety case including the technical analyses, waste acceptance criteria, and defense-in-depth protections. The NRC estimates that the licensee's labor effort will range from 7,104 to 12,432 hours (four to seven FTE). In addition, licensees will have varying implementation costs associated with updating their modeling tools, software, and other tools as required. The additional cost is estimated to range from $300,000 to $1,000,000 per licensee. The total implementation cost is estimated to range from $650,000 to $1.6M per licensee equating to approximately $2.6 to $6.4M for the industry.

4.2.2 Industry Operation Costs:

Updating of the safety case required at license renewal during facility operations.

> To ensure compliance with the Subpart C performance objectives, § 61.27 specifies the requirements for renewal of a license. While the NRC did not revise § 61.27 in this

[3] NUREG/BR-0058, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission," the NRC staff's guidance for regulatory analyses, states that, "in evaluating a new requirement...the staff should assume that all existing NRC requirements have been implemented."

rulemaking, licensees may incur additional costs to update the safety case, including new and revised technical analyses, required by this rulemaking at license renewal. For renewal, licensees are required to update their safety case (i.e., updating their technical analyses which include: the performance assessment, intruder assessment, and site stability analysis) if changes affecting the safety case or technical analyses occur. Additionally, if a site has disposed of, or plans to dispose of, significant quantities of long-lived radionuclides, the performance period analysis may also require updating. These analyses demonstrate that the performance objectives of Subpart C will continue to be met. Additionally, licensees may need to update their waste acceptance criteria, required by § 61.58, and identification of defense-in-depth protections, required by § 61.12(o). While the costs to update the technical analyses, waste acceptance criteria, and defense-in-depth protections will vary from site to site depending on whether new information warrants significant revisions, the NRC estimates that the costs to update the safety case consists of 5,328 hours (three FTE), or approximately $265,000 per licensee, with the total approximate cost to industry of $1.1M. These incremental costs may be overestimated if there are no changes at the site between license renewals that require an update to the safety case.

Updated safety case required at facility closure.

Section 61.28 requires a licensee to update its safety case (i.e., updating the technical analyses which consist of: the performance assessment, intruder assessment, and site stability analysis) with the application to amend the license for closure. If a site has disposed of significant quantities of long-lived radionuclides, the performance period analysis would also need to be updated. Similarly, licensees will need to update its identification of defense-in-depth protections as part of the final safety case. The NRC estimates that the costs for each licensee to conduct its updated technical analyses and revise its identification of defense-in-depth protections will be 4,440 hours (2.5 FTE), or approximately $220,000 per licensee, and the total estimated cost to the industry is approximately $880,000. These incremental costs may be overestimated if there were no changes at the site that would require updates to the technical analyses or identification of defense-in-depth protections after the last license renewal before the closure application is submitted.

Conducting annual reviews of waste acceptance criteria during facility operations.

Section 61.58(f) requires a licensee to review its waste acceptance criteria annually to determine whether an update is needed. The NRC estimates that each annual review of waste acceptance criteria will require 40 hours (0.02 FTE), or approximately $2,000 per licensee, with a total annual cost to the industry of approximately $8,000.

Recordkeeping requirements.

New language for § 61.80(m) requires licensees to maintain records of their audits and other reviews of program content and implementation. The NRC estimates that each recordkeeping effort will require 40 hours (0.02 FTE), or approximately $2,000 per licensee, with a total annual cost to the industry of approximately $8,000.

4.2.3 Agreement State Implementation Costs:

Conducting rulemaking and development of guidance documents.

The Agreement States develop the rule packages, procedures, and guidance to accommodate the requirements that will be added or modified by the rulemaking process. The effort to develop the rule package is estimated to require 888 hours (0.5 FTE) for each Agreement State. This will result in a total cost of approximately $42,000 per Agreement State, with a total cost for the Agreement States of approximately $168,000.

Reviewing safety case.

Agreement States will need to review each licensee's safety case required by § 61.10, including technical analyses that are required by § 61.13; waste acceptance criteria, required by § 61.58; and identification of defense-in-depth protections, required by § 61.12(o). The NRC estimates that the costs for each Agreement State to review a licensee's initial technical analyses, waste acceptance criteria, and defense-in-depth protections will be 7,992 hours (4.5 FTE). In addition, the Agreement States will have implementation costs associated with updating their modeling review tools, software, and other tools as required. This additional cost is estimated at $400,000 per Agreement State. Initial Agreement State review of a safety case is forecasted to be conducted in year 2020.

4.2.4 Agreement State Operation Costs:

Additional review of updated safety case required at licensee renewal.

Section 61.27 requires an Agreement State review a licensee's updated safety case including technical analyses, waste acceptance criteria, and identification of defense-in-depth protections to ensure compliance with the Subpart C performance objectives at license renewal. Each Agreement State reviews the updated technical analyses, waste acceptance criteria, and defense-in-depth protections as part of the license renewal authorization. The NRC estimates that these reviews will require 4,440 hours (2.5 FTE), or approximately $210,000 per Agreement State, with a total Agreement States' cost of approximately $840,000. These incremental costs may be overestimated if no changes occurred at a site between license renewals that would require updates to the technical analyses, waste acceptance criteria, or defense-in-depth protections.

Additional review required at facility closure.

Section 61.28 requires an Agreement State review a licensee's updated safety case, including technical analyses and defense-in-depth protections, at facility closure. The NRC estimates that each Agreement State review of a licensee's updated technical analyses and defense-in-depth protections will require 3,552 hours (2 FTE), or approximately $168,000 per Agreement State, with a total cost for the Agreement States of approximately $672,000. These incremental costs may be overestimated if there were no changes that occurred at the site between the last license renewal and submission of the closure

application that would require updates to the technical analyses or defense-in-depth protections.

4.2.5 NRC Implementation

Under the regulatory action, the NRC developed proposed and final rule packages, as well as the NUREG guidance document. The cost incurred to develop these documents and all rulemaking activities are considered sunk cost and not included in this regulatory analysis.

4.2.6 Public Health (Accident)

The 10 CFR Part 61 LLRW classification system remains protective of inadvertent intruders for the LLRW streams that were analyzed in the development of the regulations, because of the reasonably conservative nature of the analysis used to develop the LLRW classification system. However, inconsistencies between actual site conditions and practices at LLRW land disposal facilities, and the generic assumptions used to develop the LLRW classification system, may cause the radionuclide concentration limits to be either overly restrictive or permissive, depending on the specific site. 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 an LLRW land 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 inadvertent intruders.

It is the 10 CFR Part 61 performance objectives, rather than the LLRW classification requirements, that ultimately ensure protection of public health and safety. Therefore, if the Commission found that the LLRW classification requirements were overly permissive at a particular land disposal facility, it could impose additional requirements to ensure that the 10 CFR Part 61 performance objectives would be met. The revisions to this rule allow waste acceptance criteria to be developed from either the waste classification limits in § 61.55 or the results of the analyses required in § 61.13. Regardless of the method used to develop waste acceptance criteria, licensees must demonstrate through the analyses required under § 61.13, that the performance objectives will be met. Requiring licensees to demonstrate that waste acceptance criteria will demonstrate that the performance objectives are met will provide assurance that public health and safety will be protected, while offering the possibility for relief from unnecessary regulatory burdens for facilities with superior site characteristics, design, and operational practices.

4.2.7 Improvements in Knowledge

The new and revised analyses will help the licensee gather additional valuable information that will be used in the current and continued disposal of LLRW at its facility. This new information will ensure that LLRW streams that are significantly different from those considered during the development of the current regulations can be disposed of safely. Development of new waste

acceptance criteria should also allow licensees to optimize disposal capacity while ensuring protection of public health and safety, which is likely to reduce licensee costs.

4.2.8 Other Considerations

Under this rulemaking, licensees will be permitted to develop waste acceptance criteria from the results of the technical analyses required in § 61.13. Development of waste acceptance criteria from the results of the technical analyses provides licensees flexibility to better manage disposal capacity consistent with the risks of disposal of LLRW streams. The technical analyses would provide insights on performance of the facility that would risk inform activities such as development of facility designs and site closure plans. Site closure plans would benefit from technical analyses that identify risk significant aspects of the design to help ensure effective and efficient implementation of site closure (e.g., additional safety measures would be considered for a particular waste stream well before the application for closure).

This flexibility may allow for additional revenue streams for disposal facility operators than may be permitted using the waste classification limits, depending on the performance of the disposal site. Additionally, the new flexibility would allow disposal facility operators to consider waste for disposal that may not have been analyzed previously. This flexibility may also increase access to disposal facilities for waste generators, potentially reducing disposal costs, particularly those who may have had difficulty disposing of waste previously because it may not have met certain aspects of the waste classification limits or waste characteristic requirements. Further, new technologies could result in generation of different kinds of LLRW streams. The rule would allow industry to potentially dispose of an increased variety of waste without compromising safety. Several of the amendments would increase operational flexibility for the licensees, (e.g., § 61.58), but the benefit from increased operational flexibility is difficult to quantify. Similarly, the safety impacts associated with the flexibility to consider a wider range of LLRW will be evaluated through the licensing process, rather than requiring rulemakings for each potential future LLRW stream that is significantly different than those used to develop the LLRW classification system. In addition, ensuring that LLRW streams that are significantly different from those considered during the development of the current regulations can be disposed of safely, will minimize the likelihood that future mitigation would be required as a result of disposing of such new LLRW streams, thereby limiting potential future costs to licensees.

4.2.9 Totals

Cost to the Industry:

The rule will result in incremental costs to the industry. On average, each licensee will incur an estimated undiscounted implementation cost of $1.13M. Overall, the industry will incur an estimated undiscounted implementation cost of $4.5M.

On average, each licensee will incur an estimated undiscounted ongoing operations cost of $1.33M over the lifetime of the facility. The undiscounted cost for ongoing operations for the industry will be approximately $5.3M over the lifetime of the facilities. Each licensee will have a total undiscounted cost of $2.45M ($1.13M implementation cost plus $1.33M ongoing operations cost). Thus the total undiscounted cost to industry is $9.8M (4 x $2.45M) over the

lifetime of the facilities. These costs would be lower if no changes requiring updating of the technical analyses occurred between renewals or before closure.

Cost to the Agreement States:

The rule will result in additional costs to the Agreement States with the majority of the costs resulting from implementation. On average, each Agreement State will incur an estimated undiscounted implementation cost of $0.74M. Overall, the Agreement States will incur an estimated undiscounted implementation cost of $2.9M (4 x $0.74M).

On average, each Agreement State will incur an estimated undiscounted operations cost of $1M over the lifetime of the land disposal facility. Thus the total ongoing operations undiscounted costs to the Agreement States will be approximately $4M (4 x $1M) over the lifetime of the facilities. The total undiscounted cost to the Agreement States is $6.9M ($2.9M implementation cost plus $4M ongoing operations costs) over the lifetime of the facilities. These costs would be lower if no changes requiring updating of the technical analyses occurred between renewals or before closure.

Quantitative Results: Total Present Value for the Cost

Table 4-1 summarizes the implementation costs by entity, over the analysis period for Alternative 2. Table 4-2 summarizes the annual costs by entity, over the analysis period for Alternative 2. Table 4-3 summarizes the combined Implementation and Annual costs by entity, over the analysis period for Alternative 2. The dollars for each of these tables are round to the nearest thousandth.

Table 4-1 Total Present Value of Cost by Entity (2016 dollars)

Description	One-time Implementation Costs undiscounted	One-time Implementation Costs discounted at 3%	One-time Implementation Costs discounted at 7%
Industry Costs	$4,539,000	$4,033,000	$3,463,000
Agreement States	$2,944,000	$2,616,000	$2,246,000
Total	$7,483,000	$6,649,000	$5,709,000

Table 4-2 Summary of Annual Cost by Entity (2016 dollars)

Description	Annual Operating Costs	Annual Operating Costs undiscounted	Annual Operating Costs discounted at 3 %	Annual Operating Costs discounted at 7 %
Industry Costs	$5,295,000	$5,295,000	$3,128,000	$2,081,000
Agreement States	$4,020,000	$4,020,000	$2,384,000	$1,517,000
Total	$9,315,000	$9,315,000	$5,512,000	$3,598,000

Table 4-3 Combined Implementation and Annual Cost Summary by Entity (2016 dollars)

Description	Total combined Implementation and Annual Cost undiscounted	Total combined Implementation and Annual Cost at 3% discount rate	Total combined Implementation and Annual Cost at 7% discount rate
Industry Costs	$9,834,000	$7,160,000	$5,544,000
Agreement States	$6,964,000	$5,000,000	$3,763,000
Total	$16,798,000	$12,160,000	$9,307,000

4.3 Benefits and Costs

This section presents the benefits and costs from the rule. To the extent that the affected attributes can be analyzed quantitatively, the net effect of each alternative is calculated and presented below. However, some benefits could be evaluated only on a qualitative basis.

The NRC qualitatively examined both the direct and indirect benefits that will accrue from risks that are avoided if the NRC adopted the rule. The qualitative benefits of the action include an increased assurance that public health and safety will be protected from the disposal of LLRW

and an improved regulatory structure that facilitates implementation and better aligns 10 CFR Part 61 requirements with current health and safety standards.

Defining a compliance period is an important additional parameter for technical analyses not included in the current regulatory scheme, and is significant when evaluating LLRW streams that were not considered in the original 10 CFR Part 61 rulemaking. Currently, there is ambiguity regarding how a compliance period should be selected by an Agreement State and what timeframes should be applied to the analyses to support demonstration of compliance with different sections of the regulations.

In addition, the new and revised technical analyses, required by § 61.13 in this rule change, enhance the NRC's risk-informed regulatory framework by specifying requirements that need to be met, and by providing regulatory certainty and predictability, while allowing a licensee or applicant flexibility regarding the information or approach used to satisfy those requirements. The revised performance assessment requirements will ensure that essential elements are present in the analysis while allowing licensees to tailor the analysis to site-specific conditions. The new inadvertent intruder assessment will help ensure protection of any inadvertent intruder who occupies the disposal site or contacts the LLRW at any time after active institutional controls are removed even if the waste stream is significantly different than those used to develop the LLRW waste classification system. The new performance period analysis will help ensure that disposal of long-lived radionuclides is done in a manner that protects public health and safety.

The waste acceptance criteria, the development of which is required by § 61.58, may also allow licensees to dispose of an increased variety of waste without compromising safety which is likely to reduce costs. In some cases, disposal capacity may be increased at selected sites by using site-specific technical analyses, thereby spreading the initial capital costs over a longer operational life or additional waste volumes.

Table 4-4 summarizes the results of the benefits and costs analysis. The rulemaking alternative results in additional costs when compared to the no-action alternative. The estimated quantitative cost of the rulemaking alternative is approximately $9.3M and $12.2M (7-percent and 3-percent discount rate, respectively; See Table 4-3).

Table 4-4 Summary Table of Qualified Benefits and Quantified Costs (2016 dollars)

Net Quantitative Costs – Total Present Value in Millions ($)	Qualitative Benefits/Costs
Alternative 1: No Action Licensee: 0 NRC: 0	Qualitative Benefits: None
Alternative 2: Licensee: $7.2M using a 3 percent discount rate $5.5M using a 7 percent discount rate Agreement States: $5M using a 3 percent discount rate $3.8M using a 7 percent discount rate Total: $12.2M using a 3 percent discount rate $9.3M using a 7 percent discount rate	Qualitative Benefits: These amendments ensure that LLRW streams that are significantly different from those considered during the development of Part 61 can be disposed of safely and meet the performance objectives for land disposal of LLRW. These amendments will facilitate the use of site-specific information and up-to-date dosimetry methodologies to better ensure public health and safety is protected. Licensees will be permitted to develop waste acceptance criteria from the results of the technical analyses. Development of waste acceptance criteria from the results of the technical analyses provides licensees flexibility to better manage disposal capacity consistent with the risks of disposal of LLRW streams. This flexibility may allow for additional revenue streams for disposal facility operators than may be permitted using the waste classification limits, depending on the performance of the disposal site. Additionally, the new flexibility would allow disposal facility operators to consider future waste streams for disposal in quantities or concentrations that may not have been evaluated as part of the original 10 CFR Part 61 rulemaking. It may also enhance access to disposal facilities for waste generators, potentially reducing disposal costs, particularly for those who may have had difficulty disposing of waste previously because it did not meet certain aspects of the waste classification limits or waste characteristic requirements. The new and revised analyses will help the licensee gather additional valuable information that would be

	used in the current and continued disposal of LLRW at its facility. This new information will ensure that LLRW streams that are significantly different from those considered during the development of the current regulations can be disposed of safely. Developing new waste acceptance criteria should also allow licensees to dispose of material in a more "risk efficient" manner, which is likely to reduce licensee costs.

5. Uncertainty Analysis

As this regulatory analysis is based in part on estimates of values, it is useful to conduct a sensitivity analysis of the variables, as a part of the uncertainty analysis, to illustrate where there is the greatest amount of uncertainty. A Monte Carlo sensitivity analysis was completed with the assistance of @Risk, a software program specially designed for completing a sensitivity analysis. The Monte Carlo approach provides an answer to the question: what distribution of net costs results from multiple draws of the probability distribution assigned to key variables?

5.1 Uncertainty Analysis Assumptions

While this regulatory analysis is based on estimates of values that are sensitive to specific cost drivers, the NRC staff has performed the following analysis of the variables in which there is the greatest amount of uncertainty.

The Monte Carlo approach allows a range of possible inputs to be assigned to a distribution that is sampled in the simulation. The simulation repeatedly generates inputs to its mathematical algorithm that are selected randomly from a distribution of the possible inputs. After 10,000 simulations, the analysis provides a distribution of the results generated from variations in the values modeled. Table 5-1 summarizes the variable distributions considered in this analysis.

The Monte Carlo analysis requires identification of the variables that are uncertain; in this instance, those variables, for both industry and Agreement States, are the implementation costs as well as costs associated with updating the technical analysis at license renewal and site closure. The specific variables include the contractor costs to develop and review the required analysis, the labor hours needed to develop and review the analysis, the labor hours the Agreement States need to develop rule language, and the labor hours needed to develop and review the new updated analysis required at license renewal and site closure.

A simple approach for taking the variables into account is the Triangular (also known as Three Point Estimate) technique. This technique uses three estimates to define an approximation of the rule's cost. This technique considers three estimates for each variable: Low, High and Best. The values for the estimates are based on licensee and Agreement State feedback. Table 5-1 summarizes the variable assumptions in the analysis by licensee and Agreement State.

Table 5-1 Uncertainty Analysis Variables

Uncertainty Variable Description	Distribution	Low	Best	High
Implementation Cost				
Industry contractor cost in development of the performance assessment (PA), inadvertent intruder assessment (IA) and site stability (SS) analysis	Triangular	$ 300,000	$ 650,000	$ 1,000,000
Agreement States for review of the PA, IA and SS analysis	Triangular	$ 200,000	$ 400,000	$ 600,000
Labor Hours				
Industry hours to develop the PA, IA and SS analysis	Triangular	7,104	7,992	12,432
Agreement States hours to review the PA, IA and SS analysis	Triangular	4,440	7,104	8,880
Agreement States hours to develop new rules	Triangular	444	888	1,332
Industry hours to develop the PA, IA and SS analysis updates for license renewal	Triangular	3,552	5,328	7,104
Agreement States hours to review the PA, IA and SS analysis updates for license renewal	Triangular	2,664	4,440	5,328
Industry labor hours to develop the PA, IA and SS analysis updates for site closure	Triangular	3,552	4,440	5,328
Agreement States hours to review the PA, IA and SS analysis updates for site closure	Triangular	2,664	3,552	4,440
Labor Cost based on labor hours above				
Industry cost to develop the PA, IA and SS analysis	Triangular	$ 352,005	$ 440,063	$ 616,876
Agreement States cost to review the PA, IA and SS analysis	Triangular	$ 210,056	$ 336,090	$ 420.113
Agreement States cost to develop new rules	Triangular	$ 21,006	$ 42,011	$ 63,017
Industry cost to develop the PA, IA and SS analysis updates for license renewal	Triangular	$ 176,250	$ 264,375	$ 352,500
Agreement States cost to review the PA, IA and SS analysis updates for license renewal	Triangular	$ 126,034	$ 210,056	$ 252,068
Industry cost to develop the PA, IA and SS analysis updates for site closure	Triangular	$ 176,250	$ 220,313	$ 264,375
Agreement States cost to review the PA, IA and SS analysis updates for site closure	Triangular	$ 126,034	$ 168,045	$ 210,056

5.2 Uncertainty Analysis Results

Ten thousand simulations were run. Figure 5-1 through Figure 5-4 display the histograms of the realized costs.

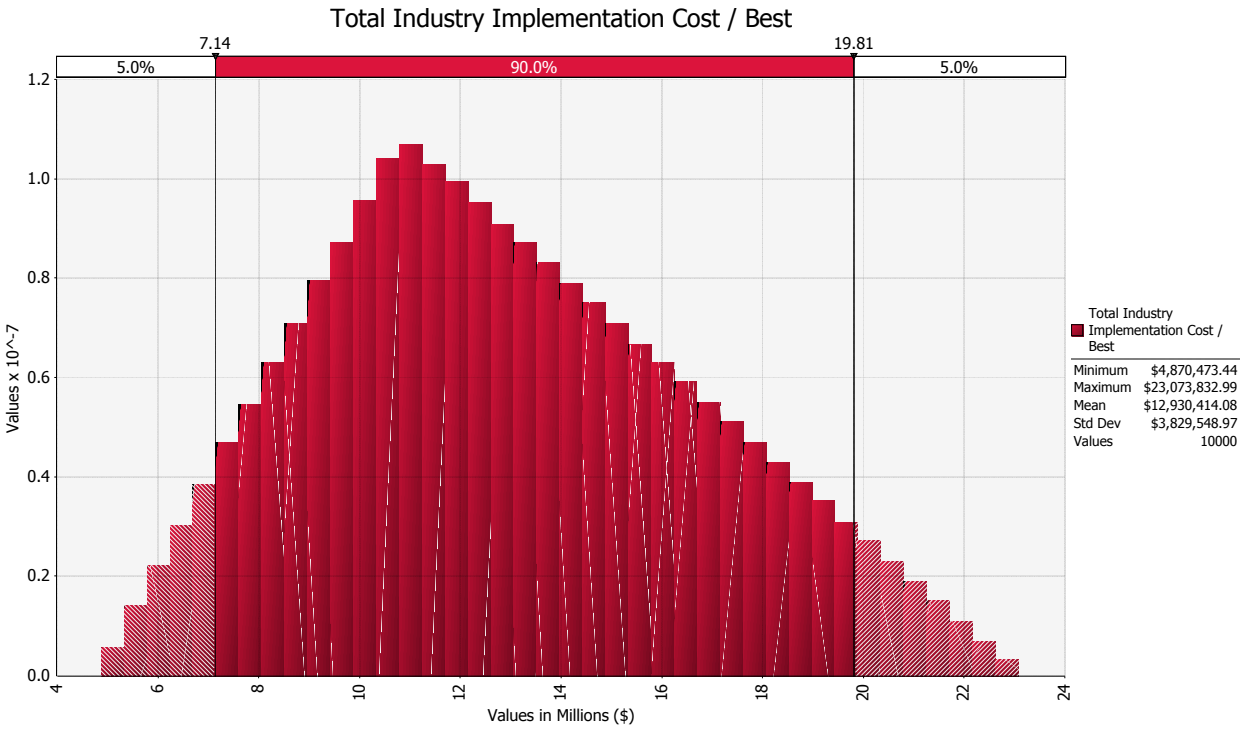

Figure 5-1

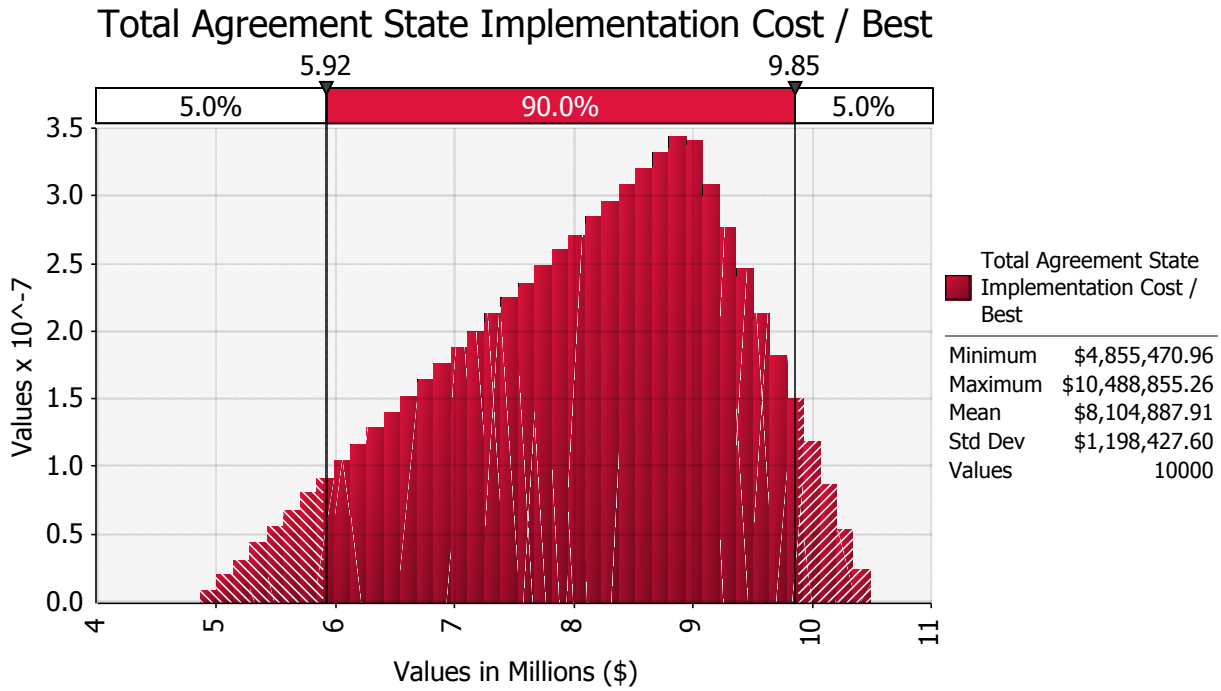

Figure 5-2

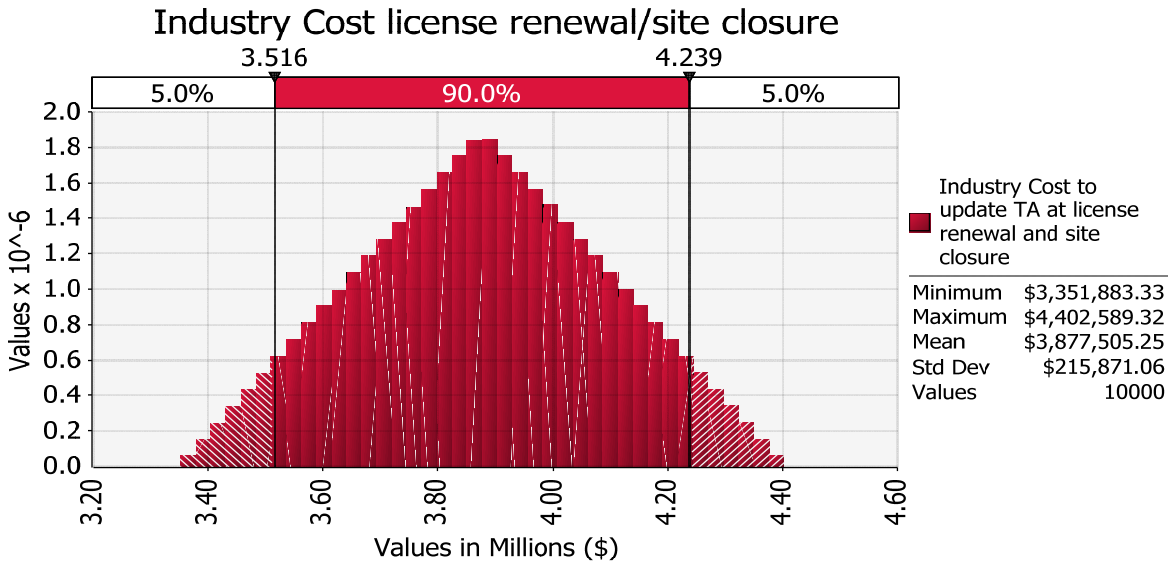

Figure 5-3

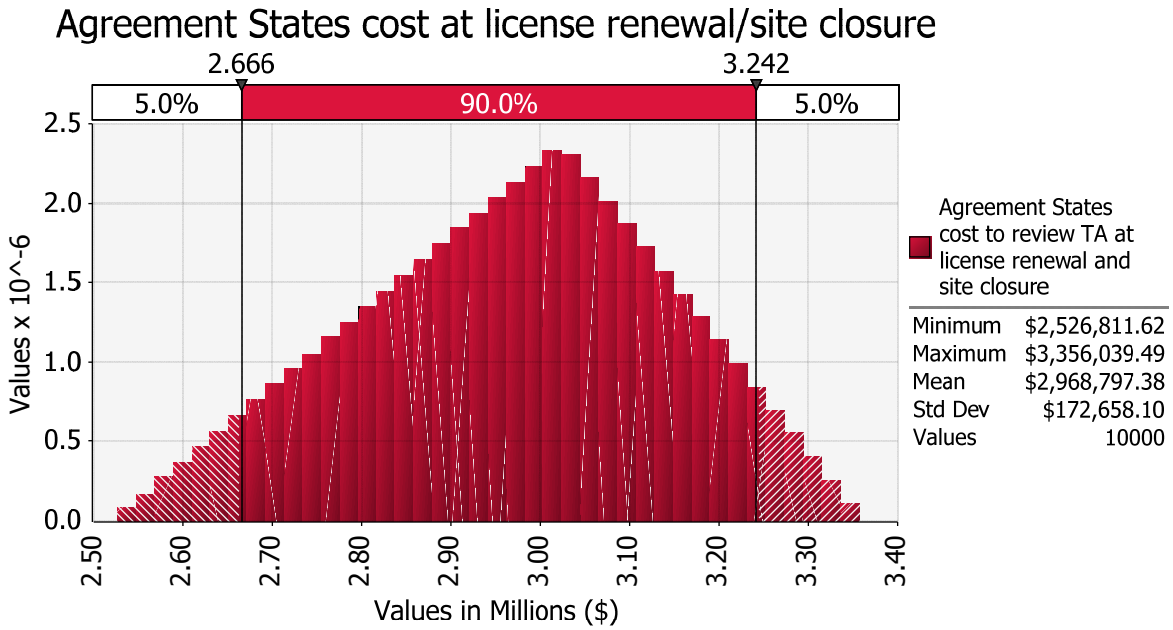

Figure 5-4

5.3 Summary of Uncertainty Analysis

A simulation analysis found that the rule would result in costs for all 10,000 simulations. The uncertainty analysis of the industry's implementation cost shows a standard deviation of $3.8M, and the uncertainty analysis of the Agreement States implementation cost shows a standard deviation of $1.2M. The uncertainty analysis of the industry's cost for license renewal and site closure shows a standard deviation of $216,000, and the uncertainty analysis of the Agreement States license renewal and site closure review cost shows a standard deviation of $173,000.

6. Decision Rationale

This regulatory analysis evaluated two alternatives. Alternative 1, the no-action alternative, will maintain the regulations as currently written. Under this option, the NRC would not modify 10 CFR Part 61. Alternative 1 avoids the costs that the rule would impose, but would not update the existing LLRW disposal requirements to better ensure protection of public health and safety. Accepting the no-action alternative does not provide the assurance that the disposal of the LLRW streams not considered in the original 10 CFR Part 61 regulatory basis complies with the performance objectives in the regulations.

Alternative 2, the rulemaking alternative, amends 10 CFR Part 61 by adding requirements for licensees and license applicants to prepare new and revised compliance and performance period analyses. The principal qualitative benefits of the regulatory action 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 without the need for future rulemakings to address those different streams on a case-by-case basis; 2) facilitating the use of site-specific information and up-to-date dosimetry methodologies in site-specific technical analyses to better 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 waste acceptance criteria should also allow licensees to dispose of material in a more risk efficient manner which is likely to reduce costs. In addition, ensuring that LLRW streams that are significantly different from those considered during the development of the current regulations can be disposed of safely minimizes the likelihood that future mitigation would be required as a result of disposing of such LLRW streams, thereby potentially reducing costs to licensees.

The new and revised analyses will help the licensee gather additional valuable information that would be used in the current and continued disposal of LLRW at its facility. This new information will ensure that LLRW streams that are significantly different from those considered during the development of the current regulations can be disposed of safely. Developing new waste acceptance criteria should also allow licensees to optimize disposal capacity while ensuring protection of public health and safety, which is likely to reduce licensee's future operational costs. The NRC concluded that the rule is cost-justified because the regulatory initiatives enhance public health and safety by ensuring the safe disposal of LLRW that was not analyzed in the original 10 CFR Part 61 regulatory basis (e.g., large quantities of DU).

7. Implementation

The final rule would take effect one year after publication in the Federal Register. The NRC staff does not expect this rule to have any impact on other requirements. However, because the NRC does not currently license any persons under 10 CFR Part 61, the NRC staff assumes that the final rule is adopted by individual Agreement States, which this regulatory analysis assumes will occur in the year 2020. The Agreement States are generally expected to publish compatible regulations within 3 years after the NRC publishes a final rule. Licensees in the Agreement States are assumed to have up to five years or until the next renewal, whichever is shorter, to develop and submit their new safety case to the Agreement States.

8. References

- NUREG/BR-0184, “Regulatory Analysis Technical Evaluation Handbook, Final Report,” U.S. Nuclear Regulatory Commission, Washington, DC, January 1997.

- NUREG/BR-0058, “Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission,” Revision 4, U.S. Nuclear Regulatory Commission, Washington, DC, September 2004.

- NUREG/CR-4627, "Generic Cost Estimates, Abstracts from Generic Studies for Use in Preparing Regulatory Impact Analyses."

- OMB Circular No. A-4, “Regulatory Analysis,” September 17, 2003.

- OMB Circular A-76 “Performance of Commercial Activities,” May 29, 2003, as amended.

- Department of Labor (U.S.), Bureau of Labor Statistics. Occupational Employment Statistics, Occupational Employment and Wages.

- NRC, “Adequacy and Compatibility of Agreement States Program,” Directive 5.9, February 1998.

Appendix A: Backfit Analysis

The NRC's backfit provisions appear in the regulations at §§ 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 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." As a result, no Backfit Analysis was performed.