



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

March 25, 2019

MEMORANDUM TO: K. Steven West
Deputy Executive Director for Materials, Waste,
Research, State, Tribal, Compliance, Administration,
and Human Capital Programs
Office of the Executive Director for Operations

Mary B. Spencer, Assistant General Counsel
for Reactor and Materials Rulemaking
Office of the General Counsel

John W. Lubinski, Director
Office of Nuclear Material Safety
and Safeguards

John B. Giessner, Deputy Regional Administrator
Region III

FROM: Paul Michalak, Chief */RA/*
Agreement State Programs Branch
Division of Materials Safety, Security, State,
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

SUBJECT: INTEGRATED MATERIALS PERFORMANCE EVALUATION
PROGRAM REVIEW OF PENNSYLVANIA

This memorandum transmits to the Management Review Board (MRB) the proposed final report (Enclosure 1) documenting the Integrated Materials Performance Evaluation Program (IMPEP) review of the Commonwealth of Pennsylvania. The review was conducted by a team of U.S. Nuclear Regulatory Commission (NRC) and Agreement State technical staff during the period of January 7-11, 2019. The team's preliminary findings were discussed with representatives of the Commonwealth of Pennsylvania on the last day of the review. The team issued a draft report to Pennsylvania on February 1, 2019, for factual comment. Pennsylvania responded to the draft report by letter dated March 13, 2019, from David Allard, Bureau of Radiation Protection Director, Department of Environmental Protection (Enclosure 2).

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Overall, the team is recommending that Pennsylvania's performance be found satisfactory for all performance indicators reviewed. Accordingly, the team recommends that the Pennsylvania Agreement State Program be found adequate to protect public health and safety and compatible with the NRC's program. The team recommends that the next IMPEP review take place in approximately 5 years with a periodic meeting in approximately 2.5 years.

The MRB meeting to consider the Pennsylvania's report is scheduled for **Tuesday, April 9, 2019, from 1:00 p.m. to 4:00 p.m. ET, OWFN-03B04**. In accordance with Management Directive 5.6, the meeting is open to the public. The agenda for the meeting is enclosed (Enclosure 3).

Enclosures:

1. Pennsylvania Proposed Final Report
2. Pennsylvania Response to Draft IMPEP Report
3. Agenda for MRB Meeting

cc: Steve Harrison, VA
Organization of Agreement States
Liaison to the MRB

SUBJECT: INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM REVIEW
OF PENNSYLVANIA

DATED: March 25, 2019

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM
REVIEW OF THE PENNSYLVANIA AGREEMENT STATE PROGRAM

JANUARY 7-11, 2019

PROPOSED FINAL REPORT

EXECUTIVE SUMMARY

This report presents the results of the Integrated Materials Performance Evaluation Program (IMPEP) review of the Commonwealth of Pennsylvania Agreement State Program (the Program). The review was conducted during the period of January 7-11, 2019, by a team comprised of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the Commonwealth of Kentucky.

Based on the results of this review, the Program's performance was found to be satisfactory for all six indicators reviewed.

The team did not make any recommendations and determined that the recommendation originally identified during the 2009 IMPEP review, and extended during the 2014 IMPEP review, should now be closed (see Section 2.0).

Accordingly, the team recommends that the Program be found adequate to protect public health and safety and compatible with the NRC's program. Based on the results of the current IMPEP review, which was the second consecutive IMPEP review with all performance indicators found satisfactory, the team recommends that the next full IMPEP review take place in approximately 5 years, with a periodic meeting in approximately 2.5 years.

1.0 INTRODUCTION

This report presents the results of the review of the Commonwealth of Pennsylvania Agreement State Program radioactive materials safety program. The review was conducted during the period January 7-11, 2019, by a team comprised of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the Commonwealth of Kentucky. Team members are identified in Appendix A. The review was conducted in accordance with the "Agreement State Program Policy Statement," published in the *Federal Register* on October 18, 2017 (82 FR 48535), and NRC Management Directive (MD) 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)," dated February 26, 2004. Preliminary results of the review, which covered the period of January 18, 2014 to January 11, 2019, were discussed with Pennsylvania Agreement State Program managers on the last day of the review.

In preparation for the review, a questionnaire addressing the common performance indicators and applicable non-common performance indicator was sent to Pennsylvania by electronic mail on October 16, 2018. Pennsylvania provided its response to the questionnaire by electronic mail on December 18, 2018. A copy of the questionnaire response is available in the NRC's Agencywide Documents Access and Management System (ADAMS) using Accession Number ML18353A699.

The Commonwealth of Pennsylvania Agreement State Program (the Program) is administered by the Bureau of Radiation Protection (the Bureau). The Bureau is part of the Department of Environmental Protection (the Department). The compliance part of the Program resides in three Regional Offices within the Commonwealth. Organization charts for Pennsylvania are available in ADAMS using Accession Number ML18354B029.

At the time of the review, the Program regulated 598 specific licenses authorizing possession and use of radioactive materials. The review focused on the radioactive materials program as it is carried out under Section 274b (of the Atomic Energy Act of 1954, as amended) Agreement between the NRC and the Commonwealth of Pennsylvania.

The team evaluated the information gathered against the established criteria for each common and applicable non-common performance indicator and made a preliminary assessment of the Program's performance.

2.0 PREVIOUS IMPEP REVIEW AND STATUS OF RECOMMENDATIONS

The previous IMPEP review concluded on January 17, 2014. The final report is available in ADAMS (Accession Number ML14121A321). The results of the review are as follows:

Technical Staffing and Training: Satisfactory
Recommendation: None

Status of Materials Inspection Program: Satisfactory
Recommendation: None

Technical Quality of Inspections: Satisfactory
Recommendation: None

Technical Quality of Licensing Actions: Satisfactory
Recommendation: None

Technical Quality of Incident and Allegation Activities: Satisfactory

Recommendation: During the 2009 IMPEP review which concluded on November 20, 2009, the team made one recommendation as follows: "The team recommends that the Commonwealth strengthen its incident response program to ensure that incidents are appropriately investigated and are promptly reported to NRC, as appropriate."

During the 2014 IMPEP review, which concluded on January 17, 2014, the team attempted to close the recommendation but concluded the following: Since the November 2009 IMPEP review, one staff member had been assigned to track incidents and ensure that reporting requirements are met and are timely. The 2014 IMPEP review indicated that, while timeliness had improved overall, notifications to the NRC were still late in 5 of the 10 cases reviewed by a matter of days or weeks in four cases and not reported in one case. In addition, communication of incidents from the Bureau to its Regional Offices had improved, and incident investigations were typically thorough, complete and comprehensive. However, in three of the 10 cases reviewed, two involving industrial radiography source retractions and one involving a contaminated package, the incident investigations were insufficient in that root causes were not identified and actions taken by the licensees to prevent similar events were not documented or reviewed to assess their effectiveness. The team recommended and the Management Review Board (MRB) agreed that the recommendation remain open.

During the 2019 IMPEP review, the team found that issues involving timeliness in reporting events identified during the two previous IMPEP reviews no longer existed. The team found that all required notifications to NRC were reported in a timely manner over the entire review period. Communications of incidents from the Bureau to the Regions were comprehensive and timely with management oversight to ensure that none were missed. Initiation of investigations by the Regional Offices was prompt and findings were rapidly conveyed to the Bureau. Incident investigations were found to be thorough, complete and comprehensive for every case reviewed. Root causes of events were identified and reviewed to assess their effectiveness. Enforcement action was taken where appropriate, for all cases reviewed.

The team determined that this recommendation should be closed.

Compatibility Requirements: Satisfactory
Recommendation: None

3.0 COMMON PERFORMANCE INDICATORS

Five common performance indicators are used to review the NRC regional and Agreement State radioactive materials programs. These indicators are: (1) Technical Staffing and Training; (2) Status of Materials Inspection Program; (3) Technical Quality of Inspections; (4) Technical Quality of Licensing Actions; and (5) Technical Quality of Incident and Allegation Activities.

3.1 Technical Staffing and Training

The ability to conduct effective licensing and inspection programs is largely dependent on having a sufficient number of experienced, knowledgeable, and well-trained technical personnel. Under certain conditions, staff turnover could have an adverse effect on the implementation of these programs, and could affect public health and safety. Apparent trends in staffing must be explored. Review of staffing also requires consideration and evaluation of the levels of training and qualification. The evaluation standard measures the overall quality of training available to, and taken by, materials program personnel.

a. Scope

The team used the guidance in State Agreements procedure SA-103, "Reviewing the Common Performance Indicator: Technical Staffing and Training," and evaluated the Program's performance with respect to the following performance indicator objectives:

- A well-conceived and balanced staffing strategy has been implemented throughout the review period.
- Agreement State training and qualification program is equivalent to NRC Inspection Manual Chapter (IMC) 1248, "Formal Qualifications Program for Federal and State Material and Environmental Management Programs."
- Qualification criteria for new technical staff are established and are followed, or qualification criteria will be established if new staff members are hired.
- Any vacancies, especially senior-level positions, are filled in a timely manner.
- There is a balance in staffing of the licensing and inspection programs.
- Management is committed to training and staff qualification.
- Individuals performing materials licensing and inspection activities are adequately qualified and trained to perform their duties.
- License reviewers and inspectors are trained and qualified in a reasonable period of time.

b. Discussion

The Program is comprised of 35 staff members when fully staffed. This includes supervisors and clerical staff. At the time of the review, there was one vacancy and that

position is currently part of a hiring freeze. During the review period, 12 staff members left the program and 11 staff members were hired. Nine of the 12 employees that left the program retired, one employee passed on, one employee left due to illness, and one employee left for the private sector. On average, positions were vacant from 2 to 4 months, while the current vacancy has been open for approximately 4 years. Despite the significant turnover in the staff, the team did not identify any performance issues during the review period. All employees hired during this review period have science degrees.

The Program has a training and qualification program that is compatible with the NRC's IMC 1248. Bureau management is very supportive of continuing education/refresher training and the training is tracked by the employees and its Section Chief. The training qualification record that is used to track milestones directed toward qualification is comprehensive and includes in-house training, on-the-job instruction, and formal courses. A mentoring program has been implemented where senior inspectors or license reviewers provide on-the-job training for junior employees.

c. Evaluation

The team determined that, during the review period, Pennsylvania met the performance indicator objectives listed in Section 3.1.a., and based on the criteria in MD 5.6, recommends that Pennsylvania's performance with respect to the indicator, Technical Staffing and Training, be found satisfactory.

d. MRB Decision

The final report will present the MRB's conclusion regarding this indicator.

3.2 Status of Materials Inspection Program

Periodic inspections of licensed operations are essential to ensure that activities are being conducted in compliance with regulatory requirements and consistent with good safety practices. The frequency of inspections is specified in IMC 2800, "Materials Inspection Program," and is dependent on the amount and kind of material, the type of operation licensed, and the results of previous inspections. There must be a capability for maintaining and retrieving statistical data on the status of the inspection program.

a. Scope

The team used the guidance in State Agreements procedure SA-101, "Reviewing the Common Performance Indicator: Status of the Materials Inspection Program," and evaluated the Program's performance with respect to the following performance indicator objectives:

- Initial inspections and inspections of Priority 1, 2, and 3 licensees are performed at the frequency prescribed in IMC 2800.
- Candidate licensees working under reciprocity are inspected in accordance with the criteria prescribed in IMC 1220, "Processing of NRC Form 241, Report of Proposed

Activities in Non-Agreement States, Areas of Exclusive Federal Jurisdiction, and Offshore Waters, and Inspection of Agreement State Licensees Operating Under 10 CFR 150.20.”

- Deviations from inspection schedules are normally coordinated between technical staff and management.
- There is a plan to perform any overdue inspections and reschedule any missed or deferred inspections, or a basis has been established for not performing any overdue inspections or rescheduling any missed or deferred inspections.
- Inspection findings are communicated to licensees in a timely manner (30 calendar days, or 45 days for a team inspection, as specified in IMC 0610, “Nuclear Material Safety and Safeguards Inspection Reports”).

b. Discussion

The Program’s inspection frequencies are the same for similar license types found in IMC 2800. The Program performed a total of 637 Priority 1, 2, 3 and initial inspections over the review period, none of which were conducted overdue. Initial inspections of new licenses were all performed within 12 months of license issuance with none conducted overdue.

A sampling of 26 inspection reports indicated that only one of the inspection findings was communicated to the licensees beyond the Program’s goal of 30 days after the inspection exit. The single untimely report, which included a violation, was issued almost 5 months after the conclusion of the inspection. The cause was a performance issue with a Program employee. The issue was addressed by the supervisor and there was no recurrence.

For each year of the review period, Pennsylvania also performed greater than 20 percent of candidate reciprocity inspections.

c. Evaluation

The team determined that, during the review period, Pennsylvania met the performance indicator objectives listed in Section 3.2.a., and based on the criteria in MD 5.6, recommends that Pennsylvania’s performance with respect to the indicator, Status of Materials Inspection Program, be found satisfactory.

d. MRB Decision

The final report will present the MRB’s conclusion regarding this indicator.

3.3 Technical Quality of Inspections

Inspections, both routine and reactive, provide assurance that licensee activities are carried out in a safe and secure manner. Accompaniments of inspectors performing inspections, and the critical evaluation of inspection records, are used to assess the technical quality of an Agreement State’s inspection program.

a. Scope

The team used the guidance in State Agreements procedure SA-102, "Reviewing the Common Performance Indicator: Technical Quality of Inspections," and evaluated Pennsylvania's performance with respect to the following performance indicator objectives:

- Inspections of licensed activities focus on health, safety, and security.
- Inspection findings are well-founded and properly documented in reports.
- Management promptly reviews inspection results.
- Procedures are in place and used to help identify root causes and poor licensee performance.
- Inspections address previously identified open items and violations.
- Inspection findings lead to appropriate and prompt regulatory action.
- Supervisors, or senior staff as appropriate, conduct annual accompaniments of each inspector to assess performance and assure consistent application of inspection policies.
- For programs with separate licensing and inspection staffs, procedures are established and followed to provide feedback information to license reviewers.
- Inspection guides are consistent with NRC guidance.
- An adequate supply of calibrated survey instruments is available to support the inspection program.

b. Discussion

The team evaluated the inspection reports and enforcement documentation, and interviewed inspectors involved in materials inspections conducted during the review period. The casework reviewed included 27 inspections conducted by 20 current and former inspectors and covered medical, industrial, commercial, academic, and research licenses.

The team found that inspection documents were thorough, complete, consistent, and of acceptable technical quality with health, safety, and security issues properly addressed. Inspection findings were clearly communicated to the licensee and violations were written with a direct link to a regulation or license condition. In the casework reviewed, every inspection addressed previously identified open items and violations.

Two team members accompanied six inspectors, two from each of the Bureau's Regional Offices, during the months of November and December in 2018. No performance issues were noted during the inspector accompaniments. The inspectors were well-prepared and thorough, and assessed the impact of licensed activities on health, safety, and security. Inspector accompaniments are identified in Appendix B.

Supervisory accompaniments were performed each year of the review period by either the Section Chief or the Program Manager. In 2014 through 2017, all inspectors were

accompanied. In 2018, all but one inspector were accompanied and the inspector who was not accompanied only performed three inspections that calendar year.

The team verified that the Bureau's Regional Offices maintain a wide variety of appropriately calibrated survey instruments to support the inspection program, and to respond to radioactive materials incidents and emergency situations. Calibration records for the instruments are maintained on file. Detection instruments are available for gamma, beta, and alpha contamination, as well as dose rates. The Regional Offices had portable multi-channel analyzers for assessing and identifying unknown sources.

c. Evaluation

The team determined that, during the review period, Pennsylvania met the performance indicator objectives listed in Section 3.3.a, and based on the criteria in MD 5.6, recommends that Pennsylvania's performance with respect to the indicator, Technical Quality of Inspections, be found satisfactory.

d. MRB Decision

The final report will present the MRB's conclusion regarding this indicator.

3.4 Technical Quality of Licensing Actions

The quality, thoroughness, and timeliness of licensing actions can have a direct bearing on public health and safety, as well as security. An assessment of licensing procedures, actual implementation of those procedures, and documentation of communications and associated actions between the Pennsylvania licensing staff and regulated community is a significant indicator of the overall quality of the licensing program.

a. Scope

The team used the guidance in State Agreements procedure SA-104, "Reviewing the Common Performance Indicator: Technical Quality of Licensing Actions," and evaluated Pennsylvania's performance with respect to the following performance indicator objectives:

- Licensing action reviews are thorough, complete, consistent, and of acceptable technical quality with health, safety, and security issues properly addressed.
- Essential elements of license applications have been submitted and elements are consistent with current regulatory guidance (e.g., financial assurance, increased controls, pre-licensing guidance).
- License reviewers, if applicable, have the proper signature authority for the cases they review independently.
- License conditions are stated clearly and can be inspected.
- Deficiency letters clearly state regulatory positions and are used at the proper time.
- Reviews of renewal applications demonstrate a thorough analysis of a licensee's inspection and enforcement history.

- Applicable guidance documents are available to reviewers and are followed (e.g., NUREG-1556 series, pre-licensing guidance, regulatory guides, etc.).
- Licensing practices for risk-significant radioactive materials are appropriately implemented including increased controls and fingerprinting orders (Part 37 equivalent).
- Documents containing sensitive security information are properly marked, handled, controlled, and secured.

b. Discussion

During the review period, the Program performed 2,697 radioactive materials licensing actions. The team evaluated 21 of those licensing actions. The licensing actions selected for review included three new applications, 11 amendments, two renewals, one termination, one completed decommissioning action, one ongoing decommissioning action, one beginning decommissioning action, and one bankruptcy.

The team evaluated casework which included the following license types and actions: broad scope medical, broad scope research and development, medical diagnostic and therapy, commercial manufacturing and distribution, industrial radiography, research and development, academic, nuclear pharmacy, gauges, self-shielded irradiators, well-logging, service providers, decommissioning actions, financial assurance, bankruptcies, and notifications. The casework sample represented work from eight of the nine license reviewers at the Program's headquarters; one license reviewer had just begun the qualification process for licensing.

The team found that the licensing actions reviewed were thorough, complete, consistent, and of acceptable quality of health, safety and security. The Program performs a complete peer review of each action. Upon completion of the initial review, the entire application file is reviewed by a second qualified license reviewer who performs a full peer review. Once this second review is completed, the action is then passed on to the Chief of the Radiation Control Division for final review and issuance.

The team evaluated the pre-licensing guidance and the pre-licensing site visit aspect of the new license application process. The Program conducted pre-licensing site visits for all unknown entities in accordance with the pre-licensing checklist. The Program only issued a license once the applicant had, as a minimum, adequate facilities and equipment, as well as a qualified radiation safety officer and materials users. In addition, a new applicant, or existing licensee adding a new location with licensed radioactive material in a quantity equal to or exceeding Category 2, has to implement increased security measures in accordance with 10 CFR Part 37 prior to the issuance of the new license.

The team noted that, for actions involving change of control, the pre-licensing checklist was not used until one of the Bureau's staff attended the IMPEP team member training in early 2018. Upon return, all actions involving transfer of control used the pre-licensing checklist. The team evaluated the process used by the Program prior to this change and

determined that the review process used by the Pennsylvania Department of State, which requires each new corporate entity be registered in the Commonwealth of Pennsylvania, is compatible with the pre-licensing guidance.

The team determined that licensees requiring financial assurance by the Program regulations had adequate funding plans and remained in compliance with financial assurance requirements throughout the review period. Financial assurance instruments were appropriately protected from loss or theft.

c. Evaluation

The team determined that, during the review period, Pennsylvania met the performance indicator objectives listed in Section 3.4.a., and based on the criteria in MD 5.6, recommends that Pennsylvania's performance with respect to the indicator, Technical Quality of Licensing Actions, be found satisfactory.

d. MRB Decision

The final report will present the MRB's conclusion regarding this indicator.

3.5 Technical Quality of Incident and Allegation Activities

The quality, thoroughness, and timeliness of response to incidents and allegations of safety concerns can have a direct bearing on public health and safety. An assessment of incident response and allegation investigation procedures, actual implementation of these procedures, internal and external coordination, and investigative and followup actions, are significant indicators of the overall quality of the incident response and allegation programs.

a. Scope

The team used the guidance in State Agreements procedure SA-105, "Reviewing the Common Performance Indicator: Technical Quality of Incident and Allegation Activities," and evaluated Pennsylvania's performance with respect to the following performance indicator objectives:

- Incident response, investigation, and allegation procedures are in place and followed.
- Response actions are appropriate, well-coordinated, and timely.
- On-site responses are performed when incidents have potential health, safety, or security significance.
- Appropriate followup actions are taken to ensure prompt compliance by licensees.
- Followup inspections are scheduled and completed, as necessary.
- Notifications are made to the NRC Headquarters Operations Center for incidents requiring a 24-hour or immediate notification to the Agreement State or NRC.
- Incidents are reported to the Nuclear Material Events Database (NMED).
- Allegations are investigated in a prompt, appropriate manner.

- Concerned individuals are notified of investigation conclusions.
- Concerned individuals' identities are protected, as allowed by law.

b. Discussion

During the review period, 92 incidents were reported to the NMED by the Program. The team selected 14 risk significant radioactive materials events to evaluate. The casework reviewed included: three medical events, one of which was reported as a potential Abnormal Occurrence; one radioactive material release/contamination event at a waste processing facility involving cobalt-60; two lost/stolen radioactive materials events; one extremity overexposure of a cyclotron technician as a result of exposure to fluorine-18; one equipment part defect on a high dose rate remote afterloading device; one security-related equipment failure of a component of the access control system to a panoramic irradiator; one radiography event involving the inability to retract the source; one shutter failure on a fixed gauge; two transportation-related events; and one leaking electron capture device foil. The Program dispatched inspectors for onsite assessment of the effectiveness of the licensee's action for all but one of the cases reviewed; that one case involved a transportation-related incident that was referred to the State of New Jersey for followup, as the shipper was a New Jersey licensee.

When an event is reported to the Program, staff and management collectively evaluate the information received to determine its health and safety significance and then decide on the appropriate response. That response can range anywhere from responding immediately to reviewing the event during the next inspection. For each incident that Program staff determined to have potential health and safety significance, the Program responded immediately. The team also found that the Program responded to events in accordance with its established procedure.

The team found that inspectors properly evaluated each event, interviewed involved individuals, and thoroughly documented their findings. Enforcement actions were taken where appropriate.

The team evaluated the Program's reporting of events to the NRC's Headquarters Operations Officer (HOO). The team noted that in each case evaluated where HOO notification was required, the Program reported all events within the required timeframe.

During the review period, 16 allegations were received by the Program. The team evaluated all 16 allegations including 13 allegations that the NRC referred to the Program during the review period, and found that the Program took prompt and appropriate action in response to the concerns raised. All of the allegations reviewed were appropriately closed, concerned individuals were notified of the actions taken, and allegeders' identities were protected whenever possible in accordance with State law.

c. Evaluation

The team determined that, during the review period, Pennsylvania met the performance indicator objectives listed in Section 3.5.a., and based on the criteria in MD 5.6, recommends that Pennsylvania's performance with respect to the indicator, Technical

Quality of Incident and Allegation Activities, be found satisfactory.

d. MRB Decision

The final report will present the MRB's conclusion regarding this indicator.

4.0 NON-COMMON PERFORMANCE INDICATORS

Four non-common performance indicators are used to review Agreement State programs: (1) Compatibility Requirements; (2) Sealed Source and Device (SS&D) Evaluation Program; (3) Low-Level Radioactive Waste Disposal (LLRW) Program; and (4) Uranium Recovery Program. The NRC's Agreement with Pennsylvania retains regulatory authority for SS&D evaluations and uranium recovery; therefore, only the first and third non-common performance indicators applied to this review.

4.1 Compatibility Requirements

State statutes should authorize the State to establish a program for the regulation of agreement material and provide authority for the assumption of regulatory responsibility under the agreement. The statutes must authorize the State to promulgate regulatory requirements necessary to provide reasonable assurance of protection of public health, safety, and security. The State must be authorized through its legal authority to license, inspect, and enforce legally binding requirements, such as regulations and licenses. NRC regulations that should be adopted by an Agreement State for purposes of compatibility or health and safety should be adopted in a time frame so that the effective date of the State requirement is not later than 3 years after the effective date of the NRC's final rule. Other program elements, as defined in Appendix A of State Agreements procedure SA-200, "Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements," that have been designated as necessary for maintenance of an adequate and compatible program, should be adopted and implemented by an Agreement State within 6 months following NRC designation.

a. Scope

The team used the guidance in State Agreements procedure SA-107, "Reviewing the Non-Common Performance Indicator: Compatibility Requirements," and evaluated Pennsylvania's performance with respect to the following performance indicator objectives. A complete list of regulation amendments can be found on the NRC website at the following address: <https://scp.nrc.gov/regtoolbox.html>.

- The Agreement State program does not create conflicts, duplications, gaps, or other conditions that jeopardize an orderly pattern in the regulation of radioactive materials under the Atomic Energy Act, as amended.
- Regulations adopted by the Agreement State for purposes of compatibility or health and safety were adopted no later than 3 years after the effective date of the NRC regulation.

- Other program elements, as defined in SA-200 that have been designated as necessary for maintenance of an adequate and compatible program, have been adopted and implemented within 6 months of NRC designation.
- The State statutes authorize the State to establish a program for the regulation of agreement material and provide authority for the assumption of regulatory responsibility under the agreement.
- The State is authorized through its legal authority to license, inspect, and enforce legally binding requirements such as regulations and licenses.
- Sunset requirements, if any, do not negatively impact the effectiveness of the State's regulations.

b. Discussion

The Commonwealth of Pennsylvania became an Agreement State on March 31, 2008. Legislative authority to create a radiation control program and enter into an Agreement with NRC is granted in the Pennsylvania Statutes, Radiation Protection Act (Act 1984-147), as amended. The Bureau is designated the Commonwealth's radiation control program and implements the Program. No legislation was passed during the review period that substantially affected the materials program. Pennsylvania regulations are not subject to sunset laws.

Pennsylvania's administrative rulemaking process takes approximately 2 years to complete which includes two rounds of review and public comment. The Commonwealth adopts NRC regulations by reference using pointers in its regulations which makes amendments to Pennsylvania's regulations effective concurrently with NRC's regulation effective dates. Because Pennsylvania's regulations point to the NRC regulations, if the NRC develops a new regulation section Pennsylvania must create a new section in its regulations which points to the NRC part.

During the review period, the Program submitted a single package containing 14 final regulation amendments to the NRC for a compatibility review. Nine of the amendments in the package were submitted beyond the due date and five were submitted in advance of their final due date. However, because Pennsylvania's process makes regulations effective concurrently with NRC's regulation effective dates, all are considered to be adopted and enforceable immediately upon NRC's effective date. Over this review period, the Program did not realize they needed to submit its final regulations to NRC for a compatibility review. Once made aware the Program submitted its final regulations to NRC for review. There are currently no overdue regulation amendments.

c. Evaluation

The team determined that, during the review period, Pennsylvania met the performance indicator objectives listed in Section 4.1.a., and based on the criteria in MD 5.6, recommends that Pennsylvania's performance with respect to the indicator, Compatibility Requirements, be found satisfactory.

d. MRB Decision

The final report will present the MRB's conclusion regarding this indicator.

4.2 Low-Level Radioactive Waste Disposal (LLRW) Program

Although the Pennsylvania Agreement State Program has authority to regulate an LLRW disposal facility, the NRC has not required States to have a program for licensing a disposal facility until such time as the State has been designated as a host State for a LLRW disposal facility. When an Agreement State has been notified or becomes aware of the need to regulate a LLRW disposal facility, it is expected to put in place a regulatory program that will meet the criteria for an adequate and compatible LLRW program. There are no plans for a commercial LLRW disposal facility in Pennsylvania. Accordingly, the team did not review this indicator.

5.0 SUMMARY

As noted in Sections 3.0 and 4.0 above, Pennsylvania's performance was found to be satisfactory for all performance indicators reviewed. The team did not make any new recommendations and determined that the recommendation originally noted during the 2009 IMPEP review and extended through the 2014 IMPEP review should be closed.

Accordingly, the team recommends that the Commonwealth of Pennsylvania Agreement State Program be found adequate to protect public health and safety and compatible with the NRC's program. Based on the results of the current IMPEP review, which was the second consecutive IMPEP review with all performance indicators found satisfactory, the team recommends that the next full IMPEP review take place in approximately 5 years, with a periodic meeting in approximately 2.5 years.

LIST OF APPENDICES

Appendix A	IMPEP Review Team Members
Appendix B	Inspection Accompaniments

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	Areas of Responsibility
Randy Erickson, Region IV	Team Leader Compatibility Requirements
John Miller, Region I	Technical Staffing and Training Technical Quality of Materials Inspections Inspector Accompaniments
Robert Gallagher, Region I	Technical Quality of Licensing Actions Inspector Accompaniments
Dennis O'Dowd, Region III	Technical Quality of Incident and Allegation Activities
Angela Wilbers, Commonwealth of Kentucky	Status of the Materials Inspection Program Technical Quality of Licensing Actions (Assist)

APPENDIX B

INSPECTION ACCOMPANIMENTS

The following inspection accompaniments were performed prior to the on-site IMPEP review:

Accompaniment No.: 1	License No.: PA-1557
License Type: Portable Gauge	Priority: 5
Inspection Date: 11/8/18	Inspector: GH

Accompaniment No.: 2	License No.: PA-1172
License Type: Industrial Radiography	Priority: 1
Inspection Date: 11/14/18	Inspector: RK

Accompaniment No.: 3	License No.: PA-1053S
License Type: Type A Broad/Service Provider	Priority: 3
Inspection Date: 11/15/18	Inspector: CR

Accompaniment No.: 4	License No.: PA-0892
License Type: Nuclear Pharmacy	Priority: 2
Inspection Date: 11/29/18	Inspector: TS

Accompaniment No.: 5	License No.: PA-0027
License Type: High Dose Afterloader	Priority: 2
Inspection Date: 12/13/18	Inspector: JK

Accompaniment No.: 6	License No.: PA-0127/PA-0127A
License Type: Type A Medical Broad/Self-Shielded Irradiator	Priority: 2
Inspection Date: 11/13-14/18	Inspector: FD



March 13, 2019

Mr. Paul Michalak
Agreement State Programs Branch
Division of Materials Safety, Security, State, and Tribal Programs
Office of Nuclear Material Safety and Safeguards
Washington, DC

Dear Mr. Michalak:

We appreciated the opportunity to have the NRC Integrated Materials Performance Evaluation Program (IMPEP) Team review the Commonwealth of Pennsylvania's Agreement State (AS) Program in January of this year and during several months of 2018, and for having the opportunity to review the draft summary report for comment. We concur the report is factually accurate, and most importantly, that our AS Program earned the highest overall NRC rating, i.e., "Satisfactory and Compatible."

However, we would like to address one item from the report. This relates to Non-Common Performance Indicators. The draft report states on page 11 "The NRC's Agreement with Pennsylvania retains regulatory authority for SS&D evaluations, LLRW disposal and a uranium recovery program..." While the NRC retains authority for SS&D evaluations and a uranium recovery program, it did not retain authority over LLRW disposal in the Commonwealth of Pennsylvania. We'd appreciate it if you could correct this item.

It was a pleasure working with the NRC/AS IMPEP Team. We always take advantage of these reviews as an opportunity to gain experience from other NRC and AS staff. Clearly this IMPEP will help Pennsylvania maintain its "Satisfactory and Compatible" rating in the years to come.

We look forward to seeing everyone at the Management Review Board meeting in Rockville, MD on April 9, 2019.

Sincerely,

A handwritten signature in black ink, appearing to read "D. J. Allard".

David J. Allard, CHP
Director
Bureau of Radiation Protection

cc: Randy Erickson, NRC Region IV
John Miller, NRC Region I
Duncan White, HQs
Lizette Roldan-Otero, HQs
Robert Johnson, HQs
PA RP Program Managers

Agenda for Management Review Board Meeting
April 9, 2019, 1:00 p.m. – 4:00 p.m. (ET), OWFN-03B04

1. Announcement of public meeting. Request for members of the public to indicate they are participating and their affiliation.
2. MRB Chair convenes meeting. Introduction of MRB members, review team members, State representatives, and other participants.
3. Consideration of the Pennsylvania's IMPEP Report.
 - A. Presentation of Findings Regarding Pennsylvania's Program and Discussion.
 - Technical Staffing and Training
 - Status of Materials Inspection Program
 - Technical Quality of Inspections
 - Technical Quality of Licensing Actions
 - Technical Quality of Incident and Allegation Activities
 - Compatibility Requirements
 - B. IMPEP Team Recommendations.
 - Recommendation for Adequacy and Compatibility Ratings
 - Recommendation for Next IMPEP Review
 - C. MRB Consultation/Comments on Issuance of Report.
4. Request for comments from Pennsylvania representatives, OAS Liaison, and State IMPEP team members.
5. Questions/comments from members of the public.
6. Adjournment.