REGULATORY BASIS FOR PROPOSED REVISIONS TO LOW-LEVEL WASTE DISPOSAL REQUIREMENTS (10 CFR PART 61)

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ABBREVIATIONS

ACRS	Advisory Committee on Reactor Safeguards
ACNW	Advisory Committee on Nuclear Waste
ADAMS	Agencywide Documents Access and Management System (of the NRC)
ALARA	As Low As Reasonably Achievable
Bq	Becquerel
Ci	Curie
CFR	*Code of Federal Regulations*
DOE	U.S. Department of Energy
DU	depleted uranium
EIS	environmental impact statement
EPA	U.S. Environmental Protection Agency
EW	exempt waste
FR	*Federal Register*
GTCC	greater-than-Class C LLW
HLW	high-level radioactive waste
IAEA	International Atomic Energy Agency
ICRP	International Commission on Radiation Protection
ILW	intermediate-level radioactive waste
LAW	low-activity radioactive waste
LES	Louisiana Energy Services
LL-α	long-lived, alpha-emitting
LLW	low-level radioactive waste
NAPA	National Academy of Public Administration
NAS	National Academy of Sciences
NCRP	National Council on Radiation Protection and Measurements
NEPA	National Environmental Policy Act
NORM	naturally occurring radioactive material
NRC	U.S. Nuclear Regulatory Commission
OECD	Organisation for Economic Co-Operation and Development
PAWG	Performance Assessment Working Group (of the NRC)
RCRA	Resource Conservation and Recovery Act
RMEI	reasonably maximally exposed individual
SC	South Carolina
Sv	Sievert
SNF	spent nuclear fuel
SRM	Staff Requirements Memorandum
TEDE	total effective dose equivalent
TOC	time of compliance
TRU	transuranic radioactive waste

TX	Texas
UK	United Kingdom
USEC	United States Enrichment Corporation
UT	Utah
VLLW	very low-level waste
VSLW	very short-lived waste
WA	Washington
WAC	waste acceptance criteria
WIPP	Waste Isolation Pilot Plant

1 BACKGROUND

The Commission first published its licensing requirements for the disposal of commercial low-level radioactive waste (LLW) in near-surface disposal facilities under Title 10 of the *Code of Federal Regulations (*10 CFR) Part 61, "Licensing Requirements for Land Disposal of Radioactive Waste," in 1982 in the *Federal Register* (FR) (47 FR 57446). In a 2009 staff requirements memorandum (SRM), SECY-08-0147, "Response to Commission Order CLI-05-20 Regarding Depleted Uranium," the Commission directed the staff to proceed with a limited rulemaking to 10 CFR Part 61 to specify an explicit requirement for a site-specific analysis or performance assessment for the disposal of depleted uranium (DU) and other long-lived isotopes in a near-surface disposal facility. The SRM also provided the technical requirements for such an analysis. Previously, such a performance assessment requirement did not explicitly exist in 10 CFR Part 61, but regulators still expected applicants and licensees to use such methods to demonstrate compliance with those regulations, as noted by the Commission in its "1995 Probabilistic Risk Assessment Policy Statement" (60 FR 42627). In a second SRM, SRM-SECY-10-0043, "Blending of Low-Level Radioactive Waste," (dated April 7, 2010), the Commission directed the staff to include blended LLW streams as part of this rulemaking initiative.

Following the 2009 solicitation of public input on an LLW performance assessment (74 FR 30175), the U.S. Nuclear Regulatory Commission (NRC) staff developed a technical basis (now called a "regulatory basis") document to support the rulemaking amendment (Agencywide Documents Access and Management System (ADAMS) Accession No. ML111040419). The agency shared the document with the NRC Agreement States, and proceeded to develop proposed rulemaking language. Following completion of draft preliminary rulemaking language (ML111150205), the NRC staff made the proposal publicly available in May 2011, and solicited stakeholder feedback (76 FR 24831).

In connection with the proposed new performance assessment requirement itself, the staff also recommended the duration of the requisite analysis − or the time of compliance (TOC) − be specified at 20,000 years to account for the presence of large quantities of long-lived isotopes, such as DU, that might be disposed of in a near-surface disposal facility. In August 2011, the staff briefed the Advisory Committee on Reactor Safeguards (ACRS) on the preliminary proposed rulemaking language and the basis for the staff-preferred TOC, for which a Committee Letter Report was issued in September 2011 (ML11256A191).

In draft proposed rulemaking language made available in 2011, the staff recommended that licensees for currently operating LLW disposal facilities and future 10 CFR Part 61 applicants conduct site-specific performance assessments to demonstrate compliance with the regulatory requirement found in 10 CFR 61.41, "Protection of the General Population from Release of Radioactivity," to protect the general public from radiation doses. The analyses would be used to identify if additional restrictions or prohibitions concerning the disposal of certain LLW streams, such as DU, at a particular site, would be necessary. The NRC intends to incorporate specific parameters and assumptions for conducting requisite analyses into a separate guidance document that would be issued for public comment before the NRC finalizes the rulemaking amendments. With respect to DU and other LLW streams with long-lived isotopes, the specific technical requirements associated with disposal of such wastes would be developed through the rulemaking process.

In a third SRM, designated COMWDM-11-0002/COMGEA-11-0002, the Commission directed staff to seek stakeholder feedback on the following four potential revisions:

(1) Whether licensees should be allowed to use International Commission on Radiation Protection (ICRP) dose methodologies in a site-specific performance assessment for the disposal of all LLW.

(2) Whether the regulations should incorporate a two-tiered approach that establishes a compliance period that covers the reasonably foreseeable future and a longer period of performance that is not *a priori* and is established to evaluate the performance of the site over longer timeframes. The period of performance is developed based on the candidate site characteristics (waste package, waste form, disposal technology, cover technology and geo-hydrology) and the peak dose to a designated receptor.

(3) Whether disposal facilities should be allowed to establish site-specific waste acceptance criteria (WAC) based on the results of the site's performance assessment and intruder assessment.

(4) Whether the provisions of the revised proposed rule that require the site-specific performance assessments and the development of the site-specific WAC, should specify a compatibility category that ensures alignment between the States and Federal Government on safety fundamentals, while providing the States with the flexibility to determine how to implement these safety requirements.

The Commission directed staff to provide an expanded proposed rule to the Commission within 18 months to address the aforementioned revisions, as well as the staff's analysis of the issues and stakeholder feedback, including the pros and cons of the potential revisions. The current schedule for the submittal of the expanded proposed rule to the Executive Director for Operations is July 2013.

Consistent with the Commission's public outreach directive, the staff has sponsored public meetings dedicated to seeking stakeholder input on the Commission's proposal to risk-inform the 10 CFR Part 61 rulemaking, directly engaged NRC Agreement State representatives, and participated in certain other previously scheduled public events and professional meetings.

2 EXISTING REGULATORY FRAMEWORK

The Commission's commercial LLW regulations apply to any near-surface (approximately the uppermost 30 meters (100 feet)) LLW disposal facility licensed after the effective date of the rule; the NRC applied many of the 10 CFR Part 61 requirements through license conditions to near-surface disposal facilities in operation on the effective date of the rule. Near-surface disposal methods include shallow-land burial, engineered land disposal techniques (such as below-ground vaults), earth-mounded concrete bunkers, and augered holes. Regulations in 10 CFR Part 61 emphasize an integrated systems approach to the disposal of commercial LLW, including site selection, disposal facility design and operation, minimum waste form requirements, and disposal facility closure. To lessen the burden on society over the long periods of time contemplated for the control of the radioactive material, and thus lessen reliance on active institutional controls, 10 CFR Part 61 emphasizes the use of passive rather than active systems to limit and retard radioactive releases to the environment. 10 CFR Part 61subparts include regulations related to: (a) general provisions and procedural licensing matters, (b) performance objectives, (c) financial assurances, (d) State and Tribal participation, and (e) records, reports, tests, and inspections. The regulations cover all phases of shallow, near-surface commercial LLW disposal from site selection through termination of active institutional controls.

10 CFR Part 61 includes the following key provisions:

- Specification of the minimum characteristics for a disposal site (10 CFR 61.50, "Disposal Site Suitability Requirements for Land Disposal Facilities").

- Definition of a three-tier waste classification system (LLW classes designated Class A, Class B, or Class C) for commercial LLW based on the concentrations of certain radionuclides (10 CFR 61.55, "Waste Classification").

- Specification of minimum waste form physical characteristics that all commercial LLW forms must meet to be acceptable for near-surface disposal (10 CFR 61.56(a) and (b)).

- Requirements for caretaker oversight in the form of active institutional controls of LLW disposal sites for a period of 100 years following facility closure (10 CFR 61.59, "Institutional Requirements").

10 CFR Part 61 Subpart C, "Performance Objectives," sets forth standards for the following:

- "Protection of the General Population from Releases of Radioactivity" (10 CFR 61.41)
- "Protection of Individuals from Inadvertent Intrusion" (10 CFR 61.42)
- "Protection of Individuals during Operations" (10 CFR 61.43)
- "Stability of the Disposal Site after Closure" (10 CFR 61.44)

To reach a licensing determination, the NRC staff must conclude, with reasonable assurance, that the proposed facility would meet the performance objectives of 10 CFR Part 61, Subpart C, and the technical requirements found in Subpart D, "Technical Requirements for Land Disposal Facilities." To demonstrate that they will meet the performance objectives in 10 CFR Part 61, license applicants need to prepare assessments of potential future dose impacts to the general population. License applicants must also demonstrate that potential inadvertent intruders into the disposal facility, who may occupy the site at any time after active institutional controls over the disposal site are removed, will be protected. The requisite technical analyses and associated information needs for both the analyses and any licensing determination based on those analyses are provided in 10 CFR 61.13(a)–(d). Thus, 10 CFR Part 61 is intended to be performance-based rather than prescriptive. The technical criteria is written in relatively general terms, allowing applicants to demonstrate how their proposals meet the respective performance objectives for the specific near-surface disposal method selected subject to site-specific conditions. The overall philosophy and concepts that underlie the regulatory requirements for 10 CFR Part 61 are provided in 10 CFR 61.7, "Concepts." As articulated in the concepts section, the Part 61 regulatory requirements ensure public health and safety are protected in the operation of any commercial LLW disposal facility.

The three-tier waste classification provides reasonable assurance that any LLW disposal facility licensed under 10 CFR Part 61 would meet the performance objectives in Subpart C. The 10 CFR Part 61 waste classification system considers stylized human intrusion scenarios as well as both the physical stability of the waste form and its isotopic concentration. The isotopic concentration limits found at 10 CFR 61.55(a) are based on the staff's understanding, as of 1980, of the characteristics and volumes of commercial LLW that were reasonably expected for commercial disposal, as well as the disposal methods then thought likely to be used. In the "Statements of Consideration," for the final rule (47 FR 57457), the Commission noted that:

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

The Commission also expressed its belief that "…to the extent practicable, waste forms or containers should be designed to maintain gross physical properties and identity over 300 years, approximately the time required for Class B waste to decay to innocuous levels..." (47 FR 57457). As noted above, when developing 10 CFR Part 61, the staff assumed that certain types of wastes were likely to go into a commercial LLW disposal facility. Part of the staff's analysis of the likely waste inventory at a hypothetical 10 CFR Part 61 facility included a survey of existing LLW generators. The survey, documented in Volume 3 of the 10 CFR Part 61 "Draft Environmental Impact Statement" (EIS), designated NUREG-0782 (NRC, 1981), revealed distinct commercial waste streams consisting of 24 radionuclides of potential regulatory interest. The staff considered these waste streams to be representative of the types of commercial LLW likely to go into a near-surface disposal facility. The NRC did not consider waste streams associated with the U.S. Department of Energy's (DOE's) nuclear defense complex (NRC, 1981, p. 3-8). In addition, large quantities of DU were not considered. The results of this survey ultimately formed the basis for the source terms used to define the allowable isotopic concentration limits − the "waste classification tables" found at 10 CFR 61.55(a) − for commercial LLW to be disposed of in a 10 CFR Part 61 licensed facility.

A primary consideration of the decision to license a LLW disposal facility should be a determination that the site and design meet the performance objectives and technical requirements contained in Subparts C and D, respectively, of 10 CFR Part 61, with reasonable assurance. Conclusions aboutthe performance of a disposal facility and of particular barriers over long periods of time will be based largely on inference, because it will not be possible to carry out test programs of sufficient duration or that simulate the full range of potential conditions expected over the time period of regulatory concern. Given this limitation, it will be necessary for potential licensees to adopt a variety of design features, develop models, perform tests, acquire data, and undertake other measures to be able to demonstrate, with reasonable assurance, that the 10 CFR Part 61 performance objectives will be met.

Since the mid-1970s, the staff has been adopting probabilistic risk assessment methods for use in the evaluation of passive disposal systems for radioactive wastes. Such methods are generally referred to as "performance assessments" (NRC 1994, 59 FR 63389). A performance assessment can be considered a type of systematic (risk) analysis in that it addresses: (a) what can happen, (b) how likely it is to happen, (c) the resulting effects, and (d) how these impacts compare to regulatory standards. See Eisenberg and others (1999, p. 849). The staff conducts performance assessments on digital computers that rely on physicochemical abstractions, mathematical models, and numerical methods of the disposal system paradigm, all subject to many simplifying assumptions, limited data, and specified boundary conditions. The essential elements of a performance assessment for a LLW disposal site are (generally): (a) a description of the site and engineered system, (b) an understanding of events likely to affect long-term facility performance, (c) a description of processes controlling the movement of radionuclides from LLW disposal units to the general environment, (d) a computation of doses to members of the general population, and (e) an evaluation of uncertainties in the computational results. See NRC (2000 p. 1-6.)

Numerically based performance assessments are just one mechanism for providing reasonable assurance that licensees will meet the requirements in 10 CFR Part 61. In this regard, the NRC does not require an accurate prediction of future states in the estimation of LLW disposal facility performance. Although a LLW performance assessment may quantitatively evaluate potential doses, these doses are not actual doses to real receptors. Performance assessments are used to understand how a system (e.g., disposal facility and natural environment) may perform. They are used to understand the potential effects of uncertainties that decision makers need to consider. There are numerous sources of uncertainty associated with projecting the future risks from disposal, including, but not limited to, natural, engineering, and societal sources. Normally, uncertainty − and especially excessive uncertainty − is mitigated by regulatory requirements to ensure that public health and safety are protected.

3 DISCUSSION

A key regulatory assumption factored into the development of 10 CFR Part 61 was that it was unrealistic to expect perpetual care of any decommissioned commercial LLW disposal site. The Commission expressed the view that such care would likely be a significant social burden on future society (46 FR 38085). To minimize such future administrative care requirements, Part 61 essentially relies on active institutional controls for a limited time duration and government ownership of the land after that period to decrease the likelihood of inadvertent disturbance of the disposal site. The regulations also rely on concentration limits for waste that can be disposed of so that if other protective measures fail, the radiological effects will not be excessive.

When it developed Title 10 Part 61, the NRC staff assumed, for the purposes of its analysis, that an inadvertent intruder occupied an LLW disposal site sometime in the future. Inadvertent intruders could engage in normal activities without knowing that they were being exposed to radiation from LLW after institutional controls over the site were no longer in place. The staff refers to this as the inadvertent intruder scenario. The Commission recognized that, taking into account the long timeframes of regulatory concern, the inadvertent intruder scenario would likely be a key factor influencing the site selection and design requirements necessary to ensure public safety. The Commission also recognized that specific design precautions, waste form specifications, or both, might be necessary to protect the public from more hazardous, long-lived LLW. To this end, the waste classification system imposes different requirements, including radionuclide concentration limits and specified physical forms, for different LLW classes. The regulations specify that for certain radionuclides prone to migration in the environment, a maximum disposal site inventory based on the characteristics of the disposal site may be established to limit potential exposures.

In addition, the regulations specify a maximum concentration of radionuclides for all waste classes so that after 500 years the remaining radioactivity would be at a level that would not pose an unacceptable hazard to an inadvertent intruder or to public health and safety (47 FR 57466). Waste with concentrations above those limits is generally unacceptable for near-surface disposal, although the Commission noted that such types of wastes may be acceptable for disposal under 10 CFR Part 61 when more stringent disposal methods are used (54 FR 22580). The Part 61 analyses considered both direct and indirect exposure pathways: direct exposure, such as through inadvertent intrusion, which was considered at 100 and 500 years; indirect exposure, such as offsite exposure to contaminated ground water, persists for more than 500 years.

The current rule provides for the protection of individuals from inadvertent intrusion by requiring licensees to demonstrate that the 10 CFR Part 61 waste classification and segregation requirements will be met and that adequate barriers to inadvertent intrusion have been included in the disposal facility design. Tables 1 and 2 of 10 CFR 61.55 provide concentration limits for select radionuclides that may be used to determine the Part 61 waste classification designation for a particular LLW type. Based on the waste classification, requirements for segregation, intruder barriers, and disposal depth are stipulated in the regulations to ensure the protection of inadvertent intruders. Dose limits for an inadvertent intruder are not provided in Part 61, but the concentrations of radionuclides established in Tables 1 and 2 assumed a (maximum) dose of 5 millisieverts per year (mSv/yr) [500 millirem per year (mrem/yr)]. The 10 CFR 61.55 waste classification tables are used to demonstrate compliance with the performance objective in 10 CFR 61.42, “Protection of Individuals from Inadvertent Intrusion.”

4 REGULATORY ISSUES

4.1 Site-Specific Performance Assessment and Other Considerations

As noted in the previous section, the Commission recognized that there might be a situation in which a commercial waste stream could be created that was not contemplated as part of the original technical basis for 10 CFR Part 61, which is found in the draft and final EISs for the rule. The radionuclides provided in the 10 CFR 61.55 waste classification tables were based on a best estimate (in 1980) of projected inventories of radioactive waste that would be disposed of in a commercial LLW disposal facility. Table 1 of 10 CFR 61.55 provides limiting concentrations for long-lived radionuclides and Table 2 of 10 CFR 61.55 provides limiting concentrations for short-lived radionuclides. Some radionuclides, such as isotopes of uranium, were not expected to be generated in sufficient quantities or concentrations to warrant inclusion in the tables.

NUREG-0782 assumed that only 629,000 megabecquerel (MBq) [17 curie (Ci)] of uranium-238 (^{238}U) and 111,000 MBq (3 Ci) of ^{235}U would be disposed of in one million cubic meters (35 million cubic feet) of waste over a 20-year generic LLW site operating life. Concentration limits for uranium were derived, but were not included in the final regulations because it was determined that the relatively small quantities of uranium waste expected to be generated by commercial facilities at the time did not warrant inclusion. Because it wasn't considered in the original technical analysis, the staff needs to consider what type of analysis is needed today to determine whether a waste stream, such as one with significant quantities of uranium, is acceptable for disposal in a 10 CFR Part 61 disposal facility. Part 61 considers potential doses to an offsite member of the public and an inadvertent intruder based on certain assumptions regarding the waste streams likely to be found in a commercial LLW disposal facility.

Although 10 CFR 61.42 requires that an inadvertent intruder be protected, the regulations do not explicitly require an intruder dose assessment to demonstrate that protection can be achieved with reasonable assurance. The NRC staff performed intruder dose calculations when it derived the concentration limits in the waste classification tables [10 CFR 61.55(a)]. The regulations currently only require that a licensee demonstrate that the waste classification and segregation requirements of the rule will be met and provide information that the barriers intended to deter inadvertent intrusion will be effective. This determination is based on a review of 10 CFR 61.13(b) and the information needs identified in Section 6.2 of NUREG-1200, "Standard Review Plan for the Review of a License Application for a Low-Level Radioactive Waste Disposal Facility," (NRC, 1994). In NUREG-1573, "A Performance Assessment Methodology for Low-Level Radioactive Waste Disposal Facilities" (NRC, 2000), the staff acknowledged that applicants and licensees are not expected to perform intruder dose analyses because the waste classification and segregation requirements found in 10 CFR 61.13(b) were developed to protect an inadvertent intruder.

As noted above, the waste classification tables and the segregation and intrusion protection requirements found in 10 CFR Part 61 were based on estimated generic waste inventory and waste characteristics derived from known commercial waste streams in 1980. For the purposes of the National Environmental Policy Act (NEPA) analysis, it was assumed that commercial LLW destined for any Part 61 disposal facility would not be substantially different in terms of radiological inventory and physical characteristics from the 37 projected waste streams ultimately evaluated. Therefore, the staff was confident that waste streams not substantially different from those evaluated in the technical analysis could be disposed of in a manner consistent with the 10 CFR Part 61 waste classification and segregation requirements.

Similarly, the staff was confident that the associated intruder dose (if calculated) would be within the limits used to develop the 10 CFR 61.55 waste classification tables. The staff had less assurance that waste streams that were significantly different from those evaluated as part of the Part 61 technical analysis would meet the inadvertent intruder protection requirements.

The licensing of new uranium-enrichment facilities in the United States has brought DU to the forefront of commercial LLW disposal issues. In the technical analysis for the draft EIS that supported the development of 10 CFR Part 61, the staff did not consider the relatively high concentrations and large quantities of DU generated by enrichment facilities. As noted above, when the draft EIS was under development, the staff specifically excluded from consideration large quantities of DU and other DOE-generated streams. Moreover, at that time the staff did not anticipate that DOE would dispose of its DU inventory or any other defense-related radioactive wastes in commercial disposal facilities, such as facilities that might be licensed under 10 CFR Part 61. With the existing DOE DU stockpile at the Paducah and Portsmouth Gaseous Diffusion Plants, and the recent licensing of commercial enrichment facilities—the Louisiana Energy Services (LES) National Enrichment Facility and the United States Enrichment Corporation (USEC) American Centrifuge Plant ─ DOE and industry will need to dispose of more than 10^9 kilograms (1 million metric tons) of depleted uranium hexafluoride (DUF_6), which will be de-converted into an oxide form for the purposes of disposal. The technical analysis in the Final EIS considered 629,000 MBq (17 Ci) of ^{238}U, compared to approximately 3.7 x 10^9 to 7.4 x 10^9 MBq (100,000 to 200,000 Ci) of ^{238}U that will be generated from LES during its 25-year lifespan (NRC, 2005b).

Besides large quantities of DU, other waste streams not considered during the original development of the regulations might need to be evaluated should generators wish to dispose of the material as commercial LLW. For example, in 2005 the *Energy Policy Act of 2005* expanded the NRC's regulatory authority under the *Atomic Energy Act* to include discrete sources of naturally-occurring radioactive material (NORM), including radium-226 that might be produced, extracted, or converted as a byproduct material. The 10 CFR Part 61 technical basis considered only a small quantity of radium-226 bearing wastes for the purposes of designating the respective waste classes.[1]

In addition, changes within the broader LLW management system could result in the generation of materials that differ from the material considered in the 10 CFR Part 61 technical basis. For example, in SECY-09-0082, "Update on Reprocessing Regulatory Framework-Summary of Gap Analysis," dated May 28, 2009 (NRC, 2009a), the staff performed a gap analysis of the current regulatory framework applicable to the potential reprocessing of spent nuclear fuel (SNF). Gap No. 16 addressed waste classification and discussed issues with DU, as well as wastes generated from reprocessing (i.e., the waste streams from reprocessing could be significantly different from the waste streams originally anticipated in the 10 CFR Part 61 technical basis). Similarly, in SECY-10-0043 (NRC 2010), the staff noted that large-scale blending of Class B and Class C concentrations of LLW with Class A to produce a Class A mixture could result in doses to an inadvertent intruder that are above 5 mSv/yr (500 mrem/yr) (i.e., the dose limit used in developing the waste classification limits in 10 CFR 61.55(a)). Industry is now contemplating this type of blending. In SECY-10-0043, the staff presented several options that could address blending, including an option that would include the evaluation of blended wastes as a unique waste stream. During the original development of 10 CFR Part 61, the staff did not evaluate

1 For example, the equivalent of 0.5 nCi/gm of radium-226, contained in about 68 kilograms (kg) (~150 pounds) of natural uranium ore (at equilibrium with its daughter products), was considered for the purposes of designating Class A LLW (47 FR 57453-57454).

large-scale blending, which could generate large volumes of LLW concentrations near the limit for Class A. As noted above, the 10 CFR Part 61 waste classification tables reflect certain assumptions about the waste streams to be disposed of, the distributions of concentrations of radionuclides in those waste streams, and how those waste streams might be combined for disposal. Blending of different classes of wastes could result in waste streams with characteristics that were not evaluated in the earlier 10 CFR Part 61 technical analyses.

4.2 Flexibility for Site-Specific Waste Acceptance Criteria

For disposal of radioactive waste, WAC are the criteria or specifications that the waste must conform to in order to be disposed in a land disposal facility. The waste classification system specified in 10 CFR 61.55 establishes concentration limits on acceptable levels of LLW that might be disposed of in a near-surface disposal facility. The waste classification system also forms the basis for integrated requirements on waste characteristics, waste segregation, and intruder barriers. These integrated requirements specify the acceptance criteria that waste must meet in order for it to be disposed in a land disposal facility licensed according to 10 CFR Part 61 and the associated operational requirements at the disposal facility. These integrated requirements were the outcome of the environmental analyses performed to develop 10 CFR Part 61 (NRC, 1981; NRC, 1982). The NRC used limiting exposures to a potential inadvertent intruder at a reference disposal facility as the principle basis for setting the classification limits, the waste form characteristics requirements, and routine operational requirements. The NRC, however, also considered other factors (e.g., long-term environmental impacts, disposal facility stability, institutional control costs, and financial impacts to small entities). Specifically, the agency derived the waste classes from an analysis that considered a combination of factors on a *nonsite-specific* basis that included radionuclide characteristics and concentrations, the waste form, the methods of emplacement, and, to some extent, generic site characteristics.

The NRC staff continues to believe that 10 CFR Part 61 protects public health and safety because of the reasonably conservative nature of the generic environmental analysis used to develop the regulations. By design, the regulations can be implemented anywhere within the contiguous 48 States. Nevertheless, because of the inconsistency between actual conditions (e.g., facility design and operation, natural environment) at operating disposal facilities and the generalizations used to develop the 10 CFR Part 61 waste classification requirements, it is possible that radionuclide concentration limits could be either overly restrictive or permissive, depending on the disposal facility. For instance, there may be future waste streams that require disposal but were not accounted for in the generic analysis, such as large quantities of concentrated DU, as discussed in the previous section. If radionuclide concentration limits are overly restrictive based on actual site characteristics, facility design, and operational practices, 10 CFR Part 61 would continue to ensure safe disposal, but it would impose unnecessary regulatory burdens. Whereas, if the concentration limits are overly permissive based on actual site characteristics, facility design, and operational practices, relying on the waste classification requirements may not adequately ensure protection of public health and safety at such a disposal facility. Therefore, the inconsistency between the analysis and current practices highlights the need for flexibility to consider site characteristics to develop site-specific WAC.

4.3 Updated Part 61 Dosimetry

The objective of modeling in a performance assessment that would be used to evaluate compliance with 10 CFR 61.41 is to provide estimates of doses to humans from radioactive releases from a LLW disposal facility after it has been closed. See NRC (2000, p. 3-75).

Regulations in 10 CFR Part 20, “Standards for Protection against Radiation,” spell out current NRC health physics practices for NRC licensees. In May 1991, the NRC updated 10 CFR Part 20 based on a dosimetric modeling and effective dose equivalent approach described in ICRP Publications 26 (1977) and 30 (1979). See 56 FR 23391. Previously, the NRC staff had recommended that for internal consistency, a LLW performance assessment be performed consistent with the approved 10 CFR Part 20 methods.[2] See NRC (2000, p. 3-78). In 1991, the 10 CFR Part 20 standards were updated to the total effective dose equivalent or TEDE approach for occupational exposure. (56 FR 23360; May 21, 1991). These updated standards implemented the ICRP recommendations found in Publication 26. Because of various considerations, including resource limitations and activities in the LLW area at the time, the dose limits in 10 CFR Part 61 were not updated to the TEDE approach.

The most recent ICRP recommendations can be found in Publication 103 (ICRP 2007)[3]; however, this edition of the ICRP recommendations has not been adopted into Federal guidance.

4.4 Summary

In summary, the proposed rulemaking would solicit public comment on the following amendments to 10 CFR Part 61:

(1) (a) Amend 10 CFR 61.41 to require 10 CFR Part 61 licensees to conduct a site-specific performance assessment for LLW disposal facilities to ensure that the facility can meet the dose requirements in this section. The analyses would be used to determine if a specific site is suitable for the disposal any LLW including DU and other waste streams containing large quantities of long-lived isotopes.

(b) The analyses timeframes for site-specific performance assessment would consist of a two-tiered approach that establishes both a compliance period and a longer period of performance that is not *a priori* and is established to evaluate the performance of the site over longer timeframes.

(c) In conducting any site-specific performance assessment, licensees should be allowed the flexibility to use the most recent recommendations of the ICRP.

(2) Amend 10 CFR 61.42 to require Part 61 licensees to conduct an intruder assessment that considers the time period after the end of the period of active institutional controls.

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2 10 CFR Part 61 license applications also may contain other assessments of potential radiological exposures using ICRP Publications 26 and 30.

3 The three-tier waste classification system codified in 10 CFR 61.55 of the regulations was based on ICRP Publication 2 recommendations. In the decades following promulgation of the Commission’s LLW regulation, the 10 CFR 61.55 waste classification tables have not been updated, although the earlier ICRP recommendations have been updated and superseded by more current editions. Recognizing the need to align the 10 CFR 61.55 waste classification tables and the most recent ICRP recommendations in SRM-SECY-08-0147, the Commission has directed the staff to budget resources to update those tables using the most recent edition of the ICRP’s recommendations. This update would include consideration of an expanded list of isotopes, as well as determine the regulatory classification of DU. Current planning assumptions now call for this effort to begin in fiscal year 2015.

(3) Amend 10 CFR 61.55 to allow licensees the flexibility of establishing a site-specific WAC based on the results of the site's performance assessment in 10 CFR 61.41 and intruder assessment in 10 CFR 61.42.

5 BASES FOR REQUESTED CHANGES

5.1 Consideration of LLW Streams Containing Large Quantities of Long-Lived Isotopes

Section 61.55(a)(6) specifies that:

> *…If radioactive waste does not contain any nuclides listed in either Table 1 or 2, then it is Class A…*

Classifying waste by default as Class A is consistent with the 10 CFR 61.42 performance objective for those wastes not significantly different from those originally considered in the development of 10 CFR Part 61. However, if waste significantly differs in quantity and concentration from what was considered in the development of Part 61, or it is disposed of in a manner inconsistent with the assumptions that were made, it may be possible to dispose of a waste stream that would meet the disposal requirements and 10 CFR 61.42 performance objectives, but would result in an intruder dose that exceeds the dose limit (i.e., 5 mSv (500 mrem)) used to develop the waste classification tables. Currently, a licensee is not required to perform an intruder dose assessment to demonstrate compliance with 10 CFR 61.42. A 2005 adjudicatory decision concerning the license for LES (NRC, 2005a; pp. 16-17) directed the staff, outside of the adjudication, "to consider whether the quantities of depleted uranium at issue in the waste stream from uranium enrichment facilities warrant amending 10 CFR 61.55(a)(6) or the 10 CFR 61.55(a) waste classification tables."

In SECY-08-0147 (NRC, 2008), the staff completed a technical analysis of the effects of near-surface disposal of large quantities of DU, such as those expected to be generated at uranium-enrichment facilities. The staff evaluated the necessity of amendments to 10 CFR 61.55(a) to ensure that large quantities of DU is disposed in a manner that meets the Subpart C performance objectives. The staff concluded that near-surface disposal of large quantities of DU may be appropriate in some circumstances, but not under all site conditions. In that analysis (SECY-08-0147, Enclosure 1), which involved a land disposal scenario for large quantities of DU, the staff identified conditions that would likely result in the 10 CFR Part 61 performance objectives not being met (e.g., shallow disposal, such as commonly associated with Class A LLW, or disposal at humid sites with a potable ground-water supply). Additionally, the staff determined that the disposal of large quantities of DU as Class A LLW with no additional restrictions could result in inadvertent intruders receiving a dose greater than 5 mSv/yr (500 mrem/yr) for both acute and chronic exposure scenarios (see Appendix A). The estimated dose would result from pathways, such as inadvertent ingestion of uranium-contaminated soil and inhalation of radon gas (a member of the uranium decay chain). These results are consistent with those found in an earlier analysis of possible DU disposal in a Part 61 disposal facility (Kozak et al., 1992). Based on the unique characteristics of the waste and additional considerations required for its disposal, the staff concluded in SECY-08-0147 that licensees should be required to conduct site-specific analyses to demonstrate compliance with the performance objectives in 10 CFR Part 61.

The primary change being considered would add explicit requirements for both a performance assessment calculation and a site-specific intruder dose assessment to account for waste streams not anticipated when the NRC originally developed 10 CFR Part 61. Requiring a performance assessment and a site-specific intruder dose assessment would ensure that the

10 CFR 61.42 performance objective would be met for the disposal of radioactive waste streams not previously considered, including DU and blended LLW.

As discussed in the Stakeholder Interactions section, the staff held two public workshops in 2009, one public workshop in 2011, three public workshops in 2012, and completed a number of other interactions to solicit feedback from stakeholders and other interested members of the public on the need for and content of a potential rulemaking for site-specific analyses in 10 CFR Part 61 (NRC 2012a, b, c; NRC 2011a; NRC 2009a, b). The participants discussed a variety of issues, including the following:

- period of performance
- waste acceptance criteria
- exposure scenarios
- source term issues
- modeling of uranium geochemistry
- modeling of radon
- general public policy issues

Participants offered very diverse responses and opinions.

5.1.1 Background on Period of Performance

The period of performance is one of the important elements of the performance assessment process. The period of performance influences what information must be provided to demonstrate compliance with the Subpart C performance objectives in 10 CFR Part 61. In general, a longer period of performance results in the consideration of more features, events, and processes. In addition, it can be more technically challenging to demonstrate compliance for a longer period of performance, compared to a shorter period of performance. The purpose of completing a performance assessment of an LLW facility is to ensure that public health and safety is protected to prescribed limits with an acceptable degree of confidence. In the NRC's terminology, that degree of confidence is described as reasonable assurance. The results of compliance analysis should not be interpreted as unequivocal numerical proof of the expected behavior of a waste disposal facility because of the uncertainties associated with the time periods involved.

Selection of a period of performance for a LLW disposal facility is a contentious issue, extending back to as early as 1995. Stakeholders continue to have strong opinions on the subject. When specifying a period of performance for a radioactive waste disposal facility, technical factors (e.g., the characteristics and persistence of the radiological hazard attributed to the waste), socioeconomic factors (e.g., transgenerational equity), and policy factors need to be considered (Nuclear Energy Agency, 1995; ICRP, 2000). In 2011 the NRC staff, based on stakeholder feedback, developed a simple approach to period of performance that afforded flexibility (NRC 2011b). The staff recommended a two-tiered approach:

- The first tier was defined by the peak annual dose *within* 20,000 years, a 0.25 mSv (25 mrem) TEDE limit for 10 CFR 61.41, and a 5 mSv (500 mrem) TEDE limit for 10 CFR 61.42

- The second tier was defined by the peak annual dose that would occur after the first tier; no dose limit was applied to the second tier.

The staff recommended this approach because it provided flexibility to allow analyses to be tailored to the waste stream. As the section below on international approaches discusses, the primary consideration by many programs in establishing regulatory requirements for the disposal of radioactive waste is the characteristics of the waste being disposed. The approach recommended by the staff could have been applied to the traditional commercial LLW disposal concept (i.e., primarily short-lived waste with limited quantities and concentrations of long-lived waste), while allowing for longer analyses for long-lived waste, if necessary. The approach accounted for the parallel effects of increasing hazard, such as with DU for example. The approach also accounted for increasing uncertainty associated with long timeframes as well as decreasing site-stability and increased ground-water transport of radioactivity, if released.

On January 19, 2012, the Commission provided additional direction to the staff to consider expanding the limited-scope revision to 10 CFR Part 61 to bring a clearer risk-informed approach that could obviate the need for a second rulemaking (NRC 2012d). The Commission identified four areas to seek stakeholder feedback and provide analysis on, one of which was in the area of the timeframe for analyses (analyses timeframe). Specifically with respect to the analyses timeframe the Commission stated:

> *A two tiered approach that establishes a compliance period that covers the reasonably foreseeable future and a longer period of performance that is not a priori and is established to evaluate the performance of the site over longer timeframes. The period of performance is developed based on the candidate site characteristics (waste package, waste form, disposal technology, cover technology and geo-hydrology) and the peak dose to a designated receptor.*

Furthermore, the Commission added:

> *In establishing a period of compliance, the staff should balance all of the principles in the National Academy of Public Administration's June 1997 report, previous agency guidance, the approaches of international and domestic agencies, and the technical considerations associated with disposal of long-lived waste.*

Analysis of the Commission's direction and associated information is found in the sections that follow.

Different terminology has been used to describe timeframes associated with the analyses of waste disposal. This document uses the following definitions:

> *Analysis timeframe* is the period of time of the analysis for which performance of the waste disposal facility following site closure is assessed. The analysis timeframe is comprised of two tiers: a) the compliance period and b) the performance period.
>
> *Compliance period* is the timeframe over which compliance with the 10 CFR 61.41 and 61.42 performance objectives are assessed.
>
> *Performance period* is the timeframe after the compliance period for which performance must be assessed when disposing of long-lived waste.

5.1.2 Past Regulatory Approaches to Analyses Timeframes

5.1.2.1 NRC

The debate concerning the specification of an appropriate analysis timeframe for waste disposal extends back as far as the early 1990s. A variety of NRC working groups discussed the merits of various approaches to defining analysis timeframes for waste disposal. The 10 CFR Part 61 regulations do not provide a value for the compliance period[4]. Staff analyzed a timeframe of 10,000 years in the draft Part 61 EIS (NUREG-0782). Previously staff had recommended a similar compliance period for the purposes of evaluating the performance of a typical commercial LLW facility in the context of the final Part 61 rule (NRC 1996). For radionuclides considered in the original Part 61 technical basis, this compliance period is considered to be sufficient to capture the risk from the short-lived radionuclides, which comprise the bulk of the activity disposed of, as well as the peak dose from the more mobile longer-lived radionuclides, which tend to bound the potential doses at longer timeframes (e.g., greater than 10,000 years).

In the context of developing NRC staff capabilities to review LLW performance assessments, the NRC formed the performance assessment working group[5] (PAWG) to engage both the public and stakeholders on this and other performance assessment-related topics. The staff presented the issue of the analysis timeframe to the Commission in SECY-96-103, "Regulatory Issues in Low-Level Radioactive Waste Performance Assessment," dated May 17, 1996 (NRC 1996a), and recommended a 10,000 year compliance period. The Commission directed the staff to provide the regulatory basis used to support an analysis timeframe of 10,000 years (NRC 1996b).

PAWG published NUREG-1573 in 2000 (NRC, 2000). The staff proposed a 10,000 year timeframe to demonstrate compliance with 10 CFR 61.41, citing its consistency with other standards and technical recommendations. Test calculations the staff had performed for a hypothetical LLW disposal facility supported the recommendations (Cady and Thaggard, 1994). The staff's LLW test-case calculations assessed a period of time for as long as 100,000 years. The test-case calculations were part of the basis for the recommendation of a 10,000 year compliance period. PAWG believed that a typical commercial LLW facility (e.g., one that was considered in the development of Part 61) would receive large amounts of short-lived waste that would decay to relatively innocuous levels within hundreds of years and contained limited amounts of long-lived waste. PAWG considered a 10,000 year compliance period sufficient to capture the risk from the short-lived radionuclides, which would be the bulk of the activity disposed, and the peaks from the more mobile long-lived radionuclides which tend to bound the potential doses at longer timeframes (greater than 10,000 years) for traditional LLW.

The recommendations of PAWG, found in NUREG-1573, noted that there could be exceptions to the 10,000 year compliance period recommendation. NUREG-1573 provided as an example the disposal of large quantities of uranium or transuranics. In that NUREG, the staff advocated the use of a second tier (i.e., performance period) that would be used to understand what effect,

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4 Different terminology has historically been used to refer to the timeframe assessed for regulatory compliance or other analyses, including performance period, time of compliance, compliance period, and other variants. The terms compliance period and performance period—as defined above—are used throughout this document.

5 The performance assessment working group (PAWG) was comprised of past and (then) present staff of the NRC to provide information and recommendations on performance assessment methodology as it relates to 10 CFR 61.41.

if any, the less-mobile radionuclides might have on meeting the 10 CFR 61.41 performance objective. Also in NUREG-1573, the staff responded to public questions about the staff's preference for a 10,000-year compliance period (See NUREG-1573, pp. B-16–B-20).

In the mid-1990s, the Advisory Committee on Nuclear Waste (ACNW) suggested regulatory principles that could be used to establish the time span for compliance (Pomeroy, 1996). ACNW recommended a two-tiered approach:

- The first tier would be established by consideration of (a) the estimated time for release and transport of the radionuclide contaminants to reach the critical group, (b) the definition of a reference biosphere and lifestyle of the critical group, and (c) uncertainty, which should be reasonably modest so as to allow extrapolation of significant processes.

- The second tier would be used to evaluate the robustness of the facility over long periods of time and should not become *de facto* regulations.

The performance objectives for the first tier were not to be applied for the second tier. With respect to a compliance period for the Yucca Mountain repository, ACNW believed the first tier should be defined using existing knowledge of the engineering and scientific aspects of the facility and the environment. They noted that the time span for the compliance period should be no shorter than an estimate of the anticipated time it takes for potential radionuclide contaminants to reach the nearest critical group and no longer than a time period over which scientific extrapolations can be made convincingly.

In a further expansion of that position, ACNW advocated a two-tiered approach for the period of analysis for LLW:

- The first tier would focus on the evaluation of the behavior of the more mobile radionuclides for some specified period of performance. The duration of the period of performance would be selected: (a) consistent with the radiological hazard, and (b) to reasonably account for the uncertainties associated with the calculation (Pomeroy, 1997).

- The second tier would evaluate the robustness of the disposal facility (and site) in light of the presence of any less-mobile radionuclides. This calculation would be used qualitatively to better understand when the peak dose might occur, as well as its timing in relation to the period of performance defined by the first tier. The analysis would have emphasized the identification of risk factors contributing to peak dose and potential management strategies to address those risks.

ACNW highlighted the difficulty in selecting a single period of performance for all LLW, which can have different waste characteristics. ACNW recognized the importance of considering deleterious surface processes, such as erosion, and also noted that engineered and natural barriers may delay releases for long periods of time. ACNW continued to advocate this binary approach to analysis timeframes in later correspondence (Garrick, 2000). In the matter of LLW streams, such as those bearing uranium, ACRS recommended the proposed rule not specify a compliance period (Abdel-Khalik, 2010). ACRS instead recommended that the analysis timeframe be judged on a case-by-case basis that considers the nature of the timing of the radiological hazard.

5.1.2.2 Other Domestic Regulatory Agencies

Table 1 (on page 20) contains the timeframes used by DOE or EPA (as well as timeframes found in 10 CFR Part 61 regulatory guidance) for various programs managing the risk from chemical or radioactive waste disposal or cleanup activities. As shown in Table 1, the approaches used differ among agencies and even within agencies. However, this does not mean there are differing levels of protection. As will be discussed in the next section on international approaches, the analyses that are required, and the timeframe associated with those analyses, are tailored to the waste characteristics and the disposal or cleanup concept. Various approaches are used to mitigate risk to future generations.

For disposal of chemically hazardous wastes under the Resource Conservation and Recovery Act (RCRA), EPA selected a 30-year compliance period. At the end of 30 years, the hazardous disposal facility could be released if the protection of public health and safety is expected. If protection is not expected, the facility would remain under regulatory control. A site decommissioned under 10 CFR Part 20 uses a 1,000-year compliance period. While this may appear to be less-protective than the 10,000-year timeframe recommended in NUREG-1573 for LLW disposal, it is important to note that the unrestricted release analysis assumes the radioactivity at the remediated site is potentially contacted immediately upon release of the site. Likewise, the residual radioactivity is already in the environmental media (i.e., soil, water). There are usually no engineered barriers and limited delays from the natural system in unrestricted release decommissioning analyses. In the vast majority of analyses, the peak risk for unrestricted release occurs during the 1,000-year compliance period and, in most cases, in the first year of release. Essentially the delays that are accounted for in the LLW disposal analyses are eliminated or greatly reduced in the site decommissioning analyses. Remediation is somewhat different than disposal in that action must be taken to protect public health and safety, whereas disposal actions can only be undertaken if they can be done so safely.

Table 1 Approaches to Analysis Timeframes for Various Waste Disposal and Management Programs

MATERIAL	HAZARD	DURATION	ACTION	TIMEFRAME REQUIREMENT	BASIS[1]
EPA RCRA	Chem	∞[2]	Disposal	30+ yrs	Nontechnical
Uranium Mill Tailings	Rad	LL	Remediate	200 yrs (<1,000 yrs)	Nontechnical
Part 20 unrestricted release	Rad	SL-LL	Remediate	1,000 yrs	Technical
DOE Order 435.1	Rad	SL-LL	Disposal	1,000 yrs	Nontechnical
LLW Disposal Facility (Part 61)	Rad	SL-LL	Disposal	[10,000 yrs][3]	Technical
EPA Underground Injection	Chem	∞	Disposal	10,000 yrs	Technical
DOE WIR	Rad	SL-LL	Remediate	DOE: 1,000 yrs[4] NRC: 10,000 yrs	Technical
DOE Siting Guideline (10 CFR 960)	Rad	LL	Disposal	100,000 yrs	Technical
EPA HLW/SNF/TRU Generic Standards	Rad	LL	Disposal	10,000 yrs	Technical
EPA HLW/SNF Site-Specific Standards	Rad	LL	Disposal	10,000 yrs–15 mrem 1,000,000 yrs–100 mrem	Technical

1 *Bases given a "technical" description are those derived primarily considering the characteristics of the waste and the attendant disposal concept. Those given a "nontechnical" description as based on policy or socioeconomic considerations.*
2 *Some chemical waste, and even some metals, will degrade in the environment.*
3 *This is the value recommended in NUREG-1573 by the Performance Assessment Working Group.*
4 *DOE has evaluated 10,000 years, and in some cases longer, in waste determinations completed since 2005.*

For the disposal of government-owned LLW, DOE specifies a compliance period of 1,000 years in DOE Order 435.1. The Order states that the performance assessment shall include calculations, for a 1,000-year period after closure, of potential doses to representative future members of the public and potential releases from the facility to provide a reasonable expectation that the performance objective is not exceeded. The DOE Order 435.1 ("Requirements") implementation guide indicates that it may be helpful to perform calculations after the compliance period to understand the performance of the facility and models, although the results of those calculations are not to be used for compliance. Exceeding the performance objectives after 1,000 years does not necessitate changes to the disposal system design, although changes can be made. In some cases, such changes have been made, while in other cases they have not.

The analysis timeframe for geologic disposal of SNF and other high-level radioactive waste (HLW) is based on a number of considerations: (a) sufficient period of time to ensure safety of humans and the environment for the release of radiation following loss of integrity of engineered barriers, (b) adequate time to incorporate significant processes and events that impose greatest risk, (c) restricted period during which uncertainties can be prescribed with reasonable assurance, and (d) sufficient time to ensure that the source term is greatly reduced and roughly equivalent to the hazard from a natural ore body (NRC 2001). The generic (i.e., for sites other than Yucca Mountain) standards and regulations for the disposal of SNF and HLW (40 CFR Part 191, "Environmental Radiation Protection Standards for Management and Disposal of Spent Nuclear Fuel, High-Level and Transuranic Radioactive Wastes," and 10 CFR Part 60, "Disposal of High-Level Radioactive Wastes in Geologic Repositories") specify a compliance period of 10,000 years. The NRC has developed site-specific standards and regulations for HLW disposal at Yucca Mountain, Nevada, in 10 CFR Part 63, "Disposal of High-Level Radioactive Wastes in a Geologic Repository at Yucca Mountain, Nevada."

EPA's standard (40 CFR Part 197, "Public Health and Environmental Radiation Protection Standards for Yucca Mountain") sets the compliance period for Yucca Mountain at 10,000 years. But the Court of Appeals for the D.C. Circuit vacated EPA's 10,000-year compliance period because it was not "…'based upon and consistent with' the findings and recommendations of the National Academy of Sciences," (NAS, 1995), as required by Section 801 of the Energy Policy Act of 1992 (42 USC § 10141 note), *Nuclear Energy Institute v. Environmental Protection Agency,* 373 F.3d 1251, 1257 (2004). The NAS stated that compliance assessment is feasible for most physical and geologic aspects of repository performance on the time scale of 1 million years at Yucca Mountain. For HLW disposal, NAS recommended that the compliance assessment be conducted for the time when the greatest risk occurs, within the limits imposed by the long-term stability of the geologic environment. NAS noted that, while there aren't scientific reasons to limit the assessment to 10,000 years, there may be policy considerations to do so. As a result of the remand, EPA developed a revised standard (i.e., different dose limit and further constraints for performance assessment for the period beyond 10,000 years) to address the difficulties and uncertainties in conducting analyses beyond 10,000 years.

The new Yucca Mountain site-specific standard relies on a tiered approach. For the first 10,000 years, the dose to the reasonably maximally exposed individual (RMEI) must not exceed 150 Sv/yr (15 mrem/yr) TEDE. Originally, from the period after 10,000 years, extending to 1 million years after closure, the EPA proposed that the dose was not to exceed 3.5 mSv/yr (350 mrem/yr) (EPA 2005). In the final standard, the dose limit applicable to the period from 10,000 years to 1 million years was set at 1 mSv/yr (100 mrem/yr). The EPA, in the *Federal Register* notice for the proposed revision of 40 CFR Part 197, provided a discussion of many of the considerations found in this paper with respect to the disposal of long-lived HLW (EPA 2005). Yucca Mountain is the only precedent in the United States for the disposal of radioactive materials in which the consideration of effects extending potentially to 1 million years is required. The NRC implemented the EPA standards in 10 CFR Part 63 (NRC 2009).

The standards for the management of uranium mill tailings in 10 CFR Part 40, Appendix A, "Criteria Relating to the Operation of Uranium Mills and the Disposition of Tailings or Waste Produced by the Extraction or Concentration of Source Material from Ores Produced Primarily for Their Source Material Content," require disposal in accordance with a design that provides reasonable assurance of control of radiological hazards for 1,000 years, to the extent reasonably achievable, and, in any case, for at least 200 years. The standard also requires perpetual governmental ownership and long-term surveillance of the site (which may include monitoring, as necessary). Therefore, no prolonged inadvertent access or use of the site is assumed during this period. The regulations apply flux limits for radon-222, averaged over the cover system, and specify standards for ground-water protection.

In development of 40 CFR Part 191, EPA proposed environmental standards for the management and disposal of spent nuclear fuel, HLW, and transuranic radioactive waste (TRU). Though not an NRC-regulated facility, the Waste Isolation Pilot Plant (WIPP), used for disposal of TRU, is somewhat analogous to the NRC-regulated activities discussed above. The Federal Government authorized WIPP under 40 CFR Part 191. In proposing and finalizing the regulations, EPA set containment requirements for 10,000 years (EPA 1982, EPA 1985). The period of 10,000 years was selected because experts believed that some aspects of the future could be reasonably predicted to allow for comparison and selection of disposal methods. EPA also believed that a geologic disposal system working for 10,000 years would continue to protect people and the environment beyond 10,000 years. A period of 10,000 years was long enough to ensure that ground-water effects would most likely be realized, and that major geologic changes would not occur. Thus, the system would be reasonably predictable.

5.1.2.3 International Approaches

The analysis timeframe is a key component of performance assessments used to evaluate the safety of integrated radioactive waste management systems. Although a number of countries operate disposal facilities for low- and intermediate-level radioactive wastes (Nuclear Energy Agency, 2002), approaches to the specification of analysis timeframes vary from country to country (Ryan, 2005; Nuclear Energy Agency, 2009). A general overview of the approaches of the international waste disposal community is provided as well as specific insights for various countries. The specific countries discussed in more detail were selected because they provide a reasonable overview of the range of approaches used internationally.

Staff performed a literature review to evaluate what other countries and international agencies use to manage the risk from long-lived waste (see references section). The selection of a period of performance is one type of approach used to identify impacts from the disposal of long-lived waste and to impose appropriate restrictions on disposal. Almost every country or organization places restrictions on how much waste can be disposed of in the near surface or does not allow near-surface disposal of long-lived waste. Most countries place explicit numerical limits on concentrations of long-lived alpha-emitting waste (LL-α). Concentration limits are set by regulators based on generic analyses and are not developed from site-specific analyses. Site-specific analyses are performed but only for waste that satisfies the generic limits. As discussed earlier, this approach is very similar to what was done in Part 61 during initial development of the regulation. Part 61 has requirements for technical analyses that are supplemented with waste concentration limits and other disposal requirements, such as minimum disposal depth for certain types of waste.

Some international programs have waste classification systems that classify waste by concentration and half lives of different isotopes. In the United States, LLW classes [(i.e., Class A, B, C, and greater-than-Class C (GTCC)] are defined by concentrations of both short- and long-lived waste. For example, Class A waste may contain radionuclides from both Table 1 and Table 2 of 10 CFR 61.55. The practical result of mixing short- and long-lived waste in the classification system is that the performance requirements, such as the compliance period, must apply to waste streams that have high inter-waste variability with respect to longevity in the environment. Some international programs—for example, France—classify waste by both concentration and half-life. The International Atomic Energy Agency (IAEA) advocates this type of classification system (IAEA 2009). Performance requirements and disposal systems can be better tailored to the specific waste characteristics. In order to ensure the safe disposal of waste significantly different from that considered in the original development of Part 61 and without changing the waste classification system, other U.S. disposal requirements need to be developed or modified so that they apply to a mix of short- and long-lived waste to ensure continued protection of public health and safety.

Figure 1 provides an overview of the types of limits or analyses used by different countries or organizations with respect to the near-surface disposal of long-lived waste.[6] The majority of programs or organizations place some type of limit on the disposal of long-lived waste in the near surface irrespective of technical analyses, and many programs apply multiple limits (i.e., defense in depth). In other words, technical analyses are used in safety decisions but they are not solely relied upon. The most common types of limits are concentration and quantity limits specified before performing site-specific analyses, and limits by either disposal concept (e.g., near-surface disposal is prohibited) and requiring “long” analyses. In this context, “long” is defined as 10,000 years or longer. The amount of information the staff found describing the approaches of various countries or organizations varied considerably. Below are select examples to illustrate the concepts and frameworks countries have used.

Many countries develop concentration limits for long-lived waste or long-lived alpha-emitting waste that are used to determine when LLW may be evaluated for consideration of disposal in the near surface and when intermediate depth or deep-geologic disposal is required. The concentration limits for long-lived alpha range from around 1E7 Becquerel (Bq)/kilogram (kg) to orders of magnitude lower. Many are on the order of 1E6 Bq/kg. The IAEA provided a waste classification system in its general safety guide on classification of radioactive waste (IAEA 2009). The IAEA developed six classes of waste based on consideration of concentrations and half-lives. Low level waste, to be disposed of in the near-surface, may include short-lived radionuclides at higher levels of activity concentrations, and also long-lived radionuclides, but only at relatively low levels of activity concentration. Figure 2 provides the conceptual illustration of the IAEA waste classification scheme. Although IAEA did not assign numerical values to the waste classes, Annex III (IAEA 2009) provided an example of how different sealed sources may be classified using the system. The boundary between LLW (near-surface disposal) and intermediate-level waste (ILW) (intermediate-depth disposal) is 4E5 Bq/kg, which is comparable to approximately 1E6 Bq/kg values derived in a number of countries.

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6 Staff reviewed a variety of references to develop the figure. The figure reflects the best available information the staff was able to obtain. There may be some uncertainty associated with the regulatory requirements of a particular program.

France has a waste classification system that is based on concentrations and half-lives, which, as mentioned previously, affords some advantages to developing regulatory requirements to manage risk. For short-lived waste, a period of performance of 300 years is used. Although institutional controls are to be maintained for this timeframe, studies still evaluate human intrusion. Waste classified as long-lived, intermediate-level waste (LL-ILW) is to be disposed of in deep-geologic disposal. Only very limited concentrations of LL-α are suitable for near-surface disposal.

Sweden sets concentration and quantity limits for shallow land disposal of radioactive waste (Sweden Radiation Safety Authority, 2009). The maximum value for alpha-active substances is 10 gigabecquerels (GBq) of long-lived waste (which is approximately 1 metric ton of fresh DU). The approach to timescales for the analyses of safety of proposed disposal actions for long-lived waste is described as as-long-as-needed, but at least 10,000 years. Sweden used a two-tier approach: The first 1,000 years using the current biosphere and including uncertainty; the second is more generic but is to be for at least 100,000 years for long-lived waste and include processes such as glaciation. This approach to timescales is used for deep-geologic disposal in Sweden, which would apply to the disposal of long-lived waste above the limit noted above. For waste that is not spent nuclear fuel or long-lived, the risk analysis is to be completed for the period of maximum consequence, up to 100,000 years.

Finland currently disposes of all waste in hard rock at depths (> 60 meters (m)), which, in accordance with the regulatory schemes of most countries, would be intermediate-depth disposal. Finland states that effects from disposal on future generations should be no higher than what is acceptable for the current generation. LLW is limited to concentrations less than 1E6 Bq/kg. The timescale for the analyses is at least several thousand years, but after this time, Finland applies additional limits to release based on natural flux rates (defined in “Guide YVL 8.4—STUK-Radiation and Nuclear Safety Authority 2001”).

Switzerland prohibits surface and near-surface disposal and limits risks from disposal to future generations no greater than what is presently acceptable (Wildi et al, 2000; Swiss Federal Nuclear Safety Inspectorate, 2009). Switzerland provides both specific activity limits, as well as absolute activity limits, in its “Radiological Protection Ordinance.” Timescales are established to provide permanent protection. The primary consideration is the hazard over time and the geology. The specific performance period is 1 million years, after which regulators compare ranges of results to natural risks. It is assumed that humans will be present when radioactivity is released to the environment.

In the United Kingdom, concentration limits are set to establish the boundary between LLW and other types of waste. For waste that can be disposed of as LLW, timescales are not explicitly defined by the regulator (Health Protection Agency, 2009). Quantitative assessments are to be performed until peak risk or until a point at which uncertainties are so great that the assessments are no longer meaningful. The point at which the results of the assessment are no longer meaningful is established by the developer of the disposal facility and not the regulator. The developer is required to explore expected scenarios and less likely scenarios. In practice, the regulators have asked for quantitative assessments out to 100,000 years, and for simple hazard assessments out to 250,000 years (Environment Agency, 2009).

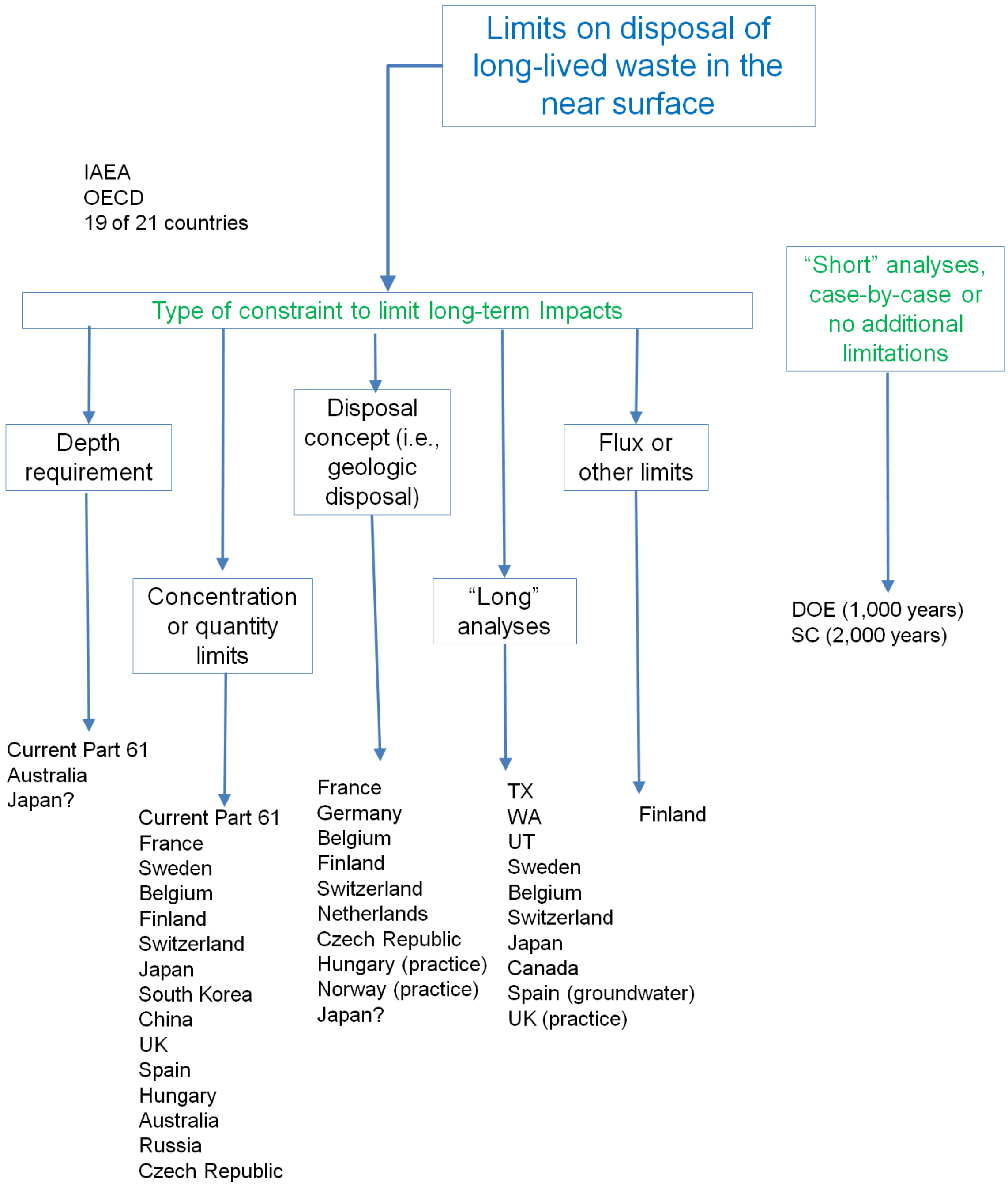


Figure 1 Types of limitations placed on near-surface disposal of long-lived radioactive waste (primarily international, but includes some domestic approaches)

Notes: Utah only requires "long" analyses for large quantities of uranium. DOE examines effects after 1,000 years for LLW disposal on a case-by-case basis.

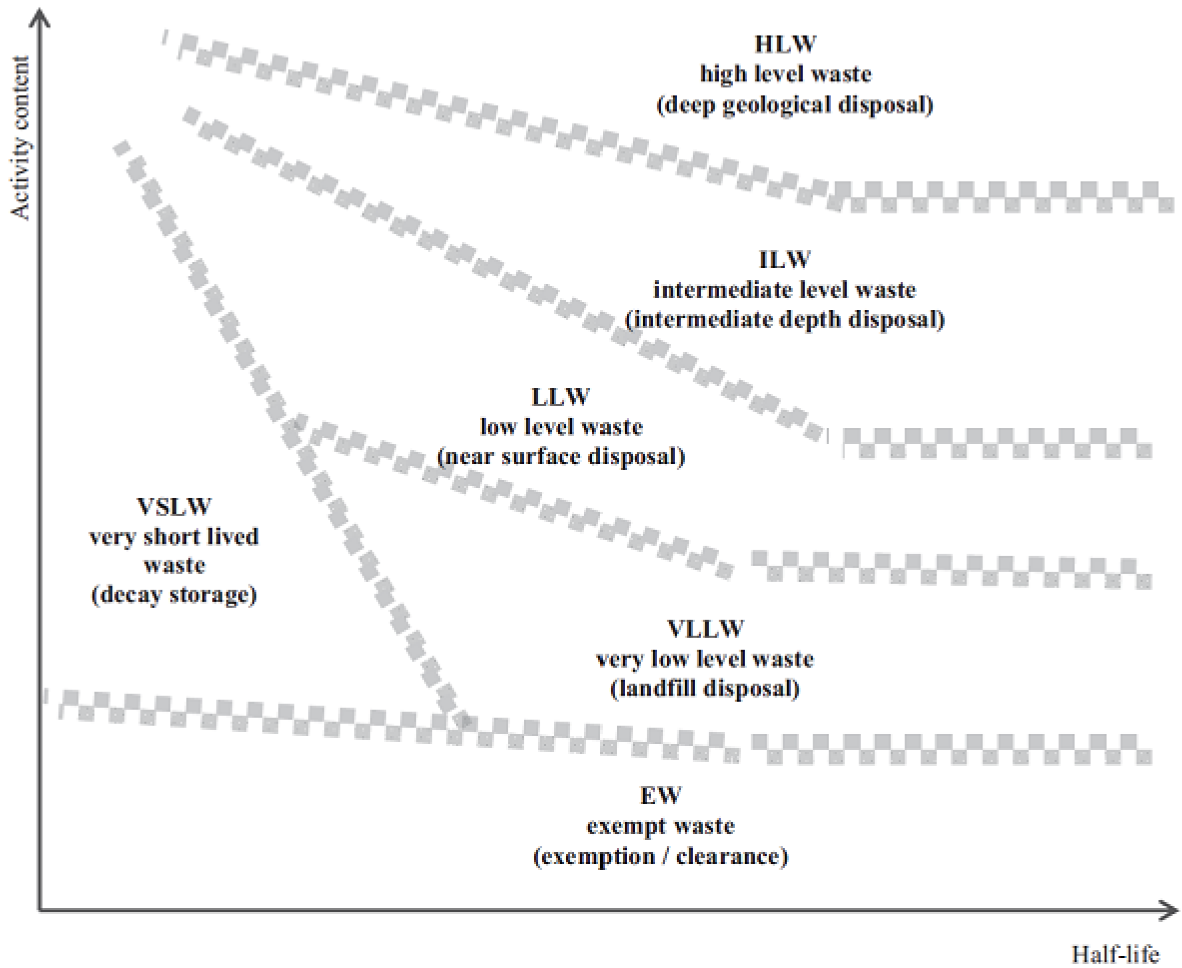


Figure 2 Conceptual illustration of the IAEA waste classification scheme

In Canada, the assessment of future effects encompasses the period of time when the maximum impact is expected to occur and future impacts are allowable only if they are no greater than today (Canadian Nuclear Safety Commission, 2004, 2006). There is no time limit prescribed on assessing effects, and developers can use bounding analyses. The timeframe used in the analysis supporting the post-closure safety assessment for the deep-geologic repository for low- and intermediate-level waste was a 1-million year baseline (Quintessa et al, 2011). A variety of technical elements can be taken into account when performing the technical assessment (e.g., hazard, engineered barriers, controls, events).

In Spain, a total quantity limit for LL-α waste is provided for near-surface disposal of LLW (27 terabecquerel (TBq) or about 10 metric tons of DU). The Spanish approach is to contain the activity for 300 years, at which point the facility can be free released. Spain establishes institutional controls for 300 years. Besides release to man, the only other perceived potential release is in the water pathway. For the ground-water pathway calculations, the timescales are set based on the longevity of the material being evaluated. For short-lived radioactivity, the calculations are performed for 1,000 years. For long-lived radioactivity, the ground-water pathway is assessed for up to 1 million years.

Belgium sets concentration limits for LL-α waste for surface disposal (4E5 to 4E6 Bq/kg) (Federal Agency for Nuclear Control, 2012). Its regulatory framework is based on the principle of isolation for as long as necessary, relying primarily on a passive approach to safety over time. For waste that meets the concentration limits, the analysis is divided into different scenarios. Expected evolution and altered evolution scenarios are evaluated up to an approximately 2,000-year cutoff time (Federal Agency for Nuclear Control, 2011). After this timeframe, penalizing scenarios are evaluated (essentially conservative scenarios used to manage long-term uncertainties). Regulators evaluate human-intrusion scenarios after the operational phase (50 years) and the nuclear regulatory control phase (300 years).

Australia isolates LLW for the time that it is hazardous, including the consideration of the in-growth of progeny (Commonwealth of Australia, 1993). Sites are to achieve stable geomorphology for the time that the waste is hazardous. The future detriment to society is not to exceed the current detriment, but there must be a net benefit for the current generation. Australia developed concentration limits and waste classes similar to those developed in the United States. Minimum disposal depth is specified for different waste classes. For example, the concentration limit for ^{238}U at a 5 m disposal depth is 1E7 Bq/kg. Australia derived the concentration limits for a scenario assumed by the regulator and conditions representative of rural Australia, where a disposal facility is most likely to be located. Those conditions include very little rainfall, no foundation in dwelling construction, and shorter exposure times compared to the scenario used to develop 10 CFR Part 61 in the United States. The assumed conditions were consistent with the environmental conditions and current practices in Australia at the time the regulations were adopted.

South Korea sets gross alpha limits of 3.7E6 Bq/kg to protect future generations. If the concentration limits are met, regulators define timescales for the analysis at about 1,000 years (Korean Institute of Nuclear Safety, 2010). Because the amount of long-lived waste is limited, the 1,000-year analysis is sufficient to assess the risk from disposal of LLW. However, South Korea also specifies that disposal facilities need to verify that leakage will not increase dramatically after this timeframe, and that there will be no acute risks. This position implies the analysis will be longer or that bounding analyses will be used.

The approaches by different international programs vary considerably in the regulatory requirements used to achieve protection of future generations from the disposal of long-lived radioactive waste. However, countries and international safety organizations consistently apply limitations on the near-surface disposal of long-lived waste (e.g., prohibit disposal, concentration limits, disposal depth requirements, flux limits, long analyses).

5.1.3 Transgenerational Equity

Transgenerational equity is the consideration of how decisions by the present generation affect future generations. It is particularly relevant for waste disposal decisions because science and technology have been shown to afford a high degree of protection to the current generation. Over extended periods of time, the level of protection afforded to future generations by actions taken by the present generation is less certain. Most regulatory programs attempt to use simple and conservative approaches to ensure public safety is protected.

The National Academy of Public Administration (NAPA) performed a study to look at transgenerational equity at the request of DOE. NAPA recognized that intergenerational decision making involves a number of variables (NAPA, 1997). According to NAPA, each generation must consider not only how its actions will affect future generations, but also how inaction will impact the current generation and may negatively affect future generations. The potential environmental effects from the disposal of LLW may extend from the current generation to future generations. NAPA outlined four basic principles:

(1) Every generation has obligations as trustee to protect the interests of future generations.

(2) No generation should deprive future generations of the opportunity for a quality of life comparable to its own.

(3) Each generation’s primary obligation is to provide for the needs of the living and succeeding generations. Near-term concrete hazards have priority over long-term hypothetical hazards.

(4) Actions that pose a realistic threat of irreversible harm or catastrophic consequences should not be pursued unless there is some countervailing need to benefit either current or future generations.

The four principles reflect trusteeship, sustainability, chain of obligation, and precaution. The NAPA framework for intergenerational decision making recognizes that there is an intergenerational obligation that must encompass broader questions than a particular narrow issue (e.g., nuclear waste disposal) since resources are finite and needs are great (Kadak, 2000).

The Organisation for Economic Co-Operation and Development (OECD) issued a collective opinion on the environmental and ethical basis of geological disposal of long-lived radioactive wastes (OECD, 1995). The mission of the OECD, of which the United States is a member country, is to promote policies that will improve the economic and social well-being of people throughout the world. The OECD developed a set of principles to be used as a guide in making ethical choices about waste management strategies. These principles were as follows:

- The liabilities of waste management should be considered when undertaking new projects.

- Those who generate the wastes should take responsibility, and provide the resources, for the management of these materials in a way that will not impose undue burdens on future generations.

- Wastes should be managed in a way that secures an acceptable level of protection for human health and the environment and affords to future generations at least the level of safety that is acceptable today. There seems to be no ethical basis for discounting future health and environmental damage risks.

- A waste management strategy should not be based on a presumption of a stable societal structure for the indefinite future, nor of technological advance. Rather, it should aim at bequeathing a passively safe situation that places no reliance on active institutional controls.

The principles expressed by NAPA and the OECD are similar in many ways. Both believe the current generation has obligations to future generations. An important difference is that NAPA expressed that near-term hazards have precedent, whereas OECD believed there is no ethical basis for discounting future health and environmental damage risk.

The United States ratified the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management on April 9, 2003 (DOE/EM-0654). Article 11, General Safety Requirements, provides requirements to ensure that in all stages of waste management, persons, society, and the environment are adequately protected from radiological risks. Article 11 specifies the following:

> *vi) Strive to avoid actions whose reasonably foreseeable repercussions on future generations are greater than those accepted for the present generation.*
>
> *vii) Attempt to prevent undue burdens from being placed on the generations of the future.*

These views are anthropocentric, with the OECD's being what would be termed a "strong" position and NAPA's and the Joint Convention being "weak" on a relative basis. Other groups and researchers have presented biocentric and ecocentric views (Stenmark, 2002). The different views represent varying opinions about which natural things have intrinsic value or moral standing. The NRC staff is not aware of a legislated rational standard to use in the development of regulatory requirements, and the Commission has not formally established a policy on transgenerational decision making.

5.1.4 Technical Considerations

Waste characteristics are one of the primary technical factors used to develop a regulatory framework to ensure protection of public health and safety from the disposal of radioactive waste. Activity and longevity (half-life) are used to determine where within the radioactive waste management framework materials should be dispositioned and what requirements need to be established to protect public health and safety. In general, longer-lived wastes are disposed of deeper than shorter-lived wastes. Figure 3 provides the relationship between waste classification and disposal concept from IAEA (Bergström et al, 2011).

The staff developed Figure 4 to illustrate the inventories received at different commercial LLW disposal facilities in a manner consistent with the objectives of a performance assessment. Performance assessments are used to take concentrations and quantities of waste and estimate the eventual environmental concentrations resulting from various release pathways and the resultant effects over various timeframes. In Figure 4, the inventories are expressed as a reduction factor needed to achieve a 25 mrem/yr TEDE result for a drinking water pathway and the associated half-live of each isotope. The analysis is for a single pathway that may not be active at a particular site. However it allows the reader to make a relative comparison of the source terms that have been received. The figure should not be used for any site-specific licensing decision.

For the isotopes plotted, the figure shows that the biggest reduction is needed for strontium-90 (^{90}Sr) with rather large reductions also needed for Americium-241 (^{241}Am) and long-lived ^{238}U and thorium-232 (^{232}Th). All of the disposal facilities the staff evaluated to develop the figure have disposed of moderate or larger quantities of long-lived waste. The bottom part of the figure (b) shows an average reduction that may be achieved by including the geochemistry of the site in the analysis. In this case, researchers applied solubility limits, which act to limit how much of some isotopes can be contained in a given volume of water. Up to half-lives of a few hundred years, the necessary reductions may be achieved by engineered barriers (e.g., waste form, containers, vaults). For long-lived waste, the reductions primarily come from the natural

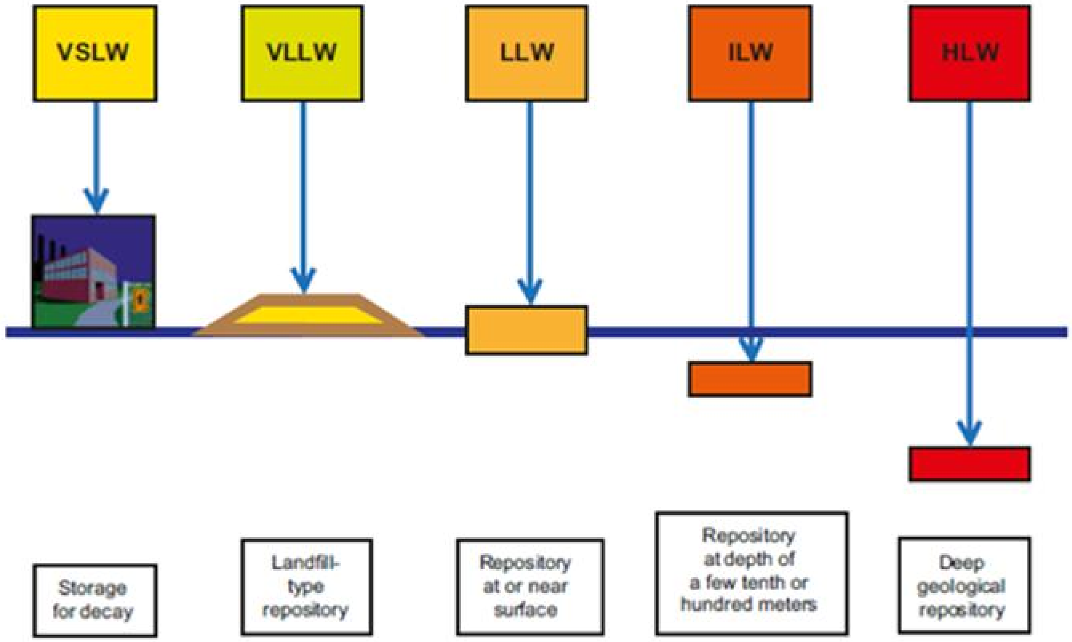


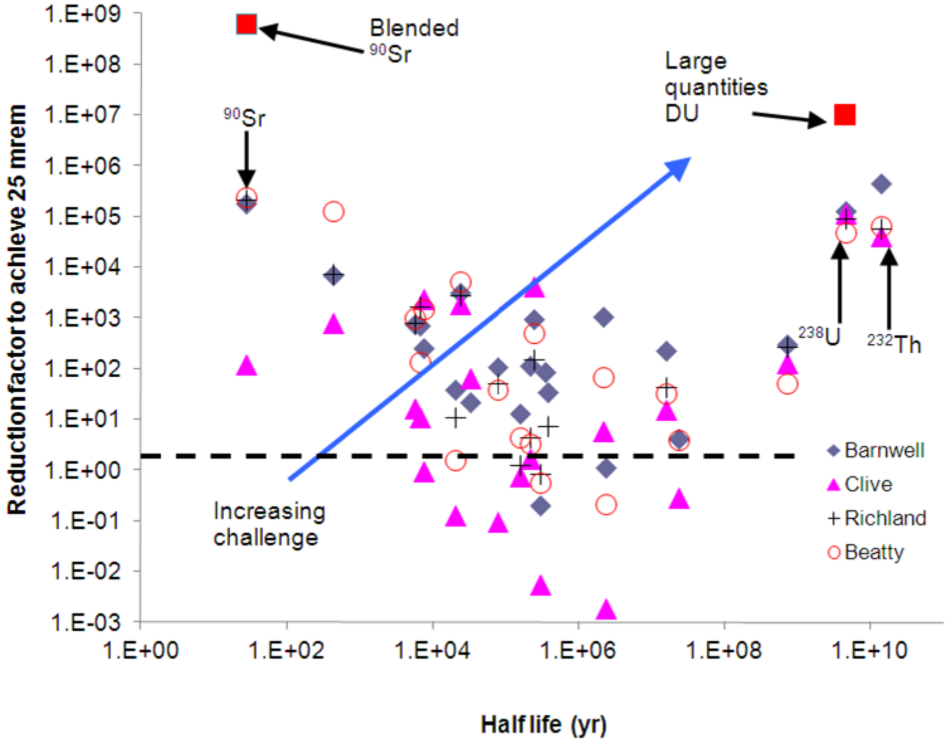
Figure 3 General relationship between waste classification and disposal concept

characteristics of the site (e.g., geochemistry, dispersion, dilution). Scientists could possibly engineer waste forms to provide enhanced retention of radioactivity, although it is not commonly done on a large-scale at commercial LLW disposal facilities in the United States.

During public interactions on the 10 CFR Part 61 rulemaking, a number of stakeholders have expressed that the inventory is dominated by short-lived isotopes and, therefore, the analysis timeframes should be commensurately short (e.g., 1,000 years or less). The disposal inventory (hazard) is dominated by the short-lived isotopes but the risk is dominated by what lasts and escapes, not by what decays in place. The performance assessment is designed for the licensee, applicant, regulator, and public to develop an understanding of what the risks may be across the whole spectrum of wastes that are disposed. Risk-informed regulations need to be based on risk, not hazard. It is not risk-informed to set the performance requirements (e.g., analysis timeframe) based on the hazard of the short-lived portion of the inventory that is expected to decay in place and not impact public health and safety.

The risk from short-lived waste [e.g., cesium-137 (^{137}Cs), ^{90}Sr] has been very well managed in commercial LLW disposal under 10 CFR Part 61, and it is expected to be minimal based on performance assessments. Management of this risk is primarily achieved by the engineering that goes into a waste disposal facility. However, the experience base to support the performance of engineered barriers over long timeframes is limited and is based on analogs rather than direct observation. The performance assessment should be expected to provide results that can be used by licensees, applicants, and regulators to evaluate and communicate the performance of the disposal site with respect to the long-lived inventory. The 10 CFR Part 61 rulemaking should address the disposal of long-lived waste. Disposal of large quantities of depleted uranium is unique because of the concentrations and quantities involved. There have been and will continue to be disposal of smaller quantities of long-lived waste in commercial LLW disposal facilities that may be significant from a risk perspective.

(a)



(b)

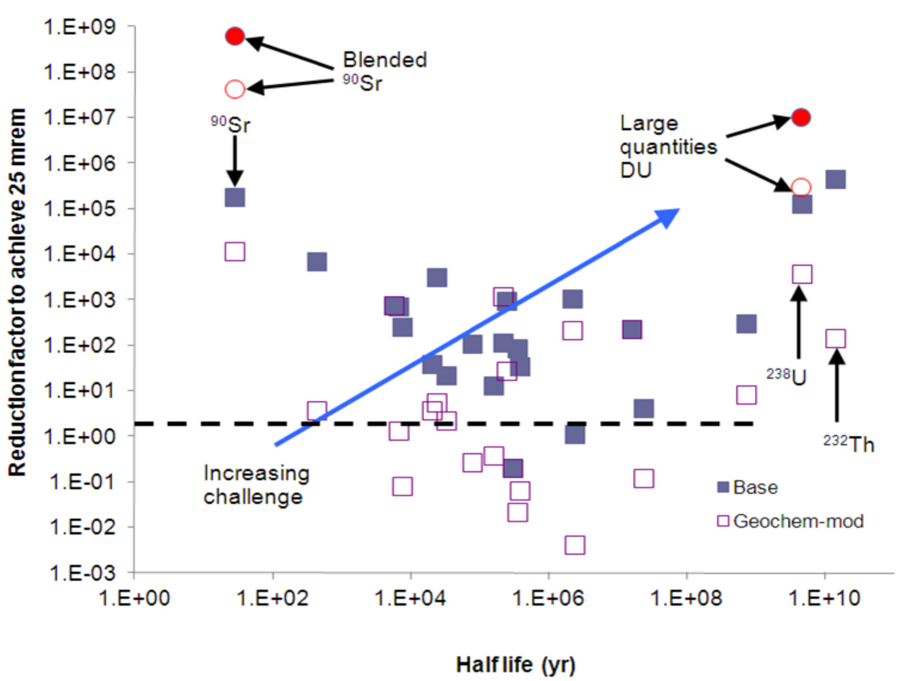


Figure 4 (a) The relative performance needed to achieve 25 mrem TEDE based on the waste inventory disposed of at four different LLW facilities; (b) The relative performance in (a) modified by the geochemistry (e.g., solubilities).

Performance assessments are used to estimate when and at what rate radioactivity may be released into the environment. Many different processes can affect the releases in a performance assessment, such as performance of engineered barriers, performance of waste forms, and transport through environmental media. These processes can create lags or delays between when the disposal facility is closed and when the radioactivity is released into the environment. For short-lived waste, these delays result in decay-in-place or decay-in-transit, which reduces or eliminates releases to the environment. For long-lived waste, these lags generally only delay eventual releases but do not reduce or eliminate them. If analyses are used to estimate the risk from long-lived waste, the regulatory requirements for the analyses should consider how performance assessment models and the systems they are evaluating perform. It is important that the process be transparent to regulators and other stakeholders so that they can evaluate how the site and waste disposal facility are estimated to perform over all relevant timeframes.

When the NRC developed 10 CFR Part 61, it recognized stability as a cornerstone of the LLW disposal concept. Under these regulations the systems in which waste are placed are meant to be sufficiently stable to ensure that public health and safety can be protected. For short-lived waste and low concentrations of long-lived waste, the waste, disposal facility, and disposal site only need to remain stable on the order of hundreds of years as per the waste classification and stability requirements found in 10 CFR 61.55 (the stability requirements differ for different classes of waste). However, for concentrated long-lived waste, instability within the waste management system could result in releases of radioactivity to the environment that endanger public health and safety. Without requirements for concentration limits, long-term analyses, disposal depth, or other requirements there would be limited assurance that long-term risks are within the range of risks that are currently acceptable today. When the NRC developed 10 CFR Part 61, facilities were not expected to be able to develop wasteforms and engineered barriers to provide complete containment for materials that may pose risk thousands of years in the future. Therefore, performance analyses are relied on to estimate what may be released and the associated effects.

Concentrated DU at disposal has a specific activity of approximately 1E7 Bq/kg. With higher activity of ^{234}U, the concentrations could be approximately 1E8 Bq/kg. After in-growth of daughters, the concentrations are approximately 1E9 Bq/kg. The highest concentration limits developed by regulatory programs for near-surface disposal of long-lived alpha waste are on the order of 1E7 Bq/kg, although at this concentration there are commonly additional restrictions on disposal. Current 10 CFR Part 61 regulations have limits on the concentrations of transuranic long-lived waste that are suitable for disposal in the near-surface environment (3.7E6 Bq/kg). Establishing concentration limits for long-lived waste can mitigate the uncertainty associated with long-term analyses, while providing protection of public health and safety in a parsimonious approach.

5.1.5 Stakeholder Feedback

The NRC has received a diverse set of written and oral comments since the topic of analysis timeframes was first discussed in the context of a site-specific analysis for 10 CFR Part 61 (circa 2009). This summary provides an overview of the key issues and positions provided to the NRC staff on analysis timeframes. The complete record of comments is found in the transcripts for the public meetings that the NRC hosted, along with the documents provided under docket number NRC-2011-0012.

In 2009, most stakeholders agreed that a compliance period should be specified in the regulations. However, they did not agree on what the appropriate compliance period should be. Some felt that 1,000 years would be appropriate; others felt that 10,000 years (as recommended in NUREG-1573) was still appropriate. Several recommended that the time of peak dose should be used. It was understood that the time of peak dose could exceed 1 million years for a waste stream such as DU. In the past couple of years, some stakeholders (including ACRS) have recommended that a compliance timeframe should not be specified in the regulations. The rationale behind not defining a compliance period is that the analyses can be more risk-informed. The duration of the compliance analyses can be based on consideration of the specific characteristics of the waste and disposal system. Some State regulators expressed interest in preserving flexibility.

Some interested parties also felt that disposal of long-lived waste in the near-surface environment above *de minimis* levels was not appropriate under any conditions. They felt that the uncertainties were too large and the risks too unknown to support near-surface disposal. For these stakeholders, a discussion of the analyses timeframes is not the essential topic because they feel that disposal of long-lived waste in the near surface should be reconsidered.

As in NUREG-1573, the staff initially recommended a two-tiered approach to the analyses timeframe (NRC, 2011b). Subsequently, the Commission approved directed the staff to consider such an approach (NRC, 2012d). The majority of stakeholders supported the use of a two-tiered approach to analyses timeframes in public meetings conducted and in written comments submitted in 2011 and 2012. A few stakeholders stated that a two-tiered approach was not necessary, but for different reasons. For instance, some of the stakeholders felt only a single tier would be necessary if regulators adopted a peak-dose approach. In addition some stakeholders felt that limiting concentrations of long-lived isotopes suitable for disposal would allow the use of a single compliance period of approximately a few thousand years, which would be suitable for short-lived waste disposal.

The NRC staff received a number of comments about selecting a numerical value for the compliance period. A few stakeholders supported a compliance period of less than 1,000 years (300 to 500 years were mentioned) for disposal of all types of waste. These stakeholders felt that the obligation of the present generation to future generations is limited and that changes to technology will allow future generations to better handle the problems they face. Several stakeholders supported the use of a 1,000-year compliance period similar to the DOE. They stated that uncertainties were too large after this time to warrant the use of dose calculations in decision making. Some also believed that it is important to establish a national policy with respect to timeframes for analyses of waste disposal problems. They stated that because DOE uses 1,000 years for LLW disposal the NRC should do the same. The other facet of the argument for using the 1,000-year timeframe was that more than 95 percent of the waste that is disposed of is short-lived and, therefore, the compliance period should be based on the short-lived activity.

Some stakeholders expressed the view that the analyses timeframe for long-lived waste such as depleted uranium should be set similar to that used for management of mill tailings (a few hundred years). Other stakeholders, as well as NRC staff, expressed concern with this approach because of the potentially substantial technical differences in the waste streams. Two primary differences between the source terms for uranium mill tailings and DU were described as the concentrations of uranium and the initial and eventual concentration of daughter radionuclides. Depleted uranium has much higher initial concentrations of uranium and much lower initial concentrations of daughter radionuclides. As a result of the much higher initial concentrations of uranium, the eventual concentrations of daughter radionuclides in DU will be much more than an order of magnitude higher than in mill tailings as the progeny approach the same concentration as the uranium. This process, however, can take thousands to millions of years. The initial uranium concentrations can be hundreds of times higher than that of mill tailings resulting from normal grade ore.

Other stakeholders believed that a longer period, such as 10,000 years, was more appropriate. They stated that current NRC guidance (NUREG-1573) recommends 10,000 years. They identified the purpose of performance assessment and periods of performance as being tools for decision making and for encouraging selection of good sites and good designs. If a site is only evaluated for a limited timeframe, the site and the design may not be sufficient for longer timeframes. These stakeholders emphasized the importance of transparency of decisions and information. One stakeholder mentioned that the Joint Convention on the Safety of Spent Fuel Management and the Safety of Radioactive Waste Management basically forbids the United States from neglecting effects that could occur at longer timeframes. A stakeholder expressed concern with the DOE approach, indicating that DOE has estimated effects after 1,000 years, in some cases, that the stakeholder believed were large and unacceptable. At least one stakeholder stated the belief that regulators were not discussing hazard, risk, and dose accurately. "Hazard" denotes the potential for harm, whereas "risk" is the magnitude of harm, weighted by its probability of occurrence. The stakeholder felt the focus on radioactivity is misguided because large quantities of radioactivity do not necessarily translate into high risk, especially for waste disposal. Some stakeholders supported longer-term analyses, but using metrics such as concentration instead of dose, because dose is based on future human activity, which they felt would be too speculative.

Some stakeholders felt that it is the obligation of the current generation to protect the future generations to the same standards as today. Therefore, they felt that the performance assessments (and compliance period) should be based on peak dose, whenever it may occur. They believed this approach would be risk-informed by taking into account the performance of different sites and designs, as well as the waste that is received.

At the July 19, 2012, public meeting, the staff engaged in a focused discussion on the points articulated in COMWDM-11-0002 (NRC 2012d) with respect to the analyses timeframe. There was limited support, and in fact strong reservations, expressed by some stakeholders for using the term "reasonably foreseeable future" to define the compliance period. Some participants felt this approach would be extremely difficult to define in a meaningful way and would not contribute to safety. Other stakeholders felt the terminology was too subjective.

There was less discussion for the performance period in a two-tiered approach. Most stakeholders that supported a two-tiered approach didn't have concerns with running calculations out to peak dose (or some very long cutoff time, such as 1 million years), but some were concerned with the concept of dose at longer timeframes. These stakeholders felt that it is not a meaningful metric because of the uncertainties associated with converting concentration of radioactivity into dose at longer timeframes and that other metrics would be more meaningful, such as concentrations. Others felt that dose was a useful metric as long as it was understood that it was to be a regulatory tool for decision making and not a prediction of the future. These stakeholders questioned how concentrations would be used to make decisions (i.e., what would be considered to be significant). Some participants expressed the view that, ultimately, concentrations are converted to dose using assumptions about people and activities based on current practices to provide a relative metric to understand how the disposal site and system are performing. The use of decision analysis for longer timeframes was advocated by some, with the concept of "As Low As Reasonably Achievable" (ALARA) being a suitable analogy. Others felt that because ingrowth of daughters from DU can result in significantly larger impacts after 10,000 years, a dose limit should be considered for the performance period. There has been and continues to be substantial disagreement among stakeholders as to the appropriate metrics. However, there has been general support for a tiered analyses requirement.

The Commission had recommended getting stakeholder feedback on defining the performance period on a site-specific basis using candidate site characteristics (waste package, waste form, disposal technology, cover technology, and geo-hydrology). A number of stakeholders expressed reservations about using primarily engineering-type components to define the performance period because they stated that the period of performance extends well beyond the timeframes over which the engineered components can be relied upon in LLW disposal. Some stakeholders felt that radiological characteristics of the waste and the characteristics of the site should be considered in establishing a period of performance. One stakeholder indicated that, depending on the assumed isotopic mass fractions of uranium isotopes, the time for a DU source term to reach within one order of magnitude of the peak activity (from production of daughters) could be shortened considerably from the approximately 20,000 years previously estimated by the NRC staff.

5.1.6 Analysis of Commission Direction

With respect to the analyses timeframe, the Commission direction to the staff on January 19, 2012, stated that the staff should provide analysis, including pros and cons, of:

> *A two tiered approach that establishes a compliance period that covers the reasonably foreseeable future and a longer period of performance that is not* a priori *and is established to evaluate the performance of the site over longer timeframes. The period of performance is developed based on the candidate site characteristics (waste package, waste form, disposal technology, cover technology and geo-hydrology) and the peak dose to a designated receptor.*

In its initial effort the staff had developed draft proposed requirements for analyses of LLW disposal that were based on a two-tiered approach. The first tier (compliance period) was based on estimating the peak annual dose within 20,000 years after closure of the waste disposal facility. The second tier was a performance period to establish how the disposal facility and site were expected to perform after 20,000 years with no dose limit. The second tier was not limited by duration *a priori*, but it would be carried out to peak. The main advantage of a tiered approach is that the technical expectations for the analyses can be commensurate with the uncertainty. When uncertainties are smaller (e.g., at shorter timeframes), more precision can be expected. When uncertainties are larger (e.g., at longer timeframes), less precision may be expected, with more emphasis placed on indicators of long-term performance of the disposal system. The tiered approach can ensure the costs of disposal to the current generation are aligned with reducing or mitigating the uncertainties of the impacts from disposal. A difficulty with the tiered approach is establishing the requirements for the tiers, especially the performance metrics for the second tier.

The Commission also directed the staff to consider a compliance period that might be regarded as the "reasonably foreseeable future," without defining how reasonably foreseeable future should be interpreted. If the language is to be interpreted to cover − but not be limited to the reasonably foreseeable future, then the direction does not add any scope to the staff's evaluation as any period considered by the staff would include the reasonably foreseeable future. The earlier draft proposed requirement for estimating peak annual dose within 20,000 years covered what the staff considered to be the reasonably foreseeable future. The reasonably foreseeable future in the context of performance assessment may be limited to as little as a few hundred years if societal uncertainties are formally included within the scope. Societal uncertainties are large and dynamic and, as a consequence, can influence the duration for which valid predictions can be made to satisfy regulations (Buser, 1997, pp. 28-29). For example, in a few hundred years Las Vegas went from being an uninhabited desert to a large city. If a disposal facility had been developed at this location, the view of the appropriate receptor scenario would likely have been significantly different 300 years ago than it is today.

Performance assessments are a regulatory tool to provide technical information to decision makers to inform the decision making process. They are not a prediction of the future. They normally contain conservative assumptions to account for different types of uncertainties, such as lack of knowledge about future system states. Most performance assessments do not attempt to model societal uncertainties. In its 1995 recommendations for Yucca Mountain standards, the National Academy of Sciences expressed the view that it was not possible to make predictions concerning future human activity. The predictions rely on the assumption that future society will be similar to today. In other words, pathways, receptors, consumption rates, physiology, etc., are all based on our current understanding of humans. For disposal of long-lived waste in the near surface, especially large quantities and concentrations, the risk posed after a few hundred or 1,000 years may be many orders of magnitude above that expected within the first few hundred years. This is primarily because of the functioning of engineered barriers and the aforementioned lags attributed to the natural system, but it can also be because of the characteristics of some wastes, such as DU.

Including societal uncertainties in the definition of the reasonably foreseeable future could result in a very short compliance period relative to both the hazard of the long-lived component of the waste and what is done in the international performance assessment community. A short assessment period with no other requirements could mean that almost any material, regardless of quantity and concentration, could be found suitable for near-surface disposal. If there isn't a mechanism to limit the concentrations of long-lived waste, the protection afforded to future generations would not be comparable to that afforded to the current generation. The purpose of moving to site-specific analyses is to allow the analyses to reflect the expected site conditions and other site-specific information, rather than to be constrained by the conditions and assumptions of a particular site. This approach was used in the development of the waste classification tables. If the requirements established for the site-specific analyses are too lax, risk information may not be conveyed because all actions would be acceptable and risks may not be identified. The requirements should allow the regulator to be able to appropriately categorize actions that are clearly acceptable from those that are clearly unacceptable.

Additionally, limiting the compliance period to the reasonably foreseeable future could set precedent for regulatory activities in other programs. A reason to limit the compliance period to a "short" duration (i.e., 1,000 years or less) that stakeholders have discussed has been uncertainty. Those stakeholders believe uncertainties increase over time and become too large and unknowable. The staff generally agrees that uncertainties increase with time. However, the staff also questions why this argument would not apply to any regulated activity. The uncertainty does not change the effect from the action; it changes regulators' ability to know with confidence what the effect is. The staff's projection of risk from an activity with large uncertainties and a large hazard would span a large range. Normally, in risk management, other requirements are put in place to mitigate the uncertainty and provide confidence that the impact is acceptable or to identify that the action is unacceptable.

The Commission also directed the staff to consider a second tier with a longer period of performance that is not *a priori* and would be used to evaluate performance of the site over longer timeframes. The Commission listed a variety of technical elements to consider, including peak dose to a designated receptor. The draft proposal from the staff included a second tier that was not *a priori* and that also included peak dose. The staff did not explicitly list candidate site characteristics (waste package, waste form, disposal technology, cover technology, and geohydrology) as the Commission did. The performance period (second tier) would only apply to the long-lived isotopes present in the waste because the short-lived isotopes will have decayed before the performance period. Several primary factors will drive the peak doses from long-lived waste: waste characteristics (e.g., how much long-lived waste is disposed of, geochemical characteristics, half-life), system evolution (e.g., natural and disruptive events), and hydrogeology. Unless significant advances are made in disposal technology, waste packaging, cover technology, and disposal technology, the staff does not anticipate that these factors will play much of a role in establishing the period of performance for the near-surface disposal of long-lived waste. Because of the dynamic nature of the near-surface environment, it is very challenging to establish the long-term performance of those characteristics, and the cost associated with doing so may be prohibitive. The peak dose from long-lived waste can occur well after hundreds of thousands of years in some cases. If no performance requirements are established for the second-tier, some stakeholders would describe the approach as a single-tiered approach.

The Commission has recommended bringing a clearer risk-informed approach to 10 CFR Part 61 to help manage uncertainties and, therefore, restrict the range of potential risk to ensure that public health and safety continue to be protected. A risk-informed approach to the timeframe of the analyses for LLW disposal may involve the use of other constraints and requirements to supplement or constrain the analyses to limit the debate about long-term uncertainties. Because of the nature of the problem, it is not feasible to risk-inform the safety analyses solely by prescribing an approach to analyses timeframes. Concentration limits for short- and long-lived waste, disposal depth, and waste characteristics requirements are used in 10 CFR Part 61 to limit short- and long-term effects from LLW disposal. The analyses prescribed in the regulation work in harmony with the other non-analyses-based requirements to mitigate uncertainties and ensure protection of public health and safety. The international community also uses a variety of constraints to supplement or replace site-specific analyses. Most limitations are derived by the regulator prior to a licensee or applicant developing technical analyses to support a site-specific licensing decision. There are multiple reasons why this is done, but the primary one is that with constraints in place less reliance is placed on the long-term analyses, achieving defense in depth.

The Commission also directed the staff to consider all of the principles provided by NAPA in its previous study funded by DOE (NAPA, 1997). The staff previously considered all of the principles provided by NAPA and therefore didn’t need to supplement that portion of the review. However, the staff supplemented its consideration of transgenerational equity with the views of OECD and has incorporated the requirements in the Joint Convention, in order to provide a broader perspective of this complex issue. As presented above in the section on transgenerational equity, the principles presented by NAPA are quite similar ─ but subtly different—from similar principles presented by other groups. The primary difference is the strength of the obligation of the current generation to protect future generations. Whereas the NAPA approach is based on a quality of life, the OECD approach is based on a level of safety. Because radiation risk at levels of radiation comparable to background radiation is not a primary driver of mortality, quality of life is preserved with radiation exposures much higher than would be allowed under current safety limits. The OECD approach strives to achieve a level of safety comparable to today, which the staff interprets as public radiation exposure limits similar to those acceptable today. Reconciliation of these differences does not appear to be feasible with technical analyses because they are based on societal judgment about the appropriateness of the approaches.

5.1.7 Options Considered

The staff considered new options, in addition to those previously considered in the initial draft of the site-specific analyses rulemaking. The initial staff proposal considered a variety of options for an approach to specifying the regulatory requirements for site-specific analyses of LLW disposal (NRC, 2011b). The approach recommended by the staff for 10 CFR 61.41 analyses was for a licensee to estimate the peak annual dose that would occur within 20,000 years following disposal and apply a 25 mrem/yr TEDE dose limit. The compliance analysis would be followed by a performance period analysis that would estimate peak annual dose to demonstrate the long-term performance of the disposal system and site. This approach would afford flexibility to tailor the analyses to the characteristics of the waste being disposed and ensure transparency with stakeholders on the potential range of long-term effects. The information below summarized new options considered.

Table 2 summarizes the options initially considered, as well as the new options that have been added. Previously the staff considered five different approaches to specifying the timeframes of the site-specific analyses. Those approaches have been supplemented with four additional options. Based on both the Commission direction and the diverse approaches used in the international regulatory community, the staff felt the options should be broadened. As discussed in the section of this document reviewing international approaches, many different approaches have been used to constrain the disposal of long-lived waste in the near-surface environment.

Option No. 6 is a variant of the current approach in 10 CFR Part 61 to waste classification and the analyses that are performed for decommissioning of sites under 10 CFR Part 20. The Part 61 waste classification system uses concentration limits derived by the NRC for fixed scenarios and conditions, and the process under 10 CFR 61.58, “Alternative Requirements for Waste Classification and Characteristics,” can be used to develop alternate classification with site-specific analyses. Tiered analyses are used for decommissioning of sites, although the analyses are specified in guidance, not in regulations. For decommissioning, the NRC developed screening values that a licensee can use to determine if a site-specific dose assessment is needed. If the screening values are not met, then a site-specific analysis can be performed using RESRAD, a computational model whose development was, in part, sponsored by the NRC. In some cases, the site may be complex or the problem may be conceptually different than the RESRAD computational model. Licensees can choose to develop their own computational models to perform the site-specific dose assessments. The tiered-analyses framework has been used successfully to decommission a large number of contaminated sites. It is risk-informed for both licensees and regulators because the type of analyses that are performed can be tailored to the problem.

As envisioned here for the analyses timeframe for near surface disposal of LLW, option No. 6 would involve:

- A compliance period of up to 10,000 years.

- A second tier (performance period) that is only applicable when long-lived, alpha-emitting waste concentrations exceed 10 nCi/g (the current Class A limit for TRU), or waste concentrations exceed one tenth of the values listed in Table 1 of 61.55.

The analyses for the second tier would use: (a) a screening process to identify if long-term analyses are necessary, and if applicable, (b) long-term, site-specific analyses to peak dose (limited to 1 million years). The performance requirement for the long-term analyses would be to maintain effects to the public ALARA. The analyses that could be used for the second tier would be described in guidance, not in regulations. The regulations would only describe the analyses at a high level.

Under this option (Table 2, Option No. 6), facilities that dispose of short-lived waste or limited quantities of long-lived waste would perform their compliance analyses, and no additional analyses would be required. If concentrations of long-lived alpha-emitting waste exceeded 10 nCi/g or if waste concentrations of other radionuclides exceeded one tenth of the values specified in Table 1 of 61.55, then the licensee would perform analyses for the second tier. It is envisioned that guidance would advocate the use of a conservative screening analysis or, if desired, a site-specific analysis for the second tier. Appropriate technical analyses for each would be described in guidance. The screening analysis would be based on a conservative approach (e.g., peak ingrowth of daughter isotopes, assume no retardation during transport, defined scenarios) to manage long-term uncertainties and ensure that public health and safety is protected. If the screening analysis results show the performance objectives will not be met, then inventory limits could be established based on the screening analysis or long-term, site-specific analyses could be performed to demonstrate that public health and safety will be protected. Using this framework, the analyses can be risk-informed. The standard for considering if the effects from the second tier are acceptable would be to maintain doses to the public ALARA.

The staff also added an option similar to the previously recommended regulatory precedent option (No. 3), but instead of a peak annual dose within 20,000 years after closure, it switched to a peak annual dose within 10,000 years following closure (Table 2, Option No. 7). This option also adds a dose limit to the second tier of the analysis of 100 mrem. Instead of setting the requirements by most strongly considering the technical aspects of the problem (e.g., waste characteristics, radionuclide transport, stability) as was done in the previous attempt, this approach would attempt to align with regulatory precedent in similar programs.

The classification of waste within the United States (not limited to LLW) is primarily based on definitions and legislation and not on technical considerations. There is a correlation, i.e., HLW is higher risk than TRU, which is higher risk than LLW, but the correlation is not perfect. If there are large quantities of concentrated, long-lived waste disposed of as LLW, from a technical perspective that waste more closely resembles HLW or TRU. For disposal of HLW under the generic geologic repository regulations in 10 CFR Part 60, a 10,000-year compliance period is specified. For disposal of TRU at the Waste Isolation Pilot Plant, a 10,000-year analysis is specified in the regulations applicable to that site (40 CFR Part 197). Specifying a peak annual dose within 10,000 years for LLW would ensure that when the concentrations of long-lived radionuclides are high, public health and safety would be protected from the disposal of LLW similar to how it is managed for disposal of HLW or TRU. Adding a dose limit to the second tier of the analyses better aligns the approach with many international programs, which establish nonsite-specific requirements for disposal of long-lived waste (e.g., concentration limits) supplemented or supplanted by other requirements, such as long-term analyses.

Table 2 Options Considered for Regulatory Requirements for Site-Specific Analyses

OPTION	TYPE *	DESCRIPTION	COMMENTS
1	Previous	No change	Timeframe for analyses undefined in regulations.
2	Previous	Peak dose	Evaluate compliance to peak dose, regardless of when it may occur.
3	Previous	Regulatory precedent	Establish compliance period based on knowledge about how different sites and wastes perform; two-tiered approach.
4	Previous	Uncertainty informed approach (CAP)	Three-tiered approach that established compliance, assessment, and performance periods for analyses based on the broad uncertainty context.
5	Previous	Other industrial metals	Approach similar to that used in the United States by EPA.
6	New	Current Part 61 and decommissioning analog	Tiered-analyses approach that allows flexibility in the type of analyses. Analyses based on single tier for most sites and wastes (10,000 years). Either screening process or long-term, site-specific analyses used for long-lived waste (if applicable, discussed in guidance). ALARA applied to the results of the second tier when screening is not used.
7	New	Regulatory precedent with long-term limits	Similar to option No. 3 but with a compliance period of 10,000 years and a 100 mrem/yr dose limit established for the second tier of the analyses.
8	New	DOE approach	Single tier of 1,000 years. No regulatory limits for effects after this period.
9	New	COM approach	Two-tiered approach: first tier of a few hundred years to 1,000 years, followed by second tier defined by considering site-specific characteristics (to peak dose but with no dose limit).
10	New	International approach	Single tier of up to a few thousand years, complemented with regulator derived concentration and quantity limits for long-lived isotopes.

** "Previous" are options from the NRC white paper (NRC, 2011b); "new" are options added in this paper.*

Option No. 8 on Table 2 is analogous to that used by DOE for the disposal of LLW. This approach would assign a 1,000-year analysis using a single tier. No limits would be prescribed for impacts that may occur after this period. This approach is based on the belief that uncertainties become so significant that the results of calculations at longer times may not be meaningful and should require careful interpretation. Implicitly, this approach is limiting the obligations of the current generation to provide a similar level of protection to distant future generations. Guidance would indicate that it may be useful to evaluate longer-term impacts and consider if modifications to the disposal system are practical. The primary challenge with this approach is that it is difficult to argue that it meets the needs of future generations. While the overall activity of LLW is dominated by short-lived radionuclides, the risk from waste disposal, as estimated under 10 CFR 61.41, is dominated by the long-lived radionuclides. As shown in

Figure 4, all waste disposal facilities in the United States dispose of some amount of long-lived waste. It isn't risk-informed to tailor the regulatory requirements to the portion of the waste that does not result in risk. Varying amounts of long-lived waste have been disposed of in all commercial LLW facilities. Appendix B provides some charts and figures showing the estimated results from different DOE performance assessment or special-analysis calculations for LLW disposal and waste incidental to reprocessing waste determinations (which are done to demonstrate that they can meet the 10 CFR Part 61 performance objectives). In many cases, the risk is very low over the first thousand years, but it increases significantly afterwards. In most cases, the risks are still projected to be low because the overall inventory of long-lived waste is managed appropriately. However, if the inventory of long-lived waste were increased significantly, such as in the case of disposal of large quantities of DU or other long-lived waste (and not otherwise limited in regulations), a performance assessment could demonstrate that the performance objectives would be met within the first 1,000 years but then be exceeded by a large margin afterwards. In fact, this result may be more expected than unexpected. The lack of a standard for action with respect to long-term impacts (after 1,000 years) could create ambiguity and non-uniformity if carried out for the disposal of LLW within the NRC's Agreement States. The decisions for additional action would be subjective, with case-by-case decisions being made by different parties using different metrics.

Option No. 9 was derived from the Commission direction, although the Commission direction is ambiguous as to the specific requirements. The staff analyzed the Commission direction in more detail in a previous section of this document. The requirements of this type of approach would involve a compliance period of somewhere between a few hundred to 1,000 years, which would cover what the staff feels is a reasonably foreseeable period. If uncertainty associated with the societal component of the problem was managed by specifying reasonably conservative scenarios, then the compliance period could be as long as 10,000 years.

The second tier of this approach would be to evaluate to peak dose without assigning dose limits, which would ensure transparency of information with stakeholders without necessitating action based on the projected impacts. If dose limits were to be assigned, then the approach to the second tier would be analogous to Table 2, Option No. 7.

The final approach considered (Option No. 10) is to use a single tier (compliance period) for the analyses of up to a few thousand years, complemented with regulator derived concentration and quantity limits for long-lived isotopes. This approach can be very effective at mitigating the impact of long-term uncertainties while avoiding unnecessary speculation and ensuring protection of public health and safety for present and future generations. The challenge in using this approach is that it is difficult to take into account different site, disposal facility, and other characteristics using this approach. To ensure protection of public health and safety the limits may need to be set at values derived for the most limiting conditions (e.g., site and design) that may be inappropriate for different conditions.

The five previous options considered are not discussed here in detail as the previous descriptions of those options are still sufficient. For further information the reader should consider the NRC document "Technical Analysis Supporting Definition of Period of Performance for Low-Level Waste Disposal" (NRC, 2011b).

5.1.8 Recommendation

Different regulatory approaches can be used to manage uncertainties. Risk-informed does not necessarily mean complex and burdensome. The original approach taken in the regulations was to establish concentration limits based on intruder analyses performed by the NRC for demonstration of compliance with 10 CFR 61.42 and to complement the generic concentration limits with site-specific analyses for demonstrating compliance with 10 CFR 61.41. This approach was taken to provide protection while avoiding excessive speculation about future human behavior.

Requiring uncertainty-informed analyses that ensure public health and safety are protected when disposing of long-lived wastes is a risk-informed approach. However, it is not risk-informed to ignore potential long-term impacts because of large uncertainties without applying other regulatory requirements to ensure public health and safety will be protected. It would also not be risk-informed to apply expensive and burdensome requirements on the present generation to offset hypothetical and unknown risks to generations long into the future. In the analyses performed in 2008 as part of the development of SECY-08-147, "Response to Commission Order CLI-05-20 Regarding Depleted Uranium," the staff estimated that DU (e.g., concentrated, long-lived waste) could be disposed of in the near-surface but only in either limited quantities or under certain conditions. Without specifying regulatory requirements to either identify when the conditions for disposal are appropriate or to prevent disposal under inappropriate conditions, public health and safety may not be adequately protected.

During the public workshops conducted by NRC staff, a variety of stakeholders expressed the view that a period of performance should be included in the regulations and assigned Compatibility Category B (which would require the Agreement States to adopt essentially identical regulations) to ensure consistency across Agreement States and to ensure that the period of performance used for regulatory basis was appropriate. The current ambiguity of the period of performance has resulted in Agreement States taking different approaches, which could influence licensing of different sites.

The staff recommends that a specific approach to establishing the analyses timeframes should be included in this revision to 10 CFR Part 61 and would recommend adopting an approach similar to Table 2, Option No. 6.

The reasons for recommending Table 2, Option No. 6 are as follows:

- It provides for tiered, risk-informed analysis that allows tailoring of the analysis to the problem.

- It is a parsimonious approach that should work well within the Agreement State regulatory framework.

- By providing a concentration limit, it provides a uniform approach for determining when analyses for the second tier are needed.

- The use of ALARA for the second tier analyses provides a framework to put the effects in the proper context, given the uncertainties.

- In the United States, many stakeholders are comfortable with a 10,000-year analysis timeframe for disposal of radioactive waste.

As discussed in an earlier section, one of the primary considerations in the previous approach proposed by the staff was the DU waste stream, as directed by the Commission in SRM-SECY-08-147. The DU radiological characteristics are somewhat unique in that there is potentially a large quantity of the material that needs to be disposed and it is very long-lived. In addition, the hazard of DU increases over very long periods of time because of the slow decay of uranium and the in-growth of daughters. The previous approach attempted to balance the radiological characteristics of the waste with the uncertainties associated with long-term performance assessment. The time for the concentration of the waste to be within one order of magnitude of the peak concentration is sensitive to the assumed isotopic mass fractions in the initial waste. At higher mass fractions of ^{234}U, this time can occur sooner. The result is that estimation of the peak annual dose within 10,000 years (compliance period) is technically equivalent to the previous staff recommendation at higher mass fractions.

The regulatory requirements the NRC establishes must be protective of public health and safety and should encourage the selection of favorable sites and result in good disposal practices.

5.2 Flexibility for Site-Specific Waste Acceptance Criteria

5.2.1 Background

Subpart D of 10 CFR Part 61 specifies technical requirements for land disposal facilities for commercial LLW. The technical requirements specify the classes and characteristics of radioactive waste that are acceptable for near-surface disposal, as well as other requirements. Regulations in 10 CFR 61.55 provide the primary criteria related to waste acceptance and identify the classes of waste acceptable for near-surface disposal (i.e., the waste classification system). Regulations in 10 CFR 61.56, “Waste Characteristics,” identify the minimum characteristics for all classes of waste and characteristics intended to provide stability of certain waste. Additionally, 10 CFR 61.52(a) specifies requirements for near-surface disposal facility operation, including segregation and intruder barrier requirements for various classes of waste. Regulations in 10 CFR 61.58 allow for other provisions for the classification and characteristics of waste on a case-by-case basis if, after evaluation, the Commission finds reasonable assurance of compliance with the performance objectives.

The NRC in 10 CFR 61.55 identifies three classes ─ A, B, and C ─ of waste based on two considerations. The first consideration accounts for the concentration of long-lived radionuclides whose potential hazard will persist long after such precautions as institutional controls, improved waste form, and deeper disposal have ceased to be effective. The second accounts for the concentration of shorter-lived radionuclides for which requirements on institutional controls, waste form, and disposal methods are effective.

Historically, waste designated as Class A generally does not contain sufficient amounts of radionuclides to be of great concern from the standpoint of exposures to intruders and migration from the disposal facility. The 100-year period of active institutional controls is intended to protect intruders from this waste class while the waste remains hazardous. Thus, 10 CFR Part 61 imposes only minimum requirements on Class A waste characteristics, as specified in 10 CFR 61.56(a), as long as the waste is segregated from higher activity waste per the operational requirement set forth in 10 CFR 61.52(a)(1).

Waste designated as Class B or C must meet more rigorous requirements on waste characteristics, as specified in 10 CFR 61.56(b), to ensure stability after disposal. Further, Class C waste, because of its higher activity, also requires additional measures at the disposal facility to protect against inadvertent intrusion. The operational requirement at 10 CFR 61.52(a)(2) specifies the additional measures needed to protect against inadvertent intrusion. Waste with activity concentrations exceeding the limits prescribed for Class C waste is generally not acceptable for near-surface disposal.

The development of the waste classification system followed directly from the performance objectives. The classification system is well-integrated with the requirements for waste characteristics and disposal facility operation. This integration stemmed from the generic nature of the analysis that the NRC staff performed to develop the general requirements of 10 CFR Part 61 in 1982 (NRC, 1981; NRC, 1982). The integrated requirements are intended to ensure, as much as possible on a nonsite-specific basis, that the performance objectives are met. The staff employed a generic methodology partly because of (a) the level of data that could be inferred or generalized for a generic system, as opposed to an analysis of a specific site where a significant quantity of site-specific information would be required and where specific facility designs for waste disposal may be considered, (b) the necessity to consider viable alternatives during different waste management phases (e.g., waste processing and disposal), and (c) the need to evaluate relative costs and impacts of alternative actions to develop generic requirements to be applied at the regional disposal sites that were envisioned by Federal policy enacted in the *Low-Level Radioactive Waste Policy Amendments Act of 1985*.

5.2.2 Other Regulatory Approaches

The NRC staff performed a review of domestic and international approaches regarding waste acceptance. In general, practices vary but are constrained between specification of criteria by the regulatory agency and development of site-specific WAC by disposal facility operators. In all cases, the regulatory authority maintains critical oversight of disposal, including approval of the waste acceptance requirements.

Domestically, all operating near-surface disposal facilities in the United States are regulated by Agreement States. Currently, the disposal facilities use WAC (e.g., EnergySolutions 2009, 2011; Texas Commission on Environmental Quality, 2012). These criteria generally specify acceptable waste and waste forms, describe the waste acceptance process, and identify shipping and manifesting requirements. Acceptable limits on radionuclides and waste characteristics are drawn from the waste classification systems implemented in corresponding Agreement State regulations that are compatible with 10 CFR Part 61. These plans also include acceptable approaches for waste characterization and certification that the waste complies with the WAC.

In addition, DOE has extensive experience implementing site-specific WAC for the disposal of government-owned LLW. DOE Manual 435.1-1 (DOE, 2011) (Manual) specifies the requirements, with accompanying implementation guidance provided in DOE G 435.1-1 (DOE, 1999). The Manual specifies technical and administrative, as well as evaluation and acceptance requirements, for all LLW for disposal. The waste acceptance requirements are generally performance-based, with several specific requirements regarding waste forms that limit acceptance of waste with certain characteristics, including free liquids, explosive and pyrophoric materials, waste generating toxic gases, and certain gaseous waste forms.

DOE also requires programs to characterize and to certify that waste complies with the WAC. The waste characterization program must identify parameters and acceptable levels of uncertainty and a minimum set of waste characterization data. The waste certification program must identify organizational responsibilities for certification; specify documentation required for generation, characterization, shipment, and certification; designate requirements for audits, retrievability, and storage of required documentation; and specify records retention. Additionally, DOE M 435.1-1 (DOE, 2011) requires that waste shall be certified before transfer to the disposal facility and that certified waste shall be managed in a manner to maintain its certification status.

Internationally, waste acceptance requirements for near-surface disposal of radioactive waste vary from country to country but are either generically specified by the regulatory body (e.g., 10 CFR Part 61) or developed by the operator on the basis of either generic or site-specific analyses, with approval of the competent regulatory authority. Regardless of how the WAC are determined, important features include radionuclide content, physical and chemical properties of the waste, fire resistance, and configuration and identification of waste containers (IAEA, 1999). In addition, a quality assurance program that recognizes the roles of both waste generators and disposal facility operators in demonstrating compliance with the waste acceptance requirements is important to ensure the safety of the facility.

5.2.3 Technical Considerations

The 10 CFR Part 61 classification system concentration limits and integrated requirements on waste characteristics, waste segregation, and intruder barriers grew out of the analyses performed to develop Part 61 (NRC, 1981; NRC, 1982). The principle basis used for setting the classification limits, waste characteristic requirements, and operational requirements was limiting exposures to a potential inadvertent intruder at a reference disposal facility, although other considerations (e.g., long-term environmental impacts, disposal facility stability, institutional control costs, and financial impacts to small entities) also contributed. Specifically, the waste class limits were derived from an analysis that considered a combination of factors including radionuclide characteristics and concentrations, the waste form, the methods of emplacement, and, to some extent, the site characteristics. These factors influenced the concentration of radionuclides transferred from the disposed waste to the access points for the intruder scenarios. The specific factors are discussed further in the following paragraphs.

The analysis evaluated 37 distinct waste streams having unique characteristics. The waste streams were projected to be routinely generated during the period from 1980 to 2000. The analysis identified the most important radionuclides present in each waste stream and determined the geometric mean of the range of activity concentrations. The volumes projected in each region for each waste stream were averaged and normalized to 1 million m^3 (40 million ft^3). The intrusion was assumed to occur into the final disposal cell into which waste was placed, thereby limiting the effects of radioactive decay.

The factor for site design and operation accounted for waste emplacement efficiency and whether intruder barriers are used to isolate certain wastes. Layering of waste was employed as a surrogate for intrusion barriers for comparative evaluation. The analyses assumed that layered waste was emplaced beneath 2 m (7 ft) of cover material and 4 to 5 m (13 to 16 ft) of other waste. After the assumed intrusion scenarios occurred, this left at least 1 m of cover material to shield the intruder. NRC staff based the assumption of placement depth on a generalization of disposal practices that were common when 10 CFR Part 61 was developed, and these may not represent the actual design and operation of modern disposal facilities. A site-specific analysis is well-suited to evaluating the unique designs and operations of a specific disposal facility.

The factor for the waste form characteristics of each waste stream included the dispersibility, leachability, presence of chelating agents, structural stability, and accessibility of radionuclides in unsolidified waste with high metal content. These characteristics affected the factor accounting for waste form and packaging. In setting the waste class limits, stable waste forms, as long as they were segregated from unstable wastes, were considered distinguishable from soil for 500 years, whereas, unstable wastes (or wastes commingled with unstable wastes) were considered indistinguishable from soil. Therefore, certain waste form characteristics, such as dispersibility, were not accounted for in the analysis for unstable waste.

In general, the analyses relied upon conservative approaches to quantify waste form characteristics on a nonsite-specific basis. The analyses relied upon an extensive effort to quantify, for comparative purposes, the waste form characteristics for the 37 waste streams that were analyzed. A similar analysis may be resource intensive to reproduce with current information for each disposal facility that elects to develop site-specific WAC as permitted by any flexibility added to an amended 10 CFR Part 61 as part of this potential rulemaking effort.

On the other hand, the characteristics considered in the generic analysis were not designed to be exhaustive. Depending on the specific site conditions, some waste form characteristics that were not analyzed by the generic analyses to develop the waste classification system may be more significant. For instance, the generic analysis to develop 10 CFR Part 61 did not consider the mechanical or thermal resistance of the waste forms to chemical and biological attack. The biochemical environment of the disposal units would likely be influenced by the site environment over the long term. Site-specific analyses are well-suited to evaluate the impact of these types of site-specific considerations.

The final factor NRC staff considered in the analysis accounted for site characteristics to a limited extent. The factor accounted for transfer factors between environmental pathways (e.g., soil-to-air) and the exposure duration caused by the activities involved. The transfer factors depend on the environmental conditions of the location of the disposal facility. The reference disposal facility was not intended to represent any particular location; rather, it was used to reflect the typical environmental conditions within its region. NRC staff chose the southeastern region because, at the time, most of the waste was produced in the eastern portion of the nation and was projected to be disposed regionally. Today, only one of the four operating disposal sites is located in the eastern United States; the other three are located in the arid or semi-arid western United States. This suggests that the reference disposal facility environmental characteristics considered in the development of 10 CFR Part 61 do not represent the environmental characteristics for the facilities in which the largest quantities of waste are currently being disposed (i.e., the western disposal facilities).

Regardless of whether the assumptions regarding the site characteristics of the reference disposal facility are consistent with current sites, the NRC staff believes that the 10 CFR Part 61 waste classification system remains protective of public health and safety for the waste streams analyzed in the development of the regulation because of the reasonably conservative nature of the analysis to develop the waste classification system. However, because of the inconsistency between actual site conditions and practices at operating disposal facilities (e.g., disposal practices and site characteristics) and the generic assumptions to develop Part 61, it is possible that radionuclide concentration limits could be either overly restrictive or permissive. If radionuclide concentration limits are overly restrictive based on actual site characteristics, facility design, and operational practices, Part 61 would continue to ensure safe disposal, but it would impose unnecessary regulatory burdens. Whereas, if the generic concentration limits are overly permissive based on actual site characteristics, facility design, and operational practices, the waste classification system may not adequately ensure protection of public health and safety at such a disposal facility should an inadvertent intrusion actually occur. Therefore, the inconsistency between the analysis and current practices highlights potential needs for flexibility to consider site characteristics to develop site-specific WAC that would provide enhanced assurance that public health and safety continue to be protected while offering the possibility for the relief of unnecessary regulatory burden for well-sited, designed, and operated sites. If the Commission found that the waste classification requirements were overly permissive at a particular disposal facility, it could impose additional requirements to ensure that the 10 CFR Part 61 performance objectives would be met. Therefore, the 10 CFR Part 61 performance objectives continue to ensure protection of public health and safety.

5.2.4 Stakeholder Comments

Stakeholders expressed a wide range of comments regarding flexibility for site-specific WAC to the NRC staff during the preparation of this document. Some stakeholders were supportive of the idea, while others raised concerns for allowing flexibility for licensees to establish site-specific WAC. This summary is intended to provide an overview of the key comments provided to the NRC staff. The complete record of comments can be found in the transcripts for the public meetings that the NRC staff hosted, as well as the written documents provided under Docket No. NRC-2011-0012.

Stakeholders who commented in favor of allowing flexibility generally cited the dated and generic aspects of the development of the waste classification scheme in 10 CFR Part 61 and its potential impact on the effective use of existing disposal capacity. These commenters believed the Commission should allow licensees to challenge the assumptions that were used to develop current waste classification criteria based on their actual site characteristics and operational practices. Many of the issues raised by these stakeholders regarding the assumptions inherent in the waste classification system are discussed above in Technical Considerations, Section 5.2.3. These stakeholders felt site-specific WAC would enhance safety by allowing licensees to recognize improvements in site selection, facility design, and disposal methods beyond what was assumed in the analysis to develop the waste classification system in Part 61.

Some of these stakeholders questioned the role of the intruder assessment in developing site-specific WAC. Specifically, they raised objections to the assumed inadvertent intrusion exposure scenarios because of the perceived low likelihood of inadvertent intrusion at some of the current disposal sites. This group of stakeholders recommended that flexibility should allow licensees to justify site-specific exposure scenarios. Some of the stakeholders who were supportive of site-specific exposure scenarios recommended public involvement in establishing the site-specific scenarios. Other stakeholders urged the Commission to maintain the illustrative intent of the inadvertent intrusion assessment to determine what waste is acceptable for disposal. They argued for the NRC to observe international guidance and historical practices regarding intrusion scenarios in the United States. Specifically, these stakeholders expressed concern about decisions based on obscure site-specific scenarios rather than more commonly accepted stylized scenarios, such as dwelling construction or agriculture, which were employed in the development of 10 CFR Part 61.

A set of the stakeholders who advocated for flexibility in this rulemaking also advocated for flexibility to consider active institutional control periods other than 100 years, as currently allowed in 10 CFR 61.59. Supporters of alternative institutional control periods indicated that the Agreement States should have flexibility to determine the active institutional control period appropriate for establishing site-specific WAC if the land owner or custodial agency agrees to accept the burden. Meanwhile, other stakeholders cautioned that the NRC should maintain the limit at 100 years as a measure of regulatory defense-in-depth.

Some of the stakeholders felt that adding flexibility to establish site-specific WAC would eliminate the need for the generic waste classification system. Other stakeholders, however, cautioned against abandoning the waste classification system currently in 10 CFR Part 61. These other stakeholders commented that the *Low-Level Radioactive Waste Policy Amendments Act of 1985* defines Federal and State responsibilities for the disposal of LLW based on 10 CFR 61.55, as in effect on January 26, 1983. Specifically, the Act, as amended in 1985, assigns responsibility for disposal of Class A, B, and C commercial LLW to the States and responsibility for disposal of commercial LLW with concentrations that exceed the limits for Class C waste to the Federal government. They argued that abandoning the waste classification system could cause confusion for stakeholders.

Some stakeholders indicated the current waste classification system provided a consistent and stable baseline of acceptability for generators. These commenters generally favored a hybrid “either/or” approach that maintains a consistent waste classification system between the regulation and the *Low-Level Radioactive Waste Policy Amendments Act of 1985*, which would help mitigate potential confusion over Federal and State responsibilities and provide a baseline for waste generators while allowing flexibility to develop site-specific WAC. However, some of these commenters indicated that the site-specific WAC should take precedence over the current waste classification system when differences arise.

Still other stakeholders commented that the waste classification system should be preserved and that the site-specific technical analyses should be used to develop waste acceptability for waste streams that are outside of the current classification system. Others indicated their preference to update the concentration limits based on current international recommendations. One of these stakeholders provided documentation (Electric Power Research Institute, 2010) detailing its own assessment of the impact to the tables.

Some stakeholders recommended that the Commission expand upon the flexibility currently permitted, on a case-by-case basis, in 10 CFR 61.58 to provide additional flexibility to consider site-specific WAC. Other stakeholders were concerned that the expanded use of 10 CFR 61.58 could result in transboundary issues in which some disposal facilities could develop site-specific WAC while others may be limited to the current waste classification system. The potential transboundary issue arises because Agreement States are currently not required to adopt the alternative requirements provision in 10 CFR 61.58 because it is designated compatibility category D. In fact, of the four operating disposal sites, the States of South Carolina and Washington have adopted the alternative requirements provision, while the States of Utah and Texas have elected not to adopt the provision.

Finally, stakeholders supportive of site-specific WAC provided mixed comments on whether the NRC should specify any requirements on waste acceptability in 10 CFR Part 61. Some commenters said all criteria for waste acceptability would naturally result from the site-specific analyses used to determine the WAC, and that the NRC would not need to specify any WAC. However, others noted that some minimal set of specific requirements could be established to limit speculation to develop site-specific WAC. These commenters were generally supportive of performance-based rather than prescriptive requirements.

Comments from Agreement States related to site-specific WAC focused on the additional resource burden required to review the site-specific analyses and provide oversight of the waste acceptance process. Some Agreement States indicated support for maintaining the current waste classification as an alternative approach. Agreement States also expressed some caution about the effect of allowing site-specific WAC on current State laws restricting the disposal of certain classes of LLW. They were, as a group, generally supportive of the NRC providing maximum flexibility for Agreement States when setting compatibility requirements for any provisions implementing flexibility to consider site-specific WAC. Some non-Agreement State stakeholders, in addition to the transboundary concerns described earlier, also expressed the view that since the WAC would be generated from the performance objectives through the site-specific analyses, their compatibility designation should be more strictly consistent with the compatibility for safety fundamentals (i.e., compatibility designation A).

Comments from stakeholders who expressed concern about, or objected to, adding flexibility to 10 CFR Part 61 for site-specific WAC focused on ways to demonstrate safety, burdens on the Agreement States to review the site-specific analyses, negative effects on public confidence, and the effect of current State laws. These stakeholders stressed that the NRC should emphasize conservatism in determining safety rather than trying to maximize disposal at a specific facility. Some of these commenters also raised concern about economic incentives for licensees to justify the acceptance of waste rather than demonstrating protection of public health and safety. These stakeholders cited the complexity and lack of transparency of site-specific analyses for the public used to develop the WAC. Their comments focused on diminishing public trust with increasing complexity and diminishing transparency. They raised concerns about whether the analyses would impose unreasonable resource burdens on their State regulators and whether they would receive adequate scrutiny. Such concerns, they argued, could diminish public confidence. Several stakeholders also shared concerns that the Commission's direction appeared to be designed to circumvent a State of Utah law that restricts disposal of waste streams designated Class B and C.

Many of the stakeholders—both supportive, neutral, and critical of adding flexibility—noted, as indicated earlier, that a move to add flexibility would require more resources to adequately and critically review the site-specific analyses upon which the WAC would be derived and be used to garner public confidence. Some of these stakeholders suggested that the NRC's program for providing assistance to States, consistent with the Agreements, be used to provide the extra resources necessary to avoid placing undue burdens on the States and to help ensure consistency in the quality of the site-specific analyses.

One stakeholder noted that, in his experience, Agreement States have not been able to execute sufficient review of performance assessments presented to them, nor have they asked for assistance from the NRC. He noted that the quality of the analyses is enforced only by consistent and thorough review. In this stakeholder's view, individual Agreement States can vary widely in their acceptance of site-specific analyses, creating a problem of inconsistency between disposal sites in different states. Several stakeholders thought that the regulatory framework or guidance may need sufficient detail to provide assurance that the quality of the site-specific analyses would be adequate to demonstrate compliance with the performance objectives and develop site-specific WAC from the results of the analyses. Some stakeholders objected to Federal review of site-specific analyses as an inappropriate intrusion into a State's responsibilities as the competent authority.

5.2.5 Analysis of Commission Direction

As part of its direction (NRC, 2012a), the Commission approved expanding the limited scope revision to 10 CFR Part 61 regarding site-specific analyses to bring a clearer risk-informed approach. The Commission directed the staff to provide a proposed rule that is expanded to include, among other issues, flexibility for disposal facilities to establish site-specific WAC based on the results of the site's performance assessment and intruder assessment.

As part of its effectiveness strategy laid out in its *Strategic Plan* (NRC, 2012b), the NRC strives through its regulatory processes to expand the use of risk-informed and performance-based insights in NRC decision making and to use state-of-the-art technologies to inform regulatory actions. A performance-based approach to regulation establishes performance and results as the primary bases for decision making. Performance-based regulations have the following attributes:

(a) Measureable, calculable, or objectively observable parameters exist or can be developed to monitor performance.

(b) Objective criteria exist or can be developed to assess performance.

(c) Licensees have flexibility to determine how to meet the established performance criteria in ways that will encourage and reward improved outcomes.

(d) A framework exists or can be developed in which the failure to meet a performance criterion, while undesirable, will not in and of itself constitute or result in an immediate safety concern.

Flexibility for a disposal facility to develop site-specific WAC based on the results of the site's performance assessment and intruder assessment would allow for the increased use of site-specific information to develop risk insights to support NRC decision making while providing flexibility for licensees to determine how best to meet the performance objectives for the specific design and operational practices of their disposal facility, as well as the specific environmental characteristics of their site.

As several stakeholders, both supportive and opposed to adding the flexibility, noted, oversight of a site-specific waste acceptance process could impose an additional resource burden upon the Agreement States (See Section 5.2.4 for a more detailed discussion of the stakeholder comments). Site-specific analyses, such as modern performance assessments, can involve complex models in a wide variety of technical disciplines, including engineering, materials science, and the earth sciences. Further, the NRC has developed guidance for licensees to use to determine concentrations that demonstrate compliance with the waste classification system. This guidance, because it is well integrated with the analysis used to develop the waste classification system, would likely not be applicable to demonstrate compliance with site-specific WAC. Therefore, licensees would need to develop acceptable methods to demonstrate that waste meets the site-specific WAC and that these methods would need to be approved by the competent regulatory authority. Agreement States, as the hosts for currently operating disposal facilities, would be responsible for reviewing these analyses and approaches for demonstrating waste acceptance as part of the licensing process when WAC are developed on a site-specific basis. The analysis to develop the waste classification system and accompanying guidance, meanwhile, was developed by the NRC.

5.2.6 Options Considered

The NRC staff considered three approaches for determining waste acceptability. First, the staff considered maintaining the current approach for determining waste acceptability, namely the generic waste classification system. The NRC staff also considered a second approach in which the current waste classification system is replaced with criteria allowing flexibility for licensees to determine site-specific WAC. Finally, the staff considered a third approach that adds flexibility to establish site-specific WAC to the existing waste classification system. As described in more detail in the following paragraphs, the NRC staff recommends the third approach to revise 10 CFR Part 61 to address the Commission's direction.

5.2.6.1 Option 1–Generic Waste Classification System

Regulations in 10 CFR Part 61 currently provide general criteria for waste acceptability for near-surface disposal through the classification and waste characteristics requirements set forth in 10 CFR 61.55 and 10 CFR 61.56. The NRC developed the waste classification system in Part 61 from an analysis performed circa 1980 of a representative disposal facility that was operated consistent with contemporaneous practices and considered a projected set of waste streams. The analysis is summarized in Background*,* Section 5.2.1 above. Because of the conservative nature of this analysis, the waste classification system is expected to be protective of public health and safety as long as disposal facilities operate within the general envelope of assumptions and approaches employed in the analyses.

However, as new practices differ from the assumptions of the original analyses, confidence in the protectiveness of the regulatory framework may become strained. For instance, new waste streams that were not considered during the development of 10 CFR Part 61 are being considered for disposal (e.g., large quantities of concentrated DU). Also, current disposal facility design and operational practices can differ from the assumptions employed in the development of the regulatory framework (e.g., disposal of waste containers in concrete vaults).

Part 61 currently allows for alternative provisions for waste acceptability (i.e., classification and characterization) on a case-by-case basis through 10 CFR 61.58. Some stakeholders suggested that the NRC staff propose the use of 10 CFR 61.58 to provide flexibility for licensees to develop site-specific WAC. However, 10 CFR 61.58 is currently designated as compatibility Category D, and Agreement States, therefore, are not required to adopt it. To date, only one Agreement State with an operating disposal facility has adopted this provision. More importantly, as discussed in Stakeholder Comments*,* Section 5.2.4, above, 10 CFR 61.58 is specific to waste classification and characteristics. It cannot be used to modify other regulations in 10 CFR Part 61. In particular, 10 CFR 61.58 cannot provide exceptions to site, environmental, or institutional requirements. Therefore, the current 10 CFR 61.58 is not appropriate to set national requirements allowing flexibility to develop site-specific WAC nor can it be used to set generic requirements for disposal facilities.

5.2.6.2 Option 2–Site-Specific Waste Acceptance

Another possible approach to provide flexibility would be for the NRC to abandon the existing waste classification system and replace it with requirements for developing site-specific WAC from the results of the site-specific analyses. The proposed approach would require disposal facility licensees to define the acceptability of waste. In defining waste streams with acceptable radionuclide concentrations or activities and waste forms, disposal facility licensees would be required to use the results of the site-specific technical analyses set forth in 10 CFR 61.13, "Technical Analyses."

One stakeholder commented that allowing licensees to develop site-specific WAC would require a demonstration beyond a simple certification statement that waste satisfies the disposal facility WAC. The generic waste classification system in 10 CFR 61.55(a)(8) imposes requirements for determining the concentrations of waste. Similarly, Appendix G, "Requirements for Transfers of Low-Level Radioactive Waste Intended for Disposal at Licensed Land Disposal Facilities and Manifests," of 10 CFR Part 20 requires LLW shippers to certify that waste is properly classified (i.e., acceptable for disposal). To facilitate compliance with these requirements, NRC staff has developed guidance on acceptable approaches for determining concentrations and adequately classifying waste.

Parallel requirements to identify acceptable approaches to characterize waste and methods for certifying waste acceptability for demonstrating compliance with site-specific WAC would ensure a similar level of compliance as 10 CFR 61.55(a)(8) and Appendix G of 10 CFR Part 20. In addition, a requirement to develop acceptable approaches would allow flexibility for disposal facility licensees to ensure that characterization and certification are compatible with the approaches used in the site-specific analyses to develop the WAC. Therefore, NRC staff agrees that beyond radionuclide limits and acceptable waste characteristics, disposal facilities also should be required to develop appropriate approaches for generators to characterize waste and methods to certify that waste meets the disposal facility acceptance criteria.

For this second option, changes would be needed to the requirements for LLW transfers intended for disposal at licensed land disposal facilities and manifests that are specified in Appendix G of 10 CFR Part 20. Section I.C.12 of Appendix G requires the shipper of waste consigned to a disposal facility to identify the waste classification per 10 CFR 61.55 on the uniform manifest. Additionally, waste not meeting the structural stability requirements of 10 CFR 61.56(b) must be identified on the shipping manifest. The requirement in Section I.C.12 of Appendix G of 10 CFR Part 20 would need to be revised since the waste classification system set forth in 10 CFR 61.55 and the stability requirements in 10 CFR 61.56(b) would no longer exist under this approach. The requirement could be deleted or revised to better reflect the new flexibility for site-specific WAC. However, any necessary revisions to Section I.C.12 of Appendix G, 10 CFR Part 20, that attempt to better reflect the added flexibility for site-specific WAC could be difficult to predict at this point given the uniqueness and diversity of WAC that could result for the various disposal sites.

Further, Section II of Appendix G to 10 CFR Part 20 requires waste generators, processors, or collectors to certify that the transported LLW is properly classified. Since this option would abandon the current waste classification system in favor of site-specific WAC, this certification requirement would need to be updated so that shippers are certifying that waste consigned to a disposal facility meets the facility's WAC.

Section III of Appendix G of 10 CFR Part 20 also places requirements on the control and tracking of radioactive waste transferred to a disposal facility. Specifically Sections III.A.1 through 3 and III.C.3 through 5 require the waste to be classified according to 10 CFR 61.55 and meet the waste characteristics requirements in 10 CFR 61.56. The container must be labeled with the appropriate waste class, and the licensee must conduct a quality assurance program to assure compliance with 10 CFR 61.55 and 61.56. While Option 2 would abandon the current waste classification system in favor of site-specific WAC, the requirements of Appendix G to 10 CFR Part 20 could continue to provide classification information on whether the waste is a Federal or State responsibility.

However, the abandonment of the waste classification system in 10 CFR Part 61.55, as proposed under this option, would require a change to these portions of Section III since abandoning the waste classification system would remove the current 10 CFR 61.55. In practice, removal of 10 CFR 61.55 would create a dual system as follows:

(a) the use of the waste classification tables from 1983, which would no longer exist in 10 CFR Part 61.55 under this option, to determine whether the waste is a Federal or State responsibility; and

(b) the use of site-specific acceptance criteria to determine if waste can be safely disposed at a disposal facility

Further, generators would classify using the abandoned waste classification system which could lead to confusion. Alternatively, the requirements of Section III of Appendix G to 10 CFR Part 20 could be revised so that generators confirm that they are meeting the WAC developed by the disposal facility operator.

Some stakeholders commented that licensees should have flexibility to consider alternative active institutional control periods in the analyses to derive site-specific WAC. These stakeholders indicated that the period assumed in the analyses should be as flexible as the land owner or site custodian will permit. To allow this flexibility when developing site-specific WAC, the NRC would need to revise 10 CFR 61.59 to permit licensees to develop site-specific WAC for periods beyond 100 years.

The NRC, during the development of 10 CFR Part 61 (NRC, 1981), considered a range of time periods for active institutional controls and indicated that a clear consensus developed during that consideration around 100 years (NRC, 1982) as an appropriate period for how long the government would need to provide custodial care. When stakeholders at that time commented that longer times would be appropriate, the NRC replied that, while the longevity of government may reasonably be assumed to extend beyond 100 years, the limit is tied to the possibility of bureaucratic error, which is more difficult to assess. For example, the government could, at some future date, accidentally permit activities on the site as a result of an incomplete records search. The NRC indicated at that time that it saw no compelling reason to abandon 100 years.

Further, other recent stakeholders have cautioned against allowing this flexibility since the institutional control period is a regulatory component of defense-in-depth by limiting the period of time over which oversight would need to be effective. International approaches for the period over which institutional controls are assumed to function vary, but generally they are limited to 300 years or less (IAEA, 2009). Therefore, allowing *unlimited* flexibility would appear to be inconsistent with current international practice regarding the longevity of institutional controls. The NRC staff continues to agree with its earlier assessment and can see no compelling reason to consider a revision to 10 CFR 61.59, particularly since the Commission did not provide staff specific direction to pursue such a revision.

Some stakeholders, as described in more detail in Stakeholder Comments, Section 5.2.4, above, provided comments in support of relying solely on site-specific WAC, while others cautioned about the abandonment of the existing waste classification system. The abandonment of the current waste classification system as part of a limited-scope rulemaking presents challenges because the waste classification requirements are well integrated with other requirements of 10 CFR Part 61. For instance, requirements for the operation of a disposal facility specifically reference the waste classes. Therefore, wholesale replacement of the waste classification system would likely expand the revisions beyond the limited nature discussed by the Commission in their direction to the staff.

Further, removal of the waste classification system from 10 CFR Part 61 would not result in total abandonment of the system because the classification of waste is referenced in the *Low-Level Radioactive Waste Policy Amendments Act of 1985*. The *Low-Level Radioactive Waste Policy Amendments Act of 1985* establishes Federal and State responsibilities for the disposal of LLW based on the waste classification system in Part 61 as it existed on January 26, 1983. Specifically, Section 102.3 of the *Low-Level Radioactive Waste Policy Amendments Act of 1985* states that the responsibilities of each State shall include the disposal of LLW generated within the State (other than by the Federal Government) that consists of or contains Class A, B, or C LLW as defined by 10 CFR 61.55 as in effect on January 26, 1983. Likewise, the *Low-Level Radioactive Waste Policy Amendments Act of 1985* states that the Federal government responsibilities shall include LLW with concentrations of radionuclides that exceed the Class C limits established in 10 CFR 61.55 as in effect on January 26, 1983.

Because the *Low-Level Radioactive Waste Policy Amendments Act of 1985* relies on 10 CFR Part 61 as it existed in 1983, removing the waste classification system from 10 CFR Part 61 would not change the assignment of responsibilities for the disposal of commercial LLW to the States and Federal government. Therefore, the existing classification system would remain relevant to assigning responsibilities to the States and Federal government, regardless of its presence in Part 61. Removal of the waste classification system may create confusion among stakeholders about how responsibility is assigned. One possible approach to avoid confusion would be to maintain a version within NRC regulations of the waste classification system for the sole purpose of aiding the definition of Federal and State responsibilities for the waste. The waste classification requirements could be relocated to an Appendix to 10 CFR Part 61 to facilitate determination of Federal-State responsibilities. Alternatively, the waste classification requirements could be included in Appendix G of 10 CFR Part 20, where waste is manifested for shipment. The purpose of Appendix G to Part 20 is to address the various regulatory information needs for the transfer and disposal of LLW. These informational needs, which were identified in the Statements of Consideration that accompany the final rule (60 FR 15664) include, among others, access to information needed for assessments to demonstrate compliance with the 10 CFR Part 61 performance objectives. This includes information that the States and Compacts believe necessary to carry out their responsibilities. Therefore, preserving the waste classification requirements in Appendix G to 10 CFR Part 20 would minimize confusion for shippers to provide accurate information that allows the States and Compacts to carry out their responsibilities.

The NRC staff cannot make changes to the *Low-Level Radioactive Waste Policy Amendments Act of 1985*, and it is therefore assuming that changes will not be made in time to accommodate any changes to the regulations. Instead, as noted above, the staff has developed a proposal that would implement this option without requiring changes to the *Low-Level Radioactive Waste Policy Amendments Act of 1985*. If the NRC adopts these changes, the Commission could request that Congress consider legislative changes in the future.

5.2.6.3 Option 3–Generic Waste Classification or Site-Specific Waste Acceptance

A third and final approach that NRC staff considered would be to allow licensees to develop site-specific WAC or comply with the existing waste classification system. Some stakeholders expressed support for this so-called *hybrid approach*. The proposed approach would still require licensees to determine the acceptability of waste. In defining waste streams with acceptable radionuclide concentrations or activities and waste forms, licensees would be allowed to use *either* the results of the site-specific technical analyses set forth in 10 CFR 61.13 *or* the waste classification requirements in 10 CFR 61.55. Beyond radionuclide limits and acceptable waste characteristics, licensees would, as discussed previously in the site-specific-only approach, need to develop strategies for characterizing waste and methods to certify that waste meets acceptance criteria.

For licensees that choose to develop WAC based on the current waste classification requirements, this approach would not result in significant additional burden to their current operating practices since operating sites, as discussed in Other Regulatory Approaches, Section 5.2.2, currently develop WAC with essentially the same type of criteria. Licensees typically develop these WAC from the existing 10 CFR Part 61 requirements and NRC guidance (e.g., "Branch Technical Position on Encapsulation and Concentration Averaging" – NRC 1995). These licensees still would be required to demonstrate through the analyses set forth in 10 CFR 61.13 that they will meet the performance objectives. The required analyses may demonstrate that additional mitigation is needed beyond the concentration limits and waste characteristic requirements for certain waste streams, particularly those that were not considered in the development of the waste classification system.

Because the hybrid approach would not alter the waste classification requirements in 10 CFR Part 61, the approach also would maintain consistency between the waste classification requirements in Part 61 and the assignment of Federal and State responsibilities in the *Low-Level Radioactive Waste Policy Amendments Act of 1985* for the disposal of commercial LLW. States would remain free to choose whether to allow disposal facilities that they regulate to accept for disposal waste beyond that defined as a State responsibility under the *Low-Level Radioactive Waste Policy Amendments Act of 1985* (i.e., radioactive waste with concentrations greater than the limits for Class C). For instance, States may choose to permit acceptance of waste designated as a Federal responsibility under the *Low-Level Radioactive Waste Policy Amendments Act of 1985* if the results of the site-specific analyses demonstrate the waste would be acceptable for disposal at a specific disposal facility. Further, under the existing regulations, though States are responsible under the *Low-Level Radioactive Waste Policy Amendments Act of 1985* for radioactive waste with concentrations less than the limits for Class C, the States have exercised flexibility to further limit disposal of certain wastes for which they are responsible at specific disposal facilities. The NRC staff proposes not to alter this flexibility under this proposed approach.

As discussed in the preceding section on the site-specific-only approach, some stakeholders commented that licensees should have flexibility to consider alternative active institutional control periods in the analyses to derive site-specific WAC. Complicating the matters discussed earlier under the site-specific-only approach, the revision associated with this hybrid approach would need to maintain the current 100-year limit for licensees that continue to use the waste classification system under the hybrid approach, since the 100-year time duration is an integral assumption in the analyses that originally derived the radionuclide concentration limits set forth in 10 CFR 61.55. Therefore, the NRC staff proposes to maintain the 100-year limit set out in 10 CFR 61.59.

The hybrid approach also would necessitate changes to the requirements for transfers of LLW intended for disposal at licensed land disposal facilities and manifests that are specified in Appendix G of 10 CFR Part 20. These changes are similar to those discussed earlier for the site-specific-only approach. Specifically, Sections I.C.12 and I.D.4 of Appendix G require the shipper of waste consigned to a disposal facility to identify the waste classification per 10 CFR 61.55 and to state if it meets the structural stability requirements of 10 CFR 61.56(b) on the uniform manifest. Since the hybrid approach preserves the waste classification system as a parallel option to added flexibility for developing site-specific WAC, these shipping manifest requirements related to waste classification would not necessarily need revision. The NRC could maintain the requirements as is or revise them to better reflect the added flexibility.

Continuing to require shipping manifests to report the class of waste as determined for 10 CFR 61.55 could be considered an unnecessary regulatory burden for disposal at sites that choose to develop site-specific WAC. On the other hand, the Commission stated that the purpose of the requirements specified in Appendix G to 10 CFR Part 20 was to address the various regulatory information needs for the transfer and disposal of LLW. These information needs, which were identified in the Statements of Consideration that accompany the final rule (60 FR 15664), include, among others, access to information needed for assessments to demonstrate compliance with the 10 CFR Part 61 performance objectives. This includes information that the States and Compacts believe necessary to carry out their responsibilities. Since the waste classification system is integral to defining Federal and State responsibility, this information could continue to report to whom (i.e., the States or the Federal Government) the responsibility for disposal of the waste falls under the *Low-Level Radioactive Waste Policy Amendments Act of 1985*. Further, deletion of this requirement would result in missing information on waste consigned to disposal facilities that continue to rely on the generic waste classification system. Therefore, the NRC staff proposes to maintain this requirement.

As previously mentioned, one of the stated purposes of the requirements specified in Appendix G to 10 CFR Part 20 is to provide access to information needed for the assessments to demonstrate compliance with the performance objectives of 10 CFR Part 61. Allowing flexibility to establish site-specific WAC based on the results of the site-specific analyses specified in 10 CFR 61.13 may not be addressed by the waste class per 10 CFR 61.55 at a facility developing site-specific WAC. The NRC staff believes information on waste acceptability at a disposal facility would be essential information to demonstrate compliance with the performance objectives. Therefore, the NRC staff proposes adding a requirement to Section I of Appendix G to specify in the uniform manifest whether the waste being shipped to a land disposal facility conforms to the facility's WAC. The addition of this requirement could also result in a revision of NRC Form 541, "Uniform Low-Level Radioactive Waste Manifest–Container and Waste Description," to conform to this new requirement and the accompanying guidance, NUREG/BR-0204, "Instructions for Completing NRC's Uniform Low-Level Radioactive Waste Manifest."

Like the site-specific-only approach, the hybrid option could require revisions to Section II of Appendix G to 10 CFR Part 20. Section II requires waste generators, processors, or collectors to certify that the transported LLW is properly *classified*. Since this option would require licensees to develop criteria for waste acceptability using either the existing waste classification system or the results of site-specific analyses, this certification requirement would need to be updated so that shippers are certifying that waste consigned to a disposal facility meets the facility's criteria for waste acceptability.

Also, either approach regarding the development of site-specific WAC (i.e., site-specific-only or the hybrid approach) would require the development of additional guidance to provide acceptable approaches for disposal facilities to develop site-specific WAC. The guidance would describe approaches for determining radionuclide limits from the technical analyses set forth in 10 CFR 61.13, certifying waste acceptability, and characterizing waste to determine compliance with the acceptance criteria.

Option 3 would require further revisions to Section III of Appendix G to 10 CFR Part 20. Section III of Appendix G imposes requirements on the control and tracking of radioactive waste transferred to a disposal facility. Specifically, Sections III.A.1 through 3 and III.C.3 through 5 require the waste to be classified according to 10 CFR 61.55 and meet the waste characteristics requirements in 10 CFR 61.56. The container must be labeled with the appropriate waste class, and the licensee must conduct a quality assurance program to assure compliance with 10 CFR 61.55 and 61.56. Since Option 3 would require licensees to develop criteria for waste acceptability using either the existing waste classification system or the results of site-specific analyses, these requirements would need to be revised so that shippers are preparing, labeling, and providing quality assurance in accordance with the disposal facility operator's criteria for waste acceptability.

5.2.7 Recommendation

The NRC staff is recommending Option 3 of the options considered in Section 5.2.6. Option 3 provides a framework for the use of either the generic waste classification system specified in 10 CFR 61.55 or the results of the analyses required in 10 CFR 61.13. Either approach, when combined with the other revisions recommended for this rulemaking, would provide reasonable assurance that public health and safety would continue to be protected during the land disposal of commercial LLW. Option 3 would provide a framework for determining waste acceptability at a disposal facility while achieving the following:

(a) providing flexibility to develop site-specific WAC, thereby fulfilling the recent Commission direction (NRC, 2012d)

(b) minimizing required revisions to 10 CFR Part 61 to implement

(c) maintaining consistency with the *Low-Level Radioactive Waste Policy Amendments Act of 1985*

(d) limiting additional regulatory burden on licensees

(e) providing States flexibility to exercise their regulatory authority within a national framework.

Option 3 also is consistent with the range of domestic and international practices for the disposal of LLW discussed in Section 5.2.2.

As discussed in more detail in Section 5.2.6.3, implementation of Option 3 would require revisions to 10 CFR Part 61 that allow for flexibility to establish site-specific WAC based either on the waste classification system specified in 10 CFR 61.55 or the results of the analyses required in 10 CFR 61.13. The revisions would specify the minimum content of the WAC, as well as require disposal facility licensees to develop approaches for generators to characterize waste and methods for generators to certify that waste meets acceptance criteria to demonstrate compliance with the site-specific acceptance criteria. The revisions to 10 CFR Part 61 for this recommended option, being performance- based, would require the NRC staff to provide guidance on acceptable approaches for determining WAC from the site-specific analyses specified in 10 CFR 61.13, develop approaches for generators to characterize waste, and design methods for generators to certify that waste meets the acceptance criteria. Additionally, as was previously discussed in more detail, implementation of Option 3 would require revisions to specific manifesting requirements specified in Sections I, II, and III of Appendix G of 10 CFR Part 20 and related guidance in NUREG/BR-0204 (NRC, 1998) that provide information considered important for demonstrating compliance with the performance objectives and for States and Compacts to carry out their responsibilities under *Low-Level Radioactive Waste Policy Amendments Act of 1985*.

5.3 Updated Part 61 Dosimetry

5.3.1 Technical Considerations

As mentioned earlier, the ICRP recommendations incorporated in the current 10 CFR Part 61 regulations date back several decades. Revising the regulations would allow licensees to use more up-to-date ICRP recommendations.

Using updated dosimetry has been raised before. In the matter of the NRC's site-specific regulations for a geologic repository for HLW at Yucca Mountain, for example, the Commission was aware of the potential for future updates to the ICRP's health physics recommendations that might be available following promulgation of its regulations in 10 CFR Part 63. As a consequence, rather than index the site-specific regulations to a particular version of the ICRP, the Commission alternatively allowed DOE to use "… the most current and appropriate …" dosimetry in its performance assessment calculations, without specifying which particular version or edition of that guidance to employ. Any updated radiation and organ or tissue weighting factors, however, would need to have been incorporated by EPA into Federal radiation guidance. The Commission also stated that, "Additionally, as scientific models and methodologies for estimating doses are updated, DOE may use the most current and appropriate (e.g., those accepted by the International Commission on Radiological Protection) scientific models and methodologies to calculate the TEDE. The weighting factors used in the calculation of TEDE must be consistent with the methodology used to perform the calculation" (NRC 2009; 74 FR 10828).

5.3.2 Stakeholder Feedback

The majority of stakeholders expressing a view on updated dosimetry supported the Commission's proposal to allow licensees the flexibility to use the latest ICRP dose methodologies in a site-specific performance assessment as part of any future rulemaking. Some stakeholders' comments concerned the latest edition of the ICRP recommendations. Some recommended that the latest edition of those recommendations (ICRP Publication 103) be specifically cited in the regulations, whereas others have suggested that the regulations be silent on this matter as the ICRP is updated periodically, and that the NRC simply afford licensees the option of using the most recent version in effect at the time of any license application submittal. Some stakeholders argued for a more comprehensive update to include both the NRC's 10 CFR Part 20 regulations, as well as the applicable EPA radiation standards.

At least one stakeholder suggested that the staff consider revisiting the dose factors used in a LLW performance assessment as part of a regular review to ensure that that performance assessment results are current. For example, stakeholders noted that DOE revisits both the ICRP and the National Council on Radiation Protection and Measurements (NCRP) recommendations on a 5-to-10-year cycle, as part of a so-called "Performance Assessment Maintenance Plan" to determine how sensitive its performance assessment results might be to changes to either of those recommendations. Under 10 CFR Part 20, licensees are required to conduct annual reviews of their respective radiation programs. This model could also be applied to any future 10 CFR Part 61 performance assessment requirement.

The NRC received several public comments in connection with the 10 CFR 61.55 waste classification tables and their relationship with the ICRP recommendations. The Commission has previously acknowledged the need to align the 10 CFR 61.55 waste classification tables with the most recent ICRP recommendations. To achieve this objective, in SRM-SECY-08-0147, the Commission had directed the staff to budget resources to update those tables using the most recent edition of the ICRP's recommendations. This update would include consideration of an expanded list of isotopes, as well as determine the regulatory classification of DU. Current planning assumptions now call for this effort to commence in fiscal year 2015.

Stakeholders also recommended integrating any ICRP-based revision to 10 CFR Part 61 with a broader initiative to update other Federal dose-based regulations, such as the EPA standards.

However, some commenters questioned the value and the safety significance in removing critical organ limits in updating the dose limits in 10 CFR 61.41. The current 10 CFR Part 61 dose limits, and several others within the regulations, are remnants from a method of calculating and limiting doses that date back to the late 1950s. These were based on recommendations in ICRP Publication 2 (1960) and were the method to calculate and limit doses until 1991 for protection of workers and the public, as described in 10 CFR Part 20. In 1991, the 10 CFR Part 20 standards were updated (56 FR 23360) to the TEDE approach, consistent with the Federal radiation protection guidance signed by the President on January 20, 1987, for occupational exposure to implement the radiation protection recommendations of the ICRP issued in ICRP Publication 26 (1977). Because of various considerations, including resource limitations and activities in the LLW area at the time, the dose limits in 10 CFR Part 61 were not updated to the TEDE approach. The draft proposed text released in May 2011 updated the dose limits consistent with the current 10 CFR Part 20.

The benefits in updating the limit to an effective dose, whether it is TEDE or a more current effective dose methodology, is that it provides a holistic evaluation of the risks of radiation, whether the worker or member of public is exposed from external radiation, inhalation, ingestion, or a mixture of all three. Because an effective dose methodology can compare, and more importantly, sum doses from different organs, exposure routes, and radionuclides, an overall risk can be evaluated. This was not possible with the critical organ system provided by ICRP Publication 2 (1959). When ICRP 2 was developed, organ weighting factors were unknown. The doses to different organs, in the critical organ system, does not account for the radiosensitivity of the organ, nor does the system use the wider range of organs and tissues evaluated with modern approaches. A holistic approach provides a large benefit in radioactive waste disposal as a range of radionuclides is co-mingled within the waste. Each radionuclide has its own predominant exposure pathway and dose rate, depending on the manner in which a member of the public may get exposed. Without a holistic method to be able to sum exposures across exposure pathways and radionuclides, a risk-informed, performance-based decision, especially when one is trying to optimize the resources to provide maximum protection within the system, is harder to make as the doses between scenarios or situations would not be comparable.

The critical organ approach was developed to limit doses from the intake of radioactive materials. In the approach, doses to a limited number of individual organ systems were calculated based on models of element (e.g., iodine collects mainly in the thyroid, ingested uranium provides doses largely to the bone and kidney, ingested cesium provides doses to multiple organ systems with total body or liver being the critical organ, etc). See NUREG-0172, "Age-Specific Radiation Dose Commitment Factors a One-Year Chronic Intake" (Battelle Pacific Northwest Laboratories, 1977).

However, the potential result of a dose to a specific organ was not well-known at the time (i.e., how comparable are 0.01 mSv (1 mrem) to the thyroid and 0.01 mSv (1 mrem) to the liver in potential cancer or other mutagenic risk?). Without this radiosensitivity information, doses could not be added together to evaluate the overall risk to the individual from radionuclides present in multiple organs. In addition, any external dose was only added to the "whole body" critical organ (which is not directly comparable to the TEDE in ICRP 26 or later). Because of the uncertainty, limits for the public were developed that gave each of the organs equal weighting, except the thyroid (for which some data was available). As stated in the response to comments on final rule for 10 CFR Part 20 (56 FR 23360), specifically, the response on the Proposed Appendix B:

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

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

The TEDE approach allows a holistic evaluation of all the exposures to an individual by allowing the summing of external exposures with internal intakes of one or more radionuclides. It provides one dose constraint to limit the risk from stochastic effects. Workers have a much higher annual TEDE dose limit (50 mSv or 5 rem) than members of the public (e.g., 1 mSv (100 mrem) from all sources, 0.25 mSv (25 mrem) for decommissioning). Because of the higher doses, limits have to be placed on individual organ and tissue systems to protect them from other effects of radiation that members of the public do not have to worry about (e.g., cataracts).

As noted in Appendix B of 10 CFR Part 20, “Annual Limits on Intake (ALIs) and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage,” consideration of nonstochastic effects is unnecessary at the dose levels established for members of the public because the organ dose can never reach the organ limit for the nonstochastic effects of 0.5 Sv/year (50 rem/year) without the TEDE dose being greater than the public dose limit (or any fraction of the public dose limit, such as 10 CFR 61.41). Therefore, in modifying a dose limit such as 10 CFR 61.41 to be consistent with 10 CFR Part 20, organ dose limits are unnecessary. The TEDE approach protects all the organ systems and provides adequate protection for both individual radionuclides, as well as situations in which members of the public could be exposed to multiple radionuclides through all exposure routes (i.e., external, inhalation, and ingestion).

The TEDE and later effective dose approaches have been used by the Agreement States in their licensing decisions for LLW, including the States of Washington, Texas, and Utah since the publication of NUREG-1573 in 2000.

5.3.3 Analysis of Commission Direction

The Commission’s direction in this area is clear and unambiguous; the question, however, rests on how it is to be implemented. One approach would be to specifically reference the current version of the ICRP recommendations approved for use by the NRC staff. The second approach would be to adopt an edition-neutral approach and only specify that licensees use the most current version of the approved recommendations in place, recognizing that the ICRP recommendations have, historically, been updated more frequently than the regulations themselves.

5.3.4 Options Considered

The NRC considered three options to address this Commission direction. First, the staff considered specifying in the regulations which version of the ICRP licensees should implement in any 10 CFR Part 61 license application. As a second option, the staff considered adopting an edition-neutral approach to addressing this issue. In 10 CFR Part 63, for example, the Commission previously approved of an approach to instruct licensees to rely on the most current and appropriate dosimetry in its performance assessment calculations consistent with Federal radiation guidance. The specific language currently in place (from 10 CFR 63.102(o), “Concepts”) reads as follows:

> *… After the effective date of this regulation, the Commission may allow [a licensee] to use updated factors, which have been issued by consensus scientific organizations and incorporated by EPA into Federal radiation guidance. Additionally, as scientific models and methodologies for estimating doses are updated, [a licensee] may use the most current and appropriate (e.g., those accepted by the International Commission on Radiological Protection) scientific models and methodologies to calculate the TEDE. The weighting factors used in the calculation of TEDE must be consistent with the methodology used to perform the calculation .... (74 FR 10828)*

These two options comport with similar recommendations that stakeholders provided.

The third option considered was to allow the rule to remain silent on this matter and address the issue in the accompanying LLW performance assessment guidance.

5.3.5 Recommendation

The staff recommends that option No. 2, above, be adopted for the purposes of the proposed rulemaking. The staff reasons that the Commission has already approved and implemented this particular type of regulatory approach. As the ICRP's recommendations have historically been updated more frequently than the Commission's LLW regulations, adopting an edition-neutral approach in the regulations would obviate the need for updating 10 CFR Part 61 at some future date in response to some comparable update to Federal radiation guidance and the associated ICRP recommendations.

5.4 Compatibility Considerations

In its January 2012 SRM, the Commission directed that the new site-specific performance assessment and site-specific WAC requirements being added to the regulations are assigned compatibility designations that "… ensure alignment between the States and Federal government on safety fundamentals, while providing the States with the flexibility to determine how to implement these safety requirements …." In connection with the staff's 2012 public outreach campaign, stakeholders did comment on compatibility. The comments received by the NRC generally were in favor of a nationally consistent set of LLW disposal standards that allowed Agreement State regulators flexibility in carrying out those standards. Disposal facility operators generally were interested in seeing compatibility designations that were marketplace neutral. They have developed business models based on a regulatory framework that is four decades old. They worried that uncertainty associated with future changes to the regulations could have unintended consequences in the marketplace.

When it came to specific compatibility recommendations, there was little stakeholder consensus. Regulatory compatibility designations will initially be recommended to the Commission by an internal *NRC Standing Committee on Compatibility,* later followed by Commission decision. Without specifically identifying that committee, at least one commenter stated that those compatibility deliberations should be more transparent to stakeholders and other interested members of the public.

6 STAKEHOLDER INTERACTIONS AND COMMENTS

The staff conducted a number of interactions with stakeholders and other interested members of the public in connection with this rulemaking. In 2009, the staff held a variety of public interactions in response to SRM-SECY-08-0147. For example, the staff sponsored two public workshops (Bethesda, Maryland; Salt Lake City, Utah) in September 2009 to solicit early feedback from interested stakeholders on major issues associated with a potential rulemaking for land disposal of LLW streams containing large quantities of long-lived isotopes, including significant quantities of DU in near-surface disposal facilities. Participants included representatives of other Federal agencies, Agreement States, LLW disposal facility operators, academia, and public interest groups. The NRC staff provided technical presentations on a variety of topics that might be included in the proposed rulemaking. Participant discussions included technical, regulatory, and legal issues. Transcripts of those meetings are available in ADAMS under Accession Nos. ML092580469, ML092580481, ML092890516, and ML092890511.

In general, the workshop participants did not dispute the overall need for the rulemaking effort. However, they did have differing views about the appropriate scope of the rulemaking. Suggestions ranged from specific changes to the current rule to limited rulemaking amendments combined with new guidance. Generally, the workshop participants stated that both the period of performance and a requirement for a site-specific analysis should be included in the rule. There were differing opinions about the appropriate performance period for a site-specific analysis. A number of participants recommended that the performance assessment calculate the estimated dose to at least 10,000 years, and some participants believed that the calculation should be extended until the time of estimated peak dose. The participants also stated that a definition of LLW streams or significant quantities of DU should not be specified as part of the rulemaking. The staff committed to considering the comments received as part of the workshops during its deliberations related to the development of the regulatory basis for the rulemaking.

In 2010, the staff briefed the Commissioner's assistants and a subcommittee and the full committee of the ACRS (Abdel-Khalik, 2010) on progress in addressing SRM-SECY-08-0147. Information related to the proposed rulemaking also has been presented to the *LLWForum* and at technical conferences.

In connection with SRM-COMWDM-11-0002/COMGEA-11-0002, "Revision to 10 CFR Part 61," the Commission directed the staff to seek stakeholder feedback on the four expanded regulatory requirements for the ongoing Part 61 rulemaking. The staff subsequently participated in six events, including three public meetings sponsored by the NRC staff in 2012. Transcripts of those meetings are available in ADAMS under the following Accession Nos.: ML120820051, ML12143A197, and ML12244A524. In connection with the NRC-sponsored public meetings, the staff also placed *Federal Register* notices, requesting comment on the Commission's 2012 expanded rulemaking direction.[7] The NRC held direct conversations with NRC Agreement States, both by telephone and in person.[8] A summary of the Agreement States' initial views on the four expanded regulatory requirements from those conversations can be found in Table 3.

7 See *Federal Register* notices dated February 22, 2012 (77 FR 10401), May 8, 2012 (77 FR 26991), and July 11, 2012 (77 FR 40817).

8 These discussions included direct telephone calls with the LLW disposal facility-sited Agreement States as well as a separate meeting with NRC Agreement States on May 18, 2012, in Orlando, Florida.

Table 3 Summary of Initial Feedback from Agreement States Concerning the Commission's January 19, 2012, Proposed Direction on Amendments to 10 CFR Part 61

Commission Direction	**Allowing licensees the flexibility to use ICRP dose methodologies in a site-specific performance assessment for the disposal of all radioactive waste.**
Agreement State Response	Those Agreement States expressing a view on this topic were mostly in support for this Commission proposal.

Commission Direction	**A two-tiered approach that establishes a compliance period that covers the reasonably foreseeable future and a longer period of performance that is not *a priori* and is established to evaluate the performance of the site over longer timeframes. The period of performance is developed based on the candidate site characteristics (waste package, waste form, disposal technology, cover technology, and geohydrology) and the peak dose to a designated receptor.**
Agreement State Response (two-tiered approach)	Agreement States expressed no opinion at this time on the merits of a two-tiered approach proposed by the Commission.
Agreement State Responses (the term "foreseeable future")	Agreement States expressed no opinion at this time on what this term might mean in the context of an LLW performance assessment. However, for the time being, some expressed general support for the 10,000-year TOC previously recommended in NUREG-1573. To the extent that there is continuing support for the currently recommended 10,000-year definition, those Agreement States that expressed an opinion on the subject suggested that the TOC compatibility category should be "C." One Agreement State (Pennsylvania) observed that it does not allow geologic disposal of LLW. This State would rely on an above-ground vault type of LLW disposal system that is heavily engineered and essentially does not rely on the geosphere to contain and isolate LLW.[9] Hence, the Pennsylvania Agreement State representative suggested that any TOC proposed by the NRC must be consistent with or provide flexibility for alternative LLW disposal concepts that do not rely on geologic isolation.

[9] See Pennsylvania Code: Title 25 ("Environmental Protection"), Chapter 236 ("Low-Level Radioactive Waste Management and Disposal"), Section 236.311 (a) and (b) – "Design Criteria/General."

Commission Direction	**Flexibility for disposal facilities to establish site-specific WAC based on the results of the site's performance assessment and intruder assessment.**
Agreement State Response	For those Agreement States expressing a view on this topic, most were in support for this Commission proposal. However, in voicing that support, Agreement States noted they would need to assume an additional regulatory burden for confirming and verifying that the waste generators comply with a disposal site's WAC. WACs can be different among the respective sites leading to an unintended interstate boundary implication. How will waste originating in one State for disposal in another demonstrate compliance with the disposal site's WAC? Secondly, where would the enforcement power reside—with the disposal site operator or the Agreement State regulator? Lastly, what enforcement power would an Agreement State have to correct disposal-related problems that might occur earlier in the waste generation cycle, prior to disposal, that take place out-of-state? Additionally, some of the Agreement States cautioned the NRC staff against introducing changes to the existing 10 CFR Part 61 that would compel them to accept large quantities of depleted uranium for disposal.

Commission Direction	**A compatibility category for the elements of the revised rule that establish the requirements for site-specific performance assessments and the development of the site-specific waste acceptance criteria that ensures alignment between the States and Federal government on safety fundamentals, while providing the States with the flexibility to determine how to implement these safety requirements.**
Agreement State Response	Agreement States expressed no opinion at this time on this particular Commission question.

Not all Agreement States expressed an opinion on the rulemaking amendments proposed by the Commission. Agreement State representatives recommended that the staff consider the additional stakeholder-suggested regulatory changes being proposed. Some Agreement State representatives expressed the view that the current 100-year duration for active institutional controls was sufficient whereas others felt that the duration should be extended to 300 years. Some Agreement State representatives also expressed the view that the revisions being proposed to 10 CFR Part 61 should not be such that they would compel the states to receive large quantities of DU. A summary of stakeholder feedback received in connection with the three identified public meetings can be found in Table 4. This table also includes some preliminary staff observations relative to each of the rulemaking directives and stakeholder responses.

The staff relied on the docket (NRC-2011-0012) used in connection with the earlier public comment request (ca. 2009-11) for written comments. In response to the staff's 2012 request, the NRC received more than 15 sets of written comments, including those from the Agreement States. Commenting organizations and entities can be found in Table 5. For the purposes of analysis, the 200 or so individual comments, questions, and suggestions could be organized basically into one of three bins. The largest bin, corresponding to more than half of the public comments received, focused on the Commission's January 2012 SRM. The disposition of the 2012 SRM-related public comments is generally described in Section 5 of this regulatory basis document; the staff is not required to and does not plan to respond to these public comments. The staff will however respond to any public comments received on the proposed rule. The remaining two bins of public comments were essentially equal in number. One corresponds to comments pertaining to SECY-10-0165, "Staff's Approach to Comprehensive

Table 4 Summary of Initial Public Feedback Concerning the Commission's January 19, 2012 Proposed Direction on Amendments to 10 CFR Part 61

Commission Direction	**Allowing licensees the flexibility to use ICRP dose methodologies in a site-specific performance assessment for the disposal of all radioactive waste.**
Stakeholder Responses	The majority of stakeholders expressing a view on this topic at the 2012 public meetings were mostly in support for this Commission proposal.
Preliminary Staff Observations	*Revising 10 CFR Part 61 to allow licensees to use the more up-to-date ICRP recommendations would align with the agency's previously stated direction to allow the use of the of the latest recommendations on a case-by-case basis.* *Using updated dosimetry has been raised before. In the matter of the NRC's geologic repository regulations for Yucca Mountain, for example, the Commission was aware of the potential for future updates to the ICRP's health physics recommendations that might be available following issuance of its regulations. Rather than tie the regulations to a particular version of the ICRP, the Commission alternatively directed DOE to use "…the most current and appropriate…" dosimetry in its performance assessment calculations, without specifying which particular version or edition of that guidance to employ (NRC 2009; 74 FR 10828).*

Commission Direction	**A two-tiered approach that establishes a compliance period that covers the reasonably foreseeable future and a longer period of performance that is not *a priori* and is established to evaluate the performance of the site over longer timeframes. The period of performance is developed based on the candidate site characteristics (waste package, waste form, disposal technology, cover technology, and geohydrology) and the peak dose to a designated receptor.**
Stakeholder Response (two-tiered approach)	The majority of stakeholders expressing a view on this topic at the 2012 public meetings were mostly in support for this Commission proposal.
Preliminary Staff Observations	*The staff has generally advocated the adoption of a two-tiered approach to the conduct of an LLW performance assessment. The NRC first advanced this position in connection with the development of NUREG-1573 (NRC 2000, p. B-17). More recently, the staff reiterated its position on the matter when it proposed a two-tiered approach in the technical basis for the so-called site-specific analysis rulemaking (NRC, 2010). Previously, the NRC's Federal advisory committees for radioactive waste have also been in favor of a tiered approach to any LLW performance assessment (Steindler 1995; Pomeroy 1996a, 1996b, 1997; Garrick 2000; Ryan 2005).*
Stakeholder Response (the term "foreseeable future")	Stakeholder response on this particular feature of the Commission's direction was mixed. DOE, its contractors, and some operating disposal site operators favored a 1,000-year TOC, as this duration aligns with the decay characteristics of "classic" types of 10 CFR Part 61 wastes. Few stakeholders, including one operating LLW disposal site operator, expressed the view that a 10,000-year TOC calculation recommended in NUREG-1573 was reasonable and achievable. Other stakeholders believe that that 10,000 years was the uppermost limit for which such calculations produce reliable results and that the duration of the analyses should somewhere between 1,000 and 10,000 years. At least one stakeholder suggested that any LLW stream whose peak occurs after 10,000 years is unacceptable for near-surface disposal. Most stakeholders held the view that any TOC requirement specified at 20,000 years was unacceptable because of questions about the scientific validity of performance assessment calculations of such long-term analyses. If the staff decided to introduce this term into the Part 61 regulatory framework but essentially not define it in terms of duration, some stakeholders suggested such a course would be ill-advised as its meaning would be ambiguous and potentially open to multiple interpretations.

Preliminary Staff Observations	*The term 'foreseeable future' is a term of art, and undefined in Part 61. Nevertheless, when it comes to what the duration of a performance assessment should be, there are many disparate views.* *The DOE-preferred 1,000-year duration for an LLW performance assessment is based on the 1997 recommendations of NAPA. The argument advanced by NAPA, however, is not physics-based and did not take into account public health and safety considerations. Rather, the NAPA recommendations are based on public policy considerations. For example, NAPA argues that future risks to society should be weighed differently from effects to the current generation, based on discounting of future health effects. Furthermore, the NAPA recommendation generally aligns with DOE's overall approach to the management of its legacy sites. Under that approach, DOE expects to retain control of about 75 percent of its legacy waste sites (National Academy of Sciences, 2000). As a consequence, DOE intends to monitor most of the waste disposal systems in its inventory for perpetuity, allowing it to remediate those systems that fail to perform as intended or expected. Previously, the Commission has noted that perpetual custodial care of a commercial LLW disposal facility following decommission is not desirable and should be limited to 100 years. (See NRC, 1982; 47 FR 57459.) The staff also noted that the NAPA 1,000-year recommendation on risks to future generations is inconsistent with EPA's radioactive waste management principles first published in 1978 (EPA, 1978; 43 FR 53263), as well as the relatively more recent collective opinion of the Nuclear Energy Agency (NEA, 1995) on this point. Both documents generally state that radioactive wastes should be managed in such a way that affords future generations the same level of protection being provided to the current generation. Coincidentally, NEA (1995, p. 13) has also argued against using discounting principles when evaluating future health and environmental risks.* *The previous 10,000-year staff recommendation concerning TOC was first introduced in SECY-96-103, based on independent NRC staff calculations (NRC 2000, pp. B-16 – B-19). Following public comment on the SECY-96-103 proposal, the staff recommended retaining the 10,000-year TOC in NUREG-1573. (See NRC, 2000.) The staff also previously argued that the lesser 1,000-yr TOC, applied to NRC decommissioning decision making, was inappropriate for LLW performance assessments because it would generally overemphasize evaluation of the performance of the engineered barriers intended to contain the wastes and not provide information on the expected performance of the geosphere, another key feature of any near-surface LLW disposal system, which itself is intended to both isolate and attenuate the radiation hazard. (See NRC, 2000, p. B-18.)* *Lastly, it is worth revisiting the findings and recommendations of the National Academy of Sciences (NAS) on EPA's technical standards intended to protect the public from potential radiation exposures associated with the operation of a proposed deep geologic repository at Yucca Mountain, Nevada. Arguably, although those findings and recommendations were directed toward the management of different radioactive waste streams, conceptually they can be looked on as a resource for guidance on how LLW disposal standards might be designed. In its review of the TOC issue, for example, NAS (1995, p. 6) found that there was no scientific basis for limiting the time period of an individual-risk standard (i.e., the TOC), which, at the time was 10,000 years for SNF and HLW. (Op cit.). The NAS panel argued that in evaluating disposal system performance, the time scale selected should be consistent with the geologic stability of the candidate site. Moreover, NAS argued that the duration of the assessment should extend to that time when the "… greatest [radiological] risk occurs, within the limits imposed by the long-term stability of the geologic environment …." (Op cit., p. 7)* *The other time-related concern addressed by NAS concerned the topic of intergenerational equity. NAS argued (p. 7) in favor of EPA's 1978 position that a health-based risk standard should be applied uniformly over time and generations so that the risks to future generations was no greater than the risks that society accepts today.*

Commission Direction	**Flexibility for disposal facilities to establish site-specific WAC based on the results of the site's performance assessment and intruder assessment.**
Stakeholder Response	The majority of stakeholders expressing a view on this topic at the 2012 public meetings were mostly in support for this Commission proposal. However, it was noted that many of the state-imposed WAC-like licensing conditions are tied to the existing 10 CFR Part 61 waste classification table concentration limits, and some States, in fact, have prohibitions against the disposal of certain Part 61-classified types of waste. Consequently, it is not readily apparent to some stakeholders how the introduction of a WAC option would be an improvement over the existing regulatory system. In this regard, some stakeholders have asked whether introducing a WAC option to Part 61is simply a back-door way of circumventing Agreement State authority on limiting disposal site inventories.
Preliminary Staff Observations	*In practice, most Agreement State regulators already impose a site-specific WAC on existing disposal sites as a licensing condition of their operating sites. This licensing feature is usually achieved by specifying some ceiling on the concentration or quantity of LLW that might be received at a particular disposal site. Incorporation of this provision into Part 61 is intended to align the regulations with current operating practice*

Commission Direction	**A compatibility category for the elements of the revised rule that establish the requirements for site-specific performance assessments and the development of the site-specific WAC that ensures alignment between the States and Federal government on safety fundamentals, while providing the States with the flexibility to determine how to implement these safety requirements.**
Stakeholder Response	The majority of stakeholders expressing a view on this topic at the 2012 public meetings were mostly in support for this Commission proposal, but with one caveat: Whatever is the compatibility designation ultimately decided upon, it should not have the unintended consequence of providing a particular disposal site with an unfair competitive advantage.
Preliminary Staff Observations	*This comment is noted.*

Table 5 Organizations and Entities Commenting on SRM-COMWDM-11-0002/COMGEA-11-0002

COMMENTOR	ADAMS ACCESSION NO(S).
Conference of Radiation Control Program Directors	ML12226A271
Council on Radionuclides and Radiopharmaceuticals	ML12208A094
EnergySolutions	ML12216A228
Electric Power Research Institute	ML12215A247
Norman Eisenberg (private individual)	ML12222A135
NSF Environmental (aka Coleman Miller)	ML12192A160
HEAL Utah	ML12222A143
Health Physics Society	ML12198A289
LLW Forum	ML12215A388
Nuclear Energy Institute	ML12219A086
Neptune & Associates	ML12222A142
Howard Pope (private individual)	ML12215A428
State of Utah/Division of Radiation Control	ML12215A305 ML12215A308
State of Texas	ML12215A359
State of Washington	ML12215A394
Waste Control Specialists	ML12222A136

Revision to 10 CFR Part 61" (dated December 27, 2010).[10] The remaining public comment bin contained miscellaneous comments; these comments bore on some aspect of the Part 61 regulatory framework in general.

SECY-10-0165: With respect to SECY-10-0165, the staff leveraged its aforementioned 2012 public outreach campaign to also seek public comment on the possible regulatory options described therein.[11]

Miscellaneous comments: The third bin of public comments corresponds to stakeholder views on regulatory issues that fall outside of earlier Commission direction found in SRM-SECY-08-0147, SECY-10-0165, or SRM-COMWDM-11-0002/COMGEA-11-0002. Some stakeholders, for example, proposed that additional changes to 10 CFR Part 61 be considered beyond those proposed by SRM-SECY-08-0147 and SRM-COMWDM-11-0002/ COMGEA-11-0002, including:

- Updating the existing waste concentration tables at 10 CFR 61.55 to reflect the latest ICRP dose conversion factors and dose methodologies.

[10] In SRM M100617B, "Briefing on Blending," (dated July 1, 2010), the Commission directed the staff to outline its approach to initiate activities in connection with a possible revision to 10 CFR Part 61 that was risk-informed and performance-based. In that paper, the staff recommended that it first engage stakeholders before commencing with any rulemaking and solicit their views on if there should be amendments to the current Part 61 and, if so, what the nature of those amendments should be. The staff noted that this approach aligned with the method originally used to develop 10 CFR Part 61.

[11] The staff's first public meeting on SECY-10-0165 was held on March 4, 2011, in Phoenix, Arizona. This was a joint meeting conducted with DOE, which, at the time, was updating its Order 435.1, which is used to manage government-generated LLW. In connection with conducting this meeting, the staff published a *Federal Register* notice dated February 28, 2011 (76 FR 10810).

- Revisiting the current regulatory basis for the duration of institutional controls at an LLW disposal facility, currently specified as 100 years in 10 CFR 61.30, "Transfer of License," and extending it to 300 years.

- Revisiting earlier assumptions concerning the minimum reporting requirements for certain isotopes cited in the 10 CFR Part 20, Appendix G, on LLW shipping manifest. [12]

- Developing criteria for the disposal of greater-than-Class C (GTCC) LLW.

- Developing clearance criteria for the disposal of low-activity radioactive waste (LAW).

Stakeholders argued that at least the first three topics cited above should be considered for inclusion in any 10 CFR Part 61 rulemaking now underway, as these additions would provide both waste generators and disposal facility operators with the regulatory flexibility necessary to manage expected future commercial LLW streams. Stakeholders also argued that technical process improvements associated with innovations in the nuclear fuel cycle, as well as new developments in international consensus standard-setting achieved following the initial promulgation of Part 61, justify the need for some of the regulatory updates now being proposed.

Another commonly submitted miscellaneous public comment concerned the wisdom of managing DU as Class A LLW. A number of commenters argued that DU is a unique waste stream distinctive from classic 10 CFR Part 61 types of LLW, and that separate disposal requirements and criteria are needed for this particular waste stream as would be the case for GTCC LLW.

Lastly, the staff received stakeholder feedback concerning proposed amendments to 10 CFR Part 61 in connection with other regulatory initiatives recently completed or currently underway. Those other initiatives include revisions to the concentration-averaging Branch Technical Position (77 FR 34411, dated June 11, 2012), the updating of the LLW Volume Reduction Policy Statement (77 FR 25760, dated May 1, 2012), and the development of SECY-10-0165. A summary of these comments, and the staff's preliminary views, can be found in Table 6. To the extent that the comments received were germane to SRM-COMWDM-11-0002/COMGEA-11-0002, the NRC staff considered them in connection with the development of this regulatory basis document and included them in Section 5 of this regulatory basis document.

Another sizeable percentage of the public comments received as part of the staff's 2012 public outreach campaign concerned the 10 CFR 61.55 waste classification tables. As mentioned earlier in this regulatory basis, the Commission already directed the staff in SRM-SECY-08-0147 to budget resources to update those tables using the most recent edition of the ICRP's recommendations. This update would include consideration of an expanded list of isotopes, as well as determine the regulatory classification of DU. Current planning assumptions now call for this effort to commence in fiscal year 2015.

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12 The specific isotopes in question cited in the public meeting included carbon-14, technectium-99, iodine-129, chlorine-36, and tritium.

Table 6 Emerging Issues Identified in Connection with Other NRC Part 61 Regulatory Initiatives

STAKEHOLDER VIEW AND RECOMMENDATION(S)	PRELIMINARY STAFF OBSERVATIONS
The existing 10 CFR Part 61 regulations are adequate. No amendments are necessary at this time.	The staff believes that Part 61 in its current form is fully protective of public health and safety. Moreover, by implementing the amendments called for in SECY-10-0165, the staff believes that an interim approach will be in place to evaluate isotopes and waste streams not previously considered in the Part 61 EIS.
Comments suggesting that the existing LLW regulations are inadequate. *Before proceeding to revise Part 61, the staff should undertake the development of a new and up-to-date EIS.* *The staff should adopt the IAEA system for the management of LLW (vis-à-vis General Safety Guide No. 1).* *The staff should adopt the DOE system employed in the management of government-owned LLW (i.e., DOE Order 435.1).*	As noted in the main body of this paper, the staff is proposing to undertake the development of a new Part 61 EIS. In SECY-10-0165 (NRC, 2010), the staff recommended as an option the adoption of the IAEA approach to the management of the full spectrum of radioactive waste, including LLW. However, some stakeholders have recommended that the staff abandon its efforts in connection with SECY-10-0165 in light of the Commission's more recent 2012 direction in SRM-COMWDM-11-0002/ COMGEA-11-0002. The staff is reminded that DOE operates under a different set of regulatory authorities than the NRC and the adoption of any such recommendation would likely require significant regulatory changes.
Depleted uranium is a unique waste stream distinctive from classic Part 61 types of LLW. Separate disposal requirements and criteria are needed for DU.	The NRC staff is sensitive to the concern raised by this comment, and this is not the first time this issue has come up for discussion. As early as 1982, the staff expressed the view that there was the need to address the uranium disposition issue separately, apart from the initial Part 61 rulemaking (NRC, 1982, p. 5-39). In 1995, in a letter to DOE, the staff later expressed the view that DU should not be disposed of in a Part 61-type of facility; rather, the staff noted that it should be disposed of in an intermediate-depth disposal facility or a mined geologic cavity (Bernero, 1995). In 1996, in SECY-96-0103, the staff recommended that discussions take place with DOE and EPA on the appropriateness of disposing of very large quantities of uranium in a near-surface LLW disposal facility. In SECY-08-0147, the staff analysis concluded that near-surface disposal of large quantities of DU may be appropriate, but not under all site conditions. Shallow disposal of large quantities of DU or disposal at humid sites with a potable ground-water pathway would likely result in the performance objectives not being met. This finding is consistent with the earlier DU disposal analysis performed by Kozak and others (1992). Later, in SRM-SECY-08-0147, the staff was directed by the Commission to determine the waste classification of DU.
The duration of the Part 61 institutional control provision should be extended from 100 years to 300 years.	The staff's preliminary observations and comments in response to this stakeholder recommendation can be found in a separate 2012 Commission paper.
The Part 61 requirements pertaining to engineered barriers should be expanded.	The staff does not have a view on the merits of this recommendation at this time. Engineered barriers are an important component of any LLW disposal facility, and the reliance on multiple barriers is consistent with the Commission's

STAKEHOLDER VIEW AND RECOMMENDATION(S)	PRELIMINARY STAFF OBSERVATIONS
	defense-in-depth policy. Section 61.56(b) of the regulations requires the LLW form be stabilized. Engineered barriers are expected to contribute to the stabilization requirement by delaying the release time for radionuclide egress, as well as providing a physical obstacle to inadvertent intrusion into the disposal facility. Intruder barriers are also expected to provide a means of limiting surface water flux into an underground disposal facility. 10 CFR 61.7(a)(2) currently requires that waste form containers maintain their structural integrity for 300 years. Furthermore, 10 CFR 61.7(a)(5) also required that intruder barriers perform their intended function for at least 500 years. Previously, the NRC staff maintained that longer credit can be taken for these features beyond that required by the regulations so long as an applicant or licensee provides suitable information and justification. (See NRC, 2000, p. xiii).
The regulations should include a *de minimis* provision.	Past efforts by the NRC to globally introduce *de minimis* or a clearance provision to Part 61 were unsuccessful. (See Ryan et al, 2007, p. 21.) As recently as 2005, the staff attempted to introduce a *de minimis* provision to the regulations in connection with amendments to 10 CFR Part 20. The Commission declined to vote on the draft proposed rule, citing the need to focus on higher-priority rulemakings. (See NRC, 2005.)
Comments concerning the 10 CFR 61.55 waste classification tables and their derivation. *The tables should be updated to reflect the latest ICRP dosimetry.* *The tables should be updated with an expanded, more comprehensive list of isotopes.*	The staff currently has an assignment from the Commission to set aside resources to update the 10 CFR 61.55 waste classification tables. See SRM-SECY-08-0147. As part of this effort, the staff will expand the list of isotopes considered beyond the original 25 evaluated in connection with the development of the Part 61 EIS.
The tables should be replaced with a system that is WAC-based.	In SECY-10-0165, the staff recommended as an option the adoption of the WAC-type of an approach to the management of LLW. In SRM-COMWDM-11-0002/COMGEA-11-0002, the Commission has proposed that licensees be allowed the flexibility to establish a site-specific WAC based on the results of the site's performance assessment and intruder assessment.
The tables should be updated to reflect uranium and its daughter products.	The staff understands the issue being raised by this recommendation and believes that, if approved by the Commission, an amendment to introduce an explicit performance assessment requirement to Part 61 would address this recommendation in the near term. However, as previously noted in this paper, the staff currently has an assignment to address this recommendation through SRM-SECY-08-0147.
The tables should be replaced with a system that is concentration and quantity-based.	In practice, most Agreement State regulators already impose site-specific WAC on existing disposal sites as a condition of their licensed operating sites. This licensing feature is usually achieved by specifying some ceiling on the concentration or quantity of LLW that might be received at a particular disposal site. Incorporation of this provision in the Part 61 would better align the regulations with current operating practice. In SRM-COMWDM-11-0002/COMGEA-11-0002, the Commission has proposed that licensees be allowed the flexibility to establish a site-specific WAC based on the results of the site's performance assessment and intruder assessment.

STAKEHOLDER VIEW AND RECOMMENDATION(S)	PRELIMINARY STAFF OBSERVATIONS
The dominance of cesium-137 in the current classification system merits reconsideration.	Although this isotope has a relatively short half-life (approximately 30 years), it decays to barium-137. Both are potentially hazardous because they are beta/gamma emitters. The inclusion of a WAC option will allow disposal facility operators the opportunity to determine what nuclides dominate performance on a site-specific basis.

Comments pertaining to the treatment of human intrusion under Part 61. *Assuming a probability of one is overly conservative and not risk-informed.*	Engineering designs are only as good as the assumptions on which they are based. Because not all operating environments can be envisioned or postulated, it is standard practice to rely on some level of over-conservatism to ensure that over the course of their service life, structures, systems, or components perform as intended, even under conditions that were not expected. This over-conservatism is commonly referred to as a “factor of safety” and is a key aspect of reliability engineering (Harr, 1984). Part 61 of 10 CFR is intended to ensure that LLW disposal facilities are designed in such a way so as to provide some specified level of safety so that the performance objectives of Subpart C will be met. Under nominal operating conditions, the regulations assume protection of the general public can be achieved, with reasonable assurance, subject to compliance with the respective provisions of the regulations. Nevertheless, because there is no previous experience in the operation of an LLW disposal facility (whose service life, by design, is much longer than any conventional engineered system) and because future human actions cannot be predicted with any degree of reliability, human disturbance of any near-surface disposal cannot be ruled-out once institutional controls cease. Thus, for the purposes of a waste disposal system, it might be argued that the human intrusion scenario corresponds to the factor-of-safety analysis applied to the LLW disposal system, although it was not explicitly acknowledged as such at the time. For this reason, the NRC staff believes it was necessary to evaluate acute doses to individuals who might unknowingly disturb a LLW disposal facility and rely on that calculation to ensure that any projected dose not exceed a specified limit.
Should human intrusion still factor into LLW disposal decision making. If so, how? If not, why not?	See discussion above.
In any future rulemaking, assumptions regarding the nature of human intrusion should be updated based on current information.	It would be useful for stakeholders to identify which specific assumptions should be updated. However, if certain human intrusion scenarios are not plausible at a particular disposal site, then consideration should be given to omitting them from any compliance demonstration.
The compatibility designation for 10 CFR 61.58 should be changed to a compatibility “B.”	This comment is noted. The staff is aware that most disposal facility operators are in favor of greater flexibility at the Agreement State level with regard to this particular regulatory requirement.
Will any new amendments to Part 61 be applied retroactively?	Any new requirements for already disposed of waste would not be imposed through this rulemaking. If the NRC were to find problems with already disposed of waste at specific sites, the NRC would issue orders to the affected licensees that would require licensee action to ensure protection of public health and

	safety. Newly identified generic problems could be addressed through orders or rulemaking, depending on the extent and the severity of the problems. Any new requirements that result from this rulemaking will apply to all future disposal actions once compatible regulations are adopted by the Agreement States that regulate the disposal facilities.
The NRC staff should take advantage of technology (i.e., webinar-like "go-to-meeting" features) when engaging the public.	The staff recognizes that discretionary resources available to stakeholders are limited, and the staff intends to rely on inexpensive, cost-effective measures, such as webinars and telephone conference calls with stakeholders and other members of the interested public.

7 STRATEGIC PLAN

The proposed rule supports the NRC's "2008–2013 Strategic Plan" in the areas of safety and organizational excellence. In the area of safety, the proposed rule supports this NRC Safety Goal (Strategy 5 − "Use of sound science and state-of-the-art methods to establish, where appropriate, risk-informed and performance-based regulations") by explicitly introducing into the 10 CFR Part 61 regulatory framework domestic and international experience from the use of quantitative performance assessment techniques to evaluate the safety of waste disposal systems. In the area of organizational excellence, the proposed rule supports the objective regarding the use of state-of-the-art technologies and risk insights to improve the effectiveness and the realisms of NRC actions, with the goals of continuous improvement (Strategy 1).

8 GUIDANCE DOCUMENTS

The staff plans to develop a new guidance document to support the review of site-specific analysis for the disposal of LLW streams containing long-lived isotopes, including large quantities of DU. A variety of technical topics can have an important effect on the analysis of the disposal of LLW streams, and some of these technical topics are not well covered in the existing LLW disposal guidance. If necessary, the guidance document could be separated into multiple documents focused on specific topics. The topics that likely will be covered include guidance on conducting risk-informed, performance-based period of performance analyses; technical analysis considerations, such as the incorporation of features, events, and processes into performance assessments; as well as other considerations, such as setting inventory limits and mitigation techniques.

9 RESOURCES

The staff estimates that the resources required for the rulemaking are 9.3 full-time equivalents (FTE) and $1.5 million in contract funding. In fiscal years (FY) 2010 and FY2011, the staff estimated, and budgeted for, 2.5 FTE by DWMEP each fiscal year. In FY 2012, the staff estimated and was allocated to the Office of Federal and State Materials and Environmental Programs (FSME), DWMEP, Division of Intergovernmental Liaison and Rulemaking (DILR), Office of Information Services (OIS), Office of the General Counsel (OGC), and Office of Administration (ADM), the following FTE:

OFFICE	FTE ALLOCATION
FSME/DWMEP	2.5
FSME/DILR	0.7
OIS	0.1
OGC	0.2
ADM	0.1

These resource estimates also take into consideration the necessary NEPA analyses, described above.

10 TIMING

The proposed rule and draft guidance document should be released for public comment sometime in calendar year 2013. The final rule and guidance would be issued in 2014.

Currently, there have been proposals for the immediate disposal of DOE-generated LLW, including large quantities of DU. The NRC staff does not anticipate that most other unique wastes will need disposal before the estimated completion date of the rule. The staff proposed to include consideration of blended wastes in the “Site-Specific Analysis for Demonstrating Compliance with Subpart C Performance Objectives” rulemaking, and the Commission subsequently directed the staff to include blended wastes in this rulemaking effort. There are no other known potential conflicts between different policy issues or legal issues that need to be resolved before the initiation of rulemaking.

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APPENDIX A

This appendix contains calculations to demonstrate how low-level radioactive waste (LLW) streams containing long-lived isotopes, if disposed of as Class A LLW can result in radiological impacts larger than those used to develop the waste classification tables for demonstration of compliance with the Title 10 of the *Code of Federal Regulations* (10 CFR) 61.42, “Protection of Individuals from Inadvertent Intrusion,” performance objective. The example provided is for shallow land disposal of concentrated depleted uranium (DU).
Assumptions:

(1) The waste is classified using the procedure found in 10 CFR 61.55, “Waste Classification.”

(2) The waste does not contain any of the radionuclides listed in Table 1 or Table 2 of 10 CFR 61.55; therefore, by regulation in 10 CFR 61.55(a)(6), it is Class A LLW.

(3) Depleted uranium waste meets all the waste characteristic requirements found in 10 CFR 61.56(a).

(4) Inhalation of dust and radon are the only pathways considered because they are sufficient to demonstrate the potential risks from disposal after the institutional control period ends.

(5) The material to be disposed of is concentrated DU oxides in the uranium oxide U_3O_8 form.

(6) The amount material to be disposed of is relatively large such that the area of land occupied by the intruder is smaller than the area necessary for the disposal of the DU waste.

(7) The average packing fraction (volume of waste per total disposal facility volume) is 0.7.

(8) The waste is disposed of in shallow trenches and covered with 1 meter of soil.

(9) A foundation for a dwelling is excavated to a depth of 3 meters (m), resulting in 2 m of waste being exhumed per m^2.

A.1 Intruder-Construction Scenario–Soil Inhalation Pathway

An inadvertent intruder occupies the site at the end of the 100-year active institutional control period and constructs a dwelling with a foundation extending to a depth of 3 m below the ground surface, into the disposal cell. The soil exhumed from the disposal cell is spread uniformly around the excavation.

INPUT	VALUE
U_3O_8 concentration (wt. %)	100
Packing fraction (m^3/m^3)	0.7
Exposure time (hours/year)	500
Breathing rate (m^3/year)	8000
Mass loading (g soil/m^3 air)	1E-3
$DCF_{inhalation}$–Class Y (mrem/pCi)	1.2E-1
U^{238} specific activity (Ci/g)	3.4E-7

The exposure time is the same value assumed in the analysis supporting the 10 CFR Part 61, “Licensing Requirements for Land Disposal of Radioactive Waste,” environmental impact statement (EIS) (NRC, 1982). The breathing rate is also the same value used in the draft EIS, which includes the technical basis for Part 61 (NRC, 1981, p. G-83). The update of the Part 61 impacts analysis methodology provided mass loading values that ranged from 0.26 to 7.4 milligrams (mg)/m^3 for humid to arid sites (Oztunali and Roles, 1986). The value used here is representative of a semi-arid site, but it is not a bounding value on a national scale. The dose conversion factor (DCF) for inhalation of uranium is from Federal Guidance Report No. 11 (U.S. Environmental Protection Agency (EPA), 1988). The solubility class is based on the International Commission on Radiation Protection (ICRP) 30 recommendation for UO2 and U3O8 (ICRP, 1979).

Concentration of uranium in soil –

$$U_{conc} = 100\ wt.\% \cdot \left(\frac{84.8\ g\ U}{100\ g\ U_3O_8}\right) \cdot 0.7 \cdot \left(\frac{2\ m\ waste}{3\ m\ total}\right) = 0.396 \frac{g\ U}{g\ total}$$

Amount of uranium inhaled during construction –

$$Mass_{inh} = \left(\frac{0.396\ g\ U}{g_{total}}\right) \cdot \left(\frac{1E-3\ g_{total}}{m^3 air}\right) \cdot \left(\frac{8000\ m^3\ air}{yr}\right) \cdot \left(\frac{1yr}{8760\ hr}\right) \cdot 500\ hr = 0.18\ g\ U$$

Dose from uranium inhalation –

$$D_{inhalation} = 0.18\ g\ U \cdot \left(3.4E-7 \frac{Ci}{g\ U}\right) \cdot \left(\frac{1E12\,pCi}{Ci}\right) \cdot \left(1.2E-1 \frac{mrem}{pCi}\right) = 7750\ mrem$$

A.2 Intruder-Construction Scenario – Radon Pathway

The calculation of the dose from radon gas to an intruder during construction of a dwelling is estimated using the approach documented in Regulatory Guide 3.64, “Calculation of Radon Flux Attenuation by Earthen Uranium Mill Tailings Covers,” to estimate the radon flux and the approach documented in the RESRAD user’s manual to convert the flux to an outdoor concentration (NRC, 1989; ANL, 2001). The assumptions relevant to each approach are provided in the original documentation and are not duplicated here. Additional assumptions include:

(1) The average radon flux through 1 meter of cover can be used to approximate the radon dose to the intruder (construction). In this scenario, an excavation is created based on the assumed disposal of waste that would result in exposure to uncovered tailings for some period of time before a foundation is established. Because this calculation is designed to demonstrate that the dose impacts are sufficiently large to necessitate a change to the regulations, the exact value by which the radon dose may exceed the implicit regulatory annual limit of 500 mrem/yr (5 (mSv/yr)) is not important.

(2) The average annual wind speed is 2 m/second (s). Annual average wind speed varies by location, time of day, and by season. A distribution of annual average wind speeds was compiled for RESRAD-Offsite, and the 50th percentile value was 4.2 m/s with a range of 1.4 m/s to 13 m/s (ANL, 2007). The average value for a 500 hour (hr) exposure period would have a considerably larger range than the annual averages. Use of 2 m/s is reasonably conservative for this calculation. Because this calculation is designed to demonstrate that the dose effects are sufficiently large to require a change to the regulations, the exact value by which the radon dose may exceed the implicit regulatory annual limit of 500 mrem is not important.

(3) The amount of material disposed of is large, such that a correction for an outdoor area factor is not necessary.

(4) The amount of material disposed of occupies an area larger than 160,000 m^2, such that the characteristic length (used below) is approximately 400 m.

(5) Parameter values given in the table below show average values representative of the area encompassed by the disposal facility.

PARAMETER	DESCRIPTION	VALUE
Φ_{soil}	Soil porosity	0.3
S_{soil}	Soil liquid saturation	0.4
Φ_{source}	Source porosity	0.4
S_{source}	Source liquid saturation	0.6
H_{rn}	Henry's law constant for radon	3.85
ρ_w	Waste density (g/m^3)	1.5
Z	Waste thickness (m)	5
Z_w	Waste depth (m)	1
DCF_{RN}	Dose conversion factor for RN-222 (mrem/pCi)	5.11E-5
$T_{1/2RN}$	Half-life of RN-222 (days)	3.82
E	Radon emanation coefficient	0.35
H_o	Height of uniform mixing of plume (m)	2
U_s	Annual average wind speed (m/s)	2
X	Effective length of waste disposal area (m)	400
i_r	Inhalation rate (m^3/yr)	8000
ex	Exposure time (hr)	500
Ra_conc	Concentration of radium (Ci/g) at time (yr): 0 1,000 10,000 100,000 1,000,000	 0 2.53E-10 8.68E-9 9.17E-8 3.17E-7

The calculation used the approach described in Regulatory Guide 3.64 to estimate the radon flux and the approach presented in the RESRAD user's manual to estimate the approximate outdoor radon concentration.
The tortuosity was represented as:

$$RG\_Tortuosity = 0.67 \cdot \exp^{-4\left(S_{soil} - S_{soil} \cdot \phi_{soil}{}^{2} + S_{soil}{}^{5}\right)} = 0.1499$$

The radon diffusivity was represented as:

$$radon\_diff = RG\_Tortuosity \cdot 1.0E-5\,\frac{m^2}{s} = 1.5E-6\,\frac{m^2}{s}$$

The following three terms are used in the equations from Regulatory Guide 3.64 to calculate radon fluxes:

$$a_c = \phi_{soil}{}^{2} \cdot radon\_diff \cdot \left(1 - \left(1 - \frac{1}{H_{rn}}\right) \cdot S_{soil}\right)^2 = 1.46E-5\,\frac{cm^2}{s}$$

$$b_c = \left(\frac{2.1E-6\ s^{-1}}{radon\_diff}\right)^{0.5} = 0.0118\ cm^{-1}$$

$$a_t = \phi_{source}{}^2 \cdot radon\_diff \cdot \left(1 - \left(1 - \frac{1}{H_{rn}}\right) \cdot S_{source}\right)^2 = 5.83E-5 \frac{cm^2}{s}$$

The flux of radon from the source is calculated with:

$$RG364\_source = Ra\_conc \cdot \rho_w \cdot E \cdot \left(2.1E-6\ s^{-1} \cdot radon\_diff\right)^{0.5} \cdot \tanh(Z \cdot b_c) = 8086 \frac{pCi}{m^2\ s}$$

The radium concentration used to calculate the source flux was the value for 10,000 years provided in the table above. The corresponding radon flux through the soil is calculated as:

$$RG364\_soil = 2 \cdot RG364\_source \cdot e^{\left(\frac{-b_c \cdot Z_w}{1+\left(\frac{a_t}{a_c}\right)^{0.5}}\right)} = 1651 \frac{pCi}{m^2\ s}$$

The flux through the soil is converted into an average annual outdoor concentration (C_o) using the approach documented on page 156 of the RESRAD manual (ANL, 1997). C_o is given by:

$$C_o = \frac{J_o\ F_{ao}}{\lambda\ H_o}\left(1 - e^{-\left(\frac{\lambda\ X}{2\ U}\right)}\right) = 98256 \frac{pCi}{m^3}$$

Where,

J_o = the radon flux from the soil (RG364_soil) in pCi/m^2 s,
F_{ao} = outdoor area factor = 1 for A > 100 m^2,

and the other parameters are identified in the table above. The radon dose is calculated as:

$$Radon\_dose = C_o \cdot i_r \cdot ex \cdot DCF_{RN} = 1923\ mrem$$

The NRC staff implemented the dose calculation using the GoldSim computer code (GoldSim Technology Group, 2004). GoldSim is a proprietary software package. To facilitate independent review, the staff saved the file as a player file. A player file can be viewed and executed without purchasing a license for the GoldSim software. This package includes the player file (RG364.gsm). Users can download the GoldSim player from http://www.goldsim.com/ Form_DownloadPlayer.asp. The file can then be used to estimate the resultant radon dose over a range of conditions, which may differ from the conditions selected for this calculation.

Because the intruder construction scenarios resulted in doses well in excess of 500 mrem/yr (5 mSv/yr), it is not necessary to perform the intruder-agriculture calculations, which typically result in much higher doses because of more pathways are involved and there are much longer exposure times.

A.3 References

Argonne National Laboratory (ANL), "User's Manual for RESRAD Version 6," ANL/EAD-4, Environmental Assessment Division, Argonne, IL, July 2001.

ANL, "User's Manual for RESRAD-Offsite Version 2," ANL/EVS/TM/07-1, Environmental Assessment Division, Argonne, IL, June 2007.

GoldSim Technology Group, "GoldSim Probabilistic Simulation Environment," Issaquah, WA, GoldSim Technology Group, LLC, 2004.

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Oztunali, O.I., and G.W. Roles, "Update of Part 61 Impacts Analysis Methodology–Methodology Report," U.S. Nuclear Regulatory Commission, NUREG/CR-4370, Vol. 1, January 1986. (ML100251399)

U.S. Environmental Protection Agency (EPA), "Federal Guidance Report No. 11: Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion," EPA-520/1-88-020, September 1988.

U.S. Nuclear Regulatory Commission, "Draft Environmental Impact Statement on 10 CFR Part 61 Licensing Requirements for Land Disposal of Radioactive Waste," Washington, D.C., NUREG-0782 , 4 vols., September 1981.

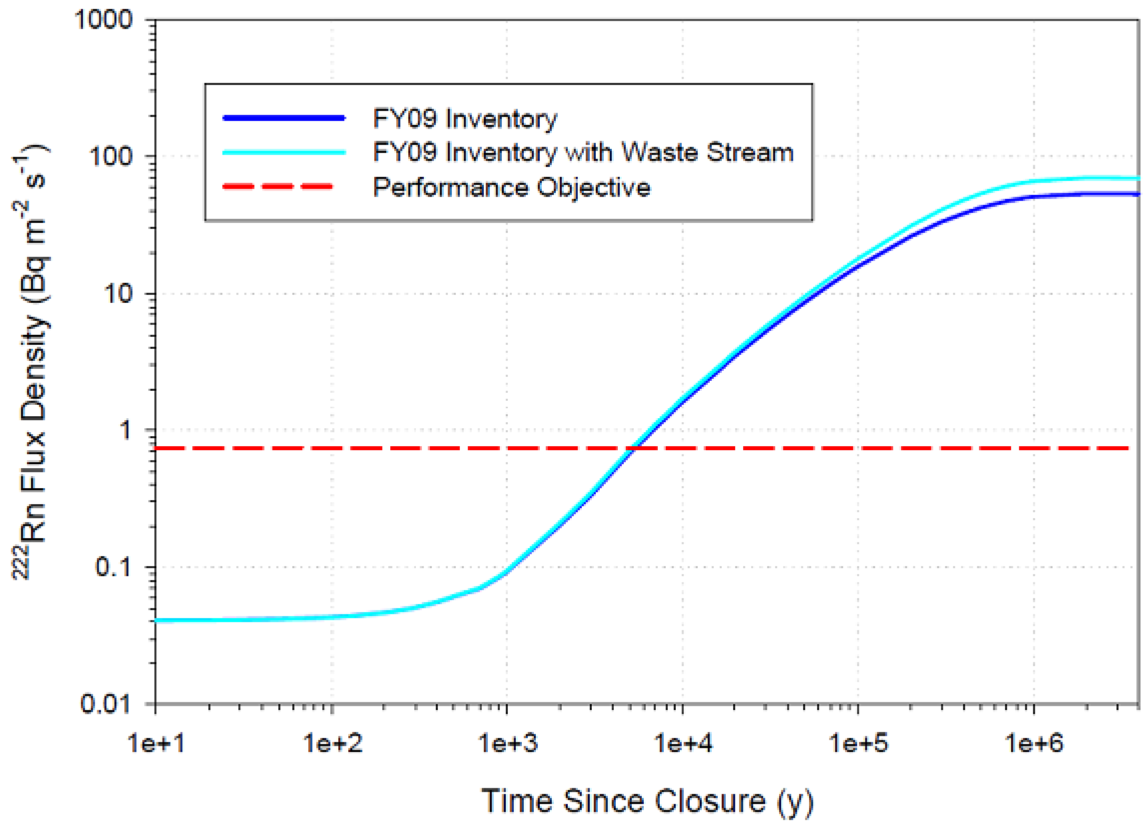
U.S. Nuclear Regulatory Commission, "Final Environmental Impact Statement on 10 CFR Part 61 Licensing Requirements for Land Disposal of Radioactive Waste," NUREG-0945, 3 vols., November 1982.

U.S. Nuclear Regulatory Commission, Regulatory Guide 3.64, "Calculation of Radon Flux Attenuation by Earthen Uranium Mill Tailings Covers," 1989.

APPENDIX B

This appendix provides a summary of projected performance of a variety of U.S. Department of Energy (DOE) systems for the disposal of low-level waste or the management of waste incidental to reprocessing. The information is intended to convey only the types of responses that are commonly generated in performance assessment models. The effects estimated in a 1,000-year timeframe are, in many cases, trivial compared to what would be estimated in 10,000 years.

References are provided below each chart or table if the reader desires additional information.



Shott, G.J., "Summary of the Special Analysis of Savannah River Depleted Uranium Trioxide Demonstrating the Before and After Impacts on the DOE Order 435.1 Performance Objective and the Peak Dose," DOE/NV/25946–1129, U.S. Department of Energy, Nevada, 2011.

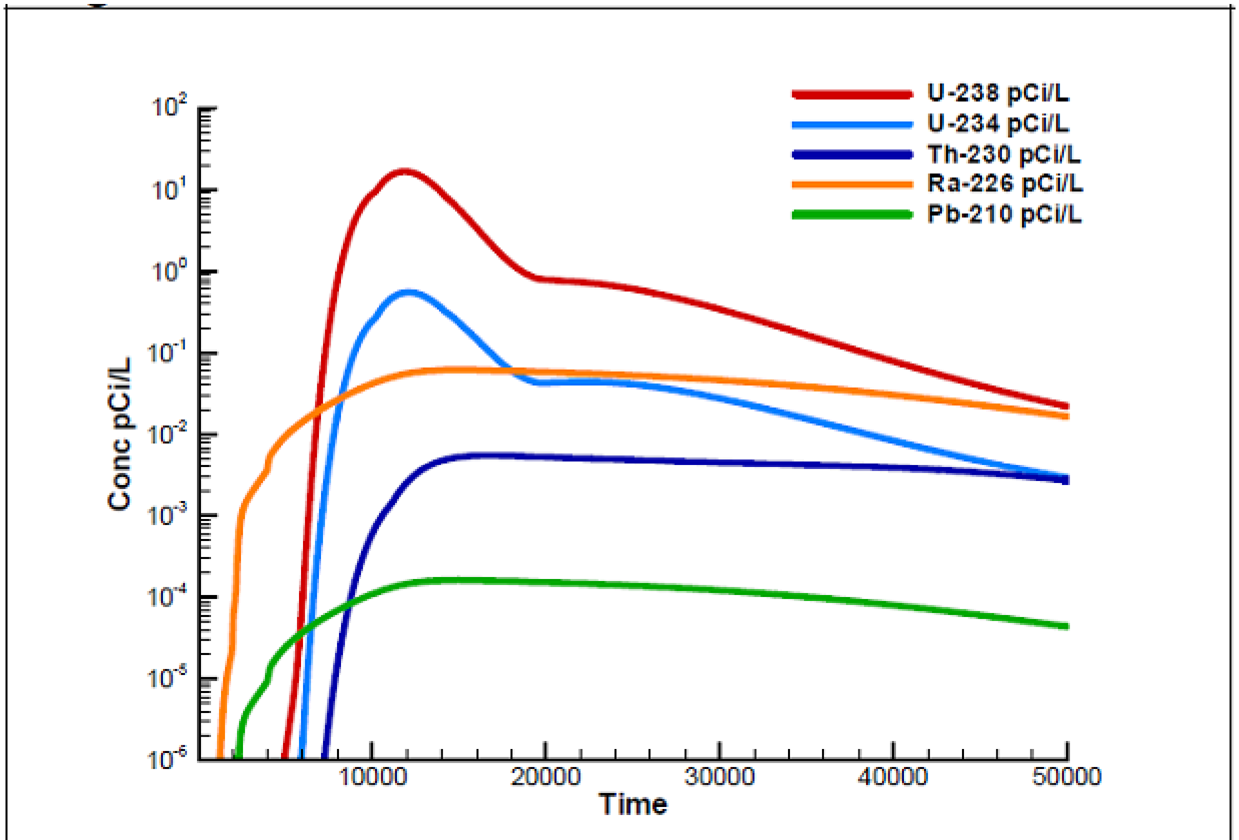


Figure A4A-91. ILV well concentration for U-238

Washington Savannah River Company (WSRC), "E-Area Low-Level Waste Facility DOE 435.1 Performance Assessment," WSRC-STI-2007-00306, REVISION 0, Washington Savannah River Company, Aiken, SC, 2008.

Table ES-1. Comparison of Estimated Impacts with Performance Objectives for Protecting the General Public. The DOE time of compliance is 1,000 years.

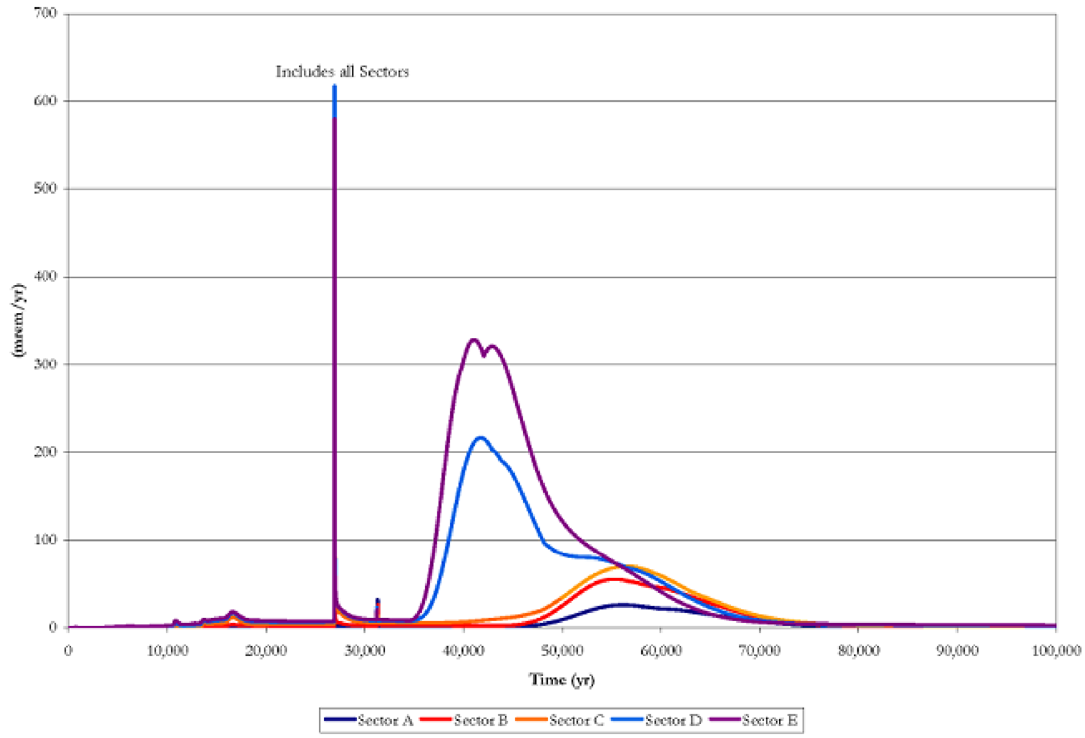
Performance Measure	Performance Objective	Estimated Peak Impact During First 1,000 years [(a)]	Estimated Peak Impact During First 10,000 years [(b)]
All-pathways [mrem in a year]	25.0		
Farmer Scenario		1.2×10^{-10}	1.8
Residential Scenario		0.73×10^{-10}	1.1
Industrial Scenario		0.22×10^{-10}	0.32
Incremental Lifetime Cancer Risk (Chemicals)*	10^{-5}	7.9×10^{-17}	5.6×10^{-7}
Hazard Index (Chemicals)*	1.0	1.8×10^{-11}	0.12

*Based on chromium, nitrate, and uranium inventory
(a) Peak impacts occur at the end of the 1,000 year period
(b) Peak impacts occur at about 2,400 years after closure

Note: The large increase in the hazard index is primarily caused by uranium.

Mann, F.M., et al., "Integrated Disposal Facility Risk Assessment," RPP-15834, Revision 0, CH2M Hill Hanford Group, Inc., Hanford, WA, 2003.

Figure 5.5-9: Member of the Public at 100m Peak Groundwater Pathway Dose Results within 100,000 Years



WRSC, "Performance Assessment for the F-Tank Farm at the Savannah River Site," SRS-REG-2007-00002, Westinghouse Savannah River Company, Aiken, SC, 2007.

Figure 5.5-4: Contributors to the Sector B 100m Peak Groundwater Pathways Dose, 20,000 Years

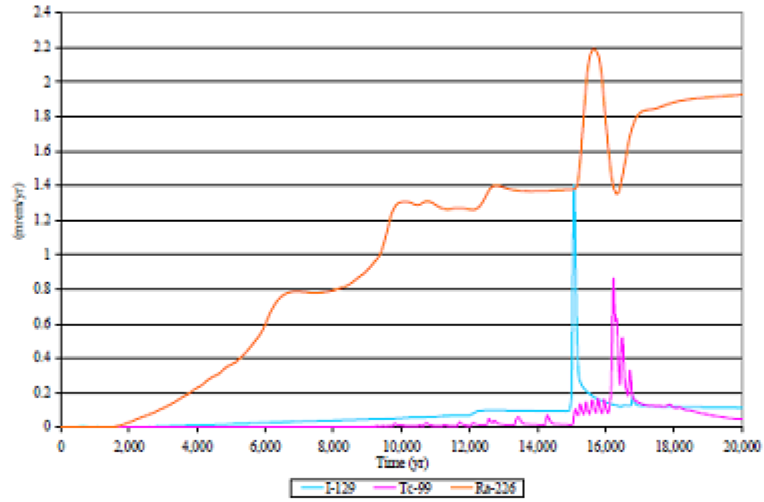
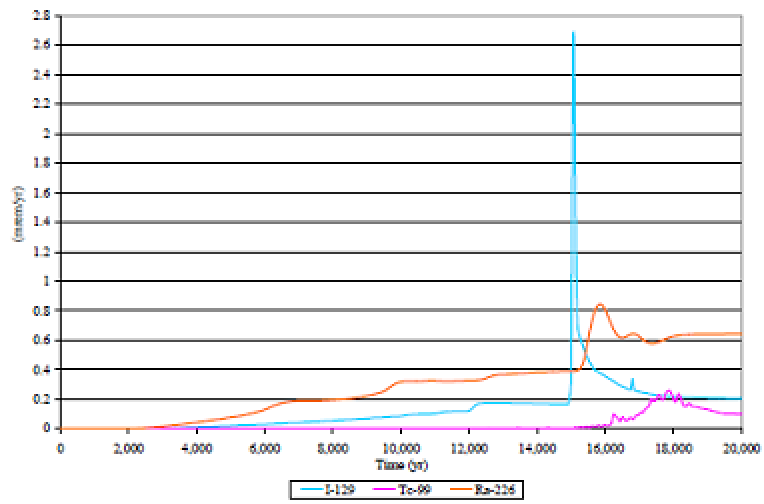


Figure 5.5-5: Contributors to the Sector I 100m Peak Groundwater Pathways Dose, 20,000 Years



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SRR Closure & Waste Disposal Authority, "Performance Assessment for the Saltstone Disposal Facility at the Savannah River Site, Prepared for DOE under Contract No. DE-AC09-09SR22505, Aiken, SC, 2009