

March 3, 2010

John Hanger, Secretary
Pennsylvania Department of Environmental Protection
Rachel Carson State Office Building
P.O. Box 2063
Harrisburg, PA 17105-2063

Dear Mr. Secretary:

On January 26, 2010, 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 Agreement State Program adequate to protect public health and safety and compatible with the U.S. Nuclear Regulatory Commission's (NRC) program.

Section 4.0, page 9, of the enclosed final report contains a summary of the IMPEP review team's findings and recommendations. Mr. Kenneth R. Reisinger's letter dated January 11, 2010, adequately discusses the Commonwealth's proposed actions for resolving the review team's recommendations. No further response is requested at this time.

Based on the results of the current IMPEP review, the next full review of the Pennsylvania Agreement State Program will take place in approximately 4 years, with a periodic meeting tentatively scheduled for November 2011. During the periodic meeting and at the next IMPEP review, NRC will evaluate the effectiveness of the Commonwealth's response to the review team's recommendations, as well as the overall implementation of your Agreement State program.

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/

Martin J. Virgilio
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 w/encl.: David Allard, Director, Pennsylvania Bureau of Radiation Protection
Steve Collins, Illinois, Organization of Agreement States Liaison to the MRB

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Distribution: See next page.

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Letter to J. Hanger from Martin J. Virgilio dated: March 3, 2010

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

NOVEMBER 16-20, 2009

FINAL REPORT

Enclosure

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 November 16-20, 2009, by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of Ohio. This was the initial review of the program since the Agreement was signed in March 2008. 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 March 31, 2008, to November 20, 2009, were discussed with Pennsylvania managers on the last day of the review.

A draft of this report was issued to Pennsylvania for factual comment on December 16, 2009. The Commonwealth responded by letter on January 11, 2010, from Kenneth R. Reisinger, Acting Director, Department of Environmental Protection (the Department). A copy of the Commonwealth's response is included as the Attachment to this report. The Management Review Board (MRB) met on January 26, 2010, to consider the proposed final report. The MRB found the Pennsylvania Agreement State Program adequate to protect public health and safety and compatible with 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. The compliance portion of the Agreement State Program resides in three Regional Offices. Organization charts for the Commonwealth, the Department, the Bureau, and the Regional Offices are included as Appendix B.

At the time of the review, the Pennsylvania Agreement State Program regulated 790 specific licenses authorizing byproduct, source, and certain special nuclear 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 August 7, 2009. The Bureau provided its response to the questionnaire on November 3, 2009. A publicly available version of the questionnaire response can be found in NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML093370717.

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 databases; (4) technical review of selected regulatory actions; (5) field accompaniments of ten 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.

Results of the review for the common performance indicators are presented in Section 2.0. Section 3.0 details the results of the review of the applicable non-common performance indicators, and Section 4.0 summarizes the review team's findings and recommendations. The review team's recommendations are comments that relate directly to program performance by the Commonwealth. A response is requested from the Commonwealth to all recommendations in the final report. Mr. Kenneth R. Reisinger's letter dated January 11, 2010, (Attachment) adequately discussed the Commonwealth's proposed actions for resolving the review team's recommendations; therefore, no further response was requested from the Commonwealth.

2.0 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.

2.1 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 any 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 Supervisor directly supervises radioactive materials licensing activities. Inspection activities are conducted out of three Regional Offices which are housed in the Deputate for Field Operations. 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 45 individuals with various degrees of involvement in the radioactive materials program. The Regional Offices devote approximately 16 full-time equivalents (FTE) to inspection, compliance, and emergency response activities, including supervisory duties. The Bureau devotes approximately 5.5 FTE to radioactive materials licensing activities, including supervisory duties.

During the review period, 8 individuals left the program, including 4 supervisors, and 13 individuals were hired, including 2 supervisors. At the time of the review, the radioactive materials program had eight vacancies for technical positions and one vacancy for a Radiation Protection Manager position. In October 2008, a Department hiring freeze was enacted. Later that year, the fee-based radioactive materials program was exempted from the freeze, but due to Commonwealth budget issues since then, hiring has been very limited in the Department. All of the vacant technical positions were newly created positions that cannot be filled until the Commonwealth's budget issues are resolved. The manager position has been vacant since

June 2009 and was being filled by an Acting Manager at the time of the review and was expected to continue until the hiring climate improves.

The Bureau has a documented training plan for technical staff that is consistent with the guidance 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 under the direction of the licensing or inspection Radioactive Materials Program Supervisors or Managers, respectively. New inspectors accompany more experienced inspectors during increasingly complex inspections and are assigned independent inspections after demonstrating competence during accompaniment evaluations by their supervisor. The review team confirmed the qualifications of all staff through review of qualification journals, training records, and documentation of supervisory accompaniments.

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. In addition, because of high demand for attendance at NRC qualification courses and in order to meet the demands of staff training and qualification, the Bureau has sponsored courses that were equivalent in scope to NRC courses. The review team concluded that the Bureau's staffing and training is adequate to carry out its regulatory duties.

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, was satisfactory.

2.2 Status of Materials Inspection Program

The review team focused on five factors while reviewing this indicator: inspection frequency, overdue inspections, initial inspections of new licenses, timely dispatch of inspection findings to licensees, and 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 Bureau managers and staff members.

The review team verified that Pennsylvania's inspection frequencies for all types of radioactive material licenses are at the same frequency as NRC's inspection frequencies, listed in IMC 2800, "Materials Inspection Program."

The Bureau conducted a total of 256 inspections of high priority (Priority 1, 2, and 3) licensees and 24 initial inspections during the review period. Of the 256 high priority inspections, the review team determined that 8 inspections were completed overdue by more than 25 percent of the inspection frequency prescribed by IMC 2800. The review team identified one high priority inspection that was overdue by more than 25 percent of the inspection frequency prescribed by IMC 2800, at the time of the review. Of the 24 initial inspections, the review team identified 5 inspections that were conducted overdue. As required by IMC 2800, initial inspections should

be conducted within 12 months of license issuance. The review team verified that there were four overdue initial inspections at the time of the review. Overall, the review team calculated that the Bureau performed 6.3 percent of its inspections overdue during the review period.

The review team evaluated the Bureau's timeliness of issuance of inspection findings. The Bureau has a goal of completing inspection reports within 30 days of the final date of the inspection. The review team determined that inspection findings are consistently issued within the 30-day goal.

During the review period, the Bureau received requests for reciprocity from 75 candidate licensees, and performed inspections of 39 percent of those licensees. The Bureau exceeded the criterion in IMC 1220 "Processing of NRC Form 241 and Inspection of Agreement State Licensees Operating Under 10 CFR 150.20," that requires on-site inspection of 20 percent of candidate licensees operating under reciprocity.

The Bureau had 67 licensees that were subject to the Increased Controls at the time of the review. Most initial Increased Control inspections were completed by the NRC prior to this review period. The review team noted that subsequent Increased Controls inspections were not being conducted consistently in all of the Regions in conjunction with routine safety inspections as recommended in the NRC Interim Guidance dated September 21, 2007. Bureau managers indicated that they were awaiting NRC's final guidance with respect to this issue.

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, was satisfactory.

2.3 Technical Quality of Inspections

The review team evaluated inspection reports, enforcement documentation, and inspection notes and interviewed a number of the responsible inspectors for 20 radioactive materials inspections conducted during the review period. The casework examined included a cross-section of inspections conducted by 16 current and former inspectors and covered a wide variety of inspection types involving initial, routine, and special inspections. The casework included inspection of various types of programs including: medical private practice, medical institution, mobile nuclear medicine service, gamma stereotactic radiosurgery, high dose-rate remote afterloaders, nuclear pharmacies, leak test services, industrial radiography, manufacturing and distribution, and portable gauges. Appendix C lists the inspection casework files reviewed.

Inspections are performed by the three Regional Offices, Southeast (Norristown), Southcentral (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.

Based on the evaluation of casework, the review team determined that inspection reports were thorough, complete, consistent, and of high quality with sufficient documentation to ensure that licensees' performances with respect to health, safety, and security were acceptable.

Inspection report documentation supported violations, recommendations made to licensees, unresolved safety issues, and discussions held with licensees during exit interviews. The Bureau has a policy to accompany all staff performing radioactive materials inspections on an annual basis. The review team verified that Regional Supervisors performed staff accompaniments of all 18 staff performing materials inspections in 2009, the first full year of the Agreement.

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 10 of the Bureau's inspectors in September and October 2009. The inspectors conducted inspections at medical facilities, industrial radiographers, a well logger, a service provider, a nuclear pharmacy, and a facility undergoing decommissioning. Three of the inspections included a review of the licensee's implementation of the Increased Controls. Appendix C lists the inspector accompaniments. The inspectors demonstrated performance-based inspection techniques and knowledge of the regulations. The inspectors were well trained, prepared for the 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. During two of the accompaniments, the inspectors did not hold exit meetings with the appropriate level of licensee management. Overall, 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, was satisfactory.

2.4 Technical Quality of Licensing Actions

The review team examined completed licensing casework and interviewed license reviewers for 26 specific licensing actions. 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, operating and emergency procedures, appropriateness of license conditions, and overall technical quality. The casework was also reviewed for timeliness, use of appropriate deficiency letters and cover letters, reference to appropriate regulations, supporting documentation, consideration of enforcement history, pre-licensing visits, peer/supervisory review, and proper signatures.

The licensing casework was selected to provide a representative sample of licensing actions completed during the initial review period. Licensing actions selected for evaluation included 6 new licenses, 2 renewals, 3 decommissioning or termination actions, and 15 amendments. Files reviewed included a cross-section of license types, including: medical diagnostic and

therapy, brachytherapy, industrial radiography, research and development, nuclear pharmacy, gauges, and manufacturers. The casework sample represented work from each of the license reviewers. A listing of the licensing casework reviewed, with case-specific comments, is provided in Appendix D.

On March 31, 2008, NRC transferred approximately 700 specific licenses to Pennsylvania's jurisdiction. The Bureau merged the NRC licenses with existing Bureau licenses for naturally occurring and accelerator-produced radioactive materials. As a result, the Bureau had approximately 790 licenses at the time of the review. The majority of the license amendments completed by the Bureau during the review period consisted of merging NRC licenses into Pennsylvania licenses and reformatting all of the NRC licenses into the Bureau's license template. The Bureau completed 12 license renewals, 47 new licenses and, 64 decommissioning licensing actions during the review period.

All licensing actions are initially entered into the Bureau's computer tracking system called eFACTS (Environment, Facility, Application, Compliance Tracking System). The licensing actions are uploaded to the eFACTS system so that information is readily available to the Regional Offices for inspection purposes. In addition, a hard copy of the licensing action is mailed to the respective Regional Office. License reviewers use checklists and boilerplate licenses specific to the type of licensing actions to ensure consistency in licenses. The Bureau uses a License Review Tracking sheet to document each licensing action's progress through the Bureau's review process. A final quality assurance review of each licensing action is performed by the Radioactive Materials Program Supervisor, who signs the completed license.

Based on the casework evaluated, the review team concluded that the licensing actions were of high quality and consistent with the NUREG-1556 guidance documents, the Commonwealth's regulations, and good health physics practices. The review team attributed the consistent use of templates and quality assurance reviews to the overall quality noted in the casework reviews.

The Bureau performs pre-licensing checks of all new applicants. The Bureau's methods incorporate the essential elements of NRC's revised pre-licensing guidance to verify that the applicant will use requested radioactive materials as intended. The Bureau checks applicants without a known radioactive materials license from another agency against records with the Pennsylvania Secretary of State's Office for proper business registration. In addition, the Bureau uses various on-line search mechanisms and interagency communications to verify the identity of individuals. If a pre-licensing visit is necessary, the Central Office requests the visit through a Regional Office. The Bureau has a policy of hand-delivering all new licenses. Therefore, each applicant is subject to an on-site evaluation of their radiation safety and security programs prior to receipt of the initial license.

The review team examined the Bureau's licensing practices regarding the Increased Controls and Fingerprinting Orders. The review team noted that the Bureau added legally binding license conditions to the licenses that met the criteria for implementing the Increased Controls, including fingerprinting, as appropriate. The review team analyzed the Bureau's methodology for identifying those licenses and found the rationale was thorough and accurate. The review team confirmed that license reviewers evaluated new license applications and license amendments using the same criteria. The Bureau requires full implementation of the Increased Controls prior to issuance of a new license or license amendment that meets the established criteria.

The Commonwealth adopted NRC regulations required for compatibility by reference, including the regulations for implementation of the National Source Tracking System (NSTS). The Bureau is considering whether to impose a legally binding license condition on licensees that are required to report to NSTS to help ensure licensees are aware of the regulatory requirement. Since the NSTS is required by regulation, the license condition would be for awareness only.

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, was satisfactory.

2.5 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 16 of 32 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.

When notified of an incident or an allegation, the appropriate Regional manager and staff discuss the initial response and the need for an on-site investigation, based on the safety significance. 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. Early in the Agreement, State managers indicated that they thought entering an incident into NMED fulfilled the NRC Headquarters Operations Center reporting requirement. Of the incidents evaluated by the review team, all were properly entered into NMED, but 7 of the 16 incidents had been not reported to NRC within the required time frame, most because of the aforementioned misconception.

The incidents selected for review included medical events, lost or stolen radioactive material, contamination events, a leaking source, a transportation event, and equipment failures. The review team determined that the Bureau's responses to incidents were thorough, complete, and comprehensive in all but two instances. Those two incidents, both involving industrial radiography source retraction problems, 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. For the incident investigations conducted in the other 14 cases, the Bureau immediately dispatched inspectors to the site when the possibility of an immediate threat to public health and safety existed. The review team noted that at the conclusion of investigations, inspectors generated narrative reports that thoroughly documented the investigations.

The failure to perform the two incident investigations cited above, and the failure to properly report numerous incidents to NRC were caused by insufficient communications within the

Bureau. 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.

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, was satisfactory.

3.0 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 the Commonwealth of Pennsylvania does not relinquish authority to regulate a sealed source and device evaluation program or a uranium recovery program, so only the first and the third non-common performance indicators were applicable to this review.

3.1 Compatibility Requirements

3.1.1 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.

In addition to its response to the questionnaire, the Commonwealth provided the review team with a copy of the legislation that affects the radiation control program. There have been no changes since the effective date of the Agreement. Pennsylvania regulations are not subject to sunset laws.

3.1.2 Program Elements Required for Compatibility

The Commonwealth's regulations for control of radiation are located in the Pennsylvania Code, Title 25, Article V, Chapters 215-240, 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 by 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 3 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 NRC regulations so that if NRC modifies a regulation, the change is automatic for the Commonwealth's regulations. If NRC develops a new regulation section, such as the upcoming 10 CFR Part 37 security requirements rule, Pennsylvania must create a new section in their regulations which points to the NRC Part. 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, was satisfactory.

3.2 Low-level Radioactive Waste Disposal Program

Although NRC's Agreement with the Commonwealth of Pennsylvania relinquishes the authority for a low-level radioactive waste (LLRW) program, the Commonwealth does not have any activities or plans for activities that fall under this authority. Accordingly, the review team did not review this indicator.

4.0 SUMMARY

As noted in Sections 2.0 and 3.0 above, Pennsylvania's performance was found satisfactory for all performance indicators reviewed. The review team made one recommendation regarding the performance of the Commonwealth. Overall, the review team recommended, and the MRB agreed, that the Pennsylvania Agreement State Program is adequate to protect public health and safety and compatible with 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 4 years.

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

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 2.5)

LIST OF APPENDIXES AND ATTACHMENT

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
Attachment	January 11, 2010 Letter from Kenneth R. Reisinger Pennsylvania's Response to the Draft Report

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	Area of Responsibility
James Lynch, Region III	Team Leader Technical Quality of Incident and Allegation Activities Inspector Accompaniments
Donna Janda, Region I	Technical Staffing and Training Compatibility Requirements Inspector Accompaniments
Solomon Sahle, FSME	Status of Materials Inspection Program
Chuck McCracken, Ohio	Technical Quality of Inspections
Rachel Browder, Region IV	Technical Quality of Licensing Actions

APPENDIX B

PENNSYLVANIA ORGANIZATION CHARTS

ADAMS Accession No.: ML093350770

APPENDIX C

INSPECTION CASEWORK REVIEWS

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

File No.: 1 Licensee: Advanced Imaging Specialists Inspection Type: Routine, Unannounced Inspection Date: 11/24/08	License No.: PA-0924 Priority: 3 Inspector: RC
File No.: 2 Licensee: Delaware County Memorial Hospital Inspection Type: Routine, Unannounced Inspection Dates: 10/30-31/08	License No.: PA-0065 Priority: 3 Inspector: JK
File No.: 3 Licensee: Northeast Radiation Oncology Center Inspection Type: Routine, Unannounced Inspection Date: 6/1/09	License No.: PA-0953 Priority: 3 Inspectors: RC, BR
File No.: 4 Licensee: UPMC Passavant Inspection Type: Routine, Unannounced Inspection Date: 9/8/09	License No.: PA-0310 Priority: 2 Inspector: DM
File No.: 5 Licensee: St. Luke's Hospital Inspection Type: Routine, Unannounced Inspection Date: 6/23/09	License No.: PA-0073 Priority: 2 Inspectors: RC, BR
File No.: 6 Licensee: Professional Service Industries, Inc. Inspection Type: Routine, Unannounced Inspection Date: 9/9/09	License No.: PA-0281 Priority: 1 Inspector: CR
File No.: 7 Licensee: Team Industrial Inspection Type: Routine, Unannounced Inspection Date: 2/24/09	License No.: PA-1176 Priority: 1 Inspectors: SB, FC
File No.: 8 Licensee: Diamond Technical Services, Inc. Inspection Type: Routine, Announced Inspection Date: 1/22/09	License No.: PA-1077 Priority: 1 Inspector: JH

File No.: 9

Licensee: Cardinal Health
Inspection Type: Routine, Unannounced
Inspection Date: 10/27/09

License No.: PA-0415
Priority: 2
Inspector: GD

File No.: 10

Licensee: Professional Inspection & Testing Services
Inspection Type: Special, Announced
Inspection Date: 5/9/08

License No.: PA-1038
Priority: 5
Inspectors: RK, GD

File No.: 11

Licensee: Keystone Oncology, LLC
Inspection Type: Routine, Unannounced
Inspection Date: 10/22/08

License No.: PA-1111
Priority: 2
Inspector: FP

File No.: 12

Licensee: Aqua Pennsylvania
Inspection Type: Routine, Announced
Inspection Date: 4/10/08

License No.: PA-0850
Priority: 5
Inspector: MM

File No.: 13

Licensee: Abington Memorial Hospital
Inspection Type: Routine, Unannounced
Inspection Date: 10/20/09

License No.: PA-0055
Priority: 3
Inspectors: EC, RC

File No.: 14

Licensee: Prime NDT Services, Inc.
Inspection Type: Routine, Unannounced
Inspection Date: 10/1/09

License No.: PA-1185
Priority: 2
Inspector: FC

File No.: 15

Licensee: Lakeshore Isotopes, LLC
Inspection Type: Routine, Announced
Inspection Date: 8/8/08

License No.: PA-0843
Priority: 2
Inspector: DM

File No.: 16

Licensee: Strube, Inc.
Inspection Type: Special/Decommissioning, Announced
Inspection Date: 10/27/09

License No.: PA-1004
Priority: 5
Inspector: JW

File No.: 17

Licensee: Holy Spirit Hospital
Inspection Type: Initial, Unannounced
Inspection Date: 10/17/08

License No.: PA-0249
Priority: 2
Inspector: GD

File No.: 18

Licensee: Acuren Inspection, Inc.
Inspection Type: Routine, Unannounced
Inspection Date: 10/21/09

License No.: PA-1063
Priority: 1
Inspectors: DS, CS, DM

File No.: 19

Licensee: Neo-Pet, LLC
Inspection Type: Routine, Unannounced
Inspection Date: 3/30/09

License No.: PA-0905
Priority: 3
Inspectors: BR, RC

File No.: 20

Licensee: Three Rivers Gamma Services
Inspection Type: Routine, Announced
Inspection Date: 1/14/09

License No.: PA-1164
Priority: 5
Inspectors: JH, CR

INSPECTOR ACCOMPANIMENTS

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

Accompaniment No.: 1

Licensee: Pocono Medical Center
Inspection Type: Routine, Unannounced
Inspection Date: 9/3/09

License No.: PA-0034
Priority: 3
Inspector: RC

Accompaniment No.: 2

Licensee: UPMC Passavant
Inspection Type: Routine, Unannounced
Inspection Date: 9/8/09

License No.: PA-0310
Priority: 2
Inspector: DM

Comments:

- a) The inspector reviewed only one patient therapy file.
- b) The inspector did not hold an inspection exit meeting with the appropriate level of licensee management.

Accompaniment No.: 3

Licensee: Professional Service Industries, Inc.
Inspection Type: Routine, Unannounced
Inspection Date: 9/9/09

License No.: PA-0281
Priority: 1
Inspector: CR

Comments:

- a) The inspector did not have a copy of the current license amendment.
- b) The inspector did not hold an inspection exit meeting with the appropriate level of licensee management.

Accompaniment No.: 4
Licensee: Superior Well Services
Inspection Type: Routine, Unannounced
Inspection Date: 9/10/09

License No.: PA-1168
Priority: 3
Inspector: CR

Accompaniment No.: 5
Licensee: Philotechnics, Ltd.
Inspection Type: Routine, Unannounced
Inspection Date: 9/11/09

License Nos.: PA-0831 and PA-0831A
Priority: 5
Inspector: DS

Accompaniment No.: 6
Licensee: Prime NDT Services
Inspection Type: Routine, Unannounced
Inspection Date: 10/1/09

License No.: PA-1185
Priority: 1
Inspector: FC

Accompaniment No.: 7
Licensee: Mercy Fitzgerald Hospital
Inspection Type: Routine, Unannounced
Inspection Date: 10/6/09

License No.: PA-0082
Priority: 3
Inspector: JK

Accompaniment No.: 8
Licensee: Strube, Inc.
Inspection Type: Special, Announced
Inspection Date: 10/27/09

License No.: PA-1004
Priority: 1
Inspector: JW

Accompaniment No.: 9
Licensee: Cardinal Health
Inspection Type: Routine, Unannounced
Inspection Date: 10/27/09

License No.: PA-0415
Priority: 2
Inspector: GD

Accompaniment No.: 10
Licensee: Precision Custom Components, LLC
Inspection Type: Routine, Unannounced
Inspection Date: 10/28/09

License No.: PA-1042
Priority: 1
Inspector: FP

APPENDIX D

LICENSE CASEWORK REVIEWS

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

File No.: 1
Licensee: Commonwealth of Pennsylvania
Type of Action: Termination
Date Issued: 5/13/09
License No.: PA-1052
Amendment No.: 01
License Reviewer: JC

File No.: 2
Licensee: WeldSonix, Inc.
Types of Action: New
Date Issued: 12/18/08
License No.: PA-1320
Amendment No.: N/A
License Reviewer: RH

File No.: 3
Licensee: Halliburton Energy Services, Inc.
Type of Action: New
Date Issued: 9/23/09
License No.: PA-1389
Amendment No.: N/A
License Reviewer: GV

Comment:

The license reviewer did not specifically identify authorization for "neutron activation logging in oil, gas [and water] wells in downhole accelerator."

File No.: 4
Licensee: Strube, Inc.
Type of Action: Amendments (Decommissioning)
Dates Issued: 4/8/09, 10/6/09
License No.: PA-1004
Amendment Nos.: 02, 03
License Reviewer: JC

File No.: 5
Licensee: Integrity Testlab, LLC
Type of Action: New
Date Issued: 10/28/08
License No.: PA-1181
Amendment No.: N/A
License Reviewers: JC, RH

Comment:

The license reviewer did not authorize depleted uranium for the model of radiography cameras authorized under the license.

File No.: 6
Licensee: Lakeshore Isotopes, LLC
Type of Action: Amendment & pending action
Date Issued: 5/9/08
License No.: PA-0843
Amendment No.: 14
License Reviewers: RH, GV

File No.: 7

Licensee: Precision Calibration and Testing Corporation
Type of Action: New
Date Issued: 11/18/08

License No.: PA-1175
Amendment No.: N/A
License Reviewer: RH

File No.: 8

Licensee: Cardinal Health
Type of Action: Amendment
Date Issued: 8/18/09

License No.: PA-0895
Amendment No.: 13
License Reviewer: JC

File No.: 9

Licensee: Weatherford International, Inc.
Types of Action: Amendment
Dates Issued: 5/9/08

License No.: PA-1030
Amendment No.: 01
License Reviewer: JC

File No.: 10

Licensee: Pennsylvania State University
Type of Action: Renewal, Amendment
Dates Issued: 4/13/09, 8/31/09

License No.: PA-0100
Amendment Nos.: 13, 14
License Reviewers: JC, RH

Comments:

- a) The license reviewers did not obtain a description of the facilities and equipment provided, such as engineering controls and barriers to protect the health and safety of the public and its employees.
- b) The license reviewers did not request the criteria used by the Radiation Safety Committee to review and approve proposed facilities and laboratories, including the use of a classification scheme for radionuclide toxicity and quantity of radioactivity used in each laboratory.

File No.: 11

Licensee: H&H X-Ray Services, Inc.
Type of Action: New
Dates Issued: 9/4/08

License No.: PA-1124
Amendment No.: New
License Reviewer: RH

Comments:

- a) The new license authorized a storage and use location in the State of Louisiana.
- b) The license reviewer did not include the appropriate 3-year leak test frequency for radiography sealed sources in storage.

File No.: 12

Licensee: Branch Radiographic Laboratories, Inc.
Type of Action: New
Dates Issued: 9/5/08

License No.: PA-1132
Amendment No.: New
License Reviewer: RH

File No.: 13

Licensee: Alliance Health Care Services, Inc.
Type of Action: Amendment
Date Issued: 9/8/09

License No.: PA-0742
Amendment No.: 17
License Reviewer: GV

File No.: 14

Licensee: Conemaugh Valley Memorial Hospital
Type of Action: Amendment
Date Issued: 10/6/09

License No.: PA-0302
Amendment No.: 16
License Reviewer: GV

File No.: 15

Licensee: St. Joseph's University, Dept of Biology
Type of Action: Amendment
Date Issued: 7/29/09

License No.: PA-1307
Amendment No.: 01
License Reviewer: CS

File No.: 16

Licensee: Carnegie Mellon University
Type of Action: Amendment
Date Issued: 8/10/09

License No.: PA-0203
Amendment No.: 22
License Reviewer: GV

Comment:

In Item 6 of the license, the license reviewer did not specify either: byproduct, source, or special nuclear material in lieu of "licensed material."

File No.: 17

Licensee: Quality Engineering Solutions
Type of Action: Amendment
Date Issued: 10/27/09

License No.: PA-1117
Amendment No.: 01
License Reviewers: GV, DG

File No.: 18

Licensee: SmithKline Beecham Pharmaceuticals
Type of Action: Amendment
Date Issued: 11/4/08

License No.: PA-0234
Amendment No.: 23
License Reviewer: RH

File No.: 19

Licensee: Lancaster General Hospital
Type of Action: Renewal
Date Issued: 11/5/09

License No.: PA-0233A
Amendment No.: 01
License Reviewers: GV, JC

File No.: 20

Licensee: University of Pittsburgh

Type of Action: Amendment

Date Issued: 11/4/09

License No.: PA-0190

Amendment No.: 28

License Reviewers: GV, CS, JC

Comment:

The license reviewer did not obtain a drawing of a new facility for this Broad Scope license.

File No.: 21

Licensee: Cardinal Health Nuclear Pharmacy Services

Type of Action: Amendment (Termination of facility)

Date Issued: 10/14/08

License No.: PA-0877

Amendment No.: 07

License Reviewer: RH

File No.: 22

Licensee: Altoona Regional Health System

Type of Action: Amendments

Dates Issued: 6/1/09, 11/5/09

License No.: PA-0016

Amendment Nos.: 23, 25

License Reviewer: JC

Comment:

The license reviewer inappropriately authorized the licensee to approve training and experience for an Authorized Medical Physicist.

File No.: 23

Licensee: Alcoa, Inc.

Type of Action: Amendment

Date Issued: 9/28/09

License No.: PA-1089

Amendment No.: 01

License Reviewers: GV, JC

APPENDIX E

INCIDENT CASEWORK REVIEWS

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

File No.: 1

Licensee: Saint Luke's Hospital

Date of Incident: 4/11/08

Investigation Date: 6/10/08

License No.: PA-0073

NMED Log No.: 080550

Type of Incident: Overexposure

Type of Investigation: Site

Comment:

The Bureau did not report this incident to the NRC Headquarters Operations Center.

File No.: 2

Licensee: Weatherford International

Date of Incident: 4/18/08

Investigation Date: 4/24/08

License No.: 42-29288-01

NMED Log No.: 080362

Type of Incident: Leaking Source

Type of Investigation: Site

Comment:

The Bureau did not report this incident to the NRC Headquarters Operations Center.

File No.: 3

Licensee: Weatherford International

Date of Incident: 7/29/08

Investigation Date: 7/31/08

License No.: 42-29288-01

NMED Log No.: 080554

Type of Incident: Abandoned Source

Type of Investigation: Site

Comment:

The Bureau did not report this incident to the NRC Headquarters Operations Center.

File No.: 4

Licensee: Lehigh Valley Hospital

Date of Incident: 7/17/08

Investigation Date: 8/21/08

License No.: PA-0232

NMED Log No.: 080555

Type of Incident: Medical Event

Type of Investigation: Site

Comment:

The Bureau did not report this incident to the NRC Headquarters Operations Center.

File No.: 5

Licensee: University of Pittsburgh Medical Center

Date of Incident: 12/4/08

Investigation Date: 12/4/08

License No.: PA-0190

NMED Log No.: 090076

Type of Incident: Medical Event

Type of Investigation: Telephone

File No.: 6

Licensee: Westinghouse Electric Company
Date of Incident: 10/29/08
Investigation Date: 10/29/08

License No.: PA-1053S
NMED Log No.: 090377
Type of Incident: Transportation
Type of Investigation: Site

File No.: 7

Licensee: The Western Pennsylvania Hospital
Date of Incident: 2/23/09
Investigation Date: 3/18/09

License No.: PA-0121
NMED Log No.: 090391
Type of Incident: Medical Event
Type of Investigation: Site

File No.: 8

Licensee: TEI Analytical Services
Date of Incident: 9/23/08
Investigation Date: 9/23/08

License No.: 37-38004-02
NMED Log No.: N/A
Type of Incident: Source Disconnect
Type of Investigation: Telephone

Comment:

The Bureau did not report this incident to the NRC Headquarters Operations Center.

File No.: 9

Licensee: Hahnemann University Hospital
Date of Incident: 12/22/08
Investigation Date: 12/22/08

License No.: PA-0927
NMED Log No.: 090465
Type of Incident: Medical Event
Type of Investigation: Telephone

File No.: 10

Licensee: Acuren Inspection
Date of Incident: 2/19/09
Investigation Date: N/A

License No.: PA-1063
NMED Log No.: 090477
Type of Incident: Equipment Failure
Type of Investigation: None

Comments:

- a) The Bureau did not investigate this incident.
- b) The Bureau did not report this incident to the NRC Headquarters Operations Center.

File No.: 11

Licensee: Geisinger Health Systems
Date of Incident: 2/26/09
Investigation Date: 4/14/09

License No.: PA-0006
NMED Log No.: 090485
Type of Incident: Lost Source
Type of Investigation: Site

File No.: 12

Licensee: Mercy Fitzgerald Hospital
Date of Incident: 3/26/09
Investigation Date: 5/7/09

License No.: PA-0082
NMED Log No.: 090540
Type of Incident: Medical Event
Type of Investigation: Site

File No.: 13

Licensee: Chester County Hospital
Date of Incident: 3/30/09
Investigation Date: 3/30/09

License No.: PA-0071
NMED Log No.: 090579
Type of Incident: Embryo/Fetus Exposure
Type of Investigation: Telephone

File No.: 14

Licensee: Drexel University
Date of Incident: 4/1/09
Investigation Date: 4/1/09

License No.: PA-1329
NMED Log No.: 090593
Type of Incident: Leaking Source
Type of Investigation: Telephone

File No.: 15

Licensee: Integrity Testlab
Date of Incident: 5/18/09
Investigation Date: N/A

License No.: PA-1181
NMED Log No.: 090594
Type of Incident: Equipment Failure
Type of Investigation: None

Comments:

- a) The Bureau did not investigate this incident.
- b) The Bureau did not report this incident to the NRC Headquarters Operations Center.

File No.: 16

Licensee: Lehigh Valley Hospital
Date of Incident: 7/29/09
Investigation Date: 8/11/09

License No.: PA-0264
NMED Log No.: 090653
Type of Incident: Medical Event (Retracted)
Type of Investigation: Site

ATTACHMENT

January 11, 2010 Letter from Kenneth R. Reisinger
Pennsylvania's Response to the Draft Report

ADAMS Accession No.: ML10019018