## POLICY ISSUE NOTATION VOTE

<u>January 11, 2008</u> <u>SECY-08-0008</u>

FOR: The Commissioners

FROM: Luis A. Reyes

**Executive Director for Operations** 

<u>SUBJECT</u>: SECTION 274b AGREEMENT WITH THE COMMONWEALTH OF

**PENNSYLVANIA** 

#### PURPOSE:

To request Commission approval of the proposed Agreement with the Commonwealth of Pennsylvania (also referred to as Pennsylvania or the Commonwealth). This paper does not address any new commitments.

#### SUMMARY:

On November 9, 2006, Governor Edward G. Rendell of Pennsylvania requested that the Commission enter into an Agreement under Section 274b of the Atomic Energy Act of 1954, as amended (the Act). The Commission, through SECY-07-0083, "Proposed Agreement Between the Commonwealth of Pennsylvania and the Commission Pursuant to Section 274 of the Atomic Energy Act of 1954, as Amended," dated May 17, 2007, agreed to publish a notice of the proposed Agreement (Enclosure 1) in the *Federal Register* (FR). The agency published the notice as required by the Act and requested comments. The public comment period ended on July 18, 2007, and the agency received two comment letters.

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

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SECY NOTE: TO BE MADE PUBLICLY AVAILABLE 5 WORKING DAYS AFTER DISPATCH OF LETTERS.

#### **BACKGROUND**:

In SECY-07-0083, the staff of the U.S. Nuclear Regulatory Commission (NRC) presented a draft of its assessment of the Pennsylvania Agreement program and discussed the statutory and policy background of the Agreement State program. The Commission approved the staff's recommendation to proceed with processing the application for the Pennsylvania Agreement program in the staff requirements memorandum (SRM) dated June 8, 2007. As required by Section 274e of the Act, the agency published the proposed Agreement in the FR on June 18, 2007 (72 FR 33541), June 25, 2007 (72 FR 34728), July 2, 2007 (72 FR 36069) and July 9, 2007 (72 FR 37268). The NRC made the full text of the staff assessment available through its Agencywide Documents Access and Management System (ADAMS) and Public Electronic Reading Room.

The Agreement will allow Pennsylvania to assume regulatory authority for byproduct materials as defined in Sections 11e.(1), 11e.(3), and 11e.(4) of the Act; source materials; special nuclear materials not sufficient to form a critical mass; and land disposal of all waste for such materials. Pennsylvania is not seeking authority to (1) conduct safety evaluations of sealed sources and devices manufactured in Pennsylvania and distributed in interstate commerce or (2) regulate Section 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

The NRC staff received two comment letters in response to a notice that the Governor of Pennsylvania has proposed to enter into an Agreement with the Commission under Section 274b of the Act. The notice appeared in the FR on June 18, June 25, July 2, and July 9, 2007. The notice contained a copy of the proposed Agreement and a summary of the NRC staff's draft assessment of the proposed Pennsylvania Agreement program.

The FR notice requested comments regarding (1) the proposed Agreement (2) the NRC staff assessment of the Pennsylvania Agreement program (3) the adequacy of the Pennsylvania Agreement program and (4) the adequacy of the Pennsylvania Agreement program staff. The comments received primarily addressed the adequacy of the Pennsylvania Agreement program and the adequacy of the Pennsylvania Agreement program staff.

In summary, the comments did not provide any new information that would change the conclusions in the staff assessment of the Pennsylvania Agreement program, and the staff has not changed the assessment in response to the comments. Enclosure 2 contains the staff analysis of public comments.

#### (2) SECY-07-0083

In SECY-07-0083, the NRC staff forwarded to the Commission the staff's conclusion that, except as discussed in criterion 20, "Qualifications of Regulatory and Inspection Personnel," of the draft NRC staff assessment of the proposed program, Pennsylvania satisfies the criteria in the Commission's policy statement and, therefore, meets the requirements of Section 274 of the

Act. The proposed Pennsylvania regulatory program, comprising statutes, regulations, and procedures, is compatible with the Commission's program and is adequate to protect public health and safety with respect to the materials covered by the proposed Agreement. With respect to criterion 20, the NRC staff committed to confirm the assurances provided by Pennsylvania concerning staff training and qualifications before the staff would be able to conclude that criterion 20 is satisfied.

Specifically, the FR notice for the proposed Agreement noted that in the course of the NRC staff's continued interactions with Pennsylvania, the NRC staff planned to verify how Bureau of Radiation Protection (Bureau or BRP) staff fit into the qualification process, which staff members are qualified in certain areas, and the basis for the determinations. The NRC staff conducted an onsite review of Pennsylvania staff training and qualifications between July 30, 2007, and August 2, 2007. The NRC provided the results of the review to the Bureau on August 16, 2007 (ADAMS Accession No. ML072320016).

While onsite, the NRC staff reviewed an updated qualification matrix for Pennsylvania materials inspectors and license reviewers. The matrix identified those materials inspectors and license reviewers who are qualified in certain areas. The NRC staff also examined individual materials inspector and license reviewer qualification journals (which included a review of the bases for qualification determinations) for those staff whom the Bureau currently intends to perform these activities.

The NRC staff identified that the journals were based upon previously approved qualification procedures. However, in several instances, some of the Bureau's procedural requirements necessary to achieve interim qualifications, primarily with respect to the satisfactory completion of formal technical training courses, had not been completed and were not currently scheduled. The NRC staff particularly noted that both inspectors and license reviewers needed additional training in the medical area. Therefore, the NRC staff requested that the Bureau provide a specific plan to implement successfully before signing the Agreement to ensure that the distribution of licensing and inspection staff qualifications is reasonably matched to the anticipated workload under the Agreement. In addition, the NRC staff requested an updated qualification matrix for Pennsylvania materials inspectors and license reviewers, based upon completing the plan.

On November 1, 2007, the NRC staff received the staff training plan and an updated qualification matrix (ADAMS Accession No. ML073120087). The plan now updates that the Commonwealth has provided the missing documentation in its qualification journals identified during the onsite review the week of July 30, 2007. Consequently, the Commonwealth has demonstrated that its staff has equivalent experience to fulfill its qualification requirements in its staffing plan. In addition, in an effort to fill the Bureau's primary gap of a lack of qualified inspectors in the medical area, the Bureau has developed and implemented alternative means to reach its immediate training goals to satisfy criterion 20 before signing the Agreement. For example, the Bureau's regional managers had scheduled training in 2007 with local facilities to enable its inspectors to gain valuable knowledge in the medical area. The Bureau will also continue to send its inspectors to NRC-sponsored training classes as they are scheduled.

The NRC staff concludes that criterion 20 is now satisfied, and as a result, the staff's final assessment (Enclosure 3) of the Pennsylvania program reflects the NRC staff analysis and verification of Pennsylvania staff training and qualifications.

#### (3) Transfer of Licenses

Currently, the NRC would transfer approximately 690 NRC licenses, either in whole or in part, to Pennsylvania's jurisdiction. The NRC will retain jurisdiction for five licenses issued to Federal agencies, Department of the Army, Defense Logistic Agencies, Health and Human Services, and one Veterans Administration.

The NRC staff is continuing to work closely with the BRP staff to effect a smooth transition. The staff is coordinating with the BRP staff on current or pending licensing, inspection, and enforcement activities involving the licenses to be transferred to ensure the smooth continuation of regulatory actions after the transfer.

#### (4) Actions Pending against Licensees To Be Transferred

At the current time, the NRC Office of Investigations has three pending investigations that may result in escalated enforcement actions against NRC licensees located within the Commonwealth. The Office of Enforcement has three other pending enforcement actions against such licensees. Additionally, five allegations are currently open related to NRC licensees within the Commonwealth. The remaining open actions that the NRC is unable to close between now and the effective date of the Agreement will either continue to be handled by the NRC with the involvement of the Commonwealth or will be transferred to the Commonwealth. The NRC will work closely with the Commonwealth on the smooth transition of authority over these open cases before the effective date of the Agreement.

(5) Outstanding Orders, Confirmatory Action letters, and 10 CFR 2.206 Petitions against Licensees that Will Transfer

The NRC issued orders and license conditions for Increased Controls (EA-05-090) to 205 licensees in Pennsylvania based on the quantities of material they are authorized to possess. Of those 205 licensees, approximately 63 licensees are implementing the Increased Controls requirements because of the quantities that they possess. As noted in SECY-07-0083, this Order will transfer to the Commonwealth. The NRC staff has approved an order to implement Increased Controls requirements for risk-significant radioactive materials, which the Commonwealth will issue to the same licensees under the proposed Agreement.

As of December 5, 2007, the NRC issued Orders Imposing Fingerprinting and Criminal History Records Check Requirements for Unescorted Access to Certain Radioactive Materials (EA-07-305) to those licensees who received the Increased Controls requirements. These orders also will transfer to the Commonwealth.

(6) Status of Decommissioning Sites and Method for Providing Information on Previously Licensed Sites

The staff maintains status summaries for all decommissioning sites, including those in Pennsylvania, on NRC's public Web site. The Commission and the public have access to the site summaries through <a href="http://www.nrc.gov/info-finder/decommissioning/complex/">http://www.nrc.gov/info-finder/decommissioning/complex/</a>. Under the Agreement, the NRC would transfer a number of complex decommissioning sites to the Commonwealth—Curtis-Wright Cheswick, Molycorp, Safety Light, Superbolt, Westinghouse (Waltz Mill), Quehanna, and Whittaker.

Although Agreement States are not required to notify the NRC when they terminate material licenses, the staff is currently working with the States to gather information on terminated licenses. The staff's annual report titled, "Status of the Decommissioning Program" summarizes information on Agreement State decommissioning sites. In addition, the staff reviews Agreement State decommissioning program activities as part of the Integrated Materials Performance Evaluation Program (IMPEP).

#### (7) Effective Date of the Agreement

The NRC and BRP staffs have targeted March 31, 2008, as the effective date for the Agreement. The Commonwealth selected this effective date to provide the additional time that the Commonwealth needed to resolve the NRC staff comments on its formal request for an Agreement and the elapsed time the Commonwealth used to complete the steps contained in the milestone schedule provided in the Office of Federal and State Materials and Environmental Management Programs (FSME) Procedure SA-700 "Processing an Agreement." Given the current schedule (Enclosure 4), the March 31, 2008, effective date will provide adequate time for the signing of the Agreement, the orderly transfer of files, and the assumption of authority by Pennsylvania. The Commonwealth has expressed its desire to have the Agreement approved as soon as possible in order to begin hiring and training additional staff. To meet the March 31, 2008, effective date and provide adequate time for the signing of the Agreement, the orderly transfer of the files, and the assumption of authority by the Commonwealth, the staff is requesting the Commission to issue the SRM on this paper before February 1, 2008.

The Commonwealth 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 NARM. On August 31, 2005, the Commission issued a time-limited waiver (70 FR 51581) of the EPAct requirements. Under the proposed Agreement, the Commonwealth will assume regulatory authority for these radioactive materials. Therefore, the time-limited waiver in the Commonwealth will terminate coincident with the effective date of the Agreement, March 31, 2008, in accordance with the "Plan for the Transition of Regulatory Authority Resulting from the Expanded Definition of Byproduct Material" (72 FR 59157).

#### **IMPLEMENTATION**:

Following execution of the Agreement, the staff will continue a program of active interaction with the Commonwealth. The program consists of the exchange of regulatory information, notices of NRC training courses, and periodic onsite reviews of the Commonwealth's program for the 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.

The staff will tentatively schedule an orientation meeting between NRC and BRP staff for 9 months after the effective date of the Agreement to discuss the initial program implementation. The first IMPEP review of the Pennsylvania Agreement 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 Pennsylvania.

If approved by the Commission, Pennsylvania will bring the number of Agreement States to 35.

#### RESOURCES:

Staff estimates approximately 3 full-time equivalents (FTE) are required in Fiscal Year (FY) 2008 to perform materials licensing, inspection, decommissioning, enforcement, allegation casework and transition activities related to Pennsylvania. These resources are included in the FY 2008 budget within the Materials Users subprogram (materials licensing and materials inspection planned activities). FSME anticipates a cost savings due to the transfer of regulatory authority to Pennsylvania, and has incorporated the resource adjustments in the FY 2008 and FY 2009 budgets accordingly.

#### 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. The 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).

#### CONCLUSION:

The NRC staff concludes that the Commonwealth of Pennsylvania satisfies the criteria in the Commission's policy statement "Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory Authority and Assumption Thereof by States Through Agreement," and therefore meets the requirements of Section 274 of the Act. The proposed Pennsylvania program to regulate Agreement program materials, comprising statutes, regulations, and procedures, is compatible with the Commission's program and is adequate to protect public health and safety with respect to the materials covered by the proposed Agreement.

#### **RECOMMENDATIONS:**

That the Commission:

#### 1. <u>Find</u>:

- a. That the proposed Pennsylvania program for the regulation of byproduct material, source material, special nuclear material in quantities not sufficient to form a critical mass, and land disposal of all waste for such materials is compatible with the Commission's program for the regulation of like material; and
- b. That the proposed Pennsylvania program is adequate to protect public health and safety within the Commonwealth with respect to the materials and uses covered by the proposed Agreement.

#### 2. Approve:

a. The proposed Agreement between the Commonwealth of Pennsylvania and the NRC pursuant to Section 274 of the Act, as set forth in Enclosure 1.

b. The proposed Agreement by February 1, 2008, 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 the Commonwealth of Pennsylvania on March 31, 2008.

#### 3. Note:

- a. Approval of the proposed Agreement will result in the termination of the Commission-issued waiver (70 FR 51581) on the effective date of the Agreement, March 31, 2008. The Commonwealth of Pennsylvania would then assume regulatory authority over NARM.
- b. The Governor of Pennsylvania desires to sign the Agreement in a formal ceremony. Additional details regarding the formal ceremony will be provided, following approval of the proposed Agreement by the Commission (Enclosure 5).
- c. Pursuant to the Act, SBREFA, and Commission guidance, the staff will inform the Speaker of the House of Representatives, the President of the Senate, the Pennsylvania congressional delegation, and the director of the Government Accountability Office of the Commission's decision.
- d. The NRC Office of Public Affairs will issue a press release.
- e. The agency will publish the text of the Agreement in the FR, as required by Section 274e of the Act, within 30 days after the Agreement is signed (Enclosure 6).

/RA By Bruce S. Mallett Acting For/

Luis A. Reyes Executive Director for Operations

#### Enclosures:

- Proposed Agreement between the NRC and the Commonwealth of Pennsylvania
- 2. Staff Analysis of Public Comments
- 3. NRC Staff Assessment of the Pennsylvania Program
- 4. Current Milestone Schedule for Processing the Proposed Agreement
- 5. Draft Letter from Chairman Dale E. Klein to Governor Edward G. Rendell
- 6. Draft *Federal Register* Notice of Agreement Signing

## **ENCLOSURE 1**

# PROPOSED AGREEMENT BETWEEN THE NRC AND THE COMMONWEALTH OF PENNSYLVANIA

## AN AGREEMENT BETWEEN THE UNITED STATES NUCLEAR REGULATORY COMMISSION AND

## THE COMMONWEALTH OF PENNSYLVANIA FOR THE

## DISCONTINUANCE OF CERTAIN COMMISSION REGULATORY AUTHORITY AND

## RESPONSIBILITY WITHIN THE COMMONWEALTH PURSUANT TO SECTION 274 OF THE ATOMIC ENERGY ACT OF 1954, AS AMENDED

WHEREAS, The United States Nuclear Regulatory Commission (the Commission) is authorized under Section 274 of the Atomic Energy Act of 1954, as amended, 42 U.S.C. § 2011 *et seq.* (the Act), to enter into agreements with the Governor of any State/Commonwealth providing for discontinuance of the regulatory authority of the Commission within the State/Commonwealth under Chapters 6, 7, and 8, and Section 161 of the Act with respect to byproduct materials as defined in Sections 11e.(1), 11e.(3), and 11e.(4) of the Act, source materials, and special nuclear materials in quantities not sufficient to form a critical mass; and,

WHEREAS, The Governor of the Commonwealth of Pennsylvania is authorized under the Pennsylvania Radiation Protection Act of July 10, 1984, P.L. 688, No. 147, as amended, 35 P.S. § 7110.101 *et seq.*, to enter into this Agreement with the Commission; and,

WHEREAS, The Governor of the Commonwealth of Pennsylvania certified on November 8, 2006, that the Commonwealth of Pennsylvania (the Commonwealth) has a program for the control of radiation hazards adequate to protect public health and safety with respect to the materials within the Commonwealth covered by this Agreement, and that the Commonwealth desires to assume regulatory responsibility for such materials; and,

WHEREAS, The Commission found on **[date]** that the program of the Commonwealth for the regulation of the materials covered by this Agreement is compatible with the Commission's program for the regulation of such materials and is adequate to protect public health and safety; and.

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

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

WHEREAS, This Agreement is entered into pursuant to the provisions of the Act;

NOW, THEREFORE, It is hereby agreed between the Commission and the Governor of the Commonwealth acting on behalf of the Commonwealth as follows:

#### ARTICLE I

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

- 1. Byproduct materials as defined in Section 11e.(1) of the Act;
- 2. Byproduct materials as defined in Section 11e.(3) of the Act;
- 3. Byproduct materials as defined in Section 11e.(4) of the Act;
- 4. Source materials:
- 5. Special nuclear materials in quantities not sufficient to form a critical mass;
- 6. The regulation of the land disposal of all byproduct, source, and special nuclear waste materials covered by this Agreement.

#### ARTICLE II

This Agreement does not provide for discontinuance of any authority and the Commission shall retain authority and responsibility with respect to the following:

- 1. The regulation of the construction and operation of any production or utilization facility or any uranium enrichment facility;
- 2. The regulation of the export from or import into the United States of byproduct, source, or special nuclear material, or of any production or utilization facility:
- 3. The regulation of the disposal into the ocean or sea of byproduct, source, or special nuclear materials waste as defined in the regulations or orders of the Commission:
- 4. The regulation of the disposal of such other byproduct, source, or special nuclear materials waste as the Commission from time to time determines by regulation or order should, because of the hazards or potential hazards thereof, not be disposed without a license from the Commission;
- 5. The evaluation of radiation safety information on sealed sources or devices containing byproduct, source, or special nuclear materials and the registration of the sealed sources or devices for distribution, as provided for in regulations or orders of the Commission.

#### ARTICLE III

With the exception of those activities identified in Articles II.1 through II.4, this Agreement may be amended, upon application by the Commonwealth and approval by the Commission, to include one or more of the additional activities specified in Article II, whereby the

Commonwealth may then exert regulatory authority and responsibility with respect to those activities.

#### **ARTICLE IV**

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

#### ARTICLE V

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

#### ARTICLE VI

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

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

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

#### **ARTICLE VII**

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

#### **ARTICLE VIII**

The Commission, upon its own initiative after reasonable notice and opportunity for hearing to the Commonwealth, or upon request of the Governor of the Commonwealth, may terminate or suspend all or part of this Agreement and reassert the licensing and regulatory authority vested in it under the Act if the Commission finds that (1) such termination or suspension is required to protect public health and safety, or (2) the Commonwealth has not complied with one or more of the requirements of Section 274 of the Act. The Commission may also, pursuant to Section

274j of the Act, temporarily suspend all or part of this Agreement if, in the judgment of the Commission, an emergency situation exists requiring immediate action to protect public health and safety and the Commonwealth has failed to take necessary steps. The Commission shall periodically review actions taken by the Commonwealth under this Agreement to ensure compliance with Section 274 of the Act which requires a Commonwealth program to be adequate to protect public health and safety with respect to the materials covered by this Agreement and to be compatible with the Commission's program.

#### **ARTICLE IX**

This Agreement shall become effective on March 31, 2008, and shall remain in effect unless and until such time as it is terminated pursuant to Article VIII.

Done at [City, State] this [date] day of [month], [year].

REGULATORY COMMISSION		
Dale E. Klein, Chairman		
FOR THE COMMONWEALTH OF PENNSYLVANIA		
Edward G. Rendell, Governor		

FOR THE UNITED STATES NUCLEAR

## **ENCLOSURE 2**

STAFF ANALYSIS OF PUBLIC COMMENTS

## STAFF ANALYSIS OF PUBLIC COMMENTS ON THE PROPOSED PENNSYLVANIA AGREEMENT

	<u>Commentors</u> :	Affiliation:
1	Frank J. Trembulak Jack Sprat	Executive Vice President, Geisinger Health System Member of the public

#### **INTRODUCTION:**

The U.S. Nuclear Regulatory Commission (NRC) staff received two comment letters in response to a notice that the Governor of Pennsylvania has proposed to enter into an Agreement with the Commission under Section 274b of the Atomic Energy Act of 1954, as amended. The agency published the notice in the *Federal Register* on June 18, June 25, July 2, and July 9, 2007. The notice contained a copy of the proposed Agreement and a summary of the NRC staff's draft assessment of the proposed Pennsylvania Agreement program.

The Federal Register notice requested comments in four categories—(1) the proposed Agreement, (2) the NRC staff assessment of the Pennsylvania Agreement program, (3) the adequacy of the Pennsylvania Agreement program, and (4) the adequacy of the Pennsylvania Agreement program staff. The comments received primarily addressed the adequacy of the Pennsylvania Agreement program and program staff

#### ADEQUACY OF THE PENNSYLVANIA AGREEMENT PROGRAM

(1) Enforcement Policies

#### **Summary of Comments**:

One commenter expressed concern about Pennsylvania's enforcement policies. The commenter urged the NRC to require Pennsylvania to have structured written guidance on how to respond to cases of deliberate misconduct with a philosophy that "must be prescriptive against civil penalty and 100% related to achieving common goals." The commenter recommends that the Agreement include specific language to ensure that Pennsylvania exercises the same approach to self-identified violations as the NRC, provides fair and impartial treatment of licensees, and protects "licensees against excessive enforcement action."

#### NRC Staff Response:

The NRC staff conducted a detailed evaluation of the Pennsylvania enforcement program description and procedures submitted in support of the Commonwealth's request for an Agreement. The evaluation used the process and criteria contained in Section 4.5 of the agency's "Handbook for Processing an Agreement," which is an appendix to Office of Federal and State Materials and Environmental Management Programs (FSME) Procedure SA-700 (hereafter referred to as the Handbook). Based on this evaluation, the staff concludes that criterion 19 of the NRC staff's draft assessment published in the *Federal Register* is satisfied.

The NRC does not require an Agreement State to exercise enforcement in the same manner as the agency does. Since Agreement States exercise their regulatory authority under their own State law, rather than the Atomic Energy Act, State enforcement policies and procedures must be consistent with State law. The NRC reviewed Pennsylvania's enforcement authority to confirm that the State is able to take effective enforcement action for violations of regulatory requirements to ensure regulatory compliance and that it provides an appeal process. This comment does not provide new information that would modify the conclusions of the staff's draft assessment. Consequently, the staff did not change the assessment as a result of this comment.

#### (2) Inspection Policies

#### **Summary of Comments:**

The letter from a commenter expressed concern that Pennsylvania's approach to inspections is not risk-informed and performance-based, but that it is "geared toward finding as many violations as possible." The commenter recommends that the Agreement include a provision that requires Pennsylvania to conduct risk-informed and performance-based inspections. In this context, the commenter also recommends that the NRC establish a "monitoring system overseeing the Commonwealth's performance in all respects of this delegated authority."

#### NRC Staff Response:

At this time, the NRC encourages, but does not require, an Agreement State regulatory program to adopt a risk-informed, performance-based approach as a matter of compatibility. 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 such an approach. Requiring Pennsylvania to do so as part of the Agreement at this time would not be appropriate.

Although it is not required to take a risk-informed, performance-based approach to inspections, Pennsylvania has submitted, as part of its request for an Agreement, inspection procedures that indicate that the Commonwealth is adopting this approach to inspections. For example, Section 2800-02 of Manual Chapter 2800 (part of the Pennsylvania Department of Environmental Protection (DEP) Inspection Manual), states that objectives of the inspection program include describing a performance-based inspection approach and continuing and enhancing risk-informed, relative priorities for routine inspections of all licensees. In addition, Section 2800-05 of Manual Chapter 2800 describes the basic requirements of the materials inspection program. Item 05.01, b.2, of this section states that, during onsite inspection activities, inspectors should use a performance-based approach to evaluate focus areas.

The NRC staff conducted a detailed evaluation of the Pennsylvania inspection program description and procedures submitted in support of the Commonwealth's request for an Agreement. The evaluation used the process and criteria contained in Section 4.4 of the Handbook. Based on this evaluation, the staff concluded that criteria 16-18 of the NRC staff's draft assessment were satisfied. This comment does not provide new information that would modify the conclusions of the staff's draft assessment. Consequently, the staff did not change the assessment as a result of this comment.

It is important to note that, unlike other Federal/State programs, Agreement States do not perform regulatory functions under a delegation of Federal authority. As provided by the Atomic Energy Act, when a State and the NRC enter into an Agreement, the NRC discontinues the exercise of its authority and the State exercises its own authority under compatible State statutes and regulations. Nevertheless, the NRC has responsibility for continuing oversight of Agreement States. After an Agreement takes effect, the Atomic Energy Act requires the NRC to ensure that the State's program remains adequate to protect public health and safety, and compatible with the NRC materials program. The agency carries out this responsibility through the Integrated Materials Performance Evaluation Program, or IMPEP. NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program," governs this program and may be viewed on the NRC Web site at http://nrc-stp.ornl.gov/procedures.html.

#### (3) Program Funding and Planning for Retirements

#### **Summary of Comments:**

The letter from a commenter asked what assurance Pennsylvania has provided that the materials licensing and inspection and decommissioning sections will have an adequate source of funding when the proposed Agreement becomes effective. The commenter also questioned whether Pennsylvania has a "contingency plan or adequate depth to assure continuity of quality service" in the event of potential pending retirements of program staff or Pennsylvania staff subject to "bumping during furloughs."

#### NRC Staff Response:

The NRC staff conducted a detailed evaluation of the Pennsylvania legal elements submitted in support of the Commonwealth's request for an Agreement. The evaluation used the process and criteria contained in Section 4.1 of the Handbook. As part of the NRC staff review of the proposed Agreement request, the staff ensured that Commonwealth law had established a program with a defined structure, that authorizes the Governor to enter into an Agreement with the Commission. The Commonwealth submitted an annual financial summary as part of its formal Agreement request.

The NRC staff notes that annual State budgeting and financial details are not specifically reviewed within FSME Procedure SA-700. Generally, a State only needs to demonstrate that a source of funding is available and sufficient to operate the regulatory program effectively. However, the staff notes that the vast majority of Bureau of Radiation Protection (BRP) staff members are paid by "restricted (fee-based) funds" and are not subject to "furloughs." Regarding annual budget approval in the Commonwealth, 2007 was the first year in more than 15 that a budget was not in place by the beginning of the fiscal year. Only a few staff members in the Radon Division who are paid with U.S. Environmental Protection Agency (EPA) grantmatching "general funds" were subject to and affected by the 1-day furlough in 2007.

The Decommissioning Section staff are funded through the material licensing fees. Through letter agreements, grants, and contracts, direct invoicing of some NRC licensees and the EPA is currently in place. Once Pennsylvania is an Agreement State, the Commonwealth will directly bill those decommissioning facility owners for oversight costs (time and materials). The Commonwealth has indicated that the current regulatory hourly fee is adequate but, that it will raise the fee in the next 12 months, in addition to raising other materials fees, to cover anticipated salary increases over the next 4 years. The NRC's hourly rates are higher because of differences in base salaries and overhead recovery. The Commonwealth estimates that current materials license fees will be close to \$3 million per year, and believes that this amount is adequate to cover current and new staff upon becoming an Agreement State.

The Agreement State program expects that only two or three staff members will be eligible to retire within the first few years following the effective date of the Agreement. The program plans to have a sufficient number of adequately qualified staff members assigned to the Agreement program before the Agreement is signed. In an effort to prepare for future loss of staff (i.e., retirements), the Commonwealth will be in the process of filling approximately 13 of 25 additional positions when the Agreement is signed. This comment does not provide new information that would modify the conclusions of the staff's draft assessment. Consequently, the staff did not change the assessment as a result of this comment.

#### (4) Termination of the Quehanna License

#### **Summary of Comments:**

In the event that the DEP Quehanna license is not terminated before the effective date of the Agreement, one commenter asked what assurance exists that the Pennsylvania Department of Conservation and Natural Resources (PA-DCNR) will agree to a license transfer "in order to avoid a conflict of interest."

#### NRC Staff Response:

The activities to support termination of the Quehanna license are well underway. Specifically, the Quehanna facility is completely decommissioned and the building rubble waste has been shipped to a low-level radioactive waste site in Utah with recent funding from PA-DCNR. A surface water discharge permit was issued by the DEP North Central Regional Office. Subsequently, the decommissioning contractor has started breaking up the concrete pads left onsite into small pieces of rubble and surveying the material for radioactive contamination. When this work is done, the NRC will perform confirmatory radiological surveys at the site. After these surveys are reviewed, the old reactor pool and pits will be filled in, and the onsite soil surfaces will be regraded. At that time, Pennsylvania has indicated that it will request license termination.

If the license termination is not complete by the effective date of the Agreement, Pennsylvania has stated that it will transfer the license to PA-DCNR, the DEP Regional Office, or another organization within the Commonwealth. BRP has indicated that it does not plan to terminate its license until after it has been transferred. Pennsylvania will be responsible for ensuring a level of independence within the Commonwealth to avoid any potential conflict of interest relative to the decommissioning of the Quehanna site. This comment does not provide new information that would modify the conclusions of the staff's draft assessment. Consequently, the staff did not change the assessment as a result of this comment.

#### ADEQUACY OF THE PENNSYLVANIA PROGRAM STAFF

#### Summary of Comments:

A commenter recommended that Pennsylvania adopt a "centralized State-wide approach" to the interpretation and enforcement of Commonwealth regulations regardless of region. The commenter further recommended that the qualifications for Pennsylvania inspectors be equivalent to that of the NRC inspectors.

#### NRC Staff Response:

Based on its assessment and the criteria contained in Sections 4.1 and 4.5 of the Handbook, the NRC staff believes that the Pennsylvania Agreement program will have a sufficient degree of coordination by the Central Office in Harrisburg to ensure fair and consistent treatment of licensees and the public across the Commonwealth.

The NRC staff also conducted a detailed evaluation of the Pennsylvania training and qualification program description and procedures submitted in support of the Commonwealth's request for an Agreement. The evaluation used the process and criteria contained in Section 4.6 of the Handbook.

The NRC staff assessment considered the level of training, both in health physics and in regulatory operations, and the past experience of the BRP staff. As part of the assessment, the NRC staff requested an analysis of the workload that the BRP expects when the Agreement takes effect. The staff compared BRP workload estimates to its own experience with NRC licensees in Pennsylvania. The NRC staff also reviewed the Commonwealth's qualification procedures (which are based on the NRC's qualification procedures), and individual qualification journals, and observation of the performance of the BRP staff participating in NRC training courses during joint inspections by NRC and BRP inspectors and during joint working sessions of NRC and BRP license reviewers.

In the course of an onsite review of staff training and qualifications, the NRC staff noted that some of the BRP procedural requirements necessary to achieve interim qualifications, primarily with respect to the satisfactory completion of formal technical training courses, had not been completed and were not currently scheduled. The NRC staff particularly noted that both inspectors and license reviewers needed additional training in the medical area. Therefore, the NRC staff requested that BRP provide a specific plan that it will implement successfully before signing the Agreement to ensure that the distribution of licensing and inspection staff qualifications is reasonably matched to the anticipated workload under the Agreement. In addition, the NRC staff requested an updated qualification matrix for Pennsylvania materials inspectors and license reviewers based upon completing the plan. On November 1, 2007, the NRC staff received the staff training plan and an updated qualification matrix (Agencywide Documents Access and Management System (ADAMS) Accession No. ML073120087). The NRC staff reviewed the plan and Pennsylvania's commitment to implement these activities before becoming an Agreement State.

Based on the review discussed above and the implementation of the BRP training plan, the NRC staff assessment concludes that BRP will have a sufficient number of adequately qualified staff members assigned to the Agreement program. The NRC believes that the Commonwealth meets the Commission's criteria for entering an Agreement and is capable of carrying out a regulatory program under an Agreement. This comment did not provide new information that would modify the conclusions of the staff's draft assessment. Consequently, the staff did not change the assessment as a result of this comment.

## **ENCLOSURE 3**

## NRC STAFF ASSESSMENT OF THE PENNSYLVANIA PROGRAM

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

This assessment examines the ability of the proposed Pennsylvania Agreement State program (the Pennsylvania program) to regulate the possession, use, and disposal of radioactive materials subject to the Atomic Energy Act of 1954 (the Act), as amended.<sup>1</sup> The U.S. Nuclear Regulatory Commission (NRC) performed this Assessment using the criteria in the Commission's policy statement entitled, "Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory Authority and Assumption Thereof by States Through Agreement" (hereafter referred to as the "criteria")<sup>2</sup> and the Office of Federal and State Materials and Environmental Management Programs (FSME) Procedure SA-700, "Processing an Agreement." The SA-700 procedure appears on the FSME Web site. 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 Pennsylvania program regulating radioactive materials would be located in the Pennsylvania Department of Environmental Protection (PADEP). PADEP is designated by law to be the State radiation control agency. Pennsylvania statute vests PADEP with the authority to issue, amend, inspect, suspend, or revoke licenses; place conditions; and issue orders or assess civil penalties.

PADEP is divided into six deputates, which are subdivided into bureaus. The Bureau of Radiation Protection (BRP), in the Deputate of Waste, Air, and Radiation Management, carries out the radiation control responsibilities. BRP is organized into four divisions—Decommissioning and Surveillance, Radiation Control, Nuclear Safety, and Radon. BRP provides radiological support to the emergency response plan for fixed nuclear facilities. The PADEP Bureau of Laboratories, with support of other agencies if needed, provides laboratory services. Pennsylvania also has six regional offices in the Deputate for Field Operations that are primarily responsible for inspection and compliance activities. All Agreement State regional activities will be conducted under programmatic policies established by the BRP Director.

Under the proposed Agreement, BRP would assume the regulatory responsibility for byproduct, source, and small quantities of special nuclear materials. The licensing of these materials will reside primarily in the BRP Division of Radiation Control (DRC) but the regional offices will also perform some licensing activities. Exceptions include the Low-Level Radioactive Waste Program, which is in the BRP Division of Nuclear Safety, and the decommissioning and environmental surveillance activities, which comprise a separate BRP division. The DRC currently regulates the possession and use of

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<sup>&</sup>lt;sup>1</sup>According to paragraph (a) of Section 274 of the Act, the radioactive materials subject to an Agreement under the Act are byproduct, source, and special nuclear materials. <sup>2</sup>The agency published the NRC Statement of Policy in the *Federal Register* on January 23, 1981 (46 FR 7540-7546); the agency then published a correction on July 16, 1981 (46 FR 36969), and a revision of criterion 9 on July 21, 1983 (48 FR 33376).

naturally occurring and accelerator-produced radioactive materials (NARM), and the use of electronic machine radiation. Again, inspections will be performed primarily out of the PADEP regional offices.

The NRC staff verified that the Pennsylvania's Radiation Protection Program design for distributing regulatory responsibilities to the program staff is similar to designs used successfully in other Agreement States and that all necessary program elements have been addressed.

The staff concludes that this criterion is satisfied.

References: Letter, with attachments, dated November 9, 2006, from Governor Rendell to Chairman Klein, request for an Agreement, Sections 4.1.1 and Section 4.1.2 (Agencywide Documents Access and Management System (ADAMS) Accession Nos. ML063330295, ML070290046, and ML070290041). Letter, with enclosures, dated March 16, 2007, from David Allard to Charles Miller, response to NRC comment letter dated January 26, 2007 (ADAMS Accession Nos. ML070790604, ML070790609, ML070790612, ML070790616, and ML070790620). Pennsylvania Statutes: Radiation Protection Act (35 P.S. §§ 7110.101-7110.703), Low-Level Radioactive Waste Disposal Act (35 P.S. §§ 7130.101-7130.906), and Section 1920-A of the Administrative Code of 1929 (71 P.S. § 510-20).

#### 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.

In conjunction with the rulemaking authority vested in the Environmental Quality Board by Section 302 of the Pennsylvania Radiation Protection Act 1984-147, PADEP has the requisite authority to promulgate rules for protection against radiation.

The NRC staff verified that the Pennsylvania has adopted the relevant NRC regulations in Title 10 Parts 19, 20, 30, 31, 32, 33, 34, 35, 36, 39, 40, 70, 71, and 150, of the *Code of Federal Regulations* into Pennsylvania Code, Title 25, "Environmental Protection," by reference. Therefore, Pennsylvania has 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 staff concludes that this criterion is satisfied.

References: Letter, with attachments, dated November 9, 2006, from Governor Rendell to Chairman Klein, request for an Agreement, Section 4.2 (ADAMS Accession Nos. ML063330295 and ML070260116). Pennsylvania Statutes: Radiation Protection Act (35 P.S. §§ 7110.101-7110.703), Low-Level Radioactive Waste Disposal Act (35 P.S. §§ 7130.101-7130.906), and Section 1920-A of the Administrative Code of 1929 (71 P.S. § 510-20). Pennsylvania regulations: Pennsylvania Code, Title 25, "Environmental Protection."

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.

Pennsylvania, 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 NRC staff verified that Pennsylvania adopted 10 CFR Part 20, "Standards for Protection against Radiation," of the NRC regulations by reference.

The staff concludes that this criterion is satisfied.

References: Letter, with attachments, dated November 9, 2006, from Governor Rendell to Chairman Klein, request for an Agreement, Section 4.2 (ADAMS Accession Nos. ML063330295 and ML070260116). Pennsylvania Statutes: Radiation Protection Act (35 P.S. §§ 7110.101-7110.703), Low-Level Radioactive Waste Disposal Act (35 P.S. §§ 7130.101-7130.906), and Section 1920-A of the Administrative Code of 1929 (71 P.S. § 510-20). Pennsylvania regulations: Pennsylvania Code, Title 25, "Environmental Protection," Chapters 215 and 219.

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 verified that Pennsylvania has adopted the NRC regulations in 10 CFR Part 20, including Subpart C, "Occupational Dose Limits," and Subpart D, "Radiation Dose Limits to Individual Members of the Public," by reference. Pennsylvania 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, Pennsylvania 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, with attachments, dated November 9, 2006, from Governor Rendell to Chairman Klein, request for an Agreement, Section 4.2 (ADAMS Accession Nos. ML063330295 and ML070260116). Pennsylvania Statutes: Radiation Protection Act (35 P.S. §§ 7110.10-7110.703), Low-Level Radioactive Waste Disposal Act (35 P.S. §§ 7130.101-7130.906), and Section 1920-A of the Administrative Code of 1929 (71 P.S. § 510-20). Pennsylvania regulations: Pennsylvania Code, Title 25, "Environmental Protection," Chapters 215 and 219.

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.

The NRC staff verified that Pennsylvania has adopted Subpart F, "Surveys and Monitoring," of 10 CFR Part 20 by reference. Therefore, Pennsylvania 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, with attachments, dated November 9, 2006, from Governor Rendell to Chairman Klein, request for an Agreement, Section 4.2 (ADAMS Accession Nos. ML063330295 and ML070260116). Pennsylvania Statutes: Radiation Protection Act (35 P.S. §§ 7110.101-7110.703), Low-Level Radioactive Waste Disposal Act (35 P.S. §§ 7130.101-7130.906), and Section 1920-A of the Administrative Code of 1929 (71 P.S. § 510-20). Pennsylvania regulations: Pennsylvania Code, Title 25, "Environmental Protection," Chapters 215 and 219.

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 verified that Pennsylvania has adopted the regulations in Subpart J, "Precautionary Procedures," of 10 CFR Part 20 by reference. Therefore, the radiation labels, signs and symbols, as well as the posting and labeling requirements in the Pennsylvania rules, are identical to those contained in the NRC regulations.

The staff concludes that this criterion is satisfied.

References: Letter, with attachments, dated November 9, 2006, from Governor Rendell to Chairman Klein, request for an Agreement, Section 4.2 (ADAMS Accession Nos. ML063330295 and ML070260116). Pennsylvania Statutes: Radiation Protection Act (35 P.S. §§ 7110.101-7110.703), Low-Level Radioactive Waste Disposal Act (35 P.S. §§ 7130.101-7130.906), and Section 1920-A of the Administrative Code of 1929 (71 P.S. § 510-20). Pennsylvania regulations: Pennsylvania Code, Title 25, "Environmental Protection," Chapters 215 and 219.

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 verified that Pennsylvania has adopted 10 CFR Part 19, "Notices, Instructions and Reports to Workers: Inspections and Investigations," by reference. Therefore, the Pennsylvania regulations pertaining to notices, instructions, and reports to workers are identical to the NRC regulations.

The staff concludes that this criterion is satisfied.

References: Letter, with attachments, dated November 9, 2006, from Governor Rendell to Chairman Klein, request for an Agreement, Section 4.2 (ADAMS Accession Nos. ML063330295 and ML070260116). Pennsylvania Statutes: Radiation Protection Act (35 P.S. §§ 7110.101-7110.703), Low-Level Radioactive Waste Disposal Act (35 P.S. §§ 7130.101-7130.906), and Section 1920-A of the Administrative Code of 1929 (71 P.S. § 510-20). Pennsylvania regulations: Pennsylvania Code, Title 25, "Environmental Protection," Chapters 215 and 220.

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

The NRC staff verified that Pennsylvania has adopted Subpart I, "Storage and Control of Licensed Material," of 10 CFR Part 20 by reference. Therefore, the Pennsylvania regulations pertaining to security and control of licensed material are identical to the NRC regulations.

The staff concludes that this criterion is satisfied.

References: Letter, with attachments, dated November 9, 2006, from Governor Rendell to Chairman Klein, request for an Agreement, Section 4.2 (ADAMS Accession Nos. ML063330295 and ML070260116). Pennsylvania Statutes: Radiation Protection Act (35 P.S. §§ 7110.101-7110.703), Low-Level Radioactive Waste Disposal Act (35 P.S. §§ 7130.101-7130.906), and Section 1920-A of the Administrative Code of 1929 (71 P.S. § 510-20). Pennsylvania regulations: Pennsylvania Code, Title 25, "Environmental Protection," Chapters 215 and 219.

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 Part 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 verified that Pennsylvania has adopted Subpart K, "Waste Disposal," of 10 CFR Part 20 by reference. Therefore, the Pennsylvania regulations pertaining to general requirements for waste disposal, including waste classification, transfer and waste manifests applicable to all licensees, are identical to the NRC regulations.

The staff 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 verified that Pennsylvania has promulgated regulations pursuant to Pennsylvania Code, Title 25, "Environmental Protection," 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, "Licensing Requirements for Land Disposal of Radioactive Waste."

The staff concludes that criterion 9(b) is satisfied.

References: Letter, with attachments, dated November 9, 2006, from Governor Rendell to Chairman Klein, request for an Agreement, Section 4.2 (ADAMS Accession Nos. ML063330295 and ML070260116). Pennsylvania Statutes: Radiation Protection Act (35 P.S. §§ 7110.101-7110.703), Low-Level Radioactive Waste Disposal Act (35 P.S. §§ 7130.101-7130.906), and Section 1920-A of the Administrative Code of 1929 (71 P.S. § 510-20). Pennsylvania regulations: Pennsylvania Code, Title 25, "Environmental Protection," Chapters 215, 219, and 236.

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 Pennsylvania has adopted the transportation requirements contained in 10 CFR Part 71, "Packaging and Transportation of Radioactive Material," by reference. Because NRC renumbered 10 CFR Part 71, a few minor changes are needed in the Pennsylvania Code, Title 25, Chapter 215. Pennsylvania has published these changes for public comment and is proceeding through the regulatory process to gain approval by the Pennsylvania Environmental Quality Board in the December 2007 timeframe. Therefore, the Pennsylvania regulations pertaining to the transportation requirements in 10 CFR Part 71 will be fully compatible with the NRC regulations in Title 10 of the *Code of Federal Regulations* before the effective date of the Agreement. Pennsylvania's regulations specifically exempt areas of exclusive NRC jurisdiction.

The staff concludes that this criterion is satisfied.

References: Letter, with attachments, dated November 9, 2006, from Governor Rendell to Chairman Klein, request for an Agreement, Section 4.2 (ADAMS Accession Nos. ML063330295 and ML070260116). Pennsylvania Statutes: Radiation Protection Act (35 P.S. §§ 7110.101-7110.703), Low-Level Radioactive Waste Disposal Act (35 P.S. §§ 7130.101-7130.906), and Section 1920-A of the Administrative Code of 1929 (71 P.S. § 510-20). Pennsylvania regulations: Pennsylvania Code, Title 25, "Environmental Protection," Chapters 215 and 230.

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 verified that Pennsylvania has adopted 10 CFR Parts 19, 20, 30, 31, 32, 33, 34, 35, 36, 39, 40, 70, 71, and 150 by reference. The NRC staff also verified that Pennsylvania adopted the relevant NRC regulations in 10 CFR Part 61 into Title 25 of the Pennsylvania Code. The records and reports referenced in criterion 11 are regulatory requirements in these parts. Therefore, Pennsylvania has adopted the necessary record and reporting requirements.

The staff concludes that this criterion is satisfied.

References: Letter, with attachments, dated November 9, 2006, from Governor Rendell to Chairman Klein, request for an Agreement, Section 4.2 (ADAMS Accession Nos. ML063330295 and ML070260116). Pennsylvania Statutes: Radiation Protection Act (35 P.S. §§ 7110.101-7110.703), Low-Level Radioactive Waste Disposal Act (35 P.S. §§ 7130.101-7130.906), and Section 1920-A of the Administrative Code of 1929 (71 P.S. § 510-20). Pennsylvania regulations: Pennsylvania Code, Title 25, "Environmental Protection."

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 verified that Pennsylvania has adopted 10 CFR 30.34, "Terms and Conditions of Licenses," by reference. Therefore, Pennsylvania regulations provide the radiation control agency with the 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.

The staff concludes that this criterion is satisfied.

References: Letter, with attachments, dated November 9, 2006, from Governor Rendell to Chairman Klein, request for an Agreement, Section 4.2 (ADAMS Accession Nos. ML063330295 and ML070260116). Pennsylvania Statutes: Radiation Protection Act (35 P.S. §§ 7110.101-7110.703), Low-Level Radioactive Waste Disposal Act (35 P.S. §§ 7130.101-7130.906), and Section 1920-A of the Administrative Code of 1929 (71 P.S. § 510-20). Pennsylvania regulations: Pennsylvania Code, Title 25, "Environmental Protection," Chapter 215.

#### PRIOR EVALUATION OF USES OF RADIOACTIVE MATERIALS

13. Prior Evaluation of Hazards and Uses, Exceptions. In the present state of knowledge, it is necessary in regulating the possession and use of byproduct, source and special nuclear materials that the State regulatory authority require the submission of information on, and evaluation of, the potential hazards, and the

capability of the user or possessor prior to his receipt of the materials. This criterion is subject to certain exceptions and to continuing reappraisal as knowledge and experience in the atomic energy field increase. Frequently there are, and increasingly in the future there may be, categories of materials and uses as to which there is sufficient knowledge to permit possession and use without prior evaluation of the hazards and the capability of the 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.

Pennsylvania has adopted, by reference, the NRC regulations containing the regulatory requirements for applying for and issuing licenses by reference.

The NRC staff verified that the Pennsylvania regulations provide that only the NRC may issue a license authorizing the distribution of agreement materials that will subsequently be exempt from regulatory control.

Since criterion 13 was adopted, the Commission has determined that the NRC will retain the regulatory authority to conduct safety evaluations of sealed sources and devices, unless the State requests assumption of the authority and has in place an adequate and compatible program to implement such authority. Pennsylvania has decided not to seek authority for evaluation of sealed sources and devices.

The staff concludes that this criterion is satisfied.

References: Letter, with attachments, dated November 9, 2006, from Governor Rendell to Chairman Klein, request for an Agreement, Section 4.2 (ADAMS Accession Nos. ML063330295 and ML070260116). Pennsylvania Statutes: Radiation Protection Act (35 P.S. §§ 7110.101-7110.703), Low-Level Radioactive Waste Disposal Act (35 P.S. §§ 7130.101-7130.906), and Section 1920-A of the Administrative Code of 1929 (71 P.S. § 510-20). Pennsylvania regulations: Pennsylvania Code, Title 25, "Environmental Protection," Chapters 215 and 217.

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 determined that Pennsylvania has committed to use the NRC licensing guidance in the NUREG-1556 series, "Consolidated Guidance about Materials Licenses," to perform technical evaluation of the proposed uses of radioactive material. In addition, Pennsylvania has developed administrative licensing procedures that define the review process for a license application, renewal, amendment, and license

termination.

The staff concludes that this criterion is satisfied.

References: Letter, with attachments, dated November 9, 2006, from Governor Rendell to Chairman Klein, request for an Agreement, Section 4.3 (ADAMS Accession Nos. ML063330295 and ML070260179). Letter, with enclosures, dated March 16, 2007, from David Allard to Charles Miller, response to NRC comment letter dated January 26, 2007 (ADAMS Accession Nos. ML070790604, ML070790609, ML070790612, ML070790616, and ML070790620).

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

The NRC staff verified that Pennsylvania has adopted 10 CFR Part 35, "Medical Use of Byproduct Material," by reference. Therefore, the Pennsylvania regulations, which include training and experience requirements for the use of radioactive materials on or in humans, are identical to the NRC requirements.

The staff concludes that this criterion is satisfied.

References: Letter, with attachments, dated November 9, 2006, from Governor Rendell to Chairman Klein, request for an Agreement, Section 4.2 (ADAMS Accession Nos. ML063330295 and ML070260116). Pennsylvania Statutes: Radiation Protection Act (35 P.S. §§ 7110.101-7110.703), Low-Level Radioactive Waste Disposal Act (35 P.S. §§ 7130.101-7130.906), and Section 1920-A of the Administrative Code of 1929 (71 P.S. § 510-20). Pennsylvania regulations: Pennsylvania Code, Title 25, "Environmental Protection," Chapters 215 and 224.

#### 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 determined that the Pennsylvania program has statutory authority to conduct inspections of licensees. The NRC staff also verified that Pennsylvania has adopted regulation, by reference, which are compatible with the equivalent parts of Title 10 of the *Code of Federal Regulations*, that contain provisions relating to inspections and tests.

The NRC staff determined that Pennsylvania has adopted a schedule for inspection of licensees at least as frequent as the schedule used by the 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 inspection procedures are similar to the NRC's procedures.

The staff concludes that this criterion is satisfied.

References: Letter, with attachments, dated November 9, 2006, from Governor Rendell to Chairman Klein, request for an Agreement, Sections 4.1, 4.2, and 4.4 (ADAMS Accession Nos. ML063330295, ML070290041, ML070290046, ML070260116, and ML070260179). Letter, with enclosures, dated March 16, 2007, from David Allard to Charles Miller, response to NRC comment letter dated January 26, 2007 (ADAMS Accession Nos. ML070790604, ML070790609, ML070790612, ML070790616, and ML070790620). Pennsylvania Statutes: Radiation Protection Act (35 P.S. §§ 7110.101-7110.703), Low-Level Radioactive Waste Disposal Act (35 P.S. §§ 7130.101-7130.906), and Section 1920-A of the Administrative Code of 1929 (71 P.S. § 510-20). Pennsylvania regulations: Pennsylvania Code, Title 25, "Environmental Protection," Chapters 215 and 220.

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

The NRC staff determined that Pennsylvania 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. BRP may obtain a search warrant upon a showing of probable cause.

The staff concludes that this criterion is satisfied.

References: Letter, with attachments, dated November 9, 2006, from Governor Rendell to Chairman Klein, request for an Agreement, Sections 4.1 and 4.4 (ADAMS Accession Nos. ML063330295, ML070290041, ML070290046, and ML070260179). Pennsylvania Statutes: Radiation Protection Act (35 P.S. §§ 7110.101-7110.703), Low-Level Radioactive Waste Disposal Act (35 P.S. §§ 7130.101-7130.906), and Section 1920-A of The Administrative Code of 1929 (71 P.S. § 510-20). Pennsylvania regulations: Pennsylvania Code, Title 25, "Environmental Protection," Chapter 215.

## 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 determined that Pennsylvania 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 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, with attachments, dated November 9, 2006, from Governor Rendell to Chairman Klein, request for an Agreement, Section 4.4 (ADAMS Accession Nos. ML063330295 and ML070260179).

#### **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 determined that the Pennsylvania program is authorized by law to enforce State rules using a variety of sanctions, including the imposition and collection of civil penalties and the issuance of orders to suspend, modify, or revoke licenses, or impound materials. The program may also present for prosecution charges of summary, misdemeanor, or felony criminal violation, as appropriate. The program is authorized to file liens for failure to pay a civil penalty.

The NRC staff also determined that the program has adopted policies and procedures to implement the enforcement authority. The Pennsylvania 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, with attachments, dated November 9, 2006, from Governor Rendell to Chairman Klein, request for an Agreement, Section 4.5 (ADAMS Accession Nos. ML063330295 and ML070260026).

#### 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 2 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, 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.

The NRC staff reviewed the organizational charts, position descriptions, training and qualification plan, and the curricula vitae for the current staff members of the Pennsylvania program, as presented with the request for an Agreement. The NRC staff findings and conclusions are presented below.

#### a. Assessment of the Agreement Materials Staffing

The staff of the Radioactive Materials Licensing Section, DRC, in the Headquarters BRP will be primarily responsible for the licensing activities of the Agreement Materials Program. The Radiation Protection Program staff working out of the PADEP regional offices will also support licensing activities. In addition, Radiation Protection Program staff working out of the PADEP regional offices will primarily be responsible for

conducting the inspection and compliance functions.

The Pennsylvania staffing needs analysis indicates that the Agreement materials program will need a total of approximately 13.5 full-time equivalent (FTE) staff. The BRP staffing plan shows that 16.8 FTE are available, which is reasonably matched to the workload for materials licensing and inspection and decommissioning activities. The staffing plan shows that none of the BRP Director's time is directly committed to Agreement materials program licensing or inspection activities. However, given the scope of the State's Radiation Control Program and the Director's experience and credentials, the Director has indicated to the review team that he expects to provide ample technical consultation and administrative support for the materials and decommissioning portion of the program. Four staff members will provide 100 percent of their time to Agreement State program activities, and 15 other staff members will provide 50 percent or more of their time to these activities. Three other staff members will commit less than 50 percent of their time. Pennsylvania's staff assessment allows time for radiological response, instructional opportunities, and training. The technical staffing analysis does not address administrative and secretarial support, however, the program narrative notes that clerical support is available in the central and all regional offices; other organizational units within PADEP will provide administrative support, such as fiscal, information technology, and legal.

There are approximately 690 NRC-specific licenses in Pennsylvania. The BRP also licenses approximately 460 NARM users. A number of facilities have both NRC and NARM licenses. BRP estimates that once these licenses are combined when the Agreement becomes effective, a net of approximately 1000 radioactive materials licenses will be in effect. Based on the BRP staffing allocation of 16.8 technical/ professional FTE devoted to the Agreement State program, the team's evaluation of the Pennsylvania's staffing analysis concludes that BRP has adequate staffing. In addition, the staff expects that a substantial portion of the Pennsylvania NARM registrants are also NRC licensees. Pennsylvania plans to combine these duplicate licenses under the Agreement, a common practice for new Agreement States. The NRC staff concludes that the estimate of 1000 licensees is reasonable, and the projected 16.8 technical/professional FTE will provide an adequate level of staffing to satisfactorily handle anticipated licensing, inspection, reciprocity, allegations, and incident response workload.

The staff concludes that the proposed Pennsylvania Agreement materials program has an adequate number of staff to meet anticipated program needs.

The staff concludes that criterion 20(a) is satisfied.

#### b. Assessment of Staff Qualifications

The NRC staff review considered the qualifications of the individuals currently on the BRP professional/technical staff who would be involved in the Agreement materials program, as well as the procedures for training and qualifying new staff members. Under the proposed Agreement, the BRP Director would be primarily responsible for the program's overall administration. He holds a masters degree in radiological sciences and protection, and he is certified by the American Board of Health Physics and has over 25 years of experience in health physics and supervision. He has 8 years of experience with the BRP as its director.

Program managers within the DRC and the regional offices will provide the immediate day-to-day supervision of the licensing, inspection, and decommissioning programs. The NRC staff review found that the two of the six managers have bachelors degrees in sciences or engineering. The other four hold masters degrees. The managers have at least 7 years experience with BRP, and most have been with BRP for 20 or more years. In addition to their regulatory program experience, several of the managers have experience in industry.

The NRC staff reviewed the educational qualifications of 20 individuals who would be involved in licensing and inspections of the Agreement materials. Except for two individuals, all have at least a bachelors degree in science or engineering. Fields of study include physics, biology, zoology, radiation science, radiation technology, environmental science, environmental engineering, and general science. One of the exceptions was trained as a radiological technologist and has extensive industry and regulatory experience, including 15 years service in BRP. The other holds a bachelors degree in educational science and has 21 years experience in BRP. The NRC staff considers that these combinations of training and experience to meet the requirements of being equivalent to a bachelor degree. The FTE assignments of these 20 individuals totals to more than the 13.5 FTE projected to be necessary by the Pennsylvania staff needs analysis.

The BRP technical staff members have extensive applicable experience. This includes experience in health physics, nuclear power, medical, industry, military, and State regulatory agencies. Most technical staff members have completed the NRC-recommended core courses or have met the requirements based on their training and prior experience. The program continues to send BRP staff to training courses to either complete core course requirements or obtain specialized or refresher training.

Pennsylvania has developed qualification procedures for license reviewers and inspectors which are similar to the NRC's procedures. The BRP technical staff are working with NRC license reviewers in NRC Region I Office and accompanying NRC staff on inspections of NRC licensees in Pennsylvania. Pennsylvania staff members are also actively supplementing their experience through direct meetings, discussions, and facility walkdowns with NRC licensees in Pennsylvania and through self-study, in-house training, and formal training.

Pennsylvania has an adequate number of trained and qualified staff in place, based on the staff needs analysis and qualification procedures.

The staff concludes that criterion 20(b) is satisfied.

References: Letter, with attachments, dated November 9, 2006, from Governor Rendell to Chairman Klein, request for an Agreement, Section 4.6 (ADAMS Accession Nos. ML063330295 and ML070260026). Letter, with enclosures, dated March 16, 2007, from David Allard to Charles Miller, response to NRC comment letter dated January 26, 2007, Letter with enclosures, dated November 1, 2007, from David Allard to Janet Schlueter, response to NRC letter dated August 16, 2007 (ADAMS Accession Nos. ML070790604, ML070790609, ML070790612, ML070790616, ML070790620, ML072320016, and ML073120087).

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

The staff concludes that this criterion is satisfied.

References: Letter, with attachments, dated November 9, 2006, from Governor Rendell to Chairman Klein, request for an Agreement, Section 4.1 (ADAMS Accession Nos. ML063330295, ML070290041, and ML070290046). Pennsylvania Statutes: Radiation Protection Act (35 P.S. §§ 7110.101-7110.703), Low-Level Radioactive Waste Disposal Act (35 P.S. §§ 7130.101-7130.906), and Section 1920-A of the Administrative Code of 1929 (71 P.S. § 510-20). Pennsylvania regulations: Pennsylvania Code, Title 25, "Environmental Protection," Chapter 215.

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; 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 verified that Pennsylvania has adopted, by reference, the agency's definition of special nuclear material in critical mass quantities by reference.

The staff concludes that this criterion is satisfied.

References: Letter, with attachments, dated November 9, 2006, from Governor Rendell to Chairman Klein, request for an Agreement, Section 4.1 (ADAMS Accession Nos. ML063330295, ML070290041, and ML070290046). Pennsylvania Statutes: Radiation Protection Act (35 P.S. §§ 7110.101-7110.703), Low-Level Radioactive Waste Disposal Act (35 P.S. §§ 7130.101-7130.906), and Section 1920-A of the Administrative Code of 1929 (71 P.S. § 510-20). Pennsylvania regulations: Pennsylvania Code, Title 25, "Environmental Protection," Chapters 215 and 217.

#### **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 determined that general statutory provisions bind PADEP to provide 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, with attachments, dated November 9, 2006, from Governor Rendell to Chairman Klein, request for an Agreement, Sections 4.1, 4.3, and 4.5 (ADAMS Accession Nos. ML063330295, ML070290041, ML070290046, ML070260179, and ML070260026). Letter, with enclosures, dated March 16, 2007, from David Allard to Charles Miller, response to NRC comment letter dated January 26, 2007 (ADAMS Accession Nos. ML070790604, ML070790609, ML070790612, ML070790616, and ML070790620). Pennsylvania Statutes: Radiation Protection Act (35 P.S. §§ 7110.101-7110.703), Low-Level Radioactive Waste Disposal Act (35 P.S. §§ 7130.101-7130.906), and Section 1920-A of the Administrative Code of 1929 (71 P.S. § 510-20).

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 PADEP has been designated by statute as the lead agency for carrying out Pennsylvania's Radiation Protection Program and has been provided by statute with the requisite legal authority to do so. In addition, to the extent that this criterion deals with duplicate regulation between a State and the NRC (see FSME Procedure SA-700 Handbook, Evaluation Criterion 4.1.1.2., paragraph b, and Evaluation Criterion 4.2.2.2), the NRC staff determined that the Pennsylvania 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 Pennsylvania and the NRC in the regulation of agreement material.

The staff concludes that this criterion is satisfied.

References: Letter, with attachments, dated November 9, 2006, from Governor Rendell to Chairman Klein, request for an Agreement, Section 4.1 (ADAMS Accession Nos.

ML063330295, ML070290041, and ML070290046). Pennsylvania Statutes: Radiation Protection Act (35 P.S. §§ 7110.101-7110.703), Low-Level Radioactive Waste Disposal Act (35 P.S. §§ 7130.101-7130.906), and Section 1920-A of the Administrative Code of 1929 (71 P.S. § 510-20).

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 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 determined that Pennsylvania Code, Title 25, "Environmental Protection," Chapter 217 (25 PA Code 217.133) 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 Pennsylvania Code. The license will expire either 90 days after receipt from PADEP of a notice of expiration of the license or on the date of expiration specified in the NRC license, whichever is earlier.

The staff concludes that this criterion is satisfied.

References: Letter, with attachments, dated November 9, 2006, from Governor Rendell to Chairman Klein, request for an Agreement, Section 4.1 (ADAMS Accession Nos. ML063330295, ML070290041, and ML070290046). Pennsylvania Statutes: Radiation Protection Act (35 P.S. §§ 7110.101-7110.703), Low-Level Radioactive Waste Disposal Act (35 P.S. §§ 7130.101-7130.906), and Section 1920-A of the Administrative Code of 1929 (71 P.S. § 510-20). Pennsylvania regulations: Pennsylvania Code, Title 25, "Environmental Protection," Chapters 215 and 217.

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 verified that the proposed Agreement commits Pennsylvania to cooperate with the NRC and the other Agreement States in the formulation of standards and regulatory programs for the protection against the hazards of radiation and to ensure that the Pennsylvania program will continue to be compatible with the NRC's program for the regulation of materials covered by the Agreement.

In a revised policy statement on the adequacy and compatibility of Agreement State programs (published September 3, 1997, at 62 FR 46517), the Commission determined that providing reports to the NRC of Agreement State licensee incidents, accidents, and other significant events is a matter of compatibility. The NRC staff determined that Pennsylvania has adopted procedures to provide such reports to the agency.

The staff concludes that this criterion is satisfied.

References: Letter, with attachments, dated November 9, 2006, from Governor Rendell to Chairman Klein, request for an Agreement, and Sections 4.1 and 4.7 (ADAMS Accession Nos. ML063330295, ML070290041, ML070290046, and ML070260026). Letter, with enclosures, dated March 16, 2007, from David Allard to Charles Miller, response to NRC comment letter dated January 26, 2007 (ADAMS Accession Nos. ML070790604, ML070790609, ML070790612, ML070790616, and ML070790620).

- 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 verified that the proposed Agreement provides for the Commission to discontinue, and the Commonwealth of Pennsylvania to assume, regulatory authority over the types of material defined in categories a, c, d, and e above.

As provided for within the Energy Policy Act of 2005, an Agreement State may assume the authority to regulate byproduct materials as defined in Section 11e.(3) of the Act and byproduct materials as defined in Section 11e.(4) of the Act. Pennsylvania has requested to assume regulatory authority over these types of byproduct material. The NRC staff verified that the proposed Agreement provides for the Commission to discontinue, and the Commonwealth of Pennsylvania to assume, regulatory authority over the types of byproduct material defined in Sections 11e.(3) and 11e.(4) of the Act.

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. Pennsylvania has chosen not to assume this authority.

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

reciprocal recognition of licenses from other jurisdictions.

The staff concludes that this criterion is satisfied.

References: Letter, with attachments, dated November 9, 2006, from Governor Rendell to Chairman Klein, request for an Agreement, Section 4.1 (ADAMS Accession Nos. ML063330295, ML070290041, and ML070290046). Pennsylvania Statutes: Radiation Protection Act (35 P.S. §§ 7110.101-7110.703), Low-Level Radioactive Waste Disposal Act (35 P.S. §§ 7130.101-7130.906), and Section 1920-A of the Administrative Code of 1929 (71 P.S. § 510-20). Pennsylvania regulations: Pennsylvania Code, Title 25, "Environmental Protection," Chapters 215 and 217.

- 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 verified that Pennsylvania has specifically listed these exceptions in Pennsylvania Code Title 25, Chapter 215 ( 25 PA Code 215.32), and therefore provides the necessary exemptions from the State's requirements for licensing of sources of radiation for NRC and U.S. Department of Energy contractors or subcontractors, in accordance with the criterion.

The staff concludes that this criterion is satisfied.

References: Letter, with attachments, dated November 9, 2006, from Governor Rendell to Chairman Klein, request for an Agreement, Section 4.2 (ADAMS Accession Nos. ML063330295 and ML070260116). Pennsylvania Statutes: Radiation Protection Act (35 P.S. §§ 7110.101-7110.703), Low-Level Radioactive Waste Disposal Act (35 P.S. §§ 7130.101-7130.906), and Section 1920-A of the Administrative Code of 1929 (71 P.S. § 510-20). Pennsylvania regulations: Pennsylvania Code, Title 25, "Environmental Protection," Chapter 215.

## STAFF CONCLUSION

The NRC staff has reviewed the proposed Agreement, the certification by Pennsylvania in the application for an Agreement in a letter dated November 9, 2006, from Governor Rendell to

Chairman Klein, and the supporting information provided by the PADEP BRP staff.

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

- (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 NRC staff has reviewed the proposed Agreement, the certification by the Commonwealth of Pennsylvania in the application for an Agreement submitted by Governor Rendell on November 9, 2006, and the supporting information provided by the PADEP BRP staff and concludes that the Commonwealth of Pennsylvania satisfies the criteria in the Commission's policy statement entitled, "Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory Authority and Assumption Thereof by States Through Agreement." Therefore, the Commonwealth of Pennsylvania meets the requirements of Section 274 of the Act. The proposed Pennsylvania program to regulate agreement materials, which includes 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.

## **ENCLOSURE 4**

CURRENT MILESTONE SCHEDULE FOR PROCESSING PROPOSED AGREEMENT

## **MILESTONE SCHEDULE**

	Estimated Event Time (Weeks)	Estimated Elapsed Time (Weeks)	Estimated Completion Date	Actual Completion Date
Team completes notation vote Commission paper, including draft staff assessment and Federal Register (FR) notice	2	2	04/12/2007	03/30/2007
NRC offices concur on Commission paper	3	5	05/03/2007	05/02/2007
EDO sends paper to Commission	2	7	05/17/2007	05/17/2007
Commission gives notation vote	2	9	05/31/2007	06/08/2007
First publication in FR	1	10	06/07/2007	06/18/2007
Public comment period ends	4	14	07/05/2007	07/18/2007
NRC request PA to develop a specific plan to address staffing and qualification	Schedule on hold			08/16/2007
Response from PA	Schedule resumed			11/01/2007
Team analyzes comments; completes final assessment and Commission paper	3	32	11/30/2007	12/05/2007
NRC offices concur on final assessment and paper	3	35	12/21/2007	01/04/2008
EDO signs paper	2	37	01/04/2008	01/11/2008
Commission SRM approving Agreement	4	41	02/01/2008	
Signing of Agreement	4	45	02/29/2008	
Effective date of Agreement	March 31, 2008			

## **ENCLOSURE 5**

DRAFT LETTER
FROM
CHAIRMAN DALE E. KLEIN
TO
GOVERNOR EDWARD G. RENDELL

The Honorable Edward G. Rendell Governor Commonwealth of Pennsylvania Harrisburg, Pennsylvania 17120

Dear Governor Rendell:

I am pleased to inform you that the U. S. Nuclear Regulatory Commission (NRC) has approved your request for an Agreement under which the NRC will discontinue and the Commonwealth of Pennsylvania will assume regulatory authority over the acquisition, possession, use, transfer, and disposal of certain byproduct material, source material and special nuclear material in quantities not sufficient to form a critical mass, as well as land disposal of all waste for such materials.

## (Details of the arrangements for the signature ceremony to be added once finalized)

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

Sincerely,

Dale E. Klein

## **ENCLOSURE 6**

# DRAFT FEDERAL REGISTER NOTICE OF AGREEMENT SIGNING

## **U. S. Nuclear Regulatory Commission**

Commonwealth of Pennsylvania: Discontinuance of Certain Commission Regulatory Authority Within the State; Notice of Agreement Between the NRC and the Commonwealth of Pennsylvania; Notice of Waiver Termination

**AGENCY:** U.S. Nuclear Regulatory Commission.

**ACTION:** Notice of Agreement between the U.S. Nuclear Regulatory Commission and the Commonwealth of Pennsylvania.

SUMMARY: This notice is announcing that on TBD-Signature ceremony date, Dr. Dale E. Klein, Chairman of the U.S. Nuclear Regulatory Commission (NRC), and Governor Edward G. Rendell of the Commonwealth of Pennsylvania signed an Agreement as authorized by Section 274b of the Atomic Energy Act of 1954, as amended (the Act). The Agreement provides for the Commission to discontinue its regulatory authority and for Pennsylvania to assume regulatory authority over the possession and use of byproduct material as defined in Sections 11e.(1), 11e.(3), and 11e.(4) of the Act, source material, special nuclear materials (in quantities not sufficient to form a critical mass), and land disposal of all waste for such materials. Under the Agreement, a person in Pennsylvania 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.

**NOTICE OF WAIVER TERMINATION:** On March 31, 2008, the Commission terminated the time-limited waivers of the Energy Policy Act of 2005 requirements granted by the Commission (70 FR 51581; August 31, 2005) to Pennsylvania for byproduct material as defined in Sections

11e.(3), and 11e.(4) of the Act.

FOR FURTHER INFORMATION CONTACT: Kim Lukes, Division of Materials Safety and State Agreements, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Telephone (301) 415-6701; e-mail kxk2@nrc.gov.

**SUPPLEMENTARY INFORMATION**: The NRC published the draft Agreement in the FR for comment once a week for 4 consecutive weeks on June 18, 2007 (72 FR 33541), June 25, 2007 (72 FR 34728), July 2, 2007 (72 FR 36069), and July 9, 2007 (72 FR 37268), as required by the Act. The public comment period ended on July 18, 2007. The Commission received two comment letters. The comments do not affect the NRC staff's assessment, which finds that the Pennsylvania Agreement materials program is adequate to protect public health and safety and compatible with the NRC's program. The proposed Pennsylvania 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 Pennsylvania, the supporting documentation submitted with the request for an Agreement, and its interactions with the staff of the Pennsylvania Bureau of Radiation Protection, the NRC staff completed an assessment of the Pennsylvania program. The agency made a copy of the staff assessment 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 **TBD-Date of SRM**, that the proposed Pennsylvania 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, <a href="http://www.nrc.gov/reading-rm/adams.html">http://www.nrc.gov/reading-rm/adams.html</a>. 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, 2007.
	For the Nuclear Regulatory Commission.
	Annette L. Vietti-Cook,

## AN AGREEMENT BETWEEN THE UNITED STATES NUCLEAR REGULATORY COMMISSION AND

## THE COMMONWEALTH OF PENNSYLVANIA FOR THE

## DISCONTINUANCE OF CERTAIN COMMISSION REGULATORY AUTHORITY AND

## RESPONSIBILITY WITHIN THE COMMONWEALTH PURSUANT TO SECTION 274 OF THE ATOMIC ENERGY ACT OF 1954, AS AMENDED

WHEREAS, The United States Nuclear Regulatory Commission (the Commission) is authorized under Section 274 of the Atomic Energy Act of 1954, as amended, 42 U.S.C. § 2011 *et seq.* (the Act), to enter into agreements with the Governor of any State/Commonwealth providing for discontinuance of the regulatory authority of the Commission within the State/Commonwealth under Chapters 6, 7, and 8, and Section 161 of the Act with respect to byproduct materials as defined in Sections 11e.(1), 11e.(3), and 11e.(4) of the Act, source materials, and special nuclear materials in quantities not sufficient to form a critical mass; and,

WHEREAS, The Governor of the Commonwealth of Pennsylvania is authorized under the Pennsylvania Radiation Protection Act of July 10, 1984, P.L. 688, No. 147, *as amended*, 35 P.S. § 7110.101 *et seq.*, to enter into this Agreement with the Commission; and,

WHEREAS, The Governor of the Commonwealth of Pennsylvania certified on November 8, 2006, that the Commonwealth of Pennsylvania (the Commonwealth) has a program for the control of radiation hazards adequate to protect public health and safety with respect to the materials within the Commonwealth covered by this Agreement, and that the Commonwealth desires to assume regulatory responsibility for such materials; and,

WHEREAS, The Commission found on **[date]** that the program of the Commonwealth for the regulation of the materials covered by this Agreement is compatible with the Commission's program for the regulation of such materials and is adequate to protect public health and safety; and,

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

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

WHEREAS, This Agreement is entered into pursuant to the provisions of the Act;

NOW, THEREFORE, It is hereby agreed between the Commission and the Governor of the Commonwealth acting on behalf of the Commonwealth as follows:

#### ARTICLE I

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

- 1. Byproduct materials as defined in Section 11e.(1) of the Act;
- 2. Byproduct materials as defined in Section 11e.(3) of the Act;
- 3. Byproduct materials as defined in Section 11e.(4) of the Act;
- 4. Source materials:
- 5. Special nuclear materials in quantities not sufficient to form a critical mass;
- 6. The regulation of the land disposal of all byproduct, source, and special nuclear waste materials covered by this Agreement.

#### ARTICLE II

This Agreement does not provide for discontinuance of any authority and the Commission shall retain authority and responsibility with respect to the following:

- 1. The regulation of the construction and operation of any production or utilization facility or any uranium enrichment facility;
- 2. The regulation of the export from or import into the United States of byproduct, source, or special nuclear material, or of any production or utilization facility:
- 3. The regulation of the disposal into the ocean or sea of byproduct, source, or special nuclear materials waste as defined in the regulations or orders of the Commission:
- 4. The regulation of the disposal of such other byproduct, source, or special nuclear materials waste as the Commission from time to time determines by regulation or order should, because of the hazards or potential hazards thereof, not be disposed without a license from the Commission;
- 5. The evaluation of radiation safety information on sealed sources or devices containing byproduct, source, or special nuclear materials and the registration of the sealed sources or devices for distribution, as provided for in regulations or orders of the Commission.

## ARTICLE III

With the exception of those activities identified in Articles II.1 through II.4, this Agreement may be amended, upon application by the Commonwealth and approval by the Commission, to include one or more of the additional activities specified in Article II, whereby the

Commonwealth may then exert regulatory authority and responsibility with respect to those activities.

## **ARTICLE IV**

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

#### ARTICLE V

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

#### ARTICLE VI

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

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

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

## **ARTICLE VII**

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

## **ARTICLE VIII**

The Commission, upon its own initiative after reasonable notice and opportunity for hearing to the Commonwealth, or upon request of the Governor of the Commonwealth, may terminate or suspend all or part of this Agreement and reassert the licensing and regulatory authority vested in it under the Act if the Commission finds that (1) such termination or suspension is required to protect public health and safety, or (2) the Commonwealth has not complied with one or more of the requirements of Section 274 of the Act. The Commission may also, pursuant to Section

274j of the Act, temporarily suspend all or part of this Agreement if, in the judgment of the Commission, an emergency situation exists requiring immediate action to protect public health and safety and the Commonwealth has failed to take necessary steps. The Commission shall periodically review actions taken by the Commonwealth under this Agreement to ensure compliance with Section 274 of the Act which requires a Commonwealth program to be adequate to protect public health and safety with respect to the materials covered by this Agreement and to be compatible with the Commission's program.

#### ARTICLE IX

This Agreement shall become effective on March 31, 2008, and shall remain in effect unless and until such time as it is terminated pursuant to Article VIII.

Done at [City, State] this [date] day of [month], [year].

FOR THE UNITED STATES NUCLEAR REGULATORY COMMISSION
Dale E. Klein, Chairman
FOR THE COMMONWEALTH OF PENNSYLVANIA
Edward G. Rendell, Governor