



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

April 30, 2018

MEMORANDUM TO: David C. Lew, Acting Regional Administrator
Region I

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

SUBJECT: FEBRUARY 21, 2018, PERIODIC MEETING UNDER THE
INTEGRATED MATERIALS PERFORMANCE EVALUATION
PROGRAM

A periodic meeting with the U.S. Nuclear Regulatory Commission Region I office was held on February 21, 2018. The purpose of the meeting was to review and discuss the status of Region I's Radioactive Materials Program. The Office of Nuclear Material Safety and Safeguards was represented by Duncan White, and myself. Specific topics and issues of importance discussed at the meeting included the status of operating plan and performance metrics, status of staffing and training, licensing and inspection activities, and a review of the program's self-assessments.

Enclosed is a general meeting summary. There were no performance concerns with respect to the Integrated Materials Performance Evaluation Program criteria identified. A Management Review Board (MRB) meeting to discuss the outcome of the periodic meeting will be scheduled at a later date. Once scheduled, video conferencing information for the MRB will be provided in a separate transmission.

I appreciate the support and preparation for this periodic meeting from the Region I management and staff.

Enclosure:
Periodic Meeting Summary

cc: James M. Trapp, Director
Division of Nuclear Materials Safety

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PERIODIC MEETING SUMMARY FOR
 NUCLEAR REGULATORY COMMISSION REGION I
 DIVISION OF NUCLEAR MATERIALS SAFETY

DATE OF MEETING: February 21, 2018

NRC Headquarters Attendees	NRC Region I Attendees
Paul Michalak, Branch Chief, Agreement State Programs Branch, Office of Nuclear Material Safety and Safeguards	Daniel Collins, Acting Deputy Regional Administrator
Duncan White, Senior Health Physicist, Agreement State Programs Branch, Office of Nuclear Material Safety and Safeguards	James Trapp, Director, Division of Nuclear Materials Safety
	Joseph Nick, Deputy Director, Division of Nuclear Materials Safety
	Donna Janda, Chief, Medical and Licensing Assistance Branch
	Arthur Burritt, Chief, Commercial, Industrial, R&D, and Academic Branch
	Raymond Powell, Chief, Decommissioning, ISFSI, and Reactor Branch
	Anne DeFrancisco, Technical Assistant
	Monica Ford, Agreement State Program Officer
	John Miller, Agreement State Program Officer

DISCUSSION:

The periodic meeting was held with the Nuclear Regulatory Commission's (NRC's) Region I program at the midpoint of the Integrated Materials Performance Evaluation Program (IMPEP) review cycle on February 21, 2018. This summary is a reflection of the topics discussed and material provided during that meeting.

TOPICS COVERED DURING THE MEETING INCLUDED:

Organization

The Region I program is located in the Division of Nuclear Materials Safety (the Division) and consists of three branches: Medical and Licensing Assistance (Branch 1); Commercial, Industrial, Research & Development (R&D), and Academic (Branch 2); and Decommissioning, Independent Spent Fuel Storage Installation (ISFSI), and Reactor Health Physics (HP) (Branch 3). Since the 2015 IMPEP, there has been reorganization within the Division with licensing assistant duties moved to the medical branch and decommissioning assuming operating reactor-related health physics duties.

Technical Staffing and Training (2015 IMPEP: Satisfactory)

The Division is composed of 42 staff members, including 31 technical staff members, 6 administrative staff and 5 supervisors/managers. Region I Branch 3 supervision and staff is primarily responsible for performing operating reactor health physics, 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, in the entire Division including Branch 3, eight staff members left the Division (via transfer to other Divisions in some cases), one staff member was externally hired, and 10 staff transferred in from other divisions within Region I.

Division vacancies that occurred during the review period did not exceed 13 months in duration. As of the time of the Periodic Meeting, there were recently filled vacancies in the radioactive materials program for health physicist positions in Branch 2 and Branch 3. Staff is planned to occupy these positions beginning in the spring 2018 and during 2019, respectively.

The Division's full time equivalent (FTE) allocation changes between 2015 and 2018 include the reduction of two FTE budgeted for the Nuclear Materials Users Business Line (NMU) Mission Support and the reduction of three FTE budgeted for NMU inspection and licensing direct work. This NMU inspection and licensing FTE reduction was due to efficiencies and resource savings associated with Project Aim re-baselining initiatives (changes in inspection frequencies, extension of license terms to 15 years, and centralization of bankruptcy reviews). Further changes are expected in fiscal years (FYs) 19 and 20 which will result in an expected overall increase of a one-half FTE for the Division; however, the most significant increase is in the spent fuel and storage business line. Decommissioning inspection resources are planned to increase, while NMU resources are planned to continue to slightly decrease.

The Division's Branch 1 and Branch 2 are where the majority of inspection and licensing work related to nuclear materials resides. The Regional Agreement State Program Officers (RSAOs) are additional technical staff qualified to inspect and license in the nuclear materials area. One Agreement State Program Officer, two Branch 2 inspectors, and two Branch 3 inspectors were qualified since the last IMPEP review.

The Division implements the NRC's Inspection Manual Chapter 1248, "Qualification Programs for Federal and State Materials and Environmental Management Programs" for training and qualifications of the radioactive materials program staff.

Refresher training for the nuclear materials technical staff requires the completion of 24 hours of training every 24 months. Refresher training for the 2015-2016 and 2017-2018 periods are being tracked in files maintained by current Branch and direct reports (RSAOs) organization and include hours for time credited to various types of training that fulfill the requirements Inspection Manual Chapter 1248 Appendix B, specifically: health and safety or security topics determined by the inspector's immediate supervisor to be beneficial to the inspector. Each current member of Branches 1 and 2 have fulfilled the 24 hour requirement for the 2015-2016 years and are currently being tracked for 2017-2018 period.

Status of the Materials Inspection Program (2015 IMPEP: Satisfactory)

From April 2015 through September 2017, the Division completed over 700 inspections, including Priority 5 type licensee inspections and general license/reciprocity type inspections. The total included 543 Priority 1, 2, and 3 inspections of which 541 were completed on time, and 11 initial inspections of which 10 were completed on time. Three inspections were not initiated in accordance with agency timeliness standards. One Priority 1 inspection and one Priority 2 inspection were not completed on time due to errors in resetting of the inspection frequency (the frequency was re-set from inspections that did not fulfill a complete routine inspection scope (an escalated enforcement follow-up and a special, specifically). One initial inspection was not completed timely and was attributed to a data entry error in the Web Based Licensing (WBL) System. The inspection was inadvertently entered into WBL as a routine inspection (allowed for a longer period of completion) and was not noticed until the one-year interval was passed.

Regarding reciprocity inspections, the Division completed over 20% of candidate inspections each calendar year (CY) from 2015-2017: CY15: 47%. CY16: 29% and CY17: 28%.

Technical Quality of Inspections (2015 IMPEP: Satisfactory)

The Division uses the appropriate NRC Inspection Manual Chapters and Inspection Procedures for all its inspections. For FY 15 through FY 17, 100 % of the qualified inspectors from Branches 1, 2 and 3 were accompanied by their respective Branch Chiefs.

The Division conducted two self-assessments (2016 and 2017) of materials inspection and licensing activities since its last full IMPEP review. The objectives of the self-assessments were to evaluate if materials inspections and licensing actions were well-documented, accurate and complete, conducted in a timely manner and by qualified staff, properly marked with regard to sensitive information, resulted in appropriate regulatory actions without significant technical or regulatory deficiencies, and were performed in accordance with NRC guidance. The self-assessments focused on: (1) the quality of the technical work (licensing and inspection); (2) the quality of the administrative work [including preparation of acceptable documents, Sensitive Unclassified Non-Safeguards Information evaluations, use of applicable checklists, forms and other required documentation]; (3) the authority of the technical staff to perform the inspections and license reviews; and (4) timeliness. Discussions were held with the responsible inspectors, license reviewers, and supervisors, as needed. The assessors were assigned licensing actions and inspections completed by other Division members and did not audit their own licensing actions or inspections.

The inspection component of the 2016 self-assessment included a review of documentation associated with 15 inspections completed by Division technical staff between March 15, 2015, and June 30, 2016. The 2017 self-assessment included a review of documentation associated with 15 inspections completed by Division technical staff between July 1, 2016 and June 30, 2017. The review of inspection activities included documentation associated with NRC Form 591Ms, Enclosure 6 records, narrative inspection reports with transmittal letters, and Notices of Violation. No inspection-related findings were identified in either the 2016 or 2017 self-assessments.

During the meeting, the Division also made available its "Inspection Process Job Aid" (dated April 2017) which provides inspection staff technical and administrative guidance for conducting inspections.

Technical Quality of Licensing Actions (2015 IMPEP: Satisfactory)

Since April 4, 2015, the Division has completed 1,048 licensing actions. These include: 38 new licenses, 745 license amendments, 48 voided licenses, 1 license abandonment, and 122 license renewals. In addition, an additional 1,044 actions were related to environmental assessment, financial assurance, notification, and decommissioning.

As discussed above, the Division conducted two self-assessments (2016 and 2017) of materials inspection and licensing activities since its last full IMPEP review. The licensing activities component of the 2016 self-assessment included a review of documentation associated with 15 licensing actions completed by Division technical staff between March 15, 2015, and June 30, 2016. The 2017 self-assessment included a review of documentation associated with 15 licensing actions completed by Division technical staff between July 1, 2016 and June 30, 2017. The review of licensing actions included new applications, amendments, renewals, terminations, and notifications. Financial assurance actions were not reviewed as they are reviewed during the annual Management Directive 8.12 "Decommissioning Financial Assurance Instrument Security Program," audit.

One licensing action finding was identified in the 2016 self-assessment. The 2016 finding identified that one letter was sent to a licensee accepting a notification action and was signed by a reviewer who had not received delegation of signature authority for the program codes associated with the license. The Division took corrective action and discussed licensing guidance with the reviewer (i.e., the reviewer may not sign documents related to licensing actions for program codes in which the reviewer has not received a delegation of signature authority). No licensing action-related findings were identified in the 2017 self-assessment.

During the meeting, the Division also made available its License Review Process Job Aid (dated March 2017) which provides licensing staff with guidance for conducting licensing reviews.

Technical Quality of Incidents and Allegations (2015 IMPEP: Satisfactory)

The Division has processes in place to maintain an effective response to incidents and allegations. Since April 4, 2015, the Division has received 57 events from its licensees: 46 reportable and 11 non-reportable. A search of the NRC's Nuclear Materials events database showed that the Division has 12 events where the record is not complete and 14 events where the record is not closed. The Division is aware of these events and is working to submit the necessary information to complete each record and close each open event. The Division identified one significant event that occurred during the review period. The event involved a broken ampule of americium-241 and is described in greater detail below. Since April 4, 2015, the Division has received 44 allegations. The Division works with the Region 1 allegations staff on intake, evaluation/follow-up, and closure of all allegations received.

Status of Metrics for the National Materials Users and Decommissioning Business Lines

Operational metrics are collected monthly and reviewed quarterly within Region I and the program office at NRC headquarters. Region I has had green, or satisfactory, performance in all of the materials and decommissioning metrics since its last full IMPEP review (i.e., 2015-2017). The operational metrics include: inspection and licensing action quality, inspections and report issuance timeliness, licensing action timeliness, enforcement action timeliness and number of disputed actions, allegations acknowledgement timeliness and response quality, and alleged identity protection.

Strategic Plan Metrics

The following are abnormal occurrences tracked by the Division for the period FY15-FY16: nine items in FY15 (all involving Agreement State licensees) and four items in FY16 (three involving Agreement State licensees and one involving an NRC licensee). The one abnormal occurrence in FY16 involving an NRC licensee was a medical event resulting in a dose equal to or greater than 10 Gy (1,000 rad) to any organ or tissue (other than a major portion of the bone marrow, the lens of the eye, or the gonads) and represents a prescribed dose or dosage that is delivered to the wrong treatment site. Physicians determined an administered dose to the patient liver's left lobe was 840 cGy (rad) higher than the intended prescribed dose (119%). During the Division's reactive inspection, conducted between July 13, 2016 and September 13, 2016, the licensee's proposed corrective actions were reviewed, accepted and will be followed up on during the next inspection.

For the FY17 period, the Division is currently tracking six abnormal occurrences; however, the report had not been finalized as of the periodic meeting. One potential abnormal occurrence involving an NRC licensee is being tracked by Region I. On August 18, 2017, a licensee, discovered that a flame-sealed glass ampoule that contained a well characterized solution of americium-241 with an activity of 47 MBq (1.27 mCi) had been broken. The activity was in an acid solution. The broken ampoule resulted in radioactive contamination of the countertop and other surfaces of a lead shielded storage area. The contamination was discovered after wipe test results identified alpha contamination on a beta/gamma source located in the same storage area. The licensee performed extensive surveys of the area and air monitoring and confirmed that the contamination was isolated to portions of that one room. The licensee issued a stop work order for all other laboratories storing similar ampoules until the extent of the condition was evaluated or mitigated. The licensee performed and received bioassay results from three personnel who were determined to be the most likely to be exposed to the contamination. One of the bioassays indicated that an individual was exposed. The licensee consulted with the Oak Ridge Associated Universities Radiation Emergency Assistance Center/Training Site (REAC/TS) program to perform additional analysis of the individual. The Division initiated a special inspection at the facility on September 26, 2017. The inspection is ongoing.

Program's Mechanisms to Evaluate Performance

Since its last IMPEP, Region I has performed a number of lesson-learned reviews and self-assessments including the two identified above in the Technical Quality of Inspections and Technical Quality of Licensing Actions sections. These efforts include:

2015

- Lesson Learned Report - Radioactive Source Recovered from the Public Domain Not in Accordance with Established Guidance: June 2015
- Self-Assessment - Region I Decommissioning Financial Assurance Program: June 2015
- Status Report - Semi-Annual Portable Survey Instrument and Sealed Source: June 2015
- Lesson Learned Report - Material Licenses Increased Controls License Condition Removal Status: December 2015

2016

- Status Report - Semi-Annual Portable Survey Instrument and Sealed Source: February 2016
- Self-Assessment - Implementation of the Pre-Licensing Guidance Described in Radiation Control Program Director Letter 08-020 (RCPD-08-020): March 2016
- Self-Assessment - Calendar Year 2016 Evaluation of Region I Decommissioning Financial Assurance Program: June 2016
- Self-Assessment - Materials Licensing and Inspection Activities: September 2016

2017

- Status Report - Semi-Annual Portable Survey Instrument and Sealed Source: June 2017
- Self-Assessment - Calendar Year 2017 Evaluation of Region I Decommissioning Financial Assurance Program: July 2017
- Follow-Up Self-Assessment - Implementation of the Pre-Licensing Guidance Described in Radiation Control Program Director Letter 08-020 (RCPD-08-020): October 2017
- Self-Assessment - Materials Licensing and Inspection Activities: September 2017

Current NRC Programmatic Initiatives

NRC staff discussed several on-going initiatives at NRC headquarters. These included: the revision of Management Directive 5.6, "Integrated Materials Performance Evaluation Program," the finalization of Management Directive 5.9, "Adequacy and Compatibility of Agreement State Programs," and the formation of General License Program Re-Evaluation Working Group (GLWG). The GLWG has been established to perform an evaluation of the existing general license (GL) program to ensure that the program results in the protection of public health and safety. The GLWG will identify recommendations for changes to the provisions of the GL program, as appropriate.

CONCLUSIONS:

The NRC staff recommends that the NRC Region I's next IMPEP review be conducted as scheduled in April 2020.