

January 15, 2013

MEMORANDUM TO: Charles A. Casto, Regional Administrator
Region III

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 III RADIOACTIVE MATERIALS PROGRAM

On December 17, 2012, 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 (NRC) Region III Radioactive Materials Program. The MRB found the program adequate to protect public health and safety.

Section 3.0, page 9, 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. Based on the results of the current IMPEP review, the next full review of the NRC Region III program will take place in approximately 5 years, with a periodic meeting tentatively scheduled mid-cycle. The program received a 1 year extension based on two consecutive IMPEPs resulting in satisfactory ratings for all indicators reviewed.

I appreciate the courtesy and cooperation extended to the IMPEP team during the review and I applaud your staff's efforts during the IMPEP review period.

Enclosure:
Region III Final IMPEP Report

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

Anne T. Boland, Director
Division of Nuclear Materials Safety



INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF THE NRC REGION III PROGRAM

September 24 - 28, 2012

FINAL 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 September 24-28, 2012, by a review team composed of technical staff members from the NRC and the State of Florida.

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 two IMPEP reviews.

The review team did not make any recommendations.

Accordingly, the review team recommended, and the Management Review Board agreed, that the NRC Region III 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 III materials program. The review was conducted during the period of September 24 – 28, 2012, by a review team composed of technical staff members from the NRC and the State of Florida. Team members are identified in Appendix A. The review was conducted in accordance with the “Implementation of the Integrated Materials Performance Evaluation Program and Rescission of Final General Statement of Policy,” published in the *Federal Register* on October 16, 1997, and [NRC Management Directive 5.6](#), “Integrated Materials Performance Evaluation Program (IMPEP),” dated February 26, 2004. Preliminary results of the review, which covered the period of August 31, 2007 to September 28, 2012, were discussed with Region III managers on the last day of the review.

A draft of this report was provided to Region III for factual comment on October 23, 2012. Region III responded by electronic mail dated November 16, 2012. A copy of the region’s response is included as an Attachment to this report. A Management Review Board (MRB) met on December 17, 2012, to consider the proposed final report. The MRB found the NRC Region III materials program adequate to protect public health and safety.

The NRC Region III materials program is administered by the Division of Nuclear Materials Safety (Division), which is headed by the Division Director. The Division Director reports directly to the Regional Administrator. An organization chart for Region III and the Division is included as Appendix B.

At the time of the review, the Region III materials program regulated 1,116 specific licenses authorizing possession and use of radioactive materials. The review focused on the radioactive materials program as it is carried out under the Atomic Energy Act of 1954, as amended.

In preparation for the review, a questionnaire addressing the common performance indicators was sent to the Division on May 30, 2012. The Division provided its response to the questionnaire on September 4, 2012. A copy of the questionnaire response can be found in the NRC’s Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML12297A211.

The review team’s general approach for conduct of this review consisted of (1) examination of the Division’s response to the questionnaire, (2) analysis of quantitative information from the Division’s databases, (3) technical review of selected regulatory actions, (4) field accompaniments of six inspectors, and (5) interviews with staff and managers. The review team evaluated the information gathered against the established criteria for each common performance indicator and made a preliminary assessment of the Division’s performance.

There were no recommendations made during the previous review.

Results of the current review of the common performance indicators are presented in Section 2.0. There were no non-common performance indicators reviewed for this IMPEP. Section 3.0 summarizes the review team’s findings.

2.0 COMMON PERFORMANCE INDICATORS

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

2.1 Technical Staffing and Training

Considerations 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 managers and staff, reviewed job descriptions and training records, and considered workload backlogs.

The Division is managed by the Director, who reports directly to the Regional Administrator. The Division is composed of three branches: the Materials Licensing Branch, the Materials Inspection Branch, and the Materials Controls, ISFSI and Decommissioning Branch. Each is headed by a Branch Chief.

At the time of the review, there were 27 technical staff members with various degrees of involvement in the radioactive materials program. The Division has a total of approximately 28.9 full-time equivalents (FTE), an increase of 5.9 FTE since the last review. The Division has two vacant positions: a GG-13 health physicist in Materials Licensing and a GG-6 Materials Processing Assistant. Filling these vacancies is on hold as a review process is being conducted to assess the needs of the Division. The review team determined that the Division's Operational Management Information (OMI) reports assist Division managers to use their staff resources efficiently. Early in the review period, there was some turnover of senior staff, and two inspectors were assigned for almost a year to evaluate a complicated enforcement activity. The Division prevented a possible backlog by procuring assistance from the other NRC Regions as well as quickly filling the vacant positions. The review team determined that staffing levels were adequate for the Region's materials program.

The Division uses Inspection Manual Chapter (IMC) 1246, "Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area," and associated procedures as its qualification and training program. Staff members are assigned increasingly complex duties as they progress through the qualification process. During the review period, three individuals successfully completed their qualification boards, one is eligible in November 2012, and two are in the Nuclear Safety Professional Development Program. To promote knowledge management and succession, the Division takes advantage of mentoring opportunities for less experienced staff. The review team found that all senior technical staff members are available and willing to provide guidance and assistance to newer staff on their assigned projects as well as guide them through their training. The review team concluded that the Division's training program is adequate to carry out its regulatory duties and noted that Division management supports the Division training program.

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

2.2 Status of Materials Inspection Program

The review team focused on five factors while reviewing this indicator: inspection frequency, overdue inspections, initial inspections of new licenses, timely dispatch of inspection findings to licensees, and performance of reciprocity inspections. The review team based its evaluation on the Division's questionnaire response relative to this indicator, data gathered from the Division's database, examination of completed inspection casework, and interviews with management and staff.

The review team verified that the Division adheres to the inspection priorities prescribed in IMC 2800, "Materials Inspection Program." The Division continues to implement its broad scope inspection initiative as discussed in previous IMPEP reports. The broad scope inspection initiative allows several partial inspections of major broad scope licensees to be conducted within the inspection cycles, as long as all inspection objectives are met through the aggregation of the partial inspections.

The review team determined that the Division conducted 797 inspections of Priority 1, 2, and 3 licensees during the review period. Twelve inspections were performed overdue by more than 25 percent of the inspection frequency listed in IMC 2800. Five of the overdue inspections were identified in 2011 based on an extensive self-assessment conducted to validate inspection and licensing tracking data in the Licensing Tracking System database. The Division conducted 196 initial inspections of new radioactive materials licenses during the review period. Of the 196 initial inspections, 3 were performed greater than 12 months after license issuance. These three were identified during a 2012 effectiveness review of corrective actions from the 2011 validation effort. Overall the review team calculated that the Division performed 1.5 percent of all Priority 1, 2, and 3 inspections and initial inspections overdue during the review period.

The review team evaluated the timeliness of issuance of inspection findings to licensees using the inspection casework reviews and the OMI reports. The review indicated that inspection reports were issued to the licensee consistently within 30 days following the conclusion of the inspection.

During the on-site portion of the review, the Division demonstrated its Inspection Planner Database to the review team. The Division independently developed this database to gain efficiency in the inspection planning process. The Inspection Planner Database is populated and updated by a monthly download from Web-Based Licensing (WBL) database. Information provided from WBL, such as a licensee's address and inspection dates, is entered automatically into the respective fields on the planning form, saving the inspector time from not having to look up or hand-write the information. After the inspections are entered, the database produces a hard copy of the inspector's proposed inspection trip for approval from his or her supervisor.

Following the inspection and/or report issuance, and after supervisory review, the administrative staff enters the completed inspection data to update WBL. In addition, the Division utilizes an electronic Inspection Book, which is populated and updated by a monthly download from the

WBL database. Information provided from the WBL, such as a licensee's address and inspection dates, is entered automatically into the respective fields in the Inspection Book. The frequent monthly updates have allowed steady progress regarding inspections in the plus 25 percent category and the Inspection Planner allows current inspections to be included with the plus 25 percent category for travel and time efficiency. This focus also helps lower the plus 25 percent category. The review team believes that the Division's database and Inspection Book could be a beneficial tool for the other NRC Regional Offices in planning their inspection activities. The database is also capable of generating the inspection information for the monthly OMI reports.

During the review period, the Division granted 45 reciprocity permits to candidate licensees based upon the criteria in IMC 1220, "Processing of NRC Form 241 and Inspection of Agreement State Licensees Operating under 10 CFR 150.20." The Division exceeded the NRC's criteria of inspecting 20 percent of candidate licensees operating under reciprocity in each of the five years covered by the review period with an overall inspection average of 54.5 percent. On August 6, 2012, the Division issued "DI IMC-1200 Processing, Approving and Tracking Reciprocity Requests," to specify the criteria for determining whether a reciprocity licensee is a candidate for inspection and what actions to take when a reciprocity notification is received from another Region. Reciprocity candidates now include Priority 1 through 3 licensees, from Region I and IV Agreement States, working at temporary job sites in Region III, as notified from Region I or IV. This change is expected to significantly increase the number of candidates for reciprocity inspection.

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

2.3 Technical Quality of Inspections

The review team evaluated the inspection reports, enforcement documentation, inspection field notes, and interviewed inspectors for 20 radioactive materials inspections conducted during the review period. The casework reviewed included inspections conducted by 12 Region III inspectors and covered inspections of various license types: medical broad scope, academic broad scope, medical diagnostic, medical therapy including high dose rate remote after loader, unsealed radioiodine therapy, and permanent implant brachytherapy, portable and fixed gauges, industrial radiography, self-shielded irradiators, nuclear pharmacy, and Increased Security Controls for Radioactive Materials Quantities of Concern (Increased Controls). Appendix C lists the inspection casework files reviewed, as well as the results of the inspector accompaniments.

Based on the evaluation of casework, the review team noted that inspections covered all aspects of the licensee's radiation safety program. The review team found that inspection reports were thorough, complete, consistent, and of high quality, with sufficient documentation to ensure that a licensee's performance with respect to health and safety was acceptable. The documentation supported violations, recommendations made to licensees, unresolved safety issues, the effectiveness of corrective actions taken to resolve previous violations and discussions held with licensees during exit interviews.

The inspection procedures utilized by Region III are consistent with the inspection guidance outlined in IMC 2800. An inspection report is completed by the inspector which is then reviewed and signed by the Branch Chief. All inspectors received annual supervisory accompaniments.

The review team determined that the inspection findings were appropriate, and prompt regulatory actions were taken as necessary. All inspection findings were clearly stated and documented in the reports and sent to the licensees with the appropriate letter detailing the results of the inspection. Region III issues to the licensee either an NRC Form 591 indicating a clear inspection, an NRC Form 591 with Severity Level IV violations, or a Notice of Violation (NOV), in letter format, which details the results of the inspection. The Branch Chief reviews all findings. When Region III issues an NOV, the licensee is required to provide, within 30 days, written corrective actions, based on the violations cited.

The review team noted that Region III has an adequate supply of survey instruments to support its inspection program. Appropriate, calibrated survey instrumentation, such as Geiger-Mueller meters, scintillation detectors, ion chambers, micro-R meters, and neutron detectors, were available. Region III's Radiation Safety Officer tracks calibration due dates. Instruments are calibrated at least annually, or as needed, by a commercial vendor with National Institute of Standards and Technology traceable sources.

Two IMPEP team members conducted accompaniments with six Region III inspectors during the weeks of July 16, July 23, and September 10, 2012. The IMPEP team members accompanied the inspectors during health and safety and security inspections of industrial radiography, self-shielded irradiators, portable and fixed gauges, medical broad scope, academic broad scope, medical diagnostic and medical therapy, including high dose rate remote after loader, unsealed radioiodine therapy, and permanent implant brachytherapy licenses. The accompaniments are identified in Appendix C. During the accompaniments, the inspectors demonstrated appropriate inspection techniques, knowledge of the regulations, and conducted performance-based inspections. The inspectors were trained, well-prepared for the inspection, and thorough in their inspections of the licensees' radiation safety programs. The inspectors conducted interviews with appropriate personnel, observed licensed operations, conducted confirmatory measurements, and utilized good health physics practices. The inspections were adequate to assess radiological health and safety and security at the licensed facilities.

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

2.4 Technical Quality of Licensing Actions

The review team examined completed licensing casework and interviewed license reviewers for 22 specific licensing actions. Licensing actions were reviewed for completeness, consistency, proper radioisotopes and quantities, qualifications of authorized users, adequacy of facilities and equipment, adherence to good health physics practices, financial assurance, operating and emergency procedures, appropriateness of license conditions, and overall technical quality. The casework was also reviewed for timeliness, use of appropriate deficiency and cover letters,

use of appropriate reference to regulations, supporting documentation, consideration of enforcement history, pre-licensing visits, peer/supervisory review, and proper signatures.

The review team selected licensing casework to provide a representative sample of licensing actions completed during the review period. Licensing actions selected included four new licenses, four renewals, three terminations, ten amendments, and one void decommissioning case. Files reviewed included a cross-section of license types: medical (e.g., broad-scope, high dose rate remote afterloader, gamma knife, and teletherapy), radionuclide production using an accelerator, nuclear pharmacy, research and development, industrial radiography, fixed gauges, manufacturers and distributors, panoramic irradiators, and special nuclear materials. The casework sample represented work from 14 license reviewers. A list of the licensing casework evaluated with case-specific comments is provided in Appendix D.

The review team found that the licensing actions were thorough, complete, consistent, and of high quality with health, safety, and security issues properly addressed. License tie-down conditions were stated clearly and were supported by information contained in the file. Requests for additional information contained clearly stated regulatory positions, were used at the proper time, and identified substantive deficiencies in the licensees' documents. Terminated licensing actions were well documented, showing appropriate transfer and survey records, as well as environmental assessments when needed. License reviewers use the Region III's certification checklists and the NUREG-1556 series guidance documents, policies, and license conditions specific to the type of licensing actions to ensure consistency in licenses. The certification checklists are highly adaptable by each license reviewer and may range from a few pages to over 60 pages because the list may include the results of the previous inspection and many reference documents. Region III also forwards non-conforming financial assurance documents to the Division of Waste Management and Environmental Protection for review via the technical assistance request process.

The Materials Licensing Branch is composed of 10 personnel who primarily work on licensing actions, a records management clerk, and a branch chief. Six of the ten license reviewers have full signature authority for licensing actions. License reviewers are responsible for reviewing the license actions before issuance to the licensee. Licenses are issued for a 10 year period under a timely renewal system. As of August 2012, Region III has 1,116 specific licensees - 15 Priority 1, 125 Priority 2, 212 Priority 3, and 764 Priority 5 licensees. The Materials Licensing Branch completes approximately 930 licensing actions per fiscal year (FY).

The review team found that incoming licensing action requests are scanned into ADAMS as a non-public document by a representative from Region III Division of Resource Management. The license action is then provided to the Chief of the Materials Licensing Branch who performs a preliminary review and has a staff member check WBL for any other pending actions. The Branch Chief then assigns the action to a license reviewer. A contractor generates a deemed timely letter for renewals, a postcard receipt with the mail control number listed for new licenses and amendments, and enters the milestones into the WBL system. Once the license reviewer's action is complete and the license is signed, the license action is provided to the Records Management Clerk who date stamps and processes the action for mailing. The contractor performs the final update to WBL.

The Chief of the Materials Licensing Branch manages the oversight of the licensing program. Until FY12, self-assessments of the licensing process were performed quarterly; as of FY12, the self-assessments are performed semi-annually. The self-assessments are critical and are used to improve staff performance and efficiency.

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

The Program performs pre-licensing checks of all new applicants, unless the applicant has a valid Agreement State license in good standing and the license reviewer obtains verification from the Agreement State regarding this particular licensee. The pre-licensing review methods incorporate the essential elements of NRC's revised pre-licensing guidance to verify that the applicant will use requested radioactive materials as intended. All pre-licensing site visits include an evaluation of the applicant's radiation safety and security programs prior to receipt of the initial license.

The review team examined Region III's licensing practices regarding the Increased Controls and Fingerprinting Orders. The review team noted that Region III uses legally binding license conditions that meet the criteria for implementing the Increased Controls Orders, including fingerprinting, as appropriate. The review team analyzed Region III's methodology for identifying those licenses and found the rationale was thorough and accurate. The review team confirmed that license reviewers evaluated new license applications and license amendments using the same criteria. Region III ensures an applicant or licensee's full implementation of the Increased Controls prior to issuance of a new license or license amendment authorizing radionuclides in quantities of concern.

The review team examined Region III's implementation of its procedure for the control of sensitive information. This procedure addresses the identification, marking, control, handling, preparation, transportation, transmission, and destruction of documents that contain sensitive information related to the Increased Controls. The review team noted that the licensing files are maintained in the NRC's ADAMS which is password protected. Hard copy files that contained sensitive information were further secured in locked file cabinets.

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

2.5 Technical Quality of Incident and Allegation Activities

In evaluating the effectiveness of Region III 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 reported for Region III in the Nuclear Materials Events Database (NMED) against those contained in the Division's files, and evaluated the casework for 20 radioactive materials incidents. A list of the incident casework examined, with case-specific

comments, may be found in Appendix E. The review team also evaluated Region III's response to 14 allegations involving radioactive materials licenses.

The review team identified 384 radioactive materials incidents in NMED for Region III during the review period, of which 165 were reportable under the NRC regulations. Incidents included eight abnormal occurrences. Reviewed incidents included the categories of medical events, lost material, equipment failure, contamination, and transportation. The review team discussed incident contents, procedures, documentation, incorporation of followup information to the NMED database, and the role of NRC Headquarters Operations Center with Division staff. A routine, monthly Division level review of open NMED documented incidents facilitates efforts for timely closure of incidents. Inspector reviews of NMED facilitate scheduling follow-up visits when site visits are deemed necessary. The review team determined that the Division's responses to incidents were complete and comprehensive. Initial responses were prompt and well-coordinated, and the level of effort was commensurate with the health and safety significance. The Division dispatched inspectors for on-site investigations in 13 of the 20 cases reviewed and took suitable enforcement and followup actions. Documentation shows that followup to the incidents was performed and was well documented in licensee report reviews, investigation inspections, enforcement actions when required, and followup inspections.

If the Division determines that an immediate onsite inspection is not warranted, via communications with the licensee and review of licensee's report, a Division instruction includes a process for closing out NMED items by preparing a letter to the licensee acknowledging receipt of the licensee's written report.

In evaluating the Division's actions in response to allegations, the review team evaluated 14 casework files. The review team noted that the allegation files are maintained by the Enforcement and Investigation Coordination Staff (EICS) of the Regional Office, which coordinates very well with the Division of Nuclear Materials Safety in addressing materials licensee allegations. The review team found records with allegations and supporting information well documented. The chronologically filed, well organized documentation makes files easy to follow from initial allegation, Allegation Review Board (ARB) meeting notes, communications with concerned individuals (CI) and licensees, and final resolution and closeout correspondence. Processes are timely, with timeliness goals being met. The ARB schedules its meetings every Monday, so that the ARB is addressing all new allegations in a timely manner. The Program notified the concerned individuals of the conclusion of their investigations when the CI is known. The review team determined that the Program adequately protected the identity of concerned individuals. The EICS performs a final file review against a multi-page verification list prior to closure of the allegation to assure completeness of the record.

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

3.0 SUMMARY

As noted in Section 2.0 above, the Region III's performance was found satisfactory for all of the performance indicators reviewed. The review team did not make any recommendations. Accordingly, the review team recommended, and the MRB agreed, that the Region III Program be found adequate to protect public health and safety. Based on the results of the current IMPEP review, the review team recommends that the next IMPEP review take place in approximately 5 years.

LIST OF APPENDICES

Appendix A	IMPEP Review Team Members
Appendix B	Region III Organization Charts
Appendix C	Inspection Casework Reviews
Appendix D	License Casework Reviews
Appendix E	Incident Casework Reviews

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	Area of Responsibility
Joseph DeCicco, FSME	Team Leader Technical Quality of Incident and Allegation Activities
Cynthia Becker, Florida	Technical Staffing and Training Status of Materials Inspection Program
Kathy Modes, Region I	Technical Quality of Licensing Actions Inspection Accompaniments
Anthony Gaines, Region IV	Technical Quality of Inspections Inspection Accompaniments

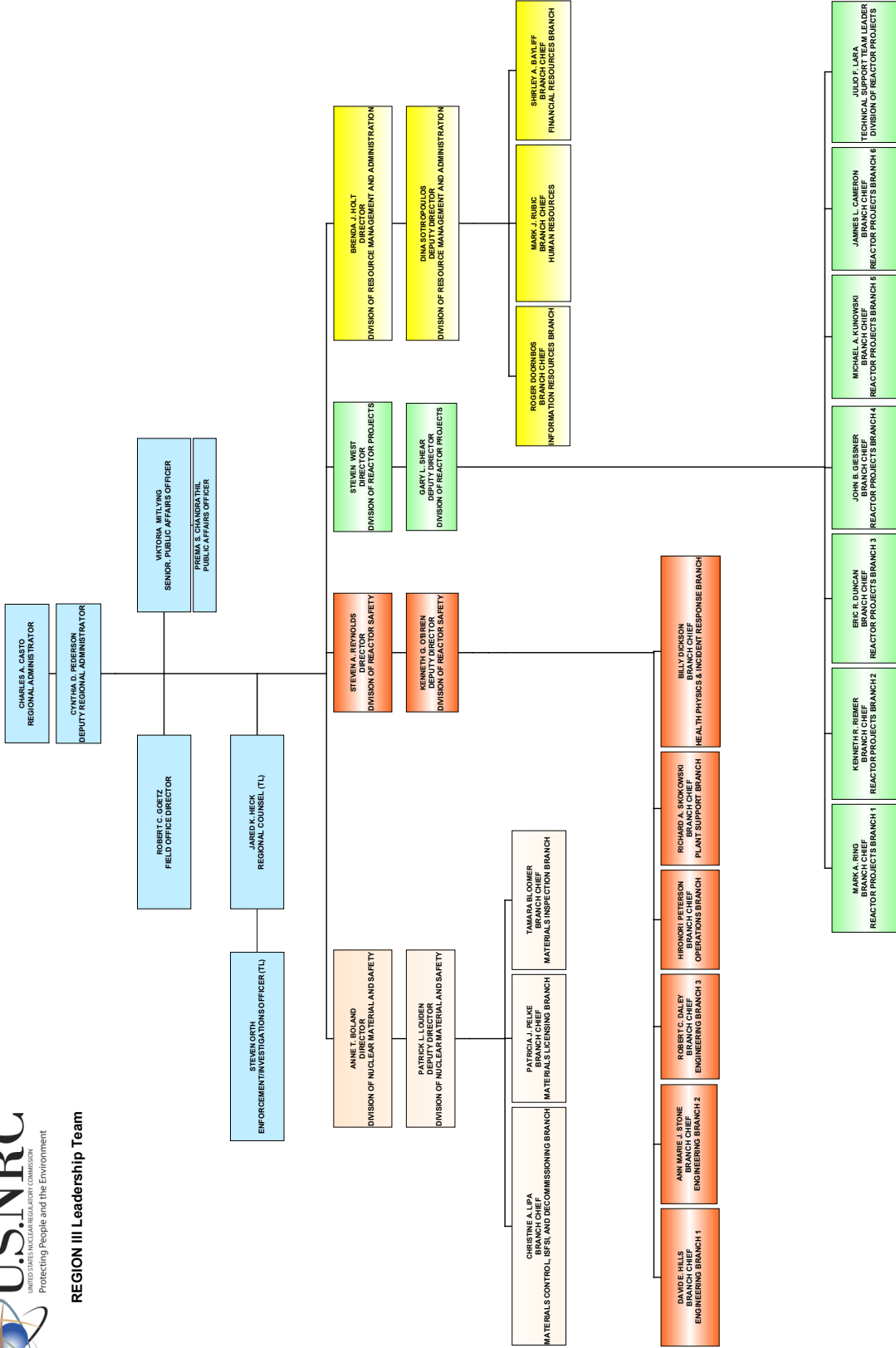
APPENDIX B

REGION III ORGANIZATION CHART

ADAMS ACCESSION NO.: ML12283A358



REGION III Leadership Team



APPENDIX C

INSPECTION CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

File No.: 1 Licensee: Indiana State University Inspection Type: Routine, Unannounced Inspection Date: 11/6/08	License No.: 13-09639-05 Priority: 5 Inspector: SM
File No.: 2 Licensee: Metaltek International Carondelet Division Inspection Type: Routine, Unannounced Inspection Date: 4/21/09	License No.: 24-26136-01 Priority: 2 Inspector: KN
File No.: 3 Licensee: University of Notre Dame du Lac Inspection Type: Routine, Unannounced Inspection Date: 8/4-6/09	License No.: 13-01983-15 Priority: 2 Inspector: ML
File No.: 4 Licensee: Allied Inspection Services, Inc. Inspection Type: Routine, Unannounced Inspection Date: 8/20/09	License No.: 21-18428-01 Priority: 1 Inspector: DP
File No.: 5 Licensee: Regents of the University of Michigan Inspection Type: Special, Announced Inspection Date: 10/29/09	License No.: 21-00215-04 Priority: 2 Inspector: GW
File No.: 6 Licensee: City of South Bend, Department of Public Works Inspection Type: Routine, Unannounced Inspection Date: 1/19/10	License No.: 13-15423-03 Priority: 5 Inspector: EK
File No.: 7 Licensee: ArcelorMittal Burns Harbor LLC Inspection Type: Routine, Unannounced Inspection Date: 2/18-19/10	License No.: 13-32670-01 Priority: 5 Inspector: RG
File No.: 8 Licensee: Washington University in St. Louis Inspection Type: Routine, Unannounced Inspection Date: 2/22-25/10	License No.: 24-00167-11 Priority: 2 Inspector: KL
File No.: 9 Licensee: De Backer and Sons, Inc. Inspection Type: Special, Announced	License No.: N/A Priority: N/A

Inspection Date: 3/16/10 Inspector: RH
File No.: 10
Licensee: Wabash College License No.: 13-07419-02
Inspection Type: Routine, Unannounced Priority: 5
Inspection Date: 5/7/10 Inspector: ML

File No.: 11
Licensee: Testing Engineers & Consultants, Inc. License No.: 21-18668-01
Inspection Type: Routine, Unannounced Priority: 5
Inspection Date: 6/7/10 Inspector: EK

File No.: 12
Licensee: Oakwood Hospital and Medical Center License No.: 21-04515-01
Inspection Type: Routine, Unannounced Priority: 2
Inspection Date: 6/10/10 Inspector: DP

File No.: 13
Licensee: American Radiolabeled Chemicals License No.: 24-21362-01
Inspection Type: Routine, Unannounced Priority: 5
Inspection Date: 8/2-6/10 and 8/9-10/10 Inspector: RG

File No.: 14
Licensee: St. Luke's Hospital of Kansas City License No.: 24-00889-01
Inspection Type: Routine, Unannounced Priority: 2
Inspection Date: 8/9-11/11 Inspector: GW

File No.: 15
Licensee: Washington University in St. Louis License No.: 24-00167-11
Inspection Type: Special, Announced Priority: 2
Inspection Date: 11/16-18/11 Inspector: RG

File No.: 16
Licensee: Midwest Testing, Inc. License No.: 24-24619-02
Inspection Type: Routine, Unannounced Priority: 5
Inspection Date: 1/31/12 Inspector: RH

File No.: 17
Licensee: Bayer CropScience LP License No.: 24-03830-01
Inspection Type: Routine, Unannounced Priority: 5
Inspection Date: 2/27/12 Inspectors: KL, BL

File No.: 18
Licensee: Alpena Regional Medical Center License No.: 21-17754-01
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 6/28-29/12 Inspector: AB

File No.: 19

Licensee: Allied Inspection Services, Inc.
Inspection Type: Routine, Unannounced
Inspection Date: 7/24/12

License No.: 21-18428-01
Priority: 1
Inspector: BL

File No.: 20

Licensee: PETNET Solutions, Inc.
Inspection Type: Routine, Unannounced
Inspection Date: 7/24/12

License No.: 41-32720-02MD
Priority: 2
Inspectors: KL, MH

INSPECTOR ACCOMPANIMENTS

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

Accompaniment No.: 1

Licensee: Dunn Paper
Inspection Type: Routine, Unannounced
Inspection Date: 7/18/12

License No.: 21-26777-01
Priority: 5
Inspector: EK

Accompaniment No.: 2

Licensee: Marathon Petroleum Company LP
Inspection Type: Initial, Announced
Inspection Date: 7/18/12

License No.: 21-32842-01
Priority: 5
Inspector: EK

Accompaniment No.: 3

Licensee: Washington University
Inspection Type: Routine, Unannounced
Inspection Date: 7/17, 19, and 20/12

License Nos.: 24-00167-11 and 24-00167-14
Priority: 2
Inspector: RG

Accompaniment No.: 4

Licensee: Washington University
Inspection Type: Routine, Unannounced
Inspection Date: 7/17, 19, and 20/12

License Nos.: 24-00167-11 and 24-00167-14
Priority: 2
Inspector: RH

Accompaniment No.: 5

Licensee: Allen Park Cardiology, P.C.
Inspection Type: Routine, Unannounced
Inspection Date: 7/23/12

License No.: 21-26792-01
Priority: 5
Inspector: BL

Accompaniment No.: 6

Licensee: Allied Inspection Services, Inc.
Inspection Type: Routine, Unannounced
Inspection Date: 7/24/12

License No.: 21-18428-01
Priority: 1
Inspector: BL

Accompaniment No.: 7

Licensee: Southeast Missouri Hospital
Inspection Type: Routine, Unannounced
Inspection Date: 7/25-26/12

License No.: 24-00128-01
Priority: 2
Inspector: AB

Accompaniment No.: 8

Licensee: Mercy Hospital
Inspection Type: Routine, Unannounced
Inspection Date: 9/10/12

License No.: 21-02187-01
Priority: 2
Inspector: AM

Accompaniment No.: 9

Licensee: McLaren – Greater Lansing
Inspection Type: Routine, Unannounced
Inspection Date: 9/11/12

License No.: 21-04073-01
Priority: 2
Inspector: AM

APPENDIX D

LICENSE CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

File No.: 1 Licensee: American Radiolabeled Chemicals Type of Action: Amendment Date Issued: 8/2/12	License No.: 24-21362-01 Amendment No.: 49 License Reviewer: KN
File No.: 2 Licensee: Spectron mrc, LLC Type of Action: New Date Issued: 5/7/11	License No.: 13-32726-02 Amendment No.: N/A License Reviewer: KN
File No.: 3 Licensee: Franciscan St. Anthony Health-Crown Point Type of Action: Renewal Date Issued: 4/27/12	License No.: 13-15933-01 Amendment No.: 28 License Reviewer: CF
File No.: 4 Licensee: Crane Army Ammunition Activity Type of Action: Termination Date Issued: 7/20/12	License No.: 13-18235-01 Amendment No.: 18 License Reviewer: CF
File No.: 5 Licensee: Solutia, Inc. Type of Action: Bankruptcy/Termination Date Issued: 10/14/09	License No.: 21-05103-02 Amendment No.: 41 License Reviewer: LH
File No.: 6 Licensee: Hidden Water, Inc. Type of Action: New & Corrected Copy Date Issued: 2/8/12 and 9/27/12	License No.: 48-32822-01 Amendment No.: N/A License Reviewer: TS
File No.: 7 Licensee: 3M Company Type of Action: Amendment Date Issued: 11/28/11	License No.: 22-00057-61 Amendment No.: 45 License Reviewer: CC
File No.: 8 Licensee: IRISNDT, Inc. Type of Action: New Date Issued: 7/6/10	License No.: 42-32791-01 Amendment No.: N/A License Reviewer: TS

File No.: 9

Licensee: University of Evansville
Type of Action: Renewal
Date Issued: 5/4/11

License No.: SNM-995
Amendment No.: 7
License Reviewer: WR

File No.: 10

Licensee: Reuter-Stokes, Inc.
Type of Action: Amendment
Date Issued: 2/22/12

License No.: SNM-1826
Amendment No.: 22
License Reviewer: CF

File No.: 11

Licensee: U.S. Environmental Protection Agency
Type of Action: Termination
Date Issued: 10/6/09

License No.: 12-10243-01
Amendment No.: 28
License Reviewers: KS, GM

File No.: 12

Licensee: Missouri Baptist Medical Center
Type of Action: Amendment
Date Issued: 7/9/12

License No.: 24-11128-02
Amendment No.: 77
License Reviewer: SF

File No.: 13

Licensee: Indiana University Medical Center
Type of Action: Renewal w/ license condition exemptions
Date Issued: 7/24/12

License No: 13-02752-08
Amendment No.: 32
License Reviewer: SF

File No.: 14

Licensee: Aptuit, LLC
Type of Action: Void w/ two-part Amendment (change of control)
Date Issued: 9/22/11 & 1/4/12

License No.: 24-15595-01
Amendment No.: 33
License Reviewer: WR

File No.: 15

Licensee: Aptuit, LLC
Type of Action: Void - Decommissioning Plan
Date Issued: 5/11/12

License No.: 24-15595-01
Amendment No.: N/A
License Reviewer: LR

File No.: 16

Licensee: St. Anthony's Medical Center
Type of Action: Amendment w/ safety culture paragraph
Date Issued: 9/4/12

License No: 24-01041-04
Amendment No.: 54
License Reviewer: FT

File No.: 17

Licensee: Providence Hospital
Type of Action: Amendment w/ safety culture paragraph
Date Issued: 9/4/12

License No.: 21-02802-03
Amendment No.: 74
License Reviewer: FT

File No.: 18

Licensee: Hot Shots Nuclear Medicine
Type of Action: New & Corrected Copies
Date Issued: 1/15/10, 1/16/10, and 1/22/10

License No.: 21-26597-02MD/21-32778-01MD
Amendment No.: N/A
License Reviewer: CC

File No.: 19

Licensee: ArcelorMittal Burns Harbor, LLC
Type of Action: Amendment
Date Issued: 9/22/10

License No: 13-32670-01
Amendment No.: 3
License Reviewer: MH

File No.: 20

Licensee: Cardinal Health
Type of Action: Amendment w/ safety culture paragraph
Date Issued: 6/21/12

License No.: 34-29200-01MD
Amendment No.: 39
License Reviewer: BP

File No.: 21

Licensee: Sigma-Aldrich Company
Type of Action: Renewal w/safety culture paragraph
Date Issued: 8/30/12

License No.: 24-16607-03
Amendment No.: 8
License Reviewer: BP

File No.: 22

Licensee: Washington University in St. Louis
Type of Action: Amendment & Corrected Copy in-progress
Date Issued: 3/11/11

License No.: 24-00167-11
Amendment No.: 76
License Reviewer: JM

APPENDIX E

INCIDENT CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

File No.: 1

Licensee: Karmanos Cancer Center
Date of Incident: 10/24/07
Investigation Date: 10/29/11-12/14/11

License No.: 21-04127-06
NMED No.: 070672
Type of Incident: Medical Event
Type of Investigation: Site

File No.: 2

Licensee: Providence Hospital
Date of Incident: 8/30/10
Investigation Date: 9/16/10

License No.: 21-02802-03
NMED No.: 100448
Type of Incident: Medical Event
Type of Investigation: Site

File No.: 3

Licensee: Deaconess Hospital
Date of Incident: 3/5/12
Investigation Date: To be determined

License No.: 13-00142-02
NMED No.: 120480
Type of Incident: Medical Event
Type of Investigation: To be determined

Comment: The 3/5/12 event was not reported to NRC until 8/16/12, with the licensee's written report letter received 8/31/12. Region is pursuing medical consultant assistance.

File No.: 4

Licensee: Calumet Testing Services, Inc.
Date of Incident: 7/22/08
Investigation Date: 9/29/08

License No.: 13-16347-01
NMED No.: 080416
Type of Incident: Equipment Failure
Type of Investigation: Site

File No.: 5

Licensee: Walmart
Date of Incident: 9/9/08
Investigation Date: 12/9/08

License No.: General
NMED No.: 080839
Type of Incident: Lost/Stolen/Abandoned RAM
Type of Investigation: Site

File No.: 6

Licensee: NUCOR Steel
Date of Incident: 2/8/12
Investigation Date: 9/26/12

License No.: 13-25975-01
NMED No.: 120098
Type of Incident: Equipment Failure
Type of Investigation: Site

File No.: 7

Licensee: Department of the Army

Date of Incident: 1/4/11

Investigation Date: 2/21/11

License No.: 12-007220-06

NMED No.: 110016

Type of Incident: Equipment Damage
Type of Investigation: Licensee Report

File No.: 8

Licensee: Department of Veteran Affairs

Date of Incident: 2/6/12

Investigation Date: 2/6/12

License No.: 03-23852-01VA

NMED No.: 120095

Type of Incident: Contamination Event
Type of Investigation: Licensee Report

File No.: 9

Licensee: Janx

Date of Incident: 1/15/09

Investigation Date: 11/16/12

License No.: 21-16560-01

NMED No.: 090080

Type of Incident: Transportation
Type of Investigation: Licensee Report

File No.: 10

Licensee: Westinghouse Electric Company, LLC

Date of Incident: 3/26/09

Investigation Date: 8/24/09 – 8/26/09

License No.: SNM-0033

NMED No.: 090479

Type of Incident: Release of RAM
Type of Investigation: Site

File No.: 11

Licensee: 3M Company

Date of Incident: 5/21/12

Investigation Date: 8/24/12

License No.: 22-00057-03

NMED No.: 120332

Type of Incident: Equipment Failure
Type of Investigation: Licensee Report

File No.: 12

Licensee: William Beaumont Hospital

Date of Incident: 4/27/11

Investigation Date: 5/2/11 – 5/5/11

License No.: 21-01333-01

NMED No.: 110193

Type of Incident: Medical Event
Type of Investigation: Site

File No.: 13

Licensee: Liberty Hospital

Date of Incident: 10/6/10

Investigation Date: 10/13/10 – 10/14/10

License No.: 24-16178-01

NMED No.: 100507

Type of Incident: Medical Event
Type of Investigation: Site

File No.: 14

Licensee: Mid-America Isotopes, Inc.

Date of Incident: 5/20/12

Investigation Date: 5/23/12

License No.: 24-26241-01MD

NMED No.: 120409

Type of Incident: Lost/Stolen/Abandoned RAM
Type of Investigation: Site

File No.: 15

Licensee: Evonik DeGussa Corp.

Date of Incident: 8/13/10

Investigation Date: 10/26/10

License No.: General

NMED No.: 100528

Type of Incident: Lost/Stolen/Abandoned RAM

Type of Investigation: Licensee report

File No.: 16

Licensee: Mallinckrodt Inc.

Date of Incident: 2/13/11

Investigation Date: 4/2/12 – 4/6/12

License No.: 24-04206-01

NMED No.: 110094

Type of Incident: Lost/Stolen/Abandoned RAM

Type of Investigation: Site

File No.: 17

Licensee: Westinghouse Electric Company, LLC

Date of Incident: 0/4/08

Investigation Date: 3/10/08

License No.: SNM-033

NMED No.: 080288

Type of Incident: Release of RAM

Type of Investigation: Site

File No.: 18

Licensee: Community Hospitals of Indiana

Date of Incident: 10/6/10

Investigation Date: 10/18/10 – 10/20/10

License No.: 13-06009-01

NMED No.: 100506

Type of Incident: Medical Event

Type of Investigation: Site

File No.: 19

Licensee: Indiana Department of Transportation

Date of Incident: 9/10/07

Investigation Date: 9/18/07

License No.: 13-26341-01

NMED No.: 070567

Type of Incident: Lost/Stolen/Abandoned RAM

Type of Investigation: Site

File No.: 20

Licensee: ATC Associates, Inc.

Date of Incident: 8/9/09

Investigation Date: 8/25/09

License No.: 13-17732-01

NMED No.: 090660

Type of Incident: Lost/Stolen/Abandoned RAM

Type of Investigation: Site

ATTACHMENT

November 16, 2012 email from Anne Boland
Region III's Response to the Draft Report
ADAMS Accession No.: ML12323A00

October 23, 2012

MEMORANDUM TO: Charles A. Casto, Regional Administrator
Region III

FROM: Joseph E. DeCicco, Senior Health Physicist **/RA/**
Division of Materials Safety and State Agreements
Office of Federal and State Materials
and Environmental Management Programs

SUBJECT: DRAFT REPORT OF THE INTEGRATED MATERIALS
PERFORMANCE EVALUATION PROGRAM REVIEW OF THE
REGION III RADIOACTIVE MATERIALS PROGRAM

A review team composed of members from the Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission (NRC) Region I and Region IV, and the State of Florida performed an Integrated Materials Performance Evaluation Program (IMPEP) review of the NRC Region III radioactive materials program during the week of September 24 – 28, 2012. I was the team leader for the review. Enclosed for your review is the draft IMPEP report that documents the review.

The review team's preliminary findings were discussed with you on the last day of the review. The review team's proposed recommendation is that the NRC Region III radioactive materials program be found adequate to protect public health and safety. The final determination of adequacy of your program, based on the review 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.

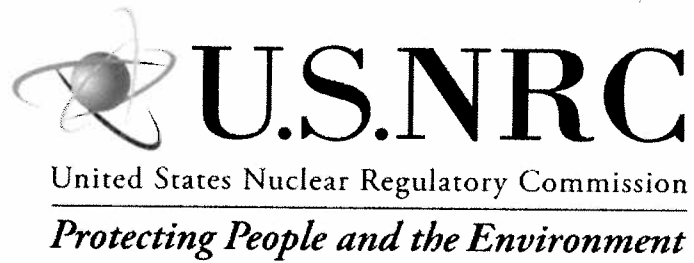
In accordance with procedures for implementation of IMPEP, we are providing you with a copy of the review team's draft report for your review and comment prior to submitting the report to the MRB. Comments are requested within 4 weeks from your receipt of this letter. This schedule will permit the issuance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

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, I scheduled the NRC Region III MRB meeting for Monday, December 17, 2012, from 2:30 to 5:00 p.m. EDT.

If you have any questions regarding the enclosed report, please contact me at (301) 415-7833.

Enclosure:
Draft NRC Region III IMPEP Report

cc w/encl: Anne T. Boland, Director
Division of Nuclear Materials Safety



INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM
REVIEW OF THE NRC REGION III PROGRAM

September 24 - 28, 2012

DRAFT REPORT

Enclosure

2.2 Status of Materials Inspection Program

The review team focused on five factors while reviewing this indicator: inspection frequency, overdue inspections, initial inspections of new licenses, timely dispatch of inspection findings to licensees, and performance of reciprocity inspections. The review team based its evaluation on the Division's questionnaire response relative to this indicator, data gathered from the Division's database, examination of completed inspection casework, and interviews with management and staff.

The review team verified that the Division adheres to the inspection priorities prescribed in IMC 2800, "Materials Inspection Program". The Division continues to implement its broad scope inspection initiative as discussed in previous IMPEP reports. The broad scope inspection initiative allows several partial inspections of major broad scope licensees to be conducted within the inspection cycles, as long as all inspection objectives are met through the aggregation of the partial inspections.

The review team determined that the Division conducted 797 inspections of Priority 1, 2, and 3 licensees during the review period. The review team identified 12 of these inspections as performed overdue by more than 25 percent of the inspection frequency listed in IMC 2800. Five of the overdue inspections were identified in 2011 based on an extensive self-assessment conducted to validate inspection and licensing tracking data in the Licensing Tracking System database. The Division conducted 196 initial inspections of new radioactive materials licenses during the review period. Of the 196 initial inspections, three were performed greater than 12 months after license issuance. These three were identified during a 2012 effectiveness review of corrective actions from the 2011 validation effort. Overall the review team calculated that the Division performed 1.5 percent of all Priority 1, 2, and 3 inspections and initial inspections overdue during the review period.

The review team evaluated the timeliness of issuance of inspection findings to licensees using the inspection casework reviews and the Division's monthly Operational Management Information (OMI) reports. The review indicated that inspection reports were issued to the licensee consistently within 30 days following the conclusion of the inspection.

During the on-site portion of the review, the Division demonstrated its Inspection Planner Database to the review team. The Division independently developed this database to gain efficiency in the inspection planning process. The Inspection ~~Book~~ is populated and updated by a monthly download from Web-Based Licensing (WBL) database. Information provided from WBL, such as a licensee's address and inspection dates, is entered automatically into the respective fields on the planning form, saving the inspector time from not having to look up or hand-write the information. After the inspections are entered, the database produces a hard copy of the inspector's proposed inspection trip for approval from his or her supervisor.

Planner Database

Following the inspection and/or report issuance, and after supervisory review, the administrative staff enters the completed inspection data to update WBL. The frequent monthly updates have allowed steady progress regarding inspections in the +25 percent category and the Inspection Planner allows current inspections to be included with the +25 percent category for travel and time efficiency. This focus also helps lower the +25 percent category. The review team believes that the Division's database could be a beneficial tool for the other NRC Regional

and inspection book

add → ** In addition, the Division utilizes an electronic Inspection Book, which is populated and updated monthly by a monthly download from WBL database. Information provided from WBL, such as a licensee's address and inspection dates, is entered automatically into the respective fields in the Inspection Book.*

results of the inspection. Region III issues to the licensee either an NRC Form 591 indicating a clear inspection, an NRC Form 591 with Severity Level IV violations, or a Notice of Violation (NOV), in letter format, which details the results of the inspection. When Region III issues an NOV, the licensee is required to provide, within 30 days, written corrective actions, based on the violations cited. The Branch Chief reviewed all findings.

The review team noted that Region III has an adequate supply of survey instruments to support its inspection program. Appropriate, calibrated survey instrumentation, such as Geiger-Mueller meters, scintillation detectors, ion chambers, micro-R meters, and neutron detectors, were available. Region III's Radiation Safety Officer tracks calibration due dates. Instruments are calibrated at least annually, or as needed, by a commercial vendor with National Institute of Standards and Technology traceable sources.

Two IMPEP team members conducted accompaniments with six Region III inspectors during the weeks of July 16, July 23, and September 10, 2012. The IMPEP team members accompanied the inspectors during health and safety and Increased Controls inspections of industrial radiography, self-shielded irradiators, portable and fixed gauges, medical broad scope, academic broad scope, medical diagnostic and medical therapy, including high dose rate remote after loader, unsealed radioiodine therapy, and permanent implant brachytherapy licenses. The accompaniments are identified in Appendix C. During the accompaniments, the inspectors demonstrated appropriate inspection techniques, knowledge of the regulations, and conducted performance-based inspections. The inspectors were trained, well-prepared for the inspection, and thorough in their ~~audit~~ ^{inspections} of the licensees' radiation safety programs. The inspectors conducted interviews with appropriate personnel, observed licensed operations, conducted confirmatory measurements, and utilized good health physics practices. The inspections were adequate to assess radiological health and safety and security at the licensed facilities.

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

2.4 Technical Quality of Licensing Actions

The review team examined completed licensing casework and interviewed license reviewers for 22 specific licensing actions. Licensing actions were reviewed for completeness, consistency, proper radioisotopes and quantities, qualifications of authorized users, adequacy of facilities and equipment, adherence to good health physics practices, financial assurance, operating and emergency procedures, appropriateness of license conditions, and overall technical quality. The casework was also reviewed for timeliness, use of appropriate deficiency and cover letters, use of appropriate reference to regulations, supporting documentation, consideration of enforcement history, pre-licensing visits, peer/supervisory review, and proper signatures.

The review team selected licensing casework to provide a representative sample of licensing actions completed during the review period. Licensing actions selected included ~~four new~~ ^{decommission} licenses, four renewals, three terminations, ten amendments, and one void. ^{case.} Files reviewed included a cross-section of license types, including: medical (e.g., broad-scope, high dose rate remote afterloader, gamma knife, and teletherapy), radionuclide production using an

accelerator, nuclear pharmacy, research and development, industrial radiography, fixed gauges, manufacturers and distributors, panoramic irradiators, and special nuclear materials. The casework sample represented work from 14 license reviewers. A list of the licensing casework evaluated with case-specific comments is provided in Appendix D.

Overall, the review team found that the licensing actions were thorough, complete, consistent, and of high quality with health, safety, and security issues properly addressed. License tie-down conditions were stated clearly and were supported by information contained in the file. Requests for additional information contained clearly stated regulatory positions, were used at the proper time, and identified substantive deficiencies in the licensees' documents. Terminated licensing actions were well documented, showing appropriate transfer and survey records, as well as environmental assessments when needed. License reviewers use the Region III's certification checklists and the NUREG-1556 series guidance documents, policies, and license conditions specific to the type of licensing actions to ensure consistency in licenses. The certification checklists are highly adaptable by each license reviewer and may range from a few pages to over 60 pages because the list may include the results of the previous inspection and many reference documents. Region III also forwards financial assurance documents to NRC headquarters, via a technical assistance request process.

NON-conforming
NRC Division - F WASTE MANAGEMENT AND ENVIRONMENTAL PROTECTION

The Materials Licensing Branch is composed of ten personnel who primarily work on licensing actions, one records management clerk, and a branch chief. Six of the ten license reviewers have full signature authority for licensing actions. License reviewers are responsible for reviewing the license actions before issuance to the licensee. Licenses are issued for a ten year period under a timely renewal system. As of August 2012, Region III has 1,116 specific licensees; 15 Priority 1, 125 Priority 2, 212 Priority 3, and 764 Priority 5 licensees. The Materials Licensing Branch completes approximately 930 licensing actions per fiscal year (FY).

for review

The review team found that incoming licensing action requests are scanned into ADAMS as a non-public document by a representative from Region III Division of Resource Management. The license action is then provided to the Chief of the Materials Licensing Branch who performs a cursory review and has a staff member check WBL for any other pending actions. The Branch Chief then assigns the action to a license reviewer. A contractor generates a deemed timely letter for renewals, a postcard receipt with the mail control number listed, and enters the milestone in the license tracking system. Once the license reviewer's action is complete and the license is signed, the license action is provided to the Records Management Clerk who date stamps and processes the action for mailing. The contractor performs the final update to WBL.

for NEWS AND AMENDMENTS

WEB-based Licensing

The Chief of the Materials Licensing Branch manages the oversight of the licensing program. Until FY12, self-assessments of the licensing process were performed quarterly; as of FY12, the self-assessments are performed semi-annually.

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

The Program performs pre-licensing checks of all new applicants, unless the applicant has a valid Agreement State license in good standing and the license reviewer obtains verification from the Agreement State regarding this particular licensee. The pre-licensing review methods incorporate the essential elements of NRC's revised pre-licensing guidance to verify that the applicant will use requested radioactive materials as intended. All pre-licensing site visits include an evaluation of the applicant's radiation safety and security programs prior to receipt of the initial license.

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

The review team examined Region III's implementation of its procedure for the control of sensitive information. This procedure addresses the identification, marking, control, handling, preparation, transportation, transmission, and destruction of documents that contain sensitive information related to the Increased Controls. The review team noted that the licensing files are maintained in the NRC's ADAMS which is password protected. Hard copy files that contained sensitive information were further secured in locked file cabinets.

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

2.5 Technical Quality of Incident and Allegation Activities

In evaluating the effectiveness of Region III 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 reported for Region III in the Nuclear Materials Events Database (NMED) against those contained in the Division's files, and evaluated the casework for 20 radioactive materials incidents. A list of the incident casework examined, with case-specific comments, may be found in Appendix E. The review team also evaluated Region III's response to 14 allegations involving radioactive materials licenses.

The review team identified 384 radioactive materials incidents in NMED for Region III during the review period, of which 165 were reportable under NRC regulations. Incidents included 8 abnormal occurrences. Reviewed incidents included the categories of medical events, lost material, equipment failure, contamination, and transportation. The review team discussed incident contents, procedures, documentation, incorporation of follow-up information to the NMED database, and the role of NRC Headquarters Operations Center with Division staff. A routine, monthly Division level review of open NMED documented incidents facilitates efforts to timely closure of incidents, as well as inspector reviews of NMED prior to license inspections. Staff collection of information is often coordinated with the inspector schedule to avail inspectors to visit licensees involved in incidents that are in close proximity to routine inspection sites. The

Difficult
sentence
to understand
please clarify

review team determined that the Division's responses to incidents were complete and comprehensive. Initial responses were prompt and well-coordinated, and the level of effort was commensurate with the health and safety significance. The Division dispatched inspectors for on-site investigations in 13 of the 20 cases reviewed and took suitable enforcement and follow-up actions. Documentation shows that follow-up to the incident is performed and well documented in investigation inspections, enforcement actions when required, and follow-up inspections. ^{WAS} _{WAS}

If the Division determines that an immediate onsite inspection is not warranted, via communications with the licensee and review of licensee's report, a Division instruction includes a process for closing out NMED items by preparing a letter to the licensee acknowledging receipt of the licensee's written report.

In evaluating the Division's actions in response to allegations, the review team evaluated 14 casework files. The review team noted that the allegation files are maintained by the Enforcement and Investigation Coordination Staff (EICS) of the Regional Office, which coordinates very well with the Division of Nuclear Materials Safety in addressing materials licensee allegations. The review team found records with allegations and supporting information well documented. The chronologically filed, well organized documentation makes files easy to follow from initial allegation, Allegation Review Board (ARB) meeting notes, communications with concerned individuals (CI) and licensees, and final resolution and closeout correspondence. Processes are timely, with timeline goals being met. The ARB schedules its meetings every Monday, so that the ARB is addressing all new allegations in a timely manner. The Program notified the concerned individuals of the conclusion of their investigations when the CI is known. The review team determined that the Program adequately protected the identity of concerned individuals. The EICS performs a final file review against a multi-page verification list prior to closure of the allegation to assure completeness of the record.

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

3.0 SUMMARY

As noted in Sections 2.0 and 3.0 above, the Region III's performance was found satisfactory for all of the performance indicators reviewed. The review team did not make any recommendations.

Accordingly, the review team recommends that the Region III Program be found adequate to protect public health and safety. Based on the results of the current IMPEP review, the review team recommends that the next IMPEP review take place in approximately 5 years.

REGION III IMPEP Draft Report
License Casework Reviews

Page D.2

File No.: 9

Licensee: University of Evansville

Type of Action: Renewal

Date Issued: 5/4/11

License No.: SNM-995

Amendment No.: 7

License Reviewer: WR

File No.: 10

Licensee: Reuter-Stokes, Inc.

Type of Action: Amendment

Date Issued: 2/22/12

License No.: SNM-1826

Amendment No.: 22

License Reviewer: CF

File No.: 11

Licensee: U.S. Environmental Protection Agency

Type of Action: Termination

Date Issued: 10/6/09

License No.: 12-10243-01

Amendment No.: 28

License Reviewers: KS, GM

File No.: 12

Licensee: Missouri Baptist Medical Center

Type of Action: Amendment

Date Issued: 7/9/12

License No.: 24-11128-02

Amendment No.: 77

License Reviewer: SF

File No.: 13

Licensee: Indiana University Medical Center

Type of Action: Renewal w/ license condition exemptions

Date Issued: 7/24/12

License No: 13-02752-08

Amendment No.: 32

License Reviewer: SF

File No.: 14

Licensee: Aptuit, LLC

Type of Action: Void w/ two-part Amendment (change of control)

Date Issued: 9/22/11 & 1/4/12

License No.: 24-15595-01

Amendment No.: 33

License Reviewer: WR

File No.: 15

Licensee: Aptuit, LLC

Type of Action: Void - Decommissioning Plan

Date Issued: 5/11/12

License No.: 24-15595-01

Amendment No.: N/A

License Reviewer: LR

File No.: 16

Licensee: St. Anthony's Medical Center

Type of Action: Amendment

Date Issued: 9/4/12 w/ safety culture paragraph

License No: 24-01041-04

Amendment No.: 54

License Reviewer: FT

File No.: 17

Licensee: Providence Hospital

Type of Action: Amendment

Date Issued: 9/4/20 w/ safety culture paragraph

License No.: 21-02802-03

Amendment No.: 74

License Reviewer: FT

** Please see
Attached comments
for specific file
numbers. (Attached*

APPENDIX E

INCIDENT CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

File No.: 1

Licensee: Karmanos Cancer Center
Date of Incident: 10/24/07
Investigation Date: 10/29/11-12/14/11

License No.: 21-04127-06
NMED No.: 070672
Type of Incident: Medical Event
Type of Investigation: Site

File No.: 2

Licensee: Providence Hospital
Date of Incident: 8/30/10
Investigation Date: 9/16/10

License No.: 21-02802-03
NMED No.: 100448
Type of Incident: Medical Event
Type of Investigation: Site

File No.: 3

Licensee: Deaconess Hospital
Date of Incident: 3/5/12
Investigation Date: To be determined

License No.: 13-00142-02
NMED No.: 120480
Type of Incident: Medical Event
Type of Investigation: To be determined

Comment: The 3/5/12 event was not reported to NRC until 8/16/12, with the licensee's written report letter received 8/31/12. Region is pursuing medical consultant assistance.

File No.: 4

Licensee: Calumet Testing Services, Inc.
Date of Incident: 7/22/08
Investigation Date: 9/29/08

License No.: 13-16347-01
NMED No.: 080416
Type of Incident: Equipment Failure
Type of Investigation: Site

File No.: 5

Licensee: Walmart
Date of Incident: 9/9/08
Investigation Date: 12/9/08

License No.: General
NMED No.: 080839
Type of Incident: Lost/Stolen/Abandoned RAM
Type of Investigation: Site

File No.: 6

Licensee: NUCOR Steel
Date of Incident: 2/8/12
Investigation Date: N/A

License No.: 13-25975-01
NMED No.: 120098
Type of Incident: Equipment Failure
Type of Investigation: Next Inspection

File No.: 15
Licensee: Evonik DeGussa Corp.
Date of Incident: 8/13/10
Investigation Date: N/A

delete
License No.: General
NMED No.: 100528
Type of Incident: ~~Lost~~ Lost/Stolen/Abandoned RAM
Type of Investigation: Licensee report

File No.: 16
Licensee: Mallinckrodt Inc.
Date of Incident: 2/13/11
Investigation Date: 4/2/12 – 4/6/12

License No.: 24-04206-01
NMED No.: 110094
Type of Incident: Lost/Stolen/Abandoned RAM
Type of Investigation: Site

File No.: 17
Licensee: Westinghouse Electric Company, LLC
Date of Incident: 0/4/08
Investigation Date: 3/10/08

License No.: SNM-033
NMED No.: 080288
Type of Incident: Release of RAM
Type of Investigation: Site

File No.: 18
Licensee: Community Hospitals of Indiana
Date of Incident: 10/6/10
Investigation Date: 10/18/10 – 10/20/10

License No.: 13-06009-01
NMED No.: 100506
Type of Incident: Medical Event
Type of Investigation: Site

File No.: 19
Licensee: Indiana Department of Transportation
Date of Incident: 9/10/07
Investigation Date: 9/18/07

License No.: 13-26341-01
NMED No.: 070567
Type of Incident: Lost/Stolen/Abandoned RAM
Type of Investigation: Site

File No.: 20
Licensee: ATC Associates, Inc.
Date of Incident: 8/9/09
Investigation Date: 8/25/09

License No.: 13-17732-01
NMED No.: 090660
Type of Incident: Lost/Stolen/Abandoned RAM
Type of Investigation: Site

** Specific dates for
 selected App. E File Numbers.*

APPENDIX E

INCIDENT CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

File No.: 1 Licensee: Karmanos Cancer Center Date of Incident: 10/24/07 Investigation Date: 10/29/11-12/14/11	License No.: 21-04127-06 NIMED No.: 070672 Type of Incident: Medical Event Type of Investigation: Site
File No.: 2 Licensee: Providence Hospital Date of Incident: 8/30/10 Investigation Date: 9/16/10	License No.: 21-02802-03 NIMED No.: 100448 Type of Incident: Medical Event Type of Investigation: Site
File No.: 3 Licensee: Deaconess Hospital Date of Incident: 3/5/12 Investigation Date: To be determined	License No.: 13-00142-02 NIMED No.: 120480 Type of Incident: Medical Event Type of Investigation: To be determined
Comment: The 3/5/12 event was not reported to NRC until 8/16/12, with the licensee's written report letter received 8/31/12. Region is pursuing medical consultant assistance.	
File No.: 4 Licensee: Calumet Testing Services, Inc. Date of Incident: 7/22/08 Investigation Date: 9/29/08	License No.: 13-16347-01 NIMED No.: 080416 Type of Incident: Equipment Failure Type of Investigation: Site
File No.: 5 Licensee: Walmart Date of Incident: 9/9/08 Investigation Date: 12/9/08	License No.: General NIMED No.: 080839 Type of Incident: Lost/Stolen/Abandoned RAM Type of Investigation: Site
File No.: 6 Licensee: NUCOR Steel Date of Incident: 2/1/08 Investigation Date: N/A	License No.: 13-25875-01 NIMED No.: 120098 Type of Incident: Equipment Failure Type of Investigation: Next Inspection

REGION III IMPEP Draft Report
Incident Casework Reviews

File No.: 7
Licensee: Department of the Army
Date of Incident: 1/4/11
Investigation Date: 2/21/11

License No.: 42-007220-06
NIMED No.: 110016
Type of Incident: Equipment Damage
Type of Investigation: Licensee Report

File No.: 8
Licensee: Department of Veterans Affairs
Date of Incident: 2/6/12
Investigation Date: 5/1/12

License No.: 03-23852-01VA
NIMED No.: 120095
Type of Incident: Contamination Event
Type of Investigation: Licensee Report

File No.: 9
Licensee: Janx
Date of Incident: 6/27/09
Investigation Date: 7/1/09

License No.: 21-16560-01
NIMED No.: 090080
Type of Incident: Transportation
Type of Investigation: Licensee Report

File No.: 10
Licensee: Westinghouse Electric Company, LLC
Date of Incident: 3/26/09
Investigation Date: 8/24/09 - 8/26/09

License No.: SNM-0033
NIMED No.: 090479
Type of Incident: Release of RAM
Type of Investigation: Site

File No.: 11
Licensee: 3M Company
Date of Incident: 5/21/12
Investigation Date: 5/21/12

License No.: 22-00057-03
NIMED No.: 120332
Type of Incident: Equipment Failure
Type of Investigation: Licensee Report

File No.: 12
Licensee: William Beaumont Hospital
Date of Incident: 4/27/11
Investigation Date: 5/2/11 - 5/5/11

License No.: 21-01333-01
NIMED No.: 110193
Type of Incident: Medical Event
Type of Investigation: Site

File No.: 13
Licensee: Liberty Hospital
Date of Incident: 10/6/10
Investigation Date: 10/13/10 - 10/14/10

License No.: 24-16178-01
NIMED No.: 100507
Type of Incident: Medical Event
Type of Investigation: Site

File No.: 14
Licensee: Mid-America Isotopes, Inc.
Date of Incident: 5/20/12
Investigation Date: 5/23/12

License No.: 24-26241-01MD
NIMED No.: 120409
Type of Incident: Lost/Stolen/Abandoned RAM
Type of Investigation: Site

Author: TEB Subject: Safety Note Date: 11/16/2012 8:38:31 AM
Addressed by the IMPEP and confirmed via e-mail dated 2/6/12

Author: TEB Subject: Safety Note Date: 11/16/2012 1:15:49 PM
no additional information, following phone call made

Author: TEB Subject: Safety Note Date: 11/15/2012 5:45:00 PM
contacted licensee, responses reviewed and requested additional information, information provided and acknowledged on Aug 24, 2012

REGION III IMPEP Draft Report
Incident Casework Reviews

File No.: 15

Licensee: Evonik DeGussa Corp.
Date of Incident: 8/13/08
Investigation Date: N/A

Type of Incident: License No.: General
NIMED No.: 100528
Type of Investigation: Licensee report

File No.: 16

Licensee: Mallinckrodt Inc.
Date of Incident: 2/13/11
Investigation Date: 4/2/12 - 4/6/12

Type of Incident: License No.: 24-04206-01
NIMED No.: 110094
Type of Investigation: Lost/Stolen/Abandoned RAM

File No.: 17

Licensee: Westinghouse Electric Company, LLC
Date of Incident: 04/08
Investigation Date: 3/10/08

Type of Incident: License No.: SNM-033
NIMED No.: 080288
Type of Investigation: Release of RAM

File No.: 18

Licensee: Community Hospitals of Indiana
Date of Incident: 10/6/10
Investigation Date: 10/18/10 - 10/20/10

Type of Incident: License No.: 13-06009-01
NIMED No.: 100506
Type of Investigation: Medical Event

File No.: 19

Licensee: Indiana Department of Transportation
Date of Incident: 9/10/07
Investigation Date: 9/18/07

Type of Incident: License No.: 13-26341-01
NIMED No.: 070567
Type of Investigation: Lost/Stolen/Abandoned RAM

File No.: 20

Licensee: ATC Associates, Inc.
Date of Incident: 8/9/09
Investigation Date: 8/25/09

Type of Incident: License No.: 13-17732-01
NIMED No.: 090660
Type of Investigation: Lost/Stolen/Abandoned RAM

Author: TEB
Subject: Study Note
Date: 11/15/2012 9:27:19 AM
data loaded for 10/24/10 phone call was done, review of 30 day report, and Enforcement Action dated 10/15/08 closed the issue

Author: TEB
Subject: Study Note
Date: 11/16/2012 11:56:06 PM
remove duplicate list