

## **POLICY ISSUE INFORMATION**

December 27, 2010

SECY-10-0165

FOR: The Commissioners

FROM: Charles L. Miller, Director  
Office of Federal and State Materials  
and Environmental Management Programs

SUBJECT: STAFF'S APPROACH TO COMPREHENSIVE REVISION TO 10 CFR  
PART 61 (SRM M100617B)

PURPOSE:

To provide the Commission with the staff's approach to initiate activities related to a risk-informed, performance-based (RI/PB) comprehensive revision to 10 CFR Part 61 ("Licensing Requirements for Land Disposal of Radioactive Waste").

SUMMARY:

In Staff Requirements Memorandum (SRM) M100617B, the Commission directed the staff to outline its approach to initiate activities in connection with a possible revision to Part 61 that is RI/PB. A RI/PB approach is discussed later in this paper and includes a resource estimate consistent with the proposed approach.

However, before the start of the rulemaking process, the staff recommends that it engage stakeholders and solicit their views on whether there should be amendments to the current Part 61 and if so, what the nature of those amendments should be.<sup>1</sup> The purpose of these meetings would be to gather information from a broad spectrum of stakeholders concerning their continued support for the existing Part 61, recommendations for specific changes to the existing rule, or suggestions for possible new approaches to commercial low-level radioactive

CONTACTS: Michael P. Lee, FSME/DWMEP  
(301) 415-6887

Donald B. Lowman, FSME/DWMEP  
(301) 415-5452

---

<sup>1</sup> This approach would comport with the methodology originally used by the staff to develop Part 61.

waste (LLW) management. In connection with any potential rulemaking action, the staff has also identified possible RI/PB options that include the following and would be discussed with stakeholders as part of any public outreach effort:

1. Risk-inform the current Part 61 waste classification framework.
2. Comprehensive revision to Part 61.
3. Site-specific waste acceptance criteria.
4. International alignment.
5. Supersede direction given in SRM-08-0147.

This paper also identifies preliminary resource estimates for each of the first four options above.

After completing the public workshops and reviewing the information provided by stakeholders, the staff will submit a notation-vote paper to the Commission summarizing suggestions for revising Part 61, and recommending an option for Commission consideration. This notation-vote paper will be submitted in 2012.

#### BACKGROUND:

The Commission's licensing requirements for the disposal of LLW in near-surface [approximately the uppermost 30 meters (100 feet)] facilities reside in Part 61. These regulations were published in the *Federal Register* in 1982 (see 47 FR 57446; December 27, 1982). The rule applies to any near-surface LLW disposal technology, including shallow-land burial, engineered land disposal methods such as below-ground vaults, earth-mounded concrete bunkers, and augered holes. The regulations 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 institutional controls, Part 61 emphasizes passive rather than active systems to limit and retard releases to the environment.

Development of the Part 61 regulation in the early 1980s was based on several assumptions as to the types of wastes likely to go into a commercial LLW disposal facility. To better understand what the likely inventory of wastes available for disposal might be, the U.S. Nuclear Regulatory Commission (NRC) conducted a survey of existing LLW generators. The survey, documented in Chapter 3 of NUREG-0782 — the Draft Part 61 Environmental Impact Statement (DEIS) — revealed that there were about 36 distinct commercial waste streams consisting of about 24 radionuclides of potential regulatory interest. The specific waste streams in question were representative of the types of commercial LLW being generated at the time. Waste streams associated with U.S. Department of Energy's (DOE's) nuclear defense complex were not considered as part of the survey, since disposal of those wastes, at that time, was to be conducted at the DOE-operated sites.

Over the last several years there have been a number of developments that have called into question some of the key assumptions made in connection with the earlier Part 61 DEIS, including:

- The emergence of potential LLW streams that were not considered in the original Part 61 rulemaking, including large quantities of depleted uranium, blended LLW, and possibly incidental wastes associated with the commercial reprocessing of spent nuclear fuel;
- DOE's increasing use of commercial facilities for the disposal of defense-related LLW streams; and
- Extensive international operational experience in the management of LLW and intermediate-level radioactive wastes that did not exist at the time Part 61 was promulgated.

The developments described above will need to be considered if the staff undertakes a revision of Part 61.

Waste from the Nation's defense programs has been managed by DOE and is not subject to Part 61. Instead, DOE has used Waste Management Order 435.1-1 to specify the disposal requirements for this waste. The current version of this order has been in place for about 10 years and it applies to 16 disposal sites within the DOE complex. Like Part 61, Order 435.1-1 places a heavy emphasis on performance assessment as part of its radioactive waste management decision-making. DOE recently started a comprehensive revision of Order 435.1-1, which it plans to complete sometime in 2011. The staff plans to consider any amendments to Order 435.1-1 as part of a comprehensive revision to Part 61.

#### DISCUSSION:

As a first step in any potential revision to Part 61, the staff recommends that it initially engage stakeholders and solicit their views on whether there should be amendments to the current Part 61 and if so, what the nature of those amendments should be. As part of the initial Part 61 rulemaking, the staff conducted four public meetings and three technical workshops to obtain stakeholder views on the scope and content of any commercial LLW regulation. At the time Part 61 was first developed (the late 1970s-early 1980s), there was little practical experience relevant to the management of LLW. The staff used the public meetings and workshops to gain a better understanding of the engineering standards and disposal practices that might need to be employed in managing commercial LLW. Because any changes to Part 61 would affect a number of stakeholders that are invested in and understand the current system, the staff believes that it would be advantageous to consult with both stakeholders and practitioners once again on whether the current Part 61 framework should be modified and if so, what kind of changes might be appropriate. Alternatively, stakeholders may also offer new ideas on how to manage commercial LLW.

As noted above, the staff plans to conduct a series of public workshops to obtain stakeholder input on whether and how best to revise Part 61. This activity is currently budgeted for fiscal year (FY) 2011. The first of the proposed stakeholder meetings will be conducted on March 4, 2011, in Phoenix, Arizona, as a joint NRC-DOE workshop on LLW management. DOE has already scheduled a public meeting to discuss the revisions to Order 435.1-1. The meeting would be held after the 2011 Waste Management Conference, which would allow the staff to take advantage of the large stakeholder presence expected at the conference. Following the Phoenix meeting, the staff plans to conduct one or more public meetings with stakeholders, subject to the availability of resources, later in calendar years 2011 and 2012.

Staff will use these meetings to gather information from a broad spectrum of stakeholders concerning their support for the existing Part 61 regulatory model for the management of commercial LLW, recommendations for specific rule changes, or suggestions for possible new approaches to commercial LLW management. Stakeholders would be invited to comment on possible RI/PB options presented by the staff or to suggest alternative regulatory strategies for the management of commercial LLW. The proposed staff options are summarized below and listed in greater detail in [Enclosure 1](#). The options are:

1. ***Risk-inform the current Part 61 waste classification framework:*** Under this option, the current Part 61 waste classification designations for Class A, Class B, and Class C LLW would be preserved, but re-evaluated in the context of the updated dosimetry developed by the International Commission on Radiation Protection (ICRP). Implementation of this rulemaking option may lead to reassignment of one or more of the 12 radionuclides between the 2 concentration tables in § 61.55(a), based on the updated ICRP dosimetry. This option is consistent with earlier Commission direction provided in SRM-SECY-08-147.
2. ***Comprehensive revision to Part 61:*** This option would involve a comprehensive revision to Part 61, consistent with RI/PB principles. However, the specific nature of those revisions have yet-to-be-defined, and would be developed in concert with stakeholders through a series of public workshops. It is expected that this option would consider both existing and emerging LLW streams and in doing so, provide for management solutions that potentially could include both near-surface as well as intermediate depth disposal.
3. ***Site-specific waste acceptance criteria:*** This option would essentially adopt the DOE system (i.e., Order 435.1-1), in whole or in part, for the management of commercial LLW. Waste generators within the DOE complex currently take into account life-cycle planning considerations which assist them in complying with site-specific waste acceptance criteria (WAC) for a particular disposal facility to ensure that Government-owned waste has an identified disposal path. By relying on a performance-based directive coupled with a site-specific WAC, DOE field managers have the flexibility to determine the quality and quantity of waste that can be disposed of at a particular site based on disposal facility site, design, and waste inventory. Similar to Option #1, this option would also focus primarily on changes to § 61.55(a).

4. **International alignment:** Under this option, NRC would consider adopting the recent recommendations of the International Atomic Energy Agency (IAEA) for the management of radioactive wastes. Those recommendations are contained in General Safety Guide-1 (GSG-1) which outlines a comprehensive management approach to radioactive wastes by relating the radiological hazard posed by a particular waste stream to a specific disposition strategy (available at [http://www-pub.iaea.org/MTCD/publications/PDF/Pub1419\\_web.pdf](http://www-pub.iaea.org/MTCD/publications/PDF/Pub1419_web.pdf)). The GSG-1 system includes waste classes that would be high-level radioactive wastes, greater-than-Class C wastes, LLW, and wastes amenable to decay in storage under the current U.S. system. The principal difference between the IAEA recommendations and the current Part 61 rule is the definition of LLW. Unlike the Part 61 definition, the IAEA system specifies sub-categories of LLW, including IAEA-designated exempt wastes (EW), as well as very low-level radioactive wastes (VLLW).
5. **Supersede direction given in SRM-08-0147:** Under this option, the Commission would maintain the status quo by superseding its earlier direction contained in SRM-SECY-08-0147, to risk-inform the waste classification tables resulting in no further changes to the existing Part 61 regulation other than the ongoing rulemaking for unique waste streams to add an explicit performance assessment requirement to Part 61.

The environmental analysis for Part 61 was completed in 1982. In support of any selected rulemaking option, the staff intends to perform an appropriate environmental review consistent with the National Environmental Policy Act of 1969 (NEPA).

In developing the five options, described in more detail in [Enclosure 1](#), the staff identified policy issues for Commission consideration. These policy issues are summarized in [Enclosure 2](#) and include the following:

- NEPA;
- The Low-Level Radioactive Waste Policy Amendments Act of 1985;
- Implementation;
- Earlier Stakeholder Interest; and
- Clearance.

While not a policy issue *per se*, the rulemaking on Part 61 would have to be coordinated with any update to Part 20 to ensure consistency on the use of the definition and concepts related to members of the public, dosimetry, and worker exposure.

In 1994 and 1995, the staff developed and the Commission approved a *Policy Statement* on probabilistic risk assessment (PRA), which was published in the *Federal Register* (59 FR 63389; December 8, 1994, and 60 FR 42622; August 16, 1995). This *Policy Statement* informed the development of RI/PB regulation, and the staff has developed a number of Commission papers

on the application of PRA to the NRC's waste disposal programs since the publication of the *Policy Statement*. A summary of these Commission papers can be found in [Enclosure 3](#).

#### STAKEHOLDER INPUT:

In connection with staff activities related to the disposition of depleted uranium and the blending of LLW, stakeholders have commented on issues that also pertain to Part 61. Some of these comments include specific recommendations on how the rule could be amended to address a key issue concerning the management of emerging yet unevaluated commercial LLW streams within the Part 61 regulatory framework. A summary of stakeholder recommendations that have been received thus far can be found in [Enclosure 2](#). Some of these recommendations will be addressed by the on-going rulemaking to introduce specific regulatory requirements for a performance assessment and an intruder analysis to the existing Part 61 rule. Other recommendations would be addressed in connection with any future LLW rulemaking, as appropriate.

#### AGREEMENT STATE VIEWS:

Concurrent with transmitting this paper to the Commission, the staff intends to provide copies to the Agreement States. The Agreement States were notified of the staff's intention to prepare this paper during the Office of Federal and State Materials and Environmental Management Programs (FSME) monthly telephone call on October 21, 2010. Separate telephone calls were conducted with representatives of the States of Washington (November 9), South Carolina and Texas (November 10), and Utah (November 18). The questions asked by the State representatives during these telephone calls included the following:

1. Is there a nexus between any of the potential actions contemplated by this Commission Paper and the on-going rulemaking to introduce specific regulatory requirements for a performance assessment and an intruder analysis to the existing Part 61 rule?
2. Had the staff decided on the duration of the period of performance for any performance assessment?
3. Would the staff consider extending the current 100-year institutional control period to some longer, more realistic timeframe on the order of about 300 years?
4. Should there be a new regulatory provision concerning the use of engineered barriers? If so, any such requirement should be technology neutral and any implementation decisions should be deferred to the licensee.

5. How would any revised commercial LLW regulation be applied? That is to say, would it apply to currently operating LLW facilities or, alternatively, would it be applied to only new licensees?<sup>2</sup>
6. How will the staff engage the Agreement States and other interested stakeholders as part of any public outreach effort in connection with any Part 61 rulemaking? (Due to budgetary constraints, some Agreement State representatives may not be able to attend planned public meetings. Web-casting could help to remedy this concern, especially for those states subject to resource limitations. It might also be advisable to independently consult with those Agreement States with operating disposal sites before seeking broader stakeholder input.)
7. Should there be any changes to the waste classification tables found at § 61.55(a), the staff should factor-in the large quantities of depleted uranium currently available for disposal as well as the progeny present in the uranium decay chain such as radon gas from radium-226. The staff should also consider other longer-lived radionuclides that are currently present in LLW streams in any analysis. Following any such review, the staff should determine whether it is appropriate to establish concentration/quantity limits for these long-lived isotopes in the Part 61 regulation.

The staff will engage the Agreement States, as well as other interested stakeholders on these and other issues, as part of the planned public workshops.

#### PATH FORWARD:

After completing the public workshops and reviewing the information provided by stakeholders, the staff will submit a notation-vote paper to the Commission summarizing their suggestions for revising NRC's regulatory framework for the management of commercial LLW, and recommending an option for Commission consideration. This notation-vote paper will be submitted in 2012.

#### RESOURCES:

The staff will use its allocated resources for this effort in fiscal year (FY) 2011 to address current Commission direction and conduct its first public meeting. Some additional resources may be re-programmed to support this effort in FY 2012, as appropriate. The preliminary resource estimates for the respective rulemaking options will be used to inform the FY 2013 budget

---

<sup>2</sup> This observation focuses on the impact any new NRC regulation might have on Agreement States whose respective LLW programs are at various experience levels.

submission. Future reprogramming requests will be coordinated with the Office of the Chief Financial Officer, as necessary.

COORDINATION:

The Office of the General Counsel has no legal objection to this paper.

**/RA/ by Josephine M. Piccone Acting for**

Charles L. Miller, Director  
Office of Federal and State Materials  
and Environmental Management Programs

Enclosures:

1. [Options for Revising Part 61](#)
2. [Key Policy Issues to be Considered](#)
3. [RI/PB within the Materials Programs](#)

## APPROACHES TO REVISING 10 CFR PART 61

### Background

In Staff Requirements Memorandum (SRM) SECY-08-0147, March 18, 2009, the staff was directed to:

...propose the necessary resources for a comprehensive revision to risk-inform the 10 CFR Part 61 waste classification framework, with conforming changes to the regulations as needed, using updated assumptions and referencing the latest International Committee on Radiation Protection [ICRP] methodology. As part of this effort, staff should also identify any corollary or conforming legislative changes necessary to support this rulemaking, if any, as well as recommendations on how to proceed absent such legislation being enacted and other agencies that may be impacted by any changes. This effort should explicitly address the waste classification of depleted uranium. In addition, this effort should include the performance of a technical analysis for public comment concerning the disposal in a near surface facility of any long-lived radionuclide, including uranium. This analysis and the resulting comments should inform the staff's eventual recommendation to the Commission on an appropriate generic requirement addressing such disposals ....

In contemplating potential changes to 10 CFR Part 61, the staff identified four options that represent a suite of approaches, any one of which could be employed consistent with the Commission's risk-informed/performance-based (RI/PB) policy pertaining to the regulation of nuclear activities. These options are outlined below in no particular order of preference. In considering these options, the staff identified potential policy issues that the Commission would need to consider. These policy issues are summarized in Enclosure 2. Lastly, there have occasionally been questions regarding what is meant by RI/PB regulation, particularly in the context of the Commission's 1995 Probabilistic Risk Assessment (PRA) *Policy Statement*. As noted in the SECY paper, the staff provided the Commission with a number of papers on RI/PB regulation and the PRA *Policy Statement*. A summary of this issue is provided in Enclosure 3.

If the Commission chooses, there is also a fifth option which would be to maintain the current *status quo* with respect to Part 61. To implement this option the Commission would supersede its earlier direction in SRM-08-0147 to risk-inform the waste classification tables at § 61.55(a).

In the early 1990s, the staff conducted a broad reassessment of its low-level waste (LLW) program at the Commission's request. As part of this reassessment, described in COMSECY-93-021, the staff identified specific areas of Part 61 that might be candidates for amendment. See Table 1. In connection with that analysis, the staff, and several of the Agreement States, expressed the view that major revisions to Part 61, along with the requirement for conforming revisions by the Agreement States, could create instability in what were then (*ca.* early 1990s) ongoing LLW siting and licensing efforts. It is not clear if those views are still widely held or even if the existing regulation represents an impediment to the development of new disposal capacity.

**Table 1. Areas in 10 CFR Part 61 Previously Identified by the Staff (NRC, 1993, Attachment B) as Potential Candidates for Amendment.**

10 CFR Part 61			1993 NRC Staff Recommendation
Requirement	Subpart	Subject Area	
10 CFR 61.29	B	Active Maintenance	In conjunction with a longer time period of institutional control, include provisions in the regulation for more inspections and preventive maintenance of the disposal facility following closure to assure that the facility is performing as intended.
10 CFR 61.41	C	Performance Objectives	Establish dose requirements more stringent than the current 25 mrem/yr for protection of the general population .
10 CFR 61.50	D	Technical Requirements for Land Disposal Facilities	Develop specific technical criteria to cover disposal in above-ground vaults, which are not currently addressed in the regulations.
10 CFR 61.50(a)	D	Site Suitability Requirements	Current requirements are considered to be "minimum" basic requirements. Past experience indicates the need for more specific siting and design requirements. More credit is also needed for performance of engineered barriers to compensate for site deficiencies.
10 CFR 61.53	D	Environmental Monitoring	In conjunction with a longer time period of institutional control, include provisions in the regulation for a period of environmental monitoring after the 100-year caretaker period.
10 CFR 61.59(a)	D	Land Ownership	Consider assigning a responsible third party to the caretaker role other than the government.
10 CFR 61.59(b)	D	Institutional Control Period	Extend governmental caretaker period for more than 100 years.
10 CFR 61.55 and 10 CFR 61.56	D	Waste Classification and Characterization	Include specific concentration-averaging requirements in the regulations.
n/a	n/a	Retrievability Option	Currently, there is no provision in the regulation to require that the wastes be recoverable should the disposal facility fail to perform as intended.
n/a	n/a	Groundwater Protection Requirements	The regulation could be made more explicit on how the ground-water resource would be protected. ACNW has previously recommended specific regulatory action in this area.

In contemplating any type of comprehensive revision to Part 61, the staff believes that several of the earlier activities associated with the initial development of Part 61 (as described in Chapter 7 of NUREG-0782) would not need to be repeated because at the time the rule was first developed, there was no accepted set of standards and practices for the disposal of commercial LLW, and now there are several decades of operating experience. In fact, a key motivation behind the development of Part 61 was the recognition that the absence of standards and practices was a major contributing factor to the poor performance and failure of many the disposal sites operating at the time.

However, from previous staff experience (and not withstanding the outcomes of any future public interactions), there is likely to be significant stakeholder resistance to any attempt to undertake a comprehensive revision to Part 61; the existing Part 61 waste classification system is well-engrained in both the commercial sector's LLW business model and the Agreement States' regulatory framework.

Nevertheless, any comprehensive RI/PB revision to Part 61 would consider the following principal activities:

- An updated waste generator survey to define the types and quantities of LLW likely to be managed in any commercial LLW disposal facility. This survey would include an evaluation of government-owned LLW that the U.S. Department of Energy (DOE) may send to a commercial LLW site as well as potential LLW streams that might be associated with any commercial spent nuclear fuel reprocessing effort and waste generated from planned new nuclear power reactors.
- A generic performance assessment analysis (i.e., a 'test case'), of sufficient complexity, to allow for the evaluation of the types and kinds of waste streams that might be managed in any commercial LLW disposal facility as well as an evaluation of the impact of any amendments to the regulatory framework for the safe management of those wastes. This effort would also include model development, analysis of results, and complete documentation of the model(s) and analyses to support the technical basis development, the proposed rulemaking, and the response to comments for the final rulemaking.<sup>1</sup>
- A new environmental analysis consistent with the *National Environmental Policy Act of 1969* (NEPA) to evaluate the environmental impacts of both the proposed (preferred) action and alternative actions relative to the disposal of the types and kinds of waste streams that might be managed in any commercial LLW disposal facility.<sup>2</sup>
- An engineering study evaluating the state-of-the-art practices and technologies bearing on the siting, design, and operation of both near-surface and intermediate depth LLW disposal facilities that would serve as the basis for any updated or new regulatory requirements concerning the disposal of commercial LLW.
- Any new guidance necessary to support a particular rulemaking option, as well as revise and consolidate existing guidance into at least two volumes: one with a focus on waste generation and one for site operation. Due to the age of most of the major guidance in the LLW arena, most of the guidance will probably need to be modernized regardless of the option selected. For example, LLW still has both a standard format and content

---

<sup>1</sup> For Options #1 and #4 and possibly Option #2, the performance assessment analyses would be the basis for new values in the existing waste classification tables or define new categories (for Option #4). For Option #3, the performance assessment analyses would evaluate the need for additional requirements to support a waste acceptance criteria type of an approach.

<sup>2</sup> The scope of this environmental review is discussed in Enclosure 2.

guide (NUREG-1199) and a standard review plan (NUREG-1200), both of which were last updated in the early 1990s, whereas most other programs have consolidated the two documents into one. As part of the last Strategic Assessment (SECY-07-0180), guidance update and consolidation was considered a medium priority due to the resources available to the program.

Also, based on past experience with the “below regulatory concern” policy issue, the *de minimis* issue has been omitted from the respective resource estimates described below. If the Commission directs the staff to consider a *de minimis* provision in any revision to Part 61, it is expected that the resource estimate would substantially increase due to heightened stakeholder interest in this topic.

Finally, if the Commission directs the staff to undertake a revision to Part 61, any of the rulemaking options outlined below (with the exception of Option #5) would be sufficient to address Gap #16, identified by the staff, pertaining to the classification of some of the radioactive wastes associated with the commercial reprocessing of spent nuclear fuel in any future NRC role. This moderate priority regulatory gap is described in SECY-09-0083 (May 28, 2009).

## **Rulemaking Options**

### **1. *Risk-Inform the Current Part 61 Waste Classification Framework***

In SRM-SECY-08-0147, the Commission previously directed the staff to budget resources to risk-inform the waste classification framework in § 61.55, with conforming changes to the regulations as needed, using updated assumptions and referencing the latest International ICRP dosimetry. When Part 61 was originally developed, staff relied on the current version of the ICRP recommendations in NRC regulations, which at the time was ICRP Publication 2 (ICRP, 1959). Consistent with previous Commission direction, this option would preserve the current Part 61 waste classification system (e.g., Class A, Class B, and Class C LLW). The staff would re-evaluate Tables 1 and 2 of § 61.55(a) in the context of newer dose conversion factors described in ICRP Publication 103 (ICRP, 2007) and determine whether the tables should be revised. Upon review, it is likely that some of the 12 radionuclides in the tables may have their concentrations adjusted, which could result in changes to the classification of some of the radionuclides. In addition, the waste classification of depleted uranium and other longer-lived radionuclides, not considered within the scope of the original analysis for Part 61, would need to be evaluated under this option.

The introduction of additional radionuclides to the § 61.55(a) tables would add a level of complexity to this rulemaking option that might require a technical re-evaluation of those provisions of the current Part 61 rule that are logically connected to those tables.

Currently, proposed resource estimates to support the scope of work envisioned under this option have anticipated some of the complexity described above.<sup>3</sup>

Based on the aforementioned discussion, a preliminary estimate of the resource needs associated with this effort is listed below.

Activity <sup>4</sup>	FTE	Dollars (\$K)
Performance Assessment Analyses	5.5	500
NEPA Analysis	1.1	1500
LLW Engineering Study	0.5	500
Project Management	2.0	0
Technical Basis Development	1.0	0
Rulemaking	1.0	0
<b>TOTAL<sup>5</sup></b>	<b>11.1</b>	<b>2500</b>

## 2. Comprehensive Revision to Part 61

As noted in the main body of this SECY paper, this option essentially involves asking stakeholders to work with the staff to develop a new Part 61. Stakeholders would be asked if there is continued support for the current Part 61 regulatory framework or whether some other option would be preferable.

The staff has considered the necessary steps to develop a comprehensive revision to Part 61. A key planning assumption is that in any potential revision to the regulation, the staff would not need to revisit some of the initial decision-making steps associated with the initial development of Part 61. See Ryan et al. (2007). Foremost among these would be questions about “*Who should be protected?*” and “*What should the level of protection be?*” These questions were essentially addressed by the Subpart C performance objectives which the staff believes continue to be fully protective of the public and would not require re-evaluation. The on-going rulemaking to add an explicit performance assessment requirement and intruder dose calculation to the current Part 61 will provide additional assurance that the regulations are adequate to protect the public health and safety.

<sup>3</sup> In SECY-08-0147 (Option 4), this option was defined somewhat differently than now proposed. The revision previously envisioned would have relied on updated methodologies and assumptions different from those originally used to develop Part 61. For example, the staff suggested that they use certain key system variables currently in Part 61 such as disposal configurations, performance periods, institutional control periods, waste forms, site conditions, exposure pathways, and receptor scenarios would be re-evaluated as part of any rulemaking. The staff is now proposing to address these issues as part of a comprehensive revision to Part 61 under Option #2 in this paper. The staff also proposed 11 full-time equivalent and \$1400K to support the work originally outlined in SECY-08-0147. The current resource estimate reflects an expanded scope of work.

<sup>4</sup> The aforementioned activities are likely to be the key schedule drivers of any comprehensive rulemaking revision as they represent those features of the rulemaking action that are technically the most challenging, will take the longest to complete, and require the largest proportion of resources dedicated to this effort.

<sup>5</sup> Total does not include currently-allocated fiscal year (FY) 2011 resources or additional resources necessary for public outreach effort during the FY 2011-12 period.

Based on the aforementioned discussion, a preliminary estimate of the resource needs associated with this effort is listed below.

Activity <sup>4</sup>	FTE	Dollars (\$K)
Waste Generator Survey	1.0	1000
Performance Assessment Analyses	6.0	500
NEPA Analysis	1.5	1500
LLW Engineering Study	0.5	500
Project Management	2.0	0
Technical Basis Development	1.0	0
Rulemaking	1.0	0
TOTAL <sup>5</sup>	13.0	3000

### 3. Site-Specific Waste Acceptance Criteria

Another plausible approach to the regulation of commercial LLW is to adopt all or some of the system employed by DOE for the management of LLW. This option focuses primarily on changes to § 61.55, but could also extend to the rest of Part 61.

Some LLW is not regulated by the Commission under the Atomic Energy Act - DOE, operating under different rules from the commercial sector, also manages and disposes of Government-owned LLW. Government-owned LLW includes waste created from past nuclear weapons production and research, environmental restoration of Federal facilities, and routine operations of the U.S. Navy's naval nuclear propulsion program.<sup>6</sup> To ensure consistent management of its facilities, DOE has relied on "orders" (i.e., policies, guidelines, and minimum requirements) supplemented by implementing manuals, which provide specific implementation instructions. The orders represent the key contractual requirements each facility operator must meet for the generation, treatment, storage, and disposal of wastes at a particular site (to the extent the service contract specifies particular orders). DOE Order 435.1-1, "Radioactive Waste Management" (DOE, 2001), covers all Government-owned high-level radioactive waste (HLW), LLW, transuranic radioactive (TRU) waste, and the radioactive components of chemically-mixed LLW. The current Order 435.1-1 contains three basic performance objectives (i.e., radiological dose criteria) that are intended to protect the public, workers, and the environment. Waste generators within the DOE complex take into account life-cycle planning considerations intended to comply with site-specific waste acceptance criteria (WAC) for a particular disposal facility to ensure that all Government-owned waste has an identified disposal path. By relying on a performance-based directive coupled to a site-specific WAC, DOE field managers have the flexibility to determine the quality and quantity of waste that can be disposed of at a particular site based on a particular disposal facility design and waste inventory. This approach is different from Part 61 which relies on generic waste classification tables in § 61.55 rather than a site-specific WAC.

<sup>6</sup> It should be noted that a greater proportion of Government-owned LLW is chemically mixed, estimated to be between 50 and 80 percent, which affects the Department's management strategy for these wastes (National Research Council, 1999, p. 25).

The implementing guidance for DOE Order 435.1-1 is DOE Manual 435.1-1 (DOE, 1999). DOE Manual 435.1-1 is similar in content to Part 61 in certain key respects. Like Part 61, DOE Manual 435.1-1 emphasizes an integrated-systems approach to LLW management and disposal, including consideration of site selection, facility design and operation, waste acceptance and waste form requirements, and disposal facility closure.<sup>7</sup> These requirements ensure that any particular site, including appropriate design and minimum waste acceptance criteria, can operate safely and comply with all applicable regulations, both during facility operation and after site closure. Similar to Part 61, DOE Order 435.1-1 has no *de minimis* provision.

Where DOE Order 435.1-1 differs from Part 61 is in how LLW is differentiated and classified for the purposes of management. DOE does not have the same three-tier classification system as Part 61. Rather, as mentioned above, all DOE-operated LLW facilities, operations, and activities have site-specific WAC to ensure that the LLW received at any particular facility can be safely managed and dispositioned. The DOE WAC includes the following elements: limits on radiological content and concentration; minimum waste form and container requirements; and certain physical prohibitions<sup>8</sup>. Each DOE disposal facility has site-specific WAC derived from a periodically updated site-specific performance assessment. Lastly, although DOE has prohibitions against the intentional blending or mixing of LLW to avoid treatment of a particular radioactive waste stream as TRU, under 40 CFR Part 191, the Department does allow mixing of LLW. Because DOE does not use the three-tiered classification system used in Part 61, “mixing to reduce the waste class” is not an issue.<sup>9</sup>

Conceptually, this third option would be to retain the Part 61 Subpart C performance objectives while eliminating the § 61.55 waste classification tables. In turn, a new provision would be added to Part 61 to require all licensees prepare a site-specific WAC, consistent with the results of a site-specific performance assessment that meets the Subpart C performance objectives. By introducing what in effect would be a radionuclide-neutral regulation, licensees would need to back-out of the performance assessment calculation an absolute value for both the isotopic concentration of radioactive material and quantity of material the disposal facility design was capable of receiving, taking into account the Part 61 performance objectives. This radionuclide-neutral regulation would require licensees to use the Part 61 performance objectives to calculate an absolute value for both the isotopic concentration and quantity of radioactive material suitable for disposal at each separate facility.

Finally, if this option were adopted, NRC staff would likely have to provide additional technical support to the Agreement States because of the expected increase in technical assistance requests to aid in the review of any site-specific performance assessments.

---

<sup>7</sup> To ensure effective management of DOE wastes, the manual focuses on the front-end of the LLW life cycle by including provisions for waste generation planning (i.e., waste minimization), waste characterization, transportation requirements, and waste certification.

<sup>8</sup> For example, waste package external surface dose rate, free liquid content, amount of void space, and certain radionuclide, chemical, or hazardous material restrictions. Current Part 61 addresses most of these prohibitions.

<sup>9</sup> Any waste streams eligible to be treated as TRU would contain a radionuclide with a half-life greater than 20 years and would have a concentration greater than 100 nCi/g, otherwise the waste stream would be considered to be LLW by DOE.

Based on the aforementioned discussion, a preliminary estimate of the resource needs associated with this effort is listed below.

Activity <sup>4</sup>	FTE	Dollars (\$K)
Performance Assessment Analyses	4.0	500
NEPA Analysis	1.0	1000
LLW Engineering Study	0.5	500
Project Management	2.0	0
Technical Basis Development	1.0	0
Rulemaking	1.0	0
TOTAL <sup>5</sup>	9.5	2000

#### 4. *International Alignment*

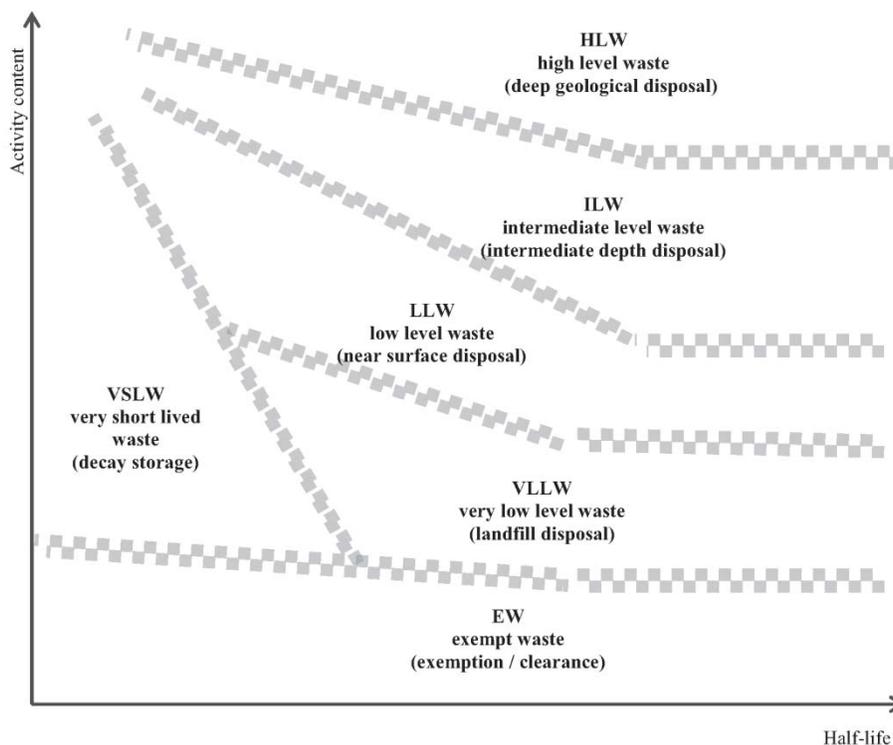
A third alternative that might be considered is to adopt the recent recommendations of the International Atomic Energy Agency (IAEA) for the management of radioactive wastes. In 2009, the IAEA established a classification scheme that accounts for both operational radioactive waste-handling as well as the disposition of those radioactive wastes. In General Safety Guide (GSG)-1, the IAEA outlined a comprehensive radioactive waste management approach by relating the radiological hazard posed by a particular waste stream to a specific disposition strategy. To this end, the IAEA classification scheme extends beyond the radioactive wastes that would be managed under any Part 61 regulatory paradigm to include those radioactive wastes streams encompassing the complete nuclear fuel cycle, including high-level and greater-than-Class C<sup>10</sup> (GTCC) radioactive wastes. The key thesis to the IAEA's waste classification scheme is that the hazard represented by short-lived radionuclides is different from that corresponding to isotopes with longer half-lives. Consequently, different management schemes are appropriate for different types of radioactive wastes. Moreover, the IAEA recommends that those waste streams that can be characterized as low-activity or even waste streams that have decayed to levels comparable to background be exempt from regulatory control and treated essentially as non-hazardous waste.

There are six waste streams that form the basis for the IAEA GSG-1 recommendations (described in Table 2). Table 2 also shows how these six waste streams in question generally correspond to the regulatory framework employed in the United States for the management of similar radioactive wastes. GSG-1 also relates these six waste streams conceptually in a diagram (see Figure 1). To help differentiate the respective waste classes, GSG-1 describes in qualitative terms what the thresholds are between the various waste classes as well as providing some general recommendations on acceptable management practices.

<sup>10</sup> IAEA-defined Intermediate Level Waste (ILW) can include either commercial GTCC-type wastes, regulated by the NRC under Part 61, or TRU wastes, regulated by the U.S. Environmental Protection Agency (EPA) under 40 CFR Parts 191 and 194, and disposed of at DOE's Waste Isolation Pilot Plant.

**Table 2. IAEA GSG-1 Waste Streams**

Type	IAEA Definition (2009, pp. 6-7)	US System
Exempt Waste (EW)	Waste that meets the criteria for clearance, exemption or exclusion from regulatory control for radiation protection purposes as described in (IAEA 2004)	§20.2001 §40.13(a)
Very-Short Lived Waste (VSLW)	Waste that can be stored for decay over a limited period of up to a few years and subsequently cleared from regulatory control according to arrangements approved by the regulatory body, for uncontrolled disposal, use or discharge. This class includes waste containing primarily radionuclides with very short half-lives often used for research and medical purposes.	10 CFR 20
Very Low-Level Waste (VLLW)	Waste that does not necessarily meet the criteria of EW, but that does not need a high level of containment and isolation and, therefore, is suitable for disposal in near surface landfill type facilities with limited regulatory control. Such landfill type facilities may also contain other hazardous waste. Typical waste in this class includes soil and rubble with low levels of activity concentration. Concentrations of longer lived radionuclides in VLLW are generally very limited.	§20.2002 §40.13(a)
Low-Level Waste (LLW)	Waste that is above clearance levels, but with limited amounts of long lived radionuclides. Such waste requires robust isolation and containment for periods of up to a few hundred years and is suitable for disposal in engineered near surface facilities. This class covers a very broad range of waste. LLW may include short lived radionuclides at higher levels of activity concentration, and also long lived radionuclides, but only at relatively low levels of activity concentration.	10 CFR 61
Intermediate-Level Waste (ILW)	Waste that, because of its content, particularly of long lived radionuclides, requires a greater degree of containment and isolation than that provided by near surface disposal. However, ILW needs no provision, or only limited provision, for heat dissipation during its storage and disposal. ILW may contain long lived radionuclides, in particular, alpha emitting radionuclides that will not decay to a level of activity concentration acceptable for near surface disposal during the time for which institutional controls can be relied upon. Therefore, waste in this class requires disposal at greater depths, of the order of tens of meters to a few hundred meters.	TRU: 40 CFR 191 and 40 CFR 194
		GTCC: 10 CFR 60 or 10 CFR 63
High-Level Waste (HLW)	Waste with levels of activity concentration high enough to generate significant quantities of heat by the radioactive decay process or waste with large amounts of long lived radionuclides that need to be considered in the design of a disposal facility for such waste. Disposal in deep, stable geological formations usually several hundred meters or more below the surface is the generally recognized option for disposal of HLW.	10 CFR 60 or 10 CFR 63



**Figure 1. Conceptual Illustration of IAEA Waste Classification System**

Like Option #3 described above, the IAEA system allows for development of site-specific WAC for LLW disposal. This option is different from Options #1 and #2; the spectrum of waste covered is much broader than that to be disposed of in a near-surface disposal facility. As indicated by both the table and the figure, the IAEA system includes wastes classes that can be regarded under the United States' system as HLW, GTCC (i.e., intermediate level waste), LLW, and wastes suitable for decay in storage. The principal difference between the IAEA and the Part 61 waste characterization schemes concerns what might generically be considered LLW. The IAEA system further separates LLW to include IAEA-designated exempt wastes (EW) as well as very low level waste (VLLW); Part 61 does not include these distinctions. For example, Part 61 does not include a provision that defines the lower radiological threshold for the application of the regulation. Although the concentration tables at § 61.55(a) provide an (upper) boundary between LLW suitable for near-surface disposal and GTCC, there is no comparable lower-level boundary in Part 61. While there is no generic exemption for low-concentration radioactive wastes, licensees that possess NRC-regulated wastes comparable to IAEA EW, can seek exemptions under the provisions of § 20.2001 or § 40.13(a).<sup>11</sup>

<sup>11</sup> Regarding wastes that are comparable to IAEA VLLW [i.e., so-called low activity radioactive waste as well as naturally-occurring radioactive material], in a very few instances, some Agreement States have sanctioned the disposal of comparable types of LLW in Subtitle C disposal cells or Subtitle D landfills regulated under the provisions of EPA's regulations pertaining to the *Resource Conservation and Recovery Act of 1996* on a case-by-case basis. See Ryan (2008).

The analysis for this option would likely be more complex than for the other options because it would focus on the full spectrum of wastes associated with the greater nuclear fuel cycle.

In summary, if the international alignment option were to be adopted, it would be necessary to develop regulatory criteria under both Parts 20 and 61 comparable to the IAEA waste class EW, VLLW, and ILW. This system would also be flexible enough to address potentially new radioactive waste streams, such as those waste streams associated with reprocessing of spent nuclear fuel as well as what might be called 'yet-to-be-defined' or future waste streams. Also, in light of the recent developments surrounding the Yucca Mountain HLW program, it may be necessary to give consideration to the development of intermediate depth disposal criteria for GTCC wastes as well.

Based on the aforementioned discussion, a preliminary estimate of the resource needs associated with this effort is listed below.

Activity <sup>4</sup>	FTE	Dollars (\$K)
Waste Generator Survey	1.0	1000
Performance Assessment Analyses	7.0	500
NEPA Analysis	2.0	2000
LLW Engineering and Storage Study	1.0	750
Project Management	2.0	0
Technical Basis Development	1.0	0
Rulemaking	1.0	0
TOTAL <sup>5</sup>	15.0	4250

### **5 *Supersede Direction Given in SRM-08-0147***

This option is essentially the *status quo* option, but would not affect the on-going rulemaking requiring the addition of an explicit performance assessment requirement to current Part 61. Under this option, the Commission would retract its earlier direction contained in SRM-SECY-08-0147 to risk-inform the current waste classification tables at § 61.55(a).

#### **References Cited**

International Atomic Energy Agency, "Classification of Radioactive Waste – General Safety Guide," Vienna, International Atomic Energy Agency Safety Standards Series No. GSG-1, 2009.

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

International Commission on Radiological Protection, "Recommendations of the International Commission on Radiological Protection," *Annals of the ICRP*, Vol. 1, No. 3, 1977. [ICRP Publication 26.]

International Commission on Radiological Protection, "Recommendations of the International Commission on Radiological Protection," *Annals of the ICRP*, 37(2-4), (2007). [ICRP Publication 1030]

National Research Council, "The State of Development of Waste Forms for Mixed Wastes – U.S. Department of Energy's Office of Environmental Management, Washington, D.C., National Academy Press, 1999.

Ryan, M.T., M.P. Lee, and H.J. Larson, "History and Framework of Commercial Low-Level Radioactive Waste Management in the United States," U.S. Nuclear Regulatory Commission, NUREG-1853, January 2007.

Ryan, M.T., Chairman/Advisory Committee on Nuclear Waste and Materials, Letter to Dale E. Klein, Chairman/U.S. Nuclear Regulatory Commission, Subject: "Advisory Committee on Nuclear Waste and Materials Low-Activity Radioactive Waste Working Group Meeting of February 13-14, 2008," April 30, 2008. [ML081220463]

U.S. Department of Energy, "Order 435.1. Subject: Radioactive Waste Management," Office of Environmental Management, July 9, 1999.

U.S. Department of Energy, "Radioactive Waste Management Manual," Office of Environmental Management, DOE M 435.1-1, June 16, 2001. [Updated edition.]

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.

## KEY POLICY ISSUES TO BE CONSIDERED IN AMENDING 10 CFR PART 61

When considering the rulemaking options described in the paper, the staff found that there are a common set of issues for Commission consideration if it chooses to amend Part 61. A brief discussion of the significance of the issue relative to the respective rulemaking options described in Enclosure 1 is also provided.

### **The *National Environmental Policy Act of 1969*, as amended**

In support of any proposed rulemaking involving a comprehensive revision to Part 61, a new environmental review would be required under the National Environmental Policy Act (NEPA), and the U.S. Nuclear Regulatory Commission's (NRC's) NEPA implementing regulations (10 CFR Part 51). In addition, NUREG-1748, "*Environmental Review Guidance for Licensing Actions Associated with NMSS Programs*," provides guidance to the NRC staff for conducting environmental reviews for certain types of agency actions, including rulemaking. NEPA mandates that Federal agencies carefully evaluate the environmental impacts of their actions prior to making decisions that affect the environment. The type of NEPA review required for each NRC rulemaking, such as those being considered under the comprehensive Part 61 revision options, depends on the effect of the proposed action on the quality of the human environment. When a specific rulemaking action is defined, the NRC staff first determines whether a categorical exclusion (CATX) is applicable for the proposed action. CATXs are categories of actions that the NRC has determined do not individually or cumulatively have a significant effect on the human environment. Criteria for identifying a CATX and a list of actions eligible for CATX are provided in § 51.22. For rulemakings, categories of actions appropriate for CATX include administrative, organizational, or procedural amendments to certain types of NRC regulations. If a CATX is applicable, the finding would be briefly documented and, although the proposed action is subject to no further NEPA review, it is still evaluated for compliance with NRC radiation protection regulations and other applicable environmental regulations.

If no CATX applies, the staff must prepare an environmental assessment (EA) under § 51.21 or an environmental impact statement (EIS) under § 51.20. An EA is typically a concise, publicly available document that provides sufficient evidence and analysis for determining whether to prepare a finding of no significant impact (FONSI) or an EIS. If the EA supports a FONSI, the environmental review process is complete. However, if the EA reveals the proposed action may significantly affect the environment and cannot be mitigated, the environmental review activities transition to the development of an EIS. Alternatively, it could be clear from the beginning of the rulemaking process that an EIS is appropriate, either because the rulemaking is a major Federal action significantly affecting the quality of the human environment (10 CFR 51.20(a)(1)) or because the Commission has determined that the action should be covered by an EIS (10 CFR 51.20(a)(2)). An EIS provides decision makers and the public with a detailed and objective evaluation of the environmental impacts, both beneficial and adverse, likely to result from a proposed action and reasonable alternatives to the proposed action. In contrast to the analysis in an EA, an EIS includes a more detailed interdisciplinary review. The EIS provides sufficient

evidence and analysis of impacts to support the final NRC action in the Record of Decision (ROD)<sup>1</sup> or other Commission documentation containing similar information. The draft and final EIS and ROD are made available to the public.

***Significance of Issue:*** *The ‘Risk-informed Waste Classification System,’ ‘Comprehensive Revision,’ and ‘Extensive International Alignment’ options may require the development of an EIS because those actions will likely involve consideration of new waste streams and isotopes, including those DOE legacy wastes, not considered in the original Part 61 EIS. Similarly, if the scope of the ‘Site-Specific WAC’ option is to include new waste streams and isotopes, an EIS may also be appropriate. It should be noted, however, that the respective NEPA actions have associated resource implications – CATX being the least resource intensive action and an EIS being the most resource-intensive action.*

### **The Low-Level Radioactive Waste Policy Amendments Act of 1985**

A change in the Part 61 classification scheme would create inconsistencies between the disposal regulations and the scheme developed by Congress to assign responsibility for the disposal of LLW. Responsibility for the disposal of LLW is assigned through the Low Level Radioactive Waste Policy Amendments Act of 1985 (LLRWPA), which assigns responsibility based on the classification of the waste in § 61.55 as it existed in January 1983. Under the current regulations, the classification for the purposes of Part 61 disposal and assigning responsibility are identical, changes to the Part 61 classification scheme would create inconsistencies between the two systems. These inconsistencies would require LLW generators to go through a two-step process prior to the disposal of LLW: (1) determine who is responsible for disposal of the LLW based upon the 1983 regulations; and (2) determine how to properly dispose of the LLW using the new Part 61 regulations.

This new process will result in four scenarios with respect to LLW that are now acceptable for disposal at a Part 61 facility: (1) Waste that is a State responsibility under the LLRWPA and that is acceptable for disposal at a Part 61 facility; (2) LLW that is a State responsibility under LLRWPA and is no longer acceptable for disposal at a Part 61 facility; (3) LLW that is a Federal responsibility and that is acceptable for disposal at a Part 61 facility; and (4) LLW that is a Federal responsibility and that is no longer acceptable for disposal at a Part 61 facility. Under these four scenarios, only one scenario, scenario (2), is of concern. The other scenarios have [or will have] disposal pathways available (i.e., at either State or Federal facilities), scenario (2), however, would result in a waste stream that is a State responsibility, but at the same time is not acceptable for disposal at a Part 61 facility.

---

<sup>1</sup> Sections 51.102-103, the ROD is a concise statement of: (a) what the decision is; (b) all alternatives considered by the NRC and specifying the alternative(s) considered to be environmentally preferable; (c) preferences among alternatives based on relevant factors; (d) whether the NRC has taken all practicable measures within its jurisdiction to avoid or minimize environmental harm from the selected alternative and if not, explain why; and (e) summarize any license conditions or monitoring programs adopted as mitigation measures, if applicable. The ROD may be integrated into any other record prepared by the Commission in connection with the proposed action [§ 51.103(c)]. The ROD may also incorporate by reference material contained in a final EIS.

For rulemaking actions, there is no applicant to provide environmental information, though in some cases there may be a petitioner for rulemaking who would supply environmental information. Generally, the environmental information needed to support the rulemaking environmental review is developed by NRC staff and contractors. Rulemaking EIS's usually do not contain site-specific information though generic sites or situations may be described.

The staff has considered this issue, and believes that it will be able to take action to address scenario 2 before it becomes a problem. LLW that is currently eligible for disposal at Part 61 facilities and would be excluded by the revisions to Part 61 will be identified by disposal facility regulators before the start of this comprehensive rulemaking as part of the process implemented by the unique waste streams rulemaking. This comprehensive look at Part 61 will allow the staff to evaluate this LLW (if any exists) and possibly develop regulations to allow for the safe disposal of this LLW at a Part 61 facility.

The one minor problem that neither rulemaking can address is the additional step discussed above that will be necessary to determine the appropriate disposal pathway for the waste. Under the new system, LLW generators will have to first assess whether the State or the Federal government is responsible for the disposal of the LLW through the LLRWPAA system. Generators will then use the new Part 61 requirements to determine how to appropriately dispose of the LLW.

**Significance of Issue:** *This issue would apply to any rulemaking option that abandons or modifies the current designation of LLW as Class A, B, or C, and GTCC.*

### **Implementation**

When selecting a particular rulemaking option, a question that arises is how the rulemaking option would be implemented. Two of the proposed options, the 'Risk-inform Waste Classification System' and the 'Site-Specific WAC,' favor limited amendments to the existing Part 61 regulation, essentially leaving the rule intact. Implementation of any rulemaking amendments suggested by either option should not be an onerous challenge to the Agreement States. By comparison, the 'Comprehensive Revision' and 'Extensive International Alignment' options imply a new regulation for the management of commercial LLW, a new Part 6X. As a practical matter, it might be advisable for any new Part 6X to apply only to future licensees. In the case of nuclear power plant licensing, for example, the Commission's regulatory philosophy currently differentiates between the existing fleet of operating plants licensed under Part 50 and those new plants currently undergoing licensing reviews under Part 52, so the existence of a licensing dichotomy in the LLW program should not be problematic. Moreover, retroactive application of any new disposal standards might prove to be impracticable to implement at existing sites, and may lead to unintended consequences for commerce in this area.

**Significance of Issue:** *The rate at which new LLW disposal sites were to be established as originally envisioned under the Low-Level Radioactive Waste Policy Act of 1980 argued against the development of a new commercial LLW regulation (a new Part 6X). Consequently, it might be advisable to rely on the approach used when Part 61 was first developed in relation to existing LLW disposal facilities. That is to say, the new Part 61 did not apply retroactively to existing disposal sites. The Agreement States were allowed to exercise discretion on how the rule was to be applied to those facilities in operation at the time. In this regard, any one of the options described in this paper could be implemented in whole or in part in the context of amendments to existing Part 61. The Agreement States, in turn, would have discretion in how those new or amended provisions of the regulation would be applied to currently-licensed LLW disposal facilities.*

## Earlier Stakeholder Interest

The staff previously received feedback on a number of ongoing initiatives related to the limited rulemaking to address unique waste streams including the blending of LLW. In the context of the unique waste streams rulemaking and its associated public workshops, the staff received the following comments:

- Modify regulations to require a site-specific analysis with a compliance period of performance of 10,000 years consistent with NUREG-1573 (“A Performance Assessment Methodology for Low-Level Radioactive Waste Disposal facilities”<sup>2</sup>) and 40 CFR Part 191. If peak dose occurs after this period, require a qualitative analysis.
- Require periodic updating of the performance assessment to reflect changed conditions at the site, past disposal history, and new methodology.
- Require a dose standard for an inadvertent intruder of 500 mrem/yr.

Regarding staff efforts in the area of blended LLW<sup>3</sup>, additional stakeholder comments were received concerning potential revisions to Part 61. These comments were obtained from the public meeting held January 14, 2010, letters from industry, interested members of the public and the March 2010 *Regulatory Information Conference*. Summarized below are examples of some of the more significant comments received:

- Engage stakeholders early and often in developing a technical basis for updating and reforming Part 61.
- Consider the full spectrum of implications of making changes to the framework of Part 61 in regard to political realities, economic consequences, and regulatory concerns.
- Require performance assessments for all waste streams demonstrating compliance with the performance objectives of Part 61 and update these performance assessments periodically.<sup>4</sup>
- Performance assessments need to use more consistent models and memorialize assumptions.
- Update the original Part 61 EIS with more recent data.

---

<sup>2</sup> NUREG-1573 (circa 2000) actually cites SECY-96-0147 as the source of the initial staff recommendation concerning the 10,000 year period of performance.

<sup>3</sup> See <http://www.nrc.gov/waste/llw-disposal/llw-pa/llw-blending.html>

<sup>4</sup> J. Lieberman and J. Greeves have commented individually, jointly, and on behalf of Talisman International, Inc. Their recommendations (designated with been a superscript ‘4’) can be found in ADAMS (ML0930904841, ML1016704081, ML1016704070, and ML1021501680). In summary, their recommendations have focused primarily on changes to §§61.13 and 61.58 of the existing rule.

- Consider the latest IAEA waste classification system and reference the latest ICRP methodology.<sup>4</sup>
- Work with DOE as they update their waste requirements (DOE Order 435.1) to ensure consistency in waste management and disposal practices on a national level.<sup>4</sup>
- Cesium-137 figures prominently in overall classification and intruder risk. Does it make sense that all our risk is predominately defined by one radionuclide?
- Make § 61.58, “*Alternative requirements for waste classification and characteristics*,” a Compatibility Level B.<sup>4, 5</sup>
- Continue with existing waste classification system which is referenced in Section 3 of the LLRWPA and is needed to establish the boundary between State and Federal responsibility.<sup>4</sup>
- Commercial LLW is currently well regulated and managed safely.
- Commercial LLW should be classified when packaged or containerized for disposal.

Finally, as noted earlier in Enclosure 1, the Advisory Committee on Nuclear Waste and Materials, and the Advisory Committee on Reactor Safeguards have provided recommendations to the Commission previously on how to improve those RI/PB aspects of Part 61. In particular, the Committee has often suggested that the § 61.55 tables should be replaced with a concentration and quantity-based provision.

***Significance of Issue:*** *Some of the comments received thus far will be addressed as part of the ongoing unique waste streams rulemaking. For any remaining stakeholder comments, the staff intends to consider all comments received in connection with any future Part 61 rulemaking.*

---

<sup>5</sup>The staff considered the use of § 61.58 when it developed SECY-08-0174. As noted in that paper, § 61.58 “may have been designed to allow licensees to perform and submit evaluations to address the performance requirements in Subpart C to Part 61 without a rule change. But the use of an exception provision like § 61.58 to *require* an additional site-specific study on certain Class A waste streams, without any associated rule change, is inconsistent with the basic premise of an exception. Specifically, the purpose of building an exception into a generally applicable rule is to allow an activity that would not otherwise be permitted, rather than to impose an additional requirement (e.g., performance of a site-specific study) on an activity that is already permitted (e.g., near-surface disposal of Class A waste). Thus, if § 61.58 were utilized to approve an alternate classification or characteristic, such action would provide additional options for a licensee, but would not require use of a particular option. Compliance with the approved alternative would not be the *only* method of compliance. Therefore, if the staff intended to use § 61.58 in order to develop an alternate waste classification or alternate characteristics for a Class A waste stream such as DU, and to *require* licensees to conform to the alternate classification or characteristics as the sole method of compliance in place of (as opposed to as an alternative to) the existing regulations, a rule change would be necessary.

## Clearance

Section 10 of the LLWPAA required that the NRC establish standards for determining when radionuclides present in waste streams in sufficiently low concentrations or quantities could be considered to be “below regulatory concern” (BRC), and thus exempt from NRC’s Part 61 LLW regulation. Before the passage of the LLWPA in 1980, the staff had already indicated its intent (45 FR 13106) to formally establish a *de minimis* level for commonly used, short-lived radioisotopes when it announced the availability of a preliminary draft version of the Part 61 regulation. The staff provided additional clarification of its *de minimis* position in the draft Part 61 DEIS. As discussed in that position, radionuclides with very short half-lives could, on a case-by-case basis, be exempt from regulation under Part 61. Alternatively, if authorized, the exemption would generally require storage of the waste for a duration of 10 half-lives of decay (for the dominant radionuclide). Afterwards, the licensee could dispose of the wastes in a manner consistent with its nonradiological properties (NRC, 1981, Volume 2, p. 2-8). In August 1986, the Commission issued a policy statement outlining its plans to establish new rules and procedures to exempt specific radioactive waste streams from regulation due to the presence of radionuclides in sufficiently low concentrations or quantities as to be BRC. The subsequent *BRC Policy Statement* (51 FR 30839) contained criteria that, if adequately addressed, would allow the Commission to act expeditiously in providing the needed regulatory relief.

Both Congress and the public received the NRC’s proposed BRC policy unfavorably. See Walker (2000, p. 120) and National Research Council (2002, pp. 52–53). Later, Congress enacted the Energy Policy Act of 1992 (H.R. 776) to revoke the Commission’s earlier policy statements. As a result, the Commission officially withdrew the policy in June 1993 (58 FR 44610).

Later, in the 1990s, the Commission decided to reexamine its approach to the regulation of BRC materials, now in reference to the control of solid materials, under Part 20, “Standards for Protection Against Radiation.” In June 1999, the Commission requested public comment on an Issues Paper on this subject (64 FR 35090). In March 2000, the NRC staff provided the Commission with a paper (SECY-00-0070) on the diversity of views expressed in public comments received on the Issues Paper. The staff also provided the status of its technical analyses and noted the related actions of international and national organizations and agencies. Based on these various factors, the staff recommended that a final decision on whether to proceed with rulemaking be deferred and that the National Academies be requested to conduct a study of alternatives for control of solid materials. SECY-00-0070 also recommended that, while the National Academies study was ongoing, the staff continue to develop a technical information base for decision-making and stay informed of international and U.S. agency activities in this area.

In response to an NRC 2000 contract request, the National Academies delivered a report entitled “The Disposition Dilemma – Controlling the Release of Solid Materials from Nuclear Regulatory Commission-License Facilities,” dated March 2002. The Commission asked the National Academies’ National Research Council to recommend changes to the decision-making process for disposition of slightly radioactive solid material, and to determine whether sufficient technical information exists to establish a consistent nation-wide system. Overall, the National Academies and others have found that the current process for disposition of slightly radioactive solid material is not explicitly based on risks to human health and is inconsistently applied. In its

report, the National Academies found that the NRC's decision-making process is workable and protects public health, but it could benefit from a new framework that uses broad input from stakeholders, including the general public, to develop and evaluate options for disposal, reuse, and recycling.<sup>6</sup> In SECY-02-0133, the staff informed the Commission of: (1) the results of a study by the National Academies; (2) staff activities related to other factors that can affect decision-making on this issue; and (3) options and recommendations for proceeding. One of the staff-recommended options was an enhanced participatory rulemaking. In SRM-SECY-02-0133 (October 25, 2002), the Commission approved the enhanced participatory rulemaking, subject to certain conditions. In SECY-05-0054 (March 31, 2005), the staff requested Commission approval to publish a proposed rule to amend Part 20 to include radiological criteria for controlling the disposition of solid materials that have no, or very small amounts of residual radioactivity resulting from licensed operations, and that originate in restricted or impacted areas of NRC-licensed facilities. In an SRM dated June 1, 2005, the Commission informed the staff of its decision to disapprove publication of the proposed rule. In the SRM, the Committee noted that its:

... decision is based on the fact that the Agency is faced with several high priority and complex tasks, that the current approach to review specific cases on an individual basis is fully protective of public health and safety, and that the immediate need for this rule has changed due to the shift in timing for reactor decommissioning. As such, the Commission is deferring this rulemaking for the time being ....

***Significance of Issue:*** *If any commercial LLW regulation is to be truly risk-informed, it will be necessary to specify some threshold for which the waste stream is exempt from regulation as the risk to human health would be indistinguishable from background levels. Also, the IAEA radioactive waste classification system recognizes an exempt class of waste.*

## References

National Research Council, "The Disposition Dilemma – Controlling the Release of Solid Materials from Nuclear Regulatory Commission-License Facilities," Washington, D.C., National Academy Press, 2002.

U.S. Nuclear Regulatory Commission, "Draft Environmental Impact Statement on 10 CFR Part 61: Licensing Requirements for Land Disposal of Radioactive Wastes," Office of Nuclear Material Safety and Safeguards, NUREG-0782, 4 Vols., September 1981.

Walker, J.S., *Permissible Dose — A History of Radiation Protection in the Twentieth Century*, Berkeley, University of California, 2000.

---

<sup>6</sup> As a starting point in determining an appropriate dose-based standard for the disposition of material, the National Academies recommended using 1 millirem per year (10 micro-Sievert per year), which is a small fraction of the radiation received annually from natural and artificial sources, such as cosmic rays and medical X-rays.

## **Risk-Informed/Performance-Based Regulation Within the Materials Programs**

The terms *risk-informed* and *performance-based* (RI/PB) are defined in NRC's *Strategic Plan: Fiscal Years 2008-2013* (NUREG-1614). The staff defined *risk-informed* as "... a decision-making approach that uses risk insights, engineering judgment, safety limits, and other factors ...." It is used for establishing requirements that focus on issues commensurate with their importance to public health and safety (e.g., the risk to human health associated with exposure to ionizing radiation). Probabilistic risk assessment (PRA) is generally understood to define the systematic method used to address three particular questions<sup>1</sup> as they relate to the performance of a particular system, including the human component. PRA is an important tool used in implementing a risk-informed approach.

As discussed in Enclosure 1, the staff provided the Commission with a number of papers on RI/PB regulation and the PRA *Policy Statement*. A summary of these papers and how they apply to the Commission's waste management programs, including low-level radioactive waste (LLW), can be found in several Commission Papers. See COMSECY-96-061, SECY-98-0138, SECY-98-0144, and SECY-99-0100.

The NRC staff defines the term *performance-based* as "... using performance assessment results as the primary bases for decision-making ...." Performance-based regulations are measurable, calculable, or have objectively observable parameters, and provide for flexibility in determining how to meet the established performance criteria. NRC's LLW disposal regulation in Part 61 contains four performance objectives, two of which are evaluated using performance assessments that use models, parameters, and assumptions about future site conditions in determining whether a disposal facility can protect people and the environment.

Upon review of the Commission papers referenced above, as well as consideration of the past Part 61 development process described in NUREG-1853, the staff believes that the current LLW regulation is mostly RI/PB, although further improvements are possible. In fact, Part 61 is likely one of the earliest examples of the application of RI/PB principles within the agency.

When considering those RI/PB principles<sup>2</sup>, it should be noted that the current Part 61 regulatory model is based on a tiered waste classification system that emphasizes an integrated systems

---

<sup>1</sup> These questions are "*What can go wrong?*", "*How likely is it?*", and, "*What are the consequences?*" These questions represent the so-called Kaplan-Garrick (1981) risk triplet.

<sup>2</sup> In these papers, the staff previously noted that nuclear materials regulatory framework for the implementation of RI/PB principles was somewhat different from the regulatory framework used for nuclear power reactors. These differences stem primarily from differences between nuclear power reactors as engineered, man-made dynamic systems as opposed to waste disposal systems, which are essentially passive, natural systems that rely on some limited engineering measures. These differences also stem from differences between the PRAs themselves that have been used to evaluate nuclear power reactor safety and performance assessments that have been widely used to evaluate the waste disposal systems. For these reasons, the staff have concluded that the reactor PRA framework is not directly applicable to nuclear material uses because of differences among the activities regulated by the Office of Nuclear Material Safety and Safeguards (NMSS, which, at the time, included NRC's LLW programs) and those of the nuclear power reactor program, individually, as well as collectively between those NMSS activities and those found in the reactor program.

Nevertheless, the staff did note in SECY-99-0100 that the respective approaches used within the agency to evaluate risk regardless of the program in question are essentially in harmony because they address the fundamental questions raised by the Kaplan-Garrick risk triplet when evaluating any potential hazard. When focusing on risk, the

approach to the disposal of commercial LLW, including site selection, disposal facility design and operation, minimum waste form requirements, and disposal facility closure. This model also relies on limited institutional controls. To reach any licensing determination, applicants must demonstrate that the performance objectives of Subpart C would be met, with reasonable assurance. To meet those performance objectives, Part 61 license applicants need to prepare an assessment of potential future dose impacts to the general population as well as to individuals that might occur as a result of the operation of a commercial LLW disposal facility. Technical analyses (presently termed 'performance assessment,' although not described as such at the time the rule was first promulgated), would be used to estimate these future radiological doses. The requisite technical analyses and associated information needs for both the analyses and any licensing determination based on those analyses are provided in § 61.13(a)-(d). As early as 1982, the staff began to undertake a variety of performance assessment-related projects intended to aid in the evaluation of various features (both natural and man-made) of a Part 61-type of facility.<sup>3</sup>

Part 61 is thus intended to be performance-oriented rather than prescriptive in the sense that the rule has four performance objectives that must be met, with the result that Part 61's technical criteria are written in relatively general terms, allowing applicants to demonstrate how their proposals meet those criteria for various specific near-surface disposal methods, consistent with the ultimate goal of meeting the performance objectives. The *Statements of Consideration* for both the draft and final rule provided the overall philosophy and concepts supporting Part 61.<sup>4</sup>

The three-tier waste classification system at § 61.55(a) provides some level of assurance that the performance objectives at § 61.42 will be met. The Part 61 classification system described in that section of Part 61 considered human intrusion scenarios, which were believed to constitute the largest potential dose to any receptor. Key decision parameters in the waste classification system are the physical stability of the waste form as well as its isotopic concentration. The concentration limits were based on the staff's understanding at the time

---

staff also found that the objectives of the materials regulatory framework were essentially the same as those for the power reactor framework, namely to: (a) enhance safety by focusing NRC and licensee resources in areas commensurate with their importance to health and safety; (b) provide a framework for using risk information in all regulatory matters; and (c) allow use of risk information to provide flexibility in licensing and operational areas.

<sup>3</sup> Many of the products associated with the NRC-sponsored research effort are described in the references cited in NUREG-1573.

<sup>4</sup> In SECY-98-0138, in specific reference to questions concerning Part 61, the staff noted that the Commission's LLW rule fundamentally demonstrated a RI/PB approach to regulation, supplemented by a secondary level of requirements that were both deterministic and prescriptive. It is important to note that prior to issuance of the *1995 PRA Policy Statement*, the staff had already in-place a long-standing strategy to risk-inform the evaluation of LLW disposal facilities through the use of performance assessment methods. See Starmer, Deering, and Weber (1988). In implementing that strategy, the staff developed a LLW performance assessment plan in 1992 outlined in SECY-92-060. Consistent with that plan, the Sandia National Laboratories was retained to provide performance assessment technical assistance to the staff, documented in Kozak et al. 1990, which led to the publication of an early LLW test case calculation in 1992 (DOE et al., 1992). The staff subsequently updated the test case (i.e., Cady and Thaggard, 1994) in connection with the development of guidance on the attributes of an acceptable LLW performance assessment methodology. In connection with the development of those recommendations, the staff was communicating with the Commission on key policy issues associated with any LLW performance assessment in SECY-96-103. In response to Commission direction, following public comment, those key policy issues were later codified in NUREG-1853 (NRC 2000) — the Branch Technical Position on LLW performance assessment. This history is outlined in more detail in Eisenberg et al. (2000).

(circa 1978) of the characteristics and volumes of LLW reasonably expected for commercial disposal through the year 2000, as well as potential disposal methods likely to be used. The NRC viewed these parameters as important because they provide the minimum information necessary for basic decisions on the safe handling and disposal of commercial LLW.

Nevertheless, upon independent review by the Commission's former Advisory Committee on Nuclear Waste and Materials, as well as more recent reviews by the Advisory Committee on Reactor Safeguards, recommendations have been advanced on how to improve the RI/PB character of Part 61.

### References Cited

Cady, R., and M. Thaggard, "Summary and Insights from the NRC Branch Technical Position Test Case," in *16<sup>th</sup> Annual U.S. Department of Energy Low-Level Radioactive Waste Management Conference (Abstracts), Phoenix, Arizona, December 13–15, 1994*, Idaho Falls, U.S. Department of Energy Idaho Operations Office, 1994.

Eisenberg, N.A., M.P. Lee, T.J. McCartin, K.I. McConnell, M. Thaggard, and A.C. Campbell, "Development of a Performance Assessment Capability in the Waste Management Programs of the U.S. Nuclear Regulatory Commission," *Risk Analysis*, 19(5):847–876, October 1999.

Kaplan, S., and B.J. Garrick, "On the Quantitative Definition of Risk," *Risk Analysis*, 1(1): 11–27, March 1981.

Kozak, M.J., M.S.Y. Chu, and P.A. Mattingly, "A Performance Assessment Methodology for Low-Level Radioactive Waste Facilities," U.S. Nuclear Regulatory Commission, NUREG/CR-5532, July 1990.

Starmer, R.J., L.G. Deering, and M.F. Weber, "Performance Assessment Strategy for Low-Level Waste Disposal Sites," in *10<sup>th</sup> Annual U.S. Department of Energy Low-Level Waste Management Conference: Conference Proceedings (Session II: Site Performance Assessment), August 30 – September 1, 1988, Denver, Colorado, EG&G Idaho, CONF-880839-Ses.II, December 1988*.

U. S. Department of Energy, Department of the Interior, Federal Aviation Administration, Food and Drug Administration, National Aeronautics and Space Administration, National Science Foundation, Nuclear Regulatory Commission, and Occupational Safety and Health Administration, "Risk Assessment – A Survey of Characteristics, Applications, and Methods Used by Federal Agencies for Engineered Systems," U.S. Nuclear Regulatory Commission, November 1992.

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, "Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities: Proposed Policy Statement," *Federal Register*, Vol. 59, No. 235, pp. 63389–63391, December 8, 1994.