April 1, 2008

MEMORANDUM TO:	Martin J. Virgilio Deputy Executive Director for Materials, Waste, Research, State, Tribal, and Compliance Programs Office of the Executive Director for Operations
	Karen D. Cyr, General Counsel
	Charles L. Miller, Director Office of Federal and State Materials and Environmental Management Programs
	Steven A. Reynolds, Director Division of Nuclear Materials Safety Region III
FROM:	/RA By K. N. Schneider for/ Aaron T. McCraw, IMPEP Project Manager Division of Materials Safety and State Agreements Office of Federal and State Materials and Environmental Management Programs
SUBJECT:	FOLLOWUP INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM (IMPEP) REVIEW OF THE OREGON AGREEMENT STATE PROGRAM

This memorandum transmits to the Management Review Board (MRB) a proposed final report (Enclosure 1) documenting the followup IMPEP review of the Oregon Agreement State Program. The followup review of the Oregon Program was conducted by an interoffice team during the period of January 28-31, 2008. The review team issued a draft report to the State on February 28, 2008, for factual comment. Oregon responded to the findings and conclusions of the review by e-mails dated March 28 and March 31, 2008, from Mr. Terry D. Lindsey, Manager, Radiation Protection Services Section. Based on the response, the State had editorial and/or clarifying comments, most of which were incorporated into the proposed final report. In addition, the State provided their regulation action plan to address an open recommendation.

The review team is recommending that Oregon's performance be found "satisfactory" for the performance indicators, Technical Quality of Licensing Actions and Compatibility Requirements, and "satisfactory, but needs improvement" for the performance indicators, Technical Quality of Inspections and Technical Quality of Incident and Allegation Activities. The review team notes that the State has made progress in management oversight of the Agreement State program activities for the two performance indicators found satisfactory, but needs improvement; however, the review team believes that additional time and actions are necessary before the Section reaches and sustains a level of satisfactory performance. Accordingly, the review team is recommending that the Oregon Agreement State Program. The review team is recommending

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that the period of Heightened Oversight of the Oregon Agreement State Program be discontinued and a period of Monitoring be initiated.

The MRB meeting to consider the Oregon report is scheduled for **Tuesday**, April **15**, **2008**, **from 3:00 p.m. - 5:00 p.m. EDT**, **in One White Flint North**, Room **3-B4**. In accordance with Management Directive 5.6, 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 301-415-1277.

Enclosures: As stated

cc: Michael R. Skeels, Ph.D., MPH, Interim Public Health Director Oregon Department of Human Services

Terry Lindsey, Manager Oregon Radiation Protection Services Section

Ken Niles, State Liaison Officer Oregon Department of Energy

Aubrey Godwin, AZ Organization of Agreement States Liaison to the MRB Management Review Board Members - 2 -

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# INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM FOLLOWUP REVIEW OF THE OREGON AGREEMENT STATE PROGRAM

January 28-31, 2008

# **PROPOSED FINAL REPORT**

**ENCLOSURE 1** 

## 1.0 INTRODUCTION

This report presents the results of the followup review of the Oregon Agreement State Program, conducted January 28-31, 2008. The followup review was conducted by a review team consisting of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the Commonwealth of Massachusetts. Review team members are identified in Appendix A. The followup review was conducted in accordance with the February 26, 2004, NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." Preliminary results of the followup review, which covered the period of August 24, 2006 to January 31, 2008, were discussed with Oregon managers on the last day of the review.

[A paragraph on the results of the MRB meeting will be included in the final report.]

The Oregon Agreement State Program is administered by the Radiation Protection Services Section (the Section). The Section is part of the Office of Environmental Public Health (the Office) in the Public Health Division (the Division). The Division is located within the Department of Human Services (the Department). Organization charts for the Division, the Office and the Section are included as Appendix B.

At the time of the review, the Section regulated approximately 348 specific licenses and 75 general licenses, including naturally-occurring or accelerator-produced radioactive material (NARM). The review focused on the radioactive 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 Oregon.

On November 7, 2006, the MRB found the Oregon Agreement State program adequate, but needs improvement, and compatible with NRC's program. Because of the significance of the findings, the MRB directed that the State be placed on Heightened Oversight. The MRB also directed that a followup review take place approximately 1 year after the 2006 IMPEP review.

Prior to the followup review, the NRC conducted a period of Heightened Oversight of the Oregon program, which included Oregon's developing and submitting a Program Improvement Plan (the Plan) in response to recommendations from the 2006 IMPEP review. Bimonthly conference calls between the NRC and the Section were conducted to discuss Oregon's progress in implementing the Plan. The Plan was submitted on January 30, 2007. Conference calls were held February 7, April 26, June 18, October 30 and December 12, 2007. A listing of correspondence and summaries from the bimonthly calls is included as Appendix C. Oregon's actions and their status, as documented in the Plan and subsequent status updates, were reviewed in preparation for this followup review.

The followup review focused on the State's performance in regard to the common performance indicators, Technical Quality of Inspections, Technical Quality of Licensing Actions, and Technical Quality of Incident and Allegation Activities, and the non-common performance indicator, Compatibility Requirements. The followup review also included evaluation of the actions taken by Oregon to address the recommendations made during the 2006 IMPEP review. Other aspects of the program not fully evaluated as part of the followup review, were discussed at a periodic meeting held in conjunction with the review. The periodic meeting summary is included as Appendix D.

In preparation for the followup review, a questionnaire addressing the applicable common and non-common performance indicators was sent to the Section on September 13, 2007. The Section provided draft responses to the questionnaire on December 24, 2007, and December 28, 2007, and provided the final response on February 4, 2008. A copy of the questionnaire responses may be found in the NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML080570519.

The review team's general approach for conduct of this followup review consisted of: (1) examination of Oregon's response to the questionnaire; (2) review of the Heightened Oversight information, including status reports; (3) review of applicable Oregon statutes and regulations; (4) analysis of quantitative information from the Section's licensing and inspection database; (5) technical evaluation of selected regulatory actions; (6) field accompaniments of one Oregon inspector; (7) analysis of information from the Section's incident and allegation tracking system; and, (8) interviews with staff and managers to answer questions or clarify issues. The review team evaluated the information gathered against the IMPEP performance criteria for the three common and one non-common performance indicators and made a preliminary assessment of the Agreement State program's performance.

Results of the review of three common performance indicators are presented in Section 2.0. Section 3.0 details the results of the review of the non-common performance indicator. Section 4 summarizes the followup review team's findings and the open recommendations.

# 2.0 COMMON PERFORMANCE INDICATORS

The followup review addressed three of the five common performance indicators used in reviewing both NRC Regional and Agreement State radioactive materials programs. These indicators are: (1) Technical Quality of Inspections, (2) Technical Quality of Licensing Actions, and (3) Technical Quality of Incident and Allegation Activities.

# 2.1 <u>Technical Quality of Inspections</u>

The review team evaluated the inspection reports, enforcement documentation, and inspection field notes and interviewed inspectors and supervisory staff for 15 radioactive materials inspections conducted during the review period. The casework reviews included inspections conducted by three radioactive materials inspectors and covered various license types, including: industrial radiography, academic and medical broadscopes, high dose-rate remote afterloaders, nuclear medicine, radiopharmaceutical therapy, brachytherapy, nuclear pharmacies, and portable gauge. The review team also evaluated documentation for two Increased Controls inspections. Appendix E lists the inspection casework reviewed, with case-specific comments, as well as the results of the review team's inspector accompaniments.

The review team's evaluations of the Section's responses to Recommendations 1 and 2 of the 2006 IMPEP report are presented below:

# Recommendation 1:

The review team recommends that the State place greater emphasis on providing sufficient detail in inspection reports to allow Section management and staff to understand the technical basis for inspection findings. (Section 3.3 of the 2006 IMPEP report)

#### Current Status:

The review team found that the State has made some improvement in inspection report documentation. Most reports were complete, and had sufficient documentation to ensure that a licensee's performance with respect to health and safety was acceptable. Since the last review, some of the inspection reports have included the scope of the licensee's program, observations of licensed activities, and independent survey results.

At the conclusion of an inspection, the inspector completes an inspection report in the inspection database. A copy of the report is also placed in the license file. Several of the reports contained sufficient detail to understand the technical basis for inspection findings; however, a number of the reports reviewed had very limited detail of the inspection results. Discussions with the Section Manager and the inspection staff indicated that performance-based inspections were conducted, but not always properly documented.

The majority of violations are documented on an Oregon Form 591. At the conclusion of an inspection, the completed Form 591 is left with the licensee, with a copy retained by the inspector for the Oregon files. If no violations are found, the Form 591 is issued alone stating that no items of noncompliance were noted. If a violation is noted, the Form 591 is issued with the appropriate violation identified. The inspector does not always keep a copy of the Form 591 cover letter for the inspection file. The cover letter is a form letter with blank spaces for the inspector to fill in the total points assigned for potential enforcement rating for each inspection. The importance of keeping records in the inspection files was discussed with the Section Manager and the Section staff. The Section Manager stated that they would ensure that the completed Form 591 and cover letter documents are always filed in the inspection files. The form 591 does contain instructions to the licensee requiring a written reply within 30 days of the date of the inspection, and the response must include the corrective actions taken or a plan to correct the items of noncompliance and the date when all corrective actions will be completed. The review team noted most of the letters were sent to the licensees in a timely manner.

When escalated enforcement is appropriate, the Division has the authority to require management conferences, suspend licenses, and impound licensed material. During the review period, legislation was passed giving the Department the authority to levy civil penalties. The Section is developing regulations that will enable them to implement civil penalties.

One Section inspector was accompanied by a review team member during inspections the week of December 2, 2007. Inspection accompaniments were performed during inspections of two industrial radiography licensees and a portable gauge licensee. The accompaniments and associated comments are identified in Appendix E. During the accompaniments, the inspector demonstrated appropriate performance-based inspection techniques and knowledge of the regulations. The inspector was well prepared and thorough in the audits of the licensees' radiation safety and security programs. Overall, the inspector utilized good health physics practices. Interviews with licensee personnel were performed in an effective manner. The inspections were adequate to assess radiological health and safety at the licensed facilities.

The review team noted that inspection reports have improved during the review period; however, the review team continued to find documentation issues in the license files. While the review team noted improvements, the improvements have not been in place long enough to

truly evaluate their effectiveness nor to demonstrate sustained performance. Thus, the review team recommends that Recommendation 1 of the 2006 IMPEP report remain open.

## Recommendation 2:

The review team recommends that the State ensure that radioactive materials inspectors are accompanied by supervisors, at least annually, to promote quality and consistency in the inspection program. (Section 3.3 of the 2006 IMPEP report)

## Current Status:

The review team noted that, since the last review, inspector accompaniments were performed annually, as required by the Section's inspection procedures. All of the inspectors were accompanied several times in 2007. The review team noted that the accompaniments were performed by the new Emergency Response/Field Operations Manager who has not completed his health physics training. Although the Emergency Response/Field Operations Manager did a thorough job of documenting the accompaniments, the accompaniments were part of his on-the-job training. The review team relayed to the Section that the accompaniments need to be performed by a supervisor or senior staff member qualified in health physics, as required by the Section's inspection procedures, until such time that the Emergency Response/Field Operations Manager is qualified by Section management to perform full accompaniments. Thus, the review team recommends that Recommendation 2 of the 2006 IMPEP report remain open.

Based on the IMPEP evaluation criteria, the review team recommends that Oregon's performance with respect to the indicator, Technical Quality of Inspections, continues to be found satisfactory, but needs improvement.

## 2.2 <u>Technical Quality of Licensing Actions</u>

The review team interviewed license reviewers, evaluated the licensing process, and examined licensing casework for 22 specific licenses. Thirty-three 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, 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, peer and supervisory review as indicated, and proper signatures. The casework was checked for retention of necessary documents and supporting data.

The casework was selected to provide a representative sample of licensing actions completed during the review period. The sample included the following license types: medical and academic broadscope, manufacturing and distribution, medical institution - limited, high dose-rate remote afterloader, gamma stereotactic radiosurgery, mobile nuclear medicine, nuclear pharmacy, industrial radiography, waste disposal service, service provider and portable gauge. Types of licensing actions selected for evaluation included 7 new licenses, 2 renewals, 17 amendments to existing licenses, and 8 license terminations. A listing of the licensing casework evaluated, with case specific comments, can be found in Appendix F.

The review team's evaluation of the Section's responses to Recommendations 3 of the 2006 IMPEP report is presented below:

#### Recommendation 3:

The review team recommends that the Section discontinue the routine use of advance authorizations pending development of a procedure and basis for issuing the authorizations. Once developed, the Section should have the practice of issuing advance authorization and the procedure reviewed by counsel and its Radiological Advisory Committee. The review should include the form and content of the authorizations, the legal basis for issuing notifications prior to issuance of a license, as well as a determination of the potential impact on health and safety issues. In addition, the review should determine the State's potential liability and the compatibility of the practice with established State and Federal regulations, including requirements imposed on distributors of devices containing radioactive material. (Section 3.4 of 2002 and 2006 IMPEP reports)

#### Current Status:

The Section Manager stated that the practice of issuing advance authorizations is no longer performed. The review team verified that no advance authorization had been issued during the review period by reviewing 33 licensing actions from 22 specific license files. The review team recommends that Recommendation 3 be closed.

The review team found that the licensing actions were generally thorough, complete, consistent, and of high quality with health and safety issues properly addressed. License tie-down conditions were stated clearly, backed by information contained in the file, and inspectible. Deficiency letters clearly stated regulatory positions, were used at the proper time, and identified substantive deficiencies in the licensees' documents. The Section has one senior staff member whose primary responsibility is licensing. At a minimum, each licensing action has a peer review and a management review.

The team did note that there were several instances where the supporting documentation was not retained or was missing. For example, 7 out of 8 termination files were missing leak test records. Two files had information missing from the file. The review team discussed with the Section Manager and the primary license reviewer the need for supporting documents to ensure the Section has enforceable documentation.

The review team noted that the Section has commenced converting the general licenses (GL) for gauge users into specific licenses. Oregon revised their regulations in 2006 to require GL gauges with more than 1 millicurie (mCi) cesium-137, 0.1 mCi of strontium-90, 1 mCi of cobalt-60, and any quantity of any transuranic isotope to be specifically licensed. Oregon's GL regulations are more restrictive than the NRC's, per the NRC's review of the final Oregon regulations, dated December 20, 2007. As noted in the NRC's Office of Federal and State Materials and Environmental Management Programs' (FSME) All Agreement State Letter 07-087, dated September 20, 2007, the NRC is continuing to hold compatibility determinations for this regulation in abeyance until a revised GL rule is published and the Agreement State implementation date becomes effective.

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

# 2.3 <u>Technical Quality of Incident and Allegation Activities</u>

In evaluating the effectiveness of the Section's actions in responding to incidents and allegations, the review team examined the Section's response to the questionnaire relative to this indicator, evaluated selected incidents reported by Oregon in the Nuclear Material Events Database (NMED) against those contained in the Section's database and files, and evaluated the casework and supporting documentation for 9 incidents, five of which were reportable to the NRC Headquarters Operations Center. A listing of incident casework examined, with case-specific comments, can be found in Appendix G.

The review team also evaluated the Section's response to one allegation involving radioactive materials referred to the State by the NRC during the review period. The team's review determined that the Section took prompt and appropriate action in response to all concerns raised. The allegation reviewed was appropriately closed, and affected individuals were notified of the actions taken.

The review team's evaluation of the Section's response to Recommendations 4 of the 2006 IMPEP report is presented below:

# Recommendation 4:

The review team recommends that the State take measures to ensure proper documentation and appropriate response, review, enforcement, and follow up of all radioactive materials incidents. (Section 3.5 of the 2006 IMPEP Report)

# Current Status:

The Section has made some progress since the last review. The review team evaluated five incidents that required reporting under NRC criteria. The incidents selected for review included the following categories: lost/stolen radioactive material, leaking source, and medical events. The review team found that incident information in NMED for Oregon was up to date and complete, with one exception: an incident involving a leaking sealed source. The Section stated that they will provide the information on the incident to the NRC's contractor responsible for maintaining NMED for inclusion in the database.

Through the reviews of the incident documentation, the review team determined that inspectors were dispatched and took appropriate followup actions for one on-site investigation, a lost material incident. The two medical events involved underexposures, and no on-site investigations were conducted. No health and safety issues were identified. Section managers determine if the event requires a call to the NRC Headquarters Operations Center, and whether the event needs to include an on-site investigation. The event is then assigned to a member of the inspection staff to complete any required followup activities. Generally, the Section relies on the licensees' 30-day incident reports for their event reports

The review team found that incident information continued to be maintained in multiple locations: the Section's database, the incident files, and the NMED files. In most cases, no single file had all of the pertinent documents. The review team found the Section's documentation was often incomplete. In one case involving a medical incident, the report was not placed in the licensee file; therefore, no follow up to the event was conducted during the next routine inspection.

The Emergency Response/Field Operations Manager is currently in the process of organizing the incidents. The review team noted that incident tracking has improved; however, the review team continued to find documentation issues in the license and incident files. Thus, the review team recommends that Recommendation 4 of the 2006 IMPEP report remain open.

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

## 3.0 NON-COMMON PERFORMANCE INDICATORS

The followup review addressed one of the non-common performance indicators used in reviewing NRC Regional and Agreement State programs, "Compatibility Requirements."

## 3.1 <u>Compatibility Requirements</u>

## 3.1.1 Legislation

Oregon became an Agreement State on July 1, 1965. Legislative authority to create an agency and enter into an Agreement with the NRC is granted in Oregon Statute 453.625. Oregon Statute 453 governs the use of radioactive materials, x-ray, emergency response, and laboratory services.

There were three legislative changes during the review period that affected the Section. One legislative change was House Bill 5032, which authorized the increase in radioactive materials licensing fees, as well as other Division fees, at a rate set in 2006. This legislative change allowed the Section to increase its fees for the first time in 14 years. The second legislative change was House Bill 2185, which provided civil penalty authority to the Division. The Section Manager anticipates completing revisions to Oregon's current rules to refer to the new public health authority and civil penalty authority within approximately 180 days. The last legislative change was House Bill 2193, which by authorization of an increase in x-ray and tanning registration and inspection program fees allowed for the permanent funding for approximately three additional full-time equivalents within the Section. Oregon has no sunset provisions either for the Section or for its regulations.

## 3.1.2 Program Elements Required for Compatibility

The State's regulations governing radiation protection requirements are contained in the Oregon Administrative Rules (OAR) 333. Oregon requires a license for possession and use of all radioactive material, including NARM. Oregon also requires registration of all machines designed to produce radiation.

The review team's evaluation of the State's response to Recommendation 5 of the 2006 IMPEP report is presented below:

## Recommendation 5:

The review team recommends that the State develop and implement an action plan to adopt NRC regulations in accordance with the current NRC policy on adequacy and compatibility. (Section 4.1.2 of the 2006 IMPEP report)

## Current Status:

The review team 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 State Regulation Status (SRS) sheet as maintained by FSME.

Since the last review, the Section has addressed a large number of NRC regulation amendments. Current NRC policy requires that Agreement States adopt certain equivalent regulations or legally-binding requirements no later than 3 years after they are effective. As the date of this review, the following two regulations are overdue:

• "Respiratory Protection and Controls to Restrict Internal Exposure," 10 CFR Part 20 amendment (64 FR 54543 and 64 FR 55524) that became effective February 2, 2000, and was due for Agreement State implementation on February 2, 2003.

The NRC reviewed and commented on the draft of this amendment on July 10, 2006. The final regulation has not been submitted for NRC review.

"Compatibility with IAEA Transportation Safety Standards and Other Transportation Safety Amendments," 10 CFR Part 71 amendment (69 FR 3697) that became effective on October 1, 2004, and was due for Agreement State implementation on October 1, 2007.

The review team discussed Oregon's ability to adopt regulations by reference for the transportation requirements. The Section Manager stated that Oregon will consider adoption by reference in order to complete the rulemaking on this amendment in 2008.

The team identified the following regulation changes and adoptions that will be needed in the future, and the State related that the regulations would be addressed in upcoming rulemaking or in the adoption of alternate legally binding requirements:

- "Minor Amendments 10 CFR Parts 20, 30, 32, 35, 40 and 70," 10 CFR amendments (71 FR 15005) that became effective March 27, 2006 and are due for State adoption by March 27, 2009.
- "National Source Tracking System Serialization Requirements," 10 CFR Part 32 with reference to Part 20 Appendix E (71 FR 65685) that became effective on February 6, 2007 and are due for State adoption by February 6, 2007. The State does not have any applicable manufacturer therefore is not required to adopt this amendment at this time.

- "National Source Tracking System," 10 CFR Part 20 amendment (71 FR 65865, 72 FR 59162) that became effective March 27, 2006 and are due for State adoption by January 31, 2009.
- "Medical Use of Byproduct Material Minor Corrections and Clarifications," 10 CFR Parts 32 and 35 amendments (72 FR 45147, 72 FR 54207) that became effective October 29, 2007 and are due for State adoption by October 29, 2010.
- "Exemptions From Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements," 10 CFR Parts 30, 31, 32 and 150 amendments (72 FR 58473) that became effective December 17, 2007 and are due for State adoption by December 17, 2010.
- "Requirements for Expanded Definition of Byproduct Material," 10 CFR Parts 20, 30, 31, 32, 33, 35, 61, and 150 amendments (72 FR 55864) that became effective November 30, 2007 and are due for State adoption by November 30, 2010.
- "Occupational Dose Records, Labeling Containers, and Total Effective Dose Equivalent," 10 CFR Parts 19 and 20 amendments (72 FR 68043) that became effective February 15, 2008 and are due for State adoption by February 15, 2011.

The review team noted that the Section continues to expend considerable effort in regulation development since the last review. One of two recently-hired managers has been assigned responsibility and oversight for rulemaking actions and regulations. The Section Manager expects to address the two overdue regulations by submitting the final regulations to the NRC for review and approval in the next upcoming rule package, within this year.

The review team recommends that Recommendation 5 of the 2006 IMPEP report be closed. The Section has developed and implemented a written action plan to ensure that the Section continues to adopt and maintain compatibility with the NRC by addressing the number of upcoming regulation changes and adoptions.

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

## 4.0 SUMMARY

The review team found Oregon's performance to be satisfactory for the indicators, Technical Quality of Licensing Actions and Compatibility Requirements, and satisfactory, but needs improvement for the indicators, Technical Quality of Inspections and Technical Quality of Incident and Allegation Activities. The review team noted that State has made progress in management oversight of the Agreement State program activities for the two performance indicators found satisfactory, but needs improvement, through reorganizing, realigning, and staffing the Section; however, the review team believes that additional time and actions are necessary before the Section reaches and sustains a level of satisfactory performance.

Accordingly, the review team recommends that the Oregon Agreement State Program continue to be found adequate, but needs improvement, and compatible with NRC's program. The

Based on the results of the review, the review team recommends that the next full IMPEP review take place in approximately 18 months.

Below are the open recommendations, as mentioned in Sections 2.0 and 3.0, for continued evaluation and implementation by the State:

## RECOMMENDATIONS

- 1. The review team recommends that the State place greater emphasis on providing sufficient detail in inspection reports to allow Section management and staff to understand the technical basis for inspection findings. (Section 2.1)
- 2. The review team recommends that the State ensure that radioactive materials inspectors are accompanied by supervisors, at least annually, to promote quality and consistency in the inspection program. (Section 2.1)
- 3. The review team recommends that the State take measures to ensure proper documentation and appropriate response, review, enforcement, and follow up of all radioactive materials incidents. (Section 2.3)

# LIST OF APPENDIXES AND ATTACHMENT

- Appendix A IMPEP Review Team Members
- Appendix B Oregon Organization Charts
- Appendix C Heightened Oversight Program Correspondence
- Appendix D Periodic Meeting Summary
- Appendix E Inspection Casework Reviews
- Appendix F License Casework Reviews
- Appendix G Incident Casework Reviews
- Attachment March 28, 2008, E-mail from Terry D. Lindsey March 31, 2008, Two e-mails from Terry D. Lindsey Oregon's Response to Draft IMPEP Report

# APPENDIX A

# IMPEP REVIEW TEAM MEMBERS

Name	Area of Responsibility
Kathleen Schneider, FSME	Team Leader Technical Quality of Incident and Allegation Activities Periodic Meeting
Linda McLean, Region IV	Technical Quality of Inspections Technical Quality of Incident and Allegation Activities Inspector Accompaniment
Michael Whalen, Massachusetts	Technical Quality of Licensing Actions
Kim Lukes, FSME	Compatibility Requirements

APPENDIX B

# OREGON ORGANIZATION CHARTS

ADAMS ACCESSION NO.: ML080570519

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# APPENDIX C

## HEIGHTENED OVERSIGHT PROGRAM CORRESPONDENCE

Minutes of Bimonthly Conference Calls:

- 1 February 7, 2007, Minutes (ML070660528)
- 2 April 26, 2007, Minutes (ML071290449)
- 3 June 18, 2007, Minutes (ML071990441)
- 4 October 30, 2007, Minutes (ML073230238)
- 5 December 12, 2007, Minutes (ML073540034)

Letters from/to Oregon:

- 1. November 29, 2006, Letter to Susan M. Allan from M. J. Virgilio Oregon Final IMPEP Report (ML063360005)
- 2. February 7, 2007, Letter to M. J. Virgilio from Susan M. Allan Response to Final IMPEP Report, including Program Improvement Plan (ML070520466)
- 3. March 5, 2007, Letter to Susan M. Allan from Janet Schlueter Approval of Program Improvement Plan (ML070660528)

# APPENDIX D

## PERIODIC MEETING SUMMARY

A periodic meeting was held with the Section Manager and the Emergency Response/Field Operations Manager by Kathleen Schneider, Team Leader, and Kim Lukes, during the followup review pursuant to the Office of Federal and State Materials and Environmental Management Programs (FSME) Procedure SA-116, "Periodic Meetings with Agreement States Between IMPEP Reviews." Topics normally documented during periodic meetings that were reviewed and documented as part of the followup review will not be discussed in this Appendix. The following topics were discussed.

#### 1. <u>Status of Recommendations from Previous IMPEP Reviews</u>

See Sections 2.0 and 3.0 for details on the status of recommendations identified during previous IMPEP reviews.

2. <u>Strengths and/or weaknesses of the State program as identified by the State including</u> identification of actions that could diminish weaknesses.

The Section Manager identified the following as the Section's strengths: new management structure, staff, cross-training of staff into different areas of expertise, and strong support for training for all staff members from upper management. The following weaknesses were identified: staff turnover, availability of scheduled training courses, and impact on the Section while preparing and participating in the recent TopOff IV Federal exercise.

3. <u>Feedback on NRC's program as identified by the State and including identification of any</u> action that should be considered by NRC.

The Regional State Agreements Officer program was identified as an NRC strength. The Section Manager also supports the resumption of the NRC's funding of State participation in NRC training courses. In addition, the Section Manager supports regional locations for NRC training courses whenever possible. He noted that the NRC still needs to maintain vigilance to ensure that notification of selection of students is at least eight weeks prior to the course. Section staff is required to obtain authorization for out-of-State travel even with NRC funding.

- 4. <u>Status of State Program Including:</u>
  - a. <u>Staffing and Training</u>:

At the time of the review, there were 19 staff members in the Section, with 7.3 full-time equivalents dedicated to the radioactive materials program. Since the last review, seven staff members have left the Section, which included the retirements of the three program managers reporting to the Section Manager. The vacant positions were in x-ray, mammography, radioactive materials, and emergency response areas. The Section has been successful in hiring six new

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staff members, including two new program managers consistent with the reorganization of the Section as discussed in 4d., below.

With the reorganization, the Emergency Response/Field Operations Manager has been designated as the NRC training coordinator. The Section is aggressively pursuing training to enable all new staff members to meet full performance in their assigned areas. The Section is also cross-training staff members to allow greater flexibility of the staff and depth of coverage of the Section's responsibilities. A Training Committee has been formed consisting of Section management staff, lead workers, and mentors to develop an integrated written training plan for new employees and ongoing staff development.

b. <u>Materials Inspection Program</u>:

The Section's inspection priorities are generally the same as the NRC's priorities, with several inspection frequencies being more frequent than for similar license types listed in IMC 2800, "Materials Inspection Program. The Section tracks all inspection activities in a computer database, which is used by program managers and staff members to determine inspection status for any licensed facility. Since the last review, 15 Priority 1, 2 and 3 inspections were completed overdue. At the time of the review, there were no overdue inspections. According to the Section Manager, the loss of staff and the TopOff IV Federal exercise impacted the inspection schedule. The Section expects to continue meeting its inspection schedule in the future.

c. <u>Regulations and Legislative Changes</u>:

See Section 3.1.

d. <u>Program Reorganizations</u>:

Since the last review, the Section has reorganized. The reorganization was executed and accomplished in a three-phased transition, which included a change from a three-program management organization to the current two-program management organization. In May 2006, during the first phase of the reorganization, a lead worker was assigned to the Radioactive Materials Licensing, Emergency Preparedness, and Tanning Program to handle increased responsibilities for program functions were divided by modality. All inspection functions are located in the Emergency Response/Field Operations Program and all licensing and regulation promulgation functions will be in the Emergency Preparedness/Licensing Program. The third phase includes the hiring of new staff members, including a position dedicated as an enforcement lead, once regulations are in place to implement HB 2185, as discussed in Section 3.1.1.

The Section considers the reorganization to be an improvement in program efficiency and functional assignments resulting in better response to incident investigations, licensing activities, and anticipated increases in portable and fixed

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> gauge facilities. An extensive cross-training program will be implemented for staff in both Programs with new assignments for technical staff to assist with radioactive materials inspection, emergency preparedness planning, and incident response duties.

e. <u>Changes in Program Budget/Funding</u>:

See Section 3.1.1 for further discussion on legislative changes regarding the funding of the radioactive materials program.

## 5. <u>Event Reporting</u>:

The Section Manager has requested training for NMED and FSME Procedure SA-300, "Reporting Material Events." Oregon staff is scheduled to participate in the training to be held in Nevada on July 17, 2008. See Section 2.2 for details on the Technical Quality of Incident and Allegation Activities.

6. <u>Response to Incidents and Allegations</u>:

See Section 2.2.

- 7. Information Exchange and Discussion:
  - a. <u>Current State Initiatives</u>:

During the discussions, the Section Manager indicated that the Attorney General's office has indicated that Oregon can issue the fingerprinting requirements through license conditions based on the NRC order.

Oregon licensing staff has received the revised pre-licensing guidance and is reviewing it. The Section plans on submitting comments resulting from the 3-month pilot period.

The Section Manager discussed that States could benefit from Security Training from the NRC to include guidance for proper protection of sensitive material. Oregon adequately protects sensitive material sent by the NRC.

The Section Manager also discussed its new initiative of increasing training with external partners (i.e. National Guard).

b. <u>State's Mechanisms to Evaluate Performance:</u>

The reorganization discussed in 4d. above was the result of a top-to-bottom review conducted by staff and management of the Division.

## APPENDIX E

## INSPECTION CASEWORK REVIEWS

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

File No.: 1 Licensee: Cardinal Health Inspection Type: Routine, Unannounced Inspection Date: 5/7/07

File No.: 2 Licensee: Oregon Health & Science University Inspection Type: Special, Announced Inspection Date: 4/30/07

Comment: Inspection report was sent out January 17, 2008.

File No.: 3 Licensee: Oregon Health & Science University Inspection Type: Special, Announced Inspection Date: 4/3/07

Comment: Inspection report was sent out January 17, 2008.

File No.: 4 Licensee: Zipper Zeman Associates Inspection Type: Initial, Unannounced Inspection Date: 12/5/07

File No.: 5 Licensee: Professional Service Industries, Inc. Inspection Type: Special, Followup, Unannounced Inspection Date: 12/4/07 License No.: ORE-90509 Priority: 1 Inspector: JS

License No.: ORE-90013 Priority: 1 Inspectors: JS, KS

License No.: ORE-90731 Priority: 1 Inspectors: JS, KS

License No.: ORE-91073 Priority: 5 Inspector: DL

License No.: ORE-90056 Priority: 1 Inspector: DL

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File No.: 6

Licensee: Oregon Health & Science University Inspection Type: Routine, Unannounced Inspection Date: 1/23/08

Comment:

Licensee reported a medical event on July 9, 2007. Event report was not placed in licensee's file; therefore, no event followup was conducted during this inspection.

File No.: 7 Licensee: RML Industries, Inc. Inspection Type: Routine, Announced Inspection Date: 12/6/07

File No.: 8 Licensee: Salem Nuclear Cardiology L.L.C. Inspection Type: Routine, Unannounced Inspection Date: 5/21/07

File No.: 9 Licensee: Mallinckrodt, Inc. Inspection Type: Routine, Unannounced Inspection Date: 11/2/07

File No.: 10 Licensee: Providence Portland Medical Center Inspection Type: Routine, Unannounced Inspection Date: 6/26/07

Comments:

- a) Licensee reported a medical event in 2005. No event followup was conducted during this inspection.
- b) The inspection report details are very limited.

File No.: 11 Licensee: Holy Rosary Medical Inspection Type: Routine, Unannounced Inspection Date: 3/15/07

Comment: The inspection report details are very limited.

File No.: 12 Licensee: Samaritan Lebanon Community Hospital Inspection Type: Routine, Unannounced Inspection Date: 8/31/06 License No.: ORE-90367 Priority: 2 Inspector: KS

License No.: ORE-90728 Priority: 1 Inspector: DL

License No.: ORE-90013

License No.: ORE-90846 Priority: 3 Inspector: JS

License No.: ORE-90702 Priority: 1 Inspector: JS

License No.: ORE-90946 Priority: 2 Inspector: KS

License No.: ORE-90990

Priority: 3

Inspector: JS

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Priority: 1

Inspector: JS

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File No.: 13 Licensee: Cascade Health Services, Inc. Inspection Type: Routine, Unannounced Inspection Date: 10/3/06

Comment: The inspection report details are very limited.

File No.: 14 Licensee: International Inspection Inspection Type: Special, Announced Inspection Dates: 9/24/07

File No.: 15 Licensee: American Red Cross/Blood Services Inspection Type: Special, Announced Inspection Date: 8/8/07 License No.: ORE-90510 Priority: 3 Inspector: KS

License No.: ORE-90651 Priority: 1 Inspector: KS

License No.: ORE-90273 Priority: 5 Inspector: DL

#### INSPECTOR ACCOMPANIMENTS

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

Accompaniment No.: 1 Licensee: Professional Services, Inc Inspection Type: Routine, Unannounced Inspection Date: 12/4/07

Accompaniment No.: 2 Licensee: Zipper Zermen Associates Inspection Type: Initial, Unannounced Inspection Date: 12/5/07

Accompaniment No.: 3 Licensee: TDY Industries, Inc Inspection Type: Routine, Unannounced Inspection Date: 12/6/07 License No.: ORE-90056 Priority: 1 Inspector: DL

License No.: ORE-91073 Priority: 5 Inspector: DL

License No.: ORE-90728 Priority: 1 Inspector: DL

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## APPENDIX F

#### LICENSING CASEWORK REVIEWS

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

File No.: 1 Licensee: St. Anthony Hospital Type of Action: Amendment Date Issued: 9/25/07

File No.: 2 Licensee: Sacred Heart Hospital Types of Action: New, Amendments Dates Issued: 8/24/06, 11/8/06, 11/9/06 License No.: ORE-90353 Amendment No.: 31 License Reviewers: DL, TL

License No.: ORE-91054 Amendment Nos.: 01, 02 License Reviewer: SM

Comment:

The radiation safety officer listed on the license does not have experience commensurate with the licensed use of the material. The review team noted that two authorized users on the license would qualify as a radiation safety officer.

File No.: 3 Licensee: Tuality/OHSU Cancer Center Type of Action: Amendment Date Issued: 1/23/07

License No.: ORE-91048 Amendment No.: 04 License Reviewer: Unknown

Comment:

New license issued 6/2/2006. File only contained amended license. All applications and correspondence were missing. The Section identified the missing documentation and is currently working with licensee to obtain copies of all correspondence.

File No.: 4 Licensee: Industrial Dynamics Co., Ltd. Type of Action: Termination Date Issued: 7/3/07

File No.: 5 Licensee: Wagner Electronics Products, Inc. Type of Action: New Date Issued: 10/19/07 Amendment No.: 08 License Reviewer: SM

License No.: ORE-90791

License No.: ORE-91078 Amendment No.: N/A License Reviewer: SM

Comment:

Incorrect program code was assigned to the license and was identified by the Section; however, the review team determined that the revised program code was still incorrect and will need additional revision.

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File No.: 6 Licensee: Samaritan Albany General Hospital Type of Action: New Date Issued: 10/19/07

File No.: 7 Licensee: Gray, Thomas & Associates, Inc. Type of Action: New Date Issued: 6/21/07

File No.: 8 Licensee: Professional Service Industries, Inc. Type of Action: Amendments Dates Issued: 9/18/06, 8/10/07

File No.: 9 Licensee: Zipper Zerman Associates Types of Action: New, Amendment Dates Issued: 6/14/07, 11/6/07

File No.: 10 Licensee: TDY Industries, Inc. Type of Action: Amendments, Renewal Dates Issued: 4/27/07, 5/30/07, 9/28/07

File No.: 11 Licensee: Oregon Health & Science University Type of Action: Amendments, Renewal Dates Issued: 5/29/07, 6/26/07, 11/6/07

Comment:

Renewal application contained only the index of the radiation safety program and not the full document expected for a type A broad license. No indication in the documentation in the file that a review of the radiation safety program had been completed.

File No.: 12 Licensee: Cardinal Health Nuclear Pharmacy Services Type of Action: Amendments Dates Issued: 1/23/07, 12/24/07, 12/28/07

File No.: 13 Licensee: Cardinal Health Nuclear Pharmacy Services Type of Action: Amendments Dates Issued: 9/25/06, 9/26/06, 10/24/07 License No.: ORE-91080 Amendment No.: N/A License Reviewer: SM

License No.: ORE-96169 Amendment No.: N/A License Reviewer: SM

License No.: ORE-90056 Amendment Nos.: 47, 48 License Reviewer: SM

License No.: ORE-91073 Amendment Nos.: N/A, 01 License Reviewer: SM

License No.: ORE-90728 Amendment Nos.: 21, 22, 23 License Reviewer: SM

License No.: ORE-90731 Amendment Nos.: 73, 74, 75 License Reviewer: SM

License No.: ORE-90703 Amendment Nos.: 32, 33, 34 License Reviewer: SM

License No.: ORE-90509 Amendment Nos.: 37, 38, 39 License Reviewer: SM Oregon Proposed Final Followup Report License Casework Reviews

File No.: 14 Licensee: Metro Metals Northwest, Inc. Type of Action: New Date Issued: 9/27/06

File No.: 15 Licensee: Radiology Corporation of America (RCOA) Type of Action: New Date Issued: 1/18/07

File No.: 16 Licensee: Ash Grove Cement Co. Type of Action: Termination Date Issued: 11/29/06 License No.: ORE-91053 Amendment No.: N/A License Reviewer: SM

License No.: ORE-91058 Amendment No.: N/A License Reviewer: SM

License No.: ORE-91049 Amendment No.: 03 License Reviewer: SM

Comment:

No leak test submitted to support termination, and no documentation in the file of recent leak test results.

File No.: 17

Licensee: Central Oregon Community Action Agency Type of Action: Termination Date Issued: 6/8/07

License No.: ORE-90977 Amendment No.: 04 License Reviewer: SM

Comment:

No leak test submitted to support termination, and no documentation in the file of recent leak test results.

File No.: 18 Licensee: Environmental Restoration Type of Action: Termination Date Issued: 8/18/06

License No.: ORE-90937 Amendment No.: 02 License Reviewer: DL

Comment:

No leak test submitted to support termination, and no documentation in the file of recent leak test results.

File No.: 19 Licensee: Hart Crowser, Inc. Type of Action: Termination Date Issued: 9/18/07

License No.: ORE-90920 Amendment No.: 03 License Reviewer: SM

Comment:

No leak test submitted to support termination, and no documentation in the file of recent leak test results.

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File No.: 20 Licensee: North Creek Analytical Group Type of Action: Termination Date Issued: 11/2/06

License No.: ORE-90953 Amendment No.: 02 License Reviewer: SM

#### Comment:

No leak test submitted to support termination, and no documentation in the file of recent leak test results.

File No.: 21 Licensee: Hamptons, Inc. Type of Action: Termination Date Issued: 5/25/07

License No.: ORE-91009 Amendment No.: 01 License Reviewer: SM

#### Comment:

No leak test submitted to support termination, and no documentation in the file of recent leak test results.

File No.: 22 Licensee: Morse Brothers, Inc. Type of Action: Termination Date Issued: 8/22/06

License No.: ORE-90894 Amendment No.: 04 License Reviewer: SM

#### Comment:

No leak test submitted to support termination. and no documentation in the file of recent leak test results.

#### APPENDIX G

#### INCIDENT CASEWORK REVIEWS

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

File No.: 1 Licensee: Cascade Steel Mill, Inc. Date of Incident: 9/7/06 Investigation Date: 9/7/07

File No.: 2 Licensee: Oregon Health Science Center Date of Incident: 6/18/07 Investigation Date: N/A

File No.: 3 Licensee: Providence Medford Medical Center Date of Incident: 6/25/07 Investigation Date: N/A

File No.: 4 Licensee: Metro South Date of Incident: 3/15/07 Investigation Date: N/A License No.: NRC 11-27071-01 NMED Log No.: 060565 Type of Incident: Lost Material Type of Investigation: On-site

License No.: ORE-90013 NMED Log No.: 070384 Type of Incident: Medical Event Type of Investigation: 30-day report

License No.: ORE-91035 NMED Log No.: 070392 Type of Incident: Medical Event Type of Investigation: 30-day report

License No.: N/A NMED Log No.: N/A Type of Incident: Lost Material/Contaminated Trash Type of Investigation: Phone

File No.: 5 Licensee: Oregon Health Science Center Date of Incident: 7/12/07 Investigation Date: N/A

License No.: ORE-90013 NMED Log No.: N/A Type of Incident: Leaking Source Type of Investigation: None

Comment: Incident was not submitted for inclusion in NMED.

File No.: 6 Licensee: Community Cancer Center Date of Incident: 4/12/07 Investigation Date: 4/12/07

License No.: ORE-90422 NMED Log No.: N/A Type of Incident: Medical Event Types of Investigations: Phone, 30-day report Oregon Proposed Final Followup Report Incident Casework Reviews

File No.: 7 Licensee: Legacy Emanuel Hospital Date of Incident: 11/1/06 Investigation Date: 3/1/07

License No.: ORE-90126 NMED Log No.: N/A Type of Incident: Medical Event Types of Investigations: Phone, 30-day report

File No.: 8 Licensee: Kaiser Interstate Radiological Oncology Date of Incident: 4/10/07 Investigation Date: 4/13/07

y License No.: ORE-90978 NMED Log No.: N/A Type of Incident: Medical Event Types of Investigations: Phone, 30-day report

File No.: 9 Licensee: Salem Hospital Date of Incident: 10/16/07 Investigation Date: 10/16/07

License No.: ORE-91006 NMED Log No.: N/A Type of Incident: Medical Event Type of Investigation: Phone, 30-day report

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## ATTACHMENT

March 28, 2008, E-mail from Terry D. Lindsey March 31, 2008, Two e-mails from Terry D. Lindsey Oregon's Response to Draft IMPEP Report

ADAMS: ML080920172 and ML080920300

## Agenda for Management Review Board Meeting April 15, 2008, 3:00 p.m. - 5:00 p.m. (EDT), OWFN-3-B4

- 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 representatives participating remotely. (Organization of Agreement States (OAS) Liaison is Aubrey Godwin of Arizona.)
- 3. Consideration of the Oregon Followup IMPEP Report.
  - A. Presentation of Findings Regarding Oregon's Program and Discussion.
    - Technical Quality of Inspections
    - Technical Quality of Licensing Actions
    - Technical Quality of Incident and Allegation Activities
    - Compatibility Requirements
  - B. Presentation of the Periodic Meeting Summary
  - C. IMPEP Team Recommendations.
    - Adequacy and Compatibility Ratings
    - Recommendation for Next IMPEP Review
  - D. MRB Consultation/Comments on Issuance of Report.
- 4. Request for comments from Oregon representatives, OAS Liaison, and State IMPEP Team Member. (State IMPEP team member is Michael Whalen of Massachusetts.)
- 5. Adjournment.
- Invitees: Martin Virgilio, DEDMRT Karen Cyr, OGC Charles Miller, FSME Steven Reynolds, RIII Aubrey Godwin, AZ Terry Lindsey, OR Robert Lewis, FSME

Kathleen Schneider, FSME Linda McLean, Region IV Kim Lukes, FSME Michael Whalen, MA Duncan White, FSME Aaron McCraw, FSME Stephen Campbell, OEDO

**ENCLOSURE 2**