



**UNITED STATES
NUCLEAR REGULATORY COMMISSION
ADVISORY COMMITTEE ON REACTOR SAFEGUARDS
WASHINGTON, DC 20555 - 0001**

November 14, 2016

The Honorable Stephen G. Burns
Chairman
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

SUBJECT: REVIEW OF SECY-16-0106, PROPOSED FINAL RULE 10 CFR PART 61,
"LOW-LEVEL RADIOACTIVE WASTE DISPOSAL"

Dear Chairman Burns:

During the 638th meeting of the Advisory Committee on Reactor Safeguards (ACRS), November 3-5, 2016, we completed our review of SECY-16-0106, the staff's proposed final rule, "Low-Level Radioactive Waste Disposal (10 CFR Part 61)." Our Subcommittee on Radiation Protection and Nuclear Materials discussed this matter during its meeting on October 18, 2016. Our meetings focused on issues raised by the ACRS in its past letter reports on this matter. During these meetings, we benefitted from discussions with the NRC staff and members of the public. We also had the benefit of the referenced documents.

CONCLUSIONS AND RECOMMENDATIONS

1. The approach in proposed final rule 10 CFR Part 61, "Low-Level Radioactive Waste Disposal" can ensure that facilities meet Commission public health and safety objectives.
2. We remain concerned about the requirement that existing operating disposal facilities need to satisfy the new performance objectives even if they do not plan to add substantial long-lived waste for disposal, especially for already-buried waste. The final rule should retain the provision that allows compliance for existing facilities on a case-by-case basis.
3. We prefer a regulatory approach consistent with that suggested in our previous reports making the site performance assessment with quantitative uncertainty analysis the basis for establishing the compliance and performance periods. The performance assessment results should inform qualitative requirements for periods exceeding the compliance period.

BACKGROUND

10 CFR Part 61, "Licensing Requirements for Land Disposal of Radioactive Waste," was promulgated by the NRC in 1982. The technical basis for the rule included analyses based on projections of low-level radioactive waste (LLRW) that were expected to be generated for the foreseeable future as determined at that time. Several changes to policy and practices have resulted in some LLRW streams which NRC did not include in the technical basis for the rule in 1982, calling into question whether these waste streams can be appropriately disposed of in a shallow land disposal facility.

The staff of the Office of Nuclear Materials Safety and Safeguard (NMSS) (or its predecessor organizations) has been working on the revision to 10 CFR Part 61, for more than ten years. The effort grew out of concern that arose during the staff review of an application to license the Louisiana Energy Services (LES) enrichment facility (now known as URENCO USA). The staff requested a Commission policy decision on how depleted uranium (DU) waste streams to be generated by the LES facility should be managed.

The draft proposed final rule is intended to address DU waste streams, as well as others including blended low-level wastes, waste streams from spent nuclear fuel reprocessing, and radium-226 bearing wastes. A major concern for these waste streams involves whether they can meet the requirements for protection of an inadvertent intruder that are included in the final rule, primarily because the waste streams contain or will produce through radioactive decay (progeny) significant quantities of long-lived radionuclides which were not specifically evaluated in the original 10 CFR Part 61 technical basis, some of which only reach their maximum activity far in the future.

We have followed this issue since 2010 and has made numerous recommendations and observations. A summary of our involvement with this issue is provided in Attachment 1 to this report.

DISCUSSION

The most difficult challenge in regulating radioactive waste disposal is providing reasonable assurance that the public will be protected long after institutional controls are terminated. The proposed final rule 10 CFR Part 61 establishes performance objectives which specify that doses to a member of the general public not exceed 25 millirem per year. The proposed final rule also specifies that doses to a postulated intruder who inadvertently interacts directly with the waste not exceed 500 millirem per year. The nominal compliance period for a disposal facility is defined as either 1,000 years or 10,000 years, depending on whether significant quantities of long-lived radionuclides exist in the waste inventory.

The proposed final rule requires that a site-specific performance assessment be conducted to demonstrate compliance with the performance objectives. A performance assessment is an analysis that identifies the features, events, and processes that could affect the disposal site performance, and estimates the potential dose as a result of releases caused by all significant features, events, and processes including uncertainties. Behavior of a disposal site is influenced by the land disposal facility design, the characteristics of the wastes, and the geologic and environmental characteristics of the site. A performance assessment considers the characteristics of the site (e.g., hydrology, meteorology, geochemistry, biology, and geomorphology) and the degradation, or alteration processes of the engineered barriers and natural system that will occur over time. Furthermore, the performance assessment identifies and evaluates the interactions between the disposal site characteristics and engineered barriers that might impact the performance of the disposal site.

The proposed final rule and its guidance, as currently structured, use the performance assessment primarily as a tool to identify scenarios that result in releases of radionuclides, to quantify their health effects to humans, and to thereby provide assurance that the facility is designed, managed, and left in a state that complies with the regulatory requirements.

Section 10 CFR 61.13 of the proposed final rule requires the licensee use the performance assessment to demonstrate that a member of the general public will not receive more than an annual dose of 25 millirem over the 1,000-year or 10,000-year duration of the facility's compliance period. The staff has briefed us on their basis for the 10,000-year period, which is founded on the projected radiotoxicity of DU.

There are many sources of uncertainty associated with projecting the future radiological risks from disposal of LLRW, including natural, engineered, and societal sources. The time scales of concern can be so long that direct observations or measurements of temporal changes on the disposal system are of limited value. Thus, assessment of future site performance must be based on models and assumptions about the physical and chemical processes involved. The nominal analysis timeframes specified in the proposed final rule account for the general observation that behavior of natural systems tends to be relatively stable and predictable until tens of thousands of years, when geomorphologic processes become highly uncertain and human experience is limited.

The staff notes that, by extending the analysis to 10,000 years, the dose from the DU decay chain would have built up to about 10% of its peak, sufficient to consider release pathway characteristics to inform the development of qualitative protective measures (i.e., defense-in-depth measures) in these time periods where uncertainty in performance analysis results is very large. Therefore, despite the fact that DU's peak radiological risk occurs after a million years, the staff has selected a nominal 10,000-year quantitative analysis time frame to avoid highly speculative and unreliable consequences. Though the impacts after 10,000 years would not be part of the compliance period calculations, they would be considered in the licensing process, and a licensee must demonstrate that the impacts after 10,000 years have been minimized to the extent reasonably achievable. The staff also noted that other domestic and international precedents support quantitative requirements that apply for time periods on the order of 10,000 years.

Significant additions in the proposed final rule are the requirement to document the facility safety case and an explicit requirement to identify provisions for defense-in-depth. Section 10 CFR 61.2 defines a safety case as a collection of information that demonstrates the assessment of the safety of a land disposal facility. This includes the required technical analyses, as well as conclusions on defense-in-depth and supporting evidence, and reasoning on the strength and reliability of the technical analyses and the assumptions made. The safety case also includes a description of the safety relevant aspects of the site, the design of the facility, and the managerial control measures and regulatory controls. Safety case, therefore, is a description of safety arguments that highlight the main evidence supporting the claim that the land disposal facility will provide long-term protection to health and safety of the public and environment.

The defense-in-depth concept has been used implicitly in waste disposal regulations in the past. Those requirements are intended to ensure that safety does not depend on one single element of the facility and includes such considerations as remote siting, waste forms that limit radionuclide release, appropriate design of engineered features, and beneficial natural geologic features of the disposal site. In general, assessments of the adequacy of defense-in-depth in isolation can lead to ineffective conclusions. Thus, a risk-informed regulatory framework should apply tailored defense-in-depth considerations to mitigate the effects from large uncertainties that are identified during the performance assessment.

The proposed final rule requires each operating facility to demonstrate compliance with the new performance objectives, even if the facility met the current 10 CFR Part 61 requirements at the time of burial and the facilities do not intend to add significant quantities of long-lived waste streams. We remain concerned about the requirement that existing operating disposal facilities need to satisfy the new performance objectives even if they do not plan to add substantial long-lived waste for disposal, especially for already-buried waste. We understand the staff's rationale, but it is essential to evaluate the feasibility and consequences of "remedial actions" available to those facilities which may not comply fully with the revised performance objectives. The final rule should retain the provision that allows compliance for existing facilities on a case-by-case basis.

An Alternative Regulatory Approach

We remain concerned that the requirements in the proposed final rule are complex and unnecessarily burdensome. An alternative approach to the rule is possible by making greater use of site performance assessments with quantitative uncertainty analyses. Performance assessments are required by the proposed final rule. Modern methods of performance assessment have greatly advanced in recent years and allow an integrated evaluation of the effects of geology, hydrology, waste form, and waste barriers. The performance assessment together with a dose limit defined by the Commission (such as 25 millirem/year) to assure adequate protection of the public health and safety can be used to integrate parts of the current rule that now have an *ad hoc* appearance. In addition to providing assurance that the general public is protected, it has become traditional to assume there is an inadvertent intrusion into the site and its waste at some time following termination of institutional controls. The performance assessment can also readily incorporate an objective examination of this stochastic event, as well as a range of possible intruder activities. In this approach, the performance assessment would be used to structure the most appropriate methods to achieve the desired performance

objectives for a particular disposal site, rather than to simply demonstrate compliance with nominal regulatory requirements which may not be well-founded for the site, its waste forms, or protection strategies.

Any performance assessment will be uncertain. The sources of these uncertainties can be identified and quantified. Defense-in-depth can be integrated explicitly into the performance assessment as a means to ameliorate the significant sources of uncertainty. This contrasts sharply with defense-in-depth being little more than an exposition of site attributes as it is in the proposed final rule. The systematic evaluation of defense-in-depth measures provides a more rational approach to minimize risk to the public.

Waste emplaced in a disposal facility licensed under the current rule will need to be included in the performance assessment. Any need for remediation of the older waste under the proposed rule would be a decision of the licensee based on the results of the performance assessment and their interest in acceptance of future waste streams. Engineering trade-offs between remediation of the old waste and treatment of the new waste would be based, again, on the results of performance assessment and would consider the potential consequences of proposed remediation activities.

The performance assessment can be used to define the compliance period based on the waste, waste form, geology, and hydrology of the site. The Commission may find it useful to define some minimal compliance period but this should not be a rigid limit. The performance assessment can also be used to show that large, sudden increases in the public dose do not occur following the period of compliance. Uncertainty quantification in the performance assessment can also be used to show when uncertainties grow sufficiently large that meaningful prognostications of waste behavior are no longer possible. Waste rules making greater use of performance assessments will facilitate future efforts to address new waste types such as 'greater than class C' waste.

While the proposed final rule 10 CFR Part 61 can ensure that facilities meet Commission objectives, it would do so in ways that add unnecessary complexity and burden to current licensees and applicants. As for the staff guidance provided in draft NUREG-2175, we received a briefing on aspects of the guidance at our meeting on November 3, 2016. We did not receive the actual document in time to complete our review.

Sincerely,

/RA/

Dennis Bley
Chairman

Attachment:
As Stated

objectives for a particular disposal site, rather than to simply demonstrate compliance with nominal regulatory requirements which may not be well-founded for the site, its waste forms, or protection strategies.

Any performance assessment will be uncertain. The sources of these uncertainties can be identified and quantified. Defense-in-depth can be integrated explicitly into the performance assessment as a means to ameliorate the significant sources of uncertainty. This contrasts sharply with defense-in-depth being little more than an exposition of site attributes as it is in the proposed final rule. The systematic evaluation of defense-in-depth measures provides a more rational approach to minimize risk to the public.

Waste emplaced in a disposal facility licensed under the current rule will need to be included in the performance assessment. Any need for remediation of the older waste under the proposed rule would be a decision of the licensee based on the results of the performance assessment and their interest in acceptance of future waste streams. Engineering trade-offs between remediation of the old waste and treatment of the new waste would be based, again, on the results of performance assessment and would consider the potential consequences of proposed remediation activities.

The performance assessment can be used to define the compliance period based on the waste, waste form, geology, and hydrology of the site. The Commission may find it useful to define some minimal compliance period but this should not be a rigid limit. The performance assessment can also be used to show that large, sudden increases in the public dose do not occur following the period of compliance. Uncertainty quantification in the performance assessment can also be used to show when uncertainties grow sufficiently large that meaningful prognostications of waste behavior are no longer possible. Waste rules making greater use of performance assessments will facilitate future efforts to address new waste types such as 'greater than class C' waste.

While the proposed final rule 10 CFR Part 61 can ensure that facilities meet Commission objectives, it would do so in ways that add unnecessary complexity and burden to current licensees and applicants. As for the staff guidance provided in draft NUREG-2175, we received a briefing on aspects of the guidance at our meeting on November 3, 2016. We did not receive the actual document in time to complete our review.

Sincerely,
/RA/
Dennis Bley
Chairman

Attachment:
As Stated

Accession No: **ML16312A116**

Publicly Available **Y**

Sensitive **N**

Viewing Rights: NRC Users or ACRS Only or See Restricted distribution

OFFICE	ACRS	SUNSI Review	ACRS	ACRS	ACRS
NAME	DWidmayer	DWidmayer	MLBanks/GS	ADVeil	ADV for DCB
DATE					

OFFICIAL RECORD COPY

Attachment

During the 570th meeting of the ACRS, March 4-6, 2010, we first heard from the staff regarding the status of rulemaking for DU and other unique waste streams. Our letter report, dated March 18, 2010, contained the following recommendation:

The staff should continue their efforts to risk-inform the regulations for disposal of DU based on site-specific, realistic performance assessments with appropriate consideration of uncertainties.

We received briefings on this proposed rulemaking during our 585th meeting on July 13-15, 2011, and our 586th meeting on September 8-10, 2011. Our letter report, dated September 22, 2011, contained the following conclusions and recommendations:

1. 10 CFR 61 should not be amended in accordance with the staff's recommendations. Rather, the staff should develop a risk informed, performance based LLW site assessment methodology using realistic characterizations of disposed radioactive materials; the features, events, and processes that can disrupt disposed waste; natural and engineered barriers; environmental transport mechanisms; and subsequent human exposure scenarios.
2. Implementation guidance for Part 61 should not specify an a priori period of performance. Rather, the performance assessment should develop a period of performance based on the features, events and processes specific to the geohydrological features of a candidate site, the technologies used to isolate wastes, and the controls used to isolate wastes from the environment and humans.
3. The approaches in recommendations 1 and 2 are equally applicable to the disposal of depleted uranium as well as other low-level waste.
4. Compliance with performance objectives of the disposal system after the institutional control period ends, as well as the possible doses to hypothetical intruders, should be evaluated considering the natural features, events, and processes for a given site for a period of time commensurate with the risk for a specific facility and site.

The Commission issued Staff Requirements Memorandum (SRM)-COMWDM-11-0002/COMGEA-11-0002 on January 19, 2012, providing direction to the staff to revise the proposed rulemaking and supporting regulatory basis and submit it to the Commission within 18 months. The SRM directed the staff to revise both the performance assessment and intruder analysis requirements:

1. Allowing licensees the flexibility to use ICRP dose methodologies in a site-specific performance assessment for the disposal of all radioactive waste.
2. A two tiered approach that establishes a compliance period that covers the reasonably foreseeable future and a longer period of performance that is not a priori and is established to evaluate the performance of the site over longer timeframes. The period of performance is developed based on the candidate site characteristics (waste package, waste form, disposal technology, cover technology and geo-hydrology) and the peak dose to a designated receptor.

3. Flexibility for disposal facilities to establish site-specific waste acceptance criteria based on the results of the site's performance assessment and intruder assessment.

During the 606th meeting of the ACRS, July 9-12, 2013, we reviewed draft SECY-13-0075, the staff's proposal to revise 10 CFR Part 61 and the associated draft implementation guidance. Our letter report, dated July 22, 2013, contained the following conclusions and recommendations:

1. The proposed rule significantly expands the regulatory requirements for the licensing of low-level waste facilities and increases regulatory burden without sufficient justification.
2. Our primary concerns about the proposed changes to 10 CFR Part 61 are the requirements to demonstrate compliance for 10,000 years and protection of the inadvertent intruder.
3. We plan to hold additional meetings to better understand the technical justification for the elements of concern in the proposed rule.
4. Previously disposed wastes should not be subjected to additional compliance evaluations as proposed by the staff.

During the 611th meeting of the ACRS, February 5-7, 2014, we completed our review of the staff's proposed revisions. Our letter report, dated February 19, 2014, contained the following conclusions and recommendations:

1. In our continuing assessment, we affirm the conclusions and recommendations in our earlier letter reports on this matter.
2. In the two-tiered assessment approach, the compliance period covering a reasonably foreseeable future should not exceed 1,000 years.
3. Wastes disposed in accordance with the existing Part 61 rule at the time of disposal should not be subjected to additional compliance evaluations. We have found no deficiencies in the existing regulations that warrant imposing new disposal requirements.
4. The proposed revisions to Part 61 contain excessive implementation detail. These details should be provided in guidance documents rather than in the rule.

The Commission issued SRM-SECY-13-0075 on February 12, 2014, providing direction to the staff to revise the proposed rulemaking and supporting regulatory basis in several ways, and requested further review of the rule requirements and implementation guidance by interested stakeholders. In the SRM, the Commission stated:

1. The Advisory Committee on Reactor Safeguards (ACRS) is encouraged to continue to provide their independent review and recommendations on the technical basis supporting this rule, and the accompanying draft guidance, during the rulemaking period.

REFERENCES

1. U.S. Nuclear Regulatory Commission, SECY-16-0106, "Final Rule: Low-Level Radioactive Waste Disposal (10 CFR Part 61) (RIN 3150-AI92)," September 15, 2016 (ML16188A290).
2. U.S. Nuclear Regulatory Commission, Draft NUREG-2175, "Guidance for Conducting Technical Analyses for 10 CFR 61," October 2016 (ML14357A072).
3. U.S. Nuclear Regulatory Commission, SECY-08-0147, "Response to Commission Order CLI-05-20 Regarding Depleted Uranium," October 7, 2008 (ML081820762).
4. Advisory Committee on Reactor Safeguards, "Status of Staff Rulemaking Efforts for Depleted Uranium and Other Unique Waste Streams," March 18, 2010 (ML100760264).
5. Advisory Committee on Reactor Safeguards, "Proposed Rulemaking to Introduce a Site-Specific Performance Assessment and Human Intrusion Analysis Requirement to 10 CFR Part 61," September 22, 2011 (ML11256A191).
6. U.S. Nuclear Regulatory Commission, Staff Requirements Memorandum-COMWDM-11-0002/COMGEA-11-0002, "Revision to 10 CFR Part 61," January 19, 2012 (ML1210190360).
7. U.S. Nuclear Regulatory Commission, SECY-13-0075, "Proposed Rule: Low-Level Radioactive Waste Disposal (10 CFR Part 61) (RIN 3150-AI92)," July 18, 2013 (ML13129A268).
8. Advisory Committee on Reactor Safeguards, "Revisions to Low-Level Radioactive Waste Disposal Requirements (10 CFR Part 61)," July 10, 2013 (ML13203A078).
9. U.S. Nuclear Regulatory Commission, Staff Requirements-SECY-13-0075, "Proposed Rule: Low-Level Radioactive Waste Disposal (10 CFR Part 61) (RIN 3150-AI92)," February 12, 2014 (ML14043A371).
10. Advisory Committee on Reactor Safeguards, "10 CFR Part 61 - Revisions to Low-Level Radioactive Waste Disposal Requirements," February 19, 2014 (ML14041A152).
11. International Commission on Radiological Protection, ICRP Publication 81, "*Radiation Protection Recommendations as Applied to the Disposal of Long-Lived Solid Radioactive Waste*," Annals of the ICRP, Vol. 28, No. 4, 2000.