

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

May 19, 2014

David J. Allard, CHP, Director Bureau of Radiation Protection Department of Environmental Protection P.O. Box 8469 Harrisburg, PA 17105-8469

Dear Mr. Allard:

On April 3, 2014, the Management Review Board (MRB) met to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) report on the Pennsylvania Agreement State Program. The MRB found the Pennsylvania program adequate to protect public health and safety and compatible with the U.S. Nuclear Regulatory Commission's (NRC) program.

Section 5.0, page 11 of the enclosed final report contains a summary of the IMPEP team's findings and recommendations. The review team determined that the performance recommendation from the 2009 IMPEP regarding the Commonwealth's incident response program remains open. Based on the results of the current IMPEP review, the next full review of the Pennsylvania Agreement State Program will take place in approximately 5 years, with a periodic meeting tentatively scheduled for April 2015. The Pennsylvania Agreement State Program received an extension of 1 year for the next IMPEP review based on two consecutive IMPEP reviews with satisfactory findings for all the performance indicators reviewed.

I appreciate the courtesy and cooperation extended to the IMPEP team during the review. I also wish to acknowledge your continued support for the Agreement State program. I look forward to our agencies continuing to work cooperatively in the future.

Sincerely,

/RA/

Michael F. Weber Deputy Executive Director for Materials, Waste, Research, State, Tribal and Compliance Programs Office of the Executive Director for Operations

Enclosure:
Pennsylvania Final IMPEP Report

cc: Patricia Gardner, New Jersey
Organization of Agreement States
Liaison to the MRB

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

JANUARY 13-17, 2014

**FINAL REPORT** 

## **EXECUTIVE SUMMARY**

This report presents the results of the Integrated Materials Performance Evaluation Program (IMPEP) review of the Pennsylvania Agreement State Program. The review was conducted during the period of January 13 - 17, 2014, by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of Alabama.

Based on the results of this review, Pennsylvania's performance was found satisfactory for all six indicators reviewed. The review team did not make any new recommendations. However, the review team determined that the recommendation from the 2009 IMPEP review, regarding the strengthening of Pennsylvania's incident response program should be kept open. Progress has been made regarding Pennsylvania's review and followup of incidents, but issues remain in thorough followup and timely reporting of incidents.

Accordingly, the review team recommended, and the Management Review Board (MRB) agreed, that the Pennsylvania Agreement State Program is adequate to protect public health and safety and is compatible with the NRC's program. This review is the second consecutive review for Pennsylvania with all performance indicators found satisfactory. Therefore, the review team recommended, and the MRB agreed, that the next IMPEP review take place in approximately five years and a periodic meeting in one year.

## 1.0 INTRODUCTION

This report presents the results of the review of the Pennsylvania Agreement State Program. The review was conducted during the period of January 13 - 17, 2014, by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of Alabama. Team members are identified in Appendix A. The review was conducted in accordance with the "Implementation of the Integrated Materials Performance Evaluation Program and Rescission of Final General Statement of Policy," published in the *Federal Register* on October 16, 1997, and NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)," dated February 26, 2004. Preliminary results of the review, which covered the period of November 21, 2009 to January 17, 2014, were discussed with Pennsylvania managers on the last day of the review.

A draft of this report was provided to Pennsylvania for factual comment on February 18, 2014. The Commonwealth responded to the findings and conclusions by email dated March 19, 2014. A copy of the Commonwealth's response is included as an Attachment to this report along with a comment resolution document. A Management Review Board (MRB) met on April 3, 2014, to consider the proposed final report. The MRB found the Pennsylvania Agreement State Program adequate to protect public health and safety, and compatible with the NRC's program.

The Pennsylvania Agreement State 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 Agreement State Program resides in three Regional Offices within the Commonwealth. Organization charts for the Department and the Bureau are included as Appendix B.

At the time of the review, the Pennsylvania Agreement State Program regulated 677 specific licenses authorizing possession and use of radioactive materials. The review focused on the radioactive materials program as it is carried out under the Section 274b. (of the Atomic Energy Act of 1954, as amended) Agreement between the NRC and the Commonwealth of Pennsylvania.

In preparation for the review, a questionnaire addressing the common and applicable non-common performance indicators was sent to the Bureau on May 6, 2013. The Bureau provided its initial response to the questionnaire on September 20, 2013. Due to the federal government shutdown in October 2013, the IMPEP review originally scheduled for October 7 - 11, 2013, was postponed until January 13 - 17, 2014. Consequently, the questionnaire was updated and resubmitted by the Commonwealth on January 28, 2014. A copy of the updated questionnaire response can be found in the NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML14031A068.

The review team's general approach for conduct of this review consisted of (1) examination of the Bureau's response to the questionnaire, (2) review of applicable Pennsylvania statutes and regulations, (3) analysis of quantitative information from the Bureau's database, (4) technical review of selected regulatory actions, (5) field accompaniments of seven inspectors, and (6) interviews with staff and managers. The review team evaluated the information gathered against the established criteria for each common and the applicable non-common performance

indicator and made a preliminary assessment of the Pennsylvania Agreement State Program's performance.

Section 2.0 of this report covers the Commonwealth's actions in response to the recommendation made during the previous review.

Results of the current review of the common performance indicators are presented in Section 3.0. Section 4.0 details the results of the review of the applicable non-common performance indicators, and Section 5.0 summarizes the review team's findings.

## 2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous IMPEP review, which concluded on November 20, 2009, the review team made one recommendation regarding the Pennsylvania Agreement State Program's performance. The status of the recommendation is as follows:

"The review 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." (Section 3.5 of the 2009 IMPEP Report)

Status: Since the November 2009 IMPEP review, one staff member has been assigned to track incidents and ensure that reporting requirements are met and are timely. The 2014 IMPEP review indicated that, while timeliness has improved overall, notifications to the NRC were still late in 5 of the 10 cases reviewed by a matter of days or weeks in 4 cases and not reported in 1 case. In addition, communication of incidents from the Central Office to the Regions improved, and incident investigations were typically thorough, complete and comprehensive. However, in 3 of the 10 cases reviewed, 2 involving industrial radiography source retractions and 1 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 followed up. This recommendation remains open.

## 3.0 COMMON PERFORMANCE INDICATORS

Five common performance indicators are used to review 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

Issues central to the evaluation of this indicator include the Bureau's staffing level and staff turnover, as well as the technical qualifications and training histories of the staff. To evaluate these issues, the review team examined the Bureau's questionnaire response relative to this indicator, interviewed managers and staff, reviewed job descriptions and training records, and considered workload backlogs.

The Bureau is managed by the Bureau Director from the Central Office located in Harrisburg. The Bureau consists of four Divisions, three of which have responsibilities for radioactive materials under the Agreement: the Radiation Control Division, the Decommissioning and Surveillance Division, and the Nuclear Safety Division. Within the Radiation Control Division, the Radioactive Materials Program Chief directly supervises radioactive materials licensing activities. Inspection and compliance activities are conducted out of three Regional Offices located in Norristown, Harrisburg, and Pittsburgh. Each Regional Office has a Radiation Protection Program Manager and Supervisor who directly supervise inspection and compliance activities in the Commonwealth.

At the time of the review, there were 48 individuals with various degrees of involvement in the radioactive materials program. The Regional Offices devote approximately 19.5 full-time equivalents (FTE) to inspection, compliance and emergency response activities, including supervisory duties. The Bureau devotes approximately 5.1 FTE to radioactive materials licensing activities, including supervisory duties. The review team determined that staffing levels were adequate for the Agreement State program.

During the review period, a total of 19 individuals left the program, including 6 managers, and 12 individuals were hired, including 2 managers. At the time of the review, the Bureau had seven vacancies for technical positions, five of which were in the radioactive materials program. There were no vacancies in program management positions at the time of the review. The vacancies have not adversely impacted inspection or licensing activities. In December 2013 a Department hiring freeze was enacted. The Bureau Director anticipates that the freeze is a short-term budget measure that will be reevaluated after a merger of the human resources offices in the Department of Environmental Protection and the Department of Conservation and Natural Resources is completed in the near future.

The Bureau has a documented training plan for technical staff that is consistent with the requirements in the NRC/Organization of Agreement States Training Working Group Report and NRC's Inspection Manual Chapter (IMC) 1246, "Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area." The Bureau uses on-the-job training to supplement formal classroom training. New licensing and inspection staff members are assigned increasingly complex duties as they progress through the qualification process. The review team noted that Bureau managers encourage and support training opportunities, based on program needs and funding. The Bureau has sponsored NRC training courses in the past and anticipates sponsoring additional courses in the future. The review team concluded that the Bureau's training program is adequate to carry out its regulatory duties and noted that Pennsylvania management supports the Bureau training program.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Pennsylvania's performance with respect to the indicator, Technical Staffing and Training, be found satisfactory.

## 3.2 Status of Materials Inspection Program

The review team focused on five factors while reviewing this indicator: (1) inspection frequency, (2) overdue inspections, (3) initial inspections of new licenses, (4) timely dispatch of inspection findings to licensees, and (5) performance of reciprocity inspections. The review team's

evaluation was based on the Bureau's questionnaire response relative to this indicator, data gathered from the Bureau's database, examination of completed inspection casework, and interviews with management and staff.

The review team verified that Pennsylvania's inspection frequencies for all types of radioactive material licenses are at least as frequent as similar license types listed in IMC 2800, "Materials Inspection Program." The review team confirmed the Bureau is conducting Increased Controls inspections in conjunction with the routine health and safety inspections.

The Bureau conducted 641 Priority 1, 2, and 3 inspections during the review period, based on the inspection frequencies established in IMC 2800. Only one of these inspections was conducted overdue by more than 25 percent of the inspection frequency prescribed in IMC 2800. The review team verified there were no overdue routine Priority 1, 2, and 3 inspections at the time of the review. In addition, the Bureau performed 85 initial inspections during the review period, none of which were conducted overdue. As required by IMC 2800, initial inspections should be conducted within 12 months of license issuance. Overall, the review team calculated that the Bureau performed less than one percent of its inspections overdue during the review period.

The review team evaluated the Bureau's timeliness in providing inspection findings to licensees. A sampling of 22 inspection reports indicated that only 1 of the inspection findings was communicated to the licensees a few days beyond the Bureau's goal of 30 days after the inspection.

The Bureau's reciprocity inspection goals are equivalent to the requirements in IMC 1220, "Processing of NRC Form 241 and Inspection of Agreement State Licensees Operating under 10 CFR150.20," which is 20 percent of candidate licensees. During the review period, the Bureau granted 85 reciprocity permits and exceeded the NRC's criteria of inspecting 20 percent of candidate licensees operating under reciprocity in each of the four years covered by the review period.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Pennsylvania's performance with respect to the indicator, Status of Materials Inspection Program, be found satisfactory.

## 3.3 Technical Quality of Inspections

The review team evaluated the inspection reports, enforcement documentation, inspection field notes, and conducted interviews, as needed, for 22 radioactive materials inspections conducted during the review period. The casework reviewed included inspections conducted by 27 current and former Bureau inspectors from three Regional Offices and the Decommissioning and Surveillance Division, and covered a wide variety of inspection types involving initial, routine, reciprocity and special inspections. The casework included inspection of various types of programs, including medical broad scope, medical institutions-therapy including gamma stereotactic radiosurgery, high dose rate remote afterloader, unsealed radioiodine therapy, permanent and temporary implant brachytherapy, medical-diagnostic, portable gauges, industrial radiography, nuclear pharmacy, well logging, decommissioning activities, research and development, service providers and Increased Security Controls for Large Quantities of

Radioactive Materials (Increased Controls). Appendix C lists the inspection casework files reviewed, as well as the results of the inspector accompaniments. Inspections are performed by the three Regional Offices, Southeast (Norristown), South Central (Harrisburg) and Southwest (Pittsburgh). Inspection files are maintained in the Regional Offices, with copies sent to the Central Office. Inspection results are transmitted to licensees via inspection letters generated by the Regional Offices. Decommissioning inspection activities are performed by the Decommissioning and Surveillance Division in Central Office.

Based on the evaluation of casework, the review team noted that inspections covered all aspects of the licensee's radiation safety programs. The review team found that inspection reports were thorough, complete, consistent, and of high quality, with sufficient documentation to ensure that a licensee's performance with respect to health and safety was acceptable. The documentation routinely noted observations by the inspector either by direct observations of licensed activities or by demonstrations requested of the licensee by the inspector. The documentation supported violations, recommendations made to licensees, unresolved safety issues, the effectiveness of corrective actions taken to resolve previous violations and discussions held with licensees during exit interviews.

The inspection procedures utilized by the Bureau are consistent with the inspection guidance outlined in IMC 2800. An inspection report is completed by the inspector(s) which is then reviewed and signed by the Section Chief at the Regional Office. The Bureau has a policy to accompany all staff performing radioactive materials inspections on an annual basis. Supervisory accompaniments were conducted annually for all inspectors by the Section Chiefs at each Regional Office.

The review team determined that the inspection findings were appropriate and prompt regulatory actions were taken, as necessary. Inspection findings were clearly stated and documented in the reports and sent to the licensees with the appropriate letter detailing the results of the inspection. The Regional Office issues to the licensee either a letter indicating a clear inspection or a Notice of Violation (NOV), in letter format, which details the results of the inspection. Notice of Violation letters are reviewed by the Compliance Specialist in the Regional Office before issuance. When the Regional Office issues an NOV, the licensee is required to provide a written corrective action plan, based on the violations cited, within 20 days.

The review team noted that the Bureau maintains an adequate supply of appropriately calibrated survey instruments to support the inspection program, as well as to respond to radioactive materials incidents and emergency conditions. The Bureau's instruments are sent to an authorized entity for calibration. The Department has a well-equipped radiochemistry laboratory to support the Agreement program. The Bureau also contracted with Oak Ridge Institute for Science and Education for technical assistance with complex decommissioning sites.

The review team accompanied seven of the Bureau's inspectors in September and October 2013. The inspectors conducted inspections at medical facilities, industrial radiographers, a HDR facility and decommissioning activities. The accompaniments are identified in Appendix C. During the accompaniments, the inspectors demonstrated performance-based inspection techniques and knowledge of the regulations. The inspectors were trained, well-prepared for their inspections, and thorough in their audits of the licensees' radiation safety programs. The

inspectors conducted interviews with appropriate personnel, observed licensed operations, conducted confirmatory measurements and utilized good health physics practices. The review team determined that the inspections were adequate to assess radiological health, safety and security at the licensed facilities.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Pennsylvania's performance with respect to the indicator, Technical Quality of Inspections, be found satisfactory.

## 3.4 Technical Quality of Licensing Actions

The review team examined completed casework and interviewed license reviewers for 29 licensing actions covering 25 specific licensees. Licensing actions were reviewed for completeness, consistency, proper radioisotopes and quantities, qualifications of authorized users, adequacy of facilities and equipment, adherence to good health physics practices, financial assurance, security requirements, operating and emergency procedures, appropriateness of license conditions, and overall technical quality. The casework was also reviewed for timeliness, use of appropriate deficiency and transmittal letters, reference to appropriate regulations, supporting documentation, consideration of enforcement history, pre-licensing visits, peer and supervisory review, and proper signatures.

The licensing casework was selected to provide a representative sample of licensing actions completed during the review period. Licensing actions selected for evaluation included 1 new license, 6 renewals, 18 amendments, and 4 license terminations. Casework reviewed included a cross-section of license types, including: industrial radiography, broad scope - medical and academic, nuclear medicine - diagnostic and therapeutic, research and development, portable gauge, nuclear pharmacy, and decommissioning. Reviewed casework included work from each license reviewer and licensing supervisor. A listing of the licensing casework reviewed can be found in Appendix D.

The review team found that the licensing actions were thorough, complete, consistent, and of high quality with health, safety, security issues and Increased Controls properly addressed. License tie-down conditions were stated clearly, supported by information contained in the file and enforceable. The review team found that actions terminating licenses were well documented, particularly for decommissioning casework which included appropriate material survey records, and contained documentation of proper disposal or transfer of radioactive material, as required. Incoming licensing actions are entered into the licensing tracking system, then assigned and controlled by the Licensing Supervisor. There were three fully qualified license reviewers including the supervisor, and one newly hired individual working towards full qualification.

The Commonwealth has adopted NRC licensing guidance and practices. License reviewers use the NRC's licensing guidance provided in the NUREG-1556 series. Licenses are created from previous actions of identical type, tracked using a local database, and closely managed by the Licensing Supervisor. A tracking form was used for each step in the licensing process to document each reviewer's action. Once completed, all licensing actions are peer reviewed by another qualified license reviewer. The Licensing Supervisor provides final quality assurance review and signs all licenses. Licenses are issued for a 10 year period under timely renewal

regulations. Decommissioning licensees requiring financial assurance by Commonwealth of Pennsylvania regulations had adequate funding plans and remained in compliance with financial assurance requirements throughout the period. Financial assurance instruments were properly reissued after being transferred from the NRC, and were appropriately protected from loss or theft.

The review team assessed implementation of the pre-licensing guidance. Implementation was noted for the essential elements of the NRC's pre-licensing guidance issued on September 22, 2008, and transmitted to the Agreement States via Office of Federal and State Materials and Environmental Management Programs (FSME) Letter RCPD-08-020, "Requesting Implementation of the Checklist to Provide a Basis for Confidence That Radioactive Material Will Be Used as Specified on a License and the Checklist for Risk-significant Radioactive Material." A basic pre-licensing checklist was incorporated into the licensing process. Eligible pre-licensing visits were assigned by the Central Office to local Regional Offices, and completed as required to ensure that the applicant will use the requested material as intended.

The review team verified that legally binding license conditions met the criteria for implementing the Increased Controls Orders, Fingerprinting Orders, and National Source Tracking System requirements, and were used appropriately. The review team evaluated the program's methodology for identifying licenses that required implementation of the Orders and found the review process to be appropriate. All license files including those containing Increased Control and Fingerprinting conditions were located in a designated, well controlled area. These licenses and corresponding cover letters were marked as containing sensitive information as required with one exception. An incoming amendment application from a research facility that requested materials quantities of concern was submitted without proper markings. Discussion with the Licensing Supervisor indicated he would follow up with the licensee to ensure documents were properly marked. For other applicable correspondence, the review team verified that the program was identifying and marking sensitive security-related information appropriately in accordance with established policy.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Pennsylvania's performance with respect to the indicator, Technical Quality of Licensing Actions, be found satisfactory.

## 3.5 Technical Quality of Incident and Allegation Activities

In evaluating the effectiveness of the Bureau's actions in responding to incidents and allegations, the review team examined the Bureau's response to the questionnaire relative to this indicator, evaluated selected incidents reported for Pennsylvania in the Nuclear Material Events Database (NMED) against those contained in the Bureau's files, and evaluated the casework for 10 of 91 reported radioactive materials incidents. A listing of the casework examined, with case-specific comments, can be found in Appendix E. The review team also evaluated the Bureau's response to nine allegations involving radioactive materials. The NRC did not refer any allegations to the State during the review period.

As a result of the review of the Pennsylvania Agreement State Program that was conducted during the period of November 16 - 20, 2009 (previous IMPEP), the review team recommended that the Commonwealth strengthen its incident response program to ensure that incidents are

appropriately investigated and are promptly reported to NRC, as appropriate. The Commonwealth implemented actions to improve its incident response program such that incidents are appropriately investigated and are promptly reported to NRC, as appropriate. For example, a Central Office Health Physicist was assigned to track incident response, including input of information into NMED and notification of events to the NRC. In addition, the Commonwealth developed and implemented a database that is used to record and monitor incidents. The database is shared between the Central and Regional offices, and it includes pertinent information about the events. Applicable staff received training on the events database in early 2010, which included required reporting of incidents to the NRC, timeliness of reporting, and entering information into NMED to close events.

When notified of an incident or an allegation, the appropriate Regional manager and staff discuss the initial response and the need for an onsite investigation, based on the safety significance of the incident. If the incident meets the reportability thresholds, as established in FSME Procedure SA-300 "Reporting Material Events," the Bureau notifies the NRC Headquarters Operations Center and enters the information into NMED, in a prompt manner. During the previous IMPEP, the review team noted that Bureau managers thought entering an incident into NMED fulfilled the reporting requirement to the NRC Headquarters Operations Center. Of the incidents evaluated during the previous IMPEP, all were properly entered into NMED, but 7 of the 16 incidents had not been reported to the NRC within the required time frame, mostly because of the aforementioned misconception.

During this IMPEP review, the review team noted that for the 10 incidents reviewed, pertinent information was entered into NMED, but in 5 of the 10 cases, the incident had not been reported to the NRC Headquarters Operations Center within the required time frame. Four of the incidents were reported late to the Headquarters Operations Center by a matter of days or weeks, while one was not reported at all. Subsequent to the onsite review, the Bureau conducted a retrospective review of the Commonwealth's 91 reported radioactive materials incidents and identified one additional incident that was not reported timely.

The previous IMPEP review team determined that the Bureau's responses to incidents were thorough, complete, and comprehensive in all but two instances. Those two incidents involved industrial radiography source retraction problems that were reported by licensees to the Central Office. The Central Office entered the information for both incidents into NMED, but did not send the information to the appropriate Regional Offices. Absent knowledge of the incidents, the Regional Offices could not perform the appropriate incident investigations.

During this IMPEP review, the incidents selected for review included medical events, lost or stolen radioactive material, a contamination event, transportation events, an overexposure, and equipment failures. The Bureau took action to ensure that the appropriate Regional Offices were made aware of the incidents. The review team determined that the Bureau's responses to incidents were thorough, complete, and comprehensive in 7 of the 10 incidents reviewed. In those seven cases, the Bureau dispatched inspectors to the site when the possibility of an immediate threat to public health and safety existed. The review team noted that the Bureau identified the causes of the incidents, reviewed corrective actions and the preventive measures to avoid similar events. Also, at the conclusion of investigations, inspectors generated narrative reports that thoroughly documented the investigations.

For 3 cases reviewed, the Bureau's response was not comprehensive or sufficient to determine root causes, contributing factors and/or preventive measures to avoid similar events. Two of the three incidents involved industrial radiography source retraction problems, while the other incident involved a contaminated package during transport. While the decision to conduct an onsite investigation is at the discretion of the Bureau and based on the significance of the event, the review team noted that the Bureau did not conduct onsite incident investigations for the two events involving industrial radiography source retraction problems because (1) for one of the two events, the Bureau had conducted a routine inspection of the licensee five days before the event and the licensee provided a detailed report of the event; and (2) for the other event, the source was secured, and the associated radiography equipment was repaired and placed back into service. The Bureau did not conduct an onsite incident investigation for the event involving the contaminated package because the shipper verified that there was no contamination at its facilities. Although the Bureau reviewed and documented each of these three incidents, it did not fully investigate in order to identify the event root cause, event contributing factors, or preventive measures to avoid a similar event. For two of the events, the Bureau conducted inspections some months afterward; however, those inspections did not include followup of the reported events.

Based on the potential issues involved with insufficient followup of the two industrial radiography source retraction events reviewed, the review team reviewed casework for five additional radiography events reported to NRC during the review period which involved source retraction issues. Based on the information provided in NMED, the review team determined that the Bureau conducted appropriate followup to these five events, including determination of root causes and preventive measures to avoid similar events. The IMPEP team determined that the Bureau followed its incident response procedures, and Bureau actions were appropriate, well-coordinated, and timely in most instances.

While timeliness of reporting incidents has improved overall, notifications to NRC were still late during the review period. In addition, communication of incidents from the Central Office to the Regions improved, and incident investigations were typically thorough, complete and comprehensive, but the exceptions noted above. Due to these issues, the review team determined that continued focus is needed on the Commonwealth's incident response program and the recommendation from the previous IMPEP should remain open. Therefore, the review team recommended, and the MRB agreed, that the Commonwealth continue to strengthen its incident response program to ensure that incidents are appropriately investigated and are promptly reported to NRC, as appropriate.

In evaluating the effectiveness of the Bureau's response to allegations, the review team evaluated the casework for nine allegations. The review team concluded that the Bureau consistently took prompt and appropriate action in response to concerns raised. The review team noted that the Bureau thoroughly documented the investigations and retained all necessary documentation to appropriately close the allegations. The Bureau notified the allegers of the conclusion of the investigations. The review team determined that the Bureau adequately protected the identity of allegers.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Pennsylvania's performance with respect to the indicator, Technical Quality of Incident and Allegation Activities, be found satisfactory.

## 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 Evaluation Program, (3) Low-Level Radioactive Waste Disposal Program, and (4) Uranium Recovery Program. NRC's Agreement with Pennsylvania does not relinquish regulatory authority for a sealed source and device evaluation, low-level radioactive waste disposal or uranium recovery

program; therefore, only the first non-common performance indicator for Compatibility Requirements applied to this review.

## 4.1 <u>Compatibility Requirements</u>

## 4.1.1 Legislation

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 Agreement State program. There have been no changes since the effective date of the Agreement. Pennsylvania regulations are not subject to sunset laws.

## 4.1.2 Program Elements Required for Compatibility

The Commonwealth's regulations for control of radiation are located in the Pennsylvania Code, Title 25, Article V, Chapters 214-240, and apply to all ionizing radiation, whether emitted from radioactive materials or produced by machines. Pennsylvania requires a license for the use, manufacture, production, transport, transfer, receipt, acquisition, possession, ownership and disposal of radiation sources. Pennsylvania also requires the registration of radiation-producing machines and radiation-producing machine service providers.

The review team evaluated the Bureau's response to the questionnaire, reviewed the status of regulations required to be adopted the Commonwealth under the Commission's adequacy and compatibility policy, and verified the adoption of regulations with data obtained from the State Regulation Status Sheet that FSME maintains. Current NRC policy requires that Agreement States adopt certain equivalent regulations or legally binding requirements no later than three years after the effective date of NRC's regulations. The Commonwealth adopts NRC regulations by reference and uses Orders or legally binding requirements such as license conditions as appropriate. Pennsylvania regulations "point" to the NRC regulations so that if the NRC develops a new regulation section, such as the requirements for physical protection of byproduct materials in 10 CFR Part 37, Pennsylvania must create a new section in its regulations which points to the NRC part. The Program is currently working on creating this new pointer to Part 37 as part of a larger amendment package and expects to meet the due date of March 19, 2016, for Agreement State adoption. The Pennsylvania regulatory process typically takes approximately two years to complete, which includes two rounds of review and public comment.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Pennsylvania's performance with respect to the indicator, Compatibility Requirements, be found satisfactory.

## 5.0 SUMMARY

As noted in Sections 3.0 and 4.0 above, Pennsylvania's performance was found satisfactory for all six performance indicators reviewed. The review team did not make any new recommendations, but determined that the recommendation from the 2009 IMPEP review should be kept open.

Accordingly, the review team recommended, and the MRB agreed, that the 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, the review team recommended, and the MRB agreed, that the next full IMPEP review take place in approximately five years and periodic meeting in one year.

Below is the review team's recommendation, as mentioned in the report, for evaluation and implementation by the Commonwealth:

#### RECOMMENDATION

1. The review 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. (Section 3.5; kept open from 2009 IMPEP review)

# LIST OF APPENDICES

Appendix A IMPEP Review Team Members

Appendix B Pennsylvania Organization Charts

Appendix C Inspection Casework Reviews

Appendix D License Casework Reviews

Appendix E Incident Casework Reviews

# APPENDIX A

# IMPEP REVIEW TEAM MEMBERS

Name	Area of Responsibility
Bryan Parker, Region III	Team Leader Status of Materials Inspection Program
Donna Janda, Region I	Technical Staffing and Training Compatibility Requirements Inspector Accompaniments
Craig Gordon, Region I	Technical Quality of Licensing Actions Inspector Accompaniments
Robert Gattone, Region III	Technical Quality of Incident and Allegation Activities
David Turberville, State of Alabama	Technical Quality of Inspections

# APPENDIX B

PENNSYLVANIA ORGANIZATION CHARTS

ADAMS ACCESSION NO.: ML13267A014

## APPENDIX C

## INSPECTION CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

File No.: 1

Licensee: Wilkes-Barre General Hospital License No.: PA-011A

Inspection Type: Routine, Unannounced with IC Priority: 2

Inspection Date: 8/24/11 Inspectors: BR, TD, MH

File No.: 2

Licensee: Temple University License No.: PA-0134

Inspection Type: Routine, Unannounced with IC Priority: 2

Inspection Date: 6/4-7, 12/12 Inspectors: JK, FC, EC

File No.: 3

Licensee: Westmoreland Hospital License No.: PA-0084

Inspection Type: Routine, Unannounced Priority: 3

Inspection Date: 7/17/13 Inspectors: CR, DM

File No.: 4

Licensee: Columbia Inspection Services, Inc. License No.: PA-0792

Inspection Type: Routine, Announced Priority: 5

Inspection Date: 8/21/12 Inspectors: FP, GH

File No.: 5

Licensee: Valley Inspection Service License No.: PA-1186

Inspection Type: Routine, Announced with IC Priority: 1
Inspection Date: 11/10/11 Inspector: RC

File No.: 6

Licensee: Certified Testing Laboratories, Inc. License No.: PA-0430

Inspection Type: Routine, Announced Priority: 1

Inspection Date: 12/10/12 Inspectors: FD, FP

File No.: 7

Licensee: Universal Well Services License No.: PA-1446

Inspection Type: Initial, Unannounced Priority: 5

Inspection Date: 8/21&23/12 Inspectors: CR, CS

File No.: 8

Licensee: Triad Isotopes License No.: PA-0479

Inspection Type: Routine, Unannounced Priority: 2
Inspection Date: 10/12-13/11 Inspector: CR

File No.: 9

Licensee: York Hospital License No.: PA-0010

Inspection Type: Routine, Unannounced Priority: 2

Inspection Date: 1/25-26/12 Inspectors: FP, FD, MF

File No.: 10

Licensee: Penn State Hershey Medical Center License No.: PA-0127

Inspection Type: Routine, Unannounced Priority: 2

Inspection Date: 1/19-20/11 Inspectors: GD, FD

File No.: 11

Licensee: Good Samaritan Health System License No.: PA-0222

Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 3/24/10 Inspector: JD

File No.: 12

Licensee: Halliburton Energy Services License No.: PA-1389

Inspection Type: Routine, Unannounced Priority: 3

Inspection Date: 1/09/13 Inspectors: CS, CR

File No.: 13

Licensee: Professional Service Industries License No.: PA-0281

Inspection Type: Routine, Unannounced with IC Priority: 1

Inspection Date: 12/20/12 Inspectors: DS, DM

File No.: 14

Licensee: Forbes Hospital License No.: PA-0350

Inspection Type: Routine, Unannounced Priority: 3

Inspection Date: 06/12/13 Inspectors: DW, DM, BB

File No.: 15

Licensee: H & H X-Ray Services License No.: PA-1124

Inspection Type: Routine, Unannounced with IC Priority: 1
Inspection Date: 4/4/11 Inspector: CR

File No.: 16

Licensee: Duraloy Technologies License No.: PA-1281

Inspection Type: Routine, Unannounced with IC Priority: 1
Inspection Date: 9/12/13 Inspector: JH

File No.: 17

Licensee: Avid Radiopharmaceuticals, Inc. License No.: PA-0988

Inspection Type: Special Priority: 5

Inspection Date: 7/19/13 Inspectors: EC, MH

File No.: 18

Licensee: Best Theratronics, LTD License No.: PA-R0063

Inspection Type: Routine, Unannounced (Reciprocity) Priority: 2

Inspection Date: 4/13/13 Inspectors: SB, MH, NN

File No.: 19

Licensee: Baker Hughes Oilfield Operations, Inc. License No.: PA-R0098

Inspection Type: Routine, Unannounced (Reciprocity) Priority: 3

Inspection Date: 4/21/10 Inspectors: RC, BR

File No.: 20

Licensee: Chase Environmental Group, Inc. License No.: PA-R0187

Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 10/28/13 Inspector: CR

File No.: 21

Licensee: Lionville Laboratory License No.: PA-1046

Inspection Type: Special Priority: D

Inspection Date: 7/31/13 Inspectors: CO, LF, BW

File No.: 22

Licensee: Dickenson College License No.: PA-0381

Inspection Type: Special Priority: 5
Inspection Date: 12/04/12 Inspector: CO

## **INSPECTOR ACCOMPANIMENTS**

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

Accompaniment No.: 1

Licensee: UPMC Altoona License No.: PA-0016

Inspection Type: Routine, Unannounced Priority: 2
Inspection Date: 9/4/13 Inspector: FD

Accompaniment No.: 2

Licensee: Pinnacle Health Hospitals License No.: PA-0037

Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 9/6/13 Inspector: MF

Accompaniment No.: 3

Licensee: Vantage Exton Radiation Oncology, LLC License No.: PA-1058

Inspection Type: Routine, Unannounced Priority: 2
Inspection Date: 9/11/13 Inspector: EC

Accompaniment No.: 4

Licensee: Prime NDT Services, Inc. License No.: PA-1185

Inspection Type: Routine, Unannounced Priority: 1
Inspection Date: 10/1/13 Inspector: SB

Accompaniment No.: 5

Licensee: Duraloy Technologies. License No.: PA-1281

Inspection Type: Routine, Unannounced Priority: 1
Inspection Date: 9/12/13 Inspector: JH

Accompaniment No.: 6

Licensee: Team Industrial Services, Inc. License No.: PA-1176

Inspection Type: Routine, Unannounced Priority: 1
Inspection Date: 10/4/13 Inspector: CS

Accompaniment No.: 7

Licensee: Global Tungsten & Powders, Inc. License No.: PA-1127A

Inspection Type: Routine, Announced Priority: D
Inspection Date: 10/1/13 Inspector: CO

## APPENDIX D

## LICENSE CASEWORK REVIEWS

File No.: 1

Licensee: CTE License No.: PA-1239

Type of Action: Termination Amendment No.:

Date Issued: 10/3/13 License Reviewers: BW/JC

File No.: 2

Licensee: Solar Testing Of PA

Type of Action: Amendment

License No: PA-1377

Amendment No.: 5

Date Issued: 7/14/12 License Reviewers: DG/JC

File No.: 3

Licensee: Affordable Services, Inc.

Type of Action: Termination

Date Issued: 6/7/13

License No.: PA-798

Amendment No.: 2

License Reviewer: JC

File No.: 4

Licensee: Penn State University

License No.: PA-100

Type of Action: Amendment

Amendment No.: 20

Date Issued: 7/11/13 License Reviewers: DG/JC

File No.: 5

Licensee: JANX License No: PA-1363
Type of Action: Amendment Amendment No.: 3

Date Issued: 2/3/12 License Reviewers: DG/JC

File No.: 6

Licensee: QISI License No.: PA-1350
Type of Action: Amendment Amendment No.: 3

Date Issued: 5/17/11 License Reviewers: RK/JC

Date 13

File No.: 7

Licensee Engineering & Inspections Hawaii, Inc.

License No.: PA-1080

Type of Action: Renewal

Amendment No.: 4

Date Issued: 3/23/13 License Reviewers: DG/JC

File No.: 8

Licensee: Lakeshore Isotopes, LLC

Type of Action: Renewal

License No: PA-0802

Amendment No.: 19

Date Issued: 9/20/12 License Reviewers: RK/JC

File No.: 9

Licensee: TEI Analytical Services, Inc.

Type of Action: Amendment

Date Issued: 7/22/13

File No.: 10

Licensee: Diamond technical Services

Type of Action: Amendment

Date Issued: 12/22/11

File No.: 11

Licensee: Penn State University Type of Action: Amendment

Date Issued: 9/18/13

File No.: 12

Licensee: Wyeth Pharmaceuticals, Inc.

Type of Action: Termination

Date Issued: 3/11/11

File No.: 13

Licensee: Chevron Mining, Inc. Type of Action: Termination

Date Issued: 12/20/10

File No.: 14

Licensee: Penn State University Type of Action: Amendment

Date Issued: 5/22/12

File No.: 15

Licensee: Strobe, Inc.

Type of Action: Amendment

Date Issued: 4/3/13

File No.: 16

Licensee: Strobe, Inc. Type of Action: Renewal

Date Issued: 10/19/13

File No.: 17

Licensee: Weatherford International, LLC

Type of Action: Amendment

Date Issued: 3/16/12

License No.: PA-1164

Amendment No.: 3

License Reviewers: RK/JC

License No.: PA-1077 Amendment No.: 4

License Reviewers: DG/JC

License No: PA-100 Amendment No.: 21

License Reviewers: DG/JC

License No.: PA-1263

Amendment No.: 2

License Reviewers: RW/JC

License No.: PA-1055S Amendment No.: 1 License Reviewer: JC

License No: PA-100 Amendment No.: 18

License Reviewers: BW/JC

License No.: PA-1004

Amendment No.: 10 License Reviewers: BW/JC

License No.: PA-1004

Amendment No.: 11

License Reviewers: BW/RW

License No: PA-1030 Amendment No.: 8

License Reviewers: DG/RK/JC

File No.: 18

Licensee: University of Pittsburgh

Type of Action: Amendment

License No.: PA-0190B

Amendment No.: 2

Date Issued: 2/18/10 License Reviewers: DG/RW/JC

File No.: 19

Licensee: Exelon PowerLabs, LLC License No.: PA-1017
Type of Action: Amendment Amendment No.: 2

Date Issued: 7/16/12 License Reviewers: DG/JC

File No.: 20

Licensee: Exelon PowerLabs, LLC License No: PA-1017
Type of Action: Renewal Amendment No.: 3

Date Issued: 1/16/13 License Reviewers: DG/JC

File No.: 21

Licensee: Temple University Health System

License No.: PA-0134

Type of Action: Amendment Amendment No.: 38

Date Issued: 3/13/13 License Reviewers: RW/DG/JC

File No.: 22

Licensee: Temple University Health System

License No.: PA-0134

Type of Action: Amandment No.: 40

Type of Action: Amendment No.: 40

Date Issued: 4/17/13 License Reviewers: RW/DG/JC

File No.: 23

Licensee: Penn State University

Type of Action: Amendment

License No: PA-100

Amendment No.: 17

Date Issued: 8/07/13 License Reviewers: DG/JC

File No.: 24

Licensee: Westinghouse Electric Co., LLC License No.: PA-1053S

Type of Action: Amendment No.: 9

Date Issued: 10/3/13 License Reviewers: BW/JC

File No.: 25

Licensee: Pottstown Medical Specialists

License No.: PA-0768

Type of Action: Panewal

Type of Action: Renewal Amendment No.: 7

Date Issued: 6/27/12 License Reviewers: DG/JC

File No.: 26

Licensee: Doylestown Hospital License No: PA-0059
Type of Action: Renewal Amendment No.: 29

Date Issued: 4/11/11 License Reviewers: DG/JC

# Pennsylvania Final IMPEP Report License Casework Reviews

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File No.: 27

Licensee: Cardiovascular Disease Specialists

Type of Action: New Date Issued: 9/30/13

File No.: 28

Licensee: Abington Memorial Hospital

Type of Action: Renewal Date Issued: 6/7/11

File No.: 29

Licensee: Lockheed Martin Type of Action: Amendment

Date Issued: 3/7/12

License No.: PA-1478 Amendment No.: New

License Reviewers: RW/JC

License No.: PA-0055 Amendment No.: 27

License Reviewers: DK/JC

License No: PA-1099 Amendment No.: 3

License Reviewers: RK/JC

## APPENDIX E

#### INCIDENT CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS ONLY.

File No.: 1

Licensee: Jeff Zell Consulting License No.: PA-37-28531-01 Date of Incident: 9/8/09 NMED Log No.: 100029 Investigation Date: 1/15/10 Type of Incident: Lost Material Type of Investigation: Site

File No.: 2

Licensee: University of Pennsylvania License No.: PA-0131 Date of Incident: 1/21/10 NMED Log No.: 100085

Investigation Dates: 3/4, 4/26-27, and 11/08/10 Type of Incident: Medical Event Type of Investigation: Site

File No.: 3

Licensee: Hillis-Carnes Engineering Associates

License No.: PA-1366 Date of Incident: 5/24/10 NMED Log No.: 100273 Investigation Date: 5/25/10 Type of Incident: Lost Material Type of Investigation: Site

Comment: The Bureau did not report this incident to the NRC Headquarters Operations

Center timely (approximately one day late); however, the Pennsylvania State Police reported the incident to the NRC Headquarters Operations Center on the

date of the incident.

File No.: 4

License No.: PA-0233 Licensee: Lancaster General Hospital Date of Incident: 6/3/10 NMED Log No.: 100314

Type of Incident: Medical Event Investigation Date: 6/21/10

Type of Investigation: Site

File No.: 5

Licensee: University of Pennsylvania License No.: PA-0131 Date of Incident: 7/7/10 NMED Log No.: 100371

Investigation Date: 8/4/10 Type of Incident: Medical Event

Type of Investigation: Site

File No.: 6

Licensee: Geisinger Health System

License No.: PA-0006

Date of Incident: 3/1/11

License No.: PA-01016

NMED Log No.: 110135

Investigation Date: 3/2/11 Type of Incident: Contaminated Pkg. Type of Investigation: Phone

#### Comments:

(1) The Bureau did not report this incident to the NRC Headquarters Operations Center; however, it emailed information about the event to NMED on the day it was notified of the event.

(2) The Bureau did not adequately review the cause of the incident.

File No.: 7

Licensee: Non-Destructive and Visual Inspection

License No.: PA-1413

Date of Incident: 10/28/11

NMED Log No.: 110569

Investigation Date: 11/03/11 Type of Incident: Overexposure Type of Investigation: Site

File No.: 8

Licensee: E & I Hawaii License No.: PA-1080

Date of Incident: 9/19/12 NMED Log No.: 120636

Investigation Date: 9/19/12 Type of Incident: Equipment Failure

Type of Investigation: Phone

## Comments:

(1) The Bureau did not report this incident to the NRC Headquarters Operations Center timely (approximately one month late).

(2) The Bureau did not adequately review the cause of the incident.

File No.: 9

Licensee: Earth Engineering, Inc.

Date of Incident: 10/26/12

License No.: PA-1040

NMED Log No.: 120676

Investigation Date: 11/01/12 Type of Incident: Theft of Material

Type of Investigation: Site

Comment: The Bureau did not report this incident to the NRC Headquarters Operations

Center timely (approximately one week late).

# Pennsylvania Final IMPEP Report **Incident Casework Reviews**

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File No.: 10 Licensee: JANX

License No.: PA-1363 Date of Incident: 5/8/13 NMED Log No.: 130373 Investigation Date: 5/9/13

Type of Incident: Equip. Damage Type of Investigation: Phone

## Comments:

(1) The Bureau did not report this incident to the NRC Headquarters Operations Center timely (approximately three months late).

(2) The Bureau did not adequately review the cause of the incident.

# **ATTACHMENT**

March 19, 2014 letter from David J. Allard Pennsylvania's Response to the Draft Report ADAMS Accession No.: ML14080A226