

POLICY ISSUE

(Notation Vote)

May 17, 2007

SECY-07-0083

FOR: The Commissioners

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

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

PURPOSE:

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

BACKGROUND:

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

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

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

DISCUSSION:

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

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

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

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

As required by Section 274e of the Act, the NRC staff will publish the proposed Agreement for comment in the FR once each week for four consecutive weeks. The FR Notice (Enclosure 5) will include a summary of the staff's draft assessment of the proposed Pennsylvania regulatory program for regulation of 11e.(1), 11e.(3), and 11e.(4) byproduct materials, source materials, special nuclear materials in quantities not sufficient to form a critical mass, and land disposal of all waste for such materials, in addition to the text of the proposed Agreement. The staff plans to follow the same process for Pennsylvania as it did for Minnesota, Utah, Wisconsin, and Oklahoma. For these Agreements, the NRC staff published the proposed Agreements in the FR for public comment, in parallel with the Commission's review of the staff's draft assessment. Once approved by the Commission, the final Agreement will be published in the *Federal Register* within 30 days after signature by the Chairman and the Governor.

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

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

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

RESOURCES:

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

CONCLUSION:

The NRC staff concludes that, except as discussed in criterion 20, Qualifications of Regulatory and Inspection Personnel, of the draft NRC staff assessment (Enclosure 6) of the proposed program, the Commonwealth of Pennsylvania satisfies the criteria in the Commission's policy statement, and therefore, meets the requirements of Section 274 of the Act. The proposed Pennsylvania program to regulate Agreement materials, as comprised of statutes, regulations, and procedures, is compatible with the program of the Commission and is adequate to protect public health and safety with respect to the materials covered by the proposed Agreement. With respect to criterion 20, once the NRC staff confirms the assurances provided by Pennsylvania concerning staff training and qualifications, the staff will be able to conclude that criterion 20 is satisfied.

COMMITMENTS:

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

1. The staff plans to confirm the assurances that Pennsylvania provided in their response to the NRC's comment letter concerning staff training and qualifications.
2. The staff will provide an updated schedule and an analysis of public comments along with the final paper to the Commission, requesting approval of the proposed Agreement.

RECOMMENDATIONS:

That the Commission:

1. Approve:

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

2. Review:

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

3. Note:

- a. The staff will place a copy of the NRC Staff Draft Assessment (summarized in the *FR* Notice) in the NRC's Public Electronic Reading Room on the Internet at <http://www.nrc.gov/NRC/ADAMS/index.html>, and into Agencywide Documents Access and Management System.
- b. The Office of Congressional Affairs will dispatch a letter to the cognizant Congressional Committees informing them that the Commission is considering entering into an amended Agreement with the Commonwealth.
- c. The Office of Public Affairs will issue a press release.
- d. FSME will dispatch a letter to the Federal Agencies listed in FSME Procedure SA-700 and all of the States.

COORDINATION:

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

/RA/

Luis A. Reyes
Executive Director
for Operations

Enclosures:

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

EDO Principal Correspondence Control

FROM: DUE: / /

EDO CONTROL: G20060965
DOC DT: 11/09/06
FINAL REPLY:

Governor Edward G. Rendell
Commonwealth of Pennsylvania

TO:

Chairman Klein

FOR SIGNATURE OF :

** GRN **

CRC NO: 06-0595

DESC:

Request Agreement Between NRC and the
Commonwealth of Pennsylvania

ROUTING:

Reyes
Virgilio
Kane
Silber
Johnson
Cyr/Burns
Collins, RI

DATE: 11/28/06

ASSIGNED TO:

CONTACT:

FSME

Miller

SPECIAL INSTRUCTIONS OR REMARKS:

Enclosure sent directly to FSME per SECY. FSME
will place enclosure in ADAMS (reference OEDO and
SECY control numbers - G20060965/LTR-06-0595).

Template: SECY-017

E-RIDS: SECY-01

OFFICE OF THE SECRETARY
CORRESPONDENCE CONTROL TICKET

Date Printed: Nov 28, 2006 10:03

PAPER NUMBER: LTR-06-0595 **LOGGING DATE:** 11/27/2006
ACTION OFFICE: EDO

AUTHOR: Edward Rendell
AFFILIATION: PA-GOV
ADDRESSEE: Dale Klein
SUBJECT: Request agreement be established between the NRC and the Commonwealth of PA

ACTION: Appropriate
DISTRIBUTION: RF

LETTER DATE: 11/09/2006
ACKNOWLEDGED No
SPECIAL HANDLING:

NOTES: FSM will ack receipt ...Kevin Hsueh x2598 has enclosures
and will place in ADAMS

FILE LOCATION: ADAMS

DATE DUE: **DATE SIGNED:**

EDO --G20060965



COMMONWEALTH OF PENNSYLVANIA
OFFICE OF THE GOVERNOR
HARRISBURG

THE GOVERNOR

November 9, 2006

Mr. Dale E. Klein, Ph.D., Chairman
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Chairman Klein:

I am writing to formally request that an agreement be established between the United States Nuclear Regulatory Commission (NRC) and the Commonwealth of Pennsylvania as authorized by Section 274 of the Atomic Energy Act of 1954, as amended, 42 U.S.C. § 2021, and Section 201 of the Pennsylvania Radiation Protection Act, Act of July 10, 1984, P.L. 688, No. 147, 35 P.S. § 7110.201. Under this agreement, the Commission will discontinue and the Commonwealth of Pennsylvania will assume regulatory authority for certain radioactive materials now under federal jurisdiction. As provided by Section 301 of the Pennsylvania Radiation Protection Act, 35 P.S. § 7110.301, the Department of Environmental Protection is the agency responsible for implementation of the agreement. The specific authority requested is for the following:

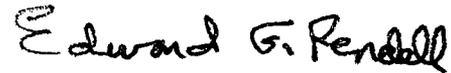
- A. Byproduct materials as defined in Section 11e.(1) of the Act,
- B. Byproduct materials as defined in Section 11e.(3) of the Act;
- C. Byproduct materials as defined in Section 11e.(4) of the Act;
- D. Source materials;
- E. Special nuclear materials in quantities not sufficient to form a critical mass; and
- F. Land disposal of all waste byproduct, source, and special nuclear materials covered by the Agreement.

I hereby certify, in accordance with Section 274(d)(1) of the Atomic Energy Act, 42 U.S.C. § 2021(d)(1), that the Commonwealth of Pennsylvania desires to assume regulatory responsibility for such materials and that the Commonwealth of Pennsylvania has a program for the control of radiation hazards adequate to protect the public health and safety with respect to the materials within the Commonwealth covered by this proposed agreement. Enclosed is information describing Pennsylvania's radiation control program and regulatory capabilities, copies of our radiation control laws, and other agreement-state application materials required by NRC guidelines and procedures. The contact person for the agreement request is Mr. David J. Allard, Director, Bureau of Radiation Protection, Pennsylvania Department of Environmental Protection. Mr. Allard can be reached by e-mail at djallard@state.pa.us or by telephone at 717-787-2480.

Dale Klein
Page 2

Our target date to become an Agreement State is October 1, 2007, and we would appreciate your expeditious consideration of this proposed Agreement to meet the schedule.

Sincerely,

A handwritten signature in black ink that reads "Edward G. Rendell". The signature is written in a cursive style with a large, prominent "E" at the beginning.

Edward G. Rendell
Governor

Enclosure

cc:

Kathleen A. McGinty, Secretary, Pennsylvania Department of Environmental Protection
David J. Allard, Director, Bureau of Radiation Protection, Pennsylvania Department of Environmental Protection

January 9, 2007

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

Dear Governor Rendell:

On behalf of the U.S. Nuclear Regulatory Commission (NRC), I am responding to your letter of November 9, 2006, in which you request an agreement between the NRC and the Commonwealth of Pennsylvania pursuant to Section 274b of the Atomic Energy Act of 1954, as amended (Act). If approved by the Commission, Pennsylvania would assume regulatory authority over the acquisition, possession, use, transfer, and disposal of source material, byproduct material as defined in Section 11e.(1) of the Act, byproduct material as defined in Section 11e.(3) of the Act, byproduct material as defined in Section 11e.(4) of the Act, and special nuclear material in quantities not sufficient to form a critical mass. The regulatory authority to be assumed would also include land disposal of all waste byproduct, source, and special nuclear materials covered by the agreement.

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

I want to assure you that the NRC staff is working diligently to complete its review in an expeditious manner. We are pleased with your continued interest in becoming an Agreement State and look forward to the continued excellent relationship we have enjoyed in the past.

Sincerely,

/RA/

Dale E. Klein

January 26, 2007

Mr. David J. Allard, Director
Bureau of Radiation Protection
Department of Environmental Protection
Rachel Carson State Office Building
P. O. Box 8469
Harrisburg, PA 17105-8469

Dear Mr. Allard:

We have completed our review of the Pennsylvania formal request for an Agreement, signed by Governor Rendell on November 9, 2006. An interoffice staff team (Review Team), identified in Enclosure 1, conducted the review. The review was based on a Commission Policy Statement that provides criteria for new agreements, and followed the Office of Federal and State Materials and Environmental Management Programs (FSME) Procedure SA-700, and Handbook, *Processing an Agreement*.

The review was conducted to determine whether the proposed Pennsylvania Program (hereafter, the Program) met the evaluation criteria for an Agreement Program that is adequate to protect public health and safety and compatible with the U.S. Nuclear Regulatory Commission (NRC) materials program. The Review Team found that the request provided information on all major program elements and reflected significant Pennsylvania staff effort. However, as reflected in the comments documented in Enclosure 2, the Review Team identified a number of areas where additional information or documentation is needed. A response to the comments is requested.

For your reference, the comments are correlated to the pertinent sections of your request and the pertinent sections of the FSME Procedure SA-700 Handbook. In addition, the results of our review of the Pennsylvania draft Order on Increased Controls included in your request were transmitted separately to the State, in a letter dated December 27, 2006, from Mr. Scott Moore, Deputy Director, Division of Materials Safety and State Agreements, FSME, to you.

Among the comments, two significant issues of concern to the NRC are the staffing level of the Program and the training and qualifications of the staff. The issues are discussed below and have been discussed by the NRC staff in telephone conversations with you and members of your staff.

First, the evaluation criteria for a new Agreement requires the Program to have an adequate number of trained and fully qualified licensing and inspection staff, before the effective date of the Agreement. Although the request describes the training and qualifications process for the Program staff, it did not appear to provide specific information confirming that an adequate number of trained and qualified licensing and inspection staff would be available in the Program at the time the Agreement is signed. The distribution of licensing and inspection staff qualifications should be reasonably matched to the workload for the categories of licenses to be transferred from NRC before the Agreement is signed.

Second, in your request, the staff-needs analysis indicated that the Program will need approximately 12.33 full-time equivalents to perform licensing activities under the Agreement. However, in another portion of your request, you stated that you plan to have only four qualified license reviewers, including two managers. We noted that the four license reviewers will be responsible not only for the approximately 460 naturally occurring or accelerator-produced radioactive materials licenses, but also the addition of approximately 670 radioactive materials licenses from NRC. Based on the discrepancy between your staff-needs analysis and the actual number of staff you plan to use, it appears that you may have overestimated your staffing needs and allocated insufficient staff to assume the regulatory workload on licensing activities to be transferred from NRC. The staff-needs analysis and staffing plan need to be revised to ensure that they are consistent.

As noted in our discussion on January 8, 2007, NRC Region I will stop processing incoming routine licensing actions approximately one month before the effective date of the Agreement. These pending licensing actions will then be transferred to the State for action upon the effective date of the Agreement. Therefore, it is expected that the licensing staff will start with a full workload when the Agreement takes effect. In contrast, NRC Region I is planning to complete all inspections that are due now and out to at least three months beyond the anticipated effective date of the Agreement. This effectively gives the Program a three month buffer period upon assumption of regulatory authority from NRC, regarding routine inspections.

Based on our review of the request, we conclude that the Program may not be adequately staffed to assume the regulatory authority being requested until: (1) the distribution of licensing and inspection staff qualifications is reasonably matched to the workload for the categories of licensees that will be transferred; and (2) the licensing group is fully staffed with individuals qualified according to your training and qualification procedures.

We understand that you have taken actions to address these two significant issues including a plan to increase interactions on licensing and inspections between NRC Region I staff and Pennsylvania staff in the upcoming months. These interactions should provide your staff with additional knowledge and experience on more complex materials licenses. The initial meeting to coordinate these activities and discuss other transition issues was held on January 12, 2007, at NRC Region I office. It is my understanding that the meeting was productive, and NRC and Pennsylvania staffs are working together on these issues.

The NRC staff notes, as it did during the January 16, 2007, conference call with your staff, that any memoranda of understanding (MOU) or protocol agreements that the NRC maintains with the Commonwealth with respect to nuclear power plants located in Pennsylvania have no affect on the NRC's review of your Agreement State request or the authority that would be relinquished if the Commission approves Pennsylvania's request. MOUs are governed by Section 274i of the Atomic Energy Act, whereas the NRC's Agreement State Program is controlled by Section 274b of the Act. Likewise, the protocol agreements to observe NRC inspections at nuclear power plants are governed by the Statement of Policy on "Cooperation with States at Commercial Nuclear Power Plants and other Nuclear Production or Utilization Facilities", and not Section 274b of the Act. Further, the NRC also does not consider Pennsylvania's Nuclear Reactor Oversight Program described in Section 2.1.1 of its Agreement State Formal Request – Program Narrative to be part of the Agreement State request review.

We are prepared to recommend that the Commission approve publication of the proposed Agreement in the *Federal Register* (FR) after all the comments identified in Enclosure 2 are resolved, and receipt of your commitment to address the staff level and distribution concerns, discussed above, before the Agreement is signed. Your commitment to address the concerns will be clearly identified in the FR notice. During the comment period, the public will be able to comment on all aspects of the Agreement, including the concerns related to staffing. After the public comment period, we will forward the Agreement to the Commission for final approval only after the Program actually achieves adequate staffing with qualified individuals. This approach presumes that all other significant issues and any public comments are resolved.

Enclosure 3, "Elapsed-Weeks Milestone Schedule," provides a current estimate of the timing associated with anticipated Agreement signing and its effective date. Based on the Milestone Schedule, the comments identified in Enclosure 2 must be resolved, and your commitment to address the staff level and distribution concerns discussed above must be received, by February 28, 2007, in order to meet your target date to become an Agreement State on October 1, 2007.

If you have any questions about the review, the information needed, or steps involved in processing the Agreement, please contact me at (301) 415-7197, or Mr. Kevin Hsueh, Team Leader for the Pennsylvania Agreement Review Team, at (301) 415-2598. Please note that, over the next few weeks, Mr. Hsueh will transition to a new management assignment and Mr. Andrew Mauer will assume the duties of the Team Leader. I would like to assure you that there will be no disruption in terms of the Review Team's ability to respond to any questions you may have, process your response to its comments, or proceed to finalize the Agreement when appropriate.

Sincerely,

/RA/

Charles L. Miller, Director
Office of Federal and State Materials
and Environmental Management Programs

Enclosures:

1. State of Pennsylvania Review Team
2. State of Pennsylvania Formal Request Comments
3. Elapsed-Weeks Milestone Schedule

We are prepared to recommend that the Commission approve publication of the proposed Agreement in the *Federal Register* (FR) after all the comments identified in Enclosure 2 are resolved, and receipt of your commitment to address the staff level and distribution concerns, discussed above, before the Agreement is signed. Your commitment to address the concerns will be clearly identified in the FR notice. During the comment period, the public will be able to comment on all aspects of the Agreement, including the concerns related to staffing. After the public comment period, we will forward the Agreement to the Commission for final approval only after the Program actually achieves adequate staffing with qualified individuals. This approach presumes that all other significant issues and any public comments are resolved.

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Sincerely,

Charles L. Miller, Director
Office of Federal and State Materials
and Environmental Management Programs

Enclosures:

1. State of Pennsylvania Review Team
2. State of Pennsylvania Formal Request Comments
3. Elapsed-Weeks Milestone Schedule

Distribution: DCD (SP05)

DIR RF

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ADWhite, RSAO/RI

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Response to Incoming Document: ML070240128 Pkg.

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DATE	1/12/07	1/12/07	1/12/07	1/24/07	1/18/07
OFFICE	OGC	RI/DNMS:D	NSIR/DSP:D	FSME:D	
NAME	FXCameron (JZorn for)	BEHolian (via DWhite e-mail)	PKHolahan	CLMiller	
DATE	1/23/07	1/19/07	1/19/07	1/ 26 /07	

STATE OF PENNSYLVANIA REVIEW TEAM

Kevin Hsueh, Office of Federal and State Materials and Environmental Management Programs (FSME)	Team Leader Regulatory Elements
Jason Zorn Office of the General Counsel	Legal Elements/Regulatory Elements
Richard Blanton, FSME	Legal, Enforcement, Technical Staffing and Training Elements
Sandra Gabriel, Region I	Licensing Elements
John Buckley, FSME	Licensing Elements
Diana Diaz-Toro, Office of Nuclear Material Safety and Safeguards (NMSS)	Licensing Elements
Duncan White, Region I	Inspection Elements
Tomas Herrera, FSME	Event and Allegation Elements
Gary Purdy, Office of Nuclear Security and Incident Response	Events and Allegation Elements

STATE OF PENNSYLVANIA FORMAL REQUEST COMMENTS

After conducting the detailed review of the Pennsylvania Agreement formal request, dated November 9, 2006, the Review Team has the following comments.

Section 4.1 Legal Elements

4.1.2 Organization of the Proposed Program

1. On page 4, a sentence, in the first paragraph of the Program Narrative, which reads: "At this time, there is no intent to license sealed source manufacturers or uranium processing facilities." The sentence needs to be revised to reflect that Pennsylvania does not request authority for the sealed source and device evaluation program and the uranium recovery program.
2. Table 1 - "PA Complex Decommissioning Sites," does not include two current complex sites that should transfer to PA - Westinghouse (Churchill Facility) and Curtiss-Wright Cheswick. Although these sites have special nuclear material (SNM), the possession limits of SNM listed on their licenses are less than the limits specified in 10 CFR 150.10 and 150.11, and thus should transfer to PA. These sites need to be included in Table 1.

4.3 Licensing Program Elements

4.3.1 Procedures for the Technical Evaluation of Proposed Uses of Radioactive Material

The Pennsylvania procedures should be revised to include the following items:

- a. Technical licensing procedures for 10 CFR Part 40 licenses (which are not addressed in the NUREG-1556 series), including standard review plans, checklists, and licensing guides.
- b. Qualifications of individual license reviewers for each license category.
- c. A qualification process for license reviewers for the complex licensed activities encountered under NRC licenses, compared to those activities currently licensed by the Program.

4.3.5 Procedures for Assuring the Technical Quality of Licenses

Pennsylvania should provide additional information to clarify the following two items:

- a. In the Administrative Licensing Procedures, Pennsylvania provided differing descriptions of its "consistent" method for supervisory review of licensing actions: Section 2.1 states that the Chief, Radioactive Materials Licensing, will review and sign all licenses, or, in his/her absence, the Chief, Radiation Control Division. However, Section 3.5 states that the Section Chief may sign the license if the Chief is not available. This needs to be clarified.
- b. Pennsylvania's staff-needs analysis indicated that the Program will need approximately 12.33 full-time equivalents to perform licensing activities under the Agreement. However, in another portion of your request, you stated that you plan to have only four qualified license reviewers, including two managers. We noted that the four license reviewers will be responsible not only for the approximately 460 naturally occurring or accelerator-produced radioactive material licenses, but also the addition of approximately 670 radioactive licenses from the U.S. Nuclear Regulatory Commission (NRC). Based on the discrepancy between your staff-needs analysis and the actual number of staff you plan to use, it appears that you may have overestimated your staffing needs and allocated insufficient staff to assume the regulatory workload on licensing activities to be transferred from NRC. Pennsylvania's staff-needs analysis and staffing plan need to be revised to ensure that they are consistent.

4.3.6 Administrative Licensing Procedures

Pennsylvania needs to address the following specific comments on the License Termination Procedure (LTP):

- a. Sections 217.131 and 217.171 of Title 25 Pennsylvania Code incorporate the license termination regulations of 10 CFR Parts 30 and 40, respectively. However, the LTP is incomplete since it does not contain provisions for implementing a number of the regulations (for example: the Timeliness Rule [30.36 (d) and 40.42 (d)]), or reviewing license termination plans and final status survey reports. These provisions are in NRC NUREG-1757. The Pennsylvania LTP should include these provisions or adopt the NUREG-1757 guidance.
- b. Section 3.1 of the LTP states, "The criteria for termination of a license is listed in 25 Pa Code 215.27 and 25 Pa Code 236.411." The Review Team noted that 25 Pa Code 215.27 is titled, "Vacating premises" and 25 Pa Code 236.411 is titled, "Site closure and decommissioning plan." The radiological criteria for license termination are incorporated by reference in 25 Pa Code 219.5. The citations of 215.27 and 236.411 need to be clarified, or revised to 219.5. In addition, please complete the table in Section 3.1 by indicating that the criteria of 10 CFR 20.1401 - 1404 are included by reference in 25 Pa Code 219.5.
- c. Section 3.4 of the LTP, states that NUREG-1575 and NUREG/CR-5849 [see sub-Section 1.2 of the LTP (Section 3.4)] can be used in the development, implementation of the LTP and the termination of the license(s). It further states that NUREG-1727 can be used to evaluate the LTP by the Radioactive Materials Program.

NUREG/CR-5849 is no longer applicable and NUREG-1727 has been superseded by NUREG-1757, and therefore the language needs to be revised accordingly.

- d. Section 4.0 identifies some types of records with no description. Additional language is needed in this section to clarify the purpose of this section.

4.4 Inspection Program Elements

4.4.1 Procedures for Inspecting Facilities Where Radioactive Materials Are Stored or Used

The Review Team identified a number of specific items during its review of the Program's inspection procedure provided as part of the request. Most of these items could be grouped into two categories: (1) those activities restricted only to NRC; and (2) superseded documents NRC no longer uses. During a conference call between the NRC Region I staff and Program staff on December 20, 2006, the Program was provided with the specific items in the inspection procedures that require modification. Pennsylvania would need to provide the modified procedures for review.

4.6 Technical Staffing and Training Program Elements

4.6.1 Technical Staff Organization

The staffing analysis provided in the formal request does not include a program staffing plan showing the number of staff members assigned to specific responsibilities, such as license review and inspection for each major category of licensee. Pennsylvania would need to provide the information for review (also see comment under Section 4.3.5.b).

4.6.3 Qualifications of Current Technical Staff

Pennsylvania's request did not identify each individual's qualifications under the State's written qualification plan. As discussed during our conference calls on January 8 and 10, 2007, one acceptable response to this comment is a matrix identifying each individual's completion of criteria (i.e., training courses) outlined in your qualification plan.

4.7 Event and Allegation Response Program Elements

4.7.1 Procedures for Responding to Events and Allegations

1. Manual Chapter 1301, page 6, reference to Appendix C should be removed because Appendix C was deleted.
2. Manual Chapter 1303 references the Office of State Programs, the Source Containment and Devices Branch, IMNS/NMSS, LLDP/NMSS. Due to the reorganization, the organization names need to be revised to the Office of Federal and State Materials and Environmental Management Programs (FSME).

3. Inspection Procedure 87103 references Incident Investigation Teams (IITs) and Augmented Inspection Teams (AITs). If the Program does not have IITs or AITs, the reference should be removed. If the Pennsylvania Bureau of Radiation Protection (BRP) has inspection teams equivalent to IITs or AITs (but does not call them IITs or AITs), the reference should be changed to Pennsylvania's name for these inspection teams.
4. The document, BRP-ALL-01, "Complaint Processing Procedure," should include procedures for handling sensitive information, if these procedures are not included in the Pennsylvania's guidance on handling of correspondence associated with complaints.
5. Sections 2.1 and 2.2 of the BRP-ALL-01 state that a staff person shall record all relevant information. It would be helpful for staff to have a list of questions to be asked during contact with the complainant or reference where staff can find a list of questions.
6. In Section 3.0 of the BRP-ALL-01, a statement is needed to reflect that the complainant should be advised that it is not always possible to protect his/her identity (particularly in cases where action was taken against the complainant by his/her employer).

4.7.2 Procedures for Identifying Significant Events and Allegations, and for Entering Reports into the Nuclear Material Events Database (NMED)

1. BRP-ER-6.10 and BRP-RM-03 reference STP Procedure SA-300. Because of the reorganization, the title of this document needs to be revised to state the FSME Procedure SA-300.
2. Clarification is needed in BRP-ER-6.10 - 3.3 regarding the position responsible for entering the report into NMED.

ELAPSED-WEEKS MILESTONE SCHEDULE*

The following events will not start until the U.S. Nuclear Regulatory Commission (NRC) sends an acknowledgment letter to the Pennsylvania Program confirming that all the Review Team's comments documented in the January 26, 2007, letter have been resolved, and Pennsylvania's commitment to address the staff level and distribution concerns discussed in that letter has been received.

Event	Event Time (Weeks)	Elapsed Times (Weeks)
Team completes Notation Vote Commission Paper, including draft staff assessment and FR Notice	2	2
NRC offices concur on Commission Paper	3	5
EDO sends Paper to Commission	2	7
Commission gives notation vote	2	9
First publication in FR	1	10
Public comment period ends	4	14
Team analyzes comments; completes final assessment and Commission Paper	4	18
HOLD, IF NECESSARY, PENDING COMPLETION OF STAFF HIRING AND QUALIFICATION BY PENNSYLVANIA	Hold	18 + Hold
NRC offices concur on final assessment and paper	3	21 + Hold
EDO signs paper	2	23 + Hold
Commission SRM approving Agreement	4	27 + Hold
Signing of Agreement	4	31 + Hold
Effective Date of Agreement	To Be Determined (Pennsylvania's target date is October 1, 2007.)	

*** Assumes that all significant issues, including sufficient qualified staff and any public comments, are resolved.**



Pennsylvania Department of Environmental Protection

Rachel Carson State Office Building

P.O. Box 8469

Harrisburg, PA 17105-8469

March 16, 2007

Bureau of Radiation Protection

717-787-2480

Fax: 717-783-8965

Dr. Charles L. Miller
Office of Federal and State Materials
and Environmental Management Programs
United States Nuclear Regulatory Commission
Two White Flint North
11545 Rockville Pike
Rockville, MD 20852-2738

Dear Dr. Miller:

We completed our revisions to our formal Agreement State (AS) request based on your January 26, 2007, letter, Enclosure 1. Given the number of revisions made, we have included both one paper copy of the revised documents as well as two identical CD-ROMs containing each of the paper files electronically. I apologize for the delay in getting this information to you; however, as one would expect, procedure revisions take a fair amount of time. If we can do anything further to help you meet our AS status target date of October 1, 2007, please do not hesitate to contact me.

Per my January 18, 2007, letter to Mr. Scott W. Moore, Deputy Director, Division of Materials and State Agreements, given the revisions stated therein and appended, we consider this issue closed and we satisfy the legal binding requirements for compatibility and health and safety established in NRC's FSME Procedure SA-200.

After conducting a review of Enclosure 2 of your January 26 letter we have prepared this point-for-point response.

Section 4.1 Legal Elements

4.1.2 Organization of the Proposed Program

1. The Narrative (Enclosure 2) has been updated to clarify that Pennsylvania does not request authority for a sealed source and device evaluation program or a uranium recovery licensing program.
2. The Narrative (Enclosure 2) has been updated and Table 1 - "PA Complex Decommissioning Sites" now includes Westinghouse (Churchill Facility) and Curtiss-Wright Cheswick.



4.3 Licensing Program Elements

4.3.1 Procedures for the Technical Evaluation of Proposed Uses of Radioactive Material

- a. In addition to selected portions of NUREG-1556 Volume 7 and 12, as licensing guidance we will be using the following documents in the evaluation of Part 40 Source Material Licenses (see Administrative Licensing Procedures, Enclosure 15):

NUREG-1520 - Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility;

NUREG-1757 - Consolidated NMSS Decommissioning Guidance;

NRC Regulatory Guide 3.67 - Standard Format and Content for Emergency Plans for Fuel Cycle and Materials Facilities; and

NRC Regulatory Guide 4.20 - Constraint on the Release of Airborne Radioactive Material to the Environment for Licensees Other Than Production Reactors.

- b. Our Manual 1246 has been updated to address the issue of license reviewer qualification. Please see Enclosure 6 through 14. Also please see our staff qualification matrices, Enclosure 5.
- c. Our Manual 1246 has been updated to address the issue of license reviewers for complex licensed activities. Please see Enclosure 6 through 14.

4.3.5 Procedures for Assuring the Technical Quality of Licenses

- a. The Administrative Licensing Procedures (Enclosure 15) have been updated to clarify the review and signature process. If the Radioactive Materials Licensing Chief is not available, the Radiation Control Chief will sign a completed license.

In addition, we have made changes to our staffing plan. Initially we had planned to use only Central Office staff to review licenses. However, based on our revised staff needs analysis we have decided to include select Regional Office staff in this process. Not only will this allow for additional FTEs for licensing activities (e.g., initial license review, second review, etc.), but it will help ensure consistent licensing actions across the state. It also bolsters our Department Continuity of Government plan. The Administrative Licensing Procedure (Enclosure 15) has been updated to allow for the use of Regional Office staff in the review of licenses.

- b. A summary of the revisions to the staff needs analysis follows (also see comment under Section 4.6.1). Your observation that we may have overestimated our staffing needs has merit. The staff needs analysis was revised in three ways. First the number and complexity of the decommissioning sites was re-evaluated and adjusted down. Second, the NRC was able to provide more up-to-date numbers of licensees. Finally, a formula used in the spreadsheet was revised to more accurately calculate our staff needs. These three adjustments resulted in a licensing staff need revision from 12.33 FTE to 6.33 FTE. Also the inspection staff need was reduced from 14.41 FTE to 7.24 FTE. See revised staff needs analysis, Enclosure 3.

A revised staffing plan, which is consistent with the staff needs analysis, is supplied as Enclosure 4. As noted above, the staffing plan now includes Regional Office staff involvement in license review. This involvement has been incorporated in our Administrative Licensing Procedures (Enclosure 15). Our current staffing plan allows for the Commonwealth to immediately assume all licensing, inspection, and decommissioning responsibilities without creating backlogs in any part of the Agreement State program. This does not assume the utilization of the one vacancy we currently have in our Radioactive Licensing Section, which will be filled shortly.

4.3.6 Administrative Licensing Procedures

- a. The License Termination Procedure (Enclosure 16) has been updated to include the additional provisions of NUREG-1757.
- b. The License Termination Procedure (Enclosure 16) has been updated to correct and clarify citations.
- c. The License Termination Procedure (Enclosure 16) has been updated to correct and clarify citations.
- d. The License Termination Procedure (Enclosure 16) has been updated to expand the description of the types of records.

4.4 Inspection Program Elements

4.4.1 Procedures for Inspecting Facilities Where Radioactive Materials Are Stored or Used

The changes to the Inspection Manual Chapters and Inspection Procedures outlined during the December 21, 2006 (note: not December 20th) conference call have been implemented. See Enclosures 22 through 44.

4.6 Technical Staffing and Training Program Elements

4.6.1 Technical Staff Organization

As we have noted in the Program Narrative, in addition to formal training, the staff presently employed in the program has decades of NARM licensing and inspection experience. This experience includes a range of activities, from simple gauges to complex broad scope, nuclear medicine and x-ray radiography operations. Thus, by virtue of their position and years of training and experience, I have granted certain managers and supervisors waivers as inspectors and license reviewers. Further, given the decade of experience involved with managing and oversight of complex decommissioning projects (e.g., Flannery Building radium-226 D&D project, Quehanna, Safety Light Corp., MolyCorp, et al.), by virtue of their position and years of experience, I have granted certain managers and supervisors waivers in the decommissioning area.

The NRC's January 26 letter requested a staffing plan broken out by each license category. As mentioned above, a staffing plan is supplied as Enclosure 4. Given the number and type of licenses we expect to receive from NRC as an Agreement State, I confirm that at this time, we have an adequate number of trained and qualified staff in place that will provide for quality licensing actions and inspections now and when the Agreement is signed. In summary, based on the enclosures with this letter, number and types of NRC licenses that will be transferred to the Commonwealth, we affirm the number of qualified program staff in our Central and Regional Offices are matched to the regulatory workload.

4.6.3 Qualifications of Current Technical Staff

A staff qualification matrix is supplied as Enclosure 5. A summary of the revisions to Manual Chapter 1246, qualification and training follows.

Only minor changes to a majority of Inspection Manual Chapter 1246 and its appendices (Enclosures 6 - 14) were made, primarily to ensure consistency throughout the chapter. However, significant changes were made to appendix B - I and B - II. In the broadest sense these revisions, similar in both B - I and B - II, deal with qualifications for specific license categories. Our initial formal request lacked this specificity. We now believe we have a workable document for managing and capturing staff training and experience, including past and future on-the-job-training required for license reviewer and inspector qualification. I again confirm that at this time, we have an adequate number of trained and qualified staff in place that will provide for quality licensing actions and inspections now and when the Agreement is signed.

We base this on the fact that we have for decades licensed and inspected a range of NARM and decommissioning activities from simple nuclear gauges to complex NARM production accelerators. To further enhance our staff's skills in licensing, our

Radioactive Materials Licensing Chief has, and continues to, work directly with NRC Region I staff to review the PA byproduct, source and small quantity special nuclear material licenses. These licenses have been chosen for their range of complexity. This Licensing Chief is using the case studies to further enhance the experience of Central and Regional Office licensing staff through in-house training. Similarly, our trained and experienced Regional inspection staff are further enhancing their experience by accompanying NRC Region I staff on PA byproduct, source and small quantity special nuclear material license inspections. These case studies and inspections involve a range of complexity within the industrial, broad scope, medical and academic license groupings. Our Decommissioning Chief and program staff has for the past decade gained significant experience with some of the most complex sites in the country. The staff inspection and licensing experience is being further supplemented and extended by direct meetings, discussions, facility walk-downs with PA NRC licensees, equipment manufacturers, and, self-study, in-house and other formal training.

Related to the staff needs analysis, you will find enclosed our staffing plan and staff qualification matrix. As noted, we do calculate having adequately qualified full-time equivalent (FTE) staff at this time. In addition to the ongoing enhancement of staff experience, it should be noted that we are hosting two NRC training courses for inspection and licensing in mid-September 2007. This training may be a first for some staff, and a refresher for others. In addition to these two formal courses, program staff continue to attend NRC training in Maryland and Tennessee. Further, we have a plan in place and continue to work diligently toward qualifying any new staff through our established procedures. In addition to formal training noted above, we plan to follow a model that relies on practical on-the-job training with experienced license reviewers and inspectors. Any deviations in our training and qualification approach, from that of NRC, will not reduce the overall capacity of staff to independently perform the work of the Agreement and protect both public health and the environment. As noted in the Program Narrative, we have approval to hire additional staff upon signing of the Agreement. Our plan is to interview through the summer and hire just before and after we become an Agreement State. Lastly, we realize that on occasion we will need to reach-back to NRC and reach-out to other Agreement States on some licensing and inspection issues. It is our understanding that this is done often formally (e.g., through the Organization of Agreement States) and informally. We will not hesitate to do so ourselves should the need arise.

4.7 Event and Allegation Response Program Elements

4.7.1 Procedures for Responding to Events and Allegations

1. The reference to Appendix C in Manual Chapter 1301 has been deleted. See Enclosure 41.

2. In Manual Chapter 1303 references to the Office of State and Tribal Programs (STP) have been changed to the Office of Federal and State Materials and Environmental Management Programs (FSME). See Enclosure 43.
3. References to IITs and AITs have been removed from Inspection Procedure 87103. See Enclosure 25.
4. BRP-ALL-01, Complaint Processing Procedure, has been updated with references to additional guidance. See Enclosure 19.
5. BRP-ALL-01, Complaint Processing Procedure, has been updated with references to additional guidance. See Enclosure 19.
6. BRP-ALL-01, Complaint Processing Procedure, has been updated with references to additional guidance. See Enclosure 19.

4.7.2 Procedures for Identifying Significant Events and Allegations, and for Entering Reports into the Nuclear Material Events Database (NMED)

1. BRP-ER-6.10 and BRP-RM-03 have been revised and are enclosed as Enclosures 17 and 18.
2. BRP-ER-6.10 has been updated and is Enclosure 18.

I would also like to take this opportunity to provide additional clarification on a few issues as follows:

First, we affirm that our Agreement State request cannot and does not include any oversight authority of nuclear power plants. However, we look forward to the continued cooperation with NRC under established memoranda of understanding (MOU) and protocol agreements.

Second, I would like to provide our procedures for adjudication of licensing actions. This documentation, Commonwealth of PA Environmental Hearing Board (EHB) Practice and Procedure Manual and Commonwealth of PA EHB Regulations, is included here as Enclosure 20 and 21. Furthermore, I would like to provide the following summary.

Appeals of all BRP licensing actions may be taken to the EHB in accordance with the EHB statute and the procedures established by the EHB in its procedural rules. The EHB is an independent adjudicative agency that hears appeals from final actions of the PADEP. Issuance of a radioactive materials license, or denial of a license application,

are final actions by the Department which are subject to appeal to the EHB. EHB adjudications can be appealed to the Pennsylvania Commonwealth Court; rights of appeal from Commonwealth Court decisions to the Pennsylvania Supreme Court are governed by Pennsylvania's Appellate Court Rules. The statute providing for the EHB is at 35 P.S. §§ 7511-7516; the EHB's Rules of Practice and Procedure are at 25 Pa. Code Ch. 1021.

Pennsylvania law does not provide for an administrative licensing proceeding akin to that utilized by the NRC in which a party may petition to intervene in the licensing proceeding and request a hearing before the Atomic Safety and Licensing Board. Rather, under Pennsylvania law any person whose rights, obligations, or interests may be affected by a final action of the Department, (i.e., any person with judicial standing), has a statutory right to a *de novo* hearing before the EHB concerning the legality of the Department action being challenged. All aspects of the Department's decision making process for a license or permit application could be subject to *de novo* review by the EHB in an appeal of the licensing action. There is no licensing "proceeding" in which an interested person may intervene prior to the final Department decision; instead, an interested person may appeal the final decision and subject the entire decision making process to a *de novo* review by an independent adjudicative agency composed of five administrative law judges.

The Department's general practice is for the issuance of a license or permit to include a cover letter containing a standard appeal rights notice; denial of a license would use the same process. Upon receipt of the final action by the Department (i.e., the decision to issue or deny the license), the licensee or prospective licensee would have 30 days to appeal the decision as of right to the EHB. An interested third party may file an appeal with the EHB of a PADEP licensing or permitting decision within 30 days of receiving notice of issuance of the license or permit.

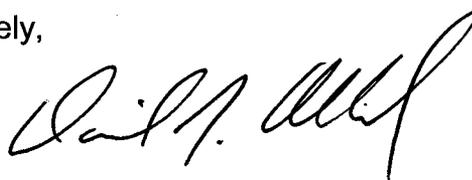
Thirdly, to support the regulated community in the transition from NRC to DEP regulation, we have planned four outreach meetings through the Commonwealth. At these meetings we will describe our department and program framework, statutes and regulations, procedures, contact information, and stress our intent to make the transition to Agreement State status as seamless as possible (i.e., use of NRC regulations, guidance, and inspection procedures).

Other miscellaneous transition plans are being implemented as well. One of which is an evaluation of our records management system and update the retention schedules. This effort will enable us to maintain the active and historical records we receive as an Agreement State more efficiently. We also understand the NRC will maintain and hold the existing licensee decommissioning financial assurance instruments until the Commonwealth has their own executed per NUREG-1757.

Finally, we realize the timeline of our application has slipped a few weeks, but it is our hope that we can meet the October 1, 2007, date for implementation of the Agreement. Given this is the beginning of the federal fiscal year and a point for NRC to invoice licensees, this effective date for the Agreement would be quite efficient for the NRC, licensees, and the Commonwealth.

If you have any questions about this letter or the enclosed revised documents, please contact me by e-mail at djallard@state.pa.us or by telephone at (717) 787-2480. Thank you.

Sincerely,

A handwritten signature in black ink, appearing to read "David J. Allard". The signature is fluid and cursive, with a large initial "D" and "A".

David J. Allard, CHP
Director
Bureau of Radiation Protection

cc: Cover Letter only
Kathleen A. McGinty, Secretary, DEP
Thomas K. Fidler, Deputy Secretary, WARM, DEP
Arthur Stephens, Governor's Office
Roy Kienitz, Governor's Office

Enclosure #	Enclosure Name
1	Dr. Charles L. Miller, January 26, 2007 letter w/ enclosures
2	Revised Narrative
3	Revised Staff Needs Analysis
4	Staffing Plan
5	Staff Qualification Matrices
	Revised DEP MC 1246 (Training and Qualification)
6	MC 1246 - Main
7	MC 1246 Appendix A
8	MC 1246 A - I
9	MC 1246 A - II
10	MC 1246 A - IX
11	MC 1246 Appendix B
12	MC 1246 B - I
13	MC 1246 B - II
14	MC 1246 B - IX
15	Revised Administrative Licensing Procedures
16	Revised License Termination Procedure
17	Revised BRP-RM-03 NMED Procedure
18	Revised BRP-ER-6.10 Radiological Incident Response
19	Revised BRP-ALL-01 Complaint Processing Procedure
20	Commonwealth of PA Environmental Hearing Board Practice and Procedure Manual
21	Commonwealth of PA Environmental Hearing Board Regulations, 25 PA Code 1021
	Revised Inspection Procedures
22	IP 83822 Radiation Protection
23	IP 86740 Inspection of Transportation Activities
24	IP 87102 Maintaining Effluents ALARA
25	IP 87103 Insp of RAM Licensees in an Incident or Bankruptcy Filing
26	IP 87124 Gauge Programs
27	IP 87125 Materials Processor - Manufacturer Programs
28	IP 87126 Industrial - Academic - Research Programs
29	IP 87130 Nuclear Medicine Programs - Written Directive Not Required
30	IP 87131 Nuclear Medicine Programs - Written Directive Required
31	IP 87132 Brachytherapy Programs
32	IP 87133 Medical Gamma Stereotactic Radiosurgery and Teletherapy Programs
33	IP 87134 Medical Broad Scope Programs
34	IP 92701 Follow-up

Enclosure #	Enclosure Name
	Revised Inspection Manual Chapters
35	MC0300 Announced and Unannounced Inspections
36	MC0610 Nuclear Material Safety Inspection Reports
37	MC0620 Inspection Documents and Records
38	MC1120 Preliminary Notifications
39	MC1220 Processing of DEP Form 241 and Inspection of Reciprocity Licensees
40	MC1301 Response to Incidents
41	MC1302 Followup and Action Lvl's for Rad Exp Contam for Events Involving Pub
42	MC1303 Requesting DOE Acceptance
43	MC2602 Decom Insp Program for RAM
44	MC2800 Materials Inspection Program

NUCLEAR REGULATORY COMMISSION

Commonwealth of Pennsylvania: Draft NRC Staff Assessment of a Proposed Agreement
Between the Nuclear Regulatory Commission and the Commonwealth of Pennsylvania

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of a proposed Agreement with the Commonwealth of Pennsylvania.

SUMMARY: By letter dated November 9, 2006, Governor Edward G. Rendell of Pennsylvania requested that the U. S. Nuclear Regulatory Commission (NRC or Commission) enter into an Agreement with the Commonwealth as authorized by Section 274 of the Atomic Energy Act of 1954, as amended (Act).

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

The proposed Agreement would release (exempt) persons who possess or use certain radioactive materials in Pennsylvania from portions of the Commission's regulatory authority.

The Act requires that the NRC publish those exemptions. Notice is hereby given that the pertinent exemptions have been previously published in the Federal Register and are codified in the Commission's regulations as 10 CFR Part 150.

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

ADDRESSES: Written comments may be submitted to Mr. Michael T. Lesar, Chief, Rulemaking, Directives and Editing Branch, Division of Administrative Services, Office of Administration, Washington, DC 20555-0001. Comments may be submitted electronically at nrerep@nrc.gov.

The NRC maintains an Agencywide Documents Access and Management System (ADAMS), which provides text and image files of NRC's public documents. The documents may be accessed through the NRC's Public Electronic Reading Room on the Internet at <http://www.nrc.gov/reading-rm/adams.html>. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC Public Document Room (PDR) reference staff at (800) 397-4209, or (301) 415-4737, or by e-mail to pdr@nrc.gov.

Copies of comments received by NRC may be examined at the NRC Public Document Room, 11555 Rockville Pike, Public File Area O-1-F21, Rockville, Maryland. Copies of the request for an Agreement by the Governor of Pennsylvania including all information and documentation submitted in support of the request, and copies of the full text of the NRC Draft

Staff Assessment are also available for public inspection in the NRC's Public Document Room--ADAMS Accession Numbers: ML070240128, ML063400549, ML070240055, ML063330295, ML070290041, ML070290046, ML070260116, ML070260179, ML070260026, ML070260119, ML070250054, ML063400559, ML070790604, ML070790609, ML070790612, ML070790616, ML070790620, and ML070890378

FOR FURTHER INFORMATION CONTACT: Mr. Andrew N. Mauer, Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Telephone (301) 415-3962 or e-mail to anm@nrc.gov.

SUPPLEMENTARY INFORMATION: Since Section 274 of the Atomic Energy Act of 1954, as amended (Act) was added in 1959, the Commission has entered into Agreements with 34 States. The Agreement States currently regulate approximately 17,600 Agreement material licenses, while the NRC regulates approximately 4,400 licenses. Under the proposed Agreement, approximately 690 NRC licenses will transfer to Pennsylvania. The NRC periodically reviews the performance of the Agreement States to assure compliance with the provisions of Section 274.

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

I. Background

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

In a letter dated November 9, 2006, Governor Rendell certified that the Commonwealth of Pennsylvania has a program for the control of radiation hazards that is adequate to protect public health and safety within Pennsylvania for the materials and activities specified in the proposed Agreement, and that the Commonwealth desires to assume regulatory responsibility for these materials and activities. Included with the letter was the text of the proposed Agreement, which is shown in Appendix A to this notice.

The radioactive materials and activities (which together are usually referred to as the “categories of materials”) that the Commonwealth of Pennsylvania requests authority over are:

(1) The possession and use of byproduct materials as defined in Section 11e.(1) of the Act;

(2) The possession and use of byproduct materials as defined in Section 11e.(3) of the Act;

¹The radioactive materials, sometimes referred to as “Agreement materials,” are: (a) byproduct materials as defined in Section 11e.(1) of the Act; (b) byproduct materials as defined in Section 11e.(3) of the Act; (c) byproduct materials as defined in Section 11e.(4) of the Act; (d) source materials as defined in Section 11z. of the Act; and (e) special nuclear materials as defined in Section 11aa. of the Act, restricted to quantities not sufficient to form a critical mass.

(3) The possession and use of byproduct materials as defined in Section 11e.(4) of the Act;

(4) The possession and use of source materials;

(5) The possession and use of special nuclear materials in quantities not sufficient to form a critical mass; and

(6) The regulation of the land disposal of byproduct materials as defined in Section 11e.(1) of the Act, source, or special nuclear waste materials received from other persons.

(b) The proposed Agreement contains articles that:

- Specify the materials and activities over which authority is transferred;
- Specify the activities over which the Commission will retain regulatory authority;
- Continue the authority of the Commission to safeguard nuclear materials and restricted data;
- Commit the Commonwealth of Pennsylvania and NRC to exchange information as necessary to maintain coordinated and compatible programs;
- Provide for the reciprocal recognition of licenses;
- Provide for the suspension or termination of the Agreement; and
- Specify the effective date of the proposed Agreement.

The Commission reserves the option to modify the terms of the proposed Agreement in response to comments, to correct errors, and to make editorial changes. The final text of the Agreement, with the effective date, will be published after the Agreement is approved by the Commission, and signed by the NRC Chairman and the Governor of Pennsylvania.

(c) The regulatory program is authorized by law under the Radiation Protection Act (35 P.S. §§ 7110.101 - 7110.703). § Section 7110.201 provides the authority for the Governor to enter into an Agreement with the Commission. Pennsylvania law contains provisions for the orderly transfer of regulatory authority over affected licensees from the NRC to the Commonwealth. After the effective date of the Agreement, licenses issued by NRC would continue in effect as Pennsylvania licenses until the licenses expire or are replaced by State-issued licenses. NRC licenses transferred to Pennsylvania which contain requirements for decommissioning and express an intent to terminate the license when decommissioning has been completed under a Commission-approved decommissioning plan will continue as Pennsylvania licenses and will be terminated by Pennsylvania when the Commission-approved decommissioning plan has been completed.

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

(d) The NRC draft staff assessment finds that the Commonwealth of Pennsylvania Bureau of Radiation Protection of the Pennsylvania Department of Environmental Protection is

adequate to protect public health and safety, and is compatible with the NRC program for the regulation of Agreement materials.

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

The NRC staff has examined the Pennsylvania request for an Agreement with respect to the ability of the radiation control program to regulate Agreement materials. The examination was based on the Commission's policy statement "Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory Authority and Assumption Thereof by States Through Agreement," (46 FR 7540; January 23, 1981, as amended by policy statements published at 46 FR 36969; July 16, 1981 and at 48 FR 33376; July 21, 1983), and the Office of Federal and State Materials and Environmental Management Programs (FSME) Procedure SA-700, "Processing an Agreement."

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

The educational requirements for the BRP staff members are specified in the Commonwealth of Pennsylvania personnel position descriptions, and meet the NRC criteria with respect to formal education or combined education and experience requirements. All current staff members hold at least bachelor's degrees in physical or life sciences, or have a combination of education and experience at least equivalent to a bachelor's degree. Several staff members hold advanced degrees, and all have had additional training plus working

experience in radiation protection. Supervisory level staff each have at least seven years working experience in radiation protection.

The BRP performed and the NRC staff reviewed an analysis of the expected workload under the proposed Agreement. Based on the NRC staff review of the BRP's staff analysis, the BRP has an adequate number of staff to regulate radioactive materials under the terms of the Agreement. The BRP will employ a staff with at least the equivalent of 17.2 full-time professional/technical and administrative employees for the Agreement materials program.

Pennsylvania has indicated that the BRP has an adequate number of trained and qualified staff in place. Pennsylvania has developed qualification procedures for license reviewers and inspectors which are similar to the NRC's procedures. The technical staff are working with NRC license reviewers in the NRC Region I Office and accompanying NRC staff on inspections of NRC licensees in Pennsylvania. Pennsylvania is also actively further supplementing their experience through direct meetings, discussions, and facility walk-downs with NRC licensees in Pennsylvania, and through self-study, in-house training, and formal training.

In the course of the NRC staff's continued interactions with Pennsylvania, the NRC staff will confirm the assurances that Pennsylvania provided concerning having an adequate number of trained and qualified staff in place, based on Pennsylvania's staff needs analysis and qualification procedures. Specifically, the NRC staff will verify how BRP staff fit into the qualification process, which staff are qualified in certain areas, and the basis for the determinations.

(b) Legislation and Regulations. 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 regulations for protection against radiation. The law provides PADEP the authority to issue licenses, issue orders, conduct inspections, and to enforce compliance with regulations, license conditions, and orders. Licensees are required to provide access to inspectors.

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

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

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

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

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

(g) Inspections and Enforcement. Pennsylvania has adopted a schedule providing for the inspection of licensees as frequently as, or more frequently than, the inspection schedule used by the NRC. The program has adopted procedures for the conduct of inspections, reporting of inspection findings, and reporting inspection results to the licensees. Pennsylvania has also adopted procedures for the enforcement of regulatory requirements, and is authorized by law to enforce the 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 to impound materials.

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

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

Pennsylvania also provides for “timely renewal.” This provision affords the continuance of licenses for which an application for renewal has been filed more than 30 days prior to the date of expiration of the license. NRC licenses transferred while in timely renewal are included under the continuation provision. The Pennsylvania Code provides exemptions from the Commonwealth's requirements for licensing of sources of radiation for NRC and U.S. Department of Energy contractors or subcontractors. The proposed Agreement commits Pennsylvania to use its best efforts to cooperate with the NRC and the other Agreement States

in the formulation of standards and regulatory programs for the protection against hazards of radiation, and to assure that Pennsylvania's program will continue to be compatible with the Commission's program for the regulation of Agreement materials. The proposed Agreement stipulates the desirability of reciprocal recognition of licenses, and commits the Commission and Pennsylvania to use their best efforts to accord such reciprocity.

III. Staff Conclusion

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

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

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

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 staff of the Bureau of Radiation Protection of the Pennsylvania Department of Environmental Protection, and concludes that, except as discussed above in Section II. "Summary of the NRC Staff Assessment of the Pennsylvania Program for the Control of Agreement Materials," (a)

“Organization and Personnel,” of this document, 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 materials, as comprised of statutes, regulations, and procedures, is compatible with the program of the Commission and is adequate to protect public health and safety with respect to the materials covered by the proposed Agreement.

With respect to discussion above in Section II. “Summary of the NRC Staff Assessment of the Pennsylvania Program for the Control of Agreement Materials,” (a) “Organization and Personnel,” once the NRC staff confirms the assurances provided by Pennsylvania concerning staff training and qualifications, the staff will be able to conclude that area is satisfied.

Dated at Rockville, Maryland, this [] day of [month], 2007.

For the Nuclear Regulatory Commission.

Janet R. Schlueter, Director
Division of Materials Safety and State Agreements
Office of Federal and State Materials
and Environmental Management Programs

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 Commonwealth under Chapters 6, 7, and 8, and Section 161 of the Act with respect to byproduct materials as defined in Sections 11e.(1), (3), and (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, 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 assuring 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 waste byproduct, source, and special nuclear 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:

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 Article II.A.1 through 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 SubSection 161b or 161i of the Act to issue rules, regulations, or orders to protect the common defense and security, to protect restricted data, or to guard against the loss or diversion of special nuclear material.

ARTICLE VI

The Commission will cooperate with the Commonwealth and other Agreement States in the formulation of standards and regulatory programs of the State and the Commission for protection against hazards of radiation and to assure that 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 assure 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 implication 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 [date], 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

DRAFT ASSESSMENT

of the proposed

PENNSYLVANIA PROGRAM FOR THE REGULATION OF AGREEMENT MATERIALS

as described in the

REQUEST FOR AN AGREEMENT

This Assessment examines the proposed Pennsylvania Program with respect to the ability of the program to regulate the possession, use, and disposal of radioactive materials subject to the Atomic Energy Act of 1954 (Act), as amended.¹ This Assessment was performed using the criteria in the Commission's policy statement "Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory Authority and Assumption Thereof by States Through Agreement" (referred to below as the "criteria")² using the Office of Federal and State Materials and Environmental Management Programs (FSME) Procedure SA-700, "Processing an Agreement.". The SA-700 procedure is posted 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 Agreement State Program for Pennsylvania 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. The authority to issue, amend, inspect, suspend, or revoke licenses, place conditions and to issue orders or assess civil penalties is vested by Statute in PADEP.

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 & Surveillance, Radiation Control, Nuclear Safety, and Radon. BRP provides radiological support to the emergency response plan for fixed nuclear facilities. Laboratory services are provided by PADEP's Bureau of Laboratories, with support of other agencies if needed. Pennsylvania also has six Regional Offices in the Deputate for Field Operations which are primarily responsible for inspection and compliance

¹According to paragraph (a) of § 274, the radioactive materials subject to an Agreement under the Act are byproduct, source and special nuclear materials.

²NRC Statement of Policy published in the Federal Register, January 23, 1981 (46 FR 7540-7546), a correction was published July 16, 1981 (46 FR 36969) and a revision of Criterion 9 published in the Federal Register, July 21, 1983 (48 FR 33376).

activities. All Agreement State regional activities will be conducted under programmatic policies established by the BRP Director.

Under the proposed Agreement, the BRP would assume the regulatory responsibility for byproduct, source, and small quantities of special nuclear materials. The licensing of these materials would 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 form their own Division of BRP. The DRC currently regulates the possession and use of Naturally Occurring and Accelerator Produced Radioactive Materials (NARM), and the use of electronic machine radiation. Again, inspections would 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, Section 4.1.1 and Section 4.1.2 (ADAMS: 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: 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 adopted the relevant NRC regulations in 10 CFR Parts 19, 20, 30, 31, 32, 33, 34, 35, 36, 39, 40, 70, 71, and 150 into Pennsylvania Code Title 25, Environmental Protection by reference. Therefore, Pennsylvania has adopted an adequate and compatible set of radiation protection regulations which apply to byproduct, source, and special nuclear materials in quantities not sufficient to form a critical mass.

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: ML063330295, 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 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: ML063330295, 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, the occupational dose limits and Subpart D, the 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: ML063330295,

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.

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 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: ML063330295, 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 regulations in Subpart J of 10 CFR Part 20 by reference. Therefore, the radiation labels, signs and symbols, and 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: ML063330295, 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 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: ML063330295, 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 of 10 CFR Part 20 by reference. Therefore, the Pennsylvania regulations pertaining to security and control of licensed material that 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: ML063330295, 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 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 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 which are 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 into 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.

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: ML063330295, 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 by reference. Due to NRC's renumbering of 10 CFR Part 71, a few minor changes are needed in the Pennsylvania Code, Title 25, Chapter 215. As of November 2006, these changes have been published for public comment and are proceeding through the regulatory process as planned. 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 by October 1, 2007. 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: ML063330295, 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 Pennsylvania Code Title 25, Environmental Protection. 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: ML063330295, 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 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: ML063330295, 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 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 NRC regulations containing regulatory requirements for applying for and issuing licenses by reference.

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

Since Criterion 13 was adopted, the Commission has determined that the regulatory authority to conduct safety evaluations of sealed sources and devices will be retained by the NRC, unless the State requests assumption of the authority and has in place an adequate and compatible program to implement the authority. 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: ML063330295, 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 to perform technical evaluation of proposed uses of radioactive material. In addition, Pennsylvania 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: ML063330295, ML070260179). Letter, with enclosures, dated March 16, 2007, from David Allard to Charles Miller, response to NRC comment letter dated January 26, 2007 (ADAMS: 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 by reference. Therefore, the Pennsylvania regulations include training and experience requirements for use of radioactive materials on or in humans, that 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: ML063330295, 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 regulations that are compatible with equivalent parts of Title 10 of the Code of Federal Regulations, which contain provisions relating to inspections and tests by reference.

The NRC staff determined that Pennsylvania has adopted a schedule for inspection of licensees at least as frequent as the schedule used by NRC. The Program staff has developed internal procedures and accompanying forms for the inspection areas which cover scheduling, preparation, performance basis, tracking and documentation of inspection results. The inspection procedures are similar to NRC 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: ML063330295, ML070290041, ML070290046, ML070260116, ML070260179). Letter, with enclosures, dated March 16, 2007, from David Allard to Charles Miller, response to NRC comment letter dated January 26, 2007 (ADAMS: 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. The 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: ML063330295, ML070290041, ML070290046, 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 provide instructions for distribution of the report to the licensee and to the State's official files.

The staff concludes that this criterion is satisfied.

References: Letter, with attachments, dated November 9, 2006, from Governor Rendell to Chairman Klein, request for an Agreement, Section 4.4 (ADAMS: ML063330295, 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 the 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 to 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 the 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: ML063330295, 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 two years of actual work experience in the field of radiation protection.

The foregoing are considered desirable qualifications for the staff who will be responsible for the actual performance of evaluation and inspection. In addition, there will probably be trainees associated with the regulatory program who will have an academic background in the physical or life sciences as well as varying amounts of specific training in radiation protection but little or no actual work experience in the field. The background and specific training of these persons will indicate to some extent their potential role in the regulatory program. These

trainees, of course, could be used initially to evaluate and inspect those applications of radioactive materials which are considered routine or more standardized from the radiation safety standpoint, for example, inspection of industrial gauges, small research programs, and diagnostic medical programs. As they gain experience and competence in the field, the trainees could be used progressively to deal with the more complex or difficult types of radioactive material applications. It is desirable that such trainees have a bachelor's degree or equivalent in the physical or life sciences and specific training in radiation protection. In determining the requirement for academic training of individuals in all of the foregoing categories, proper consideration should be given to equivalent competency which has been gained by appropriate technical and radiation protection experience.

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

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, Division of Radiation Control, in the Headquarters Office of BRP will be primarily responsible for the licensing activities of the Agreement Materials Program. The licensing activities will also be supported by the Radiation Protection Program staff working out of the PADEP Regional Offices. The inspection and compliance functions will primarily be conducted by Radiation Protection Program staff working out of the PADEP Regional Offices.

The Pennsylvania staffing needs analysis indicates a total of approximately 13.5 full-time equivalent (FTE) staff is needed for the Agreement materials program. The BRP staffing plan shows that 17.2 FTE is 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. Four staff members will provide 100% of their time committed to the Agreement State Program activities and eleven other staff members will provide 50% or more of their time to the Agreement State Program activities. Six other staff members will commit less than 50% each. Pennsylvania's staff assessment allows time for radiological response, instructional opportunities and training. Administrative and secretarial support are not addressed in the technical staffing analysis, however in the Program Narrative it is noted that clerical support is available in the central and all regional offices, and administrative support such as fiscal, IT, legal, etc, are provided by other organizational units within PADEP.

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 when 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 17.2 technical/professional FTE devoted to the Agreement State Program, the Team's evaluation of the Pennsylvania's staffing analysis concludes that the Bureau has adequate staffing. In addition, it is expected 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. NRC staff concludes the estimate of 1,000 licensees is reasonable, and the projected 17.2 FTE qualified technical/professional staff provides an adequate level of staffing to handle anticipated licensing, inspection, reciprocity, allegations and incident response workload satisfactorily.

The staff concludes that the proposed Pennsylvania agreement materials program has an adequate number of staff to meet the 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's professional/technical staff that would be involved in the Agreement Materials Program, and the procedures for training and qualifying new staff members. Under the proposed Agreement, the BRP Director would be primarily responsible for the Program's overall administration. He holds a Master's degree in Radiological Sciences and Protection. 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.

Program managers within the Division of Radiation Control and the Regions 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 Bachelor's degrees in sciences or engineering. The other four all hold Masters degrees. The managers have at least 7 years experience with the BRP, and most have been with the BRP for 19 or more years. In addition to their regulatory program experience, several of the managers have experience in industry.

NRC staff reviewed the educational qualifications of 20 individuals that would be involved in licensing and inspections of the Agreement Materials. All except two 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 the BRP. The other holds a Bachelors of Science in Educational Science and has 21 years experience in the BRP. NRC staff consider these combinations of training and experience to meet the requirements of being

equivalent to a Bachelors degree. The FTE assignments of the twenty individuals totals to more than the 13.5 FTE projected need in the Pennsylvania Staff Needs Analysis.

The BRP technical staff members have extensive applicable experience. This includes experience in the following fields: health physics, nuclear power, medical, industry, military, and in 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 provide 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 the NRC Region I Office and accompanying NRC staff on inspections of NRC licensees in Pennsylvania. Pennsylvania is also actively further supplementing their experience through direct meetings, discussions, and facility walk-downs with NRC licensees in Pennsylvania, and through self-study, in-house training, and formal training. Pennsylvania has indicated that the BRP has an adequate number of trained and qualified staff in place.

In the course of the NRC staff's continued interactions with Pennsylvania, the NRC staff will confirm the assurances that Pennsylvania provided concerning having an adequate number of trained and qualified staff in place, based on Pennsylvania's staff needs analysis and qualification procedures. Specifically, the NRC staff will verify how BRP staff fit into the qualification process, which staff are qualified in certain areas, and the basis for the determinations.

Once the NRC staff confirms the assurances provided by Pennsylvania concerning staff training and qualifications, the NRC staff will be able to conclude 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: ML063330295, ML070260026). Letter, with enclosures, dated March 16, 2007, from David Allard to Charles Miller, response to NRC comment letter dated January 26, 2007 (ADAMS: ML070790604, ML070790609, ML070790612, ML070790616, and ML070790620).

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: ML063330295, ML070290041, 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; plutonium in quantities not exceeding 200 grams; or any combination of them in accordance with the following formula: For each kind of special nuclear material, determine the ratio between the quantity of that special nuclear material and the quantity specified above for the same kind of special nuclear material. The sum of such ratios for all kinds of special nuclear material in combination should not exceed "1" (i.e., unity). For example, the following quantities in combination would not exceed the limitation and are within the formula, as follows:**

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

The NRC staff verified that Pennsylvania has adopted NRC'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: ML063330295, ML070290041, 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 the PADEP is bound by general statutory provisions with respect to providing the opportunity for public participation in rulemaking, licensing actions, and disciplinary actions. These general statutory provisions also apply to the protection of personnel radiation exposure records from public disclosure, maintaining the confidentiality of alleged, 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: ML063330295, ML070290041, ML070290046, ML070260179, ML070260026). Letter, with enclosures, dated March 16, 2007, from David Allard to Charles Miller, response to NRC comment letter dated January 26, 2007 (ADAMS: 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 Criteria 4.1.1.2., paragraph b, and 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: ML063330295, ML070290041, 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. **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 the Department 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: ML063330295, ML070290041, 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 hazards of radiation and to assure 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 Adequacy and Compatibility of Agreement State Programs (published September 3, 1997 at 62 FR 46517), the Commission determined that providing reports to NRC of Agreement State licensee incidents, accidents and other significant events is a matter of compatibility. The NRC staff determined that Pennsylvania has adopted procedures to provide such reports to 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, and Sections 4.1, 4.7 (ADAMS: ML063330295, ML070290041, ML070290046, ML070260026). Letter, with enclosures, dated March 16, 2007, from David Allard to Charles Miller, response to NRC comment

letter dated January 26, 2007 (ADAMS: 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 Sections 11e.(3) of the Act and byproduct materials as defined in 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 Section 11e.(3) and Section 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 that authority.

The proposed Agreement stipulates the desirability or reciprocal recognition of NRC and other Agreement State licenses, and commits the Commission and the State to

cooperate to accord such reciprocity. 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: ML063330295, ML070290041, 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, Environmental Protection, Chapter 215 (25 PA Code 215.32), and therefore provide the necessary exemptions from the State's requirements for licensing of sources of radiation for NRC and DOE contractors or subcontractors, in accordance with the criterion.

The staff concludes that this criterion is satisfied.

References: Letter, with attachments, dated November 9, 2006, from Governor Rendell to Chairman Klein, request for an Agreement, Section 4.2 (ADAMS: ML063330295, 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 letter dated November 27, 2006, from Governor Rendell to Chairman Klein, and the supporting information provided by the staff of the BRP of the PADEP.

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

- (a) The Governor of the State certifies that the State has a program for the control of radiation hazards adequate to protect public health and safety with respect to the agreement materials within the State, and that the State desires to assume regulatory responsibility for the agreement materials; and
- (b) The Commission finds that the State program is in accordance with the requirements of Section 274c., 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 staff of the Bureau of Radiation Protection of the Pennsylvania Department of Environmental Protection, and concludes that, except as discussed above in criterion 20, Qualifications of Regulatory and Inspection Personnel, 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 materials, as comprised of statutes, regulations, and procedures, is compatible with the program of the Commission and is adequate to protect public health and safety with respect to the materials covered by the proposed Agreement.

With respect to criterion 20, once the staff confirms the assurances provided by Pennsylvania concerning staff training and qualifications, the staff will be able to conclude that criterion 20 is satisfied.