



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

(FSME-14-016, February, Program, SA-700)

February 24, 2014

ALL AGREEMENT STATES, NON-AGREEMENT STATES,
STATE LIAISON OFFICERS

OPPORTUNITY TO COMMENT ON DRAFT REVISION TO THE OFFICE OF
FEDERAL AND STATE MATERIALS AND ENVIRONMENTAL MANAGEMENT
PROGRAMS PROCEDURE SA-700, PROCESSING AN AGREEMENT (FSME-
14-016)

Purpose: To provide the Agreement States, non-Agreement States, and State Liaison Officers an opportunity to comment on the proposed revisions to the Office of Federal and State Materials and Environmental Management Programs (FSME) Procedure SA-700, Processing an Agreement.

Background: This procedure is being revised to update current practices and organizational changes.

Discussion: Enclosed for your review and comment is the draft revision to FSME Procedure SA-700, Processing an Agreement. This procedure provides guidelines and information (1) for a State or Commonwealth to use in preparing a request to enter into an Agreement with the U.S. Nuclear Regulatory Commission (NRC); (2) for NRC staff in reviewing requests from a Governor of a State or Commonwealth to enter into an Agreement with the NRC; (3) on the formal procedural steps for responding to a Governor's request for an Agreement; and (4) on the criteria for evaluating a Governor's proposed Agreement materials program.

We would appreciate receiving your comments^{1,2,3} within 30 days from the date of this letter.

¹This information request has previously been approved by OMB 3150-01029 and was resubmitted to OMB for review of continued approval of information collection. The estimated burden per response to comply with this voluntary collection is approximately 8 hours. Send comments regarding the burden estimate to the Records and Information Services Branch (T-5F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet e-mail to infocollects.resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202 (3150-0200), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

²This information request has been approved by OMB 3150-0200 expiration 09/30/2015. The estimated burden per response to comply with this voluntary collection is approximately 8 hours. Send comments regarding the burden estimate to the Records and Information Services Branch (T-5F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet e-mail to infocollects.resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202 (3150-0200), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

³This information request has been approved by OMB 3150-0163, expiration 03/31/2016. The estimated burden per response to comply with this voluntary collection is approximately 8 hours. Send comments regarding the burden estimate to the Records and Information Services Branch (T-5F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by Internet e-mail to infocollects.resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202 (3150-0200), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

If you have any questions regarding this correspondence, please contact me at 301-415-3340 or the individual named below:

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/RA John Moses for/

Laura A. Dudes, Director
Division of Materials Safety and State Agreements
Office of Federal and State Materials
and Environmental Management Programs

Enclosures:

1. FSME SA-700, "Processing an Agreement-SA-700" (with track changes)
2. Handbook to FSME SA-700, "Handbook for Processing an Agreement"



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~~Procedure Number: SA-~~

~~Page: 1 of 13~~

~~Issue Date:~~
~~7/19/2007~~

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**Office of Federal and State Materials and Environmental Management Programs (FSME)
Procedure Approval**

Processing an Agreement - SA-700

Issue Date: ~~July 19, 2007~~

Review Date: ~~July 19, 2010~~

~~Janet R. Schlueter~~
Acting Director, MSSA

Original signed by
Laura A. Dudes ~~Janet R. Schlueter~~ Date: ~~7/19/2007~~

~~A. Duncan White~~
Branch Chief, MSSA

Original signed by
A. Duncan White Date: ~~7/17/2007~~

~~William R. RautzenTorre Taylor~~
Procedure Contact, MSSA

Original signed by
~~William R. RautzenTorre Taylor~~ Date: ~~7/17/2007~~

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NOTE

Any changes to the procedure will be the responsibility of the FSME Procedure Contact. Copies of the FSME procedures are available through the NRC website.

These Procedures were formerly issued by the Office of State and Tribal Programs (STP). Any changes to the procedure will be the responsibility of the FSME Procedure Contact as of October 1, 2006. Copies of FSME procedures will be available through the NRC website.

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I. INTRODUCTION

- A. The Atomic Energy Act (Act) authorizes the U.S. Nuclear Regulatory Commission (NRC) to enter into Agreements ~~that transfer regulatory providing for discontinuance of authority over certain radioactive materials to the States and the assumption of this regulatory authority by the States.~~ The Governor of a State initiates ~~this process the transfer by~~ formally requesting an Agreement.
- 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 proposed Agreement materials program, and
 - 3. State staff on the information to include in a request for an Agreement.
- C. As used in this procedure, the term Agreement State¹ refers to either a State or a Commonwealth. However, NRC staff should ~~take care to~~ use the proper term ~~for the particular State or Commonwealth that is requesting the Agreement~~ in the Agreement, *Federal Register* (~~FR~~), Notices (*FRN*), and other official records.

II. OBJECTIVE

- A. ~~Ensure Assure~~ that each new Agreement is consistent with the provisions of the Act, Commission policy, NRC Management Directives, and other statutory, regulatory or policy requirements;
- B. Create a ~~predictable and stable consistent~~ regulatory review process to reduce uncertainties that any prospective Agreement State would encounter;
- C. Provide for the effective, efficient, and timely review of the request by a State for

¹Section 274.n. of the Atomic Energy Act (Act)~~The Act~~ 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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an Agreement, or for an amendment to an existing Agreement; and

- D. Provide 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 Act and Agreements

Section 274 of the Act allows the Commission and a State to enter 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](#) ~~page C-1 of the Handbook~~ for Processing an Agreement.

Categories of materials that NRC may transfer are: (a) byproduct materials as defined in Section 11e.(1) through Section 11e.(4) of the Act; (b) source materials as defined by Section 11z. of the Act; (c) special nuclear materials (as defined in Section 11aa. of the Act) in quantities not sufficient to form a critical mass (as defined in 10 CFR 150.11); (d) the regulation of the land disposal of byproduct, source, or special nuclear ~~waste materials wastes~~ received from other persons; and (e) 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 ~~combination of the above~~ the above categories. **A State must assume authority over the entire category of material for which it is requesting authority under the Agreement. A State may not choose to regulate only certain types of activities within a category. A State must also have authority over all licensees within each category of material over which the State assumes authority.**

Before the Commission may approve 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. It must also be compatible with the Commission's program for the regulation of the materials. To distinguish this program from

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other radiation control activities of the State, ~~we call it~~ the program is referred to as the Agreement materials program.

The Governor must certify that the State has the required program and desires to assume ~~the~~ 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 must ~~be of sufficient detail for enable~~ the Commission to ~~determine that find~~ the State 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 laws and regulations that provides the program's framework. In accordance with Commission policy, the term "regulations" may include other forms of generic legally binding requirements. These ~~legally binding alternate~~ requirements may include license conditions, ~~or~~ orders, or any other acceptable ~~method alternative~~ as authorized by State law.

The second component is an effective organizational and administrative structure to execute and enforce the laws and regulations. The administrative structure includes implementing and operating procedures, and guidance for licensees and the ~~State~~ program staff.

The organizational structure may be a single State agency, a part of an agency, or portions of two or more agencies. In this procedure, the term "Agreement materials program" includes all State organizational units with regulatory responsibility over ~~the~~ materials specified in the Agreement.

C. NRC Staff Actions

The NRC staff evaluates the State's Agreement materials program as described in the request for an Agreement. Simultaneously, it prepares a written assessment of the program. The assessment provides the basis for a finding by the Commission that the program is adequate and compatible. The assessment should show that the program satisfies the Commission policy statement *Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory Authority*

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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 We refer to this~~ Commission policy statement is hereafter referred to as the "criteria policy statement."

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

IV. ROLES AND RESPONSIBILITIES²

- A. The Director, Office of Federal and State Materials and Environmental Management Programs (FSME), 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 and State Agreements (MSSA) and the~~ Branch Chief of the Agreement States Program ~~Branch, Branch~~ 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. Finally, the PM is the review team leader and should ~~be knowledgeable of the IMPEP program review process and have substantial experience with this process. qualify as an IMPEP team leader~~

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² ~~As of October 1, 2006, NRC reorganized its nuclear materials and Agreement State programs into two new program offices. The newly created Office of Federal and State Materials and Environmental Management Programs (FSME) is comprised of the former Office of State and Tribal Programs and two technical divisions from the Office of Nuclear Material Safety and Safeguards.~~

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- C. The review team is responsible for conducting the staff evaluation of the request according to this procedure. A team normally consists of the PM, the assigned staff contacts from other NRC offices ~~including the Office of the General Counsel (OGC), Office of Nuclear Security and Incident Response, and the affected Region. Other NRC offices should be represented if necessary),³ and Other FSME staff may be included as well as assigned.~~ The principal reviewers for licensing, inspection, staffing, and incidents and allegations should meet the IMPEP qualification requirements (NRC MD 5.10, *Formal Qualifications for Integrated Materials Performance Evaluation Program (IMPEP) Team Members*).
- D. 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 ~~usually~~ continues to coordinate contacts between the State and the Region licensing and inspection staffs. ~~The Regional State Liaison Officer (RSLO) may serve as a backup to the RSAO.~~ The RSAO ~~and RSLO~~ should keep the PM informed of these contacts.
- E. The Region and FSME are responsible for transferring NRC license files to the State (NRC MD 3.53, *NRC Records Management Program*). The PM should be kept informed of these activities.

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V. GUIDANCE

For detailed guidance on reviewing the request, including scheduling and documentation requirements, see the *Handbook for Processing an Agreement* (Handbook ~~Appendix C~~). ~~Appendix D to the Handbook Appendix C~~ contains ~~examples -samples~~ of letters and documents ~~from based on the work on recent a previous~~ Agreement request reviews. Below is an outline of each step in the process with a brief description. Cross-references to the Handbook and ~~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 Chairman declaring the State's intent to

³ ~~Office of General Counsel, Office of Nuclear Security and Incident Response, the affected Region, and other NRC offices if necessary.~~

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seek an Agreement. The letter should ~~indicate~~ 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. Initial Meeting with State after Receipt of Letter of Intent

Upon receipt of the Governor's Letter of Intent, the staff should schedule an initial meeting with the State, the NRC project manager, the Branch Chief of the Agreement State Programs Branch (ASPB), and the Regional State Agreement Officer. The purpose of this meeting is to discuss 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.

~~B.C.~~ **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 program description should address the program elements listed in ~~Section 4.0 of the Handbook, Section 4.0~~. For each program element, the State should provide information for each category of materials requested in the Agreement.

~~C.D.~~ **Draft Request for an Agreement [(Handbook, Section 3.4)]**

1. The Director of the State Agreement materials program (State ~~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 ~~and a description of the program~~ description information for all applicable elements of the Agreement materials program. It should also contain the draft text for the proposed Agreement (see NRC MD 5.8, *Proposed Section 274b Agreements With States*).
2. The State Program Director should ~~alert~~ notify the PM or the ~~Branch Chief of the ASPB, Division Director of MSSA,~~ at least two months before submitting the draft. The Director of FSME should then ask the Offices (~~discussed~~ discussed identified in Section IV.C of this procedure) to assign staff level contacts for the review team.

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3. ~~3.~~—The team reviews the draft request for completeness. ~~To be complete, the description of the program description information~~ must address all applicable program elements. It must also contain sufficient information to permit staff to conduct a detailed review of the application. Printed and photocopied documents must be legible. Information in electronic form must be readable by the agency computer resources. ~~The State should not submit any information that is not publically available, including security related information.~~
4. ~~4.~~—The team prepares a letter to the State Pprogram Director to document the results of the completeness review ~~[(sample in Handbook, Appendix D, Item CC)].~~ The Director of FSME signs the letter following Office concurrence.
5. ~~5.~~—The PM, RSAO, ~~Branch Chief of ASPB, Division Director of (DMSSA) or designee,~~ and the State Pprogram Director should schedule regular telephone conference calls on the progress of the review ~~[H]andbook, Section 3.4.4].~~ Review team members and other NRC staff may participate. Meetings should supplement the calls as needed.
6. ~~6.~~—The State should address the Agency's comments by making changes in the formal request. The State Pprogram Director should not submit a second draft, or changes to the draft, unless coordinated with the ~~Branch Chief of the ASPB. Division Director of MSSA.~~ When the changes to the formal request are completed, the Governor should sign and submit the formal request to the Chairman.

~~D-E.~~ Formal Request for an Agreement ~~[(Handbook, Section 3.5)]~~

1. The State Pprogram Director should ~~also~~ notify the PM two weeks before the Governor submits the formal request. The PM prepares a letter for signature by the Chairman acknowledging receipt of the request. ~~[(sample in Handbook, Appendix DG, Item E)]~~
2. The review team conducts a detailed evaluation of the formal request following the procedures and criteria in ~~Section 4.0 of the Handbook, Section 4.0.~~ If the State did not submit a draft request, assemble a review team to conduct a detailed review of the request.
3. If the team identifies deficiencies in the formal request, it prepares a letter to

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the State ~~p~~Program Director providing comments. Following ~~concurrency by applicable NRC Offices, Office concurrence,~~ the Director of FSME, signs the letter.

4. The State should address the comments by making revisions to the formal request ~~and~~ ~~—~~Send the revisions to the Secretary of the Commission, with a copy to the Director of FSME.

~~E.F.~~ ~~EF.~~—Work Completed by the Review Team ~~in Parallel~~ with the Review of the Formal Request

1. The team prepares a draft staff assessment addressing individually each criterion in the criteria policy statement. ~~[(sample in Handbook, Appendix D, Item FG)].~~
2. The team prepares a *Federal Register Notice* (~~n-FRN~~) ~~FR Notice~~ 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 notice~~. The ~~FRN notice~~ should also discuss any unique features of the proposed Agreement. ~~Include Attach~~ the text of the proposed Agreement, with a proposed effective date. The Director of FSME, usually signs the ~~FRN notice~~. ~~[A sample notice is in Handbook, Appendix DG, Item H]~~

~~—When the formal request satisfies the criteria policy statement, the team completes the Commission paper. The PM prepares a memo from the Division Director of MSSA transmitting the paper to the other Offices for concurrence.~~

~~—Following Office concurrence, the Director of FSME forwards the paper to the EDO for signature and transmittal to the Commission.~~

3. When the formal request satisfies the criteria policy statement, the team ~~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 must include, as enclosures, the following:
 - i. Draft staff assessment

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ii. Proposed FRN (including the summary of the draft staff assessment and proposed Agreement)

b. The paper must also include, as background, the following:

- i. Draft Congressional letters and letters to the Federal agencies [Items F.2. and 3. below]
- ii. Draft press release [Item G.2. below]
- iii. Project Schedule for processing, signing, and implementing the Agreement [Handbook, Appendix C]

4. The PM prepares a memorandum from the Division Director of MSSA transmitting the paper to the other Offices for concurrence. Following Office concurrence, the Director of FSME forwards the paper to the EDO for signature and transmittal to the Commission.

~~The paper must also include, as background, the following: Draft Congressional letters and letters to the Federal agencies, Draft press release, and Project Schedule for processing, signing, and implementing the Agreement [Handbook, Appendix C]~~

~~The Office of Public Affairs, in coordination with the PM, prepares a draft press release (sample in Handbook, Appendix C). The press release announces the publication of the proposed Agreement in the FRNF. [Handbook, Appendix D, Item I]R.~~

G. Commission approval of publication of the proposed Agreement

After the Commission approves the staff recommendations, the Office of the Secretary (SECY) will issue a Staff Requirements Memorandum (SRM). When the requirements of the SRM are satisfied, the Director of FSME signs the FRN. Once the Commission approves publication of the proposed Agreement, staff takes several actions:

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1. Staff forwards the FRN to the Office of Administration for publication.
 2. Staff prepares letters ~~Staff sends letters~~ ~~Letters are sent 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 pre-publication copy of the FRN ~~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 Chair and Co-Chair. Staff will also get the list of U.S. Senators and U.S. Representatives from OCA. The Office of Congressional Affairs sends the letters to these Committees. [Handbook, Appendix D, Item J]
 3. Staff sends a letter to the following Federal agencies informing them of the proposed Agreement, including a pre-publication 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; and
 - f. Assistant Secretary, Office of Legislative Affairs, Department of Homeland Security.
- ~~In coordination with the Office of Congressional Affairs, the PM prepares draft Congressional letters (sample in Handbook, Appendix C). The letters notify NRC's Oversight Committees and the State's delegation of the publication of the proposed Agreement.~~

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~~5. The team prepares a negative consent Commission paper ((sample in Handbook, Appendix DC, Item G)).~~

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~~The paper should request approval from the Commission to forward the FRN and FRN and proposed Agreement for publication.~~

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~~The paper must include, as enclosures, the:
Draft staff assessment~~

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~~Proposed FRN (including the summary of the draft staff assessment and the proposed Agreement).~~

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~~The paper must also include, as background, the:
draft Congressional letters and letters to the Federal agencies,
draft press release, and~~

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~~Project Schedule for processing, signing, and implementing the Agreement
((Handbook, Appendix C)Section 3.4.1).~~

~~6. The PM prepares letters (samples in Handbook, Appendix C) to notify interested Federal agencies of the FRN notice. The Agreement and nNon-Agreement States are notified by an announcement in an All States letter.~~

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~~F. Publication of the Proposed Agreement~~

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~~— Upon publication of the FRN, the PM issues a FSME letter to Agreement States, non-Agreement States, and State Liaison Officers, including a attaches a copy of the FR FRN, informing them of the proposed Agreement. [Handbook, Appendix D, Item L] notice to the All State letters notifying the Agreement States and the letters to the interested Federal agencies.~~

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~~1. The PM informs the Office of Public Affairs (OPA) of the publication so OPA can issue a press release. [Handbook, Appendix D, Item I].~~

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H. Publication of the Proposed Agreement

1. Upon publication of the FRN, the PM issues a FSME 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]

2. The PM informs the Office of Public Affairs (OPA) of the publication so OPA

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can issue a press release. [Handbook, Appendix D, Item I]

- I. End of the public comment period
 1. When the public comment period closes, the PM is responsible for preparing an analysis of the ~~comments~~-comments, working with ~~help from~~ the review team ~~as is needed~~ [Handbook, Appendix D, Item M]. ~~The Office of the General Counsel should thoroughly review the comments and the proposed responses for any possible litigation risk.~~The PM and review team should thoroughly evaluate the comments for ~~any possibilities~~any implication of legal action and highlight such possibilities to the Office of the General Counsel for its review of the comments and comment responses.
 2. The PM team prepares the final staff assessment, considering the public comments. [Handbook, Appendix D, Item N]
 - 4.3. ~~preparing an analysis of the comments.~~The PM ~~also~~ prepares a Commission paper requesting ~~seeking~~ Commission approval ~~action on~~ the proposed Agreement. ~~(sample in Handbook, Appendix C)~~[Handbook, Appendix D, Item O] The Commission paper is transmitted to other NRC Offices for review and concurrence.
 - 2.4. Enclosures to the paper are:
 - a. Final text of the proposed Agreement [Handbook, Appendix D, Item U]
 - i. 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]
 - a-b. The final staff assessment [Handbook, Appendix D, Item N]
 - c. The staff's analysis of the public comments [Handbook, Appendix D, Item M]
 - b-d. Draft letter from the Chairman to the Governor, approving the Agreement [Handbook, Appendix D, Item S]; ~~and~~

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~~Attachments to the paper are:~~

~~final text of the proposed Agreement;~~

~~a draft FRN notice~~

~~3. The following documents are included as include, as background to the paper:~~

~~4. —~~

~~5. Proposed 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]; and~~

~~6. —~~

~~7. A draft press release announcing the Agreement [Handbook, Appendix D, Item Q]~~

~~8. —~~

~~e. Sample letters and press releases are in the Handbook, Appendix C.~~

9-5. The paper must contain brief discussions of:

- a. Staff's consideration, analysis and resolution of public comments;
- b. Outstanding orders, Confirmatory Action Letters, and 2.206 petitions against licensees that will transfer;
- c. Staff coordination to resolve incomplete escalated enforcement actions. The discussion should indicate **that** we informed the State if NRC will retain jurisdiction for violations that occurred at a licensed facility while under NRC jurisdiction. **The Office of the General Counsel** has ruled that NRC has the authority under Section 234 of the Act to issue a Notice of Violation and Civil Penalty Assessment to transferred licensees. However, NRC does not have authority to require corrective actions after the Agreement is effective;
- d. The status of any complex site or other sites in decommissioning. The discussion should indicate how the State was advised to notify 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 NRC's Integrated

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Materials Management Performance Evaluation Program;

- e. How information was provided to the State regarding previously licensed sites;
 - f. Allegations and investigations in progress; however, details should not be included; and
 - g. 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. Proposed 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 draft press release announcing the Agreement [Handbook, Appendix D, Item Q]
 - c. 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 OCAOffice of Congressional Affairs for distribution once the Agreement is approved. Include a copy of the draft FRN with each form. It is not made publically available in the Agencywide Documents Management System.
- ~~10. The NRC and the State agree on the effective date for the Agreement.~~

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~~The PM inserts the date into the Agreement text~~

- ~~11. The Governor has the choice of signing the Agreement at a formal ceremony or signing by correspondence. The PM consults with the State program Director to determine the Governor's choice. The PM also determines the format of the Governor's signature block, and if the State wishes to add a State seal.~~
- ~~d. If the Chairman and Governor will hold a formal signing ceremony, the date, time and place of the ceremony must be arranged. The PM coordinates with the State staff and, through the EDO, with the Chairman's office.~~
- ~~e. 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.~~
- ~~f. If the Agreement is to be signed by correspondence, the PM asks the State program Director to provide instructions for delivery of the Agreement to the Governor.~~

J. Commission approval of the Agreement

- ~~1. The PM prepares assembles the Commission paper and attachments for concurrence by other NRC Offices involved with the review of the Agreement concurrence.~~
- ~~2. The Director of , FSME, forwards the Commission paper to the EDO following Office concurrence.~~
- 1. When 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 ~~(the~~ date of the SRM,) ~~into 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 State Pprogram

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Director to determine the Governor's choice. The PM also determines the format of the Governor's signature block, and if the State wishes to add a State seal.

- a. If the Chairman and Governor will hold a formal signing ceremony, the date, time and place of the ceremony must be arranged. 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 State Program Director to provide instructions for delivery of the Agreement to the Governor.
3. The Division Director of ~~, DMSSA, MSSA~~ forwards the Congressional letters and three copies of the Congressional Review Act form to ~~OCA~~ ~~the Office of Congressional Affairs~~.
~~Address the forms by filling the appropriate box at the top. Attach a copy of the draft FR notice FRN to each form. An example sample copy of this form the Congressional Review Act form is in Appendix DC to the Handbook.~~

K. Signing of the Agreement

1. If the Chairman and Governor will sign the Agreement at a formal ceremony:
 - a. The PM places the copies of the Agreement into individual binders.
 - 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.

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- ii. The remaining copy of the Agreement remains with FSME.
 - d. The State should receive the letter from the Chairman to the Governor approving the Agreement. [Handbook, Appendix D, Item S]
 - 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 ~~requested in Section V.C.5.c of this procedure.~~ **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 ~~s~~ **two copies** to the Director of, FSME.
 - 3. The PM delivers one copy of the signed Agreement to SECY. FSME retains the other copy in the ~~State's~~ **Agreements** file.
- L. Implementation of the Agreement
 - 1. The Division Director of ~~, DMSSA, MSSA~~ forwards the ~~FR notice~~ **FRN**, as approved in the SRM, to the Rule ~~making, Announcements,~~ **s** and Directives Branch of the Office of Administration. Section 274e.(2) of the Act requires publication of the ~~FR notice~~ **FRN** within 30 days after the Agreement is signed.
 - 2. The Region and FSME coordinate with the State on transferring license files to the State. ~~The RSAO should advise the PM of the plans for, and the progress of, the transfer.~~ **The two references below should be followed in transferring the license files:**
 - a. NRC MD 3.53, "*NRC Records and Document Management Program,*" **Records Disposition Objectives and Procedures (c), paragraph 8)**

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a.b. NRC Inspection Manual Chapter, Manual Chapter 2882, “Transfer of NRC License Files to Agreement State(s)” ~~–The RSAO should advise the PM of the plans for, and the progress of, the transfer.~~

3. The PM informs ~~alerts~~ the Office of Public Affairs (OPA) of approval of the Agreement so that OPA can ~~to~~ issue the press release announcing the approval of the ~~effective~~ Agreement.
4. ~~Staff sends letters to the NRC Congressional Oversight Committees, the U.S. Senators and the U.S. Representatives, as well as to the State Congressional delegation, providing these individuals with a pre-publication copy of the FRN 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 Chair and Co-Chair. Staff will also get the list of U.S. Senators and U.S. Representatives from OCA. 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 pre-publication 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. The Office of Congressional Affairs sends the letters to these Committees. [Handbook, Appendix D, Item R]~~
5. Staff sends a letter to the following Federal agencies informing them of the proposed Agreement, including a pre-publication 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;

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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; and
 - f. Assistant Secretary, Office of Legislative Affairs, Department of Homeland Security.
- 4.6. The staff issues a FSME 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.]
- ~~4. The PM prepares letters announcing the effective date of the Agreement. Letters go to interested Federal agencies, and the affected NRC material licensees are notified by the appropriate region. The Agreement and non-Agreement States are notified in an All States letter. The Division Director, DMSSA, signs the letters. The PM provides the new Agreement State program Director copies of the announcements.~~

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M. After the Agreement is effective

1. Approximately nine months after the Agreement becomes effective, a meeting is set up with the State Agreement materials program management. The orientation meeting is to discuss the State's implementation of the Agreement materials program (FSME Procedure SA-118, *Orientation Meeting for New Agreement States*).
2. Approximately 18 months after the Agreement becomes effective, the first IMPEP review is conducted (NRC MD 5.6)
 - a. The first IMPEP review evaluates the initial performance of the State program.
 - b. Normally, the first review is not scheduled for earlier than approximately 18 months after the Agreement becomes effective. If scheduled earlier, the State may not have completed enough regulatory actions to support an IMPEP finding.

VI. APPENDICES

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 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. NRC Management Directive 3.53, *NRC Records Management Program*, ~~June 15, 1995~~ **March 15, 2007**

~~—NRC Inspection Manual Chapter, Manual Chapter 2882, "Transfer of NRC License Files to Agreement State(s)"~~

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- D. NRC Management Directive 5.6, *Integrated Materials Performance Evaluation Program (IMPEP)*, ~~November 25, 1997~~ February 26, 2004
- E. NRC Management Directive 5.8, *Proposed 274b Agreements with States*, ~~September 9, 2004~~ June 25, 2013
- F. NRC Management Directive 5.10, *Formal Qualifications for Integrated Materials Performance Evaluation Program (IMPEP) Team Members*, January 5, 1999
- G. NRC Inspection Manual Chapter, Manual Chapter 2882, “*Transfer of NRC License Files to Agreement State(s)*,” December 3, 2001
- H. FSME~~STP~~ Procedure SA-118, *Orientation Meeting for New Agreement States*, ~~March 9, 2005~~ March 19, 2010

VIII. ADAMS REFERENCE DOCUMENTS

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	7/19/2007	FSME State Agreement Procedure, <i>Processing an Agreement – SA-700</i>	ML072160020
2	7/19/2007	FSME SA-700 Procedure, Redline/Strikeout Copy	ML072210542
3	7/19/2007	FSME SA-700 Handbook, Redline/Strikeout Copy	ML072210549
4	7/19/2007	FSME SA-700 Handbook, Appendix C, Redline/Strikeout Copy	ML072210655

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No.	Date	Document Title/Description	Accession Number
5	08/22/2006	STP-06-073, Opportunity to Comment on Draft Revision to STP Procedure SA-700, <i>Processing an Agreement</i>	ML062290300
6	01/30/2007	FSME SA-700 Procedure – Resolution of Comments	ML072210663
7	XX/XX/2014	FSME State Agreement Procedure, <i>Processing an Agreement – SA-700</i>	MLXXXXXXXXXX
8	XX/XX/2014	FSME State Agreement Procedure, <i>Processing an Agreement – SA-700, SA-700 Procedure, Track Change Version</i>	MLXXXXXXXXXX
9	XX/XX/2014	FSME SA-700 Handbook, <i>Track Change Version</i>	MLXXXXXXXXXX
10	XX/XX/2014	FSME SA-700 Handbook, <i>Appendix C, Track Change Version</i>	MLXXXXXXXXXX
11	XX/XX/2014	FSME SA-700 Handbook, <i>Appendix D, Track Change Version</i>	MLXXXXXXXXXX
9	XX/XX/2014	[insert FSME letter number] Opportunity to Comment on Draft Revision to SA-700	MLXXXXXXXXXX
10	XX/XX/2014	Summary of Comments on SA-700 (version dated XX/XX/201X)	MLXXXXXXXXXX

Handbook for Processing an Agreement

Date: ~~July 19, 2007~~

Office of Federal and State Materials and
Environmental Management Programs (FSME)
U.S. Nuclear Regulatory Commission

Contact: ~~William Rautzen Torre Taylor~~

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1.0 INTRODUCTION

1.1 Purpose

This Handbook provides guidance for the preparation and review of a State request for an Agreement. The Nuclear Regulatory Commission (NRC) staff should use the Handbook for guidance in reviewing the request, or for 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 statement by the Governor of the State and a comprehensive description of the State's Agreement materials program with supporting information. This Handbook addresses the supporting information that the State should include, and the criteria that NRC staff uses to evaluate it. The NRC staff must be able to reach a general conclusion that the information satisfies-meets the Commission's review criteria.

Section 2.0 of the Handbook 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 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 Handbook Section 2.2 below). It also includes provides references to NRC and other documents related to the specific criteria program element.

Appendix A is a cross reference table of the subsections in Handbook Section 4.0 to the criteria in the criteria policy statement, and 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 DC is a set of sample letters and documents developed in a previous review of a request for an Agreement.

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 External Internal Procedures for the Office of Federal and State Materials and Environmental Management Programs (FSME) Agreement State Program. We

¹ As of October 1, 2006, NRC reorganized its nuclear materials and Agreement State

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will describe these in more detail below. These are addressed in more detail below.

2.1.1 Federal Statutes

The Commission ~~conducts~~ implements the Agreement State program under Section 274 of the Atomic Energy Act of 1954, as amended (Act). Section 274b. authorizes the Commission to enter into an Agreement with the Governor of a State. Section 274c. of the Act specifies those regulatory authorities that must be reserved to 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, NRC discontinues, and the State assumes, regulatory responsibility 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. Handbook Section 4.1 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 three policy statements applicable to the Agreement State Program. They are discussed individually in the paragraphs below.

2.2.1 Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory Authority and Assumption Thereof by States Through Agreement (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 and compatible.

programs into two new program offices. The newly created Office of Federal and State Materials and Environmental Management Programs (FSME) is comprised of the former Office of State and Tribal Programs and two technical divisions from the Office of Nuclear Material Safety and Safeguards.

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The first 28 criteria in the **Criteria P** policy **S**statement apply to all proposed Agreement State materials programs. The last seven criteria apply only to States that **request authority to will** regulate ~~the~~ 11e.(2) byproduct material from, and operation of, uranium and thorium mills.

2.2.2 Statement of Principles and Policy for the Agreement State Programs (62 FR 46517, 9/3/97)

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

2.2.3 Policy Statement on Adequacy and Compatibility of Agreement State Programs (62 FR 46517, 9/3/97)

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

2.3 **Management Directives and State Agreement Procedures**²

NRC staff use two different types of procedures in reviewing State requests for **Agreements**. ~~Two levels of procedures guide NRC staff. First are the~~ Management Directives (MD), ~~which~~ address activities whose responsibilities extend to more than one Office. ~~Individual Office procedures are used for~~ **For** activities that are the responsibility of a single Office, ~~the Office uses Internal Procedures,~~ such as the FSME **State Agreement (SA) procedures series**. The following MDs and SAs ~~procedures provide direction and guidance for the~~ **guide the** review of a request for an Agreement.

Current copies of Management Directives may be viewed on the NRC Internet website <http://www.nrc.gov>, under the tab heading of "NRC Library," under Document Collections. **State Agreement procedures may be found at <http://nrc-stp.ornl.gov/>, under Resources and Tools, FSME procedures.**

2.3.1 NRC Management Directive 5.6, *Integrated Materials Performance Evaluation Program*

MD 5.6 provides the process and criteria for evaluating the performance of ~~both~~ Agreement State **materials programs** and ~~the~~ NRC regional materials programs. **It is also used for certain NRC Headquarters program areas**. 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

² ~~Current copies of these Management Directives may be viewed at the NRC Internet website /reading_rm/doc_collections/#man~~

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satisfactory in all applicable IMPEP performance indicators.

2.3.2 NRC Management Directive 5.8, *Proposed 274b Agreements With States*

MD 5.8 provides guidance on drafting a proposed Agreement. Handbook 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 assure the adequacy and compatibility of the proposed Agreement materials program. State requests for unique authority beyond the standard Agreement categories will require approval by the Commission. Significant changes may require special approval by the Commission.

2.3.3 NRC Management Directive 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 appropriate elements of MD 8.8, based on State requirements and law.)

2.3.4 NRC Management Directive 5.9, *Adequacy and Compatibility of Agreement State Programs*; and FSME Procedure SA-200, *Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements*

MD 5.9 implements the *Policy Statement on Adequacy and Compatibility of Agreement State Programs*. The objective of MD 5.9 is to establish the process NRC staff will follow to determine when a proposed or final Commission regulation or 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. provides the process and criteria used to identify the compatibility categories of the NRC program elements. FSME Procedure SA-200 documents the results of the process compatibility or health and safety determination for each regulation. The Appendix A to SA-200 lists each NRC regulation and program element, if it is required for adequacy or compatibility, and its designated compatibility category (i.e., for compatibility, health and safety, reserved for NRC, or not required to be adopted by the States).

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. that should be adopted by Agreement States.

2.3.5 Office of Federal and State Materials and Environmental Management Programs Internal Procedures – SA – SA- Procedure series³

The FSME procedures SA-100 through SA-105 and SA-107 through SA-110 provide guidance for the review of IMPEP performance indicators in Agreement materials programs. They

³Please check the FSME Internet website www.hsrdo.ornl.gov/nrc/procfm.htm for the most current procedures: <http://nrc-stp.ornl.gov/procedures.html>

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.

~~The STP internal procedures~~FSME procedures SA-201, *Review of State Regulations*, 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 may be useful in reviewing an Agreement request.

3.0 REVIEW PROCEDURES

3.1 General Considerations

~~As the process has developed historically,~~ 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 ~~expressing an intention to enter into~~ an Agreement. The third step is the submission of a draft request by the State program Director or designee ~~that, which~~ is reviewed by NRC. Comments are then provided to the State for resolution prior to the Governor's formal ~~submission of a request to enter into an Agreement. submittal by the Governor.~~

The fourth step is the submission of the formal ~~r~~Request for an Agreement by the Governor. If practical, all significant issues identified by NRC with the draft request will have been resolved by the State before the Governor submits the formal Request.

3.1.1 Proprietary, ~~and~~ Privacy, and Security Information

~~Normally, States should not need to submit proprietary information or information subject to the Federal Privacy Act, or a State equivalent.~~ 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. 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 DMSSA.

Certain information required in support of the Agreement request may contain security-related sensitive information. This information should not be included as part of the Agreement application since the application is a public document. Instead, the State should verify that it will follow specified procedures. For example, the State should state what procedure they will follow for pre-licensing guidance, security inspections, etc.

3.1.2 Schedule for Processing an Agreement

Appendix C contains a sample schedule for processing a request for an Agreement that is 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 NRC and the State, ~~and is often based on 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. This usually requires **at least 1 year** ~~about nine months~~ after the State submits the formal request **for an Agreement**.

In the sample schedule, **the overall we give** 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 organize** a Project Schedule with **suspenseestimated** dates, **based on the requested date of the Agreement**. The PM should update the Project Schedule **routinely as milestones are met. frequently**.

3.1.3 Form of the Request

The State may submit the request as electronic documents or on paper. 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 **WordPerfect** ~~or Microsoft~~ Word. The State should contact the PM for further information on this capability.

If the State elects to submit a request on paper, it should submit one complete copy. NRC will scan the request into the Agency 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 is of high quality necessary for scanning. good enough to be scanned**. Note that the request and supporting information is a public document. The State **should not submit any information that cannot be publically released**.

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 ~~or written requests~~ (requests other than minor clarification issues) should be **submitted in writing to the PM. The PM will also inform the Branch Chief of the Agreement State Programs Branch (ASPB) of significant issues. directed to the Division Director, DMSSA. 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 NRC staff should provide, or confirm that the State has~~ the following documents:

- a. ~~Copies of~~ Sections 11 and 274 of the Act;
- b. ~~Suggested Legislation Copies of the Suggested State Radiation Control Act,~~ published by the Council of State Governments;⁴ ~~(CSG);~~

⁴ ~~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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- c. ~~Copies of the~~ 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. ~~Copies of~~ Management Directive 5.6, *Integrated Materials Performance Evaluation Program (IMPEP)*; MD 5.8, *Proposed 274b Agreements with States*; and MD 5.9, *Adequacy and Compatibility of Agreement State Programs*; and the FSME ~~External Internal~~ Procedures SA- series, ~~if the State staff does not have Internet access.~~

Normally, prior to the receipt of a Letter of Intent, the Regional State Agreements Officer (RSAO) ~~in the region in which the State is located~~ is the NRC staff lead for responding to informal questions and requests for additional information. The RSAO should coordinate with FSME 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 ~~DMSSA~~ DMSSA.

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. ~~A sample letter is in Appendix C. See Appendix D, Item A.~~

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

3.3.2 Response to Letter

When NRC receives a letter of intent, the ~~Branch Chief of ASPB Division Director, DMSSA,~~ assigns an FSME 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. ~~A sample letter is in Appendix C. See Appendix D, Item B.~~

3.3.2.2 State Preparation of the Request for an Agreement

The PM coordinates with the RSAO and ~~maintains liaison~~ 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 progress of the State 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.

3.4 The Draft Request

Submitting a draft of the Governor's Request 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 NRC for review well before the draft request. Early review by FSME and OGC can allow time for amendments to critical legislative or regulatory provisions, if required.

3.4.2 Notification of ~~Alert for~~ Draft Request

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

3.4.3 Review of the Draft Request

The ~~review~~ team conducts a completeness review of the draft request using the evaluation criteria in ~~handbook-Handbook~~, Section 4.0, ~~based on the Criteria Policy Statement~~. The ~~review team's~~ completeness review has two objectives. First, ~~the team it-determines discovers~~ whether the Agreement materials program description ~~information-~~addresses each of the applicable elements. Second, ~~the review team judges-evaluates~~ whether the request contains sufficient information to permit ~~the review team-staff~~ to conduct a detailed review of the application.

3.4.3.1 Completeness Evaluation

Each principal reviewer evaluates the completeness of his or her assigned program element. Other team members may help in evaluating the completeness of elements. The evaluation should be completed ~~within about 8 weeks by the end of elapsed week three~~. See Appendix D, Item C.

3.4.3.2 Team Meeting

The ~~review~~ team should meet ~~during elapsed week four~~ to discuss the findings of ~~their~~its completeness review. ~~The review team~~ should also draft a letter to the State program Director or designee presenting team findings. ~~The PM should reserve use of a conference room for the~~

~~full week.~~ The individual review team members should concur on the completeness of each program element. The review team should complete its review, completeness letter and briefs the Division Director of DMSSA on the completeness review findings ~~at the end of elapsed week four~~ within 8 weeks of receipt of the draft request from the State.

3.4.3.3 Review Product

The principal review product is a letter to the State program Director or designee. If the draft request is complete, the letter should state that NRC staff believes the request is ready for submission. If the draft request is incomplete, the letter includes the team's findings and comments.

If the draft request is incomplete, the review team should also hold a conference call with the State staff to discuss the information that is incomplete or needed. The team may hold a meeting with the State staff at the State's option, following the State's receipt of the review team's written comments ~~review findings~~.

The final letter to the State is signed by the FSME Office Director. As discussed in Section 3.4.3.2 above, the review team should complete its review and documentation within 8 weeks of receipt of the draft request from the State. The completeness letter should be sent within a week after the review is complete.

~~The letter should be ready for Office concurrence by the end of elapsed week four. Following Office concurrence, FSME should dispatch the letter by the end of elapsed week six.~~

3.4.4 Telephone Conference Calls

The PM, RSAO, ~~Division Director, DMSSA, Branch Chief of ASPB, and Division Director of MSSA, or designee,~~ and the State program Director or designee should establish a schedule of periodic telephone conference calls. The calls should start during the review of the draft request. Subjects of the conference calls should include progress of the review, issues identified during the review, and additional information needed. Participants should include the PM, RSAO, and the State 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. Telephone conference calls should be planned for approximately every two weeks. The schedule can be adjusted to meet the needs of the review team. ~~Plan the calls for every other week to start, then adjust the schedule as needed.~~

3.4.5 Meetings and Visits

The PM and the RSAO should visit the State offices to gain first-hand knowledge of the State facilities and staff. If possible ~~practical~~, coordinate the visit with the State ~~after the State has received the receipt of the~~ completeness review letter and has had time to review the comments. This will give the State an opportunity to discuss the NRC's comments in preparation for ~~finalizing-formulating~~ the formal request. The State program Director or designee and senior State staff members should visit both the NRC regional and headquarters

offices. Other meetings should supplement the telephone conference calls. The PM should also coordinate and schedule meetings and visits during the State's preparation of a request, as necessary.

3.4.6 Inspection and Licensing Staff Contacts

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 inspectors and to become more familiar with the operations of licensees that will transfer under the Agreement. The State inspectors may accompany NRC before a letter of intent is submitted. After the letter of intent is submitted, State inspectors should accompany NRC inspectors on a regular basis. regularly-NRC inspectors should work closely with the State to establish schedules that work for both the State and NRC.

State license reviewers should work with the NRC Regional license reviewers, starting at least one 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 work should begin at least when the Governor submits the letter of intent. NRC and the State should give a higher priority to those licensing actions for licenses that Give preference to actions for licenses that will transfer to the State when practical.

Since these activities are centered in the Region, the RSAO usually leads coordination of these activities with the Regional liaisons and inspection staff. However, if there are any issues with coordinating these activities, by the State or by the NRC regional staff, the PM should be informed to help resolve any issues.

3.5 The Formal Request for an Agreement

The formal request should be the draft request modified to address NRC comments on the draft request. The Act requires that the Governor sign the formal request. be signed by the Governor The Governor sends a "letter of certification" with the formal request, certifying that the State is adequate and compatible to regulate the categories of materials requested under the Agreement. The Governor addresses the letter. —It should be addressed to the Chairman of the Commission. See Appendix D, Item D.

The Chairman writes to the Governor acknowledging receipt of the formal request, including positive statements of the NRC and the State working together, and committing the NRC to working expeditiously to complete the review in a timely manner. See appendix D, Item E.

The information supplied in a request 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 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 request for an Agreement. ~~information by the review team.~~ 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 the Handbook, Section 4.0, and the criteria in the criteria policy statement.

3.5.1 Project Schedule Adjustment

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

3.5.2 Review of the Formal Request

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

3.5.2.1 Principal Review Review of Program Elements

Each ~~principal reviewer~~ review team member conducts a detailed evaluation of specific ~~an~~ program element(s) of the proposed program assigned to that member. Other team members may help in evaluating the element. Review ~~t~~Team members may discuss their questions about the formal request 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, the ~~principal~~ review of the formal request should take about 4 ~~-8 weeks and be completed by the end of elapsed week 21.~~

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. On identification of a major issue(s), the review team member(s) ~~reviewer~~ should notify the PM immediately. The PM ~~alerts~~ informs the Branch Chief of ASPB ~~Division Director, DMSSA,~~ and schedules a meeting of the team to discuss the issue(s). After the meeting, the team briefs the Division Director of DMSSA, and other management ~~as appropriate as needed.~~ The State Pprogram Director or designee and Director of FSME are kept informed of the staff activity to resolve major ~~the~~ issues.

3.5.2.3 Team Findings and ~~the Draft-Draft NRC Staff Assessment~~

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~~TDuring elapsed week 22~~ the review team meets to discuss their findings and prepare the draft NRC staff assessment. ~~The PM should reserve a conference room for two weeks.~~ This step could take up to two weeks. See Appendix D, Item F.

If the request satisfies the ~~criteria policy statement criterion~~ ~~evaluation criteria~~ for a program element, the ~~rprincipal reviewer~~ review team member for that program element prepares the ~~drafts staff assessment text~~ for the relevant criteria in the criteria policy statement. ~~The review t~~Team members should concur on the findings for each program element, and the ~~draft staff assessment text~~. The ~~full~~ draft staff assessment should be completed ~~by the end of elapsed week 24~~ in about 4 weeks, as discussed in Section 3.5.2.1 above.

If the request does not satisfy the criteria policy statement criteria, the review team 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 ~~rprincipal reviewer~~ review team member prepares a draft comment. Each comment should describe the issue and, where practical, provide guidance to resolve the issue. ~~Review t~~Team members should concur on the comments.

The team prepares a letter transmitting its comments, if any, on the formal request. The letter is ~~signed by the from the~~ Director of FSME, and addressed to the State Pprogram Director or designee, ~~and should be completed by the end of elapsed week 24.~~ This step is part of the review team's work discussed in Section 3.5.2.1 and Section 3.5.2.3 above. ~~Following Office concurrence, FSME should dispatch the letter as quickly as possible.~~

The State should address the comments by submitting revised pages or sections to the formal request to the Secretary of the Commission with a copy to the Director of FSME. ~~When the~~The review tteam ~~receives the revisions, it~~ reviews ~~only~~ the revisions submitted by the State. The PM should update the schedule as needed based on when the comments are addressed by the State. ~~will need to revise the schedule.~~

3.5.4 Completion of the Review

When the review tteam concludes that ~~the all criteria in the~~ criteria policy statement ~~is are~~ ~~satisfied~~ addressed, ~~the~~ review team completes the draft staff assessment. The PM ~~and~~ completes the Commission paper and all supporting documents.

The Commission paper will include the draft *Federal Register* notice and the following documents as background: (a) draft Congressional letters; (b) draft press release; and (c) draft

Federal agency letters. See Appendix D, Items G, H, I, J, and K.

Procedures for the publication of the proposed Agreement, and for the approval, signing, and implementation of the final Agreement, are provided in Sections V.F through V.K of FSME State Agreement Procedure SA-700.

4.0 INFORMATION NEEDED AND EVALUATION CRITERIA

This section addresses the information that 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 criterion applicable to the topic. Additionally, references are provided to assist the State in preparing its Agreement request.

4.1 Legal Elements

The Act does not permit the Commission to delegate its authority to the States. Under the Act, Agreement States administer independent regulatory programs under State Statutes. Each State program must derive its authority from its own State law.

4.1.1 Authority to Establish a Program and Enter Into an Agreement

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.

Comment [Tmt3]: The acronym is not used because this is not a familiar organization and it will get lost through the extensive document.

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;
- a-b. Authorizes the program to issue licenses, including the following:
 1. authorizesAuthorizes the program to impose additional license requirements.
 2. authorizesAuthorizes the program to give exemptions from the licensure licensing requirements.
 3. authorizesAuthorizes the program to recognize the licenses of other jurisdictions (that is, reciprocity).

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3.

4. ~~makes~~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.

5. ~~authorizes~~Authorizes the program to recognize licenses transferred from NRC under the Agreement as State licenses, if necessary.

~~b-c.~~~~authorizes~~Authorizes the program to adopt regulations.

1. Specifies the procedures and requirements for adoption of regulations, including public participation.
2. Allows the program to impose requirements in the form of other generic legally binding requirements, such as orders.

~~e-d.~~Authorizes representatives of the program to enter premises and conduct inspections.

~~e-e.~~ Authorizes the program to require compliance with regulatory requirements by both licensees and unlicensed individuals.

~~e-f.~~ Authorizes the program to impose sanctions for violations of the regulations, orders, or license conditions.

~~f-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 Act, the State should submit the **State** law that authorizes the regulation of uranium and thorium ~~milling~~~~recovery~~ facilities, including disposal of mill tailings.

4.1.1.2 Evaluation Criteria

{Note: The team may use the **Council of State Government Suggested State Legislation** as guidance. However, the State is not required to follow either the content or the format of the model legislation. **If the Agreement will cover LLRW disposal, see Section 9 of the model legislation.** If the Agreement will cover Section 11e.(2) byproduct material, Section 8 of the model legislation provides valuable suggested guidance on the Statutory provisions necessary to assume **authority of 11e.(2)** byproduct material.

Comment [Tmt4]: Discussed with Dennis Sollenberger. The term "milling" is more in line of the statutory authority and of the processes that NRC regulates and the authority that will be transferred under the Agreement.

We are asking the State to submit State law over the 11e.(2) authority, if requested.

Handbook for Processing an Agreement

~~authority. If the Agreement will cover LLW disposal, see Section 9 of the model legislation.)~~

~~a.~~

~~b.a.~~ a. State law must authorize the Governor to enter into an the Agreement. It must also designate a radiation control agency and provide it the necessary legal authority to be effective. [1, 12, 19, 23, 24, 25]⁵

b. State law must not create duplications, gaps or conflicts in regulation. This includes duplications, gaps or conflicts between the State and NRC, State agencies, or State and local agencies. The law must not seek to regulate materials or activities reserved to the NRC. [241, 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 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, including the transportation to or from such sites and the performance of contract services during temporary interruptions of such transportation;
2. Prime contractors researching, developing, manufacturing, storing, testing, or transporting atomic weapons or components;
3. Prime contractors using or operating nuclear reactors or other nuclear devices in a U.S. Government-owned vehicle or vessel; and

⁵ The numbers in brackets correlate to the numbered criteria in the Commission criteria policy statement (see handbook Section 2.2.1).

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Comment [Tmt5]: The footnote is being deleted and the text brought up into the introductory paragraph to this Section. If the footnote designation is deleted in track changes, the text of the footnote will be deleted.

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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

- e.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]
- f.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]
- g.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 NRC has regarding ~~of~~ interpretation of State law. Interpretations of State law must be provided NRC will accept interpretations 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 LLW 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 ~~empower~~ the program to carry out the requirements of the Uranium Mill Tailings Radiation Control Act of 1978, as amended (UMTRCA). Specifically, the law should:

- a. Authorize the program to regulate 11e.(2) byproduct material [29]
- b. Authorize the program to require licensees to provide a financial surety arrangement.

The arrangement should ~~be such assure~~ 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 ~~environmental~~ 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; [29]
 5. ban major construction before the completion of the written environmental analysis.
- d. Require the 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; [29]
- e. Require the program, before terminating an 11e.(2) byproduct material license, to do the following:
 1. ~~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]~~
 1. 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; [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;

b.

- 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;
- f. Exempt land ownership transfer requirements of Section 83(b)(1)(A) of the Act.

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. *Statement of Principles and Policy for the Agreement State Program* (62 FR 46517, 9/3/97)

4.1.2 Organization of the Proposed Program

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

4.1.2.1 Information Needed

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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 this Handbook, Section 4.0;
- d. For each program element, cross-references to the pertinent portions of the supporting information.

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

- a. All organizational levels between the Governor and the State Program Director or designee;
- b. The organizational structure and staff of the materials program;
- c. Regional offices and staff, if any.

The State should submit a copy of each Memorandum of Understanding (MOU) that will affect the 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 MOU's describing the responsibilities of each agency. MOU's should include a discussion also describe the of processes for efforts 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 program within the State government structure. [1, 24, 33]

The 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 program uses the resources of another agency, the 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 this handbook-Section 4.6.1) of this 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 Agreement State Programs*
- d. FSME Procedure SA-200, *Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements*, Appendix B

Comment [Tmt6]: Appendix B is not relevant given the revision to SA-200. I believe the reference is to the entire SA procedure and the specific compatibility designations.

4.1.3 Content of the Proposed Agreement

An Agreement may transfer to a State 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 Atomic Energy Act;
- b. Byproduct materials as defined in section 11e.(2) of the Atomic Energy Act;
- c. Byproduct materials as defined in section 11e.(3) of the Atomic Energy Act;
- d. Byproduct materials as defined in section 11e.(4) of the Atomic Energy Act;
- e. Source materials;
- f. Special nuclear materials, in quantities not sufficient to form a critical mass.

In addition, an Agreement may transfer to a State the specific authority to conduct one or more of the following activities, which otherwise remain under 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 the transfer of all categories of materials (known as a "full Agreement"). Agreements that do not transfer all of the categories (known as a "limited Agreement") should delete the appropriate provisions as shown in MD 5.8, Handbook. **If a State requests only a subcategory of**

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Agreement material within a category, the State must submit detailed information as to why this request is needed and supporting justification. Staff must obtain ~~is to consult with the~~ Commission approval for any such requests ~~prior to proposing a final limited Agreement in instances where there is no clear precedent.~~

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 4 of MD 5.8, Handbook. If the State does not follow the standard Agreement, it must explain why. The State should provide detailed information regarding the intent of this difference from the standard Agreement and the expected outcome. ~~explanation should describe the intent and the expected effect of the deviation.~~

4.1.3.2 Evaluation Criteria

The proposed Agreement must be consistent with the purpose of Section 274 of the Act. 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 the~~ needed and supporting justification. ~~for the change and the expected result.~~ Such changes ~~will~~ may require separate approval by the Commission. The information submitted must provide a basis for the Commission to approve the change. [26, 27]

The Agreement must transfer 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~~ Handbook in MD 5.8). [27]

4.1.3.3 References

- a. Criteria Policy Statement, criterion 27
- b. NRC Management Directive 5.8, *Proposed 274b Agreements With States*

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 (CRCPD), as a

model for its regulations.⁶

4.2.1 Standards for Protection Against Radiation

The standards for protection against radiation include, **but are not limited to**:

- a. the dose limits for occupationally exposed persons and members of the public;
- b. limits on the concentration and quantity of materials released to the environment;
- ~~b-c.~~ technical definitions and terminology; units of radioactivity and radiation dose; ~~and~~ radiation symbols, labels, and warning signs.

4.2.1.1 Information Needed

The State should submit its regulations, or generic legally binding requirements, that prescribe the standards for protection against radiation.

If the State wants to regulate the disposal of low level radioactive waste at a land disposal site, it should submit its regulation equivalent to 10 CFR 61.41.

4.2.1.2 Evaluation Criteria

The State standards for protection against radiation must satisfy the criteria for compatibility category A. The criteria are given in the Handbook to MD 5.9. **A list of program elements and their compatibility or adequacy designation is provided in FSME State Agreement Procedure SA-200, Appendix A. Appendix A includes a link to the NRC regulations, by 10 CFR Part, lists the equivalent NRC regulations, with a link to a table with the compatibility designation assigned to each regulation. Additional guidance for submitting State regulations for NRC review is provided in FSME State Agreement Procedure SA-201, "Review of State Regulatory Requirements." Appendices A and B, provide additional guidance.** [2, 3, 4, 5, 6, 9a, 11, 22]

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

~~The standards must require consideration of the total occupational dose to individuals.~~ [4]

If the State adopts generic legally binding requirements other than regulations, ~~the program staff should apply assure consistency in their application~~ generic legally binding requirements

⁶If using the SSR, the State should consult with the RSAO or PM to identify any compatibility issues, and the current status of NRC's compatibility determination on specific SSR parts. Note, SSR development and promulgation may lag behind the issuance of final NRC regulations.

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 2, 3, 4, 5, 6, 9a, 11, ~~and 22~~, and 23
- b. NRC Management Directive 5.9, Adequacy and Compatibility of Agreement State Programs
- c. FSME Procedure SA 200, Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements
- d. **Applicable sections of Title 10 CFR Parts 19, 20, 30, 31, 32, 33, 34, 35, 36, 37, 39, 40, 61, 70, 71, and 150**
- e. Conference of Radiation Control Program Directors, *Suggested State Regulations*

4.2.2 Regulatory Requirements with Significant Transboundary Implications

The regulatory requirements with significant transboundary implications are, **in part, related to:**

- a. regulations that affect the movement of materials across State borders;
- b. certain other regulations, such as the limits for quantities and concentrations of materials **where the end user is** exempt from licensing, requirements for sealed sources and devices (SS&D), and the waste classification system in 10 CFR Part 61.
- ~~b-c.~~ **Other requirements where a consistent nationwide approach is necessary.**

4.2.2.1 Information Needed

The State should submit its regulations, or generic legally binding requirements, that prescribe the regulatory requirements with significant transboundary implications.

4.2.2.2 Evaluation Criteria

The State regulatory requirements with significant transboundary implications must satisfy the criteria for compatibility category B. The criteria are given in the Handbook to MD 5.9. A list of program elements and their compatibility designation is provided in FSME State Agreement Procedure SA-200, Appendix A. Appendix A includes a link to the NRC regulations, by 10 CFR Part, with a link to a table with the compatibility designation assigned to each regulation. Additional guidance for submitting State regulations for NRC review is provided in FSME State Agreement Procedure SA-201, "Review of State Regulatory Requirements." [10]

If the State adopts the NRC regulations by reference, the State rule should disclaim any intent

to regulate materials or activities over which NRC retains jurisdiction.

~~The State regulations that may have significant effect across jurisdictional boundaries must satisfy the criteria for compatibility category B. The criteria are given in the Handbook to MD 5.9. FSME Procedure SA-200, Appendix A, lists the equivalent NRC regulations. [6, 9a, 10] 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]~~

4.2.2.3 References

- a. Criteria Policy Statement, criteria 9(a) and (b), ~~6, 9a, and 10~~, and 23
- b. NRC Management Directive 5.9, *Adequacy and Compatibility of Agreement State Programs*
- c. FSME Procedure SA-200, *Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements*, Appendix A
- d. Applicable sections of Title 10 CFR Parts 19, 20, 30, 31, 32, 33, 34, 35, 36, 37, 39, 40, 61, 70, 71, and 150
- ~~d. Title 10 CFR Parts 19, 20, 30, 31, 32, 34, 35, 36, 39, 40, 61, 70, 71, and 150~~
- e.d. Conference of Radiation Control Program Directors, *Suggested State Regulations*

4.2.3 Regulatory Requirements Needed for an Orderly Pattern of Regulation ~~or Which Have Particular Health and Safety Significance~~

The regulatory requirements needed for an orderly pattern of regulation ~~are or which have particular health and safety significance are:~~

~~regulations that an Agreement State should adopt to avoid conflict, duplication, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a nationwide basis and that, if not adopted, would result in regulations whose essential objectives are needed to prevent~~ undesirable consequences. Examples of such consequences are given in MD 5.9, Handbook, Part II, Section C. ~~An Agreement State should adopt the essential objectives of the NRC regulations.~~

- ~~a. regulations needed for health and safety. Examples are given in MD 5.9, Handbook, Part II, Section E.~~

4.2.3.1 Information Needed

- a. The State should submit its regulations or generic legally binding requirements that apply the essential objectives of the NRC regulations designated compatibility category

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C. ~~or H&S.~~

- b. 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.

~~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.~~

- c. ~~If the State wants to regulate the disposal of LLRW at a commercial land disposal site, it should submit its regulations equivalent to the regulations in 10 CFR Part 61 designated compatibility category C.~~

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4.2.3.2 Evaluation criteria

- a. The State regulations or generic legally binding requirements needed for an orderly pattern of regulation must satisfy the criteria for compatibility category C. The criteria are given in the Handbook to MD 5.9. A list of program elements and their compatibility designation is provided in FSME State Agreement Procedure SA-200, Appendix A. Appendix A includes a link to the NRC regulations, by 10 CFR Part, with a link to a table with the compatibility designation assigned to each regulation. Additional guidance for submitting State regulations for NRC review is provided in FSME State Agreement Procedure SA-201, "Review of State Regulatory Requirements." [1, 7, 8, 11, 32]
- b. If the State adopts the NRC regulations by reference, the State ~~regulations~~ should disclaim any intent to regulate materials or activities over which NRC retains jurisdiction. ~~If the State adopts generic legally binding requirements other than regulations, the program staff 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]~~

~~The State regulations or generic legally binding requirements needed for an orderly pattern of regulation, or which have particular health and safety significance, shall satisfy the criteria for compatibility category C. The criteria are given in the Handbook to MD 5.9. FSME Procedure SA-200, Appendix A, lists the equivalent NRC regulations. [1, 7, 8, 11, 32]~~

4.2.3.3 References

- a. Criteria Policy Statement, criteria 1, 7, 8, 11, 23, and 32
- b. NRC Management Directive 5.9, *Adequacy and Compatibility of Agreement State Programs*
- c. FSME Procedure SA-200, *Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements*, Appendix A

c. Applicable sections of Title 10 CFR Parts 19, 20, 30, 31, 32, 33, 34, 35, 36, 37, 39, 40, 61, 70, 71, and 150

d. ~~Title 10 CFR Parts 19, 20, 30, 31, 32, 34, 35, 36, 39, 40, 61, 70, 71, and 150~~

e.d. Conference of Radiation Control Program Directors, *Suggested State Regulations*

4.2.4 Regulatory Requirements that have a Particular Health and Safety Significance

Comment [Tmt7]: Separated out Category C and H&S into 2 separate sections, to parallel earlier discussion with A and B

The regulatory requirements which have particular health and safety significance are regulations that are needed for health and safety (H&S). These are 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 NRC that embody the essential objective of the NRC program elements. Examples are given in MD 5.9, Handbook, Part II, Section E.

4.2.4.1 Information Needed

- a. The State should submit its regulations or generic legally binding requirements that apply the essential objectives of the NRC regulations designated as H&S.
- b. 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.
- c. If the State wants to regulate the disposal of LLRW at a commercial land disposal site, it should submit its regulations equivalent to the regulations in 10 CFR Part 61 designated as H&S.

4.2.4.2 Evaluation Criteria

- a. The State regulations or generic legally binding requirements needed for health and safety must meet the criteria for the category health and safety (H & S). The criteria are given in the Handbook to MD 5.9. A list of program elements and their compatibility designation is provided in FSME State Agreement Procedure SA-200, Appendix A. Appendix A includes a link to the NRC regulations, by 10 CFR Part, with a link to a table with the compatibility designation assigned to each regulation. Additional guidance for submitting State regulations for NRC review is provided in FSME State Agreement Procedure SA-201, "Review of State Regulatory Requirements." [1, 7, 8, 11, 32]
- b. If the State adopts the NRC regulations by reference, the State regulations should disclaim any intent to regulate materials or activities over which 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]

4.2.4.3 References

- a. Criteria Policy Statement, criteria 1, 7, 8, 11, 23, and 32
- b. NRC Management Directive 5.9, *Adequacy and Compatibility of Agreement State Programs*
- c. FSME Procedure SA-200, *Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements, Appendix A*
- d. Applicable sections of Title 10 CFR Parts 19, 20, 30, 31, 32, 33, 34, 35, 36, 37, 39, 40, 61, 70, 71, and 150
- e. Conference of Radiation Control Program Directors, *Suggested State Regulations*

4.3 Licensing Program Elements

The review team should be able to conclude that the State's technical licensing procedures will be protective of public health and safety. A State may adopt technical licensing procedures modeled on the NRC procedures, or those used by an existing Agreement State.

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~~~~health physics~~ issues necessary ~~to-for~~ ~~assure~~ the safe 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 procedure, the State should include standard review plans, checklists, and licensing guides.

4.3.1.2 Evaluation criteria

The ~~technical~~ procedures should ~~be detailed and complete so that State Program staff can perform a comprehensive~~ ~~ensure a thorough and equitable~~ 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 review 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. provide for information exchange between the program's inspection staff and licensing staff, as appropriate; [1]
- c. specify the required qualifications of license reviewers for each license program code. Alternately, the procedures may reference a staff qualification plan. [20]

~~Properly qualified persons (normally licensed physicians) must direct the medical use of materials. Qualifications should include prescribed minimum training and experience in the medical use of radioisotopes or radiation. The training requirements should be compatible to those in 10 CFR Part 35. [15]~~

State procedures should provide guidance for the evaluation of technical issues in license applications. The issues evaluated include: places and conditions of storage; 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 address security against unauthorized removal, and safety equipment. 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;
- 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 NRC procedures and consolidated guidance to evaluate the State procedures. However, 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. NRC Management Directive 5.6, *Integrated Materials Performance Evaluation Program (IMPEP)*
- c. FSME Procedure SA-104, *Reviewing the Common Performance Indicator, Technical Quality of Licensing Actions*
- d. NUREG-1556, *Consolidated Guidance About Materials Licenses* (all volumes)
- e. Decommissioning references: ~~specific: MARSSIM, NUREG-1757, Consolidated Decommissioning Guidance; NUREG-1575, "Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM) DG-4006, NUREG-0241, NUREG-5849~~

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4.3.2 Procedures for the Evaluation of Radiation Safety Information on Sealed Sources and Devices ~~(SS&D)~~ 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.*

4.3.2.1 Information Needed

The State should submit its procedure for evaluating radiation safety information *for sealed sources and devices.* ~~on SS&D.~~

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;
- d. content and format of the registration sheets.

For additional criteria, see the Handbook to MD 5.6, *Integrated Materials Performance Evaluation Program (IMPEP)*, Non-Common Performance Indicator 2 – Sealed Source and Device Evaluation Program. ~~the IMPEP Sealed Source & Device indicator (non-common performance indicator 2) in MD 5.6, Handbook (dated February 26, 2004 or later).~~

The review team may use 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. NRC Management Directive 5.6, *Integrated Materials Performance Evaluation Program (IMPEP)*
- d. FSME State Agreement Procedure SA-108, *Reviewing the Non-Common Performance Indicator, Sealed Source and Device Evaluation Program*

4.3.3 Procedure for Conducting the Evaluation of a Regulatory Program for a Low-level Radioactive Waste (LLRW) Land Disposal Site

The regulatory program for a commercial land disposal site for Low-level Radioactive Waste Land Disposal Site (-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, even if NRC will transfer an established site.

If 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 evaluation of an application, accompanied by the conceptual description of the program, is sufficient.

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 Low-Level Radioactive Waste 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 Low-Level Radioactive Waste Disposal License Applications Under Low-Level Radioactive Waste Policy Amendments Act*
- 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 NRC staff use in conducting environmental reviews of applications for low-level radioactive waste disposal facilities. The State might find the information useful in submitting its program information for low-level radioactive waste, if requesting this authorization].

However, NRC does not ~~we do 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;
- 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, *Standard Format and Content for the Review of a License Application for a Low-Level Radioactive Waste Disposal Facility* [ADAMS accession number ML121240809]
- c. NUREG-1200, *Standard Review Plan for the Review of a License Application for a Low-Level Radioactive Waste Disposal Facility* [ADAMS accession number ML061370484]
- d. NUREG-1300, *Environmental Standard Review Plan for the Review of a License Application for a Low-Level Waste Disposal Facility* [ADAMS accession number ML053010347]

b-e. NUREG-1274, *Review Process for Low-Level Radioactive Waste Disposal License Applications Under Low-Level Radioactive Waste Policy Amendments Act* [ADAMS accession number ML13217A156]

f. NRC Management Directive 5.6, *Integrated Materials Performance Evaluation Program (IMPEP)*, Non-Common Performance Indicator 3 – Low-Level Radioactive Waste Disposal Program

e-g. FSME Procedure SA-109, *Reviewing the Non-Common Performance Indicator, Low-Level Radioactive Waste Disposal Program*.

4.3.4 Procedure for Conducting the Evaluation of a Regulatory Program for 11e.(2) Byproduct Material including Uranium or Thorium Milling Facilities

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 NRC will transfer an established site.

If 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, we do not require the procedures to be identical to ours if they 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

- d. inspection procedures, including security related inspections.

4.3.4.3 References

- a. Criteria Policy Statement, criterion 29, 30, 31, 32, 33, 34, 35

- b. Uranium Recovery Regulations, Guidance, and Communications

- 1. This information can be found at www.nrc.gov > nuclear materials > uranium recovery. On this page, under the heading “How We Regulate,” there is a link to “regulations, guidance, and communications” that includes the regulations that are applicable to Uranium Recovery and regulatory guides and other guidance documents.

~~NRC Uranium Recovery Program Policy and Guidance Directives~~

- c. NRC Management Directive 5.6, *Integrated Materials Performance Evaluation Program (IMPEP, Non-Common Performance Indicator 14, “Uranium Recovery Program”*

b.

- d. FSME State Agreement Procedure SA-110, *Reviewing the Non-Common Performance Indicator, Uranium Recovery Program*

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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 ~~adds value to and helps assure the integrity of the application evaluation process~~. 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 ~~some form a standard process for reviewing the for-quality of licensing-quality. We do not prefer a particular form or method.~~ 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. NRC Management Directive 5.6, *Integrated Materials Performance Evaluation Program (IMPEP)*, *Common Performance Indicator 4 – Technical Quality of Licensing Actions*
- c. FSME *State Agreement Procedure SA-104, ~~Reviewing the Non-Common Performance Indicator, Sealed Source and Device Evaluation Program~~ Reviewing the Common Performance Indicator, Technical Quality of Licensing Actions*

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, Generally,~~ NRC transfers 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 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. 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 State-issued ~~licenses by the State~~. The State may propose an alternative to transferring licenses, if desired.

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. assignment of licensing actions to technical evaluators;
- c. license document preparation;
- d. tracking of action progress;
- e. the signing of completed licenses;
- f. transmittal of the signed license to the licensee;
- g. ~~maintenance of license files.~~ ~~maintenance.~~

The State should submit procedures for ~~ensuring~~ ~~assuring~~ the continued validity of licenses affected by the Agreement. ~~If NRC will transfer its licenses to the State, T~~he State should have procedures to receive, store, and regulate the licenses as State licenses. If an alternative to transferring licenses is proposed, ~~the State should submit appropriate a description of this alternative and~~ procedures ~~should be submitted~~ for ensuring the continuity of licensed activities. In either case, the transfer should produce the least interference with licensed activities or the processing of license applications ~~as that~~ 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 NRC. Often, a State will have statutory authority to accept NRC licenses as State 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

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-IMG~~ 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. ~~the~~ scheduling of inspections and the different kinds of inspections (i.e., routine, reactive, reciprocity, security, etc.).
- b. inspection frequencies, including information on conducting pre-licensing inspections
- c. the format and guidance for inspection reports.
- a-d. ~~They should also address the technical performance of inspections. The technical procedures should not address administrative matters, such as inspection fees.~~
- b-e. ~~The technical procedures should address the form and guidance for inspection reports. They should also address notification to licensees of results and giving notice to the licensee of whether or not the licensee is in compliance.~~
- f. ~~The technical procedures should address State field instrumentation and laboratory analysis, including calibration and quality assurance should be included.~~

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, status reports, etc. 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.

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 relate 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 ~~to ensure the~~ licensee's control of materials and to ~~validate-verify~~ the licensee's measurements. The State should submit a list of its instrumentation for review. The procedures should include [procedures on instrumentation 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-232, 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 ~~(QA)~~ programs should ~~also~~ 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. The procedures should provide the notice to the licensee in a short period, usually within 30 days after the inspection. [18]

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

4.4.1.3 References

- a. Criteria Policy Statement, criteria 1, 16, 18, and 36
- b. NRC Management Directive 5.6, *Integrated Materials Performance Evaluation Program (IMPEP), Common Performance Indicator 2 – Status of Materials Inspections*
- c. NRC Management Directive 5.6, *Integrated Materials Performance Evaluation Program (IMPEP), Common Performance Indicator 3 – Technical Quality of Inspections*
- d. FSME State Agreement Procedure SA-101, *Reviewing the Common Performance Indicator, Status of Materials Inspection Program*;
- e. FSME State Agreement Procedure SA-102, *Reviewing the Common Performance Indicator, Technical Quality of Inspections*
- f. NRC Inspection Manual Chapters (IMC)
 1. IMC1220, *Processing of Form 241 and Inspection of Agreement State Licensees*

Operating under 10 CFR 150.20

2. IMC 2800, *Materials Inspection Program*

4.3. IMC 2801, *Uranium Mill 11e.(2) Byproduct Material Disposal Site and Facility Inspection Program.*

e.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, www.nrc.gov: NRC Library > Document Collections > Inspection Manual > Inspection procedures. ~~87104 through 87120, and others as appropriate~~

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

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Secondary reviews of inspection reports ~~is beneficial for quality assurance purposes and can be used to evaluate the~~ ~~adds value to, and helps assure ensure 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~~ ~~assure~~ the quality of inspections and inspection reports.

4.4.2.2 Evaluation Criteria

The State should ~~also~~ have written procedures to guide program staff. ~~NRC does not have a preference~~ ~~We do not prefer~~ 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. ~~b.~~ NRC Management Directive 5.6, *Integrated Materials Performance Evaluation Program (IMPEP)*, *Common Performance Indicator 3 – Technical Quality of Inspections*
- c. FSME Procedure SA-102, *Reviewing the Common Performance Indicator, Technical Quality of Inspections*
- d. NRC Inspection Manual Chapter 2800, *Materials Inspection Program*
- e. *Inspection Manual Chapter 2801, Uranium Mill 11e.(2) Byproduct Material Disposal Site and Facility Inspection Program.*

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 ~~assure~~ 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]

Since 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

a. *NRC Inspection Manual Chapter 2800, Materials Inspection Program*

a.b. *Inspection Manual Chapter 2801, Uranium Mill 11e.(2) Byproduct Material Disposal Site and Facility Inspection Program. ~~NRC Inspection Manual Chapter 2800 and 2801~~*

4.5 **Enforcement Program Elements**

A State may adopt enforcement procedures modeled on the NRC procedures, or those used by another Agreement State. 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.

4.5.1.2 Evaluation Criteria

The State should have procedures for ~~ensuring~~ ~~assuring~~ 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. ~~[14]~~

4.5.1.3 References

- a. Criteria Policy Statement, criteria 18, 19, and 23
- b. ~~NUREG-1600, NRC Enforcement Policy~~ [available on the NRC public website at www.nrc.gov; "About NRC > How We Regulate > Oversight > Enforcement > Enforcement Policy; ADAMS accession number ML12340A295]
- c. NRC Inspection Manual Chapter 2800, *Materials Inspection Program*
- d. ~~Inspection Manual Chapter 2801, Uranium Mill 11e.(2) Byproduct Material Disposal Site and Facility Inspection Program.~~

~~NRC Inspection Manual Chapter 2800 and 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;
- 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 written, using standard wording and format when practical. [18,

19]

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; "About NRC > How We Regulate > Oversight > Enforcement > Enforcement Policy; ADAMS accession number ML12340A295]-~~NUREG-1600~~
- c. NRC Inspection Manual Chapter 2800, *Materials Inspection Program*
- d. ~~IMC 2801, Uranium Mill 11e.(2) Byproduct Material Disposal Site and Facility Inspection Program. NRC Inspection Manual Chapter 2800 and 2801~~

4.6 Technical Staffing and Training Program Elements

The State should adopt technical staffing standards similar to NRC's standards. The State may adopt training and qualification procedures modeled on NRC's procedure in *Inspection Manual Chapter 12486, Formal Qualifications Program for Federal and State Material and Environmental Management Programs*~~*Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area*~~, or on the report of the OAS/NRC working group: NRC/OAS Training Working Group, *Recommendations for Agreement State Training Programs*, STP All-Agreement States Letter SP-97-087.

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

4.6.1 Technical Staff Organization

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 ~~handbook~~ Appendix B of this Handbook.

The staffing analysis should also consider if the State will perform radiation safety reviews of

sealed sources and devices containing radioactive material ~~— evaluate the radiation safety information on SS&D containing materials~~ and register the sealed sources or devices for distribution; license a LLRW commercial land disposal site; license uranium or thorium recovery facility 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 transfer, and the other duties of the program.

4.6.1.2 Evaluation Criteria

The State is not required to use the sample forms in ~~handbook~~ Appendix B of this 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]

~~NRC does not have a specific~~ ~~We have no criteria for the~~ 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 ~~one~~ 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 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 Management Directive 5.6, *Integrated Materials Performance Evaluation Program (IMPEP)*, [Common Performance Indicator 1 – Technical Staffing and Training](#)
- c. FSME Procedure SA-103, *Reviewing the Common Performance Indicator, Technical Staffing and Training*

4.6.2 Formal Qualification Plan

The ability to conduct an effective material program depends on having enough trained and experienced staff members. Since retirements and other normal events cause the departure of staff members, there must be a plan for staff replacement.

4.6.2.1 Information Needed

The State should submit its position descriptions, and its qualification plan for the 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 engineering. An equivalent combination of education and experience may substitute for the degree. [20, 34]

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. [20, 34]

The plan should meet the training and qualification requirements in the NRC/OAS working group recommendations: NRC/OAS Training Working Group, *Recommendations for Agreement State Training Programs*, STP All-Agreement States Letter SP-97-087. Inspection Manual Chapter 12486, *Formal Qualifications Program for Federal and State Material and Environmental Management Programs*~~Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area~~, may be used as general guidance. [20]

4.6.2.3 References

- a. Criteria Policy Statement, ~~criteria 2, 20 and 34~~
- b. NRC Management Directive 5.6, *Integrated Materials Performance Evaluation Program (IMPEP)*, Common Performance Indicator 1 – Technical Staffing and Training
- a-c. NRC Inspection Manual Chapter 1246, *Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area*
- b-d. NRC/OAS Training Working Group, *Recommendations for Agreement State Training Programs*, STP All-Agreement States Letter SP-97-087⁷

⁷This report is available through the FSME Letter 97-087, dated December 17, 1987. The FSME letter may be found on the ~~Available at the~~ FSME external website: www.nrc.gov > about NRC > organization and functions > Office of Federal and State Materials and

e.e. FSME State Agreement ~~Internal~~ Procedure SA-103, *Reviewing the Common Performance Indicator Technical Staffing and Training*

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, as a minimum, show the educational level, experience, and any ~~speciality~~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~~ 20 and 34
- b. NRC Management Directive 5.6, *Integrated Materials Performance Evaluation Program (IMPEP)*, *Common Performance Indicator 1 – Technical Staffing and Training*
- c. NRC Inspection Manual Chapter 124~~86~~, *Formal Qualifications Program for Federal and State Material and Environmental Management Programs* ~~Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area~~

Environmental Management Programs > Agreement State Program (under 'related information') > Resources and Tools > FSME letters. Enter "97-087" in the "Title/number/date" field and click "retrieve letters." STP Internet website www.hsrp.ornl.gov/nrc/home.html; click on "NRC State Letters," then search for "087" in 1997 Letters

4.7 Event and Allegation Response Program Elements

A State may adopt event and allegation response procedures modeled on NRC procedures, or those used by another Agreement State. The procedures for reporting events to NRC should be modeled on FSME [State Agreement Procedure SA-300, *Reporting Material Events*](#).

4.7.1 Procedures for Responding to Events and Allegations

The [State Program](#) ~~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 ~~part~~ of the materials program under the Agreement. The [State Program](#) ~~program~~ should ~~also~~ have written procedures for reporting events to NRC, [its contractor for the Nuclear Materials Events Database \(NMED\), and to the NRC operations center for those events requiring immediate or 24 hour notifications.](#) ~~and to the Nuclear Materials Events Database (NMED).~~

The program should have written procedures for responding to allegations of violations of regulatory requirements. The program does not need to have criminal investigatory capability within the program or its parent agency. If it does not, then it should have procedures 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 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;
- 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]

4.7.1.3 References

- a. Criteria Policy Statement, criteria 1 and 11
- b. NRC Management Directive 5.6, *Integrated Materials Performance Evaluation Program (IMPEP)*, Common Performance Indicator 5 – Technical Quality of Incident and Allegation Activities
- b-c. NRC Management Directive 8.8, *Management of Allegations*
- d. NRC Inspection Manual Chapter 1301, *Response to Radioactive Material Incidents That Do Not Require Activation of the NRC Incident Response Plan*
- e. NRC Inspection Manual Chapter 1302, *Follow-up Actions and Action Levels for Radiation Exposures Associated with Materials Incidents Involving Members of the Public*
- f. NRC Inspection Manual Chapter 1303, *Requesting Emergency Acceptance of Radioactive Material by the U.S. Department of Energy (DOE)*
- e-g. NRC Inspection Manual Chapter 1330, *Response to Transportation Accidents Involving Radioactive Materials 1300 through 1303, and 1330*
- d. ~~NRC Management Directive 5.6, *Integrated Materials Performance Evaluation Program (IMPEP)*, Common Performance Indicator Number 5, "Technical Quality of Incident and Allegation Activities"~~
- h. FSME State Agreement Procedure SA-105, *Reviewing the Common Performance Indicator, Technical Quality of Incident and Allegation Activities #5, Response to Incidents and Allegation*
- e-i. FSME State Agreement Procedure SA-300, *Reporting Material Events*
- f-j. FSME State Agreement Procedure SA-400, *Management of Allegations*

4.7.2 Procedures for Identifying Significant Events and Allegations, and ~~for Submitting for Entry Entering Same~~ into the Nuclear Materials Events Database

NRC has established a database (NMED) of materials events, including incidents, accidents, and medical ~~events~~ ~~misadministrations~~. The States must report ~~to NMED~~ all events to the NRC that NRC regulations (or equivalent State regulations) require the licensees to report. The States must report events directly to NRC, its contractor for the NMED database, 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 as discussed in paragraph 4.7.2 above. ~~entering reports in the NMED database.~~

4.7.2.2 Evaluation Criteria

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

The State procedures should contain criteria for identifying reportable events. The ~~procedures~~ ~~ey~~ should include guidance ~~o~~for forwarding reporting events ~~s~~ (notification, follow up, and closeouts) to 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 should be consistent with the FSME State Agreement ~~STP~~ 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. ~~FSME State Agreement Procedure SA-300, Reporting Materials Events~~
- ~~b. Handbook on Nuclear Material Event Reporting in the Agreement States~~

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Glossary

ASPB	Agreement State Programs Branch
CFR	Code of Federal Regulations
CRCPD	Conference of Radiation Control Program Directors, Inc.
DG	Draft regulatory guide DNMS Division of Nuclear Materials Safety (NRC regional organization units)
EPACT	Energy Policy Act of 2005 FRN <i>Federal Register Notice</i>
FSME	NRC Office of Federal and State Materials and Environmental Management Programs
FTE	Full Time Equivalent of personnel effort
IMC	NRC Inspection Manual Chapter
IP	NRC Inspection Procedure
LLRW	Low-Level Radioactive Waste
MD	NRC Management Directive
MSSA	Division of Materials Safety and State Agreements
MOU	Memorandum of Understanding
NMED	Nuclear Materials Event Database
NMSS	NRC Office of Nuclear Materials Safety and Safeguards
NARM	Naturally occurring or accelerator produced materials
NRC	United States Nuclear Regulatory Commission
SA	FSME Agreement States Procedure
SSR's	<i>Suggested State Regulations</i> , published by the CRCPD
OGC	NRC Office of the General Counsel
RSOA	Regional State Agreements Officer (NRC staff)
UMTRCA	Uranium Mill Tailings Radiation Control Act of 1978, as amended

Definitions

As used in this document:

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

Commission - means the United States Nuclear Regulatory Commission

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 - includes registrations, permits, and certifications.

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 Act. 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.

Procedure - means a written statement delineating the steps in an activity 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 FSME and the DNMS of each region, but includes the support activities provided by other NRC Offices as required.

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.

Appendix A - Cross Index Table

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

Section	Program Element	Information from State	Criteria number ^(a)	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; and SA-200 Appendix B
4.1.3	Content of Agreement	Proposed Agreement	26, and 27	Criteria Policy Statement; MD 5.8
4.2	Regulatory Requirements Program Elements			

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Section	Program Element	Information from State	Criteria number ^(a)	References
4.2.1	Radiation Protection Standards	State standards for protection against radiation	2, 3, 4, 5, 6, 9a, 11, and 22 , and 23	Criteria Policy Statement; MD 5.9; SA-200; Appendix A; 10 CFR Parts 20, 30, 32, 34, 35, 37, 40, 61, 70, 71, and 150; CRCPD SSR's
4.2.2	Transboundary Requirements	State regulations with significant transboundary implications	9(a) and (b), 6, 9a, and 10, and 23	Criteria Policy Statement; MD 5.9; SA-200 Appendix A; 10 CFR Parts 19, 20, 30, 31, 32, 34, 35, 36, 37, 39, 40, 61, 70, 71, and 150; CRCPD SSR's
4.2.3	Orderly Pattern of Regulation or Health and Safety Significance	State regulations that apply the essential objectives of NRC regulations designated category C or H&S	1, 7, 8, 11, 23, and 32	Criteria Policy Statement; MD 5.9; SA-200-Appendix A; 10 CFR Parts 19, 20, 30, 31, 32, 34, 35, 36, 39, 40, 61, 70, 71, and 150; CRCPD SSR's
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); DG-4006; NUREG-0241, NUREG-5849

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Section	Program Element	Information from State	Criteria number ^(a)	References
4.3.2	Sealed Source & Device Safety Evaluations	SS&D 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	LLW 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; NRC-Uranium Recovery Program Policy and Guidance Directives 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; and SA-104
4.3.6	Licensing Administrative Procedures	Procedures for processing licensing actions	1, 13, and 25	Criteria Policy Statement
4.4	Inspection Program			

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Section	Program Element	Information from State	Criteria number ^(a)	References
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- and -102; IMC 1220; IMC - and -2800; IMC 2801; -NRC Inspection Procedures in the "JP 8XXXX" series. IP-87401 thru-87420
4.4.2	Inspections Quality Assurance	Procedures for review of inspection quality	1 and 16	Criteria Policy Statement; IMC 2800 ; MD 5.6 and SA-102; IMC 2800; IMC 2801
4.4.3	Inspection Administrative Procedures	Procedures for processing & filing inspection reports	1	Criteria Policy Statement; 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	4 , 18, 19, and 23	Criteria Policy Statement; NUREG-1600-and NRC Enforcement Policy; 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; NUREG-1600-and IMC 2800; IMC 2801

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Section	Program Element	Information from State	Criteria number ^(a)	References
4.6	Technical Staff			
4.6.1	Technical Staff Organization	Staffing plan	20 and 34	Criteria Policy Statement; MD 5.6; SA-103; recent Agreement State application
4.6.2	Formal Qualification Plan	Formal qualification plan for technical staff	2 , 20, and 34	Criteria Policy Statement; MD 5.6; IMC12486- or ; NRC/OAS Training Working Group, "Recommendations for Agreement State Training Programs"
4.6.3	Current Technical Staff Qualifications	Resumes or CV's of current technical staff	20 and 34	Criteria Policy Statement; MD 5.6; IMC12486- recent Agreement State application
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 and 8.8; IMC 1301; IMC 1302; IMC 1303; IMC 1330; SA-105; SA 300- and 300- IMG 1300--1303-1330 ; SA-400
4.7.2	Event Reporting Procedures	State NMED reporting procedures	1 and 11	Criteria Policy Statement; SA-300- Appendix ; Handbook

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**Handbook for Processing an Agreement
Appendix A**

(a) See section 2.2.1

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Appendix B - Staffing Analysis Forms

Staff Need and Resource Analysis

Instructions

Address all ~~m~~Major license ~~p~~Program ~~a~~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

- ~~1. In the Licensing and Inspection Program Areas:~~ For each License Category, enter the number of **licenses** (not **licensees**) your program will have. See the sample "STAFF NEEDS ANALYSIS" form, attached.
- Estimate the average number of licensing actions (new, renewal, amendments, and terminations) you expect to receive per year per license in that category. ~~For~~ ~~estimate~~ ~~assistance,~~ ~~you should discuss the estimates with the~~ ~~talk to your~~ NRC Region and ~~the~~ existing Agreement States about their experience.
- Estimate the number of staff days you need to process an average action.
- 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.
- 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 ~~m~~Major ~~a~~Areas of ~~the Agreement,~~ ~~your~~ ~~p~~Program. ~~Consider~~ ~~You should consider:~~ regulation development; decommissioning (including ~~c~~Complex decommissioning sites); response to incidents and allegations; contingencies and unanticipated work; and supervisory functions (including inspector accompaniments).

B. Resource Analysis

- 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.
- For each License Category, ~~add sum~~ the days available over all inspectors and enter ~~this~~

Handbook for Processing an Agreement
Appendix B

number on the "STAFF BALANCE ANALYSIS" form. ~~Balance Analysis.~~ Add Sum the days available over all license reviewers and enter this number on the ~~STAFF BALANCE ANALYSIS form~~ ~~Balance Analysis~~.

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5. Conduct a similar analysis for the other ~~mMajor-Program a~~Areas of the Agreement program.

C. Balance Analysis

1. 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 ~~pProgram a~~Areas of the Agreement: For each ~~pProgram a~~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.

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STAFF NEEDS ANALYSIS⁸

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 -therapy							
Bone Mineral							
Brachytherapy							
Teletherapy							
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							

⁸The Category of Inspections includes Security Inspections

**Handbook for Processing an Agreement
Appendix B**

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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
SS&D							

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STAFF RESOURCE ANALYSIS⁹

Staff Member											Total	
License Category	Insp	Lic	Insp	Lic								
Academic												
Broad Scope Academic												
Nuclear Med - Uptake, etc												
Nuclear Med – Imaging and Diagnostic												
Nuclear Med - therapy												
Bone Mineral												
Brachytherapy												
Teletherapy												
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												
SS&D												

⁹The Category of Inspections includes Security Inspections

STAFF BALANCE ANALYSIS¹⁰

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License Category	Inspection staff days		Licensing staff days	
	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				
Teletherapy				
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				
SS&D				

¹⁰The Category of Inspections includes Security Inspections

APPENDIX C

Schedule for Processing a Request for an Agreement

Comment [Tmt8]: Note that the process schedule has been retyped as a new document for ease of review. The main changes were to update steps for current processes and to adjust Event Times to reflect a realistic schedule.

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 timeframe requested by the State. If either the State or the NRC is not able to follow this schedule, it is unlikely that the timeframe 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. 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 Request 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 Request and receipt of the Draft Request
Receipt of draft request	0	NA	
Team concludes completeness review	8 weeks	NA	Account for administrative process and Division level management review
Completeness letter mailed, including any comments	1 week	NA	
Total time period of Part I		9 weeks from receipt of draft request	
PART II Formal Request			From this stage, the process for an Agreement takes about 1 year – 52-54 weeks.
Receipt of formal	8 weeks	8 weeks	The State should try to submit the

Comment [Tmt9]: This was 3 weeks but 3 weeks is too short.

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Appendix C**

Event	Event Time	Total Elapsed Time	Comments
request			formal request within 8 weeks of receiving NRC's completeness letter, addressing any comments NRC had on the draft request.
Team review of formal request finished	4 weeks	12 weeks	Based on no unresolved issues
Project manager completes Commission Paper, including draft staff assessment and <i>Federal Register</i> 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
FSME 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 3 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, 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 Atomic Energy Act
Public comment period ends	Week 4	4 weeks	
Review Team analyzes comments, completes the final staff assessment	4 weeks	8 weeks	

Comment [Tmt10]: This was 8 weeks but it will not take that long if the review of the draft request was thorough and all issues from that review have been resolved.

Comment [Tmt11]: This was 2 weeks. This was too short of a time period but this can be an area for adjustment to the schedule.

Comment [Tmt12]: This was 2 weeks; however, staff must account for up to 3 months for Commission review.

**Handbook for Processing an Agreement
Appendix C**

Event	Event Time	Total Elapsed Time	Comments
Commission paper			
Total time period		8 weeks	
PART IV Final processing and Commission approval			
NRC offices concur on final assessment and Commission paper	3 weeks	11 weeks	NRC offices are given 15 working days to review and concur.
FSME Office Review	2 weeks	13 weeks	
EDO sends the Commission paper to the Commission	2 weeks	15 weeks	
Total time period of Part IV		15 weeks	
Total time period of Parts II, III, and IV, not including time with the Commission		50 weeks	
Commission approves the Agreement	Up to 3 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 <i>Federal Register</i> within 30 days of the Chairman and Governor signing the Agreement	30 days		This is required by Section 274.e.(2) of the Atomic Energy Act

Comment [Tmt13]: This was 4 weeks; however, staff must account for up to 3 months for Commission review.

Appendix D – Sample Documents

NOTE: All documents in Appendix D have been replaced with a brief description of the document and not marked as a change in this revision. This will be easier for the reader in reviewing the document for any comments.

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 – the three most recent Agreements. A brief description of the document is provided as well as the Agencywide Document Access and Management System (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 (State is used generically; note that some States use the term Commonwealth) 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 Acknowledgement 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 – ML06570433

C. Completeness Letter – after review of draft application [SA-700 Procedure, Section V.D. and Handbook, Section 3.4.3.1]

The staff, signed at the division level, sends a letter to the State regarding the completeness of the 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
2. New Jersey – ML073331064

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 request 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.D. 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, positive statements of the NRC and the State working together, and 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 Proposed Agreement [SA-700 Procedure Section V.F. 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 is adequate and compatible

1. Pennsylvania – ML070890378
2. Virginia – ML083180102
3. New Jersey – ML091400097

G. Commission Paper to Publish Proposed Agreement for Public Comment [SA-700 Procedure, Section V.F. and Handbook, Section 3.5.4]

Staff prepares a paper to the Commission discussing its review of the State's request to enter into an Agreement. The paper includes the draft Staff Assessment, *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.F 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.H. 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 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.

- J. Congressional Letters Announcing publication of the proposed Agreement [SA-700 Procedure, Section V.G. and Handbook, Section 3.5.4]

Letters are sent to the NRC Congressional Oversight Committees, the U.S. Senators and the U.S. Representatives 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 Chair and Co-Chair. 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.G. 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, 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; and
- f) Assistant Secretary, Office of Legislative Affairs, Department of Homeland Security.

1. Virginia – ML083390455

- L. FSME letter to All States regarding the proposed Agreement (Agreement States, non-agreement states, state liaison officers) [SA-700 Procedure, Section V.H. and Handbook, Section 3.5.4]

Staff sends a FSME 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 I]

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 I]

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 I]

Staff prepares a paper to 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, *Federal Register* notice, Chairman's letter approving the Agreement, 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. FR notice of final agreement [SA-700 Procedure, Section I]

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

1. Virginia – ML090820150
2. New Jersey – ML092710274

Q. Press release for final agreements (Press release is not in ADAMS) [SA-700 Procedure, Section L]

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 L]

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 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.

1. New Jersey – ML092450515

S. Chairman's letter to Governor approving the Agreement [SA-700 Procedure, Section I and K]

The Chairman sends a letter to the Governor approving the Agreement.

1. Virginia – ML090820076
2. New Jersey – ML092450273

T. Letters to Federal agencies announcing final Agreement [SA-700 Procedure, Section L]

Staff sends a letter to Federal agencies announcing the final Agreement:

- 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;



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- 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 – ML083390817
- 2. New Jersey – ML092450572

U. Final Agreement [SA-700 Procedure, Section I]

- 1. Virginia – ML092720782
- 2. New Jersey – ML092450290

V. FSME Letter announcing the Agreement [SA-700 Procedure, Section L]
Staff sends a FSME letter announcing the Agreement and the effective date.

- 1. Virginia – ML090900429
- 2. New Jersey – ML0927202262

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

E-mail: 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 Agency-wide Documents Access and Management System (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

E-mail: opa.resource@nrc.gov

Site: <http://www.nrc.gov>

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 Agency-wide Documents Access and Management System (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

E-mail: opa@nrc.gov

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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 Agency-wide Documents Access and Management System (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, 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

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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 Agency-wide Documents Access and Management System (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 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, 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/>.