

UNITED STATES NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

July 8, 2022

ALL AGREEMENT STATES, CONNECTICUT, INDIANA NON-AGREEMENT STATES STATE LIAISON OFFICERS FEDERALLY RECOGNIZED TRIBES NRC NMSS, NRC REGIONS I, III AND IV

NOTIFICATION OF THE ISSUANCE OF PROCEDURE SA-700, PROCESSING AN AGREEMENT (STC-22-043)

Purpose: To inform the National Materials Program (NMP) community (States and U.S. Nuclear Regulatory Commission (NRC) and Federally Recognized Tribes that Office of Nuclear Material Safety and Safeguards (NMSS) State Agreements (SA) procedure SA-700, *Processing an Agreement*, has been revised and approved for use.

Background: The last revision of SA-700 was issued on January 26, 2015 and is available in the Agencywide Documents Access and Management Systems (ADAMS) under Accession No. ML14343A678. Since the previous issuance of SA-700, the NRC has entered into Agreements with the States of Wyoming and Vermont, in 2018 and 2019, respectively. The Wyoming and Vermont Agreements both resulted in changes in the NRC's approach to processing Agreements. The Wyoming Agreement involved extensive engagement with Federally Recognized Tribes that expressed interest in the Agreement application review process. In addition, the NRC's Tribal Policy Statement (82 FR 2402; January 9, 2017) was published during the processing of the Wyoming Agreement. In 2019, the Commission directed changes to some of the language in the Vermont Agreement.

On April 7, 2021, NRC staff issued "Notification of the Issuance, and Opportunity to Comment on the Interim Procedure SA-700, Processing an Agreement (STC-21-018)" to inform the NMP community and Federally Recognized Tribes that NMSS procedure SA-700 was approved for use as an interim procedure and to provide an opportunity to comment on the interim procedure. The comment period for the interim procedure was scheduled to end on October 15, 2021, but was extended to January 31, 2022, in "Extension of Comment Period for Interim Procedure SA-700, Processing an Agreement (STC-21-018A)" issued on September 8, 2021.

On December 10, 2020, and June 11, 2021, the Governors of Connecticut and Indiana, respectively, submitted Letter of Intents to become an Agreement State. This revision of SA-700 was issued as an interim procedure to allow the processing of the Connecticut and Indiana Agreement applications while allowing for the submission of comments by interested parties. No comments on the procedure were received from States or Tribes. NRC staff comments were accepted and incorporated into this revision.

Discussion: SA-700 has been revised to incorporate lessons learned during the review and finalization of the Wyoming and Vermont Agreements. A new appendix (Appendix E to the SA-700 Handbook) was developed to guide NRC engagement and consultation with Federally Recognized Tribes during the Agreement process.

This procedure has been uploaded to the state communications portal website for use: https://scp.nrc.gov/procedures.html. The procedure and handbook can be also found in ADAMS under Accession Nos. ML22138A414 and ML22140A396.

If you have any questions regarding this communication, please contact the individual named below:

POINT OF CONTACT: Duncan White

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Signed by Anderson, Brian on 07/08/22

Brian C. Anderson, Branch Chief State Agreement and Liaison Programs Division of Materials Safety, Security, State, and Tribal Programs Office of Nuclear Material Safety and Safeguards

STC-22-043 Notification of Issuance of Procedure SA-700, Processing An Agreement DATE July 8, 2022

DISTRIBUTION:

ADAMS Accession No.: ML22189A181

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DATE	Jul 8, 2022	Jul 8, 2022		

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Office of Nuclear Material Safety and Safeguards Procedure Approval

Processing an Agreement State Agreement (SA) Procedure SA-700

Issue Date:	June 15, 2022

Review Date: June 15, 2022

Kevin Williams

Clark, Theresa signing on behalf of Williams, Kevin

Director, NMSS/MSST on 06/15/22

Brian C. Anderson Signed by Anderson, Brian on 06/09/22

Branch Chief, NMSS/MSST/SALB

Duncan White Signed by White, Alfred on 05/27/22

Procedure Contact, NMSS/MSST/SALB

ML22138A414

NOTE

Any changes to the procedure will be the responsibility of the NMSS Procedure Contact. Copies of NMSS procedures are available through the NRC Web site at https://scp.nrc.gov

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I. INTRODUCTION

A. Section 274 of the Atomic Energy Act of 1954, as amended, (AEA) provides a statutory basis under which the U.S. Nuclear Regulatory Commission (NRC) discontinues to the States portions of its regulatory authority to license and regulate byproduct materials; source materials; and certain quantities of special nuclear materials. The Governor of a State initiates this process by formally requesting an Agreement. The mechanism for the transfer of the NRC's authority to a State is an Agreement signed by the Governor of the State and the Chairman of the Commission, in accordance with Section 274b of the AEA.

- B. This procedure describes the methods and guidelines for reviewing the request for an Agreement. It also provides guidance to:
 - 1. NRC staff on the formal procedural steps for responding to a Governor's request for an Agreement;
 - 2. NRC staff on the criteria for evaluating a State's request; and
 - 3. State staff on the information to include in a request for an Agreement.
- C. As used in this procedure, the term Agreement State refers to either a State¹ or a Commonwealth. However, NRC staff should use the term State or Commonwealth in the Agreement, *Federal Register* notices (FRN), and other official records.

II. OBJECTIVE

- A. Ensure that each new Agreement is consistent with the provisions of the AEA, Commission policy, NRC Management Directives, and other statutory, regulatory, or policy requirements;
- B. Create a consistent regulatory review process to reduce uncertainties that any prospective Agreement State may encounter;
- C. Provide for the effective, efficient, and timely review of the request by a State for an Agreement or for an amendment to an existing Agreement.
- D. Provide for an orderly transition in the discontinuance of regulatory authority by the NRC and assumption thereof by the State, as well as support the necessary budgetary planning process that accompanies the transition.

III. BACKGROUND

A. The AEA and Agreements

¹ Section 274n. of the Atomic Energy Act (AEA) considers the U.S. Territories and the District of Columbia to be States for the purpose of entering into an Agreement.

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Section 274 of the AEA allows the Commission and a State to enter into an Agreement under certain conditions. Under the Agreement, the Commission discontinues regulatory authority over the specified categories of materials. The State concurrently assumes regulatory authority for those materials. A general timeline for entering into an Agreement can be found in Appendix C of the Handbook for Processing an Agreement.

Categories of materials that the NRC may transfer are: (a) byproduct materials as defined in Section 11e.(1) through Section 11e.(4) of the AEA; (b) source materials as defined by Section 11z of the AEA; and (c) special nuclear materials as defined in Section 11aa. of the AEA in quantities not sufficient to form a critical mass (as defined in 10 CFR 150.11). Specific uses of materials that the NRC may transfer are (a) the regulation of the land disposal of byproduct, source, or special nuclear waste materials received from other persons; and (b) the evaluation of radiation safety information on sealed sources or devices containing byproduct, source, or special nuclear materials and the registration of the sealed sources or devices for distribution, as provided for in the regulations or orders of the Commission. The State may choose to assume regulatory authority over any of the above categories or uses. Generally, a State assumes authority over the entire category of material for which it is requesting authority under the Agreement. However, there may be limited circumstances when a State may choose not to regulate certain types of activities within a category of material. Commission approval is required when a State requests to regulate only certain types of activities within a category. A State must also have authority over all licensees within each category of material and activities over which the State assumes authority under the Agreement.

Before the Commission approves the Agreement, the State must have a program for the control of radiation hazards. The program must be adequate to protect public health and safety with respect to the categories of materials specified in the Agreement. For the purpose of this procedure, "public health and safety" includes security/physical protection of agreement material. Throughout this Procedure and Handbook, 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. The State's program must also be compatible with the Commission's program for the regulation of the materials. To distinguish this program from other radiation control activities of the State, the program is referred to as the Agreement materials program.

When a State expresses an interest in entering into an Agreement with NRC, NRC staff will often meet with the State management to provide an overview of Agreements, the State legislation and regulations needed, the programs the State needs to establish, and the timeline. A more detailed discussion is held after the NRC receives a Letter of Intent – this is discussed below in Section V, "Guidance."

The Governor must certify that the State has the required program and desires to assume regulatory authority over the requested categories of materials. A comprehensive description of the Agreement materials program should accompany the certification. The certification and description together make up the request for an Agreement. The information in the description should be of

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sufficient detail for the Commission to determine that the Agreement materials program is adequate and compatible with the NRC's regulatory program.

B. The Agreement Materials Program

An Agreement materials program has two basic components. The first component is a set of State legislation and regulations that provides the Agreement materials program's framework. In accordance with Commission policy, the term "regulations" may include other forms of generic legally binding requirements. These legally binding requirements may include license conditions, orders, or any other acceptable method as authorized by State law.

The second component is an effective organizational and administrative structure to execute and enforce the State's legislation and regulations. The organizational structure may be a single State agency, a part of an agency, or portions of two or more agencies. All such organizational units are included when this procedure refers to an "Agreement materials program." The administrative structure includes implementing and operating procedures and guidance for licensees and the State program staff.

C. NRC Staff Actions

The NRC staff evaluates the State's Agreement materials program that is described in the request for an Agreement. Simultaneously, the staff prepares a written assessment of the Agreement materials program. The assessment provides the basis for a finding by the Commission that the Agreement materials program is adequate and compatible. The assessment should show that the Agreement materials program satisfies the Commission policy statement *Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory Authority and Assumption Thereof by States Through Agreement*, (46 FR 7540; January 23, 1981, as amended on July 16, 1981 (46 FR 36969), and July 21, 1983 (48 FR 33376)). This Commission policy statement is hereafter referred to as the "criteria policy statement."

The assessment should also give the NRC confidence that if the State implements the Agreement materials program as presented, a review of the Agreement materials program pursuant to NRC Management Directive (MD) 5.6, Integrated Materials Performance Evaluation Program (IMPEP), will find the Agreement materials program satisfactory for all applicable indicators.

The NRC staff should also comply with the principles articulated in the NRC's Tribal Policy Statement and other relevant guidance documents to promote effective government interactions during the application process. Section IV.E. discusses the Tribal Liaison (TL), Regional State Liaison Officer (RSLO) and the Agreement State staff roles and responsibilities for interacting with tribal entities during the Agreement State application process. Section V. provides additional guidance on these interactions.

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IV. ROLES AND RESPONSIBILITIES

A. The Director of the Office of Nuclear Material Safety and Safeguards (NMSS) is responsible for the agency's review of a request from a State for an Agreement. The Director determines when the request satisfies the criteria policy statement and recommends Commission approval of the request.

- B. The Director of the Division of Materials Safety, Security, State, and Tribal Programs (MSST) is responsible for providing staffing and monitoring the review process for the State's Agreement request. The MSST Director approves correspondence and requests to the NRC Offices, the State, and Tribal governments.
- C. The Branch Chief of the State Agreement and Liaison Programs Branch (SLPB) assigns a Project Manager (PM) for the review of the Agreement request. The PM is the primary NRC staff contact for the State during the review. The PM is the review team leader and should be knowledgeable of, and have substantial experience with, the IMPEP review process.
- D. The review team is responsible for conducting the staff evaluation of the request in accordance with this procedure. A team normally consists of the PM, the assigned staff contacts from other NRC offices including the Office of the General Counsel, Office of Nuclear Security and Incident Response, and the affected Region. Other NRC offices should be represented if necessary. Other NMSS staff may also be represented, such as NMSS staff from decommissioning or uranium recovery activities. The principal reviewers for licensing, inspection, staffing, and incidents and allegations should meet the IMPEP qualification requirements.
- E. The Regional State Agreements Officer (RSAO) is usually the lead NRC contact for a State before it submits a Letter of Intent. After the State submits a Letter of Intent, the PM assumes lead responsibility. However, the RSAO continues to coordinate contacts between the State and the Region licensing and inspection staffs. The RSAO should keep the PM informed of these contacts.
- E. The NRC's TLs and RSLOs are usually the lead NRC point of contact with tribal governmental entities. For tribal interactions related to the Agreement application process, the PM will work the TL as described in Appendix E of the Handbook.
- F. The Region, the office of the Chief Information Officer (OCIO), and NMSS are responsible for transferring the NRC license files to the State. The PM should be kept informed of these activities.

V. GUIDANCE

For detailed guidance on reviewing the request including scheduling and documentation requirements, see the *Handbook for Processing an Agreement* (Handbook). Appendix D to the Handbook contains examples of letters and documents from the work on recent Agreement request reviews. Below is an outline of each step in the process with a brief

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description. Cross-references to the Handbook and/or to Appendix D for examples are included in brackets.

A. Governor's Letter of Intent [Handbook, Section 3.3 and Appendix D, Item A]

The Governor should send a letter to the NRC Chairman declaring the State's intent to seek an Agreement. The letter should include a commitment of State resources to seeking an Agreement. Based on this commitment, NRC plans for the review and commits its resources to working with the State on completion of an Agreement.

B. Meeting with State after Receipt of Letter of Intent

Upon receipt of the Governor's Letter of Intent, the NRC PM should schedule an initial meeting with the State, the Branch Chief of SLPB, and the RSAO. The purpose of this meeting is to discuss in more detail the process for becoming an Agreement State, including legislation, regulations, procedures, and the information to include in the request. Staff should also discuss the time period involved in becoming an Agreement State.

C. Initiating Outreach to Tribal Governmental Entities

Upon receipt of the Governor's Letter of Intent, the NRC PM should schedule a meeting with the TLs to identify tribal governmental entities that may be interested in the State's application. Further information on conducting tribal outreach and consultation during the application process is discussed in Appendix E of the Handbook.

D. Preparing a Request for an Agreement

When preparing a request for an Agreement, the State should consider the guidance in this procedure and the Handbook. The Agreement materials program description should address the program elements listed in Section 4.0 of the Handbook. For each program element, the State should provide information for each category of materials requested in the Agreement.

The State can also discuss the proposed Agreement materials program with other Agreement States for suggestions and recommendations. The State may find it helpful to use other Agreement materials programs' procedures as a template for establishing its own procedures.

- E. Draft Request for an Agreement [Handbook, Section 3.4]
 - 1. The State Radiation Control Program Director or equivalent Governor-appointed representative (hereafter referred to as the Program Director) should submit a draft of the State's request for an Agreement. The draft request should contain a draft letter of certification, and a description of the Agreement materials program for all applicable elements of the Agreement materials program. It should also contain the draft text for the

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proposed Agreement (see NRC MD 5.8, *Proposed Section 274b Agreements with States*).

- 2. The Program Director should notify the PM or the Branch Chief of the SLPB at least 2 months before submitting the draft. The Director of MSST should then ask the Offices (discussed in Section IV.C of this procedure) to assign staff level members of the review team.
- 3. The team conducts a detailed review of the draft request following the procedures and criteria in Section 4.0 of the Handbook. The description of the Agreement materials program should address all applicable program elements. The draft and formal requests should be submitted to the NRC electronically. The State should not submit any information that is sensitive unless coordinated with the PM.
- 4. The team prepares a letter to the Program Director to document the results of the review [Handbook, Appendix D, Item C]. The Director of MSST signs the letter.
- 5. The PM, RSAO, Branch Chief of SLPB, and the Program Director, as well as any designated State contact, should schedule regular conference calls (normally on a monthly basis) on the progress of the review [Handbook, Section 3.4.4]. Review team members and other NRC staff may participate.
- 6. The State should address the NRC's comments by making changes in its working copy of the formal request [Handbook, Section 3.5]. The Program Director should not submit a second draft, or changes to the draft, unless coordinated with the PM.
- F. Receipt of a Formal Request for an Agreement [Handbook, Section 3.5]
 - Once the State completes incorporating the NRC comments into the formal request, the Governor should sign and submit the formal request to the Chairman.
 - 2. The Program Director should notify the PM 2 weeks before the Governor submits the formal request. The PM prepares a letter for signature by the Chairman acknowledging receipt of the request [Handbook, Appendix D, Item E].
 - The review team conducts an evaluation of the formal request following the procedures and criteria in Section 4.0 of the Handbook. If the State did not submit a draft request, assemble a review team to conduct a detailed review of the request.
 - 4. If the team identifies deficiencies in the formal request, it prepares a letter to the Program Director providing comments. The Director of MSST signs the letter.

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- 5. The State should address the comments by revising the formal request and send the revisions to the Director of MSST.
- 6. The PM should work with Office of Public Affairs (OPA) several weeks in advance of the expected publication of the FRN to develop the press release [Handbook, Appendix D, Item I].
- G. Review Team's Evaluation of the Formal Request
 - 1. The team prepares a draft staff assessment addressing individually each criterion in the criteria policy statement [Handbook, Appendix D, Item F].
 - 2. The team prepares a draft FRN that announces the proposed Agreement and briefly describes the State's Agreement materials program. Include a summary of the draft staff assessment in the FRN. The FRN should also discuss any unique features of the proposed Agreement. Include the text of the proposed Agreement, with a proposed effective date. The Director of NMSS usually signs the FRN [Handbook, Appendix D, Item H].
 - 3. When the formal request, as amended by the State in response to the team's comments, satisfies the criteria policy statement, the team prepares a Commission paper [Handbook, Appendix D, Item G]. The paper should request approval from the Commission to forward the FRN and proposed Agreement for publication.
 - a. The paper should include, as enclosures, the following:
 - i. Draft staff assessment
 - ii. Draft FRN (including the summary of the draft staff assessment and draft proposed Agreement)
 - b. The paper should also include, as background, the following:
 - Draft Congressional letters and letters to the Federal agencies [Items H.3. and 4. below]
 - ii. Project Schedule for processing, signing, and implementing the Agreement [Handbook, Appendix C]
 - 4. The PM prepares a memorandum from the MSST Director transmitting the paper to the other Offices for concurrence. Following Office concurrence, the Director of NMSS forwards the paper to the Office of the Executive Director for Operations (EDO) for signature and transmittal to the Commission.
- H. Commission Approval of Publication of the Proposed Agreement

If the Commission approves the staff recommendations, the Office of the Secretary (SECY) will issue a Staff Requirements Memorandum (SRM). The staff then takes several actions:

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- 1. The Director of MSST signs the FRN with all the Commission's changes identified in the SRM.
- 2. Staff forwards the FRN to the Office of General Counsel (OGC) Legal Research Center for publication.
- 3. Staff prepares letters to the NRC Congressional Oversight Committees (Committees), the U.S. Senators and the U.S. Representatives for the affected State/Commonwealth, providing these individuals with a prepublication copy of the FRN. Staff should work with the Office of Congressional Affairs (OCA) to obtain a current list of the NRC Congressional Oversight Committees and the current Chair and Co-Chair. Staff will also get the list of U.S. Senators and U.S. Representatives from OCA. OCA sends the letters to these Committees [Handbook, Appendix D, Item J].
- 4. Staff sends a letter to the following Federal agencies informing them of the proposed Agreement, including a prepublication copy of the FRN [Handbook, Appendix D, Item K]:
 - a. Deputy Assistant Secretary of Labor, Occupational Safety and Health Administration;
 - b. Assistant Secretary, Congressional and Intergovernmental Affairs, U.S. Department of Energy;
 - c. Chairperson of Council on Environmental Quality;
 - d. Director, Center for Devices and Radiological Health, Food and Drug Administration;
 - e. Assistant Administrator for Air and Radiation, U.S. Environmental Protection Agency;
 - f. Assistant Secretary, Office of Legislative Affairs, Department of Homeland Security; and
 - g. Executive Director, Advisory Council on Historical Preservation.
- 5. Staff sends a letter and email to the interested tribal governmental entities informing them of the proposed Agreement and informing them of the upcoming public comment period [Handbook, Appendix E].
- I. Publication of the Proposed Agreement
 - 1. Upon publication of the FRN, the PM issues a State and Tribal Communication (STC) letter to Agreement States, non-Agreement States, and State Liaison Officers, including a copy of the FRN, informing them of the proposed Agreement [Handbook, Appendix D, Item L].

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- 2. Upon publication of the FRN, the staff sends a letter and email to the interested tribal governmental entities informing them of the proposed Agreement and public comment period [Handbook, Appendix E].
- 3. The PM informs the OPA of the publication so OPA can issue a press release.
- J. Preparation of Second Commission Paper to Approve Agreement
 - 1. When the public comment period closes, the PM is responsible for preparing an analysis of the comments, working with the review team [Handbook, Appendix D, Item M]. The PM and review team should thoroughly evaluate the comments for any implication of legal action and highlight such possibilities to OGC for its review of the comments and comment responses.
 - 2. The PM and review team prepares the final staff assessment, considering the public comments [Handbook, Appendix D, Item N].
 - 3. The PM prepares a second Commission paper requesting Commission approval of the draft Agreement [Handbook, Appendix D, Item O]. The Commission paper is transmitted to other NRC offices for review and concurrence.
 - 4. Enclosures to the paper are:
 - a. Final text of the draft Agreement [Handbook, Appendix D, Item U]
 - The NRC and the State agree on the effective date for the Agreement.
 The PM inserts the date into the Agreement text.
 - ii. A draft FRN announcing the approval and signing of the Agreement [Handbook, Appendix D, Item P]
 - b. The final staff assessment [Handbook, Appendix D, Item N]
 - c. The staff's analysis of the public comments [Handbook, Appendix D, Item M]
 - d. Draft letter from the Chairman to the Governor approving the Agreement [Handbook, Appendix D, Item S]
 - 5. The paper contains brief discussions of:
 - a. Staff's consideration, analysis, and resolution of public comments;
 - b. The staff's interactions with tribal governmental entities, staff's consideration of tribal input in the decision-making process, and staff's response to tribal comments [Handbook, Appendix E];
 - c. Outstanding orders, Confirmatory Action Letters, and 2.206 petitions against licensees that will transfer;

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- d. Staff coordination to resolve incomplete escalated enforcement actions. The discussion should indicate that we informed the State if the NRC will retain jurisdiction for violations that occurred at a licensed facility while under NRC jurisdiction. OGC has ruled that the NRC has the authority under Section 234 of the AEA to issue a Notice of Violation and Civil Penalty Assessment to transferred licensees. However, the NRC does not have authority to require corrective actions after the Agreement is effective;
- e. The status of any complex site or other sites in decommissioning. The discussion should indicate how the State was advised to notify the NRC when it terminates the license of a complex site. The notification from the State should indicate whether the site was released for unrestricted use as defined by the State. The decommissioning status of complex sites transferred to the State will be reviewed as part of IMPEP;
- f. How information was provided to the State regarding previously licensed sites;
- g. Allegations and investigations in progress; however, details should not be included; and
- h. The NRC resources that staff anticipates devoting to facilities in the State once the Agreement is in effect.
- 6. The following documents are included as background to the paper:
 - a. Draft letters to NRC's Congressional Oversight Committees and the State's Congressional delegation announcing the approval and signing of the Agreement [Handbook, Appendix D, Item R].
 - b. A completed copy of the General Accounting Office form, GAO-001, "Submission of Federal rules under the Congressional Review Act," providing the notifications required under the Congressional Review Act Small Business Regulatory Enforcement and Fairness Act of 1996 (Formerly Small Business Regulatory Enforcement Fairness Act). Form GAO-001 is available on the NRC website's forms library.
 - i. Three forms are completed: (1) President of the Senate, (2) Speaker of the House of Representatives, and (3) General Accounting Office
 - ii. The Agreement is considered a "non-major rule" and "routine and frequent of informational/administrative/other"
 - iii. The form is included as background to the Commission paper and submitted to the OCA for distribution once the Agreement is approved. Include a copy of the draft FRN with each form. It is not made publicly available in the Agencywide Documents Access and Management System

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K. Commission approval of the Agreement

- 1. If the Commission approves the Agreement, the PM prepares three official copies of the Agreement for signature, inserting the date of Commission approval, i.e., the date of the SRM, into the Agreement.
- 2. The Governor has the choice of signing the Agreement at a formal ceremony or signing by correspondence. The PM consults with the Program Director to determine the Governor's choice. The PM also determines the format of the Governor's signature block and whether the State wishes to add a State seal.
 - a. If the Chairman and Governor will hold a formal signing ceremony, the PM should arrange the date, time, and place of the ceremony. The PM coordinates with the State staff and, through the EDO, with the Chairman's office.
 - b. If the Agreement is to be signed by correspondence, the location at which the Chairman signs is Rockville, Maryland. The location at which the Governor signs is the State capitol unless the State specifies another location.
 - c. If the Agreement is to be signed by correspondence, the PM asks the Program Director to provide instructions for delivery of the Agreement to the Governor.
- 3. The Division Director of MSST forwards the Congressional letters and three copies of the Congressional Review Act form to OCA.
- L. Signing of the Agreement
 - 1. If the Chairman and Governor will sign the Agreement at a formal ceremony:
 - a. The PM prepares three copies of the Agreement.
 - b. The PM coordinates with SECY to place the NRC seal on each copy before the ceremony.
 - c. After signing, the Governor receives one copy of the Agreement. The PM takes the other two.
 - i. One copy of the Agreement remains with SECY
 - ii. The remaining copy of the Agreement remains with NMSS
 - d. The State should receive the letter from the Chairman to the Governor approving the Agreement [Handbook, Appendix D, Item S].

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- 2. If the Agreement is signed by correspondence:
 - a. The PM coordinates with SECY to place the NRC seal on each copy of the Agreement.
 - b. The PM coordinates with EDO and the Chairman's office to arrange for the Chairman to sign all three copies of the Agreement.
 - c. The PM sends all three copies of the Agreement to the State according to the State instructions. Include the original letter from the Chairman to the Governor approving the Agreement [Handbook, Appendix D, Item S]. After the Governor signs the Agreement, the State retains one copy and returns the other two copies to the Director of NMSS.
- 3. The PM delivers one copy of the signed Agreement to SECY. NMSS retains the other copy.
- 4. The PM informs OPA of approval of the Agreement so that OPA can issue the press release announcing the approval of the Agreement.
- M. Implementation of the Agreement
 - 1. The Division Director of MSST forwards the FRN, as approved in the SRM, for signature by SECY. Section 274e.(2) of the AEA requires publication of the FRN within 30 days after the Agreement is signed.
 - 2. The Region, OCIO, and NMSS are each responsible for preparing license files for transfer to the State. Since nearly all records will be transferred electronically to the State, the PM will have the lead to coordinate all efforts and should be kept informed of the progress.
 - 3. Staff prepares letters to the NRC Congressional Oversight Committees (Committees), and to the U.S. Senators and the U.S. Representatives for the affected State/Commonwealth, providing these individuals with a prepublication copy of the FRN. Staff should work with OCA to obtain a current list of the NRC Congressional Oversight Committees and the current Chairs and Co-Chairs. Staff will also get the list of U.S. Senators and U.S. Representatives from OCA. OCA sends the letters to these Committees [Handbook, Appendix D, Item R].
 - 4. Staff sends a letter to the following Federal agencies informing them of the proposed Agreement, including a prepublication copy of the FRN [Handbook, Appendix D, Item T]:
 - a. Deputy Assistant Secretary of Labor, Occupational Safety and Health Administration;
 - b. Assistant Secretary, Congressional and Intergovernmental Affairs, U.S. Department of Energy;
 - c. Chairperson of Council on Environmental Quality;

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- d. Director, Center for Devices and Radiological Health, Food and Drug Administration;
- e. Assistant Administrator for Air and Radiation, U.S. Environmental Protection Agency;
- f. Assistant Secretary, Office of Legislative Affairs, Department of Homeland Security; and
- g. Executive Director, Advisory Council on Historical Preservation.
- 5. The staff issues an STC letter to Agreement States, non-Agreement States, and State Liaison Officers, including a copy of the FRN, informing them of the Agreement [Handbook, Appendix D, Item V].
- 6. The staff issues an individual letter to tribal governmental entities that were contacted, consulted, or commented on the proposed agreement during the application process. The letter should inform them of the Agreement, describe how the agency considered their input during the decision-making process, and include a response to tribal comments [Handbook, Appendix E].

N. After the Agreement is Effective

- As a result of the Agreement and assumption of regulatory authority by the State, Tribes will no longer have direct involvement with the NRC on the implementation of State regulatory actions. Agreement State regulatory actions will be subject to the State's environmental, historic/cultural preservation, and tribal interaction regulations and procedures.
- 2. Approximately 9 months after the Agreement becomes effective, a meeting is set up with the State Agreement materials program management. This meeting is to discuss the State's implementation of the Agreement materials program (State Agreement Procedure SA-116, *Periodic Meetings between IMPEP Reviews*).
- 3. Approximately 18 months after the Agreement becomes effective, the first IMPEP review is conducted to evaluate the initial performance of the State program (NRC MD 5.6). The State may not have sufficient activities to assess before 18 months have elapsed.

VI. APPENDIX

Handbook for Processing an Agreement

VII. REFERENCES

- A. Sections 11 and 274 of the Atomic Energy Act of 1954, as amended
- B. Commission policy statement, *Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory Authority and Assumption Thereof by States*

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Through Agreement, (46 FR 7540; January 23, 1981), as amended on July 16, 1981 (46 FR 36969), and July 21, 1983 (48 FR 33376)

- C. Commission policy statement, *Tribal Policy Statement*, (82 FR 2402; Jan. 9, 2017) (https://www.federalregister.gov/documents/2017/01/09/2017-00091/tribal-policy-statement)
- D. Management Directive 5.1, Consultation and Coordination with Governments and Indian Tribes, July 6, 2020 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML112351312)
- E. Management Directive 5.6, *Integrated Materials Performance Evaluation Program* (*IMPEP*), July 24, 2019 (ML19213A024)
- F. Management Directive 5.8, *Proposed 274b Agreements with States*, December 28, 2020 (ML20349A296)
- G. State Liaison Procedure Regional State Liaison Officer Program, SL-100 (June 28, 2021) (ML21168A326)
- H. Tribal Procedure *TR-100, Tribal Liaison Roles and Responsibilities* (November 22, 2021) (ML 21088A259)
- I. Tribal Protocol Manual Guidance for NRC Staff (2018) (NUREG-2173, Revision 1) (ML18214A663)

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VIII. PROCEDURE VERSIONS

For knowledge management purposes, all previous revisions of this procedure, as well as associated correspondence with stakeholders, that have been entered into ADAMS are listed below.

No.	Date	Document Title/Description	Accession Number
1	07/19/2007	State Procedure, <i>Processing an Agreement</i> – SA-700	ML072160020
2	07/19/2007	FSME SA-700 Procedure, Redline/Strikeout Copy	ML072210542
3	07/19/2007	FSME SA-700 Handbook, Redline/Strikeout Copy	ML072210549
4	07/19/2007	FSME SA-700 Handbook, Appendix C, Redline/Strikeout Copy	ML072210655
5	08/22/2006	STP-06-073, Opportunity to Comment on Draft Revision to STP Procedure SA-700, <i>Processing</i> an Agreement	ML062290300
6	01/30/2007	FSME SA-700 Procedure – Resolution of Comments	ML072210663
7	02/14/2014	FSME-14-016, Opportunity to Comment on Draft Revision to SA-700	ML14035A324
8	04/07/2021	STC-21-018, Notification of the Issuance, and Opportunity to Comment on the Interim Procedure SA-700, Processing an Agreement	ML21251A092
9	06/15/2022	SA-700, Processing an Agreement Final	ML22138A414
10	06/17/2022	Handbook for Processing an Agreement Procedure SA-700	ML22140A396
11	07/08/2022	STC-22-043, Notification of Issuance of Procedure SA-700, Processing an Agreement	ML22189A181

Date: June 17, 2022

Office of Nuclear Material Safety and Safeguards U.S. Nuclear Regulatory Commission

Contact: Duncan White

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1.0 INTRODUCTION

1.1 Purpose

This Handbook provides guidance for the preparation and review of a State request for a Section 274b. Agreement as authorized by the Atomic Energy Act of 1954 (AEA), as amended. The U.S. Nuclear Regulatory Commission (NRC) staff should use the Handbook for guidance in reviewing the request or for guidance in reviewing an amendment to an existing Agreement. The State that is requesting an Agreement should use the Handbook for guidance in preparing its request.

1.2 Scope

A request for an Agreement consists of a formal request by a State's Governor, draft State Agreement, and a comprehensive description of the State's Agreement materials program with supporting information. The comprehensive description of the State's Agreement materials program should demonstrate the State's ability to regulate AEA radioactive materials under the Agreement. This Handbook addresses the supporting information that the State should include and the criteria that the NRC staff uses to evaluate it. The NRC staff must be able to reach a conclusion that the information meets the Commission's review criteria.

The different sections of the Handbook address the different areas that a State must address in submitting a request for an Agreement. Section 2.0 addresses the statutes and policies that form the basis for the guidance in the Handbook. Section 3.0 provides the detailed steps in the procedure followed by the NRC staff to evaluate the request. Section 4.0 addresses the specific supporting information needed to evaluate each element of the State's program. It provides specific criteria for evaluating the information and relates these criteria to the Commission's Criteria Policy Statement (see Section 2.2. of the Handbook below). It also includes documents related to the specific criteria. For the purpose of SA-700, *Processing an Agreement*, "public health and safety" includes security/physical protection of agreement material. Throughout this Procedure and Handbook, 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.

Appendix A is a cross reference table of the subsections in Section 4.0 of the Handbook to the criteria in the Criteria Policy Statement and in other guidance documents. Appendix B is a set of sample forms to guide the analysis of staffing needs in an Agreement materials program.

Appendix C is a sample process schedule for planning purposes for the State and NRC. Appendix D is a set of sample letters and documents developed while reviewing previous Agreement State requests. Appendix E discusses interacting with Tribal governmental entities during the application process.

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2.0 **BASIS OF THE GUIDANCE**

2.1 **Statutory Requirements**

The guidance in this Handbook is based on the requirements of Federal statutes, Commission Policies, NRC Management Directives, NRC Inspection Manual Chapters and Inspection Procedures, and State Procedures and Tribal Procedures for the Office of Nuclear Material Safety and Safeguards (NMSS), Division of Material Safety, Security, State and Tribal Program (MSST) Agreement State program. These are addressed in more detail below.

2.1.1 Federal Statutes

The Commission implements the Agreement State program under Section 274 of the AEA. Section 274b. authorizes the Commission to enter into an Agreement with the Governor of a State. Section 274c. and Section 274m. of the AEA specifies those regulatory authorities that must be reserved to the NRC. Sections 274d. through 274g. specify the Commission actions and obligations with respect to the agreements. A State that proposes to regulate 11(e).2 byproduct material is subject to additional requirements in Section 274o. It must also comply with the applicable requirements of the Uranium Mill Tailings Radiation Control Act (UMTRCA).

2.1.2 State Statutes

Under Section 274, Agreement States do not regulate materials for the NRC. Rather, the NRC discontinues, and the State assumes, regulatory authority. Each Agreement State administers an independent regulatory program. The State agency designated to conduct the Agreement materials program must have authority under State law to discharge its functions. The legal authority required depends on the categories of materials that the Commission transfers to the State in the Agreement. Section 4.1 of the Handbook contains details on the provisions of State law that are required. A State seeking an Agreement must submit copies of its statutes for review.

2.2 Commission Policy Statements

The Commission has adopted two policy statements applicable to the Agreement State program. They are discussed individually in the paragraphs below.

2.2.1 <u>Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory Authority and Assumption Thereof by States Through Agreement</u> (46 FR 7540, 01/23/81; 48 FR 33376, 7/21/83)

Known as the "Criteria Policy Statement," it describes the specific requirements that a State must meet for the Commission to approve an Agreement. It also provides the basis for the NRC staff assessment of the State's proposed Agreement materials program. The criteria in the Policy Statement are incorporated into Handbook Section 4.0. A State program that meets the Criteria Policy Statement requirements is determined to be adequate to protect public health and safety and compatible with the NRC regulatory program.

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The first 28 criteria in the Criteria Policy Statement apply to all proposed Agreement State materials programs. The last eight criteria apply only to States that request authority to regulate 11e.(2) byproduct material from, and operation of, uranium and thorium mills.

2.2.2 Agreement State Program Policy Statement (82 FR 48535, 10/18/17)

This Policy Statement describes the overall principles, objectives, and goals of the Commission's Agreement State program. The NRC and State staff, when reviewing or preparing a request for an Agreement, should consider these principles, objectives, and goals.

The Policy Statement defines the terms "adequate" and "compatible" and identifies the basic program elements necessary for an adequate Agreement State program. It also establishes five categories of compatibility with criteria for each. The NRC uses the basic program elements and compatibility criteria in the review of Agreement requests and in Integrated Materials Performance Evaluation Program (IMPEP) reviews.

2.2.3 *Tribal Policy Statement* (82 FR 2402; 1/9/17)

This Policy Statement establish principles to be followed by the NRC to promote effective government-to-government interactions with Federally recognized Tribes and encourages and facilitates Tribal involvement in the areas over which the Commission has jurisdiction. The policy articulates the NRC's six principles the NRC staff should follow to promote effective government interactions with Federally recognized tribes.

2.3 Management Directives and State Procedures

The NRC staff use two different types of procedures in reviewing State requests for agreements. Management Directives (MD) address activities whose responsibilities extend to more than one office. Individual Office procedures are used for activities that are the responsibility of a single office, such as the office level state procedures. The following MDs and state procedures provide direction and guidance for the review of a request for an Agreement.

Current copies of MDs may be viewed on the NRC Internet website. State Agreement Procedures may be found on the State Communication Portal (SCP) at: https://scp.nrc.gov/.

2.3.1 NRC MD 5.1, Consultation and Coordination with Governments and Indian Tribes

MD 5.1 addresses general responsibilities for consultation and outreach with States, Federally recognized tribes, other Federal agencies, local governments, and national or regional organizations of governmental agencies. It is the policy of the NRC to ensure appropriate consultation at the earliest possible stage between the NRC and States, local governments, other Federal agencies, and Indian Tribes, and national and regional associations regarding major interagency agreements, major organizational changes, major rules and regulations, statements of policy, guides, and standards, and major studies that may have a significant State or local impact.

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2.3.2 NRC MD 5.6, Integrated Materials Performance Evaluation Program

MD 5.6, *Integrated Materials Performance Evaluation Program (IMPEP)* provides the process and criteria for evaluating the performance of Agreement State materials programs and the NRC's materials programs. The NRC staff assessment of a request for an Agreement must conclude that the State's proposed program, if implemented as described, would be found satisfactory in all applicable IMPEP performance indicators.

2.3.3 NRC MD 5.8, Proposed 274b Agreements With States

MD 5.8 provides guidance on drafting a proposed Agreement. The Handbook to MD 5.8 includes a model Agreement. The State should draft its proposed Agreement based on this model. Changes from the model should include additional supporting information since staff must evaluate the changes to ensure the adequacy and compatibility of the proposed Agreement materials program. State requests for subcategories or responsibility for limited activities within a category of the standard Agreement will require prior approval by the Commission before the staff begins its review of the State's request for an Agreement.

2.3.4 NRC MD 5.9, Adequacy and Compatibility of Program Elements for Agreement State

Programs, and State Agreement Procedure SA-200, Compatibility Categories and

Health and Safety Identification for NRC Regulations and Other Program Elements

MD 5.9 implements, in part, the Agreement State program *Policy Statement*. The objective of MD 5.9 is to establish the process the NRC staff will follow to determine when a proposed or final Commission regulation or other program element should be adopted as a legally binding requirement by an Agreement State and whether adoption is required for compatibility or health and safety. State Agreement (SA) Procedure SA-200 documents the results of the compatibility or health and safety determination for each regulation. Appendix A to SA-200 provides a link to the SCP https://scp.nrc.gov/ that provides a table of each NRC program element and its designated category (i.e., for compatibility, health and safety, reserved to the NRC, or not required to be adopted by the States) in accordance with MD 5.8.

Section V., "Guidance," Item A, includes a link to the NRC website on which there is a section-by-section summary of compatibility and health and safety categories for the regulations in Title 10 of the *Code of Federal Regulations* (10 CFR).

2.3.5 NRC MD 8.8, Management of Allegations

MD 8.8 provides NRC policy and procedures for management of allegations. State procedures for the management of allegations for the Agreement materials program should include the applicable elements of MD 8.8, based on State requirements and law.

2.3.6 Office of Nuclear Material Safety and Safeguards – State Procedures

SA-100 Implementation of the Integrated Materials Performance Evaluation Program (IMPEP); SA-101 Reviewing the Common Performance Indicator, Status of Materials Inspection Program; SA-102, Reviewing the Common Performance Indicator, Technical Quality of Inspections; SA-103, Reviewing the Common Performance Indicator, Technical Staffing and Training, SA-104, Reviewing the Common Performance Indicator,

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through SA-105, Reviewing the Common Performance Indicator, Technical Quality of Incident and Allegation Activities; SA-107 Reviewing the Non-Common Performance Indicator Legislation, Regulations, and other Program Elements; SA-108, Reviewing the Non-Common Performance Indicator, Sealed Source and Device Evaluation Program; SA-109, Reviewing the Non-Common Performance Indicator, LLRW Disposal Program; and SA-110, Reviewing the Non-Common Performance Indicator, Uranium Recovery Program; provide guidance for the review of IMPEP performance indicators in Agreement materials programs. They supplement the guidance in MD 5.6. SA-106 addresses the IMPEP Management Review Board and does not apply to the review of a request for an Agreement.

SA-10, Joint Oversight of the National Materials Program; SA-201, Review of State Regulatory Requirements; SA-300, Reporting Material Events; SA-400 Management of Allegations; SA-600, Training Criteria for Agreement State Personnel; and SA-900, Termination of Uranium Mill Licenses in Agreement States also provide guidance that should be used when reviewing an Agreement request."

2.3.7 Office Nuclear Material Safety and Safeguards – Tribal Procedures and Manual

The Tribal Policy Manual provides basic historical information about the Federal and Tribal government relationship and advice on interacting with Tribal governments. NMSS Procedure TR-100 describes the roles and responsibilities of the Tribal Liaisons at Headquarters and the Regional State Liaison Officers in the NRC's four regional offices regarding interactions and implementation of the consultation, outreach, and engagement with Federally recognized tribes.

3.0 REVIEW PROCEDURES

3.1 General Considerations

Entering into an Agreement involves a series of steps. First, the State staff expresses interest in an Agreement and requests information. Next, the Governor sends the Chairman a "Letter of Intent," in which the Governor indicates interest in entering into an Agreement. The third step is the submission of a draft request by the State Program Director or designee for the NRC's review. The NRC provides comments to the State for resolution prior to the Governor's formal submission of a request to enter into an Agreement.

The fourth step is the submission of the formal request for an Agreement by the Governor. All significant issues identified by the NRC with the draft request should be resolved by the State before the Governor submits the formal request.

3.1.1 Proprietary, Privacy, and Security Information

All information needed to support a request for an Agreement should be in the public records of the State. Normally, States should not need to submit proprietary information or information subject to the Federal Privacy Act, or a State equivalent. The NRC can protect proprietary or Privacy Act information if the State meets the requirements of 10 CFR Part 9. Before submitting information that the State believes should be withheld from public disclosure, the State Program Director or designee should discuss the matter with the Division Director of MSST.

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Security related sensitive information should not be included as part of the Agreement application because the application is a public document. Security related information and procedures should be submitted separately. In sections of the application where States describe aspects of their program, for example, pre-licensing visits or security inspections, the State should verify that it will follow specified procedures.

3.1.2 Schedule for Processing an Agreement

The entire Agreement application process typically take 3 to 5 years from the time the Governor submits a Letter of Intent to the NRC to the time the Agreement goes into effect. During the first 2 to 3 years, the State is working to develop its application as outline in Section 4 of this Handbook plus training and qualifying its staff. Appendix C contains a sample schedule for processing the formal request for an Agreement, the last main phase of the Agreement application process. This phase usually requires about 1 year based on recent experience. The actual time required to review a request depends on the resolution of issues unique to each Agreement. The effective date of the Agreement is usually selected jointly by the NRC and the State and is often based on the fee billing cycle to avoid duplicate fees for affected licensees. A proposed date should consider the time required for the review, the signing of the Agreement, and the transfer of license files.

In the sample schedule, the overall processing milestones are stated in terms of "elapsed weeks," by each Part of the process. Starting with the sample schedule, the Project Manager (PM) should establish a Project Schedule with estimated dates, based on the requested date of the Agreement. The PM should update the Project Schedule routinely as milestones are met.

3.1.3 Form of the Request

The State may submit the request as electronic documents. The request should be complete, including the Governor's letter of certification and all supporting information.

Electronic files may be in image format such as PDF files or in text format such as Microsoft Word. The State should contact the PM for further information on appropriate formats.

If the State elects to submit a request on paper, it should submit one complete copy. The NRC will scan the request into the Agencywide Document Access and Management System (ADAMS) for distribution to the review team. Photocopies of State laws, statewide procedures, etc., are acceptable if the quality of the copy allows for scanning. Note that the request and supporting information is a public document. The State should not submit any information that cannot be publicly released. Any non-public documents required for the request should be coordinated with the PM prior to submitting to the NRC.

3.1.4 Questions

Routine questions about the program elements, review process, criteria, or progress of the review should be directed to the PM. Significant issues (requests other than minor clarification issues) should be submitted in writing to the PM. The PM will also inform the

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Branch Chief of the State Agreement and Liaison Programs Branch (SLPB) of significant issues. The State staff may also, in the same manner, contact individual members of the review team directly about comments on specific program elements. Alternately, the question will be forwarded to the review team member for response.

3.2 Expression of Interest

In response to requests for information or an expression of interest in becoming an Agreement State, the State will need the following documents:

- a. Sections 11 and 274 of the AEA;
- b. Suggested Legislation *Radiation Control Act*, published by the Council of State Governments¹;
- c. Commission Policy Statements: Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory Authority and Assumption Thereof by States Through Agreement; Policy Statement on Adequacy and Compatibility of Agreement State Programs; and Statement of Principles and Policy for the Agreement State Program;
- d. MD 5.6, MD 5.9, and the NMSS SA Procedures and SA series.

Prior to the receipt of a Letter of Intent, the Regional State Agreements Officer (RSAO) in the NRC Region in which the State is located is the NRC staff lead for responding to questions and requests for additional information. The RSAO should coordinate with MSST staff and request assistance of other NRC staff as necessary. The State should submit questions regarding Commission policy or practice in writing to the Division Director of MSST

3.3 The Letter of Intent

A Letter of Intent is a declaration by the Governor that the State is committing its resources to entering an Agreement. It should be addressed to the Chairman of the Commission.

3.3.1 Content of Letter

The letter should state a desire to enter into an Agreement and designate a contact person on the State staff. It should also suggest an effective date for the Agreement (see Appendix D, Item A, of the Handbook).

The suggested effective date for the Agreement should take into consideration the time requirements for any needed legislation, regulations, and program specific procedures. It should also consider the time needed for recruitment, training, and qualification of program staff.

¹ Council of State Governments, Suggested State Legislation, 1983, Volume 42; The Council of State Governments, Iron Works Pike, P.O. Box 11910, Lexington, Kentucky 40578; telephone: (859) 244-8000

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3.3.2 Response to Letter

When the NRC receives a Letter of Intent, the Branch Chief of SLPB assigns a MSST staff member to be the PM for processing the Agreement request.

3.3.2.1 Acknowledgment Letter

The PM prepares a response letter acknowledging receipt of the Letter of Intent. The response letter should be prepared for the signature of the Chairman (see Appendix D, Item B, of the Handbook).

3.3.2.2 State Preparation of the Request for an Agreement

The PM coordinates with the RSAO and with the State contact on actions to prepare a draft request. The PM responds to State requests for assistance and coordinates any informal staff review or agency review of State information. The PM tracks the State's progress in preparing the request for an Agreement. The PM provides current information about the State's progress to other NRC staff for budget development and work planning.

3.3.2.3 <u>Initiating Contact and Interacting with Tribal Governmental Entities During the Application Process</u>

The PM contacts the Materials Safety and Tribal Liaison Branch (MSTB) branch chief to assign a Tribal liaison to identify Tribal governmental entities that may be interested in the State's application. Further discussion of the procedures for interacting with Tribal governmental entities is discussed in Appendix E of the Handbook. However, the Tribal liaisons should plan to determine the Federally recognized tribes and engage early in the process.

3.4 The Draft Application

Submitting a draft of the application package for an Agreement aids early identification of significant issues and areas where more information is needed.

3.4.1 Early Review of Legislation and Regulations

It usually requires a considerable amount of time to enact State legislation or to adopt regulations. The State should consider submitting these elements to the NRC for review well before the draft request. Early review by MSST and Office of the General Counsel (OGC) can allow time for amendments to critical legislation or regulatory provisions, if required.

3.4.2 Notification of Draft Application

When the State notifies MSST that a draft application is forthcoming, the NRC establishes a review team. SA-700 addresses timing of the notification and the composition of the review team. The PM selects a principal reviewer for each program element of the proposed Agreement materials program.

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3.4.3 Review of the Draft Application

The review team conducts a detailed review of the draft application using the evaluation criteria in Section 4.0 of the Handbook, based on the Criteria Policy Statement. The objective of the review team's review is to determine whether the Agreement materials program description addresses each of the applicable elements.

3.4.3.1 Draft Application Evaluation

Each principal reviewer evaluates their assigned program element. Other team members may help in evaluating the elements of the draft application. The evaluation should be completed within about 8 weeks (see Appendix D, Item C, of the Handbook).

3.4.3.2 Team Meeting

The review team should meet to discuss the findings of its review of the draft application. The review team should also draft a letter to the State's Program Director or designee, presenting team findings. The review team should complete its initial review, draft a comment letter on the draft request, and brief the Division Director of MSST on the review findings within 8 weeks of receipt of the draft request from the State.

3.4.3.3 Letter to Program Director

If the draft application has no major deficiencies and the MSST Division Director agrees with the review team's findings, the letter to the Program Director or designee should state that the NRC staff believes the final application is ready for submission. If the draft application has deficiencies, the letter includes the team's comments.

If the draft application has deficiencies, the review team should also hold a meeting with the State staff to discuss the information that is incomplete or needed. The team may hold additional meetings with the State staff at the State's option, following the State's receipt of the review team's letter.

The letter to the State is signed by the MSST Director or designee. As discussed in Section 3.4.3.2 above, the review team should complete its initial review and documentation within 8 weeks of receipt of the draft request from the State.

3.4.4 Periodic Conference Calls

The PM, RSAO, Branch Chief of SLPB, and the State Program Director or designee should establish a schedule of periodic conference calls. The calls should start during the early stages of the State's preparation of their draft application. Subjects of the conference calls should include progress of the review, issues identified during the review, and any additional information needed. Participants should include the PM, RSAO, and the Program Director or designee. Other NRC and State staff should participate as appropriate. The review team members for each specific program element that will be discussed should also be present during the calls. Calls should be planned for at least monthly and can be adjusted to meet the needs of the State or the review team.

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3.4.5 Meetings and Visits

The PM and the RSAO should consider a visit at the State offices to gain first-hand knowledge of the State facilities and staff. If possible, the visit should be after the State has received the draft application review letter and has had time to review the comments. This will give the State an opportunity to discuss NRC's comments in preparation for finalizing the formal application. The State Program Director or designee and senior State staff members should also visit both the NRC regional and headquarters offices. The PM and the RSAO should also coordinate and schedule meetings and visits during the State's preparation of a request, as necessary.

3.4.6 <u>Inspection and Licensing Staff Contacts</u>

State inspectors should accompany NRC inspectors during inspections of the NRC licensee facilities in the State. This helps the State inspectors to develop technical skills needed for inspections and provides knowledge about licensee's operations that will transfer under the Agreement. The State inspectors may accompany the NRC before a submission of a Letter of Intent. After the Letter of Intent is submitted, State inspectors should accompany NRC inspectors on a regular basis. The NRC inspectors should work closely with the State to establish inspection schedules. The State can also consider contacting other nearby Agreement States regarding accompanying inspectors in those States to gain additional inspection experience.

State license reviewers should work with the NRC regional license reviewers, starting at least 1 year before the anticipated effective date of the Agreement. This will help State license reviewers become more familiar with the licensing process and with the licenses that will transfer under the Agreement. The license reviewers should begin coordination at least when the Governor submits the Letter of Intent. The State can also consider contacting other nearby Agreement States to gain general licensing assistance.

The RSAO leads coordination of these activities with the regional licensing and inspection staff. The RSAO should coordinate with the PM to help resolve any issues that arise regarding these activities.

3.5 The Formal Application for an Agreement

The formal application should be a revision of the draft application package as modified to address NRC comments. The AEA requires that the Governor sign the formal request. The Governor sends a "letter of certification" with the formal application, certifying that the State has an adequate and compatible regulatory program for the specified categories of Agreement materials requested under the Agreement. The Governor addresses the letter to the Chairman of the Commission (see Appendix D, Item D, of the Handbook).

The Chairman writes to the Governor acknowledging receipt of the formal application and committing the NRC to complete a timely review (see Appendix D, Item E, of the Handbook).

In order for an Agreement to be approved under the AEA, the information supplied in an application for an Agreement must support two findings by the Commission. First, the Commission must find that the State has an Agreement materials program that is

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adequate to protect public health and safety. Second, it must also find that the program is compatible with the NRC materials program. The Commission bases its findings on the NRC staff assessment.

The staff assessment documents the review team's evaluation of the State's application package. The assessment should describe how the program satisfies the Commission's criteria. The table in the Handbook, Appendix A, shows the relationship between the program elements in Section 4.0 of the Handbook and the criteria in the Criteria Policy Statement.

3.5.1 Project Schedule Adjustment

The sample processing schedule in Appendix C of the Handbook estimates 8 weeks for the State to prepare and submit the formal application. This is an estimate of the time required based on experience. It is not a requirement. The State should submit the formal application as soon as practical following incorporation into the application of any changes resulting from the review. The PM should adjust the Project Schedule to reflect the actual date MSST receives the formal application.

3.5.2 Review of the Formal Application

The same review team that reviewed the draft application should also review the formal application. The review team conducts a detailed review of the program description information in the formal application and verifies that each comment on the draft application has been completely addressed and that there are no further questions.

3.5.2.1 Review of Program Elements

Each review team member conducts a detailed evaluation of specific program element(s) of the proposed program assigned to that member. Other team members may also help evaluate the element. Review team members may discuss their questions about the formal application directly with the State staff; however, the PM should be informed of communications with the State.

Using the evaluation criteria in the Handbook, Section 4.0, estimates the review of the formal application should take about 4 weeks.

3.5.2.2 Major Issues

A major issue is one that raises questions about the adequacy or compatibility of the proposed State Agreement materials program. The review team member(s) should notify the PM immediately upon identification of a major issue(s). The PM informs the Branch Chief of SLPB and schedules a meeting of the team to discuss the issue(s). After the meeting, the team briefs the Division Director of MSST, and other management as needed. The State Program Director or designee and Director of MSST are kept informed of the staff activity to resolve major issues.

3.5.2.3 Team Findings and Draft NRC Staff Assessment

Once the review team completes their review of the formal application and determines that the State's request satisfies all criteria given in the Criteria Policy Statement for each

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program element, the PM prepares the draft NRC staff assessment. It is estimated that this step could take up to 4 weeks (see Appendix D, Item F, of the Handbook). The review team members should concur on the findings for the program element that they reviewed and the draft staff assessment.

If the application does not satisfy the criteria given in the Criteria Policy Statement, the PM prepares comments that the State must address (see Section 3.5.3, "Transmission of Comments to the State," below).

3.5.3 Transmission of Comments to the State

If the request does not satisfy a Criteria Policy Statement criterion, the review team member prepares a draft comment. Each comment should describe the issue and, where practical, provide guidance to resolve the issue.

The PM prepares a letter transmitting its comments, if any, on the formal application. The letter is signed by the Director of MSST and addressed to the State Program Director or designee. This step is part of the review team's work discussed in Section 3.5.2.1 and Section 3.5.2.3 above.

The State should address the comments by submitting revised pages or sections to the formal application. The PM and the review team reviews the revisions submitted by the State to ensure the State addressed the NRC's comments. The PM should update the schedule as needed based on when the comments are addressed by the State.

3.5.4 Completion of the Review

When the review team concludes that all criteria in the Criteria Policy Statement are addressed, the PM completes the draft staff assessment. The PM also completes the Commission paper that contains all supporting documents including the draft *Federal Register* notice and the following documents as background: (a) draft Congressional letters; and (b) draft Federal agency letters (see Appendix D, Items G, H, I, J, and K, of the Handbook).

Procedures for the publication of the proposed Agreement, and for the approval, signing, and implementation of the final Agreement, are provided in Section V. of State Procedure SA-700.

4.0 INFORMATION NEEDED AND EVALUATION CRITERIA

This section addresses the information that the NRC needs in order to review an Agreement request and the evaluation criteria that staff will use as a baseline. This is based on the Criteria Policy Statement and includes cross references in brackets to specific criteria applicable to the topic. Additionally, references are provided to assist the State in preparing its Agreement request.

4.1 Legal Elements

The AEA does not permit the Commission to delegate its authority to the States. Under the AEA, the NRC discontinues, and the Agreement State assumes, regulatory authority over the radioactive materials specified in the Agreement. The State administers

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independent regulatory programs under State Statutes and regulations. Each State program must derive its authority from its own State law.

4.1.1 <u>Authority to Establish a Program and Enter into an Agreement</u>

State laws should provide specific elements of authority to the Agreement materials program. In 1983, the Council of State Governments published a generic model Radiation Control Act in *Suggested State Legislation*, Volume 42. States may, but are not required to, use the Suggested State Legislation as models for their own laws.

4.1.1.1 Information Needed

For all categories of materials for which the State is requesting authority, the State should submit State law that:

- a. Establishes the Agreement materials program, defines its structure, and authorizes the Governor to enter into an Agreement with the Commission.
- b. Authorizes the program to issue licenses, including the following:
 - 1. Authorizes the program to impose additional license requirements;
 - 2. Authorizes the program to give exemptions from licensing requirements;
 - 3. Authorizes the program to recognize the licenses of other jurisdictions (that is, reciprocity);
 - 4. Makes it unlawful to acquire, possess, store, use, transfer, or dispose of materials without a valid license, or to violate the conditions of a license; and
 - 5. Authorizes the program to recognize licenses transferred from the NRC under the Agreement as State licenses.
- c. Authorizes the program to adopt regulations.
 - 1. Specifies the procedures and requirements for adoption of regulations, including public participation; and
 - 2. Allows the program to impose requirements in the form of other generic legally binding requirements, such as license conditions or orders.
- d. Authorizes representatives of the program to enter premises and conduct inspections.
- e. Authorizes the program to require compliance with regulatory requirements by both licensees and unlicensed individuals.
- f. Authorizes the program to impose sanctions for violations of the regulations, orders, or license conditions.

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g. Establishes conflict of interest and ethics regulations or procedures applicable to those portions of the State radiation control program covered by the Agreement.

If the program will include jurisdiction for licensing the receipt of low-level radioactive waste (LLRW) from others for purposes of disposal, the State should submit the law that authorizes the regulation of a LLRW disposal site.

If the program will include the regulation of byproduct material as defined in Section 11e.(2) of the AEA, the State should submit the State law that authorizes the regulation of uranium and thorium milling facilities, including disposal of mill tailings.

4.1.1.2 Evaluation Criteria

The team may use the Council of State Government Suggested State Legislation (model legislation) as guidance. However, the State is not required to follow either the content or the format of the model legislation. Note that Section 8 of the model legislation covers Section 11e.(2) byproduct material and Section 9 of the model legislation covers LLRW disposal.

- a. State law must authorize the Governor to enter into an Agreement. It must also designate a radiation control agency and provide it the necessary legal authority to be effective. [Criteria number from Policy Statement: 1, 12, 19, 23, 24, 25]
- b. State law must not create duplications, gaps, or conflicts in regulation. This includes duplications, gaps, or conflicts between the State and the NRC, State agencies, or State and local agencies. The law must not seek to regulate materials or activities reserved to the NRC. [1, 2, 21, 24, 25, 28]
- c. State law must authorize issuing licenses as the means of giving the authority to possess and use Agreement materials. It should also authorize the reciprocal recognition of specific licenses issued by the NRC or other Agreement States. [12, 13, 14. 27]
- d. State law should authorize the use of license conditions to address matters unique to the licensee. The law should allow license conditions to impose additional requirements when required to protect public health and safety. If the law restricts the use of license conditions, the State should show that they can provide adequate protection under the restrictions. The protection should be at least equivalent to using license conditions and orders. [1, 12]
- e. The law should permit exemptions from licensing requirements if the exemptions do not adversely affect public health and safety. This should include exemption(s) from the requirement to obtain a license. The law should authorize exemptions from licensing substantially equivalent to the following (or such exemptions must be included in the State's regulations). [12, 28]
 - 1. Prime contractors working for the U.S. Department of Energy (DOE) at U.S. Government-owned or controlled sites;
 - 2. Prime contractors researching, developing, manufacturing, storing, testing, or transporting atomic weapons or components;

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- 3. Prime contractors using or operating nuclear reactors or other nuclear devices in a U.S. Government-owned vehicle or vessel; and
- 4. Any other prime contractor (or subcontractors) of DOE or NRC when the State and NRC jointly determine (i) that the terms of the contract provide adequate assurance that the contractor can accomplish the work without undue risk to public health and safety and (ii) that the law authorizes the exemption.
- f. The law must authorize the Agreement materials program to enforce regulations or generic legally binding requirements other than regulations. The law may authorize another agency (such as a board of health) to adopt the regulations. When appropriate, the law should provide for public participation. [19, 23]
- g. The law must authorize inspections of licensee operations to ensure compliance with regulatory requirements. It should authorize inspections of unlicensed facilities to assess the risk resulting from accidents or environmental releases of materials. The law should permit access at all reasonable times. [17]
- h. The law must provide authority to take prompt enforcement action and should provide a variety of legal sanctions. The law should provide authority to suspend licenses and to impound materials. In cases of an imminent threat to public health and safety, the law should authorize immediate suspension without prior hearing. [19, 23]
- i. The law should authorize suspension or revocation of a license for repeated or continued noncompliance. The authority to suspend or revoke a license may be conditioned on a prior administrative or judicial hearing. The program should also have authority to seek injunctive relief and refer licensees for criminal prosecution. The program should also consider authority to impose civil or administrative monetary penalties. [19, 23]

The State must resolve any questions the NRC has regarding interpretation of State law. Interpretations of State law must be provided by the State Attorney General, or other attorney designated as legal advisor to the Agreement materials program.

4.1.1.3 Additional Evaluation Criteria for Low-Level Waste Agreements

The law must authorize appropriate restrictions on land ownership and use of sites used for disposal of LLRW for an indefinite period after closure of the site. [9b]

4.1.1.4 Additional Evaluation Criteria for 11e.(2) Byproduct Material Agreements

The law should clearly authorize the Agreement materials program to carry out the requirements of UMTRCA, as amended.

Specifically, the law should:

a. Authorize the Agreement materials program to regulate 11e.(2) byproduct material;
 [29]

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- b. Authorize the Agreement materials program to require licensees to provide a financial surety arrangement. The arrangement should be such that sufficient funds will be available to cover the costs of both decommissioning and long-term surveillance and maintenance; [29]
- c. Require the program, before issuing an 11e.(2) byproduct material license, to do the following:
 - 1. Give notice of the proposed licensing action and accept written comments during a public comment period; [29]
 - 2. Prepare a written analysis of the impact on the environment of the licensed activity; [31]
 - 3. Hold a public hearing with a transcript and cross examination; [29]
 - 4. Prepare a written decision based on evidence presented during the public comment period. The decision must be subject to judicial review; and [29]
 - 5. Ban major construction before the completion of the written environmental analysis.
- d. Require the Agreement materials program to provide an opportunity for public participation through written comments or public hearings during rulemaking. The law must also make rules subject to judicial review; and [29]
- e. Require the Agreement materials program, before terminating an 11e.(2) byproduct material license, to do the following:
 - Transfer funds collected for decommissioning and long-term surveillance and maintenance to the United States. The law must require this transfer when custody of the disposal site transfers to the United States. Funds transferred must include all funds collected from a licensee or its surety. The only exceptions are funds collected for decommissioning if it is completed; [29]
 - 2. Choose whether or not to take title to the disposal site and byproduct material; and [29]
 - 3. Obtain a determination from the Commission that all applicable standards are satisfied. [30]

The State law must consider the authorities reserved to the NRC under UMTRCA (see 10 CFR 150.15(a)), including the authority to: [30]

- a. Establish minimum standards governing reclamation, long-term surveillance or maintenance, and ownership of the 11e.(2) byproduct material;
- b. Determine, before the termination of a license, that the licensee has complied with decontamination, decommissioning and reclamation standards, and ownership requirements for sites at which 11e.(2) byproduct material is present;

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- c. Require, before termination of a license for 11e.(2) byproduct material or for any activity that results in the production of such material, that the title to the 11e.(2) byproduct material and the disposal site are transferred to the Federal government (or the State at the option of the State, provided the State exercises the option before termination of the license);
- d. Require monitoring, maintenance, and emergency measures after the license is terminated as may be necessary to protect the public health and safety for those materials and property for which the State has assumed custody;
- e. Permit use of the surface or subsurface estate, or both, of the disposal site land transferred to the United States or the State; and
- f. Exempt land ownership transfer requirements of Section 83(b)(1)(A) of the AEA.

4.1.1.5 References

- a. Criteria Policy Statement, criteria 1, 2, 9b, 12, 13, 14, 17, 19, 21, 23, 24, 25, 27,28, 29, 30, and 31.
- b. Council of State Governments Suggested State Legislation, 1983, Volume 42.
- c. Agreement State Program Policy Statement (82 FR 48535, 10/18/17).

4.1.2 Organization of the Proposed Program

The organization of an Agreement materials program provides the basic organizational structure and resources to conduct the program activities. The Agreement materials program organization thus influences the ability of the program to protect public health and safety against radiation hazards.

4.1.2.1 Information Needed

The State should submit a concise narrative description of the materials program. The narrative should include:

- a. A brief history of radiation control in the State;
- b. A description of the current structure of the program, including regional offices;
- c. Individual discussions of each of the program elements in Section 4.0 of the Handbook; and
- d. For each program element, cross references to the pertinent portions of the States' supporting documentation for the application.

The State should submit organization charts. The charts should show:

- a. All organizational levels between the Governor and the Program Director or designee;
- b. The organizational structure and staff of the Agreement materials program; and

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c. Regional offices and staff, if any.

The State should submit a copy of each Memorandum of Understanding (MOU) that will affect the Agreement materials program.

4.1.2.2 Evaluation Criteria

The organization of the Agreement materials program must cover all of the program elements in this Handbook, Section 4.0. For this criterion, it is only necessary to show that responsibility for each program element is assigned to a unit of the organization. [1]

The State may divide the program elements among separate agencies. If State law does not specify the division, the State should describe how it divides the regulatory responsibility. The State should submit copies of MOUs describing the responsibilities of each agency. MOUs should also include a discussion of efforts that will be made to assure cooperation and to ensure an orderly and consistent regulatory approach between the separate agencies. The organization charts should clearly show the position of the Agreement materials program within the State government structure. [1, 24, 33]

The Agreement materials program organization charts should show both the technical staff and support staff positions. They should show positions assigned to the program both full-time and part-time. If the Agreement materials program uses the resources of another agency, the Agreement materials program narrative description should detail the relationship. The narrative description should also discuss any use of contract services and advisory bodies. (NOTE: the criteria for evaluation of the technical staff are in Section 4.6.1 of the Handbook.) [1]

4.1.2.3 References

- a. Criteria Policy Statement, criteria 1, 24, and 33
- b. Program descriptions of existing Agreement States (from IMPEP reports or previous Agreement requests)
- c. NRC Management Directive 5.9, Adequacy and Compatibility of Program Elements for Agreement State Programs.
- d. SA-200

4.1.3 Content of the Proposed Agreement

Under an Agreement, a State may assume the authority to regulate any one or more of the following categories of materials within the State:

- a. Byproduct materials as defined in section 11e.(1) of the AEA;
- b. Byproduct materials as defined in section 11e.(2) of the AEA;
- c. Byproduct materials as defined in section 11e.(3) of the AEA;

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- d. Byproduct materials as defined in section 11e.(4) of the AEA:
- e. Source materials; and/or
- f. Special nuclear materials, in quantities not sufficient to form a critical mass.

In addition, under an Agreement, a State may assume the specific authority to conduct one or more of the following activities, which otherwise remain under the NRC jurisdiction:

- a. The regulation of the land disposal of byproduct, source, or special nuclear waste materials received from other persons;
- b. The evaluation of radiation safety information on sealed sources or devices containing byproduct, source, or special nuclear materials and the registration of the sealed sources or devices for distribution, as provided for in the regulations or orders of the Commission.

MD 5.8 contains a standard Agreement format and text. The standard Agreement is based on a state's assumption of all categories of materials. Agreements that do not include a state's assumption of all of the categories should delete the appropriate provisions as shown in MD 5.8, Handbook. If a State requests only a subcategory of Agreement material within a category, the State must submit detailed information as to why this request is needed and supporting justification. Staff must obtain Commission approval for any such requests prior to submittal of the draft request or application.

4.1.3.1 Information Needed

The State should submit a proposed Agreement. The Agreement should contain the categories of materials and specific authorities that the State wants to regulate.

The Agreement should follow the format and content of the standard Agreement in the Exhibit of MD 5.8, Handbook. If the State does not follow the standard Agreement, it should explain why.

The State should provide detailed information regarding the intent of this difference from the standard Agreement and the expected outcome.

4.1.3.2 Evaluation Criteria

The proposed Agreement must be consistent with the purpose of Section 274 of the AEA. It must promote an orderly pattern of regulation. Nothing in it may create a duplication, conflict, or gap in the nationwide program for the regulation of materials. [27]

The Agreement should be consistent with the format and content of the standard Agreement in MD 5.8. The State should delete or modify articles in the standard Agreement only as shown in MD 5.8. Any other change requires additional information describing why the change is needed and supporting justification. Such changes will require separate approval by the Commission. The information submitted must provide a basis for the Commission to approve the change. [27]

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Under an Agreement, a state must assume regulatory authority over all licensees in each category of materials listed in the Agreement. If the Agreement does not include all categories of materials and specific authorities, it should include Article III of the standard Agreement (see the exhibit to the Handbook in MD 5.8). [27]

4.1.3.3 References

- a. Criteria Policy Statement, criterion 27.
- b. NRC MD 5.8.

4.2 Regulatory Requirements Program Elements

A State may adopt regulatory requirements in a State specific format or adopt the NRC regulations by reference. Alternately, the State may use the *Suggested State Regulations (SSR)*, published by the Conference of Radiation Control Program Directors, as a model for its regulations.

4.2.1 Regulations or Legally Binding Requirements

The regulatory requirements needed for compatibility are those required for 1) the standards for the protection against radiation; 2) cross jurisdiction boundaries; and 3) the orderly pattern of regulation. The State's proposed regulations must satisfy the criteria for compatibility categories A, B and C, respectively. The criteria are given in the Handbook to MD 5.9. A list of program elements and their compatibility designation is provided in SA-200, Appendix A, for all required regulations in Parts 19, 20, 30 – 39, 40, 61, 70, 71, and 150.

The state must adopt program elements that embody the basic health and safety aspects of the NRC's program elements because of particular health and safety significance. These are the NRC program elements that are not required for compatibility but have been identified as having a particular health and safety role in the regulation of agreement material within the State. The State should adopt program elements based on those of the NRC that embody the essential objective of the NRC program elements. Examples are given in the Handbook to MD 5.9.

4.2.1.1 Information Needed

The State should submit its regulations or generic legally binding requirements required for adequacy and compatibility. The State should submit its regulations or generic legally binding requirements for all categories of material being requested under the Agreement. The State should also submit a "cross-walk" that provides the equivalent State regulation for each NRC regulation.

If the State wants to regulate the disposal of LLRW at a land disposal site, it should submit its regulations equivalent to 10 CFR 61.41, 61.42, and 61.43. If a State does not plan to regulate the disposal of LLRW at a land disposal site, it still needs to submit its regulations equivalent to 10 CFR 61.55, 61.56, and 61.57 regarding the requirements for classification, characteristics, and labeling of radioactive waste.

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If the State wants to regulate uranium and thorium mill tailings, it should submit a copy of its requirements equivalent to 10 CFR Part 40, Appendix A.

4.2.1.2 Evaluation Criteria

The State regulations must satisfy the criteria for all adequacy and compatibility categories. The criteria are given in the Handbook to MD 5.9. A list of program elements and their compatibility or adequacy designations is provided in State Agreement Procedure SA-200, Appendix A. Appendix A includes a link to a table with the adequacy or compatibility designation assigned to each regulation required in Parts 19, 20, 30 – 39, 40, 61, 70, 71, and 150. Additional guidance for submitting State regulations for NRC review is provided in SA-201. [1, 2, 3, 4, 5, 6, 7, 8, 9a, 10, 11, 22, 32]

The State's regulations must apply to all categories of materials covered by the Agreement. The regulations should also apply to all other sources of radiation regulated by the State and must require consideration of the total occupational dose to individuals. [2, 4]

The State adopts the NRC regulations by reference, the State rule should disclaim any intent to regulate materials or activities over which the NRC retains jurisdiction. If the State adopts generic legally binding requirements other than regulations, the program staff should apply generic legally binding requirements consistently. The requirements should not confuse either the licensees or the regulatory program staff. The State must show that the alternative requirements are legally binding under State law. [23]

4.2.1.3 References

- a. Criteria Policy Statement, criteria 1, 2, 3, 4, 5, 6, 7, 8, 9a, 10, 11, 22, 23, and 32
- b. MD 5.9
- c. SA-200
- d. SA-201
- e. Applicable sections of 10 CFR Parts 19, 20, 30, 31, 32, 33, 34, 35, 36, 37, 39, 40, 61, 70, 71, and 150
- f. Conference of Radiation Control Program Directors, Suggested State Regulations

4.3 Licensing Program Elements

After reviewing the State's technical procedures, the review team should determine whether the technical licensing procedures are thorough, complete, consistent, and of acceptable technical quality to address health and safety. The State's procedures should include requirements for pre-licensing verification and for ensuring enhanced security requirements are in place prior to issuing a license, where these requirements are necessary. A State may adopt technical licensing procedures modeled on the NRC procedures or those used by an existing Agreement State.

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Nontechnical administrative procedures are usually not key contributors to program performance. The review team usually reviews samples of these procedures. The team only needs to conclude that the State has written administrative procedures for licensing and that they contain no obvious major defects.

4.3.1 Procedures for the Technical Evaluation of Proposed Uses of Radioactive Material

The technical procedures address the radiation safety issues necessary for the safe and secure storage, possession, and use of the licensed materials. They do not address license fees, license file maintenance, or other materials program administrative issues.

4.3.1.1 Information needed

The State should submit its technical licensing procedures. If not part of the procedures, the State should include standard review plans, checklists, and licensing guides. If the State intends to use the NUREG-1556 series of consolidated licensing guidance, the State does not need to submit these procedures for review.

4.3.1.2 Evaluation criteria

The technical procedures should be detailed and complete so that State program staff can perform a comprehensive evaluation of the application. The procedures should cover each type of license (by program code) for which an NRC licensee will transfer to the State. Guidance documents, or copies of the procedures containing guidance, should be available to license applicants. [1, 13, 14, 15, 20, 23]

The procedures should:

- a. Address assessment of the applicant's facilities and safety equipment, training, and experience in the use of the materials for the purpose requested, and proposed managerial controls; [7,13, 14,]
- b. Address security requirements for radioactive materials with Part 37 quantities of concern and pre-licensing visits for the following:
 - 1. New entities that do not have an existing Agreement State or NRC license;
 - 2. Licensees changing ownership to an unknown entity; or
 - 3. Licensees that are significantly expanding the size or scope of their existing license. [1, 13]
- c. Provide for information exchange between the program's inspection staff and licensing staff; and [1]
- d. Specify the required qualifications of license reviewers for each license program code. Alternately, the procedures may reference a staff qualification plan. [20]

State procedures should provide guidance for the evaluation of technical issues in license applications. The issues evaluated should include places and conditions of storage, and places and conditions of use and decommissioning of facilities and equipment. Evaluation of the places of storage and use should address environmental considerations. State procedures for evaluating the conditions of storage and use should

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address safety equipment and security against unauthorized removal. Procedures for evaluating the conditions of use should address the following: [8, 13, 14]

- a. Qualification of users;
- b. Licensee operating and emergency procedures;
- c. Appropriate surveys;
- d. Personnel monitoring under the close supervision of technically qualified individuals;
 and
- e. Preparations for transport.

Procedures for evaluating decommissioning should address decontamination, disposal, and any restrictions on the future uses of the property. The procedures should also address funding and sureties. [9a, 13]

In licensing research and development, medical uses, or other activity involving multiple uses of materials, the State may issue broad scope licenses without evaluating each specific use. [13]

The team may use the NUREG-1556 series of consolidated guidance and associated guidance to evaluate the State procedures. However, the NRC does not require States to adopt the NRC procedures and consolidated guidance. The State procedures should provide the same level of detail as the equivalent NRC procedure. The State's procedures should address all significant technical issues.

4.3.1.3 References

- a. Criteria Policy Statement, criteria 1, 7, 8, 9a, 13, 14, 15, 20, and 23
- b. MD 5.6
- c. SA-104
- d. NUREG-1556, Consolidated Guidance About Materials Licenses (all volumes)
- e. Decommissioning references: NUREG-1757, Consolidated Decommissioning Guidance; NUREG-1575, Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM)

4.3.2 <u>Procedures for the Evaluation of Radiation Safety Information on Sealed Sources and</u> Devices and Registration for Distribution

Sealed sources and devices containing sealed sources are commonly manufactured in one jurisdiction and used in others. Because of the transboundary implications, safety evaluations of the sources and devices should be conducted according to similar procedures nationwide. If the State is requesting authority to perform reviews of sealed source and device applications, the State should address the information in this section.

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4.3.2.1 Information Needed

The State should submit its procedure for evaluating radiation safety information for sealed sources and devices. If the State will use contractor assistance in the evaluation, its procedures for the quality assurance of contractor performance should be submitted.

4.3.2.2 Evaluation Criteria

The State procedures should be essentially identical to the equivalent NRC procedures with respect to: [13, 23]

- a. Technical issues evaluated;
- b. Technical criteria used to decide the adequacy of the safety information provided;
- c. Use of a concurrence review; and
- d. Content and format of the registration sheets.

For additional criteria, see the Handbook to MD 5.6, Non-Common Performance Indicator – Sealed Source and Device Evaluation Program. The review team may use the NRC's consolidated guidance about applications for Sealed Source & Device evaluation and registration in NUREG-1556, Volume 3, as a guide.

4.3.2.3 References

- a. Criteria Policy Statement, criteria 13 and 23
- b. NUREG-1556, Volume 3, Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration
- c. MD 5.6
- d. SA-108

4.3.3 <u>Procedure for Conducting the Evaluation of a Regulatory Program for a Low-Level</u> Radioactive Waste Land Disposal Site

The regulatory program for a commercial land disposal site for LLRW has significant health and safety implications. It requires substantial resources beyond those needed for conducting routine licensing evaluations and inspections. If the State will regulate a site, it should have the resources and procedures to conduct a site license evaluation and inspection program.

If there is no reasonable expectation of an application for a license being submitted in the foreseeable future, the State may assume the authority without having the resources and procedures in place. In this case, information showing that the State has the authority to acquire the resources and adopt appropriate procedures before undertaking the evaluation of an application, accompanied by the conceptual description of the program, is sufficient.

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4.3.3.1 Information Needed

The State should submit a concise description of its program for regulating a commercial land disposal site. The description should include a discussion of the resources available to the program. The State should also submit its procedures for conducting the technical licensing evaluation and inspection program. If the State proposes to use contractor assistance in the evaluation, procedures for the quality assurance of contractor performance should be submitted.

4.3.3.2 Evaluation Criteria

The State procedures should contain the same level of detail as the NRC procedures in:

- a. NUREG-1199, Standard Format and Content for the Review of a License Application for a LLRW Disposal Facility;
- b. NUREG-1200, Standard Review Plan for the Review of a License Application for a Low- Level Radioactive Waste Disposal Facility;
- c. NUREG-1274, Review Process for LLRW Disposal License Applications Under LLRW Policy Amendments Act; and
- d. NUREG-1300, Environmental Standard Review Plan for the Review of a License Application for a Low-Level Waste Disposal Facility [This document is for the NRC staff use in conducting environmental reviews of applications for LLRW disposal facilities. The State might find the information useful in submitting its program information for LLRW, if requesting this authorization.].

However, the NRC does not require the procedures to be identical if they address all significant objectives. The State procedures should be consistent with the NUREG with respect to the following: [9b, 13]

- a. Technical issues evaluated;
- b. Qualifications of the personnel performing evaluations;
- c. Assuring the quality of the licensing action; and
- d. Inspection procedures, including security related inspections.

4.3.3.3 References

- a. Criteria Policy Statement [as amended in July 21, 1983, 48 FR 33376)], criteria 9b and 13
- b. NUREG-1199
- c. NUREG-1200
- d. NUREG-1300

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- e. NUREG-1274
- f. MD 5.6, Non-Common Performance Indicator LLRW Disposal Program
- g. SA-109

4.3.4 <u>Procedure for Conducting the Evaluation of a Regulatory Program for 11e.(2) Byproduct Material Including Uranium or Thorium Milling Facilities</u>

The regulatory program for 11e.(2) byproduct material including a uranium or thorium milling facility has significant health and safety implications. It requires substantial resources beyond those needed for conducting routine licensing evaluations and inspections. If the State will regulate a site, it should have the resources and procedures to conduct a site evaluation and inspection, even if the NRC will transfer an established site.

If the NRC will not transfer a licensed site or an application for a site license, and there is no reasonable expectation of an application for a license being submitted in the foreseeable future, the State may assume the authority without having the resources and procedures in place. In this case, information showing that the State has the authority to acquire the resources and adopt appropriate procedures before undertaking the implementation of a program, accompanied by the conceptual description of the program, is sufficient.

4.3.4.1 Information Needed

The State should submit a concise description of its program for regulating 11(e).2 byproduct material. The description should include a discussion of the resources available to the program. The State should also submit its procedures for conducting the technical licensing evaluations and inspections. If the State will use contractor assistance in the evaluation, it should submit procedures for assuring the quality of contractor performance.

4.3.4.2 Evaluation Criteria

The State procedures should contain the same level of detail as the equivalent NRC procedures. However, the NRC does not require the procedures to be identical to the NRC's if the State's procedures address all significant technical issues. The State procedures should be consistent with the NRC procedures with respect to the following: [29, 30, 31, 32, 33, 34, 35]

- a. Technical issues evaluated;
- b. Qualifications of the personnel performing evaluations;
- c. Ensuring the quality of the licensing action; and
- d. Inspection procedures, including security related inspections.

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4.3.4.3 References

- a. Criteria Policy Statement, criterion 29, 30, 31, 32, 33, 34, 35
- b. Uranium Recovery Regulations, Guidance, and Communications

The number of documents is too extensive to list in this document, but the relevant information can be found at https://www.nrc.gov/materials/uranium-recovery.html

- c. MD 5.6, Non-Common Performance Indicator Uranium Recovery Program
- d. SA-110

4.3.5 Procedures for Assuring the Technical Quality of Licenses

A secondary review of license applications is beneficial for quality assurance purposes and can be used to evaluate the completeness of initial reviews of license applications. Peer and supervisory review are commonly used. Larger programs may use a committee to conduct reviews of selected application evaluations recently completed. Other forms of effective quality assurance programs are acceptable.

4.3.5.1 Information Needed

The State should submit its procedures that address peer review, supervisory review, and any other method to assure the quality of licensing actions.

4.3.5.2 Evaluation Criteria

The State should have written licensing procedures that provide a standard process for reviewing the quality of licensing actions. The procedures should reflect the organization of the State program and any special requirements of State law. [1, 13]

4.3.5.3 References

- a. Criteria Policy Statement, criteria 1 and 13
- b. MD 5.6, Common Performance Indicator 4 Technical Quality of Licensing Actions
- c. SA-104

4.3.6 Administrative Licensing Procedures

The routine operation of the program requires administrative processing of licenses beyond the technical evaluations. Written procedures describing the administrative processing steps are useful to assure that all procedural requirements are completed. They may become critical if there is an unexpected turnover of senior staff.

On the effective date of the Agreement, the NRC will electronically transfer to the State those NRC licenses that the State will regulate under the authority of its Agreement. The NRC and the State must make appropriate arrangements so that there will be no

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interference with or interruption of licensed activities or the processing of license applications because of the transfer. Licensees must be able to continue their licensed activities without interruption upon transfer of the license on the effective date of the Agreement. The licensee will continue under the State regulatory framework at this point. The NRC is committed to transferring complete license files that the State can use in issuing its own license to licensees. The State can recognize the transferred NRC licenses, including licenses under timely renewal, as State licenses. Those licenses then continue in effect until they are replaced by licenses issued by the State. The State may decide to use the NRC's Web Based Licensing (WBL) system for its licensing program. Prior to the Agreement's effect date, the State should receive training and become familiar with WBL to facilitate an efficient transfer of authority over the regulated community.

4.3.6.1 Information Needed

The State should submit its administrative procedures for licensing. The procedures should address the following:

- a. Receipt of licensing actions;
- b. Timely renewal notifications;
- c. Assignment of licensing actions to technical evaluators;
- d. License document preparation;
- e. Tracking of action progress;
- f. The signing of completed licenses;
- g. Transmittal of the signed license to the licensee; and
- h. Maintenance of license files.

The State should submit procedures for ensuring the continued validity of licenses affected by the Agreement. The State should have procedures to receive, store, and regulate the licenses as State licenses. The transfer should produce the least interference with licensed activities or the processing of license applications, as is practical.

4.3.6.2 Evaluation Criteria

The State should have program specific written procedures to guide licensing program staff. The procedures should reflect the program organization and any special requirements of State law (i.e., who can sign licenses). Since these procedures do not require a thorough review, the team may review a selected sampling of the procedures instead. [1, 13]

The State must provide a statement as to how it will handle the transferred licenses from the NRC. Often, a State will have statutory authority to accept the NRC licenses as State

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licenses, with all legal authority under the State law, until the State converts the NRC license to a State license. [25]

4.3.6.3 References

a. Criteria Policy Statement, criteria 1, 13, and 25

4.4 Inspection Program Elements

A State may adopt technical inspection procedures modeled on Inspection Manual Chapter 2800 or the procedures of an existing Agreement State.

Nontechnical administrative procedures, such as a procedure for assigning inspections to inspectors, are usually not key contributors to program performance. The review team usually reviews samples of these procedures. The team only needs to conclude that the State has written administrative procedures for inspections, and that they contain no obvious major defects.

4.4.1 Procedures for Inspecting Facilities Where Radioactive Material is Stored or Used

The technical inspection procedures should address the following areas:

- a. Scheduling of inspections and the different kinds of inspections (routine, reactive, reciprocity, security, etc.);
- b. Inspection frequencies, including information on conducting pre-licensing inspections;
- c. The format and guidance for inspection reports;
- d. Performance of inspections, including performance-based criteria;
- e. Notification to licensees of results and whether or not the licensee is in compliance; and
- f. State field instrumentation and laboratory analysis, including calibration and quality assurance.

The technical procedures should not address administrative matters, such as inspection fees.

4.4.1.1 Information Needed

The State should submit inspection procedures, including inspection report formats, checklists, and status reports. Procedures submitted should cover all NRC license program codes of licensees that will transfer to the State. The State should also submit its priority schedule for inspections by program code and its schedule for reciprocity inspections.

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4.4.1.2 Evaluation Criteria

The State should perform inspections following written procedures that address inspection activities appropriate to the category of licensee being inspected. [1, 16, 18, 36]

The State should correlate inspection frequency to the amount and kind of material and type of operation licensed. Routine, initial, and reciprocity inspections should not be less frequent than NRC inspections as listed in Inspection Manual Chapter 2800. [16]

Inspection procedures should provide for information exchange between the inspection staff and the licensing staff, as appropriate. [1]

The procedures should provide guidance to the State program staff on the use of both field and laboratory instrumentation. This instrumentation is used to evaluate the licensee's control of materials and to verify the licensee's measurements. The State should submit a list of its instrumentation for review. The procedures should include procedures on instrument calibration. [16, 36]

If the Agreement covers Section 11(e).2 byproduct material, the procedures should also: [36]

- a. Provide the capability for quantitative and qualitative analysis of radionuclides associated with natural uranium and its decay chain, primarily U-238, Ra-226, Th-230, Pb-210, and Rn-222, in a variety of sample media such as will be encountered from an environmental sampling program.
- b. Provide analysis and data reduction from laboratory analytical facilities within 30 days of submittal. State acceptability of quality assurance programs should be established for the analytical laboratories. The State should make arrangements to participate in the Environmental Protection Agency quality assurance program for laboratory performance.
- c. Provide arrangements for a large number of samples in a variety of sample media resulting from a major accident to be analyzed in a time frame that will allow timely decisions to be made regarding public health and safety.

The State should notify licensees of the results of inspections in a short time period, typically within 30 days. [18]

The team may use the NRC inspection procedures as guidance to evaluate the State inspection procedures. The State procedures should provide a similar level of detail as the equivalent NRC procedure. However, the procedures are not required to be the same as the NRC's procedures as long as they address all significant technical issues. The NRC does not require States to adopt the NRC procedures.

4.4.1.3 References

- a. Criteria Policy Statement, criteria 1, 16, 18, and 36
- b. MD 5.6, Common Performance Indicator Status of Materials Inspections

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- c. MD 5.6, Common Performance Indicator Technical Quality of Inspections
- d. SA-101
- e. SA-102
- f. NRC Inspection Manual Chapters (IMC)
 - 1. NRC IMC 2602, Decommissioning Oversight and Inspection Program for Fuel Cycle Facilities and Materials Licensees
 - 2. NRC IMC 2800, Materials Inspection Program
 - 3. NRC IMC 2801, Uranium Mill 11e.(2) Byproduct Material Disposal Site and Facility Inspection Program
- g. NRC inspection procedures numerous inspection procedures in the "IP 8XXXX" series related to different byproduct material uses, transportation, uranium mill site decommissioning, etc. These inspection procedures can be found on the NRC public website, https://www.nrc.gov/reading-rm/doc-collections/insp-manual/index.html. The number of documents is too extensive to list in this document.

4.4.2 Procedures for Assuring the Technical Quality of Inspections and Inspection Reports

Secondary reviews of inspection reports are beneficial for quality assurance purposes and can be used to evaluate the accuracy and integrity of the inspection process. Peer and supervisory review are commonly used. Larger programs may use a committee to conduct reviews of selected inspections recently completed. Other forms of effective quality assurance programs are acceptable.

4.4.2.1 Information Needed

The State should submit its procedures addressing peer review, supervisory review, and any other method to ensure the quality of inspections and inspection reports.

4.4.2.2 Evaluation Criteria

The State should have written procedures to guide program staff. The NRC does not have a preference for any particular format or method. The procedures should reflect the organization of the State program and any special requirements of State law. [1, 16]

4.4.2.3 References

- a. Criteria Policy Statement, criteria 1 and 16
- b. MD 5.6, Common Performance Indicator 3 Technical Quality of Inspections
- c. SA-102
- d. NRC IMC 2602
- e. NRC IMC 2800

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f. NRC IMC 2801

4.4.3 Administrative Procedures for Inspections

The routine operation of the program requires administrative processing of an inspection report after the inspector has written it. Written procedures describing the administrative processing steps are useful to ensure that all procedural requirements are completed. They may become critical if there is an unexpected turnover of senior staff.

4.4.3.1 Information Needed

The State should submit its inspection program administrative procedures.

4.4.3.2 Evaluation Criteria

The State should have program specific written procedures. The procedures should reflect the organization of the State program and any special requirements of State statute (i.e., public disclosure or confidentiality). [1]

Because these procedures do not require a thorough review, the team may review a selected sampling of the procedures instead.

4.4.3.3 References

- a. Criteria Policy Statement, criterion 1
- b. NRC IMC 2602
- c. NRC IMC 2800
- d. NRC IMC 2801

4.5 Enforcement Program Elements

A State may adopt enforcement procedures modeled on the NRC procedures, those used by another Agreement State, or the State's existing enforcement program. The routine procedures include a notice of the violation to the licensee. Escalated enforcement procedures supplement routine enforcement procedures and are for serious or repeated violations.

4.5.1 Routine Enforcement Procedures

Routine enforcement procedures describe the actions the program takes in response to a violation of a regulatory requirement that is not serious in nature and is not a repeated violation.

4.5.1.1 Information Needed

The State should submit its procedures for routine enforcement.

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4.5.1.2 Evaluation Criteria

The State should have procedures for ensuring the fair and impartial administration of regulatory law. They should scale the actions to the seriousness of the violation. [23]

The procedures should establish standard methods of communicating sanctions to the licensee. The State should give written notice using standardized wording and format. Legal counsel should review the wording and format. [18, 19]

The procedures should include a means for tracking the completion of enforcement actions.

4.5.1.3 References

- a. Criteria Policy Statement, criteria 18, 19, and 23
- b. NRC Enforcement Policy [available on the NRC public website at www.nrc.gov]
- c. NRC IMC 2602
- d. NRC IMC 2800
- e. NRC IMC 2801

4.5.2 Escalated Enforcement Procedures

For serious or repeated violations of regulatory requirements, the program should use escalated enforcement. Escalated enforcement actions usually supplement the routine actions.

Escalated enforcement actions may include:

- a. Administrative or civil monetary penalties;
- b. Modification, suspension, or revocation of the license; and
- c. Referral for criminal prosecution.

4.5.2.1 Information Needed

The State should submit its procedures for escalating enforcement actions.

4.5.2.2 Evaluation Criteria

The State should scale the sanctions in escalated enforcement cases to the seriousness of the violation. The sanctions should be more severe than routine enforcement. [19, 23]

The procedures should address notifying the licensee of proposed escalated enforcement actions. The notice should be in writing, using standard wording and format when practical. [18, 19]

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The enforcement program element manager, or higher, should sign notices of escalated enforcement. [23]

Escalated enforcement actions should be coordinated with legal counsel. [19]

4.5.2.3 References

- a. Criteria Policy Statement, criteria 18, 19, and 23
- b. NRC Enforcement Policy [available on the NRC public website at www.nrc.gov]
- c. NRC IMC 2602
- d. NRC IMC 2800
- e. NRC IMC 2801

4.6 Technical Staffing and Training Program Elements

The State should adopt technical staffing standards similar to the NRC's standards. The State may adopt training and qualification procedures modeled on the NRC's procedures in NRC IMC 1248, Formal Qualifications Program for Federal and State Material and Environmental Management Programs.

To evaluate complex cases, the program staff may need to hire consultants or use staff from other State agencies with needed expertise.

4.6.1 <u>Technical Staff Organization</u>

The State should conduct an analysis of the expected workload and establish an appropriate staffing plan. The analysis should consider the number, distribution, and sizes of the licensees that will transfer under the Agreement. Sample forms for a staffing analysis are in Appendix B of the Handbook.

The staffing analysis should also consider if the State will perform radiation safety reviews of sealed sources and devices containing radioactive material and register the sealed sources or devices for distribution; license a LLRW commercial land disposal site; license uranium or thorium recovery facilities subject to the requirements of UMTRCA; license major manufacturers, universities with major research programs, or other large scale materials users; or will need to perform increased controls inspections on affected licensees.

4.6.1.1 Information Needed

The State should submit its program staffing plan, including organization charts. The staffing plan should show the number of staff members assigned to specific responsibilities, such as license review and inspection and for each major category of licensee. It should estimate the workload for the licensees that will be transferred to the State and the other duties of the program.

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4.6.1.2 Evaluation Criteria

The State is not required to use the sample forms in Appendix B of the Handbook. If used, the State should modify the forms as needed to reflect the mix of license programs that the State will regulate.

The State must staff the program with enough qualified personnel. The staff must consist of at least two technical staff. [20]

The NRC does not have a specific requirement for the number of staff required, but the experience of existing Agreement States should be considered. Depending on training and experience, Agreement State programs typically employ 1 to 1.5 technical staff members per 100 active licenses. Waste disposal sites or uranium mills require additional staff. The distribution of staff should be based on workload estimates that are consistent with the NRC and other Agreement State programs experience. [20, 34]

The State workload estimate should be based on the State's organization, policies, practices, and procedures. The State should not create a staffing plan based solely on the NRC staffing plan. [20]

4.6.1.3 References

- a. Criteria Policy Statement, criteria 20 and 34
- b. NRC IMC 1248
- c. NRC MD 5.6, Common Performance Indicator Technical Staffing and Training
- d. NRC/OAS Training Working Group, "Recommendations for Agreement State Training Programs" (ML101050505)
- e. SA-103

4.6.2 Formal Qualification Plan

The ability to conduct an effective material program depends on having enough trained and experienced staff members. The state should develop a formal qualification plan to address training of staff. In addition, a key to this process is having strategies in place to address staff retirements, promotions, and departures.

4.6.2.1 Information Needed

The State should submit its position descriptions and its qualification plan for formal qualification of technical staff members.

4.6.2.2 Evaluation Criteria

Each technical staff position should require a bachelor's degree in the physical or life sciences or in engineering. An equivalent combination of education and experience may substitute for the degree. [2, 34]

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The program should have a written qualification plan. It should address job specific training and experience. The plan should specify the qualification procedures, including times for completing requirements. It should address the credentialing of individuals qualified to work independently. The plan should provide for interim qualification and certification by the State Program Director or designee. IMC 1248 may be used as general guidance. [20, 34]

4.6.2.3 References

- a. Criteria Policy Statement, criteria 2, 20, and 34
- b. NRC MD 5.6, Common Performance Indicator Technical Staffing and Training
- c. NRC IMC 1248
- d. SA-103

4.6.3 Qualifications of Current Technical Staff

The program staff qualifications should cover both routine functions and emergency cases. The distribution of staff qualifications and the distribution of licensees transferred should match. For example, there should be enough inspectors qualified to inspect industrial radiography licensees that a backlog of industrial radiography inspections will not develop.

4.6.3.1 Information Needed

The State should submit the resume of each current member of the technical staff. The resume should, at a minimum, show the educational level, experience, and any specialized training.

For staff members admitted into training courses not yet completed, submit the course name or description and scheduled dates. For each current staff member, identify the individual's qualifications (including interim qualifications) under the State's written qualification plan.

4.6.3.2 Evaluation Criteria

Except for some junior positions, all staff members should meet the program's own qualification requirements. [20, 34]

The review team may consider the State's experience working with NRC inspectors and license reviewers. It may also consider experience regulating non-Agreement materials and machine-produced sources of radiation. [20, 34]

4.6.3.3 References

- a. Criteria Policy Statement, criteria 20 and 34
- b. NRC MD 5.6, Common Performance Indicator Technical Staffing and Training
- c. NRC IMC 1248

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4.7 Event and Allegation Response Program Elements

A State may adopt event and allegation response procedures modeled on the NRC procedures, or those used by another Agreement State. The procedures for reporting events to the NRC should be modeled on SA-300. SA-400 provides information on the processes for management of allegations.

4.7.1 Procedures for Responding to Events and Allegations

The Agreement materials program must have written procedures for responding to materials events within the State. The response capability may be part of another organization, such as a response organization for fixed nuclear facilities. However, response to materials events is still the responsibility of the materials program under the Agreement. The NRC has established the National Materials Event Database (NMED) for materials events, including incidents, accidents, and medical events. The Agreement materials program should have written procedures for reporting events to the NRC, its NMED contractor, and to the NRC Operations Center for those events requiring immediate or 24-hour notifications.

The program should have written procedures for responding to allegations of violations of regulatory requirements. The program does not need to have investigatory capability within the program or its parent agency if the allegations are deliberate or criminal in nature. However, the program's procedures should include steps for contacting appropriate authorities when needed.

4.7.1.1 Information Needed

The State should submit its procedures for responding to events and allegations.

4.7.1.2 Evaluation Criteria

Event response procedures should be consistent with, but need not be identical to, the NRC procedures. The procedures should address the following: [1, 11]

- a. Immediate response and actions to mitigate an event;
- b. Follow-up inspections and enforcement actions;
- c. Notifications to licensing staff;
- d. Reports to the incident file; and
- e. Notifications to other affected licensees of generic problems.

Allegation procedures should address response, follow-up, and closeout. They should also provide for protection of the identity of a person making an allegation when requested. The procedures should also provide for the protection of other sensitive information. [1, 11]

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4.7.1.3 References

- a. Criteria Policy Statement, criteria 1 and 11
- b. NRC MD 5.6, Common Performance Indicator Technical Quality of Incident and Allegation Activities
- c. NRC MD 8.8
- d. NRC IMC 1301, Response to Radioactive Material Incidents That Do Not Require Activation of the NRC Incident Response Plan
- e. NRC IMC 1302, Follow-up Actions and Action Levels for Radiation Exposures Associated with Materials Incidents Involving Members of the Public
- f. NRC IMC 1303, Requesting Emergency Acceptance of Radioactive Material by the U.S. Department of Energy
- g. NRC IMC 1330, Response to Transportation Accidents Involving Radioactive Materials
- h. SA-105
- i. SA-300
- i. SA-400

4.7.2 <u>Procedures for Identifying Significant Events and Submitting for Entry into the Nuclear Material Events Database</u>

The States must report all events to the NRC that NRC regulations (or equivalent State regulations) require the licensees to report. The States must report events directly to the NRC, its NMED contractor, or to the NRC Operations Center for events that require immediate notification or notification within 24 hours.

4.7.2.1 Information Needed

The State should submit its procedures for generating event reports. It should also submit its procedures for reporting events to the NRC. above.

4.7.2.2 Evaluation Criteria

The State procedures should assign responsibility for the completion of the reports and for ensuring the quality of the reports. The procedures should also include specific times for completion of the reports and submitting them to the NRC. The procedures should provide guidance for identifying abnormal occurrences. [1, 11]

The State procedures should contain criteria for identifying reportable events. The procedures should include guidance for reporting events (notification, follow-up, and closeouts) to the NRC or its contractor for inclusion into the NMED database, as well as procedures for reporting events to the NRC Operations Center. The State procedures

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should be consistent with the State Agreement Procedure SA-300 Handbook, *Nuclear Material Event Reporting in the Agreement States*. [1, 11]

4.7.2.3 References

- a. Criteria Policy Statement, criteria 1 and 11
- b. SA-300

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Definitions

As used in this document:

AEA - means the Atomic Energy Act of 1954, as amended.

Agreement Materials – means the materials that are regulated under the authority of the Agreement.

Agreement materials program – a term used to distinguish the program under which the materials regulated under the authority of the Agreement from that of the other radiation control activities of the State. In this procedure, the term "Agreement materials program" includes all State organizational units with regulatory responsibility over the materials specified in the Agreement.

Commission – means the collegial body of U.S. Nuclear Regulatory Commissioners and is used when relating to actions or decisions made by the body of Commissioners. Note that 10 CFR Parts 20 and 30 define "Commission" as the U.S. Nuclear Regulatory Commission and its duly authorized representatives. Note that the use of the term "Commission" is used consistently in this document as it is used in the Atomic Energy Act of 1954, as amended.

Civil penalty – means a monetary fine imposed and collected by the materials program, or by apparent agency. This is also known as an "administrative fine."

Generic legally binding requirement – means a legally enforceable statement, limited in the extent of its application, that implements or interprets law or describes procedural requirements, and that is adopted in accordance with the administrative procedures of the promulgating jurisdiction. Examples are license conditions or orders. Generic legally binding requirements differ from regulations in that they are directed to a specifically identified constituency. To be considered generic, however, the requirements should be made effective upon all members of any class of licensees or other persons upon which a regulation would have effect.

License – authorization to possess and use agreement material.

License application – means the formal request for a new license, a license renewal, or a license amendment, as appropriate, made in accordance with the administrative licensing procedures of the jurisdiction.

Materials – generally means byproduct, source, and special nuclear materials, as defined in the AEA. However, if appropriate to the context, it may include naturally occurring or accelerator-produced radioactive materials, if such radioactive materials are regulated by the same program designated to regulate byproduct, source, and special nuclear materials under the Agreement.

Memorandum of Understanding – means any formal statement of cooperation between agencies. The term "Letters of Agreement" is equivalent.

Nuclear Materials Event Database – NMED, maintained by NRC, is a historical collection of incidents and events that have occurred throughout the United States involving the use of radioactive material covered under the Atomic Energy Act of 1954, as amended. This excludes events occurring at nuclear power plants.

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Procedure – means a written statement delineating the steps in an activity and may include "policy" statements.

Program – means the organization within a jurisdiction that is specifically dedicated to the regulation of materials. It may be a separate organizational unit, or a subunit of an organization with wider responsibilities. It may also consist of the sum of the materials program elements distributed over several organizations. The NRC materials program consists primarily of NMSS and the radioactive materials program of each region, but it also includes the support activities provided by other NRC Offices as required.

U.S. Nuclear Regulatory Commission (NRC) – means the Nuclear Regulatory Commission or its duly authorized representatives. The term "NRC" is used when referring to the actions or decisions made by the NRC as an agency. Also, see" Commission" above in reference to the use of "Commission" for consistency with the Atomic Energy Act of 1954, as amended.

Radiation – means ionizing radiation only.

Regulation – means a legally enforceable statement of general applicability that implements or interprets law or describes procedural requirements, and that is adopted in accordance with the administrative procedures of the promulgating jurisdiction. The term "rule" is equivalent as used in this document.

Appendix A Cross Index Table

Program Elements, Information Required from State, Policy Statement Criteria, and References

Section	Program Element	Information from State	Criteria number (See section	References
4.1	Legal Elements			
4.1.1	Statutory Authority	Sections of State Law that authorize the program and the Agreement	1, 2, 9b, 12, 13, 14, 17, 19, 21, 23, 24, 25, 27, 28, 29, 30, and 31	Criteria Policy Statement; Suggested State Legislation; Statement of Principles and Policy for the Agreement State program
4.1.2	Program Organization	Detailed narrative description of radiation protection program	1, 24, and 33	Criteria Policy Statement; Program descriptions of existing Agreement States from IMPEP reports; MD 5.9; SA-200
4.1.3	Content of Agreement	Proposed Agreement	27	Criteria Policy Statement; MD 5.8
4.2	Regulatory Requirements Program Elements			
4.2.1	Regulations and Legally Binding Requirements	Proposed Regulations and Legally Binding Requirements	1, 2, 3, 4, 5, 6, 7, 8, 9a, 10, 11, 22, 23, and 32	Criteria Policy Statement; MD 5.9; SA-200; SA-201; 10 CFR Parts 19, 20, 30, 31, 32,33, 34, 35,36, 37, 39, 40, 61, 70, and 150; CRCPD SSR's

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Section	Program Element	Information from State	Criteria number (See section	References
4.3	Licensing Program Elements			
4.3.1	Materials licensing	Licensing Program description and procedures; licensing guides	1, 7, 8, 9a, 13, 14, 15, 20, and 23	Criteria Policy Statement; MD 5.6; SA-104; NUREG-1556 series; NUREG-1757; NUREG-1575 (MARSSIM)
4.3.2	Sealed Source & Device Safety Evaluations	Sealed Source & Device Program description and procedures	13 and 23	Criteria Policy Statement; NUREG-1556, Volume 3; MD 5.6
4.3.3	Low-level Waste Site Licensing	LLRW Program description and procedures	9b and 13	Criteria Policy Statement; NUREG- 1199; NUREG-1200; NUREG-1300; NUREG-1274; MD 5.6; SA-109
4.3.4	Uranium or Thorium Mill Licensing	11e.(2) Program description and procedures	29, 30, 31, 32, 33, 34, and 35	Criteria Policy Statement; Uranium Recovery Regulations, Guidance, and Communications; MD 5.6; SA-110
4.3.5	Licensing Quality Assurance	Procedures for review of licensing quality	1 and 13	Criteria Policy Statement; MD 5.6; SA-104
4.3.6	Licensing Administrative Procedures	Procedures for processing licensing actions	1, 13, and 25	Criteria Policy Statement
4.4	Inspection Program			
4.4.1	Inspection Procedures	Inspection Program description, inspection procedures and guides, report formats, inspection frequency	1, 16, 18, and 36	Criteria Policy Statement; MD 5.6; SA-101; SA-102; IMC 2602; IMC 2800; IMC 2801; NRC inspection procedures in the "IP 8XXXX" series.

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Section	Program Element	Information from State	Criteria number (See section	References
4.4.2	Inspections Quality Assurance	Procedures for review of inspection quality	1 and 16	Criteria Policy Statement; MD 5.6 and SA-102; IMC 2602; IMC 2800;
4.4.3	Inspection Administrative Procedures	Procedures for processing & filing inspection reports	1	Criteria Policy Statement; IMC 2602; IMC 2800; IMC 2801
4.5	Enforcement Program			
4.5.1	Routine Enforcement Procedures	Enforcement program description and procedures for routine enforcement actions, notice of violation letters	18, 19, and 23	Criteria Policy Statement; NRC Enforcement Policy; IMC 2602; IMC 2800; IMC 2801
4.5.2	Escalated Enforcement Procedures	Procedures for escalated enforcement actions, procedures for legal assistance	18, 19, and 23	Criteria Policy Statement; NRC Enforcement Policy; IMC 2602; IMC 2800; IMC 2801
4.6	Technical staff			
4.6.1	Technical staff Organization	Staffing plan	20 and 34	Criteria Policy Statement; MD 5.6; SA-103
4.6.2	Formal Qualification Plan	Formal qualification plan for technical staff	2, 20 and 34	Criteria Policy Statement; MD 5.6; IMC 1248; NRC/OAS Training Working Group, "Recommendations for Agreement State Training Programs"
4.6.3	Current Technical staff Qualifications	Resumes, certification of qualification, or curriculum vitae of current technical staff	20 and 34	Criteria Policy Statement; MD 5.6; IMC 1248

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Section	Program Element	Information from State	Criteria number (See section	References
4.7	Event & Allegation			
4.7.1	Event & Allegation Response Procedures	Program description and procedures for responding to incidents and allegations	1 and 11	Criteria Policy Statement; MD 5.6; MD 8.8; IMC 1301; IMC 1302; IMC 1303; IMC 1330; SA-105; SA-300; SA-400
4.7.2	Event Reporting Procedures	State NMED reporting procedures	1 and 11	Criteria Policy Statement; SA-300

Appendix B Staffing Analysis Forms

Staff Need and Resource Analysis

Instructions

Address all major license program areas. Note that the following is representative and may not be a complete list of technical staff activities for any particular program.

A. Staff Needs Analysis

- For each License Category, enter the number of licenses (not licenses) your program will have (see the sample "STAFF NEEDS ANALYSIS" form, attached).
- 2. Estimate the average number of licensing actions (new, renewal, amendments, and terminations) you expect to receive per year per license in that category. For assistance, you should discuss the estimates with the NRC Region and existing Agreement States about their experience.
- 3. Estimate the number of staff days you need to process an average action.
- 4. Multiply the estimates in steps 2 and 3 to derive an estimate of the number of staff days you will need to process the expected licensing actions for that category.
- 5. Repeat steps 2, 3 and 4 for inspections. Include reactive inspections, and consider preparation, travel, on-site, and report writing time.
- Conduct a similar analysis for the other major areas of the Agreement program.
 Consider regulation development; decommissioning (including complex decommissioning sites); response to incidents and allegations; contingencies and unanticipated work; and supervisory functions (including inspector accompaniments).

B. Resource Analysis

- 1. Enter staff member ID in blank boxes on top row (see the sample "STAFF RESOURCE ANALYSIS" form, attached).
- In the Licensing and Inspection Program Areas: For each License Category the individual is qualified to inspect, enter the number of days the individual will be available for inspections of those licensees.
- For each License Category the individual is qualified to review licenses, enter the number of days the individual will be available for reviewing actions of those licensees.
- 4. For each License Category, add the days available over all inspectors and enter this number on the "STAFF BALANCE ANALYSIS" form. Add the days available over all license reviewers and enter this number on the STAFF BALANCE ANALYSIS form.

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5. Conduct a similar analysis for the other major areas of the Agreement program.

C. Balance Analysis

- In the Licensing and Inspection Program Areas: For each License Category, compare the estimated number of days needed and days available for licensing and inspections. The number of days available must be at least equal to the number of days needed.
- 2 In the other program areas of the Agreement: For each program area, compare the estimated number of days needed and days available. The number of days available **must be at least equal** to the number of days needed.

STAFF NEEDS ANALYSIS

STAIT NEEDS ANALTSIS											
License Category	Number of Licenses	Licensing actions/yr	Staff days per action	Licensing staff days	Inspections per year	Staff days per inspection	Inspection staff days				
Academic											
Broad Scope Academic											
Nuclear Med - Uptake, etc											
Nuclear Med Imaging and diagnostic											
Nuclear Med											
Bone Mineral											
Brachytherapy											
Gamma Knife											
Medical – Broad Scope											
Nuclear Pharmacy											
Fixed Gauge											
Portable Gauge											

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License Category	Number of Licenses	Licensing actions/yr	Staff days per action	Licensing staff days	Inspections per year	Staff days per inspection	Inspection staff days
Industrial - other Includes irradiators							
Broad Scope Industrial							
Industrial Radiography							
Well Logging							
LLRW broker							
LLRW site							
U recovery							
SS&D							

STAFF RESOURCE ANALYSIS

Staff Member											Tot	tal
License Category	Insp	Lic										
Academic												
Broad Scope Academic												
Nuclear Med - Uptake, Etc.												
Nuclear Med – Imaging and Diagnostic												
Nuclear Med - Therapy												
Bone Mineral												
Brachytherapy												
Gamma Knife												
Medical - Broad Scope												

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Staff Member	Staff Member										Tot	al
License Category	Insp	Lic	Insp	Lic	Insp	Lic	Insp	Lic	Insp	Lic	Insp	Lic
Nuclear Pharmacy												
Fixed Gauge												
Portable Gauge												
Industrial – Other Includes Irradiators												
Broad Scope Industrial												
Industrial Radiography												
Well Logging												
LLRW Broker												
LLRW Site												
U Recovery												
Sealed Source & Device												

STAFF BALANCE ANALYSIS

	Inspection staff days		Licensing staff days	
License Category	Needed	Available	Needed	Available
Academic				
Broad Scope Academic				
Nuclear Med - Uptake, Dilution, and Excretion				
Nuclear Med – Imaging and Diagnostic				
Nuclear Med - Therapy				
Bone Mineral Analysis				
Brachytherapy				
Gamma Knife				
Medical - Broad Scope				
Nuclear Pharmacy				
Fixed Gauge				
Portable Gauge				
Industrial – other; includes irradiators				
Broad Scope Industrial				
Industrial Radiography				
Well Logging				
LLRW broker				
LLRW site				
U recovery				
Sealed Source & Device				

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APPENDIX C Schedule for Processing a Request for an Agreement

NOTE: This schedule requires that both the State requesting the agreement and the NRC follow this schedule to ensure that the Agreement is completed within the time frame requested by the State upon receipt of the formal certification from the Governor. If either the State or the NRC is not able to follow this schedule, it is unlikely that the time frame will be met. This means that the effective date of the Agreement may not be on the planned date. If, for any reason, the State or the NRC cannot meet the established goals, the schedule will be adjusted.

The goal is to process a request for an Agreement in about 1 year from receipt of the formal request and letter of certification from the Governor. There are many factors involved to meet this goal. The schedule below does not include the time the proposed Agreement and final Agreement is with the Commission for review. There are many stages in these processes where the actual time will be less than stated. The NRC staff and the State should expedite each stage to help meet the goal for the effective date of the Agreement.

Event	Event Time	Total Elapsed Time	Comments
PART I Review of the Request for an Agreement			
Notification that a Draft application will be submitted	2 months prior to submission	NA	
Review team established	4 weeks to establish the NRC staff review team.	NA	Between notification of a Draft application and receipt of the Draft application
Receipt of draft application	0	NA	
Team concludes review of draft application	8 weeks	NA	Account for administrative process and Division level management review
Review letter mailed, including any comments	1 week	NA	
Total time period of Part I		9 weeks from receipt of draft request	

Event	Event Time	Total Elapsed Time	Comments
PART II Formal Application			From this stage, the process for an Agreement takes about 1 year – 52-54
Receipt of formal application	8 weeks	8 weeks	The State should try to submit the formal application within 8 weeks of receiving NRC's draft application review letter, addressing any comments NRC had on the draft application
Team review of formal application finished	4 weeks	12 weeks	Based on no unresolved issues
Project manager completes Commission paper, including draft staff assessment and draft Federal Register notice	4 weeks	16 weeks	Account for administrative process and Division level management review
NRC Offices concur on Commission paper	3 weeks	19 weeks	NRC offices are given 15 working days to review and concur
NMSS Office Review	2 weeks	21 weeks	
EDO sends Commission paper to the Commission	2 weeks	23 weeks	At this point, the schedule is in control of the Commission
Total time period of Part II		23 weeks	This is from the receipt of the formal request for an Agreement
Commission approves publication	Up to 2 months		Staff cannot ensure the date by which the Commission will vote on a paper. Staff should include a discussion in the paper of any critical dates that need to be met in order to meet the goal for the effective date of the Agreement
PART III Publication of Federal Register Notice, Public Comment period, and analysis of public comments			
First publication in the Federal Register (noticed each week for four consecutive weeks)	1	NA	This is required by Section 274.e.(1) of the AEA
Public comment period ends	Week 4	4 weeks	

Event	Event Time	Total Elapsed Time	Comments
Review Team analyzes comments, completes the final staff assessment	4 weeks	8 weeks	
Project Manager prepares Commission paper including final staff assessment	Concurrent with review of comments	8 weeks	
Total time period		8 weeks	
PART IV Final processing and Commission approval			
NRC offices concur on final assessment and draft Commission paper	2 weeks	10 weeks	NRC offices are given 10 working days to review and concur
NMSS Office Review	2 weeks	12 weeks	
EDO sends the Commission paper to the Commission	2 weeks	14 weeks	
Total time period of Part IV		14 weeks	
Total time period of Parts II, III, and IV, not including time with the Commission		49 weeks	
Commission approves the Agreement	Up to 2 months		Staff cannot ensure the date by which the Commission will vote on a paper. Staff should include a discussion in the paper of any critical dates that need to be met in order to meet the goal for the effective date of the Agreement
Notice Agreement in the Federal Register within 30 days of the Chairman and Governor signing the Agreement	30 days		This is required by Section 274.e.(2) of the AEA

Appendix D Sample Letters and Documents

Below is a list of the type of documents involved with a request for an Agreement, NRC's review of the request, and the final documents. The examples are for Pennsylvania, Virginia, and New Jersey. Documents from these three Agreement State applications continue to be relevant for future applications. A brief description of the document is provided as well as the ADAMS accession numbers of recent examples. A cross reference to the section of the Procedure or the Handbook is included as well for further discussion.

A. Letter of Intent [SA-700 Procedure, Section V.A. and Handbook, Section 3.3]

The Governor of a State sends a Letter of Intent to the Chairman of the Commission, indicating the State's interest in entering into an agreement with the NRC. In this letter, the Governor states what categories of material over which the State wants to have regulatory authority.

- 1. Virginia ML060040246
- 2. New Jersey ML061460176
- B. Chairman's Acknowledgment of Letter of Intent [Handbook, Section 3.3.2.1]

The Chairman of the NRC writes a letter to the Governor of the State acknowledging receipt of the Governor's Letter of Intent.

- 1. Virginia ML060230433
- 2. New Jersey ML061570433
- C. Draft Application Review Letter after review of draft application [SA-700 Procedure, Section V.E. and Handbook, Section 3.4.3.1]

The staff, signed at the division level, sends a letter to the State regarding the review of the draft application. If there are any questions/deficiencies that need to be resolved in the draft application, this is the method to communicate these to the State.

- 1. Pennsylvania ML070240055
- D. Governor's Letter of Certification (formally requesting Agreement) [Handbook, Section 3.5]

The Governor sends a letter to the Chairman of the Commission formally requesting an Agreement and submitting the formal application and supporting information for an Agreement. In this letter, the Governor certifies that the State has a program that is

adequate and compatible to regulate the categories of materials for which it is requesting under the Agreement.

- 1. Pennsylvania ML063330295
- 2. Virginia ML081720184
- 3. New Jersey ML090820227
- E. Chairman's Letter Replying to the Governor's Letter of Certification [SA-700 Procedure, Section V.F. and Handbook, Section 3.5]

The Chairman of the NRC writes a letter to the Governor of the State acknowledging receipt of the Governor's Letter of Certification, explaining the NRC's review process, and assuring that the team will work expeditiously to get the review completed in a timely manner.

- 1. Pennsylvania ML063400559
- 2. Virginia ML081750456
- 3. New Jersey ML090420437
- F. NRC Staff Assessment draft Staff Assessment of draft Proposed Agreement [SA-700 Procedure Section V.G. and Handbook, Section 3.5.2.3]

The staff prepares a draft Staff Assessment based on the Criteria Policy Statement. This draft Staff Assessment documents the review of the State's request in determining that the State's program is adequate and compatible

- 1. Pennsylvania ML070890378
- 2. Virginia ML083180102
- 3. New Jersey ML091400097
- G. Commission Paper to Publish Draft Proposed Agreement for Public Comment [SA-700 Procedure, Section V.G. and Handbook, Section 3.5.4]

Staff prepares a paper for the Commission discussing its review of the State's request to enter into an Agreement. The paper includes the draft Staff Assessment, draft *Federal Register* notice, background information, etc.

- 1. Pennsylvania ML070890303, SECY-07-0083
- 2. Virginia ML082520029, SECY-08-0154
- 3. New Jersey ML090820038, SECY-09-0065
- H. Federal Register notice of Proposed Agreement [SA-700 Procedure, Section V.H and Handbook, Section 3.5.4]

A *Federal Register* notice is published for four consecutive weeks as directed in Section 274e. of the Atomic Energy Act, as amended.

- 1. Pennsylvania ML070890378
- 2. Virginia ML083190112
- 3. New Jersey ML091400154

I. Press Release for Publication of Proposed Agreement (Press release is not in ADAMS) [SA-700 Procedure, Sections V.I. and Handbook, Section 3.5.4]

Staff prepares a press release, working with the Office of Public Affairs. The Press Release announces the opportunity to comment on the proposed Agreement and includes details of what the State would have authority over under the Agreement. The press release also includes information about the staff's review and lists the States that have entered into an Agreement. Two examples for Virginia and New Jersey are attached.

J. Congressional Letters Announcing Publication of the Proposed Agreement [SA-700 Procedure, Section V.H. and Handbook, Section 3.5.4]

Letters are sent to the U.S. Senators and the U.S. Representatives on the NRC Congressional Oversight Committees, providing these individuals with a pre-publication copy of the *Federal Register* notice. Staff should work with the Office of Congressional Affairs (OCA) to obtain a current list of the NRC Congressional Oversight Committees and the current Chairs and Co-Chairs. Staff will also get the list of U.S. Senators and U.S. Representatives from OCA.

- 1. Virginia ML082830147
- 2. New Jersey ML090820386
- K. Federal Agency Letters Announcing Publication of the Proposed Agreement [SA-700 Procedure, Section V.H. and Handbook, Section 3.5.4]

Staff sends a letter to the following Federal agencies informing them of the proposed Agreement:

- a) Deputy Assistant Secretary of Labor, Occupational Safety and Health Administration:
- b) Assistant Secretary, Congressional and Intergovernmental Affairs, DOE;
- c) Chairperson of Council on Environmental Quality;
- d) Director, Center for Devices and Radiological Health, Food and Drug Administration;
- e) Assistant Administrator for Air and Radiation, U.S. Environmental Protection Agency; and
- f) Assistant Secretary, Office of Legislative Affairs, Department of Homeland Security.
- 1. Virginia ML083390455
- L. Letter to All States Regarding the Proposed Agreement (Agreement States, non-agreement states, state liaison officers) [SA-700 Procedure, Section V.I. and Handbook, Section 3.5.4].

Staff sends a State and Tribal Communication letter to All States announcing the opportunity to comment on the proposed Agreement.

1. Pennsylvania – ML071700481 (package with *Federal Register* notice – ML071700474)

- 2. Virginia ML083400439 (package with *Federal Register* notice ML083400455)
- 3. New Jersey ML091490212 (no package; *Federal Register* notice is part of the letter)
- M. Staff Analysis of Public Comments [SA-700 Procedure, Section V.J.]

Staff prepares an analysis of the public comments received on the proposed Agreement.

- 1. Virginia ML090070451
- 2. New Jersey ML091950400
- N. Final Staff Assessment [SA-700 Procedure, Section J]

Staff finalizes the Staff Assessment of the State's request to enter into an Agreement.

- 1. Virginia ML090070454
- 2. New Jersey ML091940410
- O. Commission Paper to Approve the Final Agreement [SA-700 Procedure, Section V.J.]

Staff prepares a paper for the Commission discussing its final review of the State's request to enter into an Agreement and the public comments that the NRC received. The paper includes the final Staff Assessment, draft *Federal Register* notice, comment analysis, supplemental information, etc.

- 1. Pennsylvania ML073390178 (package with all enclosures and supplemental information), SECY-08-0008
- 2. Virginia ML090070428 (package with all enclosures and supplemental information), SECY-09-0022
- 3. New Jersey ML091940200 (package with all enclosures and supplemental information), SECY-09-0114
- P. Federal Register Notice of Final Agreement [SA-700 Procedure, Section V.M.]

A notice of the final agreement is published in the *Federal Register* within 30 days after signature by the Chairman of the Commission and the Governor, as directed in Section 274e. of the Atomic Energy Act, as amended.

- 1. Virginia ML090820150
- 2. New Jersev ML092710274
- Q. Press Release for Final Agreements (Press release is not in ADAMS) [SA-700 Procedure, Section V.M.]

Staff prepares a press release, working with the Office of Public Affairs. The Press Release announces the final Agreement and includes details of what the State will have authority over under the Agreement. The press release also includes information about the staff's review and lists the States that have entered into an Agreement. Two examples for Virginia and New Jersey are attached.

R. Congressional Letters Announcing Final Agreement [SA-700 Procedure, Section V.M.] Letters are sent to the U.S. Senators and the U.S. Representatives, as well as to the

State delegation, informing these individuals of the approval of the final Agreement. Staff should work with the OCA to obtain a current list of the NRC Congressional Oversight Committees and the current Chairs and Co-Chairs. Staff will also get the list of U.S. Senators and U.S. Representatives from OCA.

- 1. Pennsylvania ML080570161
- 2. New Jersey ML092450515
- S. Chairman's Letter to Governor Approving the Agreement [SA-700 Procedure, Section V.L.]
 - 1. Pennsylvania ML080580429
 - 2. Virginia ML090820076
 - 3. New Jersey ML092450273
- T. Letters to Federal Agencies Announcing Final Agreement [SA-700 Procedure, Section V.M.]. Staff sends a letter to the following Federal agencies announcing the final Agreement:
 - a) Deputy Assistant Secretary of Labor, Occupational Safety and Health Administration;
 - b) Assistant Secretary, Congressional and Intergovernmental Affairs, DOE;
 - c) Chairperson of Council on Environmental Quality;
 - d) Director, Center for Devices and radiological Health, Food and Drug Administration:
 - e) Assistant Administrator for Air and Radiation, U.S. Environmental Protection Agency; and
 - f) Assistant Secretary, Office of Legislative Affairs, Department of Homeland Security.
 - 1. Pennsylvania ML080650223
 - 2. Virginia ML083390817
 - 3. New Jersey ML092450572
- U. Final Agreement [SA-700 Procedure, Section V.L.]
 - 1. Pennsylvania ML080580547
 - 2. Virginia ML092720782
 - 3. New Jersey ML092450290
- V. Letter Announcing the Agreement [SA-700 Procedure, Section V.M.]. Staff sends a letter to all other States, State Liaison Officers and Federally recognized Tribes announcing the Agreement and the effective date.
 - 1. Pennsylvania ML080590169
 - 2. Virginia ML090900429
 - 3. New Jersey ML092720262

ATTACHMENT

PRESS RELEASE FOR THE PROPOSED AGREEMENT AND THE FINAL AGREEMENT

COMMONWEALTH OF VIRGINIA AND STATE OF NEW JERSEY



NRC NEWS

U.S. NUCLEAR REGULATORY COMMISSION

Office of Public Affairs Telephone: 301/415-8200
Washington, D.C. 20555-0001
Email: opa@nrc.gov
Site: http://www.nrc.gov

No. 08-211 November 18, 2008

NRC CONSIDERING REQUEST BY VIRGINIA TO BECOME AN "AGREEMENT STATE"

The Nuclear Regulatory Commission is considering a request from Virginia Gov. Timothy M. Kaine to assume part of the NRC's regulatory authority over certain nuclear materials in the commonwealth. If the request is accepted, Virginia will become the 36th state to sign such an agreement with the NRC.

Under the proposed agreement, the NRC would transfer to Virginia the responsibility for licensing, rulemaking, inspection and enforcement activities for: (1) radioactive materials produced as byproducts from the production or utilization of special nuclear material (SNM-enriched uranium or plutonium); (2) naturally occurring or accelerator-produced byproduct material (NARM); (3) source material (uranium and thorium); and (4) SNM in quantities not sufficient to support a nuclear chain reaction.

If the proposed agreement is approved, it is estimated that there will be 420 total licenses in the Commonwealth of Virginia. NRC would transfer 386 licenses to the commonwealth's jurisdiction. In addition, the commonwealth would retain regulatory authority for approximately 216 NARM licenses. Approximately 180 of these NARM licenses are dually regulated by Virginia and the NRC.

By law, NRC would retain jurisdiction over commercial nuclear power plants and federal agencies using certain nuclear material in the state. In addition, NRC would retain authority for the review, evaluation and approval of sealed radioactive materials and devices containing certain nuclear materials within the state.

Before entering into the agreement, NRC must determine that Virginia's radiation control program is adequate to protect public health and safety, and is compatible with the agency's own program for regulating the radioactive materials covered in the agreement.

The proposed agreement and the NRC staff's draft assessment of the Virginia program will be published for public comment soon in the *Federal Register*, and also will be published for comment thereafter, once a week for four consecutive weeks. Comments should be sent to Michael T. Lesar, Chief, Rules Review and Directives Branch, Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

Copies of the proposed agreement, the Governor's request and supporting documents, as well as the NRC staff's assessment are available through the NRC's ADAMS. Help in using ADAMS is available by contacting the NRC Public Document Room staff at 301-415-4737 or 1-800-397-4209, or by sending an e- mail message to PDR.Resource@nrc.gov. These documents are also available for public inspection at the NRC Public Document Room at 11555 Rockville Pike, Rockville, Maryland.

Thirty-five other states have previously signed such agreements with NRC. They are: Alabama, Arizona, Arkansas, California, Colorado, Florida, Georgia, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Minnesota, Mississippi, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Utah, Washington, and Wisconsin.

More information about the Agreement State program is available on the NRC's Web site at: http://nrc-stp.ornl.gov/.



NRC NEWS

U.S. NUCLEAR REGULATORY COMMISSION

Office of Public Affairs Telephone: 301/415-8200 Washington, D.C. 20555-0001

> Email: <u>opa.resource@nrc.gov</u> Site: <u>http://www.nrc.gov</u>

No. 09-092 May 26, 2009

NRC CONSIDERING REQUEST BY NEW JERSEY TO BECOME AN "AGREEMENT STATE"

The Nuclear Regulatory Commission is considering a request from New Jersey Gov. Jon S. Corzine to assume part of the NRC's regulatory authority over certain nuclear materials in the state. If the request is accepted, New Jersey will become the 37th state to sign such an agreement with the NRC.

Under the proposed agreement, the NRC would transfer to New Jersey the responsibility for licensing, rulemaking, inspection and enforcement activities for: (1) radioactive materials produced as byproducts from the production or utilization of special nuclear material (SNM-- enriched uranium or plutonium); (2) naturally occurring or accelerator-produced byproduct material (NARM); (3) source material (uranium and thorium); (4) SNM in quantities not sufficient to support a nuclear chain reaction; and (5) the regulation of the land disposal of source, byproduct, and SNM received from other persons.

If the proposed agreement is approved, the NRC would transfer an estimated 500 licenses for radioactive material to New Jersey's jurisdiction. New Jersey would retain regulatory authority over approximately 500 NARM licensees, including 300 who also hold NRC licenses. These licensees would have their NRC and New Jersey licenses combined into a single state license. In total, New Jersey would then have jurisdiction over approximately 700 licenses.

By law, NRC would retain jurisdiction over commercial nuclear power plants and federal agencies using certain nuclear material in the state. In addition, NRC would retain authority for: (1) the review, evaluation and approval of sealed radioactive materials and devices containing certain nuclear materials; and (2) the regulation of the tailings and other wastes from uranium milling within New Jersey.

Before entering into the agreement, the NRC must determine that New Jersey's radiation control program is adequate to protect public health and safety and is compatible with the agency's own program for regulating the radioactive materials covered in the agreement.

The proposed agreement and the NRC staff's draft assessment of the New Jersey program will be published for public comment May 27 in the *Federal Register*, and repeated weekly for a total of four weeks. Comments should be sent to Michael T. Lesar, Chief, Rules Review and Directives Branch, Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

Copies of the proposed agreement, the Governor's request and supporting documents, as well as the NRC staff's assessment are available through the NRC's ADAMS. Help in using ADAMS is available by contacting the NRC Public Document Room staff at 301-415-4737 or 1-800-397-4209, or by sending an e- mail message to PDR.Resource@nrc.gov. These documents are also available for public inspection at the NRC Public Document Room at 11555 Rockville Pike, Rockville, Maryland.

Thirty-six other states have previously signed similar agreements with the NRC. They are: Alabama, Arizona, Arkansas, California, Colorado, Florida, Georgia, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Minnesota, Mississippi, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Utah, Virginia, Washington, and Wisconsin.

More information about the Agreement State program is available on the NRC's Web site at: http://nrc-stp.ornl.gov/.



NRC NEWS

U.S. NUCLEAR REGULATORY COMMISSION

Office of Public Affairs Telephone: 301/415-8200
Washington, D.C. 20555-0001
Email: opa@nrc.gov
Site: http://www.nrc.gov

No. 09-056 March 24, 2009

NRC COMPLETES VIRGINIA AGREEMENT TO REGULATE CERTAIN RADIOACTIVE MATERIALS

The Nuclear Regulatory Commission has completed an agreement with the Commonwealth of Virginia, under which Virginia will assume NRC's regulatory authority over certain nuclear materials in the state.

Virginia becomes the 36th state to sign such an agreement with the NRC. The agreement is effective March 31.

Under the agreement, the NRC will transfer to Virginia the responsibility for licensing, rulemaking, inspection and enforcement activities for: (1) radioactive materials produced as a result of processes related to the production or utilization of special nuclear material (SNM); (2) naturally occurring or accelerator-produced radioactive material (NARM); (3) source material (uranium and thorium); and (4) SNM in quantities not sufficient to form a critical mass.

The NRC will transfer 386 licenses to the commonwealth's jurisdiction. In addition, the commonwealth retains regulatory authority for approximately 216 NARM licenses. Approximately 180 of these NARM licenses currently are regulated by both Virginia and the NRC.

By law, NRC retains jurisdiction over commercial nuclear power plants and federal agencies using certain nuclear material in Virginia. In addition, NRC retains authority for the review, evaluation and approval of sealed radioactive materials and devices containing certain nuclear materials manufactured in Virginia and distributed throughout the country.

Before approving the agreement, NRC reviewed Virginia's radiation control program to ensure it is adequate to protect public health and safety and is compatible with the agency's own program for regulating the radioactive materials covered in the agreement. An announcement of the proposed agreement was published four times in the *Federal Register* in

November and December, inviting comments from the public. The agency received one comment in favor of the proposed agreement.

The agreement will be announced soon in the *Federal Register*. Copies of the agreement, the Governor's request and supporting documents, as well as the NRC staff's assessment are available through the NRC's ADAMS. Help in using ADAMS is available by contacting the NRC Public Document Room staff at 301-415-4737 or 1-800-397-4209, or by sending an email message to PDR.Resource@nrc.gov. These documents are also available for public inspection at the NRC Public Document Room at 11555 Rockville Pike, Rockville, Md.

Thirty-five other states have previously signed such agreements with NRC. They are: Alabama, Arizona, Arkansas, California, Colorado, Florida, Georgia, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Minnesota, Mississippi, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Utah, Washington, and Wisconsin.

More information about the Agreement State program is available on the NRC's Web site at: http://nrc-stp.ornl.gov/.



NRC NEWS

U.S. NUCLEAR REGULATORY COMMISSION

Office of Public Affairs Telephone: 301/415-8200 Washington, D.C. 20555-0001

Email: <u>opa.resource@nrc.gov</u> Site: <u>http://www.nrc.gov</u>

No. 09-160 September 28, 2009

NRC COMPLETES NEW JERSEY AGREEMENT TO REGULATE CERTAIN RADIOACTIVE MATERIALS

The Nuclear Regulatory Commission has completed an agreement with New Jersey, under which the state will assume NRC's regulatory authority over certain radioactive materials. New Jersey becomes the 37th NRC Agreement State, effective Sept. 30.

Under the agreement, the NRC will transfer to New Jersey the responsibility for licensing, rulemaking, inspection and enforcement activities for: (1) radioactive materials produced as byproducts from the production or utilization of special nuclear material (SNM – enriched uranium or plutonium); (2) naturally occurring or accelerator-produced byproduct material (NARM); (3) source material (uranium and thorium); (4) SNM in quantities not sufficient to support a nuclear chain reaction; and (5) the regulation of the land disposal of source, byproduct, and SNM received from other persons.

The NRC will transfer an estimated 500 licenses for radioactive material to New Jersey's jurisdiction. New Jersey will retain regulatory authority over approximately 500 NARM licensees, including 300 who also hold NRC licenses. These licensees would have their NRC and New Jersey licenses combined into a single state license. In total, New Jersey would then have jurisdiction over approximately 700 licenses.

The NRC will retain jurisdiction over commercial nuclear power plants, fuel cycle facilities and federal agencies using certain nuclear material in the state. In addition, the NRC will retain authority for: (1) the review, evaluation and approval of sealed radioactive materials and devices containing certain nuclear materials; and (2) the regulation of the tailings and other wastes from uranium milling within New Jersey.

Before approving the agreement, the NRC reviewed New Jersey's radiation control program to ensure it was adequate to protect public health and safety, and is compatible with

the agency's own program for regulating radioactive materials. An announcement of the proposed agreement was published four times in the *Federal Register* in May and June, inviting comments from the public. The agency received six comment letters – two supporting the agreement, two opposed, one that supported the rationale of states assuming regulatory authority but not the fee differences that will occur, and one general comment that did not express support or opposition.

The agreement will be announced shortly in the *Federal Register*. Copies of the agreement, the Governor's request and supporting documents, as well as the NRC staff's assessment will be available through the NRC's ADAMS document library. Help in using ADAMS is available by contacting the NRC Public Document Room staff at 301-415-4737 or 1-800-397-4209, or by sending an email message to PDR.Resource@nrc.gov. These documents are also available for public inspection at the NRC Public Document Room at 11555 Rockville Pike, Rockville, Md.

Thirty-six other states have previously signed similar agreements with the NRC. They are: Alabama, Arizona, Arkansas, California, Colorado, Florida, Georgia, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Minnesota, Mississippi, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Utah, Virginia, Washington, and Wisconsin.

More information about the Agreement State program is available on the NRC's Web site at: http://nrc-stp.ornl.gov/.

Appendix E Tribal Interactions During the Agreement Process

1.0 INTRODUCTION

1.1 Purpose

Appendix E provides NRC staff guidance for interacting with Tribal governmental entities during the Agreement State application process. The NRC staff should use Appendix E when reviewing the original request or reviewing an amendment to an existing Agreement.

1.2 Scope

Prior sections of the Handbook cover other topics that a State must address in submitting a request for an Agreement and the steps the NRC staff should take in processing the Agreement State application. In particular, Section 3.0 of the Handbook provides detailed steps in the procedure followed by the NRC staff to evaluate the request. Additional sections in SA-700 provide information concerning the procedure followed by the NRC staff for requesting public comment on the proposed Agreement, preparation of the decision paper for Commission approval, and final implementation of the Agreement. Appendix E provides information on how the NRC staff should implement the principles articulated in the NRC's Tribal Policy Statement (TPS) and Management Directive 5.1 during the Agreement State application process.

2.0 BASIS OF THE GUIDANCE

Appendix E is based on the TPS, MD 5.1, the NRC's Tribal Protocol Manual (TPM), and Tribal procedure (TR) TR-100, which provide guidance on interacting with Tribal governments. The documents are summarized below.

2.1 Tribal Policy Statement (82 FR 2402; 1/9/17)
(https://www.Federalregister.gov/documents/2017/01/09/2017-00091/Tribal-policy-statement)

On January 9, 2017, the NRC issued the TPS "to establish policy principles to be followed by the NRC to promote effective government-to-government interactions with Indian Tribes, and to encourage and facilitate Tribal involvement in the areas over which the Commission has jurisdiction.". The policy articulates the NRC's six principles the NRC staff should follow to promote effective government interactions with Federally recognized tribes.² The principles are:

1. The NRC Recognizes the Federal Trust Relationship With and Will Uphold Its Trust Responsibility to Indian Tribes.

² Federally recognized tribes are identified in the Bureau of Indian Affairs (BIA) list (check for latest list in Federal Register). The tribes meet specific criteria to receive special benefits from the Federal government.

- 2. The NRC Recognizes and Is Committed to a Government-to-Government Relationship With Indian Tribes.
- 3. The NRC Will Conduct Outreach to Indian Tribes.
- 4. The NRC Will Engage in Timely Consultation.
- 5. The NRC Will Coordinate With Other Federal Agencies.
- 6. The NRC Will Encourage Participation by State-recognized Tribes.

The policy principles apply to Agreement State applications. In particular, Principle 3 promoting Tribal outreach to keep Indian Tribes informed about the agency's actions and plans, Principle 4 promoting the NRC to provide timely notice and consult in good faith with Tribal governments, and Principle 6 encouraging participation by State-recognized tribes³ apply in this situation.

The TPS supports the NRC's Tribal outreach activities beginning at the Letter of Intent stage of an Agreement State application for Federally recognized tribes and encourages participation by State-recognized Tribes in the regulatory process. The TPS also designates the NRC's Tribal liaisons (TLs) and Regional State Liaison Officers (RSLOs) to: 1) be the primary points of contact for Indian Tribes; 2) coordinate with other programmatic offices; and 3) educate the NRC staff about Tribal issues including cultural sensitivity and the Federal Trust Responsibility.

The NRC should offer Tribal consultation under the agency's Tribal Policy Statement to Federally recognized Tribes that may be directly impacted by the agreement because they have a reservation, trust or ancestral lands within the State applying for an agreement. Staff should engage with OGC to evaluate whether an out-of-State Federally recognized Tribe has any treaty rights within the State before offering Tribal consultation. Any additional Tribal requests for consultation concerning an Agreement State application should be reviewed on their merits, in accordance with TR-100 Appendix D, and in conjunction with OGC to determine an appropriate course of action. Tribes may be interested in consultation during the Agreement State application process because Agreement State actions will be subject to the State's environmental, historic/cultural preservation, and Tribal interactions regulations and procedures.

2.2. MD 5.1 https://www.nrc.gov/docs/ML1123/ML112351312.pdf

MD 5.1 addresses general responsibilities for consultation and coordination with States, Federally recognized tribes, other Federal agencies, local governments, and national or regional organizations of governmental agencies. It is the policy of the NRC to ensure appropriate consultation at the earliest possible stage between the NRC and States, local governments, other Federal agencies, and Indian Tribes, and national and regional associations regarding major interagency agreements, major organizational changes, major rules and regulations, statements of policy, guides, and standards, and major studies that may have a significant State or local impact.

2.3 "Tribal Protocol Manual Guidance for NRC Staff" (2018) (NUREG-2173, Revision 1) (https://www.nrc.gov/docs/ML1821/ML18214A663.pdf)

³ State-recognized tribes have a special status and recognition by an individual State, but not the Federal government.

The Tribal Protocol Manual (TPM) provides basic historical information about the Federal and Tribal government relationship and advice on interacting with Tribal governments. The TPM facilitates effective consultations and interactions between the NRC and tribes related to activities within the scope of the NRC's jurisdiction. The TPM explains that tribes are unique governmental entities and are not extensions of State or local governments. Each Federally recognized tribe is a domestic, dependent sovereign nation with its own customs, culture, concerns, interests, and needs. The TPM assists NRC management and staff in recognizing these distinctions and creates a more open and productive working relationship with Tribal governments.

The TPM is a reference tool produced from multiple sources, including interviews with the NRC staff and management, other Federal agencies' personnel, and Tribal representatives who are experienced in working with Tribes. NRC management and staff can use this guide to develop and maintain government-to-government relationships with Tribal governments. The TPM supplements the NRC staff's working knowledge by providing Tribal outreach experience and practical guidance to NRC personnel who have had limited interactions with Indian Tribes.

2.4 SL-100, "Regional State Liaison Officer Program" (June 28, 2021) (L21168A326)

SL-100 describes the roles and responsibilities of the RSLOs in the fulfilling the duties in the State Liaison Officer Program (SLO). These duties include maintaining communication with Federally and State Recognized Tribal Governments affected by NRC activities including Agreement applications. The RSLOs could coordinate with the TLs on outreach and consultation activities for Agreement applications.

2.5 TR-100, "Tribal Liaison Roles and Responsibilities" (November 22, 2021 (ML21088A259)

TR-100 describes the roles and responsibilities of the TLs at Headquarters and the RSLOs⁴ in the NRC's four regional offices that share the responsibilities for the Tribal liaison functions. The document also provides information for how the NRC staff can coordinate with the TLs and RSLOs. This procedure supplements MD 5.1 and SL-100 and describes the requirements imposed on the staff by the NRC's TPS.

3.0 REVIEW PROCEDURES

3.1 Timing of Interactions

The attached table (Enclosure 1) provides a quick summary of actions that should be taken during the application process to notify tribes of: 1) the application's status, 2) general information about the Agreement State program, and 3) offers for further outreach and consultation. The table also indicates when to notify tribes of the proposed Agreement's public comment period and the effective date of the Agreement.

⁴ The term TL also refers to the RSLO throughout this document. However, the Regional Administrator needs to approve an RSLO's involvement in this matter.

3.2 Assigning Tribal Liaison and Initial Contact with State

As soon as possible after receiving the Notice of Intent from the State's Governor's Office, the SLPB PM processing the Agreement State application should contact the chief of the NMSS/MSST/Materials Safety and Tribal Liaison Branch (MSTB) for the assignment of a TL to support the application process. The TL assumes role as primary point of contact between the NRC and Tribes during the process. Shortly after assignment of the TL, the TL and PM would contact:

- 1. The State Radiation Control Program Point of Contact (State point of contact) to discuss potential Tribal interactions and State legislative rulemaking plans; and
- 2. The State Historic Preservation Office (SHPO) to help identify potentially interested tribes and discuss State's Tribal interaction policies and procedures.

The State POC for the Agreement can inform the NRC of the State's schedule for proposed legislation and rulemaking related to the State's Agreement program. The State POC and TL should also discuss potential Tribal involvement in the State's legislative or rulemaking activities. Either the State POC or the TL should directly notify the Tribal leader and Tribal Historic Preservation Officer (THPO) of interested tribes of public comment periods for relevant legislation and rulemaking during the application process. However, the NRC cannot delegate the NRC's Tribal Policy Statement or Federal Trust responsibilities to the State government.

The TL and PM should contact the SHPO to learn about the State Tribal consultation practices during their licensing process and discuss tribes that may be potentially interested in the State's application. The State Point of Contact (POC) should be copied or otherwise notified separately on correspondence that is sent to the interested tribes.

3.3 Identification of Potentially Interested Tribes

The TL should identify Tribal governmental entities that may be interested in the Agreement application and gather the Tribal leader and THPO contact information before the PM posts the NRC application on the website. Potentially interested tribes will need to be notified that if the Agreement is approved, the State would assume regulatory authority in areas outside of exclusive Federal jurisdiction. For example, the Agreement State could become the regulatory authority over a Tribal medical facility that uses radioactive material located outside a Federally recognized Tribe's reservation. Other potentially interested tribes would include out-of-state tribes with ancestral lands or treaty rights within the State. Additionally, national or regional Tribal organizations may represent a group TL will also send an email containing the initial contact letter to the tribes.

The MSST Division Director should sign the initial contact letter to the interested tribes. The SLPB and MSTB branch chief should concur on the letter before submitting the letter for signature. The initial contact letter should contain basic information on the National Materials and Agreement State programs and offers of consultation or outreach, as appropriate for the tribe.

As noted above, the letter should offer consultation, in accordance with the TPS, to Federally recognized tribes within the State, as well as to out-of-state Federally recognized tribes with ancestral lands or treaty rights within the State. For out-of-state

federally recognized tribes that have expressed an interest in NRC regulatory activities within the State but lack ancestral lands or treaty rights within the State, State-recognized tribes within the State, and national or regional Tribal governmental organizations, the letter should offer outreach. The NRC should apply the TPS and MD 5.1 criteria when considering requests for consultation from these parties. In all cases, OGC should be contacted to assess requests for consultation to ensure the appropriate interpretations of the TPS and MD 5.1 criteria.

Approximately two weeks after sending the initial contact letter, the TL should call the Tribal leaders and THPO's Office to confirm receipt of the correspondence, establish a Tribal POC, and assess the tribe's interest in consultation or additional outreach during the application process. Within two weeks after the calls, the TL should write a summary to inform the PM and SLPB and MSTB branch chiefs of the results of the initial contacts. To maintain a record, all written and electronic correspondence and phone conversation records with the tribes should be placed in ADAMS in accordance with NRC policy.

3.4 Subsequent Interactions

The TL will remain the main POC for tribes during the application process. The PM should discuss with the TL if they can continue to provide support, which could include drafting, reviewing, or sending Tribal communications, and arranging meetings and webinars between the tribes and the NRC subject matter experts during the application process.

Many of the subsequent outreach and consultation activities focus on providing additional information about the status of the application process, including the State's development of their regulations and radiation control program, the NRC's staff's review of the State's program and application package, and the public comment period. The appropriate form of communication for these matters is indicated on Table 1. The table designates the appropriate signature authority for these Tribal communications. The MSTB branch chief should concur on the SLPB written Tribal communications. The SLPB and MSTB branch chiefs should concur on TL Tribal emails. SLPB and MSTB staff should also share all Tribal communications.

In some cases, individual tribes may be involved in developing specific agreements or license conditions to address or prevent adverse impacts to historic or cultural resources. Tribes may also be interested in the future decommissioning and closure of sites that could be transferred to the State. The NRC staff should be prepared to respond to Tribal questions on these subjects and be able to offer additional outreach opportunities by phone, email, webinars, video conferencing, or face-to-face meetings with Tribal governmental leaders and subject matter experts, when appropriate. The TL should arrange subsequent meetings between tribes and the NRC subject matter experts as needed. The TPS, MD 5.1, and the TPM provide additional further information on outreach and consultation with Tribal governments.

The TL should summarize contacts with the tribes and Tribal comments and develop responses to Tribal comments for any Commission papers concerning the Agreement. The TL should also support the Commission paper to resolve Tribal comments and summarize Tribal interactions as needed.

Within two weeks after the publication of the Federal Register notice announcing the

Agreement, the TL and PM staff should draft a letter for the MSST Division Director to send to interested tribes regarding the effective date of the Agreement. The letter should also provide information on how the NRC considered a tribe's comments in the final agency decision on the Agreement application. The letter can include the final Agreement, other public documentation of the decision-making process, such as Commission papers, Staff Requirements Memoranda, and comment response documents. The TL should also send an email with this information to the Tribal leader and THPO. Additional calls or meetings with the Tribal leaders are other options to provide the tribe further information on this matter.

Sample letters are provided in Enclosure 2. To maintain a record, all written and electronic correspondence, and phone conversation records with the tribes and Tribal government organizations should be placed in ADAMS in accordance with NRC policy.

3.5 Additional Guidance and Support

The NRC staff involved with interacting with tribes during the application process are required to watch the mandatory training video "Cultural Sensitivity: Engaging Native Americans in NRC's Mission" currently available on the NRC's Talent Management System. An additional video "Tribal Interactions: Staff Support and Other Resources" provides additional information on this topic. The NRC staff can also contact the TLs and RSLOs for further advice and support for their Tribal interactions.

3.6 Enclosures

Enclosure 1 suggests times to engage tribes during the Agreement State application process.

Enclosure 2 references letters sent regarding the Wyoming and Vermont Agreements and the Connecticut and Indiana applications, which can be used as a template for developing Tribal correspondence.

Enclosure 1: Tribal Outreach Milestones During the Agreement State Application Process

Who	When	Method	Assigned to
All Federally recognized tribes ⁵ within the State	a. NRC website posted ⁷	a. Letter and Call ⁹	a. SLPB/TL ¹⁰
(Group 1)	b. Receipt of Draft Application8	b. Email	b. SLPB
	c. State's publication of draft	c. Email	c. SLPB
Out-of-state Federally recognized tribes with	regulations for comment (may be		
ancestral lands within the State (Group 2)	before receipt of Draft Application).		
	d. One month before FRN opening	d. Letter and email	d. SLPB/TL
Out-of-state Federally recognized tribes with treaty	public comment period on draft		
rights within the State (Group 3) ⁶	Agreement.		
	e. Publication of FRN opening	e. Letter and email	e. SLPB/TL
	public comment period.		
	f. Effective date of Agreement.	f. Letter and email	f. SLPB/TL
Out-of-state Federally recognized tribes that have	Same as Group 1. Letter states	Same as Group 1	Same as
expressed an interest in NRC regulatory activities	that the NRC will consider requests		Group 1
within the State and State-recognized tribes within	under the TPS.		
the State (Group 4)			
National or regional Tribal organizations (Group 5)	a. NRC website posted ¹¹	a. Letter or email	a. TL
	b. Effective date of Agreement.	b. Letter or email	b. TL
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SHPO should review NRC's list of tribes and Tribal	Same as Group 1.	Same as Group 1	Same as
organizations for accuracy			Group 1

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⁵ The Bureau of Indian Affairs (BIA) provides a list of Federally recognized tribes (check for latest list in Federal Register). Tribal liaisons can help identify and provide contact information for Federally recognized tribes, state recognized tribes, and national and regional Tribal organizations that may have an interest in the Agreement State application.

⁶ Staff should engage with OGC to evaluate whether an out-of-State Federally recognized tribe has any treaty rights within the State before offering Tribal consultation.

⁷ Agreement State application website will be posted by SALB within 6 months after the receipt of the Governor's Letter of Intent. The website will be modeled after the Wyoming and Vermont webpages and include application process milestones, frequently asked questions (Q&As),) and links to other appropriate webpages.

⁸ Draft applications can be for initial agreements or amendments.

⁹ Tribal communications should be separately addressed to the Tribal leader and the THPO (or other Tribal historic preservation official when known).

¹⁰ State Agreement and Liaison Program Branch (SALB) and Tribal Liaisons (TL) staff.

¹¹ The NRC would apply MD 5.1 criteria to Group 5 when considering offering or evaluating requests for outreach. Tribes in Group 1, 2, or 3 can also request that organizations in Group 5 represent them.

Enclosure 2: Templates for Tribal Letters

A. NRC's Letter to notify potentially interested Tribal governmental entities that the Governor sent a Letter of Intent to submit an Agreement State application. [SA-700 Handbook, Appendix E Section 3.4, and Enclosure 1 Chart]

The MSST Division Director should send the letter to Tribal leaders and Tribal Historical Preservation Officers (THPOs) after the posting of the NRC's Agreement application website (approximately 6 months after receiving the Letter of Intent).

- 1. ML22047A177 (package): Letter regarding Connecticut's Letter of Intent to Federally-recognized tribes that includes offer of consultation, fact sheet on Agreement State program, and Q&As.
- 2. ML21096A304, ML21096A305, and ML21096A306: Letter regarding Connecticut's Letter of Intent to State-recognized tribes that includes offer of outreach, fact sheet on Agreement State program, and Q&As.
- B. NRC's Letter acknowledging agreement to consultant with Federally-recognized tribe.
 - 1. ML22018A178: Letter to Osage Nation acknowledging agreement to consultant on the Indiana Agreement application.
- C. NRC's Letter to notify potentially interested Tribal governmental entities that NRC has received the State's final application. [SA-700 Handbook, Appendix E Section 3.5 and Enclosure 1 Chart]
 - 1. ML18018A863: Letter regarding final Wyoming application under review.
 - 2. ML19142A263: Letter regarding final Vermont application under review.
- D. NRC's Letter to notify potentially interested Tribal governmental entities should be issued one month before the planned publication date of the FRN announcing the public comment period for the proposed Agreement and staff assessment. [SA-700 Handbook, Appendix E Section 3.5, and Enclosure 1 Chart]
 - 1. ML19142A263: Letter regarding final Vermont application under review and upcoming publication of the FRN.
- E. NRC's Letter to notify potentially interested Tribal governmental entities of publication of FRN opening public comment period for the proposed Agreement and staff assessment. [SA-700 Handbook, Appendix E Section 3.5, and Enclosure 1 Chart]
 - ML18155A591 (package) and ML18155A592: Letter regarding FRN publication and request for comment on the proposed Wyoming Agreement and draft staff assessment.
 - 2. ML19144A181: Letters regarding FRN publication and request for comment on proposed Vermont Agreement and draft staff assessment.
- F. NRC's Letter to notify potentially interested Tribal governmental entities of the effective date of the Agreement. [SA-700 Handbook, Appendix E Section 3.5, and Enclosure 1 Chart]

The letter should include a copy of the final Agreement, the SECY paper showing the Commission's consideration of any input or comments received from Tribal governments, and NRC's response to a tribe's comments.

- 1. ML19029A403: Letter to Shoshone-Bannock Tribes regarding Wyoming agreement with response to comments.
- 2. ML19191A197: Letter providing notice of the final Vermont Agreement, no response to comments.