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 Po*licy 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.[1]

- 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.[2]

- 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

[1] 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.

[2] 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.[3]

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

Activity[4]	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
TOTAL[5]	**11.1**	**2500**

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.

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[3] 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.

[4] 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.

[5] 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[4]	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[5]	**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.[6] 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.

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[6] 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.[7] 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[8]. 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.[9]

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.

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[7] 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.

[8] 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.

[9] 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[4]	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[5]	**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[10] (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.

[10] 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

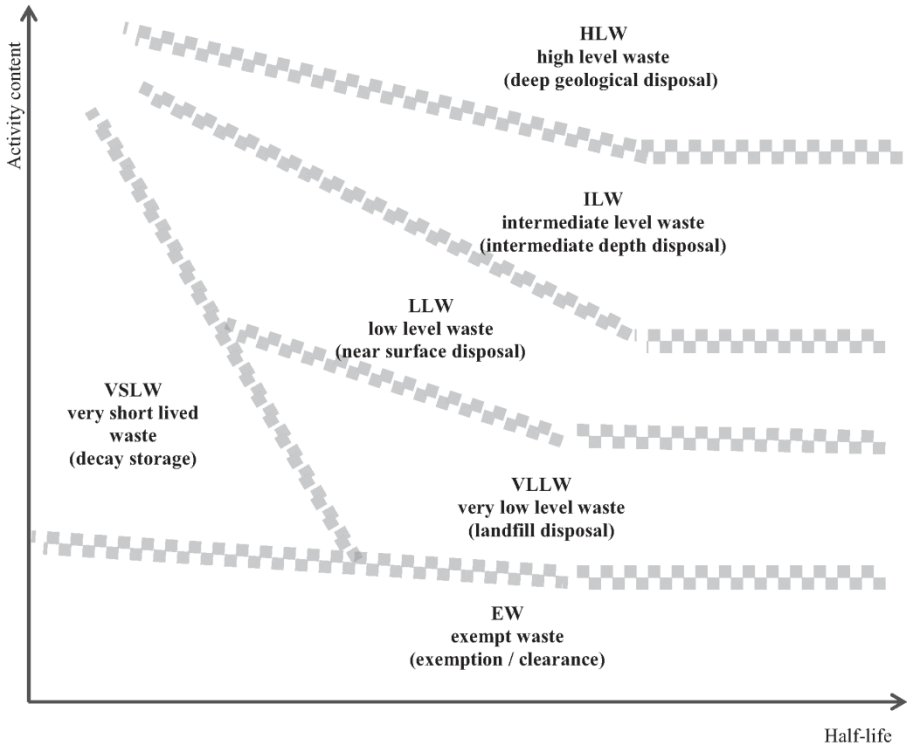

Figure 1. Conceptual Illustration of IAEA Waste Classification System

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).[11]

[11] 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[4]	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[5]	**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).

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