

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 effect 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

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Sincerely,

Charles L. Miller, Director
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and Environmental Management Programs

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STATE OF PENNSYLVANIA REVIEW TEAM

Kevin Hsueh, Office of Federal and State Materials and Environmental Management Programs (FSME)	Team Leader Regulatory Elements
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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.**