January 9, 2013

Jose T. Montero, M.D. Director Division of Public Health Services Department of Health and Human Services 29 Hazen Drive Concord, New Hampshire 03301-6504

Dear Dr. Montero:

On December 18, 2012, the Management Review Board (MRB) met to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) report on the New Hampshire Agreement State Program. The MRB found the New Hampshire program adequate to protect public health and safety and not compatible with the U.S. Nuclear Regulatory Commission's (NRC) program.

Section 5.0, page 12 of the enclosed final report contains a summary of the IMPEP team's findings and recommendations. A recommendation from the 2008 IMPEP review was held open pending development and implementation of the State's action plan to adopt the NRC regulations in accordance with the NRC policy on adequacy and compatibility. The Radiological Health Section Administrator committed to the MRB that the action plan would be submitted to the NRC in January 2013.

Based on the results of the current IMPEP review, the next full review of the New Hampshire Agreement State Program will take place in approximately four years with a periodic meeting occurring mid-cycle. In addition, the MRB directed Monitoring be initiated with Monitoring calls occurring at a frequency of every four months. According to the criteria in the NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)," 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 MRB determined that Monitoring will be a useful tool in assessing the State's progress toward completion of the overdue regulations.

#### J. Montero

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: New Hampshire Final IMPEP Report

cc w/ encl: Bill Dundulis, RI Organization of Agreement States Liaison to the MRB

> Michael J. Dumond, Administrator New Hampshire Bureau of Public Health Protection

Augustinus Ong, Administrator New Hampshire Radiological Health Section



## INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM REVIEW OF THE NEW HAMPSHIRE AGREEMENT STATE PROGRAM

OCTOBER 2 - 5, 2012

**FINAL REPORT** 

Enclosure

#### **EXECUTIVE SUMMARY**

This report presents the results of the Integrated Materials Performance Evaluation Program (IMPEP) review of the New Hampshire Agreement State Program. The review was conducted during the period October 2 - 5, 2012, by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of Kansas.

Based on the results of this review, New Hampshire's performance was found satisfactory for six performance indicators and unsatisfactory for the Compatibility Requirements indicator. The State has not yet addressed ten regulation amendments that are overdue for adoption.

The review team did not make any recommendations regarding program performance by the State. However, the review team determined that the recommendation from the 2008 IMPEP review, regarding the development and implementation of an action plan to adopt NRC regulations in accordance with the current NRC policy, should be kept open.

Accordingly, the review team recommended, and the MRB agreed, that the New Hampshire Agreement State Program is adequate to protect public health and safety and is not compatible with the NRC's program. The review team recommended, and the MRB agreed, that the next IMPEP review take place in approximately four years and that the State enter a period of Monitoring with Monitoring calls conducted every four months. The review team determined that Monitoring would be a useful tool in assessing the State's progress toward completion of the overdue regulations.

#### 1.0 INTRODUCTION

This report presents the results of the review of the New Hampshire Agreement State Program. The review was conducted October 2 – 5, 2012, by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of Kansas. 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 September 20, 2008 to October 5, 2012, were discussed with New Hampshire managers on the last day of the review.

A draft of this report was provided to New Hampshire for factual comment on November 1, 2012. The State responded by letter dated November 29, 2012. A copy of the State's response is included as an Attachment to this report. A Management Review Board (MRB) met on December 18, 2012, to consider the proposed final report. The MRB found the New Hampshire Agreement State Program adequate to protect public health and safety, and not compatible with the NRC's program.

The New Hampshire Agreement State Program is administered by the Radiological Health Section (the Section), which is part of the Bureau of Public Health Protection (the Bureau). The Bureau is located within the Division of Public Health Services (the Division). The Division is part of the Department of Health and Human Services (the Department). The Commissioner of the Department reports to the Governor. Organization charts for the Department and the Bureau are included in Appendix B.

At the time of the review, the New Hampshire Agreement State Program regulated 82 specific licenses authorizing possession and use of radioactive 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 New Hampshire.

In preparation for the review, a questionnaire addressing the common and applicable non-common performance indicators was sent to the Section on April 11, 2012. The Section provided its response to the questionnaire on September 13, 2012. A copy of the questionnaire response can be found in NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML12261A055.

The review team's general approach for conduct of this review consisted of (1) examination of the Section's response to the questionnaire, (2) review of applicable New Hampshire statutes and regulations, (3) analysis of quantitative information from the Section's database, (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 New Hampshire Agreement State Program's performance.

## 2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous IMPEP review, which concluded on September 19, 2008, the review team made one recommendation regarding the New Hampshire Agreement State Program's performance. The status of the recommendation is as follows:

"The review team recommends that the State develop and implement an action plan to adopt NRC regulations in accordance with the current NRC policy on adequacy and compatibility." (Section 4.1 of the 2008 IMPEP Report)

Status: The State has not yet developed an action plan to address this recommendation. Historically, the Administrator has been responsible for rules. Pursuant to the 2008 IMPEP, the Administrator's staffing request included one position in the Section that would be partially dedicated to regulation development and maintenance. However, the position was not allocated. During the review period, the Administrator position was vacated and subsequently filled in June 2012. The new Administrator has begun work on several of the overdue regulations. The recommendation remains pertinent and open.

## 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 <u>Technical Staffing and Training</u>

Considerations central to the evaluation of this indicator include the Section's staffing level and staff turnover, as well as the technical qualifications and training histories of the staff. To evaluate these issues, the review team examined the Section's questionnaire response relative to this indicator, interviewed managers and staff, reviewed job descriptions and training records, and considered workload backlogs.

The Section is managed by the Administrator and has two managers and four technical staff. One manager is dedicated to the Radioactive Materials Program; the other is dedicated to the Radiation Machines Program. The technical staff shares responsibility for the radioactive materials and radiation machine programs' licensing, inspection, and incident response activities. At the time of the review, the Section had 2.7 full-time equivalents (FTE) dedicated to the Radioactive Materials Program, not including the Administrator or clerical support. The Section has a dedicated staff member that coordinates the Radiological Emergency Response Program. There are two vacant positions: a part-time word processor and new Radiation Health Physicist III position. Interviews for the word processor were underway at the time of

the review. The Health Physicist III position is being finalized in Bureau management. The FTE for the position would be split between mammography and rulemaking. Therefore, the position is partially funded by the U.S. Food and Drug Administration. There is uncertainty as to when this position might be filled.

Technical staffs are classified as Radiation Health Physicists. Candidates for technical positions are required to have a bachelor's degree in a science or engineering, and certification or equivalent experience in radiation-related work. All technical staff members meet the qualification requirements for their respective positions.

During the review period, there was some turnover; however, the Section was able to fill the positions. The Administrator left the program in June 2011. The position was subsequently staffed by June 2012. A Radiation Health Physicist II position, contributing 0.45 FTE to the Radioactive Materials Program, turned over twice during the review period (4/30/2010 and 9/2/2011). On both occasions, the position was posted and staffed within 12 months of it becoming vacant.

The review team determined that the Section's staffing level is adequate for its licensing, inspection, and incident response duties. However as discussed later in this report, regulation development continues to be an ongoing challenge for the Section. The review team noted that additional staff to support rule development was proposed by the Section during the 2008 IMPEP, but State budget cuts prevented allocation of the position. The review of New Hampshire's regulations required for compatibility is discussed in Section 4.1.2. New Hampshire management is cognizant of the need for a solution to address regulation development and maintenance.

The Section has a documented training plan for technical staff 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." Staff members are assigned increasingly complex duties as they progress through the qualification process. The review team concluded that the Section's training program is adequate to carry out its regulatory duties and noted that New Hampshire's management supports the Section's training program.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that New Hampshire'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 Section's questionnaire response relative to this indicator, data gathered from the Section's database, examination of completed inspection casework, and interviews with management and staff.

The review team verified that New Hampshire's inspection frequencies for all types of radioactive material licenses are at least as frequent as similar license types listed in IMC 2800, "Materials Inspection Program." In addition, the review team confirmed the Section is conducting Increased Controls inspections in conjunction with routine health and safety inspections.

The Section conducted 39 higher priority inspections (Priority 1, 2, and 3) during the review period. One of these inspections was conducted overdue by more than 25 percent of the inspection frequency prescribed in IMC 2800. In addition, the Section performed 14 initial inspections during the review period, one of which was conducted overdue. As required by IMC 2800, initial inspections should be conducted within 12 months of license issuance. The Section purposely deferred the initial inspection pending the receipt of radioactive sources by the licensee. The Section had conducted a pre-licensing site visit of this licensee. The initial inspection was conducted one month overdue. Overall, the review team calculated that the Section performed 3.8 percent of its inspections (Priority 1, 2, 3, and Initials) overdue during the review period. At the time of the review, there were no overdue inspections.

The review team evaluated the Section's timeliness in providing inspection findings to licensees. A sampling of 14 inspection reports indicated that two of the inspection findings were communicated to the licensees beyond the Section's goal of 30 days after the inspection. The Section tracks this metric in its inspection database. Based on information collected from the database, the review team determined that 13 of 100 inspection reports were submitted to the licensee beyond 30 days. None of these occurrences contained inspection reports with a notice of violation (NOV).

The review team found that the Section issued 25 reciprocity permits over the four year review period that were candidates for inspection based upon the criteria found in IMC 1220, "Processing of NRC Form 241 and Inspection of Agreement State Licensees Operating Under 10 CFR 150.20." The Section inspected seven of the candidate licensees. The review team determined that the Section met the NRC's criteria of inspecting 20 percent of candidate licensees operating under reciprocity in each of the four years covered by the review period.

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

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

The review team evaluated the inspection reports, enforcement documentation, inspection field notes, and interviewed inspectors for 15 radioactive materials inspections conducted during the review period. The casework reviewed included inspections conducted by four Section inspectors and covered inspections of various license types: academic broad scope, medical institutions-therapy including high dose rate remote afterloader and unsealed radioiodine therapy, medical-diagnostic, fixed gauges, industrial radiography, veterinary use, self-shielded irradiators, mobile nuclear medicine, and Increased Security Controls for Large Quantities of Radioactive Materials (Increased Controls). Appendix C lists the inspection casework files reviewed, with a case-specific comment, as well as the results of the inspector accompaniments.

Based on the evaluation of casework, the review team noted that inspections covered all aspects of the licensee's radiation safety programs. The review team found that inspection reports were thorough, complete, consistent, and of high quality, with sufficient documentation to ensure that a licensee's performance with respect to health and safety was acceptable. The documentation supported violations, recommendations made to licensees, unresolved safety issues, the effectiveness of corrective actions taken to resolve previous violations and discussions held with licensees during exit interviews.

The inspection procedures utilized by the Section are consistent with the inspection guidance outlined in IMC 2800. An inspection report is completed by the inspector which is then reviewed and signed by the Section Manager. Supervisory accompaniments were conducted annually for all inspectors. The Section Manager also conducts radioactive materials inspections and was accompanied by the former Program Administrator in 2009 and 2010. The current Administrator is not a qualified inspector; therefore, to meet this requirement, the Program will use a senior staff inspector to accompany the Manager on future annual accompaniments.

The review team determined that the inspection findings were appropriate and prompt regulatory actions were taken, as necessary. Inspection findings were clearly stated and documented in the reports and sent to the licensees with the appropriate letter detailing the results of the inspection. The Section issues to the licensee either a letter indicating a clear inspection or NOV which details the results of the inspection. When the Bureau issues an NOV, the licensee is required to provide a written corrective action plan, based on the violations cited, within 30 days. All findings and corrective actions are reviewed by the Section Manager.

The review team noted that the Section has an adequate supply of survey instruments to support its inspection program as well as to respond to radioactive materials incidents and emergency response events. Instruments are calibrated at least annually, or as needed, by the manufacturer or a properly licensed facility. The Section has access to the Public Health Laboratory, which is a well-equipped and adequately staffed analytical laboratory. The Public Health Laboratory has broad analytical capabilities using liquid scintillation counters, gas proportional counters, intrinsic germanium detectors, multichannel analyzers, alpha spectroscopy, and radiochemistry.

One IMPEP team member accompanied two Section inspectors on routine inspections during the week of September 10, 2012. The inspectors were accompanied during health and safety inspections of an industrial radiography facility, including a temporary job site, and medical facility with authorization for use of unsealed radioiodine therapy. The accompaniments are identified in Appendix C. During the accompaniments, the inspectors demonstrated appropriate inspection techniques, knowledge of the regulations, and conducted performance-based inspections. The inspectors were trained, well-prepared for the inspectors conducted interviews with appropriate personnel, observed licensed operations, conducted confirmatory measurements, and utilized good health physics practices. The inspections were adequate to assess radiological health and safety and security at the licensed facilities.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that New Hampshire'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 21 specific licensing actions. Licensing actions were reviewed for completeness, consistency, proper radioisotopes and quantities, qualifications of authorized users, 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, prelicensing visits, supervisory review, and proper signatures.

The licensing casework was selected to provide a representative sample of licensing actions completed during the review period. Licensing actions selected for evaluation included three new licenses, three full renewals, one decommissioning, two termination actions, two denials and ten amendments. Files reviewed included a cross-section of license types: broadscope, medical diagnostic and therapy, brachytherapy, medical institution – private practice, industrial radiography, research/development, portable and fixed gauges, manufacturer, and self-shielded irradiators. The casework sample represented work from five license reviewers. A list of the licensing casework evaluated is provided in Appendix D.

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 and were supported by information contained in the file. Deficiency letters clearly stated regulatory positions, were used at the proper time, and identified substantive deficiencies in the licensees' documents. Terminated licensing actions were well documented, showing appropriate transfer and survey records. License reviewers use the Section's licensing guides and/or NUREG-1556 series guidance documents, policies, checklists, and standard license conditions specific to the type of licensing actions to ensure consistency in licenses.

The Section Manager has signature authority for licensing actions. The Section Manager performs a technical and supervisory review on all licensing actions before issuance to the licensee. The Section issues licenses for a 1-year period based on the collection of an annual fee; a full comprehensive technical review is completed every seven years.

The Section has two licenses that require financial assurance. The review team determined that the Section has taken appropriate steps to ensure compliance with the financial assurance requirements. The license review process appropriately identifies licensees required to maintain financial assurance.

Based on the casework evaluated, the review team concluded that the licensing actions were of high quality and consistent with the Section's licensing procedures and/or NUREG-1556 guidance documents, the State's Code of Administrative Rules, and good health physics

practices. The review team attributed the consistent use of templates, checklists and quality assurance reviews to the overall quality noted in the casework reviews.

The Section performs pre-licensing checks of all new applicants. The Section's pre-licensing review methods incorporate the essential elements of the NRC's revised pre-licensing guidance to verify that the applicant will use requested radioactive materials as intended. All new licensees receive a pre-licensing site visit which includes an evaluation of the applicant's radiation safety and security programs prior to receipt of the initial license.

The review team examined the Section's licensing practices regarding the Increased Controls and Fingerprinting Orders. The review team noted that the State uses legally binding license conditions that meet the criteria for implementing the Increased Controls Orders, including fingerprinting, as appropriate. The review team analyzed the Section's methodology for identifying those licenses and found the rationale was thorough and accurate. The review team confirmed that license reviewers evaluated new license applications and license amendments using the same criteria. The Section requires full implementation of the Increased Controls prior to issuance of a new license or license amendment that meets the established criteria. The State also used legally binding license conditions that met the criteria for implementing the requirements for two independent physical controls to secure portable gauges, packaging and transportation of radioactive materials, financial assurance for decommissioning, patient release criteria, inventory reporting for nationally tracked sources, National Source Tracking System implementation, training requirements for radiographers' assistants, and dosimetry technology.

The review team examined the Section's implementation of its process for the control of sensitive information. Files that contain sensitive information are marked as such and are secured in locked file cabinets.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that New Hampshire'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 Section's actions in responding to incidents and allegations, the review team examined the Section's response to the questionnaire relative to this indicator, evaluated selected incidents reported for New Hampshire in the Nuclear Material Events Database (NMED) against those contained in the Section's files, and evaluated the casework for four radioactive materials incidents. A listing of the incident casework examined, with case-specific comments, may be found in Appendix E. The review team also evaluated the Section's response to one allegation involving radioactive materials. No allegations were referred to the State by the NRC during the review period.

The review team examined the Program's implementation of its incident and allegation processes, including written procedures for handling allegations and incident response, file documentation, notification of incidents to the NRC Headquarters Operations Center, and the use of NMED software. The Section handles incidents and allegations in the same manner. When notified of an incident or allegation, the Manager and staff discuss the issue and

determine the level of initial response based on the health and safety risk. The Section has a spreadsheet to track the status of all incidents and allegations.

The incidents selected for review included the following categories: lost/stolen radioactive material, equipment failure, loss of control. The review team identified one incident which the State had initially reported to the NRC in a timely manner, but which should have been updated when two additional sources were determined to be missing. The Section Manager determined that not updating the event report was an inadvertent oversight on the State's part. The Section provided the updated information to the NRC Headquarters Operations Center on October 4, 2012, at the direction of the review team. The review team determined that another of the incident reports reviewed did not contain sufficient information to determine if the cause of the failure of an x-ray fluorescence analyzer (XRF) device to function as required was the result of a generic problem and whether the incident met NRC reporting requirements. During the onsite review, the inspector was not available to provide additional information on follow-up actions, so the Section Manager contacted the licensee and the gauge manufacturer and determined that the device failure was not a generic issue; however, the device failure did meet the NRC reporting criteria. The State notified the NRC Headquarters Operations Center about this event on October 5, 2012, at the direction of the review team.

Based on the potential issues the review team identified with two of the four incident files reviewed, the review team increased the sample size of incidents reviewed to determine if the problems were an isolated or chronic issue. The review team determined that upon review of four additional incident casework files, the Section responded appropriately to two of the initial incidents reviewed and all four of the additional incidents reviewed. Initial responses were prompt and well-coordinated, and the level of effort was commensurate with the health and safety significance of the incident. The Section dispatched inspectors for on-site investigations in all of the cases reviewed and took suitable enforcement and follow-up actions. The review team determined that the issues identified with two of the Section's incidents were due to isolated causes and not a chronic issue.

The review team identified six radioactive material incidents in NMED for New Hampshire during the review period, all of which required reporting. With the exception of the two updates described above, the Section reported events to the NRC in a prompt manner. The actions taken in response to incidents were documented and filed, and the data were submitted to the NRC's contractor responsible for maintaining NMED for inclusion in the database.

In evaluating the effectiveness of the Section's response to allegations, the review team evaluated the completed casework for one allegation received by the State during the review period. The review team concluded that the Section took prompt and appropriate actions in response to the concerns raised. The review team noted that the Section documented the investigation of the individual's concerns and retained all necessary documentation to appropriately close the allegation. The Section notified the concerned individual of the conclusion of its investigation. The review team determined that the Section adequately protected the identity of concerned individuals.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that New Hampshire'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 (SS&D), (3) Low-Level Radioactive Waste Disposal Program (LLRW), and (4) Uranium Recovery Program. NRC's Agreement with New Hampshire does not relinquish regulatory authority for a uranium recovery program; therefore, only the first three non-common performance indicators applied to this review.

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

#### 4.1.1 Legislation

New Hampshire became an Agreement State on May 16, 1966. The Department is authorized as the State's radiation control agency under the New Hampshire Revised Statutes Annotated (RSA) 1990, Chapter 125. The Section has been delegated to administer the State's radiation control program. The review team did not identify any legislative changes affecting the radiation control program during the review period.

#### 4.1.2 Program Elements Required for Compatibility

The New Hampshire Rules for Control of Radiation are found in He-P 4000-4095 and apply to all ionizing radiation, whether emitted from radionuclides or radiation producing machines. New Hampshire requires a license for possession and use of all radioactive material.

The review team examined the procedures used in the State's administrative rulemaking process and found that the process takes at least 12 months for rule promulgation. In practice, this process may take much longer for more complex or large rulemaking packages. After preparation of a package of draft regulations by the Section, the draft regulations are reviewed by the Department's Administrative Rules Unit. The draft regulations are then sent to the Department Commissioner for approval. Final approval of all regulations is completed by the Joint Legislative Committee on Administrative Rules. The public and other interested parties are provided an opportunity to comment on proposed rules. The State has the authority to issue legally binding requirements (e.g., license conditions) in lieu of regulations. The NRC is provided the draft and final regulations and legally binding requirements for comment. The Section submits proposed rules to the NRC for review before rules are reviewed by the New Hampshire Administrative Unit. The Section sends final rules to the NRC for review once they are finalized as New Hampshire regulation.

Final regulations in New Hampshire are subject to a sunset law. Rules expire exactly 8 years after adoption for rules filed prior to September 11, 2011. Regulations with rulemaking notices filed after September 11, 2011, now expire 10 years after the rule's effective date. After expiration, these regulations must be resubmitted in their entirety to remain in effect. Parts of New Hampshire regulations (He-P 4036 Irradiators and He-P 4039 Well Logging) were set to expire on November 23, 2012, unless re-adopted. These rules were re-adopted without incident on September 25, 2012.

The review team evaluated the Section's response to the questionnaire relative to this indicator, 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 FSME maintains.

New Hampshire submitted two legally binding license conditions to the NRC for a compatibility review early in the review period. Current NRC policy requires that Agreement States adopt certain equivalent regulations or legally-binding requirements no later than 3 years after they become effective. Both of these legally-binding requirements were overdue for State adoption at the time of submission. In addition, the following ten amendments are overdue for State adoption, some significantly longer than three years from their effective date. (Two of the following ten rules were submitted as proposed for review by the NRC, but final rules are not yet adopted).

- "Criteria for the Release of Individuals Administered Radioactive Material," 10 CFR Parts 20 and 35 amendments (62FR 4120) that became effective on May 29, 2000<sup>1</sup>.
- "Medical Use of Byproduct Material," 10 CFR Parts 20, 32, and 35 amendment (67 FR 20249), that was due for Agreement State adoption on October 24, 2005.
- "Compatibility with IAEA Transportation Safety Standards and Other transportation Safety Amendments," 10 CFR Part 71 amendment (69 FR 3697), that became effective October 1, 2007<sup>2</sup>.
- "Medical Use of Byproduct Material Recognition of Specialty Boards," 10 CFR Part 35 amendment (70 FR 16336, 71 FR 1926) that was due for Agreement State adoption on April 29, 2008.
- "Minor Amendments," 10 CFR Parts 20, 30, 32, 35, 40, and 70 amendment (71 FR 15005) that 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 amendments (72 FR 45147, 72 FR 54207) that became effective on October 29, 2007, and were due for Agreement State adoption on October 29, 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 was due for Agreement State adoption by December 17, 2010.
- "Requirements for Expanded Definition of Byproduct Material,"10 CFR Parts 20, 30, 31, 32, 33, 35, 61, 150 amendment (72 FR 55864), that was due for Agreement State adoption by November 30, 2010.
- "Occupational Dose Records, Labeling Containers, and Total Effective Dose Equivalent,"

<sup>&</sup>lt;sup>1</sup> Proposed rule submitted to the NRC on 6/6/2012. The NRC reviewed with no comment on 7/25/12.

<sup>&</sup>lt;sup>2</sup> Proposed rule submitted to the NRC on 9/15/2009. The NRC reviewed with comment on 11/20/2009.

10 CFR Parts 19 and 20 amendment (72 FR 68043) that was due for Agreement State adoption on February 15, 2011.

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

The Section is currently drafting proposed regulations for the 10 CFR Part 35 rules. However, considering the continued number of overdue amendments and lack of sustained performance in the timely adoption of regulations, the review team concluded that the New Hampshire Agreement State Program was not meeting the compatibility requirements as identified in the IMPEP evaluation criteria.

The 2008 IMPEP review team made a recommendation that the Section develop and implement an action plan to adopt NRC regulations in accordance with the current NRC policy on adequacy and compatibility. The current review team concluded that the Section did not develop and implement an action plan for adoption of NRC regulations.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that New Hampshire's performance with respect to the indicator, Compatibility Requirements, be found unsatisfactory.

#### 4.2 <u>Sealed Source and Device Evaluation Program</u>

In reviewing this indicator, the review team used three subelements to evaluate the Section's performance regarding the 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 Section's SS&D evaluation activities, the review team examined information contained in the Section's response to the IMPEP questionnaire for this indicator, verified the availability of guidance documents and procedures, and interviewed staff qualified to perform SS&D reviews. The Section performed one SS&D evaluation during the review period.

#### 4.2.1 Technical Staffing and Training

The Section has two qualified SS&D reviewers with full signature authority. Both have degrees in a physical science or engineering. One of the individuals has attended the NRC's SS&D Workshop. The other individual received on-the-job training from the Massachusetts Radiation Control Program for evaluating SS&D applications. The review team determined that, although the Section does not review many SS&D applications, the Section has the necessary knowledge and skill among the reviewers to adequately handle applications. The Section has plans to train another staff member to be an SS&D reviewer in the near future, and intends to send this person to a future NRC SS&D Workshop.

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

The Section processed one new SS&D application since the last review and performed no amendments to existing SS&D evaluations. The listing of the SS&D certificate evaluated by the review team can be found in Appendix F. The review team confirmed that the Section follows the recommended guidance from the NRC SS&D Workshop, NUREG-1556 Series Guidance, applicable and pertinent American National Standards Institute (ANSI) standards and Military Standards, ISO-9001 and New Hampshire regulations, statutes, policies and procedures. The tie-down conditions on the certificate were stated clearly and are enforceable. Deficiency letters clearly stated regulatory positions and were used at the appropriate time. A concurrence review was performed by a second SS&D evaluation-qualified reviewer. The review team found no health and safety issues relative to the SS&D evaluation.

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

No incidents related to SS&D defects involving sources or devices registered by New Hampshire were reported during the review period. Incident procedures are in place should an SS&D-related incident occur.

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

## 4.3 Low-Level Radioactive Waste Disposal Program

In 1981, the NRC amended its Policy Statement, "Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory 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. Although the New Hampshire Agreement State Program has LLRW disposal authority, NRC has not required States to have a program for licensing a LLRW disposal facility until such time as the State has been designated as a host State for a LLRW disposal facility. When an Agreement State has been notified or becomes aware of the need to regulate a LLRW disposal facility, they are expected to put in place a regulatory program which will meet the criteria for an adequate and compatible LLRW disposal program. There are no plans for a LLRW disposal facility in New Hampshire. Accordingly, the review team did not review this indicator.

## 5.0 SUMMARY

As noted in Sections 3.0 and 4.0 above, New Hampshire's performance was found satisfactory for six of seven performance indicators reviewed. The Compatibility Requirements indicator was found unsatisfactory. The review team did not make any new recommendations regarding program performance by the State and determined that the recommendation from the 2008 IMPEP review, concerning Compatibility Requirements, should be kept open.

Accordingly, the review team recommended, and the MRB agreed, that the New Hampshire Agreement State Program be found adequate to protect public health and safety, and not compatible with the NRC's program. Based on the results of the current IMPEP review, the

review team recommended, and the MRB agreed, that the next full IMPEP review take place in approximately four years with a Periodic meeting occurring mid-cycle. The mid-cycle meeting should place additional emphasis on the status of Compatibility Requirements. In addition, the review team recommended, and the MRB agreed, that a period of Monitoring be initiated with Monitoring calls occurring at a frequency of every four months. According to the criteria in the NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)," 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 determined that Monitoring will be a useful tool in assessing the State's progress toward completion of the overdue regulations.

Below is the recommendation held open from the 2008 IMPEP for evaluation and implementation by the State. The New Hampshire Agreement State Program committed to submit to the NRC in January 2013 its action plan to address the open recommendation

#### **RECOMMENDATION:**

The review team recommends that the State develop and implement an action plan to adopt NRC regulations in accordance with the current NRC policy on adequacy and compatibility.

### LIST OF APPENDICES

- Appendix A IMPEP Review Team Members
- Appendix B New Hampshire Organization Charts
- Appendix C Inspection Casework Reviews
- Appendix D License Casework Reviews
- Appendix E Incident Casework Reviews
- Appendix F Sealed Source and Device Casework Reviews

## APPENDIX A

## IMPEP REVIEW TEAM MEMBERS

Name	Area of Responsibility
Lisa Dimmick, FSME	Team Leader Technical Staffing and Training Status of the Materials Inspection Program Compatibility Requirements
Donna Janda, NRC Region I	Technical Quality of Inspections Inspector Accompaniments Technical Quality of Incident and Allegation Activities
Judee Walden, Kansas	Technical Quality of Licensing Actions
Stephen Poy, FSME	Sealed Source and Device Evaluation Program

APPENDIX B

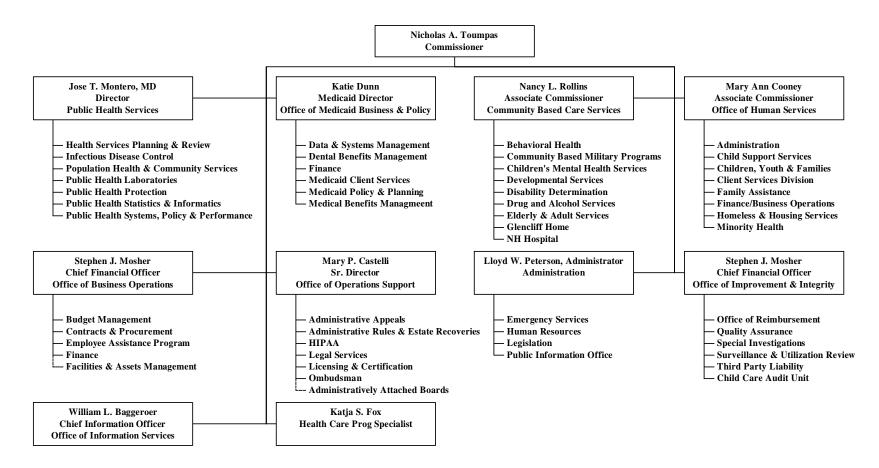
NEW HAMPSHIRE ORGANIZATION CHARTS

ADAMS ACCESSION NO.: ML12261A052

#### **IMPEP Questionnaire 2012 - ADDENDUM** New Hampshire

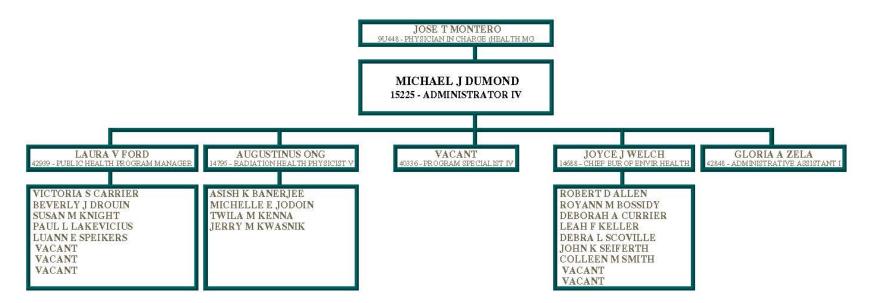
I. Technical Staffing and Training Item 2(a)

Below is the current organization chart. The Commissioner of the Department of Health and Human Services reports to the Governor.



# IMPEP Questionnaire 2012 - ADDENDUM New Hampshire

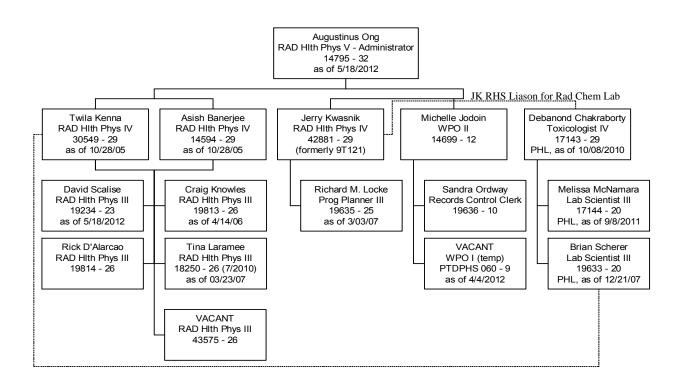
I. Technical Staffing and Training Item 2(a) (cont'd)



IMPEP Questionnaire 2012 - ADDENDUM New Hampshire

I. Technical Staffing and Training Item 2(b)

Department of Health and Human Services Division of Public Health Services Bureau of Public Health Protection Radiological Health Section Current - 09/11/12



#### APPENDIX C

#### INSPECTION CASEWORK REVIEWS

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

File No.: 1 Licensee: Trustees of Dartmouth College Inspection Type: Routine, Unannounced Inspection Dates: 11/26/08

File No.: 2 Licensee: Mary Hitchcock Memorial Hospital Inspection Type: Routine, Unannounced Inspection Date: 04/30/09

File No.: 3 Licensee: Nylon Corporation of America Inspection Type: Routine, Unannounced Inspection Date: 05/12/09

File No.: 4 Licensee: University of New Hampshire Inspection Type: Routine, Unannounced Inspection Date: 03/17/10

File No.: 5 Licensee: Quality Assurance Laboratory, Inc. Inspection Type: Routine, Unannounced Inspection Date: 08/06/09

File No.: 6 Licensee: Monadnock Community Hospital Inspection Type: Routine, Unannounced Inspection Date: 09/30/09

File No.: 7 Licensee: Trustees of Dartmouth College Inspection Type: Routine, Unannounced Inspection Date: 10/28/10

File No.: 8 Licensee: Exeter Hospital Inspection Type: Routine, Unannounced Inspection Date: 02/18/10 License No.: 382R Priority: 2 Inspector: RD

License No.: 130R Priority: 2 Inspectors: TK, RD

License No.: 142R Priority: 5 Inspector: DL

License No.: 190R Priority: 3 Inspector: RD

License No.: 439R Priority: 1 Inspectors: TK, RD

License No.: 368R Priority: 3 Inspector: TL

License No.: 276R Priority: 3 Inspectors: TK, TL

License No.: 138R Priority: 3 Inspector: TL New Hampshire Final IMPEP Report Inspection Casework Reviews

File No.: 9 Licensee: Cheshire Medical Center Inspection Type: Routine, Unannounced Inspection Date: 12/14/10

File No.: 10 Licensee: RI Consultants LLC Inspection Type: Initial, Announced Inspection Date: 09/20/11

File No.: 11 Licensee: American Health Centers, Inc. Inspection Type: Routine, Unannounced Inspection Date: 04/14/11

File No.: 12 Licensee: New England Equine Medical & Surgical Center Inspection Type: Initial, Announced Inspection Date: 11/17/11

File No.: 13 Licensee: Westinghouse Electric Company Inspection Type: Routine, Unannounced Inspection Date: 05/17/12

Comment: Inspection report issued 97 days after completion of inspection.

File No.: 14 Licensee: Southern New Hampshire Medical Center Inspection Type: Routine, Unannounced Inspection Date: 08/30/12

File No.: 15 Licensee: ABC Testing, Inc. Inspection Type: Reciprocity, Unannounced Inspection Date: 06/16/10 License No.: 256R Priority: 3 Inspectors: TL, RD

License No.: 469R Priority: 5 Inspector: RD, TK

License No.: 450R Priority: 3 Inspector: TL

License No.: 466R Priority: 5 Inspector: TK

License No.: 465R Priority: 1 Inspector: RD

License No.: 183R Priority: 3 Inspectors: TL, RD

License No.: MA 19-7781 Priority: 1 Inspector: RD New Hampshire Final IMPEP Report Inspection Casework Reviews

#### INSPECTOR ACCOMPANIMENTS

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

Accompaniment No.: 1 Licensee: Monadnock Community Hospital Inspection Type: Routine, Unannounced Inspection Date: 09/11/12

Accompaniment No.: 2 Licensee: Quality Assurance Laboratories, Inc. Inspection Type: Routine, Unannounced Inspection Date: 09/12/12 License No.: 368R Priority: 3 Inspector: TL

License No.: 439R Priority: 3 Inspector: RD

#### APPENDIX D

#### LICENSE CASEWORK REVIEWS

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

File No.: 1 Licensee: John Turner Consulting Type of Action: Amendment Date Issued: 08/31/09

File No.: 2 Licensee: Frisbie Memorial Hospital Type of Action: Amendment Date Issued: 0 8/28/12

File No.: 3 Licensee: American Health Centers, Inc. Type of Action: Amendment Date Issued: 09/25/12

File No.: 4 Licensee: Androscoggin Valley Hospital Type of Action: Amendment Date Issued: 06/10/11

File No.: 5 Licensee: Trustees of Dartmouth College Type of Actions: Broadscope Amendment/Decommission Date Issued: Decom-09/23/11, BS-09/30/11

File No.: 6 Licensee: Littleton Regional Hospital Type of Action: Renewal Date Issued: 10/27/11

File No.: 7 Licensee: Tyco Electronics Integrated Cable Systems LLC Type of Action: Renewal Date Issued: 12/30/11

File No.: 8 Licensee: Metabolic Solutions Type of Action: Amendment Date Issued: 04/28/10 License No.: 423R Amendment No.: 18 License Reviewer: TL

License No.: 357R Amendment No.: 60 License Reviewer: RD

License No.: 450R Amendment No.: 18 License Reviewer: TL

License No.: 268R Amendment No.: 42 License Reviewer: RD

License No.: 276R Amendment No.: 45 & 46 License Reviewers: RD, TL

> License No.: 263R Amendment No.: 43 License Reviewer: TK

License No.: 143R Amendment No.: 40 License Reviewer: TL

License No.: 418R Amendment No.: 19 License Reviewer: TL New Hampshire Final IMPEP Report License Casework Reviews

File No.: 9 Licensee: Metabolic Solutions Type of Action: Termination Date Issued: 12/28/10

File No.: 10 Licensee: Cardiac Associates of New Hampshire Type of Action: Termination Date Issued: 02/27/09

File No.: 11 Licensee: Northeast Electronics Inc. Type of Action: Amendment Date Issued: 01/29/10

File No.: 12 Licensee: Mary Hitchcock Memorial Hospital Type of Action: Amendment Date Issued: 04/27/09

File No.: 13 Licensee: Quality Assurance Laboratories, Inc. Type of Action: Amendment Date Issued: 03/04/10

File No.: 14 Licensee: New England Molecular Imaging LLC Type of Action: New License Date Issued: 11/22/10

File No.: 15 Licensee: Frank W. Whitcomb Construction Corp. Type of Action: Renewal Date Issued: 12/22/08

File No.: 16 Licensee: Michael Dutton DVM DABVP Type of Action: Amendment Date Issued: 03/28/11

File No.: 17 Licensee: Westinghouse Electric Company Type of Action: New License Date Issued: 02/12/10 License No.: 418R Amendment No.: 20 License Reviewer: TL

License No.: 454R Amendment No.: 02 License Reviewer: TK

License No.: 421R Amendment No.: 16 License Reviewer: DL

License No.: 130R Amendment No.: 108 License Reviewer: DL

License No.: 439R Amendment No.: 13 License Reviewer: TL

License No.: 472R Amendment No.: N/A License Reviewer: RD

License No.: 274R Amendment No.: 30 License Reviewer: CK

License No.: 453R Amendment No.: 06 License Reviewer: TK

License No.: 465R Amendment No.: N/A License Reviewer: RD New Hampshire Final IMPEP Report License Casework Reviews

File No.: 18 Licensee: Franklin Plaistow LLC Type of Action: Denial (Failure to respond) Date Issued: N/A

File No.: 19 Licensee: Frisbie Memorial Hospital Type of Action: Denial (New User) Date Issued: N/A

File No.: 20 Licensee: RI Consultants LLC Type of Action: New License Date Issued: 09/30/10

File No.: 21 Licensee: Elliot Hospital Type of Action: Renewal Date Issued: 08/19/11 License No.: 462R Amendment No.: N/A License Reviewer: RD

License No.: 57R Amendment No.: N/A License Reviewer: TL

License No.: 469R Amendment No.: 00 License Reviewers: RD, TK

> License No.: 182R Amendment No.: 99 License Reviewer: RD

#### APPENDIX E

#### INCIDENT CASEWORK REVIEWS

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

File No.: 1 Licensee: Advanced Recycling Date of Incident: 07/20/09 Investigation Date: 07/22/09

License No.: N/A Incident No.: 09-001 Type of Incident: Lost/Stolen RAM Type of Investigation: Site

File No.: 2 Licensee: Prolerized New England Company LLC Date of Incident: 04/16/10 Investigation Date: 04/16/10

License No.: 461R Incident No.: 10-001 Type of Incident: Equipment Failure Type of Investigation: Site

Comment: No record of final disposition regarding cause of stuck shutter on an XRF device. Incident not reported to NRC within required timeframe.

File No.: 3 Licensee: Saint-Gobain Performance Plastics Date of Incident: 07/14/10 Investigation Date: 08/11/10

License No.: N/A Incident No.: 10-004 Type of Incident: Lost/Stolen RAM Type of Investigation: Site

Comment: State did not update NRC event report as required after licensee determined two additional sources were lost.

File No.: 4 Licensee: McArdle Gannon Associates, Inc. Date of Incident: 12/24/10 Investigation Date: 12/24/10

License No.: MA 48-0518 Incident No.: 10-009 Type of Incident: Loss of Control Type of Investigation: Site

## APPENDIX F

## SEALED SOURCE AND DEVICE CASEWORK REVIEW

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

Registry No.: NH-1332-S-101-S Applicant Name: RI Consultants, LLC Date Issued: 09/30/2010 SS&D Type: Brachytherapy Film Source Type of Action: New Registration SS&D Reviewers: TK, AB

## ATTACHMENT

November 29, 2012 letter from Jose T. Montero New Hampshire's Response to the Draft Report ADAMS Accession No.: ML12352A061



STATE OF NEW HAMPSHIRE

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

29 HAZEN DRIVE, CONCORD, NH 03301-6527 603-271-4501 1-800-852-3345 Ext. 4501 Fax: 603-271-4827 TDD Access: 1-800-735-2964



Nicholas A. Toumpas Commissioner

José Thier Montero Director

November 29, 2012

#### CERTIFIED MAIL NO. 7006 2760 0000 9988 9045

Lisa C. Dimmick, IMPEP Project Manager Division of Materials Safety and State Agreements Office of Federal and State Materials and Environmental Management Programs United States Nuclear Regulatory Commission Mail Stop T-8 E24 Washington, D.C. 20555

#### Dear Ms. Dimmick:

We have completed the review of the draft Integrated Materials Performance Evaluation Program (IMPEP) report dated November 1, 2012. The New Hampshire Department of Health and Human Services' (DHHS) Radiological Health Section accepts the IMPEP findings as stated, and we offer the attached minor corrections to the draft report.

It is my understanding that the IMPEP review team will present its findings of the October 2-5, 2012 New Hampshire Agreement State Program review to the Management Review Board (MRB) on December 18, 2012. New Hampshire intends to fully participate in this final review process by having the New Hampshire Radiological Health Section's Administrator, Augustinus Ong, travel to the NRC for this meeting. In addition, technical and administrative staff of the New Hampshire Radiological Health Section would also like participate in the MRB via teleconference to address any of the Board's concerns.

As stated in the IMPEP findings, the deficiencies identified mainly relate to the rulemaking progress. Mr. Ong, along with the support of his staff, has developed a plan that will address the NRC's concerns about New Hampshire's rulemaking efforts. Going forward, Mr. Ong will periodically inform the NRC Region I staff as to the status of the ten identified overdue amendments. Mr. Ong will elaborate on this rulemaking plan during the upcoming MRB meeting. Lisa C. Dimmick, IMPEP Project Manager November 29, 2012 Page 2

Should you require further discussion regarding of the details of the attached comments, please contact either Twila Kenna, Ph.D., or Augustinus Ong of the Radiological Health Section at (603) 271-4588.

Sincerely,

bith areatic

Director

JTM/sao

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cc: Michael J. Dumond, Bureau Chief Bureau of Public Health Protection NH DHHS Division of Public Health Services

Augustinus Ong, Administrator Radiological Health Section NH DHHS Division of Public Health Services Lisa C. Dimmick, IMPEP Project Manager November 29, 2012 Page 3

#### NEW HAMPSHIRE'S COMMENTS TO THE INTEGRATED PERFORMANCE EVALUATION PROGRAM (IMPEP) *DRAFT* REPORT FOR REVIEW CONDUCTED OCTOBER 2-5, 2012

The following requested changes are submitted with regards to New Hampshire's draft IMPEP Report dated November 1, 2012.

Page 7, Section 3.5

The last line on page 7 should be revised to read:

"sufficient information to determine if the cause of the failure of an XRF to function as" instead.

Appendix C, Page 2

Please revise to read:

File No.: 10 Licensee: **RI** Consultants LLC Inspection Type: Initial, **Announced** Inspection Date: 09/20/11

License No.: 469R Priority: 5 Inspector: RD, TK

<u>Appendix D</u>

Please revise to read:

File No.: 2 Licensee: Frisbie Memorial Hospital Type of Action: Amendment Date Issued: 0 8/28/12

License No.: 357R Amendment No.: 60 License Reviewer: RD

#### Appendix E

The Comment for File No.: 2 should be revised to read:

"No record of final disposition regarding cause of stuck shutter on **XRF**. Incident not reported to NRC within required timeframe."