

March 24, 2011

MEMORANDUM TO: Anne T. Boland, Director
Division of Nuclear Materials Safety

FROM: James L. Lynch, State Agreements Officer */RA/*
Division of Nuclear Materials Safety

SUBJECT: 2011 MINI-IMPEP SELF-ASSESSMENT

The purpose of this self-assessment was to evaluate the status of the Division's licensing, inspection, incident and allegation response, and training programs, in preparation for the next Region III Integrated Materials Performance Evaluation Program (IMPEP) review.

The IMPEP review, originally scheduled for September 2011, has been rescheduled for the Fall 2012, in light of favorable past review findings.

The self-assessment was performed by the Regional State Agreements Officer, James Lynch, and two Senior Health Physicists, Aaron McCraw and Toye Simmons.

Overall, the team confirmed that the Division is on course for fully satisfactory findings during the next IMPEP review. The team made several suggestions to the Materials Inspection, Materials Licensing, and Materials Control, ISFSI, and Decommissioning Branches to enhance the program. These suggestions were discussed with and accepted by the respective Branch Chiefs.

The self-assessment results were discussed with you on March 24, 2011. The self-assessment plan developed for the review and the self-assessment report summarizing the results of the review are enclosed.

Any questions concerning this self-assessment may be directed to me.

Enclosures:

1. 2011 Mini-IMPEP self-assessment plan
2. 2011 Mini-IMPEP self-assessment report

CONTACT: James Lynch, SAO
630-829-9661

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- 3. 2011 Mini-IMPEP self-assessment plan
- 4. 2011 Mini-IMPEP self-assessment report

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2011 Mini-IMPEP Self-Assessment Plan

This self-assessment plan outlines a strategy for conducting a self-assessment on materials licensing, inspection, incident response, and allegation response activities. It provides a detailed description of how the assessment will be conducted and the specific assessment areas that will be covered.

Self-Assessment Start Date: January 19, 2011
Self-Assessment Completion Date: February 28, 2011

Assessors: James Lynch
Aaron McCraw
Toye Simmons

Assessment Objective

In preparation for the September 2011 IMPEP (*Note: delayed until the Fall 2012*) review of the Region III materials program, the assessors will:

- Evaluate if materials licensing actions were completed without significant technical or regulatory deficiencies and were completed in accordance with NRC guidance;
- Evaluate if inspection findings were dispositioned without significant technical or regulatory deficiencies and documented in accordance with NRC guidance;
- Evaluate if incident and allegation response activities were conducted in accordance with NRC guidance; and
- Evaluate if DNMS technical personnel have required training and refresher training to meet qualification requirements.

Scope of Review

The assessment period is between August 2007 (the last Region III IMPEP review) and the present.

The licensing assessment will include a review of documentation associated with approximately 10 licensing actions. The audit of licensing documentation will include the review of new license applications, amendments, renewals, terminations, financial assurance, and notifications.

The inspection assessment will include a review of documentation associated with approximately ten inspections. The audit of inspection documentation will include Form 591Ms, Enclosure 6 reports, narrative inspection reports, transmittal letters, and Notices of Violation.

The assessment of incident and allegation response actions will include a review of documentation associated with incident and allegation response performed during the period. The audit will include a review of response reports and Nuclear Material Events Database (NMED) notifications.

The assessment of training will include a review of documentation of staff training histories.

Schedule

January 19	Gather references and document self-assessment plan
January 19	Begin review of inspection, licensing, incident response, allegation response, and training documentation
February 11	Begin documentation of findings of the self-assessment
February 17	Provide draft documentation with findings and recommendations for corrective actions to Branch Chiefs
February 23	Provide draft documentation with findings and recommendations for corrective actions to Division Director or Deputy
February 28	Final self-assessment documentation

Interviews to be Conducted

Assessment findings will be discussed with the individual inspector or license reviewer responsible for the action under review to ensure there is a common understanding of the facts that support the finding.

Applicable Standards

Divisional Instruction DI-4.8, "Self-Assessment Process"

Regional Procedure RP-4.8, "Monitoring and Assessing Program Performance"

Manual Chapter 2800, "Materials Inspection Program"

Manual Chapter 1246, "Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area"

Temporary Instruction TI2800/038, "Inspection of the Implementation of Increased Controls for Licenses Authorized to Possess Risk Significant Radioactive Material"

Temporary Instruction TI2800/039, "Verification of Licensee Responses to NRC Requirement for Inventories of Materials Tracked in the National Source Tracking System Pursuant to Title 10, Code of Federal Regulations, Part 20.2207"

Management Directive 3.4, "Release of Information to the Public"

2011 Mini-IMPEP Self-Assessment Report

Scope and Summary

Auditors from the Division of Nuclear Materials Safety (the Division) conducted a self-assessment from January 19 through February 28, 2011, to evaluate the status of the Division's licensing, inspection, incident and allegation response, and training programs. The assessment included a review of documentation associated with 12 inspections, 12 licensing actions, 6 incident responses and 3 allegation responses completed by the Division's technical staff between August 2007 and February 2011.

The self-assessment focused on the quality and timeliness of the technical work. The inspection findings had a sound regulatory basis and resulted in appropriate regulatory actions. The licensing actions were reviewed in accordance with the applicable guidance documents in effect at the time of the action. Both licensing and inspection activities were accomplished in a timely manner and sensitive documents were appropriately categorized and marked when necessary. Technical issues were identified and correctly dispositioned. The incident and allegation responses were thorough, comprehensive and timely. The staff training was generally up-to-date and received appropriate management support.

As a result of the review, the team made seven suggestions to the Division for improvement of the materials program:

1. The team suggests that the Division develop a system to notify inspectors of ongoing reciprocity licensee activities in the Region.
2. The team suggests that the Division perform compliance checks on Agreement State licensees prior to reciprocity authorizations.
3. The team suggests that the Division place documents from voided actions in the Agencywide Document Access and Management System (ADAMS) under the new identifying numbers, if they are referenced in new actions.
4. The team suggests that the Division consider referencing the ADAMS Accession Number of incoming documents on the distribution/concurrence page of outgoing correspondence that directly responds to the incoming documents.
5. The team suggests that the Division update its Divisional Instruction to incorporate criteria for closing Nuclear Material Events Database (NMED) items where an immediate onsite inspection is not warranted and consider incorporating as a routine practice the use of acknowledgment letters as a vehicle to close NMED items.
6. The team suggests that the Division more closely manage the required refresher training needed to maintain technical qualification.
7. The team suggests that the Division approach the Technical Training Center to initiate the development of a G-102, "Fundamentals of Inspection Refresher," decommissioning training course or change the refresher training requirements.

Enclosure 2

Overall, the team confirmed that the Division is on course for fully satisfactory findings during the next Integrated Materials Performance Evaluation Program (IMPEP) review (delayed until Fall 2012). The suggestions noted above were made to enhance the materials program.

Inspection

As part of the self-assessment, the team evaluated the casework for 11 materials inspections and 1 decommissioning inspection. The casework reviewed represented the work of 13 of the Division's inspectors. The casework covered a wide variety of license types. Appendix A lists the inspection casework files reviewed. Based on the evaluation of casework, the team determined that inspections covered all aspects of the licensees' radiation safety and security programs. The team noted that the inspections covered the Increased Controls, fingerprinting, and the National Source Tracking System when appropriate. The team found that inspection reports were complete and generally of high quality with sufficient documentation to demonstrate that the licensees' performances with respect to health, safety, and security were acceptable. Inspection report documentation supported violations and other findings. The team noted minor documentation issues with some of the files that should not affect any IMPEP review findings. The details of those issues are included in Appendix A after the applicable casework.

The team also evaluated the Division's reciprocity program. The team determined that the Division met or exceeded the requirements in Inspection Manual Chapter (IMC) 1220, "Processing of NRC Form 241 and Inspection of Agreement State Licensees Operating Under 10 CFR 150.20," to inspect 20 percent of candidates licensees operating under reciprocity annually. The team noted that the Division's reciprocity lead has a very effective Microsoft Excel spreadsheet that he uses to track which reciprocity licenses are candidates for inspection. Although no performance weaknesses were identified, the team suggests that the Division consider adopting several good practices that have been observed in Agreement States or derivatives of these practices to further enhance the reciprocity program. The two practices the team suggests for consideration are as follows:

- **Notification of reciprocity.** Utah used a custom database management system programmed to provide the staff with a "pop-up" window, each day upon logging in, that indicates who is working in the State under reciprocity during the next 7-day period. If there are no licensees working under reciprocity during that time period, the "pop-up" window indicates this as well. The system also tracks who has been in the State, when, where, and for how long. North Carolina used a bulletin board to achieve the same practice as a low-tech alternative.
- **Compliance checks on reciprocity applicants.** Nevada has a policy of checking on the compliance history of a licensee requesting reciprocity approval with the Agreement State or NRC Region that issued the radioactive materials license. If the check reveals that a reciprocity applicant has outstanding compliance issues with their licensing authority (Agreement State or NRC Region), Nevada will deny the reciprocity application. This practice does not necessarily have to lead to the denial of a reciprocity application but could

also be used to make an informed decision on whether or not to perform a field inspection of the reciprocity licensee.

Licensing

The team examined licensing casework for 12 specific licenses. Licensing actions were reviewed for completeness, consistency, proper radioisotopes and quantities, adherence to good health physics practices, financial assurance, appropriateness of the license conditions, and overall technical quality. The ADAMS files were also reviewed for timeliness, use of appropriate deficiency letters and cover letters, reference to appropriate regulations, supporting documentation, consideration of enforcement history, pre-licensing visits, and proper signatures. The files were checked for easy access of necessary documents and supporting data.

The licensing casework was selected to provide a representative sample of licensing actions that were completed during the review period. The cross-section sampling included 5 new licenses, 4 amendments, 2 renewals, and 1 termination during the review period. The casework covered a wide variety of license types. Appendix B lists the licensing casework files reviewed and includes case-specific comments.

The team found two minor issues with the licenses reviewed: (1) one license had two identical license conditions (this license was subsequently corrected); and (2) for two new licenses, the original request was voided due to lack of information. For the second issue, when the actions were reinstated under a different set of identifiers (e.g., docket number, license number, control number, etc.), the original request was referenced in the tie-down condition. The team found it difficult to locate the original request without having the identifiers for the original request. The team suggests that the Division place documents from voided actions in ADAMS under the new identifying numbers, if they are referenced in new actions.

Overall, the team found that the licensing actions were thorough, complete, consistent, and of high quality with health and safety issues properly addressed. License tie-down conditions were stated clearly. Pre-licensing site visits were conducted as required by current NRC policy. Financial assurance was adequate for those licenses requiring it. Sensitive Unclassified Non-Safeguards Information (SUNSI) markings were appropriately used in accordance with current NRC policy. The licensee's compliance history was taken into account when reviewing renewal applications. A review of one termination action found that the terminated licensing actions were well documented, showing appropriate transfer records or appropriate disposal methods and records, confirmatory surveys, and survey records.

Incidents and Allegations

As part of the self-assessment, the team reviewed six randomly selected events listed as closed in NMED to evaluate the Division's performance on following up on events and subsequently closing those events in NMED. The team found 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 of the incident. The Division dispatched inspectors for onsite evaluations in a majority of the cases reviewed and took suitable enforcement and followup actions. The team determined that the Division's performance should meet the "satisfactory" level for an IMPEP review; however, the team did

note the following minor administrative issues that could be improved to enhance overall performance:

- The team noted that some event-related correspondence was not listed under the correct docket number in ADAMS. All noted instances have since been corrected after much searching for the “missing” documents in several cases. The team suggests that the Division consider referencing the ADAMS Accession Number of incoming documents on the distribution/concurrence page of outgoing correspondence that responds to the incoming documents.
- The team acknowledged and agreed with the finding and recommendation from two self-assessments of the Division’s implementation of the NMED process where the reviews recommended that the Divisional Instruction to review and close NMED items should be modified to address items that do not require an immediate onsite inspection. The team noted inconsistencies in these items being closed and then later reviewed during subsequent inspections or not being closed in a timely manner following review during an inspection. The team also noted that the use of acknowledgment letters and telephone conversation records was inconsistent in many of the cases where an immediate onsite inspection was not warranted. The team suggests that the Division update its Divisional Instruction to incorporate criteria for closing NMED items where an immediate onsite inspection is not warranted and consider incorporating as a routine practice the use of acknowledgment letters as a vehicle to close NMED items, as recently used to close an NMED item for a general licensee.

In evaluating the effectiveness of the Division's response to allegations, the team evaluated the casework for three allegations. The team concluded that the Division, in conjunction with Enforcement and Investigation Coordination Service (EICS), consistently took prompt and appropriate action in response to concerns raised. The team noted that the Division thoroughly documented its followup activities and retained all necessary documentation to appropriately close the allegations. The Division notified the allegers of the conclusion of its evaluation of the stated concerns. The team determined that the Division adequately protected the identity of allegers.

Training

The team confirmed that the Division maintained a documented training and qualification program as outlined in IMC 1246, “Formal Qualification Programs in the Nuclear Materials Safety and Safeguards Area.” Staff members maintain individual qualification cards as outlined in their qualification journals and were aware of training needed to achieve or maintain qualification. Supervisors were aware of the training needs for each of their staff members. Required refresher training courses were tracked in the Division’s monthly Operational Management Information (OMI) report. The team did identify several discrepancies related to refresher training. The team noted that refresher training courses were, on numerous occasions, taken outside of the refresher training schedule. At the time of this review, a number of staff members were several months late in taking the annual Site Access Refresher Training, biannual Radiation Worker Training, and triennial H-401 “Health Physics Topical Review Course.” The team suggests that the Division more closely manage the required refresher training needed to maintain technical qualification.

The G-102 “Fundamentals of Inspection Refresher” course is required for decommissioning inspectors, but is not offered by the NRC. The Branch Chief appropriately substituted other training in lieu of the G-102 course. The team suggests that the Division approach the Technical Training Center to initiate the development of a training course or change the refresher training requirements.

Attachment:

1. Appendix A
2. Appendix B

APPENDIX A
MATERIALS INSPECTIONS

1	Licensee Name		Inspection No.		Accession No.	
	Pontiac Osteopathic Hospital		10-01		ML102530553	
	License No.	Inspector	Inspection Type/ Program Code		Inspection Date	Inspection Result
	21-04081-03	Bramnik	Routine, Safety, 02120		8/24/10	591M
Observations/Findings		The "Next Inspection Date" on the 591M Part 3 was incorrect (August 2015 instead of August 2013). The correct next inspection date was verified in LTS.				

2	Licensee Name		Inspection Nos.		Accession Nos.	
	St. Luke's Hospital of Kansas City		09-01 09-02		ML090990137-safety ML091050358-encl. 6 ML091100050-security ML091100670-encl. 6	
	License No.	Inspector	Inspection Type/ Program Code		Inspection Dates	Inspection Results
	24-00889-01	Gattone	Routine, Safety/Security, 02110		3/17-30/09	NOVs
Observations/Findings		Inconsistent use of Inspection Number formatting, e.g. 09-01 vs. 09-001. Letters/NOVs have the 4 digit number. Enclosure 6 reports have the 5 digit number.				

3	Licensee Name		Inspection Nos.		Accession Nos.	
	Quality Testing Services, Inc.		09-01 09-02		ML091320610 – Safety ML091210661 – Security	
	License No.	Inspector	Inspection Type/ Program Code		Inspection Date	Inspection Results
	24-32292-01	Hays	Routine, Safety/Security, 03320		4/2/09	591Ms
Observations/Findings		None				

4	Licensee Name		Inspection No.		Accession No.	
	Department of the Army		10-01		ML100890258	
	License No.	Inspector	Inspection Type/ Program Code		Inspection Date	Inspection Result
	21-01222-05	Kulzer	Reactive, Safety, 03121		2/17/10	NOV
Observations/Findings		None				

5	Licensee Name		Inspection No.		Accession Nos.	
	Radiopharmacy of Indianapolis		08-01		ML081540639 – NOV ML081510766 – Insp. Rpt.	
	License No.	Inspector	Inspection Type/ Program Code		Inspection Dates	Inspection Result
	13-32637-01MD	LaFranzo	Initial, Safety, 02500		4/16-5/5/08	NOV
Observations/Findings		None				

6	Licensee Name		Inspection No.	Accession No.	
	St. Joseph Health Center		10-01	ML102370652	
	License No.	Inspector	Inspection Type/ Program Code	Inspection Dates	Inspection Result
	24-15159-01	Lambert	Routine, Safety, 02240	8/4-5/10	591M
	Observations/Findings	Incorrect Inspection Procedure referenced on 591M Part 3 (871131 instead of 87131).			

7	Licensee Name		Inspection No.	Accession No.	
	Missouri Cancer Associates, LLC		08-01	ML081550268	
	License No.	Inspector	Inspection Type/ Program Code	Inspection Date	Inspection Result
	24-32604-01	Mulay	Routine, Safety, 02230	5/20/08	591M
	Observations/Findings	Priority listed as "G2" in Part 3 of 591M. This is previous terminology that has not been used in the last several revisions of IMC 2800.			

8	Licensee Name		Inspection No.	Accession Nos.	
	Southeastern Michigan Blood Services		10-01	ML100670235 – Part 1 ML100670222 – Part 3	
	License No.	Inspector	Inspection Type/ Program Code	Inspection Date	Inspection Result
	21-15436-02	Parker	Routine, Security, 03510	2/23/10	591M
	Observations/Findings	Same inspector performed previous inspection. Part 3 narrative, although not publicly available, included misspellings and informal abbreviations (e.g., sat instead of satisfactory). Parts 1 and 3 not "packaged" in ADAMS.			

9	Licensee Name		Inspection Nos.	Accession Nos.	
	St. John's Mercy Medical Center		10-01 10-02	ML103400148 – Safety ML103370386 – Security	
	License No.	Inspector	Inspection Type/ Program Code	Inspection Dates	Inspection Results
	24-00794-03	Piskura	Routine, Safety/Security, 02240	11/3-4/10	591M – Safety; NOV, Encl. 6 – Security
	Observations/Findings	Wrong reference to the applicable supplement of the Enforcement Policy in the NOV (Supplement 6.2 referenced instead of 6.12).			

10	Licensee Name		Inspection No.	Accession Nos.	
	Mistras Holding Group		09-01	ML091970117 – Part 1 ML091970119 – Part 3	
	License No.	Inspector	Inspection Type/ Program Code	Inspection Date	Inspection Result
	12-16559-02	Warren	Followup, Security, 03320	6/30/09	591M
	Observations/Findings	Program scope not addressed. Narrative under "Program Scope" is more appropriate for "Performance Observations." Parts 1 and 3 not "packaged" in ADAMS.			

11	Licensee Name		Inspection No.	Accession No.	
	Petrochem Inspection Services		08-01	ML081070320	
	License No.	Inspectors	Inspection Type/ Program Code	Inspection Date	Inspection Result
	42-32507-01	Wiedeman/ Kulzer	Routine, Safety/Security, 03320	4/9/08	591M
	Observations/Findings	Inspection number not indicated on Part 1. No separate section for "Performance Observations," listed under "Program Scope."			

12	Licensee Name		Inspection No.	Accession No.	
	Pharmacia Corporation		10-01	ML101930188	
	License No.	Inspector	Inspection Type/ Program Code	Inspection Dates	Inspection Result
	24-32439-01	Streit/ Rodriguez	Decommissioning, 02201	5/18- 6/29/10	0610
	Observations/Findings	None			

APPENDIX B
MATERIALS LICENSING

1	Licensee Name	Mail Control No.		Accession No.		
	Hot Shots Nuclear Medicine	574125		ML110070678		
	License No.	Reviewer	License type	Action Type	Date Received	Date Issued
	21-32812-01MD	Casey	02500	New	9/3/10	12/29/10
	Observations/Findings	1. License amendment numbers 16 and 21 were the same. A corrected copy of the license was issued. 2. The original application, previously voided but reference in the license, was not under the docket number for this license in ADAMS.				

2	Licensee Name	Mail Control No.		Accession No.		
	Testing & Inspection Services	573409		ML103230569		
	License No.	Reviewer	License type	Action Type	Date Received	Date Issued
	13-32808-01	Herr	03121	New	8/18/10	11/16/10
	Observations/Findings	The original application, previously voided but referenced in the license, was not under the docket number for this license in ADAMS.				

3	Licensee Name	Mail Control No.		Accession No.		
	Payne & Dolan, Inc.	573301		ML103010142		
	License No.	Reviewer	License type	Action Type	Date Received	Date Issued
	21-32805-01	Herr	03121	New	7/28/10	10/26/10
	Observations/Findings	None				

4	Licensee Name	Mail Control No.		Accession No.		
	Cardiology Div-Midwest Medical Group	573749		ML103490808		
	License No.	Reviewer	License type	Action Type	Date Received	Date Issued
	13-26679-01	Reichhold	02201	Amendment	10/22/10	12/13/10
	Observations/Findings	None				

5	Licensee Name	Mail Control No.		Accession No.		
	Ramachandra Vemuri, M.D.	573546		ML103190747		
	License No.	Reviewer	License type	Action Type	Date Received	Date Issued
	21-32811-01	Mullauer	02201	New	9/14/10	11/12/10
	Observations/Findings	None				

6	Licensee Name	Mail Control No.		Accession No.		
	Cal Testing Services, Inc.	316653		ML0733811600		
	License No.	Reviewer	License type	Action Type	Date Received	Date Issued
	13-16347-01	Casey	03320	Amendment	11/1/07	12/3/07
	Observations/Findings	None				

7	Licensee Name		Mail Control No.		Accession No.	
	Dow Chemical Company		316392		ML072950530	
	License No.	Reviewer	License type	Action Type	Date Received	Date Issued
	21-00265-06	Mullauer	03610	Renewal	7/17/07	10/22/07
	Observations/Findings		None			

8	Licensee Name		Mail Control No.		Accession No.	
	Karmanos Cancer Center		316590		ML07312033	
	License No.	Reviewer	License type	Action Type	Date Received	Date Issued
	21-04127-06	Mullauer	02310	Amendment	10/2/07	11/7/07
	Observations/Findings		None			

9	Licensee Name		Mail Control No.		Accession No.	
	University of Detroit Mercy		316760		ML08170069	
	License No.	Reviewer	License type	Action Type	Date Received	Date Issued
	21-00241-09	Frazier	03620	Renewal	12/19/07	6/16/08
	Observations/Findings		None			

10	Licensee Name		Mail Control No.		Accession No.	
	Bureau of Indian Affairs		317903		ML0911106450	
	License No.	Reviewer	License type	Action Type	Date Received	Date Issued
	48-32735-01	Hueter	03121	New	2/2/09	4/17/09
	Observations/Findings		None			

11	Licensee Name		Mail Control No.		Accession No.	
	Midwest Engineering Services, Inc.		317927		ML0904904340	
	License No.	Reviewer	License type	Action Type	Date Received	Date Issued
	48-26074-01	Hueter	03121	Termination	2/18/09	4/29/09
	Observations/Findings		None			

12	Licensee Name		Mail Control No.		Accession No.	
	Mallinckrodt, Inc.		317405		ML083120559	
	License No.	Reviewer	License type	Action Type	Date Received	Date Issued
	24-04206-12MD	Null	02500	Amendment	8/13/08	11/7/08
	Observations/Findings		None			