

UNITED STATES NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

July 29, 2010

MEMORANDUM TO:

Marc L. Dapas, Acting Regional Administrator

Region I

FROM:

Michael F. Weber /RA/

Deputy Executive Director for Materials, Waste, Research, State, Tribal, and Compliance Programs

Office of the Executive Director for Operations

SUBJECT:

FINAL REPORT OF THE INTEGRATED MATERIALS

PERFORMANCE EVALUATION PROGRAM REVIEW OF THE

REGION I RADIOACTIVE MATERIALS PROGRAM

On July 12, 2010, the Management Review Board (MRB) met to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) report of the U.S. Nuclear Regulatory Commission's Region I radioactive materials program. The MRB found the program adequate to protect public health and safety.

Section 4.0, page 7, of the enclosed final report summarizes the results of the review. The review team made no recommendations in regard to program performance by the Region.

If you have any questions on the report, please contact Joseph DeCicco at (301) 415-7833.

I applaud your staff's efforts during the IMPEP review period and look forward to continued high level performance in the future. I would also like to thank Region I for exemplary support during the time of the team's visit.

Enclosure: Region I Final IMPEP Report

cc: J. Kinneman, Region I

CONTACT: Aaron T. McCraw, FSME/MSSA

(630) 829-9650



INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM REVIEW OF THE REGION I RADIOACTIVE MATERIALS PROGRAM

APRIL 26-30, 2010

FINAL REPORT

1.0 INTRODUCTION

This report presents the results of the review of the Region I radioactive materials program. The review was conducted during the period of April 26-30, 2010, by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of New York. 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 a Final General Statement of Policy," published in the *Federal Register* on October 16, 1997, and NRC Management Directive (MD) 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)," dated February 26, 2004. Preliminary results of the review, which covered the period of April 9, 2005, to April 30, 2010, were discussed with Region I managers on April 30, 2010.

A draft of this report was issued to Region I for factual comment on June 1, 2010. Region I responded by memorandum dated June 17, 2010, from John D. Kinneman, Director, Division of Nuclear Materials Safety (the Division). A copy of the Division's response is included as the Attachment to this report. The Management Review Board (MRB) met on July 12, 2010, to consider the proposed final report. The MRB found the NRC Region I radioactive materials program adequate to protect public health and safety.

The Region I radioactive materials program is administered by the Division, which is headed by the Division Director. The Division Director reports directly to the Regional Administrator. Organization charts for Region I and the Division are included as Appendix B.

At the time of the review, the Region I radioactive materials program regulated more than 950 specific radioactive material licenses. In addition, the Division had inspection responsibility for four power reactors in decommissioning status, five complex materials decommissioning sites, and all independent spent fuel storage installations in Region I.

In preparation for the review, a questionnaire addressing the common performance indicators was sent to Region I on January 14, 2010. The Division provided a response to the questionnaire on April 8, 2010. The Division's response can be found in NRC's Agencywide Documents Access and Management System (ADAMS) using Accession Numbers ML100980430 (memorandum) and ML100980461 (questionnaire response).

The review team's general approach for the conduct of this review consisted of: (1) examination of the Division's response to the questionnaire; (2) analysis of quantitative information from the Region's licensing, inspection, and allegation databases, as well as ADAMS; (3) technical review of selected regulatory actions; (4) field accompaniments of five Region I inspectors; and (5) interviews with staff and managers. The review team evaluated the information that it gathered against the established criteria for each common performance indicator and made a preliminary assessment of the Region I radioactive materials program's performance.

Section 2.0 of this report covers the Region's response to recommendations made during previous reviews. Results of the current review of the common performance indicators are presented in Section 3.0. Section 4.0 summarizes the review team's findings.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous IMPEP review, which concluded on April 8, 2005, the review team made no recommendations regarding program performance by the Division.

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 <u>Technical Staffing and Training</u>

Issues central to the evaluation of this indicator include the Division'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 Division's questionnaire response relative to this indicator, interviewed Division managers and staff, interviewed Region I Division of Resource Management staff, and considered any workload backlogs.

The Division is composed of four branches: (1) the Medical Branch, (2) the Commercial and R&D Branch, (3) the Materials Security and Industrial Branch, and (4) the Decommissioning Branch. The Licensing Assistance Team, managed as part of the Decommissioning Branch, consists of a Team Leader and three staff. The Licensing Assistance Team provides administrative and records management support for licensing and inspection activities for the Division. Including non-technical positions, the Division had 42 staff members on board at the time of the review. Funding for technical positions comes from the Nuclear Materials Safety Arena (26.9 full-time equivalents (FTE)) and Security and Incident Response Arena (5.1 FTE).

Since the previous review, the Division's total number of staff positions has decreased by 10, with a corresponding budget change of approximately 7 FTE. This decrease was in parallel with a loss of approximately 1,600 licenses that were transferred to 3 new Agreement States during the review period. Seven new technical staff members were hired into the Division since the last IMPEP review. During the same period, 15 technical staff members departed the program (three were among those hired during that time period). The Division had three technical vacancies at the time of the on-site review. Two positions have been vacant for approximately 1 year, while the third position was vacated just prior to the on-site review. The Division is addressing these vacancies within the constraints of overall Regional FTE levels.

The review team examined the Division's training spreadsheet, sampled some individual inspectors' qualifications, and interviewed managers concerning technical training in accordance with the requirements of Inspection Manual Chapter (IMC) 1246, "Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area." The review team found a good balance of personnel between licensing and inspecting. Technical staff members perform licensing and inspection activities. All staff members in each branch are qualified for the work they perform. Three staff members are in the inspector qualification process, the remainder of the staff being fully qualified inspectors. Two of the three staff in the qualification process are interim-qualified and are expected to complete the process by October

2010. The remaining one will complete the process within the time frame contained in IMC 1246. Of the technical staff members who work on materials and decommissioning licensing issues, 12 have full signature authority, 12 have limited signature authority, and 5 have no signature authority. Except for training purposes, staff members are assigned licensing work for which they have independent signature authority. A senior license reviewer signed out the licenses when an unqualified reviewer reviewed the license for training purposes. The Division staffing level was adequate for its workload.

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

3.2 <u>Status of Materials Inspection Program</u>

The team focused on five factors in reviewing this indicator: inspection frequency, overdue inspections, initial inspection of new licenses, timely dispatch of inspection findings to licensees, and performance of reciprocity inspections. The evaluation was based on the Division's questionnaire response relative to this indicator, data from NRC's Licensing Tracking System (LTS), examination of completed inspection casework, and interviews with Division managers and staff.

The review team verified that the Division adheres to the inspection priorities prescribed in IMC 2800, "Materials Inspection Program," by cross-checking the inspection frequencies entered in LTS for randomly selected licensees with the IMC 2800 frequencies. The review team found, in all cases, that the inspection frequencies in LTS matched the IMC 2800 inspection frequencies, unless the next inspection date was intentionally reduced by the Division based on licensee performance and in accordance with IMC 2800. The review team verified that Increased Controls inspections were being performed concurrently with routine safety inspections for applicable licensees.

Region I conducted a total of 1,207 inspections of Priority 1, 2, and 3 licensees during the review period. As noted in their response to the questionnaire, the Division identified 35 of these inspections that were conducted overdue by more than 25 percent of the inspection frequency prescribed by IMC 2800. The review team did not identify any inspections that were overdue at the time of the review. The review team found that 10 of the 35 overdue inspections were due to LTS data entry errors. During the review period, the Division instituted changes in Quality Control and monitoring in order to reduce future errors.

The review team also evaluated the Division's timeliness for conducting initial inspections. During the review period, Region I issued 395 new licenses. IMC 2800 requires initial inspections of new licenses to be conducted within 12 months of license issuance. In the questionnaire, the Division self-identified 19 initial inspections that were conducted overdue. The review team verified that there were no overdue initial inspections at the time of the review. Overall, the review team calculated that the Division conducted approximately 3 percent of Priority 1, 2, and 3 and initial inspections overdue during the review period.

The review team evaluated the Division's timeliness for issuing inspection findings during the inspection casework reviews. The Division issued inspection findings to the licensees within 30

days for 55 of the 57 inspection findings reviewed by the team. The two reports were late due to tracking errors.

During the review period, the team determined that the Division completed the required number of reciprocity inspections of candidate licensees for all years covered by the review period, except 2005. IMC 1220, "Processing of NRC Form 241 and Inspection of Agreement State Licensees Operating Under 10 CFR 150.20," requires inspection of at least 20 percent of all candidate reciprocity licensees per calendar year. In 2005, the Division inspected 3 of 19 candidate licensees or 16 percent of candidate licensees. The Division self-identified their being below the 20 percent criteria in 2005 and instituted programmatic changes to correct this issue. After 2005, the Division began requesting their reciprocity licensees to provide dates that the licensee would be available for reciprocity inspection visits. This programmatic change reduced the number of failed inspection attempts, which is not captured by the reciprocity inspections metric. The Division also increased its monitoring of reciprocity activities and was then able to meet or exceed the 20 percent criterion in each of the subsequent calendar years of the review period.

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

3.3 Technical Quality of Inspections

The review team evaluated inspection reports and documentation, enforcement documentation, and interviewed inspectors for 29 inspections that were conducted by 25 different inspectors during the review period. The casework selected included a cross-section of inspection types. These included broad scope medical, high-dose rate remote afterloader (HDR), gamma stereotactic radiosurgery, irradiator, industrial radiography, nuclear pharmacy, brachytherapy, research and development, portable gauge, well-logging, academic broad scope, waste handling/shipping, decommissioning, and medical private practice. Casework also included inspections related to reciprocity, decommissioning, events, and security. Appendix C lists the inspection files reviewed.

Based on the evaluation of casework, the review team determined that inspections covered all aspects of the licensees' radiation safety and security programs. The review team noted that inspection reports were generally 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 reports were complete, with sufficient documentation to support inspection findings, including escalated enforcement when applicable.

While on site, the review team evaluated the Division's handling and storing of sensitive information. The review team determined that documents containing sensitive information were appropriately marked, stored, and protected in accordance with NRC policy. The review team observed outgoing correspondence that was appropriately marked.

The review team determined that a supervisor accompanied all active inspectors at least once per year.

Review team members accompanied five Region I radioactive materials inspectors on nine inspections. The inspector accompaniments were conducted on the following license types: five hospitals, one medical private practice, one industrial radiography site, one research and development broadscope license facility, and one self-shielded irradiator. The accompaniments are identified in Appendix C. Each accompanied inspector demonstrated appropriate inspection methods and exhibited knowledge and understanding of applicable regulations and license conditions. The inspectors were trained, prepared, and thorough in their inspections of the licensees' program. Inspectors used good health physics practices, conducted effective interviews of licensee personnel, and used a performance-based approach. The review team determined that the inspections were adequate to assess radiological health, safety, and security.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Region I's performance with respect to the common indicator, Technical Quality of Inspections, was satisfactory.

3.4 Technical Quality of Licensing Actions

The review team examined the casework and interviewed license reviewers for 34 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, 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 letters and cover letters, reference to appropriate regulations, supporting documentation and data, consideration of enforcement history, pre-licensing visits, peer/supervisory review, and proper signatures.

The review team selected licensing casework that provided a representative sample of licensing actions completed during the review period. Licensing actions selected for evaluation included: 8 new licenses, 6 renewals, 10 amendments, 3 terminations, 4 financial assurance reviews, and 3 decommissioning cases. Casework reviewed included a cross-section of license types: decontamination service, academic broadscope, well logging, HDR, irradiator, self-shielded irradiator, research and development broadscope, gamma stereotactic radiosurgery, mobile medical service, radionuclide production using an accelerator, medical institution broad, decommissioning, medical product distribution, fixed and portable gauges, and source material military munitions testing. A listing of the licensing casework reviewed, with case-specific comments, can be found in Appendix D.

Overall, the team found that the licensing actions were thorough, complete, and consistent, of high quality, and properly addressed health, safety, and security issues. The review team found that documentation for all of the reviewed licensing cases was complete and well documented in ADAMS.

The review team randomly selected five HDR licenses to determine if the licenses had the appropriate sensitivity markings in the header and footer of each page in accordance with NRC policy. All five licenses had the appropriate sensitivity markings on each page. The review team also looked at the possession limits on the license to determine if the Increased Controls,

fingerprinting, and National Source Tracking System requirements were needed based on the authorized quantities on the license.

The review team evaluated the Division's implementation of NRC's financial assurance requirements. The review team looked at 5 of the Division's 12 self-guarantee instruments and determined that all 5 instruments were current as documented by the licensee's most current execution of their annual self test as required by Appendix E of Part 30 of Title 10 of the Code of Federal Regulations, "Energy."

The review team evaluated the Division's implementation of the pre-licensing guidance. The review team noted that the Licensing Assistance Team an established administrative process in which the pre-licensing guidance is automatically added to all licensing actions so the form can be completed during the technical review process. The license reviewers consistently screened cases and used the pre-licensing guidance, as applicable. The review team verified that the Division conducted on-site, pre-licensing visits for each applicant that was identified as an "unknown entity" per the pre-licensing guidance.

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

3.5 Technical Quality of Incident and Allegation Activities

In evaluating the effectiveness of the Division's actions in responding to incidents and allegations, the review team examined the Division's response to the questionnaire relative to this indicator, evaluated selected incidents in the Nuclear Material Events Database (NMED) in Region I's jurisdiction, and evaluated the casework for 20 radioactive materials incidents. A listing of the casework examined can be found in Appendix E. The review team also evaluated the Region's response to 13 allegations involving radioactive materials.

The incidents selected for review included lost or stolen material, damaged equipment of portable gauges, contamination, leaking source, potential overexposure, medical, transportation, and equipment failure. The review team determined that the Division's responses to incidents were thorough, complete, and comprehensive. Initial responses were prompt and well coordinated, and the level of effort was commensurate with the health and safety significance.

The review team's evaluation of incident casework revealed that all incidents were evaluated quickly for the need for on-site investigations, with several special inspections occurring within a relative short time (a few days to a week after incident notification). For less significant health and safety issues, the Division deferred review of the licensee's corrective actions until the next routine inspection. When appropriate, the Division coordinated radioactive materials incident responses with other NRC offices, as well as with other regulatory jurisdictions, such as Agreement States.

In evaluating the effectiveness of the Region's response to allegations, the review team evaluated the casework for 13 allegations involving radioactive material. The review team concluded that the Region consistently took prompt and appropriate action in response to

concerns raised. The review team determined that the Region adequately protected allegers' identities. The Region notified the allegers of the conclusion of their investigation, when possible.

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

4.0 SUMMARY

As noted in Section 3.0 above, Region I's performance was found satisfactory for all performance indicators reviewed. The review team did not make any recommendations regarding program performance. Overall, the review team recommended, and the MRB agreed, that the Region I radioactive materials program is adequate to protect public health and safety. Based on the results of the current IMPEP review, the review team recommended, and the MRB agreed, that the next full review take place in approximately 4 years.

LIST OF APPENDIXES AND ATTACHMENT

Appendix A IMPEP Review Team Members

Appendix B Region I Organization Charts

Appendix C Inspection Casework Reviews

Appendix D License Casework Reviews

Appendix E Incident Casework Reviews

Attachment June 17, 2010 Memorandum from John D. Kinneman

Region I's Response to the Draft Report

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name Area of Responsibility

Joseph DeCicco, FSME Team Leader

Technical Staffing and Training Inspector Accompaniments

Stephen Poy, FSME Status of Materials Inspection Program

Robert Dansereau, New York Technical Quality of Inspections

Roberto Torres, Region IV Technical Quality of Licensing Actions

Candace Clemons-Webb, FSME Technical Quality of Incidents and Allegation

Activities

Inspector Accompaniments

Richard Leonardi, Region IV Inspector Accompaniments

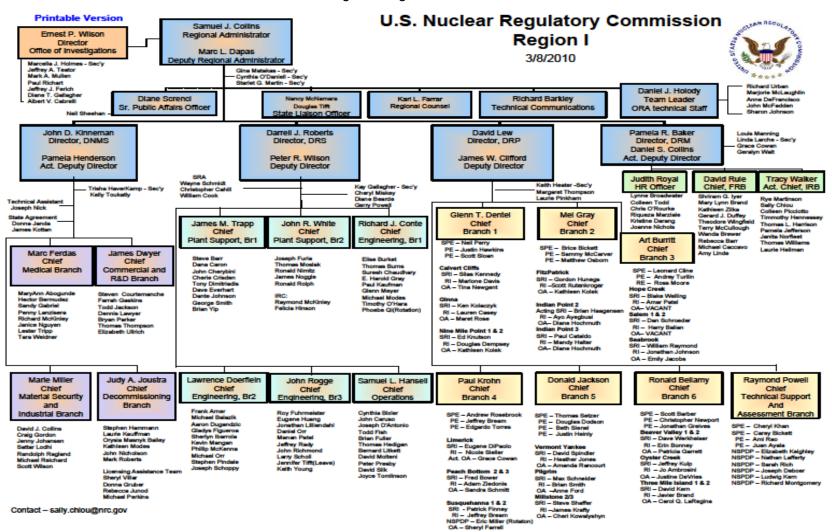
APPENDIX B

REGION I ORGANIZATION CHARTS

ADAMS ACCESSION NO.: ML101520101

Appendix B

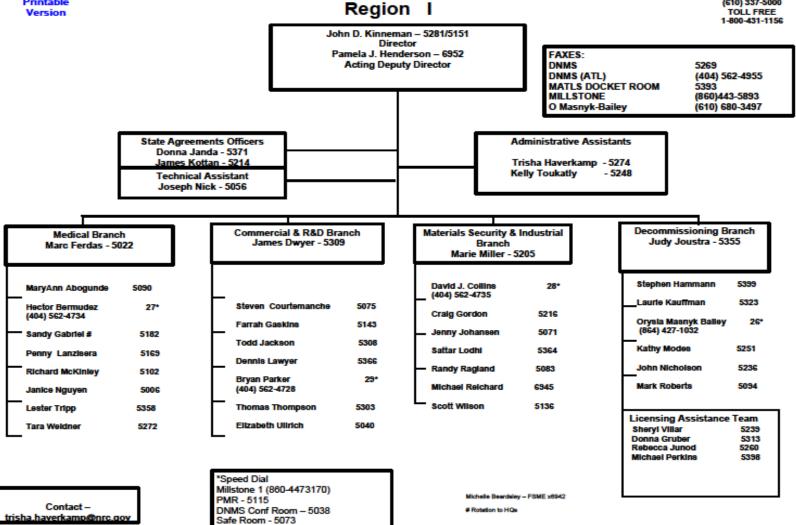
Region I Organization Charts



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DIVISION OF NUCLEAR MATERIALS SAFETY

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APPENDIX C

INSPECTION CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

File No.: 1

Licensee: Washington Hospital Center License Nos.: 08-03604-03

08-03604-05

Inspection Type: Routine Priority: 2

Inspection Dates: 11/16-18/09 Inspectors: PL, JN

File No.: 2

Licensee: Concrete Imaging, Inc. License No.: 19-31213-03

Inspection Type: Special Priority: 1

Inspection Date: 4/30/08 Inspector: DC

File No.: 3

Licensee: All Heart Medical Center License No.: 08-31224-01

Inspection Type: Routine Priority: 5

Inspection Date: 10/22/07 Inspector: DL

File No.: 4

Licensee: Pharmalogic WV, Ltd. License No.: 47-25375-01

Inspection Type: Routine Priority: 2

Inspection Dates: 8/28/09, 9/2/09 Inspectors: SC, TJ

File No.: 5

Licensee: Tracewell Services, Inc. License No.: 47-25480-01

Inspection Type: Routine Priority: 3

Inspection Date: 10/8/08 Inspector: SL

File No.: 6

Licensee: Radiac Research License No.: 31-17528-01

Inspection Type: Routine Priority: 5

Inspection Date: 7/9/07 Inspector: OMB

File No.: 7

Licensee: University of Connecticut License No.: 06-01450-47

Inspection Type: Routine Priority: 3

Inspection Dates: 1/24-25/08 Inspector: TT

File No.: 8

Licensee: Baxter Healthcare of Puerto Rico License No.: 52-21175-01

Inspection Type: Routine Priority: 2

Inspection Date: 7/27/09 Inspector: MR

Region I Final Report Page C.2 Inspection Casework Reviews

File No.: 9

Licensee: Department of the Army License No.: 29-01022-07

Inspection Type: Initial

Priority: 5 Inspection Dates: 11/20-21/06 Inspector: BU

File No.: 10

Licensee: Chemtura Corporation License No.: 06-00221-08

Inspection Type: Special Priority: 5 Inspection Date: 8/26/09 Inspector: DL

File No.: 11

License No.: 45-25477-01 Licensee: Applied Technical Services, Inc.

Inspection Type: Routine Priority: 1

Inspection Dates: 7/30/08, 11/4-5/08, 1/14/09 Inspectors: CG, JJ

File No.: 12

Licensee: Quality Inspection Services, Inc. License No.: 31-30187-01

Inspection Type: Routine Priority: 1

Inspection Dates: 3/13-14/07, 4/5/07, 8/30/07 Inspector: CG

File No.: 13

License No.: 08-30577-01 Licensee: MedStar Georgetown Medical Center

Inspection Type: Routine Priority: 2

Inspection Dates: 8/9/07, 9/4/08 Inspector: PL

File No.: 14

Licensee: Puerto Rico Highway and Transportation License No.: 52-24903-01

Authority Materials Testing Lab

Inspection Type: Routine Priority: 5 Inspection Dates: 12/15-16/08 Inspector: CG

File No.: 15

Licensee: Megan LLC, dba Fairfield Testing Laboratory License No.: 06-19279-01

Inspection Type: Routine Priority: 5 Inspection Date: 12/1/09 Inspector: CG

File No.: 16

Licensee: Roberto Buxedo Decri, M.D. License No.: 52-11897-01

Inspection Type: Routine Priority: 3

Inspection Date: 8/12/08 Inspectors: TW, LR

File No.: 17

Licensee: Yale-New Haven Hospital License No.: 06-30445-01

Inspection Type: Routine Priority: 2

Inspection Dates: 1/25-28/10 Inspectors: SG, LT Region I Final Report
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Inspection Casework Reviews

File No.: 18

Licensee: Huntington Testing and Technology, Inc.

License No.: 47-23076-01

Inspection Type: Special

Priority: 1

Inspection Dates: 9/10-12/08 Inspector: KM

File No.: 19

Licensee: Department of the Army License No.: 01-02861-05

Inspection Type: Special Priority: D

Inspection Dates: 9/27/05, 11/10/05, 11/14-15/05 Inspector: OMB

File No.: 20

Licensee: Stepan Company License No.: STC-1333

Inspection Type: Special Priority: 2

Inspection Dates: 12/8/09, 3/2/10 Inspector: MR

File No.: 21

Licensee: Concrete Imaging, Inc. License No.: 19-3123-02

Inspection Type: Special Priority: 1

Inspection Dates: 6/15-17/07 Inspector: MR

File No.: 22

Licensee: Battelle National License No. 19-31362-01

Inspection Type: Special Priority: 5
Inspection Date: 5/27/09 Inspector: LK

File No.: 23

Licensee: Varian Medical Systems License No.: 45-30957-01

Inspection Type: Special Priority: 5

Inspection Date: 1/27-29/09 Inspectors: PL, KM, SP

File No.: 24

Licensee: SAIC-Frederick License No.: 19-21091-01

Inspection Type: Routine Priority: 3

Inspection Dates: 2/27-28/07, 3/15/07 Inspectors: SH, JJ

File No.: 25

Licensee: Tidewater, Inc. License No.: MD-27-087-02

Inspection Type: Reciprocity Priority: 5

Inspection Date: 6/17/09 Inspector: KM

File No.: 26

Licensee: Puerto Rico Medical Service Authorization License No.: 52-31281-02

Inspection Type: Routine Priority: 2

Inspection Dates: 3/23-25/10 Inspectors: LT, RR

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Inspection Casework Reviews

File No.: 27

Licensee: ABB, Inc. License Nos.: 06-00217-06

SNM-1067

Inspection Type: Routine Priorities: D, 2
Inspection Dates: 12/2-3/08 Inspector: JN

INSPECTOR ACCOMPANIMENTS

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

Accompaniment No.: 1

Licensee: Danbury Hospital License No.: 06-08544-01

Inspection Type: Routine Priority: 2
Inspection Date: 3/16/10 Inspector: RM

Accompaniment No.: 2

Licensee: Bridgeport Hospital License No.: 06-01060-10

Inspection Type: Routine Priority: 2

Inspection Date: 3/18/10 Inspector: RM

Accompaniment No.: 3

Licensee: St. Mary's Hospital License No.: 06-00679-01

Inspection Type: Routine Priority: 3

Inspection Date: 3/17/10 Inspector: RM

Accompaniment No.: 4

Licensee: Hospital Perea License No.: 52-19984-01

Inspection Type: Routine Priority: 3
Inspection Date: 4/20/10 Inspector: LT

Accompaniment No.: 5

Licensee: Mayaguez Nuclear Medicine License No.: 52-25507-01

Inspection Type: Routine Priority: 3
Inspection Date: 4/21/10 Inspector: LT

Accompaniment No.: 6

Licensee: Bella Vista Hospital License No.: 52-25223-01

Inspection Type: Routine Priority: 3
Inspection Date: 4/21/10 Inspector: LT

Accompaniment No.: 7

Licensee: Testing Technologies, Inc. License No.: 45-25007-01

Inspection Type: Reciprocity Priority: 1
Inspection Date: 3/23/10 Inspector: MR

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Accompaniment No.: 8

Licensee: SAIC-Frederick License No.: 19-21091-01

Inspection Type: Routine Priority: 3
Inspection Date: 3/24/10 Inspector: DL

Accompaniment No.: 9

Licensee: Alfred I. DuPont Hospital for Children License No.: 07-16199-03

Inspection Type: Routine Priority: 5
Inspection Date: 3/10/10 Inspector: LK

APPENDIX D

LICENSING CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

File No.: 1

Licensee: Defense Logistics Agency
Action: Renewal
Date Issued: 2/17/10
License No.: STC-133
Amendment No.: 34
License Reviewer: DL

File No.: 2

Licensee: Terranearpmc, LLC

Action: New

Amendment No.: N/A

Date Issued: 3/8/10

License No.: 37-31379-02

Amendment No.: N/A

License Reviewer: SH

File No.: 3

Licensee: The Catholic University of America

Action: Financial Assurance

Date Issued: 3/8/10

License No.: 08-02075-03

Amendment No.: N/A

License Reviewer: DL

File No.: 4

Licensee: Tracewell Services, Inc.

Action: Renewal

Date Issued: 2/3/10

License No.: 47-25480-01

Amendment No.: 01

License Reviewer: SW

File No.: 5

Licensee: Tomé & Ubiñas RadioOncology

Action: Renewal

Date Issued: 3/23/10

License No.: 52-25487-01

Amendment No.: 09

License Reviewer: JN

File No.: 6

Licensee: Battelle National Biodefense Inst.

Action: New

Date Issued: 6/25/09

License No.: 19-31362-01

Amendment No.: N/A

License Reviewer: LK

File No.: 7

Licensee: Protometrix

Action: Termination

Date Issued: 5/29/09

License No.: 06-30693-01

Amendment No.: 06

License Reviewer: TT

File No.: 8

Licensee: Puerto Rico Medical Services Adm.

Action: New

Amendment No.: N/A

Date Issued: 6/4/09

License No.: 52-31281-02

Amendment No.: N/A

License Reviewer: PL

License No.: 09-31351-01

Amendment No.: N/A

License Reviewer: DL

License Reviewer: EU

File No.: 9 Licensee: RCOA Imaging Services

Action: New

Date Issued: 2/23/09

File No.: 10

Licensee: Lantheus Medical Imaging License No.: 52-25361-02 Amendment No.: N/A

Action: New

Date Issued: 11/17/09

File No.: 11

License No.: 47-05972-02 Licensee: Marshall University Action: Financial Assurance Amendment No.: N/A

Date Issued: 3/8/06 License Reviewer: SH

File No.: 12

Licensee: Entergy Nuclear Operations License No.: 20-07626-04

Action: Termination Amendment No.: 08 Date Issued: 8/21/08 License Reviewer: KM

File No.: 13

Licensee: Hotwell Services, Inc. License No.: 42-31298-01

Action: Termination Amendment No.: 03 Date Issued: 4/21/09 License Reviewer: JJ

File No.: 14

Licensee: Hotwell Services, Inc. License No.: 37-31365-01

Amendment No.: N/A Action: New Date Issued: 4/21/09 License Reviewer: JJ

File No.: 15

Licensee: Washington Hospital Center License No.: 08-03604-03

Action: Amendment Amendment No.: 47 Date Issued: 4/7/08 License Reviewer: PL

File No.: 16

Licensee: URS Corporation Infrastructure License No.: 06-31214-01

Action: New Amendment No.: N/A Date Issued: 2/1/07 License Reviewer: JS

File No.: 17

Licensee: All Heart Medical Center License No.: 08-31224-01

Action: New Amendment No.: N/A Date Issued: 3/20/07 License Reviewer: DJ

File No.: 18

Licensee: Clearon Corporation

Action: Renewal

Date Issued: 2/20/07

License No.: 47-24837-01

Amendment No.: 07

License Reviewer: SL

File No.: 19

Licensee: Department of the Navy

Action: Financial Assurance

Date Issued: 3/15/06

License No.: 45-23645-01

Amendment No.: N/A

License Reviewer: OMB

File No.: 20

Licensee: Astenjohnson, Inc.

Action: Amendment

Date Issued: 8/2/07

License No.: 39-32137-01

Amendment No.: 08

License Reviewer: TS

File No.: 21

Licensee: AstraZeneca Pharmaceuticals, LP

Action: Amendment

Date Issued: 4/3/07

License No.: 07-03990-01

Amendment No.: 44

License Reviewer: N/A

File No.: 22

Licensee: Department of the Army

Action: Amendment

Date Issued: 9/15/06

License No.: 29-01022-07

Amendment No.: 35

License Reviewer: EU

File No.: 23

Licensee: University of Connecticut

Action: Financial Assurance

Date Issued: 11/25/08

License No.: 06-01450-47

Amendment No.: N/A

License Reviewer: SC

File No.: 24

Licensee: Biocompatibles, Inc.

Action: Amendment

Date Issued: 8/25/06

License No.: 06-30764-01

Amendment No.: 11

License Reviewer: DL

File No.: 25

Licensee: Union Carbide Corporation

Action: Amendment

Date Issued: 6/20/06

License No.: 47-00260-02

Amendment No.: 50

License Reviewer: DL

File No.: 26

Licensee: ABB, Inc.

Action: Decommissioning

Date Issued: 7/8/09

License No.: 06-00217-06

Amendment No.: 62

License Reviewers: JS, JN

Licensing Casework Reviews

File No.: 27

Licensee: Defense Intelligence Agency
Action: Renewal
Date Issued: 9/22/08

License No.: 01-25316-01
Amendment No.: 08
License Reviewer: TT

File No.: 28

Licensee: Defense Logistics Agency
Action: Decommissioning
Date Issued: 2/21/07

License No.: STC-133
Amendment No.: 28
License Reviewer: DL

File No.: 29

Licensee: Department of the Army

Action: Decommissioning

Date Issued: 9/14/06

License No.: SUB-834

Amendment No.: 31

License Reviewer: EU

File No.: 30

Licensee: Divine Providence Hospital

Action: Amendment

Date Issued: 11/7/07

License No.: 37-16101-02

Amendment No.: 41

License Reviewer: SG

File No.: 31

Licensee: Tomé & Ubiñas RadioOncology

Action: Renewal

Date Issued: 3/23/10

License No.: 52-25487-01

Amendment No.: 09

License Reviewer: PL

File No.: 32

Licensee: New Milford Hospital

Action: Amendment

Date Issued: 1/11/10

License No.: 06-17892-01

Amendment No.: 26

License Reviewer: HB

File No.: 33

Licensee: Sentara CarePlex Hospital

Action: Amendment

Date Issued: 10/28/08

License No.: 45-09087-01

Amendment No.: 50

License Reviewer: SG

File No.: 34

Licensee: University of Pennsylvania License No.: 37-00118-07
Action: Amendment Amendment No.: 69
Date Issued: 10/16/06 License Reviewer: TW

APPENDIX E

INCIDENT CASEWORK REVIEWED

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

File No.: 1

Licensee: Regional Nuclear Pharmaceuticals

License No.: 29-30867

Date of Incident: 12/13/04 NMED No.: 050057 Investigation Date: 1/26/05 Type of Incident: Lost/stolen material Type of investigation: Licensee report

File No.: 2

Licensee: Fox Chase Cancer Center License No.: 37-02766-01

Date of Incident: 2/24/05
Investigation Date: 2/28/05

Type of Incident: Lost/stolen material
Type of Investigation: Licensee report

File No.: 3

Licensee: Oconee Unit 1 License No.: DPR-0038

Date of Incident: 4/11/05 NMED No.: 050226 Investigation Date: 4/12/05 Type of Incident: Transportation

File No.: 4

Licensee: University of Uniformed Services License No.: 19-08330-03

Date of Incident: 6/6/05

Investigation Date: 6/6/05

Type of Incident: Equipment failure
Type of Investigation: Licensee report

File No.: 5

Licensee: Quaker Sales Corp License No.: 37-23351-02

Date of Incident: 6/20/06 NMED No.: 060403 Investigation Date: 6/20/06 Type of Incident: Damaged equipment Type of Investigation: Licensee report

File No.: 6

Licensee: Windsor Service License No.: 37-18494-01

Date of Incident: 7/10/06 NMED No.: 060440 Investigation Date: 8/22/06 Type of Incident: Damaged equipment Type of Investigation: Site

File No.: 7

Licensee: Pennoni Associates License No.: 37-17637-02

Date of Incident: 8/19/06 NMED No.: 060526 Investigation Date: 11/17/06 Type of Incident: Lost/stolen material

Type of Investigation: Site

Type of Investigation: Event notification

Region I Final Report Incident Casework Reviews

File No.: 8

Licensee: Grandview Hospital Date of Incident: 8/28/06 Investigation Date: 8/28/06

File No.: 9

Licensee: Agilent Technologies Date of Incident: 9/22/06 Investigation Date: 9/22/06

File No.: 10

Licensee: Camden Iron and Metal

Date of Incident: 1/22/07 Investigation Date: 1/22/07

File No.: 11

Licensee: Schlumberger PTC Date of Incident: 2/14/07

Investigation Date: 3/5/07

File No.: 12

Licensee: Sibley Memorial Hospital

Date of Incident: 3/12/07 Investigation Date: 3/12/07

File No.: 13

Licensee: Hudson Global Resource Management

Date of Incident: 11/1/05 Investigation Date: 1/5/06

File No.: 14

Licensee: Blazosky Associates, Inc.

Date of Incident: 6/25/07 Investigation Date: 6/25/07

File No.: 15

Licensee: Department of the Army

Date of Incident: 8/30/08 Investigation Date: 9/11/08

License No.: 37-13187-02

NMED No.: 060577 Type of Incident: Contamination

Type of Investigation: Licensee report

License No.: 07-28762-01 NMED No.: 060708

Type of Incident: Equipment failure Type of Investigation: Licensee report

License No.: 45-00131-02

NMED No.: 070049

Type of Incident: Lost/stolen material Type of Investigation: Licensee report

License No.: 29-08636-02

NMED No.: 070130 Type of Incident: Lost/stolen material

Type of Investigation: Site

License No.: 08-07398-03 NMED No.: 070230

Type of Incident: Medical

Type of Investigation: Licensee report

License No.: 37-27891-01

NMED No.: 070348

Type of Incident: Potential overexposure
Type of Investigation: Licensee report

License No.: 37-28507-01

NMED No.: 070385

Type of Incident: Damaged equipment Type of Investigation: Licensee report

License No.: 32-04054-04 NMED No.: 080546

Type of Incident: Contamination Type of Investigation: Licensee report File No.: 16

Licensee: Froehling and Robertson, Inc.

Date of Incident: 10/16/08 Investigation Date: 10/17/08 NMED No.: 080677
Type of Incident: Transportation
Type of Investigation: Site

File No.: 17

Licensee: Construction Testing & Engineering

Date of Incident: 1/22/09

Investigation Date: 1/22/09

File No.: 18

Licensee: Department of Homeland Security

Date of Incident: 10/1/07

Investigation Date: 10/1/07

File No.: 19

Licensee: Inova Fairfax Hospital

Date of Incident: 1/8/09

Investigation Date: 1/8/09

File No.: 20

Licensee: Langan Engineering

& Environmental Services

Date of Incident: 6/29/09

Investigation Date: 6/30/09

Type of Investigation: Sit

License No.: 45-25554-01

License No.: 45-08890-02

NMED No.: 090096

Type of Incident: Damaged equipment

Type of Investigation: Site

License No.: 08-17447-01

NMED No.: 090133 Type of Incident: Lost/stolen material

Type of Investigation: Site

License No.: 45-17128-01

NMED No.: 090476 Type of Incident: Leaking source

Type of Investigation: Licensee report

License No.: 29-15786-02

NMED No.: 090569

Type of Incident: Damaged equipment

Type of Investigation: Site

ATTACHMENT

June 17, 2010 Memorandum from John D. Kinneman Region I's Response to the Draft Report

ADAMS Accession No.: ML101680279



UNITED STATES NUCLEAR REGULATORY COMMISSION REGION I

475 ALLENDALE ROAD KING OF PRUSSIA, PENNSYLVANIA 19406-1415

June 17, 2010

MEMORANDUM TO: Joseph E. DeCicco, IMPEP Team Leader

Division of Materials Safety and State Agreements

Office of Federal and State Materials

and Environmental Management Programs

FROM: John D. Kinneman, Director /RA P. J. Henderson for/

Division of Nuclear Materials Safety

Region I

SUBJECT: RESPONSE TO DRAFT REPORT - INTEGRATED MATERIALS

PERFORMANCE EVALUATION PROGRAM REVIEW OF THE

REGION I RADIOACTIVE MATERIALS PROGRAM

As requested in your June 1, 2010, memorandum, we have reviewed the draft report entitled "Integrated Materials Performance Evaluation Program (IMPEP) Review of the Region I Radioactive Materials Program." We agree with the team's proposed recommendations and the enclosed response contains minor comments related to information contained in the draft report. The review by your team was comprehensive and professional; and the draft report accurately reflects Region I's radioactive materials program performance from April 2005 to April 2010. As reflected in the draft report, we continue to implement an effective materials program at a consistently high level of performance, despite the challenges we have experienced over the past five years with the creation of three new Agreement States and implementation of several Security Orders.

We appreciate the opportunity to review the draft IMPEP report and if you have any questions regarding the enclosed comments, please contact us as listed below.

Enclosure:

As stated

cc w/enclosure:

S. Collins, RI

M. Dapas, RI

CONTACT: Marc S. Ferdas, DNMS/RI

(610) 337-5022

Region I Comments Draft Report - IMPEP Review of the Region I Radioactive Materials Program

Comment 1:

The fifth paragraph in Section 1.0 on page 1 states:

In preparation for the review, a questionnaire addressing the common performance indicators was sent to Region I on January 14, 2010. The Division provided a response to the questionnaire on April 8, 2010. A copy of the completed questionnaire response can be found in NRC's Agencywide Document Access and Management System (ADAMS) using Accession Number ML100980461.

Region I provided a response to the questionnaire on April 7, 2010, and the response was entered into ADAMS in two parts and therefore can be found using Accession Numbers ML100980430 (memorandum) and ML100980461 (response).

Comment 2:

The second paragraph in Section 3.1 on page 2 states:

The Division is composed of four branches: (1) the Medical Branch, (2) the Commercial and R&D Branch, (3) the Materials Security and Industrial Branch, and (4) the Decommissioning Branch. A six member Licensing Assistance Team managed as part of the Decommissioning Branch provides administrative support to all the branches in the Division. Including non-technical positions, the Division had 42 staff members on board at the time of the review. Funding for technical positions comes from the Nuclear Materials Safety Arena (26.9 full-time equivalents (FTE)) and Security and Incident response Arena (5.1 FTE).

The Licensing Assistance Team consists of a Team Leader and three staff for a total of four members. They provide administrative and records management support for licensing and inspection activities for the Division of Nuclear Materials Safety.

Comment 3:

The third paragraph in Section 3.1 on page 2 states:

Since the previous review, the Division's total FTE level has decreased by 10. This decrease is in parallel with a decrease of approximately 1,400 licenses that new transferred to new Agreement States during the review period.

Since the previous review, the Division's total number of <u>staff positions</u> has decreased by 10 individuals with a budget change of approximately seven FTE (39 FTE in FY 2005/32.75 FTE in FY2010). The Region has transferred approximately 1,600 licenses (PA: 700, VA: 400, NJ: 500) during the review period, not 1,400 as stated in the report.

Comment 4:

The third paragraph in Section 3.2 on page 3 states:

Region I conducted a total of 1,207 inspections of Priority 1, 2, and 3 licensees during the review period. The review team identified 12 of these inspections that were conducted overdue by more than 25 percent of the inspection frequency prescribed by IMC 2800. The review team did not identify any inspections that were overdue at the time of the review. The review team found that 9 of the 12 overdue inspections were due to LTS data entry errors. During the review period, the Division instituted changes in Quality Control and monitoring in order to reduce future errors.

As documented in the IMPEP questionnaire response (ML100980430 and ML100980461), we identified a total of 35 overdue inspections between April 2005 and April 2010 (12 overdue inspections in 2005, 8 in 2006, 9 in 2007, 4 in 2008 and 2 in 2009, 0 in 2010). Ten (10) of the 35 overdue inspections were attributed to LTS data entry errors.

Comment 5:

The sixth paragraph in Section 3.2 on page 3 states:

During the review period, the team determined that the Division completed the required number of reciprocity inspections of candidate licensees for all years covered by the review period, except 2005. IMC 1220, "Processing of NRC Form 241 and Inspection of Agreement State Licensees Operating Under 10 CFR 150.20," requires inspection of at least 20 percent of all candidate reciprocity licensees per calendar year. In 2005, the Division inspected 3 of 19 candidate licensees or 16 percent of candidate licensees. The review team identified the increased workload as a result of the implementation of the Increased Controls as an underlying cause for missing the metric in 2005.

Based on our reviews leading up to the IMPEP review, Region I was unable to identify a clear underlying cause for not performing the required number of reciprocity inspections in 2005. As stated in the draft report, the region was challenged with an extensive increased work load associated with implementation of additional security orders that were issued in 2004 and 2005. In addition, the regional staff is frequently challenged by licensee schedule changes and inspection scheduling issues associated with short term work requests or filings late in the calendar year. Through increased monitoring, Region I has met or exceeded the goal in each of the following calendar years of the review period.

Comment 6:

The fourth paragraph in Section 3.4 on page 4 states:

...One license had possession limits that would require implementation of the Increased Controls and fingerprinting requirements but did not have the required appropriate license conditions. This license was transferred to the Commonwealth of Pennsylvania when Pennsylvania became an Agreement State on March 31, 2008. Following discovery of this case, the Division notified Pennsylvania to ensure that the necessary correction has been or will be made to the license.

This particular license was considered a "straight transfer" to Pennsylvania because it did not contain a temporary job site or a location remaining in NRC jurisdiction; and the license did not need to be amended before it was transferred per FSME guidance (ADAMS Accession Number ML070400111), dated February 9, 2007. The guidance directs license reviewers to add the specified license condition at the time of the next licensing action request. In addition, it should be noted that this particular license was last amended on October 16, 2006. Therefore the license was not subject to adding the license condition prior to the transfer to the Agreement State.

Comment 7:

Appendix D - File No. 14 (page D.2), File No. 22 (page D.3), and File No. 34 (page D.4) state:

The Region did not include a required license condition on this new license.

The license identified in File No. 14 is not required to contain the license condition, because the licensee is not subject to those particular requirements. This information is tied-down to the license in License Condition 17.A (ADAMS Accession Number ML080390555).

File No. 22 involves the Army, not the Navy. This license was amended (Amendment No. 35) on September 15, 2006. As noted in comment 6 above, FSME did not instruct the Regions to apply the license condition until 2007 and noted that this condition could be applied during a review of the next licensing action request. The next licensing action was completed on June 18, 2009 when Amendment No. 36 was issued and included the license condition.

Please see comment 6 with regard to File No. 34.