

December 11, 2002

Grant K. Higginson, M.D.
Acting Administrator
Department of Human Services
Office of Health Services
800 NE Oregon Street, Suite 260
Portland, OR 97237

Dear Dr. Higginson:

On December 3, 2002, 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 Nuclear Regulatory Commission's (NRC) program.

Section 5.0, page 17, of the enclosed final report presents the IMPEP team's recommendations for the State of Oregon. We request your response to the recommendations within 30 days of your receipt of this letter.

Please note that Oregon's practice of issuing advanced authorization for licensing actions as a generic business practice, after an informal health and safety evaluation, is discussed in Section 3.4. Although this practice is not expressly prohibited, absent well-defined parameters, it appears to be questionable because the practice lacks the formality of an approved procedure. At the December 3, 2002 MRB meeting, the MRB and Oregon program management discussed discontinuing routine use of this practice until it is fully proceduralized and its legality is confirmed.

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

I appreciate the courtesy and cooperation extended to the IMPEP team during the review. We appreciate your continued support for the Radiation Control Program and the excellence in program administration demonstrated by your staff as is reflected in the team's findings. I look forward to our agencies continuing to work cooperatively in the future.

Sincerely,

/RA/

Carl J. Paperiello
Deputy Executive Director
for Materials, Research and State Programs

Enclosure: As stated

cc: Terry Lindsey, Manager
Radiation Protection Services

Roland Fletcher, MD
OAS Liaison to MRB

David Stewart-Smith
State Liaison Officer
Grant K. Higginson, M.D.
Acting Administrator
Department of Human Services
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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF OREGON AGREEMENT STATE PROGRAM

AUGUST 26-30, 2002

FINAL REPORT

U.S. Nuclear Regulatory Commission

1.0 INTRODUCTION

This report presents the results of the review of the Oregon Agreement State program. The review was conducted during the period August 26-30, 2002, by a review team consisting of technical staff members from the Nuclear Regulatory Commission (NRC) and the Agreement State of Iowa. 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 5, 1999, NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." Preliminary results of the review, which covered the period of August 14, 1998 to August 25, 2002, were discussed with Oregon management on August 30, 2002.

A draft of this report was issued to Oregon for factual comment on October 16, 2002. The State responded by letter dated November 14, 2002. The Management Review Board (MRB) met on December 3, 2002 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 Department of Human Services, Office of Public Health Systems (the Office), Radiation Protection Services Section (the Section). The Section Manager reports to the Acting Administrator for the Office. The Section is the designated radiation control agency. Organization charts for the Department of Human Services are included as Appendix B. At the time of the review, the Oregon Agreement State program regulated 403 specific licenses authorizing Agreement materials. The review focused on the materials program as it is carried out under the Section 274b. (of the Atomic Energy Act of 1954, as amended) Agreement between the NRC and the State of Oregon.

In preparation for the review, a questionnaire addressing the common and non-common performance indicators was sent to the Section on April 30, 2002. The Section provided a response to the questionnaire on August 9, 2002. A copy of the questionnaire response can be found on NRC's Agencywide Document Access and Management System using the Accession Number ML022800319.

The review team's general approach for conduct of this review consisted of: (1) examination of Oregon's responses to the questionnaire; (2) review of applicable Oregon statutes and regulations; (3) analysis of quantitative information from the radiation control program licensing and inspection data base; (4) technical review of selected licensing and inspection actions; (5) field accompaniments of three Section 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 performance criteria for each common and applicable non-common performance indicator and made a preliminary assessment of the Oregon Agreement State program's performance.

Section 2 below discusses the State's actions in response to recommendations made following the previous IMPEP review. 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 indicators, and Section 5 summarizes the review team's findings.

Recommendations made by the review team are comments that relate directly to program performance by the State. A response is requested from the State to all recommendations in the final report.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous IMPEP review, which concluded August 13, 1998, six recommendations were made and transmitted to Ms. Elinor Hall, Administrator, Office of Health Services, on October 28, 1998. The team's review of the current status of the recommendations are as follows:

RECOMMENDATIONS

1. The team recommends that Oregon continue to implement its policy for inspecting new licenses.

Current Status: During the November 18, 1999 periodic meeting, the Section recognized that they were behind in conducting some initial inspections within the six months guidance criteria in IMC 2800; however, they were fully staffed at the time and had plans to complete the overdue new license inspections by January 2000. The review team found that since November 1999, the Section again lost a significant portion of their staff. The Section has now replaced the lost personnel. They have, once again, managed to catch up with inspecting new licenses at the time of this IMPEP review. In spite of the staff turnover, the Section has implemented its policy of inspection of new licensees. This recommendation is closed.

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

Current Status: The Section was found to be fully staffed during the November 1999 periodic meeting. As noted in Section 3.3, the Section lagged behind in rulemaking since the 1999 periodic meeting due to a loss of personnel. The review team found that rulemaking was not performed until shortly before this review. The Section is now fully staffed and a procedure is now in place to cause an annual assessment of regulation status to help keep the Section on track with future rulemaking initiatives. The Section indicated that additional staffing designated specifically for rulemaking is unwarranted. This recommendation is closed.

3. The review team recommends that the Section adopt the NRC standard practice license conditions for high dose rate afterloaders (HDR) units for the casework #11 license and future HDR licenses.

Current Status: The Section has adopted the NRC standard practice license conditions for HDR units. This recommendation is closed.

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

Current Status: The Section has developed and implemented a written policy with procedures for responding to allegations. This recommendation is closed.

5. The review team recommends that management obtain a Section 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.

Current Status: The Section Manager stated that a legal review is a part of the administrative process for rulemaking. This recommendation is closed.

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

Current Status: During the 1999 periodic meeting, the Section Manager committed to having all of the rule changes completed before September 2000. However, due to management and staff turnover, the Section was not able to meet the September 2000 commitment. The Section submitted 25 draft rules to the NRC on August 26, 2002 and NRC provided draft comments to the Section on October 7, 2002. Upon receipt of NRC's final comments on the Section's draft rules, the Section indicated that they will make the necessary changes to the draft rules within 7 to 10 days. The rules will be administratively reviewed by Public Health Systems before being sent to the Department of Health Services (the Department). The rules will become effective upon signing by the Department Director, or designee, and their filing with the Secretary of State. The Section expects the rules to be effective in December 2002. The Section's new procedures, that require an annual review of the Section's regulation status, will help assure rules are adopted in a timely manner. This recommendation is closed.

During the 1998 review, eight suggestions were made for the Section to consider. The review team determined that the Section considered the suggestions and took appropriate action.

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 team focused on four factors in reviewing this indicator: inspection frequency, overdue inspections, initial inspection of new licenses, and timely dispatch of inspection findings to licensees. The review team's evaluation is based on the Section's questionnaire responses relative to the indicator, data gathered independently from the Section's licensing and inspection data tracking system, the examination of completed licensing and inspection casework, and interviews with management and staff.

The team's review of the Section's inspection priorities verified that inspection frequencies for various types of Oregon material licenses are the same as those listed in the NRC Inspection Manual Chapter (IMC) 2800. In their response to the questionnaire, the Section indicated that

there were no overdue inspections. This information was verified during the inspection casework reviews of core licensees. The Section maintains a licensee database that provides current inspection data. The licensee database contains sufficient information for proper management of the inspection program.

Due to a loss and turnover of management and staff during the review period, as discussed in Section 3.3, all inspections were not conducted at the required frequency during the review period. Specifically, based on data provided by the Section, the review team determined that during the review period, the Section had 21 of 58 core inspections that were conducted overdue by more than 25% of the NRC frequency. In addition, the team identified that five of six initial inspections did not meet the NRC inspection frequency for initial inspections, ranging from one to four months overdue. The review team determined that 30% of the core inspections were conducted at intervals that did not meet NRC inspection frequency guidance. There was no apparent health and safety impact due to the extension of the inspections. The Section fully recovered from the loss of staff in the inspection program by September of 2001. There were no overdue core inspections at the time of the review.

IMPEP criteria allows that in programs where management addresses deficiencies and completes actions to deal with overdue inspections and other aspects affecting the status of the materials inspection program, a finding of satisfactory is supported as opposed to a satisfactory with recommendations for improvement or an unsatisfactory finding. Section management was aware of the backlog of inspections and took mitigating actions such as hiring and training new staff, prioritizing inspections, and balancing staff workload to bring the program up-to-date at the time of the review. Health and safety issues were considered in the assignment of inspections, and the Section's knowledge of licensee's performance history was also considered in the decision process for deferring inspections. The actions taken by the Section were effective in that there are no overdue inspections currently and current staffing appears adequate to maintain inspection frequencies. Consequently, the review team believes that a rating of satisfactory is appropriate for this performance indicator. The review team found the Section's considerable efforts to hire and train new inspectors and reduce the inspection backlog commendable.

The review team noted that the Section is performing inspections of materials licensees on an unannounced basis, except for initial inspections. Fourteen inspection files were reviewed for report timeliness. All inspection field notes are signed by the Section Manager. The Section routinely uses the State's Safety Inspection Form 591 for inspection documentation. In most cases the Form is left with the licensee at the conclusion of the inspection. Occasionally, inspectors issued the Form from the office. All inspection reports reviewed were timely issued.

Out-of-state licensees that frequently perform work in Oregon are provided the option of requesting an Oregon State license or filing for reciprocity. A company is not required to have a business address in Oregon to obtain an Oregon license. 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 Section before the licensee enters the State to do work using licensed material. If the licensee has not entered the State within 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 Section and is considered an inspection. When the licensee

notifies the Section that they are entering the State to do work, the Section conducts inspections in the field if possible. The license is renewed annually by payment of a fee.

Out-of-state licensees that infrequently perform work in Oregon may choose to file for reciprocity. In these cases, the licensees are identified in the Section 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 the Section that they are entering the State to do work, the Section conducts inspections in the field if possible.

During the review period, the Section granted 105 reciprocity licenses, of which, 61 licenses were core licensees based upon IMC 1220. The 61 core licensees consisted of 21 Priority 1, two Priority 2, and 38 Priority 3 licensees. The Section met the IMC 1220 inspection frequencies for Priority 1 licensees by conducting 13 inspections, for Priority 2 licenses by conducting two inspections, and for Priority 3 licenses by conducting 22 inspections. The new NRC guidance requires totaling all of the Priority 1, 2, and 3 reciprocity (core) licensees, and conducting inspections of 20% of this total. Thus, the Agency met the revised NRC guidance by completing 37 inspections of the 61 licenses issued for core licensees. The review team concluded that the Section's performance with respect to reciprocity inspections is noteworthy.

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

3.2 Technical Quality of Inspections

The team evaluated the inspection reports, enforcement documentation, and inspection field notes and interviewed inspectors for 14 radioactive materials inspections conducted during the review period. The casework reviewed included all of the Section's materials license inspectors, and covered inspections of various types including fixed gauges, industrial radiography, medical (diagnostic, therapy, and brachytherapy), radiopharmacy, and academic broad scope. Appendix C lists the inspection casework files reviewed for completeness and adequacy with case-specific comments.

Based on casework, the review team noted that routine inspections covered all aspects of licensed radiation programs. Team inspections were performed when appropriate and for training purposes. The review team found that inspection reports were thorough, complete, and consistent, with sufficient documentation to ensure that licensees' performance with respect to health and safety was acceptable. The documentation adequately supported cited violations, recommendations made to licensees, unresolved safety issues and discussions held with licensees during exit interviews.

Accompaniments of three inspectors were conducted by a review team member during the week of May 14, 2002. The inspectors were accompanied during inspections of a nuclear medicine facility, a fixed gauge facility, and a radiopharmacy. The accompaniments are identified in Appendix C. During the accompaniments, each inspector 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. Each inspector conducted

interviews with appropriate licensee personnel, observed licensed operations, conducted confirmatory measurements, and utilized good health physics practices. Their inspections were adequate to assess radiological health and safety at the licensed facilities. During the review period, management accompanied all individuals who performed materials inspections.

The Section has an adequate number and types of survey meters to support the current inspection program as well as for responding to incidents and emergency conditions. The Office has a local University calibrate their survey instruments. Appropriate, calibrated survey instruments such as GM meters, scintillation detectors, ion chambers and micro-R meters were observed. Air monitoring equipment is also available for emergency use. The Section has a liquid scintillation counter and two gamma spectrometers.

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 Section's staffing level and staff turnover, as well as the technical qualifications and training histories of the staff. To evaluate these issues, the review team examined the Section's questionnaire responses relative to this indicator, interviewed Section's management and staff, reviewed job descriptions and training records, and considered any possible workload backlogs.

At the time of the last IMPEP review in late 1998, the Oregon's staffing was found to be adequate with respect to this indicator. Shortly thereafter, due to retirement of two very experienced managers who had been with the program for considerable time, the program became seriously understaffed. From mid-1999 to approximately mid-2000, the program was seriously shorthanded at both the upper management and the staff level. The transition of senior staff members to the upper management positions and the consequent need to backfill the now newly vacated staff positions took about 3 years to complete. This process was well thought out. The process resulted in two experienced senior staff members moving up to greater responsibilities and challenges in program management. In addition, the hiring of well qualified individuals brought the staff up to its full complement. The review team found, at the time of this review, the program to be fully staffed with experienced, technically qualified individuals.

The Section is headed by a Section Manager and an Assistant Manager for Radioactive Materials and the Laboratory. The radioactive materials licensing and laboratory program staff consists of a Licensing Specialist and three Environmental Health Specialists. An Emergency Response Supervisor and an Environmental Health Specialist also support the radioactive materials program. The Section is supported by an Administrative Assistant and a Clerical Specialist.

In 2000, the Section's management recognized a need for developing a computerized program for managing the day-to-day regulatory responsibilities of a complex program. As a result, a technical staff position was converted to an information technology/information management (IT/IM) programmer position. The new IT/IM programmer would facilitate the development,

implementation and maintenance of an integrated program to facilitate the management of all aspects of the regulatory program. Additionally, the Section's IT program is a "force multiplier" as it leverages the ability of the staff to efficiently carry out inspection and licensing activities while providing a powerful tool for the effective management of program resources. A programmer was hired about mid-2000 who worked exclusively in developing and refining the computer program now used by the Section. In mid-2002, all IT/IM management positions were transferred to a newly reorganized IT/IM office. The Section's programmer was lost as a result. Not only did the Section lose its programmer but it could not reclaim the position by converting back to a technical staff position.

The team observed that the Section had expended considerable effort to make up the staffing shortfall that occurred during the 1999 to 2001 time period. A significant part of the recovery of this program is identified with the development of the program management software specifically designed to enable the Section to perform its mission efficiently and effectively. The team notes that the loss of the full time, dedicated IT/IM programming support has delayed the development of new program modules and program enhancements. The lack of a dedicated IT programmer has the potential to compromise the significant advances the Section has made in the area of program management during the last 2 years and may cause a loss of efficiency and effectiveness within the program. At the time of the review, the review team found that the Section has overcome significant difficulties in the areas of inspection, staffing, and rulemaking, and the specifically designed program and the role of the Section's dedicated programmer in this success should not be overlooked. The review team recommends that the Section complete development of the program management software and continue to maintain capability in this area which is vital to successful performance of the program.

The Section has a well thought out and effective training plan for new employees. It is the Section's policy to provide training using NRC-sponsored training courses as much as possible. Although they are funded for training over the next 12 to 18 months, the Section does maximize its training dollar by attempting to utilize "space available" NRC training whenever possible thus saving their resources for travel expenses. The execution of the individual training plans appears to be suitable and appropriate for the needs of the individual and the Section. All new employees have received training that augments their work experience. The Section's training philosophy includes a concept of balancing the formal training and work experience with training experiences to allow the employee to develop a firm understanding of the health, safety and regulatory issues in a specific area before moving on to new challenges.

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 license reviewers, evaluated the licensing process, and examined licensing casework for 24 license files found in Appendix D. Licensing actions were reviewed for completeness, consistency, proper radioisotopes and quantities, qualifications of authorized users, adequate facilities and equipment, adherence to good health physics practices, financial assurance, operating and emergency procedures, appropriateness of the

license conditions, and overall technical quality. The casework files were also reviewed for timeliness, use of appropriate deficiency letters and cover letters, reference to appropriate regulations, product certifications, supporting documentation, consideration of enforcement history, pre-licensing visits, supervisory review as indicated, and proper signatures. The files were checked for retention of necessary documents and supporting data.

The licensing casework was selected to provide a representative sample of licensing actions, which were completed during the review period. Due to the Section's loss of personnel early in the review period and consequent re-staffing of the Section, casework for licenses issued within the past 2 years was given specific emphasis. The cross-section sampling focused on the Section's new licenses, amendments, renewals, and licenses terminated during the review period. The sampling included the following types: academic, broad medical, research and development, special nuclear material, industrial radiography, portable gauges, institutional nuclear medicine, private clinics, mobile nuclear medicine, radioisotope and sealed source radiotherapy; and nuclear pharmacies. Licensing actions reviewed included 10 new, one renewal, nine amendments and four termination files. A listing of the casework licenses evaluated with case specific comments can be found in Appendix D.

Overall, the review team found that the licensing actions were thorough, complete, consistent, and of acceptable quality with health and safety issues properly addressed. License tie-down conditions were stated clearly, backed by information contained in the file and inspectible. License reviewers utilize standard licensing conditions, and issue a complete license for each licensing action. Pending completion of rulemaking, license conditions were incorporated to address compatibility issues.

The Section has one senior staff member whose primary responsibility is licensing. At a minimum, each license has a peer review and a management review. Peer reviews are accomplished by inspection staff with expertise in the discipline being licensed. In addition, licenses usually undergo review by the Assistant Program Manager and a final review by the Section Manager. The Section Manager, or his designated representative, signs all licenses. The review team noted that the Section has a very efficient and effective licensing process and will process about 600 licensing actions by year's end.

Since the previous review, the Section has changed the licensing frequency. The Section issues Priority 1, 2, and medical licenses for a five-year period. Other priority licenses are now issued for a ten-year period. Since 1998, the Section adopted an abbreviated renewal process. This new process requires licensees to submit an application form tailored to the license type, verification of their radiological program changes, if any, and reaffirmation of key commitments made as part of the initial licensing process.

The 93 termination actions taken over the review period were for licensees possessing only sealed sources, uses of radiopharmaceuticals with short half-lives, or uses involving radioisotopes in microcurie amounts (e.g., in-vitro labs). 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. With regard to byproduct material in Oregon, the review team noted that there was only one major decommissioning and review effort being conducted at PCC Structural, Inc. (ORE-90354).

The review team noted that the Section issued advanced authorization for licensing actions as a generic business practice, after an informal health and safety evaluation. Various staff members granted these authorizations which were unspecific as to the requirements imposed on the licensee or applicant. Although this practice is not expressly prohibited, absent well-defined parameters, it appears to be questionable because the practice lacks the formality of an approved procedure.

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

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 Section's actions in responding to incidents, the review team examined the Section's responses to the questionnaire relative to this indicator, reviewed the incident reports for Oregon in the Nuclear Material Events Database (NMED) against those contained in the Section's files, and evaluated reports and supporting documentation for eleven incidents. A list of the incident casework examined with case-specific comments is included in Appendix E. The review team also reviewed the Section's response to three of four allegations that occurred during the review period. The fourth allegation involved State regulated material.

The incidents selected for review included the following categories: release of radioactive material, lost or stolen radioactive material, overexposure, improper use or disposal of radioactive material, equipment failure, and transportation. The review team found 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. The Section dispatched inspectors for onsite investigations when appropriate, and took suitable enforcement and follow-up actions.

The responsibility for initial response and follow-up actions to materials incidents may be assigned to any member of the Section, however on the incidents reviewed, the Section managers took the lead. Upon receipt, Section staff reviews a report, decides on the appropriate response, and gives the report a unique Section number and logs it into the Section's computer system.

The review team identified 170 incidents in NMED for Oregon during the review period including both byproduct material and other State regulated material. The Section adopted the

Office of State and Tribal Programs (STP) Procedure SA-300. The procedure provides that reports of incidents that require immediate or 24-hour notification be provided to the NRC within one working day of a licensee's notification, and that reports of incidents that require notification within 30 to 60 days be provided to the NRC monthly. However, the State frequently did not meet these timeliness goals.

The review team noted that two events were not reported to the NRC. One event involved the loss of iodine-125 brachytherapy seed(s), that required either 24-hour, or 30-day, notification as these seeds are typically in the millicurie activity range. However, since the activity was not in the report, the notification time frame could have been either 24 hours or 30 days. The Section also was asked to formerly notify NRC of the 24-hour reportable event involving a fixed gauge open shutter failure that occurred on July 9, 2001. The Section agreed to formally notify NRC in writing of these significant reportable events.

The review team also noted that the Section did not properly characterize the immediate closure of radiography operation for health and safety reasons. The closure should have been identified as an Abnormal Occurrence (AO) in NMED. The Section agreed to correct the information in NMED on this event to reflect an AO.

During the recent period from January 2002, to July 2002, a computer problem had caused approximately 27 incident reports to remain with the Section rather than being sent to the NMED contractor. Of these, approximately 8 involved byproduct material. The Section has re-transmitted all reports from this period and previous periods to the NMED contractor on, or about, August 5, 2002. The review team believes the delays in reporting incidents to NMED, prior to this year, were caused by staff shortages, the loss of the full time information technology/health physics position, and an absence of previous data entry quality assurance on the part of the Section.

The review team noted that the Section was providing information to the NMED contractor by way of electronic mail with spreadsheets attached. The NMED format was not used which caused some transmitted information to be overlooked by the contractor. This, along with an incomplete understanding by the Section of their spreadsheet software capabilities, may explain, in part, why numerous NR (Not Reported) notations were observed on the NMED database, especially in the licensee name and license number fields. The Section has committed to use the same terminology identifying incident information categories that NMED had previously adopted. The Section believes this will help lessen the chance of transmitted information from the State being overlooked by the NMED contractor in the future.

In addition, seven of the eleven incidents reviewed appeared to need updated NMED information such as contributing factors, corrective actions, or closure information. The team discussed the procedure for reporting incidents with the Section management. The Section management indicated that they would update the NMED data to include needed information. In addition, the management indicated that they would work to improve data transmission accuracy, and report incidents to NMED in a more timely manner. The review team recommends that Oregon report events requiring greater than 24-hour notification to the NRC on a monthly basis; ensure that all reports through August 2002 have been entered into NMED; correct missing data on all NMED reports submitted; update and closeout previously reported incidents; and resolve data transmittal problems.

It was noted that the Section received, but was not using the latest NMED software, and that all Section staff members had recently completed the new NMED software training. The Section uses their own Access 2000 software to track all radioactive material incidents and allegations.

The team also found that a large effort is required by the Section to review individual NMED reports and close them with the NMED contractor especially for those cases where the Section had previously determined that the information was complete and the case had been closed. At the December 3, 2002 MRB meeting, the team again noted that there are differences in report status between the Section's entries and the reports that appear in NMED. For example, reports that have been submitted as closed are indicated in NMED as open and reports that have been completed are indicated as being incomplete in NMED. Additionally, there is confusion as to who is responsible for determining when an NMED report is complete and when it should be closed. Feedback on the status and quality of the Section's reported events appear to be insufficient to identify and resolve issues within an individual report. The team was unable to resolve these issues. The MRB recommends that the NRC review, in coordination with the States, the issues of data sharing, closing and completing NMED reports, and process used to provide periodic feedback to States on the status of their submittals.

In evaluating the effectiveness of Oregon's actions responding to allegations, the review team examined the Section's questionnaire responses relative to this indicator. The casework for the three allegations involving byproduct material were reviewed. The Section evaluates each allegation using NRC Management Directive 8.8 and determines the proper level of response. The review of files indicated that the Section took prompt and appropriate action in response to the concerns raised. The review team noted that allegations were treated and documented internally in the same manner as incidents. There were no performance issues identified from the review of the allegation casework documentation. The review team noted that access to all public documents is available for inspection and copying unless specifically exempted from disclosure.

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. Only the first non-common performance indicator was applicable to this review.

4.1 Legislation and Program Elements Required for Compatibility

4.1.1 Legislation

Along with the Section's response to the questionnaire, the staff provided the review team with the opportunity to review copies of legislation that affects the radiation control program. The current statutory authority for the Section is contained in Oregon Statute 453.625. Oregon Statute 453 governs the use of radioactive materials, x-ray, emergency response and laboratory services. The Section is designated as the State's radiation control agency. The review team noted that no legislation affecting the radiation control program was passed during the review period and the enabling legislation is unchanged since the last review. Oregon has no sunset provisions either for the Section or for its regulations.

4.1.2 Program Elements Required for Compatibility

The review team examined the procedures used in the State's rulemaking process and found that the public and other interested parties are offered an opportunity to comment on proposed regulation changes. Rulemaking responsibility is assigned to the Radioactive Materials Licensing Manager. It was noted that approximately 25 draft regulations were sent to the NRC for review and comment shortly before the onsite review. The Section indicated that NRC comments on the draft regulations will be incorporated when they are received. The team noted that rule adoption has exceeded the three-year requirement since the last IMPEP review in almost all cases. Since the time of the last review, staffing was not adequate for the Section's workload as noted in Section 3.3. Because of the amount of time required to review, draft, revise, hold public hearings and process the proposed rules for adoption, management decided to give rulemaking a lower priority than licensing and overdue inspections which are "health and safety" issues. Once sufficient staff had been hired and trained, the program management proceeded to eliminate the rulemaking backlog. As a result, at the time of the review, 25 regulations had been drafted and submitted to NRC for compatibility review. The Section was provided draft NRC comments on October 7, 2002. The Section expects the rules to be effective in December 2002. One license condition was submitted to NRC for review.

To prevent a reoccurrence of this situation, a new Section policy has been implemented which will result in an annual review of the rulemaking process. During January each year, the Section will review NRC rule changes and will solicit comments from staff and others. Draft changes will be made as necessary and proposed changes will be reviewed by the RAC, as required by State Statute. Final draft regulations will be forwarded for administration review. Public comment period (usually 30 to 45 days) will occur and proposed changes will be distributed to all licensees and interested parties, including the NRC for compatibility review. A public hearing will be conducted and the final proposed rule will be prepared and promulgated. The regulation promulgation will be completed in six to nine months.

The review team evaluated the Office responses to the questionnaire, 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 STP's State Regulation Status Data Sheet. Since the previous review, the Section submitted a single rule package containing 25 rules shortly before this review. They will become effective in December 2002. All but two of the regulations submitted are overdue. Two regulations had been enacted previously by legally binding requirements. In addition, the Section was unaware of the need to submit the legally binding requirements to NRC for compatibility review. As a result of discussions with the team, the Section has agreed to submit legally binding requirements to NRC in the future.

As noted previously, the following draft regulations have been reviewed by NRC. Upon receipt of NRC's final comments on the Section's draft rules, the Section will make the necessary changes to the draft rules within 7 to 10 days. The rules will be administratively reviewed by Public Health Systems before being sent to the Department. The rules will become effective upon signing by the Department Director, or designee, and their filing with the Secretary of State. The Section expects the rules to be effective in December 2002.

- ! "Safety Requirements for Radiographic Equipment," 10 CFR Part 34 amendment (55 FR 843) that became effective on January 10, 1991;
- ! "ASNT Certification of Radiographers-Part 34," 10 CFR Part 34 amendment (56 FR 11504) that became effective January 27, 1992;
- ! "Decommissioning Recordkeeping and License Termination: Documentation Additions [Restricted Areas and Spill Sites]," 10 CFR Parts 30 and 40 amendments (58 FR 39628) that became effective on October 25, 1996;
- ! "Licensing and Radiation Safety Requirements for Irradiators-Part 36," 10 CFR Part 36 amendment (58 FR 7715) that became effective on July 1, 1996;
- ! "Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations," 10 CFR Part 34 amendment (63 FR 37059) that became effective July 9, 1998;
- ! "Transfer for Disposal and Manifests: Minor Technical Conforming Amendment," 10 CFR Part 20 amendment (63 FR 50127) that became effective on October 20, 1998;
- ! "Termination or Transfer of Licensed Activities: Recordkeeping Requirements," 10 CFR Parts 20, 30, 40, 61, and 70 amendments (61 FR 24669) that became effective on June 17, 1996;
- ! "Minor Corrections, Clarifying Changes, and a Minor Policy Change," 10 CFR Parts 20, 32 and 39 amendments (63 FR 39477 and 63 FR 45393) that became effective October 26, 1998;
- ! "Deliberate Misconduct by Unlicensed Persons," 10 CFR Parts 30, 40, 61, 70, and 150 amendments (63 FR 1890 and 13773) that became effective February 12, 1998;
- ! "Exempt Distribution of a Radioactive Drug Containing One Microcurie of Carbon-14 Urea," 10 CFR Part 30 amendment (62 FR 63634) that became effective January 2, 1997;
- ! "Radiological Criteria for License Termination," 10 CFR Parts 20, 30, 40, and 70 amendments (62 FR 39057) that became effective August 20, 1997; currently done by license conditions;

- ! "Notification of Incidents," 10 CFR Parts 20, 30, 31, 34, 39, 40, and 70 amendments (56 FR 64980) that became effective on October 15, 1991;
- ! "Quality Management Program and Misadministrations," 10 CFR Part 35 amendment (56 FR 34104) that became effective on January 27, 1992; submitted but not considered overdue as a result of NRC's decision to delay Agreement State compatibility implementation until the new Part 35 rule is implemented;
- ! "Clarification of Decommissioning Funding Requirements," 10 CFR Parts 30, 40, and 70 amendments (60 FR 38235) that became effective on November 24, 1995;
- ! "Low-Level Waste Shipment Manifest Information and Reporting," 10 CFR Parts 20 and 61 amendments (60 FR 15649 and 25983) that became effective on March 1, 1995;
- ! "Licenses for Industrial Radiography and Radiation Safety - Requirements for Industrial Radiography Operations," 10 CFR Parts 30, 34, 71, and 150 amendments (62 FR 28947) that became effective June 27, 1997; currently imposed by license condition;
- ! "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;
- ! "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;
- ! "10 CFR Part 71: Compatibility with the International Atomic Energy Agency," 10 CFR Part 71 amendment (60 FR 50248) that became effective on April 1, 1996;
- ! "Medical Administration of Radiation and Radioactive Materials," 10 CFR Parts 20 and 35 amendments (60 FR 48623) that became effective on October 20, 1995;
- ! "Radiation Protection Requirements: Amended Definitions and Criteria," 10 CFR Parts 19 and 20 amendments (60 FR 36038) that became effective on August 14, 1995;
- ! "Performance Requirements for Radiography Equipment," 10 CFR Part 34 amendment (60 FR 28323) that became effective on June 30, 1995;
- ! "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, 60 FR 322) that became effective on January 1, 1995;
- ! "Timeliness in Decommissioning of Materials Facilities," 10 CFR Parts 30, 40, and 70 amendments (59 FR) that became effective on August 15, 1997; adopted by reference to 10 CFR 30.35 and 30.36.

The following regulation was implemented by reference or by license condition:

- ! “Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act,” 10 CFR Part 20 amendment (61 FR 65120) that became effective January 9, 1997.

The Section has not submitted the following rule. They do not have any licensees affected by the requirement.

- ! “Respiratory Protection and Controls to Restrict Internal Exposures,” 10 CFR Part amendment (64 FR 54543; 64 FR 55524) that became effective February 2, 1999.

The Section will need to address the following five regulations in upcoming rulemakings or by adopting alternate legally binding requirements:

- ! “Energy Compensation Sources for Well Logging and Other Regulatory Clarifications,” 10 CFR Part 39 amendment (65 FR 20337) that became effective May 17, 2000;
- ! “New Dosimetry Technology,” 10 CFR Parts 34, 36, and 39 amendments (65 FR 63750) that became effective January 8, 2000;
- ! “Revision of the Skin Dose Limit,” 10 CFR Part 20 amendment (67 FR 16298) that became effective April 5, 2002;
- ! “Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material,” 10 CFR Parts 30, 31, and 32 amendments (65 FR 79162) that became effective February 16, 2001;
- ! “Medical Use of Byproduct Material,” 10 CFR 20, 32, and 35 amendments (67 FR 20249) that became effective October 24, 2002.

Although the State was seriously behind in rulemaking due to the reasons previously stated in this report, they made a massive effort to correct this problem once resources became available. At the time of the review, 25 draft regulations were under review by NRC. The Section committed to have these rules in place very soon, possibly by the end of December 2002. The team noted that the Section had provided for not having regulations in place by a combination of legally binding requirements, license conditions and enforcement bulletins. The team could not identify any health, safety or event response issues that would have identified a regulatory, or compatibility, gap as a result of rules not being promulgated in a timely manner. Also, the team does not question management’s decision to focus on health and safety issues, e.g., licensing, inspections and emergency response, in lieu of rulemaking until such time as resources became available to properly address the outstanding rules. In addition, the Section did address important rules by license condition or by adoption by reference during the interim. Management’s actions were effective in prioritizing the Section’s work to first address health and safety issues, e.g., licensing, inspections and event response, and then address outstanding rulemaking. Current procedures and staffing appear adequate to maintain the program’s elements and maintain a level of currency in rulemaking. The IMPEP criteria for this indicator would find the Section to be satisfactory with recommendation for improvement. The review team believes that this finding should be raised to satisfactory on

the basis of the Section's management addressing program deficiencies and completing actions to deal with the overdue situation.

In making its decision to raise the finding to satisfactory, the review team suggests that the MRB should take into consideration the Section Management's decisions to prioritize work to address health and safety concerns and to defer rulemaking activities until staff were available and trained. The Section addressed any health and safety rules by licensing actions or enforcement bulletins to affected licensees. Also, the following should be considered: the Section submitted all rules required for compatibility prior to the review; NRC's review has been completed and draft comments sent to the Section on October 7, 2002. Upon receipt of NRC's final comments on the Section's draft rules, the Section indicated that it will make the necessary changes to the draft rules within 7 to 10 days. The rules will be administratively reviewed by Public Health Systems (PHS) before being sent to the Department of Health Services (DHS). The rules will become effective upon signing by the DHS Director, or designee, and their filing with the Secretary of State. The Section expects the rules to be effective in December 2002.

Last, the MRB is also asked to consider the extensive amount of work the Section has put into rulemaking in an effort to bring all rules up to date.

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

4.2 Low-Level Radioactive Waste (LLRW) 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, Oregon's performance was found to be satisfactory for all performance indicators. Accordingly, the review team recommended, and the MRB concurred, in finding the Oregon Agreement State program adequate to protect public health and safety and compatible with NRC's program. Based on the results of the current IMPEP review, the review team recommended, and the MRB concurred, that the next full review should be in approximately four years.

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

RECOMMENDATIONS FOR THE STATE:

1. The review team recommends that the Section complete development of the program management software and continue to maintain capability in this area which is vital to successful performance of the program. (Section 3.3)
2. The review team recommends that the Section discontinue the routine use of advanced authorizations pending development of a procedure and basis for issuing the authorizations. Once developed, the Section should have the practice of issuing advance authorization and the procedure reviewed by counsel and its Radiological Advisory Committee (RAC). The review should include the form and content of the authorizations, the legal basis for issuing notifications prior to issuance of a license, as well as a determination of the potential impact on health and safety. In addition, the review should determine the State's potential liability and the compatibility of the practice with established State and Federal regulations, including requirements imposed on distributors of devices containing radioactive material. (Section 3.4)
3. The review team recommends that Oregon report events requiring greater than 24-hour notification to the NRC on a monthly basis; ensure that all reports through August 2002 have been entered into NMED; correct missing data on all NMED reports submitted; update and closeout previously reported incidents; and resolve data transmittal problems. (Section 3.5)

RECOMMENDATION FOR THE NRC:

1. The MRB recommends that the NRC review, in coordination with the States, the issues of data sharing, closing and completing NMED reports, and process used to provide periodic feedback to States on the status of their submittals.

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 | November 14, 2002 Letter from Grant K. Higginson, M.D. (without enclosure) Oregon's Response to Draft IMPEP Report |

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

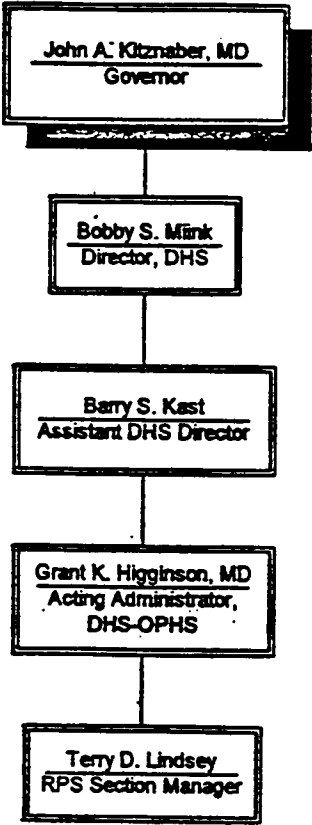
| Name | Area of Responsibility |
|------------------------|--|
| James Myers, STP | Team Leader Legislation and Program Elements Required for Compatibility Technical Staffing and Training |
| Linda McLean, RIV | Technical Staffing and Training Status of Material Inspection Program Technical Quality of Inspections |
| George Johns, IA | Technical Quality of Licensing Actions Technical Staffing and Training |
| Anthony Kirkwood, NMSS | Response to Incidents and Allegations |

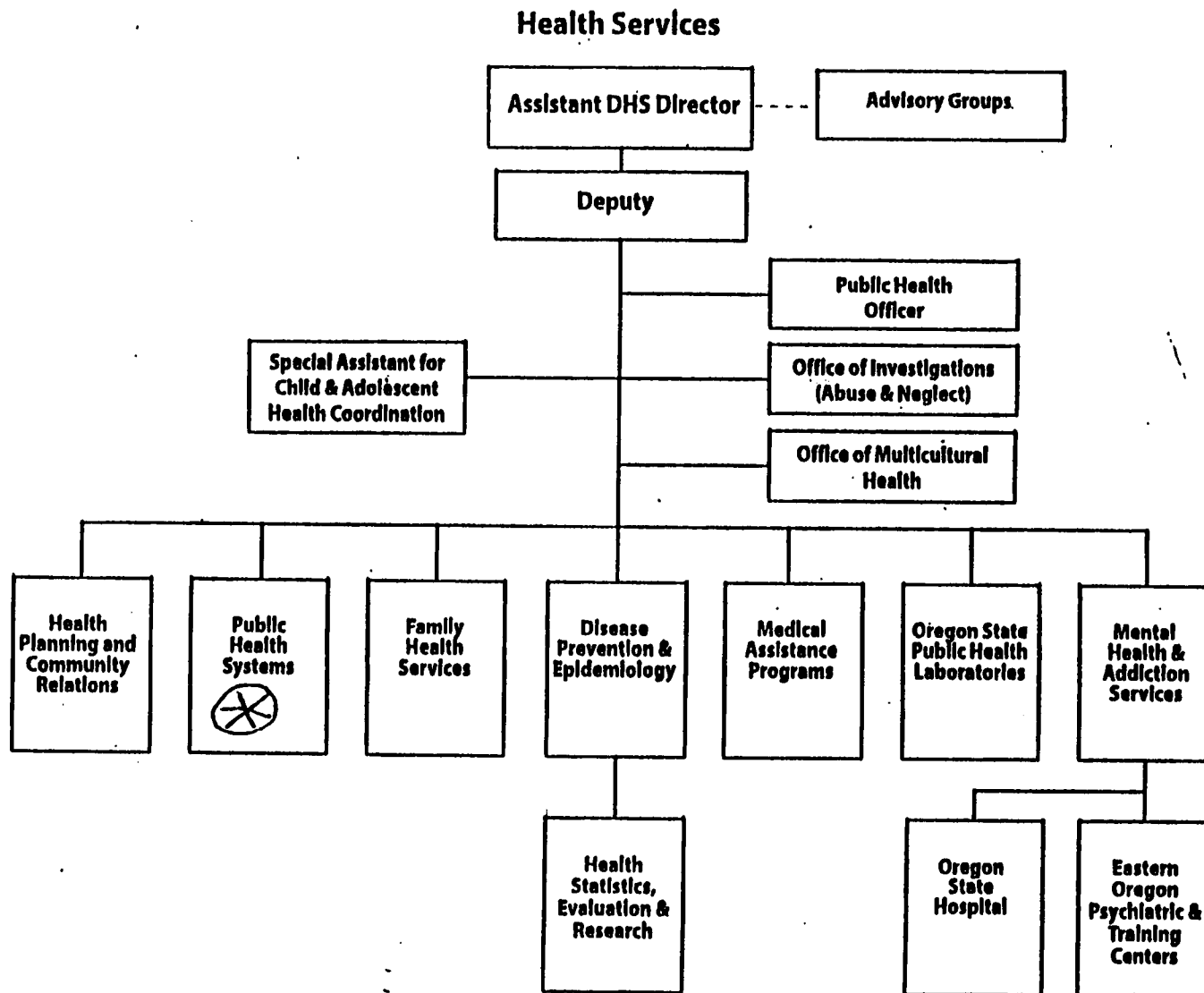
APPENDIX B

OREGON OFFICE OF RADIATION CONTROL

ORGANIZATION CHARTS
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Supervisory Organizational Chart
from RPS Section Manager
to the Governor of Oregon

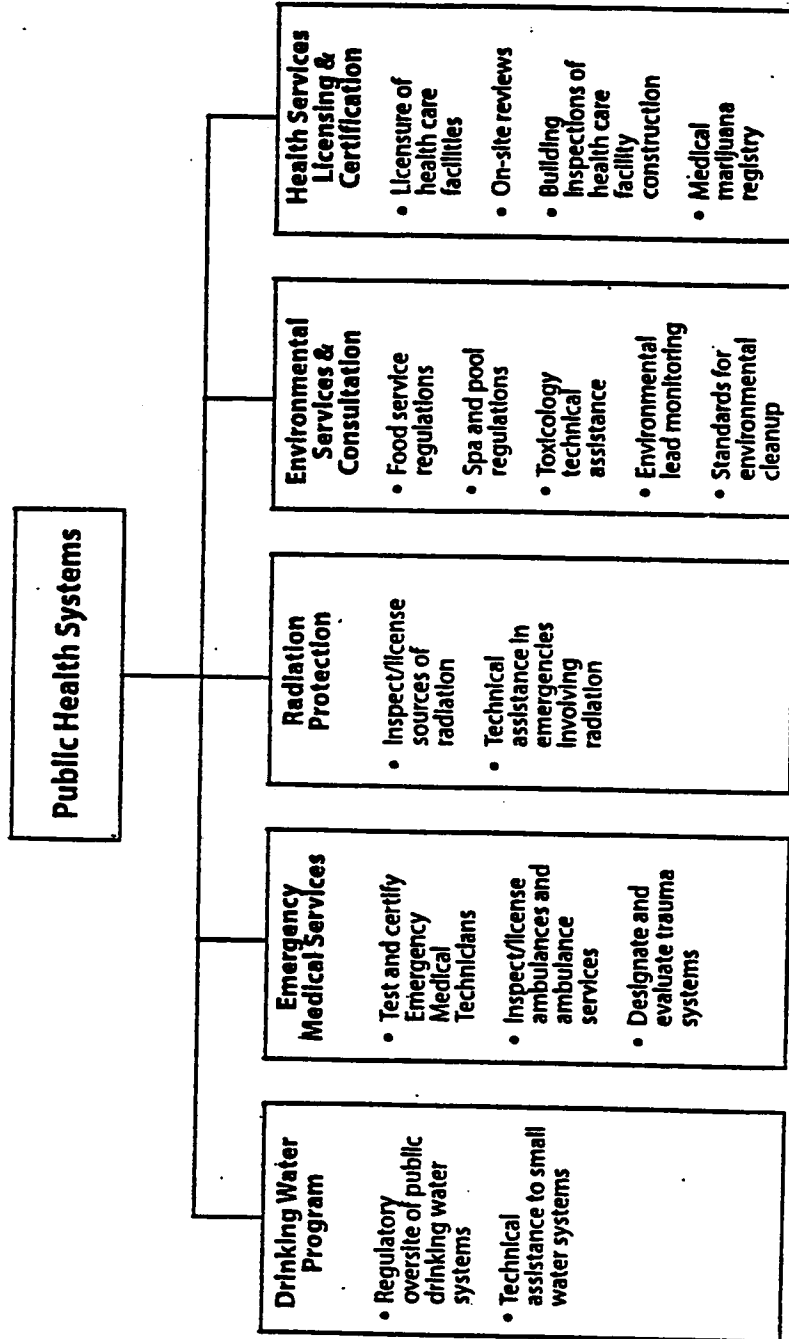




For a more detailed organization chart, see Appendix 2 on pages 76-85.

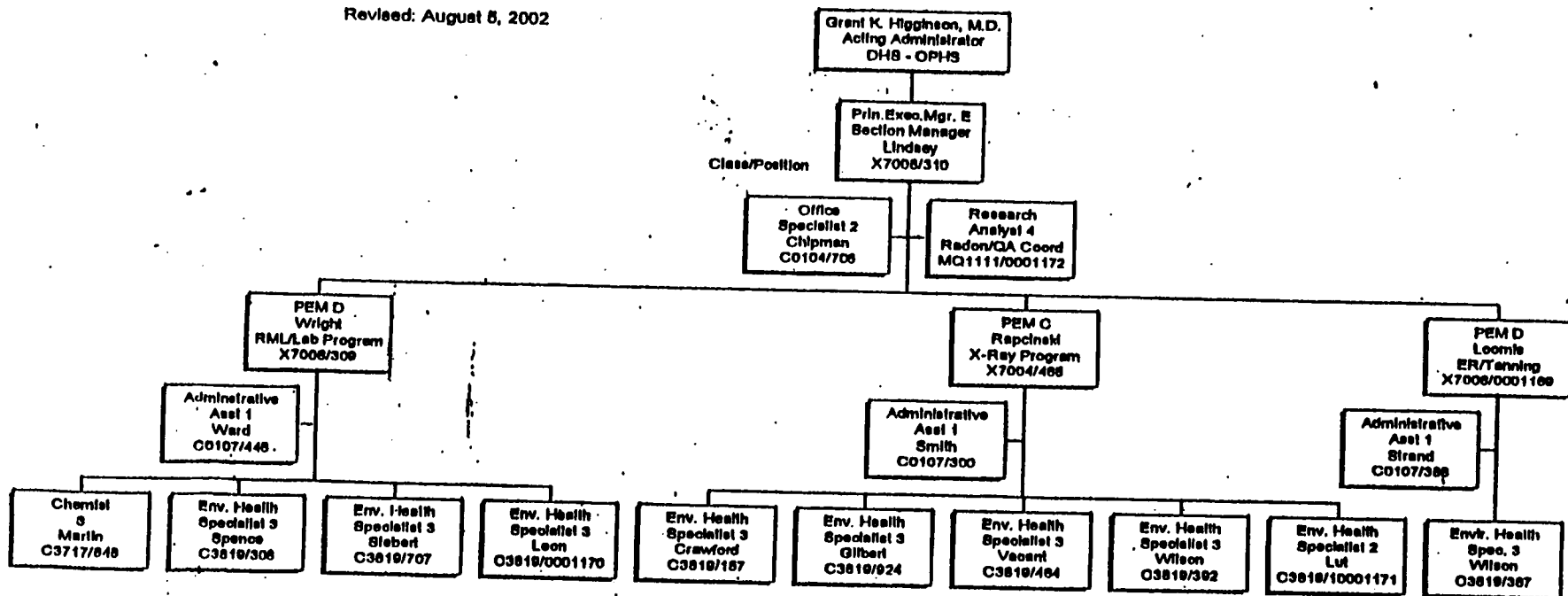
Appendix 2: Detailed Organization Chart for Health Services

Health Services



**Organizational Chart
Radiation Protection Services
Office of Public Health Systems**

Revised: August 5, 2002



ATTACHMENT

November 14, 2002 Letter from Grant K. Higginson, M.D. (without enclosure)
Oregon's Response to Draft IMPEP Report

Complete letter, with enclosure, can be found at [ML023240526](#)



Oregon

John A. Kitzhaber, M.D., Governor

November 14, 2002

Department of Human Services
STP

02 NOV 15 PM 3: 43
800 NE Oregon Street
Portland, OR 97232-2162
(503) 731-4030 Emergency
(503) 731-4014, x 660
Fax (503) 731-4081, x _____
TTY-Nonvoice (503) 731-4037

Josephine Piccone, Deputy Director
Office of State and Tribal Programs
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Subject: Response to your Letter dated October 16, 2002 (Concerning the Oregon Agreement State Program IMPEP Review Conducted August 26-30, 2002)

Dr. Piccone,

As an Agreement State, the State of Oregon has a responsibility to license and monitor the receipt, use and disposal of radioactive materials to protect the health and welfare of its citizens. To accomplish this task, legislation was passed giving Oregon Health Services statutory authority to develop rules and procedures to license and monitor radioactive materials. Radiation Protection Services is the Section charged with implementing the radioactive materials program. We look forward to, and appreciate, reviews of the licensing and inspection program.

As detailed in your report, the Integrated Materials Performance Evaluation Program (IMPEP) team provided a thorough examination of our program for the period of August, 1998 through August, 2002.

While the report reflects the current status of the program, it does not address the opportunity to exchange ideas on how to fine tune various aspects of the program. Oregon is grateful for the professional approach the team took in providing these insights. In the report there were two issues we would like to address. The team expressed a concern about Advanced Authorizations (also called Verbal Authorizations) and incident reporting.

For the first issue, Advanced Authorizations are typically used to allow licensees to order and receive radioactive materials prior to a license or license amendment being issued. This is primarily to assist licensees because of the lag time between ordering materials and actual receipt. Other types of Advanced Authorizations include new authorized users and temporary change in storage location. In the past this process has been informal and performed by either the licensing or inspection staff as required.

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Letter to Dr. Piccone, NRC HQ

November 14, 2002

Page two

Based upon the IMPEP Team's recommendations, a procedure has now been developed to formalize this process and include the types of safety considerations found in our normal licensing process. Key points in the revised process are that Advanced Authorizations will require management review and sign-off, they will expire in 30 days (this will reduce the length of time to issue the license or license amendment) and appropriate health and safety restrictions will be included in the authorization.

The second issue deals with incident reporting. The IMPEP team expressed concern about two incidents that may not have been reported timely nor were they properly categorized. Our review of the incident involving I-125 seeds indicates that it should not have been reported as "lost radioactive material".

One incident involved a prostate cancer patient who had been implanted with approximately 130 seeds. A few weeks later, his bladder was being operated on and the surgeon noticed the prostate was significantly abnormal so he removed the prostate. It was sent to pathology to determine if it was cancerous. The pathologist noticed the I-125 seeds when he tried to cross section the tissue for examination. He removed all the seeds he could find. There were just over 100 seeds. It is not unusual for seeds to be discharged by the patient while urinating. Since this is to be expected, we did not consider them "lost" in the usual sense.

The other incident was evaluated by the IMPEP team to be an AO type incident. Upon review of the criteria, they concluded that it was caused by a procedure failure. This incident involved a radiography crew performing field radiography. When the inspector arrived at the site, the crew did not have a working survey instrument or proper dosimetry and their 2 mr/hr line was only on one side and less than 6 feet away from the valve being radiographed. There were also several other items of non-compliance. At the time of this incident, we did not feel this was a procedure failure, but rather gross negligence on the part of the radiography crew and reported this as an incident rather than a 24 hour notification.

In both cases, we have reviewed the reporting requirements and agree that they should have been reported to the NRC in a more timely manner. We will make every attempt to properly evaluate incidents and report them to the NRC as required in SA-300. During the first quarter of calendar year 2003, we will also review all NMED reporting requirements against our current system of data recording and transfer to INEEL and make all necessary changes to provide fully compatible data for national materials event

reporting for the benefit of all concerned.

Letter to Dr. Piccone, NRC HQ

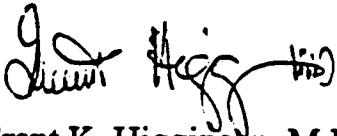
November 14, 2002

Page three

We have also enclosed our comments concerning your review of our draft rules. We anticipate having them submitted to the DHS-Health Services Administrator by November 22, 2002 and they should be to the Secretary of State's Office no later than the second week of December.

We appreciate the IMPEP team's thoroughness in conducting this valuable program review. We gained significant insight about our program and have implemented many of their useful suggestions. Should you have any questions concerning this correspondence, please contact Terry Lindsey at 503/731-4014 x660 or Ed Wright at 503/731-4014 x679.

Sincerely,

A handwritten signature in black ink, appearing to read "Grant K. Higginson, M.D.", with a stylized flourish at the end.

Grant K. Higginson, M.D.
Acting Administrator
Department of Human Services
Office of Health Services

Enclosure

Copy to: Terry D. Lindsey, RPS Section Manager