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



December 16, 2013

Suzanne Hoffman, Interim Director Oregon Public Health Division Department of Health and Human Services 800 NE Oregon Street, Suite 640 Portland, OR 97232

Dear Ms. Hoffman:

On October 29, 2013, 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 program adequate to protect public health and safety, and compatible with the U.S. Nuclear Regulatory Commission's program.

Section 5.0, page 12, of the enclosed final report contains a summary of the IMPEP team's findings and recommendations. Four of six performance indicators reviewed were found satisfactory. The indicators Technical Quality of Licensing Actions and Technical Quality of Incidents and Allegation Activities were found satisfactory, but need improvement. The review team made five new recommendations during this review in regard to program performance, and kept one recommendation open from the 2009 review. Based on the results of the current IMPEP review, the next full review of the Oregon Agreement State Program will take place in approximately 4 years, with a periodic meeting tentatively scheduled for August 2015. The corrective actions taken to address the open recommendations will be reviewed during the periodic meeting and subsequently verified for closure at the next IMPEP. No additional written response is required at this time to address the open recommendations.

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/

Michael F. Weber 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/ encl: David M. Howe, Program Director Radiation Protection Services Section Oregon Health Authority

> Robert Greger, California Organization of Agreement States Liaison to the MRB



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

AUGUST 12-16, 2013

**FINAL REPORT** 

### **EXECUTIVE SUMMARY**

This report presents the results of the Integrated Materials Performance Evaluation Program (IMPEP) review of the Oregon Agreement State Program. The review was conducted during the period of August 12–16, 2013, by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of Arizona.

Based on the results of this review, Oregon's performance was found satisfactory for the indicators Technical Staffing and Training, Status of Materials Inspection Program, Technical Quality of Inspection, and Compatibility Requirements and satisfactory, but needs improvement for the indicators Technical Quality of Licensing Actions and Technical Quality of Incidents and Allegation Activities. The finding of satisfactory but needs improvement for the indicators Technical Quality of Incident and Allegation Activities and Technical Quality of Licensing Actions remains the same from the 2009 IMPEP report and the finding of satisfactory for the indicator Technical Quality of Inspections is an improvement from the 2009 IMPEP report.

The review team made a total of five recommendations in the indicators Technical Quality of Licensing Actions, Technical Quality of Incident and Allegation Activities, and Compatibility Requirements. The review team closed two recommendations from the 2009 IMPEP report and kept one recommendation open. The open recommendation is in the indicator Technical Quality of Incident and Allegation Activities.

Accordingly, the review team recommended, and the Management Review Board (MRB) agreed, that the Oregon Agreement State Program is adequate to protect public health and safety and is compatible with the NRC's program. The review team recommended, and the MRB agreed, that the next IMPEP review take place in approximately four years.

### 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 12–16, 2013, by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of Arizona. 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 28, 2009 to August 16, 2013, were discussed with Oregon managers on the last day of the review.

A draft of this report was provided to Oregon for factual comment on September 11, 2013. The State responded by letter dated October 14, 2013. A copy of the State's response is included as an Attachment to this report. A Management Review Board (MRB) met on October 29, 2013, to consider the proposed final report. The MRB found the Oregon Agreement State Program adequate to protect public health and safety, and compatible with the NRC's program.

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

At the time of the review, the Oregon Agreement State Program regulated 315 specific licenses authorizing possession and use of radioactive 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 the 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 May 16, 2013. The Section provided its response to the questionnaire on July 25, 2013. A copy of the questionnaire response can be found in NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML13206A271.

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 two inspectors, and (6) interviews with staff and managers. The review team evaluated the information gathered against the established criteria for each common and the 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 reviews. 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.

### 2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous IMPEP review, which concluded on August 27, 2009, the review team made three recommendations regarding the Oregon Agreement State Program's performance. The status of each open recommendation is as follows:

 "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."

Status: The Section developed and utilizes a formal qualification program for all new licensing and inspection staff which clearly indicates each individuals training and qualification and their understanding of regulations and guidance. The Section separately tracks and utilizes refresher/continuing education training for its qualified inspection and licensing staff. This recommendation is closed.

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."

Status: The Section developed and implemented a protocol for the identification, marking, handling, control and protection of sensitive security-related information. Each member of the staff and management was involved in the development and implementation of the protocol. This recommendation is closed.

3. "The review team recommends that the Section implement a process to ensure all required information is submitted to the NRC's Nuclear Materials Events Database (NMED) and to also promote timely completion of NMED entries."

Status: The Section modified its protocol for incident and allegation activities to ensure that all of the required information be submitted to NMED and that entries were completed in a timely manner. The review team determined that out of the seven events that were reported to NMED, four of the incidents were not submitted to the NRC in a timely manner in accordance with the Handbook on Nuclear Material Event Reporting in the Office of Federal and State Materials and Environmental Management Programs (FSME) Procedure SA-300, *Reporting Material Events* and six incidents did not contain complete and accurate information in NMED. Therefore, the review team determined that the recommendation be kept open until the Section has had an opportunity to review incidents reported to NMED and close the incidents as appropriate, as well as, ensure that the process is consistently implemented for each incident. This recommendation remains open.

### 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

Considerations central to the evaluation of this indicator include the Section's staffing level and staff turnover, as well as the technical qualifications and training history of the staff. To evaluate these issues, 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 workload backlogs.

The Section, which is supervised by the Section Manager, is divided into two units: the Emergency Preparedness, Licensing & Administration Unit and the Emergency Response, Field Operations & Technical Services Unit. The Section is responsible for licensing, inspection, training, and emergency preparedness and response activities for radioactive materials facilities. At the time of the review, there were eight technical staff members and managers in the Section with various degrees of involvement in the radioactive materials program, totaling approximately 6.5 full-time equivalents (FTE).

Since the 2009 IMPEP review, three individuals, two technical staff and the Section Manager left the radioactive materials program. These individuals left in December 2010, February 2012, and January 2011 respectively. The Emergency Response, Field Operations, & Technical Services Manager was promoted in January 2011 to the Section Manager position. The Section hired a new Emergency Response, Field Operations, & Technical Services Manager in September of 2011. The Section also hired one new technical staff in May 2011 and transferred an individual from another area of the Section to radioactive materials in January 2013. No positions were vacant at the time of the review and no backlogs occurred in licensing or inspection actions due to the staff turnover. The Section has one administrative assistant which is adequate for the level of work generated. The review team determined that staffing levels were adequate for the Oregon Agreement State program.

The Section has a documented training plan for technical staff that is consistent with the requirements in the NRC/Organization of Agreement States Training Working Group Report and NRC's Inspection Manual Chapter (IMC) 1246, "Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area." Staff members are assigned increasingly complex duties as they progress through the qualification process. The new staff received the training plan and uses it to complete the requirements to become fully qualified license reviewers and inspectors. The review team concluded that the Section's training program is adequate to carry out its regulatory duties and noted that management supports the training program.

Oregon Revised Statue 453.645 states that the Director of the Oregon Health Authority shall appoint a Radiation Advisory Committee consisting of eight members representing various disciplines within the radiation industry. The Radiation Advisory Committee meets every four months and provides advice on radiation protection issues and regulations. The Radiation Advisory Committee has no oversight authority. The review team identified no potential conflicts of interest.

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, be found satisfactory.

### 3.2 Status of Materials Inspection Program

The review team focused on five factors while reviewing this indicator: inspection frequency, overdue inspections, initial inspections of new licenses, timely dispatch of inspection findings to licensees, and performance of reciprocity inspections. The review team's evaluation was based on the Section's questionnaire response relative to this indicator, data gathered from the Section's database, examination of completed inspection casework, and interviews with management and staff.

The review team verified that the Section's inspection frequencies for all types of radioactive material licenses are at least as frequent as or in some cases more frequent than similar license types listed in IMC 2800, "Materials Inspection Program." There are 83 license categories established by the Section. The Section assigned inspection priority codes that prescribe a more frequent inspection schedule than those established in IMC 2800 for similar license types for 43 categories.

The Section conducted 126 Priority 1, 2, and 3 inspections during the review period, based on the inspection frequencies established in IMC 2800. Three of these inspections were conducted overdue by more than 25 percent of the inspection frequency prescribed in IMC 2800. In addition, the Section performed four initial inspections during the review period, none of which were conducted overdue. As required by IMC 2800, initial inspections were conducted within 12 months of license issuance. Overall, the review team calculated that the Section performed 2.3 percent of its inspections overdue during the review period.

The review team evaluated the Section's timeliness in providing inspection findings to licensees. A sampling of 27 inspection reports indicated that one of the inspection findings reviewed was communicated to the licensee beyond the Section's goal of 30 days after the inspection. The late inspection finding was issued three months after the inspection date. The review team determined that the Section was timely in its issuance of inspection findings to its licensees.

During the review period, the Section granted 53 reciprocity permits, 42 of which were candidate licensees based upon the criteria in IMC 1220, "Processing of NRC Form 241 and Inspection of Agreement State Licensees Operating under 10 CFR 150.20." The review team determined that the Section exceeded the NRC's criteria of inspecting 20 percent of candidate licensees operating under reciprocity in three of the four years covered by the review period. The Section did not meet NRC's criteria of inspecting 20 percent of candidate licensees operating under reciprocity in calendar year 2011.

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, be found satisfactory.

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

The review team evaluated the inspection reports, enforcement documentation, inspection field notes, and interviewed inspectors for 27 radioactive materials inspections conducted by the Section during the review period. The casework reviewed included inspections conducted by one former and three current Section inspectors and covered inspections of various license types: industrial radiography including both field and fixed sites, industrial, academic and medical broad scope licenses, medical institutions including high dose rate remote after-loader, nuclear pharmacy, self-shielded irradiators, gamma knife, mobile nuclear medicine including mobile Positron Emission Tomography imaging, source material, and the State's own license for impounded materials. The casework reviewed included both initial and follow-up inspections as well as Increased Controls (IC) inspections. Appendix C lists the inspection casework files reviewed as well as the results of the inspector accompaniments.

Based on the evaluation of the casework, the review team noted that inspections covered all aspects of the licensee's radiation safety programs. The review team found that inspection reports reviewed were thorough, complete, consistent, and of high quality, with sufficient documentation to ensure that a licensee's performance with respect to health, safety and security was acceptable. The documentation supported violations, recommendations made to licensees, unresolved safety issues, and discussions held with licensees during exit interviews.

The inspection protocols utilized by the Section are consistent with the inspection guidance outlined in IMC 2800. Inspection findings including any violations are documented on Oregon Form 591 and provided to the licensee at the conclusion of the inspection. For inspections where staff is unable to complete the inspection on site because they are waiting on additional information from the licensee to complete an inspection, findings are documented by letter and dispatched to the licensee from the office.

The review team noted that the Section has an adequate supply of survey instruments to support the Section's inspection program. Calibrated survey instrumentation, such as Geiger-Mueller meters, scintillation detectors, ion chambers, micro-R meters, multi-channel analyzers and neutron detectors were available for use for inspections or for emergency response operations as needed. Instruments are calibrated by an Oregon calibration lab with National Institute of Standards and Technology traceable sources. The Section tracks each instrument, its current location, and next calibration date. The Section also analyzes radiological samples in its own laboratory which has a wide variety of analytical equipment capable of detailed radiological analysis. Staff members have been trained to operate the equipment and perform the analysis as needed.

The Section reported that supervisor accompaniments were not performed in 2010. This occurred during transitions in Section management; however accompaniments were properly performed in years 2011-2013. In one instance a new inspector was accompanied by a senior inspector instead of a supervisor. The supervisory accompaniments are documented and maintained within the Section.

Accompaniments of two Section inspectors were conducted on July 30, 2013, and July 31, 2013. The inspectors were accompanied during health, safety and security inspections of an industrial radiography facility and a gamma knife. During each of the accompaniments,

the inspectors demonstrated appropriate inspection techniques, knowledge of the regulations, and conducted performance based inspections. The inspectors were trained, well-prepared for the inspection, and thorough in their audits of the licensees' radiation safety programs. The inspectors conducted interviews with appropriate personnel, observed licensed operations, conducted confirmatory measurements, and utilized good health physics practices. The inspections were adequate to assess radiological health, safety, and security at each of the licensed facilities.

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, be found satisfactory.

### 3.4 Technical Quality of Licensing Actions

The review team examined completed casework and interviewed license reviewers for 32 licensing actions covering 31 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, security requirements, 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 and supervisory review, and proper signatures.

The 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, 6 renewals, 19 amendments, and 3 license terminations. Casework reviewed included a cross-section of license types such as industrial radiography, broad scope medical and academic, nuclear medicine diagnostic and therapeutic, research and development, portable gauge, fixed gauge, nuclear pharmacy, and veterinary. A listing of the licensing casework reviewed, with comments, can be found in Appendix D.

The review team found 12 of the 32 licensing actions either did not fully address health and safety concerns or indicated repeated examples of problems with respect to thoroughness, completeness, consistency, clarity, technical quality, and adherence to existing guidance in licensing actions. The review team concluded that actions taken in terminating licenses were appropriately documented, which included suitable material survey records and contained documentation of proper disposal or transfer of radioactive material.

The Section has three fully qualified license reviewers and one partially qualified license reviewer. A majority of the licensing actions completed during the review period were done by one individual. The partially qualified license reviewer, who transitioned to licensing in January 2013, became qualified to independently perform actions on industrial licenses in May 2013. Licenses are created and tracked using a local database. Once completed, all licensing actions are reviewed and signed by the Emergency Preparedness, Licensing & Administration Unit Manager. The Section uses the NRC's NUREG-1556 series as its licensing guidance and also has a licensing procedure flow sheet. Contrary to the Section's licensing procedure flow sheet, peer reviews of licensing actions were not being consistently performed during the review period

leading to inconsistency in licensing work products. The review team recommends that the Section follow its licensing procedure flow sheet and re-implement the peer review process to ensure consistency and accuracy for all licensing actions.

The Section identified four licensees requiring financial assurance. Three licensees had appropriate financial assurance documents in place and one licensee was still in the process of obtaining the necessary documentation and providing it to the Section. The Section stated that they were in the final stages of collecting the documentation from the last licensee and expected to have the action completed within a month. The review team identified a fifth licensee that was licensed for material in quantities requiring financial assurance but did not have the appropriate financial assurance documents in place. This license is the Section's own license and the Section stated that they did not want to lower the limits in case a situation occurred in the future that required them to take possession of material in excess of the limits requiring financial assurance. The review team determined that the Section did not possess quantities of material in excess of the limits which would require financial assurance at the time of the IMPEP review. The Section stated it would add a license condition to the license that stated that if they exceeded quantities of material in excess of those required for financial assurance, proper financial assurance documentation would need to be obtained.

The Section's license also allows for possession of radioactive material in quantities above those required for implementation of the ICs; however, the license did not contain the IC license condition nor does the Section implement the ICs since they do not possess material in excess of the quantities required for the implementation of the ICs. The Section stated that it wanted to keep the limits as stated on the license in case a situation arose that required them to take possession of radioactive material in quantities exceeding the IC threshold. The Section will add a license condition to its license stating that if it were to need to take possession of a quantity of radioactive material greater than the threshold for the IC's then the Section would implement the ICs prior to taking possession of the material.

The review team identified seven licenses where authorized users were added to the license without the proper documentation to verify the training, experience, and preceptor attestation. The review team found the Section was approving users, in some cases, with only a board certification, or only a preceptor attestation, or only a letter citing the doctor's credentials and training. In addition, the Section approved users who submitted a preceptor attestation form that was not filled out correctly. The review team recommends that the State verify that all previously approved authorized users, authorized medical physicists, radiation safety officers on medical licenses, and authorized nuclear pharmacists have the proper board certification or training requirements and preceptor attestation, since the new requirements were initiated in 2006.

The review team reviewed six license renewals. Two of these renewals were composed of only two pages and a statement mirroring "no changes since the last inspection." For these two renewals the reviewer deleted all of the previous tie-down conditions and placed the current renewal application as the only tie-down condition. The review team discussed with the Section whether or not the license in its current form was able to be inspected against and was enforceable based on commitments made in the licensee's original application. The Section stated that they were unsure if the inspectors could inspect against and issue violations against a commitment made in the initial application even though the tie down condition referencing that

application had been removed and replaced with the two page submittal referencing no changes to the license since the last inspection. The Section stated it would evaluate its current renewal process to ensure that renewed licenses were both able to be inspected against and enforceable.

The review team verified that the Section uses legally binding license conditions that meet the criteria for implementing the IC Orders, including fingerprinting, as appropriate. There are currently fifteen licenses required to meet these mandates. Files containing IC licenses are kept in a locked file drawer. The review team determined that these licenses and corresponding cover letters were marked as containing sensitive information as required, and that the Section is identifying and marking sensitive security-related information appropriately in accordance with their protocol.

The Section has access to the National Source Tracking System (NSTS) and utilizes and updates the database, as necessary, when completing certain licensing actions. The Section did not have any licensees with outstanding NSTS reconciliations for 2012.

The review team assessed the Section's implementation of the pre-licensing guidance. The Section implemented NRC's pre-licensing guidance issued on September 22, 2008, and transmitted to the Agreement States via FSME Letter RCPD-08-020, "Requesting Implementation of the Checklist to Provide a Basis for Confidence That Radioactive Material Will Be Used as Specified on a License and the Checklist for Risk-significant Radioactive Material," however the guidance is being implemented incorrectly. If the new licensee is an IC licensee then, per Section policy, they automatically get a pre-licensing visit along with a full security inspection prior to issuance of the license. However if the new licensee is not an IC licensee and the Section determines that the applicant is registered as a business with the Oregon Secretary of State then the rest of the pre-licensing checklist is not utilized. The review team discussed with the Section that a business being registered with the Oregon Secretary of State did not make the applicant known to the Section and that the Section should utilize the pre-licensing checklists as appropriate to determine if a pre-licensing visit is warranted. The review team recommends that the State develop and implement a pre-licensing protocol based on the RCPD-08-020 letter issued on September 22, 2008 to enhance the basis for confidence that radioactive materials will be used as specified on a radioactive materials license.

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, 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 and allegations, the review team examined the Section's response to the questionnaire relative to this indicator, evaluated selected incidents reported for Oregon in NMED against those contained in the Section's files, and evaluated the casework for seven incidents which were reported to NMED and for seven incidents which were not reported to NMED. A list 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 two allegations involving radioactive materials, including one allegation referred to the Section by the NRC during the review period.

The review team examined the Section's implementation of its incident and allegation processes, including written protocols for handling allegations and incident response, file documentation, and notification of incidents to the NRC Headquarters Operations Center. When notification of an incident or an allegation is received, the Section's Manager or designee determines the appropriate level of initial response.

The Section has established standard operating protocols for responding to incidents and allegations. The protocols describe the actions to be taken upon the notification of an incident or allegation, proper documentation of incidents and allegations, and entering information into the Section's radioactive materials licensing (RML) database. The Section uses the RML database to keep track of incidents and allegations. The RML database is used by inspectors to identify incidents that require follow-up during the next routine inspection. Incidents that occurred during the review period were inspected and properly documented during the next routine inspection.

The review team reviewed seven reportable radioactive material incidents in NMED for Oregon during the review period. The review team also reviewed seven radioactive materials incidents which the Section determined to be non-reportable. The incidents selected for review included the following categories: lost/stolen radioactive material, potential overexposure, medical event, equipment failure, and leaking source. The review team determined that the Section's response to incidents was complete and comprehensive. Initial responses were prompt and well-coordinated, and the level of effort was commensurate with the health and safety significance of the incident. The Section dispatched inspectors for on-site investigations in three of the cases reviewed and took suitable enforcement and follow-up actions in all of the cases reviewed.

While reviewing the casework for the seven events in NMED, the review team noted that, in six of the cases, the Section had closed the event report in NMED since the Section had concluded their follow-up/investigation but had not completed the event report in NMED by providing all of the information requested by the NMED contractor. Additionally, four of the seven cases in NMED were not reported in a timely manner in accordance with the reporting timelines established in the FSME Procedure SA-300 "Reporting Material Events." The 2009 IMPEP review team recommended that the Section implement a process to ensure all required information is submitted to NMED and to also promote timely completion of NMED entries. This review team determined that the recommendation should stay open until the Section can effectively demonstrate that the established protocol is ensuring that all required information is submitted to NMED and that reportable events are completed in NMED in a timely manner.

The review team selected an additional seven radioactive material incidents for evaluation from the Oregon RML database. The review team identified that two of the seven incidents should have been reported to the NRC Operations Center. One was a medical event that should have been reported within 24 hours after being notified by the licensee. The second incident was a lost tritium exit sign which should have been reported immediately after notification from the licensee. Additionally, there were two incidents associated with leaking radioactive sources that should have been reported to NMED within 30 days. The review team recommends that the State revise their protocol for reviewing incidents for reportability in accordance with FSME

Procedure SA-300 and to ensure timely reporting of events to the NRC Operations Center and to NMED.

In evaluating the effectiveness of the Section's response to allegations, the review team evaluated the completed casework for two allegations, including one that the NRC referred to the Section during the review period. The review team concluded that the Section took prompt and appropriate actions in response to concerns raised. One allegation was substantiated and the Section took appropriate enforcement action by issuing a notice of violation to the licensee. The other allegation was unsubstantiated. The review team noted that the Section documented the investigations of concerns and retained all necessary documentation to appropriately close the allegations. However, the review team identified that in both allegations the Section could not confirm that the concerned individuals were notified about the conclusion of the Section's investigations. The review team informed the Section's management of this issue and immediate action was taken to notify the concerned individuals and document the notification. The Section's management committed to revising the protocols to ensure that concerned individuals are notified about the conclusions of the Section's investigations of the concern(s). The review team determined that the Section adequately protected the identity of concerned individuals.

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, 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 Oregon does not relinquish regulatory authority for a sealed source and device evaluation program, low level radioactive waste disposal program, or a uranium recovery program; therefore, only the first non-common performance indicator applied to this review.

### 4.1 Compatibility Requirements

### 4.1.1 Legislation

Oregon became an Agreement State on July 1, 1965. The current effective statutory authority is contained in Volume 11 Chapter 453 Hazardous Substances, Radiation Sources, of the Oregon Revised Statutes. The Section is designated as the State's radiation control agency. The review team noted that no legislation affecting the radiation control program was passed during the review period.

### 4.1.2 <u>Program Elements Required for Compatibility</u>

The Oregon regulations governing radiation protection requirements are located in Chapter 333, Divisions 100-124 of the Oregon Administrative Rules and apply to all persons who receive, possess, use, transfer, own, or acquire any source of radiation. Oregon requires a license for the receipt, possession, use, ownership, or transfer of all radioactive material,

including byproduct, source, certain quantities of special nuclear material, accelerator-produced radionuclides, and naturally-occurring materials, such as radium. Oregon also requires registration of all equipment designed to produce x-rays or other ionizing radiation.

The review team examined the State's administrative rulemaking process and found that the process takes six months to a year from the development stage to the final approval. The final rule is submitted to the Secretary of State and then is published as a final rule. The final rule becomes effective after publication. The public, NRC, other agencies, and potentially impacted licensees and registrants are offered an opportunity to comment during the process. Comments are considered and incorporated, as appropriate, before the regulations are finalized and approved.

The review team noted that the State's rules and regulations are not subject to "sunset" laws. The State may adopt the regulations of another agency by reference and also has the authority to issue legally binding requirements (e.g., license conditions) in lieu of regulations until compatible regulations become effective.

The review team evaluated Oregon'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 that FSME maintains.

During the review period, Oregon submitted seven final regulation amendments for a compatibility review. Current NRC policy requires that Agreement States adopt certain equivalent regulations or legally-binding requirements no later than three years after they become effective. Five of the amendments were overdue for State adoption at the time of submission. The NRC's compatibility review resulted in six comments, which will need to be addressed by the State in upcoming rulemaking activities. The following five amendments were submitted overdue during this review period:

- "Minor Amendments," 10 CFR Parts 20, 30, 32, 35, 40, and 70 amendment (71 FR 15005) that was due for Agreement State adoption on March 27, 2009. [OR final rule submittal April 15, 2010]
- "Medical Use of Byproduct Material Minor Corrections and Clarifications," 10 CFR Parts 32 and 35 (72 FR 45147) that was due for Agreement State adoption on October 29, 2010. [OR final rule submittal December 14, 2011]
- "Requirements for Expanded Definition of Byproduct Material," 10 CFR Parts 20, 30, 31, 32, 33, 35, 61, 150 (72 FR 55864) that was due for Agreement State adoption on November 30, 2010. [OR final rule submittal December 14, 2011]
- "Occupational Dose Records, Labeling Containers, and Total Effective Dose Equivalent,"
   10 CFR Parts 19 and 20 amendment (72 FR 68043) that was due for Agreement State adoption on January 3, 2011. [OR final rule submittal December 14, 2011]
- "Medical Use of Byproduct Material Authorized User Clarification," 10 CFR Part 35 (74

FR 33901) that was due for Agreement State adoption on September 28, 2012. [OR final rule submittal April 29, 2013]

At the time of this review, there were no amendments overdue for adoption. The review team recommends that the State develop and implement a protocol to ensure that regulations required for adoption are adopted within 3 years as required in the Policy Statement on Adequacy and Compatibility of Agreement State Programs.

A complete list of upcoming regulation amendments that will need to be addressed can be found on the NRC website at the following address: http://nrc-stp.ornl.gov/rss\_regamendents.html.

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, be found satisfactory.

### 4.2 Low-Level Radioactive Waste Disposal Program

In 1981, the NRC amended its Policy Statement, "Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory Authority and Assumption Thereof by States Through Agreement," to allow a State to seek an amendment for the regulation of LLRW as a separate category. Although the Oregon Agreement State Program has LLRW disposal authority, NRC has not required States to have a program for licensing a LLRW 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, they are expected to put in place a regulatory program which will meet the criteria for an adequate and compatible LLRW disposal 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 above, Oregon's performance was found satisfactory for four out of six performance indicators reviewed and satisfactory, but needs improvement, for the indicators Technical Quality of Licensing Actions and Technical Quality of Incidents and Allegation Activities. The review team made five recommendations regarding program performance by the State and determined that one recommendation from the 2009 IMPEP review should be kept open.

Accordingly, the review team recommended, and the MRB agreed, that the Oregon Agreement State Program be found adequate to protect public health and safety and compatible with the NRC's program. Based on the results of the current IMPEP review, the review team recommended, and the MRB agreed, that the next full IMPEP review take place in approximately four years.

Below are the review team's recommendations, as mentioned in the report, for evaluation and implementation by the State:

### RECOMMENDATIONS

- 1. The review team recommends that the Section follow its licensing procedure flow sheet and re-implement the peer review process to ensure consistency and accuracy for all licensing actions. (Section 3.4)
- 2. The review team recommends that the State verify that all previously approved authorized users, authorized medical physicists, radiation safety officers on medical licenses, and authorized nuclear pharmacists have the proper board certification or training requirements and preceptor attestation, since the new requirements were initiated in 2006. (Section 3.4)
- The review team recommends that the State develop and implement a pre-licensing protocol based on the RCPD-08-020 letter issued on September 22, 2008 to enhance the basis for confidence that radioactive materials will be used as specified on a radioactive materials license. (Section 3.4)
- 4. 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. (Section 3.5 remains open from 2009 IMPEP)
- 5. The review team recommends that the State revise its protocol for reviewing incidents for reportability in accordance with FSME Procedure SA-300 and to ensure timely reporting of events to the NRC Operations Center and to NMED. (Section 3.5)
- 6. The review team recommends that the State develop and implement a protocol to ensure that regulations required for adoption are adopted within 3 years as required in the Policy Statement on Adequacy and Compatibility of Agreement State Programs. (Section 4.1)

### LIST OF APPENDICES

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Appendix D License Casework Reviews

Appendix E Incident Casework Reviews

Appendix F Sealed Source and Device Casework Reviews

### APPENDIX A

### IMPEP REVIEW TEAM MEMBERS

| Name                       | Area of Responsibility  |
|----------------------------|---|
| Monica Ford, Region I      | Team Leader Technical Staffing and Training Status of Materials Inspection Program Compatibility Requirements |
| Randy Erickson, Region IV  | Technical Quality of Inspections Inspector Accompaniments   |
| Brian Goretzki, Arizona    | Technical Quality of Licensing Actions  |
| Binesh Tharakan, Region IV | Technical Quality of Incidents and Allegation Activities  |

### APPENDIX B

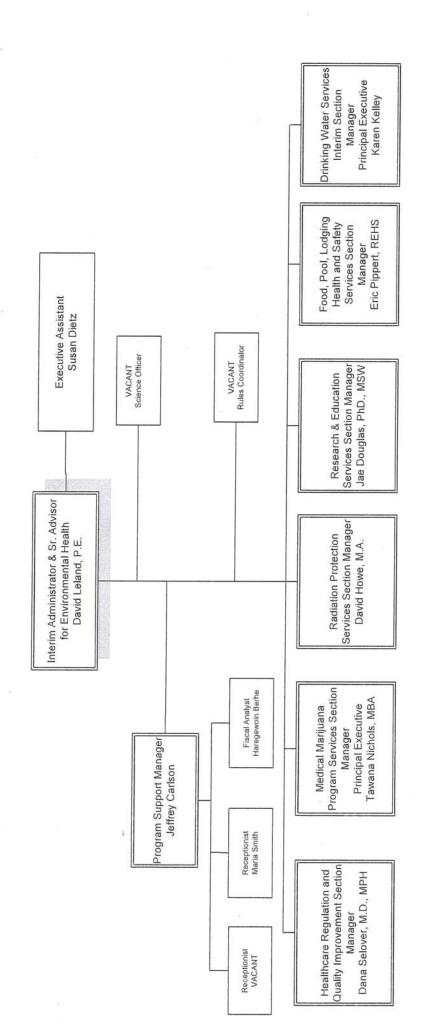
OREGON ORGANIZATION CHARTS

ADAMS ACCESSION NO.: ML13206A255

### Center for Health Protection Oregon Public Health Division

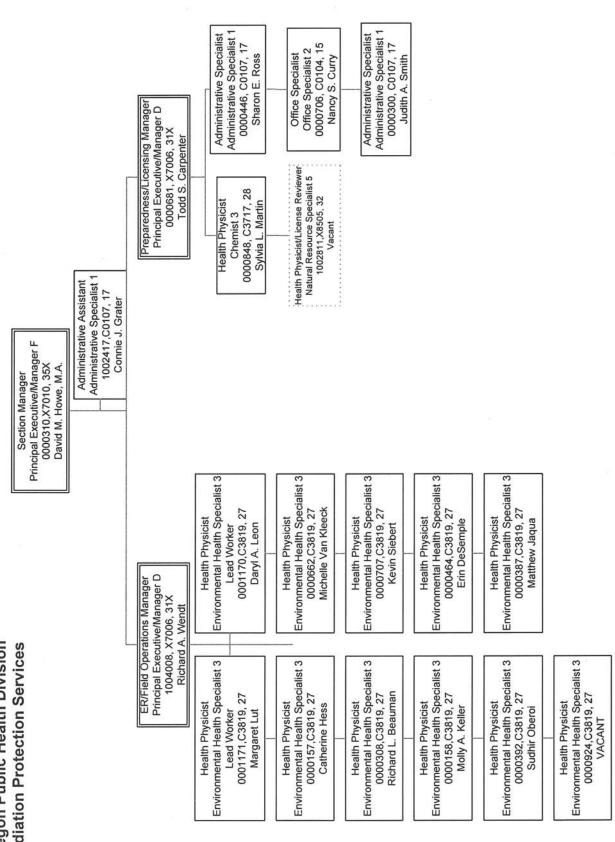
Attachment 1

## Administration

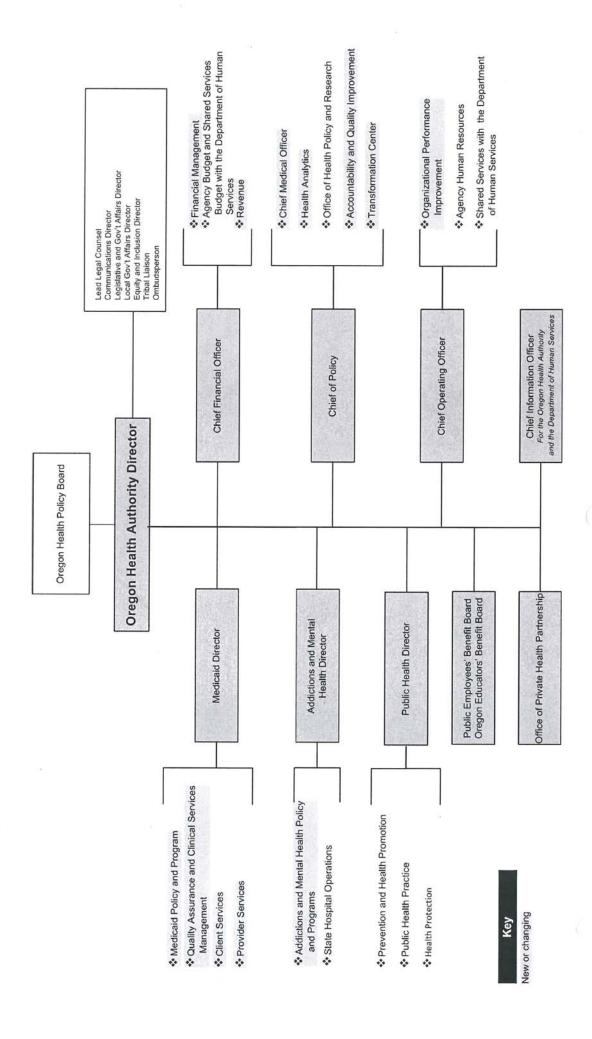


## Center for Health Protection

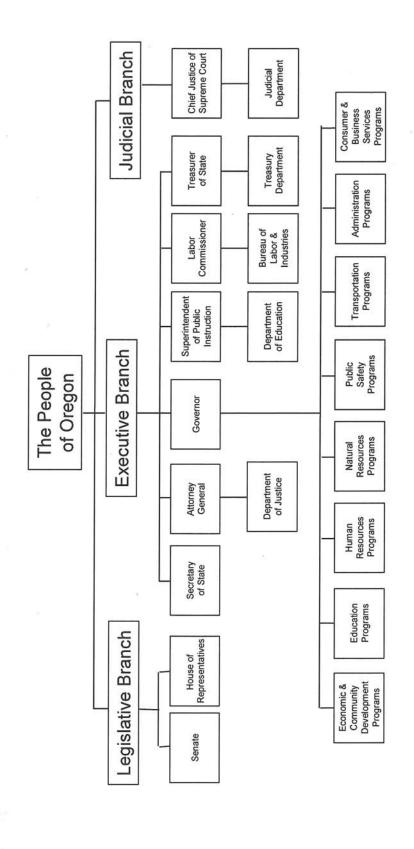
Oregon Public Health Division Radiation Protection Services



## Oregon Health Authority



# STATE OF OREGON -- ORGANIZATION CHART



### APPENDIX C

### INSPECTION CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

File No.: 1

Licensee: Oregon Health & Science University License No.: ORE-90013 Inspection Type: Special/Routine/Unannounced Priority: 2 Inspection Date: 11/15/10

Inspector: JS

File No.: 2

Licensee: Oregon Washington Laboratories License No.: ORE-91149

Inspection Type: Special/Routine/Unannounced Priority: 1 Inspection Date: 2/12/13 Inspector: DL

File No.: 3

Licensee: Providence Health & Services-Oregon License No.: ORE-90946

Inspection Type: Special/Unannounced Priority: 2 Inspection Date: 2/25/10

Inspector: JS

File No.: 4

Licensee: Acuren Inspection, Inc. License No.: ORE-90621

Inspection Type: Special/Routine/Unannounced Priority: 1

Inspection Date: 9/26/12 Inspector: RB

File No.: 5

Licensee: Peace Health Sacred Heart Medical Center License No.: ORE-91054

Inspection Type: Special/Unannounced Priority: 2

Inspection Date: 3/28/12 Inspector: KS

File No.: 6

Licensee: Professional Service Industries, Inc. License No.: ORE-99056

Inspection Type: Field/Special/Unannounced Priority: 1

Inspection Date: 2/24/10 Inspector: KS

File No.: 7

Licensee: Oregon Health & Science University License No.: ORE-90731

Priority: 3 Inspection Type: Special/Routine/Unannounced

Inspection Date: 4/13/12 Inspector: DL

File No.: 8

Licensee: TDY Industries, LLC License No.: ORE-90728

Inspection Type: Special/Routine/Unannounced Priority: 1

Inspection Date: 6/9/11 Inspector: DL Oregon Final IMPEP Report **Inspection Casework Reviews**  Page C. 2

File No.: 9

License No.: ORE-90651 Licensee: International Inspection, Inc.

Inspection Type: Special/Routine/Unannounced Priority: 1 Inspection Date: 7/30/13

Inspector: KS

File No.: 10

Licensee: Providence Health & Services, Oregon License No.: ORE-90946

Inspection Type: Special/Routine/Unannounced Priority: 2 Inspection Date: 3/20/12

Inspectors: KS

File No.: 11

Licensee: Legacy Good Samaritan License No.: ORE-91155

Inspection Type: Pre-Licensing/Special/Unannounced Priority: 2 Inspection Date: 10/18/12 Inspector: RB

File No.: 12

Licensee: Bay Area Hospital License No.: ORE-90358

Inspection Type: Routine/Unannounced Priority: 3 Inspection Date: 9/28/10 Inspector: KS

File No.: 13

Licensee: Community Cancer Center License No.: ORE-90422

Inspection Type: Routine/Unannounced Priority: 2 Inspection Date: 10/16/12 Inspector: KS

File No.: 14

Licensee: Legacy Good Samaritan Med. Center Radiation Oncology License No.: ORE-91155

Inspection Type: Initial/Special/Announced Priority: 2 Inspection Date: 3/6/12 Inspector: DL

File No.: 15

Licensee: OHA Public Health Division License No.: ORE-90269

Priority: 3 Inspection Type: Routine/Unannounced Inspection Date: 12/19/12 Inspector: RB

File No: 16

License No.: ORE-90862 Licensee: Oncology Associates of Oregon

Inspection Type: Routine/Unannounced Priority: 2 Inspection Date: 3/20/13 Inspector: KS

File No.: 17

Licensee: Cardinal Health License No.: ORE-90509

Inspection Type: Routine/Unannounced Priority: 2 Inspection Date: 11/21/12 Inspector: RB File No.: 18

Licensee: ISOSCAN License No.: ORE-91039

Inspection Type: Routine/Unannounced Priority: 3 Inspection Date: 11/9/12 Inspector: DL

File No.: 19

Licensee: SHS Mobile PET/CT License No.: ORE-91148

Inspection Type: Routine/Unannounced Priority: 3 Inspection Date: 11/27/12 Inspector: KS

File No.: 20

Licensee: Compass Oncology License No.: ORE-91121

Inspection Type: Routine/Unannounced Priority: 2 Inspection Date: 12/17/09 Inspector: JS

File No.: 21

Licensee: Mistras Services License No.: ORE-96130

Inspection Type: Reciprocity/Unannounced Priority: 3 Inspectors: KS

Inspection Date: 9/10/12

File No.: 22

Licensee: Reed College License No.: ORE-90010

Inspection Type: Routine/Unannounced Priority: 3 Inspection Date: 10/18/12 Inspectors: RB

File No.: 23

License No.: ORE-90702 Licensee: Triad Isotopes, Inc.

Inspection Type: Routine/Unannounced Priority: 2 Inspection Date: 10/12/12 Inspector: RB

File No.: 24

Licensee: PCC Structurals, Inc. License No.: ORE-90354

Inspection Type: Routine/Unannounced Priority: 2 Inspection Date: 3/23/10 Inspector: DL

File No.: 25

Licensee: H & H X-Ray License No.: ORE-96112

Inspection Type: Reciprocity/Unannounced Priority: 1 Inspection Date: 7/22/10 Inspectors: DL

File No.: 26

Licensee: Northwest Inspection, Inc. License No.: ORE-96131

Inspection Type: Reciprocity/Unannounced Priority: 1

Inspection Date: 10/25/12 Inspector: RB Oregon Final IMPEP Report Inspection Casework Reviews

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File No.: 27

Licensee: Halliburton Energy Services License No.: ORE-96058

Inspection Type: Reciprocity/Unannounced Priority: 2

Inspection Date: 6/6/13 Inspector: RB

### INSPECTOR ACCOMPANIMENTS

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

Licensee: International Inspection, Inc. License No.: ORE-90651

Inspection Type: Special/Routine/Unannounced Priority: 1

Inspection Date: 7/30/13 Inspector: KS

Licensee: Legacy Good Samaritan Medical Center License No.: ORE-91155

Inspection Type: Special/Initial/Unannounced Priority: 2

Inspection Date: 7/31/13 Inspector: DL

### APPENDIX D

### LICENSE CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

File No.: 1

Licensee: Cardinal Health 414

Type of Action: Amendment

Date Issued: 06/21/2013

License No.: ORE-91142

Amendment No.: 07

License Reviewer: SM

File No.: 2

Licensee: Eugene Sand and Gravel

Type of Action: Amendment

Dates Issued: 03/22/2013

License No.: ORE-90643

Amendment No.: 11

License Reviewer: ED

File No.: 3

Licensee: PETNET Solutions, Inc.

Type of Action: Amendment

Dates Issued: 10/04/2012

License No.: ORE-90926

Amendment No.: 26

License Reviewer: SM

Comment: An authorized nuclear pharmacist was added to the license without proper documentation regarding training, experience, and preceptor attestation.

File No.: 4

Licensee: DOW AgroSciences, LLC

Type of Action: Renewal

Date Issued: 02/27/2013

License No.: ORE-90855

Amendment No.: 12

License Reviewer: SM

Comment: A renewal application was submitted on 1/30/2013 and items 5-12 consisted of the

phrase "No changes since Agency inspection conducted May 21, 2009 or last amendment (number 11)." All of the previous tie-down conditions are removed and

the new renewal date is placed into the tie-down condition.

File No.: 5

Licensee: St. Anthony Hospital

Type of Action: Amendment

Date Issued: 03/14/2013

License No.: ORE-90353

Amendment No.: 36

License Reviewer: SM

File No.: 6

Licensee: Legacy Health Radiation Safety/Imaging

Type of Action: Amendment

Date Issued: 11/9/2012

License No.: ORE-90293

Amendment No.: 86/89

License Reviewer: SM

Comment: An authorized user was added to the license without proper documentation

regarding training, experience, and preceptor attestation.

Oregon Final IMPEP Report License Casework Reviews

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File No.: 7

Licensee: Legacy Health System Radiation Safety/Imaging

Type of Action: Amendment

Date Issued: 06/10/2013

License No.: ORE-90181

Amendment No.: 71

License Reviewer: ED/SM

Comment: An authorized user was added to the license without proper documentation

regarding training, experience, and preceptor attestation.

File No.: 8

Licensee: Klamath Pacific Company

Type of Action: Amendment

Date Issued: 03/29/2013

License No.: ORE-90985

Amendment No.: 11

License Reviewer: SM

File No.: 9

Licensee: Salem Hospital

Type of Action: Amendment

Date Issued: 03/29/2013

License No.: ORE-91006

Amendment No.: 18

License Reviewer: SM/ED

Comment: Two authorized medical physicists were added to the license without proper documentation regarding training, experience, and preceptor attestation.

File No.: 10

Licensee: Oregon Advanced Imaging

Type of Action: Amendment

Date Issued: 02/22/2013

License No.: ORE-91001

Amendment No.: 15

License Reviewer: SM/ED

File No.: 11

Licensee: NMCSI (Hillsboro Cardiology)

Types of Action: /Renewal

Dates Issued: 08/28/2012

License No.: ORE-90996

Amendment No.: 10

License Reviewer: SM

Comment: The licensee submitted a renewal application on 08/14/2012, which included an

addition of an authorized user. The authorized user was added to the license without proper documentation regarding training, experience, and preceptor

attestation.

File No.: 12

Licensee: West Valley Hospital

Types of Action: Amendment

Dates Issued: 06/13/2013

License No.: ORE-91087

Amendment No.: 04

License Reviewer: ED

File No.: 13

Licensee: Cascade Medical Imaging, LLC

Type of Action: Amendment

Date Issued: 11/27/12

License No.: ORE-91131

Amendment No.: 07

License Reviewer: SM

Oregon Final IMPEP Report License Casework Reviews

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File No.: 14

Licensee: Oncology Associated of Oregon

Type of Action: Amendment

Date Issued: 07/09/2013

License No.: ORE-90789

Amendment No.: 23

License Reviewer: SM

File No.: 15

Licensee: Asante Rogue Regional Medical Center Cardiac Studies

Type of Action: Amendment

Date Issued: 11/11/2009

License Roy.: ORE-90944

Amendment No.: 09

License Reviewer: SM

Comment: An authorized user was added to the license without proper documentation regarding training, experience, and preceptor attestation.

File No.: 16

Licensee: Four Rivers Veterinary Clinic

Type of Action: Renewal

Date Issued: 06/21/2011

License No.: ORE-90972

Amendment No.: 02

License Reviewer: SM

File No.: 17

Licensee: Providence St. Vincent Heart Clinics-Cardiology
Type of Action: Renewal
Date Issued: 10/18/2011

License No.: ORE-90793
Amendment No.: 206
License Reviewer: SM

File No.: 18

Licensee: NMCSI (Cascade Cardiology)

Type of Action: Amendment

Date Issued: 02/02/2012

License No.: ORE-91076

Amendment No.: 05

License Reviewer: SM

Comment: An authorized user added to the license without proper documentation regarding training, experience, and preceptor attestation.

File No.: 19

Licensee: Acuren Inspection, Inc.

Type of Action: Amendment

Date Issued: 12/27/2012

License No.: ORE-90621

Amendment No.: 85C

License Reviewer: SM

File No.: 20

Licensee: Eastern Oregon University

Type of Action: Termination

Date Issued: 06/28/2013

License No.: ORE-90142

Amendment No.: 31

License Reviewer: SM

File No.: 21

Licensee: Calbag Metals Company

Type of Action: Termination

Date Issued: 04/21/2011

License No.: ORE-90406

Amendment No.: 11

License Reviewer: SM

Oregon Final IMPEP Report License Casework Reviews

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File No.: 22

Licensee: Boise White Paper LLC

Types of Action: Termination

Dates Issued: 03/22/2013

License No.: ORE-90100

Amendment No.: 56

License Reviewer: SM

File No.: 23

Licensee: Curry Medical Center

Types of Action: New

Amendment No.: 01

Dates Issued: 12/20/2011

License Reviewer: SM/ED

File No.: 24

Licensee: PCC Structurals, Inc.

Type of Action: Amendment

Date Issued: 07/22/2013

License No.: ORE-90354

Amendment No.: 54

License Reviewer: SM/ED

File No.: 25

Licensee: Oregon Washington Laboratories

Type of Action: New

Date Issued: 0702/2011

License No.: ORE-91149

Amendment No.: 01

License Reviewer: SM

File No.: 26

Licensee: Silverton Hospital

Type of Action: Amendment

Date Issued: 02/17/2012

License No.: ORE-90886

Amendment No.: 22

License Reviewer: SM/ED

Comment: An authorized user added to the license without proper documentation regarding training, experience, and preceptor attestation.

File No.: 27

Licensee: Nuclear Medicine Consulting Services, Inc.

Type of Action: Amendment

Date Issued: 10/25/2012

License No.: ORE-90961

Amendment No.: 12

License Reviewer: SM/ED

Comment: An authorized user added to the license without proper documentation regarding training, experience, and preceptor attestation.

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File No.: 28

Licensee: Tuality/OHSU Cancer Center

Types of Action: Renewal

Dates Issued: 02/11/2011

License No.: ORE-91048

Amendment No.: 10/11

License Reviewer: SM

### Comments:

- a) A license renewal was submitted on 01/04/2011. The application consisted of a one page renewal with the statement "No changes since last inspection (no items of non-compliance) 3/16/2010" for items 5-12. All previous tie-down conditions were taken off and the new application was placed as the only tie-down condition.
- b) An authorized user was added on the previous amendment without sufficient information provided by the licensee.

File No.: 29

Licensee: OHA Public Health Division

Types of Action: Renewal

Dates Issued: 11/27/2012

License No.: ORE-90269

Amendment No.: 30

License Reviewer: SM

Comment: The license currently allows for quantities above those requiring implementation of

the ICs and those requiring financial assurance but does not contain a license condition requiring implementation of the ICs or contain any financial assurance

documentation in the file.

File No.: 30

Licensee: Sherman County Soil & Water Conservation District

Type of Action: New

Dates Issued: 07/11/2013

License No.: ORE-91161

Amendment No.: 1

License Reviewer: ED

Comment: The licensee submitted a new application for a portable gauge license. A prelicensing checklist was not utilized and a pre-licensing visit was not performed.

File No.: 31

Licensee: Carlson Testing, Inc.

Type of Action: Amendment

Dates Issued: 06/06/2013

License No.: ORE-90924

Amendment No.: 17

License Reviewer: DAL

### APPENDIX E

### INCIDENT CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

File No.: 1

Licensee: Jeld-Wen Wood Fiber of Oregon License No.: 90307 Date of Incident: 03/15/10 NMED No.: 100458 Investigation Date: 03/15/10 Type of Incident: Equipment Failure

Type of Investigation: Telephone/E-mail

Comment: The 24-hour notification to the NRC Headquarters Operations Center was late. It

was not made until 09/10/10; six months after the Section became aware of the

incident on 03/15/10.

File No.: 2

Licensee: Hillsboro Landfill License No.: 91120 NMED No.: 110408 Date of Incident: 08/15/11 Investigation Date: 09/01/11 Type of Incident: Lost/Stolen RAM

Type of Investigation: Site

File No.: 3

Licensee: Test America Analytical Testing License No.: 90559 Date of Incident: 06/01/12

NMED No.: 120345

Investigation Date: 06/14/12 Type of Incident: Lost/Stolen RAM

Type of Investigation: Site

Comment: The Section closed the incident on 01/10/13, but the NMED record was not

completed until 08/14/13 when it was identified by the review team.

File No.: 4

Licensee: Oregon Health and Science University License No.: 90013 Date of Incident: 08/13/12 NMED No.: 120486 Investigation Date: 08/20/12 Type of Incident: Medical Event Type of Investigation: Email

### Comments:

- a) The 24-hour notification to the NRC Headquarters Operations Center was late. It was not made until 8/20/12; six days after the licensee became aware of the incident.
- b) The Section closed the incident 09/19/12, but the NMED record was not completed until 08/14/13 when it was identified by the review team.

File No.: 5

Licensee: Evonik Corp

Date of Incident: 02/14/13

Investigation Date: 02/14/13

Type of Incident: Lost/Stolen RAM
Type of Investigation: Telephone/Email

Comment: The Section closed the incident on 06/06/13, but NMED record was not completed

until 08/14/13 when it was identified by the review team.

File No.: 6

Licensee: Oregon State Fire Marshal

Date of Incident: 09/01/10

Investigation Date: 02/17/11

Type of Incident: Lost/Stolen RAM
Type of Investigation: Telephone/Email

### Comments:

a) The 24-hour notification to the NRC Headquarters Operations Center was not made until it was identified by the Section during a self-audit on 07/19/13.

b) The Section closed the incident 09/02/11, but NMED record was not completed until 08/15/13 when it was identified by the review team.

File No.: 7

Licensee: Good Samaritan Regional Medical Center

Date of Incident: 11/01/10

Investigation Date: 01/19/11

Type of Incident: Type of Investigation: Telephone/Email

### Comments:

a) The 24-hour notification to the NRC Headquarters Operations Center was not made until it was identified by the Section during a self-audit on 07/19/13.

b) The Section closed the incident 01/10/12, but NMED record was not completed until 08/15/13 when it was identified by the review team.

File No.: 8

Licensee: Legacy Meridian Park Medical Center

Date of Incident: 11/03/11

Investigation Date: 11/09/11

Type of Incident: Medical Event
Type of Investigation: Telephone/Email

Comment: The Section did not identify this incident as a medical event and did not report it to the NRC Headquarters Operations Center the next calendar day. The review team identified this incident qualified as a medical event and informed the Section to review the incident and make the appropriate notifications. The Section reported this to NRC's Headquarters Operations Center on August 15, 2013.

Oregon Final IMPEP Report Incident Casework Reviews

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File No.: 9

Licensee: Kaiser Permanente Interstate

Date of Incident: 03/10/10

License No.: 90126

NMED No.: N/A

Investigation Date: 03/11/10 Type of Incident: Medical Event

Type of Investigation: Telephone/Email

File No.: 10

Licensee: Oregon Health and Science University License No.: 90731

Date of Incident: 10/28/09 NMED No.: N/A Investigation Date: 12/23/09 Type of Incident: Leaking Source

Type of Investigation: Telephone/Email

Comment: The 30-day report to NMED was not made until 08/15/13 when it was identified by

the review team.

File No.: 11

Licensee: Oregon State University

License No.: 90005

Date of Incident: 03/15/10 NMED No.: N/A Investigation Date: 03/15/10 Type of Incident: Leaking Source

Type of Investigation: Telephone/Email

Comment: The 30-day report to NMED was not made until 08/15/13 when it was identified by

the review team.

File No.: 12

Licensee: Carestream Health Inc. License No.: 90879

Date of Incident: 02/06/13 NMED No.: N/A

Investigation Date: 02/20/13 Type of Incident: Lost/Stolen RAM Type of Investigation: Telephone/Email

Comment: The immediate telephone report to the NRC Headquarters Operations Center was

not made for a lost tritium exit sign. The report was made on 08/15/13 when it was

identified as being reportable by the review team.

File No.: 13

Licensee: Southern Oregon Historical Society License No.: N/A

Date of Incident: 07/12/11 NMED No.: N/A

Investigation Date: 07/12/11 Type of Incident: Lost/Stolen RAM

Type of Investigation: Telephone/E-mail

File No.: 14

Licensee: Columbia Inspections License No.: 93138

Date of Incident: 07/08/10 NMED No.: 100375

Investigation Date: 07/08/10 Type of Incident: Lost/Stolen RAM

Type of Investigation: Site

### ATTACHMENT

October 14, 2013 letter from David M. Howe Oregon's Response to the Draft Report ADAMS Accession No.: ML13291A040



Health Authority

October 14, 2013

Monica Lynn Ford Regional State Agreements Officer U.S. Regulatory Commission, Region I 2100 Renaissance Blvd., Ste 100 King of Prussia, PA 19406-2713 800 NE Oregon Street, Suite 640 Portland, OR 97232 Voice 971-673-0490 FAX 971-673-0553 TTY 971-673-0372

Re: NRC IMPEP Draft Report of Oregon Agreement State Program dated September 11, 2013

Ms. Ford:

The leadership team from the Oregon Health Authority, Public Health Division, has requested that I respond directly to your letter and Preliminary IMPEP draft report of the Oregon Agreement State Program dated September 11, 2013.

The Oregon Radiation Protection Services (RPS) Section, Radioactive Materials Licensing (RML) program staff have reviewed the IMPEP Draft Report and the RPS management team has developed a plan to fully address all areas of concern noted in the IMPEP team's assessment of our program. We agree with the overall spirit and purpose of the IMPEP review program and are committed to implementing the recommendations as a way for continuous program improvement.

The action plan has been shared with my supervisor, David Leland, Interim Administrator, Center for Health Protection, and Suzanne Hoffman, Interim Director, Public Health Division. Per your request, the following action plan comments and related documents are being submitted to the MRB for their consideration.

The following responses are keyed to the six IMPEP draft report team recommendations highlighted in the Section 5.0 report Summary. In addition, two other issues were identified in Section 3.4 relating to our own RPS Radioactive Materials License which are also addressed:

1. The review team recommends that the Section follow their licensing procedure flow sheet and re-implement the peer review process to ensure consistency and accuracy for all licensing actions. (Section 3.4)

Our RPS Licensing Manager has created a "summary explanation" draft to ensure the proper procedures are followed, including that a peer review process occurs. This draft document will be reviewed by the RML staff, finalized through our Protocol Committee, and then approved by RPS management for implementation. Upon RPS management approval, the final version will be shared with RML staff to ensure adherence to the process. (A copy will be available for MRB review.)

Letter to Monica Ford October 14, 2013 Page 2

2. The review team recommends that the State verify that all previously approved authorized users (AUs), authorized medical physicists, radiation safety officers(RSOs) on medical licenses, and authorized nuclear pharmacists have the proper board certification or training requirements and preceptor attestation, since the new requirements were initiated in 2006. (Section 3.4)

Our RPS Licensing Manager has already initiated an internal audit process, (beginning with our existing licenses and working back to 2006), to verify the status of any listed AU, including medical physicists, RSOs, and nuclear pharmacists have proper board certifications, training requirements, and/or preceptor attestation. (A copy of the written process will be available for MRB review.)

Any licensee that has unqualified AUs, will be sent a corrective action letter stipulating that the unqualified AU will need to be qualified by a specified timeframe or be "grandfathered" by RPS as qualified or be removed from the license. RPS will consider "grandfathering" an AU on a case-by-case basis, dependant upon the non-availability of a preceptor to sign an attestation, and/or being in good standing with no attributable radiation safety incidents. (A copy of the corrective action letter will be available for MRB review). RPS will monitor licensee responses for compliance. Any failures to provide requested documentation or compliance will result in removal of the unqualified AU from the license.

Due to the volume of work required, the first phase to identify the pool of unqualified AUs has a completion target date of March 1, 2014. The second phase to notify licensees for corrective action will then commence.

3. The review team recommends that the State develop and implement a pre-licensing protocol based upon the RCPD-08-020 letter issued on September 22, 2008 to enhance the basis for confidence that radioactive materials will be used as specified on a radioactive materials license. (Section 3.4)

Effective immediately, on-site inspections of all new licensees will be completed. In addition, an RML License Reviewer has been assigned to create a pre-licensing and licensing protocol draft based upon the RCPD-08-020, including a peer review component and verification of unknown licensee applicants through pre-licensing on-site inspections, versus Secretary of State records check only. The draft has been reviewed by our RML staff and will be submitted to our Protocol Committee for finalization, then forwarded to RPS management for approval. RML staff will then be orientated to the new protocol and it will be implemented for all new licensee applications. (A copy of the draft protocol will be available for MRB review.)

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4. 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. (Section 3.5 remains open from 2009 IMPEP.)

Our RPS Emergency Response Manager has been assigned to create an enhanced "NMED Reporting Protocol" draft to ensure all required information is submitted to NMED, plus a component addressing timely completion of NMED entries. The draft will be reviewed by RML staff, submitted to our Protocol Committee for finalization, approved by RPS management staff for implementation and an orientation completed with RML staff.

An RML staff briefing has already been held regarding the need to provide full information for closing incidents in our own database (including an entry referencing that "closure" in NMED has occurred). [Note: All relevant RPS database incident information is to be forwarded to NMED, including a request to "close" the incident in NMED, versus just communicating that an incident is "complete"].

As a result of the 2009 IMPEP, RPS RML staff implemented a protocol to review "open incidents" at their monthly program staff meetings. However, the enhanced "NMED Reporting Protocol" will help ensure that NMED closures are also addressed at monthly RML program staff meetings. (A copy of the draft protocol will be available for MRB review.)

5. The review team recommends that the State revise their protocol for reviewing incidents for reportability in accordance with FSME Procedure SA-300 and to ensure timely reporting of events to the NRC Operations Center and NMED. (Section 3.5)

The enhanced "NMED Reporting Protocol" from number 4, also has elements to deal with reviewing incidents for reportability in accordance with FSME Procedure SA-300 and ensure timely reporting to NRC Operations Center and NMED. As with number 4, RML staff will be oriented to these specific reporting elements.

The revised/enhanced RSP protocol has items requiring an immediate evaluation of any reported incident, against both SA-300 for incidents and SA-400 for allegations to ensure timely HOO and NMED reporting of events. The RPS protocol has incorporated reporting protocol elements from SA-300/400, and New Jersey, Florida, and Arizona radiation control programs.

To reinforce the priority of timely reporting by staff, monthly RML program staff meetings will review the status of events and timeliness of reporting.

6. The review team recommends that the State develop and implement a protocol to ensure that regulations required for adoption are adopted within 3 years as required in the Policy Statement on Adequacy and Compatibility of Agreement State Programs. (Section 4.1)

Our Licensing Manager has developed a draft protocol to ensure RPS adopts final version regulations within the 3 year required period, including a time table for completing state process steps. A total completion time of 2.5 years is identified so that there is a "buffer" in the event of unforeseen circumstances that would inhibit meeting the 3 year requirement. (A copy of the draft protocol will be available for MRB review.)

[Note: During the 2009-2013 IMPEP period, RPS did submit rule packages to NRC which were initially acknowledged as being acceptable. However, NRC later informed RPS that there were issues requiring amendments to the rule packages. This affected our ability to meet the three-year requirement].

Two additional issues were identified in Section 3.4 (page 7 of the narrative), relating to our agency's Radioactive Material License. The first was to add a license condition stating that if we exceed quantities of material in excess of those required for financial assurance, that proper financial assurance documentation would be obtained. The second was to add a condition stating that if we were to need to take possession of radioactive material greater than the threshold for Increased Control's (IC's) then the Section would implement the IC's prior to taking possession of the material. Both conditions have been added to our license (A copy of our revised license will be available for MRB review.)

The Oregon Radiation Protection Services management team and staff appreciate the recommendations made by the IMPEP team members to bring our program into full compliance with the Oregon/NRC agreement. Please contact me if you have any questions concerning this correspondence.

Sincerely,

David M. Howe, Program Director

David M. Hove

Radiation Protection Services Section

Copy to: Suzanne Hoffman, Interim Director, Public Health Division

David Leland, Interim Administrator, Center for Health Protection