

July 5, 2011

MEMORANDUM TO: Michael F. Weber
Deputy Executive Director for Materials, Waste,
Research, State, Tribal, and Compliance Programs
Office of the Executive Director for Operations

Bradley W. Jones, Assistant General Counsel
for Reactor and Materials Rulemaking
Office of the General Counsel

Cynthia A. Carpenter, Acting Director
Office of Federal and State Materials
and Environmental Management Programs

Cynthia Pederson, Deputy Regional Administrator
Region III

FROM: Lisa Dimmick, Health Physicist */RA/*
Division of Materials Safety and State Agreements
Office of Federal and State Materials
and Environmental Management Programs

SUBJECT: INTEGRATED MATERIALS PERFORMANCE EVALUATION
PROGRAM REVIEW OF THE MAINE AGREEMENT STATE
PROGRAM

This memorandum transmits to the Management Review Board (MRB) a proposed final report (Enclosure 1) documenting the Integrated Materials Performance Evaluation Program (IMPEP) review of the Maine Agreement State Program. The review was conducted by an interoffice team during the period of May 2 - 6, 2011. The review team issued a draft report to the State on June 2, 2011, for factual comment. Maine responded to the findings and conclusions of the review by letter dated June 28, 2011, from Sheila Pinette, D.O., Director Maine Center for Disease Control and Prevention. Maine's response letter document can be found in ADAMS (ML111810910) and is attached to the proposed final report.

Based on the results of this review, the review team is recommending that Maine's performance be found "satisfactory" for all performance indicators reviewed. Overall, the review team is recommending that the Maine Agreement State Program be found adequate to protect public health and safety and compatible with NRC's program. Based on the results of the current

MRB Members

-2-

IMPEP review, the review team is recommending that the next IMPEP review of the Maine Agreement Stat program take place in approximately 4 years.

The MRB meeting to consider the Maine report is scheduled for **Thursday, July 21, 2011, from 2:00 p.m. to 4:00 p.m. (EST), in Two White Flint North, Room 2-B5**. In accordance with Management Directive 5.6, *Integrated Materials Performance Evaluation Program (IMPEP)*, the meeting is open to the public. The agenda for the meeting is enclosed (Enclosure 2).

If you have any questions prior to the meeting, please contact me at 301-415-0694.

Enclosures:
As stated

cc w/encl: Sheila Pinette, D.O. Director
Maine Center for Disease Control and Prevention

Robert Gallagher, Massachusetts
Organization of Agreement States
Liaison to the MRB

MRB Members

-2-

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF THE MAINE AGREEMENT STATE PROGRAM

May 2 – 6, 2011

PROPOSED FINAL REPORT

Enclosure 1

EXECUTIVE SUMMARY

This report presents the results of the Integrated Materials Performance Evaluation Program (IMPEP) review of the Maine Agreement State Program. The review was conducted during the period of May 2-6, 2011, by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the Commonwealth of Pennsylvania.

Based on the results of this review, the review team recommends that Maine's performance be found satisfactory for all common and non-common performance indicators reviewed. The review team made three recommendations regarding the performance of the Maine Agreement State Program. These recommendations include areas for improvement to correct identified performance weaknesses in Maine's Agreement State Program.

The review team recommends that the Maine Agreement State Program be found adequate and compatible with NRC's program.

Based on the results of the current IMPEP review, the review team recommends that the next IMPEP review take place in approximately four years.

1.0 INTRODUCTION

This report presents the results of the review of the Maine Agreement State Program. The review was conducted during the period of May 2 - 6, 2011, by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the Commonwealth of Pennsylvania. 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 October 14, 2006, to May 6, 2011, were discussed with Maine management on the last day of the review.

[A paragraph on the results of the Management Review Board (MRB) meeting will be included in the final report]

The Maine Agreement State Program is administered by the Radiation Control Program, which is located within the Division of Environmental Health (the Division). The Division is part of the Center for Disease Control and Prevention (the Center). The Director of the Center reports to the Commissioner for the Department of Health and Human Services (the Department). The organization chart of the Department, Center, and Program are included in Appendix B.

At the time of the review, the Maine Agreement State Program regulated 125 specific licenses authorizing byproduct, source, and certain special nuclear materials. The review focused on the materials program as it is carried out under the Section 274b (of the Atomic Energy Act of 1954, as amended) Agreement between the NRC and the State of Maine.

In preparation for the review, a questionnaire addressing the common and non-common performance indicators was sent to the Program on March 1, 2011. The Program provided its response to the questionnaire on April 22, 2011. A copy of the questionnaire response may be found in the NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML111430833.

The review team's general approach for conduct of this review consisted of: (1) examination of Program's response to the questionnaire; (2) review of applicable Maine statutes and regulations; (3) analysis of quantitative information from the Program's databases; (4) technical review of selected files; (5) one field accompaniment of a Maine inspector; and (6) interviews with staff and management to answer questions or clarify issues. The review team evaluated the information gathered against the established criteria for each common and applicable non-common performance indicator and made a preliminary assessment of the Agreement State program's performance.

Section 2.0 of this report discusses the Program's actions in response to a recommendation made during the previous review. Results of the current review for the IMPEP common performance indicators are presented in Section 3.0. Section 4.0 details results of the applicable non-common performance indicators, and Section 5.0 summarizes the review team's findings and recommendations. The recommendations made by the review team are comments that relate directly to program performance by the State. A response is requested from the State to all recommendations in the final report.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous IMPEP review, which concluded on October 13, 2006, one recommendation was made by the review team regarding the Maine Agreement State Program's performance. The team's review of the current status of the recommendation is as follows:

The review team recommends that the State evaluate current and future staffing needs and business processes to develop and implement a strategy that improves the effectiveness and efficiency of the Program and ensures its continued adequacy and compatibility. (Section 3.2)

Current Status: The review team found that during the time period covered by this review, the staffing issue and business process development had been addressed as evidenced by the improvement in the status of inspections. The program has created and utilized a database of license activities. From this database, the program can track inspection frequencies, which allowed the program to improve their inspection efficiency. This recommendation is closed.

3.0 COMMON PERFORMANCE INDICATORS

Five common performance indicators are used to review NRC Regional and Agreement State programs. These indicators include: (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 Program'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 Program's questionnaire response relative to this indicator, interviewed the Program Manager and technical staff member, reviewed job descriptions and training records, and considered workload backlogs.

The materials program is allocated two technical staff who report to the Program Manager. Currently the Program has one full-time qualified inspector/license reviewer. The second inspector/license reviewer left State employment in July 2010. The Program Manager posted the vacant position shortly after the individual left the Program. In January 2011, a State-wide hiring freeze went into effect before the position could be filled. The Program Manager is now

considering cross training an individual who is currently the Low-Level Waste Coordinator who has completed some qualification courses in the past.

In addition to the two positions in the radioactive materials program, the Program has a Nuclear Safety Inspector assigned to Maine Yankee decommissioning activities, two X-ray staff members, and two individuals assigned to the radon program.

In order to avoid backlogs in licensing and inspection activities while the hiring freeze is in effect, the Program Manager changed the inspection frequencies for several program codes that the State was inspecting at a higher frequency than that which is required by Inspection Manual Chapter 2800. There is currently no backlog in licensing or inspection activities. However, based on the vacancy in the radioactive materials program and the hiring freeze in effect, the review team recommends that the State develop and implement a strategy that addresses the existing vacancy in order to maintain the effectiveness and efficiency of the Program.

The Program has a documented training plan for technical staff that is consistent with the requirements in the NRC/Organization of Agreement States Training Working Group Report and NRC's Inspection Manual Chapter (IMC) 1246, "Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area." The Program also has on-the-job training to supplement course work so that individuals may broaden their work experience. All technical staff have at minimum Bachelor's degrees in the sciences and the Program Manager is a Professional Engineer. Staff members are assigned increasingly complex duties as they progress through the qualification process. The review team concluded that the Program's training program is adequate to carry out its regulatory duties and noted that Program management is supportive of staff training opportunities.

The review team noted that the Program had stable funding during the review period due to dedicated revenue from licensee fees. The Program instituted a two-step fee increase which became effective in May 2010. By the end of 2012, the Program anticipates that licensee fees will be at 50% of NRC's 2009 fiscal year fees.

The Advisory Committee on Radiation of the State of Maine, as consulted under the law, acts only in an advisory role to the Program. The committee meets on an as-needed basis.

Based on the IMPEP evaluation criteria, the review team recommends that Maine's Program performance with respect to the indicator, Technical Staffing and Training, be found 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 Program's questionnaire response relative to this indicator, data gathered from the

Program's database, examination of completed inspection casework, and interviews with the manager and staff members.

The review team verified that the Program's inspection frequencies for all types of radioactive materials licenses are at least as frequent as those listed in NRC's IMC 2800, "Materials Inspection Program." The Program did conduct inspections of some license types, such as medical – written directive not required, portable gauge users, and medical broad scopes, more frequently than prescribed by IMC 2800 up until January 1, 2011, at which point the Program adjusted all inspection frequencies back to those of IMC 2800. The Program indicated that this adjustment was based on a vacancy in a Program inspector position and a current hiring freeze.

The review team noted that security inspections were being performed concurrently with routine safety inspections for applicable licensees. The review team also verified that the Program conducts inspections of multiple locations of use for multi-site licenses. In all instances reviewed by the team, the Program met or exceeded the minimum criterion of 20 percent of sites for licenses with five or more locations of use listed on the license.

The Program conducted a total of 46 Priority 1, 2, and 3 (higher priority) inspections during the review period. The review team verified that 4 of the 46 higher priority inspections were conducted overdue by more than 25 percent of the inspection frequency prescribed by IMC 2800. The review team verified that no high priority inspections were overdue at the time of the review. The review team also evaluated the Program's timeliness for conducting initial inspections, and noted that the Program issued 16 new licenses during the review period. The Program conducted 14 initial inspections, of which none were conducted greater than 12 months after license issuance as prescribed by IMC 2800. The two remaining new licensees are scheduled for inspection in the remaining calendar year. Overall, the review team calculated that the Program performed 5 percent of its Priority 1, 2, and 3 and initial inspections overdue during the review period.

The review team evaluated the timeliness of issuance of inspection reports. Of the 15 inspection files reviewed, the review team identified that a majority (14 of 15 files reviewed) of the inspection findings were issued within the 30-day goal.

Reciprocity activities under IMC 1220 require inspection of 20 percent of candidate licensees operating under reciprocity annually. The Program indicated that each reciprocity licensee is considered a priority 1. During the review period, the Program received requests for reciprocity from 37 licensees and 8 inspections were conducted. The review team determined that the Program met and/or exceeded NRC's criteria.

Maine's 2007 IMPEP Final Report indicated that the indicator, Status of Materials Inspection Program was satisfactory, but needs improvement. The contributing factors leading to this rating (problems with maintaining and updating databases used for tracking inspection and licensing actions, a redeployment of staff to higher priority activities, and an extended absence of a staff member) have been addressed.

Based on the IMPEP evaluation criteria, the review team recommends that Maine's Program performance with respect to the indicator, Status of Materials Inspection Program, be found satisfactory.

3.3 Technical Quality of Inspections

The review team evaluated inspection reports, enforcement documentation, and inspection field notes, and interviewed the responsible inspector for 15 radioactive materials inspections conducted during the review period. The casework examined included a cross-section of inspections conducted by Program inspectors and covered a wide variety of inspection types: medical broad scope, medical institutions requiring written directives, medical private practice, fixed and portable gauges, industrial radiography, academic broad scope, nuclear pharmacy, and research and development. The casework included initial, routine, follow-up, reciprocity, and Increased Controls inspections. Appendix C lists the inspection casework files reviewed. Based on the evaluation of casework, the review team determined that inspections covered all aspects of the licensees' radiation safety and security programs. The review team noted that the inspections covered the Increased Controls, fingerprinting, and the National Source Tracking System when appropriate.

Inspection report documentation supported violations, recommendations made to licensees, and unresolved safety issues. In addition to paper copies that are maintained in Augusta, pertinent information about each inspection is entered into the Program's electronic filing system, which is accessible to all staff members. The review team evaluated the Program's handling and storing of sensitive documents, and determined that documents containing sensitive information were appropriately protected, segregated from other files (electronic and paper), and maintained in a manner to limit access. The review team found that outgoing correspondence was marked, as appropriate.

The review team verified that only one supervisor accompaniment was performed during the review period. The Office has no written policy or procedure to have a supervisor accompany staff performing radioactive materials inspections on an annual basis. Within the current organization chart the Radiation Control Program Manager is responsible for this duty. The review team recommends that annual supervisor accompaniments be performed for each radioactive materials staff member to ensure quality and consistency within the program. The Program indicated that its human resources section requires an employee performance review; this system might be a trigger to perform the annual accompaniments.

The review team accompanied one of the Program's inspectors on April 14, 2011. The inspector conducted an inspection of a broad scope medical licensee. The inspector accompaniment is listed in Appendix C. The inspector demonstrated performance-based inspection techniques and knowledge of the regulations. The inspector was well trained, prepared for the inspection, and thorough in his assessment of the licensee's radiation safety and security program. The inspector conducted interviews with appropriate personnel, observed licensed operations and appropriately pursued issues noted, conducted confirmatory measurements, and utilized good health physics practices. The review team determined that the inspection was adequate to assess radiological health, safety, and security at the licensed facility.

Based on the IMPEP evaluation criteria, the review team recommended that Maine's Program performance with respect to the indicator, Technical Quality of Inspection, be found satisfactory.

3.4 Technical Quality of Licensing Actions

The review team interviewed a license reviewer and examined completed licensing casework for 16 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 letters and cover letters, reference to appropriate regulations, supporting documentation, consideration of enforcement history, pre-licensing visits, peer/supervisory review, and proper signatures.

The licensing casework was selected to provide a representative sample of licensing actions completed during the review period. Licensing actions selected for evaluation included, 4 new licenses, 4 renewals, 2 decommissioning or termination actions, and 6 amendments. Files reviewed included a cross-section of license types, including: industrial radiography, broad scope medical institution, fixed gauge, limited medical institution, academic broad scope, radiopharmacy, veterinary, high dose rate remote afterloader, research and development broad scope, and self-shielded irradiators. The casework sample represented work from two license reviewers. A listing of the licensing casework reviewed 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. Deficiency letters 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. License reviewers use the Program's licensing guides, policies, checklists, and standard license conditions specific to the type of licensing actions to ensure consistency in licenses. The licensee's compliance history was taken into account when reviewing all renewal applications and major amendments. Licenses are issued for a five-year period under a timely renewal system. Licenses are signed by qualified license reviewers, which could include the Program Manager. The status of all licensing actions is tracked on a database which is updated on a routine basis.

The Program's 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. The Program hand delivers all new licenses as part of their pre-licensing review. These 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 the Program's licensing practices regarding the Increased Controls and Fingerprinting Orders. The review team noted that the State uses legally binding license conditions that meet the criteria for implementing the Increased Controls Orders, including fingerprinting, as appropriate. The review team analyzed the Program'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. The Program requires full implementation of the Increased Controls prior to issuance of a new license or license amendment that meets the established criteria.

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

3.5 Technical Quality of Incident and Allegation Activities

In evaluating the effectiveness of the Program's actions in responding to incidents and allegations, the review team examined the Program's response to the questionnaire relative to this indicator, evaluated selected incidents reported for Maine in the Nuclear Material Events Database (NMED) against those contained in the Program's files, and evaluated the casework for ten radioactive materials incidents. A listing of the incident casework examined is included in Appendix E. The review team also evaluated the Program's response to allegations involving radioactive materials.

When notified of an incident, the radioactive material staff in the Program will be assigned to investigate and document the incident and determine if the event requires a call to the NRC Headquarters Operations Center. The inspector is responsible for recording the event in the NMED local incident database and transferring updates to the NRC's contractor responsible for maintaining NMED. The Program responded to a total of 71 incidents involving radioactive materials during the review period. Fifty-seven of the events involved trash alarms. A total of ten incidents were entered into NMED. Nine of the incidents required reporting to the NRC. Monthly reports and follow-up information are submitted electronically by transmitting the appropriate contents of the local Maine NMED database to the NRC's contractor responsible for maintaining NMED. The ten incidents reviewed included a leaking gauge source, a medical event, a fire near a nuclear gauge, lost or missing tritium exit signs, and a transportation incident.

The review team noted that the Program's response to incidents was commensurate with the health and safety significance of the event. Inspectors were dispatched to the site of the incident or for investigations when appropriate. Incident reports were thorough, well-documented and timely.

During the review period, the Program received two allegations. Only one allegation involved potential by-product and source material. An evaluation indicated that thorough and appropriate action was taken in response to the concern raised. The allegation was well documented, promptly reviewed, and appropriately closed with the allogger. The Program also addressed another allegation that was received by another Maine State department; the allegation did not fall under NRC jurisdiction, but the Program took actions similar to the allegation that was reviewed. There were no performance issues identified from the review of the allegation casework.

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

4.0 NON-COMMON PERFORMANCE INDICATORS

IMPEP identifies four non-common performance indicators to be used in reviewing Agreement State Programs: (1) Compatibility Requirements; (2) Sealed Source and Device Evaluation

Program; (3) Low-Level Radioactive Waste Disposal Program; and (4) Uranium Recovery Program. The first two non-common performance indicators were applicable to this review.

4.1 Compatibility Requirements

4.1.1 Legislation

Maine became an Agreement State on April 1, 1992. The current effective statutory authority for the Program is contained in the Maine Radiation Protection Statutes in 22 MRSA § 661-690. The Radiation Control Program is designated as the State's radiation control agency. The review team noted that no legislation affecting the Program was passed during the review period.

4.1.2 Program Elements Required for Compatibility

The Maine Regulations for Control of Radiation, found in Maine Administrative Rules 10-144A CMR 220, apply to all ionizing radiation. Maine requires a license for possession and use of all radioactive material, including naturally occurring materials, and accelerator produced radionuclides. Maine also requires registration of all equipment designed to produce x-rays or other ionizing radiation.

The review team examined the State's administrative rulemaking process and found that the process takes approximately four months after filing the draft rule with the Secretary of State. Prior to filing with the Secretary of State, the draft rule is reviewed by Department management, the Attorney General's Office, and the Governor's Office. When an acceptable draft of a proposed revision to a rule has been prepared, it is sent to the Secretary of State, the public, the NRC, other agencies, and all potentially impacted licensees and registrants for comment. The Secretary of State announces a public meeting/hearing period for the proposed revision to the rule. Comments are considered and incorporated, as appropriate, before the regulations are finalized. After responding to comments, the Program forwards the proposed revision to the rule with the addressed comments to the Commissioner, the Department, and Attorney General's Office for final approval. The Commissioner and the Attorney General sign the final regulations. The State can adopt other agency's regulations by reference, but NRC regulations are not incorporated in this manner. The Program has the authority to issue legally binding requirements (e.g., license conditions) in lieu of regulations until compatible regulations become effective.

The review team evaluated the Program's response to the questionnaire relative to this indicator, reviewed the status of regulations required to be adopted by the State under the Commission's adequacy and compatibility policy, and verified the adoption of regulations with data obtained from the Office of Federal and State Materials and Environmental Management Programs' (FSME) State Regulation Status Sheet.

During the review period, 13 NRC amendments were addressed and adopted in two rule packages that were issued in November 2009 and May 2010. At the time of the review, there were no overdue NRC amendments. However, it was noted that the final published rules submitted for NRC review in March 2010 generated 22 comments. These comments list issues from nine amendments that need to be addressed to have the Maine State regulations completely meet the established compatibility and health and safety categories. There is also

one outstanding comment that resulted from the State's implementation of Regulatory Action 2001-1 addressing certain generally licensed industrial devices. The review team recommends that the State expedite action to address the comments identified in NRC letters dated August 31, 2006, and June 18, 2010, to promulgate and complete changes to the State regulations.

There are currently no NRC amendments that need to be addressed.

Based on the IMPEP evaluation criteria, the review team recommended that Maine's Program performance with respect to the indicator, Compatibility Requirements, be found satisfactory.

4.2 Sealed Source and Device (SS&D) Evaluation Program

During the period, no SS&D certificates were issued by the Program and there are currently no manufacturers of SS&Ds in the State. The State, however, does not wish to relinquish the authority to regulate SS&D manufacturers in the future. The State has committed to have a program in place prior to performing evaluations. Accordingly, the team did not review this indicator.

5.0 SUMMARY

As noted in Sections 3.0 and 4.0, Maine's performance was found satisfactory in all common and non-common indicators reviewed by the IMPEP team. The review team made three recommendations regarding the Maine Agreement State program. Accordingly, the review team recommends that the Maine Agreement State Program be found adequate to protect public health and safety, and compatible with NRC's program. Based on the results of the current IMPEP review, the review team recommends that the next full IMPEP review take place in approximately 4 years.

Below are the recommendations, as mentioned earlier in the report, for evaluation and implementation, as appropriate, by the State:

1. The review team recommends that the State develop and implement a strategy that addresses the existing vacancy in order to maintain the effectiveness and efficiency of the Program. (Section 3.1)
2. The review team recommends that annual supervisor accompaniments be performed for each radioactive materials staff member to ensure quality and consistency within the program. (Section 3.3)
3. The review team recommends that the State expedite action to address the comments identified in NRC letters dated August 31, 2006, and June 18, 2010, to promulgate and complete changes to the State regulations. (Section 4.1)

LIST OF APPENDIXES AND ATTACHMENT

Appendix A	IMPEP Review Team Members
Appendix B	Maine Organization Chart
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 Incidents and Allegations Activities Compatibility Requirements
Donna Janda, RI	Technical Staffing and Training Technical Quality of Licensing Actions Inspector Accompaniment
Dwight Shearer, Pennsylvania	Status of Materials Inspection Program Technical Quality of Inspections

APPENDIX B

MAINE ORGANIZATION CHART

ADAMS Accession No.: ML11470677

APPENDIX C

INSPECTION CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT ARE INCLUDED FOR COMPLETENESS ONLY

File No.: 1
Licensee: Maine Medical Center
Inspection Type: Routine Unannounced
Inspection Date: 4/14/11
License No.: 05611
Priority: 2
Inspector: WM

File No.: 2
Licensee: Quality Assurance Labs
Inspection Type: Routine, Unannounced
Inspection Date: 4/12/10
License No.: 05139
Priority: 1
Inspector: WM

Comment: The licensee was not notified of the inspection findings, on either a Maine form HHE-891 or form letter.

File No.: 3
Licensee: Inland Hospital
Inspection Type: Routine, Unannounced
Inspection Date: 9/24/08
License No.: 11921
Priority: 3
Inspector: SS

Comment: Corrective action from the licensee could not be located.

File No.: 4
Licensee: Penobscot Bay Medical
Inspection Type: Routine, Unannounced
Inspection Date: 4/22/10
License No.: 13701
Priority: 3
Inspectors: WM

File No.: 5
Licensee: Redington Fairview Hospital
Inspection Type: Routine, Unannounced
Inspection Date: 6/30/08
License No.: 25707
Priority: 3
Inspectors: SS

File No.: 6
Licensee: Camden Hospital for Animals
Inspection Type: Initial, Announced
Inspection Date: 10/29/07
License No.: 13207
Priority: 5
Inspector: SS

File No.: 7
Licensee: Cardinal Health
Inspection Type: Initial, Announced
Inspection Date: 12/8/09
License No.: 19233
Priority: 3
Inspector: SS

File No.: 8
Licensee: TEAM Industrial Services
Inspection Type: Reciprocity, Unannounced
Inspection Date: 4/19/07

License No.: 42-32219
Priority: 1
Inspector: SS

File No.: 9
Licensee: ACCUREN Inspection
Inspection Type: Reciprocity, Unannounced
Inspection Date: 6/2/10

License No.: 133-2008-01
Priority: 1
Inspector: SS

File No.: 10
Licensee: Bath Iron Works
Inspection Type: Routine, Unannounced
Inspection Date: 6/4/10

License No.: 23209
Priority: 1
Inspector: SS

File No.: 11
Licensee: Portland Cardiology
Inspection Type: Routine, Unannounced
Inspection Date: 4/9/10

License No.: 05739
Priority: 5
Inspector: WM

File No.: 12
Licensee: Lane Construction
Inspection Type: Routine, Unannounced
Inspection Date: 3/1/07

License No.: 19501
Priority: 5
Inspector: SS

Comment: The licensee was notified of the inspection findings outside of 30 days.

File No.: 13
Licensee: St. Mary's Regional Medical Center
Inspection Type: Routine, Unannounced
Inspection Date: 3/10/11

License No.: 01709
Priority: 3
Inspector: WM

File No.: 14
Licensee: Eastern Maine Medical
Inspection Type: Routine, Unannounced
Inspection Date: 8/12/10

License No.: 19301
Priority: 2
Inspector: WM

File No.: 15
Licensee: Mt Desert Island Biological Lab
Inspection Type: Routine, Unannounced
Inspection Date: 2/16/11

License No.: 09623
Priority: 5
Inspector: WM

INSPECTOR ACCOMPANIMENT

The following inspector accompaniment was performed prior to the on-site IMPEP review:

Licensee: Maine Medical Center
Inspection Type: Routine, Unannounced
Inspection Date: 4/14/11

License No.: 05611
Priority: 2
Inspector: WM

APPENDIX D

LICENSE CASEWORK REVIEWS

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

File No.: 1

Licensee: Camden Hospital for Animals

Type of Action: New

Date Issued: 3/7/07

License No.: 13207

Amendment No.: 0

License Reviewer: SS

File No.: 2

Licensee: SAPPI dba S.D. Warren Co.

Type of Action: Renewal

Date Issued: 3/11/09

License No: 05751

Amendment No.: 8

License Reviewer: SS

File No.: 3

Licensee: Maine Medical Center

Type of Action: Amendment

Date Issued: 3/4/11

License No.: 05611

Amendment No.: 19

License Reviewer: WM

File No.: 4

Licensee: Libertytown USA2, Inc.

dba Quality Assurance Laboratories

Type of Action: Amendment

Date Issued: 12/6/10

License No.: 05139

Amendment No.: 14

License Reviewer: WM

Comment: The file did not contain documentation of licensee's request for amendment to license for the change in ownership.

File No.: 5

Licensee: Rumford Hospital

Type of Action: Termination

Date Issued: 4/8/08

License No.: 17705

Amendment No.: 10

License Reviewer: SS

File No.: 6

Licensee: Central Maine Medical Center

Type of Action: Amendment

Date Issued: 1/11/11

License No.: 01207

Amendment No.: 13

License Reviewer: WM

File No.: 7

Licensee: Bath Iron Works

Type of Action: Renewal

Date Issued: 2/25/09

License No.: 23209

Amendment No.: 8

License Reviewers: SS, WM

File No.: 8

Licensee: Cardinal Health, Nuclear Pharmacy Services

Type of Action: New

Date Issued: 4/9/09

License No.: 19233-01MD

Amendment No.: 0

License Reviewer: WM

File No.: 9

Licensee: Redington Fairview General Hospital

Type of Action: Renewal

Date Issued: 3/12/09

License No.: 25707

Amendment No.: 11

License Reviewer: SS

File No.: 10

Licensee: Maine Medical Partners Endocrinology & Diabetes Center

Type of Action: Termination

Date Issued: 4/1/11

License No.: 05643

Amendment No.: 6

License Reviewer: WM

File No.: 11

Licensee: SAPPI Fine Paper Technology Center

Types of Action: New

Date Issued: 7/29/09

License No.: 05747

Amendment No.: 0

License Reviewer: SS

Comments: Standard license condition regarding testing of on/off mechanism was not included on the license. Tie down license condition does not include licensee's letter dated 6/24/2009 regarding procedures used to prevent unauthorized access.

File No.: 12

Licensee: Maine General Medical Center

Types of Action: Amendment

Date Issued: 2/27/07

License No.: 11623

Amendment No.: 21

License Reviewer: SS

File No.: 13

Licensee: mb-Microtec (USA) Inc.

Type of Action: New

Date Issued: 8/26/10

License No.: 05331

Amendment No.: 0

License Reviewer: WM

File No.: 14

Licensee: Maine Cardiology Associates

Type of Action: Amendment

Date Issued: 6/5/08

License No.: 05627

Amendment No.: 18

License Reviewer: SS

File No.: 15

Licensee: The Jackson Laboratory

Type of Action: Amendment

Date Issued: 8/17/10

License No.: 09507-01

Amendment No.: 10

License Reviewer: WM

File No.: 16

Licensee: University of Maine Safety & Environmental
Management

Type of Action: Renewal

Date Issued: 6/17/10

License No.: 19827-01

Amendment No.: 9

License Reviewer: WM

APPENDIX E

INCIDENT CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT ARE INCLUDED FOR COMPLETENESS ONLY

File No.: 1
Licensee: City of Presque Isle
Date of Incident: 8/1/06
Investigation Date: N/A
License No.: General
Incident Log No: ME070001 (NMED 070016)
Type of Incident: Lost material (H-3 exit sign)
Type of Investigation: None

File No.: 2
Licensee: Sappi SD Warren
Date of Incident: 1/30/07
Investigation Date: 1/31/07
License No.: ME25709
Incident Log No: ME07002 (NMED 070095)
Type of Incident: Leaking source
Type of Investigation: Phone

File No.: 3
Licensee: Aroostook Medical Center
Date of Incident: 1/16/07
Investigation Date: 5/24/07
License No.: ME03803-02
Incident Log No: ME07016 (NMED 070276)
Type of Incident: Medical event
Type of Investigation: On site

File No.: 4
Licensee: Katahdin Paper Company
Date of Incident: 8/3/07
Investigation Date: N/A
License No.: ME19401
Incident Log No: ME07028 (NMED 070693)
Type of Incident: Equipment external fire
Type of Investigation: None

File No.: 5
Licensee: Regal Cinema
Date of Incident: 12/15/07
Investigation Date: 3/11/08
License No.: General
Incident Log No: ME080012 (NMED 080179)
Type of Incident: Lost material (H-3 exit sign)
Type of Investigation: On site

File No.: 6
Licensee: Quality Assurance Laboratories
Date of Incident: 2/14/08
Investigation Date: 2/14/08
License No.: ME05139
Incident Log No: ME080006 (NMED 08216)
Type of Incident: Transportation
Type of Investigation: On site

File No.: 7
Licensee: Wal-Mart
Date of Incident: 1/9/09
Investigation Date: N/A
License No.: General
Incident Log No: ME090004 (NMED 090063)
Type of Incident: Lost material (H-3 exit sign)
Type of Investigation: None

File No.: 8
Licensee: Wal-Mart
Date of Incident: 5/1/07
Investigation Date: N/A
License No.: General
Incident Log No: ME090001 (NMED 090064)
Type of Incident: Lost material (H-3 exit sign)
Type of Investigation: None

File No.: 9

Licensee: Wal-Mart

Date of Incident: 5/1/08

Investigation Date: N/A

License No.: General

Incident Log No: ME090002 (NMED 090065)

Type of Incident: Lost material (H-3 exit sign)

Type of Investigation: None

File No.: 10

Licensee: Wal-Mart

Date of Incident: 8/7/08

Investigation Date: N/A

License No.: General

Incident Log No: ME090003 (NMED 090066)

Type of Incident: Lost material (H-3 exit sign)

Type of Investigation: None

ATTACHMENT

June 28, 2011 Letter from Dr. Sheila Pinette
Maine's Response to the Draft Report
ADAMS Accession No.: ML11810910

**Agenda for Management Review Board Meeting
July 21, 2011, 2:00 p.m. – 4:00 p.m. (EDT), TWFN-2-B5**

1. Announcement of public meeting. Request for members of the public to indicate they are participating and their affiliation.
2. MRB Chair convenes meeting. Introduction of MRB members, review team members, State representatives, and other participants.
3. Consideration of the Maine IMPEP Report.
 - A. Presentation of Findings Regarding Maine's Program and Discussion.
 - Technical Staffing and Training
 - Status of Materials Inspection Program
 - Technical Quality of Inspections
 - Technical Quality of Licensing Actions
 - Technical Quality of Incident and Allegation Activities
 - Compatibility Requirements
 - B. IMPEP Team Recommendations.
 - Recommendation for Adequacy and Compatibility Ratings
 - Recommendation for Next IMPEP Review
 - C. MRB Consultation/Comments on Issuance of Report.
4. Request for comments from Maine representatives, OAS Liaison, and State IMPEP team members.
5. Adjournment.

Invitees:	Michael Weber, DEDMRT	Lisa Dimmick, FSME
	Bradley Jones, OGC	Robert Lewis, FSME
	Cynthia Carpenter, FSME	Terrence Reis, FSME
	Cynthia Pederson, RIII	Mark Delligatti, FSME
	Robert Gallagher, MA	Duncan White, FSME
	Joseph DeCicco, FSME	Michelle Beardsley, FSME
	Donna Janda, RI	Karen Meyer, FSME
	Dwight Shearer, PA	Kathryn Brock, OEDO