

July 17, 2006

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 conducted a completeness review of your draft request for an Agreement, which you delivered to my staff on June 8, 2006. The review was conducted by an interoffice staff team identified in Enclosure 1. The review was based on the Office of State and Tribal Programs (STP) Procedure SA-700 for processing new agreements.

The initial phase of this process is a completeness review which is conducted to discover whether the Agreement materials program description information addresses each of the applicable elements, and to determine whether the draft request contains sufficient information to enable staff to conduct a detailed review of the request.

The review team found that the draft request provided information on all major program elements and reflected significant effort on the part of your staff. However, as reflected in the comments identified in Enclosure 2, the review team identified a number of areas where either the applicable program elements were not addressed, or additional information or documentation is needed in order for the staff to proceed to a detailed review of the request. Therefore, these items need to be addressed in the formal Agreement request submitted by the Governor.

While conducting the completeness review, the review team also generated some specific comments that are normally generated during the next, more detailed review phase of the Agreement request. The review team has elected to include these comments in Enclosure 3 for your consideration at this time. You may also consider addressing the comments listed in Enclosure 3 to expedite the process during the detailed review phase of the Agreement request.

Finally, the review team's conclusion that certain elements contained sufficient information to support a detailed review, does not address the ultimate adequacy or compatibility of the proposed Pennsylvania Agreement program. Once the review team's comments on the draft request are resolved, and a formal request is submitted, the staff will then proceed to the detailed review in accordance with the STP Procedure SA-700 to determine the adequacy and compatibility of the proposed Pennsylvania Agreement program.

D. J. Allard

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July 17, 2006

If you have any questions concerning the review, the information needed, or steps involved in processing the Agreement, please contact me at (301) 415-3340, or Kevin Hsueh, Team Leader for the Pennsylvania Agreement review team, at (301) 415-2598.

Sincerely,

/RA/

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

Enclosures:
As stated

D. J. Allard

-2-

July 17, 2006

If you have any questions concerning the review, the information needed, or steps involved in processing the Agreement, please contact me at (301) 415-3340, or Kevin Hsueh, Team Leader for the Pennsylvania Agreement review team, at (301) 415-2598.

Sincerely,

/RA/

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

Enclosures:
As stated

Distribution: DCD (SP05)

DIR RF

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SMinnick, RSAO/RI

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STATE OF PENNSYLVANIA COMPLETENESS REVIEW TEAM

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Office of State and Tribal Programs (STP)

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Regulatory Elements

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Office of the General Counsel

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Licensing Elements

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Licensing Elements

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Inspection Elements

Tomas Herrera, NMSS

Event and Allegation Elements

Gary Purdy,
Office of Nuclear Security
and Incident Response

Events and Allegation Elements

STATE OF PENNSYLVANIA DRAFT REQUEST COMMENTS

After conducting the completeness review of the Pennsylvania Agreement draft request, the review team has identified the following comments.

Section 4.1 Legal Elements

Section 4.1.1 Statutory Authority

Review Team Comment: The draft request contained sufficient information to enable NRC staff to conduct a detailed review.

4.1.2 Organization of the Proposed Program

Review Team Comment: The draft request contained sufficient information to enable NRC staff to conduct a detailed review.

4.1.3 Content of the Proposed Agreement

Review Team Comment: The draft request contained sufficient information to enable NRC staff to conduct a detailed review.

4.2 Regulatory Requirements Program Elements

4.2.1 Standards for Protection Against Radiation

Review Team Comment: The draft request contained sufficient information to enable NRC staff to conduct a detailed review.

4.2.2 Regulatory Requirements with Significant Transboundary Implications

Review Team Comment: The draft request contained sufficient information to enable NRC staff to conduct a detailed review.

4.2.3 Regulatory Requirements Needed for an Orderly Pattern of Regulation or Which Have Particular Health and Safety Significance

Review Team Comment: Pennsylvania needs to address the requirements of NRC Order for Increased Controls. It is the review team's understanding that Pennsylvania plans to issue an order for increased controls after it becomes an Agreement State. Pennsylvania is expected to submit a draft order to NRC for a compatibility review prior to becoming an Agreement State.

ENCLOSURE 2

4.3 Licensing Program Elements

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

Review Team Comments: While Pennsylvania stated they will follow as closely as possible the NUREG-1556 procedure for technical evaluation of proposed uses of radioactive material, the Pennsylvania request needs to include additional information with respect to technical licensing procedures. As a reference for the comments below, please see SA-700 Handbook, Section 4.3.1.2.

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

- a. portions of the NUREG-1556 series that will be followed, ways in which Pennsylvania might deviate from the NUREG-1556 guidance, and procedures for approving deviations from the NUREG-1556 guidance;
- b. technical licensing procedures for Part 40 licenses (which are not addressed in the NUREG-1556 series), including standard review plans, checklists, and licensing guides;
- c. qualifications of license reviewers for each license program code; and
- d. technical licensing procedures for evaluating decommissioning, including decontamination, disposal, and any restrictions on the future uses of the property including funding and surety issues.

Recommendation: The review team recommends that Pennsylvania revise its Agreement request to address the comments above.

4.3.2 Procedure for the Evaluation of Radiation Safety Information on Sealed Sources or Devices, and Registration for Distribution

Not Applicable to Pennsylvania Agreement request.

4.3.3 Procedures for Conducting the Technical Evaluation of a Proposed License for a Low-level Radioactive Waste Land Disposal Site

Review Team Comments: The draft request contained sufficient information to enable NRC staff to conduct a detailed review.

4.3.4 Procedure for Conducting the Technical Evaluation of a Proposed Uranium or Thorium Recovery Facility

Not applicable to Pennsylvania Agreement request.

4.3.5 Procedures for Assuring the Technical Quality of Licenses

Review Team Comment: While Pennsylvania submitted four administrative licensing procedures under Section 4.3.5, the Pennsylvania request needs to include procedures to assure the quality of licensing actions. As a reference for the comments below, please see SA-700 Handbook, Section 4.3.5.1 and 4.3.5.2.

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

- a. a consistent method for peer review of licensing actions;
- b. a consistent method for supervisory review of licensing actions; and
- c. any other method to assure the quality of licensing actions, if applicable.

Recommendation: The review team recommends that Pennsylvania revise its Agreement request to address the comments above.

4.3.6 Administrative Licensing Procedures

Review Team Comments: While Pennsylvania submitted four administrative licensing procedures under 4.3.5, the Pennsylvania request needs to include additional information with respect to administrative licensing procedures. As a reference for the comments below, please see SA-700 Handbook, Sections 4.3.6.1 and 4.3.6.2.

- 1. Pennsylvania needs to clearly establish the difference between the functions of the (1) administrative licensing procedures, and (2) the procedures to assure the technical quality of licensing actions.
- 2. The Pennsylvania procedures should be revised to address the transition of licenses affected by the Agreement (i.e., to assure the continued validity and operation of licenses).

Recommendation: The review team recommends that Pennsylvania revise its Agreement request to address the comments above.

4.4 Inspection Program Elements

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

Review Team Comments: The inspection procedures submitted in the draft request cover all the inspection manual chapters and inspection procedures with the exception of the following two procedures:

- a. MC 0620 Inspection Documentation and Records; and

- b. IP 92701 Follow-up.

Recommendation: The review team recommends that Pennsylvania include the two procedures to its Agreement request.

4.4.2 Procedures for Assuring the Technical Quality of Inspections and Inspection Reports

Review Team Comment: The draft request contained sufficient information to enable NRC staff to conduct a detailed review.

4.4.3 Administrative Procedures for Inspections

Review Team Comment: The draft request contained sufficient information to enable NRC staff to conduct a detailed review.

4.5 Enforcement Program Elements

4.5.1 Routine Enforcement Procedures

Review Team Comment: The draft request contained sufficient information to enable NRC staff to conduct a detailed review.

4.5.2 Escalated Enforcement Procedures

Review Team Comment: The draft request contained sufficient information to enable NRC staff to conduct a detailed review.

4.6 Technical Staffing and Training Program Elements

4.6.1 Technical Staff Organization

Review Team Comments: While Pennsylvania submitted technical staffing and training program elements, the Pennsylvania request needs to include additional information that should be addressed as a part of an Agreement State program request. Specifically, SA-700 Handbook, Section 4.6.1.1 request that the State submit its program staffing plan showing the number of staff members assigned to specific responsibilities, such as license review and inspection and for each major category of licensee. It should estimate the workload for the licensees that will transfer, and the other duties of the program.

The Pennsylvania draft request did not include a staffing analysis that reflects the number, distribution, and sizes of the licensees that will transfer under the Agreement.

Recommendation: The review team recommends that Pennsylvania include a staffing analysis in its Agreement request.

4.6.2 Formal Qualification Plan

Review Team Comment: The draft request contained sufficient information to enable NRC staff to conduct a detailed review.

4.6.3 Qualifications of Current Technical Staff

Review Team Comments: While Pennsylvania submitted technical staffing and training program elements, the Pennsylvania request needs to include additional information that should be addressed as a part of an Agreement State program request. Specifically, SA-700 Handbook, Section 4.6.3.1 request that for each current staff member, identify the individual's qualifications (including interim qualifications) under the State's written qualification plan.

The Pennsylvania draft request did not identify the individual's qualifications (including interim qualifications) under the State's written qualification plan.

Review Team Comment: The review team recommends that Pennsylvania include the individual's qualifications in its Agreement request.

4.7 Event and Allegation Response Program Elements

4.7.1 Procedures for Responding to Events and Allegations

Review Team Comments: While Pennsylvania submitted procedures for nuclear power plant emergency response, the Pennsylvania request needs to include written procedures for responding to materials events within the State. As a reference for the comment below, please see SA-700 Handbook, Sections 4.7.1.1 and 4.7.1.2

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

- a. immediate response and actions to mitigate an event;
- b. follow-up inspections and enforcement actions;
- c. notifications to licensing staff;
- d. reports to the incident file; and
- e. notifications to other affected licensees of generic problems.

Recommendation: The review team recommends that Pennsylvania revise its Agreement request to address the comments above.

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

Review Team Comments: While Pennsylvania submitted the NMED procedure, the Pennsylvania request needs to include additional information that should be addressed as a part of an Agreement State program request. Specifically, SA-700 Handbook, Section 4.7.2.2 describes that the State procedures should assign responsibilities for the completion of the reports, and for assuring the quality of the reports. In addition, the procedures should specify times for completion of the reports and submitting to NRC, provide guidance for identifying abnormal occurrences and should be consistent with the STP Procedure SA-300 Handbook, *Nuclear Material Event Reporting in the Agreement States*.

The procedures should be revised to include the following items:

- a. assigning responsibility for the completion of the reports;
- b. assuring the quality of the reports;
- c. specifying times for completion of the reports and submitting them to the NRC;
- d. identifying abnormal occurrences; and
- e. a process to identify NRC reportable events and forward reports (notification, follow up, and closeouts) to NRC for inclusion in NMED.

Recommendation: The review team recommends that Pennsylvania revise its Agreement request to address the comments above.

STATE OF PENNSYLVANIA

DRAFT REQUEST COMMENTS

(Specific Comments on Draft Request)

In addition to comments listed in Enclosure 2, the review team also identified the following specific comments that are normally generated during the detailed review of an Agreement request:

4.3.3 Procedures for Conducting the Technical Evaluation of a Proposed License for a Low-Level Radioactive Waste Land Disposal Site

Review Team Comments: While Pennsylvania submitted the procedure for licensing the Low-Level Radioactive Waste (LLRW) Disposal Facility, the section needs additional information that should be addressed as a part of an Agreement request. As a reference for the comment below, please see SA-700 Handbook, Section 4.3.3.2 which describes that the State procedures should contain the same level of detail as NRC procedures in NUREGs-1199, 1200 and 1274.

1. Section 2.2 of the LLRW licensing procedure states that Pennsylvania will issue three licensing documents related to the LLRW disposal facility action. One document will be analogous to NUREG-1199, another will be analogous to NUREG-1200 and the third will be a Licensing Management Plan to ensure that Pennsylvania's activities associated with the licensing process are adequately and effectively carried out. However, there is no statement indicating that Pennsylvania will implement the Licensing Management Plan analogous to NUREG-1274. Also, there is no indication that the three licensing documents will be completed and issued before Pennsylvania becomes an Agreement State.

Recommendation: The review team recommends that Pennsylvania revise its Agreement request to address the comment above.

4.3.6 Administrative Licensing Procedures

Review Team Comments:

1. Pennsylvania's Agreement State draft request Section 4.3.5, "Material Licensing Procedures," addresses the following subjects: (1) Prioritization of Licensing Actions, (2) Renewal of Licenses, (3) License Termination, and (4) Review of an Initial Application for License or an Amendment Request. It appears that these procedures are intended to address information needed in both Sections 4.3.5.1 and 4.3.6.1 of SA-700 Handbook. Two specific comments follow:
 - a. The license document preparation procedures are addressed within the four licensing procedures submitted. However, additional information with respect to the administrative process to perform review of the licensing actions is needed. Specifically, the procedures to process a licensing action do not address how the review will be performed, i.e., which standard review plans, checklists, policies

ENCLOSURE 3

and guidance will be used and how these will be used during the review. Also, these licensing procedures should identify forms, letters, reports that will be used to evaluate the licensing actions and communicate with the licensees and/or applicants.

- b. The tracking of action progress and license file maintenance are addressed in the four licensing procedures. However, the draft request only indicates that records will be maintained in both, hard copy and electronic copy. Additional information is needed on how the records will be tracked and maintained (e.g., multiple databases/files vs. one database/file, responsibility/accountability for the databases/files, identification of license, eFACTS).
2. Section 3.3 of the Renewal of Licenses procedure states that "...the reviewer shall use, as appropriate, the NUREG-1556 series...In particular Pennsylvania specific rule and policy should be reviewed if only NRC guidance was utilized." Pennsylvania needs to clarify the specific information in the NUREG-1556 Series that will be used to evaluate licensing actions for the different program codes. The Agreement request needs to include all the guidance documents that will be used by the reviewer to evaluate licensing actions.
3. The review team has the following specific comments on the License Termination Procedure:
 - 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 License Termination Procedure 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 the NRC NUREG-1757. The Pennsylvania License Termination Procedure should include these provisions or adopt the NUREG-1757 guidance.
 - b. Section 1.2 of the License Termination Procedure, "References," identifies a number of references which have been superceded by NUREG-1757, or are no longer applicable. References to NUREG 1727, NUREG/BR-0241, NUREG/CR-5849, Draft Regulatory Guide DG 4006, and NUREG-1549 should be removed.
 - c. Section 3.1 of the License Termination Procedure 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 citation of 215.27 and 236.411 needs 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.
 - d. Section 3.4 of the License Termination Procedure, states, "If an independent survey reveals possible residual activity the licensee shall be requested to submit

a sufficient License Termination Plan (LTP) such that the facility will be decontaminated to levels acceptable for restricted use. NUREG-1575 and NUREG/CR-5849 (see sub-Section 1.2 of this procedure) can be used in the development, implementation of the LTP and the termination of the license(s). NUREG 1727 can be used to evaluate the LTP by the Radioactive Materials Program."

Please confirm that the wording "acceptable for restricted use" should be changed to "acceptable for unrestricted use." Also, 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.

- e. Section 3.5.2 of the License Termination Procedure states, "If residual contamination is discovered, the facility shall be decontaminated to acceptable levels and the license revoked." This section needs to clarify who will perform the decontamination and what clean-up criteria will be used.
- f. 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.

Recommendation: The review team recommends that Pennsylvania revise its Agreement request to address the comments above.

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

The review team has the following specific comments under this Section:

- 1. A process needs to be in place to generate unique event identification numbers for the reports.
- 2. Also, the reporting requirements for 10 CFR 31.5 (c)(5) and 10 CFR 71.5 are missing. The Events and NMED procedures should be revised to include these reporting requirements.

Recommendation: The review team recommends that Pennsylvania revise its Agreement request to address the comments above.