

The Commissioners

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July 9, 1999

SECY-99-179

FOR: The Commissioners

FROM: William D. Travers /s/
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, OSP
415-2322

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 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 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 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 targetted 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.

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.

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 Congressional Letters
6. Draft Press Release
7. Draft Federal Register Notice of Agreement Signing

**AN AGREEMENT
BETWEEN
THE UNITED STATES NUCLEAR REGULATORY COMMISSION
AND
THE STATE OF OHIO
FOR THE
DISCONTINUANCE OF CERTAIN COMMISSION REGULATORY AUTHORITY
AND RESPONSIBILITY WITHIN THE STATE PURSUANT TO
SECTION 274 OF THE ATOMIC ENERGY ACT OF 1954, AS AMENDED**

Whereas, The United States Nuclear Regulatory Commission (hereinafter referred to as the Commission) is authorized under Section 274 of the Atomic Energy Act of 1954, as amended (hereinafter referred to as the Act), to enter into agreements with the Governor of any State providing for discontinuance of the regulatory authority of the Commission within the State under Chapters 6, 7, and 8, and Section 161 of the Act with respect to byproduct materials as defined in Sections 11e.(1) and (2) of the Act, source materials, and special nuclear materials in quantities not sufficient to form a critical mass; and,

Whereas, The Governor of the State of Ohio is authorized under Chapter 3748. of the Ohio Revised Code to enter into this Agreement with the Commission; and,

Whereas, The Governor of the State of Ohio certified on June 22, 1998, that the State of Ohio (hereinafter referred to as the State) has a program for the control of radiation hazards adequate to protect the health and safety of the public and to protect the environment with respect to the materials within the State covered by this Agreement, and that the State desires to assume regulatory responsibility for such materials; and,

Whereas, The Commission found on (date to be determined) that the program of the State for the regulation of the materials covered by this Agreement is compatible with the Commission's program for the regulation of such materials and is adequate to protect public health and safety; and,

Whereas, The State and the Commission recognize the desirability and importance of cooperation between the Commission and the State in the formulation of standards for protection against hazards of radiation and in assuring that State and Commission programs for protection against hazards of radiation will be coordinated and compatible; and,

Whereas, The Commission and the State recognize the desirability of reciprocal recognition of licenses, and of the granting of limited exemptions from licensing of those materials subject to this Agreement; and,

Whereas, This Agreement is entered into pursuant to the provisions of the Atomic Energy Act of 1954, as amended;

Now Therefore, It is hereby agreed between the Commission and the Governor of the State of Ohio, acting in behalf of the State, as follows:

Article I

Subject to the exceptions provided in Articles II, IV, and V, the Commission shall discontinue, as of the effective date of this Agreement, the regulatory authority of the Commission in the State under Chapters 6, 7, and 8, and Section 161 of the Act with respect to the following materials:

- 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. The regulation of the land disposal of byproduct, source, or special nuclear waste materials 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 regulations or orders of the Commission.

Article II

- A. This Agreement does not provide for discontinuance of any authority and the Commission shall retain authority and responsibility with respect to:
 - 1. The regulation of the construction and operation of any production or utilization facility or any uranium enrichment facility;
 - 2. The regulation of the export from or import into the United States of byproduct, source, or special nuclear material, or of any production or utilization facility;
 - 3. The regulation of the disposal into the ocean or sea of byproduct, source, or special nuclear waste materials as defined in the regulations or orders of the Commission;
 - 4. The regulation of the disposal of such other byproduct, source, or special nuclear material as the Commission from time to time determines by regulation or order should, because of the hazards or potential hazards thereof, not be so disposed without a license from the Commission.
 - B. Notwithstanding this Agreement, the Commission retains the following authorities pertaining to byproduct material as defined in Section 11e.(2) of the Atomic Energy Act:
 - 1. Prior to the termination of a State license for such byproduct material, or for any activity that results in the production of such material, the Commission shall have made a determination that all applicable standards and requirements pertaining to such material have been met.
 - 2. The Commission reserves the authority to establish minimum standards governing reclamation, long-term surveillance or maintenance, and ownership of such byproduct material and of land used as a disposal site for such material.
- Such reserved authority includes:
- a. The authority to establish terms and conditions as the Commission determines necessary to assure that, prior to termination of any license for such byproduct material, or for any activity that results in the production of such material, the licensee shall comply with decontamination, decommissioning, and reclamation standards prescribed by the Commission; and with ownership requirements for such materials and its disposal site;
 - b. The authority to require that prior to termination of any license for such byproduct material or for any activity that results in the production of such material, title to such byproduct material and its disposal site be transferred to the United States or the State at the option of the State (provided such option is exercised prior to termination of the license);

- c. The authority to permit use of the surface or subsurface estates, or both, of the land transferred to the United States or a State pursuant to paragraph 2.b. in this section in a manner consistent with the provisions of the Uranium Mill Tailings Radiation Control Act of 1978, provided that the Commission determines that such use would not endanger public health, safety, welfare, or the environment;
- d. The authority to require, in the case of a license, if any, for any activity that produces such byproduct material (which license was in effect on November 8, 1981), transfer of land and material pursuant to paragraph 2.b. in this section taking into consideration the status of such material and land and interests therein, and the ability of the licensee to transfer title and custody thereof to the United States or the State;
- e. The authority to require the Secretary of the Department of Energy, other Federal agency, or State, whichever has custody of such byproduct material and its disposal site, to undertake such monitoring, maintenance, and emergency measures as are necessary to protect public health and safety, and other actions as the Commission deems necessary; and
- f. The authority to enter into arrangements as may be appropriate to assure Federal long-term surveillance or maintenance of such byproduct material and its disposal site on land held in trust by the United States for any Indian Tribe or land owned by an Indian Tribe and subject to a restriction against alienation imposed by the United States.

Article III

Notwithstanding this Agreement, the Commission may from time to time by rule, regulation, or order, require that the manufacturer, processor, or producer of any equipment, device, commodity, or other product containing source, byproduct, or special nuclear material shall not transfer possession or control of such product except pursuant to a license or an exemption from licensing issued by the Commission.

Article IV

This Agreement shall not affect the authority of the Commission under Subsection 161b or 161i of the Act to issue rules, regulations, or orders to protect the common defense and security, to protect restricted data or to guard against the loss or diversion of special nuclear material.

Article V

The Commission will cooperate with the State and other Agreement States in the formulation of standards and regulatory programs of the State and the Commission for protection against hazards of radiation and to assure that State and Commission programs for protection against hazards of radiation will be coordinated and compatible. The State agrees to cooperate with the Commission and other Agreement States in the formulation of standards and regulatory programs of the State and the Commission for protection against hazards of radiation and to assure that the State's program will continue to be compatible with the program of the Commission for the regulation of materials covered by this Agreement.

The State and the Commission agree to keep each other informed of proposed changes in their respective rules and regulations, and to provide each other the opportunity for early and substantive contribution to the proposed changes.

The State and the Commission agree to keep each other informed of events, accidents, and licensee performance that may have generic implication or otherwise be of regulatory interest.

Article VI

The Commission and the State agree that it is desirable to provide reciprocal recognition of licenses for the materials listed in Article I licensed by the other party or by any other Agreement State. Accordingly, the Commission and the State agree to develop appropriate rules, regulations, and procedures by which such reciprocity will be accorded.

Article VII

The Commission, upon its own initiative after reasonable notice and opportunity for hearing to the State, or upon request of the Governor of the State, may terminate or suspend all or part of this Agreement and reassert the licensing and regulatory authority vested in it under the Act if the Commission finds that (1) such termination or suspension is required to protect public health and safety, or (2) the State has not complied with one or more of the requirements of Section 274 of the Act. The Commission may also, pursuant to Section 274j of the Act, temporarily suspend all or part of this Agreement if, in the judgement of the Commission, an emergency situation exists requiring immediate action to protect public health and safety and the State has failed to take necessary steps. The Commission shall periodically review actions taken by the State under this Agreement to ensure compliance with Section 274 of the Act which requires a State program to be adequate to protect public health and safety with respect to the materials covered by this Agreement and to be compatible with the Commission's program.

Article VIII

In the licensing and regulation of byproduct material as defined in Section 11e.(2) of the Act, or of any activity which results in production of such material, the State shall comply with the provisions of Section 274o of the Act. If in such licensing and regulation, the State requires financial surety arrangements for reclamation or long-term surveillance and maintenance of such material,

- A. The total amount of funds the State collects for such purposes shall be transferred to the United States if custody of such material and its disposal site is transferred to the United States upon termination of the State license for such material or any activity which results in the production of such material. Such funds include, but are not limited to, sums collected for long-term surveillance or maintenance. Such funds do not, however, include monies held as surety where no default has occurred and the reclamation or other bonded activity has been performed; and
- B. Such surety or other financial requirements must be sufficient to ensure compliance with those standards established by the Commission pertaining to bonds, sureties, and financial arrangements to ensure adequate reclamation and long-term management of such byproduct material and its disposal site.

Article IX

This Agreement shall become effective on August 31, 1999, and shall remain in effect unless and until such time as it is terminated pursuant to Article VIII.

Done at Columbus, Ohio this (date to be determined).

FOR THE UNITED STATES NUCLEAR REGULATORY COMMISSION

_____, Chairman

FOR THE STATE OF OHIO

_____, Governor

STAFF ANALYSIS OF PUBLIC COMMENTS ON THE PROPOSED OHIO AGREEMENT

	<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	FirstEnergy 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 Dillahunt	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)

Revised 6/14/99

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.

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. 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.

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 Programs website at <http://www.hsr.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 Agreement

Summary 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 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 its 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 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 Rulemaking

Summary 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 its rulemakings. 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."

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 Decommissioning

Summary 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 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 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 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 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.

(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 commentator 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 commentators 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 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.

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 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.

ASSESSMENT

of the proposed

OHIO PROGRAM FOR THE REGULATION OF AGREEMENT MATERIALS¹

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")² using an internal procedure developed by the Office of State 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.**

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.

¹Agreement 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.

²NRC 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).

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 rules³ 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, 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.

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

³Ohio 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.

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.**

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.

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. 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 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 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.

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.

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.**

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.

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 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.

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.

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.

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.

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 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.**

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:**

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

(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;**
 - 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 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.**

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 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 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.

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 of 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 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.

- 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.**
- 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 activity. This analysis shall be available to the public before commencement of hearings and shall include:⁴

- a. **An assessment of the radiological and nonradiological public health impacts;**

⁴It is strongly recommended that a 30-day period be provided for public review.

- 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 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.**

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 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 specialities, 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 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.

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.

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 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.**
- 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.

The Honorable Bob Taft, II
Governor of Ohio
Columbus, Ohio 43215

Dear Governor Taft:

I am pleased to inform you that the U. S. Nuclear Regulatory Commission has approved your proposed Agreement under which the NRC will discontinue and the State of Ohio will assume regulatory authority over the acquisition, possession, use, transfer, and disposal of byproduct material, source material, and special nuclear material in quantities not sufficient to form a critical mass.

(Details of the arrangements for the signature ceremony to be added here when completed)

We are pleased with your continued interest in participating in the Agreement State Program and look forward to the continued excellent relationship we have enjoyed with the State of Ohio in the past.

Sincerely,

Greta J. Dicus

The Honorable James M. Inhofe, 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.

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 Bob Graham

IDENTICAL LETTERS TO:

The Honorable Joe Barton, Chairman
Subcommittee on Energy and Power
Committee on Commerce
United States House of Representatives

The Commissioners

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Washington, D. C. 20515

cc: Representative Ralph M. Hall

Ohio Congressional Delegation

Senators

The Honorable Mike DeWine

The Honorable George V. Voinovich

Representatives

The Honorable Steve Chabot

The Honorable Rob Portman

The Honorable Tony P. Hall

The Honorable Michael G. Oxley

The Honorable Paul E. Gillmor

The Honorable Ted Strickland

The Honorable David L. Hobson

The Honorable John A. Boehner

The Honorable Marcy Kaptur

The Honorable Dennis J. Kucinich

The Honorable Stephanie Tubbs Jones

The Honorable John R. Kasich

The Honorable Sherrod Brown

The Honorable Thomas C. Sawyer

The Honorable Deborah Pryce

The Honorable Ralph Regula

The Honorable James A. Traficant, Jr.

The Honorable Robert W. Ney

The Honorable Steven C. LaTourette

OPA

D R A F T

(Source: OSP 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.

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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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 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 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