DATED: NOVEMBER 25, 1997

Mr. Jeffrey B. Schaub, Director Office of Health Management Department of Health and Human Services 6 Hazen Drive Concord, NH 03301-6527

Dear Mr. Schaub:

On November 13, 1997 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 compatible with NRC's program.

Section 5.0, page 18, of the enclosed final report presents the IMPEP team's suggestions and recommendations. We have received your letter dated October 23, 1997, and appreciate the positive actions that you and your staff have taken and are continuing to implement with regard to our comments. No response to this letter is necessary.

Based on the results of the current IMPEP review, the next review will be scheduled in four years, unless program concerns develop that require an earlier evaluation.

I appreciate the courtesy and cooperation extended to the IMPEP team during the review and your support of the Radiation Control Program. I look forward to our agencies continuing to work cooperatively in the future.

Sincerely, /RA/

Hugh L. Thompson, Jr. Deputy Executive Director for Regulatory Programs

Enclosure: As stated

cc: Diane E. Tefft, Administrator New Hampshire Radiological Health Bureau

Woodbury P. Fogg, State Liaison Officer

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM REVIEW OF NEW HAMPSHIRE AGREEMENT STATE PROGRAM AUGUST 19-22, 1997

# FINAL REPORT

U.S. Nuclear Regulatory Commission

#### 1.0 INTRODUCTION

This report presents the results of the review of the New Hampshire radiation control program. The review was conducted during the period August 19-22, 1997 by a review team comprised of technical staff members from the Nuclear Regulatory Commission (NRC) and the Agreement State of Florida. Review team members are identified in Appendix A. The review was conducted in accordance with the "Interim Implementation of the Integrated Materials Performance Evaluation Program Pending Final Commission Approval of the Statement of Principles and Policy for the Agreement State Program and the Policy Statement on Adequacy and Compatibility of Agreement State Programs," published in the <u>Federal</u> <u>Register</u> on October 25, 1995, and the September 12, 1995, NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." Preliminary results of the review, which covered the period August 19, 1994 to August 22, 1997, were discussed with New Hampshire management on August 22, 1997.

A draft of this report was issued to New Hampshire for factual comment on September 22, 1997. The State of New Hampshire responded in a letter dated October 23, 1997 (Attachment 1). The State's factual comments were incorporated in the final report. The Management Review Board (MRB) met on November 13, 1997 to consider the proposed final report. At the time of the review, the review team found the State's performance to be unsatisfactory for the indicator, Status of Materials Inspection Program. Based on the unsatisfactory performance for this indicator, the review team had originally recommended a finding of adequacy, but needs improvement and compatible. However, based on actions taken subsequent to the review, the review team found the State's performance to be satisfactory with recommendations for improvement. The MRB found the New Hampshire radiation control program was adequate to protect public health and safety and compatible with NRC's program.

The New Hampshire Agreement State program is administered by the Commissioner, Department of Health and Human Services (DHHS), Office of Health Management (OHM), Bureau of Radiological Health (BRH). The BRH regulates approximately 100 materials licenses.

The review focused on the regulatory 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 non-common indicators was sent to the State on May 29, 1997. The State provided a response to the questionnaire on August 11, 1997 and August 19, 1997. A copy of the response is included in Appendix C to this report.

The review team's general approach for conduct of this review consisted of: (1) examination of the responses to the questionnaire, (2) review of applicable New Hampshire statutes and regulations, (3) analysis of quantitative information from the BRH licensing and inspection data bases, (4) technical review of selected licensing actions and inspections, (5) field accompaniments of two materials inspectors, and

(6) interviews with staff and management to answer questions or clarify issues. The review team evaluated the information gathered against the IMPEP performance criteria for each common and non-common indicator and made a preliminary assessment of the State's performance.

Section 2 below discusses the State's actions in response to recommendations made following the previous review. Results of the current review for the IMPEP common performance indicators are presented in Section 3. Section 4 discusses results of the applicable non-common indicators, and Section 5 summarizes the review team's findings, recommendations and suggestions. Suggestions made by the review team are comments that the review team believes could enhance the State's program. The State is requested to consider suggestions, but no response will be requested. Recommendations relate directly to program performance by the State. A response will be requested from the State to all recommendations in the final report.

## 2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

The previous routine review concluded on August 19, 1994 and the final results of the review were transmitted to Dr. Charles E. Danielson, Director of the New Hampshire Division of Public Health and Services (DPHS), on January 10, 1995. In letter dated February 21, 1995 from Dr. Danielson to Mr. Richard L. Bangart, Director, Office of State Programs (OSP), and during the MRB Meeting on the 1994 review, the State responded to the 1994 program review findings, comments and recommendations. In letter dated April 24, 1995 from Mr. Bangart to Dr. Danielson, NRC evaluated the State responses and all items except those identified below were closed.

#### 2.1 Status of Items Identified During the 1994 Routine Review

The open 1994 review findings that resulted in recommendations to the State were assessed during this review. The open findings were in the following areas: (1) Status and Compatibility of Regulations; (2) Legal Assistance; (3) Enforcement Procedures; and (4) Inspection Procedures. The status of these recommendations is as follows:

(1) Status and Compatibility of Regulations. The State had not adopted rules equivalent to the following NRC regulations: "Emergency Planning Rule," which was needed by April 7, 1993; "Standards for Protection Against Radiation," which was needed by January 1, 1994; "Safety Requirements for Radiographic Equipment," which was needed by January 10, 1994; and "Notification of Incidents," which was needed by October 15, 1994. It was recommended that the Division take steps to accelerate the promulgation process and consider proposing legislation to exempt the RCP from the administrative rulemaking procedures.

Current Status: The State's corrective actions are as follows: "Emergency Planning Rule," has not been adopted by the State. Currently, the State has no licensees to which this rule would be applicable. However, the State has indicated that the requirements of this rule will be used in the review process for new license applications that would be subject to the requirements

of the rule. This rule is scheduled to be adopted in December 1997. "Standards for Protection Against Radiation," was adopted by the State in February 1995, and was reviewed by the NRC. Comments were provided to the State in letter dated August 18, 1997 to Ms. Diane Tefft, Administrator, BRH, from Mr. Paul Lohaus, "Safety Requirements for Radiographic Deputy Director, OSP. Equipment," is currently being incorporated by industrial radiography license conditions and is scheduled for adoption in December 1997. "Notification of Incidents," was adopted in February 1995 for Parts equivalent to 10 CFR Parts 20, 31, 40 and 70, and the equivalents for 10 CFR Parts 30, 34, and 39 are scheduled for adoption in December 1997. In addition, in August 1995, the New Hampshire Administrative Procedure was amended to exempt BRH regulations from the administrative rulemaking system of numbering and drafting rules. Under the revised Administrative Procedures, these rules are in compliance with the administrative rulemaking system if the wording is consistent with the language of the corresponding Federal regulations. This recommendation is closed.

(2) Legal Assistance. Legal assistance was difficult to obtain from the Attorney General's Office on routine legal matters. The review team recommended that the Department take appropriate steps to assure that the radiation control program had prompt legal assistance available when needed.

Current Status: BRH has direct access to legal counsel. As the result of a reorganization of the New Hampshire DHHS, an attorney from the Attorney General's office was assigned to the OHM. BRH is a part of OHM and it has direct access to this attorney. This recommendation is closed.

(3) Enforcement Procedures. The BRH used the 1990 draft procedures, which are modeled after Appendix C of 10 CFR Part 2, to guide the enforcement process. However, BRH must publish regulations to implement the authority to assess civil penalties and establish severity levels for enforcement actions. It was recommended that BRH consider including the revised inspection and enforcement procedures, with the provisions for severity levels and civil penalties, as part of the 1994 rulemaking package.

Current Status: BRH has not adopted the rules or policy necessary to implement severity levels and civil penalties. BRH indicated that the current enforcement policy was effective in achieving licensee compliance for the period. In addition, BRH indicated that other rules necessary for compatibility had greater priority and that changes as a result of the reorganization of the DHHS have caused them to take a "waiting" approach in the area of enforcement. This recommendation is closed and is evaluated further in Section 3.4 under the indicator "Technical Quality of Inspections."

#### (4) Inspection Procedures.

Although exit interviews are not covered in the procedures, (a) the 1994 review team determined that materials inspectors were attempting to hold exit meetings at the conclusion of an inspection with the highest level of licensee management The 1994 review team also determined, through available. interviews with the inspectors, that oral debriefings are held informally with the section supervisor after the inspector returns from an inspection. It was recommended that BRH update the general procedures in the compliance manual to include such issues as exit meetings and oral debriefings with the inspection supervisor following nonroutine inspections. It was also recommended that BRH review and update, as necessary, the compliance manual chapters for each major category of licensee to conform to the New Hampshire regulations.

Current Status: The BRH revised its procedures to include exit meetings and debriefings with the section supervisor after inspections. In addition, the compliance manual chapter was revised to conform with State regulations. This recommendation is closed.

(b) The review team found that several different versions of inspection forms (field notes) had been used over the review period. Although different inspection forms are appropriately used for different types of licensees, BRH also had several different sets of inspection forms for the same or similar type licensees. It was recommended that BRH review, update, and standardize the inspection forms used for different categories of licensees.

Current Status: This recommendation was not adopted by BRH. BRH indicated that because the rule update process is currently underway, it would not be feasible to revise inspection forms until the rulemaking process is completed; otherwise, revisions would be based upon draft regulations. However, BRH stated that it is currently using NRC inspection forms as references to supplement its current inspection forms. Moreover, during this review, the review team found that the inspection forms provided good, consistent documentation of inspection findings. This recommendation is closed.

#### 3.0 COMMON PERFORMANCE INDICATORS

IMPEP identifies five common performance indicators to be used in reviewing both NRC Regional and Agreement State programs. These indicators are: (1) Status of Materials Inspection Program; (2) Technical Staffing and Training; (3) Technical Quality of Licensing Action; (4) Technical Quality of Inspections; and (5) Response to Incidents and Allegations.

### 3.1 Status of Materials Inspection Program

The review team focused on four factors in reviewing this indicator: (1) inspection frequency, (2) overdue inspections, (3) initial inspection of new licenses, and (4) timely dispatch of inspection findings to licensees. The review team evaluation is based on the New Hampshire questionnaire responses regarding this indicator, data gathered independently from the State's licensing and inspection data tracking system, the examination of licensing and inspection casework files, and interviews with the Radioactive Material Section (RMS) Supervisor and staff.

The State revised its inspection priority system in May 1997 to closely match the NRC system. Prior to that time there were several priority categories which the State inspected more frequently than NRC. The review team's assessment of the current inspection priorities verified that inspection frequencies for various types or groups of licenses are essentially identical to those listed in the NRC Inspection Manual Chapter 2800 (IMC 2800) frequency schedule. In reviewing the State's priority schedule, the review team noted that BRH continues to have priority categories which are inspected more frequently than those of the NRC. The teletherapy category licensees are scheduled to be inspected on a two year frequency while the NRC inspects these licensees at a three year frequency. In addition, all licenses listed as NRC priority seven are inspected on a five year frequency.

The inspection frequencies of licenses selected for technical quality of inspection review were compared with the frequencies of the State's priority system and verified to be consistent and as frequent as similar license types under the IMC 2800 system.

In their response to the questionnaire, New Hampshire indicated that as of August 19, 1997, eight licenses identified as core inspections in IMC 2800 were overdue by more than 25 percent of the NRC's frequency. The review team identified 24 core material licenses from the BRH database. Thus, 33 percent (8 out of 24) of the core licenses were inspected at intervals that exceed the State's and the NRC inspection frequencies by more than 25 percent, which is unsatisfactory based on the criteria in Management Directive 5.6. For the eight overdue core inspections reported in the questionnaire, the RMS Supervisor discussed a proposed schedule to complete inspections at each facility. The overdue inspections were late by periods of time ranging from two to six months.

During the review period, BRH conducted 22 inspections. The team reviewed the RMS, "Goals and Objectives," which was revised July 7, 1997 and is used by staff to assist in implementation of program management. The review team noted that the program objective to perform four inspections per month beginning late 1996 (identified as a priority 1 goal) was not met.

For inspection planning, the RMS Supervisor reviews and updates inspection data for new and existing licenses every two to three months. During interviews with the review team, the RMS Supervisor explained that a list of initial and routine inspections coming due is generated

and offered for sign-up to inspection staff. In lieu of making specific inspection assignments, the review team found that inspection staff are expected to initiate selection of inspections from the updated list when made available by the RMS Supervisor. A review of the updated inspection due list indicated that 23 inspections were due and not scheduled, with 20 unassigned and three assigned to staff. The review team recommends that core and non-core licensees be scheduled, assigned, and inspected at regular intervals in accordance with the State's established inspection priority system.

With respect to initial inspections of new licenses, the team reviewed the inspection tracking system and found that initial inspections were usually entered into the system together with existing licenses. The review team found that inspection staff was generally able to identify licenses due for initial inspection.

BRH currently has a six month inspection frequency for all initial inspections, which is a change from its previous inspection policy. During the 1994 review, it was recommended that BRH revise its inspection priorities for initial inspections of new licenses to be no less frequent than the NRC's, which is within six months of issuance or receipt of material. In response to this recommendation, BRH indicated that it had always performed initial inspections of new licensees for priorities 1 and 2 at six months and 12 months for other priorities. The 12 month initial inspection exceeded the NRC recommended frequency of six months. BRH stated that its rationale for the longer period was that initial inspections should be reflective of complexity/hazard of licensee use and should not merely be assigned to conform with NRC and all of its new licenses were hand delivered. The New Hampshire rationale to extend the interval of time for initial inspections of priority 3 and other lower priority licensees was considered acceptable during the 1994 MRB review of the pilot IMPEP and this recommendation was closed. However, BRH changed the 12 months initial inspection frequency policy to within six months of issuance for all initial inspections.

From the review of the inspection database, BRH was not consistently implementing its revised six month initial inspection policy. The database list of 10 new licenses issued during the review period showed that initial inspections were conducted within six months for two of the licenses, one veterinarian clinic (priority 3) and a portable gauge (priority 5). Initial inspection was performed for three other new licenses at intervals of 11 months (portable gauge, priority 5), 10 months (portable gauge, priority 5), and 12 months (portable gauge, priority 5) after license issuance or material receipt. Of the remaining five new licenses, one license did not require an initial inspection because it was equivalent to a NRC general license; one medical license (NH-402R-American Health Centers Mobile Van Service, priority 2) issued on November 1,1996 had not received material and did not require an initial inspection, and three licenses needed initial inspections and had not received them. These licenses included the following: two issued in January 1997 (NH-417R-Geotechnical Services, Inc., portable gauge, priority 5, and research and development (NH-418R-Metabolic Solutions, in vitro kits, priority 5)), and one in April 1997 (NH-419R-Construction Materials Testing, portable gauge, priority 5).

The review team considered recommending that initial inspections of licensees be performed within six months of license issuance or within six months of the licensee's receipt of material and commencement of operations, consistent with IMC 2800. The review team did not provide a recommendation based upon the previous decision by the MRB. However, the review team suggests that the State clearly establish its policy for initial inspection of priority 3 and above licenses, (6 months or 12 months), and adhere to the established policy.

The timeliness of the issuance of inspection findings was also evaluated during the inspection file review. Of the 12 files examined, the correspondence for eight inspections was sent to the licensee within 30 days of the inspection date. These inspections were clear, with no deviations or violations of license requirements. Correspondence for the other inspections was sent to the licensee more than 30 days past the inspection date. In these cases varying levels of enforcement actions were identified, leading to longer evaluations of inspection results by staff. Three letters containing notices of violation were transmitted within two months of the inspection date. A team inspection of one of New Hampshire's major licensees identified significant deficiencies in the program operations. The State verbally communicated with the licensee to resolve deficiencies, but the final report dispatch occurred approximately 10 months after the inspection was performed. The review team recommends that the State review and revise its inspection report preparation process for those containing enforcement actions to ensure timely issuance of inspection findings.

New Hampshire reported in their response to the questionnaire that 41 material licensees had submitted requests for reciprocity during the review period. These 41 material licensees included nine industrial radiography, 23 portable gauges, five service, one gas chromatography, and three lixiscopes. These licensees made a total of 307 reciprocity requests. Of the 307 reciprocity requests, 143 were portable gauges and 127 were industrial radiography. Of the nine industrial radiography licensees, the State performed three inspections. This effort is below the IMC 1220 guidance to inspect 50 percent of the priority 1 reciprocity licensees. The review team suggests that the State increase reciprocity inspections to meet the inspection goals established in IMC 1220.

In a letter dated October 23, 1997 from Mr. Jeffrey E. Schaub, Director, Office of Health Management, Department of Health and Human Services, in response to the draft report, additional information was provided regarding this indicator. The letter indicated that six of the eight core inspections, which were overdue at the time of review, have been In addition, Mr. Schaub indicated that the two remaining conducted. inspections were to be completed within three weeks of the date of the (At the MRB meeting, Ms. Tefft reported that the two letter. inspections were being completed that week.) With the completion of the six inspections, eight percent (2 out of 24) of the State's core materials inspections would exceed the State's and the NRC's inspection frequency, which is satisfactory based on the criteria in Management Directive 5.6. In the draft report, the review team initially recommended that New Hampshire's performance with respect to the indicator, Status of Materials Inspection Program, be found

unsatisfactory. However, based on the actions taken by the State subsequent to the review and the IMPEP evaluation criteria, the review team recommends that New Hampshire's performance with respect to the indicator, Status of Materials Inspection Program, be found satisfactory with recommendations for improvement.

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

Issues central to the evaluation of this indicator include the radioactive materials program staffing level, technical qualifications of the staff, training, and staff turnover. To evaluate these issues, the review team examined the State's questionnaire responses relative to this indicator, interviewed selected BRH managers and staff, and considered any possible workload backlogs.

The New Hampshire organization chart shows that, at the time of the review, BRH was funded for 17 persons or 15.26 FTE's based on 1800 hrs/year/FTE. BRH consists of five sections with approximately 2 FTE's in Radon, 2.5 FTE's in Emergency Response, 2 FTE's in Radiochemistry, 3 FTE's in Radiation Machines and 3 FTE's in RMS. The remainder of the FTE's are devoted to clerical and general administrative tasks. An FTE for the BRH is considered to be 37.5 hours per week. The RMS Supervisor and five staff members devote 3.0 FTE effort to the agreement materials program which includes materials licensing, inspection, event response, and laboratory activities. These staff members also have additional responsibilities in the Radiation Machines Section and to a lesser degree in the other sections.

In comparison to other Agreement States, it appears there are a sufficient number of FTE's allocated to the agreement materials program to assure public health and safety. There has been no turnover since the last review and all of the staff have a wide range of licensing and inspection experience. There are a number of overdue core license inspections and a licensing backlog that may be partially due to the difficulty in balancing personnel between the RMS and the Radiation Machines Section since personnel are rotated between the two sections on a monthly basis, without regard to whether inefficiencies result from disruption of licensing and inspection casework in progress. At the time of the review, there were 98 pending licensing actions, 8 administrative renewals (fee collection), 60 amendments, 5 new license applications and 25 renewals. Sixty-nine of these actions were overdue by over 1 year. As noted in Section 3.1, at the time of the review, 33% of the core inspections were overdue and only 22 inspections had been performed in the last three years. In light of the current backlogs in the inspection and licensing programs, the review team recommends that the State evaluate the number of staff needed to implement the program.

BRH has established qualifications for its technical classifications, including Health Physicist 1 (HP1) and Health Physicist 2 (HP2). The Supervisor position is an HP2 with the remaining staff HP1's. Applicants at the entry level, HP1, are required to have a baccalaureate degree in a physical or life science. BRH does not have a formal documented qualification and training program for the materials staff. However, staff are assigned increasingly complex licensing and inspection duties under the direction of the RMS Supervisor. Staff are

required to demonstrate competence during review and accompaniments by the Supervisor. This information was verified through discussions with managers and staff. All of the BRH staff have attended NRC courses that include, licensing and inspection procedures, five week applied health physics, industrial radiography and medical uses, as well as courses in emergency response and portable gauges. The review team determined that all staff utilized for the agreement materials program were technically qualified by evidence of their training and experience. However, the State would benefit from a training and qualifications plan in the event of staff turnover. The review team suggests that the State develop a written training and qualifications plan.

Based on the training that program personnel have received, the State appears supportive of continued staff training, and management demonstrated a commitment to staff training during the review. However, the State has concerns as to the impact of NRC's change in policy for funding State training and is looking into other training options.

Based on the IMPEP evaluation criteria, the review team recommends that New Hampshire's performance with respect to the indicator, Technical Staffing and Training, be found satisfactory.

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

The review team examined completed licenses and casework for 13 license actions in 13 specific license files, representing the work of five license reviewers. The license reviewers and RMS Supervisor were interviewed when needed to supply additional information regarding licensing decisions or file contents.

Licensing actions were reviewed for completeness, consistency, proper radioisotopes and quantities authorized, qualifications of authorized users, adequate facilities and equipment, and operating and emergency procedures sufficient to establish the basis for licensing actions. Licenses were reviewed for accuracy, appropriateness of the license and for its conditions and tie-down conditions, and overall technical quality. Casework was reviewed for timeliness, adherence to good health physics practices, reference to appropriate regulations, documentation of safety evaluation reports, product certifications or other supporting documents, consideration of enforcement history on renewals, prelicensing visits, peer or supervisory review as indicated, and proper signature authorities. The files were checked for retention of necessary documents and supporting data.

The license casework was selected to provide a representative sample of licensing actions which had been completed in the review period and to include work by all reviewers. The sampling included three of the State's major licenses and included the following types: research and development; manufacturing and distribution; industrial radiography; nuclear medicine; mobile nuclear medicine; academic; portable gauges; and "in vitro" laboratory. Licensing actions reviewed included 3 new, 2 renewals, 7 amendments and 1 termination. In discussions with BRH management, it was noted that there were no major decommissioning efforts underway with regard to agreement material in New Hampshire. Also there were no identified sites with potential decommissioning

difficulties equivalent to those sites in NRC's Site Decommissioning Management Plan. A list of these 13 licenses with case specific comments can be found in Appendix D.

The review team found that the licensing actions were very thorough, complete, consistent, of high quality, and with health and safety issues properly addressed. The licensee's compliance history appeared to be taken into account when reviewing renewal applications as determined from documentation in the license files and/or discussions with the license reviewers. No exemptions were issued by BRH during this review period.

The review team found that terminated licensing actions were well documented, showing appropriate transfer records and survey records. A review of the licensing actions over the period showed that almost all terminations were for licensees possessing sealed sources. These files showed that documentation of proper disposal or transfer was available.

Licenses were renewed on a five year frequency. The State is extending the renewal period for certain licensees on a case-by-case basis. Licenses that are under timely renewal are amended as necessary to assure that public health and safety issues are addressed during the period that the license is undergoing the renewal process. Each licensing action receives supervisory chain review.

The review team found that the current staff is well trained and experienced in a broad range of licensing activities. The casework was reviewed for adequacy and consistency with the New Hampshire procedures. The casework review also indicated that the BRH staff follow their licensing guides during the review process to ensure that licensees submit the information necessary to support the license. The licensing guides were very similar to the NRC guides.

Based on the IMPEP evaluation criteria, the review team recommends that New Hampshire's performance with respect to the indicator, Technical Quality of Licensing Actions, be found satisfactory.

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

The team reviewed the inspection reports, enforcement documentation, and the data base information for 12 materials inspections conducted during the review period. The casework included the State's three materials inspectors and covered a sampling of different license types as follows: one broad academic; one veterinary clinic; one research and development facility; six portable gauges; nuclear medicine private practice; and two hospitals. Appendix E provides a list of the inspection cases reviewed in-depth with case-specific comments.

The inspection procedures and techniques utilized by New Hampshire were reviewed and determined to be generally consistent with the inspection guidance provided in IMC 2800. The team reviewed inspection reports and found them to be comparable with the types of information and data collected under NRC Inspection Procedure 87100 and New Hampshire procedures. Inspections were performed on an unannounced basis.

The inspection field notes provided good, consistent documentation of inspection findings. The State uses separate field notes for different types of inspections covering the areas of industrial/research development, industrial radiography, commercial irradiator (draft), medical broad-scope, portable gauges, and medical and teletherapy licenses.

Inspection reports were reviewed to determine if the reports adequately documented the scope of the licensed program, licensee organization, personnel protection, posting and labeling, control of materials, equipment, use of materials, transfer, and disposal. The reports were also checked to determine if the reports adequately documented operations observed, interview of workers, independent measurements, status of previous noncompliance items, substantiation of all items of noncompliance, and the substance of discussions during exit interviews with management. To assure consistency and quality of reports, the RMS Supervisor provided thorough review and comment, and signed all inspection correspondence and field notes. Overall, the review team found that the inspection reports showed excellent quality and attention to detail. From review of casework, reports contained only minor discrepancies from standard practices or established BRH guidance.

Routine enforcement letters were drafted by inspectors and were issued to licensees by the RMS Supervisor. When the licensee responds to a notice of violation (NOV), the response is given to the inspector to evaluate the licensee's response, and to draft a reply for the RMS Supervisor's signature. The review team noted a good practice in that the State uses a violation response review checklist to document staff reviews of the licensee response to each NOV. The review team also identified a concern related to State follow-up of licensee responses to NOVs. During review of two inspection files which resulted in significant problems with the licensee's program, it was noted that a staff follow-up inspection was not conducted to confirm that the commitments made in the licensee's correspondence were implemented. The review team recommends that appropriate State follow-up inspection be conducted to confirm implementation of licensee corrective actions when significant problems have been identified.

For the casework reviewed, documented inspection findings led to proper regulatory actions and appropriate enforcement. The RMS Supervisor stated that inspection results showed licensee compliance was acceptable during the review period and that escalated enforcement action beyond the issuance of NOVs was limited. A finding from the previous NRC review recommended the State include rules for enforcement procedures with provisions for severity levels and civil penalties. In their response to that recommendation, New Hampshire committed to revising the rules after July 1995. In evaluating the State's response to the NRC recommendation, the review team found that the rules in question were not adopted and the manual which describes the program for determining enforcement actions was not revised. The State indicated because of higher priorities and the reorganization of the DHHS, they took a "waiting" approach in the area of enforcement. The State continued to base their enforcement program primarily upon onsite inspections and NOVs. If escalated enforcement is necessary, the State DHHS has authority to issue orders.

Two inspector accompaniments identified in Appendix E were performed by a review team member on July 10, 1997 (self-shielded irradiator) and July 24, 1997 (hospital-nuclear medicine program). Of the remaining two inspectors, one was accompanied during previous assessments and the other was not yet performing independent inspections of high priority licensees. During the accompaniments, inspectors demonstrated appropriate inspection skills and knowledge of the regulations. The inspectors were well prepared and thorough in the review of licensee radiation safety programs. Inspection techniques were observed to be performance oriented, and the technical performance of the inspectors was at a high level. The inspections were adequate to assess radiological health and safety at the licensed facilities.

New Hampshire has a policy of performing annual supervisory accompaniments of inspectors. In response to the questionnaire, the State reported that supervisory inspector accompaniments were not performed during the review period. Instead, the RMS Supervisor explained that senior staff reviewed inspector methods during team inspections, inspectors debriefed with supervisory staff upon return to the office, and inspection reports received close supervisory review. Since supervisory accompaniments provide program management a better understanding of both the inspectors' abilities and competence to perform in the field, the review team suggests that the State adhere to the policy of annual supervisory accompaniments of all inspectors.

The review team noted that New Hampshire has an ample number of portable radiation detection instruments for use during routine inspections and response to incidents and emergencies. For large licensed programs, a laboratory specialist assists inspectors by taking confirmatory measurements and samples. The State uses an outside vendor for instrument service and calibration. The portable instruments used during the inspector accompaniments were observed to be operational and calibrated. The instrument storage area is co-located with the radiation counting laboratory and storage area for emergency response kits. A sampling of portable instruments maintained at each location were available and found to be within calibration.

Based on the IMPEP evaluation criteria, the review team recommends that New Hampshire's performance with respect to the indicator, Technical Quality of Inspections, be found satisfactory.

#### 3.5 <u>Response to Incidents and Allegations</u>

In evaluating the effectiveness of the State's actions in responding to incidents and allegations, the review team examined the State's response to the questionnaire regarding this indicator, reviewed the incidents reported for New Hampshire in the "Nuclear Material Events Database" (NMED) against those contained in the New Hampshire files, and reviewed the casework and supporting documentation for 14 material incidents and six allegations.

The 14 incidents selected for review included two misadministrations, one lost source, seven contamination events, three reported loss of control of radioactive material, and one non-routine event and are listed in Appendix F. Of the six allegations reviewed, NRC Region I

office referred two to the State and the other four came directly to the State from allegers.

Responsibility for initial response and follow-up actions to material incidents and allegations rests with the BRH staff. When the BRH is notified of an incident during working hours, time permitting, a staff meeting is held to discuss the approach to be taken regarding the incident. For incidents during non-work hours, each staff member has a copy of the "DHHS Initiator Handbook." The Handbook is designed to be used for response to incidents involving radioactive materials and nuclear reactors. The radioactive materials section of the Handbook is sufficient to provide guidance for responding to incidents involving radioactive materials, including transportation incidents. Copies of the Handbook and current call lists, which include beeper numbers, are distributed periodically to all appropriate persons or agencies. The State provides a 24-hour emergency number for anyone to use to report emergencies involving hazardous materials. When a radiological incident is suspected, BRH staff is contacted.

The review of incident casework, licensing casework, and interviews with staff revealed that incidents are promptly evaluated for the need for on-site investigations. For those incidents not requiring on-site investigations, copies of letters to licensees were in the licensing files indicating that the incident would be investigated during the next scheduled inspection.

In responding to incidents and allegations, BRH had taken prompt, appropriate action. The review of casework indicated that incident reports were thorough and well-documented. The incident reports were reviewed and signed by the section supervisor.

The review team also found good correlation of the State's response to the questionnaire, the incident information in the casework, and the incident information reported on the NMED system printout for New Hampshire. For discrepancies that did exist between the NMED information and the State casework, satisfactory explanations for the discrepancies were available. The reviewer obtained a May 8, 1997, "All Events - On line Report," of the incidents sent to Idaho National Environmental Engineering Laboratory (INEEL) for inclusion in the NMED The Report indicated that 21 incidents had been reported to system. NMED; however, the NMED file only included 11 of these incidents. The 10 incidents were not included for the following reasons. Although a New Hampshire licensee was involved, two incidents occurred in another State (Massachusetts) and would be listed under that State. Three incidents did not include radioactive material, and one involved non-Atomic Energy Act material. Two incidents were considered information and not reportable events, and one event involved a reactor. Τn addition, one incident was received by INEEL and should have been a part of the system but the contractor misunderstood the data.

The State has implemented an excellent tracking system for incident files. Within the past few months the State obtained access to the Internet system and is able to promptly submit information to the NMED system. The State is also updating its entries into the NMED system by submitting data on incidents that occurred in 1995 and 1996 that were

not previously reported to the NRC. The New Hampshire incident tracking system is able to manipulate data in a number of ways for regulatory use. For example, the State can retrieve data based upon license number, dates of occurrence, or the county in which the event occurred.

Based on the IMPEP evaluation criteria, the review team recommends that New Hampshire's performance with respect to the indicator, Response to Incidents and Allegations, be found satisfactory.

#### 4.0 NON-COMMON PERFORMANCE INDICATORS

IMPEP identifies four non-common performance indicators to be used in reviewing Agreement State programs: (1) Legislation and Regulations; (2) Sealed Source and Device Evaluation Program; (3) Low-Level Radioactive Waste Disposal Program; and (4) Uranium Recovery Program. New Hampshire's agreement does not cover uranium recovery operations, so only the first three non-common performance indicators were applicable to this review.

## 4.1 Legislation and Regulations

## 4.1.1 Legislative and Legal Authority

The DHHS is authorized as the State radiation control agency under New Hampshire Revised Statutes Annotated (RSA) 1990, Chapter 125. RSA 125-F:1 to F:25 covers radioactive material, RSA 125:77-b covers radioactive waste, and RSA 125-B covers emergency response. The radiation control program is administered by the BRH. No changes have occurred in the legal authority of the BRH since the previous review. As noted earlier in the report under Section 2, "Status of Items Identified in Previous Reviews," a legislative amendment was made to the New Hampshire Administrative Procedure Act in August 1995 to exempt BRH regulations from the formatting requirements of RSA 541-A:3 of the State's administrative rulemaking system.

## 4.1.2 <u>Status and Compatibility of Regulations</u>

The "New Hampshire Rules for Control of Radiation," apply to all ionizing radiation, whether emitted from radionuclides or devices.

The review team discussed the procedures used in the State's regulatory process with the BRH Administration and found that New Hampshire offers the public the opportunity to comment on proposed regulations and participate in public hearings following the comment period. Procedures also require the proposed regulations, proposed hearing date, hearing comments and analysis be well publicized. Draft copies of the proposed regulations are provided to NRC during the rule development process. Final regulations are subject to a "Sunset" law and rules expire exactly six years after promulgation for rules adopted prior to August 1994, and after eight years for rules adopted after August 1994. After expiration, these regulations must be resubmitted in their entirety to remain in effect.

The review team evaluated New Hampshire's responses to the questionnaire, NRC correspondence pertaining to the review of New

Hampshire's regulations subsequent to the August 1994 review and discussed the State's regulations or other legally binding requirements with the BRH Administrator and the RMS Supervisor to determine the status of the New Hampshire program with regard to the implementation of regulatory requirements needed to maintain compatibility through December 1997.

The State adopted two NRC regulation amendments since the 1994 review and are implementing five other NRC rules by other legally binding means or they are not currently applicable to the New Hampshire program:

- "Standards for Protection Against Radiation," 10 CFR Part 20 amendment (56 FR 61352) was needed by January 1, 1994. As noted earlier in the report, this regulation was adopted by the State in February 1995, and was reviewed by the NRC for compatibility and health and safety. This review was in accordance with the new Policy Statement on Adequacy and Compatibility of Agreement State Programs approved by the Commission by Staff Requirements Memorandum (SRM) dated June 30, 1997. Based upon this review, two comments with compatibility significance were provided to the State in letter dated August 18, 1997. The review team notes that NRC staff is currently reviewing all Agreement State equivalent regulations to Part 20, Standards for Protection Against Radiation. The reviews are being conducted outside the IMPEP process.
- "Notification of Incidents," was adopted in February 1995 for Parts equivalent to 10 CFR Parts 20, 31, 40 and 70, and the equivalents of Parts 30, 34, and 39 are scheduled for adoption in December 1997. These requirements were reviewed by the NRC as a part of the overall revision of the New Hampshire Rules for the Control of Radiation which were published in 1995. In letter dated January 3, 1997, these regulations were found to meet the compatibility requirements, at that time. In accordance with the new Policy Statement on Adequacy and Compatibility of Agreement State Programs, the review team's evaluation found these regulations would continue to be compatible.
- "Emergency Planning Rule," 10 CFR Parts 30, 40, and 70, which was needed by April 7, 1993. As noted earlier, currently the State has no licensee to which this rule is applicable. However, the State has indicated that the requirements of this rule will be used in the review process for new license applications for facilities that should be subject to these requirements. This rule is a part of the rulemaking package which is scheduled for adoption by December 1997.
- "Safety Requirements for Radiographic Equipment," which was needed by January 10, 1994. The review team verified that these requirements are being incorporated by industrial radiography license conditions. This rule is a part of the rulemaking package which is scheduled for adoption by December 1997.
- "Licensing and Radiation Safety Requirements for Irradiators," 10 CFR Part 36 amendment (58 FR 7715) which became effective on July

1, 1993 and was due by July 1, 1996. The State currently has no licensee to which this rule is applicable. However, the State has indicated that the requirements of this rule will be used in the review process for new irradiator license applications, if any are received.

- "Decommissioning Recordkeeping and Documentation Additions," 10 CFR Parts 30, 40 and 70 amendments (58 FR 39628) which became effective on October 25, 1993 and were due by October 25, 1996. The State adopted a portion of this regulation in 1993. However, the State has indicated that the requirements of this rule are being used in the review process for licenses. The remaining portion of this rule is a part of the rulemaking package which is scheduled for adoption by December 1997.
- "Self-Guarantee as an Additional Financial Mechanism," 10 CFR Parts 30, 40, and 70 amendments (58 FR 68726 and 59 FR 1618) that became effective on January 28, 1994 and was due by January 28, 1997. Note, this rule was designated as a Division 2 matter of compatibility. Division 2 compatibility allows the Agreement States flexibility to be more stringent (i.e., the State could choose not to adopt self-quarantee as a method of financial assurance). If a State chooses not to adopt this regulation, the State's regulation, however, must contain provisions for financial assurance that include at least a subset of those provided in NRC's regulations; e.g., prepayment, surety method (letter of credit or line of credit), insurance or other guarantee method (e.g., a parent company guarantee). This rule has been redesignated as Category D under the Commission's new adequacy and compatibility policy; however, NRC is currently proposing to redesignate it as Categroy D-H&S. [For category D-H&S regulations, States should adopt the essential objectives of the rule in order to maintain an adequate program.] The State currently has no licensee to which this rule is applicable. However, the State has indicated that the requirements of this rule are being used in the review process for new license applications. This rule is a part of the rulemaking package which is scheduled for adoption by December 1997.
- "Timeliness in Decommissioning of Materials Facilities," 10 CFR Parts 30, 40, and 70 amendments (59 FR 36026) that became effective on August 15, 1994 and was due by August 15, 1997. The State currently has no licensee to which this rule is applicable. However, the State has indicated that the requirements of this rule are being incorporated as conditions in licenses issued before rule promulgation. This rule is a part of the rulemaking package which is scheduled for adoption by December 1997.
- "Quality Management Program and Misadministration," 10 CFR Part 35 amendment (56 FR 34104) which became effective on January 27, 1992 and was due by January 27, 1995. BRH has not adopted the equivalent to the quality management and misadministration rule. As reported to NRC previously, BRH withheld adoption of this rule pending NRC's revision to 10 CFR Part 35. The NRC is continuing to defer compatibility findings for Agreement States that have not

yet adopted a compatible Quality Management rule until NRC issues a revised 10 CFR Part 35 rule. When the revision of 10 CFR Part 35 is completed, compatibility designations for the new rule will be established, and an effective date for Agreement State implementation will be set.

The following rules were not due during the review period but are in the rulemaking process to be adopted by December 1997:

- "Preparation, Transfer for Commercial Distribution and Use of Byproduct Material for Medical Use," 10 CFR Parts 30, 32 and 35 amendments (59 FR 61767, 59 FR 65243, 60 FR 322) that became effective on January 1, 1995 and will become due on January 1, 1998.
- "Low-Level Waste Shipment Manifest Information and Reporting," 10 CFR Parts 20 and 61 amendments (60 FR 15649, 60 FR 25983) that will become effective March 1, 1998. Agreement States are expected to have an effective rule on the same date.
- "Frequency of Medical Examinations for Use of Respiratory Protection Equipment," 10 CFR Part 20 amendments (60 FR 7900) that became effective on March 13, 1995, and will become due on March 13, 1998. Note, this rule was designated as a Division 2 matter of compatibility. Division 2 compatibility allows the Agreement States flexibility to be more stringent (i.e., the State could choose to continue to require annual medical examinations). This rule has been redesignated as Category D-H&S under the Commission's new adequacy and compatibility policy. (For category D-H&S regulations, States should adopt the essential objectives of the rule in order to maintain an adequate program.)
- "Performance Requirements for Radiography Equipment," 10 CFR Part 34 amendments (60 FR 28323) that became effective on June 30, 1995, and will become due on June 30, 1998.
- "Radiation Protection Requirements: Amended Definitions and Criteria," 10 CFR Parts 19 and 20 amendments (60 FR 36038) that became effective August 14, 1995 and will become due on August 14, 1998.
- "Medical Administration of Radiation and Radioactive Materials,"
  10 CFR Part 20.35 amendment (60 FR 48623) that became effective on October 20, 1995 and will become due on October 20, 1998.
- "Clarification of Decommissioning Funding Requirements," 10 CFR Parts 30, 40, and 70 amendments (60 FR 38235) that became effective November 24, 1995, and will become due on November 24, 1998.

While no rulemaking action has been initiated, at the time of the review the following items are on the BRH's regulatory agenda:

 "Compatibility with the International Atomic Energy Agency," 10 CFR Part 71 amendment (60 FR 50248) that became effective April 1, 1996 and will become due on April 1, 1999. The State plans to adopt this rule in 1999.

- "Termination or Transfer of Licensed Activities: Record Keeping Requirements," 10 CFR Parts 20, 30, 40, 61, 70 (61 FR 24669) that became effective on May 16, 1996. This requirement need not be in effect until May 16, 1999. The State plans to adopt this rule in 1999.
- "Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act," 10 CFR Part 20 amendment (61 FR 65119) that became effective January 9, 1997 and will become due January 9, 2000. The State plans to adopt this rule in 1999.
- "Recognition of Agreement State Licenses in Areas Under Exclusive Federal Jurisdiction Within an Agreement State," 10 CFR Part 150 amendment (62 FR 1662) that became effective on January 13, 1997 and will become due January 13, 2000. The State plans to adopt this rule in the year 2000.
- "Criteria for the Release of Individuals Administered Radioactive Material," 10 CFR Part 20.35 amendment (62 FR 4120) that became effective on January 29, 1997 and will become due January 29, 2000. The State plans to adopt this rule in the year 2000.

Based on the IMPEP evaluation criteria, the review team recommends that New Hampshire's performance with respect to the indicator, Legislation and Regulations, be found satisfactory.

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

The review team did not evaluate the State's sealed source and device (SS&D) program during this review. Although New Hampshire currently has responsibility for this area, the State did not perform any SS&D evaluations during the period of the review. The review team verified this information by review of the national SS&D registry and confirmed that the State had not issued any SS&D sheets during the review period.

## 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 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 New Hampshire 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 and 4 above, the review team found the State's performance to be satisfactory with respect to each of the indicators, Technical Staffing and Training, Technical Quality of Licensing Actions, Technical Quality of Inspections, Response to Incidents and Allegations, and Legislation and Regulations. The review team found the State's performance to be satisfactory with recommendations for improvement for the indicator, Status of Materials Inspection Program. Accordingly, the review team recommended and the MRB concurred, in finding the New Hampshire program to be adequate to protect public health and safety, and compatible with NRC's program.

Below is a summary list of recommendations and suggestions, as mentioned in earlier sections of the report, for evaluation and implementation, as appropriate, by the State.

## Recommendations:

- 1. The review team recommends that core and non-core licensees be scheduled, assigned, and inspected at regular intervals in accordance with the State's established inspection priority system. (Section 3.1)
- 2. The review team recommends that the State review and revise its inspection report preparation process for those containing enforcement actions to ensure timely issuance of inspection findings. (Section 3.1)
- 3. The review team recommends that the State evaluate the number of staff needed to implement the program. (Section 3.2)
- 4. The review team recommends that appropriate State follow-up to inspections be conducted to confirm implementation of licensee corrective actions when significant problems have been identified. (Section 3.4)

## Suggestions:

- The review team suggests that the State clearly establish its policy for initial inspection of priority 3 and above licenses, (6 months or 12 months), and adhere to the established policy. (Section 3.1)
- The review team suggests that the State increase reciprocity inspections to meet the inspection goals established in IMC 1220. (Section 3.1)
- 3. The review team suggests that the State develop a written training and qualifications plan. (Section 3.2)

4. The review team suggests that the State adhere to the policy of annual supervisory accompaniments of all inspectors. (Section 3.4)

The State uses a violation response review checklist to document staff reviews of how the licensee addresses their response to each NOV. (Section 3.4)

# LIST OF APPENDICES

Appendix A	IMPEP Review Team Members
Appendix B	New Hampshire Organization Charts
Appendix C	New Hampshire's Questionnaire Response
Appendix D	License File Reviews
Appendix E	Inspection File Reviews
Appendix F	Incident File Reviews
Attachment 1	New Hampshire's Response to Draft Report

## APPENDIX A IMPEP REVIEW TEAM MEMBERS

Name	Area of Responsibility
Cardelia H. Maupin, NRC/OSP	Team Leader Response to Incidents and Allegations Legislation and Regulations
Craig Gordon, NRC/RI	Status of Inspection Program Technical Quality of Inspections
William Passetti, FL	Technical Staffing and Training Technical Quality of Licensing Actions

# APPENDIX B

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

## ORGANIZATIONAL CHART

APPENDIX C

INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

QUESTIONNAIRE - RESPONSE