

July 9, 1999

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.

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
- (2) SECY-98-209
- (3) Transfer of Licenses
- (4) Actions Pending Against Licensees to be Transferred
- (5) Effective Date of the Agreement
- (6) Procedure for Reviewing Proposed Agreements

(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:

1. 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
2. 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:

1. 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](#).
2. 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:

1. The Governor of Ohio desires to sign the Agreement in a formal ceremony ([Attachment 4](#)).
2. 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](#)).
3. The Office of Public Affairs will issue a press release ([Attachment 6](#)).
4. 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](#)).

Contact: Richard L. Blanton, OSP
415-2322

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

ATTACHMENT 1

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

STAFF ANALYSIS OF PUBLIC COMMENTS ON THE PROPOSED OHIO AGREEMENT

Commentors:	Affiliation:
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 Kelly McGivern Holly Saelens	Ohio Chemical Council Ohio Chamber of Commerce 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. (letter received June 8, 1998 - EDO G980375)	Radiation Safety Officers

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
 - (a) Comments Supporting the Agreement
 - (b) Comments Opposing the Agreement
 - (c) Comments Requesting Delay of the Agreement
 - (e) Comments on Ohio's Approach to Decommissioning
 - (f) Other Comments on the Proposed Agreement
- (2) COMMENTS ON THE NRC STAFF ASSESSMENT
- (3) COMMENTS ON THE ADEQUACY OF THE OHIO PROGRAM STAFF
- (4) COMMENTS ON CONDITIONAL SIGNING

(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://nrc-stp.ornl.gov/procedures.html#directives>.

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

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

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

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

ATTACHMENT 4

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

ATTACHMENT 5

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
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

ATTACHMENT 6

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.

###

ATTACHMENT 7

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 Richard.Blanton@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