February 6, 2012

Michael Fine, M.D., Director
Rhode Island Department of Health
3 Capitol Hill
Providence, RI 02908

Dear Dr. Fine:

On January 17, 2012, the Management Review Board (MRB) met to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) report on the Rhode Island Agreement State Program. The MRB found the Rhode Island program adequate, but needs improvement, and compatible with the U.S. Nuclear Regulatory Commission's (NRC) program.

Section 5.0, page 13, of the enclosed final report contains a summary of the IMPEP team's findings and recommendations. Based on the results of the current IMPEP review, the next IMPEP review will take place in approximately 4 years from the current review, with an early periodic meeting scheduled in 1 year from the date of current review. The MRB determined that a period of monitoring should be initiated for Rhode Island. Monitoring is implemented when weaknesses in a program result in a less than fully satisfactory performance for one or more performance indicators.

The MRB acknowledged your response, dated January 6, 2012, to the draft report and the review team's recommendations. Your response did not fully respond to all recommendations. We would appreciate additional information from you in that regard along with further development of your action plan for the recommendations. If you wish, Monica Orendi, your Regional State Agreement Officer, can assist with the development of the action plan. Your action plan will be reviewed during the quarterly calls conducted under monitoring and subsequent reviews.

The MRB noted that due to State budget matters the Program Supervisor position has been vacant since 2008. The position has not been allowed to be filled and is not expected to be filled in Rhode Island during the current fiscal year. The MRB recognizes the challenges facing the Program including those identified by the IMPEP team, and that filling the vacant position may help to address those challenges.

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

Sincerely,

/RA/

Michael F. Weber
Deputy Executive Director for Materials, Waste,
Research, State, Tribal and Compliance Programs
Office of the Executive Director for Operations

Enclosure:
Rhode Island Final IMPEP Report

cc w/encl: Raymond Rusin, Chief
Office of Facilities Regulation

Edward W. Johnson, Deputy Director
RI Emergency Management Agency
State Liaison Officer

INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF THE RHODE ISLAND AGREEMENT STATE PROGRAM

OCTOBER 24-28, 2011

FINAL REPORT

Enclosure 1

EXECUTIVE SUMMARY

This report presents the results of the Integrated Materials Performance Evaluation Program (IMPEP) review of the Rhode Island Agreement State Program. The review was conducted during the period of October 24-28, 2011, by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of Ohio.

Based on the results of this review, the review team recommended, and the MRB agreed, that Rhode Island's performance be found unsatisfactory for the performance indicator Status of the Materials Inspection Program; satisfactory, but needs improvement, for the performance indicators Technical Quality of Inspections and Compatibility Requirements; and satisfactory for the three other indicators reviewed. The review team made six recommendations regarding the performance of the Rhode Island Agreement State Program. These recommendations include areas for improvement to correct identified performance deficiencies and weaknesses in Rhode Island's Agreement State Program. One of these recommendations remains open from the 2007 IMPEP review. The recommendations address: (1) documentation of the State's training and qualification program for license reviewers and inspectors, including the reimplementation, use, and update of licensing and inspection qualification cards for each staff member; (2) taking appropriate measures to conduct Priority 1, 2, and 3 inspections and initial inspections in accordance with the inspection priority in NRC's Inspection Manual Chapter 2800, "Materials Inspection Program"; (3) taking measures to ensure that inspection records and narrative reports are documented in accordance with the Program's Inspection Manual; (4) ensuring that a Program supervisor or other appropriately qualified senior staff member accompany each inspector, at least annually, to ensure quality and consistency in the inspection program; (5) conducting initial and subsequent security-related inspections in a manner that provides for verification of licensee compliance with the requirements; and (6) adoption of all currently overdue regulations required for compatibility and adopt future regulation amendments within their required three year time frame.

The review team recommended, and the MRB agreed, that the Rhode Island Agreement State Program be found adequate, but needs improvement, and compatible with NRC's program.

Based on the results of the current IMPEP review, and in accordance with the criteria in NRC Management Directive 5.6, the review team recommended, and the MRB agreed, that NRC initiate a period of Monitoring for Rhode Island. The review team further recommended, and the MRB agreed, that a Periodic Meeting be held within one year of the current review and that a full IMPEP review take place in four years from the date of the current review.

1.0 INTRODUCTION

This report presents the results of the review of the Rhode Island Agreement State Program. The onsite portion of the review was conducted during the period of October 24-28, 2011, by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of Ohio. Team members are identified in Appendix A. The review was conducted in accordance with the "Implementation of the Integrated Materials Performance Evaluation Program and Rescission of Final General Statement of Policy," published in the *Federal Register* on October 16, 1997, and NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)," dated February 26, 2004. Preliminary results of the review, which covered the period of October 27, 2007, to October 28, 2011, were discussed with Rhode Island managers on the last day of the review.

A draft of this report was provided to Rhode Island for factual comment on November 17, 2011. The State responded by electronic mail dated January 6, 2012. A copy of the State's response is included as an Attachment to this report. The Management Review Board (MRB) met on January 17, 2012, to consider the proposed final report. The MRB found the Rhode Island Agreement State Program adequate, but needs improvement, and compatible with the NRC's program.

The Rhode Island Agreement State Program (the Program) is administered by the Office of Facilities Regulation (the Office), in the Division of Environmental and Health Services Regulation (the Division). The Division is part of the Rhode Island Department of Health (the Department). Organizational charts for the Program, the Office, the Division, and the Department are included as Appendix B.

At the time of the review, the Rhode Island Agreement State Program regulated approximately 49 specific licenses authorizing byproduct, source, and certain special nuclear 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 Rhode Island.

In preparation for the review, a questionnaire addressing the common and applicable non-common performance indicators was sent to the Program on June 27, 2011. The Program provided its response to the questionnaire via email on October 7, 2011, with supplemental information provided on October 11, 2011 and October 20, 2011. A publicly available version of the questionnaire response can be found in NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML112840079.

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

Section 2.0 provides the status of recommendations from the previous IMPEP. The results of the review for 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 indicator, and Section 5.0 summarizes the review team's findings and recommendations. The review team's recommendations are comments that relate directly to the Program's performance. A response is requested from the State to all recommendations in the final report.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous IMPEP review, which covered the period of November 18, 2003, to October 25, 2007, the review team made two recommendations regarding program performance. The current status of the recommendations is as follows:

1. The review team recommends that the State take appropriate measures to conduct Priority 1, 2, and 3 inspections and initial inspections in accordance with the inspection priority schedule in NRC Inspection Manual Chapter (IMC) 2800. (Section 3.2 of the 2007 IMPEP report)

   Status: The review team calculated that the Program performed 28 percent of its Priority 1, 2, and 3, and initial inspections overdue during the review period. The review team found no Priority 1, 2, and 3 inspections were overdue at the time of the review. Although no initial inspections were conducted overdue during the review period, one initial inspection was overdue at the time of the review. Based on the results from the current review, the review team is unable to close this recommendation and determined that the actions taken by the State to address the recommendation have not been effective. This recommendation remains open.

2. The review team recommends that the State develop a written documentation of its radioactive materials licensing program to ensure that a memorialized program exists to train and transfer knowledge to future, as well as current, staff. (Section 3.4 of the 2007 IMPEP report)

   Status: On October 26, 2011, the Program Manager published a memo to document the specific guidance to be used by Program staff when performing licensing actions. The memo documented: (1) the conditions under which the NRC NUREG-1556 series will be used; (2) the specific circumstances where Rhode Island requires submission and verification in addition to the information requested in the NRC NUREG-1556 series; and (3) the use of Rhode Island specific pre-licensing guidance. This recommendation is closed.

3.0 COMMON PERFORMANCE INDICATORS

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

3.1 Technical Staffing and Training

Issues central to the evaluation of this indicator include the Program'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 Program's questionnaire response relative to this indicator; interviewed managers and staff; and reviewed job descriptions, training plans, and training records. The review team also considered any possible workload backlogs in evaluating this indicator.

The Program consists of four technical staff positions and a vacant Supervising Radiological Health Specialist (Program Supervisor) position. The four technical staff positions consist of three license reviewers/inspectors, whose roles vary in support of the Program, and an individual that provides support to emergency response and equipment maintenance. During the review period, one license reviewer/inspector left in January 2009 and then returned to the Program in June 2010. All four technical staff members provide partial support to the radioactive materials program ranging from 0.2 full-time equivalents (FTE) to 0.9 FTE. Based on discussions and information provided in response to the questionnaire, the team determined that 1.8 FTE are allocated to the radioactive materials program. This does not include the contribution from the vacant Program Supervisor position. With a total of 49 licenses, the level of staffing appeared adequate to perform the Program's licensing and inspection activities.

The Program Supervisor position has been vacant since October 2008. Efforts to fill the vacancy are ongoing; however, due to current State budget matters the position has not been allowed to be filled and is not expected to be approved to be filled in Rhode Island fiscal year 2012. The Rhode Island Fiscal Year 2008 Budget Act, which became effective July 1, 2007, created a restricted receipts account for deposit of the Program's licensing fees. The dedicated fund for the Program allows the radioactive materials program to be financially self-sufficient, recovering associated costs through licensing fees. Even though this dedicated fund is in place, since the State as a whole currently has budget issues, the Program has not been approved to use these dedicated funds to fill the vacant position.

The review team found that the Program trains its technical staff in a manner that is consistent with the requirements in the NRC/Organization of Agreement States Training Working Group Report and NRC's Inspection Manual Chapter (IMC) 1246, "Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area", however this training and qualification program is not formally documented. The technical staff members have degrees in a physical or life science and have several years of professional experience in radiation protection. The Program uses on-the-job training to supplement formal coursework. Staff members are typically assigned increasingly complex duties as they progress through the qualification process. The review team found that while personnel file memoranda qualification cards were in place during the last IMPEP review, they have not been updated to reflect the current qualifications of the technical staff. At the time of the review, one technical staff member was a fully qualified license reviewer/inspector, and the other technical staff member was still completing the qualification process. As a result of the lack of formal documentation of the State's training program and the lack of current or updated technical staff qualification cards, it was difficult to determine what was necessary for the one technical staff member to become fully qualified for licensing and inspection activities. The review team recommends that the State document its training and qualification program for license reviewers and inspectors,

including the reimplementation, use, and update of licensing and inspection qualification cards for each staff member.

Rhode Island statute Title 23, Chapter 23, Section 23-1.3-13 provides for the creation of an 11-member State Radiation Advisory Commission (the Advisory Commission), whose members have expertise in radiation protection and radiation health. The Advisory Commission provides advice on radiation protection issues and regulations to the Program and meets on an as-needed basis. Since the Advisory Commission functions in a purely advisory capacity, the Program has the discretion to accept or reject direction it receives from the Advisory Commission. The review team identified no potential conflicts of interest.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Rhode Island'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 in 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 Program's questionnaire response relative to this indicator, the data gathered from the Program's inspection data tracking system, the examination of completed inspection casework, and the interviews with managers and staff.

The review team verified that the Program's inspection frequencies for all types of radioactive material licenses are at least the same frequency as NRC's inspection frequencies, listed in NRC IMC 2800, "Materials Inspection Program." The review team determined that the Program conducted a total of 42 inspections of Priority 1, 2, and 3 licensees during the review period. Of the 42 Priority 1, 2, and 3 inspections, the review team determined that 12 inspections were completed overdue during the review period by more than 25 percent of the inspection frequency prescribed by IMC 2800. The review team identified that at the time of the review, no Priority 1, 2, and 3 inspections were overdue by more than 25 percent of the inspection frequency prescribed by IMC 2800. Although inspections were conducted overdue throughout the review period, the number of inspections conducted overdue was higher at the beginning of the review period. After the December 2, 2009, Periodic Meeting with NRC, the Program increased its efforts to conduct inspections in a timely manner, resulting in fewer inspections being conducted overdue during the latter part of the review period.

The review team determined that the Program issued four new licenses during the review period. Three of the initial inspections were conducted within one year of license issuance in accordance with Rhode Island's equivalent inspection manual to NRC's IMC 2800. The review team identified that one new license had not been inspected within one year of license issuance and was still overdue at the time of the review. As required by IMC 2800 and by Rhode Island's equivalent inspection manual, initial inspections should be conducted within 12 months of license issuance. This applies even if the licensee still has not received licensed material. This criterion was discussed with Program management and staff and the review team determined that the reason this initial inspection had not been conducted was due to a misunderstanding of

the criteria for initial inspections of licensees that have not possessed licensed material or performed licensed activities. The Program committed to conducting this overdue initial inspection. Overall, the review team calculated that the Program performed 28 percent of its Priority 1, 2, and 3, and initial inspections overdue during the review period.

The timely conduct of inspections has been an ongoing issue for the State. Specifically, the 2002 IMPEP also identified issues with inspection timeliness, which led to the State being placed on Heightened Oversight. A follow-up IMPEP performed in 2003 found improvement in this area, which resulted in the State being taken off Heightened Oversight. During the 2007 IMPEP review, the State was found satisfactory, but needs improvement for this indicator. The 2007 IMPEP review did not make a determination as to the percent of overdue inspections during the review period, but noted that many inspections had been conducted overdue during the review period and several were overdue at the time of the review. The 2007 IMPEP made a recommendation that the State take appropriate measures to conduct Priority 1, 2, and 3 inspections and initial inspections in accordance with the inspection priority in IMC 2800 (Section 3.2 of the 2007 IMPEP report). Based on the results from the current review, the review team determined that the recommendation regarding conducting inspections in accordance with NRC's IMC 2800 should remain open.

The review team evaluated the Program's timeliness of issuance of inspection reports. The Program has a policy of issuing the inspection findings to licensees within 30 days from the date of the inspection. Inspection reports were generally issued to the licensee within 30 days. Of the 42 inspection files reviewed, the review team identified five inspection findings that were issued beyond the 30-day goal.

During the review period, the Program granted 49 reciprocity requests to candidate licensees based upon the criteria in IMC 1220, "Processing of NRC Form 241 and Inspection of Agreement State Licensees Operating under 10 CFR 150.20". The review team determined that the Program was unable to consistently perform inspections of 20 percent of the reciprocity licensees annually. During calendar years 2008 and 2009, the Program inspected less than 20 percent of candidate licensees operating under reciprocity. However, during calendar year 2010 and for January thru October 2011 the Program inspected greater than 20 percent of candidate licensees operating under reciprocity.

Based on the IMPEP evaluation, criteria the review team recommended, and the MRB agreed, that Rhode Island's performance with respect to the indicator, Status of Materials Inspection Program, be found unsatisfactory.

3.3 Technical Quality of Inspections

The review team evaluated 13 inspection reports that included inspection records, enforcement documentation and letters to licensees. The review team also interviewed the Program Manager as well as technical staff members who were responsible for radioactive materials inspections conducted during the review period. The casework reviewed covered a wide variety of inspection types, including academic broad scope, industrial radiography, nuclear pharmacy, self-shielded irradiators, and medical-written directives required. The casework reviewed represented inspections conducted by the two current members of the technical staff. Appendix

C lists the inspection casework files reviewed as well as the results of the inspector accompaniments performed by the review team.

Based on the review of casework, the review team noted that the methodology for documenting inspections was based on the Program's Radiation Control Agency Inspection Manual, dated May 18, 2002. The Program's Inspection Manual directs the staff to document inspections in an inspection record or a narrative report. The review team found that it was the practice of the inspectors that for routine health and safety inspections, the inspectors duplicated the previous inspection record or narrative report and, if no violations were found during the current inspection, the current inspection record or narrative report largely remained the same with no additional documentation. However, if the inspectors identified a violation, they would document it in an inspection record or narrative report. The review team identified several casework files where the current inspection record or narrative report had been duplicated and was nearly identical to several previous inspection records or narrative reports. Because each inspection is a snapshot in time, it is unlikely that the snapshot remains the same from inspection to inspection. Furthermore, inspection observations of licensed activities are likely to vary from inspection to inspection. The duplication of the previous inspection record can result in a static inspection record that is fixed at a point in time several inspections prior to the current inspection. The review team found that although the inspection records and narrative reports were completely filled in by the inspectors, the technical quality of the information contained therein was lacking. For Increased Controls inspections, the review team found that it was the practice of the inspectors that if the previous inspection did not result in any violations, the current inspection was not documented in an inspection record or a narrative report.

The Program's Inspection Manual provides instructions to staff regarding methods to document inspection results. As described above, the review team found that the Program's inspection documentation practices for inspection records and narrative reports often did not follow the Program's Inspection Manual. As a result, inspection records and narrative reports did not contain sufficient detail to: describe the inspection that was conducted, areas inspected, or observations made; contain sufficient documentation to ensure that licensees' performance with respect to health, safety and security were acceptable; provide the status of violations from previous inspections; or provide sufficient information to support identified violations. The issues with respect to inspection report or narrative report technical quality were compounded due to a lack of appropriate management review resulting from the vacancy of the Program Supervisor. The review team recommends that the State take measures to ensure that inspection records and narrative reports are documented in accordance with the Program's Inspection Manual.

The review team found that during the review period, the two inspectors had not been accompanied annually by a supervisor or other senior staff member during any year of the review period. The lack of supervisory accompaniments was due, in part, to the vacant Program Supervisor position. As noted in Office of Federal and State Materials and Environmental Management Programs (FSME) Procedure SA-102, "Reviewing the Common Performance Indicator, Technical Quality of Inspections," in an Agreement State where there is a vacancy in a supervisory position, the accompaniments may be performed by an experienced senior staff member until the vacancy is filled. The review team recommends that a Program supervisor or other appropriately qualified senior staff member accompany each inspector, at least annually, to ensure quality and consistency in the inspection program.

The review team noted that the Program maintained appropriately calibrated survey instruments to support the inspection program. The instrumentation is calibrated by an outside vendor according to the manufacturer's recommendations. The vendor utilizes National Institute of Standards and Technology traceable sources to perform calibrations. The Program uses a database to track each instrument, its current location, and next calibration date.

A review team member accompanied the two inspectors during the week of September 26, 2011. One inspector was a fully qualified inspector and the other inspector was qualified to independently inspect the license type selected for the accompaniment inspection. The license types inspected as part of the accompaniments included industrial radiography and veterinary therapeutic non-human use. Two of the inspections included a review of the licensee's implementation of the Increased Controls. The accompaniments and associated comments are identified in Appendix C.

The Program's Radiation Control Agency Inspection Manual, dated May 18, 2002, as well as the recent revision dated October 2011, describes the approach to be taken by Program inspectors while conducting inspections. Both of these documents describe that inspector emphasis should be placed on observing licensee performance, and that the review of licensee records should be directed toward verifying that current operations are in compliance rather than a review of historical records, which should only occur if the inspector believes it is necessary to determine the presence of a persistent problem. During the inspector accompaniments, the review team member observed both inspectors spend the majority of their inspection time directed toward a review of historical records rather than observing licensed activities and licensee performance or interviewing workers. This matter was discussed with the inspectors, who indicated that they performed the inspections in this manner because this is the way they were trained and has become a normal practice for them. The review team member discussed this with the Program manager, who indicated that the Department is very focused on performance objectives and that he would begin taking measures to instill these practices on the Program technical staff.

During the observed inspections of the Increased Controls and Fingerprinting requirements, the inspectors did not review or verify licensee compliance with many of the requirements. This matter was discussed with the inspectors, who indicated that the practice was that if the previous inspection did not result in any violations then the matter did not require review during future inspections. The practice of not verifying licensee compliance with many of the Increased Controls requirements is contrary to the purpose of performing an inspection. The Program may wish to review NRC's inspection guidance related to initial Increased Controls inspections found in NRC Temporary Instruction 2800/038, "Inspection of the Implementation of Increased Controls for Licensees Authorized to Possess Risk Significant Radioactive Material," dated March 30, 2006, and inspection guidance for subsequent inspections of Increased Controls licensees which was transmitted to the Agreement States in RCPD 07-006,"Continuing Inspections of Increased Controls Licensees," dated September 27, 2007. The review team recommends that the State conduct initial and subsequent security-related inspections in a manner that provides for verification of licensee compliance with the requirements.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Rhode Island's performance with respect to the indicator, Technical Quality of Inspections, be found satisfactory, but needs improvement.

3.4 Technical Quality of Licensing Actions

The review team examined completed licensing casework and interviewed the staff for 15 licensing actions. 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, operating and emergency procedures, appropriateness of the license conditions, Increased Controls, and overall technical quality. The casework was also reviewed for use of appropriate deficiency 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 documents 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, one renewal, five amendments, and four terminations. Casework reviewed included a cross-section of license types, including: industrial radiography; medical broad scope; veterinary non-human use; stereotactic radiosurgery; academic broad scope; nuclear pharmacy; manufacturing and distribution; portable gauges; medical institution-written directive required; medical private practice; and research and development. A listing of the licensing casework reviewed can be found in Appendix D.

All licensing actions received by the Program are assigned a log number in the Radiation Control Program computer tracking system. The licensing action is then assigned for review to one of two license reviewers for their action. The assigned license reviewer is responsible for reviews, deficiency letters, coordination with the licensee/applicant, and finalizing the licensing action. When a licensing action is completed, a senior staff member reviews the licensing action for quality and the Program manager signs and issues the licensing action. The review team noted that the licensing actions were consistent with the licensing guidance found in the State's regulations as well as the NRC NUREG-1556 series "Consolidated Guidance About Materials Licensees."

The review team found that the licensing actions were thorough, complete, consistent, and of high quality, with health, safety, and security issues properly addressed. License tie-down conditions were stated clearly, backed by information contained in the file, and auditable. Licensees' compliance histories were taken into account when reviewing all renewal applications and major amendments.

The review team evaluated a license termination that was found to be a thorough and complete documentation of the termination process, to include an on-site inspection and verification of material transfer. The review team found that terminated licensing actions were well-documented, showing appropriate material transfer and survey records. The review team noted that confirmatory surveys were conducted, when appropriate.

The review team found that the Program addressed maximum possession limits on all active radioactive materials licenses as requested by the FSME Letter RCPD-10-007, "Requesting Implementation of a Policy on Maximum Possession Limits for Radioactive Materials Licenses" dated June 21, 2010. The review team noted that the licensing casework files examined had maximum possession limits in accordance with the guidance provided by NRC.

The review team assessed the Program's implementation of NRC's pre-licensing guidance issued on September 22, 2008, and transmitted to the Agreement States via FSME Letter RCPD-08-020, "Requesting Implementation of the Checklist to Provide a Basis for Confidence That Radioactive Material Will Be Used as Specified on a License and the Checklist for Risk-Significant Radioactive Material." The Program had incorporated the NRC pre-licensing guidance into its own Rhode Island specific "Enhanced Pre-Licensing Guidance." The review team found that the Program determined and documented the basis of confidence, through consistent use of the pre-licensing checklist and guidance, that radioactive materials will be used as intended and as described in the application or amendment request, prior to authorizing the material on the license.

The review team verified that the Program used license conditions to require licensees to follow Increased Controls and Fingerprinting requirements. The review team determined that documents containing sensitive security-related information were appropriately controlled and maintained in a manner to limit access. The Program reviews documents requested under Rhode Island Code, Chapter 38-2, "Rhode Island-Access to Public Records" to determine whether the document should be withheld from public disclosure.

Section 3.4 of the 2007 IMPEP report recommended that the State develop a written documentation of its radioactive materials licensing program to ensure that a memorialized program exists to train and transfer knowledge to future, as well as current, staff. The review team found that when processing licensing actions, the Program consistently used the licensing guidance in the NRC NUREG-1556 series "Consolidated Guidance About Materials Licensees." However, use of these licensing guidance documents was not a formalized policy within the Program. This matter was discussed with the Program Manager. Although the Program's process was to follow the licensing guidance, the process had not been documented to ensure that a memorialized program exists to train and transfer knowledge to current and future staff. During the review, the Program manager held a staff meeting with the Program staff to discuss this issue. Following the meeting, on October 26, 2011, the Program Manager published a memo to document the Rhode Island specific guidance to be used by Program staff when performing licensing actions. The memo documented: (1) the conditions under which the NRC NUREG-1556 series will be used; (2) the specific circumstances where Rhode Island requires the submission and verification in addition to the information requested in the NRC NUREG-1556 series; and (3) the use of Rhode Island specific pre-licensing guidance. This memo satisfies the recommendation from the 2007 IMPEP and the recommendation is considered closed.

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

3.5 Technical Quality of Incident and Allegation Activities

In evaluating the effectiveness of the Program's actions in responding to incidents and allegations, the review team examined the Program's response to the questionnaire relative to this indicator, evaluated selected incidents reported for Rhode Island in the Nuclear Material Events Database against those contained in the Program's files, and evaluated the casework for four radioactive materials incidents. A listing of the casework examined, with case-specific

comments, can be found in Appendix E. The review team also evaluated the Program's response to one allegation that was referred to the Program during the review period. The Program reported that it did not receive any other allegations during the review period.

In evaluating the effectiveness of the Program's response to incidents and events, the review team evaluated the program's response to four incidents. The incidents selected for review included incidents related to: contamination/transportation events, release of radioactive material, and a reported medical event. When incidents were reported to the Program by licensees, the Program in turn took actions consistent with the potential health and safety significance of the incident. For minor incidents, the Program typically followed up on the event through phone calls and emails for the licensee. In the case of the potential medical event, the Program conducted an onsite review that was performed by one of the members of the Program's technical staff as well as an individual from outside of Program staff that had extensive training and experience in conducting investigations related to the medical arena.

In evaluating the effectiveness of the Program's response to allegations, the review team identified one allegation that had been referred to the Program by NRC during the review period. The Program reported that they did not receive any other allegations during the review period. The review team found that the Program's review of the allegation referred by NRC included an on-site inspection by a member of the Program staff and was appropriate with the potential health and safety significance of the allegation.

When notification of an allegation or complaint is received, the Office's Incident Response Coordinator enters the information into the Office-wide Aspen Complaints Tracking System (ACTS). The Office Incident Response Coordinator will review the allegation and contact the appropriate State program responsible for the allegation. The Office Incident Response Coordinator, working in consultation with the Program staff, determines the appropriate initial response to an allegation or complaint. As appropriate, the pertinent information is forwarded to the Program for investigation and follow-up and/or enforcement actions. The allegations are tracked to completion in ACTS. The review team noted that Rhode Island law requires that certain documents be made available upon request from a member of the public. The Program makes every effort to protect an alleger's identity, but cannot guarantee that an alleger's identification would not be released under applicable State laws or in the event of legal proceedings.

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

4.0 NON-COMMON PERFORMANCE INDICATORS

Four non-common performance indicators are used to review Agreement State Programs: (1) Compatibility Requirements, (2) Sealed Source and Device Evaluation Program, (3) Low-level Radioactive Waste Disposal Program, and (4) Uranium Recovery Program. The NRC's Agreement with the State of Rhode Island does not relinquish authority to regulate a sealed source and device evaluation program, or a uranium recovery program, so only the first and third non-common performance indicators were applicable to this review.

4.1 Compatibility Requirements

4.1.1 Legislation

Rhode Island became an Agreement State on January 1, 1980. The currently effective statutory authority for the Program is contained in the State of Rhode Island and Providence Plantations Department of Health Rules and Regulations for the Control of Radiation, Title 23, Chapter 23-1.3. In addition to their response to the questionnaire, the State provided the review team with the opportunity to review copies of legislation that affect the radiation control program. The review team noted that no legislation affecting the Program was passed during the review period.

Rhode Island Regulations are subject to Rhode Island General Laws-42-35-4.1, requiring all regulations promulgated by State agencies to be re-filed every five years to remain effective. The radiation control regulations were last filed in January 2007 and are due to be re-filed in January 2012.

4.1.2 Program Elements Required for Compatibility

The review team examined the Program's response to the questionnaire, reviewed the status of regulations required to be adopted by the State under the Commission's adequacy and compatibility policy, and verified the adoption of regulations with data obtained from the State Regulation Status Sheet that is maintained by FSME.

The Rhode Island Rules and Regulations for the Control of Radiation (R23-1.3-RAD) apply to all sources of ionizing radiation. Rhode Island requires a license for possession and use of all radioactive material including naturally occurring materials, such as radium, and accelerator-produced radionuclides. Rhode Island also requires registration of all equipment designed to produce x-rays or other ionizing radiation, as well as non-ionizing radiation from tanning equipment.

The initial timeframe for promulgation of a proposed regulation can vary depending on the complexity and number of regulations amended. The review team examined the State's administrative rulemaking process and found that the process takes between four and 12 months once the Program prepares a proposed regulation. This variance is due in part to the document being presented to the Rhode Island Radiation Advisory Commission for review and comment. Per Rhode Island statute Title 23, Chapter 23-1.3 the Advisory Commission is strictly consultative in nature and the Program has the discretion to accept or reject any recommendations that are made. After being reviewed by the Advisory Commission, the proposed regulations go through a Regulations Subcommittee for further review and modification to produce a final document. Once the regulations are adopted in final, the regulations are then filed with the Secretary of State and become effective 20 days after filing. Discussions with the staff indicated that there are no outside factors which affect the adoption of regulations within NRC's three year time requirement. The State has the authority to issue legally-binding requirements (e.g., license conditions) in lieu of regulations until compatible regulations become effective.

Current NRC policy requires that Agreement States adopt certain equivalent regulations or legally-binding requirements no later than three years after they become effective. The review team identified the following six amendments as overdue at the time of the review, including one that was identified as overdue during the previous IMPEP review:

- "Compatibility with IAEA Transportation Safety Standards (TS-R-1) and Other Transportation Safety Amendments," 10 CFR Part 71 amendment (69 FR 3697, 58038), that became effective October 1, 2004 and was due for Agreement State adoption by October 1, 2007.

- "Minor Amendments," 10 CFR Parts 20, 30, 32, 35, 40, and 70 amendment (71 FR 15005), that became effective March 27, 2006 and was due for Agreement State adoption on March 27, 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 became effective October 29, 2007 and was 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 became effective on November 30, 2007 and was 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 became effective December 17, 2007 and was 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 became effective on February 15, 2008 and was due for Agreement State adoption by February 15, 2011.

Through discussions with the Program, the team determined that Rhode Island does have a plan in place to adopt the six currently overdue regulations which includes submission of final regulations to the NRC by the second calendar quarter of 2012.

The State will need to address the following three amendments in upcoming rulemakings or by adopting alternate legally binding requirements:

- "Medical Use of Byproduct Material – Authorized User Clarification," 10 CFR Part 35 amendment (74 FR 33901), that became effective on September 28, 2009 and is due for Agreement State adoption by September 28, 2012.

- "Licenses, Certifications, and Approvals for Materials Licensees," 10 CFR Parts 30, 36, 39, 40, 51, 70, and 150 amendment (76 FR 56951), that became effective

on November 14, 2011 and is due for Agreement State adoption by November 14, 2014.

- "Decommissioning Planning," Parts 20, 30, 40, and 70 amendment (76 FR 35512) that will become effective on December 17, 2012, and is due for Agreement State adoption by December 17, 2015.

The review team recommends that the State adopt all currently overdue regulations required for compatibility and adopt future regulation amendments within their required three year time frame.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Rhode Island's performance with respect to the indicator, Compatibility Requirements, be found satisfactory, but needs improvement.

4.2 Low-Level Radioactive Waste (LLRW) Disposal Program

In 1981, NRC amended its Policy Statement, "Criteria for Guidance of States and NRC in Discontinuance of NRC Authority and Assumption Thereof by states Through Agreement," to allow a State to seek an amendment for the regulation of LLRW as a separate category. Those States with existing Agreements prior to 1981 were determined to have continued LLRW disposal authority without the need of an amendment. Although Rhode Island has such authority to regulate a LLRW disposal facility, NRC has not required States to have a program for licensing a disposal facility until such time as the State has been designated as a host State for a LLRW disposal facility. When an Agreement State has been notified or becomes aware of the need to regulate a LLRW disposal facility, it is expected to put in place a regulatory program that will meet the criteria for an adequate and compatible LLRW program. There are no plans for a commercial LLRW disposal facility in Rhode Island. Accordingly, the review team did not review this indicator.

5.0 SUMMARY

As noted in Sections 3.0 and 4.0 above, the review team recommended, and the MRB agreed, that Rhode Island's performance be found unsatisfactory for the performance indicator Status of the Materials Inspection Program; satisfactory, but needs improvement for the performance indicators Technical Quality of Inspections and Compatibility Requirements; and satisfactory for the three other indicators reviewed. The review team made six recommendations regarding the performance of the State.

Overall, the review team recommended, and the MRB agreed, that the Rhode Island Agreement State Program be found adequate, but needs improvement, and compatible with NRC's program.

Based on the results of the current IMPEP review, and in accordance with the criteria in NRC Management Directive 5.6, the review team recommended, and the MRB agreed, that a period of Monitoring be initiated for Rhode Island. Monitoring may be used in cases where weaknesses in a program result in a less than fully satisfactory performance for one or more performance indicators. Monitoring is an informal process that allows the NRC to maintain an

increased level of communication with an Agreement State program. The review team believes that Monitoring will be a useful tool in assessing the State's progress toward addressing the programmatic issues and deficiencies identified during the review.

The review team further recommended, and the MRB agreed, that a Periodic Meeting be held within one year to assess the State's progress in addressing the open recommendations. The team recommends that the next IMPEP review take place in approximately four years from the date of the current IMPEP. The review team believes that the performance of a Periodic Meeting within one year will provide time to assess the State's progress and that if progress is not apparent, the timing of the next IMPEP review can be reassessed at that time.

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

1. The review team recommends that the State document its training and qualification program for license reviewers and inspectors, including the reimplementation, use, and update of licensing and inspection qualification cards for each staff member. (Section 3.1)

2. The review team recommends that the State take appropriate measures to conduct Priority 1, 2, and 3 inspections and initial inspections in accordance with the inspection priority in IMC 2800. (Section 3.2)

3. The review team recommends that the State take measures to ensure that inspection records and narrative reports are documented in accordance with the Program's Inspection Manual. (Section 3.3)

4. The review team recommends that a Program supervisor or other appropriately qualified senior staff member accompany each inspector, at least annually, to ensure quality and consistency in the inspection program. (Section 3.3)

5. The review team recommends that the State conduct initial and subsequent security-related inspections in a manner that provides for verification of licensee compliance with the requirements. (Section 3.3)

6. The review team recommends that the State adopt all currently overdue regulations required for compatibility and adopt future regulation amendments within their required three year time frame. (Section 4.1)

LIST OF APPENDICES

Appendix A	IMPEP Review Team Members
Appendix B	Rhode Island Organization Charts
Appendix C	Inspection Casework Reviews
Appendix D	License Casework Reviews
Appendix E	Incident Casework Reviews

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	**Area of Responsibility**
Janine Katanic, FSME	Team Leader Inspector Accompaniments Technical Quality of Inspections Technical Quality of Incident and Allegation Activities
Monica Orendi, Region I	Technical Staffing and Training Status of Materials Inspection Program Compatibility Requirements
Mark Light, Ohio	Technical Quality of Licensing Actions Technical Quality of Incident and Allegation Activities

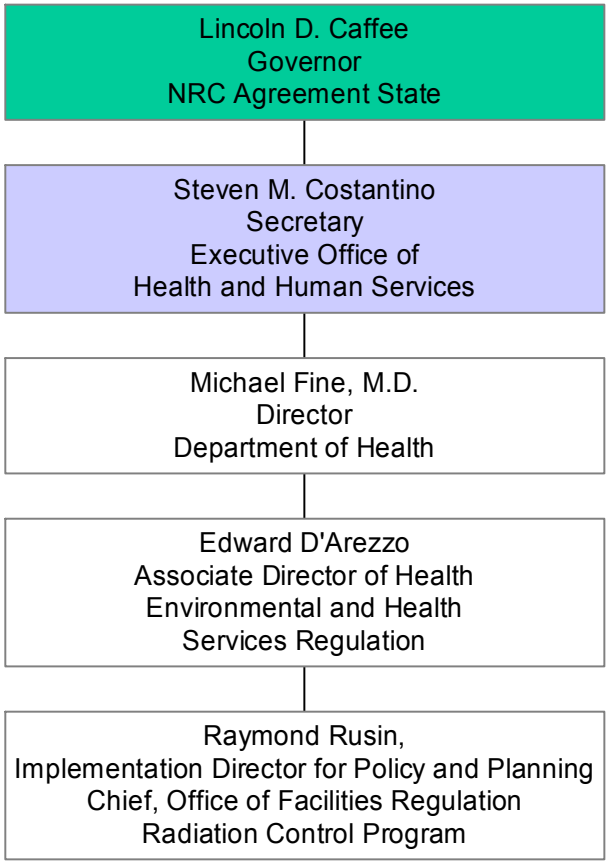
APPENDIX B

RHODE ISLAND ORGANIZATION CHARTS

ADAMS ACCESSION NO.: ML112840093

Exhibit A

Rhode Island and Providence Plantations
Radiation Control Program Hierarchy



Rhode Island Department of Health
Division of Environmental and Health Services Regulation
Office of Facilities Regulation

Exibit B

Edward D'Arezzo, Associate Director Health, EHSR

Raymond Rusin, Chief
Implementation Director for Policy and Programs
Chief, Office of Facilities Regulation

Audrey Greene
Data Unit Supervisor Grade 21A

Carol Weldon
Data Entry Control Clerk

<Vacant>
Data Entry Control Clerk

<Pending backfill>
Licensing Aide I Grade 314

Madeline Vincent
Consultant Public Health Nurse
Medicare/Medicaid Certification Unit

<Vacant>
Chief Health Program Evaluator
State Licensing Unit

Adele Renzulli, RN
Principal NCE Grade 926
Federal Inspection Workload

Arthur Pullano
Principal HFS Grade 29
LSC/LTC Enforcement

Sandra Clark
Chief, Health Professions
Complaint Investigations

William Finocchiaro,
Health Policy Analyst Grade 33
Program Systems Coordination
Federal QEIS/L2K

Darlene Skorski, RN
Principal NCE Grade 926
Licensing Workload

William Dundulis
Risk Assessment Toxicologist
Grade 35 .4 FTE

Carol Horibin
Radiation Control Specialist
Grade 30

Dennis Klaczynski,
Radiation Control Specialist
Grade 30

Charma Waring
Radiation Control Specialist
Grade 30

Shelley Regan,
Industrial Hygienist
Grade 27

Federal Certification

Vincent Baccari, Senior. HFS
<Vacant>, Senior NCE

Mark Sawyer, CSW
Marion Mulholland,RN, NCE
Joann Scappaticci,RN, NCE
Pat Buckley,RN. NCE-ML
Jennifer Olsen, PHN
Carol St. Amant, HFS
Diane Pelletier, CSW
Janice Demurjian, PT-LD
Deborah Anderton, RN, NCE
Walter Palethorpe, HFS
Elizabeth James,RN, NCE
Mary Wyrostek,RN, NCE
Noy Kulsic,RN NCE
Linda Catalano,RN NCE
Jane Off, RN, NCE
David Marquis,RN, NCE

(18 FTE's – 16 available)

Robert O'Donnell
Medicolegal Administrator
Grade 32
Public Health Investigator

Patricia Rajotte
Senior Human Services Policy &
Systems Specialist Grade 28
MDS/OASIS

Linda Julian,
Senior Public Health Promo Sp
Grade 31
Public Health Investigator

Andrew Powers,
Health Policy Analyst Grade 33
Quality Improvement/Training
Coordination

State Licensing

Normand Laliberte, RN, NCE
Julie Leone, HFS

(2 FTE's)

< 9 FTE's>

Nancy Hines,
CLIA-Laboratory
Health Policy Analyst Grade 33

Catherine Lynn, RN
Senior NCE Grade 923
Complaint Program Triage/Monitor

Deb Massaniso, RN, NCE

(1 FTE's Licensing)

Lisa Camuso,
Complaint Intake

Kathleen Gannon
Program Assistant I

Abbreviations used:

<Vacant> - Backfill needed

NCE – Nursing Care Evaluator Grade 920
HFS – Health Facility Surveyor Grade 23
RD – Registered Dietitian
MLA – Medical Leave of absence
LD – Light Duty
TRN – In Training
. . . . - Program/Technical Oversight

CSW – Clinical Social Worker Gr 27
PT – Physical Therapist
LSC - Life Safety Code
RET - Scheduled Retirement Date
S/D - Structural Deficit
Contract/temporary Staff

October 2011

Structural Staffing Deficit:
- 1 program managers (ALR – RCP)
- 9 Health Inspectors (31 total needed for workload)

APPENDIX C

INSPECTION CASEWORK REVIEWS

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

File No.: 1
Licensee: Primary Flow Signal, Inc. License No.: 3D-140-01
Inspection Type: Routine, Initial, Announced Priority: 1
Inspection Date: 4/27/10 Inspector: DK

File No.: 2
Licensee: Geisser Engineering License No.: 3L-050-01
Inspection Type: Routine, Unannounced Priority: 5
Inspection Dates: 6/14, 20/11 Inspector: DK

Comments:

1) The inspection report, which identified issues related to security as well as health and safety, was issued to the licensee on 10/7/2011, approximately 109 days after the date of the inspection.
2) Based on the information contained in the inspection records, some of the violations issued to the licensee were not well developed or well documented.

File No.: 3
Licensee: Primary Flow Signal, Inc. License No.: 3D-140-01
Inspection Type: Special, Initial, Announced Priority: 1
Inspection Date: 4/27/10 Inspector: DK

Comment:

The special inspection record did not contain sufficient information related to the inspection findings and observations.

File No.: 4
Licensee: Rhode Island Blood Center License No.: 3E-100-01
Inspection Type: Special Priority: 5
Inspection Date: 7/28/10 Inspector: CW

Comment:

The special inspection observations were not formally documented because no violations were identified.

File No.: 5
Licensee: Cardinal Health License No.: 3B-114-01
Inspection Type: Routine, Unannounced Priority: 2
Inspection Date: 1/27/10 Inspector: DK

Comment:
The inspection was performed overdue (greater than 25% of the due date) by approximately 30 days.

File No.: 6
Licensee: Brown University License No.: 3K-036-01
Inspection Type: Routine, Unannounced Priority: 3
Inspection Dates: 6/14, 15, 22/10 Inspector: DK

Comment:
The note to file dated 06/26/08 mentioned 3 specific areas that warranted review and verification during the next inspection. The inspection record did not document the inspector's review of these 3 specific items.

File No.: 7
Licensee: Brown University License No.: 3K-036-01
Inspection Type: Special, Unannounced Priority: 3
Inspection Date: 6/22/10 Inspector: DK

File No.: 8
Licensee: DiPrete Engineering, Inc. License No.: 3L-141-01
Inspection Type: Initial, Unannounced Priority: 5
Inspection Date: 3/2/11 Inspector: CW

File No.: 9
Licensee: Baker Testing Services, Inc. License No.: RMRA-08-011
Inspection Type: Reciprocity, Unannounced Priority: 1
Inspection Date: 5/12/08 Inspector: CW

File No.: 10
Licensee: St. Joseph Health Services License No.: 7B-025-01
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 4/2/08 Inspector: DK

Comment:
The inspection was performed overdue (greater than 25% of the due date) by approximately 30 days.

File No.: 11
Licensee: Rhode Island Hospital License No.: 7A-051-02
Inspection Type: Routine, Announced Priority: 2
Inspection Date: 8/2/10 Inspector: DK

Comments:

1) The inspection was performed overdue (greater than 25% of the due date) by approximately 177 days.
2) The inspection record refers to the inspector's review of license conditions that were no longer part of the license at the time of the inspection.
3) The inspection report was issued to the licensee on 11/16/10, approximately 106 days after the date of the inspection.

File No.: 12
Licensee: Rhode Island Emergency Management Agency License No.: 8A-009-01
Inspection Type: Routine and Special, Announced Priority: 5
Inspection Date: 3/4/10 Inspector: DK

Comments:

1) The inspection reports, which identified issues related to security and health and safety, was issued to the licensee on 6/4/10, approximately 92 days after the date of the inspection.
2) Some of the violations issued to the licensee were not well developed based on the information contained in the inspection records.

File No.: 13
Licensee: Rhode Island Hospital License No.: 7D-051-01
Inspection Type: Routine, Unannounced Priority: 2
Inspection Dates: 1/NR/10-8/17/10 Inspector: DK

Comments:

1) The inspection report was issued to the licensee on 11/17/10, approximately 92 days after the date of the inspection.
2) The inspection record did not document if a review was performed related to items of non-compliance that were identified during the previous inspection.
3) The inspection record did not document a review of an incident that occurred in April 2010.

INSPECTOR ACCOMPANIMENTS

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

Accompaniment No.: 1
Licensee: Ocean State Technical Services License No.: 3D-117-01
Inspection Type: Routine and Special, Announced Priority: 1
Inspection Date: 9/27/11 Inspector: CW

Comments:

1) The inspection of licensee implementation of security requirements warranted a more detailed review and verification of licensee implementation than what was performed by the inspector, especially considering that the facility layout had changed from the last inspection.
2) The inspection was not in accordance with Program's inspection guidance which directs the inspector to focus on observations rather than a review of records. Also, the inspector's methodology for asking questions of the licensee did not facilitate verification of licensee compliance.

Accompaniment No.: 2
Licensee: Electric Boat Corporation License No.: 3D-005-01
Inspection Type: Routine and Special, Announced Priority: 1
Inspection Date: 9/28/11 Inspector: DK

Comments:

1) The inspection of licensee implementation of security requirements warranted a more detailed review and verification of licensee implementation than what was performed by the inspector.
2) The inspector's methodology for asking questions of the licensee did not facilitate verification of licensee compliance.

Accompaniment No.: 3
Licensee: Ocean State Veterinary Specialists License No.: 3K-126-01
Inspection Type: Routine, Announced Priority: 5
Inspection Date: 9/29/11 Inspector: DK

Comments:

1) The inspector's methodology for asking questions of the licensee did not facilitate verification of licensee compliance.
2) The inspector did not have a thorough understanding of the proper use and operation of radiation survey and measurement instrumentation and the concept of instrument efficiency.

APPENDIX D

LICENSE CASEWORK REVIEWS

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

File No.: 1
Licensee: Primary Flow Signal, Inc. License No.: 3D-140-01
Type of Action: New Amendment No.: 0
Date Issued: 10/15/09 License Reviewer: DK

File No.: 2
Licensee: Roger Williams Radiation Therapy, LLC License No.: 7B-139-01
Type of Action: New Amendment No.: 0
Date Issued: 10/29/08 License Reviewer: WD

File No.: 3
Licensee: Rhode Island Hospital License No.: 7A-051-02
Type of Action: Amendment Amendment No.: 38
Date Issued: 07/12/10 License Reviewer: JF

File No.: 4
Licensee: Cardinal Health License No.: 3D-114-01
Type of Action: Renewal Amendment No.: 17
Date Issued: 02/14/11 License Reviewers: JF, DK

File No.: 5
Licensee: DiPrete Engineering Associates License No.: 3L-141-01
Type of Action: New Amendment No.: 0
Date Issued: 05/20/10 License Reviewer: CW

File No.: 6
Licensee: Thermo Niton Analyzers, LLC License No.: 3A-105-01
Type of Action: Termination Amendment No.: 21
Date Issued: 07/31/09 License Reviewer: DK

File No.: 7
Licensee: Thermo Niton Analyzers, LLC License No.: 3G-105-02
Type of Action: Termination Amendment No.: 14
Date Issued: 07/31/09 License Reviewer: DK

File No.: 8
Licensee: Brown University License No.: 3K-036-01
Type of Action: Amendment Amendment No.: 40
Date Issued: 10/11/11 License Reviewer: DK

Comment:
The additional safety considerations for the specific model of irradiator (Standard License Condition 75, from NUREG-1556, Volume 20, "Consolidated Guidance About Materials Licenses: Guidance About Administrative Licensing Procedures") were not included in the license conditions or alternately in tie-down documents to the license.

File No.: 9
Licensee: Navix Diagnostics License No.: 7B-109-01
Type of Action: Termination Amendment No.: 07
Date Issued: 7/12/10 License Reviewer: CW

File No.: 10
Licensee: Rhode Island Atomic Energy Commission License No.: 3K-063-01
Type of Action: Termination Amendment No.: 25
Date Issued: 04/13/09 License Reviewer: DK

File No.: 11
Licensee: Women's and Infant's Hospital of Rhode Island License No.: 1D-045-02
Type of Action: Amendment Amendment No.: 17
Date Issued: 03/14/08 License Reviewer: JF

File No.: 12
Licensee: Cardiovascular Institute of New England License No.: 7B-137-01
Type of Action: New Amendment No.: 0
Date Issued: 10/20/10 License Reviewer: CW

File No.: 13
Licensee: St. Joseph Health Services License No.: 7B-025-01
Type of Action: Amendment Amendment No.: 20
Date Issued: 07/20/2010 License Reviewer: CW

File No.: 14
Licensee: Veroscience, LLC License No.: 3K-136-01
Type of Action: Amendment Amendment No.: 3
Date Issued: 09/24/10 License Reviewer: CW

File No.: 15
Licensee: ATC Associates License No.: 3L-142-01
Type of Action: New Amendment No.: 0
Date Issued: 04/15/11 License Reviewer: CW

APPENDIX E

INCIDENT CASEWORK REVIEWS

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

File No.: 1
Licensee: Rhode Island Hospital
Date of Incident: 12/22/2009
Investigation Date: 12/23/2009
License No.: 7D-051-01
NMED No.: NA
Type of Incident: Contamination/Transportation
Type of Investigation: Phone/email

File No.: 2
Licensee: Rhode Island Hospital
Date of Incident: 12/22/09
Investigation Date: 12/24/2009
License No.: 7D-051-01
NMED No.: NA
Type of Incident: Contamination/Transportation
Type of Investigation: Phone/email

File No.: 3
Licensee: Kent Hospital
Date of Incident: 9/2/10
Investigation Date: 9/2/10
License No.: 7B-020-01
NMED No.: NA
Type of Incident: Release of Radioactive Material
Type of Investigation: Phone/email

File No.: 4
Licensee: Rhode Island Hospital
Date of Incident: 4/21/10
Investigation Date: 5/11-20/10
License No.: 7D-051-01
NMED No.: 100388
Type of Incident: Medical
Type of Investigation: Licensee Report, Site Visit

ATTACHMENT(S)

January 6, 2012 Letter from Raymond Rusin
Rhode Island's Response to the Draft Report
ADAMS Accession No.: ML120090074

Department of Health

Three Capitol Hill
Providence, RI 02908-5097

TTY: 711
www.health.ri.gov

January 6, 2012

Janine F. Katanic, Ph.D., CHP
Health Physicist
Division of Materials Safety and State Agreements
Office of Federal and State Materials
And Environmental Management Programs

RE: Draft Rhode Island IMPEP Report dated November 17, 2011

Dear Mrs. Katanic:

On behalf of the Dr. Michael Fine, Director of the Rhode Island Department of Health, I am providing comment on the draft IMPEP report referenced above.

I wish to thank you and your review team for a through and collaborative review. Staff of the radiation control program and I appreciate the opportunity to learn from both your review activities and the expertise of your team.

We find no substantive errors or disagreements with your teams observations, comments, and recommendations. That being said, I would like to mention a few specific points that, although they do not change our intention or resolve to improve our overall performance, bear documenting.

First, I believe it is important to not lose sight of the length of the review period – four years! For a small state and recognizing the unprecedented fiscal difficulties the state continues to be engulfed in, which you do acknowledge and we appreciate, the program significantly improved it's implementation of the required inspection schedule in the latter half of the period – that's performance over a two-2 year period. We believe the Department's attention to this critical detail is not an un-significant accomplishment. The RI radiation program, as you know, covers a variety of other important areas beyond materials and all in the interest of ensuring the health and safety of the public. Additionally, the Department's need to respond to public health emergencies utilizing the national incident and command system (ICS) sets priorities beyond any one program unit and can interfere with the normal workload routine, pulling staff to assist as needed, often outside their respective expertise or job function. Lastly, normal staff attrition in a small state presents an often insurmountable situation given the technical specialties of the radiation materials classifications. Section 3.3 of the report in no way sought to identify or document the "whys" of the difficulties of meeting the inspection frequencies in the first years of the review period.

The next to the last paragraph in Section 3.3, on page 7, in our estimation misrepresents or inappropriately alludes to a practice of the Rhode Island inspectors in regards to verifying licensee compliance with Increased Controls and Fingerprinting. It is the states contention that such an inference is incorrect and that in the circumstance generating this reference the licensee was cited for non-compliance. If a licensee cannot produce evidence of compliance with a condition or a credentialing requirement – they are not compliant. Subsequently, we do not agree with the wording and/or framing of that situation, however, it does not change our agreement with and plans to improve the quality of all of our inspections.

The Department concurs with a Monitoring period and welcomes the involvement, insight, and support of the NRC Regional Office. The following are tentative responses and/or action steps for each of the recommendations along with our good-faith commitment to improve the programs overall performance to the full satisfaction of the NRC:

1. The review team recommends that the State document its training and qualification program for license reviewers and inspectors, including the reimplementation, use, and update of licensing and inspection qualification cards for each staff member.

> The Office of Facilities Regulations (OFR), Radiation Control Program concurs and will update the qualifications and training documents appropriately. Additionally, OFR plans to implement this documentation system as an office protocol for all employees and classifications assigned to OFR.

2. The review team recommends that the State take appropriate measures to conduct Priority 1, 2, and 3 inspections and initial inspections in accordance with the inspection priority in IMC 2800.

> The Office of Facilities Regulations (OFR) believes the Radiation Control Program for Materials is currently in full compliance with the NRC requirements and anticipates continued compliance throughout the next IMPEP review period.

3. The review team recommends that the State take measures to ensure that inspection records and narrative reports are documented in accordance with the Program's Inspection Manual.

> The Office of Facilities Regulations (OFR) is implementing updates to both our inspection and enforcement procedures and will ensure inspection records and narrative reports comport with the updated procedures. Additionally, OFR is adopting and creating an office-wide protocol and procedure manual that will incorporate the radiation materials requirements as well as allow for the adoption of existing incident and event investigation protocols in the materials program.

4. The review team recommends that a Program supervisor or other appropriately qualified senior staff member accompany each inspector, at least annually, to ensure quality and consistency in the inspection program.

> The Office of Facilities Regulation (OFR) will immediately begin scheduling supervisory and/or accompaniment inspections consistent with both training and on-going performance requirements.

5. The review team recommends that the State conduct initial and subsequent security related inspections in a manner that provides for verification of licensee compliance with the requirements.

> The Department and the Office of Facilities Regulation understand and believe we are committed to meeting all of the requirements and criteria for ensuring Increased Control licensees are upon initial licensing and at all times fully compliant with both state and federal requirements. If there are any differences in opinion or procedure between the NRC and the OFR Radiation Control Program on how those requirements are determined and documented to be in compliance, the Department is committed to resolving those differences quickly and collaboratively with the NRC.

Thank you.

Raymond Rusin, Implementation Director for Policy and Planning

Cc: Michael Fine, MD, Director, RI Department of Health