



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

May 29, 2015

MEMORANDUM TO:

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

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

Catherine Haney, Director
Office of Nuclear Material Safety and Safeguards

Kriss M. Kennedy, Deputy Regional Administrator
Region IV

FROM:

Christian E. Einberg, Chief */RA/*
Agreement State Programs Branch
Division of Material Safety, State, Tribal and
Rulemaking Programs
Office of Nuclear Material Safety and Safeguards

SUBJECT:

INTEGRATED MATERIALS PERFORMANCE EVALUATION
PROGRAM (IMPEP) REVIEW OF THE REGION I RADIOACTIVE
MATERIALS PROGRAM

This memorandum transmits to the Management Review Board (MRB) a proposed final report (Enclosure 1) documenting the IMPEP review of the U.S. Nuclear Regulatory Commission (NRC) Region I Radioactive Materials Program (Region I). The review was conducted by a review team composed of technical staff members from the NRC, and the Commonwealths of Pennsylvania and Virginia during the period of March 30 – April 3, 2015. The review team issued a draft report to Region I on April 27, 2015, for factual comment. Region I responded to the findings and conclusions of the review by memorandum dated May 19, 2015, from Daniel H. Dorman, Regional Administrator, NRC Region I. In its response, Region I noted minor clarifications which were accepted and corrected in the report.

The review team is recommending that Region I's performance be found satisfactory for all performance indicators. Accordingly, the review team is recommending that Region I be found adequate to protect public health and safety.

The Management Review Board meeting to consider the Region I report is scheduled for **Monday, June 15, 2015, 1:00 p.m. - 4:00 p.m. (EST), in OWFN 17-B4**. In accordance with Management Directive 5.6, the meeting is open to the public. The agenda for that meeting is enclosed (Enclosure 2).

If you have any questions prior to the meeting, please contact me at (301) 415-5422.

Enclosures:

- 1) NRC RI Proposed Final Report
- 2) Meeting Agenda

cc: Earl Fordham, WA
Organization of Agreement States
Liaison to the MRB

Daniel H. Dorman, Regional Administrator
NRC Region I

David C. Lew, Deputy Regional Administrator
NRC Region I

MRB Members

-2-

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OFFICE	RIV/Team Leader	MSTR/ASPB	MSTR/ASPB
NAME	BTharakan via email w/edits	LDimmick w/edits	CEinberg
DATE	05/28/15	05/28/15	05/29/15

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

MARCH 30 – APRIL 3, 2015

DRAFT REPORT

EXECUTIVE SUMMARY

This report presents the results of the Integrated Materials Performance Evaluation Program (IMPEP) review of the U.S. Nuclear Regulatory Commission (NRC) Region I radioactive materials program. The review was conducted during the period of March 30 – April 3, 2015, by a review team composed of technical staff members from the NRC and the Commonwealths of Pennsylvania and Virginia.

Based on the results of this review, Region I's performance was found satisfactory for all performance indicators reviewed. The review team did not make any recommendations.

Accordingly, the review team recommends that the NRC Region I radioactive materials program is adequate to protect public health and safety. The review team recommends that the next IMPEP review take place in approximately 5 years.

1.0 INTRODUCTION

This report presents the results of the review of the U.S. Nuclear Regulatory Commission (NRC) Region I radioactive materials program. The review was conducted during the period of March 30 – April 3, 2015, by a review team composed of technical staff members from the NRC and the Commonwealths of Pennsylvania and Virginia. 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 (MD 5.6), “Integrated Materials Performance Evaluation Program (IMPEP),” dated February 26, 2004. Preliminary results of the review, which covered the period of May 1, 2010, to April 3, 2015, were discussed with the NRC Region I managers on the last day of the review.

The NRC Region I radioactive materials program is administered by the Division of Nuclear Materials Safety (the Division). The Division is also responsible for the oversight of decommissioning materials and reactor licensees, as well as, performing safety inspections at independent spent fuel storage installations. Organization charts for Region I can be found in the NRC’s Agencywide Documents Access and Management System (ADAMS) using the ADAMS Accession Number ML15075A410.

At the time of the review, the Division regulated 915 specific licenses authorizing possession and use of radioactive materials.

In preparation for the review, a questionnaire addressing the performance indicators was sent to Region I on January 8, 2015. Region I provided its response to the questionnaire on March 16, 2015. A copy of the questionnaire response can be found using ADAMS Accession Number ML15075A282.

The review team evaluated the information gathered against the established criteria for each common performance indicator and made a preliminary assessment of Region I’s performance. The results of this review are summarized in Section 5.0.

2.0 PREVIOUS IMPEP REVIEW AND STATUS OF RECOMMENDATIONS

The previous IMPEP review concluded on April 30, 2010. The final report is available in ADAMS using the ADAMS Accession Number ML101950072. The results of the previous review were:

Technical Staffing and Training: Satisfactory
Recommendation: None

Status of Materials Inspection Program: Satisfactory
Recommendation: None

Technical Quality of Inspections: Satisfactory
Recommendation: None

Technical Quality of Licensing Actions: Satisfactory
Recommendation: None

Technical Quality of Incident and Allegation Activities: Satisfactory
Recommendation: None

3.0 COMMON PERFORMANCE INDICATORS

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

3.1 Technical Staffing and Training

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

a. Scope

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

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

b. Discussion

The Division is composed of 41 staff members, which equals 29.4 full time equivalent staff for the radioactive materials program. The Division staff includes 30 technical staff members, 6 administrative staff and 5 supervisors/managers. Four of the technical staff and one supervisor are primarily responsible for performing reactor decommissioning and independent spent fuel storage installation inspections, which is beyond the scope of the materials program evaluated by the IMPEP review. During the review period, seven staff members left the Division, six staff members were hired, and one transferred from a different division within Region I. The period of time for each vacancy ranged from one to six months. At the time of the IMPEP review, there was one vacancy in the radioactive materials program for the Division's Technical Assistant position. The Division is planning to hire two additional staff to account for retirements and attrition. The Division implements the NRC's IMC 1248 for training and qualifications of the radioactive materials program staff.

c. Evaluation

The team determined that during the review period Region I met the performance indicator objectives listed in Section 3.1.a.

d. Results

Based on the IMPEP evaluation criteria in MD 5.6, the review team recommends that Region I's performance with respect to the indicator, Technical Staffing and Training, be found satisfactory.

3.2 Status of the Materials Inspection Program

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

a. Scope

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

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

Offshore Waters, and Inspection of Agreement State Licensees Operating Under 10 CFR 150.20.”

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

b. Discussion

The Division performed a total of 1,003 Priority 1, 2, 3, and initial inspections during the review period, of which, 7 of 864 Priority 1, 2, or 3 inspections, and 1 of 139 initial inspections were conducted overdue. The review team evaluated comprehensive reports generated from the Web-Based Licensing database and reviewed 15 inspection reports in ADAMS. The review team determined that none of the inspection reports reviewed by the team were communicated to the licensees beyond the Division’s goal of 30 days following the inspection exit. Each year of the review period, the Division performed greater than 20 percent of candidate reciprocity inspections.

c. Evaluation

The team determined that during the review period Region I met the performance indicator objectives listed in Section 3.2.a.

d. Results

Based on the IMPEP evaluation criteria in MD 5.6, the review team recommends that Region I’s performance with respect to the indicator, Status of the Materials Inspection Program, be found satisfactory.

3.3 Technical Quality of Inspections

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

a. Scope

The review team used the guidance in State Agreements procedure SA-102, “Reviewing the Common Performance Indicator: Technical Quality of Inspections,” and evaluated Region I’s performance with respect to the following performance indicator objectives:

- Inspections of licensed activities focus on health, safety, and security.

- Inspection findings are well-founded and properly documented in reports.
- Management promptly reviews inspection results.
- Procedures are in place and used to help identify root causes and poor licensee performance.
- Inspections address previously identified open items and violations.
- Inspection findings lead to appropriate and prompt regulatory action.
- Supervisors conduct annual accompaniments of each inspector to assess performance and assure consistent application of inspection policies.
- An adequate supply of calibrated survey instruments is available to support the inspection program.

b. Discussion

The Division performed 1,003 inspections during the review period. The review team evaluated reports for 10 initial inspections, 15 routine inspections, 2 reactive inspections, 3 incident follow-up inspections, and 5 reciprocity inspections performed by 22 inspectors. These inspections covered medical, industrial, commercial, academic, research, and service provider licenses. The review team interviewed 11 inspectors with regard to the inspection process, completing reports and supervisory accompaniments. Inspectors were found to be knowledgeable of the inspection process and documentation results were found to be appropriate and timely.

Accompaniments of 10 inspectors were conducted by 3 review team members in February and March 2015. The inspectors were found to be well-prepared, thorough, and conducted performance-based inspections. The inspections were adequate to assess licensed activities on health, safety and security.

The review team confirmed that Division supervisors were performing inspection accompaniments of each inspector. The review team interviewed the supervisors and found that supervisors verbally express their observations to the inspectors and document the accompaniments in the inspectors' annual performance appraisals. The Division's administrative staff tracks the supervisory accompaniments and provides status reports to Division management.

The review team interviewed Division inspection staff regarding the survey instrument program. The Division possesses an adequate supply of appropriate survey instruments and utilizes a process for checking out a survey instrument and ensuring they are properly calibrated.

c. Evaluation

The team determined that during the review period Region I met the performance indicator objectives listed in Section 3.3.a.

d. Results

Based on the IMPEP evaluation criteria in MD 5.6, the review team recommends that Region I's performance with respect to the indicator, Technical Quality of Inspections, be found satisfactory.

3.4 Technical Quality of Licensing Actions

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

a. Scope

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

- Licensing action reviews are thorough, complete, consistent, and of acceptable technical quality with health, safety, and security issues properly addressed.
- Essential elements of license applications have been submitted and elements meet current regulatory guidance (e.g. financial assurance, increased controls, pre-licensing guidance).
- License reviewers, if applicable, have the proper signature authority for the cases they review independently.
- License conditions are stated clearly and are inspectable.
- Deficiency letters clearly state regulatory positions and are used at the proper time.
- Reviews of renewal applications demonstrate a thorough analysis of a licensee's inspection and enforcement history.
- Applicable guidance documents are available to reviewers and are followed (e.g., NUREG-1556 series, pre-licensing guidance, regulatory guides, etc.).
- Licensing practices for risk significant radioactive materials are appropriately implemented including increased controls and fingerprinting orders (Part 37 equivalent).
- Documents containing sensitive security information are properly marked, handled, controlled and secured.

b. Discussion

During the review period, the Division performed 3,453 radioactive materials licensing actions. The review team evaluated 32 radioactive materials licensing actions. The licensing actions selected for review included 7 new applications, 10 amendments, 7 renewals, 4 terminations, 2 financial assurance, and 2 medical exemption requests. The review team evaluated casework which included the following license types and actions:

broad scope, medical diagnostic and therapy, accelerator, commercial manufacturing and distribution, industrial radiography, research and development, academic, nuclear pharmacy, gauges, self-shielded irradiators, service providers, waste brokers, decommissioning actions, and financial assurance. The casework represented work from 21 license reviewers.

The review team identified that portable gauge licenses, specifically new and renewal actions, issued by the Division did not include a commitment from the licensee to the most updated version of Appendix H of NUREG-1556, Volume 1, Revision 1, "Program Specific Guidance about Portable Gauge Licenses." In 2005, an errata was issued that updated Appendix H from "Operating and Emergency Procedures" to "Operating, Emergency, and Security Procedures." The absence of the most updated Appendix H guidance on the license did not represent a safety or security concern because the security of portable gauges is a regulatory requirement. The Division has committed to ensuring that the licensee provides a commitment on the updated version of Appendix H for all future portable gauge licenses.

c. Evaluation

The team determined that during the review period Region I met the performance indicator objectives listed in Section 3.4.a.

d. Results

Based on the IMPEP evaluation criteria in MD 5.6, the review team recommends that Region I's performance with respect to the indicator, Technical Quality of Licensing Actions, be found satisfactory.

3.5 Technical Quality of Incident and Allegation Activities

The quality, thoroughness, and timeliness of response to incidents and allegations of safety concerns can have a direct bearing on public health and safety. An assessment of incident response and allegation investigation procedures, actual implementation of these procedures, internal and external coordination, and investigative and follow-up procedures and actions will be a significant indicator of the overall quality of the program.

a. Scope

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

- Incident response, investigation, and allegation procedures are in place and followed.
- Response actions are appropriate, well-coordinated, and timely.

- On-site responses are performed when incidents have potential health, safety or security significance.
- Appropriate follow-up actions are taken to ensure prompt compliance by licensees.
- Follow-up inspections are scheduled and completed, as necessary.
- Notifications are made to the NRC Headquarters Operations Center for incidents requiring a 24-hour or immediate notification to the Agreement State or NRC.
- Incidents are reported to the Nuclear Material Events Database.
- Allegations are investigated in a prompt, appropriate manner.
- Concerned individuals are notified of investigation conclusions.
- Concerned individuals' identities are protected, as allowed by law.

b. Discussion

During the review period, 106 incidents were reported to the Division. The review team evaluated 18 radioactive materials incidents which included 6 cases of lost, stolen, or abandoned radioactive materials, 5 medical events, 5 incidents of damaged equipment, 1 leaking source incident, and 1 notification of a dose to an embryo/fetus. The Division dispatched inspectors for onsite follow-up for nine of the cases reviewed. The other nine events were followed up by telephone and a follow-up inspection at a later date.

During the review period, the Division received 85 allegations. The review team evaluated 12 allegations.

c. Evaluation

The team determined that during the review period Region I met the performance indicator objectives listed in Section 3.5.a.

d. Results

Based on the IMPEP evaluation criteria in MD 5.6, the review team recommends that Region I's performance with respect to the indicator, Technical Quality of Incident and Allegation Activities, be found satisfactory.

5.0 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.

Accordingly, the review team recommends that the NRC Region I radioactive materials program be found adequate to protect public health and safety. Based on the results of the previous and current IMPEP reviews, the review team recommends that the next full IMPEP review take place in approximately 5 years.

LIST OF APPENDICES

Appendix A	IMPEP Review Team Members
Appendix B	Inspection Accompaniments

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	Area of Responsibility
Binesh Tharakan, CHP Region IV	Team Leader Technical Staffing and Training Technical Quality of Incidents and Allegation Activities
David Spackman NMSS	Status of Materials Inspection Program
Mike Welling Commonwealth of Virginia	Technical Quality of Inspections Inspection Accompaniments
Lizette Roldan-Otero, PhD Region IV	Technical Quality of Licensing Actions Inspection Accompaniments
Frank Pepper Commonwealth of Pennsylvania	Technical Quality of Incidents and Allegation Activities
Bryan Parker Region III	Inspection Accompaniments

APPENDIX B

INSPECTION ACCOMPANIMENTS

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

Accompaniment No.: 1 License Type: Medical Institution, WD Required Inspection Date: 2/24/15	License No.: 52-25430-03 Priority: 3 Inspector: RE
Accompaniment No.: 2 License Type: Eye Applicator Strontium-90 Inspection Date: 2/25/15	License No.: 52-11897-01 Priority: 3 Inspector: LT
Accompaniment No.: 3 License Type: Medical Institution, WD Required Inspection Date: 2/25/15	License No.: 52-23044-01 Priority: 3 Inspector: LT
Accompaniment No.: 4 License Type: Medical Private Practice, WD Required Inspection Date: 2/26/15	License No.: 52-24937-01 Priority: 3 Inspector: FG
Accompaniment No.: 5 License Type: Academic Type A Broad Scope Inspection Date: 3/3/15	License No.: 08-02075-03 Priority: 3 Inspector: TJ
Accompaniment No.: 6 License Type: Medical Broad Scope Inspection Date: 3/4/15	License No.: 10-12044-03 Priority: 2 Inspector: HB
Accompaniment No.: 7 License Type: Medical Institution, WD required Inspection Date: 3/5/15	License No.: 10-06493-02 Priority: 3 Inspector: HB
Accompaniment No.: 8 License Type: High-Dose Rate Remote Afterloader Inspection Date: 3/16-17/15	License No.: 07-12153-02 Priority: 2 Inspector: PL
Accompaniment No.: 9 License Type: Radiography Inspection Date: 3/18/15	License No.: 07-30791-01 Priority: 1 Inspector: SW
Accompaniment No.: 10 License Type: Medical Institution, WD required w/therapy modalities Inspection Date: 2/18/15	License No.: 47-19142-01 Priority: 3 Inspector: SS

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Inspection Accompaniments

Page B.2

Accompaniment No.: 11
License Type: High-Dose Rate Remote Afterloader
Inspection Date: 2/18/15

License No.: 47-31304-02
Priority: 2
Inspector: SS

Accompaniment No.: 12
License Type: Academic Type A Broad Scope
Inspection Date: 3/24-25/15

License No.: 47-23035-03
Priority: 3
Inspector: BU

Accompaniment No.: 13
License Type: Medical Institution, WD Required
Inspection Date: 3/19/15

License No.: 06-06941-01
Priority: 3
Inspector: BG

**Agenda for Management Review Board Meeting
June 15, 2015, 1:00 p.m. – 4:00 p.m. (ET), OWFN-17B04**

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

Invitees:

Michael Weber, DEDMRT
Mary Spencer, OGC
Catherine Haney, NMSS
Kriss Kennedy, RIV
Earl Fordham, WA
Binesh Tharakan, RIV
Lizette Roldan-Otero, RIV
David Spackman, NMSS
Michael Welling, VA
Frank Pepper, PA
David Lew, RI
Joseph Nick, RI

Josephine Piccone, NMSS
Pamela Henderson, NMSS
Christian Einberg, NMSS
Lisa Dimmick, NMSS
Joe O'Hara, NMSS
Karen Meyer, NMSS
Bryan Parker, RIII
Jack Foster, OEDO
Monica Ford, RI/RSOA
Daniel Dorman, RI
Daniel Collins, RI
Donna Janda, RI/RSOA