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

Dear Ms. Selecky:

The U.S. Nuclear Regulatory Commission (NRC) uses the Integrated Materials Performance Evaluation Program (IMPEP) in the evaluation of Agreement State programs. Enclosed for your review is the draft IMPEP report, which documents the results of the Agreement State review held in Washington on May 5-9, 2008. I was the team leader for the review. The review team's preliminary findings were discussed with you on the last day of the review. The review team's proposed recommendations are that the Washington Agreement State Program be found adequate to protect public health and safety and compatible with NRC's program.

NRC conducts periodic reviews of Agreement State programs to ensure that public health and safety are adequately protected from the potential hazards associated with the use of radioactive materials and that Agreement State programs are compatible with NRC's program. The process, titled IMPEP, employs a team of NRC and Agreement State staff to assess Agreement State and NRC Regional radioactive materials programs. All reviews use common criteria in the assessment and place primary emphasis on performance. Four additional areas applicable to your program have been identified as non-common performance indicators and are also addressed in the assessment. The final determination of adequacy and compatibility of each program, based on the review team's report, is made by a Management Review Board (MRB) composed of NRC managers and an Agreement State program manager, who serves as a liaison to the MRB.

In accordance with procedures for implementation of IMPEP, we are providing you with a copy of the review team's draft report for your review and comment prior to submitting the report to the MRB. Comments are requested within four weeks from your receipt of this letter. This schedule will permit the issuance of the final report in a timely manner that will be responsive to your needs.

The team will review your response, make any necessary changes to the report, and issue it to the MRB as a proposed final report. Our preliminary scheduling places the Washington MRB meeting in the week of July 21, 2008. I will coordinate with you to establish the date for the MRB review of the Washington report. The NRC will provide invitational travel for you or your designee to attend the MRB meeting at NRC Headquarters in Rockville, Maryland. The NRC has video conferencing capability if it is more convenient for the State to participate through this medium. Please contact me if you desire to establish a video conference for the meeting.

- 2 -

If you have any questions regarding the enclosed report, please contact me at (630) 829-9661.

Thank you for your cooperation.

Sincerely,

/RA/

James L. Lynch State Agreements Officer

Enclosure:

Draft Washington IMPEP Report

cc w/encl:

Gary Robertson, Director Office of Radiation Protection Department of Health 111 Israel Road, SE P. O. Box 47827 Olympia, WA 98504-7827 Letter to Mary Selecky from James L. Lynch dated June 5, 2008.

bcc (via ADAMS e-mail distribution):
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# INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM REVIEW OF THE WASHINGTON AGREEMENT STATE PROGRAM

May 5-9, 2008

**DRAFT REPORT** 

#### 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 managers on the last day of the review.

[A paragraph on the results of the Management Review Board (MRB) meeting will be included in the final report.]

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 of Health (the Department). Organization charts for the [Department/Division/Office/etc.] are included in Appendix B.

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

In preparation for the review, a questionnaire addressing the common and applicable non-common 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 to answer questions or clarify issues. 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 non-common performance indicators, and Section 5.0 summarizes the review team's findings.

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

During the previous IMPEP review, which concluded on September 12, 2003, the review team made one recommendation in regard to 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 Management Review Board 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. Staff members are required to have a Bachelor's degree or equivalent experience in a physical or biological science or engineering.

The Office maintains training and qualification records for each staff member. The review team noted that Office managers encourages and supports 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 5.7 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 recommends that Washington's performance with respect to the indicator, Technical Staffing and Training, be found satisfactory.

#### 3.2 Status of Materials Inspection Program

The review team focused on five factors while reviewing this indicator: inspection frequency, overdue inspections, initial inspections of new licenses, timely dispatch of inspection findings to licensees, and performance of reciprocity inspections. The review team's evaluation was based on the 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 Priority 1, 2, and 3 licensees during the 5-year review period. In their response to the questionnaire, the Office indicated that there were no overdue inspections of those Priority 1, 2, and 3 licensees. The review team verified 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 verified that there were no overdue initial inspections at the time of the review.

The review team evaluated the Materials Section's timeliness of issuance of inspection reports. 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 exceeded 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 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. Subsequent inspections of Increased Controls licensees evaluated the pertinent aspects of the security measures.

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

#### 3.3 Technical Quality of Inspections

The review team evaluated inspection reports, enforcement documentation, inspection field notes, and interviewed 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 ensure 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, 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 Program Manager yearly. He accompanied each Health Physicist every other year. In the interim years, Program Managers performed accompaniments of the Health Physicists. The Materials Section uses this system so that the Health Physicists have the benefit of being accompanied by various 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 were held in individual color coded folders, identifying each licensee 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, as well as to respond to radioactive materials incidents and emergency conditions. 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, located in the downtown Seattle area. 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. The inspectors conducted inspections 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 recommends that Washington's performance with respect to the indicator, Technical Quality of Inspections, be found 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, 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 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 casework was checked for retention of necessary documentation and supporting data.

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, approximately 10 percent of licensing actions are reviewed by the Program Managers. 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 quality noted in the casework reviews.

The Materials Section has a practice of transmitting 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' licensees. The nuclear pharmacy licensees have agreed to maintain appropriate document 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 recommends that the State's practice of transmitting copies of amended medical licenses to nuclear pharmacies for verification of license possession limits, be found a good practice.

The Office requires certain licensees to maintain financial assurance for decommissioning. 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's evaluation revealed 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 reviewed licensing actions involving removal of a building or site from the license. 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. In one instance, the Materials Section performed confirmatory surveys and found that contamination levels were not as presented within the licensee's report. The Materials Section now requires the licensee to amend their license at all times when they decommission an area of use under the broad scope license. The acceptable methodology for performing calculations and determining sampling criteria were derived with the help and guidance of the Environmental Radiation Monitoring and Assessment Section. 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 Departments 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. The Materials Section implemented aspects of the revised guidance on a limited scale and is assessing whether additional actions will be required for compatibility.

The review team examined the Materials Section's licensing practices in regard to the 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 recommends that Washington's performance with respect to the indicator, Technical Quality of Licensing Actions, be found satisfactory.

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

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, based on the safety significance. 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, typically by e-mail, using the information template established for NMED. If the investigation is complex and extends over a period of time, NMED is appropriately updated, using the NMED software. 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 Materials Section immediately dispatched inspectors to a site when the possibility of an immediate threat to public health and safety existed. When no immediate threat was present and the Materials Section determined that the licensee had qualified, competent individuals investigating the incident, the Materials Section generally responded telephonically with an on-site followup at a later date. 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 Materials Section notified 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 recommends that Washington's performance with respect to the indicator, Technical Quality of Incident and Allegation Activities, 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) 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 Compatibility Requirements

#### 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 was scheduled to take place on May 30, 2008. The State will file the results of that public hearing within a few days of the public hearing. The fee increase will potentially go 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 State 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 in the State of Washington applies as NRC amendments are from a Federal agency, and have had much of the background rulemaking work done for the State, such as 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 evaluated the Office's response to the questionnaire relative to this indicator, reviewed the status of regulations required to be adopted by the State under the NRC's adequacy and compatibility policy, and verified the adoption of regulations with data obtained from the State Regulation Status Sheet that FSME maintains.

The review team noted that Washington is 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, is currently under compatibility review by NRC staff.

Since the previous review, the State submitted seven packages covering eight amendments for compatibility reviews. With these submissions, Washington is up-to-date on regulation development. The review team reminded Office managers that NRC-identified 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 recommends that Washington's performance with respect to the indicator, Compatibility Requirements, be found satisfactory.

#### 4.2 Sealed Source and Device Evaluation Program

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 Technical Quality of the Product Evaluation Program

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 recommends that Washington's performance with respect to the indicator, Sealed Source and Device Evaluation Program, be found 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 suggests 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.

#### 4.3.1 Technical Staffing and Training

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 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 maintain the quality and performance of the LLRW program.

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.

#### 4.3.2 Status of Low-Level Radioactive Waste Disposal Inspection

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 Technical Quality of Licensing Actions

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 Technical Quality of Incident and Allegation Activities

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 recommends that Washington's performance with respect to the indicator, Low-Level Radioactive Waste Disposal Program, be found 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.

#### 4.4.2 <u>Status of Uranium Recovery Inspection Program</u>

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 was more frequent than those prescribed in 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.

The review team determined that inspection reports were issued within 30 days of inspections. The Waste Section Supervisor promptly reviewed all inspection reports. Appropriate followup actions were conducted when items of noncompliance were identified. Inspection casework files were easily retrieved and accessible.

#### 4.4.3 Technical Quality of Inspections

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 supervisors 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 mine and milling facilities, 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 Technical Quality of Licensing Actions

During the review period, the uranium recovery staff processed one licensing action in 2007 for the renewal of Dawn's license. Dawn's license expired in 2003 and was placed in timely renewal until 2007.

The review team evaluated documentation associated with the review of Dawn's 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 Technical Quality of Incident and Allegation Activities

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. Uranium recovery program staff members effectively surveyed the affected area for contamination. There were no allegations reported for the Washington uranium recovery program during the review period.

Based on the IMPEP evaluation criteria, the review team recommends that Washington's performance with respect to the indicator, Uranium Recovery Program, be found satisfactory.

#### 5.0 SUMMARY

As noted in Sections 3.0 and 4.0, the review team found Washington's performance to be 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 potential good practice. Accordingly, the review team recommends that the Washington Agreement State Program be found 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 recommends that the next full IMPEP review take place in approximately four years.

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

The State has a practice of transmitting 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)

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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

## 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.: ML081140419

#### APPENDIX C

#### INSPECTION CASEWORK REVIEWS

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

File No.: 1

Licensee: University of Washington License No.: WN-C001-1

Inspection Type: Special, Announced Priority: 3
Inspection Date: 10/27/06 Inspector: AG

File No.: 2

Licensee: University of Washington License No.: WN-C001-1

Inspection Type: Followup, Unannounced Priority: 3

Inspection Date: 6/8/06 Inspectors: AG, JS

Comment: Inspection letter was sent 53 days after the inspection.

File No.: 3

Licensee: Pacific Health Physics License No.: WN-L0167-1

Inspection Type: Routine, Announced Priority: 5

Inspection Date: 2/7/07 Inspectors: AG, JS

File No.: 4

Licensee: IsoRay, Inc. License No.: WN-L0213-1

Inspection Type: Routine, Announced Priority: 5
Inspection Date: 11/1/07 Inspector: AG

inspector.

File No.: 5

Licensee: IsoRay, Inc. License No.: WN-L0213-1

Inspection Type: Termination, Announced Priority: 5
Inspection Date: 11/2/07 Inspector: AG

File No.: 6

Licensee: Battelle Memorial Institute License No.: WN-L027-1

Inspection Type: Routine, Announced Priority: 3

Inspection Dates: 6/14/06 Inspectors: AG, JS

File No.: 7

Licensee: Swedish Medical Center License No.: WN-M008-1

Inspection Type: Routine, Unannounced Priority: 2

Inspection Date: 3/16/06 Inspector: CD

File No.: 8

Licensee: Puget Sound Radiosurgery License No.: WN-M0268-1

Inspection Type: Routine, Unannounced Priority: 2

Inspection Date: 4/16/08 Inspector: CD

Licensee: Edge Testing and Inspection License No.: WN-IR062-1

Inspection Type: Special, Announced Priority: 1

Inspection Date: 7/20/06 Inspector: CL

File No.: 10

Licensee: Edge Testing and Inspection License No.: WN-IR062-1

Inspection Type: Routine, Announced Priority: 1

Inspection Date: 7/20/06 Inspector: PW

File No.: 11

Licensee: Cardinal Health Spokane License No.: WN-NP004-1

Inspection Type: Field, Unannounced Priority: 2

Inspection Dates: 10/3/07 Inspector: VD

File No.: 12

Licensee: Cardiology Associates License No.: WN-M0215-1

Inspection Type: Routine, Unannounced Priority: 5

Inspection Date: 1/9/08 Inspector: JK

File No.: 13

Licensee: Rainland Farm Equine Clinic License No.: WN-M0285-1

Inspection Type: Initial, Announced Priority: 5

Inspection Date: 4/2/08 Inspector: JS

File No.: 14

Licensee: Vancouver Clinic PET/CT License No.: WN-M0278-1

Inspection Type: Routine, Unannounced Priority: 5

Inspection Date: 3/24/08 Inspector: SM

File No.: 15

Licensee: Phoenix Central Lab for Pets License No.: WN-L0210-1

Inspection Type: Initial, Announced Priority: 5

Inspection Dates: 8/5/04 Inspector: PW

File No.: 16

Licensee: PND Engineers License No.: WN-I0553-1

Inspection Type: Routine, Unannounced Priority: 5

Inspection Date: 9/7/05 Inspectors: WL, AG

File No.: 17

Licensee: Seattle Cancer Care Alliance License No.: WN-M0225-1

Inspection Type: Termination, Announced Priority: 3

Inspection Date: 11/4/03 Inspector: PW

Licensee: Atlas Casting & Technology License No.: WN-IR006-1

Inspection Type: Routine/Special, Announced Priority: 2

Inspection Date: 11/20/07 Inspector: SM

File No.: 19

Licensee: Infectious Disease Research Institute License No.: WN-L0222-1

Inspection Type: Initial, Announced Priority: 5

Inspection Dates: 11/16/06 Inspector: JS

File No.: 20

Licensee: Infectious Disease Research Institute License No.: WN-L0222-1

Inspection Type: Followup, Announced Priority: 5

Inspection Dates: 12/15/06 Inspector: JS

File No.: 21

Licensee: Whitman College License No.: WN-C010-1

Inspection Type: Routine, Announced Priority: 5

Inspection Date: 6/20/07 Inspector: VD

File No.: 22

Licensee: KeyMaster Technologies, Inc. License No.: WN-I0282-1

Inspection Type: Routine, Announced Priority: 5

Inspection Date: 10/24/07 Inspector: CL

File No.: 23

Licensee: Kennewick General Hospital License No.: WN-M0178-1

Inspection Type: Routine, Unannounced Priority: 3

Inspection Date: 10/21/03 Inspector: CD

File No.: 24

Licensee: Providence St. Peter Hospital License No.: WN-M085-1

Inspection Type: Routine, Unannounced Priority: 3

Inspection Date: 9/21/07 Inspector: JK

File No.: 25

Licensee: Oregon Washington Laboratories License No.: WN-IR070-1

Inspection Type: Special, Unannounced Priority: 1

Inspection Date: 12/8/06 Inspector: CL

File No.: 26

Licensee: ISOSCAN, LLC License No.: WN-M0257-1

Inspection Type: Routine, Unannounced Priority: 5

Inspection Date: 2/19/08 Inspector: VD

License No.: WN-L0224-1 Licensee: VLST Corporation

Inspection Type: Routine/Special, Announced Priority: 3 Inspection Date: 4/17/08

Inspector: AG

File No.: 28

Licensee: The Doctor's Clinic License No.: WN-M0254-1

Inspection Type: Routine, Announced Priority: 3

Inspection Date: 4/15/08 Inspector: VD

File No.: 29

Licensee: Puyallup Ambulatory Surgery Center License No.: WN-L0275-1

Inspection Type: Routine, Unannounced Priority: 3

Inspection Date: 4/14/08 Inspector: JK

File No.: 30

Licensee: Thermo Electron Corporation License No.: RECIP-046

Inspection Type: Reciprocity, Unannounced Priority: 5

Inspection Date: 5/26/06 Inspector: VD

File No.: 31

License No.: RECIP-060 Licensee: Voith Fabrics

Inspection Type: Reciprocity, Unannounced Priority: 5

Inspection Date: 10/26/05 Inspector: SM

File No.: 32

Licensee: J. L. Shepherd & Associates License No.: RECIP-027

Inspection Type: Reciprocity/Special, Announced Priority: 5

Inspection Date: 7/6/07 Inspector: VD

File No.: 33

Licensee: Alpha Omega Services, Inc. License No.: RECIP-046

Inspection Type: Reciprocity/Special, Announced Priority: 5

Inspection Dates: 12/4-5/07 Inspector: VD

File No.: 34

Licensee: Thermo Electron Corporation License No.: RECIP-010

Inspection Type: Reciprocity, Unannounced Priority: 3

Inspection Date: 9/16/04 Inspector: VD

File No.: 35

Licensee: US Ecology, Inc. License No.: WN-I019-2

Inspection Type: Routine, Announced Priority: Monthly

Inspection Date: 1/18/07 Inspector: SM

Licensee: US Ecology, Inc. License No.: WN-I019-2

Inspection Type: Routine, Announced Priority: 1

Inspection Date: 6/21/07 Inspector: ME

File No.: 37

Licensee: US Ecology, Inc. License No.: WN-I019-2

Inspection Type: Routine, Announced Priority: 1

Inspection Date: 10/25/07 Inspector: KS

File No.: 38

Licensee: Perma-Fix NW License No.: WN-I0393-1

Inspection Type: Routine, Announced Priority: 1

Inspection Dates: Various Inspectors: KS, ME

File No.: 39

Licensee: Dawn Mining Company License No.: WN-1043-2

Inspection Type: Routine, Announced Priority: 1

Inspection Dates: Various Inspectors: DS, ME, KS, DT

File No.: 40

Licensee: Dawn Mining Company License No.: WN-1043-2

Inspection Type: Special, Announced Priority: 1

Inspection Dates: Various 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 License No.: WN-M0275-1

Inspection Type: Routine, Unannounced Priority: 3

Inspection Date: 4/14/08 Inspector: JK

Accompaniment No.: 2

Licensee: The Doctor's Clinic License No.: WN-M0254-1

Inspection Type: Routine, Unannounced Priority: 3

Inspection Date: 4/15/08 Inspector: VD

Accompaniment No.: 3

Licensee: Puget Sound Radiosurgery, LLC License No.: WN-M0268-1

Inspection Type: Routine, Unannounced Priority: 2

Inspection Date: 4/16/08 Inspector: CD

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Accompaniment No.: 4

Licensee: VLST Corporation License No.: WN-L0224-1

Inspection Type: Routine, Announced Priority: 5

Inspection Date: 4/17/08 Inspector: AG

Accompaniment No.: 5

Licensee: Dawn Mining Company License No.: WN-I043-2

Inspection Type: Routine, Announced Priority: 1

Inspection Date: 4/15/08 Inspectors: DS, JR

Accompaniment No.: 6

Licensee: US Ecology, Inc. License No.: WN-I019-2

Inspection Type: Routine, Announced Priority: 1

Inspection Dates: 4/16-17/08 Inspectors: KS, SM

#### 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

License No.: WN-L0213-1

Amendment No.: N/A

License Reviewer: AG

File No.: 2

Licensee: Puget Sound Radiosurgery

Type of Action: New

Date Issued: 6/24/05

License No.: WN-M0268-1

Amendment No.: N/A

License Reviewer: CD

File No.: 3

Licensee: Troxler Electronic Laboratories

Type of Action: Renewal

Date Issued: 4/11/07

License No.: WN-I0466-1

Amendment No.: 4

License Reviewer: PK

File No.: 4

Licensee: Geotech Consultants, Inc.

Type of Action: Renewal

Date Issued: 5/24/06

License No.: WN-I0278-1

Amendment No.: 9

License Reviewer: KS

File No.: 5

Licensee: PetNet Solutions, Inc. - Kent

Type of Action: Renewal

Date Issued: 10/24/06

License No.: WN-NP009-1

Amendment No.: 10

License Reviewer: KS

File No.: 6

Licensee: Cardinal Health 412, Inc.

Type of Action: Termination

Date Issued: 10/24/03

License No.: WN-NP010-1

Amendment No.: 3

License Reviewer: PW

#### 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-L0201-1

Amendment No.: N/A

License Reviewer: AG

Licensee: Washington State University

Type of Action: Amendment

Date Issued: 11/27/07

License No.: WN-C003-1

Amendment No.: 70

License Reviewer: AG

File No.: 9

Licensee: Advanced Inspection Technologies, Inc.

Type of Action: Amendment

Date Issued: 3/5/08

License No.: WN-IR071-1

Amendment No.: 2

License Reviewer: CL

#### 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

License No.: WN-IR069-1

Amendment No.: 3

License Reviewer: CL

File No.: 11

Licensee: Caliber Inspections

Type of Action: Renewal

Date Issued: 9/25/06

License No.: WN-IR001-1

Amendment No.: 36

License Reviewer: SM

File No.: 12

Licensee: Alliance Imaging, Inc.

Type of Action: Amendment

Date Issued: 10/12/07

License No.: WN-M0222-1

Amendment No.: 22

License Reviewer: CD

File No.: 13

Licensee: Medi-Physics d/b/a GE Healthcare

Type of Action: Routine

Date Issued: 9/17/07

License No.: WN-NP002-1

Amendment No.: 30

License Reviewer: CD

File No.: 14

Licensee: The Boeing Company

Type of Action: Renewal

Date Issued: Pending

License No.: WN-I005-1

Amendment No.: 66

License Reviewer: CL

File No.: 15

Licensee: ICOS Corporation

Type of Action: Amendment

Date Issued: 6/27/06

License No.: WN-L0142-1

Amendment No.: 18

License Reviewer: VD

Licensee: Molecular Imaging Corporation

License No.: WN-M0228-1

Type of Action: Termination

Amendment No.: 6

Type of Action: Termination Amendment No.: 6
Date Issued: 8/9/06 License Reviewer: VD

File No.: 17

Licensee: Northwest Hospital Gamma Knife License No.: WN-M0201-1

Type of Action: Amendment No.: 15
Date Issued: 1/31/08

Amendment No.: 15
License Reviewer: VD

File No.: 18

Licensee: Rainland Farm Equine Clinic License No.: WN-M0255-1

Type of Action: New Amendment No.: N/A
Date Issued: 4/4/07 License Reviewer: JS

File No.: 19

Licensee: Evergreen State College

Type of Action: Amendment

License No.: WN-C019-1

Amendment No.: 17

Date Issued: 6/2/04 License Reviewer: AG

File No.: 20

Licensee: Inland Cardiology Associates License No.: WN-M0167-1

Type of Action: Amendment Amendment No.: 22
Date Issued: 9/26/06 License Reviewer: JS

File No.: 21

Licensee: Whidbey General Hospital License No.: WN-M0217-1

Type of Action: Amendment No.: 8
Date Issued: 1/4/08

Amendment No.: 8
License Reviewer: JK

File No.: 22

Licensee: Yakima Heart Center License No.: WN-M0244-1

Type of Action: Renewal Amendment No.: 4
Date Issued: 1/7/08 License Reviewer: JK

File No.: 23

Licensee: Klickitat County Public Works

License No.: WN-I0569-1

Type of Action: New
Date Issued: 9/28/06
Amendment No.: N/A
License Reviewer: PW

File No.: 24

Licensee: Wormer and Associates License No.: WN-I0534-1

Type of Action: Termination Amendment No.: 2
Date Issued: 6/27/06 License Reviewer: PW

Licensee: James A. Sewell & Associates

Type of Action: Renewal

Date Issued: 6/12/06

License No.: WN-I0385-1

Amendment No.: 7

License Reviewer: PW

File No.: 26

Licensee: Three Rivers Regional Wastewater Plant

Type of Action: Termination

Date Issued: 3/27/08

License No.: WN-I0104-1

Amendment No.: 9

License Reviewer: SM

File No.: 27

Licensee: Solomon Park Research Institute

Type of Action: Renewal

Date Issued: 12/12/06

License No.: WN-L0199-1

Amendment No.: 2

License Reviewer: SM

File No.: 28

Licensee: Northwest Technical Services

Type of Action: New

Date Issued: 12/2/06

License No.: WN-I0570-1

Amendment No.: N/A

License Reviewer: SM

File No.: 29

Licensee: Perma-Fix NW

Type of Action: Amendment

Date Issued: 11/30/05

License No.: WN-I0393-1

Amendment No.: 22

License Reviewer: KS

File No.: 30

Licensee: Perma-Fix NW

Type of Action: Amendment

Date Issued: 1/16/08

License No.: WN-I0508-1

Amendment No.: 24

License Reviewer: KS

File No.: 31

Licensee: US Ecology, Inc.

Type of Action: Amendment

Date Issued: 10/20/05

License No.: WN-I019-2

Amendment No.: 31

License Reviewers: Various

File No.: 32

Licensee: US Ecology, Inc.

Type of Action: Amendment

Date Issued: 6/7/07

License No.: WN-I019-2

Amendment No.: 34

License Reviewers: KS, AT

File No.: 33

Licensee: US Ecology, Inc.

Type of Action: Amendment

Date Issued: 12/27/07

License No.: WN-I019-2

Amendment No.: 35

License Reviewer: KS

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File No.: 34

License No.: WN-I043-2

Licensee: Dawn Mining Company
Type of Action: Renewal
Date Issued: 1/18/07 Amendment No.: 24 License Reviewers: Various

#### 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

License No.: WN-M008-1

NMED Log No.: 030933

Type of Incident: Overexposure

Type of Investigation: Telephone

File No.: 2

Licensee: Northwest Inspection

Date of Incident: 7/25/04

Investigation Date: 7/26/04

License No.: WN-IR065-01

NMED Log No.: 040552

Type of Incident: Lost/Stolen Material

Type of Investigation: Telephone

File No.: 3

Licensee: Cardinal Health

Date of Incident: 8/15/05

Investigation Date: 8/19/05

Type of Incident: Lost/Stolen Material
Type of Investigation: Telephone/Site Visit

File No.: 4

Licensee: Earth Consultants

Date of Incident: 11/19/05

Investigation Date: 11/19/05

Type of Incident: Damaged Equipment
Type of Investigation: Telephone/Site Visit

File No.: 5

Licensee: Fort James Operating Company License No.: WN-I0228-1

Date of Incident: 5/5/06 NMED Log No.: 060409 Investigation Date: 5/23/06 Type of Incident: Lost/Stolen Material Type of Investigation: Telephone

File No.: 6

Licensee: Auburn Regional Medical Center License No.: WN-M0149-1

Date of Incident: 5/30/06

Investigation Date: 6/5/06

Type of Investigation: Telephone

File No.: 7

Licensee: Sacred Heart Medical Center License No.: WN-M031-1

Date of Incident: 10/8/03 NMED Log No.: 030807 Investigation Date: 10/8/03 Type of Incident: Release of RAM Type of Investigation: Telephone

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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 SS&D Type: (AA) Manual Brachytherapy Applicant Name: IsoRay, Inc.

Date Issued: 9/17/04 Seviewers: CD, AG

File No.: 2

Registry No.: WA-1032-D-102-S SS&D Type: (B) Medical Radiography Imaging Applicant Name: GE Healthcare Type of Action: Amendment Date Issued: 10/31/04 Reviewers: CD, AS

#### Comment:

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