

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)¹ 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.

¹ 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 LLRWPA 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”²) 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 LLW³, 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.⁴
- Performance assessments need to use more consistent models and memorialize assumptions.
- Update the original Part 61 EIS with more recent data.

² 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.

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

⁴ 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.⁴
- 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.⁴
- 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.^{4, 5}
- 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.⁴
- 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.*

⁵The 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.⁶ 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.

⁶ 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.