December 12, 2007

MEMORANDUM TO: James L. Caldwell, Regional Administrator
Region III

FROM: Martin J. Virgilio ***/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 (IMPEP) REVIEW OF THE REGION III RADIOACTIVE MATERIALS PROGRAM

On November 13, 2007, the Management Review Board (MRB) met to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) report of the U.S. Nuclear Regulatory Commission's Region III radioactive materials program. The MRB found the program to be adequate to protect public health and safety. Based on the results of the review, the MRB concluded that the next full IMPEP review of the Region III radioactive materials program should take place in approximately 4 years.

Section 4.0, page 8, 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 and identified two good practices.

If you have any questions, please contact Aaron McCraw at (301) 415-1277.

We appreciate your staff's efforts during the IMPEP review period, especially during the time of the team's visit. We likewise appreciate the performance of the Region III program and look forward to our continued interaction.

Enclosure:
Region III Final IMPEP Report

cc: Mark A. Satorius, RIII

Steven A. Reynolds, RIII

Jared Thompson, Arkansas
Organization of Agreement States
Liaison to the MRB

December 12, 2007

MEMORANDUM TO: James L. Caldwell, Regional Administrator
Region III

FROM: Martin J. Virgilio ***/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 (IMPEP) REVIEW OF THE REGION III RADIOACTIVE MATERIALS PROGRAM

On November 13, 2007, the Management Review Board (MRB) met to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) report of the U.S. Nuclear Regulatory Commission's Region III radioactive materials program. The MRB found the program to be adequate to protect public health and safety. Based on the results of the review, the MRB concluded that the next full IMPEP review of the Region III radioactive materials program should take place in approximately 4 years.

Section 4.0, page 8, 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 and identified two good practices.

If you have any questions, please contact Aaron McCraw at (301) 415-1277.

We appreciate your staff's efforts during the IMPEP review period, especially during the time of the team's visit. We likewise appreciate the performance of the Region III program and look forward to our continued interaction.

Enclosure:
Region III Final IMPEP Report

cc: Mark A. Satorius, RIII

Steven A. Reynolds, RIII

Jared Thompson, Arkansas
Organization of Agreement States
Liaison to the MRB

DISTRIBUTION: EDATS: FSME-2007-0037
See next page.

ML073330366

OFFICE	FSME/DMSSA		FSME/DMSSA		FSME/DMSSA		Tech Editor	
NAME	ATMcCraw:kk		ADWhite		RJLewis		CPoland	
DATE	11/30/07		11/30/07		11/30/07		12/04/07	
OFFICE	FSME		DEDMRT					
NAME	GPangburn		MJVirgilio					
DATE	12/06/07		12/12/07					

OFFICIAL RECORD COPY

MEMORANDUM TO J. CALDWELL FROM M. VIRGILIO DATED: December 12, 2007

Distribution: **EDATS: FSME-2007-0037**

DMSSA RF
EDO RF
RidsFsmeOD
RidsSecyCorrespondenceMailCenter
KLukes, FSME/DMSSA
JLynch, Region III/RSAO
SHammann, Region I
RLeonardi, Region IV
Robin Rademacher, NC
DDiaz-Toro, OEDO
APowell, OCA (2 copies)
KCyr, OGC
FCameron, OGC
CMiller, FSME
JSchlueter, FSME

DCD (SP01)

Chairman Klein
Commissioner Jaczko
Commissioner Lyons
SECY

United States Nuclear Regulatory Commission

Protecting People and the Environment

INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF THE NRC REGION III RADIOACTIVE MATERIALS PROGRAM

August 27-30, 2007

FINAL REPORT

ENCLOSURE

1.0 INTRODUCTION

This report presents the results of the review of the U.S. Nuclear Regulatory Commission (NRC) Region III radioactive materials program. The review was conducted during the period of August 27-30, 2007, by a review team comprised of technical staff members from the NRC and the State of North Carolina. 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 the February 26, 2004, NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." Preliminary results of the review, which covered the period of March 29, 2003, to August 30, 2007, were discussed with Region III managers on the last day of the review.

A draft of this report was issued to the Region for factual comment on September 25, 2007. Region III responded by e-mail on October 22, 2007, from Steven A. Reynolds, Director, Division of Nuclear Materials Safety (the Division). A copy of the Region's response is included as the Attachment to this report. The Management Review Board (MRB) met on November 13, 2007, to consider the proposed final report. The MRB found the Region III radioactive materials program to be adequate to protect public health and safety.

The Region III radioactive materials program is administered by the Director of the Division, who reports directly to the Regional Administrator. Organization charts for Region III and the Division are included as Appendix B. At the time of the review, the Division regulated approximately 1,250 specific licenses authorizing the possession and use of radioactive materials.

In preparation for the review, a questionnaire addressing the common performance indicators was sent to the Division on April 12, 2007. The Division provided its response to the questionnaire on August 10, 2007. A copy of the questionnaire response may be found in the NRC's Agencywide Documents Access and Management System (ADAMS) using Accession Number ML072680482.

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 licensing, inspection, and allegation databases, as well as ADAMS; (3) technical review of selected regulatory actions; (4) field accompaniments of four of the Division's radioactive materials inspectors; and (5) interviews with staff and managers to answer questions or clarify issues. 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.

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

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous IMPEP review, which concluded on March 28, 2003, the review team made no recommendations in regard to program performance.

3.0 COMMON PERFORMANCE INDICATORS

IMPEP identifies five common performance indicators to be used in reviewing 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

Issues central to the evaluation of this indicator include the Division's staffing level and staff turnover, as well as the technical qualifications and training histories of the staff. To evaluate these issues, the review team examined the Division's questionnaire response relative to this indicator; interviewed Division managers and staff; and reviewed job descriptions, training plans, and training records. The review team also considered any possible workload backlogs in evaluating this indicator.

During the 2003 IMPEP review, the Division was composed of four branches: the Materials Licensing Branch, the Materials Inspection Branch, the Decommissioning Branch, and the Fuel Cycle Branch. During the review period, the NRC's Regional Fuel Cycle Inspection Program was consolidated in the Region II Atlanta Office, effectively eliminating the Division's Fuel Cycle Branch. The Division currently operates with the Materials Licensing Branch, the Inspection Branch, and the Decommissioning Branch; each headed by a Branch Chief.

At the time of the review, the Division was staffed with 23 direct full time equivalents (FTE), a reduction of 2.5 direct FTE from the previous IMPEP review. The decrease in FTE can be attributed to the transfer of approximately 415 radioactive materials licenses to two States that became Agreement States during the review period (Wisconsin in 2003 and Minnesota in 2006). Overall, staffing was relatively stable over the review period. The review team noted that there was considerable turnover in the Decommissioning Branch Chief position; however, the turnover did not appear to affect the Decommissioning Branch's performance during the review period. At the time of the review, the Division had no vacant positions.

The review team determined that the Division's Operational Management Information (OMI) reports help Division managers efficiently use their staff resources. Despite the reduction in direct FTE, the Division has been capable of taking on additional workload, such as Increased Controls inspections. The Division is also assisting the Region I radioactive materials program by performing inspections in Region I while Region I is focusing its resources on the proposed Section 274b. (of the Atomic Energy Act) Agreement with the Commonwealth of Pennsylvania. The Division has also been very active in contributing resources to NRC Working Groups and IMPEP reviews of other NRC Regional Offices and Agreement State programs.

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. During the review period, one individual successfully completed the Nuclear Safety Professional Development Program (NSPDP) and achieved inspector qualification. At the time of the review, one NSPDP participant in the Decommissioning Branch was undergoing inspector qualification and training. This individual is expected to complete the required qualifications and training by July 2008. Division managers are supportive of staff training opportunities. A majority of the Division’s radioactive materials inspectors have attended the NRC’s Security Systems and Principles Course.

To promote knowledge management, the Division takes advantage of mentoring opportunities of less experienced staff. New staff is assigned a specific senior technical staff member as a mentor. The review team found that all senior technical staff members are willing to provide guidance and assist newer staff on their assigned projects.

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, was satisfactory.

3.2 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’s evaluation was based 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 Division managers and staff.

The review team verified that the Division adheres to the inspection priorities prescribed in IMC 2800, “Materials Inspection Program.” The Division appropriately modified inspection schedules in response to revisions to IMC 2800 during the review period. The review team noted that the Division continues to implement its broad scope inspection initiative as discussed in the 1999 and 2003 IMPEP reports. This initiative allows several partial inspections of major broad scope licensees to be conducted within the inspection cycle, as long as all inspection objectives are met through the aggregation of the partial inspections.

The review team determined that the Division conducted 752 inspections of Priority 1, 2, and 3 licensees during the review period. The review team identified five of these inspections as performed overdue by more than 25 percent of the inspection frequency listed in IMC 2800. Three of the overdue inspections can be attributed to input errors into the Licensing Tracking System (LTS). For these three cases, the inspection priorities changed because of program code changes; however, the dates of the next inspections were not modified in LTS, thereby causing the inspections to be performed based on their previous inspection priority. The review team determined that the Division conducted 207 initial inspections of new radioactive materials licenses during the review period. Of the 207 initial inspections, two were performed greater than 12 months after license issuance. Overall, the review team calculated that the Division performed 0.7 percent of all Priority 1, 2, and 3 inspections and initial inspections overdue during the review period.

During the on-site portion of the review, the Division demonstrated its Inspection Planner Database to the review team. This database was independently developed by the Division to gain efficiency in the inspection planning process. The database is populated and updated by monthly downloads from LTS. Information provided from LTS, such as a licensee's address and inspection dates, can be automatically entered into the respective fields on the planning form when a licensee's name or license number is selected, saving the inspector time by 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, the inspector can input the completion data to generate an update for LTS. At this time, the database cannot automatically update LTS. Any changed information must be manually entered into LTS. With the ability to automatically update LTS, the Division's database would be a more powerful, time-saving tool. The review team believes that the Division's database could be a beneficial tool for the other NRC Regional Offices. The database is also capable of generating the inspection information for the monthly OMI reports.

The review team evaluated the timeliness of issuance of inspection findings to licensees using the inspection casework reviews and the Division's monthly OMI reports. Inspection reports were generally issued to the licensee within 30 days, with the majority of findings being issued at the conclusion of the inspection via NRC Form 591.

During the review period, the Division granted 36 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 review team determined that the Division exceeded the NRC's goal of inspecting 20 percent of candidate licensees operating under reciprocity in each of the four years covered by the review period.

The review team determined that the Division adequately planned for the initial set of Increased Controls inspections of the affected licensees. The Division's prioritization methodology was consistent with the prioritization methodology provided by NRC Headquarters. The Division has 80 licensees that are implementing the Increased Controls. At the time of the review, the Division had performed 48 Increased Controls inspections, including all 18 inspections that were to be completed in the first year of implementation. Division managers were confident that all Increased Controls inspections would be completed within the Commission's allotted time frame.

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, was satisfactory.

3.3 Technical Quality of Inspections

The review team evaluated the inspection reports, enforcement documentation, inspection field notes, and interviewed inspectors for 21 radioactive materials inspections conducted during the review period. The casework reviewed included inspections conducted by 12 of the Division's inspectors and covered inspections of various license types, including: medical broad scope, medical institutions requiring written directives, mobile medical, fixed and portable gauges, industrial radiography, research and development broad scope, irradiator, medical therapy,

nuclear pharmacy, manufacturer and distribution broad scope, exempt distribution, special nuclear material, decommissioning, Increased Controls, and reciprocity. Appendix C lists the inspection casework files reviewed, as well as the results of the inspector accompaniments.

The review team found that inspection reports were generally thorough, complete, consistent, and of high quality, with sufficient documentation to ensure that a licensee's performance with respect to health, safety, and security was acceptable. Inspection findings led to appropriate and prompt regulatory action, when necessary. Based on the review of casework, the review team concluded that routine inspections covered all aspects of the licensees' radiation safety programs commensurate with licensed activities.

The inspection procedures utilized by the Division are generally consistent with the inspection guidance outlined in IMC 2800 and other NRC inspection procedures. The most notable deviation is the Division's broad scope inspection initiative. This initiative increases the communication with several large licensees and provides the Division some flexibility in scheduling and completing inspections of these facilities.

Supervisory accompaniments were generally conducted annually for all inspectors. The Branch Chiefs made a total of 144 accompaniments during the review period. Two inspectors each had one annual accompaniment which was missed; however, both of these inspectors have many years' experience inspecting radioactive materials licensees. Inspectors receive verbal feedback at the time of the accompaniments, and a portion of the inspectors' annual performance appraisals address their inspection skills, as demonstrated during the accompaniments.

The review team observed that the Division maintains an adequate supply of survey instruments to support their inspection program. Appropriate, calibrated survey instrumentation, such as Geiger-Mueller (GM) meters, scintillation detectors, ion chambers, and micro-R meters, was observed to be available. Instruments are calibrated annually through a commercial calibration service. The Division uses a contract laboratory for radioanalysis of samples taken during inspections.

Accompaniments of four Division inspectors were conducted by two IMPEP team members during the weeks of July 30, August 6, and August 20, 2007. The inspectors were accompanied during health and safety inspections of medical institutions and Increased Controls inspections. The accompaniments are identified in Appendix C. During the accompaniments, all of 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 audits of the licensees' radiation safety programs and implementation of the Increased Controls orders. 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 Increased Controls 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, was satisfactory.

3.4 Technical Quality of Licensing Actions

The review team examined completed licensing casework and interviewed license reviewers for 22 specific licenses. Licensing actions were reviewed for completeness, consistency, proper radioisotopes and quantities, qualifications of authorized users, adequate facilities and equipment, adherence to good health physics practices, financial assurance, operating and emergency procedures, appropriateness of the license conditions, Increased Controls, and overall technical quality. The casework was also reviewed for timeliness, use of appropriate deficiency letters and cover letters, reference to appropriate regulations, product certifications, supporting documentation, consideration of enforcement history, pre-licensing visits, supervisory review as indicated, and proper signatures. The casework was checked for retention of necessary documents and supporting data.

The licensing casework was selected to provide a representative sample of licensing actions completed during the review period. The review team evaluated 30 licensing actions, covering the work of 11 license reviewers. Licensing actions selected for evaluation included 6 new licenses, 2 renewals, 19 amendments, 2 terminations, and 1 reciprocity request. The sampling included the following license types: research and development broad (master material license), research and development, medical (broad, private practice - no written directive, gamma knife, and high dose-rate remote afterloader), industrial radiography, portable gauge, fixed gauge, panoramic irradiator, decommissioning, manufacturing and distribution, and nuclear pharmacy. A listing of the licensing casework evaluated can be found 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, backed by information contained in the file, and auditable. Licenses and correspondence are generated using standardized conditions and formats. Licensing staff appropriately used licensing guides, policies, and standard license conditions. Licensees' compliance histories were taken into account when reviewing all renewal applications and major amendments. At the time of the review, the Division had no licensing actions pending beyond the established acceptable turnaround times. Licenses are issued for a 10-year period.

Each licensing action is given a technical review by a license reviewer. All license reviewers have signature authority. The Licensing Branch Chief performs a technical and supervisory review on files in accordance with established policy. Regular meetings of licensing staff allow opportunity for managers to introduce, implement, and provide and gather feedback on new or ongoing initiatives. Licensing actions selected by the Licensing Branch Chief are peer reviewed as part of quarterly meetings to augment the Division's other quality assurance and quality control measures.

The review team evaluated the Division's reciprocity licensing activities. Requests for reciprocity from Agreement State licensees and other NRC Regions are processed promptly. Expiration dates on Agreement State licenses are verified. For Agreement State licenses expiring within the current calendar year, authorization for reciprocal work in Region III terminates on the date of expiration unless the licensee can provide an updated license, which would extend their reciprocal recognition through the end of the calendar year.

The review team evaluated the Division's financial assurance and decommissioning activities. Ongoing financial assurance reviews are tracked through LTS, including milestones. Review of the files and milestones reported for open files revealed applicant/licensee turnaround times to be the source of delays in issuance. The review team found that terminations and amendments to remove or release locations for either controlled or uncontrolled use were well-documented, showing appropriate material transfer and survey records. The review team identified no performance issues with the Division's financial assurance and decommissioning activities.

The Division developed a decommissioning guidance website through Region III's internal website. The decommissioning guidance website contains links to pertinent information and guidance documents for decommissioning, such as NUREGs, and also includes a number of out-of-print and hard-to-find documents. Maintenance of the website is performed in-house by the Division, and as additional useful documents are identified or suggested, the webmaster adds them to the website. The review team recommended, and the MRB agreed, that the Division's decommissioning guidance web site be identified as a good practice.

The review team examined the list of licensees that were determined to meet the criteria for the Increased Controls. The review team determined that the appropriate licensees were issued Orders that required implementation of the Increased Controls. While no new licenses requiring the Increased Controls have been issued since May 2006, the Division has a process in place for evaluating new license applications' subjectivity to the Increased Controls. During the amendment process, the Division reviews requested authorization limits and works with the licensees to either impose the Increased Controls via license condition or to cap authorization limits to eliminate the need for the Increased Controls.

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, was satisfactory.

3.5 Technical Quality of Incident and Allegation Activities

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

The review team identified 202 radioactive materials incidents in NMED for Region III during the review period, of which 166 were reportable under NRC criteria. The incidents selected for review included the following categories: medical, lost/stolen material, exposure to embryo/fetus, and equipment failure. The review team discussed incident and allegation procedures, file documentation, NMED, and the role of the NRC Headquarters Operations Center with Division staff and managers. The Division is responsible for initial response and followup actions to radioactive materials incidents. The review team determined that the Division's response to incidents was 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 a majority of the cases reviewed and took suitable enforcement and followup actions.

The Division has created a picture gallery of radioactive material-related photographs. The gallery, which is organized by types of use and modality, contains photographs and schematic diagrams of devices, sources, and facilities. The gallery provides the Division with the ability to include pictures and diagrams in incident briefings to enhance the effectiveness of the briefings to individuals that may not be knowledgeable of such sources, devices, or facilities. The gallery also provides the Division with an excellent source of visual aids for inclusion in non-incident-related discussions and presentations, such as in-house training courses or topical seminars. The gallery can also be used to educate new staff members on the appearance and use of such devices, sources, and facilities. The review team recommended, and the MRB agreed, that the Division's picture gallery be identified as a good practice.

In evaluating the effectiveness of the Division's actions in response to allegations, the review team evaluated the casework for 13 allegations. The review team held interviews with the Regional Allegations Coordinators, Division managers, and Division technical staff regarding the handling of allegations, as well as reviewed the Division's response to the questionnaire relative to this indicator. The Division adheres to NRC Management Directive 8.8, "Management of Allegations," in the handling of allegations. The review team's evaluation of casework, associated documentation, and interviews with staff and managers revealed that the Division has an effective and efficient program for managing radioactive materials allegations. The casework review indicated that the Division took prompt and appropriate action in response to all concerns raised. All of the allegations reviewed were appropriately closed, and appropriate parties were notified of the actions taken.

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, was satisfactory.

4.0 SUMMARY

As noted in Section 3.0, Region III's performance was found satisfactory for all performance indicators reviewed. The review team made no recommendations regarding program performance and identified two good practices. Accordingly, the review team recommended, and the MRB agreed, that the NRC Region III radioactive materials program was adequate to protect public health and safety. Based on the results of the current IMPEP review, the review team recommended, and the MRB agreed, that the next full IMPEP review of the NRC Region III radioactive materials program take place in approximately 4 years.

LIST OF APPENDIXES AND ATTACHMENT

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
Attachment	October 22, 2007, E-mail from Steven Reynolds Region III's Response to Draft IMPEP Report

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	**Area of Responsibility**
Aaron McCraw, FSME	Team Leader Technical Staffing and Training Status of Materials Inspection Program
Stephen Hammann, Region I	Technical Quality of Inspections Inspector Accompaniments
Robin Rademacher, NC	Technical Quality of Licensing Actions
Richard Leonardi, Region IV	Technical Quality of Incident and Allegation Activities Inspector Accompaniments

APPENDIX B

REGION III ORGANIZATION CHARTS

ADAMS ACCESSION NO.: ML072680567

APPENDIX C

INSPECTION CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS ONLY.

File No.: 1
Licensee: Mallinckrodt, Inc. License No.: 24-04206-01
Inspection Type: Routine, Unannounced Priority: 2
Inspection Dates: 9/18-22/06 Inspectors: DW, BH

File No.: 2
Licensee: Hayes Testing Laboratory License No.: KY-201-168-05
Inspection Type: Reciprocity Priority: N/A
Inspection Date: 7/27/07 Inspector: GP

File No.: 3
Licensee: Holland Community Hospital License No.: 21-18502-01
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 3/21/05 Inspectors: SM, EK

File No.: 4
Licensee: Capital Pharmacy License No.: 21-26597-01MD
Inspection Type: Routine, Unannounced Priority: 2
Inspection Date: 1/19/06 Inspector: GP

File No.: 5
Licensee: Mathy Construction Company License No.: 48-18722-01
Inspection Type: Routine, Unannounced Priority: 5
Inspection Date: 4/16/07 Inspector: EK

File No.: 6
Licensee: Lone Star Industries, Inc. License No.: 13-12374-01
Inspection Type: Routine, Unannounced Priority: 5
Inspection Date: 11/30/05 Inspector: TG

File No.: 7
Licensee: Centocor Biologics, LLC License No.: 24-32396-01
Inspection Type: Routine, Unannounced Priority: 5
Inspection Date: 3/28/06 Inspector: ML

File No.: 8
Licensee: University of Minnesota License No.: 22-00187-46
Inspection Type: Special Priority: N/A
Inspection Dates: 1/31-2/23/05 Inspectors: ML, SB

File No.: 9
Licensee: MTI Industries, Inc. License No.: 12-23905-01E
Inspection Type: Initial, Announced Priority: 5
Inspection Date: 5/25/05 Inspector: SM

File No.: 10
Licensee: Jackson Community College License No.: SNM-1171
Inspection Type: Special, Announced Priority: N/A
Inspection Date: 7/13/05 Inspector: GW

File No.: 11
Licensee: Mid-Michigan Diagnostic License No.: 21-32601-01
Inspection Type: Initial, Announced Priority: 3
Inspection Date: 5/11/06 Inspector: KL

File No.: 12
Licensee: Indiana University School of Medicine License No.: 13-18384-01
Inspection Type: Special, Unannounced Priority: 5
Inspection Dates: 8/22/06, 10/25/06 Inspector: JM

File No.: 13
Licensee: JANX Integrity Group License No.: 21-16560-01
Inspection Type: Special, Announced Priority: 2
Inspection Dates: 1/17-19/07 Inspector: BH

File No.: 14
Licensee: Michigan State University License No.: 21-00021-30
Inspection Type: Special, Announced Priority: 2
Inspection Dates: 2/26-28/07 Inspector: DW

File No.: 15
Licensee: Bronson Methodist Hospital License No.: 21-13125-01
Inspection Type: Special, Announced Priority: 2
Inspection Dates: 8/23-24/07 Inspector: DP

File No.: 16
Licensee: DBI, Inc. License No.: NE-02-46-01
Inspection Type: Reciprocity Priority: N/A
Inspection Date: 2/15/07 Inspector: GW

File No.: 17
Licensee: Hennepin County Medical Center
License No.: 22-11070-01
Inspection Type: Routine, Unannounced
Priority: 2
Inspection Date: 3/11/05
Inspector: DP

File No.: 18
Licensee: U.S. Steel Corporation
License No.: 21-10459-01
Inspection Type: Routine, Unannounced
Priority: 5
Inspection Date: 2/12/07
Inspector: SB

File No.: 19
Licensee: Sigma-Aldrich Company
License No.: 24-16273-01
Inspection Type: Routine, Unannounced
Priority: 3
Inspection Dates: 9/29-30/05
Inspector: DP

File No.: 20
Licensee: University of Michigan
License No.: 21-00215-04
Inspection Type: Routine, Announced
Priority: 2
Inspection Dates: 8/29-9/2/05
Inspectors: DW, SB

File No.: 21
Licensee: University of Michigan
License No.: 21-00215-04
Inspection Type: Routine, Announced
Priority: 2
Inspection Dates: 1/22-25/07
Inspector: DW

INSPECTOR ACCOMPANIMENTS

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

Accompaniment No.: 1
Licensee: Bloomington Hospital
License No.: 13-10408-02
Inspection Type: Routine, Unannounced
Priority: 3
Inspection Date: 8/9/07
Inspector: GW

Accompaniment No.: 2
Licensee: Henry Ford Hospital
License No.: 21-04109-16
Inspection Type: Special, Announced
Priority: 1
Inspection Dates: 8/23-24/07
Inspector: ML

Accompaniment No.: 3
Licensee: Heart Care Group, The
License No.: 24-32625-01
Inspection Type: Initial, Announced
Priority: 5
Inspection Date: 7/23/07
Inspector: DP

Accompaniment No.: 4
Licensee: SSM DePaul Health Center
License No.: 24-02490-03
Inspection Type: Routine, Unannounced
Priority: 2
Inspection Date: 7/23/07
Inspector: DP

Accompaniment No.: 5
Licensee: Army, Department of
License No.: 24-32221-01
Inspection Type: Special, Announced
Priority: 3
Inspection Dates: 7/24-25/07
Inspector: DP

Accompaniment No.: 6
Licensee: Army, Department of
License No.: 24-15095-01
Inspection Type: Routine, Announced
Priority: 3
Inspection Date: 7/24/07
Inspector: DP

Accompaniment No.: 7
Licensee: St. Luke's Hospital
License No.: 24-01570-03
Inspection Type: Routine, Unannounced
Priority: 2
Inspection Date: 7/26/07
Inspector: DP

Accompaniment No.: 8
Licensee: Community Memorial Hospital
License No.: 21-20250-01
Inspection Type: Routine, Unannounced
Priority: 3
Inspection Date: 8/8/07
Inspector: KL

Accompaniment No.: 9
Licensee: Schoolcraft Memorial Hospital
License No.: 21-16542-03
Inspection Type: Routine, Unannounced
Priority: 5
Inspection Date: 8/8/07
Inspector: KL

Accompaniment No.: 10
Licensee: Dickinson County Memorial
License No.: 21-18889-01
Inspection Type: Routine, Unannounced
Priority: 3
Inspection Date: 8/9/07
Inspector: KL

APPENDIX D

LICENSE CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS ONLY.

File No.: 1
Licensee: Saint Joseph's Hospital — License No.: 13-32277-01
Type of Action: Termination — Amendment No.: 11
Date Issued: 5/7/07 — License Reviewer: WR

File No.: 2
Licensee: Heart & Wellness Institute, PC — License No.: 21-32654-01
Type of Action: New — Amendment No.: N/A
Date Issued: 6/22/07 — License Reviewer: JM

File No.: 3
Licensee: William Beaumont Hospital — License No.: 21-01333-02
Types of Action: New, Amendments — Amendment Nos.: 0-2
Dates Issued: 12/13/06, 4/4/07, 7/30/07 — License Reviewer: TS

File No.: 4
Licensee: William Beaumont Hospital — License No.: 21-01333-01
Type of Action: Amendments — Amendment Nos.: 81, 82
Dates Issued: 10/10/06, 12/13/06 — License Reviewer: TS

File No.: 5
Licensee: Gateway Constructors — License No.: 24-32656-01
Type of Action: New — Amendment No.: N/A
Date Issued: 6/27/07 — License Reviewers: KN, JM

File No.: 6
Licensee: St. Mary's University of Minnesota — License No.: 22-00027-06
Type of Action: Termination — Amendment No.: 21
Date Issued: 10/13/05 — License Reviewer: KN

File No.: 7
Licensee: Goshen General Hospital — License No.: 13-18845-01
Type of Action: Amendment — Amendment No.: 35
Date Issued: 6/27/07 — License Reviewer: TS

File No.: 8
Licensee: Warner-Lambert, LLC — License No.: 21-01443-06
Type of Action: Amendment — Amendment No.: 60
Date Issued: 12/19/06 — License Reviewer: WS

File No.: 9
Licensee: American Radiolabeled Chemicals
Type of Action: Amendment
Date Issued: 7/28/06
License No.: 24-21362-01
Amendment No.: 37
License Reviewers: KN, PL

File No.: 10
Licensee: Warner-Lambert, LLC
Type of Action: Amendment
Date Issued: Pending
License No.: 21-01443-06
Amendment No.: N/A
License Reviewer: WS

File No.: 11
Licensee: Missouri Baptist Medical Center
Type of Action: Amendment
Date Issued: 1/26/07
License No.: 24-11128-02
Amendment No.: 64
License Reviewer: JM

File No.: 12
Licensee: Battelle Memorial Institute
Type of Action: Renewal
Date Issued: 6/7/07
License No.: SNM-7
Amendment No.: 33
License Reviewer: MM

File No.: 13
Licensee: Michigan Cardiology, P.C.
Types of Action: New, Amendments
Dates Issued: 8/25/03, 10/9/03, 6/30/05, 3/7/06
License No.: 21-32468-01
Amendment Nos.: 0-3
License Reviewers: CC, JM

File No.: 14
Licensee: Kraft Foods, Inc.
Types of Action: New, Amendment
Dates Issued: 5/17/04, 2/8/06
License No.: 12-32496-01
Amendment Nos.: 0, 1
License Reviewers: LH, WR

File No.: 15
Licensee: Radiopharmacy of Indianapolis
Type of Action: New
Date Issued: 4/3/07
License No.: 13-32637-01MD
Amendment No.: N/A
License Reviewer: TS

File No.: 16
Licensee: Testing Engineers & Consultants, Inc.
Type of Action: Renewal
Date Issued: 1/17/07
License No.: 21-18668-01
Amendment No.: 17
License Reviewer: LH

File No.: 17
Licensee: Midwest Research Institute
Type of Action: Amendment
Date Issued: 6/12/07
License No.: 24-02564-02
Amendment No.: 59
License Reviewer: KN

File No.: 18
Licensee: Whitney & Associates, Inc.
Type of Action: Reciprocity
Date Issued: 8/29/07
License No.: IL-01683-01
Amendment No.: N/A
License Reviewer: GP

File No.: 19
Licensee: Department of Veteran Affairs
Type of Action: Amendments
Dates Issued: 6/8/07, 8/28/07
License No.: 03-23853-01VA
Amendment Nos.: 5, 6
License Reviewer: CF

File No.: 20
Licensee: SSM DePaul Health Center
Type of Action: Amendment
Date Issued: 3/2/07
License No.: 24-02490-03
Amendment No.: 51
License Reviewer: CC

File No.: 21
Licensee: 3M Company
Type of Action: Amendment
Date Issued: 5/14/07
License No.: 22-00057-61
Amendment No.: 38
License Reviewer: CC

File No.: 22
Licensee: Elite Inspection Service Co., Inc.
Type of Action: Amendment
Date Issued: 5/2/07
License No.: 13-26712-01
Amendment No.: 10
License Reviewer: KN

APPENDIX E

INCIDENT CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS ONLY.

File No.: 1
Licensee: University of Michigan
Date of Incident: 4/1/03
Investigation Date: 4/9/03
License No.: 21-00215-04
Incident Log No.: NMED 030267
Type of Incident: Medical
Type of Investigation: Site

File No.: 2
Licensee: Washington University/Medical Center
Date of Incident: 7/9/03
Investigation Date: 7/22/03
License No.: 24-00167-11
Incident Log No.: NMED 030564
Type of Incident: Medical
Type of Investigation: Site

File No.: 3
Licensee: Lakeland Medical Center
Date of Incident: 11/11/03
Investigation Date: 11/19/03
License No.: 21-04177-01
Incident Log No.: NMED 030921
Type of Incident: Medical
Type of Investigation: Site

File No.: 4
Licensee: Indiana University Medical Center
Date of Incident: 9/15/04
Investigation Date: 11/3/04
License No.: 13-02752-03
Incident Log No.: NMED 040819
Type of Incident: Lost/Stolen RAM
Type of Investigation: Licensee Report

File No.: 5
Licensee: Imaging Subsurface, Inc.
Date of Incident: 11/2/04
Investigation Date: 11/4/04
License No.: 21-32050-01
Incident Log No.: NMED 040798
Type of Incident: Unsecured RAM
Type of Investigation: Site

File No.: 6
Licensee: William Beaumont Hospital
Date of Incident: 6/8/04
Investigation Date: 6/10/04
License No.: 21-01333-01
Incident Log No.: NMED 040415
Type of Incident: Medical
Type of Investigation: Site

File No.: 7
Licensee: University of Minnesota
Date of Incident: 1/25/05
Investigation Date: 1/31/05
License No.: 22-00187-46
Incident Log No.: NMED 050065
Type of Incident: Medical
Type of Investigation: Site

File No.: 8
Licensee: St. John's Mercy Medical Center
Date of Incident: 3/9/05
Investigation Dates: 3/15-16/05
License No.: 24-00794-03
Incident Log No.: NMED 050143
Type of Incident: Medical
Type of Investigation: Site

File No.: 9
Licensee: Porter Valparaiso Hospital Campus
Date of Incident: 2/16/05
Investigation Date: 2/23/05
License No.: 13-17073-01
Incident Log No.: NMED 050098
Type of Incident: Medical
Type of Investigation: Site

File No.: 10
Licensee: Saint Mary's Health Care
Date of Incident: 2/16/06
Investigation Date: 2/28/06
License No.: 21-01078-01
Incident Log No.: NMED 060123
Type of Incident: Contamination
Type of Investigation: Licensee Report

File No.: 11
Licensee: Southeast Missouri State University
Date of Incident: 2/17/06
Investigation Date: 2/21/06
License No.: 24-09296-02
Incident Log No.: NMED 060124
Type of Incident: Contamination
Type of Investigation: Site

File No.: 12
Licensee: Indiana University Medical Center
Date of Incident: 3/29/06
Investigation Dates: 4/3-4/06
License No.: 13-02752-03
Incident Log No.: NMED 060216
Type of Incident: Medical
Type of Investigation: Site

File No.: 13
Licensee: Indiana University Medical Center
Date of Incident: 3/29/06
Investigation Dates: 4/3-4/06
License No.: 13-02752-03
Incident Log No.: NMED 060219
Type of Incident: Medical
Type of Investigation: Site

File No.: 14
Licensee: Saint Joseph Health Center
Date of Incident: 6/28/06
Investigation Dates: 7/10-11/06
License No.: 24-15159-01
Incident Log No.: NMED 060430
Type of Incident: Medical
Type of Investigation: Site

File No.: 15
Licensee: University of Missouri
Date of Incident: 10/3/06
Investigation Date: 10/4/06
License No.: 24-09296-02
Incident Log No.: NMED 060124
Type of Incident: Lost/Stolen RAM
Type of Investigation: Licensee Report

File No.: 16
Licensee: Hackley Hospital
Date of Incident: 1/8/07
Investigation Dates: 1/11-12/07

License No.: 21-04125-01
Incident Log No.: NMED 070024
Type of Incident: Medical
Type of Investigation: Site

File No.: 17
Licensee: Community Hospitals of Indiana, Inc.
Date of Incident: 4/18/07
Investigation Date: 4/25/07

License No.: 13-06009-01
Incident Log No.: NMED 070235
Type of Incident: Medical
Type of Investigation: Site

File No.: 18
Licensee: Washington University in St. Louis
Date of Incident: 5/29/07
Investigation Date: 6/5/07

License No.: 24-00167-11
Incident Log No.: NMED 070339
Type of Incident: Overexposure
Type of Investigation: Site

File No.: 19
Licensee: Lester E. Cox Medical Center
Dates of Incidents: 7/10,17,24/07
Investigation Date: 8/2/07

License No.: 24-01143-06
Incident Log No.: NMED 070471
Type of Incidents: Medical
Type of Investigation: Site

File No.: 20
Licensee: Soil & Materials Engineers, Inc.
Date of Incident: 6/25/07
Investigation Date: 6/26-27/07

License No.: 21-17158-02
Incident Log No.: NMED 070387
Type of Incident: Equipment Failure
Type of Investigation: Site

ATTACHMENT

October 22, 2007, E-mail from Steven Reynolds
Region III's Response to Draft IMPEP Report

ADAMS: ML072970853