

Comment Resolution Document

Summary of Comments Received on SA-700, *Processing an Agreement*

I. Sent to the Agreement States, Non-Agreement States, and State Liaison Officers for Comment: FSME-14-016, February 24, 2014

Comments Received:

- a. Commonwealth of Virginia, Letter dated March 27, 2014
- b. Organization of Agreement States, Letter dated March 27, 2014

Commonwealth of Virginia; Letter dated March 27, 2014

Comment 1: Editorial changes were provided throughout the document. These are not listed individually in the comment resolution.

Response: Editorial changes were made in the document where needed.

Comment 2: The use of "program" versus "agreement materials program" is not consistent. Virginia recommends that "Agreement materials program" be used throughout the documents.

Response: The NRC staff has changed the document to use the term "Agreement materials program" throughout the document and has made every effort to be consistent in this use. In some circumstances, "program" is the appropriate word.

Comment 3: The distinction between the "NRC," "Commission," and "Staff" is not always clear. This should be discussed at the beginning of each document.

Response: The comment has been evaluated along with similar comments. Staff has made efforts to make the distinction more clear. The distinction was not added to the beginning of each document; however, staff included these terms in the definition in an attempt to address the distinction. The Atomic Energy Act of 1954, as amended (AEA), uses the term "Commission." Staff used "Commission" where appropriate to remain consistent with the AEA.

Comment 5: The documents should not list the "State Agreement Program Director" as the point of contact. The state may not have a Program Director in place or may want someone else such as their Radioactive Materials Program Director to be the point of contact during the agreement deliberation process. Virginia recommends that it be changed to "State contact" throughout the document.

Response: The NRC staff agrees with this comment in part. Typically, NRC staff is working with a high level manager as the State begins the process of entering into an Agreement. This person is involved throughout the process even if a lower level manager or staff contact is involved in the day-to-day interactions. The document

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was revised to read "State Radiation Control Program Director, or equivalent Governor appointed representative (hereafter, referred to as the Program Director).

Comment 6: The document should include more verbiage about contacting other agreement states and/or using their procedures.

Response: The NRC staff agrees with this comment. The document has been evaluated and a discussion of contacting other Agreement States and/or using those States procedures has been added to Section V., "Guidance," Item C, in the Handbook.

Comment 7: Some sections include information regarding the uranium milling category, but does not include information regarding the low-level waste category. Virginia recommends that information regarding the low-level waste category be included in these sections.

Response: The NRC staff evaluated this comment along with other similar comments. Upon further evaluation, the NRC staff has retained specific information related to uranium mills and low-level radioactive waste disposal in some sections of the Handbook, deleted the information in other sections, or retained one or the other as appropriate.

Please refer to specific comment responses related to this issue below in the comments from the U.S. Nuclear Regulatory Commission, Office of the General Counsel. These will be comment numbers 8, 9, 12, and 13.

Regarding Section 4.4.1.2 of the Handbook, there are specific requirements related to quantitative and qualitative analysis. These requirements are unique to byproduct material defined in Sec. 11e.(2) of the AEA. This information is included to ensure that the State is aware of these requirements and includes procedures for quantitative and qualitative analysis in its request for an Agreement. This information is needed only if the State intends to regulate byproduct material defined in Sec. 11e.(2).

Comment 8: [Introduction, Item A.]: Virginia recommended using similar language as is on the NRC website in the discussion of Section 274 Agreements under the AEA.

Response: The document was changed in part to use language similar to that on the NRC website.

Comment 9: In Section V.D.1.2 of the procedure, it is not clear what is meant by "PM team."

Response: The procedure was corrected to state "PM and review team."

Comment 10: In Section 2.3.2 of the Handbook, it does not make sense to state "significant changes may require special approval by the Commission" because the entire Agreement requires approval by the Commission.

Response: Agreements have standard categories of material, as stated in the AEA, for which the State can request authority for under its Agreement, as well as authority for sealed source and device registration and low level radioactive waste disposal. The intent of this statement is to make clear that the NRC staff must get approval

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from the Commission for any proposals a State might submit to create subcategories of these standard categories. Such proposals will require approval by the Commission before the NRC staff begins its review of the request for an Agreement. The procedure has been revised to make this clearer.

Comment 11: [Section 3.4.5 of the Handbook]: Virginia disagrees that State staff should visit [NRC] regional and Headquarters offices and recommends this be deleted.

Response: The intent of the State management and senior staff visiting the NRC regional office and the NRC Headquarters office is to provide an opportunity for the State management and senior staff to become familiar with the different licensees and to work directly with NRC staff to learn about the different types of licenses that will transfer to the State's authority. No changes were made to the document based on this comment.

Comment 12: [Section 3.4.6 of the Handbook]: Virginia recommends including information about the State contacting other nearby Agreement States to inquire about accompanying that State's inspectors and for licensing assistance.

Response: NRC staff agrees with this comment and has including additional information regarding contacting other nearby Agreement States for additional guidance on inspections and licensing.

Comment 13: [Section 3.5.3 of the Handbook]: Virginia noted that there is no verbiage on what to do after reviewing the State response. Recommend adding verbiage.

Response: This section has been revised to clarify that the review team will review the revisions to ensure the State has addressed the NRC's comments.

Comment 14: [Section 4.2.2 of the Handbook]: Virginia stated that the discussion on Significant Transboundary Implications should matche the definition being made by the A&C working group.

Response: The Adequacy and Compatibility Working Group [the A&C working group referenced in the comment] was revising the Policy Statement on Adequacy and Compatibility which includes a proposed revision to the definition of significant transboundary implications. However, the policy statement is not complete and has not received final Commission approval. Therefore, no revision to the Handbook can be made at this time to address this comment.

Comment 15: [Section 4.2.2.1 of the Handbook]: Virginia recommends deleting this section as the State must submit all regulations for review.

Response: Throughout the document, there is a section called "Information Needed" for the different criteria. Each of these includes a statement for the State to submit its regulations, or generic legally binding requirements. No changes have been made to the document as a result of this comment.

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Comment 16: [Section 4.2.3 of the Handbook]: Virginia recommends changing "Orderly Pattern of Regulation" as it is not clear what this is.

Response: This section of the Handbook is addressing Compatibility Category C which is discussed in the Policy Statement on Adequacy and Compatibility of Agreement State Programs as well as in Management Directive 5.9, *Adequacy and Compatibility of Agreement State Programs*.

The Policy Statement on Adequacy and Compatibility of Agreement State Programs sets the agency policy on adequacy and compatibility. The compatibility categories are established in this policy statement. Category C, *Other Commission Program Elements*, are the other Commission program elements that are important for an Agreement State to have in order to avoid conflicts, duplications, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a nationwide basis.

"Orderly Pattern of Regulation" originates in the Atomic Energy Act of 1954, as amended, in Section 274a.(3). It states "to promote an orderly regulatory pattern between the Commission and State governments with respect to nuclear development and use and regulation of byproduct, source, and special nuclear materials.

Regulations that are assigned a Compatibility Category C are regulations that States need to adopt at a level that meets the essential objectives of the regulation; however, States can be more restrictive than the NRC's regulations. This ensures that there is a minimum level of regulatory control over those uses of radioactive material and provides for some assurances that, on a nationwide basis, radioactive material being used for the purpose specified in the regulations are used safely and that the regulations protect public health and safety.

No changes have been made to the document based on this comment.

Comment 17: [Section 4.2.4.2 of the Handbook]: Virginia questioned why the regulations need to disclaim any intent to regulate materials or activities over which NRC retains jurisdiction. The Agreement dictates what the State can and cannot regulate.

Response: The intent of this Section is to address when States adopt NRC regulations by reference. The State must specifically state that its regulations do not apply to materials or activities over which NRC retains jurisdiction. If a State adopts NRC regulations by reference, the State must indicate, in a legal manner, to what those regulations will not apply. Otherwise, it might not be clear to a member of the public or a licensee and create confusion.

Comment 18: [Section 4.3.6.1 of the Handbook]: Virginia recommends adding licensee renewal notification in the list of required elements.

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Response: NRC staff believes that this comment is regarding a process for licensees to be under "timely renewal." NRC staff agrees with this comment. Information has been added to include a process for "timely renewal notifications" for licensees.

Comment 19: [Appendix A of the Handbook]: Virginia recommends deleting transboundary requirements from the document.

Response: While NRC staff recognizes that the definition of Compatibility Category B for "significant transboundary implications" will potentially be changing as a result of work on the Policy Statement on Adequacy and Compatibility, the revision to the policy statement is not complete. Regardless of the final outcome of the policy statement revision, there will still be some form of "transboundary" category that Agreement States will have to address in their respective Agreement materials program.

Therefore, no changes are being made to this procedure based on possible revisions to the policy statement.

Organization of Agreement States, Letter dated March 27, 2014

Comment 1: Editorial changes were provided throughout the document. These are not listed individually in the comment resolution.

Response: Editorial changes were made in the document where needed.

Comment 2: The use of "program" and "Agreement materials program" is not consistent.

Response: The NRC staff has changed the document to use the term "Agreement materials program" throughout the document and has made every effort to be consistent in this use. In some circumstances, "program" is the appropriate word.

Comment 3: The distinction between the "NRC," "Commission," and "Staff" is not clear at times. This should be discussed at the beginning of each document.

Response: The comment has been evaluated along with another similar comment. Staff has made efforts to make the distinction more clear. The distinction was not added to the beginning of each document; however, staff included these terms in the definition in an attempt to address the distinction. The Atomic Energy Act of 1954, as amended (AEA), uses the term "Commission." Staff is using "Commission" where appropriate to remain consistent with the AEA.

Comment 4: The documents should not list the "State Agreement Program Director" as the point of contact as the state may not have a program director hired yet or they may want someone else to be the point of contact during the agreement process. Recommend changing these references to the generic terms "State" or "staff."

Response: The NRC staff agrees with this comment in part. Typically, the NRC staff is working with a high level manager as the State begins the process of entering into an Agreement. This person is involved throughout the process even if a lower level manager or staff contact is involved in the day-to-day interactions. The document was revised to read "State Radiation Control Program Director, or

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equivalent Governor appointed representative (hereafter, referred to as the Program Director).

Comment 5: The document should include more verbiage about contacting other agreement states and/or using their procedures

Response: The NRC staff agrees with this comment. The document has been evaluated and a discussion of contacting other Agreement States and/or using those States procedures has been added to Section V., "Guidance," Item C, in the Handbook.

Comment 6: In Section I.A. of the procedure, recommend using language from the NRC website related to the statutory basis under which NRC enters into an Agreement with a State.

Response: The document was changed in part to use language similar to that on the NRC website.

Comment 7: In Section V.D.1.2 of the procedure, it is not clear what is meant by "PM team."

Response: The procedure was corrected to state "PM and review team."

Comment 8: In Section 2.3.2 of the Handbook, recommend deleting "State requests for unique authority beyond the standard Agreement categories will require approval by the Commission." This statement does not make sense because the entire agreement requires approval by the Commission.

Response: Agreements have standard categories of material, as stated in the AEA, for which the State can request authority for under its Agreement, as well as authority for sealed source and device registration and low level radioactive waste disposal. The intent of this statement is to make clear that the NRC staff must get approval from the Commission for any proposals a State might submit to create subcategories of these standard categories. Such proposals will require approval by the Commission before the NRC staff begins its review of the request for an Agreement. The procedure has been revised to make this clearer.

Comment 9: In section 3.5.3 of the Handbook, recommend adding information on actions taken after reviewing the State response.

Response: This section has been revised to clarify that the review team will review the revisions to ensure the State has addressed NRC's comments.

Comment 10: In Section 4.2.1.1 of the Handbook, recommend adding information in the section on regulating uranium recovery.

Response: The NRC staff evaluated this comment along with other similar comments. Upon further evaluation, the NRC staff has retained specific information related to uranium mills and low-level radioactive waste disposal in some sections of the Handbook, deleted the information in other sections, or retained one or the other as appropriate.

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Please refer to specific comment responses related to this issue below in the comments for the U.S. Nuclear Regulatory Commission, Office of the General Counsel. These will be comment numbers 8, 9, 12, and 13.

Comment 11: In Section 4.2.2 of the Handbook, recommend ensuring that this section meets the definition of significant transboundary implications that is being developed by the Adequacy and Compatibility Working Group.

Response: The Adequacy and Compatibility Working Group was revising the Policy Statement on Adequacy and Compatibility which includes a proposed revision to the definition of significant transboundary implications. However, the policy statement is not complete and has not received final Commission approval. Therefore, no revision to the Handbook can be made at this time to address this comment.

Comment 12: In Sections 4.2.2.1 and 4.2.3.1 of the Handbook, recommend deleting these sections because all of the State's regulations are submitted as part of the application process.

Response: Throughout the document, there is a section called "Information Needed" for the different criteria. Each of these includes a statement for the State to submit its regulations, or generic legally binding requirements. No changes have been made to the document as a result of this comment.

Comment 13: In Section 4.2.4.2.b of the Handbook, it is unclear why the State regulations would need to disclaim any intent to regulate materials or activities over which NRC retains jurisdiction. The Agreement and the State's statutes both define the State's authority. Recommend deleting this requirement.

Response: The intent of this Section is to address when States adopt NRC regulations by reference. The State must specifically state that its regulations do not apply to materials or activities over which NRC retains jurisdiction. If a State adopts NRC regulations by reference, the State must indicate, in a legal manner, to what those regulations will not apply. Otherwise, it might not be clear to a member of the public or a licensee and create confusion. This section of the Handbook is not being deleted.

Comment 14: In Section 4.3.1.2 of the Handbook, recommend including requirements for pre-licensing verification and ensuring enhanced security requirements are in place prior to issuing a license.

Response: NRC agrees with this comment. Information about pre-licensing verification and ensuring enhanced security requirements are in place has been included in this section.

Comment 15: In Section 4.3.6.1 of the Handbook, recommend adding licensee renewal notification in the list of required elements.

Response: NRC staff believes that this comment is regarding a process for licensees to be under "timely renewal." NRC staff agrees with this comment. Information has been added to include a process for "timely renewal notifications" for licensees.

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Comment 16: In Section 4.4.1.2 of the Handbook, recommend adding information about Low Level Radioactive Waste to this Section.

Response: The NRC staff does not agree with this comment. This section addresses the evaluation criteria for the Inspection Program Elements. It is intended to be inclusive of all program codes of licensees that will transfer to the State. While there is specific information related to Section 11(e).2 byproduct material, it is because of unique needs for quantifiable and qualitative laboratory analysis. These requirements are unique to byproduct material defined in Sec. 11e.(2) of the AEA. This information is included to ensure that the State is aware of these requirements and includes procedures for quantitative and qualitative analysis in its request for an Agreement. This information is needed only if the State intends to regulate byproduct material defined in Sec. 11e.(2).

Comment 17: Appendix A of the Handbook, recommend deleting transboundary requirements from the table.

Response: This table is a summary cross-walk for the State's use in preparing its application to enter into an Agreement. Transboundary requirements are specifically addressed in the Policy Statement, "Criteria for Guidance of States and NRC in discontinuance of NRC Regulatory Authority and Assumption Thereof by States Through Agreement." There are many regulations throughout Title 10 of the Code of Federal Regulations that are assigned a compatibility category B, significant transboundary implications. It is included in the table along with all of the other requirements from the Criteria Policy Statement to assist the State in its application. No changes were made to the document based on this comment.

II. Sent to the U.S. Nuclear Regulatory Commission Offices for Comment by Memorandum dated February 24, 2014

Comments Received:

- a. U.S. Nuclear Regulatory Commission, Region I; Division of Nuclear Materials Safety; email dated April 2, 2014
- b. U.S. Nuclear Regulatory Commission, Region IV; Division of Nuclear Materials Safety; email dated March 21, 2014
- c. U.S. Nuclear Regulatory Commission, Office of Nuclear Security and Incident Response; Division of Preparedness and Response; Materials and Waste Security Branch email dated March 20, 2014
- d. U.S. Nuclear Regulatory Commission; Office of Public Affairs; email dated February 26, 2014
- e. U.S. Nuclear Regulatory Commission; Office of Federal and State Materials and Environmental Management Programs; Division of Materials Safety and State Agreements; Source Management and Protection Branch; email dated April 1, 2014
- f. U.S. Nuclear Regulatory Commission; Office of the General Counsel; email dated August 5, 2014

U.S. Nuclear Regulatory Commission, Region I; Division of Nuclear Materials Safety; email dated April 2, 2014

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Comment 1: Editorial changes were provided throughout the document. These are not listed individually in the comment resolution.

Response: Editorial changes were made as needed.

Comment 2: On page 1, Section 2.1, "Statutory requirements," refers to "External Procedures" for the Office FSME Agreement State Program. As we do not define these procedures as external procedures elsewhere in the document, I suggest that "external" be replaced with FSME State Agreement Procedures for consistency throughout the Handbook (see Section 2.3 of the Handbook).

Response: The procedures are now referenced as NMSS State Procedures. This will address procedures addressing State and State Liaison issues. On the NMSS external website, these procedures can be found under "NMSS Procedures" under Resources and Tools.

Comment 3: In the definitions, we define Commission as meaning "the United States Nuclear Regulatory Commission." However, on page 1 of the handbook, in the Purpose section, we state "The Nuclear Regulatory Commission (NRC)." Using both the words "NRC" and "Commission" to define the United States Nuclear Regulatory Commission could be confusing.... Suggest for consistency either using "NRC" or "Commission...." The NRC staff made every effort to ensure consistent use of these two terms.

Response: The NRC staff agrees with this comment. The term "Commission" is used throughout the Atomic Energy Act of 1954, as amended (AEA), in Section 274. Therefore, the term "Commission" will be used wherever necessary for consistency with the AEA. Based on this and other comments, as well as guidance from the Office of the General Counsel, the Definitions will be revised as well to define the Commission and the NRC.

Comment 4: In Section 4.6 of the Handbook, it references the NRC/OAS Training Working Group report. However, this report is no longer equivalent to Inspection Manual Chapter 1248... Suggest removing the reference to this document from Section 4.6 of the Handbook.

Response: The reference to the NRC/OAS Training Working Group report has been deleted.

Comment 5: In the Introduction, Item C., of the Handbook, the footnote should be moved to the word "State..." since the footnote describes what the Act defines a "State" to be.

Response: This change has been made to the document.

Comment 6: In the Introduction, Item C.,]: Are there any Commonwealth's that aren't already an agreement state? Throughout the procedure we state for example "assumption of regulatory authority by the States" or "assumption thereof by the State." This sentence leads me to believe that we should be saying state or Commonwealth (if there are still Commonwealths that have not entered into an agreement with the State.

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Response: This item is to make clear that some States are referred to as "State" or as "Commonwealth." For ease of reading in the document, the term "State" is used throughout the document (as noted); however, the NRC staff should use the proper term, "State" or "Commonwealth" as appropriate in all documents and correspondence for the State or Commonwealth requesting an Agreement.

While there are no more non-Agreement States that are referred to as "Commonwealth," there are two territories, Puerto Rico and the Northern Mariana Islands, which are referred to as Commonwealth. Also, the document is intended to be inclusive regardless of the current status. For many reasons, a State or Commonwealth could return its Agreement or the NRC may find cause to revoke an Agreement. Therefore, the document was not revised.

Comment 7: [Background, Item A.]: In the AEA, the Commission originally meant the Atomic Energy Commission which is now the Nuclear Regulatory Commission. Earlier in the document, Nuclear Regulatory Commission is abbreviated as the NRC. Using the word "Commission" gives the impression that we mean the five membered body [of the Commission].

Response: Item A will remain consistent with terminology given in the AEA. However, NRC staff will evaluate the use of "NRC" and "Commission" throughout the document to ensure the proper term is used consistently. See response to Comment 3 above as well.

Comment 8: [Section IV., Item C.] Include the Office of Administration in the list of members of the review team.

Response: This change was not made to the document. The Office of Administration (ADM) is not a member of the review team. ADM does support the review team in the development and processing of *Federal Register* notices, as well arrange for publication of the *Federal Register* notices.

Comment 9: [Section V., Item B.] This initial meeting is usually held before a letter of intent is submitted. It is usually requested by the State in order to garner support throughout upper management...Is it necessary to repeat this meeting just because a letter of intent is received...

Response: The commenter is correct in that there is an initial information meeting with the State or Commonwealth when there is an interest expressed to enter into an Agreement. This information meeting is supported by the Regional State Agreement Officer, Regional management, and Headquarters management. However, the meeting discussed in Item B. is a meeting that is held after a letter of intent is submitted. In this meeting, NRC staff and management meet with State or Commonwealth staff and management to discuss the process and everything that is needed in order to complete the request to enter into an Agreement. No changes have been made to the document based on this comment.

**U.S. Nuclear Regulatory Commission, Region IV; Division of Nuclear Materials Safety;
email dated March 21, 2014**

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Comment 1: Editorial changes were provided throughout the document. These are not listed individually in the comment resolution.

Response: Editorial changes were made in the document where needed.

Comment 2: In Section 4.2.1.1 of the Handbook, 10 CFR 61.41. should be Part 61, Subpart C.

Response: Section 4.2.1.1 of the Handbook is a subsection of 4.2, Regulatory Program Elements. This section is within the discussion of Standards for Protection against Radiation. Section 61.41 of 10 CFR Part 61 is the addresses the protection of the general population from releases of radioactivity. Sections 61.42 and 61.43 also address radiation protection standards; therefore, these sections have been included as well.

U.S. Nuclear Regulatory Commission, Office of Nuclear Security and Incident Response; Division of Preparedness and Response; Materials and Waste Security Branch email dated March 20, 2014

Comment 1: There is no emphasis on security throughout the document – the Procedure and the Handbook. Since Part 37 is now in place, the procedure should include security when discussing public health and safety.

Response: The document has been revised to clarify that security/physical protection of agreement material is an inherent part of public health and safety. Whenever public health and safety are addressed, it is understood to include security as well. This has been added in to Section III.A., Background in the Procedure as well as in the Scope of the Handbook.

Comment 2: Minor editorial changes were provided throughout the document. These are not listed individually in the comment resolution.

Response: Editorial changes were made in the document.

Comment 3: Be consistent in the use of Agreement State materials program, Agreement State Program, and Agreement materials program.

Response: In response to this comment as well as other comments NRC received, the NRC staff has made every effort to use the term "Agreement materials program" consistently throughout the document.

Comment 4: A suggestion was made to emphasize security in Section 4.1.1.2, item h., of the Handbook to SA-700. Item h. states that in cases of an imminent threat to public health and safety, the law should authorize immediate suspension without prior hearing. A comment was made that due to the lack of required security for Category 1 or Category 2 quantities of radioactive material, the State can require specific measures be performed (e.g., suspension and secured storage until appropriate security measures are put in place).

Response: Information was added to the Handbook within the Scope that includes a discussion that "public health and safety" includes security/physical protection of

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agreement material" and that whenever public health and safety is discussed, it is also understood that security/physical protection of agreement material is a part of public health and safety.

Comment 5: In section 4.3.1, include "and secure" after "safe."

Response: The document has been revised to include "and secure."

Comment 6: Consider including additional definitions such as Letter of Intent; Agreement State Materials Program; Regional State Agreements Officer; and Nuclear Material Events Database. The NRC staff believed that other terms were addressed in the procedure and/or Handbook clearly.

Response: Several definitions have been added based on this and other comments including Agreement Materials, Agreement Materials Program, and Nuclear Material Events Database.

Comment 7: In the Staff Needs Analysis, in Appendix B, if a license category was created for Category 1 and Category 2 quantities of radioactive material, these should be included in this table.

Response: A separate license category for Category 1 and Category 2 quantities of radioactive material was not created; therefore, no changes were made to Appendix B based on this comment.

U.S. Nuclear Regulatory Commission; Office of Public Affairs; email dated February 26, 2014

Comment: Staff should modify the documents to make clear that staff needs to notify OPA well in advance of Federal Register Notices about (1) seeking comment on a proposed agreement and the staff's draft assessment and (2) when the agreement has been approved but before it is published in the Federal Register.

Response: The documents have been revised to make clear that NRC staff should work with OPA several weeks in advance of when a press release needs to be issued.

U.S. Nuclear Regulatory Commission; Office of the General Counsel (OGC); email dated August 5, 2014

Comment 1: Editorial changes were provided throughout the document. These are not listed individually in the comment resolution.

Response: Editorial changes were made in the document where needed.

Comment 2: [Section 2.3.2 of the Handbook]: There is a sentence that states, "State requests for unique authority beyond the standard Agreement categories will require approval by the Commission." Explain what "unique authority" means.

Response: This sentence has been revised to make it clearer. The intent is that when States request a subcategory out of a main category of material over which the State can

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request authority, this proposal will require review and approval by the Commission prior to the NRC staff beginning its review of the draft application request.

Comment 3: [Section 3.4 of the Handbook]: Recommend clarifying that the draft request is an application package not just a letter from the governor.

Response: In Section 3.3, the Letter of Intent is discussed and addressed. Section 3.4 is addressing the Draft Request, which is the application. The suggested revision to change "Governor's Request" to "application package" was made to this section for clarification.

Comment 4: Throughout the Handbook, OGC noted that some time periods seemed short especially if OGC review is need for "no legal objection."

Response: No changes were made to the time periods based on this comment. Please note that OGC will always get documents for review following typical NRC processes and time frames for comment. OGC will receive documents for review during the normal office review time frame and this is separate from any review as part of the review team.

Comment 5: [Section 4.1.1.2 of the Handbook]: In paragraph e.1., what is the source of the statement "including the transportation to or from such sites and the performance of contract services during temporary interruptions of such transportation"?

Response: This language is included in Section 30.12(a). This language has been removed from the Handbook since it goes beyond the statements in the criteria policy statement.

Comment 6: [Section 4.1.1.2 of the Handbook]: In paragraph i., the staff says that the State must resolve any questions NRC has regarding interpretation of State law. OGC questioned why this is being limited to the NRC since this would also be true of any comments from the public or from an Agreement State Performance Concern.

Response: This paragraph is addressing the initial review of the State's application request and any questions that the NRC has on the State's law. NRC staff will definitely address any comments received on the proposed Agreement from the public comment during that process. NRC will address any Agreement State Performance Concerns in accordance with established procedures for addressing such concerns. This is a separate process removed from the initial review of the State's application request.

Comment 7: [Section 4.1.3 of the Handbook]: The commenter indicated that NRC has not agreed to granting authority over subcategories of material – when the NRC considers 11e.(2) or 11e.(3) or 11e.(4), it is not considered a subcategory. The commenter also indicated that the NRC has allowed specific facilities or sites to remain under NRC jurisdiction in Agreement States but that is case-by-case based on specific factors.

Response: The commenter is correct in that the byproduct material defined in Sec.11e.(2), Sec.11e.(3), or Sec. 11e.(4) of the AEA are not considered a subcategory. The NRC will approve subcategories provided certain criteria are met. Such approvals

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are on a case-by-case basis and with Commission approval. It is not a common and routine request.

The NRC has not allowed specific facilities or sites to remain under NRC jurisdiction in Agreement States, even on a case-by-case basis, and would never consider doing so. Licensees would stay under NRC jurisdiction only if the State did not assume responsibility of the category of material for which the licensee had authorization or if the material was covered under Section 274m. of the AEA and common defense and security.

Comment 8: [Section 4.1.1.4 of the Handbook]: OGC asked why there is extensive detail for 11e.(2) authority versus low-level radioactive waste disposal and sealed source and device evaluations.

Response: Section 4.1.1.4 of the Handbook, "Additional Evaluation Criteria for 11e.(2) Byproduct Material Agreements," includes very specific criteria related to Uranium Mill Tailings Radiation Control Act of 1978. These requirements are based, in part, on the AEA and the criteria policy statement. The requirements for low-level radioactive waste disposal and sealed source and device evaluations do not include additional specific criteria beyond that already required in the regulations and included in the criteria policy statement.

No additional information was added to this section to address low-level radioactive waste or sealed source and device evaluations.

Comment 9: [Section 4.2.1.1 of the Handbook]: Consider including the regulations for sealed source and device evaluations and for the materials regulated under Sec. 11.e.(2).

Response: The regulations for sealed source and device evaluations and for the materials regulated under Sec. 11.e.(2) are included, in part, within the regulations for standards for protection against radiation. It would be redundant to repeat these regulations within this section. Additional language was added to make clear that the State needs to submit its regulations or generic legally binding requirements for all categories of material for which the State is requesting authorization.

Sections 61.41 through 61.43 are specifically included as these paragraphs specifically relate to the protection of the general population from releases of radioactivity. The NRC staff is including these paragraphs to ensure that these provisions are not overlooked by the State if the State is requesting authority for low-level radioactive waste disposal.

Comment 10: [Section 4.2.1.2 of the Handbook]: Recommend reviewing accuracy of the second paragraph because States regulate non-AEA materials such as x-rays or radon. Also, should the public dose also apply?

Response: This section applies to the evaluation criteria in evaluating a State's standards for protection against radiation. This paragraph states that the State's standards should also apply to all other sources of radiation regulated by the State. This statement is accurate. States should not have different standards for AEA materials, x-rays, radon, etc.

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Public dose is included in the standards for radiation protection. Occupational dose is the dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to radiation or to radioactive material from licensed and unlicensed sources of radiation, whether in the possession of the licensee or other person. The statement, "The standards must require consideration of the total occupational dose to individuals," is intended as a reminder that all sources of occupational dose must be considered.

Comment 11: [Section 4.2.2 of the Handbook]: Consider including occupational workers qualifications in item b. of this section.

Response: Qualifications for occupational workers are not being included in this section as an example. While training for occupational workers in some areas of use is considered within the category of "significant transboundary implications," there may be others that are encompassed within general discussions of training requirements. Additionally, there may be changes and revisions as changes are made and training may not always a "significant transboundary implication."

Comment 12: [Section 4.2.3.1 of the Handbook]: It is not clear why uranium and thorium mill tailings is being specifically addressed and why sealed source and device evaluations and waste disposal are not being included in this section.

Response: The NRC staff agrees with this comment in part. An additional statement was added to make clear that the State should submit regulations and generic legally binding requirements for all categories of material being requested under the Agreement.

The NRC staff retained the paragraph regarding uranium and thorium mill tailings and 10 CFR Part 40, Appendix A. There are specific requirements in Sec. 274o. of the AEA such that States are required to adopt standards for the protection of the public health, safety, and the environment which are equivalent, to the extent practicable, or more stringent than, standards adopted and enforced by the Commission for the same purpose. Therefore, the NRC staff determined it was important to retain this information in this section of the Handbook.

The paragraph regarding low-level radioactive waste was removed. There is nothing inherently unique or directed by statute regarding low-level radioactive waste disposal such as that in Sec. 274o. of the AEA.

Comment 13: [Section 4.2.4.1 of the Handbook]: Why are uranium and thorium mill tailings and low-level radioactive waste disposal being specifically addressed in this section?

Response: The NRC staff agrees with this comment. The two paragraphs have been deleted. An additional statement was added to make clear that the State should submit regulations and generic legally binding requirements for all categories of material being requested under the Agreement.

Comment 14: [Section 4.3.4.4 of the Handbook]: Recommend listing the specific relevant documents in the reference section for Uranium Recovery Regulations.

Response: The specific relevant documents are not being listed because the list is too extensive. There are numerous references to regulations, guidance documents, and regulatory guides that span two-three pages. It is more efficient to direct the reader to the location on the website where these documents can be found. No changes were made to the document based on this comment.

Comment 15: [Section 4.3.6 of the Handbook]: What is the alternative to transferring the licenses when the Agreement becomes effective? Since NRC will not have any regulatory authority over these licensees, the documentation should go to the Agreement State.

Response: This language was in the previous version of this Handbook and it is not clear what the previous author intended by this statement. However, States always have an option to propose an alternative process. For example, now that the NRC maintains all the official records electronically in the Agencywide Document Access and Management System, a State could ask that all license files be copied and transferred via an electronic means, such as on a CD. Therefore, the NRC staff is retaining an option for the State to propose an alternative means of taking possession of the licenses.

Comment 16: [Section 4.3.6.2 of the Handbook]: What is the origin of the information in the second paragraph regarding the State providing a statement as to how it will handle transferred licenses from the NRC?

Response: This paragraph is based on criterion 25 in the policy statement, "Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory Authority and Assumption Thereof by States Through Agreement."

Comment 17: [Section 4.4.1.2 of the Handbook]: OGC questioned the origin of the statement, "The State should make arrangements to participate in the Environmental Protection Agency quality assurance program for laboratory performance."

Response: This statement is part of criterion 36 in the policy statement, "Criteria for Guidance of States and NRC in discontinuance of NRC Regulatory Authority and Assumption Thereof by States Through Agreement." This is part of the additional criteria for States regulating uranium or thorium processors.

Comment 18: [Section 4.6 of the Handbook]: In the second paragraph, consider including information that States can also receive assistance from the NRC.

Response: This comment is related to the paragraph that addresses the fact that, for complex cases, program staff may need to hire consultants or use staff from other State agencies with needed expertise. States need to be able to start an Agreement program without relying on NRC resources, even with paying for this resource.

The NRC does have a process by which States can request technical assistance on occasion when needed, at a cost. However, this is not a common, routine practice. The NRC will not enter into an arrangement to perform regular complex casework on a routine basis for a State. The intent of possible technical assistance from the NRC is for unique, emerging technologies for which there is not extensive experience and often the State and the NRC are working together to

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evaluate the technical issues.

Comment 19: [Definitions in the Handbook]: Consider including the term "Agreement materials" in the list of definitions.

Response: The Definitions are being revised to include several definitions based on comments received on the procedure and Handbook. The term "Agreement Materials" has been included in the Definitions.

U.S. Nuclear Regulatory Commission; Office of Federal and State Materials and Environmental Management Programs; Division of Materials Safety and State Agreements; Source Management and Protection Branch; email dated April 1, 2014

Comment 1: Editorial changes were provided throughout the document. These are not listed individually in the comment resolution.

Response: Editorial changes were made in the document where needed.

Comment: Several Agencywide Document Management System accession numbers were provided to include in the examples provided in Appendix D to the Handbook.

Response: These accession numbers were included in Appendix D.

Comment: On page 34 of the Handbook, Section 4.3.6, second paragraph – consider including a reference to coordinating communication with the licensees about the transfer.

Response: Inspection Manual Chapter 2882, *Transfer of NRC License Files to Agreement State(s)*, has been added to the list of References for this section. This Inspection Manual Chapter will be revised in the future to reflect current practices.