



STP Procedure Approval

Processing an Agreement - SA-700

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NOTE

The STP Director's Secretary is responsible for the maintenance of this master copy document as part of the STP Procedure Manual. Any changes to the procedure will be the responsibility of the STP Procedure Contact. Copies of STP procedures will be distributed for information.



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1. INTRODUCTION

The Atomic Energy Act (Act) authorizes the Nuclear Regulatory Commission (NRC) to enter Agreements that transfer regulatory authority over certain materials to the States. The Governor of a State initiates the transfer by requesting an Agreement.

This procedure describes the methods and guidelines for reviewing the request for an Agreement. It also provides guidance to:

- NRC staff on the formal procedural steps for responding to a Governor's request for an Agreement,
- NRC staff on the criteria for evaluating a State's proposed Agreement materials program, and
- State staff on the information to include in a request for an Agreement.

As used in this procedure, the term "State" refers to either a State or a Commonwealth. However, NRC staff should take care to use the proper term in the Agreement, *Federal Register* (FR) Notices, and other official records.

II. OBJECTIVE

- A. 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. Provide for the effective, efficient, and timely review of the request by a State for an Agreement, or for an amendment to an existing Agreement; and
- C. Provide an orderly transition in the discontinuance of regulatory authority by the NRC and assumption thereof by the State.

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.

Categories of materials that NRC may transfer are: (a) by-product materials as defined in Section 11e.(1) of the Act; (b) by-product materials as defined in Section 11e.(2) of the Act; (c) source materials as defined by Section 11z of the Act; (d) 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); (e) the regulation of the land disposal of byproduct, source, or special nuclear material wastes received from other persons; and (f) 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 categories.

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 other radiation control activities of the State, we call it the "Agreement materials program."

The Governor must certify that the State has the required program and desires to assume the regulatory authority. 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 enable the Commission to find the State Agreement materials program adequate and compatible.

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 accord with Commission policy, the term "regulations" may include other forms of generic legally binding requirements. These alternate requirements may include license conditions or orders, 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 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 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 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). We refer to this Commission policy statement 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 RESPONSIBILITIES

- A. The Director, Office of State and Tribal Programs (STP), is responsible for the Agency's review of a request for an Agreement. The Director determines when the request satisfies the criteria policy statement, and recommends Commission approval of the request.
- B. The STP Project Manager (PM) is responsible for completing the Agency's review of a request for an Agreement. The PM is the primary NRC staff contact for the State during the review. Finally, the PM is the review team leader and should qualify as an IMPEP team leader.
- 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,¹ and other NRC staff as assigned. The principal reviewers for licensing, inspection, staffing, and incidents and allegations should meet the IMPEP qualification requirements (NRC MD 5.10).
- 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 backup to the RSAO. The RSAO and RSLO should keep the PM informed of these contacts.
- E. The Region and the Office of Nuclear Materials Safety and Safeguards are responsible for transferring NRC licensee files to the State (NRC MD 3.53). The PM should be kept informed of these activities.

V. GUIDANCE

For detailed guidance on reviewing the request, including scheduling and documentation requirements, see the *Handbook for Processing an Agreement* (Handbook Appendix C). Handbook Appendix C contains samples of letters and documents based on a previous Agreement request review.

¹ Office of Nuclear Materials Safety and Safeguards, Office of General Counsel, the Incident Response Organization, and the affected Region.

A. Governor's Letter of Intent (Handbook Section 3.3 and Appendix C)

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

B. Preparing a Request for an Agreement

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

C. 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 program description information for all applicable elements of the Agreement materials program. It should also contain draft text for the proposed Agreement (NRC MD 5.8).
2. The State program Director should alert the PM or the Director, STP, at least two months before submitting the draft. The Director, STP, should then ask the Offices (identified in Section IV.C of this procedure) to assign staff level contacts for the review team.
3. The team reviews the draft request for completeness. To be complete, 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.
4. The team prepares a letter to the State program Director to document the results of the completeness review (sample in Handbook Appendix C). The Director, STP, signs the letter following Office concurrence.

5. The PM, RSAO, and the State program Director should schedule regular telephone conference calls on the progress of the review (handbook Section 3.4.4). Review team members and other NRC staff may participate. Meetings should supplement the calls as needed.
6. The State should address the Agency's comments by making changes in the formal request. The State program Director should not submit a second draft, or changes to the draft, unless coordinated with the Director, STP. When the changes to the formal request are completed, the Governor should sign and submit the formal request to the Chairman.

D. Formal Request for an Agreement (Handbook Section 3.5)

1. The State program Director should alert 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 C).
2. The review team conducts a detailed evaluation of the formal request following the procedures and criteria in 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 the State program Director providing comments. Following Office concurrence, the Director, STP, signs the letter.
4. The State should address the comments by making revisions to the formal request. Send the revisions to the Secretary of the Commission, with a copy to the Director, STP.

E. 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 C).
2. The team prepares a *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 notice. The *FR* notice should also discuss any unique features of the proposed Agreement. Attach the text of the proposed Agreement, with a proposed effective date. The Director, STP, usually signs the *FR* notice. A sample notice is in Handbook Appendix C.

3. The PM, in coordination with the Office of Public Affairs, prepares a draft press release (sample in Handbook Appendix C). The press release announces the publication of the proposed Agreement in the *FR*.
4. 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.
5. The team prepares a negative consent Commission paper (sample in Handbook Appendix C).
 - a. The paper should state that staff intends to forward the *FR* Notice for publication ten days after the Executive Director for Operations (EDO) signs the paper, unless the Commission directs otherwise.
 - b. The paper must include, as attachments:
 - (1) the draft staff assessment,
 - (2) the proposed *FR* notice (including the proposed Agreement and summary of the draft staff assessment).
 - c. The paper must also include, as background:
 - (1) the draft Congressional letters,
 - (2) the draft press release, and
 - (3) the Project Schedule for processing, signing, and implementing the Agreement (Handbook Section 3.4.1).
6. The PM prepares letters (samples in Handbook Appendix C) to notify interested Federal agencies of the *FR* notice. The Agreement and Non-Agreement States are notified by an announcement on the STP-Announcements listserver.

F. Publication of the Proposed Agreement

When the formal request satisfies the criteria policy statement, the team completes the Commission paper. The PM prepares a memo (sample in Handbook Appendix C) from the Director, STP, transmitting the paper to the other Offices for concurrence.

1. Following Office concurrence, the Director, STP, forwards the paper to the EDO for signature and transmittal to the Commission.
2. After the 10-day negative consent period, the Office of the Secretary (SECY) will issue a Staff Requirements Memorandum (SRM). When the requirements of the SRM are satisfied, the Director, STP, signs the *FR* notice. The *FR* notice is forwarded to the Rules and Directives Branch, Office of Administration.
3. The Congressional letters accompany the notice. The STP secretaries will incorporate changes from the SRM, if any, and enclose a pre-publication copy of the *FR* notice. The Rules and Directives Branch will forward the letters to the Office of Congressional Affairs.
4. Upon publication, the PM attaches a copy of the *FR* notice to the letters notifying the Agreement States and the interested Federal agencies. The PM informs the Office of Public Affairs of the publication.

G. End of the public comment period

When the public comment period closes, the review team considers, and prepares an analysis of the comments. They also prepare a paper seeking Commission action on the proposed Agreement (sample in Handbook Appendix C). The team prepares the final staff assessment, considering the public comments.

1. Attachments to the paper are:
 - a. final text of the proposed Agreement;
 - b. a draft *FR* notice announcing the approval and signing of the Agreement;
 - c. the final staff assessment;

- d. the staff's analysis of the public comments; and
 - e. a completed copy of the General Accounting Office form providing the notifications required under the Small Business Regulatory Enforcement and Fairness Act of 1996 (SBREFA). This form is available at the GAO website.
2. Include, 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; and
 - b. a draft press release announcing the Agreement.

Sample letters and press releases are in Handbook Appendix C.

3. 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 we informed the State if NRC will retain jurisdiction for violations that occurred at a licensed facility while under NRC jurisdiction. OGC has ruled that NRC has the authority under Section 234 of the Act to issue a Notice of Violation and Civil Penalty Assessment. However, NRC does not have authority to require corrective actions after the Agreement is effective;
 - d. the status of any site decommissioning management plan (SDMP) or other sites in decommissioning. The discussion should indicate how the State was advised to notify NRC when it terminates the license of an SDMP 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 SDMP sites transferred to the State will be reviewed as part of NRC's "Integrated Management Performance Evaluation Program;"

- e. how we provided information to the State regarding previously licensed sites;
 - f. allegations and investigations in progress, but should give no details; and
 - g. the NRC resources that staff anticipates devoting to facilities in the State with the Agreement in effect.
4. The NRC and State staffs agree on the effective date for the Agreement. The PM inserts the date into the Agreement text.
5. 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 learn the Governor's choice. The PM also learns the format of the Governor's signature block, and if the State wishes to add a 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.

H. Commission approval of the Agreement

1. The PM assembles the Commission paper and attachments for concurrence.
2. The Director, STP, forwards the Commission paper to the EDO following Office concurrence.
3. When the Commission approves the Agreement:
 - a. The PM prepares three official copies of the Agreement for signature, inserting the date of Commission approval (the date of the SRM) into the Agreement.
 - b. The Director, STP, forwards the Congressional letters, and three copies of the SBREFA form, to the Office of Congressional Affairs. Address the forms by filling the appropriate box at the top. Attach a copy of the draft *FR* notice to each form.

I. 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.
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.G.5.c of this procedure. After the Governor signs the Agreement, the State retains one copy and returns the others to the Director, STP.
3. The PM delivers one copy of the signed Agreement to SECY. STP retains the other copy in the Agreements file.

J. Implementation of the Agreement

1. The Director, STP, forwards the *FR* notice, as approved in the SRM, to the Rules and Directives Branch of the Office of Administration. Section 274e.(2) of the Act requires publication of the *FR* notice within 30 days after the Agreement is signed.
2. The Region and NMSS coordinate with the State on transferring license files to the State (NRC MD 3.53). The RSAO should advise the PM of the plans for, and the progress of, the transfer.
3. The PM alerts the Office of Public Affairs to issue the press release announcing the effective Agreement.
4. The PM prepares letters announcing the effective date of the Agreement. Letters go to interested Federal agencies, and NRC material licensees. The Agreement and Non-Agreement States are notified by an announcement on the STP-Announcements listserver. The Director, STP, signs the letters. The PM provides the new Agreement State program Director copies of the announcements.

K. After the Agreement is effective

1. When the Agreement becomes effective, the PM is usually redesignated as the Agreement State Project Officer (ASPO) for the State (STP Procedure SA-117).
2. Approximately nine months after the Agreement becomes effective, the ASPO and the RSAO meet with the State Agreement materials program management. The meeting is to discuss the State's implementation of the Agreement materials program. (STP Procedure SA-118).

3. 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

1. Sections 11 and 274 of the Atomic Energy Act of 1954, as amended.
2. 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).
3. NRC Management Directive 3.53, *NRC Records Management Program*, June 15, 1995
4. NRC Management Directive 5.6, *Integrated Materials Performance Evaluation Program (IMPEP)*, November 25, 1997.
5. NRC Management Directive 5.8, *Proposed 274b Agreements With States*, November 21, 1997
6. NRC Management Directive 5.10, *Formal Qualifications for Integrated Materials Performance Evaluation Program (IMPEP) Team Members*, January 5, 1999
7. STP Procedure SA-117, *Agreement State Project Officers*, September 11, 1998
8. STP Procedure SA-118, *Orientation Meeting for New Agreement States*, July 14, 1999

Handbook for Processing an Agreement

Date: April 2, 2001

**Office of State and Tribal Programs
U.S. Nuclear Regulatory Commission**

Contact: Richard L. Blanton

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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 statement by the Governor 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 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 provides references to NRC and other documents related to the 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 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 Internal Procedures for the Office of State and Tribal Programs (STP) Agreement State Program. We will describe these in more detail below.

2.1.1 Federal Statutes

The Commission conducts the Agreement State program under Section 274 of the Atomic Energy Act of 1954, as amended (Act). Section 274b authorizes the Commission to enter 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. 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 (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.

The first 28 criteria in the policy statement apply to all proposed Agreement State materials programs. The last seven criteria apply only to States that will regulate the tailings materials 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 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 Directives and Procedures¹

Two levels of procedures guide NRC staff. First are the Management Directives (MD), which address activities whose responsibilities extend to more than one Office. For activities that are the responsibility of a single Office, the Office uses Internal Procedures, such as the STP SA series. The following MD's and SA's guide the review of a request for an Agreement.

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 and the NRC regional materials programs. The NRC staff assessment of a request for an Agreement must conclude that the State's proposed program, if implemented as described, would be found satisfactory in all applicable IMPEP performance indicators.

2.3.2 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 the model. Changes from the model should include additional supporting information since staff must evaluate the changes to assure the adequacy and compatibility of the proposed Agreement program. Significant changes may require special approval by the Commission.

¹ Current copies of these Management Directives may be viewed at the STP Internet website www.hsr.d.o.gov/nrc/procfm.htm

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 appropriate elements of MD 8.8)

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

MD 5.9 provides the process and criteria used to identify the compatibility categories of the NRC program elements. It implements the *Policy Statement on Adequacy and Compatibility of Agreement State Programs*. STP Procedure SA-200 documents the results of the process. The Appendix to SA-200 lists each NRC regulation and program element and its compatibility category that should be adopted by Agreement States.

2.3.5 Office of State and Tribal Programs Internal Procedures - SA series²

The STP procedures SA-100 through SA-105 and SA-107 through SA-110 provide guidance for the review of IMPEP indicators in Agreement material programs. They supplement the guidance in MD 5.6. SA-106 addresses the IMPEP Management Review Board and does not apply to the review of a request for an Agreement.

The STP internal 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 a request.

3.0 REVIEW PROCEDURES

3.1 General Considerations

As the process has developed historically, entering an Agreement is a series of steps. First, the State staff expresses interest in an Agreement, and requests information. Next, the Governor sends the Chairman a letter expressing an intention to enter an Agreement. The third step is the submission of a draft request by the State program Director.

² The SA series is under development, and not all of the referenced procedures are final. Please check the STP Internet website www.hsr.doe.gov/nrc/procfm.htm for the most current procedures.

The detailed review process begins with the fourth step: the Governor submits a formal Request for an Agreement. If practical, resolve all significant issues with the draft request and the proposed Agreement materials program before the Governor submits the formal Request.

3.1.1 Proprietary and Privacy 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. 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 should discuss the matter with the Director of the NRC Office of State and Tribal Programs (Director, STP).

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. 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 about nine months after the State submits the formal request.

In the sample schedule, we give processing milestones in terms of "elapsed weeks." Starting with the sample schedule, the project manager (PM) should organize a Project Schedule with suspense dates. The review team should update the Project Schedule 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. NRC is setting up the capability to accept electronic files by Internet. The State should contact the STP 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 good enough to be scanned.

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 should be directed to the Director, STP. The State staff may also contact individual members of the review team directly about comments on specific program elements. Alternately, the question will be forwarded to the 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 NRC staff should provide, or confirm that the State has the following:

- a. Copies of Sections 11 and 274 of the Act;
- b. Copies of the *Suggested State Radiation Control Act*, published by the Council of State Governments (CSG);
- 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 MD 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 STP 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) is the NRC staff lead for responding to informal questions and requests for additional information. The RSAO should coordinate with STP staff and request assistance of other NRC staff as necessary. The State should submit questions regarding Commission policy or practice in writing to the Director, STP.

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 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.

The suggested effective date for the Agreement should take into consideration the time requirements for any needed legislation, regulations, 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 Director, STP, assigns an STP staff member to be the PM for processing the Agreement.

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.

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 STP and OGC can allow time for amendments to critical legislative or regulatory provisions, if required.

3.4.2 Alert for Draft Request

When the State alerts STP that a draft request is forthcoming, NRC establishes a review team. Section V.C.2 in procedure SA-700 addressed timing of the alert, and the makeup of the review team. The PM and the team leader select a principal reviewer for each element of the proposed Agreement materials program.

3.4.3 Review of the Draft Request

The team conducts a completeness review of the draft request using the evaluation criteria in handbook Section 4.0. The completeness review has two objectives. First, it discovers whether the Agreement materials program description information addresses each of the applicable elements. Second, it judges whether the request contains sufficient information to permit 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 by the end of elapsed week three.

3.4.3.2 Team Meeting

The team should meet during elapsed week four to discuss the findings of their completeness review. They should also draft a letter to the State program Director presenting team findings. The PM should reserve use of a conference room for the full week. Team members should concur on the completeness of each program element. The team briefs the Director, STP, on the completeness review findings at the end of elapsed week four.

3.4.3.3 Review Product

The principal review product is a letter to the State program Director. 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 team should also hold a conference call with the State staff. The team may hold a meeting with the State staff at the State's option, following the State's receipt of the team's written review findings.

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

3.4.4 Telephone Conference Calls

The PM, RSAO, and the State program Director 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. Other NRC and State staff should participate as appropriate. 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 practical, coordinate the visit with the State's receipt of the completeness review letter. This will give the State an opportunity to discuss the NRC's comments in preparation for formulating the formal request. The State program Director 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. 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 regularly.

State license reviewers should work with the NRC Regional license reviewers, starting at least one year before the anticipated effective date of the Agreement. The work should begin at least when the Governor submits the letter of intent. 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 their coordination of.

3.5 The Formal Request for an Agreement

The formal request should be the draft request modified to address NRC comments on the draft. The Act requires that the formal request be signed by the Governor. It should be addressed to the Chairman.

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 evaluation of the information by the review team. The assessment should describe how the program satisfies the Commission's criteria. The table in handbook Appendix A shows the relationship between the program elements in handbook Section 4.0 and the criteria in the criteria statement.

3.5.1 Project Schedule Adjustment

The sample processing schedule in handbook Appendix C allots 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 STP receives the formal request.

3.5.2 Review of the Formal Request

The team conducts a detailed review of the program description information in formal request. The same team that reviewed the draft request for completeness should also review the formal request.

3.5.2.1 Principal Review

Each principal reviewer conducts a detailed evaluation of an element of the proposed program. Other team members may help in evaluating the element. Team members may discuss their questions about the formal request directly with the State staff. Using the evaluation criteria in handbook Section 4.0, the principal review should 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, the reviewer should notify the PM immediately. The PM alerts the Director, STP, and schedules a meeting of the team to discuss the issue. After the meeting, the team briefs the Director, STP, and other management as appropriate. The State program Director is kept informed of the staff activity to resolve the issue.

3.5.2.3 Team Findings and the Draft Assessment

During elapsed week 22 the team meets to discuss their findings and prepare the draft NRC staff assessment. The PM should reserve a conference room for two weeks.

If the request satisfies the evaluation criteria for a program element, the principal reviewer drafts assessment text for the relevant criteria in the criteria policy statement. Team members should concur on the findings for each program element, and the assessment text. The full draft assessment should be completed by the end of elapsed week 23.

3.5.3 Transmission of Comments to the State

If the request does not satisfy a criteria policy statement criterion, the principal reviewer prepares a draft comment. Each comment should describe the issue and, where practical, provide guidance to resolve the issue. Team members should concur on the comments.

The team prepares a letter transmitting its comments, if any, on the formal request. The letter is from the Director, STP, to the State program Director, and should be completed by the end of elapsed week 22. Following Office concurrence, STP 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, STP. When the team receives the revisions, it reviews only the revisions. The PM will need to revise the schedule.

3.5.4 Completion of the Review

When the team concludes that the criteria policy statement is satisfied, it completes the draft staff assessment and the Commission paper. 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 STP Procedure SA-700.

4.0 INFORMATION NEEDED AND EVALUATION CRITERIA

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 an Agreement

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

4.1.1.1 Information Needed

For all categories of materials the State should submit State law that:

- a. establishes the materials program, defines its structure, and authorizes the Governor to enter an Agreement with the Commission;
- b. authorizes the program to issue licenses;
 - 1. authorizes the program to impose additional license requirements.
 - 2. authorizes the program to give exemptions from the licensure requirements.
 - 3. authorizes the program to recognize the licenses of other jurisdictions.
 - 4. makes it unlawful to acquire, possess, store, use, transfer, or dispose of materials without a valid license, or to violate the conditions of a license.
 - 5. authorizes the program to recognize licenses transferred from NRC under the Agreement as State licenses, if necessary.
- c. 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.
- d. authorizes representatives of the program to enter premises and conduct inspections.
- e. authorizes the program to require compliance with regulatory requirements by both licensees and unlicensed individuals.

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

If the program will include jurisdiction for licensing the receipt of low-level radioactive waste (LLW) from others for purposes of disposal the State should submit the law that authorizes the regulation of a LLW 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 law that authorizes the regulation of uranium and thorium recovery facilities including disposal of mill tailings.

4.1.1.2 Evaluation Criteria

(Note: The team may use the CSG suggested 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 Section 11e.(2) byproduct material, Section 8 of the model legislation provides valuable suggested guidance on the Statutory provisions necessary to assume 11e.(2) byproduct material authority. If the Agreement will cover LLW disposal, see Section 9 of the model legislation.)

- a. State law must authorize the Governor to enter the Agreement. It must also designate a radiation control agency and provide it the necessary legal authority to be effective. [1, 24]³
- 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 NRC. [21, 24]
- c. State law must authorize issuing licenses as the means of giving the authority to possess and use materials. It should also authorize the reciprocal recognition of specific licenses issued by NRC or other Agreement States. [13, 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. [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 from the requirement to

³ The numbers in brackets correlate to the numbered criteria in the Commission criteria policy statement (see handbook Section 2.2.1).

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): [28]

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

The State must resolve any questions of interpretation of State law. NRC will accept interpretations provided by the State Attorney General, or other attorney designated as legal advisor to the 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.

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

The law should clearly empower the program to carry out the requirements of the 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 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; [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]

- (2) choose whether or not to take title to the disposal site and byproduct material; [30]
- (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 150.15a), including the authority to: [30]

- a. Establish minimum standards governing reclamation, long-term surveillance or maintenance, and ownership of the 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;
- 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 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, 9b, 12, 13, 17, 19, 21, 23, 24, 27, 28, 29, 30, and 31
- b. Council of State Governments *Suggested State Legislation*, 1983
- 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 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

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.

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

- a. All organizational levels between the Governor and the State program Director;
- b. The structure and staff of the materials program;
- c. Regional offices and staff.

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 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 also describe the efforts to assure cooperation and to ensure an orderly and consistent regulatory

approach. 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) [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. STP Procedure SA-200, *Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements*, Appendix B

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 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. Source materials;
- d. 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 (a so called "full Agreement"). Agreements that do not transfer all of the categories should delete the appropriate provisions as shown in MD 5.8, Handbook.

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 Exhibit 1 of MD 5.8, Handbook. If the State does not follow the standard Agreement, it must explain why. The 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 the need for the change and the expected result. Such changes 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 in MD 5.8). [27]

4.1.3.3 References

- a. Criteria Policy Statement, criteria 26, and 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.⁴

4.2.1 Standards for Protection Against Radiation

The standards for protection against radiation include:

- 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;
- 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. STP Procedure SA-200, Appendix A, lists the equivalent NRC regulations. STP Procedure SA-201, Appendices A and B, provide additional guidance. [2, 3, 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. [2]

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

⁴If using the SSR, the State should consult with the RSAO or PM to identify any compatibility issues.

If the State adopts generic legally binding requirements other than regulations, it should assure consistency in their application. 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.

4.2.1.3 References

- a. Criteria Policy Statement, criteria 2, 3, 4, 5, 6, 9a, 11, and 22
- b. NRC Management Directive 5.9, *Adequacy and Compatibility of Agreement State Programs*
- c. STP Procedure SA-200, *Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements*, Appendix A
- d. Title 10 CFR Parts 20, 30, 35, 40, 61, 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:

- 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 exempt from licensing, requirements for sealed sources and devices (SS&D), and the waste classification system in 10 CFR Part 61.

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

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. STP Procedure SA-200, Appendix A, lists the equivalent NRC regulations. [6, 9a, 10]

4.2.2.3 References

- a. Criteria Policy Statement, criteria 6, 9a, and 10
- b. NRC Management Directive 5.9, *Adequacy and Compatibility of Agreement State Programs*
- c. STP Procedure SA-200, *Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements*, Appendix A
- d. Title 10 CFR Parts 20, 30, 34, 39, 40, 70, 71, and 150
- e. 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 or which have particular health and safety significance are:

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

4.2.3.1 Information Needed

The State should submit its regulations, or generic legally binding requirements, that apply the essential objectives of the NRC regulations designated compatibility category C or D/H&S.

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 the disposal of LLW at a land disposal site, it should submit its regulations equivalent to the regulations in 10 CFR Part 61 designated compatibility category C or D/H&S.

4.2.3.2 Evaluation criteria

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 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. STP 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, and 32
- b. NRC Management Directive 5.9, *Adequacy and Compatibility of Agreement State Programs*
- c. STP Procedure SA-200, *Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements*, Appendix A
- d. Title 10 CFR Parts 19, 20, 30, 31, 32, 34, 35, 36, 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 health physics issues necessary to 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 procedures should assure a thorough and equitable evaluation of the application. The procedures should cover each type 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, 23]

The procedures should:

- a. address the applicant's facilities and safety equipment, training and experience in the use of the materials for the purpose requested, and proposed managerial controls; [13]
- 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.

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. [13, 14]

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: [13]

- a. qualification of users;
- b. licensee operating and emergency procedures;
- c. appropriate surveys;
- d. personnel monitoring under the close supervision of technically competent 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. [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, we do 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. They should address all significant technical issues.

4.3.1.3 References

- a. Criteria Policy Statement, criteria 1, 13, 14, 15, 20, and 23
- b. NRC Management Directive 5.6, *Integrated Materials Performance Evaluation Program (IMPEP)*
- c. STP Procedure SA-104, *Reviewing Common Performance Indicator #4, Technical Quality of Licensing Actions*
- d. NUREG-1556, *Consolidated Guidance About Materials Licenses* (all volumes)
- e. Decommissioning specific: MARSSIM, DG-4006, NUREG-0241, NUREG-5849

4.3.2 Procedures for the Evaluation of Radiation Safety Information on Sealed Sources and Devices, and Registration for Distribution

Sealed sources, and devices containing sealed sources, are commonly manufactured in one jurisdiction and used in others. Because of the transboundary implications, safety evaluations of the sources and devices should be conducted according to similar procedures nationwide.

4.3.2.1 Information Needed

The State should submit its procedure for evaluating radiation safety information 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]

- 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 IMPEP SS&D indicator (non-common performance indicator 2) in MD 5.6, Handbook (dated November 25, 1997 or later).

The review team may use NRC's consolidated guidance about applications for SS&D evaluation and registration in NUREG-1556, Volume 3, as a guide.

4.3.2.3 References

- a. Criteria Policy Statement, criterion 13
- b. NUREG-1556, *Volume 3, Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration*

4.3.3 Procedure for Conducting the Technical Evaluation of a Proposed License for a Low-level Radioactive Waste Land Disposal Site

The technical evaluation of a land disposal site for LLW has significant health and safety implications. It requires substantial resources beyond those needed for conducting routine licensing evaluations. If the State will regulate a site, it should have the resources and procedures to conduct a site evaluation, 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 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 evaluation.

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 NUREG-1199, 1200, and 1274. However, 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: [9, 13]

- a. technical issues evaluated;
- b. qualifications of the personnel performing evaluations;
- c. assuring the quality of the licensing action.

4.3.3.3 References

- a. Criteria Policy Statement, criteria 9 and 13
- b. NUREG-1199, NUREG-1200, NUREG-1300, NUREG-1274

4.3.4 Procedure for Conducting the Technical Evaluation of a Proposed Uranium or Thorium Recovery Facility

The technical evaluation of a uranium or thorium recovery facility has significant health and safety implications. It requires substantial resources beyond those needed for conducting routine licensing evaluations. If the State will regulate a site, it should have the resources and procedures to conduct a site evaluation, 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.

4.3.4.1 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 evaluation.

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: [35]

- a. technical issues evaluated;
- b. qualifications of the personnel performing evaluations;
- c. assuring the quality of the licensing action.

4.3.4.3 References

- a. Criteria Policy Statement, criterion 35
- b. NRC Uranium Recovery Program Policy and Guidance Directives

4.3.5 Procedures for Assuring the Technical Quality of Licenses

Secondary review 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 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 of review for 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)*
- c. STP Procedure SA-104, *Reviewing Common Performance Indicator #4, 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.

Generally, NRC transfers to the State those NRC licenses that the State will regulate. The State recognizes the transferred NRC licenses, including licenses under timely renewal, as State licenses. Those licenses continue in effect until they are replaced by State issued licenses. 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. license file maintenance.

The State should submit procedures for assuring the continued validity of licenses affected by the Agreement. If NRC will transfer its licenses to the State, the State should have procedures to receive, store, and regulate the licenses as State licenses. If an alternative to transferring licenses is proposed, appropriate procedures should be submitted. In either case, the transfer should produce the least interference with licensed activities or the processing of license applications 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]

The State must provide procedures for the continued operation of transferred NRC licensees. [25]

4.3.6.3 References

- a. Criteria Policy Statement, criteria 1 and 25

4.4 Inspection Program Elements

A State may adopt technical inspection procedures modeled on IMC 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 scheduling of inspections and the different kinds of inspections (i.e., routine, reactive, reciprocity, etc.). They should also address the performance of inspections. The technical procedures should not address administrative matters, such as inspection fees.

The technical procedures should address the form and guidance for inspection reports. They should also address giving notice to the licensee of whether or not it is in compliance.

The technical procedures should address field instrumentation and laboratory analysis. Calibration and quality assurance should be included.

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]

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 IMC 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 on the use of both field and laboratory instrumentation to ensure the licensee's control of materials and to validate the licensee's measurements. The State should submit a list of its instrumentation for review. The procedures should include 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;
- 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 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 approximately the same level of detail as the equivalent NRC procedure. However, the procedures are not required to be uniform if they address all significant technical issues. 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)*
- c. STP Procedures SA-101, *Reviewing Common Performance Indicator #1, Status of Materials Inspection Program*; and SA-102, *Reviewing Common Performance Indicator #2, Technical Quality of Inspections*
- d. NRC Inspection Manual Chapters 1220, and 2800
- e. NRC Inspection Procedures 87101 through 87120

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

Secondary review of inspection reports adds value to, and helps assure the 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 are acceptable.

4.4.2.1 Information Needed

The State should submit its procedures addressing peer review, supervisory review, and any other method to 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. We do not prefer any particular form 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. NRC Management Directive 5.6, *Integrated Materials Performance Evaluation Program (IMPEP)*
- c. STP Procedure SA-102, *Reviewing Common Performance Indicator #2, Technical Quality of Inspections*
- d. NRC Inspection Manual Chapter 2800

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 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.

4.4.1.3 References

- a. Criteria Policy Statement, criterion 1
- b. NRC Inspection Manual Chapter 2800

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 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]

The procedures should include a means for tracking the completion of enforcement actions. [1]

4.5.1.3 References

- a. Criteria Policy Statement, criteria 1, 18, and 23
- b. NUREG-1600
- c. NRC Inspection Manual Chapter 2800

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. the 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. [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. NUREG-1600, *NRC Enforcement Policy*
- c. NRC Inspection Manual Chapter 2800

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 IMC 1246, or on the report of the OAS/NRC working group.

To evaluate some complex cases, the staff may need to 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.

The staffing analysis should also consider if the State will: evaluate the radiation safety information on SS&D containing materials and register the sealed sources or devices for distribution; license a LLW land disposal site; license uranium or thorium recovery facility subject to the requirements of UMTRCA; or will license major manufacturers, universities with major research programs, or other large scale materials users.

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. 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 individuals. [20]

We have no criteria 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 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)*

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 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]

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. [20]

The plan should meet the training and qualification requirements in the NRC/OAS working group recommendations. IMC 1246 may be used as general guidance. [20]

4.6.2.3 References

- a. Criteria Policy Statement, criterion 20
- b. NRC Management Directive 5.6, *Integrated Materials Performance Evaluation Program (IMPEP)*
- c. NRC Inspection Manual Chapter 1246
- d. NRC/OAS Training Working Group, *Recommendations for Agreement State Training Programs*, STP All-Agreement States Letter SP-97-087⁵
- e. STP Internal Procedure SA-103

4.6.3 Qualifications of Current Technical Staff

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

⁵Available at the STP Internet website www.hsrdo.org/nrc/home.html; click on "NRC-State Letters," then search for "087" in 1997 Letters

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 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]

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]

4.6.3.3 References

- a. Criteria Policy Statement, criterion 20
- b. NRC Management Directive 5.6, *Integrated Materials Performance Evaluation Program (IMPEP)*
- c. NRC Inspection Manual Chapter 1246

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 STP Procedure SA-300.

4.7.1 Procedures for Responding to Events and Allegations

The 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, it is still part of the materials program under the Agreement.

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 8.8, *Management of Allegations*
- c. NRC Inspection Manual Chapter 1300 through 1303, and 1330
- d. NRC Management Directive 5.6, *Integrated Materials Performance Evaluation Program (IMPEP)*
- e. STP Procedure SA-105, *Reviewing Common Performance Indicator #5, Response to Incidents and Allegations*

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

NRC has established a database (NMED) of materials events, including incidents, accidents, and medical misadministrations. The States must report to NMED all events that NRC regulations (or equivalent State regulations) require the licensees to report.

4.7.2.1 Information Needed

The State should submit its procedures for generating event reports. It should also submit its procedures for 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 the quality of the reports. They should specify times for completion of the reports and submitting them to NRC. The procedures should provide guidance for identifying abnormal occurrences. [1, 11]

The procedures should contain criteria for identifying reportable events. They should guide forwarding reports (notification, follow up, and closeouts) to NRC for inclusion in NMED. The State procedures should be consistent with the 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. STP Procedure SA-300 Appendix, *Handbook on Nuclear Material Event Reporting in the Agreement States*

Glossary

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)
FTE	Full Time Equivalent of personnel effort
IMC	NRC Inspection Manual Chapter
IP	NRC Inspection Procedure
MD	NRC Management Directive
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 (not subject to the Act)
NRC	United States Nuclear Regulatory Commission
SA	Office of State and Tribal Programs Agreement States Procedure
SSR's	<i>Suggested State Regulations</i> , published by the CRCPD
OGC	NRC Office of the General Counsel
STP	NRC Office of State and Tribal Programs
RSAO	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. 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.

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

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.

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

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, 9b, 12, 13, 17, 19, 21, 23, 24, 27, 28, 29, 30, and 31	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	Program descriptions from IMPEP reports; MD 5.9; and SA-200 Appendix B
4.1.3	Content of Agreement	Proposed Agreement	26, and 27	MD 5.8
4.2	Regulatory Elements			
4.2.1	Radiation Protection Standards	State standards for protection against radiation	2, 3, 4, 5, 6, 9a, 11, and 22	MD 5.9; SA-200 Appendix A; 10 CFR Parts 20, 30, 35, 40, 61, 71, and 150; SSR's
4.2.2	Transboundary Requirements	State regulations with significant transboundary implications	6, 9a, and 10	MD 5.9; SA-200 Appendix A; 10 CFR Parts 20, 30, 34, 39, 40, 70, 71, and 150; SSR's

Section	Program Element	Information from State	Criteria number ^(a)	References
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 D/H&S	1, 7, 8, 11, and 32	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; SSR's
4.3	Licensing Program			
4.3.1	Materials licensing	Licensing Program description and procedures; licensing guides	1, 13, 14, 15, 20, and 23	MD 5.6; SA-104; NUREG-1556 series; MARSSIM, DG-4006, NUREG-0241, NUREG-5849
4.3.2	SS&D Safety Evaluations	SS&D Program description and procedures	13	NUREG-1556, Volume 3
4.3.3	Low-level Waste Site Licensing	LLW Program description and procedures	9, and 13	NUREG-1199, NUREG-1200, NUREG-1300, NUREG-1274
4.3.4	Uranium or Thorium Mill Licensing	11(e).2 Program description and procedures	35	NRC Uranium Recovery Program Policy and Guidance Directives
4.3.5	Licensing Quality Assurance	Procedures for review of licensing quality	1, and 13	MD 5.6; and SA-104
4.3.6	Licensing Administrative Procedures	Procedures for processing licensing actions	1, and 25	

Section	Program Element	Information from State	Criteria number ^(a)	References
4.4	Inspection Program			
4.4.1	Inspection Procedures	Inspection Program description, inspection procedures and guides, report formats, inspection frequency	1, 16, 18, and 36	MD 5.6; SA-101 and 102; IMC 1220 and 2800; IP 87101 thru 87120
4.4.2	Inspections Quality Assurance	Procedures for review of inspection quality	1, and 16	IMC 2800; MD 5.6 and SA-102
4.4.3	Inspection Administrative Procedures	Procedures for processing & filing inspection reports	1	IMC 2800
4.5	Enforcement Program			
4.5.1	Routine Enforcement Procedures	Enforcement program description and procedures for routine enforcement actions, notice of violation letters	1, 18, and 23	NUREG-1600 and IMC 2800
4.5.2	Escalated Enforcement Procedures	Procedures for escalated enforcement actions, procedures for legal assistance	18, 19, and 23	NUREG-1600 and IMC 2800
4.6	Technical Staff			
4.6.1	Technical Staff Organization	Staffing plan	20, and 34	MD 5.6; recent Agreement State application

Section	Program Element	Information from State	Criteria number ^(a)	References
4.6.2	Formal Qualification Plan	Formal qualification plan for technical staff	20, and 34	MD 5.6; IMC1246 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	MD 5.6; IMC1246; 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	MD 5.6 and 8.8; SA-105 and 300; IMC 1300 - 1303, 1330
4.7.2	Event Reporting Procedures	State NMED reporting procedures	1, and 11	SA-300 Appendix

(a) See section 2.2.1

Appendix B
Staffing Analysis Forms

Staff Need / Resource Analysis

Instructions

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

A. Need 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 "NEED ANALYSIS" form, attached.
2. Estimate the average number of licensing actions (new, renewal, amendments, and terminations) you expect to receive per year per license in that category. For estimate assistance, talk to your NRC Region and the existing Agreement States about their experience.
3. Estimate the number of staff days you need to process an average action.
4. Multiply the estimates in steps 2 and 3 to derive an estimate of the number of staff days you will need to process the expected licensing actions for that category.
5. Repeat steps 2, 3 and 4 for inspections. Include reactive inspections, and consider preparation, travel, on-site, and report writing time.

6. Conduct a similar analysis for the other Major Areas of your Program. You should consider: regulation development; decommissioning (including SDMP sites); response to incidents and allegations; contingencies and unanticipated work; and supervisory functions (including inspector accompaniments).

B. Resource Analysis

1. Enter staff member ID in blank boxes on top row. See the sample "RESOURCE ANALYSIS" form, attached.
2. 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.
3. For each License Category the individual is qualified to review licenses, enter the number of days the individual will be available for reviewing actions of those licensees.
4. For each License Category, sum the days available over all inspectors and enter on the Balance Analysis. Sum the days available over all license reviewers and enter on the Balance Analysis.
5. Conduct a similar analysis for the other Major Program Areas.

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 Program Areas: For each Program Area, compare the estimated number of days needed and days available. The number of days available **must be at least equal** to the number of days needed.

STAFF NEEDS ANALYSIS

License Category	Number of Licenses	Licensing actions / yr	Staff days per action	Licensing staff days	Inspections per year	Staff days / inspection	Inspection staff days
Academic							
Broad Scope Academic							
Nuclear Med - Uptake, etc							
Nuclear Med - Imaging							
Nuclear Med - therapy							
Bone Mineral							
Brachytherapy							
Teletherapy							
Medical - Broad Scope							
Nuclear Pharmacy							
Fixed Gauge							
Portable Gauge							
Industrial - other							
Broad Scope Industrial							
Industrial Radiography							
Well Logging							
LLW broker							

LLW site							
U mill							
SS&D							

STAFF RESOURCE ANALYSIS

Staff Member											Total	
License Category	Insp	Lic	Insp	Lic	Insp	Lic	Insp	Lic	Insp	Lic	Insp	Lic
Academic												
Broad Scope Academic												
Nuclear Med - Uptake, etc												
Nuclear Med - Imaging												
Nuclear Med - therapy												
Bone Mineral												
Brachytherapy												
Teletherapy												
Medical - Broad Scope												
Nuclear Pharmacy												
Fixed Gauge												
Portable Gauge												
Industrial - other												
Broad Scope Industrial												

Industrial Radiography												
Well Logging												
LLW broker												
LLW site												
U mill												
SS&D												

STAFF BALANCE ANALYSIS

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				
Nuclear Med - Therapy				
Bone Mineral Analysis				
Brachytherapy				
Teletherapy				
Medical - Broad Scope				
Nuclear Pharmacy				
Fixed Gauge				
Portable Gauge				
Industrial - other				
Broad Scope Industrial				
Industrial Radiography				
Well Logging				
LLW broker				

LLW site				
U mill				
SS&D				

Appendix C

Sample Letters and Documents

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PROCESSING SCHEDULE for NEW AGREEMENTS

<u>Event</u>	<u>Event time</u> <u>Weeks</u>	<u>Elapsed times</u> <u>Weeks</u>
Part 1 - Review of the Request for an Agreement		(24)
Notification that a Draft Request will be submitted		(2 months prior to submittal)
Review team established		(between notification and receipt of draft)
Receipt of draft request ¹	0	0
Team concludes completeness review	3	3
A completeness comment letter mailed ²	3	6
Receipt of formal request	8	14
Team review of formal request finished ³	8	22
Team completes negative consent Commission Paper, including draft staff assessment and FR notice	2	24
Part 2 - FR publication & public comment period		(16)
NRC Offices concur on Commission Paper	3	27
EDO sends Paper to Commission	2	29
Commission gives negative consent	2	31
First publication in FR	1	32
Public comment period ends	4	36
Team analyzes comments; completes final assessment and Commission paper	4	40
Part 3 - Final processing and Commission approval		(13)
NRC Offices concur on final assessment and paper	3	43
EDO signs paper	2	45
Commission SRM approving Agreement	4	49
Effective date of Agreement	4	53

¹presumes a two month alert by State, allowing four weeks to establish the NRC staff review team

²presumes two week office concurrence

³presumes no unresolved issues

Letter of Intent



GEORGE V. VOINOVICH
GOVERNOR

STATE OF OHIO
OFFICE OF THE GOVERNOR
COLUMBUS 43266-0601

April 5, 1991

Kenneth M. Carr, Chairman
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Mr. Carr:

The role of the U.S. Nuclear Regulatory Commission in the State of Ohio has been rather significant over the past several decades. Ohio has been blessed with a vast amount of industry, much of which utilizes radioactive material in their industrial applications. In addition, academia and the health professions certainly share in the statewide usage of radioactive material.

While such usage benefits all of us, radiation safety has always been a prime concern. Because of this, I feel that the State of Ohio should play a vital role in the radiation protection of its people. Toward that end, it is our intent to pursue the possibility of an agreement with the U.S. Nuclear Regulatory Commission for transfer of authority for the control of radioactive material to the State of Ohio pursuant to Section 274b of the Atomic Energy Act of 1954, as amended.

To facilitate our inquiry into the Agreement State Program, I am requesting your assistance to the Radiological Health Program staff of the Ohio Department of Health in this effort. Your staff can reach the Administrator of the Radiological Health Program at (614) 644-2727 to initiate this contact.

Thank you for helping in this manner. All of us look forward to a continuing, cooperative effort to enhance radiation safety within the State of Ohio.

Sincerely,

George V. Voinovich
Governor

GVV:cc

cc: Edward G. Kilroy, M.D., Director, Ohio Department of Health
Robert E. Owen, Administrator, Radiological Health Program
A. Bert Davis, Administrator, USNRC Region III Office

Governor's Letter of Certification



GEORGE V. VOINOVICH
GOVERNOR

STATE OF OHIO
OFFICE OF THE GOVERNOR
COLUMBUS 43266-0601

JUN 22 1998

REC'D BY SDF Shirley Ann Jackson, Chairman
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555
3 AUG 98 2:41

Dear Chairman Jackson:


I am writing to formally request that an agreement be established between the United States Nuclear Regulatory Commission and the State of Ohio as authorized under Section 274b of the Atomic Energy Act of 1954, as amended, and the Ohio Revised Code, Chapter 3748.03. Under this agreement the Commission will discontinue and the State of Ohio will assume certain regulatory authority for radioactive materials now under federal jurisdiction. As provided by R.C. Section 3748.03(B), the Department of Health is the agency responsible for the implementation of the agreement. The specific authority requested is for the following:

- A. Byproduct materials as defined in Section 11e(1) of the Act,
- B. Byproduct materials as defined in Section 11e(2) of the Act,
- C. Source materials,
- D. Special nuclear materials in quantities not sufficient to form a critical mass,
- E. Commercial disposal of low-level radioactive waste, and
- F. Sealed source and device review.

I certify that the State of Ohio wants to assume regulatory authority and oversight responsibility for such materials, and that the State of Ohio has an adequate program for the control of radiation hazards covered by this proposed agreement. Enclosed is information describing Ohio's radiation control program and regulatory capabilities, as well as a copy of our radiation control laws and rules.

Your expeditious consideration of this proposed agreement is most appreciated.

Sincerely,


George V. Voinovich
Governor

William Ryan, Director, Ohio Department of Health
Roger Suppes, Chief, Bureau of Radiation Protection, Ohio Department of Health



Completeness Letter

(Name), Director
Radiation Control Program
Address
City, State, Zip

Dear _____:

We have conducted a completeness review of your draft request for an Agreement dated _____. The review was conducted by an inter-office staff team identified in Enclosure 1. The review was based on a Commission Policy Statement that provides criteria for new agreements, and an Office of State and Tribal Programs (STP) procedure for processing new agreements, described in further detail below.

The completeness review was conducted to determine whether the draft application contained sufficient information to enable staff to conduct a detailed review of the application. The team found that the draft application provided information on all major program elements and reflected significant effort on the part of your staff. The team also identified several areas where additional clarifying information or documentation is needed. Our comments are contained in Enclosure 1. Please note that our comments only address those elements where additional information is needed. The team concluded other program elements contained sufficient information to support a detailed review. The Commission's Policy Statement, *"Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory Authority and Assumption Thereof by States through Agreements,"* specifies the criteria the Commission will apply in making its finding that a proposed State Agreement program is adequate to protect public health and safety and compatible with NRC's regulatory program, as required by the Atomic Energy Act [Effective January 23, 1981 (46 FR 7540), and amended by Policy Statements published July 16, 1981 (46 F. R. 36969) and July 21, 1983 (48 FR 33376)]. Under this process, the staff prepares a written assessment of the State's program, based on a review of the States request against the criteria, to support the Commission's finding.

A procedure has been developed that provides guidance for preparation and review of a request for an Agreement. The procedure, STP Procedure SA-700, *Processing a Request for an Agreement*, and the Appendix, "Handbook for Processing an Agreement," is based on the above policy criteria, the performance indicators set out in Management Directive 5.6, *"Integrated Materials Performance Evaluation Program (IMPEP),"* and staff experience in reviewing previous Agreement requests. A copy of the procedure and handbook is enclosed (Enclosure 2).

Completeness Letter

The handbook to SA-700, which identifies the necessary documentation for a complete application, was used by staff to identify any additional information and documentation necessary to complete your request for an Agreement. For your reference, the comments are correlated to the pertinent sections of your draft application. We would also appreciate any comments you might have on the usefulness of the procedure and handbook.

After you have an opportunity to review our comments, we would welcome an opportunity to meet with you to review the comments, and answer any questions concerning the review, the information needed, or steps involved in processing of the Agreement. Please contact me at (301) 415-3340, or (PM name) at (301) 415-23xx to arrange the meeting.

Sincerely,

Paul H. Lohaus, Director
Office of State and Tribal Programs

Enclosures:
As stated

Chairman's Letter Replying to the Request for an Agreement

The Honorable _____
Governor of _____
(City), (State) (Zip code)

Dear Governor _____:

I have received your letter with enclosures, dated _____, in which you request an agreement between the Nuclear Regulatory Commission (NRC) and the (State) (Commonwealth) of _____ pursuant to section 274b of the Atomic Energy Act of 1954, as amended (AEA). In your request, (State) would assume regulatory authority over the acquisition, possession, use, transfer, and disposal of source material, byproduct material as defined in section 11e.(1) of the AEA, byproduct material as defined in Section 11e.(2) of the AEA, i.e., tailings from uranium or thorium milling, and special nuclear material in quantities not sufficient to form a critical mass. The regulatory authority to be assumed would also include conducting safety-related evaluations of sealed sources and devices.

As required by the AEA, the NRC staff is preparing an assessment of the compatibility of the (State) program with the NRC's program and the adequacy of (State)'s program to protect public health and safety. NRC will publish a summary of the assessment along with the proposed agreement in the Federal Register for public comment. The AEA requires that the notice be published once each week for four consecutive weeks. A press release concerning your request will also be issued at that time. After the expiration of the comment period, the Commission will consider any comments received and make a final decision on your request. We will promptly inform you of our decision. As we complete the review of your application and the public comment process, NRC staff will coordinate with (State) staff to develop a revised schedule for the effective date of the future agreement.

We are pleased with your continued interest in becoming an Agreement State and look forward to the continued excellent relationship we have enjoyed in the past.

Sincerely,

Chairman

NRC Staff Assessment

NOTE to USERS: The **BOLD** text in the numbered paragraphs is the statement of criteria taken from the Commission Policy Statement as published in the FR. It should be reproduced EXACTLY, including errors. Specific comments about the Ohio program are for illustration only. Replace or modify as appropriate.

ASSESSMENT

of the proposed

OHIO PROGRAM FOR THE REGULATION OF AGREEMENT MATERIALS⁴

as described in the

Request for an Agreement

This assessment, prepared by the NRC staff, examines the proposed radiation control program of the State of Ohio with respect to the ability of the program to regulate the possession, use, and disposal of radioactive materials subject to the Atomic Energy Act of 1954 (Act), as amended. The assessment was performed using the criteria in the Commission's policy statement "Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory Authority and Assumption Thereof by States Through Agreement" (referred to below as the "criteria")⁵ using an internal procedure developed by the Office of State and Tribal Programs. Each criterion, and the NRC staff's assessment related thereto, is addressed separately below.

OBJECTIVES

1. **Protection. A State regulatory program shall be designed to protect the health and safety of the people against radiation hazards.**

⁴Agreement materials are those radioactive materials covered by the Act over which regulatory authority may be transferred to a State under the provisions of section 274.

⁵NRC Statement of Policy published in the Federal Register January 23, 1981 (46 FR 7540-7546), a correction was published July 16, 1981 (46 FR 36969) and a revision of Criterion 9 published in the Federal Register July 21, 1983 (48 FR 33376).

NRC Staff Assessment

The proposed Ohio program for regulating agreement materials would be located within the existing Bureau of Radiation Protection, an organizational unit of the Ohio Department of Health. The Bureau's Nuclear Materials Safety Section currently has responsibility for licensing and inspection of radioactive materials that occur naturally or are produced by particle accelerators. Under the proposed Agreement, the section would also be given primary responsibility for licensing and inspection of the byproduct, source, and special nuclear materials. The Bureau also has responsibility for the regulation of machine produced radiation, and non-ionizing radiation.

Support to the Nuclear Materials Safety Section would be provided by other Bureau of Radiation Protection sections for responding to incidents and emergencies, the decommissioning of licensed sites and facilities, the management of low-level radioactive waste, and the laboratory analysis of radioactive material samples.

The authority to issue, suspend, or revoke licenses, and to issue orders or assess administrative fines is vested by law in the Director of the Department of Health.

The NRC staff review verified that the Ohio program design for distributing regulatory responsibilities to the program staff is similar to designs used successfully in other Agreement States, and that all necessary program elements have been addressed. The staff concludes that the design of the proposed Ohio program for agreement materials satisfies the criterion.

References: *Program Narrative Description*, and *Organizational Charts of the Bureau of Radiation Protection*, in the Request for an Agreement by Governor Voinovich, as revised.

RADIATION PROTECTION STANDARDS

2. **Standards.** The State regulatory program shall adopt a set of standards for protection against radiation which shall apply to byproduct, source and special nuclear materials in quantities not sufficient to form a critical mass.

The authority to promulgate rules⁶ for the control of exposure to sources of radiation is vested in the Public Health Council of the Ohio Department of Health by Section 3748.04 of the Ohio Revised Code. The NRC staff review verified that the Council has adopted,

⁶Ohio uses only the term "rules" while NRC uses both "rules" and "regulations." For the purposes of this analysis, the terms "rule" and "regulation" are presumed to be interchangeable.

NRC Staff Assessment

by reference, the NRC regulations in 10 CFR Parts 19, 20, 30, 31, 32, 33, 34, 35, 36, 40, 61, 70, 71, and 150 that were in effect as of October 19, 1998, into Chapter 3701-39 of the Ohio Administrative Code. The Ohio rules have the same applicability as the NRC regulations to materials covered by the Agreement, except that the Ohio rules apply in addition to naturally occurring and accelerator produced radioactive materials.

Ohio rule 3701-39-021 (A) adopts the NRC regulations, and specifies that references to the NRC shall be construed as references to the Director of the Department of Health. It is noted, however, that Ohio has adopted the NRC regulations as entire Parts, including sections that address regulatory matters reserved to the Commission. Ohio has adopted a provision in Rule 3701-39-021 (A) excepting such sections from being construed as references to the Director of the Department of Health. The NRC staff concludes that Ohio will not attempt to enforce the regulatory matters reserved to the Commission. In accordance with NRC Management Directive 5.9, this approach is considered compatible.

The NRC staff concludes that the adoption by Ohio of the NRC regulations by reference satisfies the criterion.

References: Ohio Revised Code, Section 3748.04; and rule 3701-39-21 of the Ohio Administrative Code.

3. **Uniformity in Radiation Standards.** It is important to strive for uniformity in technical definitions and terminology, particularly as related to such things as units of measurement and radiation dose. There shall be uniformity on maximum permissible doses and levels of radiation and concentrations of radioactivity, as fixed by 10 CFR Part 20 of the NRC regulations based on officially approved radiation protection guides.

Ohio law requires the Public Health Council to adopt rules that are compatible with the equivalent NRC regulations and that are equally stringent to, or to the extent practicable more stringent than, the equivalent NRC regulations. The Council has adopted the NRC regulations in 10 CFR Part 20 that were in effect on October 19, 1998, by reference.

The NRC staff review verified that the resultant Ohio rules contain all of the provisions that are necessary in order to be compatible with the regulations of the NRC on the effective date of the Agreement between the State and the Commission. The adoption by reference assures the uniformity of the standards.

The NRC staff concludes that the criterion is satisfied.

NRC Staff Assessment

References: Ohio Revised Code Section 3748.04; and rule 3701-39-21 of the Ohio Administrative Code.

4. **Total Occupational Radiation Exposure.** **The regulatory authority shall consider the total occupational radiation exposure of individuals, including that from sources which are not regulated by it.**

The NRC staff review verified that Ohio has adopted the NRC regulations in 10 CFR Part 20 by reference, including Subpart C, the occupational dose limits, and Subpart D, the dose limits for individual members of the public. Ohio licensees are required to consider the radiation doses to individuals from all sources of radiation, except background radiation and radiation from medical administrations. As in the case of NRC licensees, Ohio licensees are required to consider the radiation dose whether the sources are in the possession of the licensee or not.

The NRC staff concludes that the requirements of the criterion are satisfied.

Reference: Rule 3701-39-21 of the Ohio Administrative Code.

5. **Surveys, Monitoring.** **Appropriate surveys and personnel monitoring under the close supervision of technically competent people are essential in achieving radiological protection and shall be made in determining compliance with safety regulations.**

NRC requires surveys and monitoring pursuant to Subpart F of 10 CFR Part 20. The NRC staff review verified that Ohio has adopted Subpart F by reference. Ohio licensees thus would be required to conduct surveys and personnel monitoring to the same standards as is required of NRC licensees.

The NRC staff concludes that the criterion is satisfied.

Reference: Rule 3701-39-21 of the Ohio Administrative Code.

6. **Labels, Signs, Symbols.** **It is desirable to achieve uniformity in labels, signs, and symbols, and the posting thereof. However, it is essential that there be uniformity in labels, signs, and symbols affixed to radioactive products which are transferred from person to person.**

NRC Staff Assessment

The NRC staff review verified that Ohio has adopted the NRC regulations in Subpart J of 10 CFR Part 20 by reference. The radiation labels, signs and symbols, and the posting and labeling requirements in the Ohio rules thus are identical to those contained in the NRC regulations.

The NRC staff concludes that the required degree of regulatory uniformity is provided and this criterion is satisfied.

Reference: Rule 3701-39-21 of the Ohio Administrative Code.

7. **Instruction. Persons working in or frequenting restricted areas shall be instructed with respect to the health risks associated with exposure to radioactive materials and in precautions to minimize exposure. Workers shall have the right to request regulatory authority inspections as per 10 CFR 19, Section 19.16 and to be represented during inspections as specified in Section 19.14 of 10 CFR 19.**

The NRC staff review verified that Ohio has adopted the NRC regulations in 10 CFR Part 19 by reference, and the NRC staff concludes that the criterion is satisfied.

It is noted that the NRC regulations and definitions in 10 CFR Parts 19 and 20 have been amended since the Commission adopted the criteria. In particular, 10 CFR 19.12 was amended effective August 14, 1995 (60 FR 36038; July 13, 1995). Criterion number seven reflects, in part, the pre-amendment rule. In performing the review, NRC staff has considered the amended statement of the rule, which requires instruction to be provided to all individuals who, in the course of their employment, are likely to receive an occupational dose in excess of 100 millirem in one year, whether the dose is received in a restricted area or not. Since Ohio has adopted the current 10 CFR 19.12 by reference, the Ohio rule is compatible with the current NRC rule.

Reference: Rule 3701-39-21 of the Ohio Administrative Code.

8. **Storage. Licensed radioactive material in storage shall be secured against unauthorized removal.**

The NRC staff review confirmed that Ohio has adopted Subpart I of 10 CFR Part 20 by reference. The NRC staff concludes that the criterion is satisfied.

Reference: Rule 3701-39-21 of the Ohio Administrative Code.

NRC Staff Assessment

9. **Radioactive Waste Disposal.** (a) **Waste disposal by material users.** The standards for the disposal of radioactive materials into the air, water and sewer, and burial in the soil shall be in accordance with 10 CFR Part 20. Holders of radioactive material desiring to release or dispose of quantities or concentrations of radioactive materials in excess of prescribed limits shall be required to obtain special permission from the appropriate regulatory authority.

Requirements for transfer of waste for the purpose of ultimate disposal at a land disposal facility (waste transfer and manifest system) shall be in accordance with 10 CFR 20. The waste disposal standards shall include a waste classification scheme and provisions for waste form, applicable to waste generators, that is equivalent to that contained in 10 CFR Part 61.

The NRC staff review confirmed that Ohio has adopted Subpart J of 10 CFR Part 20 and Part 61 effective on October 19, 1998, by reference. The Ohio rules would thus impose the same waste disposal requirements, including waste classification and waste manifests, as the current NRC regulations. NRC staff concludes that criterion 9(a) is satisfied.

Reference: Rule 3701-39-21 of the Ohio Administrative Code.

(b) **Land Disposal of waste received from other persons.** The State shall promulgate regulations containing licensing requirements for land disposal of radioactive waste received from other persons which are compatible with the applicable technical definitions, performance objectives, technical requirements and applicable supporting sections set forth in 10 CFR Part 61. Adequate financial arrangements (under terms established by regulation) shall be required of each waste disposal site licensee to ensure sufficient funds for decontamination, closure and stabilization of a disposal site. In addition, Agreement State financial arrangements for long-term monitoring and maintenance of a specific site must be reviewed and approved by the Commission prior to relieving the site operator of licensed responsibility (Section 151(a)(2), Pub. L. 97-425).

Ohio has requested authority under the proposed Agreement to regulate the disposal of low-level radioactive waste received from other persons at a land disposal site. The NRC staff review verified that Ohio has adopted rules equivalent to the regulations in 10 CFR Part 61 by reference.

The review disclosed that Ohio law specifies, in Revised Code Section 3747.07, the technology to be utilized for waste disposal at any land disposal site located in Ohio.

NRC Staff Assessment

Another agency of the State, the Ohio Low-level Radioactive Waste Facility Development Authority, is designated by law to be the owner of the site. The Authority would select an operator for the site who would be the site licensee during operations, and during the institutional control period after closure of the site. At the end of the institutional control period, the operator would transfer the site license to the Authority.

NRC staff concludes that the provisions of Ohio law and rules related to the management of low-level radioactive waste would provide the same protection as is provided by the NRC requirements, and that the proposed Ohio program for the management of low-level radioactive waste received from other persons at a land disposal site would be compatible with the program of the Commission.

References: Ohio Revised Code - Title 37 Chapter 47 and Title 37 Chapter 48; rule 3701-39-21 of the Ohio Administrative Code.

10. Regulations Governing Shipment of Radioactive Materials. **The State shall, to the extent of its jurisdiction, promulgate regulations applicable to the shipment of radioactive materials, such regulations to be compatible with those established by the U.S. Department of Transportation and other agencies of the United States whose jurisdiction over interstate shipment of such materials necessarily continues. State regulations regarding transportation of radioactive materials must be compatible with 10 CFR Part 71.**

The NRC staff review verified that Ohio has adopted 10 CFR Part 71 by reference. Staff notes that Part 71 also contains requirements related to the licensing of packaging for use in transporting radioactive materials. As discussed in criterion 2, Ohio would not attempt to enforce portions of the regulations related to activities, such as approving packaging designs, which are reserved to NRC. Based on these considerations, the NRC staff concludes that criterion 10 is satisfied.

Reference: Rule 3701-39-21 of the Ohio Administrative Code.

11. Records and Reports. **The State regulatory program shall require that holders and users of radioactive materials (a) maintain records covering personnel radiation exposures, radiation surveys, and disposals of materials; (b) keep records of the receipt and transfer of the materials; (c) report significant incidents involving the materials, as prescribed by the regulatory authority; (d) make available upon request of a former employee a report of the employee's exposure to radiation; (e) at**

NRC Staff Assessment

request of an employee advise the employee of his or her annual radiation exposure; and (f) inform each employee in writing when the employee has received radiation exposure in excess of the prescribed limits.

The NRC staff review verified that Ohio has adopted 10 CFR Parts 19, 20, 30, 31, 32, 33, 34, 35, 36, 40, 61, 70, 71, and 150 by reference. The records and reports referenced in criterion 11 are regulatory requirements of these Parts. NRC staff concludes that by adopting the regulations, Ohio has adopted the requirements, and criterion 11 is satisfied.

Reference: Rule 3701-39-21 of the Ohio Administrative Code.

12. Additional Requirements and Exemptions. **Consistent with the overall criteria here enumerated and to accommodate special cases and circumstances, the State regulatory authority shall be authorized in individual cases to impose additional requirements to protect health and safety, or to grant necessary exemptions which will not jeopardize health and safety.**

The NRC staff review confirmed that Ohio State law provides the radiation control program authority to impose, by order or license condition, additional health and safety requirements beyond the requirements specified in law and the rules. The program also has the legal authority to grant reasonable and necessary exceptions to the regulatory requirements, either by order or license condition. Ohio has adopted 10 CFR 30.34, *Terms and conditions of licenses*, by reference.

NRC staff concludes that the criterion is satisfied.

References: Ohio Revised Code - Title 37 Chapter 48; and rule 3701-39-21 of the Ohio Administrative Code.

PRIOR EVALUATION OF USES OF RADIOACTIVE MATERIALS

13. Prior Evaluation of Hazards and Uses, Exceptions. **In the present state of knowledge, it is necessary in regulating the possession and use of byproduct, source and special nuclear materials that the State regulatory authority require the submission of information on, and evaluation of, the potential hazards, and the capability of the user or possessor prior to his receipt of the materials. This criterion is subject to certain exceptions and to continuing reappraisal as knowledge and experience in the atomic energy field increase. Frequently there are, and increasingly in the future there may be, categories of materials and uses as to which there is sufficient**

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knowledge to permit possession and use without prior evaluation of the hazards and the capability of the possessor and user. These categories fall into two groups -- those materials and uses which may be completely exempt from regulatory controls, and those materials and uses in which sanctions for misuse are maintained without pre-evaluation of the individual possession or use. In authorizing research and development or other activities involving multiple uses of radioactive materials, where an institution has people with extensive training and experience, the State regulatory authority may wish to provide a means for authorizing broad use of materials without evaluating each specific use.

Since Ohio has adopted the current NRC regulations by reference, the Ohio regulatory requirements for issuing a license would be the same as those of NRC. The NRC staff review confirmed that the Bureau of Radiation Protection has procedures for the processing of applications for licensing. The procedures specify the actions to be accomplished, identify (by position) the staff responsible for accomplishing the actions, and identify resources such as forms and guides to be used. The procedures cover the processing actions from the response to the first contact by the applicant, to the delivery of the signed license. The procedures include a mechanism for tracking the overall progress of an application, and a docket numbering system to identify documents associated with the application. Staff concludes that the procedures provide reasonable confidence that the regulatory requirements would be met, or, where appropriate, exceptions granted.

The NRC staff review verified that the Ohio rules provide that a license authorizing the distribution of agreement materials that will subsequently be exempt from regulatory control may be issued only by the NRC.

Since criterion nine was adopted, the Commission has determined that the regulatory authority to conduct safety evaluations of sealed sources and devices may be retained by the NRC, unless the State requests assumption of the authority and has in place an adequate and compatible program to implement the authority. Ohio has requested the authority to conduct safety evaluations of sealed sources and devices.

NRC staff evaluated the Ohio rules, policies and procedures related to the sealed source and device safety evaluation program element, and determined that the program would be adequate and compatible.

The NRC staff concludes that the Ohio program meets the requirements of criterion 13.

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References: Rule 3701-39-21 of the Ohio Administrative Code; *Ohio Program for the Licensing of Radioactive Materials*, and the *Ohio Sealed Source and Device Review and Registration Program*, in the Request for an Agreement by Governor Voinovich, as revised.

14. **Evaluation Criteria.** In evaluating a proposal to use radioactive materials, the regulatory authority shall determine the adequacy of the applicant's facilities and safety equipment, his training and experience in the use of the materials for the purpose requested, and his proposed administrative controls. States should develop guidance documents for use by license applicants. This guidance should be consistent with NRC licensing and regulatory guides for various categories of licensed activities.

The NRC staff review determined that the Ohio licensing procedures manual addresses the specific elements listed in the criterion. The Ohio licensing procedures are similar to NRC licensing procedures.

The Ohio guidance for licensees and applicants is based on the regulatory guidance that NRC uses. NRC is currently revising the format of its licensing guidance, but the content of the guidance is generally the same as it was under the old format. Thus, the use of the old NRC format in the Ohio guidance does not lead to inconsistencies between the NRC and Ohio programs.

NRC staff concludes that the criterion is satisfied.

Reference: *Ohio Program for the Licensing of Radioactive Materials*, in the Request for an Agreement by Governor Voinovich, as revised.

15. **Human Use.** The use of radioactive materials and radiation on or in humans shall not be permitted except by properly qualified persons (normally licensed physicians) possessing prescribed minimum experience in the use of radioisotopes or radiation.

The NRC staff review verified that Ohio has adopted 10 CFR Part 35 by reference. The NRC training and experience requirements for persons to be licensed for the use of agreement materials on or in humans is specified in Part 35. NRC staff concludes that Ohio rules specify the same requirements.

Reference: Rule 3701-39-21 of the Ohio Administrative Code.

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INSPECTION

16. **Purpose, Frequency.** The possession and use of radioactive materials shall be subject to inspection by the regulatory authority and shall be subject to the performance of tests, as required by the regulatory authority. Inspection and testing is conducted to determine and to assist in obtaining compliance with regulatory requirements. Frequency of inspection shall be related directly to the amount and kind of material and type of operation licensed, and it shall be adequate to insure compliance.

The NRC staff review confirmed that the Ohio program has statutory authority to conduct inspections of licensees. Ohio has adopted 10 CFR Part 30, containing provisions relating to inspections and tests, by reference.

The program has also adopted a schedule for the inspection of licensees at least as frequently as the schedule used by NRC. The procedures also cover the conduct of inspections, and specify the actions to be accomplished and identify (by position) the staff responsible for accomplishing the actions. The scheduling procedures address prioritizing licences due for inspection and provide flexibility for the optimization of inspection related travel. These provisions are similar to those in NRC procedures.

The NRC staff concludes that the criterion is satisfied.

References: Rule 3701-39-21 of the Ohio Administrative Code; and the *Inspection Program for Radioactive Materials*, in the Request for an Agreement by Governor Voinovich, as revised.

17. **Inspections Compulsory.** Licensees shall be under obligation by law to provide access to inspectors.

The NRC staff review confirmed that Ohio law provides authority for Ohio radiation control program inspectors to enter public or private property at all reasonable times, for the purpose of determining compliance with the law and rules.

Reference: Ohio Revised Code section 3748.13.

18. **Notification of Results of Inspection.** Licensees are entitled to be advised of the results of inspections and to notice as to whether or not they are in compliance.

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The NRC staff review determined that Ohio has adopted procedures to convey a copy of the formal inspection report to the licensees, both when violations are found, and when no violations are found. The procedures identify (by position) the staff responsible and specify the time limit for preparing the inspection report, the process for management review and approval, and provide instructions for distribution of the report to the licensee and to the State's official files.

The NRC staff concludes that the criterion is satisfied.

Reference: *Ohio Inspection Program for Radioactive Materials*, in the Request for an Agreement by Governor Voinovich, as revised.

ENFORCEMENT

19. **Enforcement.** Possession and use of radioactive materials should be amenable to enforcement through legal sanctions, and the regulatory authority shall be equipped or assisted by law with the necessary powers for prompt enforcement. This may include, as appropriate, administrative remedies looking toward issuance of orders requiring affirmative action or suspension or revocation of the right to possess and use materials, and the impounding of materials; the obtaining of injunctive relief; and the imposing of civil or criminal penalties.

The NRC staff review confirmed that the Ohio program is authorized by law to enforce the State rules using a variety of sanctions, including the imposition of administrative fines and the issuing of orders to suspend, modify or revoke licenses, or to impound materials. The program may seek restraining orders, civil penalties, and criminal sanctions with the assistance of the attorney general.

The program has adopted a policy and procedures to implement the enforcement authority. The Ohio enforcement procedures are similar to the NRC enforcement procedures with respect to classifying the severity of violations.

The NRC staff concludes that the criterion is satisfied.

References: Ohio Revised Code Chapter 3748; and the *General Statement of Policy Enforcement Actions*, in the Request for an Agreement by Governor Voinovich, as revised.

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PERSONNEL

20. Qualifications of Regulatory and Inspection Personnel. The regulatory agency shall be staffed with sufficient trained personnel. Prior evaluation of applications for licenses or authorizations and inspection of licensees must be conducted by persons possessing the training and experience relevant to the type and level of radioactivity in the proposed use to be evaluated and inspected. This requires competency to evaluate various potential radiological hazards associated with the many uses of radioactive material and includes concentrations of radioactive materials in air and water, conditions of shielding, the making of radiation measurements, knowledge of radiation instruments--their selection, use and calibration--laboratory design, contamination control, other general principles and practices of radiation protection, and use of management controls in assuring adherence to safety procedures. In order to evaluate some complex cases, the State regulatory staff may need to be supplemented by consultants or other State agencies with expertise in geology, hydrology, water quality, radiobiology and engineering disciplines.

To perform the functions involved in evaluation and inspection, it is desirable that there be personnel educated and trained in the physical and/or life sciences, including biology, chemistry, physics and engineering, and that the personnel have had training and experience in radiation protection. For example, the person who will be responsible for the actual performance of evaluation and inspection of all of the various uses of byproduct, source and special nuclear material which might come to the regulatory body should have substantial training and extensive experience in the field of radiation protection. It is desirable that such a person have a bachelor's degree or equivalent in the physical or life sciences, and specific training - radiation protection.

It is recognized that there will also be persons in the program performing a more limited function in evaluation and inspection. These persons will perform the day-to-day work of the regulatory program and deal with both routine situations as well as some which will be out of the ordinary. These people should have a bachelor's degree or equivalent in the physical or life sciences, training in health physics, and approximately two years of actual work experience in the field of radiation protection.

The foregoing are considered desirable qualifications for the staff who will be responsible for the actual performance of evaluation and inspection. In addition, there will probably be trainees associated with the regulatory program who will

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have an academic background in the physical or life sciences as well as varying amounts of specific training in radiation protection but little or no actual work experience in this field. The background and specific training of these persons will indicate to some extent their potential role in the regulatory program. These trainees, of course, could be used initially to evaluate and inspect those applications of radioactive materials which are considered routine or more standardized from the radiation safety standpoint, for example, inspection of industrial gauges, small research programs, and diagnostic medical programs. As they gain experience and competence in the field, the trainees could be used progressively to deal with the more complex or difficult types of radioactive material applications. It is desirable that such trainees have a bachelor's degree or equivalent in the physical or life sciences and specific training in radiation protection. In determining the requirement for academic training of individuals in all of the foregoing categories, proper consideration should be given to equivalent competency which has been gained by appropriate technical and radiation protection experience.

It is recognized that radioactive materials and their uses are so varied that the evaluation and inspection functions will require skills and experience in the different disciplines which will not always reside in one person. The regulatory authority should have the composite of such skills either in its employ or at its command, not only for routine functions, but also for emergency cases.

Based on the review of the organizational charts and position descriptions for the Ohio program, and the curricula vitae for the current program staff members, the NRC staff concluded that the Bureau has a staffing plan that provides a sufficient number of adequately trained technical staff.

1. Assessment of the Agreement Materials Staffing

There are approximately 593 NRC licenses in Ohio, of which NRC staff estimates about 574 would become Ohio licensees under the proposed Agreement. Unlike the practice of the NRC, Ohio would not usually license more than one program type (for example, industrial radiography and portable gauges) in a single license. Because of this difference, Ohio estimates that the 574 NRC licensed programs that would transfer would be converted to more than 600 Ohio licenses. These would be added to the approximately 170 NARM registrations that the Bureau currently is converting to licenses.

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In addition, Ohio estimates that approximately 300 NRC general licenses transferred under the Agreement would be converted to Ohio specific licenses. The NRC general licenses involved authorize possession and use of devices which contain quantities of radioactive material greater than 100 millicuries in sealed sources. This more stringent approach (issuing specific licenses rather than general licenses) to regulating the subject devices has been previously considered by NRC and found compatible in existing Agreement States.

Ohio estimates that the Bureau would regulate a total of approximately 1100 specific licenses. Based on NRC's past experience in other new Agreement States, NRC staff estimate that about 80% of the Ohio NARM licensees also hold NRC materials licenses. If Ohio were to continue the NRC licensing practice of allowing more than one program type in a single license, maintaining the general licenses, and were to combine the NARM and agreement materials licenses of individual licensees, the NRC staff estimate that the Bureau would have about 600 specific licenses in effect.

The current Bureau organizational chart shows that 24 professional/technical positions, including supervisors, and the Bureau Chief, will be associated with the agreement materials program. The Nuclear Materials Safety Section, which has responsibility for licensing and inspection, has 12 staff positions and three supervisors. NRC staff estimates, based on the experience of other Agreement States, that approximately 50% of the supervisors' time would be available for technical licensing and inspection activities. NRC staff credits the Nuclear Materials Safety Section with effectively 13.5 FTE of professional/technical staff.

There is no current quantitative guideline in this area, however, NRC previously used a guideline indicator of 1.0 to 1.5 FTE per 100 licenses when reviewing existing Agreement State programs. Using 13.5 technical/professional FTE in the Nuclear Materials Safety Section, and the NRC estimate of 600 licensees, there will be approximately 2.25 technical/professional FTE per 100 licenses. While this number may appear high, NRC staff notes that the Ohio staff members have limited agreement materials regulatory program experience compared to the existing Agreement State programs where the guideline indicator was applied. In addition, the Bureau will regulate several large licensees, including major universities with large research programs and manufacturers of sealed sources and devices. For these reasons, NRC staff concludes the number of staff in the proposed Ohio program is appropriate.

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Ohio will have a sealed source and device (SS&D) safety evaluation program element regulating 13 active manufacturers. Responsibility for this program element will be located in the Technical Services Section, with support from the other Bureau sections. Contractor assistance, if required, would be obtained.

NRC staff notes that, in the future, the Bureau may license and regulate a low-level radioactive waste disposal site. Neither the Bureau nor NRC expect an application for a waste disposal site license to be made in the near future. Further, when an application is received, the Bureau has plans to add staff and to supplement the Bureau staff with contractors.

Based on the above, the NRC staff concludes that the proposed Ohio agreement materials program staffing plan would provide an adequate number of personnel to meet the anticipated program needs.

When the Federal Register notice was published, the Bureau had 18 filled professional/technical and supervisor positions in the agreement materials program. In view of the anticipated work load and the Bureau staff experience level, NRC staff concluded that it could not be assured that the program would be successful at this level of staffing. In response to NRC staff comments, Ohio conducted an analysis which determined that a minimum staff of 21 professional/technical FTE, including five supervisors, would be needed to operate the program when the Agreement becomes effective. NRC staff reviewed the Ohio analysis and concurred that the minimum staff would provide a sufficient number of staff to initiate the Agreement program. Ohio committed to fill at least the open supervisor position and two of the staff positions with qualified individuals before the Agreement is signed.

Subsequent to the publication of the Federal Register notice, NRC determined that the license of the Battelle Memorial Institution for the Columbus - West Jefferson site will not be transferred to Ohio. Under the Atomic Energy Act, the Commission may not transfer a license authorizing special nuclear material in quantities sufficient to form a critical mass. The Commission's regulations in 10 CFR Part 150 provide a quantity formula to implement that restriction. The Battelle site is currently under decommissioning, but the licensee has determined that special nuclear material in greater than a formula quantity remains on site. In addition, a portion of the license of Reuter-Stokes authorizing special nuclear materials in greater than a formula quantity will be split off and retained by NRC.

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Based on these changes, Ohio re-analyzed the projected workload and its staffing level needs. The original analysis indicated 21 professional/technical FTE with approximately 0.6 FTE assigned to oversight of the decommissioning of the Battelle site, and approximately 13 percent of staff time available to provide for unforeseen resource needs, or contingencies during the transition. The re-analysis indicates that with NRC retaining the Battelle license, 20 professional/technical FTE is adequate to meet the first year needs, with approximately 11 percent of staff time available for unforeseen needs and contingencies. NRC staff has reviewed the re-analysis and agrees with it. On this basis, we conclude that Ohio has met the commitment to have an adequate number of staff members.

2. Assessment of Staff Qualifications

The NRC staff review considered the qualifications of the individuals currently on the Bureau professional/technical staff that would be involved in the agreement materials program, and the Bureau's procedures for training and qualifying new staff members.

Under the proposed Agreement, the chief of the Bureau would be the agreement materials program director, and would be primarily involved with the program's administration. NRC staff estimates that only about five percent of the chief's effort would be on technical issues. The Bureau chief holds a master's degree in public health, and is a registered sanitarian. He has been with the Department of Health since 1970, and has been chief of the Bureau since 1995. From 1987 to 1995 he was the chief of the former Division of Environmental Health, which included the former Bureau of Radiological Health.

The immediate day-to-day supervision of the agreement materials program would be provided by five supervisors: the supervisor of Medical Licensing and Inspection, the supervisor of non-Medical Licensing and Inspection, the Nuclear Materials Safety Section Program Administrator, the Technical Services Section Manager, and the Decommissioning Section Supervisor. The Licensing and Inspection supervisors report to the Program Administrator, who reports to the Bureau Chief. The Technical Services Section Manager, and the Decommissioning Section Supervisor, also report to the Bureau Chief.

The Technical Services Manager holds a bachelors degree in physics and has 16 years experience in state radiation control programs. He has been the section manager since the 1995 reorganization. From 1989 to 1995 he was the Chief of the former Bureau of Radiological Health. Prior to 1989 he served as a health physicist with the US Army, and the States of Florida and South Carolina.

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The Nuclear Materials Safety Section Program Administrator holds a bachelors degree in biology and has 19 years experience in state radiation control programs. She has been the program administrator since 1996. From 1993 to 1996 she was the Supervisor of Radioactive Materials starting in the former Bureau of Radiological Health. She also has 14 years experience in radiation control programs in Indiana and Illinois.

The Decommissioning Section Supervisor holds a bachelors degree in biology and has four years experience in the Ohio radiation control program. She also has 14 years experience in industry as a health physicist.

The Supervisor of the Medical Licensing and Inspection group holds a bachelors degree in Environmental management. He is a registered Radiation Protection Technologist with 14 years experience as a health physicist in medical, nuclear reactor, and as a health physics instructor in US Army training programs. The Supervisor of the non-Medical Licensing and Inspection group holds a bachelors degree in Applied Science & Technology with specialization in Radiation Protection. He is a registered Radiation Protection Technologist with 13 years experience. His experience includes 10 years with the U.S. Navy and civilian nuclear reactors. He has been with the Bureau for 3 years.

The non-supervisory staff members are all trained in physics, health physics, Nuclear Science, or Nuclear Engineering; or in life sciences including radiologic technology, biophysics, microbiology, and public health. Two staff members have more than five years experience in the state radiation control programs, five members have between two and five years experience, and eight have less than two years. Seven of the staff have 10 years or more total experience in health physics, radiation protection, or use of radiation and radioactive materials, and six others have between five and 10 years.

All non-supervisory staff members have at least a bachelors degree or equivalent, one holds a Ph.D., and three hold masters degrees. One staff member has been trained in both radiologic technology and nuclear medicine technology non-degree programs, plus has nine years working experience.

The agreement materials program staff members have also completed NRC specialty training courses provided for NRC and Agreement State regulatory personnel. Various staff members have completed training courses related to materials facilities licensing procedures, materials facilities inspection procedures, safety requirements for industrial radiography, safety requirements for medical uses of radioactive materials, sealed source and device safety evaluation, safety requirements for transportation of radioactive material, safety requirements for well-logging, and safety requirements for medical

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teletherapy. In addition, program staff have accompanied NRC inspectors and worked with NRC licensing staff to obtain additional on-the-job experience.

The Bureau has adopted a written program for the training and qualification of staff members, which covers both new staff members and the continuing qualification of existing staff. Criterion 20 contains no specific elements to address such programs. However, NRC staff notes that the Ohio agreement materials program will be evaluated under the Commission's Integrated Materials Performance Evaluation Program (IMPEP). One IMPEP criterion addresses staff training and qualifications, and an element of the IMPEP criterion addresses training and qualification plans. NRC staff reviewed the plan, and concludes that it satisfies the IMPEP criterion element.

The Bureau has committed to training and qualifying each individual staff member to function in the areas of responsibility to which the individual is assigned, and to having a distribution of individual staff member qualifications which matches the expected distribution of categories of licensees to be transferred from NRC. For example, there must be enough inspectors qualified to inspect industrial radiography operations that the program is able to inspect the number of industrial radiography licensees transferred without developing a backlog. The Bureau has committed to completing the training and qualification of the minimum staff before the Agreement is signed.

Based on the above, the NRC staff review concluded that when the Ohio staff is filled, trained, and qualified in accordance with the Bureau plans, it will have sufficient knowledge and experience in radiation protection, the use of radioactive materials, the standards for the evaluation of applications for licensing, and the techniques of inspecting licensed users of agreement materials to satisfy the criterion.

References: *Program Narrative Description; Organizational Charts of the Bureau of Radiation Protection; Training Program for Health Physics Personnel and Licensing, Inspection, and Decommissioning Technical Professional Staff Training and Qualification Procedure; and Current Staff Curricula Vitae*; in the Request for an Agreement by Governor Voinovich, as revised.

21. Conditions Applicable to Special Nuclear Material, Source Material and Tritium.
Nothing in the State's regulatory program shall interfere with the duties imposed on the holder of the materials by the NRC, for example, the duty to report to the NRC, on NRC prescribed forms (1) transfers of special nuclear material, source material and tritium and (2) periodic inventory data.

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The NRC staff review found that the Ohio law provides an exemption from the law, and rules adopted under the law, to persons subject to regulation by the NRC. Ohio also adopted 10 CFR Part 150 by reference to further inform persons of the exemptions and reservations of NRC authority under the Agreement. The NRC staff conclude that the criterion is satisfied.

Reference: Ohio Revised Code - Title 37 - Chapter 48, Section 3748.21; Ohio Administrative Code, Chapters 3701-38 and 3701-39.

22. Special Nuclear Material Defined. **Special nuclear material, in quantities not sufficient to form a critical mass, for present purposes means uranium enriched in the isotope U-235 in quantities not exceeding 350 grams of contained U-235; uranium 233 in quantities not exceeding 200 grams; plutonium in quantities not exceeding 200 grams; or any combination of them in accordance with the following formula: For each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all of the kinds of special nuclear material in combination should not exceed "1" (i.e., unity). For example, the following quantities in combination would not exceed the limitation and are within the formula, as follows:**

$$\frac{175 \text{ (grams contained U-235)}}{350} + \frac{50 \text{ (grams U-233)}}{200} + \frac{50 \text{ (grams Pu)}}{200} = 1$$

(This definition is subject to change by future Commission rule or regulation.)

The NRC staff review verified that Ohio has adopted 10 CFR Part 150 by reference, including the definition of the term "special nuclear material in quantities not sufficient to form a critical mass" therein. Staff concludes that the criterion is satisfied.

Reference: Rule 3701-39-21 of the Ohio Administrative Code.

ADMINISTRATION

23. Fair and Impartial Administration. **State practices for assuring the fair and impartial administration of regulatory law, including provision for public participation where appropriate, should be incorporated in procedures for:**

- a. **Formulation of rules of general applicability;**

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- b. **Approving or denying applications for licenses or authorization to possess and use radioactive materials, and**
- c. **Taking disciplinary actions against licensees.**

The NRC staff review confirmed that the Ohio radiation control program is bound by general statutory provisions with respect to providing the opportunity for public participation in rulemaking, licensing actions, and disciplinary actions. The program has adopted procedures to implement the law. The law also provides for the administrative and judicial review of actions taken by the program.

NRC staff has reviewed the pertinent procedures and determined that the criterion is satisfied.

References: Ohio Revised Code section 119; *Ohio Program for the Licensing of Radioactive Materials*, and *General Statement of Policy, Enforcement Actions*, in the Request for an Agreement by Governor Voinovich, as revised.

24. **State Agency Designation. The State should indicate which agency or agencies will have authority for carrying on the program and should provide the NRC with a summary of that legal authority. There should be assurances against duplicate regulation and licensing by State and local authorities, and it may be desirable that there be a single or central regulatory authority.**

The NRC staff review confirmed that the Ohio Department of Health is designated by law to be the State's radiation control agency. The Ohio low-level radioactive waste facility development authority is designated by law as the agency to adopt regulatory standards for the suitability of any proposed disposal site. The Department of Health would license and regulate the site after the Board has selected a site and the operator. The legal advisor to the Bureau of Radiation Control has confirmed that regulation of radioactive materials by local authorities is not permitted.

NRC staff concludes that the criterion is satisfied.

References: Ohio Revised Code sections 3747.05, 3748.02, and 3748.09.

25. **Existing NRC Licenses and Pending Applications. In effecting the discontinuance of jurisdiction, appropriate arrangements will be made by NRC and the State to ensure that there will be no interference with or interruption of licensed activities or**

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the processing of license applications by reason of the transfer. For example, one approach might be that the State, in assuming jurisdiction, could recognize and continue in effect, for an appropriate period of time under State law, existing NRC licenses, including licenses for which timely applications for renewal have been filed, except where good cause warrants the earlier reexamination or termination of the license.

The NRC staff review confirmed that Ohio law contains a provision which deems the holder of an NRC license on the effective date of the proposed Agreement to possess a similar license issued under the Ohio law and rules. These licenses would expire either 90 days after receipt, from the Ohio radiation control program, of a notice of expiration of such license or on the date of expiration specified in the NRC license, whichever is later. The Ohio law also provides that no license shall expire during the 90 days immediately following the effective date of the Agreement.

We noted a difference between Ohio and NRC requirements for the decommissioning of licensed facilities. NRC will terminate a license with restrictions on the future use of the site in accordance with the provisions of 10 CFR Part 20, Subpart E. Ohio law does not permit the termination of a license unless the site is suitable for release without restriction. For cases in which NRC would permit license termination under restricted conditions, Ohio will issue a special license for possession of the residual contamination in lieu of terminating the license. The license will contain restrictions equivalent to those imposed under Subpart E; thus, the only difference is that in Ohio the license will not be terminated. The Commission has determined (SECY-98-209) that the Ohio approach to decommissioning is compatible.

Ohio has also agreed not to impose standards more stringent than the NRC standards on facilities already decommissioned under a terminated NRC license, or on NRC licensees transferred to Ohio that have an NRC approved decommissioning plan.

NRC staff has concluded that the Ohio program satisfies criterion 25.

Reference: Ohio Revised Code section 3748.03.

26. **Relations With Federal Government and Other States. There should be an interchange of Federal and State information and assistance in connection with the issuance of regulations and licenses or authorizations, inspection of licensees, reporting of incidents and violations, and training and education problems.**

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The NRC staff review verified that the proposed Agreement commits Ohio to use its best efforts to cooperate with the NRC and the other Agreement States in the formulation of standards and regulatory programs for the protection against hazards of radiation and to assure that Ohio's program will continue to be compatible with the Commission's program for the regulation of agreement materials.

Since criterion 26 was adopted, the Commission has determined in the revised policy statement on Adequacy and Compatibility of Agreement State Programs (published 9/3/97 at 62 FR 46517) that providing reports to NRC of Agreement State licensee incidents, accidents and other significant events is a matter of compatibility. Ohio has adopted procedures to provide such reports to NRC. NRC staff concludes that the criterion is satisfied.

References: Proposed Agreement between the State of Ohio and the Nuclear Regulatory Commission, Article VI; and the NRC Policy Statement on Adequacy and Compatibility of Agreement State Programs.

27. Coverage, Amendments, Reciprocity. **An Agreement providing for discontinuance of NRC regulatory authority and the assumption of regulatory authority by the State may relate to any one or more of the following categories of materials within the State, as contemplated by Public Law 86-373 and Public Law 95-604:**
- a. **Byproduct materials as defined in Section 11e(1) of the Act,**
 - b. **Byproduct materials as defined in Section 11e(2) of the Act,**
 - c. **Source materials,**
 - d. **Special nuclear materials in quantities not sufficient to form a critical mass,**
 - e. **Low-level wastes in permanent disposal facilities, as defined by statute or Commission rules or regulations containing one or more of the materials stated in a, c, and d above but not including byproduct material as defined in Section 11e(2) of the Act;**

but must relate to the whole of such category or categories and not to a part of any category. If less than the five categories are included in any discontinuance of jurisdiction, discontinuance of NRC regulatory authority and the assumption of regulatory authority by the State of the others may be accomplished subsequently

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by an amendment or by a later agreement.

Arrangements should be made for the reciprocal recognition of State licenses and NRC licenses in connection with out-of-jurisdiction operations by a State or NRC licensee.

The NRC staff review verified that the proposed Agreement provides for the Commission to discontinue, and the State of Ohio to assume, regulatory authority over all five of the above categories. Furthermore, since the criterion was adopted, the Commission has determined that the Agreement States may assume the authority to evaluate the safety of sealed sources and devices to be distributed in interstate commerce as a separate sixth portion of the Agreement, or to allow NRC to retain that authority. Ohio has chosen to assume that authority.

Reference: Proposed Agreement between the State of Ohio and the Nuclear Regulatory Commission, Articles I, II, and III; NRC Staff Requirements Memorandum SECY-95-136, dated June 30, 1995.

The proposed Agreement stipulates the desirability of reciprocal recognition of licenses, and commits the Commission and the State to use their best efforts to accord such reciprocity. Ohio has also adopted 10 CFR Part 150 by reference, including § 150.20 providing for the reciprocal recognition of licenses.

NRC staff concludes that the criterion is satisfied.

References: Proposed Agreement between the State of Ohio and the Nuclear Regulatory Commission, Article VII; and rule 3701-39-21 of the Ohio Administrative Code.

28. **NRC and Department of Energy Contractors. The State should provide exemptions for NRC and DOE contractors which are substantially equivalent to the following exemptions:**

- a. **Prime contractors performing work for the DOE at U.S. Government-owned or controlled sites;**
- b. **Prime contractors performing research in, or development, manufacture, storage, testing, or transportation of, atomic weapons or components thereof;**
- c. **Prime contractors using or operating nuclear reactors or other nuclear**

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devices in a U.S. Government-owned vehicle or vessel; and

- d. **Any other prime contractor or subcontractor of DOE or NRC when the State and the NRC jointly determine (I) that, under the terms of the contract or subcontract, there is adequate assurance that the work thereunder can be accomplished without undue risk to the public health and safety and (ii) that the exemption of such contractor or subcontractor is authorized by law.**

The NRC staff review verified that Ohio has adopted 10 CFR Part 30 by reference, including §30.12 wherein the specified exemptions are contained. Based on this, the NRC staff concludes that the Ohio regulations do provide exemptions from the State's requirements for licensing of sources of radiation for NRC and DOE contractors or subcontractors in accordance with this criterion.

Reference: Ohio Administrative Code, Chapters 3701-38 and 3701-39.

NOTE to USERS: The additional criteria need not be addressed for Agreements that will NOT cover section 11(e).2 byproduct material.

Additional Criteria for States Regulating Uranium or Thorium Processors and Wastes Resulting Therefrom After November 8, 1981

29. **Authority.** State statutes or duly promulgated regulations should be enacted, if not already in place, to make clear State authority to carry out the requirements or Public Law 95-604, Uranium Mill Tailings Radiation Control Act (UMTRCA) as follows:
- a. **Authority to regulate the tailings or wastes produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content.**

The NRC staff review verified that Ohio law authorizes the assumption of regulatory authority over "byproduct material" which is defined to include the tailings or wastes produced by the extraction or concentration of uranium or thorium from any ore processed primarily for its source material content.

Staff notes that no NRC licensee in Ohio currently conducts any activity which produces or uses byproduct material as defined in section 11e.(2) of the Act, nor is there any

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deposit of ore known to the NRC staff which is likely to be extracted for its source material content. Ohio has indicated that the authority to regulate 11e.(2) byproduct material is sought in order to enable the regulation of such material when used in research and development activities, or when it exists as contamination resulting from activities previously conducted at a site in Ohio.

References: Ohio Revised Code, sections 3748.01 and 3748.03.

- b. **That an adequate surety (under terms established by regulation) will be provided by the licensee to assure the completion of all requirements established by the (cite appropriate State agency) for the decontamination, decommissioning, and reclamation of sites, structures, and equipment used in conjunction with the generation or disposal of such byproduct material.**

The NRC staff review verified that Ohio law requires the Public Health Council to adopt rules requiring adequate funding for long-term surveillance and specifying acceptable forms of financial guaranties (sureties).

Reference: Ohio Revised Code, section 3748.04.

- c. **If in the States' licensing and regulation of byproduct material or of any activity which produces byproduct material, the State collects funds from the licensee or its surety for long-term surveillance and maintenance of such material, the total amount of the funds collected by the State shall be transferred to the U.S. if custody of the byproduct material and its disposal site is transferred to the Federal Government upon termination of the State license. (See 10 CFR 150.32.) If no default has occurred and the reclamation or other bonded activity has been performed, funds for the purpose are not to be transferred to the Federal Government. The funds collected by the State shall be sufficient to ensure compliance with the regulations the Commission establishes pursuant to Section 161X of the Atomic Energy Act.**

The NRC staff review verified that Ohio law requires the collection of funds for long-term surveillance, and that Ohio has adopted 10 CFR 150.32 by reference.

References: Ohio Revised Code, section 3748.04; and rule 3701-39-21 of the Ohio Administrative Code.

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- d. **In the issuances of licenses, an opportunity for written comments, public hearing (with transcript) and cross examination is required.**
- e. **In the issuances of licenses, a written determination of the action to be taken based upon evidence presented during the public comment period and which is subject to judicial review is required.**
- f. **A ban on major construction prior to completion of the written environmental analysis stipulated in Criterion 31.**
- g. **An opportunity shall be provided for public participation through written comments, public hearings, and judicial review of rules.**

Ohio asserts that the State's administrative procedures law provides the general authority and process for public notice and public hearings with regard to issuing licenses. The NRC staff notes that the specific requirements in criteria items d. through g. are prescribed in 10 CFR 150.31, *Requirements for Agreement State regulation of byproduct material*. The NRC staff review verified that Ohio has adopted 10 CFR 150.31 by reference.

References: Ohio Revised Code, section 119; and rule 3701-39-21 of the Ohio Administrative Code.

The NRC staff review concluded that it is unlikely that any application for a license to process ore for its source material content will be made in Ohio, but that the legal and regulatory basis exists for the Bureau to evaluate such an application if one were submitted. Staff concludes that Ohio meets the requirements of the criterion.

30. **Supporting Legislation. In the enactment of any supporting legislation, the State should take into account the reservations of authority to the U.S. in UMTRCA as stated in 10 CFR 150.15a and summarized by the following:**

- a. **The establishment of minimum standards governing reclamation, long-term surveillance or maintenance, and ownership of the byproduct material.**
- b. **The determination that prior to the termination of a license, the licensee has complied with decontamination, decommissioning and reclamation standards, and ownership requirements for sites at which byproduct material is present.**

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- c. **The requirement that prior to termination of any license for byproduct material, as defined in Section 11e.(2), of the Atomic Energy Act or for any activity that results in the production of such material, title to such byproduct material and the disposal site be transferred to the Federal Government or State at the option of the State, provided such option is exercised prior to termination of the license.**
- d. **The authority to require such monitoring, maintenance, and emergency measures after the license is terminated as necessary to protect the public health and safety for those materials and property for which the State has assumed custody pursuant to Pub. L. 95-604.**
- e. **The authority to permit use of the surface or subsurface estate, or both of the land transferred to the United States or State pursuant under provision of the Uranium Mill Radiation Tailings Control Act.**
- f. **The authority to exempt land ownership transfer requirements of Section 83(b)(1)(A).**

The NRC staff review verified that, as authorized by law, Ohio has adopted 10 CFR 150.15(a) by reference. NRC staff concludes that this meets the requirements of criterion 30.

References: Ohio Revised Code, section 3748.04; and rule 3701-39-21 of the Ohio Administrative Code.

31. **Environmental Assessment. It is preferable that State statutes contain the provisions of Section 6 of the Model Act, But the following may be accomplished by adoption of either procedures by regulation or technical criteria. In any case, authority for their implementation should be adequately supported by statute, regulation or case law as determined by the State Attorney General.**

In the licensing and regulation of ores processed primarily for their source material content and for the disposal of byproduct material, procedures shall be established which provide a written analysis of the impact on the environment of the licensing

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activity. This analysis shall be available to the public before commencement of hearings and shall include:⁷

- a. An assessment of the radiological and nonradiological public health impacts;
- b. An assessment of any impact on any body of water or groundwater;
- c. Consideration of alternatives to the licensed activities; and
- d. Consideration of long-term impacts of licensed activities (see Item 36b. (1).

The NRC staff review verified that Ohio has adopted 10 CFR 150.31 by reference. The provisions of criterion 31 are contained in subsection 150.31(b)(3). NRC staff concludes that this meets the requirements of criterion 31.

References: Ohio Revised Code, section 3748.04; and rule 3701-39-21 of the Ohio Administrative Code.

32. **Regulations.** State regulations should be reviewed for regulatory requirements, and where necessary incorporate regulatory language which is equivalent to the extent practicable or more stringent than regulations and standards adopted and enforced by the Commission, as required by Section 274o (see 10 CFR 40 and 10 CFR 150.31(b)).

The NRC staff review verified that Ohio has adopted 10 CFR Part 40, and 10 CFR 150.31(b) by reference.

References: Rule 3701-39-21 of the Ohio Administrative Code.

33. **Organizational Relationships Within the States.** Organizational relationships should be established which will provide for an effective regulatory program for uranium mills and mill tailings.

- a. Charts should be developed which show the management organization and lines of authority. This chart should define the specific lines of supervision from program management within the radiation control group and any other

⁷It is strongly recommended that a 30-day period be provided for public review.

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department within the State responsible for contributing to the regulation of uranium processing and disposal of tailings. When other State agencies or regional offices are utilized, the lines of communication and administrative control between the agencies and/or regions and the Program Director should be clearly drawn.

- b. Those States that will utilize personnel from other State Departments or Federal agencies in preparing the environmental assessment should designate a lead agency for supervising and coordinating preparation of this environmental assessment. It is normally expected that the radiation control agency in Agreement States will be the lead agency. The basic premise is that the lead agency is required to prepare the environmental assessment. Utilization of an applicant's environmental report in lieu of a lead agency assessment of the proposed project is not adequate or appropriate. However, the lead agency may prepare an environmental assessment based upon an applicant's environmental report. Other credible information may be utilized by the State as long as such information is verified and documented by the State.
- c. When a lead agency is designated, that agency should coordinate preparation of the statement. The other agencies involved should provide assistance with respect to their areas of jurisdiction and expertise. Factors relevant in obtaining assistance from other agencies include the applicable statutory authority, the time sequence in which the agencies become involved, the magnitude of their involvement, and relative expertise with respect to the project's environmental effects.

In order to bring an environmental assessment to a satisfactory conclusion, it is highly recommended that an initial scoping document be developed which clearly delineates the area and scope of work to be performed by each agency within a given time constraint.

- d. For those areas in the environmental assessment where the State cannot identify a State agency having sufficient expertise to adequately evaluate the proposal or prepare an assessment, the State should have provisions for obtaining outside consulting services. In those instances where non-governmental consultants are utilized, procedures should be established to avoid conflict of interest consistent with State law and administrative procedures.

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Medical consultants recognized for their expertise in emergency medical matters, such as the Oak Ridge and Hanford National Laboratories, relating to the intake or uranium and its diagnosis thereof associated with uranium mining and milling should be identified and available to the State for advice and direct assistance.

During the budget preparation, the State should allow for funding costs incurred by the use of consultants. In addition, consultants should be available for any emergencies which may occur and for which their expertise would be needed immediately.

The NRC staff review determined that the provisions of criterion 33 are not addressed by the Ohio program. As noted above, however, staff knows of no deposit of ore in Ohio which is likely to be extracted for its source material content. Further, Ohio has indicated that the authority to regulate byproduct material as defined in section 11e.(2) of the Act is sought in order to enable the regulation of such material as it may be used in research and development activities, or as it may exist as site contamination. The Act, however, requires the Commission to maintain an orderly pattern of regulation, which the Commission believes to prohibit any Agreement which divides regulatory authority within a category of materials. The Commission can not transfer authority over 11e.(2) material only for the uses identified by Ohio.

Current Commission policy does allow a State to assume and retain regulatory authority over a category of materials for which no license or application for license exists. Further, if the legal and regulatory structure to regulate the materials exists, a State program is compatible even if it does not have the organizational structure to regulate the materials in place, but can establish one if an application is received. The NRC staff concludes that the Ohio program does have the authority to develop the organizational structure and relationships required by criterion 33, should an application for a license to process ore for its source material content be received. On this basis, staff concludes that the Ohio program satisfies the requirements of criterion 33.

34. **Personnel. Personnel needed in the processing of the license application can be identified or grouped according to the following skills: Technical; Administrative; and Support.**
- a. **Administrative personnel are those persons who will provide internal guides, policy memoranda, reviews and managerial services necessary to assure completion of the licensing action. Support personnel are those persons who**

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provide secretarial, clerical support, legal, and laboratory services. Technical personnel are those individuals who have the training and experience in radiation protection necessary to evaluate the engineering and radiological safety aspects of a uranium concentrator. Current indications are that 2 to 2.75 total professional person years' effort is needed to process a new conventional mill license, in situ license, or major renewal, to meet the requirements of UMTRCA. This number includes the effort for the environmental assessment and the in-plant safety review. It also includes the use of consultants. Heap leach applications may take less time and is expected to take 1.0 to 1.5 professional staff years' effort, depending on the circumstances encountered. Current indications are that the person years effort for support and legal services should be one secretary for approximately 2 conventional mills and ½ staff years for legal services for each noncontested mill case. The impact on environmental monitoring laboratory support services is difficult to estimate but should be added into the personnel requirements.

In addition, consideration should be given to various miscellaneous post-licensing ongoing activities including the issuance of minor amendments, inspections, and environmental surveillance. It is estimated that these activities may require about 0.5 to 1 person years effort per licensed facility per year, the latter being the case for a major facility. These figures do not include manpower for Title I activities of UMTRCA.

- b. In evaluating license applications the State shall have access to necessary specialties, e.g., radiological safety, hydrology, geology and dam construction and operation.

In addition to the personnel qualifications listed in the "Guide for Evaluation of State Radiation Control Programs," Revision 3, February 1, 1980, the regulatory staff involved in the regulatory process (Radiation) should have additional training in Uranium Mill Health Physics and Environmental Assessments.

- c. Personnel in agencies other than the lead agency are included in these total person year numbers. If other agencies are counted in these numbers then it shall be demonstrated that these personnel will be available on a routine and continuing basis to a degree claimed as necessary to successfully comply with the requirements of UMTRCA and these criteria. The arrangements for

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making such resources available shall be documented, such as an interagency memorandum of understanding and confirmed by budgetary cost centers.

The NRC staff review determined that the provisions of criterion 34 are not addressed by the Ohio program. However, the discussions in criterion 33 also apply here. On this basis, staff concludes that Ohio program satisfies the requirements of criterion 34.

35. **Functions To Be Covered. The States should develop procedures for licensing, inspection, and preparation of environmental assessments.**

a. Licensing

- (1) Licensing evaluations or assessments should include in-plant radiological safety aspects in occupational or restricted areas and environmental impacts to populations in unrestricted areas from the plant.**
- (2) It is expected that the State will review, evaluate and provide documentation of these evaluations. Items which should be evaluated are:**
 - (a) Proposed activities;**
 - (b) Scope of proposed action;**
 - (c) Specific activities to be conducted;**
 - (d) Administrative procedures;**
 - (e) Facility organization and radiological safety responsibilities, authorities, and personnel qualifications;**
 - (f) Licensee audits and inspections;**
 - (g) Radiation safety training programs for workers;**
 - (h) Radiation safety program, control and monitoring;**
 - (I) Restricted area markings and access control;**
 - (j) At existing mills, review of monitoring data, exposure records, licensee audit and inspection records, and other records applicable to existing mills;**
 - (k) Environmental monitoring;**
 - (l) Emergency procedures, radiological;**
 - (m) Product transportation; and**
 - (n) Site and physical decommissioning procedures, other than tailings.**
 - (o) Employee exposure data and bioassay programs.**

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b. Environmental Assessment

- (1) The environmental evaluation should consist of a detailed and documented evaluation of the following items:**
 - (a) Topography;**
 - (b) Geology;**
 - (c) Hydrology and water quality;**
 - (d) Meteorology;**
 - (e) Background radiation;**
 - (f) Tailings retention system;**
 - (g) Interim stabilization, reclamation, and Site Decommissioning Program;**
 - (h) Radiological Dose Assessment;**
 - (1) Source terms**
 - (2) Exposure pathway**
 - (3) Dose commitment to individuals**
 - (4) Dose commitment to populations**
 - (5) Evaluation of radiological impacts to the public to include a determination of compliance with State and Federal regulations and comparisons with background values**
 - (6) Occupational dose**
 - (7) Radiological impact to biota other than man**
 - (8) Radiological monitoring programs, pre-occupational and operational**
 - (i) Impacts to surface and groundwater, both quality and quantity;**
 - (j) Environmental effects of accidents; and**
 - (k) Evaluation of tailings management alternatives in terms of regulations.**
- (2) The States are encouraged to examine the need to expand the scope of the assessment into other areas such as:**
 - (a) Ecology;**
 - (b) Environmental effects of site preparation and facility construction on environment and biota;**
 - (c) Environmental effects of use and discharge of chemicals and fuels; and**
 - (d) Economic and social effects.**

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c. Inspections

- (1) As a minimum, items which should be inspected or included during the inspection of a uranium mill should adhere to the items evaluated in the in- plant safety review. The principal items recommended for inspection are:**
 - (a) Administration;**
 - (b) Mill circuit, including any additions, deletions, or circuit changes;**
 - (c) Accidents/Incidents;**
 - (d) Part 19 or equivalent requirements of the State;**
 - (e) Action taken on previous findings;**
 - (f) A mill tour to determine compliance with regulations, and license conditions;**
 - (g) Tailings waste management in accordance with regulations and license conditions (see NRC Reg. Guide 3.11.1);**
 - (h) Records;**
 - (I) Respiratory protection in accordance with license conditions or 10 CFR Part 20.**
 - (j) Effluent and environmental monitoring;**
 - (k) Training programs;**
 - (l) Transportation and shipping;**
 - (m) Internal review and audit by management;**
 - (n) Exit interview; and**
 - (o) Final written report documenting the results of the inspection and findings on each item.**
- (2) In addition, the inspector should perform the following:**
 - (a) Independent surveys and sampling.**
- (3) Additional guidance is contained in appropriate NRC regulatory and inspection guides. A complete inspection should be performed at least once per year.**

d. Operational Data Review

- (1) In addition to the reporting requirements required by the regulations or license conditions, the licensee will submit in writing to the regulatory agency within 60 days after January 1 and July 1 of each year, reports specifying the quantity of each of the principal radionuclides released to unrestricted areas in liquid and in gaseous**

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effluents during the previous six months of operation. This data shall be reported in a manner that will permit the regulatory agency to confirm the potential annual radiation doses to the public.

- (2) All data from the radiological and non-radiological environmental monitoring program will also be submitted for the same time periods and frequency. The data will be reported in a manner that will allow the regulatory agency to conform the dose to receptors.

The NRC staff review determined that the provisions of criterion 35 are not addressed by the Ohio program. However, for the reasons discussed in criterion 33, staff concludes that Ohio program satisfies the requirements of criterion 35.

36. Instrumentation. The State should have available both field and laboratory instrumentation sufficient to ensure the licensee's control of materials and to validate the licensee's measurements.

- a. The State will submit its list of instrumentation to the NRC for review. Arrangements should be made for calibrating such equipment.
- b. Laboratory-type instrumentation should be available in a State agency or through a commercial service which has 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.

Analysis and data reduction from laboratory analytical facilities should be available to the licensing and inspection authorities in a timely manner. Normally, the data should be available within 30 days of submittal. State acceptability of quality assurance (QA) programs should also be established for the analytical laboratories.

- c. Arrangements should also be completed so that a large number of samples in a variety of sample media resulting from a major accident can be analyzed in a time frame that will allow timely decisions to be made regarding public health and safety.

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- d. Arrangements should be made to participate in the Environmental Protection Agency quality assurance program for laboratory performance.**

The NRC staff review determined that the provisions of criterion 36 are not addressed by the Ohio program. However, for the reasons discussed in criterion 33, staff concludes that Ohio program satisfies the requirements of criterion 36.

STAFF CONCLUSION

Section 274d of the Atomic Energy Act of 1954, as amended, states that "The Commission shall enter into an agreement under subsection b of this section with any State if:

- (1) The Governor of that State certifies that the State has a program for the control of radiation hazards adequate to protect the public health and safety with respect to the materials within the State covered by the proposed agreement, and that the State desires to assume regulatory responsibility for such materials; and
- (2) The Commission finds that the State program is in accordance with the requirements of subsection o. and in all other respects compatible with the Commission's program for the regulation of such materials, and that the State program is adequate to protect the public health and safety with respect to the materials covered by the proposed amendment."

The NRC staff has reviewed the proposed Agreement, the certification of Ohio Governor Voinovich, and the supporting information provided by the staff of the Bureau of Radiation Protection of the Ohio Department of Health, and concludes that, except as discussed above in criterion 20, Qualifications of Regulatory and Inspection Personnel, the State of Ohio satisfies the criteria in the Commission's policy statement "Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory Authority and Assumption Thereof by States Through Agreement," and therefore meets the requirements of Section 274 of the Act. The proposed Ohio program to regulate agreement materials, as comprised of statutes, regulations, procedures, and apparatus, is compatible with the program of the Commission and is adequate to protect public health and safety with respect to the materials covered by the proposed Agreement.

Negative Consent Commission Paper to Publish Proposed Agreement

NOTE to USERS: Specific comments about the Ohio program are for illustration only. Replace or modify as appropriate.

FOR: The Commissioners

FROM: William D. Travers
Executive Director for Operations

SUBJECT: PROPOSED AGREEMENT BETWEEN THE STATE OF OHIO AND
THE COMMISSION PURSUANT TO SECTION 274 OF THE ATOMIC
ENERGY ACT OF 1954, AS AMENDED

PURPOSE:

To inform the Commission of the staff's schedule for publication of a Federal Register (FR) notice containing the proposed Agreement with Ohio.

SUMMARY:

By letter dated June 22, 1998, Governor George A. Voinovich requested that the Commission enter into an Agreement with the State of Ohio under Section 274b of the Atomic Energy Act of 1954, as amended (Act). As required by Section 274e of the Act, staff proposes to publish the text of the proposed Agreement in the FR. The FR notice will include a summary of the staff's draft assessment of the proposed Ohio regulatory program for materials subject to the Agreement, and identify three specific conditions related to the Ohio program staff that must be met before the Agreement is signed. Comments on the Agreement, the assessment, and the conditions will be requested.

BACKGROUND:

Section 274b of the Act authorizes the Commission to enter into an agreement with the Governor of a State providing for the discontinuance of the regulatory authority of the Commission with

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respect to certain materials. The Commission, in 1981, adopted the revised policy statement entitled, "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 by statements published on July 16, 1981 (46 FR 36969), and on July 21, 1983, (48 FR 33376), referred to hereafter as the "policy statement." Subsequently, staff adopted an internal procedure for applying the policy statement in the processing of a new agreement. The criteria elements and approaches in these documents form the basis for the staff's evaluation of the Ohio request.

DISCUSSION:

In his letter, Governor Voinovich requested that the Commission enter into an Agreement with the State of Ohio pursuant to Section 274b of the Act. Governor Voinovich certified that Ohio has a program for the control of radiation hazards which is adequate to protect public health and safety within the State with respect to the materials covered by the proposed Agreement. The Governor further certified that the State wishes to assume the regulatory responsibility for those materials. Copies of Governor Voinovich's letter, and Chairman Jackson's response, are attached (Attachments 1 and 2). The addition of Ohio will bring the number of Agreement States to 31.

The Governor requested that authority for all six categories of materials transferrable under an Agreement be discontinued by the Commission. The categories of materials are: (1) byproduct materials as defined in Section 11e.(1) of the Act; (2) byproduct materials as defined in Section 11e.(2) of the Act (i.e., uranium and thorium milling activities); (3) source materials; (4) special nuclear materials in quantities not sufficient to form a critical mass; (5) the regulation of the land disposal of 11e.(1) byproduct, source, or special nuclear waste materials received from other persons; and (6) the evaluation of radiation safety information on sealed sources or devices containing 11e.(1) byproduct, source, or special nuclear materials and the registration of the sealed sources or devices for distribution, as provided for in regulations or orders of the Commission.

The text of the proposed Agreement is included in the proposed FR notice in Attachment 3. Originally, an effective date for the Agreement of December 1, 1998, was proposed. This date proved impractical for several reasons. First, Ohio was unable to hire, train, and qualify an adequate staff by that date; and second, further development of the program's procedures and regulatory guidance was needed.

In addition, the processing of the Agreement request was delayed because Ohio adopted, in statute, a definition of the term "decommissioning" which does not permit the termination of a license unless the licensed premises are decontaminated sufficiently to meet the criteria for

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unrestricted release. Staff analyzed the issue and developed the position that the Ohio definition is not inconsistent with the NRC approach to license termination under restricted release conditions, as provided in 10 CFR Part 20, Subpart E. Ohio's approach to decommissioning and the rationale for the staff position was presented to the Commission in SECY-98-209, and accepted in the SRM dated November 20, 1998, as compatible with NRC's approach.

NRC staff notes that Ohio may still not have an adequate program staff when the Agreement is otherwise ready to take effect. In response to NRC staff comments concerning the proposed program staff, Ohio conducted an analysis which determined that a minimum staff of 21, including five supervisors, would be needed to operate the program when the Agreement becomes effective. NRC staff reviewed the Ohio analysis and concurs that the minimum staff would provide a sufficient number of staff to initiate the Ohio Agreement program.

As of December 15, 1998, Ohio had filled 18 positions, including four supervisors, and was actively working to fill the other vacancies. NRC staff is unable to estimate the time required to fill the positions, but notes that Ohio has experienced problems previously in hiring staff. For this reason, NRC staff recommends that Ohio be required to have the minimum staff of 21 positions filled before the Agreement is signed.

The Act requires the proposed Agreement to be published in the Federal Register once a week for four consecutive weeks. NRC staff estimates that 90 to 120 days will be required to complete the formal processing of the Agreement, starting the day it is published for the first time. If publication is delayed until the Ohio staff is filled, the Agreement could be delayed beyond the current objective of having an agreement in effect by March 31, 1999.

To minimize the delay and resource impacts, NRC staff proposes to publish the proposed Agreement without waiting for the Ohio staff positions to be filled. Under this proposal, NRC staff will receive and address public comments, then if appropriate, propose Commission acceptance of the Agreement with the proviso that the Agreement will not be signed until the Ohio program satisfies three conditions as discussed below. This proposal allows the NRC staff and the Commission to satisfy the requirements in the Act for executing the Agreement in parallel with the recruitment, training, and qualification of the Ohio staff. Ohio will be provided 60 to 70 days of additional time to complete staffing without incurring a delay in the effective date of the Agreement.

The Agreement would not be signed until three commitments made by Ohio are met. First, the State will fill the vacant supervisor position and two of the vacant staff positions with qualified individuals. Second, the distribution of individual staff member qualifications will match the expected distribution of categories of licensees to be transferred from NRC. For example, there

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must be enough inspectors qualified to inspect industrial radiography operations that the program is able to inspect the number of industrial radiography licensees transferred from NRC without developing a backlog. Third, each individual staff member will be qualified, in accordance with the Ohio training and qualification plan, to function in the areas of responsibility to which the individual is assigned.

NRC staff recognizes that the Ohio position descriptions for technical staff specify educational requirements consistent with the educational requirements for equivalent NRC staff. Ohio also has a formal plan for the training and qualification of technical staff that provides assurance of staff competence equivalent to the assurance provided by NRC Inspection Manual Chapter 1246. These factors, combined with the three conditions, will assure that the Ohio program has an adequate number of trained and qualified individual staff members. The three conditions will be clearly identified in the FR notice, and public comment invited.

The Commission should also note staff's effort to have the Agreement in effect on March 31, 1999. NRC regulations in 10 CFR 171.17 provide, for those licensees transferred to Ohio jurisdiction, a 50% rebate of the annual license fees without further Commission action, if the Agreement becomes effective before April 1, 1999. The rebate would amount to approximately \$1.05 million. If the effective date of the Agreement is delayed beyond March 31, 1999, special Commission action would be required to provide any rebate of the fees. In addition, a delay beyond March 31, 1998 may also result in an additional \$450,000 in fees being levied on NRC licensees by Ohio, under a law adopted to fund the development of the Agreement program.

Based on experience with the 1997 Massachusetts Agreement, and estimating approximately the same time for processing the Ohio Agreement, staff projects an effective date for the Ohio Agreement after April 1, 1999. For the Massachusetts Agreement, staff obtained Commission consent prior to publishing the proposed Agreement in the Federal Register for public comment. The Commission reviewed the staff's preliminary assessment of the Massachusetts program, then approved the publication by notation vote. To improve timeliness, staff proposes to publish the proposed Agreement for public comment in parallel with the Commission's review of the staff's draft assessment. Staff will include an analysis of the public comments in the final decision paper on the Agreement requesting Commission approval of the Agreement. This approach will also allow the Commission to consider public comments when making a decision on the Agreement.

Along with the parallel review by the Commission and the public, staff will seek to shorten the processing time by assigning the Agreement a high priority, and completing as much of the staff work in parallel as possible.

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The NRC staff believes that the Ohio request for an Agreement, as supplemented with additional information in response to NRC staff comments, with the proviso related to the program staff as discussed above, meets the criteria set forth in §274 of the Act and in the policy statement. This conclusion is based on the NRC staff assessment of the proposed program against the 32 criteria contained in the policy statement (Attachment 4).

SCHEDULE:

The staff plans to forward the notice of the proposed Agreement to the FR five working days after this paper is forwarded to the Commission.

COORDINATION:

This paper has been coordinated with the Office of the General Counsel, which has no legal objection. The Office of the Chief Financial Officer has reviewed this Commission paper, and has no objections.

RECOMMENDATIONS:

That the Commission:

1. Review:

The proposed Agreement between the State of Ohio and the Nuclear Regulatory Commission pursuant to Section 274 of the Act (Attachment 3), and the draft of the NRC staff assessment of the Ohio regulatory program (Attachment 4), in parallel with the publication of the proposed Agreement in the FR.

2. Note:

- a. Staff will place a copy of the full staff assessment (summarized in the FR notice) in the Public Document Room. (Attachment 4)
- b. Governor Voinovich's letter was acknowledged by a letter from the Chairman (Attachment 2).

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- c. The Office of Congressional Affairs will dispatch a letter to the cognizant Congressional Committees informing them that the Commission is considering entering into an Agreement with the State (Attachment 6).
- d. The Office of Public Affairs will issue a press release (Attachment 7).

William D. Travers
Executive Director
for Operations

NOTE to USERS: The handling of attachments for SECY papers has changed since the Ohio Agreement was signed. (SEE memo from James L. Blaha dated November 10, 1999.) This sample document has been modified from the original to reflect the revised directions.

Attachments:

- 1. Letter from Governor Voinovich to Chairman Jackson
- 2. Acknowledgment Letter from Chairman Jackson to Governor Voinovich
- 3. Draft Federal Register Notice, including the Proposed Agreement
- 4. Draft NRC Staff Assessment of the Proposed Ohio Agreement Materials Program

Include as background material:

- a. Draft Letter to Congress
- b. Draft Press Release

Press Release for Publication of Proposed Agreement

**NRC CONSIDERING REQUEST BY OHIO
TO BE AN 'AGREEMENT STATE'**

The Nuclear Regulatory Commission is considering a request from Ohio Governor George V. Voinovich that Ohio assume part of NRC's regulatory authority over certain nuclear materials. If the agreement is accepted, Ohio will become the 31st state to sign such an agreement with NRC.

Under the agreement, NRC would transfer to Ohio the responsibility for licensing, rulemaking, inspection and enforcement concerning the use of (1) radioactive materials produced as byproducts of the operation of nuclear reactors; (2) uranium and thorium source materials; and (3) small quantities of fissionable materials.

The agreement also would allow the state to regulate the land disposal of radioactive waste and to conduct safety evaluations of sealed radioactive sources and devices for medical and industrial use. The agreement would also allow Ohio to regulate the tailings from uranium or thorium milling activities, although there are no uranium or thorium mills in Ohio.

By law, NRC retains jurisdiction over regulation of nuclear reactors and other major nuclear facilities. It also continues to regulate Federal agencies which use nuclear materials and companies which distribute such materials (as in smoke detectors) to members of the public.

If the agreement is approved, about 550 NRC licenses, most of them for medical and industrial uses, would be transferred to the jurisdiction of the State of Ohio.

Before entering into the agreement, NRC must determine that the state'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, along with an assessment of the Ohio proposed regulatory program, is published for public comment in the (date) edition of the Federal Register and also will be published once each week for the next three weeks. Interested persons are invited to comment on the proposed agreement, the Ohio program for radiation control, and the NRC staff's assessment of the Ohio program. In particular, NRC is interested in comments on the plan to "condition" the completion of the agreement to the fulfilment of commitments by Ohio to hire and train program staff members. Comments should be sent to _____, Chief, Rules and Directives Branch, Division of Administrative Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

NUCLEAR REGULATORY COMMISSION

FR Notice of Proposed Agreement

State of Ohio: NRC Staff Assessment of a Proposed Agreement
Between the Nuclear Regulatory Commission and the State of Ohio

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of a proposed Agreement with the State of Ohio.

SUMMARY: By letter dated June 22, 1998, Governor George V. Voinovich of Ohio requested that the U. S. Nuclear Regulatory Commission (NRC) enter into an Agreement with the State as authorized by Section 274 of the Atomic Energy Act of 1954, as amended (Act).

Under the proposed Agreement, the Commission would give up, and Ohio would take over, portions of the Commission's regulatory authority exercised within the State. As required by the Act, NRC is publishing the proposed Agreement for public comment. NRC is also publishing the summary of an assessment by the NRC staff of the Ohio regulatory program. Comments are requested on the proposed Agreement, especially its effect on public health and safety. Comments are also requested on the NRC staff assessment, the adequacy of the Ohio program staff, and the State's program staff, as discussed in this notice.

The proposed Agreement would release (exempt) persons who possess or use certain radioactive materials in Ohio from portions of the Commission's regulatory authority. The Act requires that NRC publish those exemptions. Notice is hereby given that the pertinent exemptions have been previously published in the Federal Register and are codified in the Commission's regulations as 10 CFR Part 150.

DATES: The comment period expires ____ (30 days after date of **FIRST** publication) ____ .
Comments received after this date will be considered if it is practical to do so, but the Commission cannot assure consideration of comments received after the expiration date.

NOTE to USERS: The requirement to publish once a week for four consecutive weeks is unique to Agreements under the Atomic Energy Act. Be prepared to explain the requirement, and the objective of ending the comment period 30 days after the first publication. Be sure to check the FR on the second week to assure the comment end date is not reset.

AD

DRESSES: Written comments may be submitted to Mr. _____, Chief, Rules and

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Directives Branch, Division of Administrative Services, Office of Administration, Washington, DC 20555-0001. Copies of comments received by NRC may be examined at the NRC Public Document Room, 2120 L Street, NW. (Lower Level), Washington, DC. Copies of the proposed Agreement, copies of the request for an Agreement by the Governor of Ohio including all information and documentation submitted in support of the request, and copies of the full text of the NRC staff assessment are also available for public inspection in the NRC's Public Document Room.

FOR FURTHER INFORMATION CONTACT: _____, Office of State and Tribal Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Telephone (301) 415-2____ or e-mail _____@nrc.gov.

NOTE to USERS: Specific comments about the Ohio program are for illustration only. Replace or modify as appropriate. Confirm or update all numbers.

SUPPLEMENTARY INFORMATION: Since Section 274 of the Act was added in 1959, the Commission has entered into Agreements with 31 States. The Agreement States currently regulate approximately 16,000 agreement material licenses, while NRC regulates approximately 5800 licenses. Under the proposed Agreement, approximately 550 NRC licenses will transfer to Ohio. NRC periodically reviews the performance of the Agreement States to assure compliance with the provisions of Section 274.

Section 274e requires that the terms of the proposed Agreement be published in the Federal Register for public comment once each week for four consecutive weeks. This notice is being published in fulfillment of the requirement.

I. Background

(a) Section 274d of the Act provides the mechanism for a State to assume regulatory authority, from the NRC, over certain radioactive materials¹ and activities that involve use of the materials.

¹ The radioactive materials, sometimes referred to as "agreement materials," are: (a) byproduct materials as defined in Section 11e.(1) of the Act; (b) byproduct materials as defined in Section 11e.(2) of the Act; (c) source materials as defined in Section 11z. of the Act; and (d) special nuclear materials as defined in Section 11aa. of the Act, restricted to quantities not sufficient to form a critical mass.

In a letter dated June 22, 1998, Governor Voinovich certified that the State of Ohio has a

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program for the control of radiation hazards that is adequate to protect public health and safety within Ohio for the materials and activities specified in the proposed Agreement, and that the State desires to assume regulatory responsibility for these materials and activities. Included with the letter was the text of the proposed Agreement, which is shown in Appendix A to this notice.

The radioactive materials and activities (which together are usually referred to as the "categories of materials") which the State of Ohio requests authority over are:

(1) the possession and use of byproduct materials as defined in Section 11e.(1) of the Act; (2) the generation, possession, use, and disposal of byproduct materials as defined in Section 11e.(2) of the Act; (3) the possession and use of source materials; (4) the possession and use of special nuclear materials in quantities not sufficient to form a critical mass; (5) the regulation of the land disposal of byproduct materials as defined in Section 11e.(1) of the Act, source, or special nuclear waste materials received from other persons; and (6) the evaluation of radiation safety information on sealed sources or devices containing byproduct materials as defined in Section 11e.(1) of the Act, source, or special nuclear materials and the registration of the sealed sources or devices for distribution, as provided for in regulations or orders of the Commission.

(b) The proposed Agreement contains articles that:

- Specify the materials and activities over which authority is transferred;
- Specify the activities over which the Commission will retain regulatory authority;
- Continue the authority of the Commission to safeguard nuclear materials and restricted data;
- Commit the State of Ohio and NRC to exchange information as necessary to maintain coordinated and compatible programs;
- Provide for the reciprocal recognition of licenses;
- Provide for the suspension or termination of the Agreement;
- Provide for the transfer of any financial surety funds collected by Ohio for reclamation or long-term surveillance of sites for the disposal of byproduct materials (as defined in Section 11e.(2) of the Act) to the United States if custody of the material and the disposal site are transferred; and
- Specify the effective date of the proposed Agreement. The Commission reserves the option to modify the terms of the proposed Agreement in response to comments, to correct errors, and to make editorial changes. The final text of the Agreement, with the effective date, will be published after the Agreement is approved by the Commission, and signed by the Chairman of the Commission and the Governor of Ohio.

(c) Ohio currently regulates the users of naturally-occurring and accelerator-produced radioactive materials. The regulatory program is authorized by law in Section 3748 of the Ohio Revised Code. Subsection 3748.03 provides the authority for the Governor to enter into an Agreement with the Commission. Ohio law contains provisions for the orderly transfer of

FR Notice of Proposed Agreement

regulatory authority over affected licensees from NRC to the State. After the effective date of the Agreement, licenses issued by NRC would continue in effect as Ohio licenses until the licenses expire or are replaced by State issued licenses. NRC licenses transferred to Ohio which contain requirements for decommissioning and express an intent to terminate the license when decommissioning has been completed in accordance with a Commission approved decommissioning plan will continue as Ohio licenses and will be terminated by Ohio when the Commission approved decommissioning plan has been completed.

(d) As described below, the proposed Agreement will be signed only after the fulfillment of commitments by Ohio to hire, train, and qualify a sufficient number of professional/technical staff. Contingent on the fulfillment of these commitments, the NRC staff assessment finds that the Ohio program is adequate to protect public health and safety, and is compatible with the NRC program for the regulation of agreement materials.

NOTE to USERS: After this sample document was published, the staffing needs of the Ohio program changed. The State's commitments and the NRC contingencies became moot. However, since the commitments and contingencies had been published, additional effort was required to explain why they were not being fulfilled. Based on this experience, the publication of conditions or State commitments in the *FR* notice should be **strongly avoided**.

II. Summary of the NRC Staff Assessment of the Ohio Program for the Control of Agreement Materials

NRC staff has examined the Ohio request for an Agreement with respect to the ability of the radiation control program to regulate agreement materials. The examination was based on the Commission's policy statement "Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory Authority and Assumption Thereof by States Through Agreement" (referred to herein as the "NRC criteria") (46 FR 7540; January 23, 1981, as amended).

(a) **Organization and Personnel.** The agreement materials program will be located within the existing Bureau of Radiation Protection (Bureau) of the Ohio Department of Health. The program will be responsible for all regulatory activities related to the proposed Agreement.

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The educational requirements for the Bureau staff members are specified in the Ohio State personnel position descriptions, and meet the NRC criteria with respect to formal education or combined education and experience requirements. All current staff members hold at least bachelor's degrees in physical or life sciences, or have a combination of education and experience at least equivalent to a bachelor's degree. Several staff members hold advanced degrees, and all staff members have had additional training plus working experience in radiation protection. Supervisory level staff have more than ten years working experience each in radiation protection.

The Bureau currently has staff vacancies, which it is actively recruiting to fill. In response to NRC comments, the Bureau performed, and NRC staff reviewed, an analysis of the expected Bureau workload under the proposed Agreement. Based on the analysis, Ohio has made three commitments. First, the Bureau will employ a staff of at least 21 full-time professional/technical employees for the agreement materials program. Second, the distribution of the qualifications of the individual staff members will be balanced to the distribution of categories of licensees transferred from NRC. For example, there will be enough inspectors trained and qualified to inspect industrial radiography operations that the program will be able to inspect all of the industrial radiography licensees transferred from NRC without developing a backlog of overdue inspections. Third, each individual on the staff will be qualified in accordance with the Bureau's training and qualification procedure (including use of interim qualification) to function in the areas of responsibility to which the individual is assigned. In the case of individuals assigned to review radiation safety information on sealed sources or devices containing byproduct materials as defined in Section 11e.(1) of the Act, source, or special nuclear materials, this commitment includes assuring that the individuals will be able to:

- Understand and interpret, if necessary, appropriate prototype tests that ensure the integrity of the products under normal, and likely accidental, conditions of use,
- Understand and interpret test results,
- Read and understand blueprints and drawings,
- Understand how the device works and how safety features operate,
- Understand and apply appropriate regulations,
- Understand the conditions of use,
- Understand external dose rates, source activities, and nuclide chemical form, and
- Understand and utilize basic knowledge of engineering materials and their properties.

(b) Legislation and Regulations. The Ohio Department of Health is designated by law in Chapter 3748 of the Ohio Revised Code to be the radiation control agency. The law provides the Department the authority to issue licenses, issue orders, conduct inspections, and to enforce compliance with regulations, license conditions, and orders. Licensees are required to provide access to inspectors. The Public Health Council is authorized to promulgate regulations.

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The law requires the Public Health Council to adopt rules that are compatible with the equivalent NRC regulations and that are equally stringent to, or to the extent practicable more stringent than, the equivalent NRC regulations. The Council has adopted, by reference, the NRC regulations in Title 10 of the Code of Federal Regulations that were in effect on October 19, 1998. The adoption by reference is contained in Chapter 3701-39-021 of the Ohio Administrative Code (OAC). The Board of Health has extended the effect of the rules, where appropriate, to apply to naturally occurring radioactive materials and to radioactive materials produced in particle accelerators, in addition to agreement materials.

Ohio rule 3701-39-021 (A) specifies that references to the NRC shall be construed as references to the Director of the Department of Health. It is noted, however, that Ohio has adopted most of the NRC regulations as entire Parts, including sections that address regulatory matters reserved to the Commission. Ohio has adopted a provision in Rule 3701-39-021 (A) excepting such sections from being construed as enforced by the Director of the Department of Health. The OAC also contains a provision to avoid interference with licensees when they are complying with regulatory requirements which the Act specifies NRC must enforce and when they are complying with NRC regulatory requirements from which the State licensees have not been exempted by the proposed Agreement. The NRC staff concludes that Ohio will not attempt to enforce the regulatory matters reserved to the Commission. In accordance with NRC Management Directive 5.9, "Adequacy and Compatibility of Agreement State Programs," this approach is considered compatible.

The NRC staff review verified that the Ohio rules contain all of the provisions that are necessary in order to be compatible with the regulations of the NRC on the effective date of the Agreement between the State and the Commission. The adoption of the NRC regulations by reference assures that the standards will be uniform. The Ohio regulations are different from the NRC regulations with respect to the decommissioning of a licensed facility and the termination of the license. Current NRC regulations permit a license to be terminated when the facility has been decommissioned, i.e., cleaned of radioactive contamination, such that the residual radiation will not cause a total effective dose equivalent greater than 25 millirem per year to an average member of the group of individuals reasonably expected to receive the greatest exposure. Normally, the NRC regulations require that the 25 millirem dose constraint be met without imposing any restrictions regarding the future use of the land or buildings of the facility ("unrestricted release"). Under certain circumstances, NRC regulations in 10 CFR Part 20, Subpart E, allow a license to be terminated if the 25 millirem dose constraint is met with restrictions on the future use ("restricted release"). Ohio law does not allow a license to be terminated under restricted release. Ohio will instead issue special "decommissioning-possession only" licenses as an alternative to license termination under restricted release. The Commission has concluded that Ohio's approach, although different, is compatible.

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(c) Storage and Disposal. Ohio has also adopted, by reference, the NRC requirements for the storage of radioactive material, and for the disposal of radioactive material as waste. The waste disposal requirements cover both the disposal of waste generated by the licensee and the disposal of waste generated by and received from other persons.

(d) Transportation of Radioactive Material. Ohio has adopted the NRC regulations in 10 CFR Part 71 by reference. Part 71 contains the requirements licensees must follow when preparing packages containing radioactive material for transport. Part 71 also contains requirements related to the licensing of packaging for use in transporting radioactive materials. Ohio will not attempt to enforce portions of the regulations related to activities, such as approving packaging designs, which are reserved to NRC.

(e) Recordkeeping and Incident Reporting. Ohio has adopted, by reference, the sections of the NRC regulations which specify requirements for licensees to keep records, and to report incidents or accidents involving materials.

(f) Evaluation of License Applications. Ohio has adopted, by reference, the NRC regulations that specify the requirements which a person must meet in order to get a license to possess or use radioactive materials. Ohio has also developed a licensing procedures manual, along with the accompanying regulatory guides, which are adapted from similar NRC documents and contain guidance for the program staff when evaluating license applications.

(g) Inspections and Enforcement. The Ohio radiation control program has adopted a schedule providing for the inspection of licensees as frequently as, or more frequently than, the inspection schedule used by NRC. The program has adopted procedures for the conduct of inspections, the reporting of inspection findings, and the report of inspection results to the licensees. The program has also adopted, by rule in the OAC, procedures for the enforcement of regulatory requirements.

(h) Regulatory Administration. The Ohio Department of Health is bound by requirements specified in State law for rulemaking, issuing licenses, and taking enforcement actions. The program has also adopted administrative procedures to assure fair and impartial treatment of license applicants. Ohio law prescribes standards of ethical conduct for State employees.

(i) Cooperation with Other Agencies. Ohio law deems the holder of an NRC license on the effective date of the proposed Agreement to possess a like license issued by Ohio. The law provides that these former NRC licenses will expire either 90 days after receipt from the radiation control program of a notice of expiration of such license or on the date of expiration specified in the NRC license, whichever is later. In the case of NRC licenses that are terminated under restricted conditions pursuant to 10 CFR 20.1403 prior to the effective date of the proposed

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Agreement, Ohio deems the termination to be final despite any other provisions of State law or rule. For NRC licenses that, on the effective date of the proposed Agreement, contain a license condition indicating intent to terminate the license upon completion of a Commission approved decommissioning plan, the transferred license will be terminated by Ohio in accordance with the plan so long as the licensee conforms to the approved plan.

Ohio also provides for "timely renewal." This provision affords the continuance of licenses for which an application for renewal has been filed more than 30 days prior to the date of expiration of the license. NRC licenses transferred while in timely renewal are included under the continuation provision. The OAC provides exemptions from the State's requirements for licensing of sources of radiation for NRC and U.S. Department of Energy contractors or subcontractors. The proposed Agreement commits Ohio to use its best efforts to cooperate with the NRC and the other Agreement States in the formulation of standards and regulatory programs for the protection against hazards of radiation and to assure that Ohio's program will continue to be compatible with the Commission's program for the regulation of agreement materials. The proposed Agreement stipulates the desirability of reciprocal recognition of licenses, and commits the Commission and Ohio to use their best efforts to accord such reciprocity.

III. Staff Conclusion

Subsection 274d of the Act provides that the Commission shall enter into an agreement under subsection 274b with any State if:

(a) The Governor of the State certifies that the State has a program for the control of radiation hazards adequate to protect public health and safety with respect to the agreement materials within the State, and that the State desires to assume regulatory responsibility for the agreement materials; and

(b) The Commission finds that the State program is in accordance with the requirements of Subsection 274o, and in all other respects compatible with the Commission's program for the regulation of materials, and that the State program is adequate to protect public health and safety with respect to the materials covered by the proposed Agreement.

On the basis of its assessment, the NRC staff concludes that the State of Ohio meets the requirements of the Act, conditioned on completion of the commitments made in regard to the program staff. The State's program, as defined by its statutes, regulations, personnel, licensing, inspection, and administrative procedures, is compatible with the program of the Commission and adequate to protect public health and safety with respect to the materials covered by the proposed Agreement.

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NRC will continue the formal processing of the proposed Agreement, however, the signing of the Agreement will be contingent upon the Bureau's completion of the staffing commitments.

IV. Small Business Regulatory Enforcement Fairness Act

In accordance with the Small Business Regulatory Enforcement Fairness Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of the Office of Management and Budget (OMB).

Dated at Rockville, Maryland, this 5th day of March, 1999.

For the Nuclear Regulatory Commission.

_____, Director
Office of State and Tribal Programs

NOTE to USERS: A proposed Agreement is not an action by the Commission, so the *FR* notice should be signed by the Director, STP. If the notice is signed by the Secretary of the Commission, publication may be delayed (approximately two weeks in the Ohio Agreement).

{Insert the Text of the Proposed Agreement Here}

Congressional Letter Announcing Proposed Agreement

The Honorable ____, Chairman
Subcommittee on ____
Committee on ____
United States Senate
Washington, D. C. 20510

Dear Mr. Chairman:

This is to inform the Subcommittee that by letter dated June 22, 1998, Governor ____ on behalf of the (State) (Commonwealth) of ____ submitted a proposed Agreement between the U.S. Nuclear Regulatory Commission and the (State) (Commonwealth) of ____ under Section 274 of the Atomic Energy Act of 1954, as amended.

An announcement of the proposed Agreement, along with a summary of the NRC staff assessment of the proposed (State or Commonwealth name) program will be published in the Federal Register. A pre-publication copy of the Federal Register Notice is enclosed.

We will inform you when the Commission has completed its consideration of the proposed Agreement.

Sincerely,

Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosure:
As stated

IDENTICAL LETTERS TO:

{Contact OCA to obtain a current list of names}

Federal Agency Letter Announcing Publication of Proposed Agreement

Mr. ____, Assistant Secretary*
Occupational Safety & Health
Administration
U.S. Department of Labor
200 Constitution Avenue
Washington, D.C. 20210

Dear Mr. ____:

Governor ____, on behalf of the (State) (Commonwealth) of ____, has submitted a request that the NRC enter into an Agreement with the (State) (Commonwealth) pursuant to Section 274 of the Atomic Energy Act of 1954, as amended. Under the proposed Agreement, the (State) (Commonwealth) would assume responsibility for regulating byproduct material, source material and special nuclear material in quantities not sufficient to form a critical mass.

Enclosed for your information is the Federal Register notice published on _____ in which NRC staff summarizes its assessment of the (State or Commonwealth name) program for exercising this regulatory authority. The comment period ends _____.

Sincerely,

_____, Director
Office of State and Tribal Programs

Enclosure:
Federal Register Notice

* name from yellow book

Federal Agency Letter Announcing Publication of Proposed Agreement

Identical letters to: {names from yellow book}

Mr.____, Assistant Secretary
Congressional, Public and
Intergovernmental Affairs
U.S. Department of Energy N3641
1000 Independence Ave, S.W.
Washington, D.C. 20585-0001

Ms.____, Assistant Administrator
for Air and Radiation
U.S. Environmental Protection Agency 401
M Street, S.W.
Washington, D.C. 20460

ALL AGREEMENT AND
NON-AGREEMENT STATES

Ms.____, Chairman
Council on Environmental Quality
722 Jackson Place N.W.
Washington, D.C. 20503-0002

Dr.____, Director
Center for Devices & Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850-3229

Commission Paper to Approve Proposed Agreement

FOR: The Commissioners

FROM: William D. Travers
Executive Director for Operations

SUBJECT: SECTION 274b AGREEMENT WITH THE STATE OF OHIO

PURPOSE:

To request Commission approval of the proposed Agreement with Ohio.

SUMMARY:

The Governor of Ohio has requested that the Commission enter into an Agreement under Section 274b of the Atomic Energy Act. The Commission, through SECY-99-039, agreed to publish a notice of the proposed Agreement in the Federal Register (FR). The notice was published as required by the Act and comments accepted. The comment period ended on April 12, 1999.

Based on staff's review of the proposed Ohio program and analysis of the comments, staff recommends that the Commission approve the Agreement (Attachment 1).

BACKGROUND:

In SECY-99-039, staff presented a draft of its assessment of the proposed Ohio Agreement and discussed the statutory and policy background of the Agreement State program. As required by Section 274e of the Atomic Energy Act, the proposed Agreement was published in the Federal Register on March 11, 1999 (64 FR 12187), March 18, 1999 (64 FR 13453), March 25, 1999 (64 FR 14473), and April 1, 1999 (64 FR 15837). The full text of the NRC staff assessment was made available in the Public Document Room, and on the Internet at the NRC external website.

Interested persons were invited to submit comments, with comments specifically requested in four categories: (a) the proposed Agreement, (b) the NRC staff Assessment, (c) the adequacy of the Ohio program staff, and (d) the proposal to condition signing of the Agreement on three commitments by the Bureau of Radiological Health (Bureau) to provide an adequate staff.

Contact: Richard L. Blanton, STP
415-2322

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The Agreement will allow Ohio to assume regulatory authority over byproduct material (both 11e.(1) and 11e.(2)), source material, and special nuclear material (SNM) in quantities not sufficient to form a critical mass. Ohio will also assume authority to conduct the safety evaluation of sealed source and devices manufactured in Ohio and distributed in interstate commerce, and to regulate the disposal of low-level radioactive waste at a land disposal site as described in 10 CFR Part 61.

DISCUSSION:

(1) Public Comments

Twenty-four comment letters were received in response to the FR notice. An unsolicited comment letter received in June 1998 was held and the comments considered along with the comments received in response to the FR notice. Comments were received on each of the four specific categories for which comments were requested.

A number of commentors urged a delay of at least one year before signing the Agreement. The commentors expressed concerns about (1) the qualifications of the program staff in the Bureau, (2) the Bureau's adoption by reference of the NRC regulations, and (3) Ohio's approach to decommissioning.

With respect to the first concern, the commentors noted that the delay would allow the Bureau staff to gain regulatory experience by conducting the existing naturally occurring and accelerator-produced radioactive material (NARM) program. However, the NRC staff assessment concluded that the Bureau staff meets the Commission's criteria without the need for additional experience. Staff does not agree that delaying the Agreement is appropriate.

The Commission should note that the Bureau made three commitments regarding staffing which were published in the FR notice. One of the commitments was to employ at least 21 FTE professional/technical members before the Agreement is signed. This number was based on an analysis by the Bureau of its projected first-year workload including licensees expected to be transferred. The analysis included 0.6 FTE assigned to the decommissioning of the Battelle Memorial Institute Columbus - West Jefferson site, and approximately 13 percent of total staff time available to provide for unforeseen needs.

Since the publication of the FR notice, NRC staff has determined that the Battelle Columbus - West Jefferson license, along with the SNM portion of the Reuter-Stokes license will not be transferred to Ohio. Both licenses authorize SNM in greater than formula quantity. Ohio re-analyzed the projected workload with NRC retaining these two licenses. They concluded that 20

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professional/technical FTE will cover the initial workload, with approximately 11 percent of total staff time available to provide for unforeseen needs. The Bureau continues to actively recruit to fill the 21st position, however, it does not believe that filling the position is critical to the implementation of the Agreement. Staff concurs with this re-analysis.

According to the Ohio staff, the commitments regarding the training and qualification of staff and the distribution of staff qualifications will be completed in accordance with the Bureau procedure by July 16, 1999.

With respect to the second concern, the adoption of NRC regulations by reference is consistent with the Commission policy on the adequacy and compatibility of Agreement State programs. For the third concern, the Commission, in SECY-98-209 approved the NRC staff's position in regard to the Ohio definition of "decommissioning," and the approach that will be used by Ohio to decommissioning and license termination. The staff's analysis of the comments is in Attachment 2.

Staff reviewed the draft assessment of the Ohio program giving full consideration to the comments, and made three changes. The assessment of criterion 20 was changed to reflect the fulfillment of the Bureau's staffing commitments, and the assessment of criterion 25 was expanded to include a description of the Commission's decision on the decommissioning issue. In addition, a minor correction was made to the assessment of criterion 1 to reflect a reorganization which transferred the machine produced and non-ionizing radiation programs to the Bureau. This change does not impact on the Agreement program. The rest of the assessment remains as drafted. The final staff assessment is in Attachment 3.

(2) SECY-98-209

In the November 20, 1998 Staff Requirements Memorandum (SRM), the Commission directed that staff address three requirements in this paper. First, the Commission directed staff to explore the legal need to amend the NRC licenses transferred to Ohio to reflect Commission approved decommissioning plans. The Bureau had requested that licenses with Commission approved decommissioning plans be amended to include a condition indicating the intent of the Commission to terminate the license when the approved plan was completed. Staff determined that Ohio will continue the NRC licenses with the conditions, based on the Ohio legal position that all license conditions on the NRC license remain in effect when transferred under the Agreement, even if they do not otherwise meet Ohio standards. Staff has amended the NRC licenses with approved decommissioning plans that will transfer to Ohio.

Second, the Commission directed the staff to work with Ohio to assure that information in NRC files on the close-out of formerly-licensed sites identified in the Oak Ridge study was made

Commission Paper to Approve Proposed Agreement

available to Ohio. This information, which consisted of a copy of the Region III prepared close-out memorandum for each identified site, was sent to the Bureau.

Third, the Commission expressed particular concern about, and directed the staff to examine, the decommissioning of the Shelwell Services, Incorporated, site. The Shelwell license will not be amended since the staff considers the probabilistic approach described in SECY-98-117 to be the "NRC-approved decommissioning plan." This position eliminated the need for submittal of a formal license termination plan by the licensee. Staff has reviewed this approach with Ohio and the Bureau has indicated that it considers the Commission's approval of SECY-98-117 to be a generic equivalent to a license condition, and intends to follow the course described therein. Staff notes that the licensee's discrete sources and contaminated soil have been disposed of. Staff expects the license will be terminated before the Agreement becomes effective. Staff continues to provide current information on this site to the Bureau.

(3) Transfer of Licenses

Currently, there are approximately 593 NRC materials licenses in Ohio. Staff has identified 574 that will be transferred to the State in whole or in part. NRC will retain 19 licenses, including Federal agencies, exempt distribution, and the two licenses authorizing possession of greater than formula quantities of SNM.

One of these, the Battelle Memorial Institute Columbus - West Jefferson Division, is in decommissioning. Staff expects to retain this Battelle license until decommissioning is complete. The other SNM licensee, Reuter-Stokes, Inc., also authorizes byproduct materials, and the licensed program is active. NRC will retain only the SNM portion of this license.

Approximately 64 licensees based in Ohio are expected to split their licenses, and to hold both NRC and Ohio licenses based on locations of use.

Staff is working with the Bureau staff to effect a smooth transition. Staff has coordinated with the Bureau staff on current or pending licensing, inspection, and enforcement activities involving the licensees to be transferred, to assure the smooth continuation of regulatory actions after the transfer.

(4) Actions Pending Against Licensees to be Transferred

The Office of Enforcement has no current or pending enforcement actions or confirmatory action letters against licensees that will transfer to Ohio under the Agreement. Staff is reviewing a technical assistance request from Region III which may result in an escalated enforcement action

Commission Paper to Approve Proposed Agreement

against a licensee that will transfer. The Office of Investigations (OI) has an open investigation which may result in an escalated enforcement action against a licensee that will transfer.

Another licensee, Advanced Medical Systems, has requested a hearing because staff proposed to deny the renewal of the license. Staff has provided information concerning the proposed effective date of the Agreement to the hearing officer.

(5) Effective Date of the Agreement

The NRC and Bureau staffs have targeted August 31, 1999, as the effective date for the Agreement. To meet this date and provide adequate time for an orderly transfer of license files, and assumption of authority by Ohio on the effective date of the Agreement, the Commission should approve the Agreement by August 16, 1999.

(6) Procedure for Reviewing Proposed Agreements

Staff has considered and is implementing modifications to the review procedure for proposed Agreements to improve efficiency, without reducing the quality of the reviews. For Ohio, staff published the proposed Agreement in the FR in parallel with, rather than subsequent to, the initial Commission consideration of the Agreement. Staff plans to further modify the procedure in future Agreements by using a self directed team approach and performing only one comprehensive review of the application. The single comprehensive review would be preceded by a preliminary team review of the application for completeness to assist the applicant State to assemble the information needed for the comprehensive review. The team members will represent the Offices of State Programs, Nuclear Material Safety and Safeguards, General Counsel, the effected Region, and the Incident Response Operations. The modified procedure is being implemented in draft for the review of the proposed Pennsylvania Agreement.

IMPLEMENTATION

Following the execution of an Agreement, staff continues a program of active interaction with the new Agreement State. This program consists of the exchange of regulatory information, notices of NRC training courses, and periodic on-site reviews of the State's program for the regulation of agreement materials. Communications are generally more frequent with a new Agreement State during the first years after the Agreement is signed. The regulatory information exchanged includes reports of incidents, significant enforcement actions, and amendments to policies, regulations, or guidance.

Commission Paper to Approve Proposed Agreement

An orientation meeting of NRC and Bureau staff will be planned to occur about nine months after the Agreement becomes effective to discuss the initial program implementation. The first Integrated Materials Performance Evaluation Program (IMPEP) review of the Ohio program is planned for about 18 to 24 months after the effective date of the Agreement. Routine Agreement State program IMPEP reviews usually occur at 12 to 48 month intervals, with good performance resulting in the longer intervals between program reviews.

If approved by the Commission, Ohio will bring the number of Agreement States to 31.

COORDINATION:

The Office of the General Counsel has no legal objection to this Commission paper. The Office of the Chief Financial Officer has reviewed this Commission paper for resource implications and has no objections. Staff has obtained concurrence from the Office of Management and Budget (OMB) that this action does not constitute a "major rule" under the Small Business Regulatory Enforcement and Fairness Act of 1996 (SBREFA).

RECOMMENDATION:

That the Commission:

1. Find:

- a. That the proposed Ohio program for the regulation of byproduct material, source material, and SNM in quantities not sufficient to form a critical mass is compatible with the Commission's program for the regulation of like material; and
- b. That the proposed Ohio program is adequate to protect public health and safety within the State with respect to the materials and uses covered by the proposed Agreement.

2. Approve:

- a. The proposed Agreement between the State of Ohio and the Nuclear Regulatory Commission pursuant to Section 274 of the Act, as set forth in Attachment 1.
- b. The proposed Agreement by August 16, 1999, if practicable, to afford adequate time for the signing of the Agreement, the orderly transfer of license files, and the assumption of regulatory authority by Ohio on August 31, 1999.

Commission Paper to Approve Proposed Agreement

3. Note:

- a. The Governor of Ohio desires to sign the Agreement in a formal ceremony (Attachment 4).
- b. Pursuant to the Atomic Energy Act, SBREFA, and Commission guidance, the Speaker of the House of Representatives, the President of the Senate, the Ohio Congressional delegation, and the director of the General Accounting Office will be informed of the Commission's decision (Attachment 5).
- c. The Office of Public Affairs will issue a press release (Attachment 6).
- d. The text of the Agreement will be published in the Federal Register, as required by Section 274e, within 30 days after the Agreement is signed (Attachment 7).

William D. Travers
Executive Director
for Operations

Attachments:

1. Proposed Agreement
2. Analysis of Public Comments
3. NRC Staff Assessment of the Ohio Program
4. Draft Letter to Ohio Governor Taft
5. Draft Federal Register Notice of Agreement Signing

Include as background:

- a. Draft Press Release
- b. Draft Congressional Letters

FR Notice of Signed Agreement

U. S. NUCLEAR REGULATORY COMMISSION

State of Ohio: Discontinuance of Certain Commission Regulatory Authority Within the State.

AGENCY: U. S. Nuclear Regulatory Commission.

ACTION: Notice of Agreement with the State of Ohio.

SUMMARY: On August __, 1999, Greta J. Dicus, Chairman of the U. S. Nuclear Regulatory Commission (NRC) and Governor Bob Taft of the State of Ohio signed an Agreement as authorized by Section 274b of the Atomic Energy Act. The Agreement provides for the Commission to discontinue its regulatory authority over source, byproduct and special nuclear materials (in quantities not sufficient to form a critical mass) in the State of Ohio, and for Ohio to assume the regulatory authority.

Under the Agreement, a person in Ohio possessing these materials is exempt from certain Commission regulations. The exemptions have been previously published in the Federal Register and are codified in the Commission's regulations as 10 CFR Part 150. The Agreement is published here as required by Section 274e of the Act.

FOR FURTHER INFORMATION CONTACT: Richard L. Blanton, Office of State and Tribal Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.
Telephone (301) 415-2322 or e-mail RLB@NRC.GOV.

The draft Agreement was published in the Federal Register for comment once a week for four consecutive weeks (see, e.g. 64 FR 12187, March 11, 1999) as required by the Act. The public comment period ended on April 12, 1999. A total of 25 comment letters were received and were considered by the NRC staff. After considering the comments, the request for an Agreement by the Governor of Ohio, the supporting documentation submitted with the request for an

FR Notice of Signed Agreement

Agreement, and its interactions with the staff of the Ohio Department of Health, Bureau of Radiological Health, the NRC staff completed an assessment of the Ohio program. Based on the staff's assessment, the Commission determined on ____ __, 1999, that the proposed Ohio program for the control of radiation hazards is adequate to protect public health and safety, and that it is compatible with the Commission's program.

Copies of the comment analysis by the NRC staff, the staff assessment, and the Commission's decision may be viewed at the NRC website, <http://www.nrc.gov>.

(The text of the Agreement is contained in Attachment 1. It will be added here when the notice is submitted to the Federal Register.)

Dated at Rockville, Maryland, this ____ day of _____, 1999.

For the U. S. Nuclear Regulatory Commission.

Annette L. Vietti-Cook

Secretary of the Commission

Note to Users: Unlike the earlier *FRN*, this one announces a formal action of the Commission and should be signed by the Secretary of the Commission.

Press Release for Signed Agreement

OPA

D R A F T

(Source: STP Request)

**NRC APPROVES OHIO AGREEMENT TO REGULATE
USE OF CERTAIN RADIOACTIVE MATERIALS**

The Nuclear Regulatory Commission has approved an agreement which allows the state of Ohio to assume part of NRC's regulatory authority over the use of certain radioactive materials. The agreement was published in the Federal Register in March, and will become effective (date).

Under the agreement, NRC will transfer to Ohio the responsibility for licensing, rulemaking, inspection and enforcement concerning the use of (1) radioactive materials produced as byproducts of the operation of nuclear reactors; (2) uranium and thorium source materials; and (3) small quantities of fissionable materials.

The agreement also allows the state to regulate the land disposal of radioactive waste and to conduct safety evaluations of sealed radioactive sources and devices for medical and industrial use.

Press Release for Signed Agreement

Approximately 574 current NRC licenses, most of them for medical and industrial uses, will be transferred to Ohio's jurisdiction. The Ohio Department of Health will administer the regulatory program.

NRC will continue to have regulatory jurisdiction over the Davis-Besse and Perry nuclear power plants near Toledo and Painesville, Ohio, and over the U.S. Enrichment Corporation's uranium enrichment facility near Portsmouth, Ohio.

The NRC has determined that the state'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.

Ohio becomes the 31st State to sign such an agreement with NRC. Other States which have previously assumed this authority are: Alabama, Arizona, Arkansas, California, Colorado, Florida, Georgia, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maryland, Massachusetts, Mississippi, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Maine, Oregon, Rhode Island, South Carolina, Tennessee, Texas, Utah and Washington.

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Congressional Letter for Signed Agreement

The Honorable George V. Voinovich, Chairman
Subcommittee on Clean Air, Wetlands, Private
Property and Nuclear Safety
Committee on Environment and Public Works
United States Senate
Washington, D. C. 20510

Dear Mr. Chairman:

We are pleased to inform the Subcommittee that, pursuant to Section 274 of the Atomic Energy Act of 1954, as amended (Act), entitled "Cooperation With States," the Commission on ____ __, 1999, approved an Agreement with the State of Ohio under which the State will assume certain regulatory authority over byproduct materials as defined in both Section 11e.(1) and Section 11e.(2) of the Act, source materials, and special nuclear materials in quantities not sufficient to form a critical mass. The State will also assume regulatory authority over the land disposal of wastes containing source, byproduct and special nuclear materials by persons other than the licensees which generated the waste.

In his June 22, 1998, request that the Commission enter into an Agreement, then Governor George V. Voinovich certified that Ohio has a program for the control of the radiation hazards associated with the materials covered by the Agreement which is adequate to protect public health and safety. Governor Voinovich further certified that the State desires to assume the regulatory responsibility for such materials.

The proposed Agreement, along with a summary of the NRC staff assessment of the proposed Ohio program, was published in the Federal Register for public comment as required by Section 274e of the Act. Copies of the proposal and supporting documentation were made available for inspection at the Commission's Public Document Room.

Congressional Letter for Signed Agreement

The Commission has determined that the Ohio program for the regulation of agreement materials is compatible with the Commission's equivalent program, and adequate to protect public health and safety with respect to the materials covered by the Agreement. NRC staff will conduct periodic reviews of the Ohio program to ensure that the terms of the Agreement continue to be met.

Sincerely,

Dennis K. Rathbun, Director
Office of Congressional Affairs

cc: Senator Joseph I. Lieberman

IDENTICAL LETTERS TO:

{OCA to provide current list}

The Honorable Joe L. Barton, Chairman
Subcommittee on Energy and Air Quality
Committee on Energy and Commerce
United States House of Representatives
Washington, D. C. 20515

cc: Representative Rick Boucher

Members of the Ohio Congressional Delegation

Senators

Representatives

Letter to Federal Agencies for Signed Agreement

Mr. Charles N. Jeffress, Assistant Secretary
Occupational Safety & Health
Administration
U.S. Department of Labor
200 Constitution Avenue, NW
Washington, DC 20210

Dear Mr. Frodyma:

This is to advise the Department that under Section 274 of the U. S. Atomic Energy Act of 1954, as amended, the Nuclear Regulatory Commission has approved an Agreement with the State of Ohio. This Agreement transfers to the State the Commission's regulatory authority over byproduct material, source material and special nuclear material in quantities not sufficient to form a critical mass. The Agreement became effective August 31, 1999. Enclosed is a copy of the Agreement for your information.

Sincerely,

Paul H. Lohaus, Director
Office of State and Tribal Programs

Enclosure:
As stated

Letter to Federal Agencies Signed Agreement

Identical letters to:

Mr. John C. Angell, Assistant Secretary
for Congressional and Intergovernmental
Affairs
U.S. Department of Energy
Washington, D.C. 20585-0800

Ms. Janet L. Yellen, Chairman
Council on Environmental Quality
Old Executive Office Building
17th Street and Pennsylvania Ave.
Washington, D.C. 20502

Dr. D. Bruce Burlington, Director
Center for Devices & Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850-3229

Ms. Robert W. Perciasepe, Assistant
Administrator for Air and Radiation
U.S. Environmental Protection Agency
401 M Street, SW.
Washington, D.C. 20460

ALL AGREEMENT AND
NON-AGREEMENT STATES

Staff Analysis of Public Comments

STAFF ANALYSIS OF PUBLIC COMMENTS

	<u>Commentors:</u>	<u>Affiliation:</u>
1	Susan Hiatt	Member, Ohio Radiation Advisory Council
2	Ronald Scala	Consultant
3	Ashok Dhar	Mgr., Radiological Affairs - Mallinckrodt, Inc.
4	John Stetz	First Energy Nuclear Operating Company
5	Daniel Swanson	Ohio Radioactive Materials Users Group
6	Ken Lovins	Consultant
7	Richard Sites	Ohio Hospital Association
8	Edward Janzow	Employee - Frontier Technology Corporation
9	Treva Janzow	Employee - Frontier Technology Corporation
10	Dwayne Carl	Employee - Frontier Technology Corporation
11	Toma Caldarea	Employee - Frontier Technology Corporation
12	David Robbins, PhD	Researcher - University of Cincinnati
13	Jerry Lingrel, PhD	Research Professor - University of Cincinnati
14	Victoria Morris, MS	Radiation Safety Officer - U. of Cincinnati
15	Charles Burnham, PhD	Senior Research Associate - U. of Cincinnati
16	Michelle Croyle	Research Associate - University of Cincinnati
17	N. A. Granholm, PhD	Asst. Professor/Researcher - U. of Cincinnati
18	K. J. Kelley, MD	Physician/Researcher - University of Cincinnati
19	Joanne Schneider	Researcher - University of Cincinnati
20	Robert Peterson, Jr.	Radiation Safety Officer - Ohio State University
21	Dave Dillahun	Ohio Chemical Council
	Kelly McGivern	Ohio Chamber of Commerce
	Holly Saelens	Ohio Manufacturers Association
22	Walter Carey, PhD	Chairman, Ohio Radiation Advisory Council
23	Charles Jeffress,	Asst. Secretary - U.S. Dept. of Labor - OSHA
24	Thomas Mohaupt, MS	Radiation Safety Officer - Wright State University
25	Victoria Morris, et. al.	Radiation Safety Officers
	(letter received June 8, 1998 - EDO G980375)	

Staff Analysis of Public Comments

INTRODUCTION:

NRC staff received 25 comment letters in response to a notice that the Governor of Ohio has proposed to enter into an Agreement with the Commission under 274b of the Atomic Energy Act. The notice was published in the Federal Register (FR) on March 11, March 18, March 25, and April 1, 1999. The notice contained a summary of our draft assessment of the proposed Ohio program.

We received letters from the Ohio Radiation Advisory Council and an individual member of the council, two radiation safety consultants, four individuals who are employees of a manufacturing company licensee, two other licensee companies, the radiation safety officers of three universities, eight university researchers, three industry associations or trade groups. A letter from a group of 18 concerned individuals representing academic, industrial, and health facility licensees was received prior to the publication of the FR notice. We considered the comments in this early letter along with the comments we received in response to the FR notice.

In the FR notice, comments were requested in four categories: (1) the proposed Agreement; (2) the NRC staff assessment of the Ohio radiation control program; (3) the adequacy of the Ohio program staff; and (4) the proposal to condition the signing of the Agreement on three commitments by Ohio to provide an adequate staff. Only a few of the comment letters addressed all four categories.

(1) COMMENTS ON THE PROPOSED AGREEMENT

Comments regarding the proposed Agreement have been grouped into six principal areas: (a) Supporting the Agreement; (b) Opposing the Agreement; (c) Requesting Delay of the Agreement; (d) Ohio Rulemaking; (e) Ohio's Approach to Decommissioning; and (f) Other.

(a) Comments Supporting the Agreement

Summary of Comments:

Letters from the Ohio Radiation Advisory Council, an individual member of the council, and the Ohio Hospital Association support prompt approval of the Agreement. The council and the member cite the rulemaking process as offering opportunities for stakeholder involvement, and note that "... the Bureau [of Radiological Health] has made much progress in the areas of staffing, training, rule making, and operational activities." The Hospital Association agrees with the assessment of the Ohio program by the NRC staff.

Staff Analysis of Public Comments

Thirteen commentors support the Agreement, but request that it be delayed. The commentors give two reasons in support of the delay. First, they ask that the Agreement be delayed until the Bureau staff has gained more experience administering Ohio's existing program to regulate naturally occurring and accelerator-produced radioactive material (NARM). A consultant recommends delaying the Agreement for a minimum of one year. He comments: "Having performed consulting services to a number of licensees during this transition period I am concerned that Ohio is not fully prepared to accept the responsibility of being an agreement state." He notes the experience of the NRC program and states: "This is experience that NRC has obtained over many years and experience that [the Bureau] cannot hope to obtain in just one year of licensing and inspecting facilities that utilize NARM." The Ohio Radioactive Materials Users Group comments: "We believe that this [delay] is prudent given the significant new licensing responsibilities that [the Bureau] faces with the transfer of Agreement State authority." A licensee company, the university researchers and university radiation safety officers give similar comments.

Second, commentors note that the Bureau has adopted by reference the NRC regulations, and ask that the Agreement be delayed until the Bureau has adopted "Ohio specific" rules. Several commentors refer to a commitment by the Bureau to its stakeholders to adopt Ohio specific rules to replace the NRC regulations adopted by reference. For example, the Ohio Radioactive Materials Users Group requests that the Agreement be "... deferred until all of the principal rules necessary for implementing Ohio's radiological regulatory program are issued."

Most of the commentors give both staff experience and the lack of Ohio specific rules as reasons for delaying the Agreement.

Four commentors support the Agreement without recommending either promptness or delay. One commentor does not express either support of, or opposition to, the Agreement.

NRC staff response:

The comments encouraging prompt approval of the Agreement support the NRC staff's plan to complete the staff assessment documenting that the Commission's criteria for entering into an Agreement are satisfied, and then to request the Commission to approve the Agreement and place it into effect. These comments are consistent with the Commission's process for approval of an Agreement.

In regard to the comments on the experience of the Bureau staff, we note that the Commission's criteria for entering an Agreement are based on NRC's experience with the Agreement State Program under Section 274b of the Atomic Energy Act, and with the existing Agreement States.

Staff Analysis of Public Comments

These criteria provide guidance for assessing a proposed Agreement State regulatory program in the major areas of legal authority, regulatory standards, staffing, licensing, inspection, and enforcement. If the regulatory program of a proposed Agreement State which meets these criteria is, in the staff's view, prepared for and capable of assuming responsibilities under an Agreement. Experience with a NARM regulatory program is considered only so far as provides an additional demonstration of the State's capabilities.

In addition to our assessment of the written program policies, procedures and plans, we assessed the performance of the Bureau staff participating in NRC sponsored training courses, during joint inspections by NRC and Bureau inspectors, and during joint working sessions of NRC and Bureau license reviewers. Based on the performance of the Bureau staff during these interactions, we are confident that they have the ability to assume and carry out their regulatory responsibilities under the Agreement.

With respect to the request to delay the Agreement until the Bureau adopts a set of "Ohio specific" rules, the Commission policy statement on the Adequacy and Compatibility of Agreement State Programs provides the flexibility for an Agreement State to adopt regulatory requirements in alternate legally enforceable forms, such as laws, orders, or license conditions, if permitted by the laws of the State. Historically, we know that a number of existing Agreement States have adopted, or have considered adopting, individual NRC regulations by reference. The usual rationale for adopting by reference is to reduce the expenditure of State resources while maintaining compatibility with the NRC. In view of this, and since the Bureau is permitted to adopt NRC regulations by reference, we have no reason to delay the Agreement pending the adoption of Ohio specific rules.

(b) Comments Opposing the Agreement

Summary of Comments:

Comment letters from one consultant and from four employees of a manufacturing company licensee express opposition to the Agreement. The consultant commented that the Bureau will not be able to conduct an adequate program because "... they lack the knowledge, ability and qualifications to administer a regulatory program of the scope you propose to hand over."

The four employees of a manufacturing company express concern that the licensee will suffer economic burdens, such as increased costs due to delays in receiving licenses or amendments, and that the licensee will be subject to regulation by both Ohio and NRC. They also express concern that public health and safety will be endangered due to the untimely actions.

Staff Analysis of Public Comments

NRC staff response:

We recognize that the Agreement may have different economic impacts on individual licensees. However, economic impacts are not addressed when reviewing a proposed Agreement. We focus our review on health and safety issues and on assuring that the regulatory program meets the Commission's criteria.

In response to the concern that public health and safety will be endangered by the Agreement, we do not agree. The Commission's criteria for entering an Agreement, and the staff's process for assessing the proposed program, are based on NRC's experience with the Agreement State program and the existing Agreement States. The Commission's criteria provide guidance for assessing a proposed program in the major areas of legal authority, regulatory standards, staffing, licensing, inspection, and enforcement. Our assessment of the Bureau using the criteria concluded that its program will be able to perform adequately.

We also note that NRC has responsibility for a continuing oversight of Agreement States. After an Agreement takes effect, the Atomic Energy Act requires NRC to assure that the State's program remains adequate to protect public health and safety, and compatible with the NRC materials program. We carry out this responsibility through a procedure known as the Integrated Materials Performance Evaluation Program, or IMPEP. A copy of the procedure, NRC Management Directive 5.6, may be viewed on the NRC Office of State and Tribal Programs website at <http://www.hsrdoornl.gov/nrc/procfm.htm>.

We do not agree with the comments that the Agreement should be denied. The Commission has a statutory obligation to enter into the requested Agreement if it finds that the State program is adequate and compatible. Our assessment concluded that the Bureau's program meets the Commission's criteria, and this supports a positive finding of adequacy and compatibility. The comments do not provide a basis for reversing that conclusion.

(c) Comments Requesting Delay of the AgreementSummary of Comments:

Comments from a licensee company, two industrial groups, a consultant, two universities, and four university employees request that the Agreement be delayed. Several of the commentors suggest a delay of at least one year.

As discussed above, the commentors give two reasons in support of the delay. First, they note that the Bureau staff has limited regulatory experience, and ask that the Agreement be delayed

Staff Analysis of Public Comments

until the staff has gained more experience with the NARM program. For example, a consultant comments: "Having performed consulting services to a number of licensees ... I am concerned that Ohio is not fully prepared to accept the responsibility of being an agreement state." He notes the experience of the NRC program and states: "This is experience that NRC has obtained over many years and experience that ODH cannot hope to obtain in just one year of licensing and inspecting facilities that utilize NARM." The Ohio Radioactive Materials Users Group comments that: "We believe that this [delay] is prudent given the significant new licensing responsibilities that ODH faces with the transfer of Agreement State authority." A licensee company, the university researchers and university radiation safety officers give similar comments.

Second, commentors note that the Bureau has adopted the NRC rules by reference, and ask that the Agreement be delayed until the Bureau has adopted it's own rules. Several commentors refer to a commitment by the Bureau to adopt Ohio specific rules to replace the NRC rules adopted by reference. The Ohio Radioactive Materials Users Group recommends that the Agreement be "... deferred until all of the principal rules necessary for implementing Ohio's radiological regulatory program are issued." The University of Cincinnati comments that it "... is not requesting that the NRC deny the state of Ohio agreement state status. However, it is requesting the NRC postpone agreement state status until such time as: ... [t]he BRP demonstrates satisfactory ability to communicate with licensees in a timely fashion regarding draft rules, new/updated rules and other important regulatory issues."

Most of the commentors give both staff experience and the lack of Ohio specific rules as reasons for delaying the Agreement.

NRC staff response:

Although the Bureau staff does not have the extensive experience of NRC or existing Agreement States in the regulation of radioactive materials, we do not agree that the Bureau staff needs to gain more experience in order to perform adequately. As we noted above, the staff believes that a State which meets Commission's criteria for entering an Agreement is capable of carrying out a regulatory program under an Agreement. Also, experience with a NARM regulatory program is considered only so far as provides an additional demonstration of the State's capabilities. Our assessment of the Bureau included observing the performance of the Bureau staff participating in NRC training courses, during joint inspections by NRC and Bureau inspectors, and during joint working sessions of NRC and Bureau license reviewers. Based on the performance of the Bureau staff during these interactions, we are confident that they have the ability to perform adequately.

Also as noted above, the Commission policy statement on the Adequacy and Compatibility of Agreement State Programs provides the flexibility for an Agreement State program to adopt

Staff Analysis of Public Comments

regulatory requirements in alternate legally enforceable forms, if permitted by the laws of the State. Since the Bureau is permitted by Ohio law to adopt NRC regulations by reference, we have no basis to delay the Agreement pending the adoption of Ohio specific rules.

(d) Comments on Ohio RulemakingSummary of Comments:

The member of the radiation advisory council commented that the Ohio rulemaking process offers numerous opportunities for stakeholder involvement. She further commented that these public participation opportunities exceed those offered by the NRC in most of its rulemaking. She concluded by stating that: "The Department's commitment to public involvement is commendable and is one of the advantages to Ohioans of the State becoming an Agreement State." The Radiation Advisory Council commented that it supports the rules that have been developed by the Bureau.

A licensee company suggested that the Ohio rule on decommissioning with continuing licensure should be issued for public comment before promulgating it as an alternative to the NRC rule providing for license termination under restricted release. The commentor also asked how Ohio will adopt the NRC's revision to the medical rules in 10 CFR Part 35.

The University of Cincinnati expressed concern over the slow progress by the Bureau to adopt Ohio specific rules. The commentor noted: "the [Bureau] has found it difficult to get rules drafted and approved expeditiously when their responsibility has been limited to NARM. The University of Cincinnati is concerned that further and longer delays will occur if the scope of responsibility is increased as significantly as it would be with agreement state status." A university researcher commented: "As a researcher I am concerned with the lack of Ohio specific regulations for radioactive material ... that the lack of specific rules ... will negatively impact my research due to instability in regulatory interpretation and over regulation by BRP staff." Another researcher commented: "I hope that the NRC agreement with the State of Ohio could be delayed until such time that the State of Ohio develops a specific program and a set of rules for use of radioactive material" The other researchers made similar comments.

The Ohio State University observed "Once the transfer of Agreement State authority occurs, there will be an instant backlog of licensing work and regulatory demands placed on the Bureau of Radiation Protection, which will dilute their available resources. The Ohio State University strongly advocates the adoption of permanent State of Ohio rules prior to the granting of Agreement State authority."

Staff Analysis of Public Comments

NRC staff response:

We agree that the Ohio laws and procedures encourage public participation in rulemaking and our assessment found that the Ohio rulemaking procedures meet the Commission's criteria. As we discussed above, other Agreement State programs have adopted individual NRC rules by reference. We have no report of this practice creating a problem for licensees.

In regard to the comment that the Ohio decommissioning rule should be issued for public comment, we understand that the rule was adopted in accordance with Ohio administrative procedures. We also understand that this included an opportunity for public comment.

Concerning the comment that rulemaking may be delayed due to resource impacts caused by the Agreement, our assessment of the Bureau's staffing plan includes consideration of the resources needed for rulemaking. We expect the Bureau to adopt the rules it needs for an adequate and compatible radiation control program. These rules should be adopted in a reasonable time period, usually within three years after the effective date of the equivalent NRC rule. We conclude that the necessary resources are available, and the comments do not provide a reason to change that conclusion.

In regard to the comment that there will be an instant backlog of licensing and other regulatory work when the Agreement takes effect, NRC and Ohio staff are working to minimize any backlog. We plan to complete, to the extent possible, the processing of outstanding license and amendment applications before transfer of regulatory responsibility to the Bureau. However, in some cases, we may not have completed work and it may be necessary to stop work at a point that will be convenient to both NRC and the Bureau. In addition, any applications received within about 60 days of the anticipated effective date that do not require immediate processing will be deferred and transferred. We will transfer to the Bureau all of the information we gathered and work we completed up to the stopping point. As a result of these efforts, we expect there will be only a minimal backlog in licensing case work transferred.

We also plan to have completed all regularly scheduled inspections due within 3 months after the Agreement takes effect. Therefore, we do not anticipate transferring any backlog of inspections.

(e) Comments on Ohio's Approach to DecommissioningSummary of Comments:

Letters from two licensee companies expressed concern over the Ohio approach to the decommissioning of licensed facilities, and the State requirements for the termination of the

Staff Analysis of Public Comments

licenses. The comments expressed concern over the compatibility of the Ohio program with the NRC program, and the potential for dual and inconsistent standards for decommissioning being imposed on Ohio licensees by Ohio and NRC. One company commented: "The additional requirements imposed on the transfer or sale of a decommissioned site after decommissioning which requires approval from the Ohio Department of Health is likewise inconsistent, overreaching and represents a potential deterrent to economic development in the State."

NRC staff response:

We considered the concerns expressed in these comments and presented similar questions about the compatibility of the Ohio approach to the Commission (SECY-98-209). Ohio law does not permit the termination of a license unless the site is suitable for release without restriction. For cases in which NRC would permit license termination under restricted conditions, Ohio will issue a special license for possession of the residual contamination in lieu of terminating the license. The license will contain restrictions equivalent to those imposed under subpart E; thus, the only difference is that in Ohio the license will not be terminated. Given this, the Commission determined that the Ohio requirements for decommissioning are compatible with the NRC program.

The Commission also directed us to work with the Bureau staff to assure that licensees are not subjected to dual standards. (Staff Requirements Memorandum (SRM) for SECY-98-209. Both the paper and the SRM are available in the Public Document Room, and on the NRC external website.) The Bureau has stated that it will not impose standards more stringent than the NRC standards on facilities already decommissioned under a terminated NRC license, or on NRC licensees transferred to Ohio that have an NRC approved decommissioning plan.

The Ohio approach to decommissioning is discussed in criterion 25 in the draft staff assessment. In consideration of these comments, we expanded the discussion in the staff assessment to include a description of the Commission's decision on the decommissioning issue.

(f) Other Comments on the Proposed Agreement**Summary of Comments:**

A licensee company commented on the difference in approaches between the Bureau's processing of NARM registration applications and the NRC processing of license applications. The letter expressed concern that the Bureau will adopt its same approach for licensing and administration of the byproduct materials programs. Six examples of the differences were given. This commentor also expressed concern that the transfer of regulatory authority will be disruptive. He

Staff Analysis of Public Comments

suggested that the State learn from the experiences in transferring authority in 1997 when the Commission signed an Agreement with Massachusetts.

Letters from four employees of a manufacturing licensee company expressed concern that the Agreement will impose significantly increased regulatory burdens and costs because the licensee would be subject to regulation by both NRC and the Bureau. They expressed concern that NRC will regulate their use of type A shipping containers and the export of the sources they make, and that the Bureau will conduct the safety evaluation of the sources and regulate the manufacturing of the sources. They are concerned that they will be required to have licenses and be inspected by both agencies, and will have to pay fees to both.

The University of Cincinnati commented that radioactive materials and radiation producing machines, such as medical x-ray machines, will be subject to different safety standards. The commentor also described incidents of poor communication between the licensee and the Bureau. The commentor reported that "the BRP provided the University of Cincinnati with a regulatory guide for development of the University's NARM license. However, in recent letters received from the BRP, it appears the BRP may have abandoned this regulatory guide without informing licensees. In letters from the BRP requesting additional information, the guide is never mentioned. Instead the BRP continually references a NRC draft NUREG (i.e., NUREG-1556 vol. 11)." The university expressed concern that long delays in approving licenses and license amendment requests will occur.

A licensee company commented that "the regulatory reforms currently under progress at the NRC (Risk Informed regulations), should be addressed through this agreement process."

The comments from the radiation advisory council noted that significant improvements have been made by the Bureau in addressing the concerns expressed by the licensees.

NRC staff response:

In regard to the comment on the differences between Ohio and NRC licensing evaluations, we note that Ohio may have used different procedures in the past. However, the Bureau has now adopted a procedure that is similar to the procedure used by NRC. The Bureau also will use licensing guidance adopted from NRC licensing guidance. We expect as a result that any differences between NRC and Ohio in approving similar licenses will be insignificant to health and safety.

We considered each of the six examples of differences in licensing approach provided in the comment letter. Two of the examples involve the Bureau's interaction with other Ohio

Staff Analysis of Public Comments

authorities. Although we have no criteria related to such interactions (they are controlled by State law, policy, or MOUs), we do expect the Bureau to comply with the administrative requirements of the State. Therefore, we concluded that the comments do not provide a basis for changing our assessment.

Three other examples indicate that the Bureau requested information that could be reviewed during inspections as part of a risk-informed, performance-based regulatory approach. We have no compatibility provision for an Agreement State regulatory program to adopt a risk-informed, performance-based approach at this time. The Commission may determine at a later date, based on NRC experience and after consultation with the Agreement States, that risk-informed, performance-based regulation should be a matter of compatibility. In this case, the States will be required to adopt it. Requiring Ohio to adopt such an approach now as part of the Agreement would not be appropriate.

The final example asserts that the Bureau did not issue letters to registrants that had filed timely requests for renewal. The Bureau does not agree with the comment, and states that copies of such letters are kept in the license files. We note that while NRC issues such letters and the Bureau's current procedures call for them to be issued, this is not a matter of adequacy or compatibility.

In regard to the suggestion that the Bureau learn from the experiences of Massachusetts, we understand that the Bureau staff has held discussions with the staff of the Massachusetts program. We also note that the NRC Regional Offices have similarly discussed the experiences in implementing the Massachusetts Agreement. We believe that these discussions meet the intent of the comment, and that they are part of the reasonable efforts being taken to minimize or avoid any disruption of the regulatory process.

In regard to the comment on shipping radioactive materials, it should be noted that NRC does not approve type A shipping containers. We do approve type B containers for the US Department of Transportation (DOT), because Type B containers are used only for the shipment of radioactive materials. Type A containers are DOT specification containers that may be used for shipping a variety of substances, including radioactive materials. Under the Agreement with Ohio, the use of type A shipping containers by the licensee will be inspected by the Bureau. The export of sources from the United States will fall under an NRC general license for which there is no inspection or fee. Thus, the licensee should normally interact only with the Bureau, and we do not agree that this will be a dual regulation.

In response to the comment on different safety standards for materials and electronic radiation producing machines, such as medical x-ray machines, we note that NRC does not have any

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authority to set standards for the use of the machines. The operation of the machines is subject to regulation by the State, in both Agreement and non-Agreement States. Any differences in the safety standards should be addressed with the State authorities.

Regarding the comments on communication, we note that although there is no specific criteria related to the communication between a State program and its licensees, Commission policy does expect the State to be an effective regulator. Good communication between a regulator and its licensees is important for effective regulation. We anticipate that, under the Agreement communication will be enhanced as the program and licensees gain experience working with each other. The comments of the radiation advisory council suggest that this is occurring. Thus, the other comments do not provide a basis for us to change our assessment of the program's adequacy.

(2) COMMENTS ON THE NRC STAFF ASSESSMENT

Summary of Comments:

Three comments directly addressed the assessment of the Ohio program by the NRC staff. All three generally concurred with the assessment. A licensee company said: "We believe that the NRC Staff Assessment as published in both the subject Federal Register Notice and SECY-98-209 represents a thorough and complete review of Ohio's program adequacy and compatibility." The other licensee company noted that the assessment indicates that the Ohio program will not be more restrictive than the NRC program.

The Ohio Hospital Association agreed with the assessment by the NRC staff that "the State of Ohio meets the requirements of the Atomic Energy Act of 1954, as amended, Ohio's program, as defined by its statutes, regulations, personnel, licensing, inspection and administrative procedures, is compatible with the NRC program and adequate to protect the public health and safety."

NRC staff response:

The Atomic Energy Act and the Commission policy on Adequacy and Compatibility allow a State program flexibility in program administration, provided the program is adequate to protect public health and safety and compatible with the NRC program. The NRC staff assessment found that the Ohio program is both adequate and compatible.

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(3) COMMENTS ON THE ADEQUACY OF THE OHIO PROGRAM STAFF**Summary of Comments:**

Ten of the eleven letters that commented on the Bureau staff expressed concern about the educational background, training in health physics and regulatory proceedings, and the regulatory experience of the professional/technical staff members. Commentors observed that Ohio historically had a limited registration program for NARM users. The Ohio Radiation Advisory Council, however, stated that the Bureau had made progress in the area of staffing with 20 positions filled. The Council further said "Significantly, several licensees have been complimentary regarding the knowledge and professionalism of the inspector (s)."

Another commentor said "It is essential that all of the staff (current and new) members are qualified (education and experience) to provide adequate radiation protection and nuclear licensing regulatory services." The other commentors agreed.

A consultant stated "I can assure you that they lack the knowledge, ability and qualifications to administer a regulatory program of the scope you propose to hand over." A university researcher said "As a researcher I am concerned with ... the modest amount of experience the BRP has in overseeing radioactive material programs ... that the ... minimal staff experience will negatively impact my research due to instability in regulatory interpretation and over regulation by BRP staff." Seven other researchers offered similar comments.

Comments from four employees of a licensee company expressed concern that the number of Ohio professional/technical staff members will be insufficient "... to have the extensive knowledge and experience of the NRC staff." They were particularly concerned about the Bureau staff's knowledge of the specialized needs of users of "... unencapsulated transplutonic materials (and other high-specific-activity alpha emitters) in radiologically significant quantities ..." and the Bureau staff's training to evaluate the safety of sealed sources containing those materials. They recommended that "facilities licensed to possess and handle unencapsulated transplutonic materials continue to be licensed and regulated by the NRC to assure an adequate regulator knowledge base." and said "We strongly prefer that sealed source safety evaluation and registration continue to be performed by the NRC because of their greater knowledge and experience base."

Comments by the universities and the university researchers expressed concern that the inexperience of the Bureau staff will result in over-regulation and will impede academic research. The University of Cincinnati noted that "the number of staff is only a small part of the University of Cincinnati's concern with staffing. The primary staffing concern is experience." And "Staff

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number is an issue when the turnover rate at the BRP is considered. The BRP during the last few years has had what is perceived to be a very high turnover rate. Many individuals do not stay long enough to make it through their probation period or to get their names known by NARM users in the state of Ohio.” The comments included examples of interactions with Bureau staff to illustrate the concerns. The University also expressed concern with the lack of experience the Bureau has with licensing and inspection, especially with the variety and number of licensees in the State of Ohio.

The Ohio Radioactive Materials Users Group commented that they are “... concerned that ODH would have its resources so diluted that it would not be able to properly staff the licensing, enforcement, and regulatory program while at the same time supporting the development of final Ohio rules.”

NRC staff response:

Our assessment has considered the level of training, both in regulatory health physics and in regulatory operations, and the past experience of the Bureau staff. As part of our assessment, we asked for an analysis of the workload that the Bureau expects when the Agreement takes effect. We compared the Bureau's estimates to our own experience of the workload for NRC licensees in Ohio. Based on this, our assessment concluded that the Bureau has a sufficient number of staff members assigned to the Agreement program.

Since the completion of the draft assessment, it has been determined that the license issued to the Battelle Memorial Institution for the Columbus - West Jefferson site will not be transferred to Ohio. Under the Atomic Energy Act, the Commission may not transfer a license authorizing special nuclear material in quantities sufficient to form a critical mass. The Commission's regulations in 10 CFR Part 150 provide a quantity formula to implement that restriction. The Battelle site is currently under decommissioning, but the licensee has determined that special nuclear material in greater than formula quantity remains on site. In addition, a portion of the license of Reuter-Stokes authorizing special nuclear materials in greater than formula quantity will be split off and retained by NRC.

Based on these changes, the Bureau has re-analyzed the projected workload. The original analysis concluded that a staff of 21 professional/technical FTE covered the workload with approximately 0.6 FTE assigned to the Battelle decommissioning, and approximately 13 percent of total staff time available to provide for unforeseen resource needs. The re-analysis indicates that with NRC retaining the Battelle license, a reduction to 20 professional/technical FTE is acceptable. NRC staff has reviewed the re-analysis and agrees with it. On this basis, we believe Ohio has met the commitment to have an adequate number of staff members.

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The Bureau has also committed to a procedure for qualifying staff members for the work they are assigned. The procedure is similar to the procedure used to qualify NRC license reviewers and inspectors. Part of the qualification process is an experience requirement. Our assessment considered the Bureau's qualification procedure and concluded that it is adequate.

The Bureau committed to completing the training and at least the interim qualification of staff members before the Agreement is signed. Interim qualification means that the individual is trained and experienced sufficiently to perform adequately at least the inspection or evaluation of one type of license. For example, an inspector could attain interim qualification to inspect only medical private practice licensees. To be fully qualified under the Bureau's qualification plan, the inspector would need to be qualified to inspect all of the types of medical licenses issued by the Bureau. To assure adequacy, the Bureau must have a distribution of full and interim qualified staff that matches the distribution of its licensees. The Bureau schedule is for the qualifications to be completed by July 16, 1999.

In consideration of the concern about a high turnover rate for Bureau staff, we requested additional information from the Bureau. The Bureau reports that in the past the turnover rate was high, however, it has been lower in recent years. The Bureau reports that only one person has left in the past year, an individual with a Ph.D. who left for a higher paying job.

Our assessment concluded that the Bureau staff is capable of adequately carrying out their duties under the Agreement. It further concluded that if the training and qualification procedure is followed, the Bureau will continue to have an adequate staff. The comments do not provide a basis for changing our conclusions.

(4) COMMENTS ON CONDITIONAL SIGNING

Summary of Comments:

Six commentors addressed the proposal to condition the signing of the Agreement on the fulfillment by the Bureau of the commitments to have an adequate program staff. All of the comments were fully supportive. One commentor noted: "It is imperative that the State of Ohio complies with its commitment to hire a sufficient number of qualified individuals to administer and enforce this Agreement Program." A licensee company commented: "We urge the NRC to adhere to the assurances in its Assessment and allow the Agreement to be signed by the NRC and become effective only if Ohio fulfills its commitment[s] ..." A third commentor said: "We trust that if Ohio is unable to meet these commitments on or before the effective date of the Agreement (July 22, 1999), the NRC will not sign the proposed Agreement until such commitments are accomplished by the Ohio Department of Health." The Ohio Radioactive Materials Users Group

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agreed with the NRC staff approach.

Ohio Radiation Advisory Council noted that "When the Bureau of Radiation Protection staffing plan has been completed to the Nuclear Regulatory Commission's satisfaction, the Bureau will be fully prepared to assume responsibility for Atomic Energy Act material regulations."

The only additional suggestions offered were to delay signing the Agreement for a period of at least one year, as discussed previously.

NRC staff response:

As discussed above, our assessment now concludes that the Bureau will have an adequate staff with 20 professional/technical members, rather than 21 as discussed in the FR notice. There are no other changes. The Bureau reports that the qualification and distribution commitments will be complete by July 16, 1999. On this basis, we conclude that the commitments have been fulfilled.

Additional Sample Letters and Documents	ADAMS Accession Number
Oklahoma Governor's Letter of Certification	ML 003676195
NRC Staff Assessment for the Oklahoma Agreement	ML 003711657
Negative Consent Commission Paper to Publish the Proposed Oklahoma Agreement (SECY-00-0101)	ML 003711657
Press Release for Publication of the Proposed Oklahoma Agreement	ML003711070
FR Notice of the Proposed Oklahoma Agreement	ML003711070
Commission Paper to Approve the Oklahoma Agreement (SECY-00-0166)	ML003736485
FR Notice of Signed Oklahoma Agreement	ML003736485
Press Release for Signing of the Oklahoma Agreement	ML003736485
Congressional Letter for Signed Oklahoma Agreement	ML010300260