UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

December 5, 2009

Mel Kohn, M.D.
Director
Oregon Public Health Division
Department of Human Services
800 NE Oregon Street, Suite 640
Portland, OR 97232-2162

Dear Dr. Kohn:

On November 10, 2009, the Management Review Board (MRB) met to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) report on the Oregon Agreement State Program. The MRB found the Oregon Agreement State Program adequate to protect public health and safety, but needs improvement, and compatible with the U.S. Nuclear Regulatory Commission's (NRC) program. The MRB extended the period of monitoring of the Oregon Agreement State Program. As part of the monitoring process, NRC will conduct calls with the appropriate representatives from the Oregon Radiation Protection Services Section every 3 months.

Section 5.0, page 12, of the enclosed final report contains a summary of the IMPEP review team's findings and recommendations. We request your evaluation and response to the recommendations within 30 days from receipt of this letter.

Based on the results of the current IMPEP review, the next full review of the Oregon Agreement State Program will take place in approximately 3 years to accommodate the State's request to conduct IMPEP reviews when the Oregon Legislature is not in session. A periodic meeting to review the State's progress of addressing the team's recommendations is tentatively scheduled for August 2010.

I appreciate the courtesy and cooperation extended to the IMPEP team during the review. I also wish to acknowledge your continued support for the Agreement State Program. I look forward to our agencies continuing to work cooperatively in the future.

Sincerely,

/RA/

Martin J. Virgilio
Deputy Executive Director for Materials, Waste,
Research, State, Tribal, and Compliance Programs
Office of the Executive Director for Operations

Enclosure:
Oregon Final IMPEP Report

cc w/enclosure: See next page.

cc w/encl: Gail R. Shibley, Administrator
Office of Environmental Public Health

Terry D. Lindsey, Manager
Oregon Radiation Protection Services Section

Ken Niles, State Liaison Officer
Oregon Department of Energy

Cindy Cardwell, TX
Organization of Agreement States
Liaison to the MRB

INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF THE OREGON AGREEMENT STATE PROGRAM

August 24-27, 2009

FINAL REPORT

Enclosure

1.0 INTRODUCTION

This report presents the results of the review of the Oregon Agreement State Program. The review was conducted during the period of August 24-27, 2009, by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of California. Team members are identified in Appendix A. The review was conducted in accordance with the "Implementation of the Integrated Materials Performance Evaluation Program and Rescission of Final General Statement of Policy," published in the *Federal Register* on October 16, 1997, and NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)," dated February 26, 2004. Preliminary results of the review, which covered the period of August 25, 2006, to August 27, 2009, for the performance indicators, Technical Staffing and Training and Status of Materials Inspection Program; and the period of February 1, 2008, to August 27, 2009, for the other performance indicators; were discussed with Oregon managers on the last day of the review.

A draft of this report was issued to Oregon for factual comment on September 30, 2009. The State responded by e-mail dated October 23, 2009, from Terry Lindsey, Manager, Radiation Protection Services Section (the Section). A copy of the State's response is included as the Attachment to this report. The Management Review Board (MRB) met on November 11, 2009, to consider the proposed final report. The MRB found the Oregon Agreement State Program adequate to protect public health and safety, but needs improvement, and compatible with NRC's program. The MRB extended the period of monitoring of the Oregon Agreement State Program.

The Oregon Agreement State Program is administered by the Section in the Division of Public Health (the Division). The Division is part of the Oregon Department of Human Services (the Department). Organization charts for the State and the Section are included in Appendix B.

At the time of the review, the Oregon Agreement State Program regulated approximately 400 specific licenses authorizing byproduct, source, and certain special nuclear materials. 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 NRC and the State of Oregon.

In preparation for the review, a questionnaire addressing the common and applicable non-common performance indicators was sent to the Section on June 15, 2009. The Section provided a response to the questionnaire on July 29, 2009. A copy of the questionnaire response can be found in the NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML092720448.

The review team's general approach for conduct of this review consisted of: (1) examination of the Section's response to the questionnaire; (2) review of applicable Oregon statutes and regulations; (3) analysis of quantitative information from the Section's database; (4) technical review of selected regulatory actions; (5) field accompaniments of four inspectors; and (6) interviews with staff and managers. 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 Oregon Agreement State Program's performance.

Section 2.0 of this report covers the State's actions in response to recommendations made during previous review. Results of the current review of the common performance indicators are presented in Section 3.0. Section 4.0 details the results of the review of the applicable non-common performance indicators, and Section 5.0 summarizes the review team's findings and recommendations. The review team's recommendations 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 followup IMPEP review, which concluded on January 31, 2008, the review team left three recommendations open regarding program performance that were identified during the prior IMPEP review, which concluded on August 24, 2006. The status of the open recommendations is as follows:

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)

   Status: The review team found that the Section has continued their improved inspection documentation, with most reports containing sufficient documentation to adequately communicate the scope of the inspection, the scope of the licensee's program, the observed licensee activities, independent survey results, and specific inspection findings to support findings communicated to licensees. The review team noted isolated documentation issues rather than systemic problems. The review team noted that the Field Operations/Emergency Response Manager has been auditing the quality of inspection documentation, including inspection reports, and has instituted actions to correct individual performance issues that he identifies. This recommendation is closed.

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)

   Status: The review team was informed by the Section Manager that the Field Operations/Emergency Response Manager was considered qualified to perform full accompaniments by mid-2008, based on training he had received by that time. The review team noted that at least one accompaniment was made annually of each inspector subsequent to that time. The Section Manager further stated that the lead radioactive material inspector would also accompany each inspector annually in order to further strengthen this aspect of the Section's performance. This recommendation is closed.

3. The review team recommends that the State take measures to ensure proper documentation and appropriate response, review, enforcement, and followup of all radioactive materials incidents. (Section 2.3)

Status: The review team reviewed approximately 100 incident files and found inadequate followup for one medical licensee that had several medical events (under doses) that should have been reported to NMED. The overall incident followup as demonstrated in the other files was considered acceptable. This recommendation is closed.

3.0 COMMON PERFORMANCE INDICATORS

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

3.1 Technical Staffing and Training

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

The day-to-day operations of the Oregon Agreement State Program are executed by the Section. The Section is composed of two management units: the Emergency Preparedness, Licensing & Administration Unit and the Emergency Response, Field Operations & Technical Services Unit. Each unit is headed by a Manager. Staff members in the Section perform licensing, inspection, training, and emergency preparedness and response activities for radioactive materials facilities.

The Section has approximately 5.25 full-time equivalents assigned to perform the technical aspects of the radioactive materials program. The Section's radioactive materials program staff is composed of four technical staff members, a medical physicist, and two supervisors. One staff member is assigned primarily to licensing activities. The inspection workload was split among the other three technical staff members. In addition, the Section is cross-training staff from other areas of the Section (e.g., tanning and x-ray) to augment the radioactive materials inspection program. One tanning inspector was recently qualified to conduct gauge inspections, and the x-ray staff assists in incident response. The review team concluded that the Section's staffing level is adequate to carry out its regulatory duties.

The review team noted that Section management encourages and supports training opportunities based on program needs and funding. The Section's training and qualification program for technical staff uses the technical course requirements in NRC Inspection Manual Chapter (IMC) 1246, "Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area."

Technical staff qualification is achieved through a combination of education and experience, formal classroom training, and on-the-job training. The review team noted that, while the Section maintains records of formal classroom training for each staff member, it does not maintain records of self-study or on-the-job qualification training, such as training in applicable

regulatory requirements. This issue was identified during the inspector accompaniments where a new inspector was not familiar with the portable gauge security regulatory requirements. The inspector's qualification training had not included a comprehensive review of the applicable regulations pertinent to portable gauge inspection. The review team observed through interviews, casework examinations, and inspector accompaniments that, while the staff was in general technically qualified to perform inspection and licensing activities, some critical knowledge of regulatory requirements and guidance documents was in need of improvement in the licensing and inspection programs. Sections 3.3 and 3.4 of this report contain the review team's specific observations related to needed improvements in training. The review team recommends the State develop and use a documented formal qualification program (including refresher training) for inspection and licensing staff that would include journals that clearly indicate each individual's training and qualification including oral and/or written evaluation of their understanding of regulations and guidance documents.

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

3.2 Status of Materials Inspection Program

The review team focused on five factors in 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 is based on the Section's response to the questionnaire relative to this indicator, data gathered from the Section's licensing and inspection database, examination of completed inspection casework, and interviews with Section managers and staff.

The review team verified that the Section's inspection priorities, with the exception of one category of license, were at least as frequent as the inspection priorities prescribed by NRC's IMC 2800, "Materials Inspection Program." The Section performs inspection of many license categories more frequently than prescribed by IMC 2800. The one exception noted by the review team was for medical therapy - emerging technology licenses. The Section inspects this category of license every 3 years; whereas, IMC 2800 calls for inspections of this license type every 2 years. This discrepancy resulted in an inspection being performed overdue by IMC 2800 standards during the review period. The discrepancy was corrected by the Section. The review team noted that the Section corrected the inspection priority discrepancies for source material and special nuclear material possession licenses noted during the 2006 IMPEP review.

The Section conducted 137 Priority 1, 2, and 3 or initial inspections during the review period. Using information gathered from the Section's database, the review team identified eight inspections conducted overdue during the review period, six of which were initial inspections. Four of the six overdue initial inspections occurred because Section staff thought initial inspections were due by the end of the 1-year anniversary month, not within the 1-year period. The review team noted that the length of time inspections were conducted overdue ranged from 3 to 355 days. The review team verified that there were no overdue inspections at the time of the review. The review team calculated that the Section conducted approximately 6 percent of all Priority 1, 2, and 3 and initial inspections overdue during the review period.

The Section's policy is to issue inspection results to licensees at the conclusion of the on-site inspection using an Oregon 591 form. Only in infrequent circumstances, such as escalated enforcement or the need for further evaluation of inspection findings, are the inspection results not provided to licensees before the inspectors leave the inspection sites. The review team verified that inspection finding were communicated to licensees within 30 days of completion of the inspections.

The Section receives notifications of reciprocity work within Oregon at a rate of 2-3 per work day which are forwarded to the inspection group. Typically all reciprocity work is inspected if the reciprocity licensee hasn't been inspected within the preceding twelve months. Most of the reciprocity licensees are NRC Priority 5 licensees. Usually, no more than 15 NRC Priority 1-3 licensees request reciprocity per year. Reciprocity inspections of candidate licensees during the years 2006 to 2009 (through July 31, 2009) totaled 5, 5, 7, and 3, respectively, which corresponded to at least 20 percent per year. The review team noted that in the two reciprocity inspections reviewed in which regulatory violations were identified, the inspection results were communicated to the licensing State.

The Section has 14 licenses subject to the Increased Controls. The initial inspections of 12 of the 14 licenses were completed in the first year, with the remaining two completed in the second year. Although documentation was not located that described the prioritization methodology utilized for scheduling the initial inspections, the methodology described by Section staff met the criteria of COMSECY-05-0028. The review team noted that continuing Increased Controls inspections were conducted in conjunction with applicable routine inspections and that new licensees subject to the Increased Controls are inspected for compliance prior to receiving authorization to possess materials in risk-significant quantities.

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

3.3 Technical Quality of Inspections

The review team evaluated the inspection reports, enforcement documentation, and inspection field notes for 16 radioactive materials inspections conducted during the review period, and accompanied each of the four current inspectors on field inspections. The casework examined included a cross-section of inspections conducted by the four current inspectors and covered a wide variety of inspection types. These included: industrial radiography, high dose-rate remote afterloader, mobile nuclear medicine - positron emission tomography, broad scope industrial, medical - therapy, gamma knife, medical - diagnostic and imaging, nuclear pharmacy, portable gauge, and research and development. The casework also included reciprocity and Increased Controls inspections. Appendix C lists the inspection casework reviewed and includes case-specific comments.

Based on the evaluation of casework, the review team determined that inspections covered almost all aspects of the licensees' radiation safety and security programs. The review team noted instances where areas were either missed during the inspection or not described in the inspection reports. The inspections for Increased Controls licensees appropriately addressed licensee compliance with the Increased Controls requirements. Licensee progress on

implementation of the finger printing and national source tracking requirements were not consistently addressed in inspection reports; however, an independent tracking system of the licensees' implementation statuses was maintained by the Section that demonstrated that all required licensees had addressed the requirement.

Documents involving Increased Controls information were maintained in a locked file cabinet with limited access; however, the documents (both licensing and inspection) were not marked as security sensitive information. Although there were no instances of improper release of information, the review team was concerned that without proper marking the likelihood of release was much greater. The review team recommends that the State develop and implement a procedure for the control of sensitive or security-related information that provides guidance to identify, mark, handle, and protect such information.

The review team noted that the Section is continuing its efforts to upgrade inspection procedures. Currently, one procedure, covering fixed and portable gauges, has been formally adopted, with several others in various stages of development. Pending completion of the upgraded procedures, a mixture of draft and existing Section inspection procedures and NRC inspection procedures are being utilized by inspectors. In one instance during the review team accompaniments, an important inspection issue (securing of portable gauges), and one of lesser importance, were not covered by the inspector. The review team discussed with the Section the benefits of the emphasis on continued development of inspection procedures and training in use of these procedures.

With infrequent exceptions, inspection findings were routinely provided to licensees at the conclusion of inspections using an Oregon 591 form. An inspection report is routinely generated after returning to the office. In addition to the Oregon 591 form that is left at the time of the inspection, the Section also provides the inspection report to the licensee with a cover letter communicating the significance of the inspection findings. The Section uses a severity of non-compliances system based on a severity level scale of 1-5. The review team noted inconsistency in applying this system and the assigning of severity levels which could be addressed by completion of procedures and training in this area. The Section committed to implement an enforcement procedure that includes typical violations and related severity levels.

The review team verified that the Section maintains an adequate supply and types of calibrated survey instruments to support the inspection program, and to respond to incidents and emergencies. The Section has the capability to conduct gamma analysis of samples and can contract for additional analyses, as needed.

The review team accompanied four inspectors in July 2009. The inspectors conducted inspections at a portable gauge user, a nuclear pharmacy, an industrial radiographer, and a hospital. Appendix C lists the inspector accompaniments and includes the review team's observations. In general, the inspectors used good inspection techniques including use of performance based criteria. The inspectors were trained, prepared for the inspections, and thorough in their audits of the licensees' radiation safety and security programs. The inspectors conducted interviews with appropriate personnel, observed licensed operations, conducted confirmatory measurements, and utilized good health physics practices. The inspectors held entrance and exit meetings with the appropriate level of licensee management. The review team determined that the inspections were adequate to assess radiological health, safety, and

security at the licensed facilities with one exception. During one accompaniment, the inspector did not identify a portable gauge licensee's failure to provide two independent physical controls to secure gauges from unauthorized removal, for both storage and transportation. The inspector was unfamiliar with this regulatory requirement, as well as other applicable Oregon regulations. The review team found that the Section individual who had been assigned to train this inspector also was found not to be knowledgeable of the Oregon regulation to secure portable gauges from unauthorized removal. The remaining two Oregon inspectors were knowledgeable of the requirement. The inspection procedure carried by an inspector referenced the two-physical-control requirement in somewhat general terms. The review team noted that, while the portable gauge licensee was subsequently informed of the regulatory requirement for two independent physical controls for their portable gauge, the licensee was not cited for the non-compliance.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Oregon's performance with respect to the indicator, Technical Quality of Inspections, was satisfactory, but needs improvement.

3.4 Technical Quality of Licensing Actions

The review team examined completed licensing casework and interviewed license reviewers for 19 licensing actions involving 17 specific licenses. 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 correspondence, reference to appropriate regulations, supporting documentation, consideration of enforcement history, pre-licensing visits, peer or 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 3 new licenses, 11 amendments, 3 renewals, and 2 license terminations. Files reviewed included a cross-section of license types, including: medical diagnostic and therapy, brachytherapy, gamma knife, nuclear pharmacy, cyclotron, academic, medical broad scope, fixed and portable gauge, and industrial radiography. A listing of the licensing casework reviewed, with case-specific comments, can be found in Appendix D.

Overall, the review team found that the licensing actions were complete and addressed health and safety issues. In most cases, the staff followed appropriate licensing guides during the review process to ensure that licensees submit information necessary to support their request. Deficiency correspondence was used, as appropriate, to obtain additional information from the applicant or licensee. The Section has one senior staff member whose primary responsibility is licensing and a second staff member is being cross-trained to conduct licensing actions. At a minimum, each licensing action has a peer review and a management review. The licensing manager signs licenses.

The review team examined the Section's licensing practices in regard to the Increased Controls, Fingerprinting Orders, and the National Source Tracking System. The review team noted that

the Section added legally binding license conditions to the licenses that met the criteria for implementing these requirements in a timely manner. The Section evaluates new license applications and license amendments to determine the applicability of enhanced security requirements.

The Section uses NRC's pre-licensing guidance to evaluate new licensees to determine when and how to perform pre-licensing visits of new applicants or licensees requesting radioactive material possession limits in quantities of concern. The review team evaluated the casework for the pre-licensing visits of new applicants performed during the review period and found that the visits were appropriately performed and well documented.

The review team found that actions terminating licenses were well documented, and included the appropriate material survey records. All files reviewed contained documentation of proper disposal or transfer.

Section staff stated that they use licensing procedures include use of the NUREG-1556 series and the NRC's Title 10 Code of Federal Regulations (CFR) Part 35.1000 licensing guidance. However, the review team observed inconsistent use of this guidance for certain licensing actions that are complex and/or infrequently encountered. The review team identified potential health and safety and regulatory compliance issues with several major licensing actions. These complex actions raised several significant regulatory issues that were not properly addressed in the licensing process such as proper exemption for a new gamma knife design, proper training information for an authorized nuclear pharmacist, adequate information for licensing a Type A broad scope license, and the need for two independent controls on portable gauge devices.

During the review, the Section took immediate action to address several licensing actions that the review team identified as deviating from licensing guidance and Oregon regulations. The review team discussed the need for additional training in regulations and licensing guidance/implementation through a more formal qualification/training program as discussed in Section 3.1 of this report. In addition, the review team discussed the benefits of engaging the services of another Agreement State to provide both didactic training and/or mentoring in the more complex licensing procedures. This could be used to train the successor(s) to the senior reviewer and could also benefit the licensing manager's training effort.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Oregon's performance with respect to the indicator, Technical Quality of Licensing Actions, was satisfactory, but needs improvement.

3.5 Technical Quality of Incident and Allegation Activities

In evaluating the effectiveness of the Section's actions in responding to incidents, the review team examined the Section's response to the questionnaire relative to this indicator, evaluated selected incidents reported for Oregon in Nuclear Material Events Database (NMED) against those contained in the Section's files, and evaluated the casework for seven radioactive material incidents. A listing of the incident casework examined, with case-specific comments, can be found in Appendix E. The review team also evaluated the Section's response to one allegation involving radioactive material received directly by the States. NRC did not forward any allegations to the State during the review period.

The Section has written procedures for responding to incidents and allegations. The procedures addressed the actions to be taken upon the notification of an incident or allegation and an event tracking database system that flags events for follow up during the next routine inspection. Although the inspectors conducting the next inspection were identifying the event in their inspection report, they did not always discuss whether they actually followed up on the licensee's action in response to the event.

The incidents selected for review included lost or stolen radioactive material, an overexposure, release of contaminated waste, unauthorized access to a radiation area, and medical events. The review team also reviewed approximately 100 incident files to determine if there were incidents that should have been reported to NMED. The review team found that the Section's responses were thorough, complete, and comprehensive for all but two of the seven incidents evaluated. Initial responses were prompt and well coordinated, and the level of effort was commensurate with the health and safety significance. The exceptions are noted below.

The review team determined that two medical events were not adequately reviewed. The medical events occurred at the same licensed facility. The events involved yttrium microspheres and were reportable because the total doses delivered differed from the prescribed dose by 20 percent or more. The same facility had two other events involving the release of contaminated waste for disposal and resulted in a licensee management meeting with the Section.

The medical events were reviewed by the Section's medical physicist telephonically and by e-mail correspondence with the facility's radiation safety officer; however, no on-site reviews were conducted. Given the fact that the same licensee had recurring under dose events involving microspheres, an on-site investigation would have been the appropriate response. The review team discussed this with Section management, and they agreed that, given the number of incidents with this licensee, they should have conducted an on-site review of the incidents.

Through the review of the information for the events in NMED, the review team noted that, in all cases the Section had closed but not completed the events, although the Section's investigation or followup had concluded. In addition, the two aforementioned medical events were either not reported to the NRC's Operations Center or not reported in a timely manner. The review team recommends that the Section implement a process to ensure all required information is submitted to NMED and to also promote timely completion of NMED entries.

The Section received one anonymous allegation during the review period. The review team concluded that the Section took prompt and appropriate action in response to the one anonymous allegation. The Section substantiated four of the five concerns raised by the alleger and issued a notice of violation to the individual. Since the allegation was anonymous no notification of the alleger was possible. Allegers requesting anonymity are informed that every effort would be made to protect his/her identity, but anonymity cannot be guaranteed.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Oregon's performance with respect to the indicator, Technical Quality of Incident and Allegation Activities, was satisfactory, but needs improvement.

4.0 NON-COMMON PERFORMANCE INDICATORS

Four non-common performance indicators are used to review 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. NRC's Agreement with the State of Oregon does not relinquish authority to regulate a sealed source and device evaluation program or a uranium recovery program, so only the first and the third non-common performance indicators were applicable to this review.

4.1 Compatibility Requirements

4.1.1 Legislation

Oregon became an Agreement State on June 22, 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. The Section is designated as the State's radiation control agency. The review team noted that no significant legislation affecting the radiation control program was passed since the previous review.

4.1.2 Program Elements Required for Compatibility

The State's regulations governing radiation protection requirements are contained in Oregon Administrative Rules (OAR) 333. Oregon requires a license for the possession and use of all radioactive material. Oregon also requires registration of all machines specifically designed to produce x-rays or other ionizing radiation. The review team noted that the State's rules and regulations are not subject to "sunset" provisions.

The Oregon rulemaking process has five major steps in the process. After the staff drafts the rule, the package goes to the Attorney General's office for legal review or to the Radiation Advisory Committee for review. The package is submitted to NRC as a proposed rule. The package is submitted to the Rules Coordinator for the Department. The rule is submitted to the Oregon Bulletin for public comment. The final rule is submitted to the Secretary of State and issued as a final rule. The final rule becomes effective after publication. This process takes approximately six months from the initial staff draft of a rule package.

The review team evaluated the Section'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 State Regulation Status sheet as maintained by NRC's Office of Federal and State Materials and Environmental Management Programs.

Since the previous IMPEP review, the Section has addressed five NRC regulation amendments in either draft or final packages. These actions included two time-sensitive changes addressing the National Source Tracking System and Fingerprinting requirements.

Current NRC policy requires that Agreement States adopt certain equivalent regulations or legally binding requirements within the 3-year time period after the effective date of NRC's final rule. At the time of the review, the following regulation amendments were overdue:

- "Compatibility with IAEA Transportation Safety Standards and Other Transportation Safety," 10 CFR Part 71 amendment (69 FR 3697), that was due for State adoption by October 1, 2007.

  Status: The proposed regulation was submitted and reviewed by NRC. Comments were provided. A final rule should be completed by early 2010.

- "Minor Amendments," 10 CFR Parts 20, 30, 32, 35, 40 and 70 amendment (71 FR 15005), that was due for State adoption by March 27, 2009.

  Status: Oregon submitted the proposed rule to NRC for a compatibility review on September 22, 2009. The rule was under review at the time of the MRB meeting on November 10, 2009.

In addition, the Section Manager indicated that the NRC comments on two final regulations and one proposed regulation are being addressed in a regulation package to be submitted later this fall and should be effective in early 2010. Oregon's regulations will be up-to-date with the completion of this rule package.

The following amendments will need to be addressed by the Sections in future rulemakings or by adopting alternate generic legally binding requirements:

- "Medical Use of Byproduct Material – Minor Corrections and Clarifications," 10 CFR Parts 32 and 35 amendment (72 FR 45147, 54207), that is due for Agreement State adoption by October 29, 2010.

- "Requirements for Expanded Definition of Byproduct Material," 10 CFR Parts 20, 30, 31, 32, 33, 35, 61, and 150 amendment (72 FR 55864), that is due for Agreement State adoption by November 30, 2010.

- "Exemptions from Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements," 10 CFR Parts 30, 31, 32, and 150 amendment (72 FR 58473), that is due for Agreement State adoption by December 17, 2010.

- "Occupational Dose Records, Labeling Containers, and Total Effective Dose Equivalent," 10 CFR Parts 19 and 20 amendment (72 FR 68043), that is due for Agreement State adoption by February 15, 2011.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Oregon's performance with respect to the indicator, Compatibility Requirements, was satisfactory.

4.2 Low-level Radioactive Waste Disposal Program

In 1981, NRC amended its Policy Statement, “Criteria for Guidance of States and NRC in Discontinuance of NRC Authority and Assumption Thereof by states Through Agreement” to allow a State to seek an amendment for the regulation of low-level radioactive waste (LLRW) as a separate category. Those States with existing Agreements prior to 1981 were determined to have continued LLRW disposal authority without the need of an amendment. Although the Oregon Agreement State Program has authority to regulate a LLRW disposal facility, NRC has not required States to have a program for licensing a disposal facility until such time as the State has been designated as a host State for a LLRW disposal facility. When an Agreement State has been notified or becomes aware of the need to regulate a LLRW disposal facility, it is expected to put in place a regulatory program that will meet the criteria for an adequate and compatibility LLRW program. There are no plans for a LLRW disposal facility in Oregon. Accordingly, the review team did not review this indicator.

5.0 SUMMARY

As noted in Sections 3.0 and 4.0, Oregon’s performance was found satisfactory for three performance indicators and satisfactory, but needs improvement, for the performance indicators, Technical Quality of Inspections, Technical Quality of Licensing Actions, and Technical Quality of Incident and Allegation Activities. The review team made three recommendation regarding program performance by the State. Overall, the review team recommended, and the MRB agreed, that the Oregon Agreement State Program be found adequate to protect public health and safety, but needs improvement, and compatible with NRC's program. Based on the results of the current IMPEP review, the review team recommends that the Oregon Agreement State Program remain on monitoring with a periodic meeting held in approximately 1 year to assess the program’s progress in addressing the recommendations. The next full IMPEP review of the Oregon Agreement State Program will take place in approximately 3 years to accommodate the State’s request to conduct the IMPEP review when the State Legislature is not in session.

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

1. The review team recommends the State develop and use a documented formal qualification program (including refresher training) for inspection and licensing staff that would include journals that clearly indicate each individual’s training and qualification including oral and/or written evaluation of their understanding of regulations and guidance documents.

2. The review team recommends that the State develop and implement a procedure for the control of sensitive or security-related information that provides guidance to identify, mark, handle, and protect such information.

3. The review team recommends that the Section implement a process to ensure all required information is submitted to NMED and to also promote timely completion of NMED entries.

LIST OF APPENDIXES AND ATTACHMENT

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	**Area of Responsibility**
Dennis Sollenberger, FSME	Team Leader Compatibility Requirements
Linda McLean, Region IV	Technical Staffing and Training Technical Quality of Incident and Allegation Activities
Robert Greger, California	Status of Materials Inspection Program Technical Quality of Inspections Inspector Accompaniments
Sandra Gabriel, Region I	Technical Quality of Licensing Actions

APPENDIX B

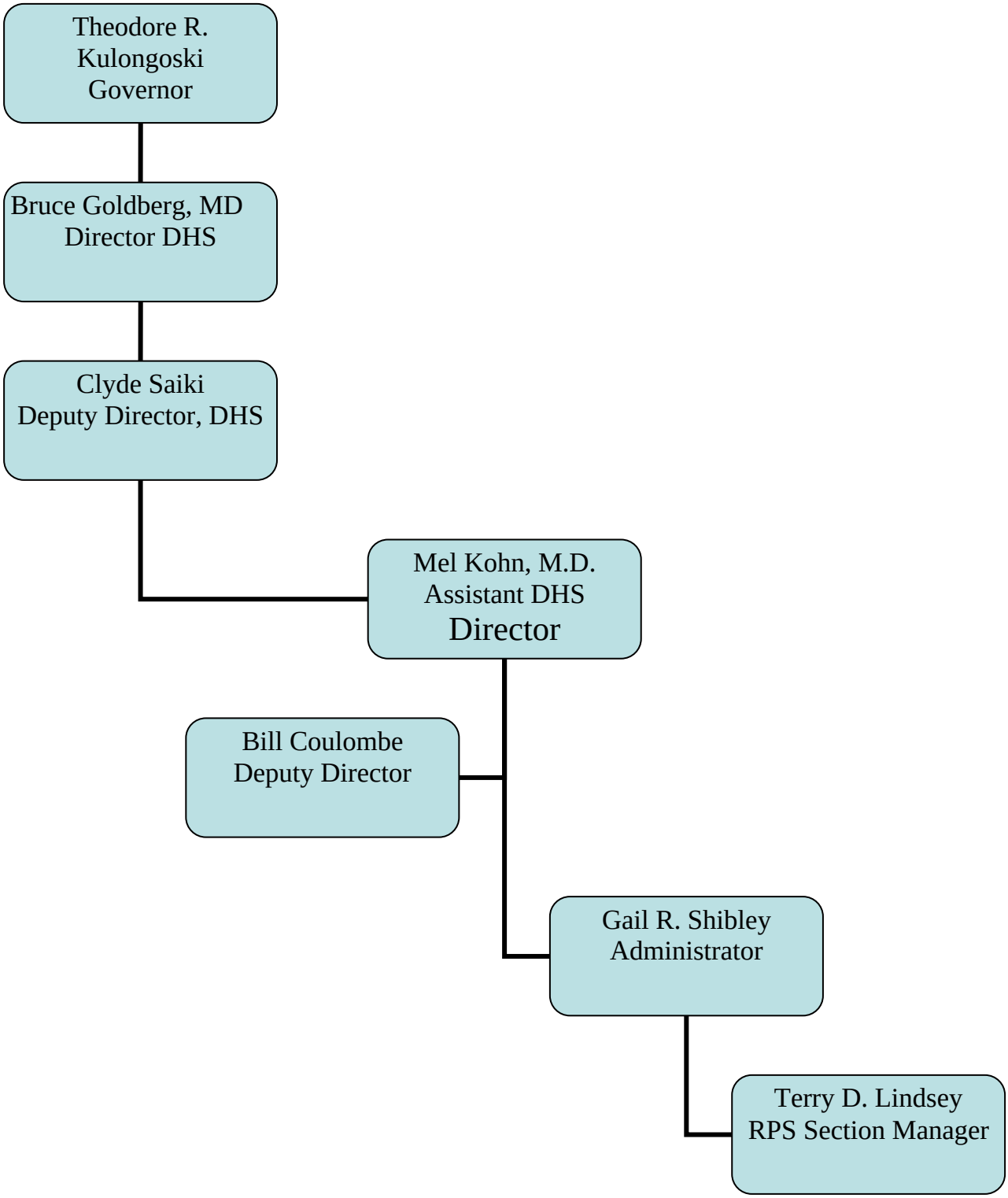
OREGON ORGANIZATION CHARTS

ADAMS ACCESSION NO.: ML092720519

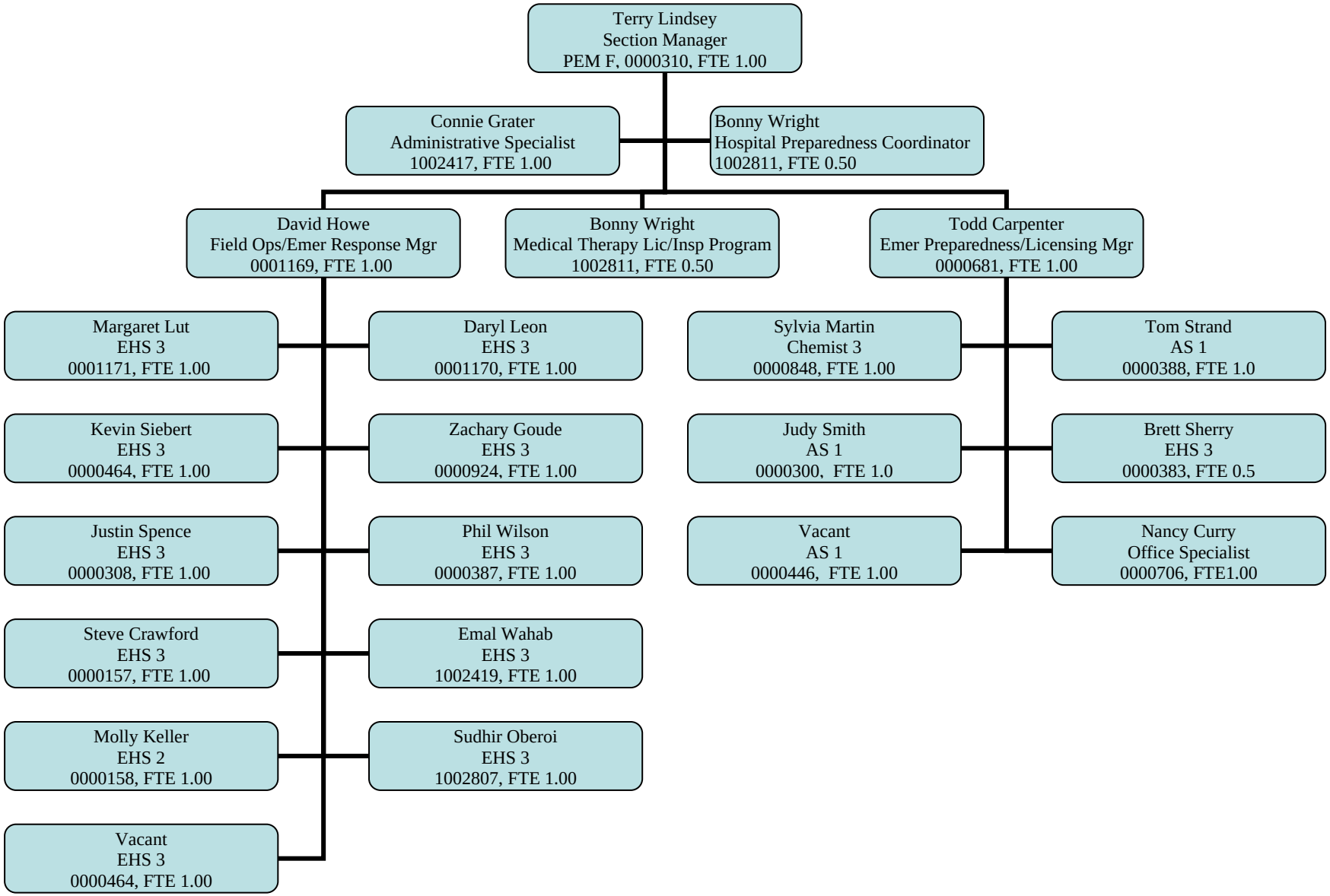
Supervisory Organizational Chart

From Governor to the Radiation Protection Services Section Manager

Attachment 2



OREGON STATE PUBLIC HEALTH DIVISION
Office of Environmental Public Health
Radiation Protection Services
ATTACHMENT 3



APPENDIX C

INSPECTION CASEWORK REVIEWS

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

File No.: 1
Licensee: Jim Turin and Sons, Inc. License No.: ORE-90887
Inspection Type: Routine, Announced Priority: 5
Inspection Date: 7/27/09 Inspector: PW

Comment:
The Section sent a followup letter informing the licensee of the regulatory requirement with which they were not complying. The letter did not cite the licensee for this regulatory violation.

File No.: 2
Licensee: Mallinckrodt, Inc. License No.: ORE-90702
Inspection Type: Routine, Unannounced Priority: 2
Inspection Date: 7/28/09 Inspector: JS

File No.: 3
Licensee: Providence Hood River Memorial Hospital License No.: ORE-90800
Inspection Type: Routine, Announced Priority: 5
Inspection Date: 7/29/09 Inspector: KS

Comment:
Inspection documentation did not support recommendation to licensee.

File No.: 4
Licensee: Acuren Inspection, Inc. License No.: ORE-90621
Inspection Type: Routine, Unannounced Priority: 1
Inspection Date: 11/20/08 Inspector: DL

File No.: 5
Licensee: Gene Tools, LLC License No.: ORE-91044
Inspection Type: Routine, Unannounced Priority: 5
Inspection Date: 11/1/06 Inspector: JS

Comment:
The inspection was performed 60 days overdue.

File No.: 6
Licensee: International Inspection License No.: ORE-90651
Inspection Type: Routine, Announced Priority: 1
Inspection Date: 2/27/09 Inspector: DL

Comment:
The file, which was maintained in locked storage, contained information not appropriately marked.

File No.: 7
Licensee: Net Compliance Environmental services, LLC License No.: ORE-96152
Inspection Type: Reciprocity, Unannounced Priority: 5
Inspection Date: 5/21/09 Inspector: KS

File No.: 8
Licensee: Oncology Associates of Oregon License No.: ORE-91030
Inspection Type: Routine, Unannounced Priority: 2
Inspection Date: 2/23/09 Inspector: KS

Comment:
The inspection was conducted 1 month overdue.

File No.: 9
Licensee: GN Northern, Inc. License No.: ORE-96129
Inspection Type: Reciprocity, Unannounced Priority: 5
Inspection Date: 7/27/09 Inspector: DL

File No.: 10
Licensee: Engineering & Testing Innovation, Inc. License No.: WN-IR072-1
Inspection Type: Reciprocity, Unannounced Priority: 1
Inspection Date: 1/14/09 Inspector: JS

File No.: 11
Licensee: Providence Portland Medical Center License No.: ORE-90946
Inspection Type: Special, Announced Priority: 2
Inspection Date: 2/20/08 Inspector: JS

Comments:
a) Due to oversight identified by Section, initial letter to licensee was not sent until July 6, 2009.
b) The file, which was maintained in locked storage, contained information not appropriately marked.

File No.: 12
Licensee: Samaritan Albany General Hospital License No.: 91080
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 10/29/08 Inspector: JS

Comment:
The inspection was conducted 10 days overdue.

File No.: 13
Licensee: Pacific Agricultural Laboratory License No.: 93172
Inspection Type: Routine, Unannounced Priority: NA
Inspection Date: 6/19/09 Inspector: DL

File No.: 14
Licensee: PCC Structurals, Inc. License No.: 90232
Inspection Type: Routine, Announced Priority: 2
Inspection Date: 3/28/08 Inspector: DL

Comment:
The inspection Supervisory conducted his review of inspection report 8 months after inspection.

File No.: 15
Licensee: Oregon Imaging Center License No.: 90931
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 1/14/09 Inspector: JS

File No.: 16
Licensee: Oregon Health & Science University License No.: ORE-90013
Inspection Type: Routine, Unannounced Priority: 2
Inspection Dates: 6/15-16/09 Inspector: KS

Comments:
a) The report did not describe the full scope of licensed activities for this broad scope program and what activities were inspected. Not all areas inspected were documented indicating licensee compliance status.
b) The inspector did not follow up on previous Y-90 liver microsphere events.

INSPECTOR ACCOMPANIMENTS

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

Accompaniment No.: 1
Licensee: Jim Turin and Sons, Inc. License No.: ORE-90887
Inspection Type: Routine, Announced Priority: 5
Inspection Date: 7/27/09 Inspector: PW

Comment:

The inspector failed to identify non-compliances that existed for lack of use of two independent physical controls that form tangible barriers to secure portable gauges from unauthorized removal whenever portable gauges are not under the control and constant surveillance of the licensee.

Accompaniment No.: 2
Licensee: Mallinckrodt, Inc. License No.: ORE-90702
Inspection Type: Routine, Unannounced Priority: 2
Inspection Date: 7/28/09 Inspector: JS

Accompaniment No.: 3
Licensee: Providence Hood River Memorial Hospital License No.: ORE-90800
Inspection Type: Routine, Announced Priority: 5
Inspection Date: 7/29/09 Inspector: KS

Accompaniment No.: 4
Licensee: Acuren Inspection, Inc. License No.: ORE-90621
Inspection Type: Routine, Unannounced Priority: 1
Inspection Date: 7/30/09 Inspector: DL

Comment:

The inspector should have selected which licensee vehicle would be inspected instead of allowing the licensee to make the selection.

APPENDIX D

LICENSE CASEWORK REVIEWS

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

File No.: 1
Licensee: Providence Portland Medical Center — License No.: ORE-90946
Types of Action: Amendment — Amendment No.: 7
Dates Issued: 1/7/08 — License Reviewers: DL, SM

Comments:
a) The file did not address that this was a new gamma knife design, inconsistent with certain existing gamma knife regulatory requirements. The licensing staff had the NRC licensing guidance for this specific design but did not use it in the evaluation.
b) The file did not contain information regarding authorized user or authorized medical physicist training for this device model, emergency procedures, spot-check procedures, or facility safety features.

File No.: 2
Licensee: Portland Adventist Medical Center — License No.: ORE-90158
Type of Action: Amendment — Amendment No.: 101
Date Issued: 4/1/09 — License Reviewer: SM

Comments:
a) The file for this amendment to add TheraSphere use only addressed a small portion of the licensing guidance for emergent technologies. The file did not demonstrate that users had the appropriate clinical experience, and addressed only one of the “licensing commitments providing regulatory relief.”
b) A physician who was not already a 35.390 or 35.490 user was authorized for TheraSphere use.

File No.: 3
Licensee: Pet-Net Pharmaceutical Services, Inc. — License No.: ORE-90926
Types of Action: Amendment — Amendment No.: 16
Dates Issued: 5/26/09 — License Reviewer: SM

Comment:
The file did not contain documentation to demonstrate that the proposed Authorized Nuclear Pharmacist (ANP) met all the regulatory requirements.

File No.: 4
Licensee: PET NET Solutions, Inc. License No.: ORE-90927
Type of Action: Amendment Amendment No.: 15
Dates Issued: 5/27/09 License Reviewer: SM

Comment:
The file did not contain documentation to demonstrate that the proposed ANP met the educational and preceptor requirements.

File No.: 5
Licensee: Oregon Medical Laboratories License No.: ORE-90360
Type of Action: Amendment Amendment No.: 32
Date Issued: 3/18/09 License Reviewer: SM

Comment:
The new license condition allowing the Radiation Safety Officer to train irradiator users did not specify the content of the training program and training records to be maintained.

File No.: 6
Licensee: Western Professional, Inc. License No.: ORE-90344
Type of Action: Renewal Amendment No.: 37
Date Issued: 4/8/08 License Reviewer: SM

File No.: 7
Licensee: P.E.T. Imaging Services, LLC License No.: ORE-91007
Type of Action: Renewal Amendment No.: 10
Date Issued: 5/12/08 License Reviewer: SM

File No.: 8
Licensee: Arclin Surfaces, Inc. License No.: ORE-91096
Type of Action: New Amendment No.: N/A
Date Issued: 2/17/09 License Reviewer: SM

File No.: 9
Licensee: C.M.T.I. Inc. License No.: ORE-91115
Type of Action: New Amendment No.: N/A
Date Issued: 3/19/09 License Reviewer: DL

Comment:
Contrary to standard Oregon practice, the license had no specific license condition to address the requirement for two independent physical controls to secure portable gauges from unauthorized removal.

File No.: 10
Licensee: Cascade Healthcare Community, Inc. License No.: ORE-91008
Type of Action: New Amendment No.: N/A
Date Issued: 4/9/08 License Reviewer: SM

File No.: 11
Licensee: Samaritan Albany General Hospital License No.: ORE-91080
Type of Action: Amendment Amendment No.: 3
Date Issued: 6/17/09 License Reviewer: SM

File No.: 12
Licensee: Pope and Talbot, Inc./Cascade Pacific Pulp, LLC License No.: ORE-90576
Type of Action: Amendment Amendment No.: 16
Date Issued: 9/30/08 License Reviewer: SM

Comment:
Bankruptcy/change of control was addressed in an amendment to the existing license rather than in termination of the existing license and issuance of a new license.

File No.: 13
Licensee: Boise White Paper LLC License No.: ORE-90100
Type of Action: Amendment Amendment No.: 51
Date Issued: 3/18/09 License Reviewer: SM

File No.: 14
Licensee: Lewis and Clark College License No.: ORE-90079
Type of Action: Termination Amendment No.: 42
Date Issued: 6/8/09 License Reviewer: DL

File No.: 15
Licensee: AA Testing Services, Inc. License No.: ORE-90969
Type of Action: Termination Amendment No.: 4
Date Issued: 7/28/09 License Reviewer: DL

File No.: 16
Licensee: Oregon Health & Science University License No.: ORE-90013
Type of Action: Renewal, Amendment Amendment Nos.: 101, 103
Date Issued: 2/18/09 License Reviewer: SM

Comments:
a) The renewal file did not contain the significant information necessary for proper evaluation of a Type A broad license renewal application.
b) The renewal file did not contain any of the information for self-shielded irradiators.

File No.: 17
Licensee: Salem Hospital License No.: ORE-91006
Type of Action: Amendments Amendment Nos.: 12, 13
Date Issued: 7/28/09 License Reviewer: SM

APPENDIX E

INCIDENT CASEWORK REVIEWS

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

File No.: 1
Licensee: Oregon Health Sciences University — License No: ORE-90013
Date of Incident: 5/7/09 — NMED Event No.: 090563
Investigation Date: 5/12/09 — Type of Incident: Medical
Type of Investigation: Phone

Comments:
a) The event is still open.
b) The Section did not conduct an on-site inspection.
c) The event was not reported to the Headquarters Operations Center in a timely manner.

File No.: 2
Licensee: Oregon Health Sciences University — License No: ORE-90013
Date of Incident: 9/23/08 — OR Event No.: 080079
Investigation Date: 9/24/08 — Type of Incident: Medical
Type of Investigation: Phone

Comments:
a) The event was not entered into the Nuclear Materials Event Database (NMED).
b) The event was not reported to the Headquarters Operations Center.
c) The Section did not conduct an on-site investigation.

File No.: 3
Licensee: Oregon Health Sciences University — License No: ORE-90013
Date of Incident: 8/14/08 — OR Event No.: 080068
Investigation Date: 8/14/08 — Type of Incident: Contaminated Trash
Type of Investigation: Site

File No.: 4
Licensee: Oregon Health Sciences University — License No: ORE-90013
Date of Incident: 2/14/09 — OR Event No.: 090008
Investigation Date: 2/14/09 — Type of Incident: Contaminated Trash
Type of Investigation: Site

File No.: 5
Licensee: Oregon Health Sciences University
Date of Incident: 2/6/08
Investigation Date: N/A
License No: ORE-90731
NMED Event No.: 080074
Type of Incident: Potential Overexposure
Type of Investigation: None

File No.: 6
Licensee: International Inspection
Date of Incident: 6/12/09
Investigation Date: N/A
License No: ORE-90651
OR Event No.: 09033
Type of Incident: Unauthorized Access
Type of Investigation: None required

File No.: 7
Licensee: Cardinal Health
Date of Incident: 2/11/08
Investigation Date: N/A
License No: ORE-90703
OR Event No.: N/A
Type of Incident: Stolen Material
Type of Investigation: None required

ATTACHMENT

October 23, 2009 Letter from Terry Lindsey
Oregon's Response to Draft IMPEP Report

ADAMS Accession No.: ML09306029

From: Terry D LINDSEY [terry.d.lindsey@state.or.us]
Sent: Friday, October 23, 2009 8:04 PM
To: Sollenberger, Dennis
Cc: Connie J GRATER; Daryl A LEON; David M HOWE; Justin I SPENCE; Kevin H SIEBERT; Sylvia L MARTIN; Todd S CARPENTER
Subject: Re: Draft IMPEP report in WORD
Attachments: Response to Draft IMPEP Report 102309.doc

Dennis,
I promised you a response today, so here it is. I have used Track Changes for your convenience. I will also review with my staff next week to see if I missed anything. Thank you for providing the Word version for editing./tdl

Terry D. Lindsey, Manager
Radiation Protection Services
Environmental Public Health
Public Health Division
Department of Human Services
800 NE Oregon Street, Suite 640
Portland, Oregon 97232
Phone # (971) 673-0499
Fax # (971) 673-0553
terry.d.lindsey@state.or.us

>>> "Sollenberger, Dennis" <Dennis.Sollenberger@nrc.gov> 10/20/2009 8:00 AM >>>
Terry:

Attached is the WORD version of the draft IMPEP report.

The tentative date and time for the Oregon MRB is **November 10, 2009 from 1:00 to 2:30 pm**. This was the time that the primary MRB members were available. Will this date and time work for Oregon? We need to put out the public meeting notice, so I would appreciate a prompt response on your availability for the meeting at this time.

Thank you.

Dennis Sollenberger

Sorry, I hit the send button before I attached the letter.

E-mail Properties

Mail Envelope Properties (4AE1E1E9.764C.0008.0)

Subject: Re: Draft IMPEP report in WORD
Sent Date: 10/23/2009 8:03:57 PM
Received Date: 10/23/2009 8:03:57 PM
From: Terry D LINDSEY

Created By: terry.d.lindsey@state.or.us

Recipients:
Dennis.Sollenberger@nrc.gov (Sollenberger, Dennis)
Tracking Status: None
connie.j.grater@state.or.us (Connie J GRATER)
Tracking Status: None
daryl.a.leon@state.or.us (Daryl A LEON)
Tracking Status: None
david.m.howe@state.or.us (David M HOWE)
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Post Office:
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Files	Size	Date & Time
MESSAGE	373903	10/23/2009
Response to Draft IMPEP Report 102309.doc	364608	

Options
Expiration Date:
Priority: olImportanceNormal
ReplyRequested: False
Return Notification: False

Sensitivity: olNormal
Recipients received:

3.0 COMMON PERFORMANCE INDICATORS

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

3.1 Technical Staffing and Training

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

The day-to-day operations of the Oregon Agreement State Program are executed by the Section. The Section ~~has two programs~~ is comprised of two management units: ~~the Radioactive Materials Licensing,~~ Emergency Preparedness, Licensing & Administration Unit and Emergency Response, Field Operations & Technical Services Unit~~Tanning Program and the Electronic Products Program.~~ ~~Each~~ Each unit~~program~~ is headed by a ~~Program~~ Manager. Staff members in the Section perform licensing, inspection, ~~and~~ training, emergency response and preparedness activities for radioactive materials facilities.

The Section has approximately 5.25 full-time equivalents assigned to perform the technical aspects of the radioactive materials program. The Section's radioactive materials program staff is composed of four technical staff members, a medical physicist, and two supervisors. One staff member is assigned primarily to licensing activities. The inspection workload was split among the other three technical staff members. In addition, the Section is cross-training staff from other areas of the Section (e.g., tanning and x-ray) to augment the radioactive materials inspection program. One tanning inspector was recently qualified to conduct gauge inspections, and the x-ray staff assists in incident response. The review team concluded that the Section's staffing level is adequate to carry out its regulatory duties.

The review team noted that Section management encourages and supports training opportunities based on program needs and funding. The Section's training and qualification program for technical staff uses the technical course requirements in NRC Inspection Manual Chapter (IMC) 1246, "Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area."

Technical staff qualification is achieved through a combination of education and experience, formal classroom training, and on-the-job training. The review team noted that, while the Section maintains records of formal classroom training for each staff member, it does not maintain records of self-study or on-the-job qualification training, such as training in applicable regulatory requirements. This issue was identified during the inspector accompaniments where a new inspector was not familiar with the portable gauge security regulatory requirements. The inspector's qualification training had not included a comprehensive review of the applicable regulations pertinent to portable gauge inspection. The review team observed through interviews, casework examinations, and inspector accompaniments that, while the staff was in

The Section receives notifications of reciprocity work within Oregon at a rate of 2-3 per work day which are forwarded to the inspection group. Typically all reciprocity work is inspected if the reciprocity licensee hasn't been inspected within the preceding twelve months. Most of the reciprocity licensees are NRC-priority 5 licensees. Usually, no more than 15 NRC-priority 1-3 licensees request reciprocity per year. Reciprocity inspections of candidate licensees during the years 2006 to 2009 (through July 31, 2009) totaled 5, 5, 7, and 3, respectively, which corresponded to at least 20 percent per year. The review team noted that in the two reciprocity inspections reviewed in which regulatory violations were identified, the inspection results were communicated to the licensing State.

The Section has 14 licenses subject to the Increased Controls. The initial inspections of 12 of the 14 licenses were completed in the first year, with the remaining two completed in the second year. Although documentation was not located that described the prioritization methodology utilized for scheduling the initial inspections, the methodology described by Section staff met the criteria of COMSECY-05-0028. The review team noted that continuing Increased Controls inspections were conducted in conjunction with applicable routine inspections and that new licensees subject to the Increased Controls are inspected for compliance prior to receiving authorization to possess materials in risk-significant quantities.

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

3.3 Technical Quality of Inspections

The review team evaluated the inspection reports, enforcement documentation, and inspection field notes for 16 radioactive materials inspections conducted during the review period, and accompanied each of the four current inspectors on field inspections. The casework examined included a cross-section of inspections conducted by the four current inspectors and covered a wide variety of inspection types. These included: industrial radiography, high dose-rate remote afterloader, mobile nuclear medicine - positron emission tomography, broad scope industrial, medical - therapy, gamma knife, medical - diagnostic and imaging, nuclear pharmacy, portable gauge, and research and development. The casework also included reciprocity and Increased Controls inspections. Appendix C lists the inspection casework reviewed and includes case-specific comments.

Based on the evaluation of casework, the review team determined that inspections covered almost all aspects of the licensees' radiation safety and security programs. The review team noted ~~several~~ instances where areas were either missed during the inspection or not described in the inspection reports. The inspections for Increased Controls licensees appropriately addressed licensee compliance with the Increased Controls requirements. Licensee progress on implementation of the finger printing and national source tracking requirements were not consistently addressed in inspection reports. However, an independent tracking system of their implementation status was maintained by the Section which demonstrated that all required licensees had addressed the requirement.

Documents involving Increased Controls information were maintained in a locked file cabinet with limited access; however, the documents (both licensing and inspection) were not marked as security sensitive information. Although there were no instances of improper release of information, the review team was concerned that without proper marking the likelihood of release was much greater. The review team recommends that the State develop and implement a procedure for the control of sensitive or security-related information that provides guidance to identify, mark, handle, and protect such information. Note: All security related files were properly secured and the Section is currently developing a written protocol to consistently identify, mark, handle and protect this information in a consistent manner from receipt to destruction of files. Guidance provided by the IMPEP team from RIS documents from 2005 and 2008 is being evaluated for current practices approved by NRC to adopt for the Section. {Todd Carpenter is coordinating this effort for completion by end of current calendar quarter.}

The review team noted that the Section is continuing its efforts to upgrade inspection procedures. Currently, one procedure, covering fixed and portable gauges, has been formally adopted, with several others in various stages of development. Pending completion of the upgraded procedures, a mixture of draft and existing Section inspection procedures and NRC inspection procedures are being utilized by inspectors. In one instance during the review team accompaniments, an important inspection issue (securing of portable gauges), and one of lesser importance, were not covered by the inspector. The review team discussed with the Section the benefits of the emphasis on continued development of inspection procedures and training in use of these procedures.

With infrequent exceptions, inspection findings were routinely provided to licensees at the conclusion of inspections using an Oregon 591 form. An inspection report is routinely generated after returning to the office. ~~Even though~~In addition to a 591 form being~~is~~ left at the time of the inspection, a cover letter is also routinely ~~sent to~~provided during the closeout meeting with licensees communicating the significance of the inspection findings. The Section uses a severity of non-compliances system based on a severity level scale of 1-5. The review team noted inconsistency in applying this system and the assigning of severity levels which could be addressed by completion of procedures and training in this area. Note: The Section Information Technology Specialist is currently working with RML staff to review all Oregon Administrative Rule citations and related Severity Levels for inclusion in a new enforcement procedure to be used in all Oregon RPS inspection programs. This model will interface with new Oregon Public Health Division authority under Oregon Revised Statutes (ORS 431.262 to assess Civil Penalties for significant violation to administrative rules. The new Division 124 rules have been reviewed by the Radiation Advisory Committee and Oregon Assistant Attorney General for adoption upon next rule filing.

The review team verified that the Section maintains an adequate supply and types of calibrated survey instruments to support the inspection program, and to respond to incidents and emergencies. The Section has the capability to conduct gamma analysis of samples and can contract for additional analyses, as needed.

The review team accompanied four inspectors in July 2009. The inspectors conducted inspections at a portable gauge user, a nuclear pharmacy, an industrial radiographer, and a hospital. Appendix C lists the inspector accompaniments and includes the review team's observations. In general, the inspectors used good inspection techniques including use of

performance based criteria. The inspectors were trained, prepared for the inspections, and thorough in their audits of the licensees' radiation safety and security programs. The inspectors conducted interviews with appropriate personnel, observed licensed operations, conducted confirmatory measurements, and utilized good health physics practices. The inspectors held entrance and exit meetings with the appropriate level of licensee management. The review team determined that the inspections were adequate to assess radiological health, safety, and security at the licensed facilities with one exception. During one accompaniment, the inspector did not identify a portable gauge licensee's failure to provide two independent physical controls to secure gauges from unauthorized removal, for both storage and transportation. The inspector was unfamiliar with this regulatory requirement, as well as other applicable Oregon regulations. The review team found that the Section individual who had been assigned to train this inspector also was found not to be knowledgeable of the Oregon regulation to secure portable gauges from unauthorized removal. Note: Oregon adopted the identical language to the federal rules for physical controls to secure portable gauges under OAR 333-102-0305(28) and also has an additional requirement in License Condition 17 for portable gauge licensees to require locking of the gauge and gauge case to prevent unauthorized or accidental removal of the sealed source from its shielded position. {This additional security measure was sent out as an Enforcement Bulletin to all Oregon portable gauge licensees following theft of several gauges (and subsequent recovery of all but one – which is still being tracked). The license condition has since replaced the Enforcement Bulletin.}The remaining two Oregon inspectors were knowledgeable of the requirement. The inspection procedure carried by an inspector referenced the two-physical-control requirement in *somewhat general terms*. The review team noted that, while the portable gauge licensee was subsequently informed of the regulatory requirement for two independent physical controls for their portable gauge, the licensee was not cited for the non-compliance. Note: Oregon RML staff are currently reviewing the current inspection guidance for portable gauges to clarify both the OAR 333-102-0305(28) rule and the additional License Condition 17 gauge locking requirement for consistent enforcement during future inspections in Oregon.

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License Condition 17 and OAR 333-102-0305(28) text provided for information at MRB meeting:
License Condition 17 currently in portable gauge licenses for Oregon Licensees:
17. Each portable nuclear gauge shall have a lock or outer locked container designed to prevent unauthorized or accidental removal of the sealed source from its shielded position. The gauge or its container shall be locked when in transport or when not under the direct surveillance of an authorized user.

333-102-0305

Specific Terms and Conditions of License

(28) Security requirements for portable devices containing licensed radioactive materials. Each portable device containing licensed radioactive materials must be secured using a minimum of two independent physical controls that form tangible barriers to prevent unauthorized removal or use, whenever the portable device is not under the direct control and constant surveillance of the licensee.

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Based on the IMPEP evaluation criteria, the review team recommends that Oregon's

Section staff stated that they use licensing procedures include use of the NUREG-1556 series and the NRC's 10 CFR 35.1000 licensing guidance. Note: The Section has reviewed 10 CFR 35.1000 and has received approval from the Radiation Advisory Committee to adopt similar language as OAR 333-116-0465 during the next rule filing. However, the review team observed inconsistent use of this guidance for certain licensing actions that are complex and/or infrequently encountered. The review team identified potential health and safety and regulatory compliance issues with several major licensing actions. These complex actions raised several significant regulatory issues that were not properly addressed in the licensing process such as proper exemption for a new gamma knife design, proper training information for an authorized nuclear pharmacist, adequate information for licensing a Type A broad scope license, and the need for two independent controls on portable gauge devices. Comment: The Section has adopted identical language to federal rules to properly secure gauges as OAR 333-102-0305(28) with text provided above for MRB review. Copies of Oregon Administrative Rules have also been printed and provided to all RML inspection staff for use during inspection activities. In the interim, all inspection staff will be provided with the complete set of rules for reference during field inspections. Section staff are transitioning to electronic files and use of computers for accessing administrative rules in the future. Upon completion of this Electronic File Reporting system in the next few months, inspection staff will have access to dedicated netbook computers with complete administrative rules for use during inspections.

During the review, the Section took immediate action to address several licensing actions that the review team identified as deviating from licensing guidance and Oregon regulations. The review team discussed the need for additional training in regulations and licensing guidance/implementation through a more formal qualification/training program as discussed in Section 3.1 of this report. In addition, the review team discussed the benefits of engaging the services of another Agreement State to provide both didactic training and/or mentoring in the more complex licensing procedures. This could be used to train the successor(s) to the senior reviewer and could also benefit the licensing manager's training effort.

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, but needs improvement.

3.5 Technical Quality of Incident and Allegation Activities

In evaluating the effectiveness of the Section's actions in responding to incidents, the review team examined the Section's response to the questionnaire relative to this indicator, evaluated selected incidents reported for Oregon in Nuclear Material Events Database (NMED) against those contained in the Section's files, and evaluated the casework for eight radioactive material incidents. A listing of the incident casework examined, with case-specific comments, can be found in Appendix E. The review team also evaluated the Section's response to one allegation involving radioactive material received directly by the States. NRC did not forward any allegations to the State during the review period.

Note: One allegation concerning purchase of a nanocurie amount of purified Thorium by a element collector was received and investigated by the Section and California radiation staff during the reporting period. This incident has been closed with no further action recommended.

The Section has written procedures for responding to incidents and allegations. The procedures addressed the actions to be taken upon the notification of an incident or allegation and an event tracking database system that flags events for follow up during the next routine inspection. Although the inspectors conducting the next inspection were identifying the event in their inspection report, they did not always discuss whether they actually followed up on the licensee's action in response to the event.

The incidents selected for review included lost or stolen radioactive material, an overexposure, release of contaminated waste, unauthorized access to a radiation area, and medical events. The review team also reviewed approximately 100 incident files to determine if there were incidents that should have been reported to NMED. The review team found that the Section's responses were thorough, complete, and comprehensive for all but three of the eight incidents evaluated. Initial responses were prompt and well coordinated, and the level of effort was commensurate with the health and safety significance. Three exceptions are noted below.

The review team determined that three medical events were not adequately reviewed. The medical events occurred at one licensed facility. The events all involved yttrium microspheres and were reported because the total doses delivered differed from the prescribed dose by 20 percent or more. The same facility had two other events involving the release of contaminated waste for disposal and resulted in a licensee management meeting with the Section.

The medical events were reviewed by the Section's medical physicist telephonically and by e-mail correspondence with the facility's radiation safety officer; however, no on-site reviews were conducted. Given the fact that the same licensee had recurring under dose events involving microspheres, an on-site investigation would have been the appropriate response. The review team discussed this with Section management, and they agreed that, given the number of incidents with this licensee, they should have conducted an on-site review of the incidents.

Through the review of the information for the events in NMED, the review team noted that, in all cases the Section had closed but not completed the events, although the Section's investigation or followup had concluded. In addition, two medical events (under doses) and a potential overexposure were not reported to the NRC's Operations Center. The review team recommends that the Section implement a process to ensure all required information is submitted to NMED and to also promote timely completion of NMED entries.
Comment: The Section has conducted an onsite investigation of the related Y-90 Therasphere and Sirasphere incidents at Oregon License number ORE-90013 and will scheduling a meeting with Licensee management and radiation safety personnel to review findings by mid November.

The Section received one anonymous allegation during the review period. The review team concluded that the Section took prompt and appropriate action in response to the one anonymous allegation. The Section substantiated four of the five concerns raised by the alleger and issued a notice of violation to the individual. Since the allegation was anonymous no notification of the alleger was possible. Allegers requesting anonymity are informed that every effort would be made to protect his/her identity, but anonymity can not be guaranteed.

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,

be found satisfactory, but needs improvement.

4.0 NON-COMMON PERFORMANCE INDICATORS

Four non-common performance indicators are used to review 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. NRC's Agreement with the State of Oregon does not relinquish authority to regulate a sealed source and device evaluation program or a uranium recovery program, so only the first and the third non-common performance indicators were applicable to this review.

4.1 Compatibility Requirements

4.1.1 Legislation

Oregon became an Agreement State on June 22, 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. The Section is designated as the State's radiation control agency. The review team noted that no significant legislation affecting the radiation control program was passed since the previous review. Legislation passed during the 2007 Legislative Session has been codified in Oregon Revised Statutes as ORS 431.262 (see below) and will be incorporated into the Oregon Administrative Rules under a new Division 124 to add Civil Penalty authority for all Section regulatory program during the next rule filing. The draft rule was approved by the Radiation Advisory Committee on October 14, 2009.

Oregon Revised Statutes – Chapter 431

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431.262 Authority of Department of Human Services and local public health administrators to enforce public health laws; authorized actions; rules; penalties. *(1) The Department of Human Services and local public health administrators shall have the power to enforce public health laws. The enforcement powers authorized by this section include, but are not limited to, the authority to:*

(a) Investigate possible violations of public health laws;

(b) Issue subpoenas requiring testimony or the production of physical or other evidence;

(c) Issue administrative orders to enforce compliance with public health laws;

(d) Issue a notice of violation of a public health law and impose a civil penalty as established by rule not to exceed $500 a day per violation;

(e) Enter private property at any reasonable time with consent of the owner or custodian of the property to inspect, investigate, evaluate or conduct tests, or take specimens or samples for testing, as may be reasonably necessary to determine compliance with any public health law;

(f) Enter a public place to inspect, investigate, evaluate, conduct tests, or take specimens or samples for testing as may be reasonably necessary to determine compliance with the provisions of any public health law;

(g) Seek an administrative warrant from an appropriate court authorizing the inspection, investigation, evaluation or testing, or taking of specimens or samples for testing, if denied entry to property;

(h) Restrict access to contaminated property;
(i) Require removal or abatement of a toxic substance on any property and prescribe the proper measures for the removal or abatement;
(j) Maintain a civil action to enforce compliance with public health laws, including a petition to a court for an order imposing a public health measure appropriate to the public health threat presented;
(k) Refer any possible criminal violations of public health laws to a district attorney or other appropriate law enforcement official; and
(L) Request the Attorney General to assist in the enforcement of the public health laws.
(2) Any administrative actions undertaken by the state under this section shall comply with the provisions of ORS chapter 183.
(3) State and local law enforcement officials, to the extent resources are available, must assist the Department of Human Services and local public health administrators in ensuring compliance with administrative or judicial orders issued pursuant to this section.
(4) Nothing in this section shall be construed to limit any other enforcement authority granted by law to a local public health authority or to the state. [2007 c.445 §4]

4.1.2 Program Elements Required for Compatibility

The State's regulations governing radiation protection requirements are contained in Oregon Administrative Rules (OAR) 333. Oregon requires a license for the possession and use of all radioactive material. Oregon also requires registration of all machines specifically designed to produce x-rays or other ionizing radiation. The review team noted that the State's rules and regulations are not subject to "sunset" provisions.

The Oregon rulemaking process has five major steps in the process. After the staff drafts the rule, the package goes to the Attorney General's office for legal review or to the Radiation Advisory Committee for review. The package is submitted to NRC as a proposed rule. The package is submitted to the Rules Coordinator for the Department. The rule is submitted to the Oregon Bulletin for public comment. The final rule is submitted to the Secretary of State and issued as a final rule. The final rule becomes effective after publication. This process takes ~~approximately~~ at least six months from the initial staff draft of a rule package.

The review team evaluated the Section'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 State Regulation Status sheet as maintained by NRC's Office of Federal and State Materials and Environmental Management Programs.

Since the previous IMPEP review, the Section has addressed five NRC regulation amendments in either draft or final packages. These actions included two time-sensitive changes addressing the National Source Tracking System and Fingerprinting requirements.

Current NRC policy requires that Agreement States adopt certain equivalent regulations or legally binding requirements within the 3-year time period after the effective date of NRC's final

Comment:
The file, which was maintained in locked storage, contained information not appropriately marked.

File No.: 7
Licensee: Net Compliance Environmental services, LLC License No.: ORE-96152
Inspection Type: Reciprocity, Unannounced Priority: 5
Inspection Date: 5/21/09 Inspector: KS

File No.: 8
Licensee: Oncology Associates of Oregon License No.: ORE-91030
Inspection Type: Routine, Unannounced Priority: 2
Inspection Date: 2/23/09 Inspector: KS

Comment:
The inspection was conducted 1 month overdue.

File No.: 9
Licensee: GN Northern, Inc. License No.: ORE-96129
Inspection Type: Reciprocity, Unannounced Priority: 5
Inspection Date: 7/27/09 Inspector: DL

~~Comment:~~
~~The file, which was maintained in locked storage, contained information not appropriately marked.~~
This comment is apparently an error. This is a portable gauge licensee not subject to additional marking or handling requirements.

File No.: 10
Licensee: Engineering & Testing Innovation, Inc. License No.: WN-IR072-1
Inspection Type: Reciprocity, Unannounced Priority: 1
Inspection Date: 1/14/09 Inspector: JS

File No.: 11
Licensee: Providence Portland Medical Center License No.: ORE-90946
Inspection Type: Special, Announced Priority: 2
Inspection Date: 2/20/08 Inspector: JS

Comments:
a) Due to oversight identified by Section, initial letter to licensee was not sent until July 6, 2009.
b) The file, which was maintained in locked storage, contained information not appropriately marked.

File No.: 12
Licensee: Samaritan Albany General Hospital License No.: 91080
Inspection Type: Routine, Unannounced Priority: 3

Inspection Date: 10/29/08 Inspector: JS

Comment:
The inspection was conducted 10 days overdue.

File No.: 13
Licensee: Pacific Agricultural Laboratory License No.: 93172
Inspection Type: Routine, Unannounced Priority: NA
Inspection Date: 6/19/09 Inspector: DL

File No.: 14
Licensee: PCC Structurals, Inc. License No.: 90232
Inspection Type: Routine, Announced Priority: 2
Inspection Date: 3/28/08 Inspector: DL

Comment:
The inspection Supervisory conducted his review of inspection report 8 months after inspection.

File No.: 15
Licensee: Oregon Imaging Center License No.: 90931
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 1/14/09 Inspector: JS

File No.: 16
Licensee: Oregon Health & Science University License No.: ORE-90013
Inspection Type: Routine, Unannounced Priority: 2
Inspection Dates: 6/15-16/09 Inspector: KS

Comments:
a) The report did not describe the full scope of licensed activities for this broad scope program and what activities were inspected. Not all areas inspected were documented indicating licensee compliance status.
b) The inspector did not followup on previous Y-90 liver microsphere events. The Section has reviewed this file and noted that four incidents were included in the inspection report and appropriately reviewed with the licensee during the inspection, including two Y-90 events and two waste handling incidents. A record of this inspection file will be provided for the MRB review.

INSPECTOR ACCOMPANIMENTS

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

Accompaniment No.: 1
Licensee: Jim Turin and Sons, Inc. License No.: ORE-90887
Inspection Type: Routine, Announced Priority: 5

APPENDIX E

INCIDENT CASEWORK REVIEWS

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

File No.: 1
Licensee: Oregon Health Sciences University
Date of Incident: 5/7/09
Investigation Date: 5/12/09
License No: ORE-90013
NMED Event No.: 090563
Type of Incident: Medical
Type of Investigation: Phone

Comments:
a) The event is still open.
b) The Section did not conduct an on-site inspection.
c) The event was not reported to the Headquarters Operations Center. (Comment: This event has an NMED Event number and may have been reported late, but was clearly reported.)

File No.: 2
Licensee: Oregon Health Sciences University
Date of Incident: 9/23/08
Investigation Date: 9/24/09
License No: ORE-90013
OR Event No.: 080079
Type of Incident: Medical
Type of Investigation: Phone

Comments:
a) The event was not entered into the Nuclear Materials Event Database (NMED).
b) The event was not reported to the Headquarters Operations Center.
c) The Section did not conduct an on-site investigation.

File No.: 3
Licensee: Oregon Health Sciences University
Date of Incident: 6/18/07
Investigation Date: N/A
License No: ORE-90013
OR Event No.: 080138
Type of Incident: Medical
Type of Investigation: None

Comments:
a) The event was not entered into NMED.
b) The event was not reported to Headquarters Operations Center.
c) The event was not followed up at next routine inspection.

File No.: 4
Licensee: Oregon Health Sciences University
Date of Incident: 8/14/08
Investigation Date: 8/14/08
License No: ORE-90013
OR Event No.: 080068
Type of Incident: Contaminated Trash
Type of Investigation: On-site

File No.: 5
Licensee: Oregon Health Sciences University
Date of Incident: 2/14/09
Investigation Date: 2/14/09
License No: ORE-90013
OR Event No.: 090008
Type of Incident: Contaminated Trash
Type of Investigation: On-site

File No.: 6
Licensee: Oregon Health Sciences University
Date of Incident: 2/6/08
Investigation Date: N/A
License No: ORE-90731
OR Event No.: 080131 (O8-0008)
Type of Incident: Potential Overexposure
Type of Investigation: None

Comment:
The Section did not submit this potential overexposure event to NMED. Comment: See NMED Event 08-0074.

File No.: 7
Licensee: International Inspection
Date of Incident: 6/12/09
Investigation Date: N/A
License No: ORE-90651
OR Event No.: 09033
Type of Incident: Unauthorized Access
Type of Investigation: None required

File No.: 8
Licensee: Cardinal Health
Date of Incident: 2/11/08
Investigation Date: N/A
License No: ORE-90703
OR Event No.: N/A
Type of Incident: Stolen Material
Type of Investigation: None required