SUMMARY OF PUBLIC AND ADVISORY COMMITTEE ON REACTOR SAFEGUARDS INTERACTIONS AND COMMENTS RECEIVED IN RESPONSE TO PRELIMINARY DOCUMENTS FOR LOW-LEVEL RADIOACTIVE WASTE DISPOSAL (10 CFR PART 61) RULEMAKING

BACKGROUND:

In September 2009, the staff conducted two public workshops to solicit public input on the technical basis for the proposed rule. Transcripts for these workshops can be found at Agencywide Documents Access and Management System (ADAMS) Accession Nos. ML092580469, ML092580481, ML092890511, and ML092890516. The staff also briefed the Advisory Committee on Reactor Safeguards (ACRS), Radiation Protection and Nuclear Materials Subcommittee, on December 16, 2009, and the full ACRS on March 4, 2010, on the status of this rulemaking. The ACRS provided a letter report (ADAMS Accession No. ML100760264), dated March 18, 2010, to the Commission that recommended methods to address certain low-level radioactive waste (LLRW) performance assessment issues. In a response to the ACRS letter, the staff noted that it would consider the Committee's advice and recommendations. As a result of comments received from these workshops and ACRS interactions, the staff developed a regulatory basis document titled "Technical Basis for Proposed Rule to Amend 10 CFR Part 61 to Specify Requirements for the Disposal of Unique Waste Streams, Including Large Quantities of Depleted Uranium" (ADAMS Accession No. ML111040419) and started the 10 CFR Part 61 limited-scope rulemaking. On May 3, 2011, the staff published preliminary proposed rule language, an associated regulatory basis document, and an issue paper titled "Technical Analysis Supporting Definition of Period of Performance for Low-level Waste Disposal" (ADAMS Accession No. ML111030586) on http://www.regulations.gov, for public comment (76 FR 24831). In conjunction with the publication of the preliminary documents, the staff conducted a public meeting on May 18, 2011, in Rockville, MD, to discuss the preliminary proposed rule language and its associated regulatory basis documents. A summary and transcript of this meeting can be found at ADAMS Accession No. ML111570329. The comment period for the preliminary proposed rule language ended on June 18, 2011; the U.S. Nuclear Regulatory Commission (NRC) received 15 comment letters from a diverse group of people, including public interest groups, industry, and other government organizations. The comment letters for the May 2011 preliminary proposed rule language are available on http://www.regulations.gov under Docket ID NRC-2011-0012.

On January 19, 2012, in Staff Requirements Memorandum (SRM)-COMWDM-11-0002/COMGEA-11-0002, "Revisions to Part 61," dated January 19, 2012 (ADAMS Accession No. ML120190360), the Commission directed the staff to expand the ongoing limited-scope revision to 10 CFR Part 61 to include the following issues: 1) allowing the licensees the flexibility to use International Commission on Radiological Protection (ICRP) dose methodologies in a site-specific performance assessment for the disposal of all radioactive LLRW; 2) developing 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; 3) providing flexibility for disposal facilities to establish site-specific LLRW acceptance criteria based on the results of the site's performance assessment and intruder assessment; and 4) recommending a compatibility category for the elements of the revised rule that ensures alignment between the States and Federal Government on safety fundamentals, while providing the States with the flexibility to determine how to implement these safety requirements. Based on the Commission's direction, the NRC staff revised the regulatory basis document associated with

this rulemaking, "Regulatory Basis for Proposed Revisions to Low-Level Waste Disposal Requirement (10 CFR Part 61)" (ADAMS Accession No. ML12356A242) and developed a second version of the preliminary rule language.

Comments on Revised Preliminary Proposed Rule Language:

In connection with SRM-COMWDM-11-0002/COMGEA-11-0002, "Revision to 10 CFR Part 61," the Commission directed the staff to seek public feedback on the four expanded regulatory requirements for the ongoing 10 CFR Part 61 rulemaking. The staff conducted three public meetings in 2012 to solicit public input. Transcripts of those meetings are available under ADAMS Accession Nos. ML120820051, ML12143A197, and ML12244A524. In connection with the NRC-sponsored public meetings, the staff also placed *Federal Register* notices, requesting comment on the Commission's 2012 expanded rulemaking direction. The staff also held direct conversations with the Agreement States, both by telephone and in person. A summary of the Agreement States and the public initial views on the four expanded regulatory requirements is included in Section 6, 'Stakeholder Interactions and Comments," of the revised regulatory basis document.

On December 7, 2012, the staff published the revised preliminary proposed rule language and the revised regulatory basis document on http://www.regulations.gov for public comment (77 FR 72997). The comment period ended on January 7, 2013. The NRC received 25 comment letters from a diverse group of people, including those from public interest groups, industry, and government organizations. The comment letters are also available on http://www.regulations.gov under Docket ID NRC-2011-0012.

In general, comment letters from the December 7, 2012, solicitation both supported and opposed the staff's proposed rulemaking approach.

In the preliminary proposed rule language, the staff proposed a compliance period of 10,000 years. Commenters suggested their preferences for a range for the compliance period from 500 to 1,000 years, 10,000 years, 20,000 years, and out to peak annual dose. Some commenters felt that the results of site-specific technical analyses would not be meaningful considering the large uncertainty resulting from a 10,000-year compliance period. Others suggested that, in addition to evaluating uncertainties in the performance assessment, the NRC should also apply a dose limit for the time period beyond the compliance period.

The staff also proposed a requirement to perform analyses during the post-10,000 year performance period. The performance period analyses required by proposed 10 CFR 61.13(e), "Technical analyses," would require licensees or license applicants to prepare performance period analyses (i.e., after 10,000 years) that assess how the LLRW disposal facility and site characteristics limit the potential long-term radiological impacts, consistent with available data and current scientific understanding. The analyses would use the as low as reasonably achievable (ALARA) dose methodology as a metric to indicate the impacts from disposal of LLRW during the performance period. Commenters supported the proposed performance period analyses requirement, but believed that ALARA is not an appropriate methodology to use, since ALARA has been traditionally used in association with a prescribed dose limit (e.g., in 10 CFR Part 20) and the staff's proposed performance period analyses do not have a prescribed dose limit. Other commenters suggested that an alternative to the staff's proposed performance period metric that uses a high dose limit or "realistic threat of catastrophic

consequences" would be more appropriate. Based on public comments, the staff reconsidered its approach and replaced the ALARA requirement with a requirement that the disposal facility "minimize exposures to the extent reasonably achievable."

In the preliminary proposed rule language, the staff proposed to permit the development of criteria for LLRW acceptance based on the results of site-specific technical analyses. Some commenters expressed concerns that the LLRW acceptance criteria (proposed 10 CFR 61.58, "Waste acceptance") for determining the acceptability of LLRW for disposal at any given LLRW disposal facility, "must not either explicitly or by interpretation be a means to by-pass the existing waste classification requirements of Subpart 61.55." These commenters requested that "the existing classification system of low-level radioactive waste remain in place, with the ability of a state, such as Utah, to enforce state prohibitions on wastes with higher radioactive levels." Other commenters believed that site-specific LLRW acceptance criteria would allow State regulators a greater level of control and certainty over LLRW originating in another State. Some commenters suggested that there should be a requirement to annually update the LLRW acceptance criteria every 5 years and further clarify in the regulation that the disposed LLRW must meet the LLRW acceptance criteria. Based on the comments, the staff revised the proposed rule language to require a licensee to conduct an annual review of the LLRW acceptance criteria to determine if they need to be updated. The staff also made revisions to clarify that the disposed LLRW must meet the LLRW acceptance criteria.

Finally, the staff also proposed to allow the use of updated dosimetry modeling techniques in conducting the proposed site-specific technical analyses. Some commenters believed that, by abandoning the current organ dose methodology in 10 CFR Part 61, the NRC's regulations would be less protective of public health and safety. Other commenters were supportive of the proposal to allow licensees or license applicants the flexibility to use the latest ICRP dose methodologies in a site-specific performance assessment.

Some commenters suggested that the NRC should adopt the strictest Agreement State compatibility level to ensure consistency in the implementation of the proposed requirements among the Agreement States, while others suggested a more flexible compatibility level and that the NRC work with the States so that there would be no unintended consequences resulting from the proposed requirements.

Some commenters questioned the applicability of the proposed requirements to existing facilities, asking "if a sited state made the determination to apply Part 61 to a facility that was licensed at the time Part 61 originally was adopted, would the sited state then be required to apply the current revisions to that facility?" Other commenters suggested that clarification should be made in the proposed rule regarding whether current LLRW disposal facilities that are regulated by the Agreement States would need to comply with these requirements or would be "grandfathered." Based on comments, the staff recommends that the proposed requirements would apply to current licensees and license applicants.

<u>Advisory Committee on Reactor Safeguards Comments</u>:

The staff also met with the ACRS, Radiation Protection and Nuclear Materials Subcommittee on June 23 and August 17, 2011, and the full ACRS on July 13 and September 8, 2011, to provide an update and solicit the Committee's views on certain technical issues related to the 10 CFR Part 61 rulemaking and implementation guidance document developments. The transcripts for

these meetings can be found in ADAMS (Accession Nos. ML11187A276, ML11242A170, ML11221A059, and ML11256A117, respectively).

The staff briefed the ACRS on the May 2011 preliminary proposed rule language, the associated regulatory basis documents, and the comments received from the public. Following the staff's briefings, the ACRS provided a letter report (ADAMS Accession No. ML11256A191), dated September 22, 2011, to the Commission. This report fundamentally disagreed with the NRC's current and proposed regulatory framework for LLRW disposal. In the report, the ACRS recommended that the compliance period for the performance assessment should be a site-specific time span, not a specified period of 20,000 years. The ACRS also disagreed with the current treatment of inadvertent intruders and indicated that, with respect to the proposed requirements, compliance with the performance objectives 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. In a response letter dated November 3, 2011 (ADAMS Accession No. ML112911386), the staff explained that the proposed amendments to 10 CFR Part 61 would allow licensees flexibility to demonstrate compliance with performance objectives using site-specific analyses. The staff also indicated that its proposed approach for a two-tiered period of performance is consistent with 1) Commission direction to specify parameters of analyses; 2) public feedback to specify a compliance period; and 3) previous recommendations of the Advisory Committee on Nuclear Waste to consider adopting the two-tiered approach.

The NRC staff again briefed the ACRS Radiation Protection and Nuclear Materials Subcommittee on April 9 and June 18 and the full committee on July 10, 2013. Summaries and transcripts of these meetings can be found at the ACRS' website, http://www.nrc.gov/about-nrc/organization/acrsfuncdesc.html. The staff awaits receipt of the ACRS' comment letter following the recent full committee meeting.

Agreement States Comments:

On September 28, 2011, the staff provided a pre-decisional copy of the initial draft of the proposed rule and draft implementation guidance document to the Agreement States for review and comment. On November 9, 2011, the NRC received a comment letter from the Conference of Radiation Control Program Directors (CRCPD). The letter stated that the CRCPD's comments were consistent with the ACRS's comments in the ACRS letter report dated September 22, 2011. The CRCPD also stated that, because of the large volumes of depleted uranium at existing LLRW disposal facilities, some States with disposal sites were initially concerned that there would be a need for site remediation due to the proposed revised requirements for long-term site performance standards for unique LLRW streams. The CRCPD indicated that its concern could be addressed through "grandfathering." However, the CRCPD stated that it was still concerned because assuring compliance with the 10 CFR Part 61 performance objectives after 20,000 years would be difficult. The CRCPD supported the ACRS's position of a site-specific approach regarding the compliance period.

On November 30, 2011, the NRC received a comment letter from the Utah Division of Radiation Control (DRC). The DRC recommended several changes to the initial draft of the proposed rule text, such as new definitions and clarifications. The DRC also recommended that a longer time period than the 20,000-year proposal should be considered for the intruder assessment

because of the long half-life of depleted uranium and the significant in-growth of radium-226. Additionally, the DRC recommended that the NRC establish a maximum dose limit for the period beyond 20,000 years because of the burden that it would place on Agreement States in the absence of a dose limit. Finally, the DRC noted that the four Agreement States that currently host LLRW disposal facilities specify concentration limits for Ra-226; whereas, the NRC does not have any LLRW concentration limits for Ra-226 specified in 10 CFR 61.55.

On March 13, 2013, the staff provided a pre-decisional copy of the revised draft proposed rule language, based on comments received from the revised preliminary proposed rule language, to the Agreement States for review and comment. On April 12, 2013, the NRC received a comment letter from the CRCPD. The letter stated that the CRCPD is concerned that an unintended consequence of the proposed requirements of 10 CFR Part 61 would be a need to remediate existing LLRW disposal facilities, and this concern should be addressed through "grandfathering" of LLRW that are already disposed in existing facilities. In addition, the CRCPD recommended deleting the proposed requirements in 10 CFR 61.13, “For licensees with licenses for land disposal facilities in effect on the effective date of this subpart, such analyses shall be submitted within one year of the effective date of this subpart” and allowing the State to decide whether a current licensee should submit the analyses or be reviewed during an inspection. The staff believes that a submittal timeframe should be specified to clarify when the analyses must be submitted. However, the staff revised the required submittal timeframe from “one year of the effective date” to “at the next license renewal or within five years of the effective date of this subpart, whichever comes first,” to provide a more reasonable timeframe for the licensees to conduct the required analyses. The staff also would note that performing the analyses proposed and developing acceptance criteria for future receipt of LLRW shipments would not result in a necessity for immediate site remediation activities with respect to existing LLRW. The staff recognizes that the results of the analyses may impact evaluations conducted at the time of license termination for the disposal facility.

On April 12, 2013, the NRC received a comment from the State of Kentucky. The State of Kentucky commented that while it understands that utilizing site-specific technical analyses and foregoing specific inclusion of uranium limits in the 10 CFR 61.55(a) tables allows for more flexibility and “fairness” to a potential licensee intending to open a LLRW disposal facility, it believes that some of the proposed regulatory changes stop short of what should be protective in certain scenarios. The State of Kentucky stated that it further believes the long-term hazards of these types of waste justify a “hard” regulatory requirement of deeper burial, in arid conditions, with significant depth to any water table. The State of Kentucky expressed its concern that, without express prohibition of sites and designs that should not be utilized to store extremely long-lived waste forms, such sites will be proposed and be justified with models, despite the inherent risks.

On April 12, 2013, the NRC received a comment letter from the State of Washington. The letter stated that the State of Washington supports the staff’s proposed two-tiered approach and the 10,000-year compliance period. However, the State of Washington stated that it believes, given the extraordinarily large uncertainties associated with these timeframes, dose limits should not be applied to the performance period. The State of Washington also stated that it agrees with the staff’s recommended approach of adopting an edition neutral approach in order to allow for the most up-to-date ICRP recommendations to be utilized and supports the concept of allowing States to develop their own waste acceptance criteria.

On April 13, 2013, the NRC received a comment letter from the Organization of Agreement States (OAS). The letter stated that the OAS does not agree with the statement that 10 CFR 61.58 would have significant transboundary implications associated with the staff's proposed designation of Compatibility Category "B" for this section, without including specific examples or more explanation to support the proposed compatibility designation. The OAS recommends the compatibility be changed to a "C." The staff agrees with the OAS and revised the proposed compatibility designation of 10 CFR 61.58 from Compatibility Category "B" to Compatibility Category "C." The OAS also recommends the deletion of the sentence, "For licensees with licenses for land disposal facilities in effect on the effective date of this subpart, such analyses shall be submitted within one year of the effective date of this subpart," and allowing the state to decide whether a current licensee should submit the analyses or be reviewed during an inspection. The staff believes that a submittal timeframe should be specified to clarify when the analyses must be submitted. The staff revised the required submittal timeframe from "one year of the effective date" to "at the next license renewal or within five years of the effective date of this subpart, whichever comes first," to provide a more reasonable timeframe for the licensees to conduct the required analyses.

On April 17, 2013, the NRC received a comment letter from the DRC. The DRC recommended several changes to the initial draft of the *Federal Register* notice and proposed rule text, such as proposed Table A of proposed 10 CFR 61.13(e) and clarifications. The DRC stated that it is concerned with the staff's approach to comparing the proposed Table A limits, found in proposed 10 CFR 61.13(e), to LLRW concentrations averaged over the entire disposal site and that this approach is different than Utah's current practice of addressing LLRW licensing actions on an embankment-specific basis. The DRC stated that it believes its practice would allow a licensing agency to determine if a licensee is able to take credit for low activity inventory already in the ground to "dilute" higher activity concentrations that may be proposed. Therefore, the DRC proposed to revise the description of the proposed Table A in the *Federal Register* notice to reflect that the Table A values will be compared against either the LLRW concentrations averaged over the entire disposal site, or the average for a given disposal embankment, at the discretion of the licensing agency such as an Agreement State. The DRC also encouraged the staff to develop implementation guidance to aid the States that host LLRW disposal facilities in determining how often LLRW sampling and analysis need to be performed and how much time can be allowed to elapse between the results of the technical analyses and the time of disposal. The DRC also requested the NRC consider the likely increased resource burden on States that host LLRW disposal facilities resulting from the proposed amendments. The staff has prepared a guidance document to facilitate the implementation of the proposed rule and a draft regulatory analysis (enclosure 2) to examine the costs and benefits of this proposed regulation.

On May 6, 2013, the NRC received a comment letter from the Texas Commission on Environmental Quality (TCEQ). The TCEQ stated that it recommends that the definition of "Performance period" be expanded to include some type of demonstration period such as time at which peak dose occurs or another metric such as cost-benefit analysis. The TCEQ also stated that it believes the applicability of dose limits, 500 millirem per year in the proposed 10 CFR 61.42(a) and 25 millirem per year in the current 10 CFR 61.41(a), may be unclear and recommended that the NRC define which dose limits apply to which receptors. The comment letter was submitted after the closing of the comment period. The staff plans to consider the TCEQ comments as part of the review of comments on the proposed rule.

Staff's Analysis

In general, comments from stakeholders on the staff's preliminary proposed rule language appear equally divided between support for and opposition to the staff's proposed rulemaking approach. After careful consideration, the staff concluded that its approach is viable, and that none of the alternate approaches are more clearly preferable in achieving the Commission's direction for the reasons elaborated upon in the draft *Federal Register* notice for the proposed rule. The staff has reviewed and considered all the comments received during the comment period. Where appropriate, the staff made changes to the preliminary proposed rule language based on public comments, including those from the industry, the ACRS, and the Agreement States. Because the comment period for the preliminary proposed rule documents is outside of the formal rulemaking process, the staff did not and does not intend to provide written responses to the commenters. The public will have an additional opportunity to comment on the rule language when it is published as a proposed rule in accordance with the provisions of the Administrative Procedures Act. The staff will respond to any such comments in the Statements of Consideration for the final rule.