RULEMAKING ISSUE
(Affirmation)

September 15, 2016 SECY-16-0106

FOR: The Commissioners

FROM: Victor M. McCree
Executive Director for Operations

SUBJECT: FINAL RULE: LOW-LEVEL RADIOACTIVE WASTE DISPOSAL (10 CFR PART 61) (RIN 3150-AI92)

PURPOSE:

The purpose of this paper is to request Commission approval to publish a final rule in the *Federal Register* (FR) that would amend Title 10 of the *Code of Federal Regulations* (10 CFR) Parts 20, "Standards for Protection Against Radiation," and Part 61, "Licensing Requirements for Land Disposal of Radioactive Waste." The staff intends to publish implementing guidance concurrently with the final rule. Other than that commitment, this paper does not address any new commitments or resource implications.

SUMMARY:

The final 10 CFR Part 61 rule would do the following: 1) revise the existing technical analysis for protection of the general public to include either a 1,000-year compliance period or a 10,000-year compliance period depending on the quantities of long-lived radionuclides that have been or plan to be disposed at the site; 2) add a new technical analysis for the protection of inadvertent intruders that would include a compliance period and a dose limit; 3) add a new post-10,000-year performance period analysis for disposal sites that have low-level radioactive waste (LLRW) containing significant quantities of long-lived radionuclides; 4) add a new requirement to update the technical analyses at site closure; 5) add a new requirement to

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develop site-specific criteria for the future acceptance of LLRW for disposal based on the results of the technical analyses, the existing LLRW classification requirements, or a combination of both; 6) add a new description of safety case and a new requirement to identify defense-in-depth protections and describe their capabilities; and 7) facilitate implementation and better align the requirements with current safety standards. These amendments ensure that the LLRW streams that are significantly different from those considered during the development of the existing 10 CFR Part 61 regulations will be disposed of safely and meet the performance objectives for land disposal of LLRW.

BACKGROUND:

The regulations for the disposal of commercial LLRW in land disposal facilities are set forth in 10 CFR Part 61. The U.S. Nuclear Regulatory Commission (NRC) originally adopted these regulations in 1982 (47 FR 57446). Although the NRC has never licensed any land disposal facilities under this part, the Agreement States that currently or plan to license LLRW land disposal facilities must adopt compatible versions of these regulations.

In SECY-13-0075, "Proposed Rule: Low-Level Radioactive Waste Disposal (10 CFR Part 61) (RIN3150-AI92)," dated July 18, 2013, (Agencywide Documents Access and Management System (ADAMS) Accession No. ML13128A160), the NRC staff provided the Commission with a proposed rule to amend 10 CFR Part 61. The Commission approved publication of the proposed rule in a staff requirements memorandum (SRM), SRM-SECY-13-0075, dated February 12, 2014 (ADAMS Accession No. ML14043A371). After making Commission directed changes, the NRC published the proposed rule for an initial 120-day comment period in the FR (80 FR 16081) on March 26, 2015. The public comment period closed on July 24, 2015. After receiving extension requests, the staff reopened the comment period by publication of a notice in the FR (80 FR 51964) on August 27, 2015; the comment period closed on September 21, 2015.

The NRC received 2,401 comment letters (including approximately 2,300 form letters) representing individuals, public interest groups, Native American Tribal Governments, industry groups, licensees, and state and federal agencies. The comments encompassed a wide variety of viewpoints that are summarized and responded to in Section IV, "Public Comment Analysis," of the *Federal Register* notice (FRN) for this final rule (Enclosure 1).

The NRC staff briefed the Advisory Committee on Reactor Safeguards (ACRS), Radiation Protection and Nuclear Materials Subcommittee and full committee eight times before publication of the proposed rule. The staff is scheduled to brief the ACRS subcommittee in October 2016 and the full committee in November 2016 on the final rule; the ACRS requested that the meetings occur after the draft final rule would be publicly available in order to keep the meetings open to the public. Shortly after the November ACRS meeting, the ACRS will provide a letter report with recommendations and conclusions directly to the Commission.

DISCUSSION:

The staff is proposing amendments to 10 CFR Part 61 to: 1) require LLRW disposal licensees and license applicants to conduct updated and new technical analyses, as well as develop site-specific LLRW acceptance criteria; 2) add new definitions and concepts; and 3) introduce amendments to facilitate implementation and better align the requirements with current health

and safety standards (i.e., 10 CFR Part 20 requirements). The technical analyses required by the amendments would include: 1) an updated[1] analysis to demonstrate protection of the general population, called a "performance assessment," which would use a defined compliance period; 2) a new analysis to demonstrate protection of inadvertent intruders, called an "inadvertent intruder assessment," which would also use a defined compliance period; and 3) a new performance period analysis, called a "performance period analysis," to evaluate how the disposal system could mitigate the risk from the disposal of significant quantities of long-lived radionuclides after the compliance period. The technical analyses would also need to be periodically reviewed and updated (e.g., at each renewal, with any application to amend the license for closure, and as necessary to update waste acceptance criteria). In addition, the rule would add a new description of safety case and incorporate a new requirement to identify defense-in-depth protections and describe their capabilities.

In SECY-13-0075, the staff recommended a compliance period of 10,000 years followed by a performance period covering timeframes after 10,000 years. A performance period analysis would only be required if a site contained significant quantities of long-lived radionuclides. During the compliance period, the licensee would demonstrate compliance with the performance objectives, and during the performance period, the licensee would demonstrate how the facility design would mitigate any long-term impacts. In the performance period analysis, the licensee would also communicate the uncertainties associated with disposing of long-lived radionuclides. The performance period analysis was to be used to identify the need to limit the disposal of certain wastes to ensure proper management of the uncertainties. In SRM-SECY-13-0075, the Commission directed the staff to publish the proposed rule with a compliance period of 1,000 years, a "protective assurance period" from 1,000 to 10,000 years with a dose goal of 5 milliSieverts (mSv) per year (500 millirem (mrem) per year), and a performance period that extended beyond 10,000 years after site closure. That SRM also directed the staff to assign a compatibility category of Category B to the most significant provisions of the rule.

In response to NRC's request for public comment on the proposed rule, a number of commenters indicated that the tiered approach presented in the proposed rule appeared more complicated than necessary and recommended using something simpler. In addition, many individuals expressed concerns that the proposed approach was reducing health and safety protections. These comments appeared to stem from the perception that the 5 mSv (500 mrem) per year dose goal associated with the proposed protective assurance period was significantly higher than the 0.25 mSv (25 mrem) annual dose limit during the compliance period. Some commenters also stated that it would be unreasonable to impose additional specific requirements on owners of land disposal facilities that exclusively disposed of traditional LLRW (i.e., waste that did not include significant quantities of long-lived radionuclides). These commenters expressed concerns that all operators were being lumped together and that the proposed rule was not differentiating between the various disposal sites. In light of these comments, the staff is now recommending a simpler approach tailored to the waste that will be disposed. The approach in the final regulation is comprised of only a compliance period and a performance period. However, the compliance period would be either 1,000 years or

[1] The terms "updated" and "new" are comparing the new regulatory requirements to the existing requirements developed in 1982. For example, the performance assessment is an updated analysis because technical analysis to demonstrate compliance with § 61.41 is required in the original 10 CFR Part 61; this rulemaking has only updated the terminology and some of the associated requirements.

10,000 years, depending upon the inventory and concentration of long-lived radionuclides disposed of at the land disposal facility. A performance period analysis is only necessary if the licensee uses a 10,000-year compliance period (i.e., significant quantities of long-lived radionuclides have been or will be disposed at the land disposal facility). This approach is site-specific and will consider the inventory and risk posed by the waste to a member of the public, which is consistent with an ACRS recommendation that the timeframe for the analysis be a "site-specific time span derived from a performance assessment" (ADAMS Accession No. ML11256A191).

In the proposed rule, the NRC had included a Table A in § 61.13 of the rule language to designate what were considered to be threshold values for determining if significant quantities of long-lived radionuclides were present at the site, thus requiring performance period analyses. Commenters expressed concern with the technical basis for the table. As a result, the staff re-evaluated the table and determined that while the table is useful with respect to examining impacts associated with § 61.42 (i.e., inadvertent intruder assessment), it may not always provide sufficient protection with respect to § 61.41 (i.e., performance assessment). Because of this, the staff has moved the proposed Table A to the associated guidance (NUREG-2175, "Guidance for Conducting Technical Analyses for 10 CFR Part 61" (ADAMS Package Accession No. ML16218A504)[2], and instead is requiring that if a licensee opts to use a 1,000-year compliance period, the licensee must include a technical rationale as to why the longer 10,000-year timeframe is not necessary. This technical rationale may consist of a simple evaluation of the inventory to demonstrate that the performance objectives would not be exceeded or use other criteria that is found acceptable by the regulator. Licensees may still use Table A as part of their rationale, but must demonstrate that the selected concentrations provide adequate protection for their site, or they may develop other concentration or quantity limits using site-specific factors. The development of the technical rationale is not expected to be burdensome and if it becomes overly complex, the licensee should consider using the longer compliance period. Acceptable approaches for determining the duration of the compliance period are discussed in greater detail in NUREG-2175. Not imposing a single numeric timeframe for the compliance period allows licensees for sites that do not have significant quantities of long-lived radionuclides to limit their performance assessments to 1,000 years, and requires only licensees for sites with significant quantities of long-lived radionuclides to prepare analyses for the 10,000-year period. Included in this approach is a requirement that licensees limit doses to 0.25 mSv (25 mrem) to any member of the public during the compliance period, independent of the time frame chosen, thus addressing stakeholder concerns with respect to the perceived relaxation of standards regarding the dose goal that was associated with the proposed protective assurance period. This approach also aligns with the current regulations of two Agreement States, Texas and Utah, where licensees have indicated that they would like to potentially receive large quantities of depleted uranium for disposal at their sites.

The staff also received a significant number of comments regarding the compatibility category for many of the rule changes. Most commenters expressed concerns that compatibility Category B, as proposed, limited flexibility of the Agreement States and would, in fact, reduce the levels of protection currently provided by the Agreement States. The Agreement State requirements are, in some cases, already more stringent than those included in the proposed rule. After consideration of the comments, the staff is recommending that the compatibility

[2]NUREG-2175, "Guidance for Conducting Technical Analyses for 10 CFR Part 61," will be publicly available upon publication of the final rule in the Federal Register.

category be designated Category C for: 1) the definition of "compliance period;" and 2) § 61.58, which relates to waste acceptance criteria, characterization methods, and certification program. These changes will allow Agreement States with already operating land disposal facilities, which all currently require a compliance period longer than 1,000 years, the flexibility to continue to use much of their existing regulatory system. In addition, this approach should also reduce implementation costs for the Agreement States and their licensees, while allowing them to maintain an equivalent or more conservative regulatory system.

Three other significant areas of concern raised by commenters were: 1) backfit; 2) grandfathering under § 61.1(a); and 3) classification of depleted uranium. Some commenters asserted that the rule changes would result in financial impacts to licensees where facilities were licensed under regulations other than 10 CFR Part 61 (e.g., uranium enrichment facilities), and therefore the NRC should have conducted a backfit evaluation. The staff has reviewed the issue and determined that because 10 CFR Part 61 does not contain a backfit provision and given that the backfit rule has never required the NRC to analyze costs to parties that may experience "passed along," costs (i.e., those costs experienced by entities not directly subject to the rule changes; for example, impacts to waste generators affected by a rule on the licensing of land disposal facilities), a backfit evaluation is not required.

Some commenters claimed that existing operating sites should be "grandfathered" under § 61.1(a). The staff has reviewed the commenters stated basis for "grandfathering" and determined that the language referred to by commenters in § 61.1(a) (i.e., "Applicability of the requirements in this part to Commission licenses for waste disposal facilities in effect on the effective date of this rule will be determined on a case-by-case basis") was included in the original rule (i.e., the 1982 promulgation of 10 CFR Part 61) in order to facilitate an easy transition for LLRW disposal facilities already in existence in 1982 to a new regulatory scheme. In 1982, LLRW disposal was regulated through requirements in 10 CFR Part 20. The changes made by this rule build upon the existing regulatory requirements found in 10 CFR Part 61 by expanding the types of analyses required and defining the scope of such analyses, but do not create a new regulatory scheme. In order to avoid future confusion, the staff is removing the associated phrasing in § 61.1(a) from the regulations in the final rule. Other commenters also requested that the current rule be deferred until depleted uranium was classified under the existing waste classification system, while other commenters stated classification was unnecessary. Under the original 10 CFR Part 61, depleted uranium falls into a default categorization of Class A LLRW because, at the time of the original promulgation of the regulations, there was no expectation that significant quantities of depleted uranium would be disposed of at commercial LLRW land disposal facilities. Because the assumption is no longer true, the commenters indicated that depleted uranium should be reclassified before this current rulemaking is completed, with the expectation that depleted uranium would no longer be classified as Class A LLRW if it were categorized using the methodologies used during the original promulgation of 10 CFR Part 61. The staff reviewed this matter and concluded that this rulemaking should allow for the safe disposal of depleted uranium and other radionuclides regardless of their classification, and therefore recommends completing the rulemaking without first re-evaluating the classification of depleted uranium. In addition, in the SRM to SECY-13-0001, "Staff Recommendations for Improving the Integration of the Ongoing 10 CFR Part 61 Rulemaking Initiatives," dated March 26, 2013 (ADAMS Accession No. ML13085A318), the Commission directed the staff to provide a Commissioners' Assistants note regarding the need to update the waste classification tables through rulemaking *after* the current 10 CFR Part 61 rulemaking is completed.

Finally, some commenters expressed concern about the intended complexity of the defense-in-depth analysis required by § 61.13(f) in the proposed rule. Although the staff intended that this analysis be a qualitative summary of the other technical analyses required in § 61.13, commenters interpreted the proposed § 61.13(f) as requiring the licensee to undertake a new complex, quantitative analysis. To better clarify the staff's original intent, this requirement has been removed from § 61.13, "Technical analysis," and placed in § 61.12, "Specific technical information." The requirement has also been rephrased to indicate that defense-in-depth protections need to be identified and their capabilities described for the land disposal facility to make it clear that a complex, quantitative defense-in-depth analysis is not required.

The staff has also made a number of conforming and clarifying changes based upon the public comments. For instance, commenters provided a range of views regarding concerns and uncertainties in selecting specific exposure scenarios to be used in the inadvertent intruder assessment that indicate the regulation, at a minimum, needed further clarification to achieve an appropriate balance in the specification of exposure scenarios for the intruder assessment. To clarify, the staff has revised the definition of an inadvertent intruder in § 61.2 and the requirements in § 61.13(b)(1) for the types of activities to include in an inadvertent intruder assessment in order to limit unnecessary and unsupported speculation regarding activities and pursuits that could occur far in the future and result in exposures to LLRW. Specifically, the staff has replaced resource exploration and exploitation with drilling for water as a normal activity, and clarified that reasonably foreseeable pursuits need to be consistent with activities and pursuits in and around the site at the time the analysis is performed. In addition, in agreement with some public comments, certain details of overall objectives that were originally included in the proposed rule language have instead been moved to guidance.

The staff intends to publish the final version of NUREG-2175 concurrently with the publication of this final rule. A draft of NUREG-2175 (ADAMS Accession No. ML15056A516) was published for comment along with the proposed rule, with the public comment period extending between March 26, 2015, and September 21, 2015. Seven comment letters were received on the draft NUREG from individuals, public interest groups, industry, licensees, and federal agencies. Several commenters requested that the NRC provide an additional public comment period on the guidance document after the 10 CFR Part 61 final rule is issued, but before the draft NUREG became final. However, the staff has already received and incorporated significant comments with respect to NUREG-2175 and rather than hold an additional public comment period at this time, the staff has concluded it would be better to issue the final NUREG-2175 with the final rule and seek additional public comment, if necessary, during any future updates to that guidance document. Other commenters recommended that specific areas of the guidance document be clarified and made more consistent with the proposed rule language, such as the defense-in-depth discussion. The staff has addressed the comments received on the draft NUREG, as well as incorporated conforming changes resulting from the final rule revisions, during development of the final NUREG.

In addition to the FRN for this final rule, the staff is providing the Commission with a final regulatory analysis (Enclosure 2) in support of this rulemaking. The regulatory analysis has been improved through the gathering of more quantitative cost data provided by the Agreement States and licensees. The regulatory analysis estimates that the industry will incur an implementation cost of $4.5 million, followed by an annual cost of $5.3 million during the regulatory analysis period (i.e., the time period starting at the present day and continuing

through the lifetime of each current licensee), while the Agreement states with operating licensees will incur an implementation cost of $2.9 million, followed by an ongoing operations cost of $4 million over the regulatory analysis period. The rule ensures that LLRW streams that are significantly different from those considered during the development of Part 61 can be disposed of safely and meet the performance objectives for land disposal of LLRW. The amendments will facilitate the use of site-specific information and up-to-date dosimetry methodologies to better ensure public health and safety is protected. Under the final rule, licensees will be permitted to develop waste acceptance criteria from the results of the technical analyses. This approach provides licensees with flexibility to better manage disposal capacity consistent with the risks of disposal of LLRW streams. The staff concluded that the rule is cost-justified because the regulatory initiatives enhance public health and safety by ensuring the safe disposal of LLRW (e.g., large quantities of depleted uranium) that was not analyzed in the original 10 CFR Part 61 regulatory basis. If approved by the Commission, the regulatory analysis will be published concurrently with the final rule.

As described in Section XI, "Environmental Assessment and Final Finding of No Significant Environmental Impact," of the associated FRN for this final rule, the staff determined that adoption of the final rule would not be a major Federal action significantly affecting the quality of the human environment and, therefore, an environmental impact statement is not required. The final rule adds new, and amends some of the existing, requirements in 10 CFR Part 61. The final rule does not authorize either the construction of LLRW disposal facilities or the disposal of additional LLRW in existing land disposal facilities. Licensees and applicants would need to request and receive separate regulatory approval before construction of new disposal facilities or disposal of additional LLRW in existing facilities could proceed. Consequently, because this rulemaking will not result in any physical impacts to the environment, the NRC has determined that the proposed action would not result in any significant environmental impact.

This final rule addresses the NRC's Strategic Plan safety goal to "Ensure the safe use of radioactive materials." Specifically, the final rule minimizes public exposure and prevents unintended releases of radioactive materials to the environment for LLRW that contains significant quantities of long-lived radionuclides. It also enhances the risk-informed and performance-based regulatory framework by providing information on defense-in-depth protections that enhance the efficiency and effectiveness of regulatory reviews. Additionally, in a 2008 analysis, provided in SECY-08-0147, "Response to Commission Order CLI-05-20 [In the Matter of Louisiana Energy Services, October 19, 2005)) (ADAMS Accession No. ML052930035)] Regarding Depleted Uranium," dated October 7, 2008 (ADAMS Accession No. ML081820762), involving a land disposal scenario for significant quantities of depleted uranium, the NRC identified conditions that would likely result in the land disposal facility not meeting the original performance objectives in §§ 61.41 and 61.42. The final rule enhances regulatory effectiveness by resolving the identified potential safety issue.

The staff was previously directed by the Commission to undertake two additional activities upon completion of this rulemaking. In SRM-SECY-15-0094, "Historical and Current Issues Related to Disposal of Greater-Than-Class C Low-Level Radioactive Waste," dated December 22, 2015 (ADAMS Accession No. ML15356A623), the Commission directed the staff to develop a regulatory basis for possible Greater-Than-Class C rulemaking within 6 months of publication of this final rule. As indicated earlier, in SRM-SECY-13-0001, the Commission directed the staff to provide a Commissioners' Assistants note regarding the need to update the waste classification

tables through rulemaking; the Commission directed the staff to complete this action after the current Part 61 rulemaking is completed. These future activities will be coordinated.

Agreement State Interactions:

A copy of the draft final rule FRN was provided to the Agreement States so they could have an early opportunity for review. Comments were received from five Agreement States, the Board of the Organization of Agreement States, and the Board of Directors for the Conference of Radiation Control Program Directors. The commenters were supportive of the changes made from the proposed rule and reflected in the final rule. Only two Agreement States provided specific comments (mostly editorial or requests for clarification). The NRC staff revised the Statement of Considerations accordingly. Regarding an Agreement State request that the Agreement States be provided 3 years from the effective date of the final rule to issue compatible regulations, the staff decided to retain the 3-year compatibility requirement from the date of publication as is normal for most rulemakings, having concluded that this will provide sufficient time for the Agreement States to issue compatible regulations.

The NRC staff has analyzed the final rule in accordance with the procedures established within Part III of the Handbook to Management Directive 5.9, “Categorization Process for NRC Program Elements.”

The final rule is a matter of compatibility between the NRC and the Agreement States, thereby requiring consistency among NRC and Agreement State requirements. The staff made changes to the compatibility category for certain sections of the rule from those published in the proposed rule in response to public comments. Most of these changes allow the Agreement States greater flexibility to maintain aspects of their existing programs (primarily timeframes). To accomplish this, the definition of “compliance period” and §§ 61.41(b), 61.42(b), and 61.58 were changed from Category B to Category C. These compatibility category changes require the Agreement States to meet the essential objectives of the NRC requirements to avoid conflicts, duplications, or gaps; however, the Agreement States may implement more restrictive requirements.

The Standing Committee on Compatibility reviewed the final rule and agreed that the amendments to the NRC regulations resulting from this final rule are a matter of compatibility between the NRC and the Agreement States. The Committee made suggestions for minor revisions to the Statement of Considerations, which the staff implemented. The Committee agrees with the staff’s compatibility designations.

COMMITMENTS:

Final guidance will be issued concurrently with the final rule.

RECOMMENDATIONS:

That the Commission:

1. Approve for publication in the FR the notice of final rulemaking (Enclosure 1).

2. Certify that this rule, if adopted, will not have significant impact on a substantial number of small entities, to satisfy the requirement of the Regulatory Flexibility Act, 5 U.S.C. 605(b). This certification is included in the enclosed FRN.

3. Note:

   a. That the Chief Counsel for Advocacy of the Small Business Administration will be informed of the certification and the reasons for it, as required by the Regulatory Flexibility Act, 5 U.S.C. 605(b);

   b. A final Regulatory Analysis has been prepared for this rulemaking (Enclosure 2);

   c. A final Environmental Assessment and Finding of No Significant Impact have been prepared for this rulemaking and is included in the FRN;

   d. The staff has determined that this action is not a "major rule," as defined in the Congressional Review Act of 1996 [5 U.S.C 804(2)] and has confirmed this determination with the Office of Management and Budget (OMB). The appropriate Congressional and Government Accountability Office contacts will be informed;

   e. The appropriate Congressional committees will be informed;

   f. A press release will be issued by the Office of Public Affairs when the final rulemaking is filed with the Office of the Federal Register; and

   g. The final rule contains amended information collection requirements subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, et seq.) that must be submitted to the OMB for its review and approval before publication of the final rule in the FR.

RESOURCES:

The estimated resources to complete the rule are minimal (less than one Full Time Equivalent). These resources are within existing budget allocations.

COORDINATION:

The Office of the General Counsel has no legal objection to the final rulemaking. The Office of the Chief Financial Officer has reviewed this Commission Paper for resource implications and has no objections.

/RA/

Victor M. McCree
Executive Director
for Operations

Enclosures:
1. *Federal Register* Notice
2. Regulatory Analysis

COORDINATION:

The Office of the General Counsel has no legal objection to the final rulemaking. The Office of the Chief Financial Officer has reviewed this Commission Paper for resource implications and has no objections.

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Enclosures:
1. *Federal Register* Notice
2. Regulatory Analysis

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