



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

October 28, 1998

Ms. Elinor Hall, Administrator
Oregon Health Division
Department of Human Resources
800 NE Oregon Street, Suite 925
Portland, OR 97232

Dear Ms. Hall:

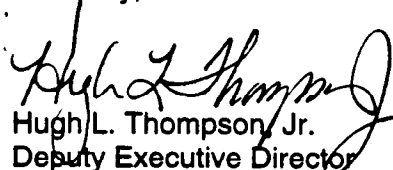
On October 13, 1998, the Management Review Board (MRB) met to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) report on the Oregon Agreement State Program. The MRB found the Oregon program adequate to assure public health and safety and compatible with NRC's program.

Section 5.0, page 13, of the enclosed final report presents the IMPEP team's recommendations and suggestions. We received Mr. Ray Paris' September 30, 1998 letter which described the actions taken in response to the team's recommendations. We request no additional information.

Based on the results of the current IMPEP review, the next full review will be in approximately 4 years.

I appreciate the courtesy and cooperation extended to the IMPEP team during the review and your support of the Radiation Control Program. I look forward to our agencies continuing to work cooperatively in the future.

Sincerely,


Hugh L. Thompson, Jr.
Deputy Executive Director
for Regulatory Programs

Enclosure:
As stated

cc: Ray D. Paris, Manager
Oregon Health Division

David Stewart-Smith
Oregon State Liaison Officer

Ms. Elinor Hall, Administrator
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DCD (SP01)
 PDR (YES NO)

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF OREGON AGREEMENT STATE PROGRAM

August 10-13, 1998

FINAL REPORT

U.S. Nuclear Regulatory Commission

1.0 INTRODUCTION

This report presents the results of the review of the Oregon radiation control program. The review was conducted during the period August 10-13, 1998 by a review team comprised of technical staff members from the Nuclear Regulatory Commission (NRC) and the Agreement State of California. Review 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 a Final General Statement of Policy," published in the Federal Register on October 16, 1997, and the November 25, 1997, revised NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." Preliminary results of the review, which covered the period July 11, 1996 to August 13, 1998, were discussed with Oregon management on August 13, 1998.

A draft of this report was issued to Oregon for factual comment on September 16, 1998. The State responded in a letter dated September 30, 1998 (Attachment 1). The Oregon's factual comments were considered by the team and accommodated in the report. The Management Review Board (MRB) met on October 13, 1998 to consider the proposed final report. The MRB found the Oregon radiation control program was adequate to protect public health and safety and compatible with NRC's program.

The Oregon Agreement State program is administered by the Radiation Protection Service (RPS) in the State Health Division of the Department of Human Resources. Organization charts for the Department of Human Resources are included as Appendix B.

At the time of the review, the Oregon RPS regulated 352 specific licenses, including limited and broad scope medical institutions, academic institutions, industrial radiography, fixed and portable gauge units, and nuclear pharmacy licensees.

The review focused on the materials program as it is carried out under the Section 274b. (of the Atomic Energy Act of 1954, as amended) Agreement between the NRC and the State of Oregon.

In preparation for the review, a questionnaire addressing the common and non-common performance indicators was sent to the State on June 4, 1998. The State provided a response to the questionnaire on June 26, 1998. During the review, discussions with State staff resulted in the responses being further developed. A copy of their final response is included in Appendix F to the draft report.

The review team's general approach for conduct of this review consisted of: (1) examination of Oregon's response to the questionnaire; (2) review of applicable Oregon statutes and regulations; (3) analysis of quantitative information from the RPS licensing and inspection data base; (4) technical review of selected licensing and inspection actions; (5) field accompaniments of two RPS inspectors; and (6) interviews with staff and management to answer questions or clarify issues. The review team evaluated the information that it gathered against the IMPEP criteria for each common and applicable non-common performance indicator and made a preliminary assessment of the RPS performance.

Section 2 below identifies that there were no recommendations resulting from the follow-up review conducted in 1996. The previous full program review conducted in 1995 found the Oregon program compatible, but withheld a finding of adequacy. The 1996 follow-up review closed all of the recommendations from the 1995 review, noted a delay in adoption of

regulations, and found the Oregon program adequate. Results of the current review for the IMPEP common performance indicators are presented in Section 3. Section 4 discusses results of the applicable non-common performance indicator, and Section 5 summarizes the review team's findings, recommendations, and suggestions. The review team identified two good practices in the RPS. Recommendations made by the review team are comments that relate directly to program performance by the State. A response is requested from the State to all recommendations in the final report. Suggestions are comments that the review team believes could enhance the State's RPS. The State is requested to consider suggestions, but no response is requested.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous follow-up review, which concluded on July 11, 1996, no recommendations were made although one open item, concerning delays in rulemaking activities, was noted in the report. This open item is discussed further in section 4.1.

3.0 COMMON PERFORMANCE INDICATORS

IMPEP identifies five common performance indicators to be used in reviewing both NRC Regional and Agreement State programs. These indicators are: (1) Status of Materials Inspection Program; (2) Technical Quality of Inspections; (3) Technical Staffing and Training; (4) Technical Quality of Licensing Actions; and (5) Response to Incidents and Allegations.

3.1 Status of Materials Inspection Program

The review team focused on four factors in reviewing this indicator: (1) inspection frequency, (2) overdue inspections of licenses, (3) initial inspections of new licenses, and (4) timely dispatch of inspection findings to the licensee and corrective action. The review team's evaluation is based on Oregon's questionnaire responses relative to this indicator, data gathered independently from the State's licensing and inspection data tracking system, the examination of completed inspection casework, and interviews with the RPS manager, the Radioactive Material Program (RMP) manager, and inspection and licensing staff.

The State's inspection frequencies are compatible with NRC program codes and inspection priorities. They are the same as NRC's, with the exception that portable gauge licenses are inspected more frequently than NRC, 4 years versus 5 years by NRC.

In their response to the questionnaire, Oregon indicated that as of June 26, 1998 no licensees, which were identified as requiring core inspections in IMC 2800, were overdue. Throughout the review period, less than 10 percent of the number of core licensees were inspected at frequencies exceeding the intervals in IMC 2800 by more than 25 percent.

The RPS policy, which adopts the guidance in IMC 2800, Section 04.03a, states that new licenses are inspected within six months of issuance of the license. The RPS does not normally extend the 6 month period in cases where the licensee does not receive material or initiate licensed activities. There were 43 initial inspections of in-state licensees due during the review period. Of those due, 24 (55%) were not inspected within the 6 month requirement. The team noted that 41 of the initial inspections were completed within 7 months and the remaining 2 inspections were completed within 8 months. The team recommends that Oregon continue to implement its policy for inspecting new licenses.

The RMP manager indicated that the RPS accelerated the inspection workload and eliminated the entire backlog by the end of July 1998. The accelerated workload resulted in 19 inspections being completed in June 1998 and 15 completed in July 1998. The team verified from the records that as of August 13, 1998 there were 352 active licenses and all inspections were current.

An internally generated monthly report to management tracks inspections that are completed and overdue. All licenses are entered into the RPS database and printouts allow an easy determination of the status of inspections at a given time period.

Reciprocity licensees are handled in the following manner:

1. Out-of-state licensees that frequently perform work in Oregon are provided the option of requesting an Oregon State license. When the license is issued they are listed in the database under their home state address. The company is not required to have an address in Oregon and the license application process simply consists of a review of their home State or NRC license. Each license includes a special condition that requires notification to the RPS before the licensee enters the State to do work using licensed material. Six months after the out-of-state license is issued, the licensee is mailed an "inspection by mail" form which is mailed back to the RPS and is considered an initial inspection. When the licensee notifies RPS that they are entering the State to do work, the RPS inspects them in the field if possible. The license is renewed annually by payment of a fee.
2. Out-of-state licensees that infrequently perform work in Oregon may choose not to apply for an Oregon State license. In these cases, the licensees are identified in the RPS database using license numbers that are coded to indicate that reciprocity is granted on each occasion work is to be performed in Oregon. When the licensee notifies RPS that they are entering the State to do work, the RPS inspects them in the field if possible. Seven of these licenses were listed on the August 1998 printout.

Two of the ten inspection reports of out-of-state licensees that were reviewed were inspected by mail. All others had an onsite inspection completed following their notification that they were entering the State to do work using sources. The State met the inspection percentage goals for conducting inspections of reciprocity licensees as outlined in Appendix III of NRC Inspection Manual Chapter 1220 (IMC 1220).

The review team did not consider the "inspection by mail" a valid inspection because the form only asks the make and model of devices used by the licensee and the names of their operators. The review team suggests that the RPS consider using another term such as "status report" rather than call the "inspection by mail" process for out-of-state licenses an inspection.

In 1984, the RPS instituted a program that tracks registered general license (GL) devices (i.e., gamma gauges and in-vitro test kits). Although other States track such devices, Oregon's implementation practices of the program are unique. In addition to requiring accountability of the devices, the State will also perform onsite inspections and request additional information (e.g., leak test results) from the general licensee. The program for registering these GL devices has been recognized by NRC which is considering adoption of a similar program nationwide. The

review team recommends that the Management Review Board recognize Oregon's GL device tracking program as a good practice.

The RPS uses Safety Inspection Form 591 for inspections to report the findings to the licensee at the conclusion of the inspection. The inspector indicates any violations found on the form and the licensee signs it acknowledging receipt and understanding of the nature of any violations. The form requires posting by the licensee. If an inspector is not certain of a finding, he will return to the RPS and discuss the matter with the RMP manager. In these cases, the licensee will be sent a letter outlining the violations and requiring a written response. The letter requires posting by the licensee. The issuance of inspection findings is timely with letters to the licensee being sent within two weeks of the inspection.

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.

The team notes that one finding from the 1995 full program evaluation was the development of a significant number of overdue inspections. However, at the time of the 1996 follow-up review visit, all overdue inspections had been eliminated.

3.2 Technical Quality of Inspections

The team reviewed inspection reports, enforcement documentation, inspection field notes, and interviewed inspectors for 16 materials inspections conducted during the review period. The casework included all of the State's materials inspectors, including the RMP manager, and covered: medical (5), medical (HDR) (1), mobile medical (1), industrial broad scope (1), portable gauge (4), radiography (2), academic broad scope A (1), and pharmacy (1) inspections. A review team member performed accompaniments of two State inspectors on three separate inspections of licensed facilities. Appendix C lists the completed inspections reviewed with case-specific comments as well as the results of the accompaniments.

Inspection findings appear to lead to appropriate regulatory action. Although the RPS does not have administrative penalties, they can pursue penalties through the Attorney General's office. The RPS also uses Office Hearings to achieve escalated enforcement. One escalated enforcement case that used an Office Hearing was reviewed. The licensee had several serious violations on their initial inspection and eventually requested termination of their license due to increased enforcement activities of the RPS. The review team noted that the participation of the RPS manager in the Office Hearing was not documented. The review team suggests that all attendees, including senior managers, be documented in future enforcement activities involving meetings or hearings with licensees.

All enforcement letters reviewed were written in the appropriate regulatory language and directed the licensee to post the enforcement letter as the State does not use a Notice of Violation form. Follow up to enforcement letters was evident and complete. All enforcement cases were resolved promptly.

There were 229 inspections performed during the review period. Through 1998 to date, 89 inspections have been completed. The RPS uses NRC inspection guides and checklists. The team reviewed the inspection field notes and, with the exceptions noted below and in Appendix C, found them to be comparable with the types of information and data collected under NRC Inspection Procedure (IP) 87100 and thorough with all items checked and written comments where necessary. The inspection field notes provided documentation of the licensee's program including: posting; storage and use of radioactive material; receipt, transfer, and disposal of radioactive material; inventory; leak tests; radiation protection program; personnel monitoring; training; independent measurements; and inspection findings. The review team also noted the inspectors observed licensed operations or had operations demonstrated whenever possible. The review team noted that the inspector used NRC's checklist for Nuclear Medicine operations to perform a high dose rate (HDR) inspection. It was also noted that the inspection reports did not use the most recent version of NRC checklists and, therefore, there was no section to document the scope of the operation. The review team suggests that the RPS obtain and use the HDR inspection checklist and the latest version of inspection checklists found in IMC 87100. The RPS management policy is to conduct unannounced inspections whenever possible. Announced inspections usually involve initial inspections or inspections at licensees in geographically-distant locations from Portland. Inspection reports were signed by management. The RMP manager was aware of inspection findings through de-briefing by the inspector. In response to the questionnaire and through discussions with the RMP manager, the State reported the number and type of supervisory accompaniments performed during the review period. All inspectors were accompanied annually. The RPS manager accompanied the RMP manager during various licensee management meetings throughout the review period.

The RPS uses a rating system to score the licensee after an inspection. A low score can lead to the shortening of the inspection frequency down to 75% of the actual due date or, if the score is extremely low, then the licensee is subject to escalated enforcement or a follow up review within 6 months.

The RPS employs a unique method for educating the licensee of Oregon's regulations as they pertain to the licensees' operation. At the conclusion of each inspection, the inspector provides a checklist to the licensee that specifies Oregon's administrative rule requirements applicable to the licensee. The licensee can use this checklist to facilitate the annual review of their radiation safety program. Additionally, the inspectors routinely utilize a form to document their "vertical slice" approach to their inspections where several types of radioactive sources are tracked from their receipt on through to disposal. The review team recommends that use of the checklist and the form and the resulting discussions with licensees during the inspection, be recognized as a good practice by the Management Review Board.

The RPS has an adequate supply of survey instruments to support the inspection program. Each inspector and the supervisor have a kit with Ludlum meters and probes to monitor all isotopes. All survey equipment is calibrated annually by Oregon State University under a calibration license issued by Oregon. In addition, the RPS operates a small laboratory to count wipes and analyze samples obtained during inspections, follow-up actions, or licensing terminations. The laboratory participates in the routine Environmental Protection Agency (EPA) - Environmental Monitoring

and Safety Laboratory (EMSL) cross-check program and is used routinely by inspectors taking wipe samples. Gamma spectroscopy quality assurance (QA)/quality control (QC) appears adequate with routine use of a National Institute for Standards and Technology (NIST)-traceable mixed gamma standard. The RPS has a liquid scintillation counter and germanium detector system for gamma spectroscopy and a portable multichannel analyzer. Samples are also sent out to contract labs for analysis as necessary.

Two inspectors were accompanied by a review team member during the period of June 23-24, 1998. One inspector was accompanied during an unannounced inspection of an institutional nuclear medicine facility with brachytherapy on June 23, 1998. The other inspector was accompanied on June 24, 1998 during unannounced inspections of a research and development facility using americium-241, and another facility that manufactures iodine-125 test kits. These accompaniments are listed in Appendix C.

During the accompaniments, the State inspectors demonstrated appropriate inspection techniques and knowledge of the regulations. The inspectors were equipped with, and used, appropriate and calibrated survey and safety equipment. The inspectors were well prepared and thorough in their reviews of the licensees' radiation safety programs. Overall, the technical performance of the inspectors was excellent, and their inspections were adequate to assess radiological health and safety at the licensed facilities.

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

3.3 Technical Staffing and Training

Issues central to the evaluation of this indicator include the radioactive materials program staffing level and staff turnover, as well as the technical qualifications and training histories of the staff. To evaluate these issues, the review team examined the State's questionnaire responses relative to this indicator, and interviewed RPS management and staff, and considered any possible workload backlogs.

At the time of the review, Oregon's radioactive materials program was staffed by the RPS manager, RMP manager, three full time technical staff, and one full time administrative staff member. All staff have been with the RPS for the entire review period. One staff member each from the Electronics Products Program and the Emergency Response Program also provide partial support in rulemaking and event response activities, respectively. In general, the team found that the current staffing level is adequate, except the team noted that there was minimal staff time devoted to rulemaking efforts due to licensing and inspection needs. The State also identified this area as a weakness in the IMPEP questionnaire. Given the status of rulemaking actions as discussed in Section 4.1.2, the review team recommends that the RPS management assess whether additional staffing is warranted to complete overdue rulemaking actions and to ensure timely completion of upcoming rulemaking actions.

Based on the response to the IMPEP questionnaire and discussions with the RPS and RMP managers, the review team noted that during the review period one technical staff member retired from the radioactive materials program in March 1998. This vacancy was recently filled by an individual who is expected to receive a Master's Degree in Health Physics in December 1998. The review team also noted that the individual exceeds the minimum requirements for the position.

There are currently no vacancies in the radioactive materials program, however, the team was advised that the RMP manager will retire in December 1998. The RPS manager stated that he intends to fill the upcoming vacancy by making a nationwide announcement. Discussions with staff indicate that a significant loss of program history and knowledge of current procedural practices will be experienced. The review team suggests timely filling of the impending RMP manager vacancy with a well qualified individual and that revisions to written procedures to reflect current operations continue to be developed.

A written and RPS management approved training policy implements the guidelines in the October 1997 NRC/OAS Training Working Group Recommendations for Agreement State Training Programs. The RPS manager requires each staff member to successfully complete the basic courses identified for materials inspectors and license reviewers. Waivers from specific courses may be granted, at the manager's discretion, for individuals with extensive work experience and education in a specific topic area. The RPS manager indicated that funding for basic training is available. A review of Oregon's training records and interviews with the staff identified two staff members, a member of the technical staff and an administrative assistant who performs licensing assistant duties, that should attend the Licensing Practices and Procedures course or its equivalent to fully address their training needs. The technical staff member is currently registered for the September 1998 presentation of the course. The review team suggests that the administrative assistant attend the Licensing Practices and Procedures course or its equivalent to enhance effectiveness in performance of licensing assistant duties.

The review team also noted that the documentation of staff training is not up to date and does not have management sign-off when a course is completed or waived for an individual. The review team suggests that the RPS training form be updated to reflect the completion of the Teletherapy and Brachytherapy course by an inspection staff member and that the training form be modified to allow for management sign-off of completed and waived courses.

In discussions with the RPS, the team found that there are no radiation oversight boards and, therefore, the team determined that there is no potential for conflict of interest issues.

Based on the IMPEP evaluation criteria, the review team recommends that Oregon's performance with respect to the indicator, Technical Staffing and Training, be found satisfactory.

3.4 Technical Quality of Licensing Actions

The review team interviewed the RMP manager, evaluated the licensing process, and examined licensing casework for 32 specific licenses. Licensing actions were reviewed for completeness, consistency, proper radioisotopes and quantities authorized, qualifications of authorized users, adequate facilities and equipment, and operating and emergency procedures sufficient to establish the basis for licensing actions. Licenses were reviewed for accuracy, appropriateness of the license and its conditions, and overall technical quality. The casework was reviewed for timeliness, adherence to good health physics practices, reference to appropriate regulations,

documentation of safety evaluation reports, product certifications or other supporting documents, consideration of enforcement history on renewals, pre-licensing visits, supervisory review as indicated, and proper signature authorities. The files were checked for retention of necessary documents and supporting data including terminated licenses.

The licensing casework was selected to provide a representative sample of licensing actions which had been completed during the review period and included all amendments to the selected casework since the previous review. The cross-section sampling focused on the State's core licenses in priorities 1, 2, and 3; new licenses issued; renewals; and licenses terminated during the review period. The sample included the following licensing types: broadscope academic; broadscope medical; research and development; source material; industrial radiography; portable gauges, institutional nuclear medicine; private clinics, mobile nuclear medicine; therapy; and nuclear pharmacy. Licensing actions reviewed included 3 new, 7 renewals, 38 amendments, and 4 terminations. A listing of the casework licenses with case specific comments can be found in Appendix D.

Licenses are renewed on a 5 year frequency. Licenses that are under timely renewal are amended as necessary to assure that public health and safety issues are addressed during the period that the license is undergoing the renewal process. Each licensing action receives an initial review by one individual, then a second technical review by a senior health physicist. All licenses are signed by the RPS manager or his designee.

The review team found that the licensing actions were generally very thorough, complete, of high quality, and with health and safety issues properly addressed. The licensee's compliance history is taken into account when reviewing renewal applications and amendments as determined from documentation in the license files and discussions with the license reviewers and inspectors. Some comments were made on files as identified in Appendix D. Following the team's discussion of these comments, the RMP manager initiated actions to resolve the comments. The review team suggests that the comments in Appendix D be reviewed for actions as appropriate.

The casework review also confirmed that, with one exception, the materials staff follows the State's licensing guides which have been patterned after the NRC guides. The State has one license for a HDR brachytherapy device (Appendix D, casework number 11), in which two license conditions do not contain the same information as similar conditions utilized as standard practice by NRC and other Agreement States. A copy of a model NRC license with standard practice license conditions for an HDR unit was provided to the State during the review. The review team recommends that the State adopt the NRC standard practice license conditions for HDR units for the casework #11 license and future HDR licenses.

All licensing actions were signed by management. Deficiencies are addressed by letters and documented telephone inquiries which use appropriate regulatory language.

The State provided a listing of 58 licenses that have been terminated since the last review. A review of termination actions over the period showed that most of the terminations were for licensees possessing only sealed sources and/or for uses of radiopharmaceuticals with short half lives. Four termination files were selected for review based upon the potential for residual contamination, and to confirm the State's termination procedures. The review team found that terminated licensing actions were well documented, showing appropriate transfer records or appropriate disposal methods and records, confirmatory surveys, and survey records.

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.

3.5 Response to Incidents and Allegations

In evaluating the effectiveness of the State's actions in responding to incidents, the review team examined the State's response to the questionnaire regarding this indicator, reviewed selected incidents reported for Oregon in the "Nuclear Material Events Database" (NMED) against those contained in the Oregon files, and reviewed the casework and supporting documentation for 11 material incidents and 10 allegations. There were no medical related events during the review period that met the definition of a misadministration. A list of selected incident files examined along with case specific comments is contained in Appendix E.

The review team interviewed the RPS Manager, the RMP manager, and the individual responsible for Emergency Response tracking. The subject areas discussed with staff included the State's incident and allegation process, tracking system, file documentation, Freedom of Information Act, NMED, and notification of incidents to the NRC Emergency Operations Center. The staff was familiar with NRC's "Handbook on Nuclear Event Reporting in the Agreement States" and Procedure Number: SA-300, "Reporting Material Events," dated February 1998. Reports have been submitted appropriately for NMED entry. The review team noted to management the Commission's position that, under the Policy Statement on Adequacy and Compatibility of Agreement State Programs, it is mandatory for Agreement States to report events to the NRC.

The State has consistently reported incidents, that require immediate or 24-hour reporting by the State licensee, to the NRC Operations Center. However, there were multiple written policies and procedures for incident response dated from 1984 to the present within the State's policy and procedure manual. The review team suggests that the policies and procedures for responding to incidents be consolidated into one policy or procedure.

When notification of an incident or an allegation is received, the individual receiving the report sends an electronic message to the staff providing information of the incident or allegation. The RMP manager usually directs the initial response and evaluates the need for an on-site investigation. An Incident Report Checklist and Summary form is used to document and track the staff's response to an incident or allegation.

The review team found that the State's actions were appropriate. Initial responses were prompt and well-coordinated, and the level of effort was commensurate with the health and safety significance. Inspectors were dispatched for onsite investigations in 7 of the 11 incidents reviewed. Of those 7 onsite investigations, 6 were conducted on the same day of the notification, and 1 was conducted within 2 days of the notification. When appropriate, the State took suitable enforcement action that required corrective measures by the licensee.

During the review period, there were 2 allegations referred to the State by NRC and there were 11 allegations that the State handled directly. The State promptly contacts the alleged, conducts an inspection when appropriate, and informs the alleged of the outcome of the investigation. Although the State's responses to allegations were satisfactory, the review team found that the State had no written policy or procedures for responding to allegations. The RPS advises alleged that they can provide reasonable assurance that any information they provide

will be kept confidential but are not able to guarantee confidentiality unless all of the five criteria specified in State statute 192.502(4) are met. The review team recommends that the State develop a written policy with procedures for responding to allegations.

Based on the IMPEP evaluation criteria, the review team recommends that Oregon's performance with respect to the indicator, Response to Incidents and Allegations, be found satisfactory.

4.0 NON-COMMON PERFORMANCE INDICATORS

IMPEP identifies four non-common performance indicators to be used in reviewing Agreement State programs: (1) Legislation and Program Elements Required for Compatibility; (2) Sealed Source and Device Evaluation Program; (3) Low-Level Radioactive Waste Disposal Program; and (4) Uranium Recovery Program. Oregon recently turned back the sealed source and device evaluation program portion of their Agreement and Oregon's Agreement does not include uranium recovery program authority.

4.1 Legislation and Program Elements Required for Compatibility

4.1.1 Legislation

Along with their response to the questionnaire, the State provided the review team with the opportunity to review copies of legislation that affects the radiation control program. The currently effective statutory authority for the RPS is contained in Oregon Statute 453.625. The Radiation Protection Service 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 Program Elements Required for Compatibility

The Oregon Regulations for Control of Radiation, found in Oregon Administrative Rules 453.605-453.755, apply to all ionizing radiation, whether emitted from radionuclides or devices. Oregon requires a license for possession and use of all radioactive material including naturally occurring materials, such as radium, and accelerator-produced radionuclides. 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 up to six months after filing the draft administrative rule with the Secretary of State. Prior to filing with the Secretary of State, the draft administrative rule is reviewed by management and legal counsel (for fiscal impact issues) within the Department of Human Resources Office of the Administrator. When an acceptable draft proposed revision to a rule has been prepared, it is sent to the Secretary of State, all potentially impacted licensees and registrants, and the NRC for comment. The Secretary of State announces a public comment/hearing period for the proposed revision to the rule. After responding to comments, the RPS forwards the proposed revision to the rule with the addressed comments to the Office of the Administrator for final approval. Comments are considered and incorporated as appropriate before the regulations are finalized. The State has the authority to issue legally binding requirements (e.g., license conditions) in lieu of regulations until compatible regulations become effective.

The team evaluated Oregon's responses to the questionnaire and reviewed the status of regulations required to be adopted by the State during the review period. No regulations were adopted by the State during the review period. The review team noted that Oregon prepared initial drafts of the NRC regulation amendments required to be adopted, however, they have not been finalized and, therefore, they have not been adopted. As stated in Section 3.3, the State identified this area as a weakness. Discussions with management indicate that they believe the requirements in the revised NRC regulations are covered by license conditions and/or through incorporation by reference in their current administrative rules. No legal position has been made to this effect. The review team recommends that management obtain a State legal view on their interpretation that existing administrative rules require the implementation of all new requirements in the revised NRC regulations where required for compatibility purposes.

The State has not adopted the following regulations; however, they anticipated adoption by late 1999.

- "Licensing and Radiation Safety Requirements for Irradiators," 10 CFR Part 36 amendment (58 FR 7715) that became effective July 1, 1993.
- "Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use," 10 CFR Parts 30, 32, and 35 amendments (59 FR 61767 and 65243) that became effective January 1, 1995.
- "Frequency of Medical Examinations for Use of Respiratory Protection Equipment," 10 CFR Part 20 amendment (60 FR 7900) that became effective March 13, 1995.
- "Low-Level Waste Shipment Manifest Information and Reporting," 10 CFR Parts 20 and 61 amendments (60 FR 15649 and 25983) that became effective March 1, 1998. The Agreement States are to promulgate their regulations no later than March 1, 1998 so that NRC and the State would require this national system to be effective at the same time.
- "Radiation Protection Requirements: Amended Definitions and Criteria," 10 CFR Parts 19 and 20 amendments (60 FR 36038) that became effective August 14, 1995.
- "Clarification of Decommissioning Funding Requirements," 10 CFR Parts 30, 40, and 70 amendments (60 FR 38235) that became effective November 24, 1995.
- "Compatibility with the International Atomic Energy Agency," 10 CFR Part 71 amendment (60 FR 50248) that became effective April 1, 1996.
- "Medical Administration of Radiation and Radioactive Materials," 10 CFR Parts 20 and 35 amendments (60 FR 48623) that became effective October 20, 1995.
- "Termination or Transfer of Licensed Activities: Record Keeping Requirements," 10 CFR Parts 20, 30, 40, 61, 70 amendments (61 FR 24669) that became effective June 17, 1996.
- "Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act," 10 CFR Part 20 amendment (61 FR 65119) that became effective January 9, 1997.

- “Recognition of Agreement State Licenses in Areas Under Exclusive Federal Jurisdiction Within an Agreement State,” 10 CFR Part 150 amendment (62 FR 1662) that became effective February 27, 1997.
- “Criteria for the Release of Individuals Administered Radioactive Material,” 10 CFR Parts 20 and 35 amendments (62 FR 4120) that became effective May 29, 1997.
- “Licenses for Industrial Radiography and Radiation Safety - Requirements for Industrial Radiography Operations,” 10 CFR Parts 30, 34, 71, 150 amendments (62 FR 28947) that became effective June 27, 1997.
- “Radiological Criteria for License Termination,” 10 CFR Parts 20, 30, 40, 70 amendments (62 FR 39057) that became effective August 20, 1997.

The State indicated they anticipate adoption of the overdue regulations and the regulations which require adoption through 2000, by late 1999. A recommendation that Oregon examine the rule procedures and adopt compatible regulations within the 3 year time frame was made during the July 29, 1995 full review. A delay in regulation adoption was also noted during the July 11, 1996 follow-up review. The review team recommends that RPS management evaluate rulemaking activities to ensure that NRC rule changes are adopted within the specified 3 year time period.

It is noted that Management Directive 5.9, Handbook, Part V, paragraph (1)(c)(iii), provides that the above regulations should be adopted by the State as expeditiously as possible, but not later than three years after the effective date of the new Commission Policy Statement on Adequacy and Compatibility, i.e., September 3, 2000.

Based on the IMPEP evaluation criteria, the review team recommends that Oregon’s performance with respect to the indicator, Legislation and Program Elements Required for Compatibility, be found satisfactory.

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

In April of 1998, the Commission approved the turnback of the SS&D Program to NRC. There were two sealed source device actions completed by the State during the review period. One action involved the administrative reactivation of a terminated registry that formerly was registered by NRC, and the other action was a custom evaluation that is authorized for use only in the State of Oregon. The State has discussed these actions with NMSS and committed to forwarding these files to NRC at the conclusion of the review. The associated licensing actions were reviewed under the Technical Quality of Licensing Actions (Common Indicator 3.4). Therefore, this indicator was not reviewed.

4.3 Low-Level Radioactive Waste (LLW) Disposal Program

In 1981, the 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 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 Oregon 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 and 4 above, the review team found Oregon's performance for the common and non-common performance indicators to be satisfactory. Accordingly, the review team recommended and the MRB concurred in finding the Oregon Agreement State Program to be adequate to protect public health and safety and compatible with NRC's program.

Below is a summary list of recommendations and suggestions, as mentioned in earlier sections of the report, for implementation and evaluation, as appropriate, by the State.

RECOMMENDATIONS:

1. The team recommends that Oregon continue to implement its policy for inspecting new licences (Section 3.1).
2. The review team recommends that the RPS management assess whether additional staffing is warranted to complete overdue rulemaking actions and to ensure timely completion of upcoming rulemaking actions (Section 3.3).
3. The review team recommends that the State adopt the NRC standard practice license conditions for HDR units for the casework #11 license and future HDR licenses (Section 3.4).
4. The review team recommends that the State develop a written policy with procedures for responding to allegations (Section 3.5).
5. The review team recommends that management obtain a State legal view on their interpretation that existing administrative rules require the implementation of all new requirements in the revised NRC regulations where required for compatibility purposes (Section 4.1.2).
6. The review team recommends that RPS management initiate rulemaking activities to ensure that NRC rule changes are adopted within the specified 3 year time period (Section 4.1.2).

SUGGESTIONS:

1. The review team suggests that the RPS consider using another term such as “status report” rather than call the “inspection by mail” process for out-of-state licenses an inspection (Section 3.1).
2. The review team suggests that all attendees, including senior managers, be documented in future enforcement activities involving meetings or hearings with licensees (Section 3.2).
3. The review team suggests that the RPS obtain and use the HDR inspection checklist and the latest version of inspection checklists found in IMC 87100 (Section 3.2).
4. The review team suggests timely filling of the impending RMP manager vacancy with a well qualified individual and that revisions to written procedures to reflect current operations continue to be developed (Section 3.3).
5. The review team suggests that the administrative assistant attend the Licensing Practices and Procedures course or its equivalent to enhance effectiveness in performance of licensing assistant duties.
6. The review team suggests the RPS training form be updated to reflect the completion of the Teletherapy and Brachytherapy course by an inspection staff member and that the training form be modified to allow for management sign-off of completed and waived courses (Section 3.3).
7. The review team suggests that the comments on Appendix D be reviewed for actions as appropriate (Section 3.4).
8. The review team suggests that policies and procedures for responding to incidents be consolidated into one policy or procedure (Section 3.5).

GOOD PRACTICES:

1. In 1984, the RPS instituted a program that tracks registered general license (GL) devices (i.e., gamma gauges and in-vitro test kits). Although other States track such devices, Oregon’s implementation practices of the program are unique. In addition to requiring accountability of the devices, the State will also perform onsite inspections and request additional information (e.g., leak test results) from the general licensee. The program for registering these GL devices has been recognized by NRC which is considering adoption of a similar system nationwide. The review team recommends that the Management Review Board recognize Oregon’s GL device tracking program as a good practice (Section 3.1).
2. The RPS employs a unique method for educating the licensee of Oregon’s regulations as they pertain to the licensees’ operation. At the conclusion of the inspection, the inspector provides a checklist to the licensee that specifies the Oregon’s administrative rule requirements applicable to the licensee. The licensee can use this checklist to facilitate the annual review of their radiation safety program. Additionally, the inspectors routinely utilize a form to document their “vertical slice” approach to their inspections where several types of radioactive sources are tracked from their receipt on through to disposal. The review team recommends that use of the checklist and the form, and the resulting discussions with

licensees during the inspection be recognized as a good practice by the Management Review Board (Section 3.2).

LIST OF APPENDICES AND ATTACHMENTS

Appendix A	IMPEP Review Team Members
Appendix B	Oregon Organization Charts
Appendix C	Inspection Casework Reviews
Appendix D	License Casework Reviews
Appendix E	Incident Casework Reviews
Attachment 1	State's Response to Proposed Final Report Dated September 30, 1998

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	Area of Responsibility
Tom O'Brien, OSP	Team Leader Technical Staffing and Training Legislation and Program Elements Required for Compatibility
Donald Bunn, California	Status of Materials Inspection Program Technical Quality of Inspections
Sally Merchant, NMSS	Response to Incidents and Allegations
Richard Woodruff, Region II	Technical Quality of Licensing Actions

APPENDIX B

State of Oregon

DEPARTMENT OF HUMAN RESOURCES
OREGON HEALTH DIVISION
RADIATION PROTECTION SERVICES

ORGANIZATION CHARTS

Department of Human Resources

GOVERNOR

**Jean I. Thome
Acting Director**

**Bob Mink
Deputy Director**

**Office of the Director
PROGRAM OFFICES
(Assistant Directors)**

**Hersh Crawford
(acting)
Office of Medical
Assistance Prog.**

**Jeff Kushner
Alcohol & Drug
Abuse Programs**

**Chad Cheriel
Office of
Health Policy**

**Peggy Timm
Volunteer
Program**

**DIVISIONS
(Assistant
Directors)**

**Steve Minnich
Adult & Family
Services Division**

**Kay Toran
Children's Services
Division**

**Elinor Hall
Health
Division**

**Jim Wilson
Senior and Disabled
Services Division**

**Joi Southwell
Vocational
Rehabilitation
Division**

**Barry Kast
Mental Health and
Developmental Disability
Services Division**

**Office of the Director
ADMINISTRATION
(Assistant Directors)**

**John Cuddy
Information
Systems**

**Ken Miller
Program and
Finance**

**John Heilman
Employee
Services**

**Clyde Saiki
Special Proj.
Coord.**

**Jim Sellers
Communications**

**Ken Johnson
Audit**

OFFICE OF THE ADMINISTRATOR
Elinor Hall, Administrator
Grant Higginson, Health Officer

CROSS AGENCY & SPECIAL PROGRAMS
(Within Office of the Administrator)

ADMINISTRATIVE & PROGRAM SERVICES
Claudia Bingham

CERTIFICATE OF NEED
Jana Fussel

COMMUNICATIONS & PLANNING
Bonnie Widerburg/Claudia Black

OFFICE OF MULTICULTURAL HEALTH
Suganya Sockalingam

COMMUNITY SERVICES
Carol Allen

PLANS REVIEW
Roscoe Lawless

HEALTH RELATED LICENSING PROGRAM
Sue Wilson

BUDGET SERVICES
Kent Copeland

PURCHASING
Karil Schaefer

FACILITIES/MAIL CENTER
Dick Herno

CENTER FOR CHILD & FAMILY HEALTH

MATERNAL & CHILD HEALTH SYSTEM
Lorraine Duncan

WOMEN/REPRODUCTIVE HEALTH
Anne Olson

CHILD/ADOLESCENT HEALTH
Jill Skrezyna

IMMUNIZATION
Lorraine Duncan/Betty Finewout

WIC
Donalda Dodson

CENTER FOR ENVIRONMENT & HEALTH SYSTEMS
Tom Johnson

DRINKING WATER
Dave Leland

EMERGENCY MEDICAL SERVICES & SYSTEMS
Gregg Lander

HEALTH CARE LICENSURE & CERTIFICATION
Kathleen Smail

RADIATION PROTECTIVE SERVICES
Ray Paris

ENVIRONMENTAL SERVICES & CONSULTATION
Ron Hall

CENTER FOR DISEASE PREVENTION & EPIDEMIOLOGY
Dave Fleming

ACUTE AND COMMUNICABLE DISEASE
Paul Cieslak

HIV/STD/TB
Mark Loveless

HEALTH PROMOTION & CHRONIC DISEASE PREVENTION
Jane Moore

ENVIRONMENTAL OCCUPATIONAL & INJURY EPIDEMIOLOGY
Narda Tolentino

CENTER FOR HEALTH STATISTICS
Edward Johnson

CENTER FOR PUBLIC HEALTH LABORATORIES
Mike Skeels

NEWBORN SCREENING
Richard Miyahira

VIROLOGY/IMMUNOLOGY
Christianne Biggs

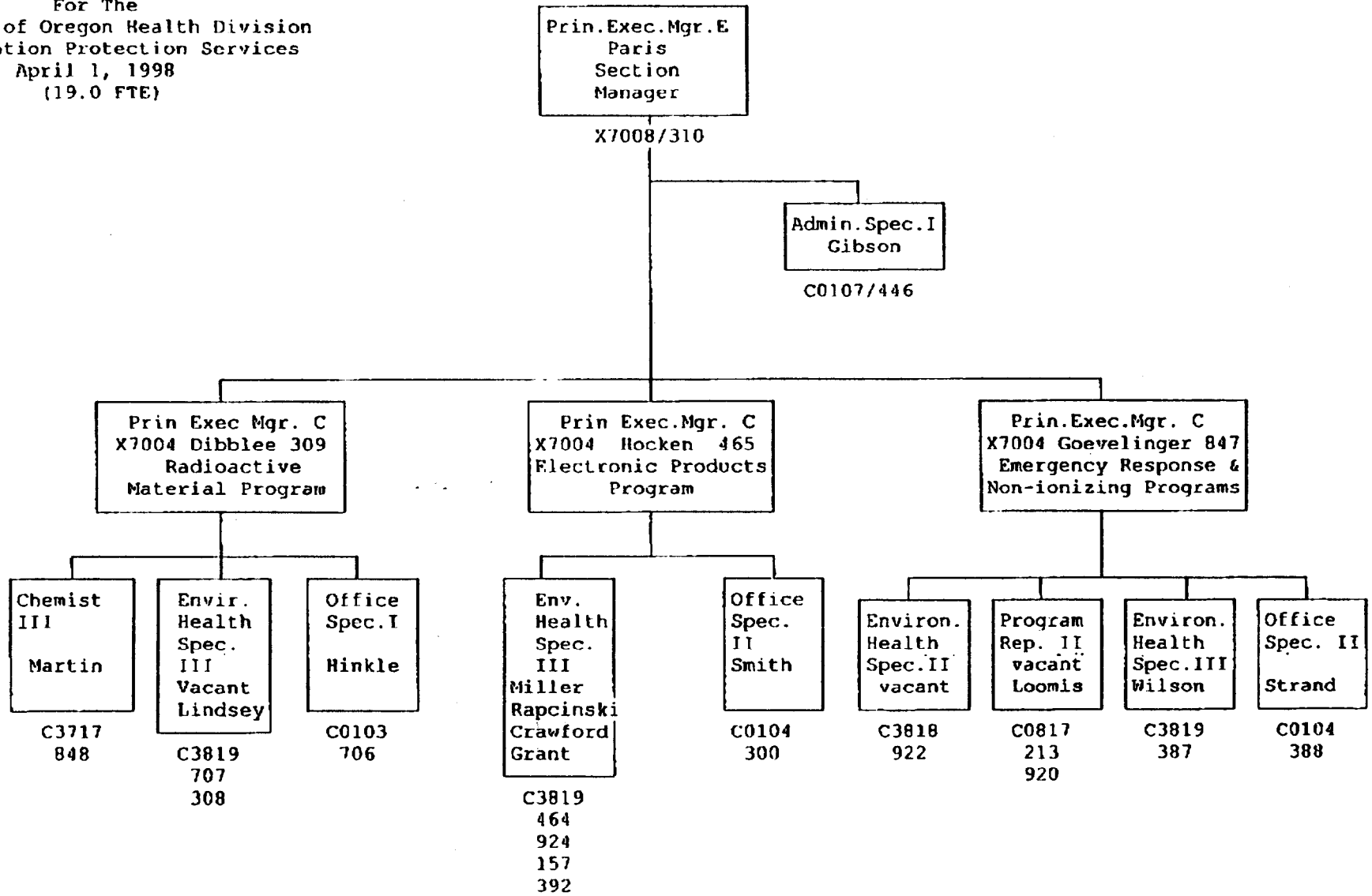
GENERAL MICROBIOLOGY
Robert Sokolov

LABORATORY LICENSURE & CERTIFICATION
Audrene Horton

QUALITY ASSURANCE & OPERATIONS
Wayne Jeffers

Organizational Chart

For The
 State of Oregon Health Division
 Radiation Protection Services
 April 1, 1998
 (19.0 FTE)





Oregon

John A. Kitzhaber, M.D., Governor

Department of Human Resources

Health Division

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September 30, 1998

Richard L. Bangart, Director
Office State Programs
US Nuclear Regulatory Commission
Washington, D.C. 20555-0001



Dear Mr. Bangart:

This is in response to your September 16, 1998 letter requesting comments on the draft report of the Integrated Materials Performance Evaluation Program (IMPEP) review of Oregon's Radioactive Materials Program on August 10-13, 1998.

The draft report includes six (6) recommendations that relate directly to performance by the State. The report requested that the State respond to each recommendation. The following are our responses:

- 1) The team recommends that Oregon heighten its management oversight of the inspection due dates of new licenses to ensure inspections are performed in accordance with RPS policy.

Oregon has adopted the guidance in IMC 2800, Section 04.03a that states new licenses are inspected within six months of issuance of license. The IMPEP team found that 55% of the (i.e. 24 out of 43) new licenses were not inspected within the 6 month requirement. However, the team also found that 95% (i.e. 41 out of 43) of the new licenses were inspected within 7 months and all were completed within 8 months.

It is true that Oregon did not specifically meet the criteria in Section 04.03a of IMC 2800. However, it is important to keep in mind that "performance" is a key word under the new IMPEP criteria. Seventy two percent, 72%, (31 out of 43) of the new licensees inspected within the 6 month period had no items of noncompliance. There were no (zero) items of noncompliance among the other 28% that affected the health and safety of the public or those using the radioactive material. This reflects the outstanding work RPS staff does during the initial licensing process to educate new licensees on

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health and safety issues relating to the radioactive material they are about to possess.

It should be noted that the team found all inspections current with the 352 licensees and that the state met the inspection percentage goals for conducting inspections of reciprocity licensees as outlined in IMC 1220. Therefore, Oregon does not agree with the IMPEP team finding that the Status of Materials Inspection Program, be found satisfactory with recommendation for improvement.

We fully recognize the importance of doing on-site inspections of new licensees and believe six (6) months to be a reasonable goal within which to have the first on-site inspection completed. The criteria in Management Directive 5.6 and Section 04.03a/2800 MC that requires material licensees to be inspected within 6 months should be reviewed against IMPEP performance guidelines. To strictly adhere to 6 months we feel is too prescriptive and reflects back to previous protocol NRC used to review Agreement State programs. There must be allowances for states to incorporate "performance" into their inspection protocol of new licensees. Oregon's emphasis on educating new licensees on health and safety issues during the licensure process has proven effective. We believe our initial inspection process is adequate to protect health and safety and feel the finding for this Common Performance Indicator should be "Satisfactory."

We recommend NRC seriously reevaluate IMC 2800, Section 04.03a and incorporate language to allow "performance" to be part of the determination of how soon new licensees need to be inspected. The "performance" would obviously not be based upon a particular licensee, but rather how new licensees generally perform within a state. Specifically, we feel it would be better to use the word "goal" rather than "shall" for inspecting new licensees within 6 months. We plan to change our own policy to reflect the same.

2) The review team recommends that the RPS management assess whether additional staffing is warranted to complete overdue rulemaking actions and to ensure timely completion of upcoming rulemaking actions.

RPS Management has assessed staffing and workload. Additional staffing

does not appear to be warranted at this time. Initial steps already have been taken to update applicable Administrative Rules relating to the Radioactive Materials Program, as well as our X-ray and Tanning Device Programs.

- 3) The review team recommends that the State adopt the NRC standard practice license conditions for HDR units for the casework #11 license and future HDR licenses:

RPS will adopt and incorporate in applicable licenses the above standard license condition for HDR units in the State.

- 4) The review team recommends that the State develop a written policy with procedures for responding to allegations.

The State has written the policy with procedures for responding to allegations.

- 5) The review team recommends that management obtain a State legal view on their interpretation that existing administrative rules require the implementation of all new requirements in the revised NRC regulations where required for compatibility purposes.

The State has already taken initial steps to update the Administrative Rules to adopt applicable language from the revised NRC regulations where required for compatibility purposes. The State has noted the NRC regulations identified by the IMPEP team as needing to be addressed.

Since the State will soon be adopting language from applicable NRC regulations and amending the Administrative Rules accordingly, it is not deemed necessary to obtain a State legal view on existing Administrative Rules. Prospectively, the State will seek a legal opinion to determine if existing Administrative Rules and/or appropriate license conditions meet the criteria for compatibility for new NRC regulations.

- 6) The review team recommends that RPS management initiate rulemaking activities to ensure that NRC rule changes are adopted within the specified 3 year time period.

RPS management is well aware of the three year time period of adopting NRC rule changes. Management discussed this issue with the IMPEP team. It is important to keep in mind that State Radiation Protection Agencies have many more Administrative Rules to maintain than just those applicable to the Radioactive Materials Program. The administrative rule revision process is time consuming. Therefore, prior to initiating the process all programs are evaluated to determine the need for amending applicable rules. If only a few changes are needed, it is not uncommon to distribute information and/or enforcement bulletins to registrants and/or licensees as an interim measure. Licenses may also be administratively changed as an interim measure in lieu of a full formal rule change. The State has the option of incorporating an emergency rule if a situation so warrants. Emergency rules become effective immediately. However, regular procedures of the Administrative Procedures Act must be completed later, (i.e. fiscal impact statements, public comment, etc.).

As mentioned above if in the future license conditions are to be used in lieu of Administrative Rules, the State will have a legal review to determine statutory authority as well as compatibility issues prior to implementation. RPS management will continually strive to initiate rule making activities to ensure that NRC rule changes are adopted within the specified 3 year time period.

Thank you for the opportunity to comment on the draft report. If you have any questions or need additional information please let me know.

Sincerely,



Ray D. Paris, Manager
Radiation Protection Services

c: Elinor Hall, MPH
Administrator Health Division