

**RESPONSES TO COMMENTS ON THE “GUIDANCE
FOR THE REVIEWS OF PROPOSED DISPOSAL
PROCEDURES AND TRANSFERS OF RADIOACTIVE
MATERIAL UNDER 10 CFR 20.2002 AND 10 CFR
40.13(A),” ISSUED ON OCTOBER 19, 2017**

Introduction

This document addresses public comments that the U.S. Nuclear Regulatory Commission (NRC) received on the draft guidance document, “Guidance for the Reviews of Proposed Disposal Procedures and Transfers of Radioactive Material Under 10 CFR 20.2002 and 10 CFR 40.13(a),” which was published in October 2017 for public comment. The original guidance document for the review of Alternative Disposal Requests (ADRs), EPPAD 3.5, “Review, Approval, and Documentation of Low-Activity Waste Disposals In Accordance with 10 CFR 20.2002 and 10 CFR 40.13(a),” was issued in 2009 and provided information on the ADR review process. This original guidance document was revised to improve the ADR process.

Public Meetings and Outreach

The staff provided notice of the draft guidance document in the *Federal Register* ([82 FR 48727](#), October 19, 2017). This *Federal Register* notice, which can be accessed on www.regulations.gov by searching on docket ID [NRC-2017-0198](#), provided background information regarding the draft guidance document, solicited public comments, and provided notice of the NRC's plans to hold a public meeting to discuss the document and receive comments on the proposed changes. The draft guidance document was placed on an NRC Web page, “10 CFR 20.2002 Process for Alternative Disposals,” which can be found at <https://nrcweb.nrc.gov/waste/llw-disposal/10cfr20-2002-process.html>.

In December 2017, the staff received a request from a public stakeholder to extend the comment period for the draft guidance document, in order to allow more time for members of the public to submit their comments. As a result, the NRC decided to reopen the comment period, and the staff provided notice of the reopened comment period in the *Federal Register* ([82 FR 60632](#), December 21, 2017). This comment period closed on January 17, 2018.

A public meeting was held on October 19, 2017, at the NRC's headquarters in Rockville, MD, with a webinar and facilitated bridge line set up to enhance public participation. A second public webinar was also held on November 16, 2017. Notices for the October 2017 public meeting and the November 2017 public webinar were on the NRC's public meeting notification website (<https://www.nrc.gov/pmns/mtg>). Transcripts, meeting notices, and meeting agendas can be found via the NRC Web page and in ADAMS.

In addition to the public meeting and webinar, the draft guidance document was discussed with Agreement State representatives during the Organization of Agreement States (OAS) monthly call on July 20, 2017. The staff also presented at the annual OAS Meeting on August 24, 2017, providing an update on the status of the draft guidance document, highlighting changes, answering questions, and considering how to best support its use in Agreement States. The NRC issued State and Tribal Communications (STC) Letter STC-17-073 on October 20, 2017, to inform the Agreement States that the NRC published a *Federal Register* notice requesting comment on the draft guidance document. On November 9, 2017, the NRC issued STC-17-076, “Notification of Webinar Regarding the Final Draft Revision of ‘Guidance for the Reviews of Proposed Disposal Procedures and Transfers of Radioactive Material Under 10 CFR 20.2002 and 10 CFR 40.13(a),’” to inform the Agreement States of the staff's plans to conduct a webinar to discuss the revisions of the draft guidance document. In addition, the reopened comment period and its *Federal Register* notice were discussed during the OAS call on December 21, 2017, and STC-17-081 was issued on December 22, 2017.

Public Comments on the Draft Guidance Document

During the public comment period for the draft guidance document, the NRC received 18 written comment letters, which are available in ADAMS and on www.regulations.gov under docket ID [NRC-2017-0198](https://www.regulations.gov/docket/NRC-2017-0198). The commenters and the ADAMS Accession Numbers for their letter submissions are listed in Table 1.

Table 1: Comment Letters Formally Submitted

Comment Letter #	Organization, if stated	ADAMS Accession No.
1	Shirley Xu	ML17304A061
2	Texas Commission on Environmental Quality	ML17349A143
3	EnergySolutions	ML17355A128
4	US Ecology, Inc.	ML17355A129
5	OAS	ML17355A130
6	New York State Energy Research & Development Authority	ML17355A131
7	Anonymous	ML17355A132
8	Anonymous	ML17355A133
9	Anonymous	ML17355A134
10	Anonymous	ML17355A135
11	Anonymous	ML17355A136
12	Anonymous	ML17355A137
13	Anonymous	ML17355A138
14	U.S. Department of Energy (DOE)	ML18060A073
15	Nuclear Information and Resource Service	ML18060A076
16	Anonymous	ML18068A048
17	U.S. Army Corps of Engineers Radiation Safety Support Team	ML18060A077
18	Nuclear Energy Institute	ML18046A057

Disposition of Comments

The following pages summarize the comments received on the draft guidance document and discuss their disposition. Parenthetical numbers after each comment refer to the comment letter number, which can be tracked to the commenter and the source document as listed in Table 1. The NRC categorized and consolidated comments according to subject area, as reflected in Table 2.

Table 2: Comment Categories

Section	Category
A	General
B	Policy/Rulemaking
C	Agreement State/Regulatory Overlap
D	Unimportant Quantities of Radioactive Material
E	Performance Assessment
F	Compliance Period and the Analysis Timeframes
G	Radon
H	Other Off-Site Disposals - Release of Solid Material with Volumetric Contamination
I	Transportation
J	Cumulative Impacts

Similar comments were further grouped together and summarized. Responses were prepared for each comment summary. This appendix contains comment summaries and the NRC responses to these summaries.

A. General Comments

Comment A-1: (Comment Letter 1)

The commenter indicated that the text in Section 3 of the draft guidance document, which stated that the “staff will not approve exempt distribution licenses if there is not an intended use of the byproduct material,” is in conflict with NRC practice in regard to § 32.11. The commenter indicated that the NRC does issue exempt distribution licenses under § 32.11 for gemstone distribution, even though the byproduct material contained in gemstones is unintentionally introduced into the gemstones.

Response:

The purpose of this statement in Section 3 was to explain why seeking an exempt distribution license for disposal of small quantities of radioactive waste is inappropriate and the NRC is unlikely to approve such an application. If the material will be disposed of, then it does not have an intended purpose and, therefore, the applicant could not satisfy the requirements in § 32.11(b) to provide a description of the “intended use of the byproduct material.” Guidance on exempt distribution licensing is contained in NUREG-1556, Vol. 8, Rev. 1, “Program-Specific Guidance About Exempt Distribution Licenses.” Relevant to this comment, this guidance explains in Appendix C, on page C-9 that applicants for the exempt distribution of gemstones must request an exemption from § 32.11(c), because § 32.11(c) prohibits the incorporation of exempt concentrations into products or materials designed for application to human beings and gemstones are “applied to human beings,” (i.e., the jewelry will be worn on a person’s body). Absent such an exemption from the regulations, an applicant must satisfy all regulatory requirements to obtain an exempt distribution license. In an effort to streamline the guidance and focus on ADRs, the discussion on exempt distribution licenses has been removed.

Comment A-2: (Comment Letter 3)

A commenter indicated that the text in Section 5.1, which stated that “[t]he PM [Project Manager] also ensures that the guidelines in the regulation, this document, and the NRC’s Principles of Good Regulation are adhered to throughout the process,” confuses the terms regulations and guidance. The commenter requested that the statement be revised to “...the regulations, the guidelines in this document...”

Response:

The staff agrees with this comment. Based on this comment, Section 5.1 of the guidance document was revised.

Comment A-3: (Comment Letter 3)

A commenter stated that the NRC should develop a publicly available tracking system that collects ADRs in a single location.

Response:

SECY-07-0180 provides the results of the staff's strategic assessment of the NRC's LLW regulatory program, including a prioritized listing of ongoing and future staff actions and activities. The development and implementation of a national waste tracking system was listed as Task 20. The strategic assessment indicated that the NRC and Agreement States already have programs that ensure the safe and secure use of radioactive waste, this task does not contribute significantly to safety, security, effectiveness, or openness, and that the regulatory burden to the NRC and Agreement States licensees would be significant. Accordingly, it was assigned a low priority.

Following this strategic assessment, the staff decided to conduct a new programmatic assessment of the NRC's LLW regulatory program, which was documented in SECY-16-0118. The programmatic assessment indicated that this task would involve rulemaking activities.

As described by these assessments, the development of a tracking system would be completed if resources become available and is a low priority at this time since it would not have the necessary benefit to safety and security commensurate with the regulatory burden that would be created. Accordingly, a tracking system for ADRs is not being developed at this time. As stated in Section 6.1.2, the staff determined that with proper profiling of documents in ADAMS, these documents can be readily accessed by the public. No revisions to the document were made in response to this comment.

Comment A-4: (Comment Letter 3)

A commenter stated that the following text from Footnote 24 in Section 7.5 of the draft guidance document should be moved to the main body of the document because it contains specific guidance for a reviewer: "A draft SER and EA (see Sections 7 and 8) should be prepared prior to transmittal of the draft RAI. Although RAIs may be developed during the acceptance review, they should be limited to obvious information insufficiencies."

Response:

The staff agrees with this comment. Based on the comment, Section 7.5 of the guidance document was revised to move the text in Footnote 24 to the main body.

Comment A-5: (Comment Letters 3, 11)

Two commenters raised concerns with the guideline in Section 10.2 of the draft guidance that no special enhanced communication measures are necessary when the proposed § 20.2002 disposal will be in a facility that routinely disposes of large quantities of similar radioactive materials. One commenter proposed deleting this language because routineness is not a reasonable standard for ascertaining when enhanced communication measures are necessary. The second commenter noted that the guideline seemed to contradict the following language in Section 7.2.1 of the draft guidance: "the potential for the same individual to be involved in concurrent scenarios is physically constrained by the relatively limited amount of materials that

could be released from licensed facilities, geographical distances between licensees, and the different locations where scenarios could occur.”

Response:

The staff developed the guidelines included in Section 10.2 of the guidance document for determining when a request does not need additional outreach measures as part of Option 2 in SECY-06-0056. The Commission approved Option 2 on March 31, 2006 in the SRM-SECY-06-0056. This option recognized that there are significant differences in the types of § 20.2002 disposals that are requested by licensees, and that a graded approach for transparency may be appropriate.

These guidelines were developed to define and document a more systematic approach for interacting with the public and obtaining input on particular requests than past practice. The guidelines are intended to be used to determine if something is significant for the purposes of needing enhanced communication, not whether the disposal is risk significant in general. Although a disposal in a facility that routinely disposes of large quantities of similar radioactive material is not necessarily less risk significant, the need for enhanced communication may be less because the community will be more familiar with this type of hazard and the disposal of similar waste in the community has already been vetted. Additionally, Section 10.3, “Outreach Measures for Enhanced Communications,” states: “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, the licensee, or for other reasons.” This guidance allows for flexibility to take additional outreach measures, even if the proposed disposal is intended to be in a facility that routinely disposes of large quantities of similar radioactive materials.

To further clarify that the purpose of these guidelines is limited to the need for additional public outreach, the phrase, “a request would not be considered significant and no special measures would be necessary when” in Section 10.2 of the guidance document was revised to “a request would not be considered significant and no special *enhanced communication* measures would be necessary when.” Additionally, as described in the Comments on Cumulative Impacts Section of this appendix, Section 7.2.1 was revised to better describe the possibility for an individual to receive a dose from waste from multiple ADRs.

Comment A-6: (Comment Letters 7, 17)

Section 1 of the draft guidance document stated, “the purpose of this procedure is to provide guidance for U.S. Nuclear Regulatory Commission (NRC) staff and describe the process for documenting, reviewing, and approving (on a case-by-case basis) requests received from licensees, license applicants, and other entities for alternative disposal of licensed material.” Two commenters indicated that “other entities” needs to be defined.

Response:

The staff has received requests from “other entities,” such as Agreement States and other organizations, in the form of TARs. Accordingly, Sections 1 and 6.1.1 were revised to add more clarity.

Comment A-7: (Comment Letters 10, 12)

Sections 5.1 and 11 of the draft guidance document reference various responsibilities to be performed by the NRC PMs. Two commenters stated that, as currently written, the draft guidance document assigns responsibilities to the NRC PM (e.g., coordinating reviews among all internal and external parties involved with the various aspects of the review) that are not the responsibility of the NRC and would be better suited to be performed by the licensees.

Response:

The staff agrees with this comment. Based on the comment, Sections 5.1 and 11 were revised.

Comment A-8: (Comment Letter 3)

A commenter stated that NRC office instructions regarding Regulatory Audits should be referenced within the guidance document.

Response:

The staff agrees with this comment. Section 7.5 of the document was revised to include references to NRC office instructions regarding Regulatory Audits as a result of this comment.

B. Comments Concerning Policy/Rulemaking**Comment B-1: (Comment Letters 4, 13, 17)**

One commenter stated that the NRC's regulations regarding disposal have different dose bases. The commenter recommended that the NRC should harmonize its regulations regarding disposal to use a consistent dose basis. Two other commenters suggested that the performance-based dose criteria for ADRs submitted under § 20.2002 should be the same as the criteria for evaluations of § 40.13(a) requests. The commenters specifically recommended that the dose criteria for requests submitted under § 20.2002 be revised to 0.25 mSv per year (25 mrem per year). The commenters provided multiple reasons why consistency in the dose criteria would be appropriate.

Response:

The staff acknowledges that different parts of the NRC regulations regarding disposal have different dose bases. With regard to § 20.2002 and § 40.13(a), the staff also acknowledges differences in dose criteria specified in the ADR guidance for those specific types of disposals or transfers. However, in all cases, the public dose limit in § 20.1301 applies. As affirmed by the National Academy of Sciences, the NRC's current approach to release of solid materials is sufficiently protective of public health. Revisions to the dose standards or bases of the NRC's regulations are outside the scope of the guidance document. Furthermore, based on Commission direction, no revisions to the dose criteria in the guidance document were warranted.

The "few mrem" dose criterion for § 20.2002 requests was initially established as a staff practice and then developed further through issue papers (SECY papers), and Commission direction (SRMs) (e.g., SECY-03-0069, Attachments 4 and 5; SECY-06-0143; SECY-07-0060, Attachment 1). The dose criterion is also repeated in staff guidance (e.g., NUREG-1757, Vol. 1, Rev. 2, Sections 15.11 and 15.12). For § 40.13(a) disposals, the dose criteria were separately developed through policy papers and Commission direction. The staff notes that the criteria for § 40.13(a) disposals are not simply 0.25 mSv per year (25 mrem per year) as implied by one commenter. Rather, the dose benchmarks, as described in Section 7.2.2 of the guidance document, indicate that the staff will still consider transfer and disposal requests where the estimated dose is expected to exceed 0.25 mSv per year (25 mrem per year). In sum, the dose criteria for both § 20.2002 requests and § 40.13(a) reviews are well-established staff practice, in accordance with Commission direction. Section 7.2.1 of the guidance document was revised to further document the NRC's current practice.

Comment B-2: (Comment Letter 17)

One commenter recommended that the NRC consider granting disposal facilities an exemption from licensing (including for disposal) for unimportant quantities of source material and potentially any radionuclides covered in the permitting performance assessment (i.e., the performance assessment for the State or other permit under which the facility operates). The commenter similarly recommended that the NRC consider granting disposal facilities an exemption from licensing based on a very low level of special nuclear material.

Response:

This comment involves a policy decision, which is outside of the scope of this guidance. The staff's established practice and policy is to evaluate of ADRs under § 40.13(a) on a case-by-case basis. The staff considers it appropriate to evaluate the need for an exemption concurrent with each ADR evaluation. This includes requests related to VLLW, source material, and special nuclear material. Current staff practice is to issue the exemption (when one is needed) along with the ADR approval. The staff notes that disposal facilities are already exempt from licensing to the extent they receive unimportant quantities of source material under the existing exemption in § 40.13(a). No revisions to the document were made in response to this comment.

Comment B-3: (Comment Letter 15)

The commenter expressed concern that there is no clear public notification of the § 20.2002 and § 40.13(a) applications to enable the public to be involved in the process. According to the commenter, the full spectrum of health effects from low continuous doses of radiation are not addressed in 10 CFR Part 20 radiation regulations of the NRC. Specifically, the regulations only protect for cancer, although radiation causes other health effects and disproportionately impacts women, youth, babies, and the gene pool. Additionally, the commenter indicated that the draft guidance document ignores the totality of radiation releases and exposures from the nuclear fuel chain and that there is no limit on the number of clearances that will be permitted and the number to which members of the public will be exposed.

Response:

With regard to public participation in the § 20.2002 and § 40.13(a) review process, the commenter is directed to Section 9.1.1 of the guidance document, which discusses opportunities for hearings for license amendments. In addition, the staff makes the applications publicly available as part of the review process, and for those applications that are less routine or that may have high public interest, additional public notification, as well as notification up to and including the Commission, which is described in Section 10 of the guidance document.

The dose limits in 10 CFR Part 20, and consideration of nuclear fuel cycle doses are outside the scope of the guidance document.¹ The document provides an acceptable method for meeting the dose limits in the 10 CFR Part 20 regulations and does not change any of the dose limits. The NRC considers the dose limits in 10 CFR Part 20 to be protective of human health and safety.

¹ Although considered outside the scope of the guidance document, certain radiation protection regulations in 10 CFR Part 20 consider protection of sensitive groups. For example, the effluent concentration values listed in Appendix B, Table 2, Column 1, for those radionuclides for which the stochastic limit is governing, the limits derived for adults are adjusted by a factor of 2 to consider other age groups.

With respect to cumulative impacts associated with multiple clearances, the NRC's approval of § 20.2002 ADRs have been infrequent in the past. The guidance document does not include a new provision for tracking the approvals because the staff did not consider it necessary to track them for the following reasons: (a) releases of materials via § 20.2002 are made in compliance with licensee's approved programs and NRC regulations; (b) the NRC inspects licensees' radiation protection programs and survey records, including how licensee's implement their § 20.2002 approvals; and (c) the staff estimates that exposures associated with the release of materials via § 20.2002 are low (e.g., individual disposals are constrained to a maximum of a few millirem).

The guidance document does not expand nor reduce the scope of types of proposals that would be considered acceptable for review. The NRC's current approach for using § 20.2002 to dispose of materials is considered protective of public health and safety by the National Academy of Sciences and the staff,² and allows for the review of licensee's requests on a case-by-case basis. Additional information is provided in Section H of this Appendix, Comments Concerning Release of Solid Material with Volumetric Contamination.

Although outside the scope of the guidance document, with respect to the comment regarding NRC's consideration of the totality of nuclear fuel chain releases and exposures, Tables S-3 and S-4 (§ 51.51 and § 51.52, respectively) evaluate the environmental impacts of the uranium fuel cycle for reactor licensing. These tables were evaluated and supplemented in NUREG-1437, "Generic Environmental Impact Statement for License Renewal of Nuclear Plants: Main Report," (1996) to support reactor license renewal. The findings in NUREG-1437 (1996) were reaffirmed in NUREG-1437, Rev. 1 (2013), and any new and significant information on uranium fuel cycle impacts and other environmental impacts is considered in the environmental reviews for each reactor license renewal application.

Comment B-4: (Comment Letter 18)

A commenter suggested that "the draft guide be revised to more clearly articulate when, if ever, an approval under 10 CFR 20.2002 is needed in cases involving licensed radioactive material on or within a licensee's site." The commenter noted that the draft guidance on page 7 appeared to conflict with the guidance on page 27. The guidance on page 7 is that § 20.2002 may be used for an alternative disposal procedure such as burial on a licensee's site; however, the guidance on page 27 states that "for onsite disposal, no exemption is needed."

In addition, the commenter presents a discussion of "residual radioactive material" and a view that "if the material can be determined to be residual radioactive material as defined in 10 CFR 20.1003 and reasonably expected to meet the criteria for release at the time of license termination, then its burial would not necessitate a 10 CFR 20.2002 application."

Response:

The first part of the comment raises the question of the distinction between "authorizations" for disposal and an "exemption" from licensing requirements for possession of licensed material. In the context of § 20.2002, the NRC uses the terms "authorization" and "exemption" in the following manner. A § 20.2002 "authorization" is a regulatory approval to dispose of licensed material (e.g., LLW) in a manner not otherwise authorized by waste disposal regulations in § 20.2001. An exemption excuses an unlicensed facility from the requirement that it obtain a

² The Commission indicated in SRM-SECY-05-0054 that the current approach to review specific cases on an individual basis is fully protective of public health and safety consistent with the finding of the National Academy of Sciences.

license for possession of material that is otherwise required by NRC's regulations (e.g., § 30.3, "Activities requiring license," for byproduct material). Exemptions are issued by NRC in accordance with regulations governing its specific exemption authority (e.g., § 30.11, "Specific exemptions," for byproduct material) or by Agreement States within their jurisdiction.

Regarding authorization for disposals, most licensed production and utilization facilities are licensed to possess byproduct material. However, most facilities are not authorized to dispose of material on-site. Also, the waste disposal regulations in § 20.2001 do not allow on-site disposal without specific authorization under § 20.2002. Therefore, licensees desiring to dispose of licensed material on-site must obtain an authorization under § 20.2002.

Historically, some licensees have submitted applications to NRC for on-site or off-site disposal under § 20.2002. The NRC has reviewed and approved certain § 20.2002 applications, including on-site disposals. The NRC's current regulatory framework requires NRC's prior approval under § 20.2002 for on-site burials of radioactive waste. The Atomic Energy Commission (AEC), the predecessor agency to the NRC, authorized the burial of certain quantities of radioactive waste in soil without prior agency approval under § 20.304. However, on January 28, 1981, the Commission removed § 20.304 from its regulations (45 FR 71761). The Commission concluded that it was inappropriate to continue generic authorizations of burials pursuant to § 20.304 without regard to factors such as location of burial, concentrations of radioactive material, form of packaging, and notification of the NRC. Since the removal of § 20.304 from NRC's regulations, on-site burials of radioactive material (i.e., burial at other than licensed LLW facilities) were only authorized under § 20.302, which required NRC's prior approval. The NRC later revised and renumbered § 20.302, which is currently § 20.2002.³ Therefore, the phrase "such as burial on a licensee's site" on page 7 of the draft guidance is consistent with the current NRC practice.

Regarding exemptions from licensing requirements for possession of licensed material, by definition, facilities licensed to possess material do not need an exemption from the licensing requirement if they intend to maintain possession of licensed material on their site following a § 20.2002 approval. However, an unlicensed facility, such as a commercial landfill, would need to obtain a license or an exemption if it wishes to possess the licensed material approved for release via the § 20.2002 review process.

Regarding the residual radioactivity, the commenter raises the matter of requirements for disposal versus storage until the time of license termination. The NRC regulations on waste disposal are provided in 10 CFR Part 20, Subpart K – "Waste Disposal," §§ 20.2001 – 20.2008. As explained above, none of the NRC's current regulations on waste disposal, regardless of the level of residual radioactivity, allow on-site burial, except as authorized under § 20.2002. A licensee is authorized to store licensed material onsite in accordance with 10 CFR Part 20, Subpart I, "Storage and Control of Licensed Material." If a licensee is storing licensed material on-site for disposition at a later date, such as at the time of license termination, the licensee would not need a § 20.2002 authorization for disposal. However, the licensee should maintain records in accordance with § 50.75(g), § 70.25(g), and § 72.30(f).

In response to these comments, Sections 2 and 3 of the guidance document have been revised to address on-site storage and exemption from licensing requirements for possession of material, respectively.

³ As stated in RIS 2016-11, § 20.2002 replaced § 20.302 (56 FR 23403, May 21, 1991).

Comment B-5: (Comment Letters 9, 13, 17)

Three comments were received on the dose criteria for the workers at the RCRA facility. The commenters noted that the workers at the RCRA facilities accepting radioactive wastes are trained as radiation workers and are monitored for exposure. One commenter recommended that these workers should be considered radiation workers and their dose should not be limited to 0.05 mSv per year (5 mrem per year). Another commenter recommended that the NRC rely on measured dose to assess compliance. A commenter recommended that the same criterion should not be used for on-site and off-site disposal. This commenter further stated that the guidance said that the off-site disposal must be at a facility permitted by a State or Federal agency. The commenter recommended that the guidance should allow consideration of the State's permitting process and other Federal agency standards, such as Occupational Safety and Health Administration and DOT, which limit exposures to site workers, as well as facility design and controls that serve to limit exposures to members of the public.

Response:

The NRC does not require off-site disposal facilities to be permitted, though many of the off-site disposals approved under ADRs are at facilities permitted under RCRA regulations. The NRC does not rely on the permitting or regulatory requirements of another agency. Section 7.1.2 in the document was revised to clarify this point. The facility is exempt from licensing requirements under the AEA, pursuant to an exemption issued by the NRC or an Agreement State. Therefore, upon arrival at the facility, the material is no longer subject to NRC and Agreement State regulations.

For the purpose of evaluating ADRs, the staff has considered workers at non-licensed facilities to be members of the public. Since these facilities are non-licensed, these facilities would not be subject to the NRC's occupational dose limits in Subpart C of 10 CFR Part 20.

The doses allowed by regulations such as the Occupational Safety and Health Administration and DOT regulations are much higher than the "few mrem" criterion used in evaluating § 20.2002 requests. Additionally, the requirement in § 20.2002(d) is for the doses to be ALARA. The staff does consider properties of the facility (e.g., burial depth) when evaluating what exposure pathways and scenarios are plausible at the site.

Additionally, the NRC evaluates and approves the ADR prior to the waste being shipped to a non-licensed disposal facility. The NRC approval is therefore based on the projected dose to the workers at the disposal facility and needs to be evaluated before the waste is shipped. The NRC is unable to rely on dosimetry that measures the actual dose from the waste disposed under the ADR to the disposal facility workers when approving the ADR because the worker exposure to the waste will not have occurred yet.

C. Comments Concerning Agreement State/Regulatory Overlap

Comment C-1: (Comment Letter 6)

A commenter requested additional clarity on issues related to license termination and intergovernmental communications between the NRC and Agreement and Non-Agreement States. Specifically, the document should acknowledge that in the event of an NRC license termination of a fuel cycle facility in an Agreement State, radiological regulatory authority over the site reverts to the Agreement State upon license termination. Further, concurrence of final conditions for the site should be received from the Agreement State regulatory program to avert any circumstances of future restrictions on site development by the Agreement State.

Response:

The majority of issues discussed in this comment deal with license termination and, therefore, are outside the scope of this guidance document. The issues of intergovernmental coordination, especially with State agencies, are discussed in Section 11. No revisions to the document were made in response to this comment.

Comment C-2: (Comment Letter 6)

A commenter stated that the draft guidance document breaks with past precedent and is not consistent with the commenter's understanding of Agreement State roles. According to the commenter, while in the past, the NRC deferred to the New York Agreement State program for alternative on-site disposals at the Ginna Nuclear Power Plant because the site will eventually fall under Agreement State authority following termination of the NRC license, the draft guidance document appeared to indicate that NRC retains that responsibility. The commenter asserted that the rationale for this change has not been explained, and that no such change to Agreement State roles is appropriate under law and relevant State agreements.

Response:

As noted in the guidance, RIS 2016-11 clarified the application process for obtaining approvals to dispose of LLW in accordance with § 20.2002 regulations, or equivalent Agreement State regulations. The RIS informed NRC licensees, Agreement State Radiation Control Program Directors, and State Liaison Officers that Information Notice 86-90 "incorrectly stated that in cases where a nuclear reactor facility is located in an Agreement State, the NRC does not have the legal basis for performing the reviews and granting approvals." The RIS clarified that NRC licensees must receive approval from the NRC under § 20.2002, not the Agreement State, for an alternative disposal procedure for waste that is created as a result of NRC licensed activities.

During the decommissioning and the license termination process, the NRC licensees must meet the NRC's requirements for decommissioning. No revisions to the document were made in response to this comment.

Comment C-3: (Comment Letter 6)

A commenter stated that the discussion in Section 11 should be expanded to acknowledge that a § 20.2002 approval does not override other State regulations that may prohibit such disposals, nor a disposal facility's right to refuse disposal of any waste, even if acceptable to the pertinent regulators.

Response:

The staff agrees with this comment. Section 11 of the guidance document was revised to acknowledge that a § 20.2002 approval does not override other State regulations.

Comment C-4: (Comment Letter 17)

The commenter indicated that Section 12.2 of the draft guidance document states, "Approvals of ADRs apply to NRC licensees and non-licensees," but that it only provides one example, is vague as written, and is unclear if other non-licensees would be impacted by the requirements in the draft guidance document. The commenter provided examples for which it is unclear if they would be considered non-licensees under the guidance, including a site being remediated under Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) (which has evaluations that rely on risk rather than dose assessments) and projects that included AEA exempted materials. The commenter recommended that the guidance should specify when a non-licensee, and what non-licensees, are subject to its requirements.

Response:

The NRC maintains agreements with other Federal agencies, including the EPA, to avoid issues involving dual regulation. In cases such as the example provided in the comment, the NRC would most likely monitor the EPA's actions regarding a site being remediated under CERCLA and only get involved if issues are determined by the NRC staff to impact public health and safety in accordance with NRC's regulations.

With regards to NRC's regulations, non-licensees are not required to follow the regulations in 10 CFR Part 20. However, if they possess NRC-licensable material they are subject to the applicable NRC regulations. Although the staff reserves the right to issue a license to an individual found to possess NRC-licensable material if circumstances are warranted, the preferred approach is to work with the non-licensees to resolve the issue on a case-by-case basis without licensing actions. Based on this comment, Section 12 of the guidance document was revised to provide examples of situations where the NRC may perform an ADR review for non-licensees.

Comment C-5: (Comment Letter 17)

The commenter expresses concern over potential inefficiencies when two Federal agencies are involved in the proposed action. The commenter stated that if the licensee is a Federal agency, it too would be required to perform an Environmental Assessment (EA) and, thus, two EAs would be required at an increased cost to the government. Additionally, the commenter asked if the NRC would prepare an EA for an action for which a CERCLA decision document is completed.

Response:

With respect to the first situation wherein the potential exists for two Federal agencies each to prepare their own EA, NRC's regulations at 10 CFR Part 51, which implement the NEPA, allow for the adoption of another Federal agency's Environmental Impact Statement (see Appendix A to Subpart A of 10 CFR 51). NUREG-1748 states that "[s]imilar procedures exist for using another agency's EA." (Section 1.6.1 of NUREG-1748). When adopting another agency's EA, the staff guidance states that NRC "takes full responsibility for the scope and content of any adopted EA" and that the NRC must prepare its own FONSI and record of decision.

The NRC's regulations in 10 CFR Part 51 also provide for the option of Federal agencies cooperating in the preparation of an EA and the recognition of a lead Federal agency in those situations (see § 51.10(b)(2)). Cooperating agencies may be appropriate where the other Federal agency has jurisdiction by law or special expertise related to specific environmental issues of concern. Cooperating agencies are discussed further in Section 4.2.4.2 of NUREG-1748.

Additionally, in other situations where the Federal agency is an NRC licensee, the Federal agency may not be required to prepare an EA, but rather may provide environmental information in the form of an environmental report to the NRC to support NRC's EA preparation. With respect to the commenter's question of whether a CERCLA decision document would suffice for NRC's environmental review and EA preparation, the NRC notes that another agency's preparation of a CERCLA decision document does not absolve the NRC of its obligations under NEPA. However, to the extent applicable, the NRC may be able to incorporate information provided in the CERCLA evaluation to aid in its EA preparation. No revisions to the document were made in response to this comment.

Comment C-6: (Comment Letter 2)

Section 9.0 of the draft guidance document states "If the requester is an NRC licensee and the unlicensed facility is located in an Agreement State, then the NRC would approve the disposal request and the Agreement State would issue an exemption to the unlicensed facility." A commenter stated this should be modified to clarify that only States that have the equivalent of § 20.2002 in their State rules can issue this exemption. Texas does not have the equivalent of § 20.2002 in its rules and thus has no legal or regulatory authority to exempt an alternative disposal procedure request for disposal at an unlicensed facility that was approved by the NRC under § 20.2002.

Response:

A § 20.2002 request in which a licensee or applicant seeks approval for off-site disposal at an unlicensed facility is often a two-step process. First the regulatory authority (the NRC or the Agreement State) that issued the license for use of the radioactive material approves the alternative method of off-site disposal under § 20.2002 or equivalent Agreement State regulation. Then, the unlicensed disposal facility that intends to take possession of the licensed material must an exemption, or other form of approval, from the Agreement State in which the disposal facility is located or the NRC if the disposal facility is located in a non-Agreement State.

In the example raised by the commenter, the Agreement State does not need a § 20.2002 equivalent regulation because the Agreement State may exercise its authority to grant an exemption for the receiving facility. Approval under § 20.2002, or the equivalent Agreement State regulation or exemption authority, is for the generator of the waste, not the receiving facility.

Comment C-7: (Comment Letter 5)

A commenter stated that Section 7.2.2 should clarify that some source material that is exempt under § 40.13(a) may be classified as either Technologically Enhanced Naturally Occurring Radioactive Material (TENORM) or diffuse NARM and may be regulated under separate regulations by the states, either Agreement or Non-Agreement. According to the commenter, these state regulations may not allow for materials to be disposed in the same manner as described in this draft guidance document.

Response:

The EPAAct modified the AEA to add NARM to the definition of byproduct material in Section 11e.(3). Therefore, the applicable regulations for NARM fall within 10 CFR Part 30. It is important to note that the NRC regulates both discrete sources of radium and contamination originating from discrete sources of radium (which could be interpreted as what the commenter was referring to in using the term "diffuse" NARM). The NRC does not regulate TENORM, which may be regulated by the States.

D. Comments Concerning Unimportant Quantities of Radioactive Material

Comment D-1: (Comment Letters 2, 3)

Two commenters asked for clarification on the limited types and quantities of source material that fall under the exemption for unimportant quantities of source material in § 40.13(a) and where transfers under § 40.51(b)(3) could potentially result in scenarios which could exceed the public dose limits in 10 CFR Part 20. The commenters also requested further guidance on the regulatory basis for and requirement for review and approval of certain transfers under § 40.51(b)(3) (i.e., there is no rule requiring review and approval). In this same vein, a commenter asserted that if the draft guidance purported to require NRC prior approval for

§ 40.13(a) requests, this position would be contrary to the All Agreement States letter (FSME-12-025), which states that a licensee may transfer unimportant quantities of source material to persons exempt under § 40.13(a) without any specific licensing action by the NRC (or Agreement State). The commenter went on to state that if the NRC thinks these types of transfers require regulatory approval, it should revise its regulations to impose the regulatory standard.

Response:

As stated in SECY-00-0201, doses greater than 1 mSv per year (100 mrem per year) could result from the transfer of unimportant quantities of source material. Based on this comment, Section 3 of the guidance document was revised to reference SECY-00-0201 and additional information was provided, including examples of when public doses could be exceeded based on the analysis provided in NUREG-1717.

The commenters correctly noted there is no regulatory requirement to obtain NRC approval prior to the transfer. However, the licensee could perform a screening level or more detailed analysis to determine if the doses are significant (e.g., above 0.25 mSv per year (25 mrem year), which is the level at which the Commission requested it be kept informed of the transfer [see SRM-SECY-00-0201]). Alternatively, the licensee could provide information to the NRC to allow the NRC to determine potential doses from the transfer.

With regard to the basis for the review and approval of certain transfers under § 40.51(b)(3), on February 2, 1999, the Commission directed the staff, in SRM-COMSECY-98-022, "Proposal to Permanently Dispose of "Unimportant Quantities" of Source Material Without a License Pursuant to 10 CFR 40.13(a)" to provide recommendations for developing a more risk-informed and coherent set of requirements for licensing source material in 10 CFR Part 40, including possible revisions to § 40.13(a). In response, the staff prepared SECY-99-259, "Exemption in 10 CFR Part 40 for Materials less than 0.05 Percent Source Material - Options and Other Issues Concerning the Control of Source Material."

On March 9, 2000, the Commission issued SRM-SECY-99-259, which directed the staff to take a number of actions to resolve issues associated with regulation of source material under 10 CFR Part 40. Among these actions was the development of a proposed rule to amend § 40.51(b)(3) and (4) to require prior Commission approval for transfers of less than 0.05 weight percent source material from licensees to persons exempt under § 40.13(a). The staff developed the proposed rule in SECY-00-0201. The NRC Commission approved publication of the proposed rule to amend § 40.51 to require NRC approval for licensee transfers of unimportant quantities of source material to exempt persons for the purpose of disposal subject to the comments and changes provided in the SRM. Although the Commission in SRM-SECY-03-0106, approved delay of the rule pending the outcome of two related rulemakings, the Commission directed 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. The staff continues to review risk-significant transfers of unimportant quantities of source material when requested and as directed by the Commission.

Although the commenter who referenced the All Agreement States letter (FSME-12-025) correctly noted that prior NRC review and approval of transfers of unimportant quantities of source material is not a regulatory requirement, an assessment may be prudent in certain cases to ensure that the risk associated with the transfer of unimportant quantities of source material is acceptably low. The staff agrees with the commenter's concern regarding imposing regulatory

standards through guidance. Consistent with the regulations, Section 3 of the guidance document was revised to more clearly indicate that licensees are not required to submit applications to the NRC nor receive NRC approval for § 40.13(a) requests. The staff continues to review § 40.13(a) 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 § 40.13(a) transfer requests may be pursued in the future.

E. Comments Concerning Performance Assessment

Comment E-1: (Comment Letter 9)

A commenter suggested that the basement intruder scenario should be excluded from consideration when a facility has covenants or permit conditions that restrict the future use of the property in perpetuity.

Response:

The staff does not consider covenants and permit conditions in the determination of scenarios to analyze for ADRs because the NRC considers the disposal to be similar to an unrestricted release. In the case of disposals performed under ADRs, the NRC does not have a mechanism to ensure that the covenants or permit conditions are maintained in perpetuity and the NRC does not have a mechanism to ensure that the regulations by other agencies are followed in the future.

However, as described in a previous comment response and in Section 7.1.2 of the guidance document, the staff considers properties of the facility (e.g., burial depth) when evaluating what exposure pathways and scenarios are plausible at the site. For example, if the waste is going to be buried at a depth that precludes the building of a basement into the waste, the basement excavation scenario can be excluded, though a well drilling intrusion scenario should still be considered.

Comment E-2: (Comment Letter 3)

A commenter stated that the draft guidance document should be explicit regarding the requirement for an inadvertent intruder analysis.

Response:

Intrusion scenarios similar to inadvertent intruder analyses conducted to support compliance with § 61.42 for LLW should be considered when evaluating the dose associated with the ADR procedures involving subsurface burials. In response to this comment, the staff added specific reference to intrusion scenarios in the “on-site disposal” section of the guidance document where the guidance referred to NUREG-1757, Vol. 2, Appendix J for development of scenarios for evaluating on-site disposals. Section 7.1.2 indicated dose assessments should consider intrusion into the waste.

However, the term “inadvertent intruder analysis” was not used in the draft guidance and will not be included in the final guidance document. The term “inadvertent intrusion” is exclusively used in 10 CFR Part 61 (e.g., § 61.42). On-site disposals reviewed under § 20.2002 for decommissioning facilities ultimately fall under the license termination rule in Subpart E of 10 CFR Part 20. The term “inadvertent intrusion” is not used in Subpart E of 10 CFR Part 20; therefore, the staff purposely avoided the use of terms “inadvertent intrusion” or “intruder” in the document to describe scenarios involving on-site receptors intruding into disposed waste at a decommissioned facility. The final guidance document is not intended to be exhaustive and

incorporates assessment approaches described in decommissioning and LLW disposal guidance, as appropriate (e.g., NUREG-1757, Vol. 2).

F. Comments Concerning Compliance Period and the Analysis Timeframes

Comment F-1: (Comment Letters 3, 14, 16)

Several commenters expressed concern with reference to NUREG-2175 for analysis timeframes for off-site disposal and thought the analysis timeframe should be consistent with the compliance period for on-site disposals of 1,000 years, which is consistent with the LTR in § 20.1401(d). The commenters also indicated that the NRC should use a 1,000 year compliance period for ADR requests consistent with Commission direction in SRM-SECY-16-0106, and DOE Manual 435.1-1, "Radioactive Waste Management Manual."

Response:

Differences in assessment methods between on-site and off-site disposals are attributable to differences in the likely types of materials to be disposed on-site and off-site. On-site disposals ultimately fall under the LTR (in Subpart E of 10 CFR Part 20) for decommissioning facilities with clear direction provided in the rule or in the statement of considerations for the rule with respect to compliance period and consideration of radon.

Materials shipped off-site for disposal can involve residual radioactivity above concentration limits for unrestricted release of a site under the LTR (e.g., excavated materials above clean-up levels at a decommissioning site that are shipped to an off-site facility for disposal). Off-site disposals associated with § 40.51(b)(3) transfers could also involve relatively large volumes of source material with concentrations that would be above limits under the LTR (e.g., unimportant quantities of source material under § 40.13(a) or 0.05 weight percent equates to a concentration of approximately 170 pCi per gram of uranium-238 for natural uranium compared to a screening value for unrestricted release of 0.5 pCi per gram for uranium-238 when the dose contributions of the chain are considered; or a concentration of 58 pCi per gram of thorium-232 compared to a screening value of 1.1 pCi per gram for thorium-232). Also, off-site disposals may cumulatively involve significantly larger quantities of disposed materials (e.g., multiple disposals of material may occur over time at an off-site disposal facility). Therefore, the risk associated with off-site disposals could be higher than on-site disposals.

Although the hazard associated with disposals under § 20.2002 and § 40.13(a) in a RCRA, or other type of, disposal facility is expected to be relatively low compared to disposal of LLW in a LLW disposal facility, the same controls and barriers relied on for performance at a LLW disposal facility may not be present or relied on at a RCRA facility. Therefore, an adequate assessment of risk is needed to ensure that public health and safety is protected and that appropriate mitigative measures are taken to reduce risk, if deemed appropriate.

The term "compliance period" is not used in the § 20.2002 guidance for off-site disposals (rather, the term "analysis timeframes" is used), because there is currently no compliance period specified in § 20.2002, nor in LLW waste disposal rules and associated guidance, which may be used to provide guidance for ADR reviews involving off-site burial.

In practice, 10,000 year analysis or evaluation periods have been used to capture the peak dose of more mobile long-lived radionuclides for LLW disposal. 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 for ADRs, the risk associated with alternative disposal procedures under § 20.2002 may not be adequately assessed considering shorter analysis periods (e.g., if long-lived waste is present and driving the risk of the disposal). If significant quantities of long-lived waste are present, analysis periods beyond 1,000 years might be appropriate. For § 20.2002 disposals and § 40.51(b)(3) transfers to a disposal facility, cases where analysis periods longer than 1,000 years are needed may be the exception and, in many cases, shorter evaluation periods can be easily justified. To determine if longer analysis periods are needed, screening assessments or other types of evaluations could be performed, which are not expected to be resource intensive. Furthermore, analysis periods longer than 1,000 years, when needed to better understand disposal facility risk, will assist the staff with preparation of an EA to inform the decision-making process in furtherance of NEPA objectives.

A commenter noted that the “compliance” period for off-site burial disposals in the § 20.2002 guidance differs from DOE Manual 435.1-1 and 10 CFR Part 40. The U.S. Environmental Protection Agency (EPA) is responsible for setting standards for uranium mill tailings sites, which are reflected in 10 CFR Part 40, Appendix A. After uranium mill tailings sites are remediated to EPA standards, DOE is responsible for long-term care of these sites, while for ADR disposals there is no assumption of long-term custodial care. Significant differences in regulatory schemes between ADR disposals and uranium mill tailings sites makes comparisons between the different sets of requirements inappropriate. Reconciling differences in regulatory programs between Federal agencies (NRC, EPA, and DOE) is outside the scope of this guidance document.

As the commenters noted, SRM-SECY-16-0106 directed staff to specify a 1,000 year compliance period in the proposed 10 CFR Part 61 rule. The staff is currently in the process of revising LLW guidance found in draft NUREG-2175 and the draft proposed rule for public comment. However, this rule and guidance have not yet been finalized. NUREG-2175 represents the latest NRC staff guidance associated with disposal of LLW and is generally appropriate for use as guidance for preparing performance assessments for disposal of radioactive waste, including those associated with ADRs involving off-site burial. Current plans are to revise NUREG-2175 consistent with SRM-SECY-16-0106, which may address the commenters’ concerns regarding compliance period. However, it is also important to note that the compliance period in the proposed rule has been assigned Compatibility C and some States may determine that a longer compliance period is needed.

Based on these comments, Section 7.1.2 of the guidance document was revised to provide more clarity.

G. Comments Concerning Radon

Comment G-1: (Comment Letters 5, 14, 16, 17)

Several commenters pointed out the difference between the need for consideration of radon for on-site and off-site disposals. The commenters thought that radon should not be considered for

off-site disposals as it is for on-site disposals. The commenters also recommended that the guidance for off-site disposals be updated to be consistent with 10 CFR Part 40 and DOE Manual 435.1-1. One commenter indicated that while radon dose to site workers should be considered, future and off-site receptor dose assessment requirements should be the same as LTR requirements.

Response:

As stated in response to comment letters 3, 14, and 16, related to differences in the compliance period, differences in assessment methods between on-site and off-site disposals are attributable to differences in the likely types of materials to be disposed on-site and off-site. On-site disposals ultimately fall under the LTR (in Subpart E of 10 CFR Part 20) for decommissioning facilities with clear direction provided in the rule or in the statement of considerations for the rule with respect to the compliance period and consideration of radon.

Materials shipped off-site for disposal can involve residual radioactivity above concentration limits for unrestricted release of a site under the LTR (e.g., excavated materials above clean-up levels at a decommissioning site shipped to an off-site facility for disposal). Off-site disposals associated with § 40.51(b)(3) transfers could also involve relatively large volumes of source material with concentrations that would be above limits under the LTR (e.g., unimportant quantities of source material under § 40.13(a) or 0.05 weight percent equates to a concentration of approximately 170 pCi per gram of uranium-238 for natural uranium compared to screening levels for unrestricted release of 0.5 pCi per gram for the uranium-238 decay chain). Off-site disposals may also cumulatively involve significantly larger quantities of disposed materials. Therefore, the risk associated with off-site disposals could be higher than on-site disposals.

It is important to note that the LTR requirements in 10 CFR Part 20, Subpart E do not address radon. However, the statements of consideration for the LTR only indicate radon could generically be demonstrated to be indistinguishable from background when radium, the precursor to radon, meets the requirements for unrestricted release. The statements of consideration went on to state that in some cases it would not be practical to achieve clean-up levels for radon precursors within the limits for unrestricted release, and in these cases, restricted release may be an option to limit doses by limiting access to the site and radon mitigation may be considered (62 FR 39083, July 21, 1997). Therefore, radon could be an issue with higher concentration materials above unrestricted release levels. Because higher concentrations of radon-bearing waste may be disposed of at an off-site disposal facility compared to what may remain at an unrestricted release site (e.g., contaminated materials above clean-up levels under the LTR or associated with § 40.51(b)(3) transfers are often disposed of in off-site disposal facilities) without the benefit of engineered and natural system barriers present at a LLW disposal site, a significant radon dose could result from the disposal of waste at an off-site disposal facility if adequate steps are not taken to reduce the risk. The assessment should demonstrate that members of the public are adequately protected, or mitigative measures can be taken to further reduce the risk to acceptable levels (e.g., increase the depth of disposal or take credit for the passive performance of an engineered cover).

Additionally, the definition of background radioactivity in § 20.1003 indicates that radon resulting from the decay of source or special nuclear material is not considered background radiation and radon resulting from the decay of source or special nuclear material must therefore be considered when demonstrating that the public dose limits in § 20.1301 are met. Because § 20.2002 requires that the public dose limits are met, background radon cannot be subtracted when demonstrating that the public dose limits are met under § 20.2002. As stated in § 20.1003, "Definitions:"

Background radiation means radiation from cosmic sources; naturally occurring radioactive material, including radon (except as a decay product of source or special nuclear material); and global fallout as it exists in the environment from the testing of nuclear explosive devices or from past nuclear accidents such as Chernobyl that contribute to background radiation and are not under the control of the licensee. 'Background radiation' does not include radiation from source, byproduct, or special nuclear materials regulated by the Commission.'

With respect to the comments noting inconsistencies between the ADR guidance, other NRC regulations, and other Federal agency regulations, the staff disagrees with some of the comments and others are outside the scope of the guidance document. As stated above, consideration of radon for ADRs involving off-site burial is consistent with NRC's regulations in 10 CFR Part 20 (i.e., § 20.1301). With respect to differences between treatment of radon in 10 CFR Part 20 versus 10 CFR Part 40 regulations, EPA is responsible for setting standards for uranium mill tailings sites, which are reflected in 10 CFR Part 40, Appendix A. Given the significant differences in the underlying regulatory schemes, comparisons between the treatment of radon in 10 CFR Part 20 and 10 CFR 40 regulations is inappropriate. Reconciling differences in regulatory programs between Federal agencies (NRC, EPA, and DOE) is outside the scope of this guidance document.

H. Comments Concerning Other Off-Site Disposals - Release of Solid Material with Volumetric Contamination

Comment H-1: (Comment Letter 3)

A commenter noted that alternate disposal by reuse or recycling has not appeared in previous drafts of the guidance document and stated that the regulatory basis for this means of alternate disposal is not clear. The commenter noted that § 20.2002 does not reference recycling, that § 20.1003 does not contain a definition of disposal that includes recycling, and that § 20.2001(a) requires that licensees only dispose of licensed material via the means listed in this section of the regulations, which does not include recycling. The commenter proposed that NRC either provide a regulatory basis for approving recycling and reuse as alternate means of disposal, as well as an analysis by OGC that authorizes this interpretation, or delete the recycling and reuse section of the guidance.

Response:

The NRC acknowledges that § 20.1003 does not include a definition of the term "disposal." The regulation at § 20.2001(a) requires that licensees only dispose of licensed material in the ways listed in this section of the regulations. This list does not explicitly include recycling. However, this list includes disposal "[a]s authorized under § 20.2002," and § 20.2002 provides that licensees or applicants may apply for approval of proposed procedures, "not otherwise authorized in the regulations." Therefore, the regulations specifically allow licensees to request, and for the NRC to grant, approval of alternative disposal procedures not explicitly included in the regulations.

Furthermore, Section 7.1.3 of the guidance document was revised to note that the NRC allows for the release of solid material with slight levels of volumetric contamination under § 20.2002 on a case-by-case basis as described in NUREG-1757, Vol. 1, Rev. 2. The Commission has found this approach to reviewing specific cases on an individual basis to be fully protective of health and safety, as noted in SRM-SECY-05-0054. This revised section of the guidance document does not expand or reduce the scope of proposals that would be considered acceptable for review.

Comment H-2: (Comment Letter 6)

The commenter stated, “The Draft Guidance states that the applicable regulatory standard for allowing alternative disposal by recycling is 100 mrem/yr, even though it states that NRC generally only allows ‘a few millirem’ for these approvals.” The commenter also stated that an unambiguous national standard, vetted through an open public process, needs to be in place before allowing any additional trace contaminated material to be recycled, and that the policy and decisions should be from a single Federal entity. The commenter further indicated that allowing interpretation by Agreement States on the applicable regulatory standard for allowing alternative disposal by recycling will result in confusion in the recycling industry and reluctance of many States to allow contaminated material to enter the recycling materials stream. The commenter indicated that the guidance does not provide a way to prevent recycled materials from being introduced into consumer products, and without such assurance, does not support allowing the introduction of trace contamination into the recycling product stream.

Response:

The draft guidance document did not state that a 1mSv per year (100 mrem per year) dose standard is acceptable for ADRs, including these types of licensees’ requests. Section 7.2 of the draft guidance document explained that the public dose limit is 1mSv per year (100 mrem per year), but that the NRC typically approves § 20.2002 requests that are “no more than a few mrem per year.”

As noted in the response above, Section 7.1.3 of the guidance document was revised to note that the NRC allows for the release of solid material with slight levels of volumetric contamination under § 20.2002 on a case-by-case basis as described in NUREG-1757, Vol. 1, Rev. 2. The Commission has found this approach to reviewing specific cases on an individual basis to be fully protective of health and safety, as noted in SRM-SECY-05-0054. This revised section of the guidance document does not expand or reduce the scope of proposals that would be considered acceptable for review.

Comment H-3: (Comment Letter Section 15)

A commenter expressed opposition to the release and exemption of radioactive materials and wastes from radioactive regulatory control through what the commenter considers to be “the use and the expansion of use of 10 CFR 20.2002 (case-by-case exemptions) and 10 CFR 40.13(a)” as “being interpreted as a generic clearance level.” The commenter also expressed concern that, through the ADR approval process, waste would not only be introduced into industrial and solid waste landfills, but into commercial recycling and reuse in the open marketplace.

Response:

The document neither expands nor reduces the scope of § 20.2002. ADRs under § 20.2002 are reviewed and approved on a case-by-case basis, and the regulation and NRC’s implementation of the regulation is not a “generic clearance level.” For example, the § 20.2002 approval process entails case-specific dose modeling and an analysis of the potential impacts for each § 20.2002 ADR submitted to the NRC to ensure that public health and safety are protected. A similar review process is used for § 40.51(b)(3) transfers of unimportant quantities of source material under § 40.13(a).

The staff acknowledges the commenter’s concerns regarding the potential for recycling of materials into consumer products. As noted above, Section 7.1.3 of the guidance document was revised noting that the NRC allows for the release of solid material with slight levels of volumetric contamination under § 20.2002 on a case-by-case basis as described in NUREG- 1757, Vol. 1, Rev. 2. The Commission has found the approach of reviewing specific

cases on an individual basis to be fully protective of health and safety, as noted in SRM-SECY-05-0054. This revised section of the guidance document does not expand or reduce the scope of proposals that would be considered acceptable for review.

I. Comments Concerning Transportation

Comment I-1: (Comment Letters 4, 8, 17)

Three comments were received that recommended that the dose to transportation workers should not be included in the assessment of ADRs. The commenters stated that the transportation of radioactive materials was regulated by DOT regulations in 49 CFR Subtitle B. The commenters also noted that a dose assessment like the one in the draft guidance document is not required by the DOT regulations and the dose limits in the DOT regulations were different than those in the draft guidance document. Additionally, the commenters all noted that the same transport company might be used, regardless of whether the material was shipped to a licensed facility or an unlicensed facility, and it was unclear why the different requirements could apply.

One of the commenters stated that they sent a letter to the NRC in 2011 (ADAMS Accession No. ML112291006) in which they recommended that the transportation workers not be included in the dose assessments. The commenter further stated that the NRC responded that the issues raised required a thorough and formal evaluation and that the NRC would follow up to this request in future correspondence, but that the NRC did not follow up on these issues in future correspondence.

Response:

The staff agrees with these comments and Section 5.2 was revised to remove the requirement to analyze the dose during transportation for ADRs. Unless transferred to another licensee authorized to accept the material, the radioactive material is the responsibility of the licensee while in transit. The licensee is subject to § 71.5, which states that each licensee who transports licensed material outside the site of usage, or where transport is on public highways, or who delivers licensed material to a carrier for transport, shall comply with the applicable requirements of the DOT regulations in 49 CFR Parts 107, 171 through 180, and 390 through 397, appropriate to the mode of transport. Because the licensee is responsible for the radioactive material until it reaches its destination, the transport of the material is subject to NRC inspections and the NRC can enforce the regulations in § 71.5. The transportation workers are subject to the requirements in 49 CFR Parts 107, 171 through 180, and 390 through 397 and are protected by those requirements.

Also, the dose from transporting similar waste types was previously evaluated and was found to be acceptable. For example, in NUREG-0782, "Draft Environmental Impact Statement on 10 CFR Part 61 Licensing Requirements for Land Disposal of Radioactive Waste" and NUREG-0945, "Final Environmental Impact Statement on 10 CFR Part 61 Licensing Requirements for Land Disposal of Radioactive Waste," the projected dose from the shipment of LLW was analyzed. The staff has reviewed these analyses and finds that the potential transportation impacts from waste disposed under § 20.2002 are bounded by the Draft EIS and Final EIS analyses for radionuclides considered in these analyses because the activities of the radionuclides evaluated are generally lower in waste disposed of under § 20.2002 than in wastes evaluated in the EISs. Current practice for packaging and transport of the waste is comparable to that assumed in the EISs. Differences between the packaging and transport of waste disposed under a § 20.2002 request and the disposal of waste analyzed in the EISs would not be expected to result in a significantly higher dose for the § 20.2002 waste than for

the scenario analyzed in the EISs. With respect to transfers to persons exempt under § 40.13(a), the dose to transportation workers from the transport of material covered by § 40.13(a) (i.e., 0.05% by weight uranium and thorium) was evaluated in NUREG-1717. The calculated doses were low (i.e., less than 10 mrem).

Comment I-2: (Comment Letter 3)

A commenter questioned the technical basis for the statement in the draft guidance document that the use of ADR procedures may reduce the overall radiological and non-radiological risk relative to disposal, specifically, “although these materials could be disposed of in a LLW disposal facility licensed under 10 CFR Part 61, use of alternative disposal methods under § 20.2002 may reduce overall risk (e.g., risk associated with increased transportation distances and associated radiological and non-radiological impacts).”

Response:

As detailed in several EISs (e.g., NUREG-1496, Vol.1 and NUREG-0586), increased transportation distances can lead to greater transportation risks, as the transportation risk is directly related to transport distance. Transportation risks may also represent a significant fraction of the overall risk to the public associated with a Federal action (e.g., NUREG-0586). The § 20.2002 approval process provides additional waste disposal options not otherwise authorized in the regulations, which could allow licensees to make use of closer disposal facilities and, thus decrease the transport distance to a disposal facility. Therefore, transportation risk, as well as potentially the overall risk, may be decreased with additional disposal options. No revisions to the guidance document were made in response to this comment.

J. Comments Concerning Cumulative Impacts

Comment J-1: (Comment Letters 3, 15)

One commenter provided multiple comments related to cumulative impacts and the ADR approval process. In all cases, the commenter’s focused on cumulative doses associated with the disposal of radioactive material. Another comment requested additional guidance on the process used for assessing cumulative doses associated with off-site disposals. The commenter also noted that the guidance document includes an example of cumulative doses from multiple sources of exposure from multiple § 20.2002 authorizations at contiguous locations, but does not discuss cumulative doses from multiple sources of exposure at a single location (e.g., exposure to multiple shipments of radioactive material at a single burial site). A separate comment requested a technical basis for not assessing cumulative impacts from multiple sources simply because each dose, individually, is projected to cause a very small dose (< 0.01 mSv).

Response:

With respect to worker dose, cumulative dose to workers from multiple disposals at the same disposal facility is not expected to be of concern. The § 20.2002 approval process considers requests that typically result in doses to a member of the public, which for a RCRA facility includes all exposure groups, including workers, that are no more than a few millirem per year. 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 most cases. Permitting only a few millirem from each approval inherently limits the cumulative impacts when considering past, present, and reasonably foreseeable future approvals at a single disposal facility.

However, in certain cases, cumulative dose impacts to a member of the public following closure of the disposal facility may be more significant. This is because for certain pathways, such as the groundwater pathway, the total inventory disposed in the disposal facility is directly related to annual dose to the member of the public following closure. Over many years of operation, the total inventory may be significantly higher than the inventory associated with a single disposal request leading to significantly higher projected doses to members of the public. Therefore, in certain cases (e.g., when the member of the public dose and specifically the groundwater pathway is found to dominate the risk from the disposal facility), cumulative impacts should be considered. In contrast, the annual dose to a worker is limited to the individual shipments that occur over the course of a year (i.e., the dose to workers from buried waste is typically negligible).

If found to be potentially significant, cumulative impacts should also be assessed as part of the environmental review process. Individual licensees or disposal facilities may decide to keep track of cumulative doses as part of their recordkeeping program (e.g., cumulative dose from radiological disposals at the U.S. Ecology Idaho site are tracked in accordance with their Idaho RCRA permit to ensure doses remain below the WAC post closure dose limit of 0.015 mSv (15 mrem)). While there are no regulatory requirements related to calculating, maintaining, and/or submitting cumulative dose records for members of the public related to § 20.2002 actions, licensee and facility assessments can be relied on to assess cumulative dose impacts in environmental assessments.

The staff agrees with the comment that the document should include a discussion of cumulative doses associated with multiple disposals at a single location. Based on the comment, Section 7.2.1 of the guidance document was revised.