



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

August 18, 2017

MEMORANDUM TO: Cynthia D. Pederson, Regional Administrator  
Region III

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

SUBJECT: DRAFT REPORT OF THE INTEGRATED MATERIALS  
PERFORMANCE EVALUATION PROGRAM REVIEW OF  
THE U.S. NUCLEAR REGULATORY COMMISSION REGION III  
MATERIALS PROGRAM

The Integrated Materials Performance Evaluation Program (IMPEP) review was conducted during the period of July 17–21, 2017, by a team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the States of Arizona and New Jersey. Enclosed for your review is the draft IMPEP report that documents the review.

The team's preliminary findings were discussed with you and your staff on the last day of the review. The team's proposed recommendation is that the NRC Region III materials program be found adequate to protect public health and safety. The final determination of adequacy of your program, based on the team's report, is made by a Management Review Board (MRB) composed of NRC managers and an Agreement State program manager, who serves as a liaison to the MRB.

In accordance with procedures for implementation of IMPEP, the team is providing you with a copy of the draft report for your review and comment prior to submitting the report to the MRB. Comments are requested within 4 weeks from your receipt of this report. This schedule will permit the issuance of the final report in a timely manner that will be responsive to your needs.

CONTACT: Lance Rakovan  
(301) 415-2589

C. Pederson

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The team will review your response, make any necessary changes to the report, and issue it to the MRB as a proposed final report. Coordinating with your staff, we have scheduled the Region III MRB meeting for October 12, 2017, from 1:00 p.m. - 3:00 p.m. EDT.

If you have any questions regarding the enclosed report, please contact me at (301) 415-5804.

Enclosure:

NRC Region III Draft IMPEP Report

cc: John B. Giessner, Director  
Division of Nuclear Materials Safety

Christine A. Lipa, Deputy Director  
Division of Nuclear Materials Safety

SUBJECT: DRAFT REPORT OF THE INTEGRATED MATERIALS PERFORMANCE  
EVALUATION PROGRAM REVIEW OF THE U.S. NUCLEAR REGULATORY  
COMMISSION REGION III MATERIALS PROGRAM

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF THE U. S. NUCLEAR REGULATORY COMMISSION

REGION III MATERIALS PROGRAM

JULY 17–21, 2017

**DRAFT REPORT**

Enclosure

## **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 III materials program. The review was conducted during the period of July 17–21, 2017, by a team composed of technical staff members from the NRC and the States of Arizona and New Jersey.

Based on the results of this review, Region III's performance was found satisfactory for all five indicators reviewed. The findings for the indicators remain unchanged from the previous three IMPEP reviews. The team did not make any recommendations for improvement regarding Region III's performance.

Accordingly, the team recommends that the Region III materials program be found adequate to protect public health and safety. The 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 III materials program. The review was conducted during the period of July 17–21, 2017, by a team composed of technical staff members from the NRC and the States of Arizona and New Jersey. 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 September 29, 2012, to July 21, 2017, were discussed with NRC Region III managers on the last day of the review.

In preparation for the review, a questionnaire addressing the common performance indicators was sent to Region III on November 1, 2016. Region III provided its response to the questionnaire on June 9, 2017. A copy of the questionnaire response is available in NRC’s Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML17220A142.

The NRC Region III materials program is administered by the Division of Nuclear Materials Safety (the Division). The Division is composed of three branches: the Materials Inspection Branch (MIB), the Materials Licensing Branch (MLB), and the Materials Control, ISFSI, and Decommissioning Branch. Organization charts for Region III are available in the ADAMS (Accession Number ML17214A715).

At the time of the review, the Region III materials program regulated 989 specific licenses authorizing possession and use of radioactive materials.

The team evaluated the information gathered against the established criteria for each common performance indicator and made a preliminary assessment of the Region III’s performance.

## 2.0 PREVIOUS IMPEP REVIEW AND STATUS OF RECOMMENDATIONS

The previous IMPEP review concluded on September 28, 2012. The final report is available in ADAMS (Accession Number ML12361A041). The results of the review and the status of recommendation(s), if applicable, are as follows:

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

Overall finding: Adequate to protect public health and safety

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

- A well-conceived and balanced staffing strategy has been implemented throughout the review period.
- Agreement State training and qualification program is equivalent to NRC Inspection Manual Chapter (IMC) 1248, "Formal Qualifications Program for Federal and State Material and Environmental Management Programs."
- Qualification criteria for new technical staff are established and are being followed or 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 of 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 includes 32 technical staff members, 4 administrative staff, and 5 supervisors/managers for total of 40.3 full-time equivalents for the materials program. Three 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. Currently, there is one vacancy in the decommissioning branch and two vacancies in the materials licensing branch. These vacancies will not be filled as they are expected to be absorbed in the Fiscal Year 2018 staffing plan. During the review period, 13 staff members left the Division and 11 staff members were hired. The positions were vacant from one to six months. The MIB has 10 fully qualified inspectors and 1 inspector undergoing qualification, and the MLB has 5 fully qualified license reviewers and 5 reviewers undergoing qualification. The Division implements IMC 1248 for training and qualifications of the materials program staff, which includes the 24 hours of refresher training every two years. Individuals performing materials licensing and inspection activities are adequately qualified and trained to perform their duties.

c. Evaluation

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

d. Results

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

3.2 Status of 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 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 team used the guidance in State Agreements procedure SA-101, "Reviewing the Common Performance Indicator: Status of the Materials Inspection Program," and evaluated Region III'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 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 878 Priority 1, 2, 3, and initial inspections during the review period, of which, one Priority 2 inspection and one initial inspection were conducted overdue for a total of less than one percent of inspections being conducted overdue. The team evaluated the timeliness of issuance of inspections findings to licensees. The team evaluated reports generated from the Web-Based Licensing database and reviewed 27 inspection reports. The team found that none of the inspection reports reviewed were communicated to the licensees beyond Division’s goal of 30 days after 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 III met the performance indicator objectives listed in Section 3.2.a.

d. Results

Based on the IMPEP evaluation criteria in MD 5.6, the team recommends that Region III’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 team used the guidance in State Agreements procedure SA-102, “Reviewing the Common Performance Indicator: Technical Quality of Inspections,” and evaluated Region III’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, or senior staff as appropriate, conduct annual accompaniments of each inspector to assess performance and assure consistent application of inspection policies.
- For programs with separate licensing and inspection staffs, procedures are established and followed to provide feedback information to license reviewers.
- For Agreement States, inspection guides are consistent with NRC guidance.
- An adequate supply of calibrated survey instruments is available to support the inspection program.

b. Discussion

The team evaluated the inspection reports and enforcement documentation, and interviewed inspectors involved in materials inspections for 30 inspections conducted during the review period. The casework reviewed included inspections conducted by 19 of Region III's inspectors and covered medical, industrial, commercial, academic, research, and service provider licenses. The team observed that inspection findings were well-founded, and inspection activities focused on health, safety, and security issues.

Team members accompanied six program inspectors in May 2017. The inspectors were found to be well-prepared, thorough, and conducted performance-based inspections. The inspections were adequate to assess the impact of licensed activities on health, safety, and security. The inspector accompaniments are identified in Appendix B.

The team confirmed that Division supervisors consistently performed inspector accompaniments. During the review period, 87 inspector accompaniments were performed and the team did not identify any instances where an inspector did not have an annual inspector accompaniment.

The 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 the instruments are properly calibrated.

c. Evaluation

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

d. Results

Based on the IMPEP evaluation criteria in MD 5.6, the team recommends that Region III'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, as well as security. An assessment of licensing procedures, actual implementation of those procedures, and documentation of communications and

associated actions between the RIII licensing staff and regulated community is a significant indicator of the overall quality of the licensing program.

a. Scope

The team used the guidance in State Agreements procedure SA-104, "Reviewing the Common Performance Indicator: Technical Quality of Licensing Actions," and evaluated Region III'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 are consistent with 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 can be inspected.
- 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, Region III performed 3,775 radioactive materials licensing actions. The team evaluated 28 radioactive materials licensing actions. The licensing actions selected for review included 6 new applications, 14 amendments, 3 renewals, and 5 terminations. The 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, decommissioning actions, financial assurance, and bankruptcies. The casework sample represented work from 12 license reviewers. The team found that licensing actions were thorough, complete, consistent, and of acceptable technical quality with health, safety, and security issues properly addressed. The licensing cases reviewed demonstrated that proper guidance was followed, and deficiency letters and license conditions were well supported by information contained in the licensing files.

c. Evaluation

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

d. Results

Based on the IMPEP evaluation criteria in MD 5.6, the team recommends that Region III'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 followup actions, are a significant indicator of the overall quality of the incident response and allegation programs.

a. Scope

The 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 III'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 followup actions are taken to ensure prompt compliance by licensees.
- Followup 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 (NMED).
- 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, 152 incidents were reported in NMED for Region III licensees. The team evaluated 17 radioactive materials incidents which included 3 lost/stolen radioactive materials, 4 medical events, 5 damaged equipment, 3 leaking sources, 1 release of radioactive material, and 1 transportation. The Division dispatched inspectors for onsite followup for 12 of the cases reviewed. The team determined that the Division's responses to incidents were prompt, complete, comprehensive, well-coordinated, and commensurate with the health and safety significance.

During the review period, 84 allegations were received by Region III staff, including 22 allegations that were referred to the Agreement States. The team evaluated 10 allegations from the review period. The team found the allegation files were well documented and the process to final resolution was timely.

c. Evaluation

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

d. Results

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

#### 4.0 NON-COMMON PERFORMANCE INDICATORS

Four non-common performance indicators are used to review Agreement State programs, and as applicable, NRC programs: (1) Compatibility Requirements, (2) Sealed Source and Device Evaluation Program, (3) Low-Level Radioactive Waste Disposal Program, and (4) Uranium Recovery Program. There are no non-common performance indicators applicable to the Region III materials program.

#### 5.0 SUMMARY

As noted in Sections 3.0 and 4.0 above, Region III's performance was found to be satisfactory for all performance indicators reviewed. The team did not make any recommendations for improvement regarding Region III's performance, and there were no recommendations from prior IMPEP reviews to close.

Accordingly, the team recommends that the NRC Region III materials program be found adequate to protect public health and safety. Based on the results of the current IMPEP review, the 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

<b>Name</b>	<b>Area of Responsibility</b>
Lisa Dimmick, NRC/NMSS	Team Leader
Brian Goretzki, AZ	Technical Staffing and Training Status of Material Inspection Program
John Miller, NRC Region I	Technical Quality of Inspections Inspection Accompaniments
Lizette Roldan-Otero, NRC/NMSS	Technical Quality of Incidents and Allegations Inspection Accompaniments Team Leader-in-Training
Nancy Stanley, NJ	Technical Quality of Licensing Actions

## APPENDIX B

### INSPECTION ACCOMPANIMENTS

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

Accompaniment No.: 1	License No.: 21-00741-08
License Type: <i>Academic Type A Broadscope</i>	Priority: 3
Inspection Date: 5/1-2/17	Inspector: DO

Accompaniment No.: 2	License No.: 41-32720-06
License Type: <i>Accelerator</i>	Priority: 2
Inspection Date: 5/2/17	Inspector: LF

Accompaniment No.: 3	License No.: 41-32720-05MD
License Type: <i>Nuclear Pharmacy</i>	Priority: 2
Inspection Date: 5/3/17	Inspector: LF

Accompaniment No.: 4	License No.: 21-18428-01
License Type: <i>Industrial Radiography</i>	Priority: 1
Inspection Date: 5/4/17	Inspector: EH

Accompaniment No.: 5	License No.: 21-26488-01
License Type: <i>HDR</i>	Priority: 2
Inspection Date: 5/22/17	Inspector: ZS

Accompaniment No.: 6	License No.: 21-04127-06
License Type: <i>Gamma Knife, Irradiator, HDR</i>	Priority: 2
Inspection Date: 5/23-24/17	Inspector: RC

Accompaniment No.: 7	License No.: 21-01190-05
License Type: <i>HDR, Y-90</i>	Priority: 2
Inspection Date: 5/25/17	Inspector: NT