

Risk-Informing 10 CFR Part 61-11463

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ABSTRACT

This paper will explore current regulatory issues with 10 CFR PART 61, “Licensing Requirements for Land Disposal of Radioactive Waste.” Part 61 combined a purely deterministic approach with a very prescriptive waste classification system (A, B, C, and GTCC) with some aspects of a risk-informed, performance-based approach. The regulatory framework established under Part 61 has generally stood the test of time being protective of the public health and safety. However, there are a number of deficiencies in Part 61 that if addressed could make the rule more performance-based and risk-informed.

The paper will provide the authors views on updating Part 61 to make it a risk-informed, performance-based rule thereby addressing deficiencies in the current regulation. This would include: requiring site specific performance assessment for both the public and intruder scenarios; setting a time of compliance for such calculations; setting a specific intruder dose standard; use of modern ICRP dose conversion recommendations; requiring periodic updates to the performance assessment to account for unique waste streams and improved site specific knowledge; upgrade compatibility requirements for 10 CFR 61.58; and stating in 10 CFR 61.55 the point in time for classifying waste.

I. INTRODUCTION

The United States Nuclear Regulatory Commission (NRC) promulgated requirements for the licensing of low-level radioactive waste (LLW) disposal sites in 1982. These regulations published on December 27, 1982 (47 FR 57463) are codified at 10 CFR Part 61. There is a substantial regulatory history for Part 61 that is relevant in understanding the rule.¹ For example, the waste classification system in 10 CFR 61.55 is based on the analysis in the draft and final Environmental Impact Statements that supported the Part 61 rulemaking.² NUREG-1853, History and Framework of Commercial Low-Level Radioactive Waste Management in the United States, issued by the NRC Advisory Committee on Nuclear Waste provides a good overview of the regulatory framework for LLW disposal in the United States.

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¹ Relevant documents include: Advanced Notice of Proposed Rulemaking, 43 FR49811 (October 25, 1978); Notice of Availability of a Preliminary Draft Regulation, 45 FR13104 (February 26, 1980); Notice of Proposed Rulemaking, 46 FR 38061 (July 24, 1981); Draft Environmental Impact Statement (EIS) (NUREG-0782) September 1981; and Final EIS (NUREG-0945) November 1982. NRC has also issued various guidance documents over the years addressing LLW disposal such as NUREG-1573, A Performance Assessment Methodology for Low-Level Radioactive Waste Disposal Facilities (2000).

² Id.

The framework of Part 61 provides both deterministic and performance based requirements. From a deterministic perspective, a disposal site must meet specific technical requirements as provided in 10 CFR 61.50-61.59. These technical requirements include criteria in 10 CFR 61.55 for classifying waste as class A, B, C, or greater than class C. From a performance based perspective, 10 CFR 61, 12, and 13 provide that the site must be subject to a technical analysis (commonly called a performance assessment) demonstrating that the site meets the performance objectives of Part 61, Subpart C. Thus, notwithstanding meeting the technical requirements, site must meet the performance objectives. The result is a systems approach that considers the integrated performance of all the disposal system performance, i.e., the site, the waste form, the engineering and facility design, the operation, and the closure, in determining whether the performance objectives have been met. This paper will be addressing the interplay of the technical and performance based provisions and the need to revise Part 61 to achieve a more risk informed result.

In considering Part 61 it is important to appreciate that Part 61 is a regulation of the NRC applicable to persons subject to the jurisdiction of the NRC. No site has actually been licensed under its provisions as the disposal sites in the United States are in Agreement States.³ Nevertheless, since Agreement States must maintain requirements which are adequate and compatible with NRC requirements, Part 61 is considered the LLW disposal standard in the United States. Agreement States use Part 61 as the standard for their LLW disposal regulations.

In the authors' view, the regulatory framework established under Part 61 has generally stood the test of time being protective of the public health and safety. However, there are a number of deficiencies in Part 61 that if addressed could make the rule more performance-based and risk-informed. These deficiencies became apparent in recent years as a result of concern over disposal of waste streams that were not fully considered in the draft and final environmental impact statements (EIS)⁴ that provided the support for the waste classification criteria in 10 CFR 61.55. These waste streams consisted of large quantities of depleted uranium and blended waste at or near the class A limits. The NRC is in the midst of a rulemaking to address depleted uranium and blended waste.⁵ The State of Utah has issued a regulation to address depleted uranium.

In addition, the NRC as a result of questions raised by the subject of depleted uranium is preparing for a comprehensive revision of the Part 61 framework. The NRC staff is due to have issued a paper to the Commission addressing the NRC "staff's approach to initiate activities related to a risk-informed, performance-based comprehensive revision to Part 61" after this paper was submitted to Waste Management in December 2010.⁶

³ Section 274 of the Atomic Energy Act of 1954, as amended (42 USC 2021), provides that the NRC can relinquish its authority over certain activities to states that meet certain requirements. Such states, called Agreement States, must maintain programs including regulations that are compatible with NRC requirements and be adequate to protect the public health and safety.

⁴ See EISs referenced in note 1.

⁵ Response to Commission Order CLI-05-20 Regarding Depleted Uranium, SECY-08-0147 (October 7, 2008); SRM on SECY-08-0147 (March 18, 2009); Blending of Low-Level Radioactive Waste, SECY-10-0043 (April 7, 2010); and SRM on SECY-10-0043 (October 13, 2010).

⁶ SRM, Briefing on Blending, July 1, 2010).

Within the United States, the Department of Energy (DOE) has a different regulatory framework governing the disposal of LLW from its activities. DOE unlike the NRC has not included a prescriptive approach in its Order 435.1 that addresses the requirements for LLW disposal in the DOE complex. DOE requires a site-specific performance assessment demonstrating that performance objectives similar to those in Part 61 are met. DOE does not include the classification system that commercial LLW is subject to. The DOE framework is a performance-based, risk-informed system. DOE is in the process of updating its Order 435.1. We strongly believe that the NRC and DOE should work closely together to harmonize their approaches so that there is one federal standard for the disposal of LLW in the United States.

The authors of this paper have an interest in safe and efficient disposal of radioactive waste having worked in this area while at the NRC and as consultants to the Department of Energy and private companies since retiring from the NRC. We have extensive experience working with Part 61, waste incidental to reprocessing (WIR), and section 3116 the Ronald Regan National Defense Authorization Act of 2005 (NDAA).⁷ This paper is based on the perspectives gained from that experience and the comments that the authors have presented to the NRC on the current rulemakings impacting Part 61.⁸ It provides a pragmatic approach to modernizing and risk-informing Part 61 that should take a minimum of additional resources and effort.

II. CURRENT NRC RULEMAKINGS

As noted above, the NRC is considering disposal issues associated with depleted uranium, unique waste, and blended waste streams. The regulatory concern is whether the existing regulatory structure provides a safe pathway for the disposal of these materials since the quantities and concentrations of radionuclides in these waste streams today are different from that considered in the development of Part 61. This concern is understandable given the time that has past and changes during the past three decades since the promulgation of Part 61 involving uses of radioactive material, waste management processes, and regulatory direction.

In accordance with the direction from the Commission, the current rulemaking focuses on depleted uranium and blended waste establishing a requirement to perform site specific performance assessments for these waste streams demonstrating that the performance objectives of Part 61 have been met. The staff has also indicated in the SECY papers that technical requirements will need to be added to Part 61 to assure that the site specific performance assessments are consistent with the analysis performed in the Part 61 FEIS and to be protective of the public health and safety. This approach appears to only address the specific waste streams that are of current concern, i.e., depleted uranium and blended waste, putting off issues with

⁷ Waste incidental to reprocessing (WIR) and section 3116 of the NDAA relate to the determination of when waste from reprocessing should be considered LLW and not high-level waste. A key component of that determination is a performance assessment demonstrating that the performance objectives of Part 61 are met. Thus, this experience is directly relevant to Part 61 as is NRC guidance such as NUREG-1854, NRC Staff Guidance for Activities Related to DOE Waste Determinations (2007).

⁸J. Lieberman and J.T. Greeves, Comments on Potential Rulemaking for Safe Disposal of Unique Waste Streams Including Significant Quantities of Depleted Uranium -74 FR 30175 (October 30, 2009)(ML093090484); J. Lieberman, SECY-10-0043 Blending of Low-Level Radioactive Waste (June 8,2010) (ML101670408); J.T. Greeves, SECY-10-0043 Blending of Low-Level Radioactive Waste (June 13,2010) (ML101670407); and J. Lieberman and J.T. Greeves, SECY-10-0043 Blending of Low-Level Radioactive Waste (July 29,2010) (ML102150168).

other waste streams for the update of Part 61. The staff is at the initial stage in its process of developing its strategy for a revision of Part 61. The staff has indicated that they are considering at least the following four options:

- 1) Modify the Waste Classification Framework
- 2) Align with the DOE approach in DOE 435.1
- 3) Align with the IAEA approach
- 4) Modify current rulemaking⁹

The first of the above three approaches would require a substantial effort. The staff recognizes a comprehensive revision of Part 61 has the potential to be controversial, complicated, and protracted.¹⁰ It has noted to the Commission that such a rulemaking may take 5 years. In the authors' view, five years may be a conservative estimate for a comprehensive review.

III. REVISED APPROACH

We believe that the NRC can modernize and risk-inform Part 61 in a substantially shorter time period by adopting the fourth approach, modifying the current rulemaking on depleted uranium and blended waste. In our view, the current rulemaking should address the following seven elements which are addressed below:

- 1) Requiring a site-specific performance assessment for all waste streams,
- 2) Setting time of compliance,
- 3) Providing an intruder dose standard for the intruder performance objective,
- 4) Providing for use of modern ICRP methods,
- 5) Providing for periodic updating of the site-specific performance assessment to make it more consistent with the DOE approach
- 6) Compatibility upgrade for 10 CFR 61.58
- 7) Stating in 10 CFR 61.55 the point in time for classifying (currently in 10 CFR Part 20, Appendix G)

A. Requiring a site-specific performance assessment for all waste streams (10 CFR 61.12 & 61.13)

Recent experience has shown that future additional waste streams will be identified that have characteristics that are different from that considered in the development of Part 61. These are what you might call the known unknowns that a regulatory scheme should be able to address. The solution is to provide as part of the current Part 61 rulemaking that each disposal site is required to have a site-specific performance assessment demonstrating compliance with the performance objectives of Part 61 that encompasses all of the waste at the site. This would reflect a risk-informed performance based approach. With this approach there will be assurance that all waste disposed at a disposal site will meet the performance objectives of Part 61 and,

⁹ Presentation of Larry W. Camper, Director, Division of Waste Management and Environmental Protection, Office of Federal and State Materials and Environmental Management Programs at the *2010 RADWASTE SUMMIT Low-Level Waste Regulatory Initiatives* (September 8, 2010).

¹⁰ Id.

therefore, the public health and safety will be protected. As the Commission stated in the Louisiana Energy Services proceeding, CLI-05-05 at page 11, January 18, 2005:

In the end, the "bottom line for disposal" of low-level radioactive wastes are the *performance objectives* of 10 C.F.R. Subpart C, which set forth the ultimate standards and radiation limits for (1) protection of the general population from releases of radioactivity; (2) protection of individuals from inadvertent intrusion; (3) protection of individuals during operations; (4) and stability of the disposal site after closure. Thus, while there may not yet be detailed technical criteria established for all of the kinds of land disposal that might be proposed under Part 61, criteria can be developed "on a case-by-case basis," as needed. After all, any technical requirements are "intended to help ensure that the performance objectives established in Subpart C are met," but they are "not the end in themselves, ... [only] a means of achieving the end," which are the performance standards. (Citations omitted)

This should not be an onerous addition to the current rulemaking. Currently, the requirements in 10 CFR 61.12 and 13 address the need to demonstrate that the performance objectives will be met. However, these provisions have been interpreted by some to not require the submittal of a site-specific performance assessment. As to protection against the intruder, NRC appears to have accepted the provisions of 10 CFR 61.52 (a)(2) for either five meter depth or the 500 year intruder barrier to meet the performance objectives of 10 CFR 61.42. While these depths and barriers may be sufficient in many cases to meet the performance objectives, without a site-specific performance assessment there is no assurance that the performance objectives will be met for all waste packages regardless of the concentrations and quantities of the radionuclides.

It is recognized that the NRC has issued various guidance documents over the years that can be read as not necessarily requiring a site-specific intruder analysis for Class A waste. See NUREG-1573, Performance Assessment Methodology for Low-level Waste Disposal Facilities (2002).¹¹ However, NUREG-1573 states that separate intruder scenarios analyses may be necessary in cases where the projected waste spectra are fundamentally different from those considered in the technical analyses supporting the Part 61 draft environmental impact statement. Thus, we agree with the Staff statement in SECY 10-0043, at page 18 that

because the requirement to conduct a site-specific inadvertent intruder analysis is not specifically identified in 10 CFR Part 61 and may not be well understood, there is a concern that applicants or licensees could misinterpret the regulations to only require compliance with the concentration limits in the waste classification tables for ensuring protection of the intruder, as required by 10 CFR § 61.42.

Therefore, the NRC should clarify 10 CFR 61.13 to provide clear notice that low-level waste disposal sites must have a performance assessment that demonstrates that the performance objectives of Part 61 are met for all waste streams and not just for depleted uranium and blended waste. Specifically, 10 CFR 61.13 should include language providing that:

¹¹ NUREG-1573 at page 1-13, footnote 7 states that "separate intruder scenario dose analyses are not envisioned to be included in an LLW performance assessment" based on 10 CFR 61.13(b). Section 61.13(b) provides that a demonstration be made that adequate barriers have been provided. In my view, a performance assessment is necessary to provide that demonstration.

The specific technical information must also include a site specific performance assessment to demonstrate that the performance objectives of subpart C of Part 61 will be met.

Such an approach would harmonize with DOE's Order 435.1 and be consistent with recent NRC guidance on waste incidental to reprocessing (WIR).

B. Setting time of compliance for purposes of the performance assessment (10 CFR 61.13)

Part 61 does not specify a time of compliance for purposes of the analyses required for the rule. For a consistent level of protection of the public health and safety and uniformity for regulators and sites, Part 61 should adopt a compliance period of 10,000 years consistent with NUREG-1573 and 40 CFR Part 191. However, recognizing the peak dose may occur after this period, the rule should require a qualitative analysis if the peak occurs beyond 10,000 years for input into the environmental analysis consistent with section 3.2.3 of NUREG-1573, to determine if there is a need for environmental mitigation. This is also consistent with Section IV.A.6 of the Decommissioning Criteria for the West Valley Demonstration Project at the West valley Site (67 FR 5003, 5006, February 1, 2002). See also section 4.1.1.1 of NUREG-1854, NRC Staff Guidance for Activities Related to US DOE Waste Determinations (2007). A period of compliance in the rule would assure consistent assessment of compliance by all parties.

Recognizing that performance assessments require the use of assumptions and scenarios that may change over the compliance period, Part 61 should provide that the assumptions and scenarios used in performance assessments be reasonably foreseeable to avoid undue speculation and overly conservative approaches. NRC should permit licensees to justify, site-specific assumptions and exposure scenarios based on reasonably foreseeable circumstances to evaluate the critical group that could reasonable encounter material that is released from the disposal cell after the institutional control period. This would include residential use; farming; resident farming; and any other reasonable use consistent with the current environment of the specific site. For example, a site would not be expected to consider a groundwater pathway if the groundwater was not useable for irrigation or human consumption. In addition, the assumptions for the performance analyses would not need to project changes in society, the biosphere, human biology, or increases or decreases of human knowledge or technology except for foreseeable changes to the geology, hydrology, and climate based upon cautious, but reasonable assumptions of the changes in these factors that could affect the disposal site. The actual details for performing performance assessments consistent with the regulatory language would be treated in NRC guidance which can be updated periodically by the NRC without a rule change.

Specifically, 10 CFR 61.13 should include providing language that:

The performance assessment be preformed for a compliance period of 10,000 years using reasonably foreseeable assumptions and scenarios. If the peak dose occurs after 10,000 years, a qualitative analysis shall be prepared up to the time of the peak dose for consideration in the site's long term environmental impact.

C. Providing an intruder dose standard for the intruder performance objective (10 CFR 61.42)

10 CFR 61.42 currently requires "...protection of any individual inadvertently intruding into the disposal site and occupying the site or contacting the waste;" however, the regulations are silent on the specific dose standard to apply. Section 61.42 should be amended to provide a dose standard for an intruder of 500 mr/yr. This would provide in the rule the dose standard that currently is only stated in guidance. It is noted that the 500 millirem was the standard proposed in Part 61 in 1981. (46 FR 38081, July 24, 1981). The Statement of Considerations for the final rule did not object to the number. It was removed apparently at the request of EPA because of its concern of how one would monitor it or demonstrate compliance with it, but not because EPA disagreed with it. (47 FR57446, 57449, December 27, 1982). A dose standard of 500 mr/yr is also used as part of the license termination rule dose standard for intruders (10 CFR 20.1403). A dose standard in the rule would assure consistent assessment of compliance for all sites.

Specifically, 10 CFR 61.42 should include providing language that:

The intrusion must not result in an annual dose exceeding an equivalent of 500 millirems total effective dose equivalent for a compliance period of 10,000 years.

D. Providing for use of modern ICRP methods (10 CFR 61.41)

The performance objective for the public dose, 10 CFR 61.41, is based on ICRP 2, a standard that is more than 50 years old. The dose methodology in 10 CFR Part 20 is based on ICRP 26 and 30. Part 20 establishes the radiation protection standard used by both Agreement states and NRC. We recommend that 10 CFR 61.41 be updated to reflect the annual dose methodology used in 10 CFR Part 20 rather than the methodology used in Part 61. This is consistent with the approach taken in sections 3.3.7.1.2 and 3.3.7.3.1 of NUREG 1573; footnote 6 of the Decommissioning Criteria for the West Valley Demonstration Project at the West Valley Site (67 FR 5003, 5005, Feb 1, 2002); and section 4.6.1.3 of NUREG-1854.

Specifically, 10 CFR 61.41 should include providing language that:

Concentrations of radioactive material which may be released to the general environment in ground water, surface water, air, soil, plants, or animals must not result in an annual dose exceeding an equivalent of 25 millirems total effective dose equivalent for a compliance period of 10,000 years to any member of the public.

E. Providing for periodic updating of the site-specific performance assessment to make it more consistent with the DOE approach (10 CFR 61.13)

As noted above, a risk-informed performance based disposal framework is dependent on the performance assessment demonstrating that the performance objectives are met. To implement this approach it is necessary that not only the design be tested by the demonstration that the performance objectives will be met, but that current disposal practices be consistent with the inputs to the performance assessment that demonstrated that the performance objectives have been met. Over time the waste streams that the disposal site operator will receive will likely

change, new information may be obtained about the site and its performance, and new analyses may be developed. Part 61 should provide that there be periodic updating of the performance assessment to reflect changes in source terms, changed conditions at the site, past disposal history, and new methodology, if any. However, this does not necessarily mean that a completely new performance assessment would need to be developed. Depending on the scope and detail of an existing performance assessment, a current performance assessment may only need minor changes to update it. In the period between the updates, if a new waste stream is planned for disposal that is not encompassed by the site's existing performance assessment, a special assessment may be needed to demonstrate that the performance objectives will still be met. This approach is consistent with the approach taken by DOE at its disposal sites under DOE Order 435.1.

Specifically, 10 CFR 61.13 should include providing language that:

The performance assessment must be updated for Commission approval at a five year frequency unless the license provides an alternative period for updating it.

F. Compatibility upgrade for 10 CFR 61.58

The requirement to have performance assessments done for all waste streams that demonstrate that the performance objectives of Part 61 are met with periodic updating will assure that Part 61 is a risk informed, performance based rule. We appreciate that some may argue that one cannot risk inform Part 61 without either removing the classifications system described in 10 CFR 61.55 or updating it to reflect more recent knowledge since the development of the EIS for Part 61 in the 1980s and new dose methodology. However, in our view such an effort will take substantial resources and time and is not necessary. It is also not clear that such a result will be useful since any new classification system like the current classification system would likely be based on performance assessments for a generic site that will not reflect an actual site. Moreover states have licensed sites based on the current system. A change will be controversial taking on what some may view as "sacred cows" and could in the authors' view even result in adverse legislation similar to what happened to the NRC with its "below regulatory concern" effort. There is also benefit to have a classification system for uniform interstate commerce even if it is not perfect.

Thus, we propose continuing with the existing classification system which is referenced in section 3 of the Low-Level Radioactive Waste Policy Amendments Act of 1985 and is needed to establish the boundary between State and Federal responsibility. To the extent that the existing classification system is not sufficiently protective for unique waste streams, the requirement to perform a site-specific performance assessment demonstrating that the site meets the performance objectives of Part 61 will compensate for any potential weaknesses resulting from the waste classification. If the existing classification would produce overly conservative results, then the regulator can under the existing 10 CFR 61.58 authorize other provisions for the classification and characteristics of waste on a specific basis if it finds reasonable assurance of compliance with the performance objectives in subpart C. For this reason, 10 CFR 61.58 should be given a higher compatibility level. This would not mean that an Agreement State must always exercise its provisions, but it must have the discretion to do so.

Not all states, have adopted 10 CFR 61.58 as this section is currently a compatibility level D which means the provision is not required for compatibility. The change to compatibility level is important to risk informing Part 61 by assuring that the performance assessment process compensates for any weakness in the current classification system. In our view, compatibility level B, which would provide for agreement states adopting essentially identical requirements, is needed because waste disposal impacts generators across the nation and, therefore, has significant direct transboundary implications. This is the same level that is applied to the classification system in 10 CFR 61.55.

G. Stating in 10 CFR 61.55 the point in time for classifying (currently in 10 CFR Part 20, Appendix G)

As a result of the bending of waste issue, questions have arisen concerning the timing of classification decisions and the different polices of various states. The purpose of classification under Part 61 is to support the disposal process. The waste classification impacts requirements applicable to disposal. From a disposal perspective, what matters for classification is the waste that is being sent to the disposal site. Waste processing may affect the nature of the waste such that its concentration may be increased or decreased. It is the resulting concentration that is important for classification and disposal. For processed waste its concentration prior to disposal is irrelevant for purposes of Part 61 as that is not the waste concentration that is being disposed.

As stated by the Staff in SECY-10-0043,

waste is not required to be classified at intermediate points between its generation and disposal, such as processing and storage, because the characteristics of the waste at these intermediate points do not directly affect its safe disposal. Once waste is ready for disposal, it must be classified.

The NRC regulations reflect this concept in section III of Appendix G of 10 CFR Part 20. Section III addresses the timing of classification decisions in the context of transportation and manifests. Section III A. provides that licensees who transfer radioactive waste to a disposal site or to a waste collector (non-processor or non-packager) shall classify and label each package to identify its classification in accordance with 10 CFR 61.55. However, if the waste is to be sent to a processor for waste treatment or repackaging, section III C. provides that the processor shall classify and label each package to identify its classification in accordance with 10 CFR 61.55. This is a compatibility B requirement as it has significant direct transboundary implications. Accordingly Agreement states' requirements should be essentially identical to Appendix G of Part 20.

Some licensees may choose to classify material based on its concentration when it leaves the generator's site to go to a processor. Such a classification has no regulatory affect given the provisions of Appendix G and more importantly has no impact on disposal safety because the concentration may be modified (increased or decreased) during the treatment process. To clarify this and prevent confusion with multiple classifications, the timing of classification in Appendix G of Part 20 should also be in Part 61. Specifically, 10 CFR 61.55 should include language providing that:

For purposes of classification of wastes, waste shall be classified when packaged or containerized for disposal. For waste packaged or treated at a licensed waste processor, only the classification made by the processor prior to shipment directly to the disposal site shall be used for purpose of Part 61.

This language would make Part 61 consistent with Appendix G of Part 20 and should be at a compatibility level B similar to Appendix G.

III. CONCLUSION

We agree that 10 CFR PART 61, “Licensing Requirements for Land Disposal of Radioactive Waste,” needs to be updated to address the lessons learned over the last 30 years. It should account for the recent experience gained by the NRC staff review of practices for the disposal of waste incidental to reprocessing under the Ronald Regan National Defense Authorization Act of 2005. It should also account for recent experience associated with depleted uranium and blended waste discussions with stakeholders.

In our view the pragmatic approach described in this paper for updating Part 61 to address the current deficiencies will modernize and risk-inform Part 61 with a minimum of additional resources and effort. This would include: requiring site specific performance assessment for both the public and intruder scenarios; setting a time of compliance for such calculations; setting a specific intruder dose standard; use of modern ICRP dose conversion recommendations; requiring periodic updates to the performance assessment to account for unique waste streams and improved site specific knowledge; upgrade compatibility requirements for 10 CFR 61.58; and stating in 10 CFR 61.55 the point in time for classifying waste.