

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

August 21, 2008

Ms. Mary C. Selecky Secretary Washington State Department of Health 101 Israel Road, SE P.O. Box 47890 Olympia, WA 98504-7890

Dear Ms. Selecky:

On July 22, 2008, the Management Review Board (MRB) met to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) report on the Washington Agreement State Program. The MRB found the Washington Agreement State Program adequate to protect public health and safety and compatible with the U.S. Nuclear Regulatory Commission's program.

Section 5.0, page 19, of the enclosed final report contains a summary of the IMPEP review team's findings. Based on the results of the current IMPEP review, the next full review of the Washington Agreement State Program will take place in approximately 4 years, with a periodic meeting tentatively scheduled for April 2010.

The MRB recognized that this review marked the third consecutive IMPEP review in which the Washington Agreement State Program was found adequate to protect public health and safety, compatible with the NRC's program, and satisfactory for all performance indicators reviewed. These are the highest possible ratings for an IMPEP review. I applaud your staff for their dedication to excellence in radiation protection.

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

Sincerely,

#### /**RA**/

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

Enclosure: Washington Final IMPEP Report

cc w/encl.: See next page

cc w/encl.: Gary Robertson, Director Washington Office of Radiation Protection

> Matthew Steuerwalt, State Liaison Officer Washington Office of the Governor

Jack Ferruolo, Rhode Island Organization of Agreement States Liaison to the MRB



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

May 5-9, 2008

**FINAL REPORT** 

Enclosure

#### 1.0 INTRODUCTION

This report presents the results of the review of the Washington Agreement State Program. The review was conducted during the period of May 5-9, 2008, by a review team comprised of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of North Carolina. Team members are identified in Appendix A. The review was conducted in accordance with the "Implementation of the Integrated Materials Performance Evaluation Program and Rescission of Final General Statement of Policy," published in the *Federal Register* on October 16, 1997, and the February 26, 2004 NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." Preliminary results of the review, which covered the period of September 13, 2003, to May 9, 2008, were discussed with Washington State managers on the last day of the review.

A draft of this report was issued to the State of Washington for factual comment on June 5, 2008. The State responded by letter on June 27, 2008, from Mary C. Selecky, Secretary, Department of Health (the Department). A copy of the State's response is included as the Attachment to this report. The Management Review Board (MRB) met on July 22, 2008, to consider the proposed final report. The MRB found the Washington Agreement State Program to be adequate to protect public health and safety and compatible with NRC's program.

The Washington Agreement State program is administered by the Office of Radiation Protection (the Office) in the Division of Environmental Health. The Division is part of the Department. Organization charts for the Department and Office are included in Appendix B.

At the time of the review, the Washington Agreement State program regulated 447 specific licenses authorizing the use of byproduct, source, and special nuclear material. The review focused on the radioactive materials program as it is carried out under the Section 274b. (of the Atomic Energy Act of 1954, as amended) Agreement between the NRC and the State of Washington.

In preparation for the review, a questionnaire addressing the common and applicable noncommon performance indicators was sent to the Office on January 14, 2008. The Office provided its response to the questionnaire on April 18, 2008. A copy of the questionnaire response may be found in the NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Numbers ML081140419 and ML081140420.

The review team's general approach for conduct of this review consisted of: (1) examination of Washington's response to the questionnaire; (2) review of applicable Washington statutes and regulations; (3) analysis of quantitative information from the Office's database; (4) technical review of selected regulatory actions; (5) field accompaniments of eight inspectors; and (6) interviews with staff and managers. The review team evaluated the information gathered against the established criteria for each common and applicable non-common performance indicator and made a preliminary assessment of the Washington Agreement State Program's performance.

Section 2.0 of this report covers the State's actions in response to recommendations made during the previous review. Results of the current review of the common performance indicators

are presented in Section 3.0. Section 4.0 details the results of the review of the applicable noncommon performance indicators, and Section 5.0 summarizes the review team's findings.

#### 2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous IMPEP review, covering the period of September 14, 1999 through September 12, 2003, the review team made one recommendation regarding program performance. The current status of the recommendation is as follows:

The review team recommends that the Office develop and implement a plan to adequately and consistently address the financial assurance for decommissioning portions of material license regulations. (Section 3.4 of the 2003 IMPEP report)

Current Status: Office management presented a plan to NRC's MRB on December 10, 2003, describing the steps to be taken to address the financial assurance requirements for material licenses. The review team confirmed that adequate financial assurance reviews were being performed by a consultant. In the near future, the Office plans to have the consultant train staff members to perform financial assurance reviews. The training is scheduled to occur by September 2009. This recommendation is closed.

#### 3.0 COMMON PERFORMANCE INDICATORS

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

#### 3.1 Technical Staffing and Training

Issues central to the evaluation of this indicator include the Office'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 Office's questionnaire response relative to this indicator, interviewed Office managers and staff, reviewed job descriptions and training records, and considered any possible workload backlogs.

The Office is managed by the Office Director and two Regional Directors. The Office is comprised of seven sections split between the two Regions. The Western Regional Director is located in the Olympia Office and is responsible for the operations of three sections: the Radioactive Materials Section (the Materials Section), the X-ray Section, and the Information Management and Process Development Section. The Eastern Regional Director is located in the Richland Office and is responsible for the operations of four sections: the Radioactive Air Emissions Section, the Environmental Radiation Monitoring and Assessment Section, the Radiological Emergency Preparedness Section, and the Waste Management Section (the Waste Section). The Agreement State program is primarily administered by the Materials Section and the Waste Section, with the other sections providing various degrees of support. Staffing and training for the Materials Section will be covered in this section of the report, and

staffing and training for the Waste Section will be covered in Sections 4.3.1 and 4.4.1 of the report.

The Materials Section is responsible for radioactive materials licensing, inspection, and emergency response activities. At the time of the review, the Materials Section employed eight technical staff members and an administrative staff member. The technical staff members, called Health Physicists, perform licensing, inspection, and emergency response activities. The Materials Section is headed by the Materials Section Supervisor. Three senior staff members act as Program Managers for three major licensee groups: medical, industrial, and laboratories. The other technical staff members are assigned to assist the Program Managers.

Four staff members left the Materials Section during the review period. One of the individuals was promoted to a position in the Waste Section, and the other three either resigned or were terminated. The Office was able to fill the vacancies in an expedient manner. At the time of the review, the Materials Section was fully staffed.

The Materials Section has a documented training and qualification program for staff members who perform licensing and inspection duties and investigate incidents. The training and qualification program is equivalent to NRC Inspection Manual Chapter (IMC) 1246, "Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area" and is consistent with the NRC and Organization of Agreement States (OAS) Training Working Group Recommendations for Agreement State Training Programs. Qualification is achieved through a combination of education and experience, formal classroom training, and on-the-job training. New staff members are required to have a Bachelor's degree in a physical or biological science or engineering and a minimum of 2 years experience in the use of radiation.

The Office maintains training and qualification records for each staff member. The review team noted that Office managers encourage and support training opportunities, based on program needs and funding. The review team concluded that the Materials Section's staffing and training is adequate to carry out its regulatory duties.

The Materials Section is a 100 percent fee-supported regulatory program. Licensees are assessed an annual fee to cover the costs associated with amendments, routine inspections, and investigations. New license applicants are assessed a small fee to cover the initial prelicensing inspection costs. In addition, the Office receives a small apportionment from the State general fund to cover costs associated with incident response for the entire program.

In early 2008, the Washington legislature approved a proposed rule to increase fees. A public hearing for the rulemaking was scheduled for May 30, 2008. The proposed rule would increase fees for radioactive material licensees by up to 30 percent and x-ray registrants by up to 40 percent. Approval of the rulemaking will allow the Office to add 2.5 full-time equivalents (FTE), of which 1.0 FTE would be dedicated to the Materials Section. The fee increase would avoid a projected budget shortfall, which may have required a reduction in staff levels, and would allow a planned upgrade to the Office's computer database.

The Office initiated a major effort to focus on organizational development and leadership. Using leadership models, concepts, and theories, Office managers, with the assistance of a full-time specialist, implemented a number of in-house information gathering forums. These forums were

designed to engage staff members at all levels of the organization in the development of Office values, mission, and vision, as well as strategic and succession planning. The Office performs effectiveness monitoring for key activities, including the effectiveness of managers. Built into the process is executive coaching of the Office and Regional Directors. Staff reaction to the process appeared to be favorable.

The State of Washington does not have an established State radiation oversight board. If the Office determines that advice is needed on a particular subject, a group of licensee representatives is convened to act in an advisory role to the Office.

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

#### 3.2 <u>Status of Materials Inspection Program</u>

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

The review team's evaluation of the Office's inspection priorities verified that inspection frequencies for all types of Washington material licenses are at least the same frequency as those listed in IMC 2800, "Materials Inspection Program." Some categories of licenses were assigned inspection priority codes that prescribe a more frequent inspection schedule than those prescribed in IMC 2800.

The Materials Section conducted a total of 440 inspections of high priority (Priority 1, 2, and 3) licensees during the 5-year review period. The review team determined that no inspections were performed overdue or were overdue at the time of the review. The review team also evaluated the Materials Section's timeliness for conducting initial inspections. The review team noted that the Materials Section conducted 24 initial inspections during the review period. All were inspected within one year, in accordance with IMC 2800 guidelines.

The review team evaluated the Materials Section's timeliness of issuance of inspection reports and determined that the Materials Section has an effective and efficient process that helps ensure that inspection findings are communicated to licensees in a timely manner. Inspection findings are communicated to the licensee using a form (DOH 322-015) similar to NRC's Form 591, "Safety Inspection Report and Compliance Inspection." These forms are generally used for infractions or deficiencies. A completed form is typically issued on-site upon the completion of an inspection or included in a notice of correction letter. The review team determined that, if not issued at the conclusion of the onsite inspection, these forms were issued within 30 days of the inspection. Of the 34 inspection files reviewed by the review team, one inspection summary was issued beyond the 30-day goal.

During the review period, the Materials Section received requests for reciprocity from 144 licensees. The review team determined that the Materials Section conducted reciprocity inspections of 20 percent of those licensees during the review period. The Section met the criterion in IMC 1220 "Processing of NRC Form 241 and Inspection of Agreement State Licensees Operating Under 10 CFR 150.20," that requires on-site inspection of 20 percent of candidate licensees operating under reciprocity.

The review team determined that the Materials Section adequately planned for the initial set of Increased Controls inspections for materials security measures of affected licensees. The review team evaluated the Materials Section's prioritization methodology and found it acceptable. The Materials Section identified 29 licensees that were subject to the Increased Controls and performed all of the first-year inspections in a timely manner. The review team determined that the Materials Section re-evaluated the pertinent aspects of the security measures during subsequent routine safety inspections following the initial Increased Controls inspections.

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

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

The review team evaluated inspection reports, enforcement documentation, inspection field notes, and interviewed the responsible inspectors for 34 radioactive materials inspections conducted during the review period. The casework examined included a cross-section of inspections conducted by one former and eight current inspectors and covered a wide variety of inspection types. These included medical, academic, and research and development broadscope licensees; industrial radiography; well logging; self-shielded irradiator; service provider; gamma knife; positron emission tomography; veterinarian nuclear medicine; medical; nuclear pharmacy; portable gauges; and reciprocity licensees. The review also included both initial and followup Increased Controls inspections. Appendix C lists the inspection casework files reviewed, with case-specific comments, as well as the results of the inspector accompaniments.

Based on the evaluation of casework, the review team determined that inspections covered all aspects of the licensees' radiation safety programs. The review team noted that inspection reports were generally thorough, complete, consistent, and of high quality with sufficient documentation to support that licensees' performances with respect to health, safety, and security were acceptable. Inspection report documentation supported violations, recommendations made to licensees, unresolved safety issues, and discussions held with licensees during exit interviews.

The Materials Section's inspection procedures are consistent with the inspection guidance found in IMC 2800. At the conclusion of each inspection, the inspectors have the option to send inspection findings from the office or to use a form similar to NRC's Form 591 that can be left with the licensee at the conclusion of the inspection. The Materials Section uses this form to document both clear inspections and inspections identifying infractions, deficiencies, or recommendations. The inspector can require a written response from the licensee describing

corrective actions to address any infractions, deficiencies, or recommendations. Inspectors can also use this form to document investigations, field site surveys, and close-out surveys. Violations are considered the most severe type of finding and can only be dispatched from the office after management review and approval.

The Materials Section performed quality assurance peer reviews on at least 20 percent of all inspection documentation. All inspection documentation is entered into the Office's electronic filing system, which is accessible to all staff members.

The Materials Section performs staff accompaniments annually. The Materials Section Supervisor accompanied each Health Physicist yearly. He accompanied each Program Manager every other year. In the interim years, Program Managers performed accompaniments of each other. The Materials Section uses this system so that the Program Managers have the benefit of being accompanied by other senior staff members and not just the Materials Section Supervisor.

The review team determined that documents involving Increased Controls inspections were protected, segregated from the electronic file storage system, and maintained in a locked file cabinet with limited access. Files are maintained in visually distinct folders so staff can easily differentiate them from other files for licensees subject to the Increased Controls. Documents observed were sufficiently marked as sensitive information to be withheld from public disclosure.

The review team verified that the Office maintains an adequate supply of appropriately calibrated survey instruments to support the inspection program, and to respond to radioactive materials incidents. Instruments used to support the materials inspection program are sent either to the University of Washington Calibration Laboratory, or the manufacturer, for calibration.

The Office receives laboratory and sample analysis support from the State laboratory. The State laboratory is a licensee of the Office and performs sample analysis for multiple programs within the Department. The laboratory has a wide array of analytical equipment capable of detailed radiochemistry analysis. The equipment includes high purity germanium detectors, gamma counters, and various scintillation counters.

The review team accompanied four of the Section's inspectors during the week of April 14-17, 2008, at a nuclear cardiology office, two surgery centers performing radioactive seed implants, a gamma knife center, and a research facility using a self-shielded irradiator. The inspectors demonstrated appropriate performance-based inspection techniques and knowledge of the regulations. The inspectors were well trained, prepared for the inspections, and thorough in their audits of the licensees' radiation safety programs. The inspectors conducted interviews with appropriate personnel, observed licensed operations, conducted confirmatory measurements, and utilized good health physics practices. The inspectors held entrance and exit meetings with the appropriate level of licensee management. The review team determined that the inspections were adequate to assess radiological health, safety, and security at the licensed facilities.

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

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

The review team examined completed licensing casework and interviewed license reviewers for 28 specific licenses. Licensing actions were reviewed for completeness, consistency, possession authorization, qualifications of authorized users, adequacy of facilities and equipment, adherence to good health physics practices, financial assurance, operating and emergency procedures, appropriateness of license conditions, and overall technical quality. The casework was also reviewed for timeliness, use of appropriate deficiency letters and cover letters, reference to appropriate regulations, supporting documentation, consideration of enforcement history, pre-licensing visits, peer/supervisory review, and proper signatures.

The licensing casework was selected to provide a representative sample of licensing actions completed during the review period. Licensing actions selected for evaluation included five new licenses, nine renewals, nine amendments, and five license terminations. Files reviewed included a cross-section of license types, including: medical diagnostic and therapy, brachytherapy, gamma knife, industrial radiography, nuclear pharmacies, and industrial licensees. The casework sample represented work from each of the license reviewers. A listing of the licensing casework reviewed, with case-specific comments, may be found in Appendix D.

All licensing actions in the Materials Section are assigned a tracking number and logged into a computer tracking system. For routine amendments, the action is then given to a license reviewer. For new license applications, the Materials Section sends a letter notifying local government officials of the proposed use of radioactive materials in their jurisdiction. State law (Revised Code of Washington (RCW) 70.98.80) requires this notification. Local officials have 20 days from the date of the notification to provide written comment on the proposed facility. After this 20-day period has elapsed, the application is assigned to a reviewer.

If needed, the reviewer generates a deficiency letter and produces a draft licensing action upon final resolution of all deficiency items. The draft licensing action receives a quality assurance (QA) review by peer license reviewers. Corrections are made, as needed, and the licensing action is issued. The license reviewers in the Materials Section have signature authority and sign their own licensing actions. The QA reviewer initials each final licensing action, and places a QA checklist in the file. Each license reviewer uses boilerplate licenses specific to the type of licensing actions (i.e., industrial, medical, or laboratory) to ensure consistency in standard licenses. As another QA measure, the Materials Section Supervisor reviews approximately 10 percent of all licensing actions that the Materials Section issues.

The review team noted the licensing actions were of high quality and consistent with the Material Section's procedures, the State's regulations, and good health physics practices. The consistent use of templates and peer reviews contribute to the overall high quality noted in the casework reviews.

The Materials Section transmits copies of medical licenses they have amended within a calendar quarter to each of their nuclear pharmacy licensees. This enables the pharmacy to

cross-reference with the "hard copy" they maintain on file. The State's nuclear pharmacy licensees support this practice, as it allows them to have a current copy of their clients' licenses. The nuclear pharmacy licensees have agreed to maintain appropriate control over the license documents in their possession. This practice will continue until the nationwide electronic license verification system is populated and functional. The review team recommended, and the MRB agreed, that the State's practice of transmitting copies of amended medical licenses to nuclear pharmacies for verification of license possession limits, is a good practice.

The review team evaluated several license files where financial assurance for decommissioning was required. Those licensees have submitted the decommissioning funding plan required under Washington's regulations. The review team determined that the Office has appropriately identified licensees required to maintain financial assurance and have taken appropriate steps to ensure the licensees remain compliant with the financial assurance requirements. Financial instruments are appropriately protected from loss or theft.

The review team found that decommissioning licensing actions were well documented, showing appropriate transfer records and/or appropriate disposal methods and records, confirmatory surveys, and survey records. License terminations were well documented, showing appropriate transfer and survey records.

The Materials Section performs pre-licensing checks of all new applicants and new authorized users. The method incorporates the use of elements identified in the NRC's NUREG-1556, Volume 20, "Consolidated Guidance About Materials Licenses - Guidance About Administrative Licensing Procedures," to verify that the applicant will use requested radioactive materials as intended. Methods used include checks with the Washington Secretary of State's office and local office of the Department of Revenue. Additionally, the reviewers use various on-line search mechanisms and interagency communication to verify the identity of individuals. The Materials Section has a policy of hand-delivering all new licenses. Each applicant is subject to an on-site evaluation of their radiation safety and security programs prior to license receipt. This practice ensures that applicants have adequate radiation safety and security programs in place prior to the licensees' taking possession of radioactive material. This also serves as the "pre-licensing visit." The Materials Section was aware of NRC's recent revision of the pre-licensing guidance and has implemented the essential objectives of the revised guidance.

The review team examined the Materials Section's licensing practices regarding Increased Controls and Fingerprinting Orders. The review team noted that the Materials Section added legally binding license conditions to the licenses that met the criteria for implementing the Increased Controls, including fingerprinting, as appropriate. The review team analyzed the Section's methodology for identifying those licenses and found the rationale was thorough and accurate. License reviewers evaluate new license applications and license amendments using the same criteria.

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

In evaluating the effectiveness of the Materials Section's actions in responding to incidents and allegations, the review team examined the Office's response to the questionnaire relative to this indicator, evaluated selected incidents reported for Washington in the Nuclear Material Events Database (NMED) against those contained in the Materials Section's files, and evaluated the casework for 15 of 60 reported radioactive materials incidents. A listing of the casework examined can be found in Appendix E. The review team also evaluated the Materials Section's response to five allegations involving radioactive materials reported directly to the State during the review period. The NRC did not refer any allegations to the State during the review period.

When notified of an incident or an allegation, the Materials Section Supervisor and staff discuss the initial response and the need for an on-site investigation. The Materials Section maintains a database for tracking the status of all incidents and allegations. If the incident meets the reportability thresholds, as established in the NRC's Office of Federal and State Materials and Environmental Management Programs (FSME) Procedure SA-300 "Reporting Material Events," the Materials Section promptly notifies the NRC Headquarters Operations Center. If the investigation is complex and extends over a period of time, NMED is appropriately updated, using the established template. Of the incidents evaluated by the review team, all had been reported to the NRC within the required time frame and been properly completed in NMED.

The incidents selected for review included both medical and industrial events involving lost or stolen radioactive material, overexposures, damaged equipment, contamination events, a release of radioactive material, and equipment failures. The review team determined that the Materials Section's responses to incidents were thorough, complete, and comprehensive. Initial responses were prompt and well coordinated, and the level of effort was commensurate with the health and safety significance. The review team noted that at the conclusion of investigations, inspectors generated narrative reports that thoroughly documented the investigations. Records were stored in the Office's electronic filing system and were marked appropriately.

The review team discussed the reporting of incidents involving certain naturally occurring and accelerator-produced material (NARM) with the Office managers. A review of the tracking database verified that no incidents involving NARM had been reported since the November 30, 2007 waiver termination date for expansion of the definition of "byproduct material," as established by the Energy Policy Act of 2005. Office managers understood the requirement to report NARM events to the NMED contractor.

In evaluating the effectiveness of the Materials Section's response to allegations, the review team evaluated the casework for five allegations. The review team concluded that the Materials Section consistently took prompt and appropriate action in response to concerns raised. The review team noted that the Materials Section thoroughly documented the investigations and retained all necessary documentation to appropriately close the allegations. The review team determined the allegers of the conclusion of their investigation. The review team determined that the Materials Section adequately protected the identity of allegers.

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

#### 4.0 NON-COMMON PERFORMANCE INDICATORS

IMPEP identifies four non-common performance indicators to be used in reviewing Agreement State Programs: (1) Compatibility Requirements; (2) Sealed Source and Device Evaluation Program; (3) Low-level Radioactive Waste Disposal Program; and (4) Uranium Recovery Program. Washington's Agreement includes all of the non-common performance indicators.

#### 4.1 <u>Compatibility Requirements</u>

#### 4.1.1 Legislation

Washington became an Agreement State in 1966. The Department is designated as the State's radiation control agency and implements the radiation control program. The effective statutory authority for control of radioactive materials is contained in RCW 70.98, "Nuclear Energy and Radiation" and RCW 70.121, "Mill Tailings, Licensing and Perpetual Care." The program also is affected by RCW 70.94, "Washington Clean Air Act."

During the review period, the Washington legislature passed a proposed bill affecting the radiation control program, giving the Office permission to increase radioactive materials license fees up to 30 percent and x-ray registrant fees up to 40 percent. A public hearing on the fee increase bill took place on May 30, 2008. The State filed the results of that public hearing within a few days of the public hearing. The fee increase went into effect 30 days after that filing date.

#### 4.1.2 Program Elements Required for Compatibility

The RCW applies to all ionizing radiation and provides the statutory authority for radioactive materials, the low-level radioactive waste, and the uranium mill programs. Regulations are provided in the Washington Administrative Code. Washington requires a license for possession and use of all radioactive material, including NARM. Washington 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 approximately 6 to 8 months from the developmental stage to the final adoption by the Secretary of Health and filing with the Code Reviser's Office, after which the rules become effective in 31 days. Washington can adopt NRC amendments in this short time frame as "Exception" rules. An Exception rule is allowed when the program adopts a Federal rule without material change. This shortened process relies on the Federal rulemaking work which provides equivalent documentation to the State's required initial Reasoning for the Rulemaking, Economic Impact Analysis, Small Business Economic Impact Statements, and Legislatively Significant Analysis (cost benefit analysis).

The public, the NRC, other agencies, and all potentially affected licensees and registrants are offered an opportunity to comment during the rulemaking process. Comments are considered and incorporated, as appropriate, before the regulations are finalized, approved, and filed. The Office also has the authority to issue legally binding requirements (e.g., license conditions) in lieu of regulations until compatible regulations become effective.

The review team noted that Washington was up to date on all but one NRC regulatory amendment currently required for compatibility. That amendment, "Compatibility with IAEA Transportation Safety Standards," which was due for Agreement State adoption by October 2007, was reviewed for compatibility by NRC staff subsequent to the IMPEP review. On June 18, 2008, the NRC notified the State of the results of the compatibility review. NRC staff had two comments on the State's final rule that will need to be addressed.

Since the previous IMPEP review, the State submitted seven packages covering eight amendments for compatibility reviews. The review team reminded Office managers that NRCidentified comments on one earlier submitted regulation package, "Requirements for Certain Generally Licensed Industrial Devices," have yet to be resolved.

The review team identified the following NRC amendments that the State will need to address in the future. The Office Director related that the amendments would be addressed in upcoming rulemakings or in the adoption of alternate legally binding requirements:

- "National Source Tracking System," 10 CFR Part 20 amendment (71 FR 65685), that is due for Agreement State adoption by January 31, 2009.
- "Medical Use of Byproduct Material Minor Corrections and Clarifications," 10 CFR Parts 32 and 35 amendment (72 FR 45147 and 72 FR 54207), that is due for Agreement State adoption by October 29, 2010.
- "Requirements for Expanded Definition of Byproduct Material," 10 CFR Parts 20, 30, 31, 32, 33, 35, 61, and 150 amendment (72 FR 55864), that is due for Agreement State adoption by November 30, 2010.
- "Exemptions From Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements," 10 CFR Parts 30, 31, 32 and 150 amendment (72 FR 58473), that is due for Agreement State adoption by December 17, 2010.
- "Occupational Dose Records, Labeling Containers, and Total Effective Dose Equivalent," 10 CFR Parts 19 and 20 amendment (72 FR 68043), that is due for Agreement State adoption by February 15, 2011.

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

4.2

In reviewing this indicator, the review team used three subelements to evaluate the Materials Section's performance regarding the Sealed Source and Device (SS&D) Evaluation Program. These subelements were: (1) Technical Staffing and Training; (2) Technical Quality of the Product Evaluation Program; and (3) Evaluation of Defects and Incidents Regarding SS&Ds.

In assessing the Materials Section's SS&D evaluation activities, the review team examined information contained in the Office's response to the IMPEP questionnaire for this indicator. The review team evaluated all SS&D evaluations and supporting documents processed during the review period. The Materials Section conducted one new SS&D evaluation and issued one amendment to an existing registration since the last review. The review team noted the staff's use of guidance documents and procedures, interviewed staff members involved in SS&D evaluations, and verified the use of regulations and inspections to enforce commitments made in the applications.

# 4.2.1 Technical Staffing and Training

The Materials Section has six reviewers who are qualified to perform safety evaluations of SS&D applications. All have degrees in a physical science or engineering and have attended the NRC's SS&D Workshop. The review team interviewed staff members involved in the reviews and determined that they were familiar with the procedures used in the evaluation of a device/source and had access to applicable reference documents.

# 4.2.2 <u>Technical Quality of the Product Evaluation Program</u>

The review team evaluated all SS&D actions issued during the review period. One of the actions, a NARM source distributor, was performed on behalf of the State of Wisconsin. This casework reviewed represented the efforts of three of the six SS&D reviewers. A list of SS&D casework examined, with case-specific comments, may be found in Appendix F.

Analysis of the casework and interviews with staff members confirmed that the Materials Section follows the recommended guidance from the NRC's SS&D Workshop and NUREG-1556, Volume 3, Revision 1, "Consolidated Guidance About Materials Licenses – Applications for Sealed Source and Device Evaluation and Registration." The review team confirmed that all applicable and pertinent American National Standards Institute standards, NUREG-1556 Series guides, NRC Regulatory Guides, and applicable references were available and used appropriately in performing the SS&D reviews

Registrations clearly summarized the product evaluations to provide license reviewers with adequate information to license the possession and use of the products. Deficiency letters clearly stated regulatory positions and all health and safety issues were addressed. The review team determined that the product evaluations were thorough, complete, consistent, of acceptable technical quality, and adequately addressed the integrity of the products during use and under accident conditions.

#### 4.2.3 Evaluation of Defects and Incidents Regarding SS&Ds

No incidents related to SS&D defects involving sources or devices registered by the State of Washington were reported during the review period. Incident procedures are in place should an SS&D-related incident occur. Office managers were aware of the need to look at such incidents as potentially generic in nature with possible wide-ranging effects.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Washington's performance with respect to the indicator, Sealed Source and Device Evaluation Program, was satisfactory.

#### 4.3 Low-level Radioactive Waste (LLRW) Disposal Program

In reviewing this indicator, the review team used five subelements to evaluate the Waste Section's performance regarding the LLRW disposal program. These subelements were: (1) Technical Staffing and Training, (2) Status of Low-level Radioactive Waste Disposal Inspection, (3) Technical Quality of Inspections, (4) Technical Quality of Licensing Actions, and (5) Technical Quality of Incident and Allegation Activities.

The Waste Section currently licenses US Ecology, Inc. (USE) to receive, handle, process, store, and dispose of LLRW at the Hanford site. The Waste Section also licenses the Perma-Fix Processing Facility and various aspects of the Uranium Milling and Mining Industry (see Section 4.4, below).

The Department's administration of its regulatory roles and responsibilities are properly included as part of the periodic IMPEP reviews. In conducting the review, it became apparent that implementation of some aspects of its regulatory program, particularly design and construction of a permanent cover for closed disposal trenches is dependent on administrative and technical decisions of another State agency, the Washington Department of Ecology (Ecology). This agency holds the long-term lease with the federal government and it is the State agency responsible for regulation of non-radioactive, hazardous constituents in disposed waste. Its authority derives in part from the State's Model Toxics Control Act. Over a decade ago, Ecology asserted its interest in conducting site investigations, particularly in the unsaturated zone beneath old, closed disposal units in order to ascertain the presence and characteristics of substances that are under Ecology's, not Department of Health, regulatory purview. Ecology's continuing investigations have significantly impacted the Department regarding the timing for implementation of a permanent disposal unit cover; the cover design; and the availability of funds for such implementation.

Based on the above, the review team suggested that the MRB consider the feasibility and appropriateness of inclusion of aspects of the Ecology program that are related to the regulatory oversight of the Hanford LLRW facility be considered for inclusion in the next IMPEP review. The MRB directed NRC staff to research this issue and inform them and the State of the resolution.

maintain the quality and performance of the LLRW program.

The Waste Section currently has nine full-time and part-time technical, managerial, and administrative staff members, with a total staffing level of 5.2 FTE devoted to the LLRW program. The LLRW program is also supported by the Environmental Monitoring and Assessment Section, the Emergency Preparedness Section, and the Air Emissions Section. The staff that currently supports the LLRW program includes the Waste Section Supervisor, an administrative assistant, and staff members with diversified backgrounds in health physics, engineering, and earth sciences. During the review period, the staff was relatively stable; therefore, the Waste Section was able to maintain a high level of technical competency. Since the 2003 IMPEP review, one staff member associated with the LLRW program left the Waste Section and has been reassigned to support other activities within the Office. She was replaced with an individual qualified in health physics and environmental engineering. The review team determined that, at the time of the review, the Waste Section's staffing level was adequate to

The Waste Section has a documented training and qualification program for staff members to perform licensing, inspection, and investigations of LLRW activities. The Waste Section has an established procedure for staff training consistent with the NRC/OAS Training Working Group Recommendations and IMC 1246. The Waste Section Supervisor indicated that they are in the process of reviewing and updating procedures, including the training procedure.

The review team determined that, for the most part, Waste Section staff members completed the required training and recommended training courses in accordance with Office requirements and consistent with IMC 1246. In a number of cases, training files were supplemented with a supervisory memo specifying the exact duties for which a staff member was qualified, but training records for several individuals were not complete. Based on interviews with the technical and administrative staff and an examination of staff qualifications, duties, and functions, the review team concluded that the Waste Section staff was highly qualified, with sufficient training, to carry out their regulatory duties. Office managers, after discussion with review team members, stated that they would update contents of several training forms in accordance with State procedures and supplement training files with summaries of education and experience provided by individuals, in an effort to improve training records. Subsequent to the review, the Waste Section Supervisor reported that the updated training records were placed in the files.

# 4.3.2 <u>Status of Low-level Radioactive Waste Disposal Inspection</u>

The disposal site is inspected annually, consistent with IMC 2800. Annual inspections are completed over the course of the year using partial inspections, with each partial inspection focusing on a different area. In addition to the annual inspections, the Waste Section on-site representative performs monthly inspections of the site and confirms licensee inspections in accordance with the requirements of the facility license. The review team confirmed the frequency of inspections through an analysis of inspection report files and interviews with the inspectors. The Waste Section Supervisor and inspection staff use a spreadsheet to track the status of inspections. This spreadsheet lists the portion of the annual inspection, the date of last inspection, and the inspector assigned to each portion of the annual inspection. A copy of this

spreadsheet was placed in the annual inspection files for Calendar Years 2005, 2006, 2007, and 2008.

The review team determined that inspection findings are communicated to the licensee in a timely manner. The Waste Section issues inspection findings to the licensee using a form similar to NRC's Form 591, which is typically issued on site upon completion of an inspection or included in a notice of correction letter issued within 30 days of the inspection.

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

The Waste Section's inspection procedures detail the frequency of inspections, inspection preparation requirements, inspection reporting requirements, and a checklist of licensing requirements. The procedures also include appropriate forms and sample letters for documenting findings.

The review team determined that the Waste Section monthly and annual inspections were thorough, technically accurate, complete, consistent, and of high quality with sufficient documentation to ensure that the licensee's performance with respect to protecting health and safety was acceptable. A review of the completed inspection reports revealed that inspection records are reviewed promptly by the Waste Section Supervisor. The review team found that followup inspections addressed previously identified open items and past violations. An annual summary is provided in each file identifying open items for the year and whether or not they were closed. The files contain the inspection checklist, field notes, notices to the licensee, and some digital photographs of the site. On-site files include information on waste generators, weekly summary of shipments, fence-line surveys performed by the inspectors, and waste container inspections. The review team also determined that supervisory accompaniments of each inspector were completed annually and documented.

On April 16-17, 2008, a review team member accompanied two Waste Management Section inspectors at USE's facility as indicated in Appendix C. The inspectors were well prepared and thorough in their review of the aspects of the licensee's radiation safety program included in the current module (site security, external dosimetry, radiological surveys, vehicle surveys, posting, interviews and follow-up). They conducted proper entrance and exit interviews with licensee management and safety staff. They covered the scope of the current inspection, discussed the status of previous identified items of noncompliance and clearly articulated any current noncompliances. Inspectors conducted interviews with non-supervisory site personnel during the course of the inspection to ascertain perspective on licensee commitment to safety and training. During the accompaniments, the inspectors demonstrated appropriate performance-based inspection techniques and knowledge of the regulations. The inspections were adequate to assess radiological health and safety at the licensed facility.

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

Since the 2003 IMPEP review, several factors impacted the licensing program for LLRW disposal. These included the completion of an Environmental Impact Statement (EIS) related to key decisions at the disposal facility; license renewal; implementation of new security requirements; investigation of ground contaminants, pursuant to the State Model Toxics Control

Act; and expansion of the definition of byproduct material, pursuant to the Energy Policy Act of 2005.

The USE license establishes regulatory conditions and procedures that the licensee must comply with regarding waste acceptance, site operation, and environmental monitoring. The license also contains conditions for the eventual closure and decommissioning of the LLRW site. The USE license was in timely renewal since January 1997 until it was renewed in October 2005 to accommodate information and enhancements discussed in the final EIS, initiated under the provisions of the State Environmental Policy Act, for the LLRW facility. These include considerations for design, implementation and funding of a final site cover as well as technical justification for quantities of diffuse waste. The Department and the Department of Ecology jointly prepared the EIS. The EIS provided a summary of the bases for regulatory decisions regarding relicensing, allowable amounts of diffuse waste, and a permanent disposal unit cover. It also included a provision for site investigation that addressed the Department of Ecology's concerns regarding hazardous, non-radioactive constituents.

The review team examined the final EIS, environmental monitoring data, and technical evaluations in support of licensing decisions and interviewed most of the staff involved in the preparation of these documents. The review team found that these documents were thorough, complete, consistent, and of acceptable technical quality.

The review team evaluated the four license amendments to the USE license that the Waste Section issued during the review period, as indicated in Appendix D. These amendments involved revisions to the facility standards manual, changes in monitoring frequency, and implementation of new security requirements. The review team also analyzed the basis for classification of radium-226, because discrete sources of radium-226 are now part of NRC's regulatory authority. The review team found that the licensing actions were thorough, complete, consistent, and of high quality, with health, safety, and security issues properly addressed.

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

The review team found that the Waste Section has procedures in place for handling incidents and allegations. The procedures for handling incidents include information on what constitutes an incident, appropriate documentation of an incident, reference to NRC abnormal occurrence criteria for States, and tracking of incident by management. The procedures for handling allegations include information on protecting the identity of the alleger, documentation of the allegation, and tracking the allegation by management. During the review period, the Waste Section received no reports of incidents or allegations pertaining to the LLRW disposal program.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Washington's performance with respect to the indicator, Low-Level Radioactive Waste Disposal Program, was satisfactory.

#### 4.4 Uranium Recovery Program

In reviewing this indicator, the review team used five subelements to evaluate the Waste Section's performance regarding the uranium recovery program. These subelements were:

- (1) Technical Staffing and Training, (2) Status of Uranium Recovery Inspection Program,
- (3) Technical Quality of Inspections, (4) Technical Quality of Licensing Actions, and
- (5) Technical Quality of Incident and Allegation Activities.

At the time of the review, the Waste Section had one licensed conventional mill site, Dawn Mining Company (Dawn). This site was placed in shutdown and initiated reclamation and decommissioning activities in 2001.

# 4.4.1 Technical Staffing and Training

Since the last IMPEP review, the uranium recovery program lost one half-time staff member and gained one full-time staff member, with a total staffing level of 1.7 FTE devoted to the uranium recovery program. The uranium recovery staff has a wide range of technical expertise including: materials licensing, inspection, civil engineering, geology, groundwater hydrology, geochemistry, and environmental science. Several members of the uranium recovery staff participated in inspections of the Dawn site during the review period. The review team determined that the Waste Section's staffing level is adequate to maintain the quality and performance of the uranium recovery program.

Interviews with uranium recovery staff members and reviews of training and qualification records revealed that the uranium recovery staff is experienced, technically competent, and has a good understanding of regulatory processes and requirements. The uranium recovery staff has the health physics and hydrology expertise necessary to adequately regulate the reclamation activities at the Dawn site.

Although the review team was satisfied that uranium recovery staff had the necessary experience and expertise to effectively regulate Dawn reclamation activities, documentation of training and qualification of uranium recovery staff members was not up to date for all program staff. Office managers committed to appropriately updating the training records of uranium recovery staff. Subsequent to the review, the Waste Section Supervisor reported that the training records, including summaries of education and experience, were placed in the files.

# 4.4.2 Status of Uranium Recovery Inspection Program

During the review period, the Office conducted annual inspections at the Dawn site, which covered all aspects of the uranium recovery program including: site security, personnel dose monitoring, internal audits, training, radiological controls and surveys, operations, environmental monitoring, instrumentation, site posting, and respiratory protection.

In addition to the comprehensive annual inspections, uranium recovery staff members conducted numerous inspections of significant activities at the Dawn site. During significant activities, uranium recovery staff conducted weekly inspections and collected water samples for analysis.

Based on the evaluation of inspection files, the review team determined that the Waste Section's inspection frequency exceeded the requirements of IMC 2801, "Uranium Mill and 11e.(2) Byproduct Material Disposal Site and Facility Inspection Program." The review team concluded that there were no overdue inspections.

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

The review team noted that the Waste Section's inspection program and procedures were consistent with NRC Inspection Procedure 87654, "Uranium Mill, In-Situ Leach Uranium Recovery, 11e.(2) Byproduct Material Disposal Site Decommissioning Inspection." Inspectors typically and appropriately observed licensee operations and made independent measurements during inspections, as appropriate. Inspectors used relevant procedures with checklists, previous inspection reports, and other background information for implementing their inspections. Annual comprehensive inspections covered all appropriate functional areas. The review team found that the inspection reports provided appropriate depth of coverage, addressed license conditions and the regulations, and demonstrated that the inspectors pursued corrective actions for items of noncompliance that were identified.

During the review period, the uranium recovery inspectors were accompanied by their supervisor annually. These accompaniments were adequately documented. The review team found that the Waste Section Supervisor routinely met with the uranium recovery inspectors to review inspection findings and to plan follow-up strategy regarding corrective actions.

On April 15, 2008, a review team member accompanied two Waste Section inspectors at the Dawn facility, as indicated in Appendix C. The inspectors were well prepared and thorough in their review of the aspects of the licensee's radiation safety program. They conducted proper entrance and exit interviews with licensee management and safety staff.

Inspectors conducted interviews with non-supervisory site personnel during the course of the inspection to ascertain perspective on licensee commitment to safety and training. During the accompaniments, the inspectors demonstrated appropriate performance-based inspection techniques and knowledge of the regulations. The inspections were adequate to assess radiological health and safety at the licensed facilities.

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

During the review period, the uranium recovery staff processed one licensing action in 2007 for the renewal of Dawn's license.

The review team evaluated documentation associated with the review of Dawn's renewal application and the issuance of the renewal including several deficiency letters and the amended license. The review team determined that the license amendment application was adequately evaluated, processed, and documented.

The review team noted that Dawn is required to submit the following annual reports: ALARA (acronym for "as low as is reasonable achievable") Audit Report, Environmental Monitoring Report, Facility Utilization Report, Closure Cost Estimate, and Integrated Project Schedule. The review team determined that the Waste Section staff adequately reviewed the incoming reports.

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

The review team found that the Waste Section has appropriate procedures in place for handling incidents and allegations.

During the review period, uranium recovery staff members responded to one incident in the uranium recovery area. The review team determined that the Office's response to the incident was thorough, complete, and comprehensive. There were no allegations reported for the Washington uranium recovery program during the review period.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Washington's performance with respect to the indicator, Uranium Recovery Program, was satisfactory.

#### 5.0 SUMMARY

As noted in Sections 3.0 and 4.0, Washington's performance was found satisfactory for all nine performance indicators. The review team made no recommendations in regard to program performance by the State. The review team identified one good practice. Overall, the review team recommended, and the MRB agreed, that the Washington Agreement State Program was 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 agreed, that the next full IMPEP review take place in approximately 4 years.

Below is the good practice, as mentioned earlier in the report:

The State transmits copies of medical licenses they have amended within a calendar quarter to each of their nuclear pharmacy licensees. This enables the pharmacy to cross-reference with the "hard copy" they maintain on file. The State's nuclear pharmacy licensees support this practice, as it allows them to have a current copy of their clients' licenses. (Section 3.4)

### LIST OF APPENDIXES AND ATTACHMENT

- Appendix A IMPEP Review Team Members
- Appendix B Washington Organization Charts
- Appendix C Inspection Casework Reviews
- Appendix D License Casework Reviews
- Appendix E Incident Casework Reviews
- Appendix F Sealed Source & Device Casework Reviews
- Attachment June 27, 2008, Letter from Mary C. Selecky Washington's Response to Draft IMPEP Report

# APPENDIX A

# IMPEP REVIEW TEAM MEMBERS

Name	Area of Responsibility							
James Lynch, Region III	Team Leader Technical Staffing and Training							
William Rautzen, FSME	Status of Materials Inspection Program Compatibility Requirements							
Randy Erickson, Region IV	Technical Quality of Inspections Technical Quality of Incident and Allegation Activities Inspector Accompaniments							
J. Marion Eaddy, III, North Carolina	Technical Quality of Licensing Actions Sealed Source and Device Evaluation Program							
James Shaffner, FSME	Low-level Radioactive Waste Disposal Program Inspector Accompaniments							
John Buckley, FSME	Uranium Recovery Program							

APPENDIX B

WASHINGTON ORGANIZATION CHARTS

ADAMS ACCESSION NO.: ML082070058



# 2006-2007 Organization Chart Washington State Government

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#### OFFICE OF RADIATION PROTECTION



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#### APPENDIX C

#### INSPECTION CASEWORK REVIEWS

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

File No.: 1 Licensee: University of Washington Inspection Type: Special, Announced Inspection Date: 10/27/06 File No.: 2 Licensee: University of Washington Inspection Type: Followup, Unannounced Inspection Date: 6/8/06 Comment: Inspection letter was sent 53 days after the inspection. File No.: 3 Licensee: Pacific Health Physics Inspection Type: Routine, Announced Inspection Date: 2/7/07 File No.: 4 Licensee: IsoRay, Inc. Inspection Type: Routine, Announced Inspection Date: 11/1/07 File No.: 5 Licensee: IsoRay, Inc. Inspection Type: Termination, Announced Inspection Date: 11/2/07 File No.: 6 Licensee: Battelle Memorial Institute Inspection Type: Routine, Announced Inspection Dates: 6/14/06 File No.: 7 Licensee: Swedish Medical Center Inspection Type: Routine, Unannounced Inspection Date: 3/16/06 File No.: 8 Licensee: Puget Sound Radiosurgery Inspection Type: Routine, Unannounced Inspection Date: 4/16/08

License No.: WN-C001-1 Priority: 3 Inspector: AG

License No.: WN-C001-1 Priority: 3 Inspectors: AG, JS

License No.: WN-L0167-1 Priority: 5 Inspectors: AG, JS

License No.: WN-L0213-1 Priority: 5 Inspector: AG

License No.: WN-L0213-1 Priority: 5 Inspector: AG

License No.: WN-L027-1 Priority: 3 Inspectors: AG, JS

License No.: WN-M008-1 Priority: 2 Inspector: CD

License No.: WN-M0268-1 Priority: 2 Inspector: CD

File No.: 9 Licensee: Edge Testing and Inspection Inspection Type: Special, Announced Inspection Date: 7/20/06

File No.: 10 Licensee: Edge Testing and Inspection Inspection Type: Routine, Announced Inspection Date: 7/20/06

File No.: 11 Licensee: Cardinal Health Spokane Inspection Type: Field, Unannounced Inspection Dates: 10/3/07

File No.: 12 Licensee: Cardiology Associates Inspection Type: Routine, Unannounced Inspection Date: 1/9/08

File No.: 13 Licensee: Rainland Farm Equine Clinic Inspection Type: Initial, Announced Inspection Date: 4/2/08

File No.: 14 Licensee: Vancouver Clinic PET/CT Inspection Type: Routine, Unannounced Inspection Date: 3/24/08

File No.: 15 Licensee: Phoenix Central Lab for Pets Inspection Type: Initial, Announced Inspection Dates: 8/5/04

File No.: 16 Licensee: PND Engineers Inspection Type: Routine, Unannounced Inspection Date: 9/7/05

File No.: 17 Licensee: Seattle Cancer Care Alliance Inspection Type: Termination, Announced Inspection Date: 11/4/03 License No.: WN-IR062-1 Priority: 1 Inspector: CL

License No.: WN-IR062-1 Priority: 1 Inspector: PW

License No.: WN-NP004-1 Priority: 2 Inspector: VD

License No.: WN-M0215-1 Priority: 5 Inspector: JK

License No.: WN-M0285-1 Priority: 5 Inspector: JS

License No.: WN-M0278-1 Priority: 5 Inspector: SM

License No.: WN-L0210-1 Priority: 5 Inspector: PW

License No.: WN-I0553-1 Priority: 5 Inspectors: WL, AG

License No.: WN-M0225-1 Priority: 3 Inspector: PW

File No.: 18 Licensee: Atlas Casting & Technology Inspection Type: Routine/Special, Announced Inspection Date: 11/20/07

File No.: 19 Licensee: Infectious Disease Research Institute Inspection Type: Initial, Announced Inspection Dates: 11/16/06

File No.: 20 Licensee: Infectious Disease Research Institute Inspection Type: Followup, Announced Inspection Dates: 12/15/06

File No.: 21 Licensee: Whitman College Inspection Type: Routine, Announced Inspection Date: 6/20/07

File No.: 22 Licensee: KeyMaster Technologies, Inc. Inspection Type: Routine, Announced Inspection Date: 10/24/07

File No.: 23 Licensee: Kennewick General Hospital Inspection Type: Routine, Unannounced Inspection Date: 10/21/03

File No.: 24 Licensee: Providence St. Peter Hospital Inspection Type: Routine, Unannounced Inspection Date: 9/21/07

File No.: 25 Licensee: Oregon Washington Laboratories Inspection Type: Special, Unannounced Inspection Date: 12/8/06

File No.: 26 Licensee: ISOSCAN, LLC Inspection Type: Routine, Unannounced Inspection Date: 2/19/08 License No.: WN-L0222-1 Priority: 5 Inspector: JS

License No.: WN-L0222-1 Priority: 5 Inspector: JS

License No.: WN-C010-1 Priority: 5 Inspector: VD

License No.: WN-I0282-1 Priority: 5 Inspector: CL

License No.: WN-M0178-1 Priority: 3 Inspector: CD

License No.: WN-M085-1 Priority: 3 Inspector: JK

License No.: WN-IR070-1 Priority: 1 Inspector: CL

License No.: WN-M0257-1 Priority: 5 Inspector: VD

File No.: 27 Licensee: VLST Corporation Inspection Type: Routine/Special, Announced Inspection Date: 4/17/08

File No.: 28 Licensee: The Doctor's Clinic Inspection Type: Routine, Announced Inspection Date: 4/15/08

File No.: 29 Licensee: Puyallup Ambulatory Surgery Center Inspection Type: Routine, Unannounced Inspection Date: 4/14/08

File No.: 30 Licensee: Thermo Electron Corporation Inspection Type: Reciprocity, Unannounced Inspection Date: 5/26/06

File No.: 31 Licensee: Voith Fabrics Inspection Type: Reciprocity, Unannounced Inspection Date: 10/26/05

File No.: 32 Licensee: J.L. Shepherd & Associates Inspection Type: Reciprocity/Special, Announced Inspection Date: 7/6/07

File No.: 33 Licensee: Alpha Omega Services, Inc. Inspection Type: Reciprocity/Special, Announced Inspection Dates: 12/4-5/07

File No.: 34 Licensee: Thermo Electron Corporation Inspection Type: Reciprocity, Unannounced Inspection Date: 9/16/04

File No.: 35 Licensee: US Ecology, Inc. Inspection Type: Routine, Announced Inspection Date: 1/18/07 License No.: WN-L0224-1 Priority: 3 Inspector: AG

License No.: WN-M0254-1 Priority: 3 Inspector: VD

License No.: WN-L0275-1 Priority: 3 Inspector: JK

License No.: RECIP-046 Priority: 5 Inspector: VD

License No.: RECIP-060 Priority: 5 Inspector: SM

License No.: RECIP-027 Priority: 5 Inspector: VD

License No.: RECIP-046 Priority: 5 Inspector: VD

License No.: RECIP-010 Priority: 3 Inspector: VD

License No.: WN-I019-2 Priority: Monthly Inspector: SM

File No.: 36 Licensee: US Ecology, Inc. Inspection Type: Routine, Unannounced Inspection Date: 6/21/07

File No.: 37 Licensee: US Ecology, Inc. Inspection Type: Routine, Unannounced Inspection Date: 10/25/07

File No.: 38 Licensee: Perma-Fix NW Inspection Type: Routine, Announced Inspection Dates: Various

File No.: 39 Licensee: Dawn Mining Company Inspection Type: Routine, Announced Inspection Dates: Various

File No.: 40 Licensee: Dawn Mining Company Inspection Type: Special, Announced Inspection Dates: Various

## License No.: WN-I019-2 Priority: 1 Inspectors: ME, SM, KS

License No.: WN-I019-2 Priority: 1 Inspectors: KS, SM, ME

License No.: WN-I0393-1 Priority: 1 Inspectors: KS, ME, SM

License No.: WN-1043-2 Priority: 1 Inspectors: DS, ME, KS, DT

> License No.: WN-1043-2 Priority: 1 Inspector: DS

#### INSPECTOR ACCOMPANIMENTS

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

Accompaniment No.: 1 Licensee: Puyallup Ambulatory Surgery Center Inspection Type: Routine, Unannounced Inspection Date: 4/14/08

Accompaniment No.: 2 Licensee: The Doctor's Clinic Inspection Type: Routine, Unannounced Inspection Date: 4/15/08

Accompaniment No.: 3 Licensee: Puget Sound Radiosurgery, LLC Inspection Type: Routine, Unannounced Inspection Date: 4/16/08 License No.: WN-M0275-1 Priority: 3 Inspector: JK

License No.: WN-M0254-1 Priority: 3 Inspector: VD

License No.: WN-M0268-1 Priority: 2 Inspector: CD

Accompaniment No.: 4 Licensee: VLST Corporation Inspection Type: Routine, Announced Inspection Date: 4/17/08

Accompaniment No.: 5 Licensee: Dawn Mining Company Inspection Type: Routine, Announced Inspection Date: 4/15/08

Accompaniment No.: 6 Licensee: US Ecology, Inc. Inspection Type: Routine, Announced Inspection Dates: 4/16-17/08 License No.: WN-L0224-1 Priority: 5 Inspector: AG

License No.: WN-I043-2 Priority: 1 Inspectors: DS, JR

License No.: WN-I019-2 Priority: 1 Inspectors: KS, SM

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#### APPENDIX D

#### LICENSE CASEWORK REVIEWS

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

File No.: 1 Licensee: IsoRay, Inc. Type of Action: New Date Issued: 7/19/04

File No.: 2 Licensee: Puget Sound Radiosurgery Type of Action: New Date Issued: 6/24/05

File No.: 3 Licensee: Troxler Electronic Laboratories Type of Action: Renewal Date Issued: 4/11/07

File No.: 4 Licensee: Geotech Consultants, Inc. Type of Action: Renewal Date Issued: 5/24/06

File No.: 5 Licensee: PetNet Solutions, Inc. - Kent Type of Action: Renewal Date Issued: 10/24/06

File No.: 6 Licensee: Cardinal Health 412, Inc. Type of Action: Termination Date Issued: 10/24/03

Comment:

Primary reviewer was not qualified to perform nuclear pharmacy reviews. Program Manager indicated that this amendment was for training.

File No.: 7 Licensee: deCODE biostructures Type of Action: Renewal Date Issued: In process License No.: WN-L0213-1 Amendment No.: N/A License Reviewer: AG

License No.: WN-M0268-1 Amendment No.: N/A License Reviewer: CD

License No.: WN-I0466-1 Amendment No.: 4 License Reviewer: PK

License No.: WN-I0278-1 Amendment No.: 9 License Reviewer: KS

License No.: WN-NP009-1 Amendment No.: 10 License Reviewer: KS

License No.: WN-NP010-1 Amendment No.: 3 License Reviewer: PW

License No.: WN-L0201-1 Amendment No.: N/A License Reviewer: AG

File No.: 8 Licensee: Washington State University Type of Action: Amendment Date Issued: 11/27/07

File No.: 9 Licensee: Advanced Inspection Technologies, Inc. Type of Action: Amendment Date Issued: 3/5/08

Comment:

License authorized possession of a source in excess of license guidance which limits quantities without specific topic areas being addressed. Justification was not clearly documented in renewal application. Interview with license reviewer and Program Manager indicated that the variance had been evaluated prior to approval.

File No.: 10 Licensee: U2 Technology, Inc. Type of Action: Termination Date Issued: 4/19/07

File No.: 11 Licensee: Caliber Inspections Type of Action: Renewal Date Issued: 9/25/06

File No.: 12 Licensee: Alliance Imaging, Inc. Type of Action: Amendment Date Issued: 10/12/07

File No.: 13 Licensee: Medi-Physics d/b/a GE Healthcare Type of Action: Routine Date Issued: 9/17/07

File No.: 14 Licensee: The Boeing Company Type of Action: Renewal Date Issued: Pending

File No.: 15 Licensee: ICOS Corporation Type of Action: Amendment Date Issued: 6/27/06 Amendment No.: 70 License Reviewer: AG

License No.: WN-C003-1

License No.: WN-IR071-1 Amendment No.: 2 License Reviewer: CL

License No.: WN-IR069-1 Amendment No.: 3 License Reviewer: CL

License No.: WN-IR001-1 Amendment No.: 36 License Reviewer: SM

License No.: WN-M0222-1 Amendment No.: 22 License Reviewer: CD

License No.: WN-NP002-1 Amendment No.: 30 License Reviewer: CD

License No.: WN-I005-1 Amendment No.: 66 License Reviewer: CL

License No.: WN-L0142-1 Amendment No.: 18 License Reviewer: VD

File No.: 16 Licensee: Molecular Imaging Corporation Type of Action: Termination Date Issued: 8/9/06

File No.: 17 Licensee: Northwest Hospital Gamma Knife Type of Action: Amendment Date Issued: 1/31/08

File No.: 18 Licensee: Rainland Farm Equine Clinic Type of Action: New Date Issued: 4/4/07

File No.: 19 Licensee: Evergreen State College Type of Action: Amendment Date Issued: 6/2/04

File No.: 20 Licensee: Inland Cardiology Associates Type of Action: Amendment Date Issued: 9/26/06

File No.: 21 Licensee: Whidbey General Hospital Type of Action: Amendment Date Issued: 1/4/08

File No.: 22 Licensee: Yakima Heart Center Type of Action: Renewal Date Issued: 1/7/08

File No.: 23 Licensee: Klickitat County Public Works Type of Action: New Date Issued: 9/28/06

File No.: 24 Licensee: Wormer and Associates Type of Action: Termination Date Issued: 6/27/06 License No.: WN-M0228-1 Amendment No.: 6 License Reviewer: VD

License No.: WN-M0201-1 Amendment No.: 15 License Reviewer: VD

License No.: WN-M0255-1 Amendment No.: N/A License Reviewer: JS

License No.: WN-C019-1 Amendment No.: 17 License Reviewer: AG

License No.: WN-M0167-1 Amendment No.: 22 License Reviewer: JS

License No.: WN-M0217-1 Amendment No.: 8 License Reviewer: JK

License No.: WN-M0244-1 Amendment No.: 4 License Reviewer: JK

License No.: WN-I0569-1 Amendment No.: N/A License Reviewer: PW

License No.: WN-I0534-1 Amendment No.: 2 License Reviewer: PW

File No.: 25 Licensee: James A. Sewell & Associates Type of Action: Renewal Date Issued: 6/12/06

File No.: 26 Licensee: Three Rivers Regional Wastewater Plant Type of Action: Termination Date Issued: 3/27/08

File No.: 27 Licensee: Solomon Park Research Institute Type of Action: Renewal Date Issued: 12/12/06

File No.: 28 Licensee: Northwest Technical Services Type of Action: New Date Issued: 12/2/06

File No.: 29 Licensee: Perma-Fix NW Type of Action: Amendment Date Issued: 11/30/05

File No.: 30 Licensee: Perma-Fix NW Type of Action: Amendment Date Issued: 1/16/08

File No.: 31 Licensee: US Ecology, Inc. Type of Action: Amendment Date Issued: 10/20/05

File No.: 32 Licensee: US Ecology, Inc. Type of Action: Amendment Date Issued: 6/7/07

File No.: 33 Licensee: US Ecology, Inc. Type of Action: Amendment Date Issued: 12/27/07 License No.: WN-I0385-1 Amendment No.: 7 License Reviewer: PW

License No.: WN-I0104-1 Amendment No.: 9 License Reviewer: SM

License No.: WN-L0199-1 Amendment No.: 2 License Reviewer: SM

License No.: WN-I0570-1 Amendment No.: N/A License Reviewer: SM

License No.: WN-I0393-1 Amendment No.: 22 License Reviewer: KS

License No.: WN-I0508-1 Amendment No.: 24 License Reviewer: KS

License No.: WN-I019-2 Amendment No.: 31 License Reviewers: Various

License No.: WN-I019-2 Amendment No.: 34 License Reviewers: KS, AT

> License No.: WN-I019-2 Amendment No.: 35 License Reviewer: KS

File No.: 34 Licensee: Dawn Mining Company Type of Action: Renewal Date Issued: 1/18/07

License No.: WN-I043-2 Amendment No.: 24 License Reviewers: Various

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#### APPENDIX E

#### INCIDENT CASEWORK REVIEWS

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

File No.: 1 Licensee: Swedish Medical Center Date of Incident: 11/17/03 Investigation Date: 11/18/03

File No.: 2 Licensee: Northwest Inspection Date of Incident: 7/25/04 Investigation Date: 7/26/04

File No.: 3 Licensee: Cardinal Health Date of Incident: 8/15/05 Investigation Date: 8/19/05

File No.: 4 Licensee: Earth Consultants Date of Incident: 11/19/05 Investigation Date: 11/19/05

File No.: 5 Licensee: Fort James Operating Company Date of Incident: 5/5/06 Investigation Date: 5/23/06

File No.: 6 Licensee: Auburn Regional Medical Center Date of Incident: 5/30/06 Investigation Date: 6/5/06

File No.: 7 Licensee: Sacred Heart Medical Center Date of Incident: 10/8/03 Investigation Date: 10/8/03 License No.: WN-M008-1 NMED Log No.: 030933 Type of Incident: Overexposure Type of Investigation: Telephone

License No.: WN-IR065-01 NMED Log No.: 040552 Type of Incident: Lost/Stolen Material Type of Investigation: Telephone

License No.: WN-NP005-1 NMED Log No.: 050617 Type of Incident: Lost/Stolen Material Type of Investigation: Telephone/Site Visit

License No.: WN-L061-1 NMED Log No.: 050773 Type of Incident: Damaged Equipment Type of Investigation: Telephone/Site Visit

> License No.: WN-I0228-1 NMED Log No.: 060409 Type of Incident: Lost/Stolen Material Type of Investigation: Telephone

License No.: WN-M0149-1 NMED Log No.: 060380 Type of Incident: Contamination Event Type of Investigation: Telephone

> License No.: WN-M031-1 NMED Log No.: 030807 Type of Incident: Release of RAM Type of Investigation: Telephone

File No.: 8 Licensee: Virginia Mason Medical Center Date of Incident: 11/29/06 Investigation Date: 12/5/06

File No.: 9 Licensee: Zipper Zeman Associates Date of Incident: 4/13/05 Investigation Date: 4/13/05

File No.: 10 Licensee: Acuren Inspection Date of Incident: 6/30/05 Investigation Date: 7/29/05

File No.: 11 Licensee: UW Harborview Gamma Knife Date of Incident: 11/16/06 Investigation Date: 11/22/06

File No.: 12 Licensee: IsoRay, Inc. Date of Incident: 10/4/06 Investigation Date: 10/4/06

File No.: 13 Licensee: Washington DOT Spokane Date of Incident: 9/28/07 Investigation Dates: 10/2/07

File No.: 14 Licensee: Siemens Medical Solutions Date of Incident: 10/21/04 Investigation Date: 10/21/04

File No.: 15 Licensee: PLSA Engineering Date of Incident: 8/8/04 Investigation Date: 8/9/04 License No.: WN-M048-1 NMED Log No.: 060744 Type of Incident: Release of RAM Type of Investigation: Telephone

License No.: WN-I0507-1 NMED Log No.: 050268 Type of Incident: Lost/Stolen Material Type of Investigation: Telephone

> License No.: WN-IR067-1 NMED Log No.: 050511 Type of Incident: Overexposure Type of Investigation: Telephone

> License No.: WN-M0219-1 NMED Log No.: 060716 Type of Incident: Overexposure Type of Investigation: Telephone

License No.: WN-L0213-1 NMED Log No.: 060630 Type of Incident: Lost/Stolen Material Type of Investigation: Telephone/Site Visit

License No.: WN-L035-1 NMED Log No.: 070608 Type of Incident: Damaged Equipment Type of Investigation: Telephone/Site Visit

> License No.: WN-L030-1 NMED Log No.: 040765 Type of Incident: Lost/Stolen Material Type of Investigation: Telephone

License No.: WN-I0143-1 NMED Log No.: 040564 Type of Incident: Lost/Stolen Material Type of Investigation: Telephone/Site Visit

#### APPENDIX F

## SEALED SOURCE & DEVICE CASEWORK REVIEWS

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

File No.: 1 Registry No.: WA-1220-S-101-S Applicant Name: IsoRay, Inc. Date Issued: 9/17/04

SS&D Type: (AA) Manual Brachytherapy Type of Action: New Reviewers: CD, AG

File No.: 2 Registry No.: WA-1032-D-102-S Applicant Name: GE Healthcare Date Issued: 10/31/04

SS&D Type: (B) Medical Radiography Imaging Type of Action: Amendment Reviewers: CD, AS

Comment:

Registration sheet issued by Washington on behalf of a NARM distributor in Wisconsin.

# ATTACHMENT

June 27, 2008, Letter from Mary C. Selecky Washington's Response to Draft IMPEP Report

ADAMS Accession No.: ML081840314



#### STATE OF WASHINGTON

#### DEPARTMENT OF HEALTH

PO Box 47890 • Olympia, Washington 98504-7890 Tel: (360) 236-4501 • FAX: (360) 586-7424 • TDD Relay Service: 1-800-833-6388

June 27, 2008

James L. Lynch, State Agreements Officer United States Nuclear Regulatory Commission 2443 Warrenville Road, Suite 210 Lisle, Illinois 60532-4352

Dear Mr. Lynch:

It was a pleasure to meet you and your team during the recent Integrated Materials Performance Evaluation Program review of our Office of Radiation Protection. These reviews provide valuable feedback on our program efforts by highlighting where improvements can be made, while at the same time validating the exemplary practices that are occurring. As you may imagine, I am very pleased with the positive feedback your team provided on our program efforts.

I appreciate the opportunity to comment on the draft report of your review. My staff has provided a few technical comments, which are enclosed.

Again, thank you for your team's thoroughness in helping Washington maintain not just an "adequate and compatible" program, but one that is a national leader. Protecting our residents from the potential harmful effects of radiation is one of the key program areas in our Environmental Health Division, and we will work with the results of your review to continue to make improvements in our efforts.

Sincerely,

Duyc Selecty

Mary C. Selecky Secretary

Enclosure

RECEIVED JUL 0 2 2008

# The Department of Health Office of Radiation Protection's technical comments on Draft Report – Integrated Materials Performance Evaluation Program Review of Washington Agreement State Program – May 5-9, 2008

Page 3 – 3rd paragraph – the last sentence states "Staff members are required to have a Bachelor's degree or equivalent experience ... "This is incorrect since a degree in a physical or biological science or engineering is required; there is no substitute. Furthermore, "two years experience in the use of radiation" is required in addition to the degree. If your focus is the basic educational requirement, this sentence can be corrected by deleting "or equivalent experience."

Page 3 – 4th paragraph – second line – verb tense correction as follows "...Office managers encourage and support training ..."

Page 3 – 6th paragraph – 4th line – "Approval of the rulemaking will allow the Office to add 2.5 full-time equivalents..." (not 5.7 as stated)

Page 6 – 3rd paragraph – Needs to be re-written as follows: "The Materials Section performs staff accompaniments annually. The Materials Section Supervisor accompanied each Health Physicist yearly. He accompanied each Program Manager every other year. In the interim years, Program Managers performed accompaniments of each other. The Materials Section uses this system so that the Managers have the benefit of being accompanied by other senior staff members and not just the Materials Section Supervisor."

Page 6 - 6th paragraph - 2nd line - delete "downtown"; the state laboratory is north of Seattle.

Page 7 – 4th paragraph – 8th line – the last two sentences are redundant. We suggest combining the two sentences to read as follows: "As another QA measure, the materials Section supervisor reviews approximately ten percent of all licensing actions that the Materials Section issues."

Page 8 – 4th paragraph – 6th line – should read "...local office of the Department of Revenue."

Page 9 – 4th paragraph – 9th line – we do not use NMED software. The sentence should read "…NMED is appropriately updated, using the established template."

Page 11 – 2nd paragraph – 3rd line – change "State" to "Health" – the final rule adoption is by the Secretary of Health prior to filing with the Code Reviser.

Page 11 – 2nd paragraph – 5th line – change last full sentence to read: "An Exception rule is allowed when the program adopts a federal rule without material change. This shortened process relies on the federal rulemaking work which provides equivalent documentation to the State's required initial Reasoning for the Rulemaking, Economic Impact Analysis, Small Business Economic Impact Statement, and legislatively Significant Analysis (cost benefit analysis)."

Page 14 – 3rd paragraph – 3rd line – insert "Environmental" to correctly identify "the Environmental Monitoring and Assessment Section."

Page 14 – 5th paragraph – add concluding sentence "The Section Supervisor reported that the updated training records were placed in the files within 30 days of the close of this review." (We can provide documentation if needed by the Team)

Page 15 - 1st paragraph – delete blank line in the 3rd line of the paragraph.

Page 17 – last paragraph – add concluding sentence "The Section Supervisor reported that the updated training records, including summaries of education and experience, were placed in the files within 30 days of the close of this review."

Page 18 – 6th paragraph – 2nd line – "supervisors" should be "supervisor".

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Appendix C, page C.5 – File # 36 should be noted as an Unannounced inspection, and add SM and KS as inspectors.

Appendix C, page C.5 – File # 37 should be noted as an Unannounced inspection, and add SM and ME as inspectors.

Appendix C, page C.5 - File # 38 - add SM as an inspector.