

ENCLOSURE 2

STAFF ANALYSIS OF PUBLIC COMMENTS

STAFF ANALYSIS OF PUBLIC COMMENTS ON THE PROPOSED PENNSYLVANIA AGREEMENT

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

INTRODUCTION:

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

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

ADEQUACY OF THE PENNSYLVANIA AGREEMENT PROGRAM

(1) Enforcement Policies

Summary of Comments:

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

NRC Staff Response:

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

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

(2) Inspection Policies

Summary of Comments:

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

NRC Staff Response:

At this time, the NRC encourages, but does not require, an Agreement State regulatory program to adopt a risk-informed, performance-based approach as a matter of compatibility. The Commission may determine at a later date, based on NRC experience and after consultation with the Agreement States, that risk-informed, performance-based regulation should be a matter of compatibility. In this case, the States will be required to adopt such an approach. Requiring Pennsylvania to do so as part of the Agreement at this time would not be appropriate.

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

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

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

(3) Program Funding and Planning for Retirements

Summary of Comments:

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

NRC Staff Response:

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

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

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

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

(4) Termination of the Quehanna License

Summary of Comments:

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

NRC Staff Response:

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

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

ADEQUACY OF THE PENNSYLVANIA PROGRAM STAFF

Summary of Comments:

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

NRC Staff Response:

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

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

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

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

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