Appendix C
Sample Letters and Documents

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Processing Schedule for New Agreements

Note: This schedule requires adherence by both parties to properly work. If either party does not, it is unlikely the 53 week Agreement date will be met. If the either party doesn't meet the listed goals, the overall timeline will be adjusted accordingly.

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

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

[2]presumes two week office concurrence

[3]presumes no unresolved issues

Letter of Intent

COMMONWEALTH of VIRGINIA

Office of the Governor

Mark R. Warner
Governor

December 14, 2005

Nils J. Diaz, Ph.D., Chairman
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Re: Letter of intent to Enter into an Agreement with the U.S. Nuclear Regulatory Commission

Dear Dr. Diaz:

Virginia is fortunate to have a strong industrial sector, a vibrant academic community and an impressive healthcare system, all of which use radioactive materials. This usage has resulted in a significant presence of the U.S. Nuclear Regulatory Commission in the Commonwealth.

While such usage benefits all of us, radiation safety has always been a prime concern. Accordingly, I feel the Commonwealth should assume a more prominent role in the protection of its citizens from unnecessary radiation. Toward that end, it is our intent to pursue an agreement with the U.S. Nuclear Regulatory Commission for transfer of authority for the control of radioactive materials to the Commonwealth of Virginia pursuant to Section 274b of the Atomic Energy Act of 1954, as amended.

To facilitate our participation into the Agreement State Program, I am hereby directing Khizar Wasti, Ph.D., Director, Division of Health Hazards Controls, Virginia Department of Health, to coordinate the process with your staff. Dr. Wasti can be contacted by telephone at (804) 864-8182, or by email at khizar.wasti@vdh.virginia.gov. All of us look forward to a continuing, cooperative effort to enhance radiation safety within the Commonwealth of Virginia.

Sincerely,

Mark R. Warner

Mark R. Warner

State Capitol • Richmond, Virginia 23219 • (804) 786-2211 • TTY (804) 371-8015 • www.governor.virginia.gov

Chairman's Acknowledgment of Letter of Intent

January 31, 2006
The Honorable Timothy M. Kaine
Governor of Virginia
Richmond, Virginia 23219

Dear Governor Kaine:

I am responding on behalf of the U.S. Nuclear Regulatory Commission (NRC) to former Governor Mark Warner's letter of December 14, 2005, requesting that the NRC and the Commonwealth of Virginia establish an agreement pursuant to Section 274b of the Atomic Energy Act of 1954, as amended (AEA). Under the proposal, Virginia would assume regulatory authority over the acquisition, possession, use, transfer, and disposal of byproduct material as defined in Section 11e.(1) of the AEA, source material, and special nuclear material in quantities not sufficient to form a critical mass.

An initial discussion on the interest of Virginia becoming an Agreement State was held on January 10, 2006, between Janet Schlueter, Director of NRC's Office of State and Tribal Programs, and Dr. Khizar Wasti, Director of the Division of Health Hazards Controls in Virginia's Department of Health. Under separate cover letter, the NRC staff will provide Dr. Wasti background information on the Agreement State Program, the criteria and process to become an Agreement State, and reference material. In addition, the NRC would welcome the opportunity to provide a briefing on the Agreement State Program to Dr. Wasti and appropriate staff.

Ms. Shawn Rochelle Smith, Office of State and Tribal Programs, has been assigned as the NRC Project Manager for assisting Virginia in the process of becoming an Agreement State. If you or your staff have any questions or wish to obtain additional information about the Agreement State Program, please contact Ms. Schlueter (301-415-3340 or jrs1@nrc.gov) or Ms. Smith (301-415-2620 or srs3@nrc.gov).

I thank you for your letter of intent to become an Agreement State and look forward to continuing an excellent working relationship with the Commonwealth of Virginia.

Sincerely,

/RA/

Nils J. Diaz

Governor's Letter of Certification

5458

STATE OF MINNESOTA
Office of Governor Tim Pawlenty
130 State Capitol ♦ 75 Rev. Dr. Martin Luther King Jr. Boulevard ♦ Saint Paul, MN 55155

July 6, 2004

Nils J. Diaz, Chairman
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Chairman Diaz:

I am writing to formally request that an agreement be established between the United States Nuclear Regulatory Commission and the State of Minnesota as authorized under Section 274b of the Atomic Energy Act of 1954, as amended, and the Minnesota Statutes Section 144.1202. Under this agreement the US Nuclear Regulatory Commission will discontinue certain regulatory authority for radioactive materials now under federal jurisdiction and that authority will be assumed by the State of Minnesota. As provided by Minnesota Statutes Section 144.1202, subd. 2, the Department of Health is the agency responsible for the implementation of the agreement. The specific authority requested is for the following:

A. Any radioactive material (except special nuclear material) yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material (i.e., byproduct materials as defined in Section 11e(1) of the Atomic Energy Act of 1954, as amended)
B. Source materials
C. Special nuclear materials in quantities not sufficient to form a critical mass

I certify that the State of Minnesota wants to assume regulatory authority and oversight responsibility for such materials, and that the State of Minnesota has an adequate program for the control of radiation hazards covered by this proposed agreement. Enclosed are volumes 1 through 4 of the formal application, which contain a copy of the radioactive materials rules and describe Minnesota's radiation control program as well as its regulatory capabilities.

Your expeditious consideration of this proposed agreement is most appreciated.

Sincerely,

Tim Pawlenty
Governor

Voice: (651) 296-3391 or (800) 657-3717 Fax: (651) 296-2089 TDD: (651) 296-0075 or (800) 657-3598
Web site: http://www.governor.state.mn.us An Equal Opportunity Employer
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Completeness Letter

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

Dear _____:

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

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

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

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

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

Sincerely,

Director
Office of Federal and State Materials and
Environmental Programs

Enclosures:
As stated

Chairman's Letter Replying to the Request for an Agreement

The Honorable_____
Governor of_____
(City), (State) (Zip code)

Dear Governor _____:

I have received your letter with enclosures, dated _____, in which you request an agreement between the Nuclear Regulatory Commission (NRC) and the (State) (Commonwealth) of _____ pursuant to section 274b of the Atomic Energy Act of 1954, as amended (AEA). In your request, (State) would assume regulatory authority over the acquisition, possession, use, transfer, and disposal of source material, byproduct material as defined in section 11e.(1) of the AEA, byproduct material as defined in Section 11e.(2) of the AEA, i.e., tailings from uranium or thorium milling, and special nuclear material in quantities not sufficient to form a critical mass, any discrete source of radium-226 that is produced, extracted, or converted after extraction, for use for a commercial, medical, or research activity; or any material that has been made radioactive by use of a particle accelerator; and is produced, extracted, or converted after extraction, for use for a commercial, medical, or research activity as defined in Section 11e.(3) of the EPAct, any discrete source of naturally occurring radioactive material, other than source material, that would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and is extracted or converted after extraction for use in a commercial, medical, or research activity as defined in Section 11e.(4) of the EPAct. The regulatory authority to be assumed would also include conducting safety-related evaluations of sealed sources and devices.

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

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

Sincerely,

Chairman

NRC Staff Assessment

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

ASSESSMENT OF THE PROPOSED
MINNESOTA PROGRAM FOR THE REGULATION OF AGREEMENT MATERIALS
AS DESCRIBED IN THE REQUEST FOR AN AGREEMENT

This Assessment examines the proposed Minnesota Program 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.[4] This Assessment was performed using the criteria in the Commission's policy statement "Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory Authority and Assumption Thereof by States Through Agreement" (referred to below as the "criteria")[5] using an internal procedure developed by the Office of State and Tribal Programs (STP). Each criterion, and the staff 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 Minnesota Program for regulating agreement materials would be located within the existing Radiation Control Unit (RCU) of the Section of Asbestos, Indoor Air, Lead, and Radiation, in the Division of Environmental Health, an organizational unit of the Minnesota Department of Health (MDH). MDH's current radioactive materials program has responsibility for registration, inspection, emergency response, and fee collection for naturally-occurring or accelerator-produced radioactive materials (NARM). The RCU also has responsibility for the regulation of electronic product radiation and non-ionizing radiation at academic, medical, and industrial facilities. The RCU also conducts environmental sampling statewide and near the two Minnesota nuclear power plants. Under the proposed Agreement, the RCU would assume responsibility for licensing and inspecting byproduct, source, and small quantities of special nuclear material.

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[4]According to paragraph (a) of § 274, the radioactive materials subject to the Act are byproduct, source and special nuclear materials.

[5]NRC 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).

An Intra-Agency Agreement between the RCU and the Public Health Laboratory within the MDH has been established to provide laboratory analysis of radioactive material samples. In addition, an Interagency Agreement between the MDH and the University of Minnesota, Department of Environmental Health and Safety, ensures that the RCU has radiological waste disposal support.

The authority to issue, amend, suspend, or revoke licenses, place conditions and to issue orders or assess administrative fines is vested by Statute in the Commissioner of the MDH.

The NRC staff review verified that the Minnesota 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.

Although there are other Minnesota agencies, besides the MDH, that have been historically delegated by the State certain authority to regulate activities involving radioactive materials, those other agencies are not given any authority under the Agreement. The staff has determined that activities by these other agencies will not impact the Agreement.

The staff concludes that this criterion is satisfied.

References: Letter dated July 6, 2004, from Governor Pawlenty to Chairman Diaz, request for an Agreement, Section 4.1.1, Statutory Authority and Section 4.1.2, Program Organization, and additional related correspondence between the NRC and the State (ADAMS: ML041960496, ML041960499, ML052440344, ML050130375, ML050140452, ML051330043, ML051740384, ML051650073, ML052200424), and the Section 4.1.1 reference to Internet site: http://www.revisor.leg.state.mn.us/stats. At this Internet site see the following Mn. Stats. 115.069,116C.705 through 116C.83, 216B.1691, 216B.243, 216B.2421 through 216B.2423, and Minnesota Regulations 4410.4300 and 4410.4400. In addition, see Minnesota documents at:
http://www.me3.org/issues/nuclear/eqbnukes1.html
http://www.me3.org/issues/nuclear/eqbnukes2.html
http://www.me3.org/issues/nuclear/eqbnukes3.html
http://www.leg.state.mn.us/lrl/issues/prairieisland.asp
http://www.puc.state.mn.us/docs/orders/04-0001.pdf
http://www.house.leg.state.mn.us/hrd/pubs/nucwaste.pdf
http://www.puc.state.mn.us/docs/briefing_papers/b05-0022.pdf
http://www.house.leg.state.mn.us/hrd/pubs/nucxcel.pdf.

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**.

Under the proposed Minnesota Program, the authority to promulgate rules for the control of radiation rests with the MDH in accordance with Mn. Stat. 144.12, *Regulations, enforcement, licensees, fees*. The MDH is also provided radiation control authority by Mn. Stats., 144.1202, and 144.1203, Training, rulemaking. Minnesota also has ancillary statutes that relate to MDH activities, dealing with record and data keeping, giving false information, surety requirements, inspection, fees, and other matters.

The NRC staff verified that the MDH adopted the relevant NRC regulations in 10 CFR Parts 19, 20, 30, 31, 32, 33, 34, 35, 36, 39, 40, 70, 71, and 150 into Minnesota Rules Chapter 4731,

Radiation Safety, June 24, 2004 and January 1, 2005. Therefore, MDH has adopted an adequate and compatible set of radiation protection regulations which apply to byproduct, source, and special nuclear materials in quantities not sufficient to form a critical mass.

Minnesota does have additional statutes, identified in the staff's review, which are not part of its program for the regulation of agreement materials but which potentially intrude upon areas reserved to the NRC. Whether or not these Minnesota statutes are preempted by Federal law, they concern areas over which Minnesota is not seeking authority as part of this Agreement, and the staff is satisfied that these statutes will not affect Minnesota's regulation of agreement material. The staff view is that these statutes are outside the scope of the Agreement and therefore, not within the scope of inquiry as to this criterion.

The staff has, however, considered these statutes and program elements in making its determination as to this criterion. For example, a radiation dose standard of 0.054 millirem/year for the Prairie Island Nuclear Power Plant (Prairie Island) independent spent fuel storage installation (ISFSI) appears to have been agreed upon as the result of a negotiation between the State of Minnesota and the licensee and was memorialized in an order by the Minnesota Public Utility Commission (MPUC). In December 2004, NRC initiated discussions with the MDH regarding the radiation dose standard at the Prairie Island ISFSI and a potential similar radiation dose standard at the proposed Monticello Nuclear Power Plant (Monticello) ISFSI. When the MDH became aware of NRC's concerns with respect to the proposed Monticello ISFSI, they interacted with the Minnesota Environmental Quality Board (MEQB). MDH informed the MEQB that radiation dose standards at the proposed Monticello ISFSI would be reserved to the NRC. Based on this information, the MEQB revised the Environmental Impact Statement Scoping Decision to reflect NRC's jurisdiction at the ISFSI. The Monticello Decision provides that Federal regulations preempt State regulation of radiological health and safety standards applicable to nuclear power plants and ISFSIs. This effort by the MDH iterates a proactive approach with respect to assuring that preemption issues are dealt with in an acceptable manner. The staff is satisfied that Minnesota will not regulate in areas reserved to the NRC in matters concerning or affecting the proposed Agreement or materials regulated under the Agreement.

Therefore, the staff concludes that this criterion is satisfied.

References: Letter dated July 6, 2004, from Governor Pawlenty to Chairman Diaz, request for an Agreement, Section 4.1.1 and Section 4.1.2, and additional related correspondence between the NRC and the State (ADAMS: ML041960496, ML041960499, ML052440344, ML050130375, ML050140452, ML051330043, ML051740384, ML051650073, ML052200424), and the Section 4.1.1 reference to Internet site: http://www.revisor.leg.state.mn.us/stats . (At this Internet site see the following Mn. Stats.115.069,116C.705 through 116C.83, 216B.1691, 216B.243, 216B.2421 through 216B.2423, and Minnesota Regulations 4410.4300 and 4410.4400) and history of law at: http://www.leg.state.mn.us/lrl/issues/prairieisland.asp.)
In addition, see Minnesota documents at: http://www.me3.org/issues/nuclear/eqbnukes1.html
http://www.me3.org/issues/nuclear/eqbnukes2.html
http://www.me3.org/issues/nuclear/eqbnukes3.html
http://www.leg.state.mn.us/lrl/issues/prairieisland.asp
http://www.puc.state.mn.us/docs/orders/04-0001.pdf
http://www.house.leg.state.mn.us/hrd/pubs/nucwaste.pdf
http://www.puc.state.mn.us/docs/briefing_papers/b05-0022.pdf
http://www.house.leg.state.mn.us/hrd/pubs/nucxcel.pdf

3. Uniformity of 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.

Minnesota, by statute, must promulgate and enforce rules for the regulation of byproduct, source, and special nuclear material that are in accordance with Section 274 of the Act, as amended. The State has adopted a rule compatible with 10 CFR Part 20. The staff review verified that the Minnesota rules' technical definitions and terminology; units of measurement and dose; and permissible doses, levels of radiation and concentrations of radioactivity are consistent with those in NRC regulations.

Minnesota has applied a 0.054 millirem/year radiation dose standard to the Prairie Island ISFSI facility, which is discussed in the staff's analysis of Criterion 2, above. For the reasons stated there, the NRC staff is satisfied that this radiation dose standard will not affect regulation of material under the proposed Agreement.

In addition, the staff review further noted that Mn. Stat. 116C.71 contains definitions different from the NRC definitions with respect to the terms "Byproduct Material," "Disposal," "High Level Waste," "Radiation," and "Radioactive Waste." However, the statute states that these definitions are applicable only for the purposes of sections 116C.71 to 116C.74 of the Minnesota Statutes, which do not relate to the MDH, the State agency responsible for carrying out the proposed Agreement, or to the regulation of materials under which Minnesota is seeking authority under this Agreement. MDH's regulations, which do apply to agreement material, contain definitions of these terms compatible with those of the Commission. In addition, RCU has, in writing, assured the staff that it will not apply the definitions in Mn. Stat. 116C.71 to the regulation of agreement material, and will inform other Minnesota State agencies of the need to conform the statutory definitions to the NRC definitions. The staff is satisfied that the Minnesota Program provides for the uniformity of radiation standards and definitions.

The staff concludes that this criterion is satisfied.

References: Letter dated July 6, 2004, from Governor Pawlenty to Chairman Diaz, request for an Agreement, Section 4.1.1 and Section 4.1.2, and additional related correspondence between the NRC and the State (ADAMS: ML041960496, ML041960499, ML052440344, ML050130375, ML050140452, ML051330043, ML051740384, ML051650073, ML052200424), and the Section 4.1.1 reference to Internet site: http://www.revisor.leg.state.mn.us/stats . (At this Internet site see the following Mn. Stats.115.069,116C.705 through 116C.83, 216B.1691, 216B.243, 216B.2421 through 216B.2423, and Minnesota Regulations 4410.4300 and 4410.4400) and history of law at: http://www.leg.state.mn.us/lrl/issues/prairieisland.asp.)
In addition, see Minnesota documents at: http://www.me3.org/issues/nuclear/eqbnukes1.html
http://www.me3.org/issues/nuclear/eqbnukes2.html
http://www.me3.org/issues/nuclear/eqbnukes3.html
http://www.leg.state.mn.us/lrl/issues/prairieisland.asp
http://www.puc.state.mn.us/docs/orders/04-0001.pdf
http://www.house.leg.state.mn.us/hrd/pubs/nucwaste.pdf
http://www.puc.state.mn.us/docs/briefing_papers/b05-0022.pdf
http://www.house.leg.state.mn.us/hrd/pubs/nucxcel.pdf

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 Minnesota has adopted rules equivalent to the NRC regulations in 10 CFR Part 20, including Subpart C, the occupational dose limits and Subpart D, the dose limits to individual members of the public. Minnesota licensees are required to consider the radiation doses to individuals from all sources of radiation, except background radiation and radiation from medical procedures. Like NRC licensees, Minnesota licensees are required to consider the radiation dose whether the sources are in the possession of a licensee or not.

The staff concludes that this criterion is satisfied.

References: Letter dated July 6, 2004, from Governor Pawlenty to Chairman Diaz, request for an Agreement, Section 4.2, and additional related correspondence between the NRC and the State (ADAMS: ML041960496, ML041960499, ML052440344, ML050130375, ML050140452, ML051330043, ML051740384, ML051650073, ML052200424), and Chapter 4731 Radiation Safety, §§ 4731.2020 through 4731.2095.

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 Minnesota has adopted a rule compatible with Subpart F. Therefore, Minnesota licensees are required to conduct surveys and personnel monitoring to the same standards required of NRC licensees.

The staff concludes that this criterion is satisfied.

References: Letter dated July 6, 2004, from Governor Pawlenty to Chairman Diaz, request for an Agreement, Section 4.2, and additional related correspondence between the NRC and the State (ADAMS: ML041960496, ML041960499, ML052440344, ML050130375, ML050140452, ML051330043, ML051740384, ML051650073, ML052200424), and Chapter 4731 Radiation Safety, §§ 4731.2220 and 4731.2230.

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 Minnesota has adopted regulations compatible with NRC regulations in Subpart J of 10 CFR Part 20. Therefore, the radiation labels, signs and symbols, and the posting and labeling requirements in the Minnesota rules are identical to those contained in the NRC regulations.

The staff concludes that this criterion is satisfied.

References: Letter dated July 6, 2004, from Governor Pawlenty to Chairman Diaz, request for an Agreement, Section 4.2, and additional related correspondence between the NRC and the State (ADAMS: ML041960496, ML041960499, ML052440344, ML050130375, ML050140452, ML051330043, ML051740384, ML051650073, ML052200424), and Chapter 4731 Radiation Safety, §§ 4731.2300 through 4731.2350.

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 Minnesota has adopted regulations compatible with 10 CFR Part 19.

The staff concludes that this criterion is satisfied.

References: Letter dated July 6, 2004, from Governor Pawlenty to Chairman Diaz, request for an Agreement, Section 4.2, and additional related correspondence between the NRC and the State(ADAMS: ML041960496, ML041960499, ML052440344, ML050130375, ML050140452, ML051330043, ML051740384, ML051650073, ML052200424), and Chapter 4731 Radiation Safety, §§ 4731.1040 through 4731.1060.

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

The NRC staff review verified that Minnesota has adopted a rule compatible with Subpart I of 10 CFR Part 20.

The staff concludes that this criterion is satisfied.

References: Letter dated July 6, 2004, from Governor Pawlenty to Chairman Diaz, request for an Agreement, Section 4.2, and additional related correspondence between the NRC and the State (ADAMS: ML041960496, ML041960499, ML052440344, ML050130375, ML050140452, ML051330043, ML051740384, ML051650073, ML052200424), and Chapter 4731 Radiation Safety, §§ 4731.1040 through 4731.1060.

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 Minnesota has adopted rules that are compatible with Subpart K of 10 CFR Part 20 - Waste Disposal. This regulation deals with general requirements for waste disposal including waste classification, transfer and waste manifests and are applicable to all licensees.

The staff's analysis of Criterion 3, above, identifies Minnesota statutory definitions, separate from the program for the regulation of agreement material (MDH), which are different from NRC definitions of those terms. For the reasons discussed under Criterion 3, the staff is satisfied that those definitions will not affect the regulation of material under the Agreement.

The staff therefore concludes that Criterion 9(a) is satisfied.

(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).

The NRC staff review confirmed that Minnesota is not seeking authority to regulate the land disposal of low-level radioactive waste. Therefore, Criterion 9(b) does not apply to Minnesota.

References: Letter dated July 6, 2004, from Governor Pawlenty to Chairman Diaz, request for an Agreement, Section 4.2, and additional related correspondence between the NRC and the State (ADAMS: ML041960496, ML041960499, ML052440344, ML050130375, ML050140452, ML051330043, ML051740384, ML051650073, ML052200424), and Chapter 4731 Radiation Safety, §§ 4731.2400 through 4731.2450.

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 verified that Minnesota has adopted regulations compatible with 10 CFR Part 71 - Transportation. Minnesota does have statutes, separate from its program for the regulation of agreement materials, that pertain to the transportation of radioactive material; however, those statutes do not apply to the transportation of agreement material. Minnesota's regulations specifically exempt areas of exclusive NRC jurisdiction.

The staff concludes that this criterion is satisfied.

References: Letter dated July 6, 2004, from Governor Pawlenty to Chairman Diaz, request for an Agreement, Section 4.1 and Section 4.2, and additional related correspondence between the NRC and the State (ADAMS: ML041960496, ML041960499, ML052440344, ML050130375, ML050140452, ML051330043, ML051740384, ML051650073, ML052200424), and Chapter 4731 Radiation Safety, 4731.0400 through 4731.0424, the Section 4.1.1 reference to Internet site: http://www.revisor.leg.state.mn.us/stats. (At this Internet site see the following Mn. Stats.115.069,116C.705 through 116C.83, 216B.1691, 216B.243, 216B.2421 through 216B.2423, and Minnesota Regulations 4410.4300 and 4410.4400) and history of law at: http://www.leg.state.mn.us/lrl/issues/prairieisland.asp.)

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 Minnesota has adopted rules compatible with 10 CFR Parts 19, 20, 30, 31, 32, 33, 34, 35, 36, 39, 40, 70, 71, and 150. The records and reports referenced in Criterion 11 are regulatory requirements in these parts. Minnesota has adopted the record and reporting requirements.

The staff concludes that this criterion is satisfied.

References: Letter dated July 6, 2004, from Governor Pawlenty to Chairman Diaz, request for an Agreement, Section 4.2, and additional related correspondence between the NRC and the State (ADAMS: ML041960496, ML041960499, ML052440344, ML050130375, ML050140452, ML051330043, ML051740384, ML051650073, ML052200424), and Chapter 4731 Radiation Safety.

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 Minnesota State law provides the radiation control agency authority to impose, by order or license condition, additional health and safety requirements beyond the requirements specified in law and the rules. The agency also has the legal authority to grant reasonable and necessary exceptions to the regulatory requirements, either by order or license condition. Minnesota has adopted a rule which is compatible with 10 CFR 30.34, Terms and conditions of licenses.

The staff concludes that this criterion is satisfied.

References: Letter dated July 6, 2004, from Governor Pawlenty to Chairman Diaz, request for an Agreement, Section 4.1 and 4.2, and additional related correspondence between the NRC and the State (ADAMS: ML041960496, ML041960499, ML052440344, ML050130375, ML050140452, ML051330043, ML051740384, ML051650073, ML052200424), Mn. Stats. 144.12 and 144.99 and Chapter 4731 Radiation Safety, Section 4731.3075.

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 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 processor 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**

specific use.

Minnesota has adopted regulations containing regulatory requirements for applying for and issuing licenses, which are compatible with NRC's regulations.

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

Since Criterion 13 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. Minnesota has decided not to seek authority for evaluation of sealed sources and devices.

The staff concludes that this criterion is satisfied.

References: Letter dated July 6, 2004, from Governor Pawlenty to Chairman Diaz, request for an Agreement, Section 4.2, and additional related correspondence between the NRC and the State (ADAMS: ML041960496, ML041960499, ML052440344, ML050130375, ML050140452, ML051330043, ML051740384, ML051650073, ML052200424), Chapter 4731 Radiation Safety.

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 regulatory guides for various categories of licensed activities.**

The NRC staff review determined that the Minnesota Program has established series of checklists, regulatory guides and licensing procedure guides and a set of applicable forms. Minnesota has developed a series of State developed regulatory guides for use by license applicants. The NRC staff determined that the licensing procedure guides cover the handling of license applications from the point of submittal through issuance of the completed license. The Minnesota licensing procedures are similar to NRC's procedures.

The staff concludes that this criterion is satisfied.

References: Letter dated July 6, 2004, from Governor Pawlenty to Chairman Diaz, request for an Agreement, Section 4.3, and additional related correspondence between the NRC and the State (ADAMS: ML041960496, ML041960499, ML052440344, ML050130375, ML050140452, ML051330043, ML051740384, ML051650073, ML052200424).

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.**

In April 2004, the NRC amended 10 CFR Part 35 to change its requirements for recognizing specialty boards whose certifications may be used to demonstrate the adequacy of the training and experience (T&E) of individuals to serve as Radiation Safety Officers, authorized medical physicists, authorized nuclear pharmacists, or authorized (physician) users. The final rule also revises the requirements for demonstrating the adequacy of T&E for pathways other than the

board certification pathway. Agreement States are required to adopt a compatible rule. In a letter dated May 25, 2005, the Manager of the Asbestos, Indoor Air, Lead and Radiation Section, responding to NRC staff comments, committed to incorporating the new Part 35 requirements in their program as a license condition and in their appropriate guidance documents.

Based on this commitment, the staff concludes that this criterion is satisfied.

References: Letter dated July 6, 2004, from Governor Pawlenty to Chairman Diaz, request for an Agreement, Section 4.2, and additional related correspondence between the NRC and the State (ADAMS: ML041960496, ML041960499, ML052440344, ML050130375, ML050140452, ML051330043, ML051740384, ML051650073, ML052200424), Chapter 4731 Radiation Safety, §§ 4731.4400-4731.4527.

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 confirmed that the Minnesota Program has statutory authority to conduct inspections of licensees. Minnesota has adopted regulations compatible with equivalent parts of 10 CFR containing provisions relating to inspections and tests.

Minnesota has adopted a schedule for inspection of licensees at least as frequent as the schedule used by NRC. The Program staff has developed internal procedures and accompanying forms for the inspection areas which cover scheduling, preparation, performance basis, tracking and documentation of inspection results. The Program staff has also established a computerized tracking system. The inspection procedures are similar to NRC procedures.

The staff concludes that this criterion is satisfied.

References: Letter dated July 6, 2004, from Governor Pawlenty to Chairman Diaz, request for an Agreement, Sections 4.1, Mn. Stat. 144.99, and Section 4.4, and additional related correspondence between the NRC and the State (ADAMS: ML041960496, ML041960499, ML052440344, ML050130375, ML050140452, ML051330043, ML051740384, ML051650073, ML052200424).

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

The NRC staff review confirmed that Minnesota law provides authority for radiation control Program inspectors to enter public or private property at all reasonable times for the purpose of investigating conditions related to radiation use.

The staff concludes that this criterion is satisfied.

References: Letter dated July 6, 2004, from Governor Pawlenty to Chairman Diaz, request for an Agreement, Section 4.1, Mn. Stat. 144.99, and Section 4.4, and additional related correspondence between the NRC and the State (ADAMS: ML041960496, ML041960499, ML052440344,

ML050130375, ML050140452, ML051330043, ML051740384, ML051650073, ML052200424).

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 Minnesota 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 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 staff concludes that this criterion is satisfied.

References: Letter dated July 6, 2004, from Governor Pawlenty to Chairman Diaz, request for an Agreement, Section 4.4, and additional related correspondence between the NRC and the State (ADAMS: ML041960496, ML041960499, ML052440344, ML050130375, ML050140452, ML051330043, ML051740384, ML051650073, ML052200424).

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 Minnesota Program is authorized by law to enforce the State rules using a variety of sanctions, including the imposition of administrative fines, and the issuance of orders to suspend, modify or revoke licenses, or to impound materials. The Program may assess civil penalties in accordance with State Law and Department regulations.

The Program has adopted policies and procedures to implement the enforcement authority. The Minnesota enforcement procedures are similar to the NRC procedures with regard to the use of severity levels for violations.

The staff concludes that this criterion is satisfied.

References: Letter dated July 6, 2004, from Governor Pawlenty to Chairman Diaz, request for an Agreement, Section 4.1, Mn. Stats. 144.12, 144.99, and Section 4.5, and additional related correspondence between the NRC and the State (ADAMS: ML041960496, ML041960499, ML052440344, ML050130375, ML050140452, ML051330043, ML051740384, ML051650073, ML052200424).

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 inspections 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 of 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 science, 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 are 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 the 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 Minnesota Program, training and qualification plan, and the curricula vitae for the current staff members,

the NRC staff concludes that the RCU has a staffing plan that provides a sufficient number of adequately trained and qualified technical staff.

a. Assessment of the Agreement Materials Staffing

There are approximately 154 NRC specific licenses in Minnesota. The RCU also conducts a registration and inspection program for NARM users which accounts for approximately 45 registrants.

The staff of the RCU will be responsible for implementing the agreement materials program. The Minnesota staffing plan allocates a total of approximately 5.0 full-time equivalent (FTE) staff for the agreement materials program, including the Program Supervisor. Since submission of the Agreement request, one staff member has left the Program. This position was filled with a new hire in December 2004. The RCU supervisor plans to devote 50% of his time to the agreement materials program, including management review of licensing and inspection actions, personnel responsibilities, rules development, accompaniment of inspectors for annual management review, general supervision, and other management duties. Four staff members will devote 100% of their time to the Agreement State Program activities and one other staff member will provide 30%. Minnesota's staff assessment used 80% of the full-time employees' time in their staffing analysis. They assume that the other 20% of the employees' time will be devoted to radiological response, instructional opportunities and training. One full-time administrative assistant provides support to the Program.

Based on the RCU staffing allocation of 5.0 technical and administrative FTE for the Program, and subtracting the Program Supervisor and administrative assistants, the technical/ professional staffing level devoted to the Agreement State Program is 3.5 FTE. The Team's evaluation of the State's staffing analysis concludes that adequate staffing exists without the new hire's FTE. The RCU supervisor is using this additional FTE to provide flexibility and backup to the radioactive materials program.

Minnesota estimates they will have responsibility for 199 licenses (154 from NRC and 45 existing NARM registrants). The RCU Staff Resource Analysis projects that approximately 172 licensing staff days will be needed and 259 licensing staff days are available; 368 inspection staff days are needed and 531 are available each year. This projection is based on data from the NRC Region III Office. This level of inspection effort will keep the inspection program current.

Based on the workload analysis, NRC staff concludes the initial 3.5 FTE qualified technical\professional staff provides an adequate level of staffing to handle anticipated licensing, inspection, reciprocity, allegations and incident response workload satisfactorily.

The staff concludes that the proposed Minnesota agreement materials program has an adequate number of staff to meet the anticipated Program needs.

b. Assessment of Staff Qualifications

The NRC staff review considered the qualifications of the individuals currently on the RCU's professional/technical staff that would be involved in the agreement materials program, and the procedures for training and qualifying new staff members. Under the proposed Agreement, the RCU Supervisor would direct the agreement materials program and would be primarily responsible for the Program's administration and will provide the immediate day-to-day supervision of the agreement materials program. He holds a Bachelor's degree in Physics and Philosophy. He has over 20 years of experience in health physics and supervision. He has 10

years of experience in an agreement material program from another State and 10 years of radiological experience in the U.S. Navy.

Based on the NRC staff review, three of the five non-supervisory staff members have at least a Bachelor's degree in physical life sciences or engineering. One staff member has a Master's degree in public health and a Bachelor's degree in engineering; one staff member has a Bachelor's degree in applied studies concentration in radiological science and an Associate degree in radiologic technology; one staff member has a Master's degree in materials science engineering, a Bachelor's degree in chemistry, and a Bachelor's degree in chemical engineering; and the two other staffers are former radiologic technologists with significant experience and training in radiation protection.

The RCU technical staff members have extensive radiation science experience. This includes work in health physics and nuclear power in private industry, the military and in State regulatory agencies. Technical staff members have completed the NRC-recommended core courses or have received waivers from the RCU manager, based on their training and prior experience. The new hire has taken the inspection and licensing courses and is scheduled to attend the remaining core training courses in the next year.

Two technical staff have had on-the-job training working with NRC license reviewers in the NRC Region III Office and all of the fully-qualified technical staff members have accompanied NRC staff on inspections of NRC licensees in Minnesota. Several of the technical staff have also spent time in neighboring Agreement States receiving licensing and inspection training.

The NRC staff believes that the RCU technical staff identified by the State to participate in the agreement materials program are trained and qualified in accordance with the RCU plans, 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.

The staff concludes that the proposed Minnesota Program has a sufficient number of adequately trained staff to meet the anticipated program needs. The staff concludes that this criterion is satisfied.

References: Letter dated July 6, 2004, from Governor Pawlenty to Chairman Diaz, request for an Agreement, Sections 4.6, and additional related correspondence between the NRC and the State (ADAMS: ML041960496, ML041960499, ML052440344, ML050130375, ML050140452, ML051330043, ML051740384, ML051650073, ML052200424).

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 did not note any aspects of the Minnesota Program that could potentially interfere with duties imposed on a holder of materials by the NRC. In addition, Minnesota's regulations specifically exempt areas of exclusive NRC or other Federal jurisdiction from State regulation. The staff is therefore satisfied that the Minnesota Program will not interfere with duties imposed on the holder of materials by the NRC.

Therefore, the staff concludes that this criterion is satisfied.

References: Letter dated July 6, 2004, from Governor Pawlenty to Chairman Diaz, request for an Agreement, Section 4.1.1, Statutory Authority and Section 4.1.2, Program Organization, and additional related correspondence between the NRC and the State (ADAMS: ML041960496, ML041960499, ML052440344, ML050130375, ML050140452, ML051330043, ML051740384, ML051650073, ML052200424), and the Section 4.1.1 reference to Internet site: http://www.revisor.leg.state.mn.us/stats. (At this Internet site see the following Mn. Stats. 115.069,116C.705 through 116C.83, 216B.1691, 216B.243, 216B.2421 through 216B.2423, and Minnesota Regulations 4410.4300 and 4410.4400) and history of law at: http://www.leg.state.mn.us/lrl/issues/prairieisland.asp and http://www.house.leg.state.mn.us/hrd/pubs/nucxcel.pdf.

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 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 (grams contained U-235)/350 + 50 (grams U-233)/200 + 50 (grams PU)/200 = 1

The NRC staff determined that Minnesota's definition of special nuclear material in critical mass quantities in 4731.0315,*Critical Mass,* is compatible with that of the Commission's.

The staff concludes that this criterion is satisfied.

References: Letter dated July 6, 2004, from Governor Pawlenty to Chairman Diaz, request for an Agreement, Section 4.1.1, Statutory Authority and Section 4.1.2, Program Organization, and additional related correspondence between the NRC and the State (ADAMS: ML041960496, ML041960499, ML052440344, ML050130375, ML050140452, ML051330043, ML051740384, ML051650073, ML052200424), and the Section 4.1.1 reference to Internet site: http://www.revisor.leg.state.mn.us/stats. (At this Internet site see the following Mn. Stats. 115.069,116C.705 through 116C.83, 216B.1691, 216B.243, 216B.2421 through 216B.2423, and Minnesota Regulations 4410.4300 and 4410.4400) and history of law at: http://www.leg.state.mn.us/lrl/issues/prairieisland.asp and http://www.house.leg.state.mn.us/hrd/pubs/nucxcel.pdf.

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 process and use radioactive materials; and
c. Taking disciplinary actions against licensees.

The NRC staff review confirmed that the MDH is bound by general statutory provisions with respect to providing the opportunity for public participation in rulemaking, licensing actions, and disciplinary actions. These general statutory provisions also apply to the protection of personnel radiation exposure records from public disclosure, maintaining the confidentiality of allegers, and administrative and judicial requirements for requesting and holding hearings on enforcement matters.

The staff concludes that this criterion is satisfied

References: Letter dated July 6, 2004, from Governor Pawlenty to Chairman Diaz, request for an Agreement, Section 4.1, Mn. Stat. 144.99, and additional related correspondence between the NRC and the State (ADAMS: ML041960496, ML041960499, ML052440344, ML050130375, ML050140452, ML051330043, ML051740384, ML051650073, ML052200424), and the Section 4.1.1 reference to Internet site: http://www.revisor.leg.state.mn.us/stats. (At this Internet site see the following: Mn. Stat. 14.05 through 14.28.)

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 determined that the MDH is designated by Mn. Stat. 144.1202 to be the lead agency for the carrying out the terms of the proposed Agreement, which will assure against duplicate regulations or licensing by State and local authorities. In addition, to the extent that this criterion deals with duplicate regulation between a State and the NRC (see STP Procedure SA-700 Handbook, Evaluation Criteria 4.1.1.2., paragraph b, and 4.2.2.2), the staff determined that the Minnesota Program, which specifically excludes from State regulation any areas in which the jurisdiction of the NRC or another Federal agency is exclusive, gives sufficient assurance against duplicate regulation between Minnesota and the NRC in the regulation of agreement material.

Therefore, the staff concludes that this criterion is satisfied.

References: Letter dated July 6, 2004, from Governor Pawlenty to Chairman Diaz, request for an Agreement, Section 4.1.1, Statutory Authority and Section 4.1.2, Program Organization, and additional related correspondence between the NRC and the State (ADAMS: ML041960496, ML041960499, ML052440344, ML050130375, ML050140452, ML051330043, ML051740384, ML051650073, ML052200424), and the Section 4.1.1 reference to Internet site: http://www.revisor.leg.state.mn.us/stats. (At this Internet site see the following Mn. Stats. 115.069,116C.705 through 116C.83, 216B.1691, 216B.243, 216B.2421 through 216B.2423, and Minnesota Regulations 4410.4300 and 4410.4400) and history of law at: http://www.leg.state.mn.us/lrl/issues/prairieisland.asp and http://www.house.leg.state.mn.us/hrd/pubs/nucxcel.pdf.

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 Mn. Stat. 144.1202 contains a provision that deems the holder of an NRC license on the effective date of the proposed Agreement to possess a like license under the Minnesota Radiation Safety Code. The license will expire on the expiration date on the NRC license.

The staff concludes that this criterion is satisfied.

References: Letter dated July 6, 2004, from Governor Pawlenty to Chairman Diaz, request for an Agreement, Section 4.1. Mn. Stat. 144.1202, and additional related correspondence between the NRC and the State (ADAMS: ML041960496, ML041960499, ML052440344, ML050130375, ML050140452, ML051330043, ML051740384, ML051650073, ML052200424).

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 Minnesota 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 the Minnesota Program will continue to be compatible with the NRC's program for the regulation of agreement materials.

In a revised Policy Statement on Adequacy and Compatibility of Agreement State Programs (published September 3, 1997 at 62 FR 46517), the Commission determined that providing reports to NRC of Agreement State licensee incidents, accidents and other significant events is a matter of compatibility. Minnesota has adopted procedures to provide such reports to NRC.

Therefore, the staff concludes that this criterion is satisfied.

References: Letter dated July 6, 2004, from Governor Pawlenty to Chairman Diaz, request for an Agreement, Section 4.1, and additional related correspondence between the NRC and the State (ADAMS: ML041960496, ML041960499, ML052440344, ML050130375, ML050140452, ML051330043, ML051740384, ML051650073, ML052200424), and the Section 4.1. reference to Internet site: http://www.revisor.leg.state.mn.us/stats. (At this Internet site see the following Mn. Stats.115.069,116C.705 through 116C.83, 216B.1691, 216B.243, 216B.2421 through 216B.2423, and Minnesota Regulations 4410.4300 and 4410.4400), and history of law at: http://www.leg.state.mn.us/lrl/issues/prairieisland.asp and http://www.house.leg.state.mn.us/hrd/pubs/nucxcel.pdf. The Minnesota response to NRC's comments on the final application dated December 14, 2004 (ADAMS: ML050130375).

27. **Coverage, Amendments, Reciprocity. An amendment 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 material as defined in Section 11e(1) of the Act,
b. Byproduct material as defined in Section 11e(2) of the Act,
c. Source material,
d. Special nuclear material 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 Minnesota to assume, regulatory authority over the types of material defined in categories a, c, and d above.

Since this 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 portion of the Agreement, or to allow NRC to retain that authority. Minnesota has chosen not to assume that authority.

References: Proposed Agreement between the State of Minnesota and the Nuclear Regulatory Commission, Articles I, II, and III in the request for an Agreement by Governor Pawlenty.

The proposed Agreement stipulates the desirability or reciprocal recognition of NRC and other Agreement State licenses, and commits the Commission and the State to cooperate to accord such reciprocity. Minnesota's regulation provides for the reciprocal recognition of licenses from other jurisdictions.

References: Proposed Agreement between the State of Minnesota and the Nuclear Regulatory Commission, Article VII; Mn. Reg. 4731.0355.

Therefore, the staff concludes that this criterion is satisfied.

References: Letter dated July 6, 2004, from Governor Pawlenty to Chairman Diaz, request for an Agreement, Section 4.1, and additional related correspondence between the NRC and the State (ADAMS: ML041960496, ML041960499, ML052440344, ML050130375, ML050140452, ML051330043, ML051740384, ML051650073, ML052200424), and the Section 4.1. reference to Internet site: http://www.revisor.leg.state.mn.us/stats. (At this Internet site see the following Mn. Stats.115.069,116C.705 through 116C.83, 216B.1691, 216B.243, 216B.2421 through 216B.2423, and Minnesota Regulations 4410.4300 and 4410.4400), and history of law at: http://www.leg.state.mn.us/lrl/issues/prairieisland.asp and http://www.house.leg.state.mn.us/hrd/pubs/nucxcel.pdf.

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 site;

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 Minnesota has adopted 10 CFR Parts 30, 40 and 70 compatible rules including §§ 30.12, 40.11 and 70.11 wherein the specified exemptions are contained. Based on this, the NRC staff concludes that the Minnesota regulations do provide for exemptions from the State's requirements for licensing of sources of radiation for NRC and DOE contractors or subcontractors in accordance with the criterion.

The staff concludes that this criterion is satisfied.

NOTE to USERS: Additional Criteria must be addressed for Agreements that will cover section 11(e).2 byproduct material.

References: Letter dated July 6, 2004, from Governor Pawlenty to Chairman Diaz, request for an Agreement, Section 4.2, and additional related correspondence between the NRC and the State (ADAMS: ML041960496, ML041960499, ML052440344, ML050130375, ML050140452, ML051330043, ML051740384, ML051650073, ML052200424), and Chapter 4731 Radiation Safety.

STAFF CONCLUSION

The NRC staff has reviewed the proposed Agreement, the certification by Minnesota in the application for an Agreement in letter dated July 6, 2004, from Governor Pawlenty to Chairman Diaz, and the supporting information provided by the staff of the RCU of the MDH.

Section 274d. of the Act provides that the Commission shall enter into an Agreement under Section 274b. with any State if:

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

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

The staff concludes that:

On the basis of this Assessment, the State of Minnesota meets the requirements of the Act. The

Minnesota Program, as defined by its statutes, regulations, personnel, licensing, inspection, and administrative procedures, is compatible with the program of the NRC and adequate to protect public health and safety with respect to the materials covered by the proposed Agreement. Although the State has statutes, not a part of the Minnesota Program, which potentially intrude on matters reserved to the NRC, these statutes do not deal with the regulation of agreement materials, and the staff is satisfied that these statutes will not affect or interfere with the regulation of materials under the proposed Agreement.

As a policy matter, if the NRC enters into an Agreement with the State of Minnesota, it will not in any way be precluded in the future from taking up with the State its regulation in matters potentially reserved to the NRC, because the NRC is ceding no authority to Minnesota in the areas covered by the Minnesota statutes in question. There is no indication that Minnesota statutes have actually interfered with the regulation of reactors or other matters in which the NRC has exclusive jurisdiction, and the staff is satisfied that there is no actual or potential health, safety, or security significance with respect to the Minnesota statutes in question, nor have affected licensees raised any preemption issues with respect to the Minnesota statutes.

In addition, the policy consequences of refusing to enter into an Agreement with Minnesota on the basis of these statutes are considerable. First of all, to do so would contradict the Commission's stated policy on compatibility, as found in the Commission's 1997 Policy Statement, which in the definition of compatibility restricts the scope of compatibility to the regulation of agreement materials. Second, to consider statutes which are not part of a State's submitted program for the regulation of material under the Agreement would go beyond the scope of the Agreement itself and force the staff, before entering into an Agreement, to perform a wide-ranging search of State statutes and regulations that have little or nothing to do with regulation of materials under the proposed Agreement. In addition, this experience will likely prove extremely frustrating to Minnesota and could potentially discourage other States to enter into Section 274b. Agreements with the NRC, being that State executive governments will often have little direct control over statutes enacted by the State Legislatures that are separate from the States' proposed program for the regulation of agreement materials.

Commission Paper to Publish Proposed Agreement

Note to Users: This is no longer a Negative Consent Commission Paper. Specific comments about the Utah program are for illustration only. Replace or modify as appropriate.

POLICY ISSUE
(Notation Vote)

May 17, 2007 SECY-07-0083

FOR: The Commissioners

FROM: Luis A. Reyes
Executive Director for Operations /RA/

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

PURPOSE:

To request Commission approval to publish the proposed Agreement with the Commonwealth of Pennsylvania and a summary of the draft U.S. Nuclear Regulatory Commission (NRC) staff assessment of the Pennsylvania regulatory program in the *Federal Register* (FR) for public comment.

BACKGROUND:

Section 274b of the Atomic Energy Act of 1954, as amended (Act) authorizes the Commission to enter into an Agreement with the Governor of a State providing for the discontinuance of the regulatory authority of the Commission with respect to certain materials. In 1981, the Commission adopted the revised policy statement entitled, "Criteria for Guidance of States and Nuclear Regulatory Commission (NRC) in Discontinuance of NRC Regulatory Authority and Assumption Thereof by States Through Agreement" (46 FR 7540; January 23, 1981), as amended by statements published on July 16, 1981 (46 FR 36969), and on July 21, 1983 (48 FR 33376), referred to hereafter as the "policy statement." The Office of Federal and State Materials and Environmental Management Programs (FSME) Procedure SA-700, "Processing

CONTACT: Andrew N. Mauer, FSME/DMSSA
301-415-3962

an Agreement," was subsequently adopted as an internal procedure for applying the policy statement to the processing of a new Agreement. The criteria and approaches in these documents form the basis for the staff's evaluation of the Pennsylvania request.

DISCUSSION:

By letter dated November 9, 2006, Governor Edward G. Rendell requested that the Commission enter into an Agreement with the Commonwealth of Pennsylvania under Section 274b of the Act. The Governor requested that the Commission discontinue its regulatory authority for 11e.(1), 11e.(3), and 11e.(4) byproduct materials, source materials, special nuclear materials not sufficient to form a critical mass, and land disposal of all waste for such materials, and allow Pennsylvania to assume regulatory authority for such material under the Agreement.
Governor Rendell certified that Pennsylvania has a program for the control of radiation hazards that is adequate to protect public health and safety within the Commonwealth with respect to the materials covered by the proposed Agreement. The Governor further certified that the Commonwealth wishes to assume the regulatory responsibility for those materials. Copies of Governor Rendell's letter and Chairman Klein's response are enclosed (Enclosures 1 and 2, respectively).

The NRC staff provided comments to Pennsylvania on its formal Agreement request by letter dated January 26, 2007 (Enclosure 3). In these comments, the staff identified several needed procedural revisions and/or updates and also identified two significant staffing concerns related to the staffing level of the program and the training and qualifications of the staff. Pennsylvania responded to the NRC comments and submitted revised sections of its Agreement request in a letter dated March 16, 2007 (Enclosure 4).

The NRC staff has verified that each of the comments that were provided to Pennsylvania has been addressed through the modifications and clarifications provided in their letter. In the course of the continued interactions between the NRC and Pennsylvania, the NRC staff plans to confirm the assurances that Pennsylvania provided, which indicate they have an adequate number of trained and qualified staff in place, based on their staff needs analysis and qualification procedures. In addition, the staff notes that Pennsylvania is continuing with efforts to enhance the licensing and inspection skills of their staff through attendance at NRC formal training courses, in-house training, and continued close coordination with NRC Region I licensing and inspection staff on a broad range of licensed activities.

The effective date of the Agreement proposed by Pennsylvania is October 1, 2007. However, given the additional time that Pennsylvania used to resolve the staff comments on their formal request for an Agreement, the current schedule as provided for in FSME Procedure SA-700 "Processing an Agreement," would result in an Agreement approximately four weeks later than the date proposed by Pennsylvania. The current schedule is provided as background information to this paper. Once the staff confirms the assurances provided by Pennsylvania concerning staff training and qualifications, and following the public comment period and the resolution of public comments, the NRC staff will be prepared to recommend that the Commission approve the proposed Agreement. The NRC staff will include an updated schedule (including a revised effective date for the Agreement, if appropriate), along with an analysis of the public comments, as part of the final paper to the Commission recommending approval of the Pennsylvania Agreement request.

As required by Section 274e of the Act, the NRC staff will publish the proposed Agreement for comment in the FR once each week for four consecutive weeks. The FR Notice (Enclosure 5) will include a summary of the staff's draft assessment of the proposed Pennsylvania regulatory program for regulation of 11e.(1), 11e.(3), and 11e.(4) byproduct materials, source materials, special nuclear materials in quantities not sufficient to form a critical mass, and land disposal of all waste for such materials, in

addition to the text of the proposed Agreement. The staff plans to follow the same process for Pennsylvania as it did for Minnesota, Utah, Wisconsin, and Oklahoma. For these Agreements, the NRC staff published the proposed Agreements in the FR for public comment, in parallel with the Commission's review of the staff's draft assessment. Once approved by the Commission, the final Agreement will be published in the *Federal Register* within 30 days after signature by the Chairman and the Governor.

The Pennsylvania Department of Environmental Protection (DEP) has the requisite authority to promulgate rules for protection against radiation. The NRC staff verified that the Pennsylvania DEP adopted the relevant NRC regulations in 10 CFR Parts 19, 20, 30, 31, 32, 33, 34, 35, 36, 39, 40, 70, 71, and 150 into Pennsylvania Code Title 25, Environmental Protection by reference. The NRC staff also verified that Pennsylvania adopted the relevant NRC regulations in 10 CFR Part 61 into Pennsylvania Code Title 25, Environmental Protection. The NRC staff has also approved an order, which Pennsylvania will issue, to implement Increased Controls requirements for risk-significant radioactive materials for certain Pennsylvania licensees under the proposed Agreement. This order will replace the order that NRC issued (EA-05-090) to these licensees that will transfer to Pennsylvania. As a result of the renumbering of 10 CFR Part 71 in 2004, Pennsylvania is proceeding with necessary revisions to their regulations to ensure compatibility, and these revisions will be effective by October 1, 2007. Therefore, on the proposed effective date of the Agreement, Pennsylvania will have adopted an adequate and compatible set of radiation protection regulations that apply to byproduct, source, and special nuclear materials in quantities not sufficient to form a critical mass. The NRC staff also verified that Pennsylvania will not attempt to enforce regulatory matters reserved to the Commission.

Pennsylvania currently regulates the users of naturally-occurring and accelerator-produced radioactive materials (NARM). The Energy Policy Act of 2005 (EPAct) expanded the Commission's regulatory authority over byproduct materials as defined in Sections 11e.(3) and 11e.(4) of the Act, to include certain naturally-occurring and accelerator-produced radioactive materials. On August 31, 2005, the Commission issued a time-limited waiver (70 FR 51581) of the EPAct requirements. Under the proposed Agreement, Pennsylvania would assume regulatory authority for these radioactive materials. Therefore, if the proposed Agreement is approved, the Commission would terminate the time-limited waiver in Pennsylvania coincident with the effective date of the Agreement.

If the proposed Agreement is approved, approximately 690 NRC licenses would be transferred to Pennsylvania's jurisdiction. In addition, Pennsylvania would retain regulatory authority for approximately 460 NARM licenses.

RESOURCES:

The Commonwealth of Pennsylvania has a proposed effective date for the Agreement of October 1, 2007. NRC Region I has sufficient resources budgeted within the Materials Users subprogram (Materials Licensing and Materials Inspection planned activities) to perform materials licensing, inspection, decommissioning, enforcement, allegation casework and transition activities related to Pennsylvania through a portion of FY 2008, in the event that the October 1, 2007, date is not met. These resources are estimated to be approximately 3 FTE for a portion of FY 2008.

CONCLUSION:

The NRC staff concludes that, except as discussed in criterion 20, Qualifications of Regulatory and Inspection Personnel, of the draft NRC staff assessment (Enclosure 6) of the proposed program, the

Commonwealth of Pennsylvania satisfies the criteria in the Commission's policy statement, and therefore, meets the requirements of Section 274 of the Act. The proposed Pennsylvania program to regulate Agreement materials, as comprised of statutes, regulations, and procedures, 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. With respect to criterion 20, once the NRC staff confirms the assurances provided by Pennsylvania concerning staff training and qualifications, the staff will be able to conclude that criterion 20 is satisfied.

COMMITMENTS:

Listed below are the actions or activities committed to by the staff in this paper.

1. The staff plans to confirm the assurances that Pennsylvania provided in their response to the NRC's comment letter concerning staff training and qualifications.

2. The staff will provide an updated schedule and an analysis of public comments along with the final paper to the Commission, requesting approval of the proposed Agreement.

RECOMMENDATIONS:

That the Commission:

1. Approve:

   Publication of the FR Notice once a week for four consecutive weeks, as required by the Act.

2. Review:

   The proposed Agreement between the Commonwealth of Pennsylvania and the NRC pursuant to Section 274 of the Act, and the draft of the NRC staff assessment of the Pennsylvania regulatory program, in parallel with the publication of the proposed Agreement in the FR.

3. Note:

   a. The staff will place a copy of the NRC Staff Draft Assessment (summarized in the *FR* Notice) in the NRC's Public Electronic Reading Room on the Internet at http://www.nrc.gov/NRC/ADAMS/index.html, and into Agencywide Documents Access and Management System.

   b. The Office of Congressional Affairs will dispatch a letter to the cognizant Congressional Committees informing them that the Commission is considering entering into an amended Agreement with the Commonwealth.

   c. The Office of Public Affairs will issue a press release.

   d. FSME will dispatch a letter to the Federal Agencies listed in FSME Procedure SA-700 and all of the States.

COORDINATION:

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

/RA/

Luis A. Reyes
Executive Director
for Operations

Enclosures:
1. Letter from Governor Rendell to Chairman Klein dated November 9, 2006
2. Acknowledgment Letter from Chairman Klein to Governor Rendell dated January 9, 2007
3. Letter from Charles L. Miller to David J. Allard dated January 26, 2007
4. Letter from David J. Allard to Charles L. Miller dated March 16, 2007
5. Draft *Federal Register* Notice, including the Summary of the Draft Staff Assessment and the Proposed Agreement
6. Draft NRC Staff Assessment of the Proposed Pennsylvania Byproduct Materials Program

Include as background material:
a. Draft Letter to Congress
b. Draft Press Release
c. Letter to Federal Agencies for Signed Agreement

Press Release for Publication of Proposed Agreement

NRC CONSIDERING REQUEST BY MINNESOTA TO BE AN "AGREEMENT STATE"

The Nuclear Regulatory Commission is considering a request from the governor of Minnesota to assume part of the NRC's regulatory authority over certain nuclear materials in the state. If the request is accepted, Minnesota will become the 34th state to sign such an agreement with the NRC.

Under the proposed agreement, the NRC would transfer to Minnesota the responsibility for licensing, rulemaking, inspection and enforcement activities for: (1) radioactive materials produced as a byproduct of processes related to the production or utilization of special nuclear material (SNM); (2) source material (uranium and thorium); and (3) SNM in quantities not sufficient to support a nuclear chain reaction.

If the agreement is approved, approximately 167 NRC licenses, many of them for medical and industrial uses, would be transferred to Minnesota's jurisdiction. The NRC would retain jurisdiction over a number of activities identified in 10 CFR Part 150, including regulation of commercial nuclear power plants and federal agencies using certain nuclear material in the state. In addition, NRC would retain authority for the review, evaluation and approval of sealed sources and devices containing certain nuclear materials within the state.

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

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

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

FR Notice of Proposed Agreement

NUCLEAR REGULATORY COMMISSION

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

AGENCY: Nuclear Regulatory Commission.

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

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

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

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

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

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

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

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

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

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

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

I. Background

(a) Section 274d of the Act provides the mechanism for a State to assume regulatory authority, from the NRC, over certain radioactive materials[1] and activities that involve use of the materials.

In a letter dated June 22, 1998, Governor Voinovich certified that the State of Ohio has a program for the control of radiation hazards that is adequate to protect public health and safety within Ohio for the materials and activities specified in the proposed Agreement, and that the State desires to assume regulatory responsibility for these materials and activities. Included with the letter was the text of the proposed Agreement, which is shown in Appendix A to this notice.

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

NOTE to USERS: Add 11e.(3) and 11e.(4) materials to this paragraph.

The radioactive materials and activities (which together are usually referred to as the "categories of materials") which the State of Ohio requests authority over are:
(1) the possession and use of byproduct materials as defined in Section 11e.(1) of the Act; (2) the generation, possession, use, and disposal of byproduct materials as defined in Section 11e.(2) of the Act; (3) the possession and use of source materials; (4) the possession and use of special nuclear materials in quantities not sufficient to form a critical mass; (5) the regulation of the land disposal of byproduct materials as defined in Section 11e.(1) of the Act, source, or special nuclear waste materials received from other persons; and (6) the evaluation of radiation safety information on sealed sources or devices containing byproduct materials as defined in Section 11e.(1) of the Act, source, or special nuclear materials and the registration of the sealed sources or devices for distribution, as provided for in regulations or orders of the Commission.

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

(c) Ohio currently regulates the users of naturally-occurring and accelerator-produced radioactive materials. The regulatory program is authorized by law in Section 3748 of the Ohio Revised Code. Subsection 3748.03 provides the authority for the Governor to enter into an Agreement with the Commission. Ohio law contains provisions for the orderly transfer of regulatory authority over affected licensees from NRC to the State. After the effective date of the Agreement, licenses issued by NRC would continue in effect as Ohio licenses until the licenses expire or are replaced by State issued licenses. NRC licenses transferred to Ohio which contain requirements for decommissioning and express an intent to terminate the license when decommissioning has been completed in accordance with a Commission approved decommissioning plan will continue as Ohio licenses and will be terminated by Ohio when the Commission approved decommissioning plan has been completed.

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

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

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

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

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

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

The Bureau currently has staff vacancies, which it is actively recruiting to fill. In response to NRC comments, the Bureau performed, and NRC staff reviewed, an analysis of the expected Bureau workload under the proposed Agreement. Based on the analysis, Ohio has made three commitments. First, the Bureau will employ a staff of at least 21 full-time professional/technical employees for the agreement materials program. Second, the distribution of the qualifications of the individual staff members will be balanced to the distribution of categories of licensees transferred from NRC. For example, there will be enough inspectors trained and qualified to inspect industrial radiography operations that the program will be able to inspect all of the

industrial radiography licensees transferred from NRC without developing a backlog of overdue inspections. Third, each individual on the staff will be qualified in accordance with the Bureau's training and qualification procedure (including use of interim qualification) to function in the areas of responsibility to which the individual is assigned. In the case of individuals assigned to review radiation safety information on sealed sources or devices containing byproduct materials as defined in Section 11e.(1) of the Act, source, or special nuclear materials, this commitment includes assuring that the individuals will be able to:
--Understand and interpret, if necessary, appropriate prototype tests that ensure the integrity of the products under normal, and likely accidental, conditions of use,
--Understand and interpret test results,
--Read and understand blueprints and drawings,
--Understand how the device works and how safety features operate,
--Understand and apply appropriate regulations,
--Understand the conditions of use,
--Understand external dose rates, source activities, and nuclide chemical form, and
--Understand and utilize basic knowledge of engineering materials and their properties.

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

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

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

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

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

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

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

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

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

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

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

(i) Cooperation with Other Agencies. Ohio law deems the holder of an NRC license on the effective date of the proposed Agreement to possess a like license issued by Ohio. The law provides that these former NRC licenses will expire either 90 days after receipt from the radiation control program of a notice of expiration of such license or on the date of expiration specified in the NRC license, whichever is later. In the case of NRC licenses that are terminated under restricted conditions pursuant to 10 CFR 20.1403 prior to the effective date of the proposed Agreement, Ohio deems the termination to be final despite any other provisions of State law or rule. For NRC licenses that, on the effective date of the proposed Agreement, contain a license condition indicating intent to terminate the license upon completion of a Commission approved decommissioning plan, the transferred license will be terminated by Ohio in accordance with the plan so long as the licensee conforms to the approved plan.

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

III. Staff Conclusion

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

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

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

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

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

IV. Small Business Regulatory Enforcement Fairness Act

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

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

For the Nuclear Regulatory Commission.
_____, Director
Office of State and Tribal Programs

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

(Insert the Text of the Proposed Agreement Here)

Congressional Letter Announcing Proposed Agreement

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

Dear Mr. Chairman:

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

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

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

Sincerely,

_____, Director
Office of Congressional Affairs

Enclosure:
As stated

IDENTICAL LETTERS TO:

{Contact OCA to obtain a current list of names}

Federal Agency Letter Announcing Publication of Proposed Agreement

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

Dear Mr. ___:

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

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

Sincerely,

_____, Director
Division of Materials Safety
and State Agreements
Office of Federal and State Materials and
Environmental Management Programs

Enclosure:
Federal Register Notice

* name from yellow book

Identical letters to: {names from yellow book}

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

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

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

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

NOTE to USERS: Add Department of Homeland Security to the list of Agencies to notify.

ALL AGREEMENT AND
NON-AGREEMENT STATES

Commission Paper to Approve Proposed Agreement

POLICY ISSUE
NOTATION VOTE

FOR: The Commissioners

FROM: Luis A. Reyes
Executive Director for Operations

SUBJECT: SECTION 274b AGREEMENT WITH THE STATE OF MINNESOTA

PURPOSE:

To request Commission approval of the proposed Agreement with the State of Minnesota.

BACKGROUND:

The Governor of Minnesota requested that the Commission enter into an Agreement under Section 274b of the Atomic Energy Act of 1954, as amended (Act). The Commission, through SECY-05-0170, "Proposed Agreement Between the State of Minnesota and the Commission Pursuant to Section 274 of the Atomic Energy Act of 1954, as Amended," agreed to publish a notice of the proposed Agreement (Enclosure 1) in the Federal Register (FR). The notice was published as required by the Act and comments were requested. The public comment period ended on December 9, 2005, and no comments were received.

In SECY-05-0170, staff presented a draft of its assessment of the Minnesota Agreement and discussed the statutory and policy background of the Agreement State program. The Commission approved the staff's recommendation to proceed with processing the State of Minnesota Agreement application in the Staff Requirements Memorandum (SRM) dated November 3, 2005. As required by Section 274e of the Act, the proposed Agreement was published in the FR on November 9, 2005 (70 FR 68102), November 16, 2005 (70 FR 69609), November 23, 2005 (70 FR 70894) and November 30, 2005 (70 FR 71863). The full text of the staff assessment was made available at the U.S. Nuclear Regulatory Commission's (NRC) Agencywide Documents Access and Management System (ADAMS) and Public Electronic Reading Room.

CONTACTS: Kathleen Schneider, STP
415-2320

Aaron McCraw, STP
415-1277

SECY PAPER TO BE RELEASED TO PUBLIC 5 DAYS AFTER DISPATCH OF LETTER TO THE GOVERNOR.

The Agreement will allow the State of Minnesota to assume regulatory authority for: (1) byproduct materials as defined in 11e.(1) of the Act; (2) source materials; and (3) special nuclear materials in quantities not sufficient to form a critical mass. Minnesota is not seeking authority to: (a) conduct safety evaluations of sealed sources and devices manufactured in Minnesota and distributed in interstate commerce; (b) regulate the disposal of low-level radioactive waste at a land disposal site as described in 10 CFR Part 61; or (c) regulate 11e.(2) byproduct material resulting from the extraction or concentration of source material from ore processed primarily for its source material content, and its management and disposal.

DISCUSSION:

(1) Public Comments

No comments on the proposed Agreement were received as of the date of this paper. The comment period expired on December 9, 2005.

(2) SECY-05-0170

In the November 2, 2005, Staff Requirements Memorandum, the Commission directed the staff to address two editorial changes in the Draft Staff Assessment. These changes were addressed and are reflected in the version of the Draft Staff Assessment referenced in the FR notice on the proposed Agreement.

(3) Transfer of Licenses

Currently, there are approximately 150 NRC licensees in Minnesota. Staff has identified approximately 150 licenses that will be transferred to the State in whole or in part. NRC will retain one license which was issued to a Federal agency.

Staff is working with the Minnesota Radiation Control Unit (RCU) staff to effect a smooth transition. The staff has coordinated with the RCU staff on current or pending licensing, inspection, and enforcement activities involving the licenses 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 Investigations has one pending investigation which may result in an escalated enforcement action against a Minnesota licensee. The Region III office anticipates that this case will be referred to the Office of Enforcement (OE) for final action before the Agreement becomes effective; however, final resolution of this case remains with NRC and may occur after the Agreement becomes effective. OE has no other current or pending enforcement actions or confirmatory action letters against licensees.

(5) Effective Date of the Agreement

The NRC and RCU staffs have targeted March 31, 2006, as the effective date for the Agreement. As noted in SECY-05-0170, Minnesota staff indicated that they do not want Minnesota licensees to receive two fee bills during the year the Agreement is effective. Therefore, Minnesota staff indicated that, if the Agreement effective date is after March 31, 2006, Minnesota would request NRC to delay the effective date until September 1, 2006, to eliminate billing of Minnesota licensees by both NRC and Minnesota. To meet the March 31, 2006, effective date, and provide adequate time for signing of the Agreement, an orderly transfer of files, and assumption of authority by Minnesota, it would be most efficient if the Commission would issue the SRM on this paper by February 17, 2006.

IMPLEMENTATION:

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

An orientation meeting between NRC and RCU staff will be tentatively scheduled for nine months after the effective date of the Agreement to discuss the initial program implementation. The first Integrated Materials Performance Evaluation Program (IMPEP) review of the Minnesota Agreement State program will be tentatively scheduled for 18 months after the effective date of the Agreement. Subsequent routine IMPEP reviews will occur at 4-year intervals. The interval may be shortened if performance weaknesses are identified during routine reviews or other interactions with the State.

In addition, by way of a memorandum dated December 9, 2005, the staff informed the Commission that the State of Minnesota committed to issue, inspect, and enforce the increased controls for Minnesota licensees at the time the Section 274b Agreement becomes effective.

If approved by the Commission, Minnesota will bring the number of Agreement States to 34.

RESOURCES:

Resources for transfer of licenses are allocated within the current NRC budget.

COORDINATION:

This paper has been coordinated with the Office of the General Counsel, which has no legal objection. The Office of the Chief Financial Officer has reviewed this paper for resource implications and has no objections. Staff has obtained concurrence from the Office of

Management and Budget that this action does not constitute a "major rule" under the Small Business Regulatory Enforcement and Fairness Act of 1996 (SBREFA).

RECOMMENDATIONS:

That the Commission:

1. Find:

   a. That the proposed Minnesota program for the regulation of byproduct material, source material, and special nuclear material 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 Minnesota 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 Minnesota and the NRC pursuant to Section 274 of the Act, as set forth in Enclosure 1.

   b. The proposed Agreement by February 17, 2006, 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 Minnesota on March 31, 2006.

3. Note:

   a. The Governor of Minnesota does not desire to sign the Agreement in a formal ceremony. Three formal copies of the Agreement will be provided, upon approval by the Commission, for signature by the Chairman then forwarded for signature by the Governor of Minnesota.

   b. Pursuant to the Act, SBREFA and Commission guidance, the Speaker of the House of Representatives, the President of the Senate, the Minnesota Congressional delegation and the director of the General Accounting Office will be informed of the Commission's decision.

   c. The Office of Public Affairs will issue a press release.

d. The text of the Agreement will be published in the FR as required by Section 274e of the Act, within 30 days after the Agreement is signed (Enclosure 4).

/RA/

Luis A. Reyes
Executive Director
for Operations

Enclosures:
1. Proposed Agreement
2. NRC Staff Assessment of the Minnesota Program
3. Draft Letter to Minnesota Governor
4. Draft Federal Register Notice of Agreement Signing

Include as background:
a. Draft Press Release
b. Draft Congressional Letters

FR Notice of Signed Agreement

U. S. Nuclear Regulatory Commission

State of Minnesota: Discontinuance of Certain Commission Regulatory Authority Within the State; Notice of Agreement Between the NRC and the State of Minnesota

AGENCY: U. S. Nuclear Regulatory Commission.

ACTION: Notice of Agreement between the NRC and the State of Minnesota.

SUMMARY: This notice is announcing that on February 3, 2006, Dr. Nils J, Diaz, Chairman of the U. S. Nuclear Regulatory Commission (NRC), and on March 2, 2006, Governor Tim Pawlenty of the State of Minnesota signed an Agreement as authorized by Section 274b. of the Atomic Energy Act of 1954, as amended (Act). The Agreement provides for the Commission to discontinue its regulatory authority and for Minnesota to assume regulatory authority over the possession and use of byproduct material as defined in Section 11e.(1) of the Act, source material, and special nuclear materials (in quantities not sufficient to form a critical mass). Under the Agreement, a person in Minnesota possessing these materials is exempt from certain Commission regulations. The exemptions have been previously published in the Federal Register (FR) 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: Aaron T. McCraw, Office of State and Tribal Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Telephone (301) 415-1277; e-mail ATM@NRC.GOV.

SUPPLEMENTARY INFORMATION: The draft Agreement was published in the FR for

comment once a week for four consecutive weeks (see, e.g., 70 FR 68102, November 9, 2005) as required by the Act. The public comment period ended on December 9, 2005. The Commission received no comments. The proposed Minnesota Agreement is consistent with Commission policy and thus meets the criteria for an Agreement with the Commission.

After considering the request for an Agreement by the Governor of Minnesota, the supporting documentation submitted with the request for an Agreement, and its interactions with the staff of the Minnesota Department of Health, the NRC staff completed an assessment of the Minnesota program. A copy of the staff assessment was made available in the NRC's Public Document Room (PDR) and electronically on NRC's web site. Based on the staff's assessment, the Commission determined on January 26, 2006, that the proposed Minnesota program for control of radiation hazards is adequate to protect public health and safety, and compatible with the Commission's program.

Documents may be examined, and/or copied for a fee, at the NRC's PDR, located at One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland. Documents referred to in this notice and other publicly available documents are available electronically at the NRC's Public Electronic Reading Room on the Internet at the NRC web site, http://www.nrc.gov/reading-rm/adams.html. From this site, the public can gain entry into the NRC's Agencywide Document Access and Management System (ADAMS), which provides text and image files of NRC's public documents. If you do not have access to ADAMS or if there

are problems in accessing the documents located in ADAMS, contact the NRC PDR reference staff at 1-800-397-4209, 301-415-4737 or by e-mail to pdr@nrc.gov.

Dated at Rockville, Maryland, this _____day of _____, 2006.

For the Nuclear Regulatory Commission.

_____

Annette L. Vietti-Cook,

Secretary of the Commission.

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

Press Release for Signed Agreement

NRC COMPLETES MINNESOTA AGREEMENT

TO REGULATE USE OF CERTAIN RADIOACTIVE MATERIALS

The Nuclear Regulatory Commission has completed an agreement with the state of Minnesota to assume part of the agency's regulatory authority over certain radioactive materials in the state. Minnesota becomes the 34th state to sign such an agreement with the NRC. The agreement will become effective March 31, 2006.

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

The NRC will transfer approximately 150 licenses, most for medical and industrial uses of radioactive material, to Minnesota's jurisdiction. The NRC will retain jurisdiction over a number of activities identified in 10 CFR Part 150, including regulation of commercial nuclear power plants and federal agencies using certain nuclear material in the state. In addition, NRC will retain authority for the review, evaluation and approval of sealed sources and devices

containing certain nuclear materials manufactured in Minnesota and distributed throughout the country.

Before approving the agreement, NRC reviewed Minnesota's radiation control program to ensure it was adequate to protect public health and safety and was compatible with NRC's program for regulating the radioactive materials covered in the agreement. An announcement of the proposed agreement was made in November, inviting comments from the public. No comments were received.

The agreement will be announced shortly in the *Federal Register*. Copies of the agreement, the Governor of Minnesota's request and supporting documents, as well as the NRC staff's assessment will be available through the NRC's ADAMS online document library. Help in using ADAMS is available by contacting the NRC Public Document Room staff at (301) 415-4737 or 1 (800) 397-4209, or by e-mail at PDR@nrc.gov .

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

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Congressional Letter for Signed Agreement

The Honorable George V. Voinovich
Chairman, Subcommittee on Clean Air, Climate Change,
and Nuclear Safety
Committee on Environment and Public Works
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

This is 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 January 26, 2006 approved an Agreement with the State of Minnesota under which the State will assume certain regulatory authority over byproduct materials in Section 11e.(1) of the Act, source materials, and special nuclear materials in quantities not sufficient to form a critical mass. The Agreement was signed by Chairman Nils J. Diaz on February 3, 2006, and by Governor Tim Pawlenty on March 2, 2006. The Agreement will become effective on March 31, 2006.

The proposed Agreement, along with a summary of the U.S. Nuclear Regulatory Commission's assessment of the proposed Minnesota program, was published in the *Federal Register* for public comment as required by Section 274e. of the Act. Copies of the proposed Agreement and supporting documentation were made available for inspection at the Commission's Public Document Room. No public comments were received.

The Commission has determined that the Minnesota 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. U. S. Nuclear Regulatory Commission staff will conduct periodic reviews of the Minnesota program to ensure that the terms of the Agreement continue to be met.

Sincerely,

Rebecca L. Schmidt, Director
Office of Congressional Affairs

cc: Senator Thomas R. Carper

IDENTICAL LETTERS TO:
{OCA to provide current list}

Members of the Minnesota Congressional Delegation

Senators

Representatives

Letter to Federal Agencies for Signed Agreement

Mr. Jonathan L. Snare, Acting Assistant Secretary
Occupational Safety and Health Administration
U. S. Department of Labor
200 Constitution Avenue, N.W.
Washington, DC 20210

Dear Mr. Snare:

This is to advise the Department that under Section 274 of the Atomic Energy Act of 1954, as amended, the U.S. Nuclear Regulatory Commission (NRC) has approved an Agreement with the State of Minnesota. This Agreement transfers to the State the Commission's regulatory authority over byproduct material, source material and special nuclear material in quantities not sufficient to form a critical mass. The Agreement becomes effective on March 31, 2006. Enclosed is a copy of the Agreement for your information.

Sincerely,

/RA/
Janet R. Schlueter, Director
Office of State and Tribal Programs

Enclosure:
As stated

Identical letters to:

_____, Acting Assistant Secretary
Congressional and Intergovernmental Affairs
U. S. Department of Energy N3641
1000 Independence Avenue, S.W.
Washington, DC 20585-0001

_____
Assistant Administrator for Air and Radiation
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

_____, Chairman
Council on Environmental Quality
722 Jackson Place N.W.
Washington, DC 20503-0002

_____, Director
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850-3229

NOTE to USERS: Add Department of Homeland Security to the list of Agencies to notify.

Staff Analysis of Public Comments

STAFF ANALYSIS OF PUBLIC COMMENTS

	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	First Energy Nuclear Operating Company
5	Daniel Swanson	Ohio Radioactive Materials Users Group
6	Ken Lovins	Consultant
7	Richard Sites	Ohio Hospital Association
8	Edward Janzow	Employee - Frontier Technology Corporation
9	Treva Janzow	Employee - Frontier Technology Corporation
10	Dwayne Carl	Employee - Frontier Technology Corporation
11	Toma Caldarea	Employee - Frontier Technology Corporation
12	David Robbins, PhD	Researcher - University of Cincinnati
13	Jerry Lingrel, PhD	Research Professor - University of Cincinnati
14	Victoria Morris, MS	Radiation Safety Officer - U. of Cincinnati
15	Charles Burnham, PhD	Senior Research Associate - U. of Cincinnati
16	Michelle Croyle	Research Associate - University of Cincinnati
17	N. A. Granholm, PhD	Asst. Professor/Researcher - U. of Cincinnati
18	K. J. Kelley, MD	Physician/Researcher - University of Cincinnati
19	Joanne Schneider	Researcher - University of Cincinnati
20	Robert Peterson, Jr.	Radiation Safety Officer - Ohio State University
21	Dave 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. (letter received June 8, 1998 - EDO G980375)	Radiation Safety Officers

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

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

NRC staff response:

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

Also as noted above, the Commission policy statement on the Adequacy and Compatibility of Agreement State Programs provides the flexibility for an Agreement State program to adopt 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 of its rulemaking. She concluded by stating that: "The Department's commitment to public involvement is commendable and is one of the advantages to Ohioans of the State becoming an Agreement State." The Radiation Advisory Council commented that it supports the rules that have been developed by the Bureau.

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

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

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

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 in1997 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 unforseen 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.