John A. Stephens, Commissioner Department of Health and Human Services 129 Pleasant Street Concord NH. 03301-3857

Dear Commissioner Stephens:

On September 28, 2004, 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 IMPEP review was conducted June 21-25, 2004. The MRB found the New Hampshire program adequate, but needs improvement, and not compatible with the U.S. Nuclear Regulatory Commission's (NRC) program. Based on slow progress to qualify new staff, inability to hire a permanent Administrator and slow progress in adopting compatible State regulations, the MRB agreed with the team's recommendation that the program continue on heightened oversight.

New Hampshire has been on heightened oversight since the 2001 IMPEP review. Although the program will continue on heightened oversight, the review team noted continued program improvements that have been implemented by New Hampshire since the February 2003 follow-up review. These program improvements include: reduction of the licensing backlog; elimination of the inspection backlog; implementation of a new fee schedule which provides increased, designated funding for the program; designation of a new salary schedule that provides technical staff increased earning potential as well as additional promotion potential; reclassification of the Section Administrator position; and hiring new technical staff. These actions have demonstrated a high level of Department of Health and Human Services management support for the Agreement State program, and a continued commitment to operating a fully satisfactory program in the future.

As you know, heightened oversight is an increased monitoring process used by NRC to follow the progress of improvement needed in an Agreement State program. It involves preparation of a program improvement plan, bimonthly conference calls, and submission of status reports prior to each call with the appropriate New Hampshire and NRC staffs. We request that you prepare and submit a revised program improvement plan as part of your response to the recommendations in Section 5 of the enclosed final report, "Integrated Materials Performance Evaluation Program, Review of New Hampshire Agreement State Program - Final Report." I ask that you have your staff dialogue with Paul Lohaus on the required elements of the revised plan to ensure that measures of success, and milestones to achieve the success measures, are clearly identified. The plan should be submitted within 30 days of this letter. Upon review of the revised program improvement plan, the staff will schedule the first conference call. The initial conference call should be scheduled and conducted no later than November 22, 2004. Based on the results of the current IMPEP review, a follow-up review will be scheduled during the period June 2005 - September 2005. The follow-up review will cover the State's action on the recommendations from the June 2004 review.

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

Sincerely,

/RA/

Martin J. Virgilio
Deputy Executive Director for
Materials, Research and
State Programs

cc: Mary Ann Cooney, Director
Division of Public Health Services
Department of Health and Human Services

Alice Bruning, Administrator
Division of Public Health Services

Kathryn Frey
Division of Public Health Services

Dennis O'Dowd, Supervisor Radiological Health Section Department of Health and Human Services

Bruce Cheney, State Liaison Officer Director, Department of Safety

Roland Fletcher, Maryland OAS Liaison to the MRB

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

Sincerely,

/RA/

Martin J. Virgilio
Deputy Executive Director for
Materials, Research and
State Programs

cc: Mary Ann Cooney, Director bcc: Chairman Diaz

Division of Public Health Services

Commissioner McGaffigan, Jr.

Department of Health and Human Services

Commissioner Merrifield

Alice Bruning, Administrator Division of Public Health Services

Kathryn Frey Division of Public Health Services

Dennis O'Dowd, Supervisor Radiological Health Section Department of Health and Human Services

Bruce Cheney, State Liaison Officer Director, Department of Safety

Roland Fletcher, Maryland OAS Liaison to the MRB

Distribution: DCD (SP01) PDR (YES**T**)

DIR R JStrosnider, NMSS

DWhite, RI KCyr, OGC
JHarris, Kansas PHolahan, NMSS
ISchoenfeld, OEDO TCombs, OCA (2)
CMiller, NMSS/IMNS FCameron, OGC
RStuckmeyer, NMSS/IMNS STreby, OGC

AMcCraw

ADAMS: ML042750209

DOCUMENT NAME: C:\Documents and Settings\ATM\Desktop\2004 NH Final Report and Letter.wpd

To receive a copy of this document, indicate in the box: "C" = Copy without attachment/enclosure "E" = Copy with attachment/enclosure "N" = No copy

OFFICE	STP	STP:DD	STP:D	DEDMRS	
NAME	KSchneider:gd	JMPiccone	PHLohaus	MJVirgilio	
DATE	10/01/04	10/01/04	10/01/04	10/07/04	

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

June 21-25, 2004

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 of June 21-25, 2004, by a review team comprised of technical staff members from the Nuclear Regulatory Commission (NRC) and the Agreement 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 a Final General Statement of Policy," published in the Federal Register on October 16, 1997, and the February 26, 2004, NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." Preliminary results of the review, which covered the period of February 6, 2003 to June 25, 2004 for the indicators Technical Staffing and Training, Status of Materials Inspection Program, and Compatibility Requirements, and the period June 30, 2001 to June 25, 2004 for the other performance indicators were discussed with New Hampshire management on June 25, 2004.

A draft of this report was issued to New Hampshire for factual comment on July 21, 2004. The State responded in a letter dated August 11, 2004. At the time of the review, the review team found New Hampshire's performance to be satisfactory for five performance indicators. The review team found New Hampshire's performance to be satisfactory, but needs improvement for the indicator "Technical Staffing and Training" and unsatisfactory for the indicator "Compatibility Requirements." Based on slow progress to qualify new staff, inability to hire a permanent Administrator and slow progress in adopting compatible State regulations, the review team recommended that the New Hampshire program continue to be "Adequate, But Needs Improvement," and "Not Compatible," and that the program continue on heightened oversight.

On September 28, 2004, the Management Review Board (MRB) met to consider the proposed final report with New Hampshire staff. New Hampshire has been on heightened oversight since the 2001 IMPEP review. The review team noted and the MRB agreed that continued program improvements have been implemented by New Hampshire since the February 2003 follow-up review. These program improvements include: reduction of the licensing backlog; elimination of the inspection backlog; implementation of a new fee schedule which provides increased, designated funding for the program; designation of a new salary schedule that provides technical staff increased earning potential as well as additional promotion potential; reclassification of the Section Administrator position; and hiring new technical staff. These actions have demonstrated a high level of Department of Health and Human Services management support for the Agreement State program, and a continued commitment to operating a fully satisfactory program in the future.

The MRB concurred in the individual findings by the review team for each indicator and concurred in the review team's recommendation for a period of heightened oversight to continue to assess the progress of New Hampshire in implementing corrective actions. The MRB found the New Hampshire radiation control program was adequate, but needs improvement, and not compatible with NRC's program.

The MRB directed that: (1) a revision to the program improvement plan should be prepared and submitted as part of the responses to the recommendations found in Section 5; and (2) that a follow-up review be conducted during the period June-September 2005. Under heightened oversight, bimonthly conference calls will take place with New Hampshire staff, with a written progress report submitted to NRC staff two weeks prior to each call.

Historically, the New Hampshire Agreement State program has been administered by the Bureau of Radiological Health located within the Office of Community and Public Health, Department of Health and Human Services (the Department) as described in the 2003 follow-up IMPEP review. The Department Commissioner is appointed by and reports to the Governor.

To increase efficiency, the Department was reorganized on July 1, 2004. Under the reorganization, the Radiological Health Section (the Section) is located in the Bureau of Prevention Services (the Bureau), Division of Public Health Services (the Division), Office of Program Operations, within the Department. The new organization charts for the Department, Division, and Section are included as Appendix B. The New Hampshire Agreement State program was in transition to the new organization during the week of the on-site portion of the review. The review team used the new organization names and titles in this report even though the Agreement State program operated as a Bureau instead of a Section during the review period.

In preparation for the review, a questionnaire addressing the common and non-common performance indicators was sent to the State on April 2, 2004. The Section provided a response to the questionnaire on June 14 and June 18, 2004. A copy of the questionnaire response can be found on NRC's Agency-wide Document Access and Management System using the Accession Numbers ML 041900333 and ML 041900390.

At the time of the follow-up review, the New Hampshire Agreement State program regulated approximately 79 specific licenses authorizing Agreement materials. 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.

The review team's general approach for conduct of this review consisted of: (1) examination of New Hampshire's response to the questionnaire; (2) review of applicable New Hampshire statutes and regulations; (3) analysis of quantitative information from the Section's licensing and inspection data base; (4) technical evaluation of selected licensing and inspection actions; (5) field accompaniments of a New Hampshire inspector; and (6) interviews with staff and management to answer questions or clarify issues. The team evaluated the information that it gathered against the IMPEP performance criteria for each common and applicable non-common performance indicator and made a preliminary assessment of the radiation control program's performance.

Section 2 below discusses the State's actions in response to recommendations made following the previous IMPEP review and the team's conclusions regarding close out of the recommendations. 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 performance indicators, and Section 5 summarizes the review team's findings and recommendations. Recommendations made by the review team are comments that relate directly to program performance by the Division. A response is requested from the Division to all recommendations in the final report.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous IMPEP review, which concluded on June 29, 2001, six recommendations were made and transmitted to Donald L. Shumway, Commissioner, Department of Health and Human Services on November 6, 2001. During the follow-up IMPEP review which concluded on February 6, 2003, two recommendations were closed (Numbers 1 and 3 from the 2001 report). The final follow-up report was transmitted to Ms. Dunn on June 11, 2003. The team's evaluation of the current status of all open recommendations is as follows:

1. The review team recommends that the Bureau take the appropriate management measures to conduct inspections (both initial and core) in accordance with the State's

established inspection priority system. (Section 3.1) (Recommendation 2 from the 2001 report)

Current Status: The Section has taken the appropriate management measures to conduct inspections in accordance with their assigned inspection frequencies. At the time of the review, there were no overdue inspections and the inspection backlog had been eliminated. The Radioactive Materials Program Supervisor has also developed a five-year inspection management plan. This recommendation is closed.

2. The review team recommends that the Department take the necessary actions to address the staff turnover and staff vacancies as appropriate. (Section 3.3) (Recommendation 4 from the 2001 report)

Current Status: Since the 2003 follow-up IMPEP review, the two vacant staff positions were filled. The Department received approval for a new Radiation Health Physicist series that provides increased salary potential and an extended career ladder. This new series should help with staff hiring and retention. With the implementation of the new fees system on July 1, 2003, all Section positions are fee supported and, as such, they are not subject to the State-wide hiring freeze. On June 23, 2004, the Division received final approval for the salary upgrade and reclassification of the Section Administrator position. This position was known as the Bureau Administrator prior to the reorganization. The review team believes that the Department has taken the necessary actions to address the staff turnover and staff vacancies. This recommendation is closed.

3. The review team recommends that the Bureau examine and change the business processes and organization of the Section to improve the effectiveness and efficiency of the program. (Section 3.3) (Recommendation 5 from the 2001 report)

Current Status: As noted in the 2003 follow-up IMPEP review, the practice of rotating staff on a routine basis was discontinued. With the retirement of the Radioactive Machines Program Supervisor, the Radioactive Materials Program Supervisor assigns work to the staff, as necessary. However, the two new staff members have mainly worked in the Radioactive Machines Program and need to complete their qualifications as license reviewers and inspectors within the Radioactive Materials Program (See Section 3.1). With the reclassification of the Section Administrator position from an Administrator II to a Health Physicist V, the Department will begin recruiting for this permanent position. A new reorganization went into effect on July 1, 2004. Two staff members who were transferred to the Department of Safety in January 2004 returned to the Section. Continuation of contractor support after June 30, 2004 (in both licensing and inspection activities) for the Radioactive Materials Program is under evaluation by Department management.

Until a permanent Section Administrator is hired and the Section has a period of satisfactory performance under the new organization without contract support, the review team believes that the program is still fragile and needs additional time to implement the new organization, complete new staff qualification, and stabilize program performance with permanent staff. The MRB agreed that this recommendation is open, however the MRB directed staff to revise this recommendation to reflect that a reorganization had occurred. The recommendation is revised as follows: The review

team recommends that the Section continue to examine and change the business processes of the Section to improve the effectiveness and efficiency of the program.

4. The review team recommends that the Bureau develop and implement an action plan to adopt NRC regulations in accordance with current policy on adequacy and compatibility. (Section 4.1.2) (Recommendation 6 from the 2001 report)

Current Status: The Division has taken limited action to adopt overdue regulations due to focusing efforts of existing staff and contractors on improvements to the licensing and inspection programs. The Section Administrator vacancy significantly impacts this indicator since historically this individual has had the responsibility for rulemaking. Since the 2003 follow-up IMPEP review, the Department has adopted two regulations required for compatibility and has prepared six additional amendments presently under review with the Department's Bureau of Legal Services and Regulation. See additional discussion in Section 4.1. This recommendation remains open.

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) Technical Staffing and Training (2) Status of Materials Inspection Program; (3) Technical Quality of Inspections; (4) Technical Quality of Licensing Actions; and (5) Technical Quality of Incident and Allegation Activities.

3.1 Technical Staffing and Training

Issues central to the evaluation of this indicator include the 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 Division and Section management and staff, reviewed job descriptions and training records, and considered any possible workload backlogs.

There have been a number of staff and organizational changes impacting the Section since the February 2003 follow-up IMPEP review. The Section is authorized for ten positions under the new organization. These positions include the Section Administrator, Radioactive Materials Program Supervisor (the Supervisor), Radiation Machine Program Supervisor, five Radiation Health Physicists, Program Planner, and two administrative support staff.

The Section has experienced staff turnover through retirements and transfers since the 2003 follow-up review that continue to impact performance of the Section. The Section Administrator position has been vacant since April 2002. The Radiation Machine Supervisor retired in April 2004 and the Supervisor has been acting in both positions in addition to his routine duties. In August 2003, the radiochemistry laboratory and environmental monitoring program was transferred to Public Health Laboratories within the Department. Three positions, including a health physicist position funded by the Centers for Disease Control and Prevention (CDC) for bioterrorism were transferred along with the radiological emergency program to the Department of Safety. With the July 2004 reorganization, two radiological emergency positions have been transferred back to the Section.

The Section reported that 2.3 FTE were utilized by the Section, which includes management time but excludes the efforts for radiological emergency response and contract support for the

licensing and inspection programs. The Section reported approximately 0.2 FTE for contract support for the licensing and inspection programs during the past fiscal year which expired on June 30, 2004. Due to State liability constraints, the Division is exploring the viability of renewing the contract support for the fiscal year that began on July 1, 2004.

Successful candidates for technical positions at the entry level are required to have a bachelor's degree in science and a master's degree or additional radiation related work experience and training for positions beyond entry level. The team noted that all of the staff satisfied the degree requirements when hired. At the present, two of the four technical staff perform the majority of the licensing and compliance activities with support from the contractors. One health physicist (senior staff member) and the Supervisor are fully qualified as inspectors and license reviewers. The two newest staff members dedicate the majority of their time to the Radiation Machine Program. Although hired in July and August 2003 respectively, both new staff members have taken several of the required courses during the past year, but have had limited casework and field time to support achieving qualification as independent license reviewers and inspectors in the Radioactive Materials Program. The senior staff member is currently performing the majority of the licensing reviews. The other experienced health physicist is qualified to conduct inspections of most categories of licensees in the State and conducts the majority of the inspections; however, there are still categories of license inspections that additional field work is required for full qualifications as an inspector. The individual is currently undergoing training in these areas. The individual has not yet received any qualifications as a license reviewer, but is also undergoing training towards licensing qualifications.

As noted in the 2003 follow-up IMPEP report, New Hampshire finalized their training and qualification policy and supporting documentation following NRC Manual Chapter (MC) 1246. The health physicist hired in 2002 is currently being qualified under this policy and, as noted above, has achieved qualifications as an inspector for the majority of license categories. The review team discussed with the Supervisor additional enhancements for casework to establish qualification as a license reviewer. With the limited number of licensees available to New Hampshire, the review team discussed with the Supervisor the need to develop innovative approaches to provide relevant casework and on-the-job training for staff. Training support from surrounding Agreement States or NRC Region I could supplement the available casework to accelerate the qualification process for all staff conducting materials activities.

The Supervisor stated that the four Health Physicists are expected to divide their activities equally between the Radioactive Materials Program and the Radiation Machine Program once all training and qualification requirements are complete. The review team noted that the loss of the senior staff member or the Supervisor could have an adverse effect on the radioactive materials program until all technical staff are fully trained and qualified. The review team recommends that the Section establish a plan for the new staff to promptly complete all training and qualification requirements in order to be qualified as independent license reviewers and inspectors.

The Section receives advice from the Radiation Advisory Committee, which the Section Administrator is an ex-officio member and by statute holds the position of the Technical Secretary. The review team identified no conflict of interest concerns.

Since April 2002, the Department conducted nationwide searches for the Section Administrator position. Although their searches found qualified staff, two offers for the Administrator position were declined due to low salaries. On June 23, 2004, the Governor and his Executive Council approved reclassification of the Section Administrator position from an Administrator II position

to a Radiation Health Physicist V position so that New Hampshire can competitively recruit in the health physics community. The Department is again initiating its search and is expecting to attract qualified candidates with the increased salary in order to fill this position.

In early January 2003, the recently elected Governor froze all vacant positions including the Section Administrator position. On July 1, 2003, the new fee structure was adopted and since then the Section has been fully funded without general funds. The vacant positions are now fee supported and, as such, they are not subject to the hiring freeze. However all vacant positions undergo a Department administrative review before a waiver is granted to fill the position. A waiver was granted on June 17, 2004 to fill one of the vacant administrative staff positions.

With the adoption of the new fee system, funds are available for out of state travel for training purposes and the contract support for the program. Approval for out of state travel must still undergo Department administrative approval. Each of the new staff members have attended several courses in 2003 and are scheduled for additional training. One new staff member will be attending the Five-week Health Physics course held in Oak Ridge, Tennessee.

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, but needs improvement.

3.2 Status of Materials Inspection Program

The team focused on five factors in reviewing this indicator: inspection frequency, overdue inspections, initial inspection of new licensees, the timely dispatch of inspection findings to licensees, and the performance of reciprocity inspections. The evaluation is based on the Section's questionnaire response relative to this indicator, data gathered independently from the Section's licensing and inspection data tracking system, the examination of completed licensing and inspection casework, and interviews with managers and staff.

A review of the Section's inspection priorities revealed that the inspection frequencies for various types of licenses are at least as frequent as similar license types listed in the November 25, 2003 revision to MC 2800 including performing initial inspections within one year of license issuance. The Section utilizes an inspection tracking spreadsheet and the Supervisor has developed a five-year inspection management plan.

In response to the questionnaire, the Section indicated that no inspections were currently overdue by more than 25 percent of the NRC frequency. The team reviewed lists of information for all inspections conducted and all new licenses issued during the period and verified this information. During this period, the Section had 21 core licenses, including eight new licenses. Several inspections were completed early with the assistance of a contractor to provide the Section the opportunity to complete other responsibilities including training new staff. Three routine core inspections were conducted to eliminate the backlog identified in February 2003. The Section's efforts to address and correct the inspection backlog are commendable.

The review team evaluated the timeliness of the communication of inspection results to the licensees by reviewing inspection data and files for 15 inspections since the follow-up review. Ten inspection results were communicated within 30 days after the date of the inspection. Four of the reports were issued between six and 42 days overdue. One complex inspection with multiple violations conducted in November 2003 still has not been issued. The Section has been in communication with this licensee to address some of the identified violations through an

amendment to the license. However, in discussions with the review team, the Section stated that the inspection report will be issued shortly.

The review team determined that the Section granted 13 core reciprocity licenses during the review period. The Section satisfied the 20 percent criteria prescribed in MC 1220 by conducting five inspections of core reciprocity licensees during the review period.

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

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

The review team evaluated field interview forms, inspection reports, and enforcement referrals for 12 radioactive materials inspections conducted during the review period. The review team also interviewed inspectors to clarify casework information. The casework reviewed included inspections conducted by three current and one former Section inspector (including one contractor), and covered inspections of various types including industrial radiography, medical institution - written directive required, brachytherapy, irradiator greater than 10,000 curies, academic type A broad scope, and manufacturing. Appendix C lists the inspection casework files reviewed for completeness and adequacy with case-specific comments.

Based on the casework file reviews, the review team found that routine inspections covered all aspects of each licensee's radiation protection program. The inspection reports were thorough, complete, consistent, and of high quality, with sufficient documentation to ensure that licensee's performance with respect to health and safety was acceptable. The documentation adequately supported any cited violations. Exit interviews were held with appropriate licensee personnel. Team inspections were performed when appropriate and for training purposes. The inspection procedures utilized by the Section were consistent with inspection guidance in MC 2800.

The Supervisor generally conducts supervisory accompaniments of material inspectors once a year. The team determined that the Section's senior staff member had not been accompanied for two years. The team discussed this issue with staff and determined that this inspector was primarily focused on licensing casework during this period. The Supervisor indicated that in the future, all inspectors will be accompanied annually. Supervisory accompaniments are documented in the inspection reports.

The review team accompanied one Section inspector on June 9, 2004 during an inspection at a medical institution which is identified in Appendix C. During the accompaniment, the inspector demonstrated appropriate performance-based inspection techniques and knowledge of the regulations. The inspector was well prepared and thorough in his review of the licensee's radiation safety program. The inspection was adequate to assess radiological health and safety at the licensed facility.

The Section has an adequate number and selection of survey meters to support the current inspection program as well as for responding to incidents and emergency conditions. The Section has contractors who calibrate their survey instruments on an annual basis. Prepared emergency field kits are also available for emergency use. The Section also has a well equipped analytical laboratory including a liquid scintillation counter, intrinsic germanium detectors coupled to multichannel analyzers and a low background beta-gamma counter. The

laboratory also has the capacity to analyze wipes, water samples, soil samples and other environmental media.

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.

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

The review team examined completed licensing casework and interviewed the staff for 12 specific licenses. Licensing actions were evaluated for completeness, consistency, proper isotopes and quantities used, qualifications of authorized users, adequate facilities and equipment, and operating and emergency procedures sufficient to establish the basis for licensing actions. Licenses were evaluated for overall technical quality including accuracy, appropriateness of the license, its conditions, and tie-down conditions. Casework was evaluated 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; pre-licensing visits; peer or supervisory review as indicated; and proper signature authority. The files were also checked for retention of necessary documents and supporting data.

Licensing casework was selected to provide a representative sample of licensing actions that were completed during the review period. The sampling included the following types of licenses: research and development, industrial radiography, medical (institution and private practice), portable gauge, fixed gauge and broad scope academic. Licensing actions selected for evaluation included one new license, two renewals, eight amendments and one termination. A list of the licenses evaluated with case-specific comments can be found in Appendix D.

Overall, the review team found that the licensing actions were thorough, complete, consistent, and of acceptable quality with health and safety issues properly addressed. License tie-down conditions were stated clearly, backed by information contained in the file, and are inspectable. The licensee's compliance history was taken into account when reviewing renewal applications and amendments. The senior staff member properly used appropriate licensing guides and standard license conditions.

The Section performed reviews on seven new license applications, 10 license terminations and 383 other licensing actions during the review period. The team reviewed one license authorizing a 13,000 Ci irradiator of cesium-137, which appears to not be fully compliant with the requirements of 10 CFR Part 36 by license condition, procedural commitments, or regulation. In the draft of this report, the review team had recommended that the Section immediately take action to bring the irradiator licensee into full compliance with 10 CFR Part 36 by adopting regulations compatible with 10 CFR Part 36, by license condition, procedural commitments, regulation, or other legally binding requirements. On July 29, 2004, the Section implemented 10 CFR Part 36 by license condition and completed this action. The Section sent the license condition to NRC for review on August 11, 2004 and was informed by NRC that the license conditions were acceptable. See Section 4.1 for further discussion on regulation adoption.

All licensing actions are reviewed by the senior staff member who closely monitors the timeliness of licensing actions. All completed licensing actions are then reviewed by the Supervisor, who as acting Section Administrator signs all licensing documents. The team also

found that terminated licensing actions were adequately documented. In general, the files included the appropriate material transfer records and survey records. No potentially significant health and safety issues were identified except with the following observation. There was a commitment made by the Section during the 2001 IMPEP to ensure financial assurance is provided for the two academic broad scope licensees authorized to possess radioactive material in quantities requiring financial assurances. It was noted in 2001 that these licensees did not actually possess quantities of radioactive materials requiring financial assurance. The Section agreed to have the licensees either submit financial assurance or reduce the authorized possession limits of radioactive material. Financial assurance has been received for one of the licensees, but there is no documentation in the file to suggest an amendment has been performed to reduce the possession limits of radioactive material or demonstrate financial assurance for the second licensee. During the review, the Supervisor discussed this issue with the licensee who is presently undergoing license renewal.

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.

3.5 Technical Quality of Incident and Allegation Activities

In evaluating the effectiveness of the Section's actions in responding to incidents, the review team examined the Section's response to the questionnaire relative to this indicator, reviewed the incident reports for New Hampshire in the Nuclear Material Events Database (NMED) against those contained in the Section's files, and evaluated reports and supporting documentation for nine incidents. A list of the incident casework examined with case-specific comments is included in Appendix E. The review team also reviewed the Section's response to three allegations involving radioactive material, including one allegation referred to the State by the NRC during the review period.

The incidents selected for review included the following event categories: medical misadministration, radiation overexposure, loss of radioactive material, abandoned radioactive material and transportation. The review team found that the Section's response to incidents was complete and comprehensive. Initial responses were prompt and well-coordinated, and the level of effort was commensurate with the health and safety significance. The Section dispatched inspectors for on-site investigations when appropriate, and took suitable enforcement and follow-up actions. The Section's response efforts were generally well documented in the incident files and sometimes included pictures and time lines.

The responsibility for initial response and follow-up actions to materials incidents is assigned to one or more of the Section's health physicists. Upon receipt, staff reviews the report with the Supervisor or the senior staff member and decide on the appropriate response. Reports are given a unique tracking number. Documentation related to an incident is either placed in the appropriate license file or if no specific licensee is involved, the report is placed in a general incident file.

In response to the questionnaire, the Section reported that none of the radiological incidents met the criteria for reporting to NRC. Prior to the on-site review, the team queried the NMED database and identified nine incidents reported by the Section. Further evaluation by the team concluded that four of the incidents did require reporting to NRC. During the on-site review, a review of the Section incident files identified an additional five reports that were submitted to the NMED contractor but were not included in the national database since the incidents involved

NARM and did not involve lost or stolen radioactive material. No additional incidents in the Section's incident files required reporting.

For a majority of the review period, one individual was assigned the task of submitting incident reports to the NMED contractor. With the departure of this individual from the Section earlier this year, the responsibility for submitting reportable events to NRC has been assigned to another individual in the Section. The Section did not use the NMED local database due to technical issues, but these have been recently resolved and the Section plans to start using the NMED local database to track all events.

In evaluating the effectiveness of New Hampshire's actions in responding to allegations, the review team examined the Section's questionnaire response relative to this indicator, and the Section's allegation procedure. The casework for all three allegations received by the Section was reviewed. One allegation was referred to the State by the NRC and two were reported directly to the Section. The Section evaluates each allegation and determines the proper level of response. The review of the casework indicated that the Section took prompt and appropriate action in response to the concerns raised. Each of the allegations reviewed were appropriately closed, and the allegations could not be located at the time of the review, but the team concluded that the Section's response was appropriate based on discussions with the NRC Regional Office at the conclusion of the Section's investigation. There were no performance issues identified from the review of the casework documentation.

The review team noted that New Hampshire's Right to Know law requires that all public documents be made available for inspection and copying; however, the State does have the discretion to withhold sensitive information. The State can protect an alleger's identity.

Based on the IMPEP evaluation criteria, the review team recommends 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

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

4.1 Compatibility Requirements

4.1.1 Legislation

In evaluating this indicator, the team reviewed the Section's response to the questionnaire relative to this indicator and copies of legislation, and held discussions with the Supervisor and Division management. The Department is authorized as the State's radiation control agency under the New Hampshire Revised Statutes Annotated (RSA) 1990, Chapter 125. Legislation that affects the Section includes RSA 125-F:1-25, Radiological Health Program; RSA 107-B, Civil Defense Act; and RSA 125 B: 1, New England Compact Radiological Health Protection. The legislation for the Radiological Health Program was amended in 2003 to authorize the

collection of fees to cover the cost of the program and the Civil Defense Act was amended to change the designated agency.

4.1.2 <u>Program Elements Required for Compatibility</u>

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

The review team examined the procedures used in the Section's regulatory process and found that the public, licensees, and other interested parties are offered an opportunity to comment on proposed regulations. The NRC is provided with drafts for comment. After preparation of a package of draft regulations by the Section, the draft regulations are reviewed by the Department's Administrative Rules Unit prior to approval by the Department Commissioner. Final approval of all regulations is done by the Joint Legislative Committee on Administrative Rules. Rule promulgation typically requires six to 12 months. Final regulations in New Hampshire are subject to a sunset law and rules expire exactly eight years after adoption. After expiration, these regulations must be resubmitted in their entirety to remain in effect.

The 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 NRC's Office of State and Tribal Program's (STP) Regulations Assessment Tracking System.

The 2001 IMPEP review of the New Hampshire program determined that 13 NRC amendments required for compatibility had not been adopted. Eight of these amendments had not been adopted in a time frame of less than three years after the effective date of their adoption by the NRC in accordance with the Commission's adequacy and compatibility policy and thus would be adopted overdue. The 2001 review team and MRB found the State's performance for this indicator to be unsatisfactory. As discussed in Section 2.0, the 2001 review team made a recommendation that the Section develop and implement an action plan to adopt NRC regulations in accordance with the current Commission policy on adequacy and compatibility. The State's Program Improvement Plan presented to the NRC in December 2001 included specific milestones for steps toward the adoption of NRC regulations required for compatibility.

During the 2003 follow-up IMPEP review, the Section had not yet taken action to adopt overdue regulations due to focusing efforts of existing staff and contractors on improvements to the licensing and inspection programs. Preparing draft regulations and moving them through the administrative process is a responsibility of the Section Administrator. As noted in Section 3.1, this position has been vacant since April 2002. The number of overdue NRC amendments increased from eight to 11 and the total number of NRC amendments not adopted increased from 13 to 16.

The 2003 follow-up IMPEP review team also noted that 16 of the 40 regulations that comprise the radiation regulations had expired, including six important to the Agreement State Program. The expired sections included: He-P 4037: Transportation of Radioactive Material; He-P 4061: Land Disposal for Low-Level Radioactive - Technical Requirements for Waste Classification; 4062: Requirements for Transfer of Low-Level Radioactive Waste for Disposal at Land Disposal Facilities - Manifest, Records, Reports, Quality Assurance and Audits; He-P 4070: Fees; 4090: Annual Limits of Intakes (ALI) and Derived Air Concentrations (DAC) of

Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sanitary Sewers; and He-P 4092: Quantities of Radioactive Materials Requiring Labeling. The team expressed concern that these expired regulations might impact the State's ability to implement a complete regulatory program. In their April 28, 2003 response to the draft follow-up IMPEP report, the State submitted a rulemaking schedule to address regulation adoption in several phases and assigned a staff member to work on the rulemaking. Since the 2003 follow-up IMPEP review, the State adopted the six expired regulations in a rule package in September 2003.

During the bimonthly teleconference calls held July 24, 2003, September 25, 2003 and December 4, 2003 after the 2003 follow-up IMPEP review, the Division management and staff indicated that the State was on schedule to complete the draft rulemaking package to address all overdue NRC amendments by April 30, 2004. During the February 5, 2004 teleconference call, Section staff indicated that the State was attempting to meet its April 30, 2004 schedule with the exception of the medical amendments. The Division staff noted during the April 19, 2004 teleconference call that the previous momentum on all overdue and due regulations had been slowed by the significant workload in the Section and a State reorganization that included transferring two Section staff members to the Department of Safety. The September 2003 regulation adoption, mentioned in the previous paragraph, included two overdue NRC amendments. At the time of this review, the draft regulations for six NRC amendments were under review by the Department's Administrative Rules Unit with an anticipated final adoption by the end of 2004. Eight additional NRC amendments are currently being developed by the Section. One amendment was adopted through legally binding requirements on July 29, 2004 as noted in Section 3.4.

The following 12 regulations are overdue. Current NRC policy requires that Agreement States adopt certain equivalent regulations or legally binding requirements no later than three years after they are effective. The Section will need to promptly address these regulations in upcoming rule making or by adopting alternate legally binding requirements.

- "Timeliness in Decommissioning of Materials Facilities," 10 CFR Parts 30, 40 and 70 amendments (59 FR 36026) that became effective August 15, 1994. This amendment is currently under review by the Department's Administrative Rules Unit.
- "Termination or Transfer of Licensed Activities: Recordkeeping Requirements," 10 CFR Parts 20, 30, 40, 61, 70 amendments (61 FR 24669) that became effective June 17, 1996. This amendment is currently under review by the Department's Administrative Rules Unit.
- "Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act," 10 CFR Part 20 amendment (61 FR 65120) that became effective January 9, 1997. This amendment is currently under review by the Department's Administrative Rules Unit.
- "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 February 27, 1997. This amendment is currently being developed by the Section.
- "Criteria for the Release of Individuals Administered Radioactive Material," 10 CFR Parts 20 and 35 amendments (62 FR 4120) that became effective May 29, 1997.

Portions of the Part 20 amendment are designated as Category A for compatibility. This amendment is currently being developed by the Section.

- *Radiological Criteria for License Termination," 10 CFR Parts 20, 30, 40, and 70 amendments (62 FR 39057) that became effective August 20, 1997. Parts of this amendment are designated as A or B for compatibility. This amendment is currently under review by the Department's Administrative Rules Unit.
- "Deliberate Misconduct by Unlicenced Persons," 10 CFR Parts 30, 40, 61, 70, 71, and 150 (63 FR 1890; 63 FR 13733) that became effective on February 12, 1998. This amendment is currently being developed by the Section.
- "Minor Corrections, Clarifying Changes, and a Minor Policy Change," 10 CFR Parts 20, 35, and 36 amendments (63 FR 39477; 63 FR 45393) that became effective October 26, 1998. Portions of this amendment are designated as Category A for compatibility. This amendment is currently being developed by the Section.
- *Respiratory Protection and Controls to Restrict Internal Exposures," 10 CFR Part 20 amendment (64 FR 54543; 64 FR 55524) that became effective February 2, 2000. Portions of this amendment are designated as Category B for compatibility. This amendment is currently being developed by the Section.
- "Energy Compensation Sources for Well Logging and Other Regulatory Clarifications," 10 CFR Part 39 amendment (65 FR 20337) that became effective May 17, 2000. Portions of this amendment are designated as Category B for compatibility. The Section is proposing adoption by reference to NRC regulations. This amendment is scheduled for a public hearing on October 19, 2004. The Section submitted the amendment to NRC for review on September 27, 2004. The State currently has no licensees requiring this amendment.
- "New Dosimetry Technology," 10 CFR Parts 34, 36, and 39 amendments (65 FR 63749) that became effective January 8, 2001. The State currently has one licensee requiring this amendment. The Section amended the license on September 27, 2004 and also submitted the legally binding conditions for NRC's review on the same date.
- "Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material," 10 CFR Parts 30, 31, and 32 amendments (65 FR 79162) that became effective Feb. 16, 2001. Portions of this amendment are designated as Category B for compatibility. This amendment is currently being developed by the Section.

The Section will need to address the following four regulations in upcoming rule makings or by adopting alternate legally binding requirements:

- "Revision to the Skin Dose Limit," 10 CFR Part 20 amendment (67 FR 16298) that became effective April 5, 2002. Portions of this amendment are designated as Category A for compatibility. This amendment is currently under review by the Department's Administrative Rules Unit.
- "Medical Use of Byproduct Material," 10 CFR Parts 20, 32, and 35 amendments (67 FR 20249) that became effective April 24, 2002. Portions of these amendments are designated as either Category A or B for compatibility.

- Financial Assurance for Materials Licenses," 10 CFR Parts 30, 40 and 70 amendments (68 FR 57327) that became effective December 3, 2003.
- "Compatibility with IAEA Transportation Safety Standards (TS-R-1) and Other Safety Amendments," 10 CFR Part 71 amendments (69 FR 3698), that will become effective on October 1, 2004.

The review team determined that, at the time of the review, the State has not adopted 16 NRC amendments to regulations required for compatibility. Twelve of these amendments are overdue and will be adopted in a time frame greater than three years after the effective date of their adoption by the NRC. The remaining four regulations will need to be adopted starting in April 2005. Six of the overdue NRC amendments are designated as Compatibility Category A or B, as indicated above. Although there are currently draft regulations for six NRC amendments in the administrative adoption process and the State has made progress since the 2003 follow-up review, the State continues to adopt most NRC amendments after the three-year effective date of the NRC's final rule. Based on the State's performance, the review team considers the recommendation in Section 4.1.2 of the 2001 IMPEP report still open.

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

4.2 Sealed Source and Device (SS&D) Evaluation Program

In assessing the New Hampshire SS&D evaluation program, the review team examined the information provided in the response to the IMPEP questionnaire relative to this indicator. The team evaluated the one new SS&D registry sheet issued during the review period, and the supporting document files. The team also evaluated the use of guidance documents and procedures, and interviewed the staff currently conducting SS&D evaluations.

4.2.1 Technical Staffing and Training

The last SS&D registration sheet with byproduct material was issued by the State in 1986. A second SS&D sheet with accelerator produced material was issued in 1994. Due to the Section's lack of experience in the evaluation of SS&D applications, the technical review of the SS&D application received by the Section during the review period was conducted by two SS&D reviewers with extensive experience, one currently employed by the Commonwealth of Massachusetts and the second reviewer recently retired from the Commonwealth of Kentucky. The individual from Massachusetts is fully qualified to review SS&D applications in accordance with Massachusetts' training policy. The other individual was fully qualified to review SS&D applications prior to retirement in accordance with Kentucky's training policy. A portion of the technical review was also conducted by one of the Section's health physicists who is also a licensed metallurgical engineer.

The review team evaluated the qualifications of the two individuals who signed the registration certificate. The Supervisor participated in the review of the 1994 sheet and met the minimum qualifying criteria with a bachelor's of science degree in Biology and attendance at NRC's SS&D workshop. The second individual did not have any prior experience or formal training with SS&D evaluations. With the uncertainty in obtaining other Agreement State or contractor support for future evaluations, the team discussed the need for a second qualified individual to review SS&D applications and sign the registration sheets. The Supervisor indicated that the

individual with the engineering background would probably be sent to the next SS&D Workshop offered by the NRC.

The team also reviewed the Section's training policy and determined that the policy did not include requirements for SS&D reviewers. The review team recommends that the Section modify their training and qualification program to include requirements for individuals to evaluate SS&D applications and sign the registration sheets.

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

4.2.2 Technical Quality of the Product Evaluation Program

The review team evaluated the one new SS&D application that the Section completed during the review period. Specific comments regarding the team's review can be found in Appendix F. The SS&D reviewers reported that they used the guidance in NUREG-1556, Volume 3. The team's review of the casework, and interviews with the staff, confirmed that the Section followed the NRC SS&D guidance. Appropriate standards and Regulatory Guides were available and used when performing the review. The documentation for the evaluation is kept in the license's docket folder for the manufacturer. As noted in Appendix F, some of the documentation was not available for team's review.

The depth and scope of the product evaluation was good. The team noted that the SS&D checklist was used to generate a detailed and thorough deficiency letter. The review team did not identify any missed health and safety issues in the reviewed application.

The team also identified two registration sheets issued by the State in 1986 and 1994. Both manufacturers are no longer in business and no sources distributed under their licenses are still in use. The Supervisor initiated the process to inactivate both sheets.

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

4.2.3 Evaluation of Defects and Incidents Regarding SS&D

There were no defects or incidents for this device.

Based on the IMPEP evaluation criteria, the review team recommends that New Hampshire's performance with respect to the sub-indicator Evaluation of Defects and Incidents Regarding SS&D, be found satisfactory.

4.2.4 Summary

Based on the IMPEP evaluation criteria, the review team recommends 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 (LLRW) 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 such disposal authority, NRC has not required States to have a program for licensing a disposal facility until such time as the State has been designated as a host State for a LLRW disposal facility. When an Agreement State has been notified or becomes aware of the need to regulate a LLRW disposal facility, 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 evaluate this indicator.

5.0 SUMMARY

As noted in Sections 3 and 4 above, the review team and the MRB found New Hampshire's performance to be satisfactory with respect to the indicators, Status of Materials Inspection Program, Technical Quality of Inspections, Technical Quality of Licensing Actions, Technical Quality of Incident and Allegation Activities, and SS&D Evaluation Program. The team and the MRB found New Hampshire's performance to be satisfactory, but needs improvement, for the indicator, Technical Staffing and Training. The team and the MRB found New Hampshire's performance to be unsatisfactory for the indicator, Compatibility Requirements. Accordingly, the review team recommended and the MRB concurred that the New Hampshire Agreement State Program be found adequate, but needs improvement, and not compatible with NRC's program. The review team recommended and the MRB concurred that the period of Heightened Oversight be continued to assess the progress of the State in implementing corrective actions. The State should update their Program Improvement Plan, which addresses the recommendations as mentioned in earlier sections of the report, and listed below.

- 1. The review team recommends that the Section continue to examine and change the business processes of the Section to improve the effectiveness and efficiency of the program. (Section 2) (Recommendation 5 from the 2001 report)
- 2. The review team recommends that the Section develop and implement an action plan to adopt NRC regulations in accordance with current policy on adequacy and compatibility. (Section 2) (Recommendation 6 from the 2001 report)
- 3. The review team recommends that the Section establish a plan for the new staff to promptly complete all training and qualification requirements in order to be qualified as independent license reviewers and inspectors. (Section 3.1)
- 4. The review team recommends that the Section modify their training and qualification program to include requirements for individuals to evaluate SS&D application and sign the registration sheet. (Section 4.2.1)

LIST OF APPENDICES AND ATTACHMENT

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 Review

Attachment

August 11, 2004 Letter from Mary Ann Cooney New Hampshire's Response to Draft IMPEP Report

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name Area of Responsibility

Kathleen Schneider, STP Team Leader

Technical Staffing and Training

Status of Materials Inspection Program

Duncan White, Region I Technical Quality of Inspections

Inspector Accompaniment

Technical Quality of Incident and Allegation

Activities

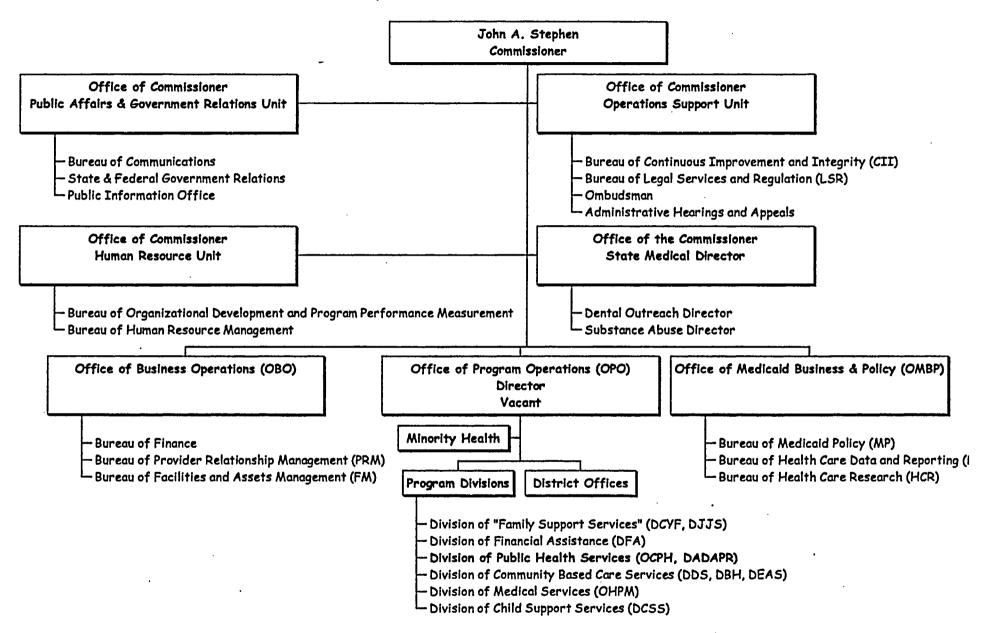
Compatibility Requirements

Sealed Source and Device Evaluation Program

James Harris, Kansas Technical Quality of Licensing Actions

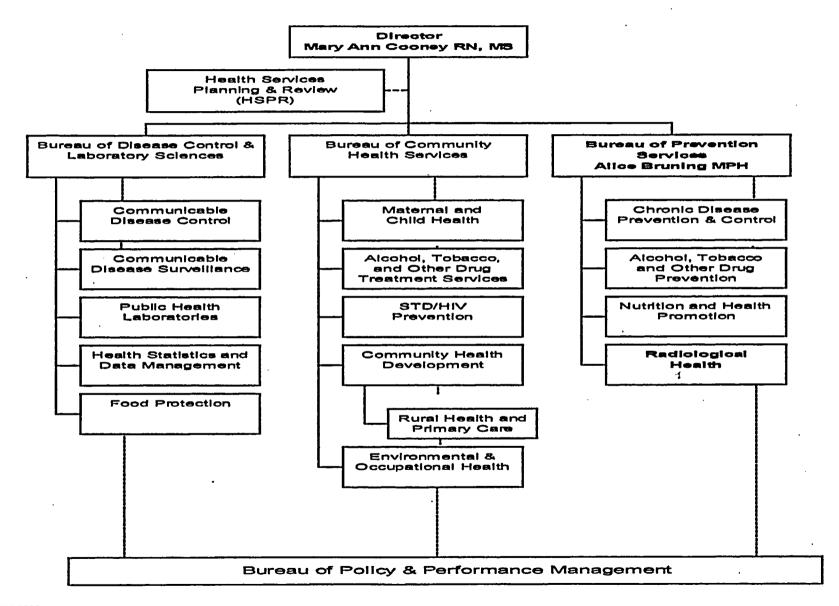
APPENDIX B NEW HAMPSHIRE ORGANIZATION CHARTS ML041910052

Department of Health and Human Services

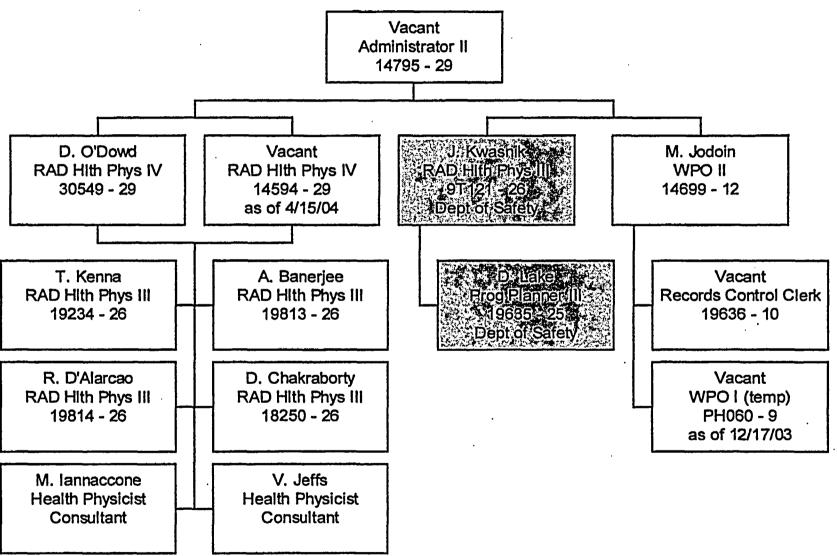


Organizational Chart A

Division of Public Health Services



Division of Public Health Services Radiological Health Section Current - 06-15-04



^{*}Positions in gray currently with Department of Safety. In process to be transferred back July 1, 2004, pending Fiscal Committee and Governor and Council Action