DIVISION OF DECOMMISSIONING, URANIUM RECOVERY, AND WASTE PROGRAMS

GUIDANCE FOR THE REVIEWS OF PROPOSED DISPOSAL **PROCEDURES AND TRANSFERS OF RADIOACTIVE MATERIAL UNDER** 10 CFR 20.2002 AND 10 CFR 40.13(A)

Published April 2020

Division of Decommissioning, Uranium Recovery, and Waste Programs Office of Nuclear Material Safety and Safeguards U.S. Nuclear Regulatory Commission Washington, DC 20555-0001



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HISTORY OF THIS GUIDANCE

The NRC staff published an initial draft for interim use on August 31, 2009 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML092460058). The NRC staff considered comments received on the initial draft in preparing a revised draft guidance document, which was published for public comment on October 19, 2017 (ADAMS Accession No. ML17229B588, *Federal Register* (FR) Notice at <u>82 FR 48727</u>). A summary of the comments on the revised draft guidance document, as well as the NRC staff responses, is available at ADAMS Accession No. ML19295F140. This document incorporates numerous changes made in response to the comments received on the draft guidance document, as well as interactions with NRC stakeholders.

Rev. #	Date	ADAMS Accession No.	Description
0	August 2009	ML092460058	This version of the guidance was the initial draft for interim use and was designated EPPAD 3.5.
1	October 2017	ML17229B588	This draft guidance document provides additional information and detail to various sections throughout the guidance, as well as descriptions for processes, instructions, and bases. It also adds information regarding regulatory documents that have been issued, various reference documents, and Commission papers.
2	April 2020	ML18296A068	This revised document addresses stakeholder comments received on previous draft versions, as well as recent interaction with stakeholders on the alternative disposal approval process.

APPLICABILITY

This document is intended for NRC staff use when performing reviews of requests for alternative disposals under the provisions of Title 10 of the *Code of Federal Regulations* (10 CFR) Section 20.2002, "Method for obtaining approval of proposed disposal procedures," and Section 40.13, "Unimportant quantities of source material." This guidance may be used by Agreement State staff performing similar reviews, as appropriate.

This document is not a substitute for NRC or Agreement State¹ regulations, and compliance with it is not required. This document describes approaches and methods that the NRC considers acceptable for use in alternative disposal requests and describes the NRC's process for reviewing such requests. Approaches and methods different from those described in this document may be acceptable if they include a basis for the NRC to make the determinations needed to evaluate and approve the requests.

¹ Under section 274 of the Atomic Energy Act of 1954, as Amended (AEA), the NRC may enter into an agreement with a State for discontinuance of the NRC's regulatory authority over some material licensees within the State (i.e., Agreement State). The State must first show that its regulatory program is compatible with the NRC's and adequate to protect public health and safety. Agreement States may ask for assistance from the NRC to review alternative disposal requests per the Technical Assistance Request (TAR) process. The list of Agreement States can be located with this link: https://scp.nrc.gov/asdirectory.html.

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List of Acronyms and Abbreviations

ADAMS	Agency-Wide Documents Access and Management System
ADR	Alternative Disposal Request
AEA	Atomic Energy Act of 1954, as amended
ALARA	As Low As is Reasonably Achievable
CAC	Cost Activity Code
CATEX	Categorical Exclusion
CFR	<i>Code of Federal Regulations</i>
DORL	Division of Operating Rector Licensing
DORL	U.S. Department of Transportation
DOT	Division of Decommissioning, Uranium Recovery, and Waste Programs
DUWP	Division of Waste Management and Environmental Protection
DWMEP	Environmental Assessment
EA	Environmental Impact Statement
EIS	Energy Policy Act of 2005
EPAct	Enterprise Project Identifier
EPID	Environmental Protection and Performance Assessment Directorate
EPPAD	Environmental Review Materials Branch
ERMB	Finding of No Significant Impact
FONSI	<i>Federal Register</i>
FR	<i>Federal Register</i>
FSME	Office of Federal and State Materials and Environmental Management
ft IP LLW LTR LWR m MCNP mrem MSST mSV NARM NEPA NRC NMSS NRO NRR NSIR OGC OMB PAWG	Programs Feet Inspection Procedure Low-Level Waste or Low-Level Radioactive Waste License Termination Rule Light Water Reactor meter Monte Carlo N-Particle Transport Code millirem Division of Materials Safety, Security, State, and Tribal Programs millisievert Naturally-Occurring and Accelerator-Produced Radioactive Material National Environmental Policy Act U.S. Nuclear Regulatory Commission Office of Nuclear Materials Safety and Safeguards Office of Nuclear Materials Safety and Safeguards Office of Nuclear Reactor Regulation Office of Nuclear Reactor Regulation Office of Nuclear Safety and Incident Response Office of the General Counsel Office of Management and Budget Performance Assessment Working Group
PM	Project Manager
RAI	Request for Additional Information
RCRA	Resource Conservation and Recovery Act
RESRAD	RESidual RADiation
RG	Regulatory Guide
RIS	Regulatory Issue Summary

RTAB	Risk and Technical Analysis Branch
SER	Safety Evaluation Report
SNM	Special Nuclear Material
SOC	Statement of Considerations
SRM	Staff Requirements Memorandum
STC	State and Tribal Communications
SUNSI	Sensitive Unclassified Non-Safeguards Information
TAR	Technical Assistance Request
TEDE	Total Effective Dose Equivalent
TER	Technical Evaluation Report
VLLW	Very Low-Level Waste
WAC	Waste Acceptance Criteria
WDTS	Waste Disposal Tracking System

Executive Summary

This document describes the NRC process for documenting, reviewing, and approving (on a case-by-case basis) requests for alternative disposals under the provisions of Title 10 of the *Code of Federal Regulations* (10 CFR) Section 20.2002, "Method for obtaining approval of proposed disposal procedures," and Section 40.13, "Unimportant quantities of source material."

The term "alternative" is used in this case because pursuant to 20.2002, the licensee or applicant could propose to dispose of the licensed material by a procedure other than those methods provided in the regulations (e.g., an alternative to disposal in a facility licensed under 10 CFR Part 61, "Licensing Requirements for Land Disposal of Radioactive Waste").

Although § 20.2002 and § 40.13(a) reviews are similar in many respects, there are differences that are described in this document. Where there are differences between the procedures for handling the different types of requests, a sub-section for each type of request is provided. Otherwise, they will be referred to collectively as Alternative Disposal Requests (ADRs).

In addition to describing the processes associated with performing these ADR reviews, this document also discusses the roles and responsibilities of others involved in aspects of these reviews. This document includes discussion and guidance on the following topics:

- relevant regulations and guidance documents;
- the approval process;
- technical reviews;
- environmental reviews;
- coordination and communications with State and Federal agencies; and
- non-licensee reviews.

This document has been prepared for use primarily by staff in the Division of Decommissioning, Uranium Recovery, and Waste Programs of the Office of Nuclear Material Safety and Safeguards at the U.S. Nuclear Regulatory Commission. However, because ADRs are also received by the NRC Regional Offices, the Office of Nuclear Reactor Regulation, and Agreement States, this guidance has been developed to support their reviews.

1.0 Purpose

The purpose of this document is to provide guidance for the U.S. Nuclear Regulatory Commission (NRC) staff and describe the process under Title 10 of the *Code of Federal Regulations* (10 CFR) Section 20.2002, "Method for obtaining approval of proposed disposal procedures," and Section 40.13, "Unimportant quantities of source material," for documenting, reviewing, and dispositioning (on a case-by-case basis) requests received from licensees and applicants to dispose of material. The term "alternative" is used in this case because the licensee or applicant, under § 20.2002, proposes to dispose of the licensed material by a procedure not otherwise authorized in the regulations (e.g., an alternative to disposal in a 10 CFR Part 61, "Licensing Requirements for Land Disposal of Radioactive Waste," facility). The NRC staff may authorize these requests for alternative disposal under the provisions of § 20.2002 or § 40.13(a).²

The NRC staff typically considers approval of alternative disposal requests (ADRs) for very low-level waste (VLLW) on a case-by-case basis. The term VLLW does not have a statutory or regulatory definition, but is described in the VLLW Scoping Study as material created during the conduct of licensed activities, which contains some residual radioactivity, including naturally occurring radionuclides, that may be safely disposed of in hazardous or municipal solid waste landfills (*Federal Register* (FR) Notice at 83 FR 6319; February 14, 2018). Although these materials could be disposed in a low-level waste (LLW) disposal facility licensed under 10 CFR Part 61, use of alternative disposal procedures under § 20.2002 may reduce overall risk (e.g., risk associated with increased transportation distances and associated radiological and non-radiological impacts) and may preserve disposal capacity at LLW disposal facilities for higher risk waste streams, while also providing reasonable assurance of adequate protection of public health and safety and protection of the environment.

Although NRC reviews of § 20.2002 and § 40.13(a) requests are similar in many respects, there are a few differences that are described in this document. Where there are differences between the procedures for review of § 20.2002 and § 40.13(a) requests, a sub-section for each type of request is provided. Otherwise, requests will be referred to collectively as ADRs. In addition to describing the processes for performing these reviews, this document also discusses the roles and responsibilities of other parties involved in various aspects of these reviews.

2.0 Scope

This document outlines the steps that the NRC staff should take to document, review, and disposition an ADR of licensed material, including:

• confirming documents sent by the licensee have been added to the NRC public document system (Agency-Wide Documents Access and Management System (ADAMS));

² Paragraph (b)(3) of 10 CFR 40.51, "Transfer of source or byproduct material," allows for the transfer of licensed by-product or source material to any person exempt from licensing requirements to the extent permitted by such exemption. Section 40.13(a) of 10 CFR provides an exemption from the licensing requirements and regulations in 10 CFR Part 40, "Domestic Licensing of Source Material," to any person who receives, possesses, uses, transfers, or delivers source material in any chemical mixture, compound, solution, or alloy in which the source material is by weight less than 0.05 percent. For ease of reference, only the regulation in § 40.13(a) is referenced in this document when referring to § 40.51(b)(3) transfers of "unimportant quantities of source material" under § 40.13(a).

- establishing an Enterprise Project Identifier (EPID) and a Cost Activity Code (CAC) for monitoring time charged to the project consistent with agency guidance on fee billable and non-fee billable activities;
- performing an acceptance review for completeness and acceptability for docketing;
- providing public notice of the request, if applicable;
- conducting a technical review of the request;
- preparing a Safety Evaluation Report (SER) or other documentation of the review;
- preparing an Environmental Assessment (EA), if necessary;
- coordinating with State regulatory agencies and disposal site operators as needed; and
- implementing a Communication Plan, where applicable, including conducting public meetings and any other interactions or outreach, as appropriate.

The original version of this document (ADAMS Accession No. ML092460058, dated August 31, 2009), called EPPAD 3.5, was prepared for interim use by staff in the NRC's Office of Federal and State Materials and Environmental Management Programs (FSME), Division of Waste Management and Environmental Protection (DWMEP). Following the merger of FSME and the Office of Nuclear Material Safety and Safeguards (NMSS),³ the corresponding division for waste programs is the NMSS Division of Decommissioning, Uranium Recovery, and Waste Programs (DUWP). Within DUWP, the Risk and Technical Analysis Branch (RTAB) staff are often requested to perform a safety evaluation and determine the acceptability of proposed ADRs. A revised draft guidance document reflected this reorganization.

On October 17, 2017, the revised draft guidance document was issued for public comment (ADAMS Accession No. ML17229B588; <u>82 FR 48727</u>). The public comment period closed on January 17, 2018. The NRC staff considered the comments received on the revised draft, and where appropriate, this document was revised in response to the comments received during the public comment period. A summary of the comments on the revised draft guidance document, as well as the NRC staff responses, is available at ADAMS Accession No. ML19295F140. This document incorporates numerous changes made in response to the comments received on the draft guidance document, as well as interactions with NRC stakeholders.

Out of Scope

This document does not cover all releases⁴ of licensed materials from regulatory control; it only covers those requests for alternative disposal procedures that are submitted for NRC or Agreement State approval under § 20.2002 or § 40.13(a).

³ As noted in NMSS Policy and Procedure 5-1, Revision 3, "Reactor Decommissioning Program Procedures for Interfacing with the Office of Nuclear Reactor Regulation," this merger occurred on October 1, 2014, as the result of an NRC internal reorganization.

⁴ The release of materials using the § 20.2002 process is consistent with other disposition provisions in 10 CFR Part 20 that allow for the release of material (e.g., § 20.2003 and § 20.2005).

With regard to discrete sources of radium-226, the Energy Policy Act of 2005 (EPAct) expanded the Atomic Energy Act of 1954, as amended (AEA), definition of byproduct material to include discrete sources of radium-226 that are used for "commercial, medical, or research activity."⁵ The regulations at 10 CFR 20.2008, "Disposal of certain byproduct material," include provisions for the disposal of byproduct materials, including discrete sources of radium, (i) in a LLW disposal facility or (ii) at a disposal facility authorized to dispose of such material in accordance with any Federal or State solid or hazardous waste law (e.g., a Resource Conservation and Recovery Act (RCRA) Subtitle C disposal facility). In accordance with these requirements, the disposal of discrete sources of radium-226 under § 20.2008 do not require prior approval by the NRC and are outside of the scope of this guidance.⁶

This document does not address specific aspects of ADRs for disposal of water containing EPAct 11e.(2) byproduct material from uranium recovery licensees (including land application, deep well injection, and shallow well injection of such water). However, the general guidance in this document is applicable to ADRs from uranium recovery licensees. Additional guidance is provided in NUREG-1569, "Standard Review Plan for In Situ Leach Uranium Extraction License Applications," and NUREG-1620, "Standard Review Plan for the Review of a Reclamation Plan for Mill Tailings Sites Under Title II of the Uranium Mill Tailings Radiation Control Act of 1978."

Extended (long-term) on-site storage of LLW must comply with 10 CFR 20.1801, "Security of stored material," and 10 CFR 20.1802, "Control of material not in storage," but does not require specific approval from the NRC and is not within the scope of this document. Extended storage of LLW is addressed in Regulatory Issue Summary (RIS) 2011-09, "Available Resources Associated With Extended Storage Of Low-Level Radioactive Waste," SECY 94-198, "Review of Existing Guidance Concerning the Extended Storage of Low-Level Radioactive Waste," and Regulatory Guide (RG) 4.22, "Decommissioning Planning During Operations."

3.0 Regulatory Requirements

The AEA and NRC regulatory framework requires possessors of radioactive materials to hold a license authorizing such possession or to be exempted from licensing requirements (e.g., under the specific exemption provisions of § 30.11(a), § 40.14(a), and § 70.17(a)).

10 CFR Part 20

The purpose of the regulations in 10 CFR Part 20, "Standards for Protection Against Radiation," is "to control the receipt, possession, use, transfer, and disposal of licensed material." The

⁵ The regulations at 10 CFR 20.1003, "Definitions," provide definitions for "discrete source" and "byproduct material." "Byproduct material" is defined later in this document and in the regulations. The NRC has defined a "discrete source" as "a radionuclide that has been processed so that its concentration within a material has been purposefully increased for use for commercial, medical, or research activities." Discrete sources of radium-226 and naturally occurring radioactive material (other than source material) are referenced and included within the definition for byproduct material.

⁶ Section 651(e)(1)(A) of the EPAct (§11e.(3) of the AEA; 42 U.S.C. 2014(e)) amended the definition of byproduct material to include "any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after [August 8, 2005] for use for a commercial, medical, or research activity." On November 30, 2007, the NRC implemented this provision of the EPAct by amending the definition of byproduct material in 10 CFR Parts 20, 30, 50, 72, 150, 170, and 171 to be consistent with the EPAct in the final rule "Requirements for Expanded Definition of Byproduct Material" (72 FR 55864; October 1, 2007), which is referred to as the Naturally-Occurring and Accelerator-Produced Radioactive Material (NARM) rule.

disposal mechanisms authorized pursuant to § 20.2001 include use of a land disposal facility, transfer to an authorized recipient, decay in storage, release in effluents, or as authorized in § 20.2002 (proposed disposal procedures), § 20.2003 (release into sanitary sewerage), § 20.2004 (treatment or disposal by incineration), § 20.2005 (specific wastes), or § 20.2008 (certain byproduct material).

Licensees or applicants have used the specific process set out in § 20.2002 to seek approval for alternative disposal procedures for solid (and other) materials. To obtain a § 20.2002 approval, a licensee or applicant must demonstrate that doses are maintained as low as is reasonably achievable (ALARA) and within the dose limits in 10 CFR Part 20. In practice, § 20.2002 is most often used for off-site burial of VLLW at RCRA facilities. However, § 20.2002 may also be used for other methods of disposal not otherwise authorized in the regulations, including various disposal procedures not involving burial.

In addition, on-site disposals in accordance with § 20.2002 must be addressed by licensees as part of the decommissioning of the facility to ensure that when the license is terminated, the site meets the criteria in the license termination rule (LTR) in Subpart E, "Radiological Criterial for License Termination," of 10 CFR Part 20. Volume 1 of NUREG-1757, "Consolidated NMSS Decommissioning Guidance," Section 15.12, "Onsite Disposal of Radioactive Materials under 10 CFR 20.2002," addresses the unique considerations for on-site disposal in greater detail, especially regarding decommissioning activities.

10 CFR Part 30

The regulations in 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," apply to byproduct material. The regulation at 10 CFR 30.3, "Activities requiring license," provides requirements for obtaining a license for byproduct material. The specific exemption regulation at § 30.11(a) states that the Commission may, upon application of any interested person or upon its own initiative, grant exemptions from the requirements of the regulations in 10 CFR Part 30, as well as Parts 31 through 36 and 39, as authorized by law, and upon determination that the exemptions will not endanger life or property or the common defense and security and are in the public interest.

10 CFR Part 40

The regulations in 10 CFR Part 40, "Domestic Licensing of Source Material," establish procedures and criteria for the issuance of licenses to receive title to, receive, possess, use, transfer, or deliver source and byproduct materials, and establish and provide for the terms and conditions upon which the Commission will issue such licenses.⁷ The regulation at 10 CFR 40.3, "License requirements," provides requirements for obtaining a license for source material. The specific exemption regulation at § 40.14(a) states that the Commission may, upon application of any interested person or upon its own initiative, grant exemptions from the requirements of the regulations in 10 CFR Part 40 as authorized by law, and upon determination that the exemptions will not endanger life or property or the common defense and security and are in the public interest.

The regulations in Paragraph (b)(3) of 10 CFR 40.51, "Transfer of source or byproduct material," provide for the transfer of licensed source material to any person exempt from the licensing

⁷ See 10 CFR 40.1, "Purpose."

requirements of the AEA, as well as the regulations in 10 CFR Part 40, to the extent permitted by the exemption. The regulations in § 40.13 provide for exemptions from the licensing requirements for certain materials containing uranium and thorium that are referred to as "unimportant quantities." One of these exemption provisions, § 40.13(a), is for "chemical mixtures, compounds, solutions, or alloys" in which the source material is by weight less than 0.05 percent. Section 40.13(a) exempts any person from the requirements for an NRC license "to the extent that such person receives, possesses, uses, transfers, or delivers source material in any chemical mixture, compound, solution, or alloy in which source material is by weight less than one-twentieth of 1 percent (0.05 percent) of the mixture, compound, solution, or alloy." The 0.05 percent by weight limit was chosen based on concentrations of source material that were considered economically feasible to process when the regulation was originally promulgated. Therefore, § 40.51(b)(3) provides licensees or applicants with a mechanism for transfer of unimportant quantities of source material, some of which fall under § 40.13(a).

Although § 40.51(b)(3)⁸ does not require the NRC's prior written approval for transfers of unimportant quantities of source material to exempt persons, if requested by the licensee or applicant, the NRC staff will, on a case-by-case basis, review and approve such transfers. It should be noted that, for some limited types and quantities of materials that fall under the exemption criteria in § 40.13(a), transfers under § 40.51(b)(3) could result in scenarios where the public dose limits in 10 CFR Part 20 are exceeded (see reference in SECY-00-0201, "Proposed Rule - 10 CFR Part 40 Amendments to Require NRC Approval for Transfers from Licensees to Exempt Persons," to NUREG-1717, "Systematic Radiological Assessment of Exemptions for Source and Byproduct Material").⁹ Based on the concern that the public dose limit could be exceeded, the NRC staff initiated a rulemaking to change § 40.51.

The proposed rule (67 FR 55175; August 28, 2002) would have modified § 40.51 to require NRC staff approval for transfer of any source material derived from its specifically licensed material to persons exempt under § 40.13(a) or equivalent Agreement State regulations. The proposed rule also stated that pending publication of the final rule, the Commission will continue its current policy of approving requests to transfer material to exempt persons under § 40.13(a) or equivalent Agreement State regulations on a case-by-case basis. In SECY-03-0106, "Update on Proposed Rule Changes to 10 CFR 40.51," the NRC staff recommended postponing the final rulemaking until related policy issues that had an impact on the rulemaking were resolved. In Staff Requirements Memorandum (SRM)-SECY-03-0106, the Commission approved the postponement of the rulemaking to amend § 40.51 while stating, "[t]he staff should continue their current practice of reviewing licensees' requests for transfer or disposal of unimportant quantities of source material under § 40.13(a), and, when justified, issue case specific exemptions based on previous Commission guidance." The § 40.51 rulemaking was withdrawn on July 29, 2016 (81 FR 49863), in part because "the NRC has, on a case-by-case basis, successfully dealt with the issues this rulemaking activity would have addressed." As a result, the NRC staff continues to review § 40.51(b)(3) transfer requests submitted to the NRC for approval. However, if these case-by-case efforts are deemed no longer successful, rulemaking to require prior NRC approval of § 40.51(b)(3) transfers may be pursued in the future.

⁸ The regulation at 10 CFR 40.51(b)(3) provides for the transfer of source material to persons "exempt from the licensing requirements of the Act and regulations" in 10 CFR Part 40, to the extent permitted in the exemption.

⁹ As referenced in SECY-00-0201, NUREG-1717 provides examples of cases where the public dose limit in 10 CFR Part 20 could be exceeded, including during processing of zircon and handling of phosphate slag in building and road construction.

10 CFR Part 70

The regulations in 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material," establish procedures and criteria for the issuance of licenses to own, acquire, deliver, receive, possess, use, and transfer special nuclear material. These regulations also provide the terms and conditions upon which the Commission will issue special nuclear material (SNM) licenses.¹⁰ The regulations at 10 CFR 70.3, "License requirements," provide requirements for obtaining a license for special nuclear material. The specific exemption regulation at § 70.17(a) states that the Commission may, upon application of any interested person or upon its own initiative, grant exemptions from the requirements of the regulations in 10 CFR Part 70 as authorized by law, and upon determination that the exemptions will not endanger life or property or the common defense and security and are in the public interest.

10 CFR Part 71

The regulations in 10 CFR Part 71, "Packaging and Transportation of Radioactive Material," establish requirements for packaging, preparation for shipment, and transportation of licensed material. The licensee or applicant for an ADR is responsible for the radioactive material until the transfer is completed to the off-site facility receiving the material (e.g., a disposal facility). Therefore, the transport of the material for disposal remains the responsibility of the licensee or applicant, and the transport is subject to NRC inspections. The transportation regulations in 10 CFR 71.5, "Transportation of licensed material," and associated U.S. Department of Transportation (DOT) regulations also need to be met.

4.0 Related Guidance on the Role of Agreement States

In addition to the regulatory requirements discussed above, the NRC staff should be familiar with the All Agreement States letter FSME-12-025, "Clarification of the Authorization for Alternate Disposal of Material Issued Under 10 CFR 20.2002 and Exemption Provisions in 10 CFR," and RIS 2016-11, "Requests to Dispose of Very Low-Level Radioactive Waste Pursuant to 10 CFR 20.2002," which outline responsibilities for reviewing and approving ADRs and issuing exemptions for disposal of the material.

As RIS 2016-11 stated, a licensee must submit its § 20.2002 request to the regulatory authority that issued the license for use of the radioactive material. For example, for reactor licenses, the appropriate regulatory authority to which a licensee must submit its § 20.2002 request is the NRC. For materials licenses issued by the NRC, a licensee must submit its § 20.2002 request to the NRC. For materials licenses issued by Agreement States, a licensee must submit its request to the Agreement State that issued its license. If the Agreement State has not adopted regulations equivalent to § 20.2002, then the Agreement State may approve the request from a materials licensee through application of its specific exemption authority, as appropriate.

In addition, the proposed disposal facility must either: (1) hold a license to receive and dispose of the material or (2) receive an approval, usually in the form of an exemption, to receive and dispose of the material. If the proposed disposal facility is in NRC jurisdiction, then the facility must either obtain a license or an exemption from the NRC. If the proposed disposal facility is in Agreement State jurisdiction, then the disposal facility must either obtain an exemption or other approval from the Agreement State. The technical reviews associated with these two

¹⁰ See 10 CFR 70.1, "Purpose."

regulatory actions are discussed in Section 8 of this document. For disposal actions that involve the NRC and an Agreement State, efforts should be coordinated, as described in Section 12, to minimize duplicate review efforts.

5.0 Schedule

The level of effort required for the ADR review should be commensurate with the risk, safety and security significance, as well as the complexity associated with the request. The schedule should consider the level of effort required to coordinate with other entities (e.g., Agreement States, DOT). Simple requests may have shorter review periods, but more complex requests, such as those that require Requests for Additional Information (RAIs) (see Section 8.5) or enhanced stakeholder interactions (see Sections 11.2 and 11.3) could take significantly longer.

Examples of situations in which a regulatory action may be considered complex include:

- it is the first of a kind;
- it is especially voluminous;
- it involves a large number of NRC branches in the review (i.e., it will require extensive coordination to determine scope for each branch and development of the evaluation);
- it will require an Advisory Committee on Reactor Safeguards or Advisory Committee on the Medical Uses of Isotopes review;
- it relates to an unresolved generic safety issue; or
- it involves issues with parameters that have a limited margin of acceptable values.

6.0 Responsibilities

NMSS has the overall lead responsibility for the ADR review process. In particular, NMSS will review and disposition requests by materials licensees or applicants, as well as shutdown reactors in decommissioning after they have been transitioned from the Office of Nuclear Reactor Regulation (NRR) to NMSS. However, other offices, including NRC Regional offices, may also review and disposition ADRs. For instance, the NRR Division of Operating Reactor Licensing (DORL) will coordinate all ADR reviews within NRR for operating reactors and shutdown reactors that have not been transferred to NMSS. DORL may request assistance from NMSS using the NRC's technical assistance request (TAR) process. The staff should consult NMSS Policy and Procedure 5-1, "Reactor Decommissioning Program Procedures for Interfacing with the Office of Nuclear Reactor Regulation," and NRR Office Instruction COM-101, "NRR Interfaces with NMSS," for additional information on processing TARs, as well as to establish roles and responsibilities for permanently shutdown reactors that are in transition from NRR to NMSS.¹¹ In addition, Agreement States are encouraged to coordinate with NMSS on ADR reviews for Agreement State licensees requesting disposals at facilities located in non-Agreement States.

¹¹ NMSS Policy and Procedure 5-1 and NRR Office Instruction COM-101 can be used to enhance oversight of the decommissioning of nuclear power reactors and research and test reactors as they transition from reactor operation to decommissioning. Both of these documents are internal NRC procedures that are non-public.

6.1 Project Manager

The role of the NMSS Project Manager (PM) is to manage the NRC's review of the ADR, which may include performing portions of the review (for example, an environmental review (see Section 9)), as well as coordinating the review of different portions of the request performed by other NRC staff. Depending on the complexity of the review, the PM may need assistance from technical staff in various areas, including environmental assessment, criticality, transportation, security, and dose modeling. If it is determined during the review that RAIs are required, the PM is responsible for evaluating and transmitting RAIs to the licensee or applicant. The PM also ensures that the regulations, the guidelines in this document, and the NRC's Principles of Good Regulation are adhered to throughout the process. PMs, along with the technical staff, are jointly responsible for ensuring that the NRC's goals are met.

The PM will maintain an awareness of the external and internal parties involved in the ADR and the associated reviews, including any affected States. The PM is responsible for ensuring agency procedures for project documentation, as well as internal and external meetings are followed. The PM will maintain the relevant documents for ready access by the technical staff and will be responsible for transmitting information to and from the licensee or applicant and the technical reviewers. The PM will keep the necessary NRC management updated on the status of the review of the disposal request. The PM is also responsible for working with the licensing assistant and other staff, as applicable, in order to open EPID numbers to ensure fee recovery and allow for tracking of the work activities.

Upon receipt of incoming documents from the licensee or applicant, the PM will ensure they are screened for proprietary or other sensitive information and placed into ADAMS with the appropriate profile, as applicable. The PM is also responsible for setting up and conducting both internal meetings with the NRC review team and external meetings with licensees or applicants, including providing opportunities for public participation as necessary. When appropriate, the PM will prepare a public meeting notice, to be posted on the external NRC Website no less than ten days prior to the meeting date and will prepare and issue a public meeting summary within thirty days following the meeting.

Briefings to NRC management related to a specific facility are typically handled by the PM responsible for that facility with support from technical staff. In the case of operating reactors, that would be the DORL PM for the specific reactor making the ADR. The NMSS PM and technical staff may provide assistance as needed. Allegations regarding a specific request are to be referred to the appropriate Allegations Coordinator for action.

6.2 Risk Analyst

The NMSS technical staff who review the dose modeling aspects of ADRs are typically selected from RTAB in DUWP. The Risk Analyst is responsible for conducting a technical review of the licensee's or applicant's ADR and documenting the review in a Technical Evaluation Report (TER) in accordance with the applicable guidance. This evaluation should ensure that radiation exposures to members of the public are within the dose limits established by the NRC (see Section 8). The overall technical review document is the SER, but the product developed by RTAB staff is usually – especially for TARs – only a portion of the SER and thus, has a more limited scope for the ADR review. Specifically, the Risk Analyst will perform the following:

- An acceptance review and a technical review of the licensee's or applicant's dose assessment and associated documents will be conducted, including the review of technical reports, and/or review of the development and implementation of conceptual and mathematical models to assess radiological impacts relating to the disposal. The licensee's dose assessment should include evaluation of radiological impacts to members of the public, including workers at the receiving facility or site.
- In conducting the technical review, the Risk Analyst should use a risk-informed, performance-based approach, focusing on those aspects of the review that are expected to have the greatest effect on the results. The Risk Analyst may use the results of sensitivity and uncertainty analysis conducted by the licensee or applicant, or the NRC staff could perform its own independent modeling, including sensitivity or uncertainty analysis, to help inform the technical review.
- The Risk Analyst may be asked to provide information to support the environmental review (see Section 9), in addition to the safety review, and should be cognizant of how the review results are integrated into the overall evaluation and decision-making process.
- The Risk Analyst should document their findings, usually in the form of a TER or other form of SER input to the PM (e.g., email or Word document that is not placed in ADAMS). The Risk Analyst should confer with the PM, at the initial stage of the technical review, on the form or type of document needed. Formal TERs are provided in response to TARs. The TER usually provides the main content of the SER. A TER needs to describe the nature of the technical review, specifically what the analyst reviewed, and a basis for why the analyst finds the dose analysis to be acceptable or unacceptable. The documentation of the analyst's findings should be reviewed by the technical Branch Chief prior to providing it to the PM. All Branch Chiefs whose staff contribute significantly to the SER will review and concur on the SER, including the RTAB Chief. Accordingly, the plan for the overall technical review needs to allow time in the schedule for the SER review and concurrence process.
- The Risk Analyst also supports meetings with licensees or applicants to address dose modeling and other aspects of the technical review. The Risk Analyst is expected to take the lead during parts of the meeting related to their technical review area.

6.3 Other Technical Reviewers

At the initial stage of the technical review, the PM should identify other technical staff needed to support the review (e.g., environmental reviewer or transportation reviewer). The evaluation documentation provided by these other reviewers should be reviewed by their Branch Chief prior to providing it to the PM. All Branch Chiefs whose staff contribute significantly to the SER will review and concur on the SER. These reviewers may also support meetings with applicants or licensees that address their aspects of the technical review. The reviewer is expected to take the lead during parts of the meeting related to their technical review area.

7.0 Work Planning and Acceptance Review

7.1 Receipt and Initial Processing

The following sections provide information to be considered when the ADR is received.

7.1.1 Initial Review

Licensees and Applicants

Licensees and applicants should submit the original ADR document(s) in accordance with the applicable NRC regulations (e.g., the requirements in § 20.2002) and guidance. The documents must be submitted on the docket, under oath or affirmation, and may be submitted by mail or electronically. This also applies to supplements to the ADR (e.g., responses to RAIs).

Licensees and applicants may include the information listed below in their ADRs, in addition to the information explicitly required by § 20.2002. For example, some of the following items may be useful for the NRC staff in preparing the associated SER and EA (if needed):

- Requested issuance date;
- Requested implementation period;
- If applicable, a statement that the submittal contains trade secrets, privileged, or confidential commercial or financial information, and a request to withhold the information, in accordance with 10 CFR 2.390, "Public inspections, exemptions, requests for withholding;"
- Discussion of whether the submittal includes any regulatory commitments;
- Discussion of environmental considerations; and
- Discussion of whether the submittal is based on precedent.

NRC Staff

The PM will ensure that the original ADR document(s), as well as any supplements, are placed into ADAMS and distributed according to the distribution list established by the PM.¹² As appropriate, the NRC's Document Control Desk¹³ will docket the document(s) and provide distribution according to the internal distribution established by the docket. To facilitate processing, the PM may also request that a licensee or applicant submit a copy directly to the PM, along with the original submittal sent to the Document Control Desk.

The PM and technical staff will also review the submittal for the presence of any sensitive unclassified non-safeguards information (SUNSI), which includes proprietary information and security-related information. SUNSI requires special handling in accordance with the applicable regulations and processes. As part of the review, the PM and technical staff will evaluate the information to determine if they agree with the applicant's or licensee's SUNSI justification and determine whether any information should be withheld. Specific information on the NRC's procedures for handling SUNSI can be found in Management Directive 12.6, "NRC Sensitive

¹² Management Directive 3.53, "NRC Records and Document Management Program," and other applicable guidance provide information that should be utilized.

¹³ The regulations provided within § 20.1007, § 30.6, § 40.5, and § 70.5, and § 50.4, provide information on how applications filed under the applicable regulations may be submitted to the Commission.

Unclassified Information Security Program," and in applicable NMSS guidance.¹⁴ In addition, the PM should coordinate with the licensee or applicant to determine whether any supplemental information provided after the initial submittal contains SUNSI. Normally, ADRs do not contain proprietary information.

7.1.2 Tracking Requests

Upon receipt of an ADR from a licensee or applicant and its assignment to the responsible office or region, the PM will work with the time and labor coordinator to obtain an EPID number (and a CAC, if required) for the request, as applicable. EPIDs and CACs provide a means of tracking the work effort to ensure appropriate billing, and as such should be linked to the initial letter with the ADR from the licensee or applicant.

The Waste Disposal Tracking System (WDTS), which was initially developed by DWMEP (now DUWP) was created to track § 20.2002 requests, but is no longer maintained.¹⁵ This database includes a listing of VLLW disposal requests from 1981 to 2006. Since 2006, these requests have been added to ADAMS. The PM ensures that the ADRs and associated documentation are entered into ADAMS with the appropriate profiles ("20.2002 Requests" or "40.13(a) Requests") such that they can accessed and tracked.¹⁶

7.2 Acceptance Review

After the PM requests an EPID number, and as soon as practical following receipt of the ADR, the PM and the technical staff will perform an acceptance review to ensure the administrative and technical sufficiency of the information provided in the request.

The acceptance review will typically include a review for completeness of the application to determine if there are significant analyses or evaluations missing from the ADR, as well as to determine if there are significant, obvious problems with the information and analyses provided.

Specifically, the review would include, but would not be limited to:

- (1) an evaluation of the sufficiency of the disposal request to address the criteria in § 20.2002 and/or § 40.13(a), including associated guidance; and
- (2) a determination that there are no significant technical deficiencies that may preclude completion of the SER and environmental review (see Sections 8 and 9).

The acceptance review should be completed within 30 days following receipt of the request. Following the acceptance review, the PM will send a letter to the licensee or applicant acknowledging the start of the review. In addition, the staff should review the justification for proprietary information (see Section 7.1.1) as soon as practical.

¹⁴ Previously, this was DWMEP Procedure 1.9, Section 1.9.5, "Handling Sensitive Information."

¹⁵ A memorandum from DWMEP to NRR and the NRC Regions (ADAMS Accession No. ML060180325) has instructions for use of the WDTS. This restricted database is available on the internal NRC Web page at <u>http://papaya.nrc.gov/NMSS/WDTSSQL/home/index.cfm.</u>

¹⁶ SECY-07-0180, "Strategic Assessment of Low-Level Radioactive Waste Regulatory Program," listed Task 10, "Develop and implement national waste tracking system," as one of the low priority tasks that may be completed as resources allow. VLLW associated with ADRs will be considered for inclusion in this tracking system.

If, during the acceptance review, the technical reviewers or PM identify missing information needed to complete the acceptance review, the NRC staff should contact the licensee or applicant with clarifying questions. The extent of the missing information may impact the timeline for completing the acceptance review, as well as completion of the review and approval process for the overall ADR.

8.0 Technical Reviews

8.1 Considerations

Technical reviews of ADRs need to consider a description of the source term associated with the material to be disposed, a description of the disposal site, and discussions regarding conceptual and mathematical models and parameters used in the licensee's or applicant's dose assessment related to the ADR. In some cases, the licensee or applicant may provide screening or other types of bounding analyses that alleviate the need to develop site- or problem-specific dose assessments or use sensitivity and uncertainty analysis when performing the dose assessments. In those cases, sufficient details should be provided in the ADR submittal to ensure that conditions are consistent with, or bounded by, the underlying assumptions in the screening analyses used to estimate the radiological impacts to members of the public and demonstrate that the radiological criteria in Section 8.2 if this document are met. Depending on the complexity of the proposed ADR, sensitivity and uncertainty analyses may be needed to provide confidence that the potential dose from the disposal is not underestimated.

The Risk Analyst will review the material provided by the licensee or applicant as part of the ADR, considering the most current version of guidance provided in NUREG-1757, Volume 2, "Consolidated Decommissioning Guidance – Characterization, Survey, and Determination of Radiological Criteria - Final Report." Specifically, Chapter 5, "Dose Modeling Evaluations," and Appendix I, "Technical Basis for Site-Specific Dose Modeling Evaluations," of NUREG-1757 provide information on conducting dose assessment reviews, and Appendix J, "Assessment Strategy for Buried Material," provides guidance specifically related to burials. NUREG-1573, "A Performance Assessment Methodology for Low-Level Radioactive Waste Disposal Facilities," may also be consulted for guidance on performing dose assessment reviews for disposals involving burial of radioactive material in an unlicensed disposal facility.¹⁷ Specific acceptability of licensee or applicant approaches will depend on the proposed alternative disposal procedure.

As needed, the analyst should also review approaches outlined in previously-approved VLLW disposals and/or other technical reports, such as NUREG-1640, "Radiological Assessments for Clearance of Equipment and Materials from Nuclear Facilities," and NUREG-1717, to assess doses associated with specific sites and specific exposure scenarios. However, when considering the use of previously-approved approaches and technical reports, it is important to consider their regulatory purpose and scope. For example, NUREG-1640 and NUREG-1717 contain generic analyses and were not intended to be used as reference documents for the assessment of specific conditions at a site. Although one or more of the exposure scenarios in those reports may be applicable to the disposal option being considered, the parameter values

¹⁷ As of January 2019, the NRC staff was in the process of incorporating Commission direction to finalize an update to NUREG-2175, "Guidance for Conducting Technical Analyses for 10 CFR Part 61." The guidance represents the NRC staff's latest approach to the review of performance assessments for LLW disposal activities, and it should be consulted when it becomes available for use.

selected for those scenarios may not be appropriate for the licensee's or applicant's site, thereby requiring further justification beyond referencing a generic scenario in a technical report. Therefore, the basis for using assumptions from previously approved approaches and technical reports, instead of values specific to the conditions associated with the disposal request, should be provided in the licensee's or applicant's and NRC staff's analysis.

8.1.1 On-Site Disposals (§ 20.2002 requests only)

Licensees may request approval of on-site VLLW disposals during operations prior to decommissioning and license termination. In these cases, the dose from on-site disposals will be included in any future dose evaluations for license termination. The contributions to the potential dose to the average member of the critical group from all sources of residual radioactivity remaining at the site, including any on-site disposals, must be considered in demonstrating that the LTR criteria are met.¹⁸ For example, the NRC staff would review whether the decommissioning assumptions for the site (e.g., unrestricted versus restricted release) are changed by the proposed on-site disposal activities. The review would, in part, focus on the hazard level at the time of decommissioning, and the potential for migration of radionuclides from the disposal location prior to decommissioning.

To ensure consistency with future dose modeling and demonstrate compliance with the radiological criteria for license termination, the licensee may choose to develop site-specific scenarios and models following guidance in NUREG-1757, Volume 2, when evaluating the potential dose associated with on-site disposals (e.g., see NUREG-1757, Volume 2, Appendix I). Licensees should reference NUREG-1757, Volume 2, Appendix J, for guidance on consideration of scenarios related to intrusion into buried waste.

Guidance provided in NUREG-1757, Volume 1, Section 15.12, indicates that the NRC's current practice is to not approve requests for on-site disposal that result in doses exceeding a "few millirem" per year consistent with the SRM for SECY-06-0143, "Stakeholder Comments and Path Forward on Decommissioning Guidance to Address License Termination Rule Analysis Issues." Although the NRC will consider requests for on-site disposals using dose criteria other than a few millirem per year, disposal requests with projected doses significantly greater than a few millirem per year should be carefully reviewed to ensure that the benefit of approval outweighs the risk of creating a future legacy site.

Section 15.12.2.1, "Current Practice of a Few Millirem Per Year," of NUREG-1757, states that the "few millirem" per year criterion encompasses a 0–0.05 millisieverts (mSv) per year, or 0-5 millirem (mrem) per year, total effective dose equivalent. Since, at the time of license termination, there may be multiple sources of residual radioactivity, including on-site disposals, constraining doses from on-site disposals to a few millirem per year will help increase the likelihood that the entire site will meet the LTR criteria without the need for remediation of the on-site disposal. Requests for on-site disposal of VLLW should consider the doses from all previous on-site disposals. Accordingly, the few millirem per year dose criterion includes the cumulative dose from all previous on-site disposals, although the doses from each of the disposals do not necessarily need to be summed (e.g., if the areas are not co-located or along the same flow path, it may not be necessary to sum the doses from each on-site disposal).

¹⁸ Guidance on the consideration of cumulative dose impacts is provided in NUREG-1757, Volume 2, Appendix K, "Dose Modeling for Partial Site Release."

In most cases, because the doses from on-site disposals are expected to be a small fraction of the dose limit for unrestricted use of a site found in 10 CFR 20.1402, "Radiological criteria for unrestricted use," the NRC staff does not need to consider potential doses from radon from source material, byproduct, or special nuclear material, consistent with the statements of consideration for the LTR (62 FR 39083; July 21, 1997).¹⁹ Likewise, in most cases, on-site disposal dose analyses should be calculated for the peak dose within 1,000 years of the expected date of license termination of the facility, consistent with regulations in the LTR in Subpart E of 10 CFR Part 20. If controls are in place to limit receptor activities and access that may otherwise result in exposure from the on-site disposal, the licensee may be able to take credit for radioactive decay up until the expected date of license termination.

8.1.2 Off-Site Disposals

Licensees or applicants may request approval to dispose of VLLW off-site under § 20.2002 or § 40.13(a). Off-site disposals are most often at a disposal facility with a State or Federal permit that is not a licensed LLW disposal facility, e.g., a RCRA facility. For these situations, each § 20.2002 or § 40.13(a) approval should confirm that the waste being disposed satisfies the waste acceptance criteria (WAC) of the proposed disposal facility (as established by the State or Federal permit or other regulatory mechanism).

In accordance with § 20.2002, licensees must submit (a) a description of the waste, including the physical and chemical properties important to risk evaluation, and the proposed manner and conditions of waste disposal; (b) an analysis and evaluation of the pertinent information on the nature of the environment; (c) the nature and location of other potentially affected licensed and unlicensed facilities; and (d) analyses and procedures to ensure that the doses are maintained ALARA and within the dose limits in Part 20. The licensee's submittal should be sufficient to ensure that the staff has an adequate understanding of the waste expected to be transferred for the proposed disposal, including volumes, form, radionuclides, and concentrations. In addition, the request should detail the acceptable waste characteristics for the receiving facility, which may be the bounding concentrations and volumes associated with the approval of the disposal. These characteristics may become a condition of the approval. The NRC staff's review may also include verification that the correct waste will be identified, packaged, and shipped.

An unlicensed facility must receive approval, usually in the form of an exemption, to receive and dispose of waste. The NRC staff's review of an exemption request for an unlicensed disposal facility within NRC jurisdiction may encompass (a) methods for, and constraints on, how the waste will be disposed; (b) specific processes used by the disposal facility for placing the material in the disposal cell; (c) how members of the public (including workers at the disposal facility, who are not radiation workers) may be exposed; the dose estimates for these members of the public; and (d) analyses of long-term impacts from the disposal of the waste to other members of the public. In the exemption review, waste characteristics (e.g., volume, radionuclides, concentration) can be assumed, and these characteristics will form the bounds of the approval (i.e., the WAC). The NRC's review of an exemption request includes a review of the ability of the waste generator to meet the waste acceptance criteria.

¹⁹ The statement of considerations (SOC) for the LTR indicate that due to the impracticality of distinguishing between naturally occurring radon and radon resulting from licensed activities, the licensee does not need to demonstrate that radon from licensed activities is indistinguishable from background on a site-specific basis. The SOC further state that this demonstration can be made on a generic basis by showing that radium, the principal precursor to radon, meets the unrestricted release criteria. In some cases, the concentrations of radon precursors cannot be reduced to unrestricted release levels and restricted release may be used to limit dose. In these cases, the NRC will consider the practicality of radon mitigation to reduce doses to levels that are ALARA.

In the case of a § 20.2002 request for off-site disposal at a facility located in an Agreement State, the NRC staff should focus their review of the § 20.2002 request on whether the licensee's or applicant's waste characterization and proposed disposal procedures will ensure that the waste being transferred will meet the acceptable waste characteristics at the proposed disposal facility. Confirmation that the waste meets these criteria may involve a need for the NRC staff to communicate with the Agreement State to ensure that the characteristics of the proposed disposal facility are fully understood.

Although § 20.2002 does not specify a dose limit, as previously discussed, NUREG-1757, Volume 1, references "a few mrem" per year (i.e., 0.05 mSv per year (5 mrem per year)) as one potential guideline for on-site disposals. While the guidance in NUREG-1757 refers specifically to on-site disposals, 0.05 mSv per year (5 mrem per year) may be and has previously been used as a benchmark for evaluating the dose for off-site disposals. Nonetheless, acceptable values for the total dose may vary based on unique scenarios for both on-site and off-site disposals and are evaluated on a case-by-case basis. The dose guidelines for evaluating requests for § 40.13(a) disposals are described in detail in Section 8.2.2.

With respect to the exposure scenarios that should be evaluated for off-site disposals, guidance provided in NUREG-1757, Volume 2, Appendix I and Appendix J, may be consulted by the Risk Analyst. For modeling disposal in unlicensed waste disposal facilities, guidance is also found in NUREG-1573. NUREG-1573 includes guidance on analysis timeframes for performance assessments.²⁰ Depending on the type of waste disposed, short analysis timeframes and compliance periods similar to those used for decommissioning may be appropriate for § 20.2002 requests. In some cases (e.g., when long-lived waste is driving the risk), longer analysis timeframes may be warranted to better understand disposal risk and to inform decision-making (e.g., to support the environmental review).

The Risk Analyst should ensure that potential exposure groups are evaluated for each stage of the off-site disposal, including the dose to disposal workers at the receiving site and dose to members of the public after closure of the disposal facility. As discussed above, NUREG-1640 and NUREG-1717 may be used to assess potential dose to members of the public from various exposure scenarios, including dose to a disposal worker at the disposal facility, or other exposure scenarios. The reviewer should ensure the ADR submittal includes a description of how the technical analyses from the licensee or applicant are used to support the specific

²⁰ As stated in NUREG-1573, "The PAWG [Performance Assessment Working Group] is concerned that reliance on shorter compliance periods may result in an over-reliance on engineered barriers, to an extent that the performance of the natural setting would not be sufficiently evaluated, and would not consider peak dose, should it occur beyond the 1,000-year period. Assessments beyond 10,000 years can be carried out, to ensure that the disposal of certain types of waste does not result in markedly high doses to future generations, or to evaluate waste disposal at arid sites with extremely long ground-water travel times. However, assessments of doses occurring after 10,000 years are not recommended for use as a basis for compliance with the performance objective." While over-reliance on engineered barrier performance may not be a concern in a § 20.2002 assessment, the risk associated with alternative disposals under § 20.2002 may not be adequately assessed when considering shorter analysis periods (e.g., if long-lived waste is present and driving the risk of the disposal). Although the NRC staff issued a draft rule requiring a 10,000 year compliance period for disposal of significant quantities of long-lived waste, the Commission in SRM-SECY-16-0106, "Final Rule: Low-Level Radioactive Waste Disposal (10 CFR Part 61)," directed staff to reinstate the 1,000 year compliance period from an earlier version of the proposed rule with a specific dose limit of 25 mrem per year (0.25 mSv per year) and adopt a longer period of performance assessment (the period of which would be based on site-specific considerations and a "reasonable analysis"). However, the rule and associated guidance based on this Commission direction are not yet finalized.

request, how the analyses apply to the request, and should include supplemental analyses, as appropriate, to ensure that the risk is not underestimated for the specific ADR being considered.

The Risk Analyst should ensure that both on- and off-site receptors are considered in dose assessments for waste disposal facilities. The reviewer does not need to independently verify licensee dose assessments, but instead should verify that the dose assessments are reasonable and are based on a sound technical approach. If needed, the reviewer may independently use simple dose assessment methods to scope or bound the problem and then use more sophisticated approaches, if necessary. Radon from source, byproduct, or SNM should be considered, as appropriate, for off-site disposals.²¹

The following general guidelines should also be considered by the reviewer during evaluations related to off-site disposals in a licensed or unlicensed waste disposal facility:

- Dose assessments evaluate dose to members of the public, including workers at the disposal facility.
- Dose assessments should consider placement of groundwater monitoring well(s) at the point(s) of maximum exposure at the boundary of the disposal facility, unless appropriate justification can be made to eliminate the groundwater pathway. Well placement should bound the cumulative impacts of multiple disposals at the downgradient boundary of the disposal site.
- Sensitivity analysis may be helpful in better understanding the impact of placing a well(s) within the disposal facility if elevated areas of radioactivity are present, or if there is a large distance between the disposal location and the facility boundary.
- If disposals are being proposed in a non-RCRA facility, or other facilities where long-term controls are not in place:
 - Dose assessments should consider intrusion into the waste (e.g., a basement is excavated or a well is drilled into the waste and the waste is brought to the surface where it can potentially expose a member of the public).²²

²¹ Given the potentially higher concentrations and dose associated with off-site disposals (e.g., soil with concentrations of residual radioactivity above clean-up levels for unrestricted release under the LTR, or concentrations of source material that could lead to doses approaching the public dose limits), radon dose should be considered if found to be significant and important to the decision-making process.

²² The reviewer should be aware that commonly used decommissioning codes such as RESidual RADiation (RESRAD) and RESRAD-OFFSITE are not equipped to calculate external dose to members of the public who may be exposed to residual radioactivity underground (e.g., dose to a member of the public residing in a basement). RESRAD and RESRAD-OFFSITE consider receptors located on the ground surface and not within a basement located underground and surrounded by a source of radioactivity. The reviewer may be able to use other codes such as Monte Carlo N-Particle Transport Code (MCNP) or Microshield to calculate effective "shielding factors" for use in RESRAD to estimate the dose to members of the public for the basement excavation scenario, or other source/receptor geometries not included in the RESRAD conceptual model. Alternatively, the licensee or applicant may be able to manage uncertainty with conservative assumptions using information from the literature or other arguments (Barr et al., 2010).

- The licensee or applicant can take credit for a thick cover to eliminate exposure scenarios involving intrusion into the waste (e.g., if a cover is not expected to be eroded to a thickness less than 3 meters (m), or 10 feet (ft), during the evaluation period, then the basement excavation scenario could be eliminated from the dose assessment as basement excavations are typically less than 3 m (10 ft)).
- The reviewer should consider if the licensee or applicant takes credit for the WAC that may constrain the total inventory or concentrations of waste placed in the disposal facility. For example, the WAC for the U.S. Ecology Idaho disposal facility was used to limit the dose from intrusion into the waste for § 20.2002 requests submitted by Hematite.²³
- The reviewer should consider if the licensee or applicant uses a graded approach for dose modeling. For example, if the licensee or applicant can demonstrate that the dose is less than the benchmark dose limits using screening or bounding exposure scenarios, no additional analysis may be necessary. In some cases, the licensee or applicant may need to evaluate reasonably foreseeable exposure scenarios. For more complex²⁴ disposal requests, the licensee or applicant may also need to consider less likely, but plausible exposure scenarios. In those cases, ADRs with doses above a few millirem per year may be acceptable considering the likelihood of the scenario (e.g., doses may be higher than a few millirem per year for less likely, but plausible scenarios).

8.1.3 Other Off-Site Disposals - Release of Solid Material with Volumetric Contamination

The NRC may approve the release of solid material with slight levels of volumetric contamination under § 20.2002 on a case-by-case basis, consistent with the guidance in Section 15.11, "Controlling the Disposition of Solid Materials," of NUREG-1757, Volume 1. The guidance states that evaluations of licensee or applicant requests for approval to release volumetrically contaminated material are evaluated using the guidance discussed in the June 1999 Issues Paper (64 FR 35090; June 30, 1999) and in three All-Agreement State letters.²⁵ The Commission has found the approach of reviewing specific cases for the release of solid material with slight levels of volumetric contamination on an individual basis to be fully protective of health and safety, as noted in SRM-SECY-05-0054, "Proposed Rule: Radiological Criteria for Controlling the Disposition of Solid Materials." This section of the ADR guidance document does not expand or reduce the scope of ADRs that would be considered acceptable for review.

²³ Additional information is available at ADAMS Accession No. ML111441087.

A more complex disposal request may be characterized by higher projected doses close to the dose limit benchmark, or one in which there is less certainty with respect to future exposure scenarios. If the risk from the disposal is expected to be very low, the licensee or applicant may be able to perform the dose modeling using bounding exposure scenarios without the need to evaluate alternative exposure scenarios.

²⁵ STP-00-0070, "Case-Specific Licensing Decisions on Release of Soils from Licensed Facilities;" STP-01-081, "Case-Specific Licensing Decisions on Release of Soils from Licensed Facilities;" and STP-03-003, "Update on Case-specific Licensing Decisions on Controlled Release of Concrete from Licensed Facilities."

8.2 Dose Guidelines

8.2.1 10 CFR 20.2002 Requests

The 10 CFR Part 20 dose limit for individual members of the public is 1 mSv per year (100 mrem per year) total effective dose equivalent (TEDE).²⁶ The NRC typically approves § 20.2002 requests that will result in a dose to a member of the public (including all exposure groups) that is no more than "a few mrem per year."²⁷ The NRC selected this criterion because it is a fraction of the natural radiation dose (approximately one percent of the radiation exposure received by members of the public from background radiation), a fraction of the annual public dose limit, and an attainable objective in the majority of cases. The use of "a few mrem per year" could also satisfy the § 20.2002 ALARA requirement, if the requestor provides a sufficient basis for this finding. Although the NRC staff will consider requests for on-site disposals of radioactive materials under § 20.2002 that exceed a few millirem per year, in the approval of these requests, the prevention of future legacy sites will be a primary consideration.²⁸

8.2.2 10 CFR 40.13(a) Requests

The regulations in § 40.51(b)(3) do not specifically require the NRC's prior written approval for transfers of unimportant quantities of source material to exempt persons. However, if requested by the licensee or applicant, the NRC staff will, on a case-by-case basis, review and, if appropriate, approve such transfers. The Commission, in SRM-SECY-03-0106, directed the staff to "...continue their current practice of reviewing licensees' requests for transfer or disposal of unimportant quantities of source material under § 40.13(a), and, when justified, issue case specific exemptions based on previous Commission guidance." Commission guidance found in SRM-SECY-00-0201 provides dose benchmarks associated with review of § 40.13(a) transfer requests involving disposal in appropriate facilities such as a RCRA Subtitle C facility. These dose benchmarks are summarized below:

 The NRC staff will normally approve requests for § 40.51(b)(3) transfers in accordance with § 40.13(a) if the estimated dose to a member of the public is unlikely to exceed a dose limit of 0.25 mSv per year (25 mrem per year).

NUREG-1757, Volume 1, Section 15.12.2.1 clarifies that doses of less than 0.05 mSv per year (5 mrem per year) are consistent with the "few millirem per year" criterion, which is the current practice for approval of on-site disposals. At the time of license termination, there may be multiple sources of residual radioactivity, including on-site disposals. By generally constraining doses from on-site disposals to a few mrem per year, it is likely that the entire site will meet the LTR criteria without the need for remediation of the on-site disposal.

²⁶ See 10 CFR 20.1301, "Dose limits for individual members of the public."

Additional information is available in SECY-03-0069, "Results of the License Termination Rule Analysis," Attachments 4, "Results of Evaluation for Relationship Between LTR and On-Site Disposal Under 10 CFR 20.2002," and 5, "Results of Evaluations of the Relationship between the License Termination Rule and the Current Case-by-Case Approach for Controlling the Disposition of Solid Materials," SECY-06-0143, "Stakeholder Comments and Path Forward on Decommissioning Guidance to Address License Termination Rule Analysis Issues," SECY-07-0060, Attachment 1, "List of Stakeholder Comments on NUREG-1757, Draft Supplement 1," and NUREG-1757, Volume 1, Sections 15.11, "Controlling the Disposition of Solid Materials," and 15.12.

²⁸ NUREG-1757, Volume 1, Section 15.12.2.2, "Other Dose Criteria," provides additional details.

- The NRC staff should inform the Commission of requests that the NRC receives for evaluation of material within the 0.25 mSv per year (25 mrem per year) to 1 mSv per year (100 mrem per year) range, as well as their resolution status.
- The NRC staff may also submit applications for Commission approval with calculated exposures above 1 mSv per year (100 mrem per year) if the staff determines such approvals are justified due to the unique circumstances of the specific case under review.

SRM-SECY-00-0201 refers specifically to releases of material for disposal in certain facilities (e.g., a RCRA Subtitle C facility authorized for such material). The SRM further notes that if releases of exempt material for other purposes are sought, the NRC staff should evaluate the acceptability of the potential dose on a case-by-case basis. Therefore, the dose benchmarks listed above are only applicable for releases or disposal activities involving burial of the exempt or unimportant quantities of source material under § 40.13(a). Since larger uncertainty exists with respect to the ultimate disposal pathways and exposure scenarios associated with other types of releases or disposal activities not involving burial, lower dose limit benchmarks may be more appropriate for those types of transfers.

8.3 Criticality and Physical Security Reviews

For § 20.2002 requests involving SNM, the potential for criticality will need to be addressed in the SER. These requests should be coordinated with DUWP, which will ensure that the ADR is sent to the appropriate division for review by staff who will provide expertise in the review and evaluation of criticality safety for SNM. These NMSS staff members may also provide input to the SER for these instances.

Although physical security is not expected to be an issue for the types of disposals requested in ADRs because the concentrations are so low, certain cases may require special consideration. For example, disposals of SNM would require an exemption from the 10 CFR Part 70 requirements for security. As needed, the PM should request technical assistance from the Office of Nuclear Safety and Incident Response (NSIR) in reviewing and evaluating any security issues associated with a proposed alternative disposal procedure involving special nuclear material. NSIR staff should also provide input to the SER for these instances.

8.4 Safety Evaluation Reports

Although there is no specific regulatory requirement to issue an SER as part of the disposition of an ADR, the NRC staff is obligated to document decisions in accordance with Management Directive 3.53, Handbook 1, Part I, "Recordkeeping Requirements." Specifically, Management Directive 3.53 notes that, in order to provide adequate documentation of the organization, functions, policies, decisions, procedures, and essential transactions of the NRC, records shall be created and maintained that are sufficient to document the formulation and execution of basic policies and decisions and necessary actions taken, including all significant decisions and commitments reached orally (person to person, by telecommunications, or in conference).

Consistent with the above discussion, the SER provides the technical, safety, and regulatory basis for the NRC's decision regarding a specific ADR. The SER should provide sufficient information to explain the NRC staff's rationale to someone unfamiliar with the licensee's or applicant's request. The SER should include a brief description of the proposed ADR, the regulatory requirements related to the issue, and an evaluation that explains why the NRC

staff's disposition of the request satisfies the regulatory requirements. Given that the SER serves as the record of the NRC staff's disposition of an ADR, the information relied upon in the SER that is supplied by the licensee or applicant should be appropriately documented in ADAMS. This is not meant to hinder the effectiveness or use of questions and clarifications by telephone or in meetings. However, if the information is important in the NRC staff's decision-making process and is not otherwise in the public domain or reasonably inferred by the staff, it must be formally provided by the licensee or applicant.

In performing a review of the ADR, the Risk Analyst may determine the need for additional information to complete their review. The Risk Analyst may prepare RAIs as needed to support the ADR review (see Section 8.5 below for additional guidance). In some cases, the PM will add input as appropriate from criticality safety and/or physical security reviewers, where disposals involve SNM (see Section 8.3). When the Risk Analyst completes the technical review, the Risk Analyst will submit a final SER input or TER to the PM. The PM will then prepare the final SER and obtain concurrence from the RTAB Branch Chief, in addition to Branch Chiefs for other branches that may have contributed to the review, the PM's Branch Chief, the Office of the General Counsel (OGC), and the appropriate signature authority to approve the ADR request (typically a Division Director or Deputy Division Director).

For off-site disposals within NRC's jurisdiction in non-Agreement States, such as disposals in an unlicensed landfill, the SER should contain the following or similar language in the conclusions section for § 20.2002 approvals, as appropriate:

Further, in accordance with the provisions of 10 CFR [30.11, 40.14, and/or 70.17], ²⁹ "the Commission may, upon application by an interested person or upon its own initiative, grant such exemptions from the requirements of the regulations as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest." Based on the above analyses, the material authorized for disposal poses no danger to public health and safety, does not involve information or activities that could potentially impact the common defense and security of the United States, and it is in the public interest to dispose of wastes in a controlled environment such as that provided by the unlicensed landfill [may want to add more descriptive detail on case-specific basis, (e.g., state-regulated landfill)]. Therefore, to the extent that the material authorized for disposal in this § 20.2002 approval is otherwise licensable, the NRC staff approved the ADR and concludes that the material authorized for disposal is no longer subject to further AEA and NRC licensing requirements and [name of disposal facility] is exempt from the requirement to hold a license to receive and dispose of the material.

Examples of historical ADR reviews are provided in Table 1, including examples of SERs.

8.5 Requests for Additional Information

The NRC staff may issue RAIs to licensees or applicants that request approval of alternative disposal procedures. RAIs fill in information gaps in the ADR submittal that allow the NRC staff to make a more fully informed decision regarding whether or not the regulatory criteria have been met. RAIs are necessary when the information is not included in the initial submittal, is not

²⁹ The regulations in § 30.11, § 40.14, and § 70.17 all provide criteria for "Specific exemptions."

contained in any other docketed correspondence, or cannot reasonably be inferred from the information readily available to the NRC staff. RAIs should be directly related to the applicable regulatory requirements associated with the request. RAIs should also be consistent with the applicable codes, standards, and guidance (e.g., Regulatory Guides, NUREGs). RAIs should not be used as general information requests or as a means to encourage commitments from licensees or applicants.

The purpose of the RAIs is to ensure that adequate information is obtained in order to perform a review of the ADR. RAIs should be in the form of a request for information, clarification, or revision to the licensee's or applicant's submittal. RAIs should also be as specific as possible to avoid confusion by the licensee or applicant and should reference specific portions of regulations and/or guidance, when applicable. In all cases, the regulatory and technical basis (e.g., reference to a specific regulation or guidance) and risk significance, if applicable, for the requested information should be included. A draft SER and EA (see Section 8 and Section 9) should be prepared prior to transmittal of the RAIs to help determine the importance (or relative insignificance) of additional information needs.

During the review of the ADR, the technical reviewers should notify the PM that information gaps in the licensee's or applicant's submittal may require issuing RAIs. Following the development of the draft RAI, the PM should review³⁰ the draft RAI and consider the need for the RAI. The request should then be transmitted to the licensee or applicant, including an opportunity for the licensee or applicant to have a clarifying call with the NRC staff. In addition, if requested or otherwise practical, the PM should hold a meeting or conduct a telephone conference with the licensee or applicant prior to transmittal of the formal RAI letter to identify and discuss significant issues or deficiencies and the NRC staff's expectations. The PM and the technical reviewers should use these meetings or teleconferences to clarify issues and answer basic questions. The PM and the technical reviewers will also highlight any significant issues or deficiencies for management attention as they arise.

The PM will create a concurrence package containing the RAIs and a cover letter for review by the PM's Branch Chief. The RAI questions should normally be included as an enclosure to a letter to the licensee or applicant. The PM would develop this cover letter, which should:

- Identify the document being reviewed and any previous RAIs (as appropriate);
- Summarize significant questions;
- Refer to the enclosure(s) for the complete questions (if one is provided);
- Discuss the opportunity for a meeting or conference call, if appropriate, to discuss the RAI;
- Include an expected response date; and
- Identify the PM as the point of contact for the response.

The NRC staff should use appropriate communications, such as meetings and teleconferences, to the maximum extent possible in order to improve clarity and understanding both during the development of draft RAIs and after sending RAIs to licensees or applicants. Engagement with

³⁰ Although RAIs may be developed during the acceptance review phase, they should be limited to obvious information insufficiencies and not specific requests for additional technical information.

licensees or applicants should facilitate the NRC staff's understanding of the submittals, reduce the number of RAIs needed, and heighten licensees' or applicants' understanding of RAIs and their ability to respond effectively. These interactions are to be conducted in accordance with the applicable NRC policies and documented, as appropriate, in ADAMS.

Site visits and conference calls with the licensee or applicant have been found to limit the number of RAIs and decrease the overall review time. The PM should document any site visits and conference calls with the licensee or applicant. In some cases, it may be warranted to perform a regulatory audit, in order to identify additional information that a licensee or applicant should formally submit. Following the audit, the information needed should be requested via the RAI process. Regulatory Audits are conducted per NRC Office Instructions (e.g., NRR Office Instruction LIC-111, "Regulatory Audits").

9.0 Environmental Reviews

NRC approvals of ADRs may require the preparation of an EA.³¹ NUREG-1748, "Environmental Review Guidance for Licensing Actions Associated with NMSS Programs," contains guidance for NMSS staff on how to comply with the National Environmental Policy Act (NEPA) for NRC licensing decisions. NUREG-1748 should be referred to for additional guidance, including the proper format and content of an EA. NRR Office Instruction LIC-203, "Procedural Guidance for Preparing Categorical Exclusions, Environmental Assessments, and Considering Environmental Issues," contains guidance for NRR staff on how to comply with NEPA for ADRs from power reactors and other 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," licensees.

An EA is a concise public document that contains an analysis of the impacts of the proposed action on the environment and provides sufficient evidence and analysis for determining whether to prepare an environmental impact statement (EIS)³² or a Finding of No Significant Impact (FONSI).³³ The regulations in 10 CFR 51.21, "Criteria for and identification of licensing and regulatory actions requiring environmental assessments," and 10 CFR 51.30, "Environmental assessment," provide requirements for EAs. The regulations in 10 CFR 51.32, "Finding of No Significant Impact," specify the content of a FONSI and the regulations in 10 CFR 51.35, "Requirement to publish finding of no significant impact; limitation on Commission action," require that the FONSI be published in a Federal Register Notice (FRN) before the approval of the associated ADR is issued. Before the FONSI is published, the approved EA should be placed in ADAMS under the appropriate docket and made publicly available, or captured in full in the FONSI FRN. An example FRN containing an EA/FONSI, as well as a sample memorandum letter regarding the FRN, is referenced in Table 1.

³¹ Section 20.2002 approvals for materials licensees may fall within the scope of the categorical exclusions (CATEXs) at § 51.22(c)(14) or § 51.22(c)(11), because § 20.2002 approvals for materials licensees are completed by license amendment and those CATEXs apply to amendments to materials licenses.

³² As stated in NUREG-1748, an EIS is prepared for a major federal action significantly affecting the quality of the human environment. It is typically a publicly available document detailing the environmental impacts associated with the proposed action and reasonable alternatives.

³³ As indicated in NUREG-1748, the EA should provide sufficient evidence and analysis of impacts to support a determination of a finding of no significant impacts (i.e., FONSI). If an EA does not result in a FONSI, then the potential impacts from the proposed activities require the preparation of an EIS.

With regard to the content of EAs for ADRs, both radiological and non-radiological impacts should be considered when preparing an EA, including consideration of impacts associated with transportation of radioactive materials to the receiving facility. In some cases, licensees, applicants, or the NRC staff may rely on assessments performed and documented in generic environmental impact statements, such as NUREG-0586, "Final Generic Environmental Impact Statement on Decommissioning of Nuclear Facilities," NUREG-1496, "Generic Environmental Impact Statement in Support of Rulemaking on Radiological Criteria for License Termination of NRC-Licensed Nuclear Facilities," and NUREG-0170, "Final Environmental Statement on the Transportation of Radioactive Materials by Air and Other Modes," to support preparation of the EA. Alternatives to the proposed action should be considered, as appropriate, including evaluation of alternative disposal procedures and alternative transportation modes or routes. In some cases, it may be appropriate for licensees or applicants to include mitigating actions that can be taken to reduce environmental impacts (e.g., constraints on concentrations or quantities of materials disposed, depth of burials, or other constraints). The NRC staff will initially rely on the analyses and information provided by the licensee or applicant in its ADR in drafting the EA.

The EA for ADRs is prepared by the PM, technical staff, regional staff, or the Environmental Review Materials Branch (ERMB) staff in NMSS. The PM may receive support from the ERMB to review EAs that are developed by the PM or other staff. The PM should consult with the ERMB Branch Chief to determine if a TAR is needed to review an EA or if ERMB assistance is needed to prepare the EA. The ERMB Chief will respond to the PM with the name of the staff member assigned to conduct the review. The results of the ERMB review of an EA may be documented in an email or memo to the PM and the PM's Branch Chief. The basic details of the environmental review process are in Sections 1.3 and 1.4 of NUREG-1748. After appropriate review and development of a basis for issuing an EA, the EA should be developed and include statements similar to the following, as appropriate:

- For the introduction and/or identification of the proposed action: "[t]his proposed action would also exempt the site authorized for disposal of the low-contaminated material from further AEA and NRC licensing requirements."
- For the environmental impacts of the proposed action: "[t]he proposed action and attendant exemption of the site from further AEA and NRC licensing requirements will not significantly increase the probability or consequences of accidents, no changes are being made in the types of any effluents that may be released off site, and there is no significant increase in occupational or public radiation exposure at the off-site disposal facility."³⁴

Prior to finalizing the EA, the PM should consult with the appropriate State regulatory agencies, as well as potentially affected Federally-recognized Tribes that may be impacted by approval of the ADR.³⁵ In general, this may include coordination with agencies such as the individual States' Department of Health and consultation with State-recognized Tribes. The PM should seek the assistance of the Materials Safety and Tribal Liaison Branch in the Division of Materials Safety, Security, State, and Tribal Programs (MSST) to identify the appropriate Tribal

³⁴ Note that the second bullet is referring to releases that occur at the off-site disposal facility after the transfer of radioactive material is complete and is not referring to the transfer of material from the licensee's site to another site, which could be considered an increase in off-site releases.

³⁵ NUREG-1748, and NUREG-1757, Volume 1, Appendix D, "DP [Decommissioning Plan] Evaluation Checklist," in particular, provide additional guidance on these consultations. Additional information on Tribal interactions, as well as the NRC's consultation responsibilities under NEPA during the preparation of EAs that may impact Tribes, is contained in the NRC's Tribal Policy Statement (82 FR 2402; January 9, 2017).

official(s). The PM should also seek the assistance of the State Agreement and Liaison Programs Branch in MSST to identify the appropriate State official(s) to which to send the EA.

The PM should send the draft EA to the State and potentially affected Tribes where the proposed disposal (or receiving) facility is located, as well as the State and potentially affected Tribes where the licensee or applicant submitting the disposal request is located, with a specified review schedule provided (a 30-day review period is recommended). Any comments received on the draft EA should be addressed as appropriate and incorporated into the final EA, which will be included in the FRN. A summary of the EA with a reference to the full EA in ADAMS, or the entire text of the EA, can be provided in the FONSI FRN. The PM will prepare the FRN for the EA/FONSI and forward it to OGC's Legal Research Center for publication in the *Federal Register*. If applicable, ERMB should be on concurrence for the FRN. The PM will perform a SUNSI review to make sure all referenced documents are publicly available.

Section 12 provides guidance for additional coordination measures for ADRs. Although standard practice is to publish a final EA after consultation with the affected States and Tribes, in certain cases, a draft EA may also be published for public comment. The regulations in 10 CFR 51.33, "Draft finding of no significant impact; distribution," provide a list of circumstances in which it may be appropriate to issue a draft EA and FONSI for public comment, including a finding by the appropriate NRC staff director that the preparation of a draft FONSI would further the purposes of NEPA. The PM should consult with NMSS management to determine if this additional step is appropriate.

Section 11 below, as well as SECY-06-0056, Enclosure 3, "Options for Improving Transparency in the 10 CFR 20.2002 Process," provides guidelines on when an ADR may require public outreach to improve transparency in the approval process, especially in regard to drafting the associated EA. As applicable, ERMB should be consulted to determine if public outreach should be conducted as part of the EA process and/or in accordance with NEPA. In addition, ERMB should be consulted depending on the extent of consultation needed under Section 106 of the National Historic Preservation Act, Section 7 of the Endangered Species Act, and the Magnuson-Stevens Fishery Conservation and Management Act.

10.0 Final Documentation

There are three possible outcomes of the NRC staff's ADR review that require formal final documentation: (1) approval of the request (with a license amendment or with a letter, which may include an enclosed SER); (2) denial of the request; or (3) an acknowledgement letter if the licensee or applicant withdraws the request.

10.1 License Amendments

Typically, the NRC approves ADR requests from materials and fuel cycle licensees with a license amendment and approves ADRs from reactors with a letter and an enclosed SER.³⁶

³⁶ SECY-06-0056, "Improving Transparency in the 10 CFR 20.2002 Process," and SECY-07-0060, "Basis and Justification for Approval Process for § 20.2002 Authorizations and Options for Change," indicate that the NRC uses two different approval processes for § 20.2002 disposal requests and provide the bases for these processes. As noted in SECY-07-0060, the NRC typically does not amend reactor licenses as part of the § 20.2002 approval process as it does licenses for materials and fuel cycle facilities. In SRM-SECY-07-0060, the Commission approved the NRC staff's recommendation to continue approving reactor § 20.2002 requests by

10.1.1 Notice for Opportunity for Hearing

Any person whose interest may be affected by the granting, renewal, or amendment of a license may file a request for a hearing. Regulations governing a request for a hearing are contained in 10 CFR Part 2, "Agency Rules of Practice and Procedure," and in particular 10 CFR 2.309, "Hearing requests, petitions to intervene, requirements for standing, and contentions."³⁷ A license amendment is typically not required for proposed ADRs for reactors, but typically is required for proposed ADRs for materials and fuel cycle licensees, as noted in the preceding section. If a license amendment is required to approve the ADR, then as soon as practicable following the satisfactory completion of the acceptance review, the PM will provide notice of an opportunity for a hearing via FRN.³⁸

If the licensee or applicant submits supplemental information that expands the scope of the proposed license amendment beyond the description in the NRC staff's original notice, then re-noticing of the proposed amendment might be required. As such, it is recommended that the description of the proposed amendment in the original notice be brief and broadly characterize the aspects of the amendment in a form such that the general public can readily understand the purpose of the amendment. As applicable, the FRN should be prepared in accordance with the instructions provided above and applicable regulations and guidance. The PM should consult with OGC if further clarification is needed on individual ADRs.

10.2 Exemptions from the Requirements for a Possession License

10 CFR 20.2002 Requests

The § 20.2002 approval to dispose of licensed material in accordance with the procedures proposed in the ADR is issued to the NRC or Agreement State applicant or licensee. For off-site disposals, the off-site facility must obtain an exemption from the NRC or an exemption or other approval from an Agreement State in order to receive and dispose of the waste. This exemption is cited in the approval letter and/or license amendment. The specific language in the cover letter should be similar to the following, as appropriate, if the request is approved:

In accordance with the provisions of 10 CFR [30.11, 40.14, and/or 70.17], "the Commission may, upon application by an interested person or upon its own initiative, grant such exemptions from the requirements of the regulations . . . as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest." To the extent that the material authorized for disposal in this § 20.2002 approval is otherwise licensable, the NRC staff concludes that the site authorized for disposal is exempt from further AEA and NRC licensing requirements. The enclosed safety evaluation report concludes that the

letter and fuel cycle and material licensee requests by license amendment. Likewise, the NRC staff should also approve § 40.13(a) requests from reactor licensees by letter and requests from fuel cycle and material licensees by license amendment.

³⁷ Instructions and requirements are also provided in 10 CFR Part 2, "Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders," which is available at <u>https://www.nrc.gov/aboutnrc/regulatory/adjudicatory/part2revisions.html</u>. FSME Policy and Procedure 6-9, "FSME Staff Support of the Hearing Process in 10 CFR Part 2" (non-public), and other documents provide additional guidance.

³⁸ Additional information can be found on the NRC Web page under "Hearing Opportunities and License Applications" (<u>https://www.nrc.gov/about-nrc/regulatory/adjudicatory/hearing-license-applications.html</u>).

exemption(s) are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest. The NRC staff also evaluated the environmental impacts of the exemption(s) and determined that granting the exemption(s) would not result in any significant impacts. For this action, an Environmental Assessment and Finding of No Significant Impact were prepared and published in the *Federal Register* (XX FR XXXX). Accordingly, pursuant to § *[30.11, 40.14, and/or 70.17]*, the exemption(s) are granted and effective immediately.

For on-site disposals, no exemption from the NRC is needed, because the radioactive material is already licensed by the NRC and remains under the control of the licensee. When the license is terminated, the dose associated with residual radioactivity remaining at the site, including on-site disposals, will be evaluated to ensure the LTR criteria are met for release of the site.

10 CFR 40.13 Requests

The regulations in § 40.13(a) codify an exemption; therefore, the regulatory authority would not need to issue a concurrent specific exemption. The regulations in § 40.13(a) exempt any person from NRC licensing requirements "to the extent that such person receives, possesses, uses, transfers, or delivers source material in any chemical mixture, compound, solution, or alloy in which source material is by weight less than one-twentieth of 1 percent (0.05 percent) of the mixture, compound, solution, or alloy." The regulations in § 40.51(b)(3) provide licensees a mechanism for transfer of unimportant quantities of source material, which are automatically exempt from licensing under § 40.13(a).

10.3 Approval of Alternative Disposal Requests

Once the technical review of the ADR is complete and the SER is ready for issuance, the PM will prepare the approval package for concurrence (see Sections 8 and 9 for more information). This package should include:

- A cover letter;
- A license amendment (NMSS) or an approval letter (NRR) in an enclosure (if required);
- The SER as an enclosure; and
- Reference to the EA (which may result in a FONSI) that was published in an FRN.

In addition, OGC shall review and concur on all ADR packages for legal adequacy and defensibility (i.e., obtaining a determination of no legal objection).³⁹

Following issuance of the ADR approval, the PM will update the docket file (if applicable) and will close the associated EPID if no follow-up actions are required.

³⁹ Although specific to NRR, NRR Office Instruction COM-109, "NRR Interfaces with the Office of General Counsel," provides further details regarding OGC review and interactions.

10.4 Denial of Alternative Disposal Requests

The NRC staff recognizes that some ADRs may not satisfy the applicable NRC regulations and should be denied. Early management attention and engagement should be provided whenever the NRC staff is considering denial of an ADR. Whenever a denial is being considered, a Branch Chief-level meeting between the technical branches, PMs, and other applicable NRC staff should be held at the earliest opportunity. If the outcome of that meeting is anything other than alignment to continue the NRC staff's review, and in particular, if it is determined that the ADR should be denied, the appropriate managerial level should be briefed expeditiously. The Branch Chiefs should collaborate to prepare a joint briefing with options and recommendations, even if differing views exist. If a denial recommendation is supported, a denial SER should be prepared and documented in ADAMS.

Assuming the appropriate Division Director (or other delegated authority) agrees with the denial, the PM will have initial contact with the licensee or applicant to arrange for a teleconference, informing the licensee or applicant that the NRC staff plans to deny the ADR, and informing the licensee or applicant that the staff will discuss the basis for denial during the call (which may include the Division Director). The PM should also coordinate with the applicable technical reviewers to arrange for them to be available during the teleconference. The technical reviewers should be prepared to discuss their technical positions.

During the call, the Division Director or designee (with assistance from the technical reviewers as necessary) will provide the basis for the NRC staff's plan to deny the ADR. The Division Director or designee will offer the licensee or applicant an opportunity to withdraw⁴⁰ the ADR or to request a public meeting for further discussion of the issues. The Division Director or designee should make it clear that if the licensee or applicant neither submits a formal withdrawal in writing by a specific date (e.g., 3 to 5 days from the call), nor requests a public meeting by the same date, the NRC staff will issue the ADR denial.

As indicated previously, the NRC staff should prepare an SER documenting the basis for a denial of the ADR, which can be done in parallel with the activities described above. The denial SER does not need to address all aspects of the licensee's or applicant's request, but should be sufficient to support a conclusion that the ADR is not acceptable (i.e., the SER does not need to address aspects of the ADR that are acceptable). The PM should also prepare an ADR denial transmittal letter and an FRN noticing the denial, if applicable. The PM should obtain concurrences from the applicable Branch Chiefs and OGC. The Division Director (or Deputy Director, if delegated this responsibility) is added to the concurrence block and is the signature authority for the ADR denial transmittal letter.

10.5 Withdrawal of Alternative Disposal Requests

The licensee or applicant may choose to withdraw its ADR based on its own initiative or in response to the NRC's plan to deny the request. If the licensee or applicant decides to

⁴⁰ The regulations in 10 CFR 2.107 provide criteria for "Withdrawal of applications."

withdraw the ADR, the PM should prepare an acknowledgement letter documenting the withdrawal.⁴¹ If applicable, the PM should also prepare an FRN noticing the withdrawal.⁴²

If the licensee or applicant decided to withdraw the ADR in response to the NRC's plan to deny the request, the draft SER documenting the basis for the denial of the ADR should be included as an enclosure to the acknowledgement letter to ensure that an adequate record of the NRC staff's decision-making process is captured as an Official Agency Record (i.e., consistent with the requirements in Management Directive 3.53 as discussed previously in this document). If the licensee or applicant does not withdraw the ADR or request a public meeting by the date set during the formal ADR denial call, the PM should obtain the Division Director's (or designee's) concurrence and signature on the denial package and formally issue the denial.

11.0 Communications

It is expected that most ADRs will involve routine communications as described in this guidance document, such as submission of an ADR, RAIs and RAI responses, and issuance of an SER. However, there may be some ADRs for which the PM, technical reviewers, and management decide that additional communications are needed, and for which a communication plan may be completed.⁴³ In addition, in SRM-SECY-06-0056 the Commission directed the staff to inform the Commission when it receives a 10 CFR 20.2002 disposal request it deems "significant."

11.1 Communication Plans for Alternative Disposal Requests with High Public Interest

The PM should assemble a communication plan when the PM, technical staff, and management determine, on a case-by-case basis, that an ADR may involve a high level of interest from the public. The goal of a communication plan is to develop methods to effectively communicate with stakeholders regarding the ADR review. The primary purpose of these communications is to further facilitate stakeholder awareness and understanding of how the NRC ensures the safety of these disposals and to support the NRC's goal of openness in its regulatory processes.

A communication plan may include information to identify key messages, the audience and stakeholders, and other information, such as the availability of documents in ADAMS and applicable information on the NRC Website. The communication plan may also include a public meeting⁴⁴ or teleconference, as well as other opportunities for stakeholder interaction.

In accordance with the direction provided in SRM-SECY-06-0056, the following tools should be included in the communication plan:

⁴¹ A 10 CFR Part 50 license amendment withdrawal letter template is available as an example (ADAMS Accession No. ML082260953).

⁴² A 10 CFR Part 50 license amendment withdrawal FRN template is available as an example (ADAMS Accession No. ML14013A020).

⁴³ More information on communication plans is provided in "Communication Plan: Disposal of Low-Activity Radioactive Waste Using the U.S. Nuclear Regulatory Commission's Regulation in 10 CFR 20.2002" (ADAMS Accession No. ML092460037), and SECY-06-0056. These documents also discuss enhanced communications.

⁴⁴ All public meetings should be conducted in accordance with Management Directive 3.5, "Attendance at NRC Staff-Sponsored Meetings," and posted on the public NRC Website in accordance with agency procedures. Public meeting notification will be provided 10 days in advance of the meeting date.

- An FRN announcing the receipt of a significant § 20.2002 request, as outlined in Section 5;
- If necessary, provisions for one or more public meetings, preferably in the vicinity of the proposed disposal facility; and
- A Fact Sheet describing the proposed disposal.

11.2 Determination of the Need for Enhanced Communications

The Commission directed the NRC staff, in SRM-SECY-06-0056, to implement special outreach measures for significant § 20.2002 requests. These outreach measures help the NRC staff anticipate stakeholder concerns and requests for involvement, increase transparency for significant ADRs, and help reduce the staff resources used to respond to stakeholder concerns. Although these enhanced measures were developed for § 20.2002 requests, they may also be implemented for significant § 40.51(b)(3) requests to transfer unimportant quantities of source materials under § 40.13(a) to exempt persons.

Early in the ADR review process, the PM should determine which, if any, outreach measures are needed for a specific § 20.2002 request. SECY-06-0056, Enclosure 3, provides that a § 20.2002 request would not be considered significant and no special enhanced communication measures would be necessary when:

- The proposed § 20.2002 disposal will be in a facility that routinely disposes of large quantities of similar radioactive materials, in accordance with its permit;
- The proposed § 20.2002 disposal involves small quantities and concentrations of materials (e.g., incinerator ash from research facilities disposed of in accordance with Policy and Guidance Directive 8-10, "Disposal of Incinerator Ash as Ordinary Waste");
- The proposed disposal involves a high degree of certainty that the scenarios and assumptions used for the dose analyses are appropriate, based on past approvals, and will ensure that doses to a member of the public will not be above "a few millirem per year;"⁴⁵ or
- The proposed disposal is on a licensee's site.

In SRM-SECY-06-0056, the Commission indicated that the NRC staff should inform the Commission when it receives a § 20.2002 request that it deems "significant." The PM should do this through methods of communication determined to be appropriate. Regarding release of certain types of solid materials with volumetric contamination (see Section 8.1.3), it is likely that such cases would involve enhanced communications, to ensure stakeholder concerns are adequately considered and addressed in the decision-making process.

11.3 Outreach Measures for Enhanced Communications

If enhanced communication and outreach measures are necessary, the PM and the technical reviewers should discuss the need for these measures with their Branch Chiefs.

⁴⁵ As noted in Section 7, less likely but plausible exposure scenarios may be analyzed to risk-inform the decision. The staff should evaluate the relative likelihood and magnitude of the peak predicted dose for less likely, but plausible alternative exposure scenarios when determining the risk-significance of the § 20.2002 disposal request and the need for enhanced public outreach efforts.

Notwithstanding the above guidelines, there could also be instances in which a public meeting is warranted, based on requests from the public, elected officials, the State, Tribal officials, the licensee or applicant, or for other reasons.

Additionally, when enhanced outreach is appropriate, the PM should also consider sending the draft final SER for review to the State and potentially affected Tribes where the disposal will take place, as well as the State and potentially affected Tribes where the applicant is located.

Additional details on the outreach measures to be employed for enhanced communication will be contained within the communication plan for significant § 20.2002 requests.

12.0 Coordination

The review and approval of a § 20.2002 request can involve multiple regulators. For example, activities such as disposals from NRC licensees at RCRA facilities located in an Agreement State are regulated by State agencies. Coordination between the regulators is important because § 20.2002 approvals do not supersede a disposal facility's state RCRA permit or State regulations, nor obligate a facility to accept a waste stream.

As mentioned previously, a licensee should submit its § 20.2002 request to the regulatory authority that issued its license. When the NRC staff receives a § 20.2002 request associated with on-site disposal at an NRC-licensed site in an Agreement State, the NRC staff may notify the Agreement State. For off-site disposals, in cases where both the NRC and an Agreement State are involved in the review of a proposal to use alternate procedures to dispose of waste off-site, the NRC staff should coordinate with the Agreement State reviewers to share information and analyses to avoid duplicative efforts to the greatest extent practicable.

Upon receipt of the § 20.2002 request, the PM should review the incoming request from the licensee or applicant to determine what, if any, coordination needs to be made with the State regulatory agency regarding the acceptability of the proposed disposal at a specific facility, as well as to minimize duplicate efforts during the review process. The PM should contact the RCRA permitting agency and, if necessary and acceptable to the State agency, the disposal facility operator, and provide them with a copy of the disposal authorization request, if the licensee or applicant has not already provided it.

As described in Section 9, the PM should send the draft EA to the State where the proposed disposal facility is located, as well as the state where the licensee or applicant submitting the disposal request is located. As described in Section 11, the PM should also consider sending the draft final SER for review to the state(s), the disposal facility, and the requester. Any comments from the state, the requester, or the disposal facility should be considered accordingly (see Section 8.4). Examples of past reviews where NRC performed the review for the release of the material and an Agreement State approved disposal are included in Table 1.

In addition, there are situations that are not directly related to licensee and license applicant requests and that may require special considerations. Examples of situations that fall under this category include, but are not limited to:

• Former NRC licensees whose license has been terminated through the site decommissioning process, who then discover additional radioactive material on the site that needs to be disposed of; and

 Individuals who were not previously NRC licensees who possess radioactive material other than radium that requires disposal (radium can be disposed via § 20.2008 per definitions (3) and (4) for byproduct material in § 20.1003).

The NRC staff will review requests that fall into this category on a case-by-case basis.

13.0 Paperwork Reduction Act

Paperwork Reduction Act

This Staff Guidance provides guidance for implementing voluntary and mandatory information collections in 10 CFR Parts 20 and 40 that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et. seq.). These information collections were approved by the Office of Management and Budget (OMB), approval numbers 3150-0014 and 3150-0020. Send comments regarding this information collection to the Information Services Branch (O-1F13), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to Infocollects.Resource@nrc.gov, and to the OMB reviewer at: OMB Office of Information and Regulatory Affairs (3150-0014 and 3150-0020), Attn: Desk Officer for the Nuclear Regulatory Commission, 725 17th Street, NW Washington, DC 20503; e-mail: oira submission@omb.eop.gov.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the document requesting or requiring the collection displays a currently valid OMB control number.

Congressional Review Act

This document is a rule as defined in the Congressional Review Act (5 U.S.C. §§ 801-808). However, OMB has not found it to be a major rule as defined in the Congressional Review Act.

13.1 Regulatory Analysis

The NRC has prepared a regulatory analysis related to this updated guidance document. The analysis examines the costs and benefits of the guidance alternatives considered by the NRC. The regulatory analysis can be found at ADAMS Accession No. ML20072L323.

14.0 References

14.1 Code of Federal Regulations

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- 2. 10 CFR Part 20, "Standards for Protection Against Radiation"
- 3. 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material"
- 4. 10 CFR Part 40, "Domestic Licensing of Source Material"

- 5. 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities"
- 6. 10 CFR Part 51, "Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions"
- 7. 10 CFR Part 61, "Licensing Requirements for Land Disposal of Radioactive Waste"
- 8. 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material"
- 9. 10 CFR Part 71, "Packaging and Transportation of Radioactive Material"

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14.2 Historical Very Low-Level Waste Documentation

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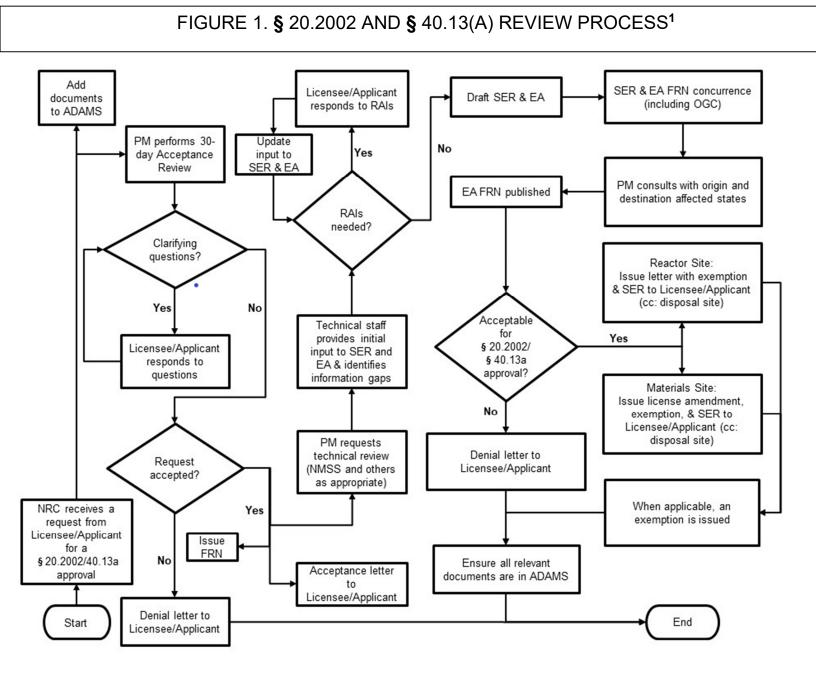
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- 60. SRM-COMSECY-98-022, "Proposal to Permanently Dispose of "Unimportant Quantities" of Source Material Without a License Pursuant to 10 CFR 40.13(a)," February 2, 1999. <u>https://www.nrc.gov/reading-rm/doc-collections/commission/comm-secy/1998/1998-022comsrm.pdf</u>
- 61. Temporary Instruction 2800/043, "Inspection of Facilities Potentially Contaminated With Discrete Radium-226 Sources," May 9, 2018. (ADAMS Accession No. ML17297B921)

TABLE 1. EXAMPLES OF § 20.2002 AND § 40.13(a) REVIEWS

These examples are accessible via ADAMS. These examples are provided for reference only. When preparing an approval package for an alternative disposal procedure request, be sure to follow all current laws, guidance, policies, and procedures.

Example 1	Request for Alternative Disposal of Wastes from the Safety Light Corporation Site at the US Ecology Idaho Facility Under § 20.2002 (October 28, 2013):
	Approval Letter, Safety Evaluation Report, <i>Federal Register</i> notice, and Environmental Assessment (ADAMS Accession Nos. ML13263A297, ML13295A688, and ML13296A807)
Example 2	Response to Honeywell Request to Ship Unimportant Quantities (September 21, 2012):
	10 CFR 40.13(a) Approval Letter and Safety Evaluation Report (ADAMS Accession Nos. ML12242A388 and ML12235A303)
Example 3	Request to Dispose of Camp Doha Waste per § 40.13 (September 13, 2007):
	§ 40.13(a) Disposal Request and Approval Letter with Safety Evaluation Report (ADAMS Accession No. ML072340221)
Example 4	Issuance of Hematite Amendment No. 65 Approving Westinghouse Hematite Request For Alternate Disposal of Specified Low-Activity Radioactive Material and Granting Exemptions to § 30.3 and § 70.3 (April 29, 2015):
	§ 20.2002 Approval Letter, Safety Evaluation, Environmental Assessment, and Amendment (ADAMS Accession Nos. ML15086A365, ML15086A413, ML15029A064, and ML15086A419)



¹ As discussed in Section 10.1.1, there may be a request for a hearing, which is described in 10 CFR 2.309.