



UNITED STATES
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

April 15, 1998

Howard K. Koh, M.D., M.P.H.
Commissioner
Massachusetts Department of Public Health
305 South Street, 7th Floor
Jamaica Plain, MA 02130

Dear Dr. Koh:

On April 6, 1998 the Management Review Board (MRB) met to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) report on the Massachusetts Agreement State Program. The MRB found the Massachusetts program adequate to protect public health and safety and compatible with NRC's program.

Section 5.0, page 15, of the enclosed final report presents the IMPEP team's recommendations and suggestions. We request your evaluation and response to the recommendations within 30 days from receipt of this letter.

Based on the results of the current IMPEP review, the next full review will be scheduled in four years, unless program concerns develop that require an earlier evaluation. We will keep the Commonwealth informed of our plans to review Massachusetts' sealed source and device evaluation program prior to a full IMPEP review.

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,


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

Enclosure:
As stated

cc: Robert Hallisey, Director
Radiation Control Program
Massachusetts Department of Public Health

A. David Rodham, State Liaison Officer

Ray D. Paris
Organization of Agreement States Liaison
to the Management Review Board

INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF MASSACHUSETTS AGREEMENT STATE PROGRAM

JANUARY 12-16, 1998

FINAL REPORT

U.S. Nuclear Regulatory Commission

ENCLOSURE 1

1.0 INTRODUCTION

This report presents the results of the initial review of the Massachusetts radiation control program. The review was conducted during the period January 12-16, 1998, by a review team comprised of technical staff members from the Nuclear Regulatory Commission (NRC) and the Agreement State of Georgia. 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 November 25, 1997 NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." Preliminary results of the review, which covered the period March 21, 1997 to January 16, 1998, were discussed with Massachusetts management on January 16, 1998.

A draft of this report was issued to Massachusetts for factual comment on February 10, 1998. The Commonwealth responded in a letter dated March 16, 1998 (Attachment 1). The Commonwealth's factual comments were considered by the team and accommodated in the report. The Management Review Board (MRB) met on April 6, 1998 to consider the proposed final report. The MRB found the Massachusetts radiation control program was adequate to protect public health and safety and compatible with NRC's program.

The Massachusetts Agreement State program is administered by the Radiation Control Program (RCP) located in the Department of Public Health (MDPH). Organization charts are included as Appendix B. The Massachusetts program regulates approximately 435 licenses authorizing agreement materials, plus an additional 90 licenses authorizing only Naturally Occurring and Accelerator Produced Radioactive Material (NARM).

The review focused on the materials program as it is carried out under the Section 274b. (of the Atomic Energy Act of 1954, as amended) Agreement between the NRC and the Commonwealth of Massachusetts.

The Massachusetts Regulations for Control of Radiation, found in Chapter 105 of the Code of Massachusetts Regulations, Section 120.000, apply to all ionizing radiation, whether emitted from radionuclides or devices. Massachusetts requires a license for possession, and use, of all radioactive material including naturally occurring materials, such as radium, and accelerator-produced radionuclides. Massachusetts also requires registration of all equipment designed to produce x-rays or other ionizing radiations.

In preparation for the review, a questionnaire addressing the common and non-common indicators was sent to the Commonwealth on October 14, 1997. The Commonwealth provided a response to the questionnaire on December 12, 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 Massachusetts' response to the questionnaire; (2) review of applicable Massachusetts statutes and regulations; (3) analysis of quantitative information from the radiation control program licensing and inspection data base; (4) technical review of selected licensing and inspection actions; (5) field accompaniments of four Massachusetts inspectors; 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 non-common indicator and made a preliminary assessment of the radiation control program's performance.

A draft of this report was issued to Massachusetts for factual comment on February 10, 1998. The State responded in a letter dated March 16, 1998 (Attachment 1). The State's factual comments were considered by the team and accommodated in the report.

Section 2 below, Status of Items Identified in Previous Reviews, is not applicable to the Commonwealth as this was the initial program 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 and recommendations. Suggestions made by the review team are comments that the review team believes could enhance the Commonwealth's program. The Commonwealth is requested to consider suggestions, but no response is requested. Recommendations relate directly to program performance by the Commonwealth. A response is requested from the Commonwealth to all recommendations in the final report.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

The Commonwealth of Massachusetts became an Agreement State on March 21, 1997. The agreement includes byproduct material as defined in Section 11(e).1, source and special nuclear materials, low-level radioactive waste disposal and sealed source and device evaluations. It does not include byproduct material as defined in Section 11(e).2.

This was the initial program review. A management orientation meeting was held with the Commonwealth on June 18, 1997. The purpose of the meeting was to discuss the status of the program and the initial program activities following the transfer of authority. No attempt to evaluate the performance of the program was made at that meeting.

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 Quality of Inspections; (3) Technical Staffing and Training; (4) Technical Quality of Licensing Actions; and (5) Response to Incidents and Allegations.

3.1 Status of Materials Inspection Program

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

The team's review of the Commonwealth's inspection priorities verified that the Commonwealth's inspection frequencies for various types or groups of licenses are at least as frequent as similar license types or groups listed in the NRC Inspection Manual Chapter 2800 (IMC 2800) frequency schedule. Four license categories are scheduled for more frequent inspections by the Commonwealth than similar NRC licensees, as follows:

<u>Type of License</u>	<u>Massachusetts Frequency (years)</u>	<u>NRC Frequency (years)</u>
Teletherapy	2	3
Self-Shielded Irradiators	3	5
General License Distribution- in-vitro kits	3	5
Source Material-Other	3	5

With respect to initial inspections of new licenses, the team evaluated the inspection tracking data system and verified that initial inspections were entered into the computerized tracking system together with existing licenses. A review of the inspection tracking system showed that initial inspections are not always differentiated from routine inspections. Thus, some initial inspections are scheduled at regular inspection frequencies instead of the six month frequency required by program procedures.

A review of the database identified 14 new licenses issued since the Agreement, by the Commonwealth. Four licenses had initial inspections due during the review period. Of these four, one license was inspected within the six month window, one was inspected a month late and two licenses are overdue for inspection (both due in December 1997.) The team did not identify any licenses transferred to the Commonwealth by the NRC which were overdue for initial inspections. The review team recommends that initial inspections of licensees be performed within six months of the licensee's receipt of licensed material, within six months after commencement of licensed activities, or within one year of license issuance, whichever comes first, consistent with IMC 2800.

In response to the questionnaire, Massachusetts indicated that two core inspections were overdue by more than 25% of the scheduled frequency. Those two inspections have since been performed and thus the only inspections overdue are the initial inspections identified above.

Since the effective date of the Agreement, Massachusetts has authorized reciprocity to 31 licensees. Of the 31 reciprocal licenses, 3 were teletherapy/irradiator source replacement firms, 7 were industrial radiographers, 6 were service companies and 15 were gauge or device users. To date, the RCP performed only two inspections of reciprocity licensees, one irradiation source replacement and one industrial radiographer.

Reciprocity requests are recorded in the tracking system but inspections have rarely been performed. The Acting Supervisor indicated that short lead times and inefficient internal handling of reciprocity requests were impediments to performing reciprocity inspections. Recently, internal changes were made to bring all reciprocity requests immediately to the attention of the Acting Supervisor, allowing him to make decisions to divert inspectors for reciprocity inspections. This improved system was evidenced during the review when a reciprocity request was received by the program, referred in a timely manner to the Acting Supervisor, and an inspector was dispatched to

the site. The review team recommends that the Commonwealth increase the number of reciprocity inspections to better evaluate the health and safety implications of out-of-state companies working in Massachusetts.

The timeliness of the issuance of inspection findings was also evaluated during the inspection file review. Of 23 inspection findings examined, the correspondence for 14 inspections was sent to the licensee within 30 days of the inspection date. For the other nine inspections, the correspondence was sent to the licensee from 33 to 81 days after the inspection. Three of the cases involved escalated enforcement or were delayed while waiting for further information from a licensee, and six cases were late because of inspector workloads and lack of urgency by inspectors. The Acting Supervisor indicated that this was an area in which he sees room for improvement and is emphasizing timeliness to staff during training meetings. Another factor which contributes to delays in the issuance of inspection findings is that some inspection staff office locations are in a temporary trailer. Consolidation of staff into one area in a single building (planned for March 1998) should help improve timeliness. The review team suggests that the Commonwealth issue inspection findings in a more timely manner to meet the 30-day program goal.

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

3.2 Technical Quality of Inspections

The team reviewed the inspection reports, enforcement documentation, and inspection field notes and interviewed inspectors for 18 out of 49 materials inspections conducted during the review period. Of the 18 inspections evaluated all were unannounced. The casework included six of the Commonwealth's materials license inspectors, and covered inspections of various types including: research and development, broad scope medical, broad scope academic, nuclear laundry, veterinary, medical institution, industrial radiography, decontamination, calibration, in-vitro laboratory, broad scope manufacturer, portable gauge, nuclear pharmacy, and manufacturing and distribution licensees. Appendix D lists the inspection files evaluated in-depth with case-specific comments.

Numerous interviews and discussions were held with the Commonwealth inspectors during the week of the review. The inspectors demonstrated a good working knowledge of radiological health and safety. The Acting Supervisor actively communicates with his staff and discusses each inspection with the inspectors and he signs off on all inspection reports. Inspection records and field notes indicate that each inspector is competent and experienced in the area(s) that he/she has inspected. Inspection field notes and written narratives were of good quality and the files were generally complete. The appropriate inspection forms were used for the type of inspection conducted. Violations were identified and adequately documented in the inspection reports. In six cases, inspection reports were inconsistent with inspection letters sent to the licensees with respect to documentation of apparent violations originally identified in the report.

During the week of December 8, 1997, a review team member performed accompaniments of four Commonwealth inspectors on separate inspections of licensed facilities (See Appendix D). The

inspections included a nuclear gauge manufacturer, an academic institution, a research and development company and a hospital nuclear medicine program. 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 programs. Inspection techniques were observed to be performance-oriented and the technical performance of all four inspectors was excellent. The inspections were adequate to assess radiological health and safety at the licensed facilities.

The team evaluated the Commonwealth's laboratory support process. The Department of Public Health's environmental radiation laboratory is responsible for the calibration and maintenance of radiation monitoring equipment. This laboratory operates under the RCP. Survey instruments are sent out for calibration on an annual basis to an approved calibration laboratory. Each inspector is assigned a kit with a calibrated survey instrument and several types of radiation detection probes. The instruments are capable of detecting alpha, beta, gamma and neutron radiation. Instrumentation available includes: GM meters, rate meters, pocket dosimeters, sodium iodide scintillation probes, end window GM tubes, alpha scintillators, alpha/beta scintillators and pancake probes. The lab is also equipped with germanium detectors (gamma spectroscopy), gas flow proportional counters, and liquid scintillation counters for sample counting and analysis.

The team also reviewed activities with respect to supervisor accompaniments of inspectors. Thus far, in the 10-month history of the program, management has accompanied only three of eight inspectors on field inspections. The importance of supervisory accompaniments of inspectors was discussed with the Acting Supervisor and RCP Director. The accompaniments allow first-hand assessment of performance and assure appropriate and consistent application of policies and guides. The review team recommends that program managers conduct annual field accompaniments of each inspector to assess performance.

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

3.3 Technical Staffing and Training

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 Commonwealth's questionnaire responses relative to this indicator, interviewed program management and staff, and considered any possible workload backlogs.

The Acting Supervisor stated that all technical staff positions require the equivalent of a bachelor's degree in the sciences. Positions are classified as either Environmental Engineers or as Environmental Analysts.

The RCP, with approximately 525 licenses, has a planned staffing level of one supervisor, 11 Environmental Engineers, one Environmental Analyst and two administrative personnel responsible for the radioactive materials program, including the NARM Licensing program. The current technical staffing level is 9.0 FTE with three technical positions (Environmental Engineers) vacant. Technical staff perform both inspection and licensing functions. The Supervisor position is filled in an acting capacity. Based on review results, this staffing level is adequate for a program of this size. Strains identified in other areas of the program (reciprocity inspections, inspection report timeliness, etc.) and anticipated significant increases in the Sealed Source and Device program workload indicate that the RCP would greatly benefit from the filling of the vacant positions.

The RCP Director stated that filling of the vacant Environmental Engineer positions is in process and two of the three positions are currently posted. The review team recommends that, due to current program demands and the projected increase in workload, program management closely monitor the filling of the RCP vacancies.

The RCP has a documented training and qualification program in place for the staff which is taken directly from the NRC's IMC 1246, "Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area." The technical staff is well qualified from an education and experience standpoint. Staff has attended many core training courses but experienced a decrease in attendance at NRC-sponsored courses during the transition from NRC to State funding. For example, three staff have not attended the Transportation of Radioactive Materials course, no one has attended the Root Cause/Incident Investigation Workshop and only one staff member has completed the Health Physics Technology course. All of these courses are core training courses in the RCP qualification program. One new staff member (hired in August 1997) has not yet attended any of the required training courses but is scheduled to attend courses as they become available. Training funds are now available from the licensee fee base and no training travel roadblocks exist, according to the RCP Director.

Alternate training efforts are being initiated by the Commonwealth, both alone and in conjunction with other New England states, to bring training courses to the area. The RCP does not have a formal mechanism by which management certifies that an inspector or license reviewer has met qualifications in a particular area of responsibility. The Acting Supervisor, however, is aware of each staff member's training and experience and assigns licensing actions and inspections to those with appropriate training in the specific modality, as verified by the team during file reviews and discussions with staff members. The review team recommends that the Commonwealth manage the training program to ensure that staff receive required training courses to fulfill RCP qualification requirements for inspectors and license reviewers.

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

3.4 Technical Quality of Licensing Actions

The review team examined completed licensing casework and interviewed the reviewers for 12 specific licenses. Licensing actions were evaluated for completeness, consistency, proper isotopes and quantities authorized, qualifications of authorized users, adequacy of 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 of its conditions and tie-down conditions, and overall technical quality.

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 authorities. The files were checked for retention of necessary documents and supporting data.

The licensing 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 cross-section sampling included the following types: radiopharmaceutical manufacturer; manufacturer of generally licensed products; industrial radiography; pool irradiator; self-shielded irradiator; research and development; medical teletherapy; and high dose remote afterloader. Licensing actions included 3 new licenses, 11 amendments, and 1 termination. A list of these licenses may be found in Appendix E.

The licenses transferred from NRC to the Commonwealth are being reissued as Massachusetts licenses when amendments to these licenses are issued. Where a Commonwealth license for naturally occurring or accelerator produced materials exists in addition to a transferred NRC license, the Massachusetts licenses are being combined with the reissued agreement materials licenses. This action is consistent with the plan expressed in the request for the Agreement. For the purpose of this review, the team classified the reissued licenses as "amendments" rather than "new licenses."

It was noted that in nearly all of the licensing actions reviewed, a pre-existing NRC license was available for use as the basis for the Commonwealth license. In the few actions which did not involve a transferred NRC license, appropriate Commonwealth review procedures were followed and checklists were used.

In discussions with program management, it was noted that Massachusetts was continuing the major decommissioning efforts NRC had underway at the time of the Agreement. There were no new identified sites with potential decommissioning difficulties equivalent to those sites in NRC's Site Decommissioning Management Plan.

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

3.5 Response to Incidents and Allegations

In evaluating the effectiveness of the Commonwealth's actions in responding to incidents and allegations, the review team examined the Commonwealth's response to the questionnaire relative to this indicator and reviewed the incidents reported for Massachusetts in the "Nuclear Material Events Database (NMED)" against those contained in the Massachusetts casework and license files, and supporting documentation, as appropriate for nine incidents. The team reviewed the

Commonwealth's response to the two allegations received during the review period. A list of the incident casework with comments is included in Appendix F.

The nine incidents selected for evaluation included three misadministrations, four lost sources, one reported loss of control of radioactive material, and one equipment failure. Of the two allegations evaluated, the NRC Region I office referred one to the Commonwealth and the other one came directly to Massachusetts.

Responsibility for initial response and follow-up actions to material incidents and allegations rests with the RCP staff. When the Commonwealth is notified of an incident during working hours, the assigned "Officer of the Day" takes the incoming notification and briefs the Acting Supervisor or the RCP Director to determine the approach to be taken regarding the incident. The Commonwealth provides a 24-hour emergency number for anyone to use to report emergencies involving hazardous materials. When a radiological incident is reported after work hours, RCP staff is contacted at home.

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 incident and licensing files indicating that the incident would be investigated during the next scheduled inspection. In response to incidents, the RCP had taken prompt, appropriate action. The evaluation of casework indicated that incident reports were thorough and well-documented. The incident reports were reviewed and signed by the Acting Supervisor.

The evaluation of the two allegation cases indicated that the RCP had taken prompt and appropriate action in response to the allegers' concerns. Further review of the casework and a staff interview determined that the RCP did not provide periodic feedback. An acknowledgment of one allegation was not sent back to the allexer and a follow-up communication was not completed discussing the findings of the RCP's investigation into the allegation in accordance with the Commonwealth's written procedures. The review team recommends that the RCP provide written periodic feedback on the disposition of allegations to allegers in accordance with Commonwealth procedures.

The review team found good correlation of the Commonwealth's response to the questionnaire and the incident information in the casework. The review team also queried the incident information reported on the NMED system for Massachusetts which identified only two reported incidents. The team interviewed the staff person responsible for incident coordination and determined that the additional incidents had been forwarded for inclusion in the NMED system, but were not yet loaded on the system at the time of the review.

Based on the IMPEP evaluation criteria, the review team recommends that Massachusetts' 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 Program Elements Required for Compatibility; (2) Sealed Source and Device Evaluation Program; (3) Low-Level Radioactive Waste Disposal Program; and (4) Uranium Recovery Program. Massachusetts' 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 Program Elements Required for Compatibility

4.1.1 Legislation

Along with their response to the questionnaire, the Commonwealth provided the review team with the opportunity to review copies of legislation that affect the radiation control program. Legislative authority to create an agency and enter into an agreement with the NRC is granted in Massachusetts General Law Chapter 111. The Department of Public Health is designated as the Commonwealth's radiation control agency. The review team noted that the legislation had previously been found adequate during the review of the Commonwealth's request for an Agreement, and there had been no changes.

4.1.2 Program Elements Required for Compatibility

The review team examined the procedures used in the Commonwealth's regulatory process and found that they are unchanged from the descriptions provided in the application for the Agreement. Proposed regulations are presented to the Public Health Council with a proposal to seek public comment. After a schedule of public hearings is completed and comments received are addressed, final regulations are presented to the Public Health Council for adoption. The adopted regulations are filed with the Secretary of State for publication.

The team evaluated Massachusetts' responses to the questionnaire and noted that there have been no regulations adopted by the Commonwealth since the March 21, 1997, signing of the Agreement. The Commonwealth had adopted, before the Agreement was signed, all regulations identified as due prior to June 30, 1998.

The team found that the Commonwealth is addressing the following NRC regulation amendment:

- ! "Compatibility with the International Atomic Energy Agency," 10 CFR Part 71 amendment (60 FR 50248) that became effective April 1, 1996. In order to avoid a "whip-saw" effect on licensees transferred from NRC to the Commonwealth, Massachusetts was required to adopt regulations or alternate legally binding requirements equivalent to all NRC regulations in effect on the effective date of the Agreement. The Commonwealth was unable to promulgate regulations equivalent to the new Part 71 in time, and agreed to issue an order to all licensees to comply with the

requirements of new Part 71 pending their adoption of equivalent rules. The team confirmed that the order was issued, and that draft rules equivalent to new Part 71 are being prepared for public comment.

The Commonwealth has not yet adopted the following regulations, but intends to address them in rulemakings or by adopting alternate generic legally binding requirements:

- ! "Radiation Protection Requirements: Amended Definitions and Criteria," 10 CFR Parts 19 and 20 amendments (60 FR 36038) that became effective August 14, 1995.
- ! "Medical Administration of Radiation and Radioactive Materials," 10 CFR Parts 20 and 35 amendments (60 FR 48623) that became effective on October 20, 1995.
- ! "Clarification of Decommissioning Funding Requirements," 10 CFR Parts 30, 40, and 70 amendments (60 FR 38235) that became effective November 24, 1995.
- ! "Termination or Transfer of Licensed Activities: Record Keeping Requirements," 10 CFR Parts 20, 30, 40, 61, 70 (61 FR 24669) that became effective on June 17, 1996.
- ! "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.
- ! "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 February 27, 1997.
- ! "Criteria for the Release of Individuals Administered Radioactive Material," 10 CFR Parts 20 and 35 amendments (62 FR 4120) that became effective on May 29, 1997.
- ! "Licenses for Industrial Radiography and Radiation Safety - Requirements for Industrial Radiography Operations," 10 CFR Parts 30, 34, 71, 150 amendment (62 FR 28947) that became effective on June 27, 1997.
- ! "Radiological Criteria for License Termination," 10 CFR Parts 20, 30, 40, 70 amendment (62 FR 39057) that became effective on August 20, 1997.

It is noted that Management Directive 5.9, Handbook, Part V, paragraph (1)(c)(iii), provides that the above regulations should be adopted by the Commonwealth as expeditiously as possible, but not later than three years after the effective date of the new Commission Policy Statement on Adequacy and Compatibility, i.e., September 3, 2000.

Based on the IMPEP evaluation criteria, the review team recommends that Massachusetts' performance with respect to the indicator, Legislation and Program Elements Required for Compatibility, be found satisfactory.

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

In assessing the Commonwealth's Sealed Source & Device (SS&D) evaluation program, the review team examined information provided by the Commonwealth in response to the IMPEP questionnaire on this indicator. A review of all completed SS&D evaluations and supporting documents covering the review period was conducted. The review team interviewed the staff and Acting Supervisor responsible for SS&D evaluations and examined the staff's use of guidance documents and procedures.

The Commonwealth has adopted the use of the NRC's NUREG-1550, "Standard Review Plan for Applications for Sealed Source and Device Evaluations and Registrations," Regulatory Guide 6.9, "Establishing Quality Assurance Programs for the Manufacture and Distribution of Sealed Sources and Devices Containing Byproduct Material," and Policy & Guidance Directive 84-22, Revision 1, "What Source and Device Designs Require an Evaluation," as standard reviewer guidance. Staff uses the template registration certificates and checklist from NUREG-1550 to assist in the review of SS&Ds and to help to ensure that all pertinent issues are addressed. The Commonwealth also uses a tracking sheet to track correspondence and staff work regarding SS&D actions. The Acting Supervisor responsible for SS&D evaluations must audit the SS&D package and sign off on the tracking sheet before any action can be closed and the registration certificate issued.

4.2.1 Technical Quality of the Product Evaluation Program

The review team examined all four of the SS&D registration certificate actions for the review period. The registration certificates reviewed covered the period since the Commonwealth became an Agreement State and represented cases completed by three of the four staff members authorized to sign registration certificates. The SS&D registration certificates issued by the Commonwealth and evaluated by the review team are listed with case-specific comments in Appendix G. The review team suggests that the Commonwealth consider the SS&D comments identified in Appendix G and take action as the Commonwealth deems appropriate.

Interviews with staff indicated that not all staff were aware of the current SS&D policies and procedures. The team believes that in order to have a sound program and ensure that reviews are performed consistently, it is important that all reviewers are working from a standard policy and that the policy remains in place until a change is approved by management.

The team noted one item in particular. Interviews with staff indicated that not all staff were aware that there was an established policy on what constitutes a concurrence review. Some staff had individually determined that concurrence reviews should be performed as independent reviews. Discussions with management indicate that the current policy is to require that all aspects of the SS&D review will be addressed, but to allow an interdependency between the reviewers. For example, in any particular evaluation, each reviewer does not have to be able to perform all aspects of the SS&D review, provided that at least one of the reviewers can adequately evaluate each issue. Under the Massachusetts program, full signature authority is granted to all reviewers, even though each reviewer may not be qualified to perform all areas of an evaluation.

Although this policy was compatible with the guidelines in the previous version of Management Directive 5.6, it is not compatible with the current guidelines in Management Directive 5.6, which specifically states:

“An independent technical review of the application and proposed certificate of registration is performed by a second individual and supports the finding that the product is acceptable for licensing purposes. (It is important to keep in mind that the independent technical reviewer must concur with the initial review.), and

“A concurrence review includes an independent technical review of the materials submitted by the applicant and the documents generated by the initial reviewer. The concurrence review includes evaluation of each area addressed during the initial review (e.g., construction of the product, labeling, and prototype testing), but the concurrence review is not to the same level of detail as the initial review (i.e., it is not necessary to review every page of the applicant’s submittal). The concurrence review must be focused on ensuring that the product meets all applicable regulations, that the product would not pose any health or safety concerns, and that the registration certification provides an adequate basis for licensing. This concurrence review by a second qualified reviewer is necessary in view of the potential health and safety implication resulting from the widespread distribution of sealed sources and devices.”

The purpose of these guidelines is to ensure that each area of the evaluation is addressed by two qualified individuals.

Full signature authority should be given only to those reviewers that are qualified to perform all areas of the evaluation. Limited signature authority to perform specific areas of the evaluation could be granted to reviewers not having qualifications in all areas.

Each evaluation should be performed by two individual reviewers with full signature authority, that each perform complete evaluations. As an alternative, one of these individual reviewers may be replaced by a team, where two or more reviewers combine to cover the areas in the evaluation. It should be stressed that the team must perform a complete evaluation and that their review is independent of the individual reviewer. The designated leader for the team will sign the registration certificate.

The review team recommends that the Commonwealth review current policy and procedures, and update or establish policy and procedures as necessary, including definition of concurrence reviews consistent with the current Management Directive 5.6.

4.2.2 Technical Staffing and Training

The Commonwealth reported that three staff members and the Acting Supervisor currently have authority to sign SS&D evaluations, with a combined staff effort equaling approximately one FTE dedicated to performing safety evaluations. The balance of staff time is spent in licensing actions and inspections. The Commonwealth reported that four actions were completed during the review period. It was noted during the review that the Commonwealth is expecting, in the next several

months, a large influx in the number of registration certificates (an estimated 200) that it will be responsible for when Amersham transfers a major product line to its Massachusetts office. This could result in a significant increase in the staff time necessary to address SS&D issues and should be considered in future staffing plans.

The Acting Supervisor has a B.S. in Physics, a Masters in Radiation Physics, a Ph.D. in Biophysics and has some experience in source manufacture. The first staff member has an Associates Degree in Radiological Sciences, is a Registered Radiologic and Nuclear Medicine Technologist, and had done NARM SS&Ds previous to doing byproduct SS&Ds. The second staff member has a B.S. in Mechanical Engineering and has experience in areas providing knowledge of the radiological aspects. The third staff member has a B.S. in Nuclear Engineering and a Masters in Radiological Science. The staff member stated that this Nuclear Engineering degree did not contain significant study in the areas of mechanics and design engineering. He has been to one of the NRC's SS&D Workshops. At the time of the review, this staff member had been assigned cases, but had not yet signed any.

In general, SS&D staff are well trained in Health Physics principles. Due to the fact that only four actions were processed by the Commonwealth since becoming an Agreement State, the basis for assessing the adequacy of the engineering design analysis skills of the Commonwealth staff was limited. However, based on the interviews with the staff, it appears that three of the staff may not have a strong background, through formal training and prior experience, in the area of engineering design analysis. In addition, it does not appear that the cases involving NARM are numerous enough or complex enough to provide significant experience in the engineering design analysis area. To address this issue, program managers stated that qualified engineering contractors are readily available for consultation, if needed.

The review identified that the Commonwealth does not have a clear policy on how signature authority will be granted. The current Management Directive 5.6 states:

“All initial and concurrence reviews are performed by persons having adequate training, and

“... Newly hired employees need to be technically qualified. Professional staff should have a bachelor's degree or equivalent training in the physical and/or life sciences. Both initial and concurrence reviewers should be able to:

- Understand and interpret, if necessary, appropriate prototype tests that ensure the integrity of the products under normal and likely accidental conditions of use,
- Understand and interpret test results,
- Read and understand blueprints and drawings,
- Understand how the device works and how safety features operate,
- Understand and apply appropriate regulations,
- Understand the conditions of use,
- Understand external dose rates, source activities, and nuclide chemical form, and
- Understand and utilize basic knowledge of engineering materials and their properties.”

The team discussed the importance of a qualification program in the SS&D area. Such a program would assure that for reviewers to be given SS&D signature authority, they would first be evaluated to ensure that the reviewer meets established minimum standards through experience, training, and/or formal education to enable the reviewer to fully address all issues in the areas for which they are being granted signature authority. The qualification program would also assure that reviewers complete a sufficient number of cases which are critiqued by a qualified SS&D reviewer to determine whether the reviewer adequately identified and addressed all pertinent issues. The review team recommends that the Commonwealth establish a signature authority qualification program for all, including current, SS&D reviewers.

4.2.3 Evaluation of Defects and Incidents Regarding SS&Ds

The Commonwealth reported one incident involving product failure. This incident involved an Amersham industrial radiography guide tube end stop. A user of the end stops reported that on two occasions the source broke through the tip of the end stop during use. The manufacturer was made aware of the incident and investigated it. A determination was made by the manufacturer that it was not a generic issue, that the cause of the failure was due to wear on the outside of the end stop due to excessive use, and that use of collimators over the end stop contributed to the wear. The Commonwealth agreed with the determination. The incident file indicated that, at one point, there were discussions that Amersham would issue a notice to its users reminding them that they should be alert for, and inspect for, significant wear on the end stops, and should not use end stops which show signs of excessive use or significant wear. Since there was no positive commitment by Amersham for this, there was no follow-up in the incident file on this issue to determine whether the notice was issued.

The review team examined the Commonwealth's evaluation of this incident and determined that relevant issues were addressed.

Based on the IMPEP evaluation criteria, the review team recommends that Massachusetts' performance with respect to the indicator, Sealed Source and Device Evaluation Program, be found satisfactory with recommendations for improvement.

4.3 Low-Level Radioactive Waste (LLRW) Disposal Program

Massachusetts requested and received LLRW disposal authority in the March 21, 1997 Agreement. NRC does not require 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. The Commonwealth does have appropriate legislation and regulations compatible with 10 CFR Part 61. The legislation and regulations are unchanged since the Agreement became effective. There are no plans for a LLRW disposal facility in Massachusetts. 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 Commonwealth of Massachusetts' performance to be satisfactory for the indicators, Status of Materials Inspection Program, Technical Quality of Inspections, Technical Staffing and Training, Technical Quality of Licensing Actions, Response to Incidents and Allegations, and Legislation and Program Elements Required for Compatibility. The review team found the Commonwealth of Massachusetts' performance to be satisfactory with recommendations for improvement for the indicator, Sealed Source and Device Evaluation Program. Accordingly, the team recommended and the Management Review Board concurred, in finding Massachusetts 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 Commonwealth.

RECOMMENDATIONS:

1. The review team recommends that initial inspections of licensees be performed within six months of the licensee's receipt of licensed material, within six months after commencement of licensed activities, or within one year of license issuance, whichever comes first, consistent with IMC 2800. (Section 3.1)
2. The review team recommends that the Commonwealth increase the number of reciprocity inspections to better evaluate the health and safety implications of out-of-state companies working in Massachusetts. (Section 3.1)
3. The review team recommends that program managers conduct annual field accompaniments of each inspector to assess performance. (Section 3.2)
4. The review team recommends that, due to current program demands and the projected increase in workload, program management closely monitor the filling of the RCP vacancies. (Section 3.3)
5. The review team recommends that the Commonwealth manage the training program to ensure that staff receive required training courses to fulfill RCP qualification requirements for inspectors and license reviewers. (Section 3.3)
6. The review team recommends that the RCP provide written periodic feedback on the disposition of allegations to allegeders in accordance with Commonwealth procedures. (Section 3.5)
7. The review team recommends that the Commonwealth review current policy and procedures, and update or establish policy and procedures as necessary, including definition of concurrence reviews consistent with the current Management Directive 5.6. (Section 4.2.1)

8. The review team recommends that the Commonwealth establish a signature authority qualification program for all, including current, SS&D reviewers. (Section 4.2.2)

SUGGESTIONS:

1. The review team suggests that the Commonwealth issue inspection findings in a more timely manner to meet the 30-day program goal. (Section 3.1)
2. The review team suggests that the Commonwealth consider the SS&D comments identified in Appendix G, and take action as the Commonwealth deems appropriate. (Section 4.2.1)

LIST OF APPENDICES AND ATTACHMENTS

Appendix A	IMPEP Review Team Members
Appendix B	Massachusetts Organization Charts
Appendix C	Massachusetts' Questionnaire Response
Appendix D	Inspection File Reviews
Appendix E	License File Reviews
Appendix F	Incident File Reviews
Appendix G	Sealed Source and Device Reviews
Attachment 1	Massachusetts' Response to Review Findings

APPENDIX A

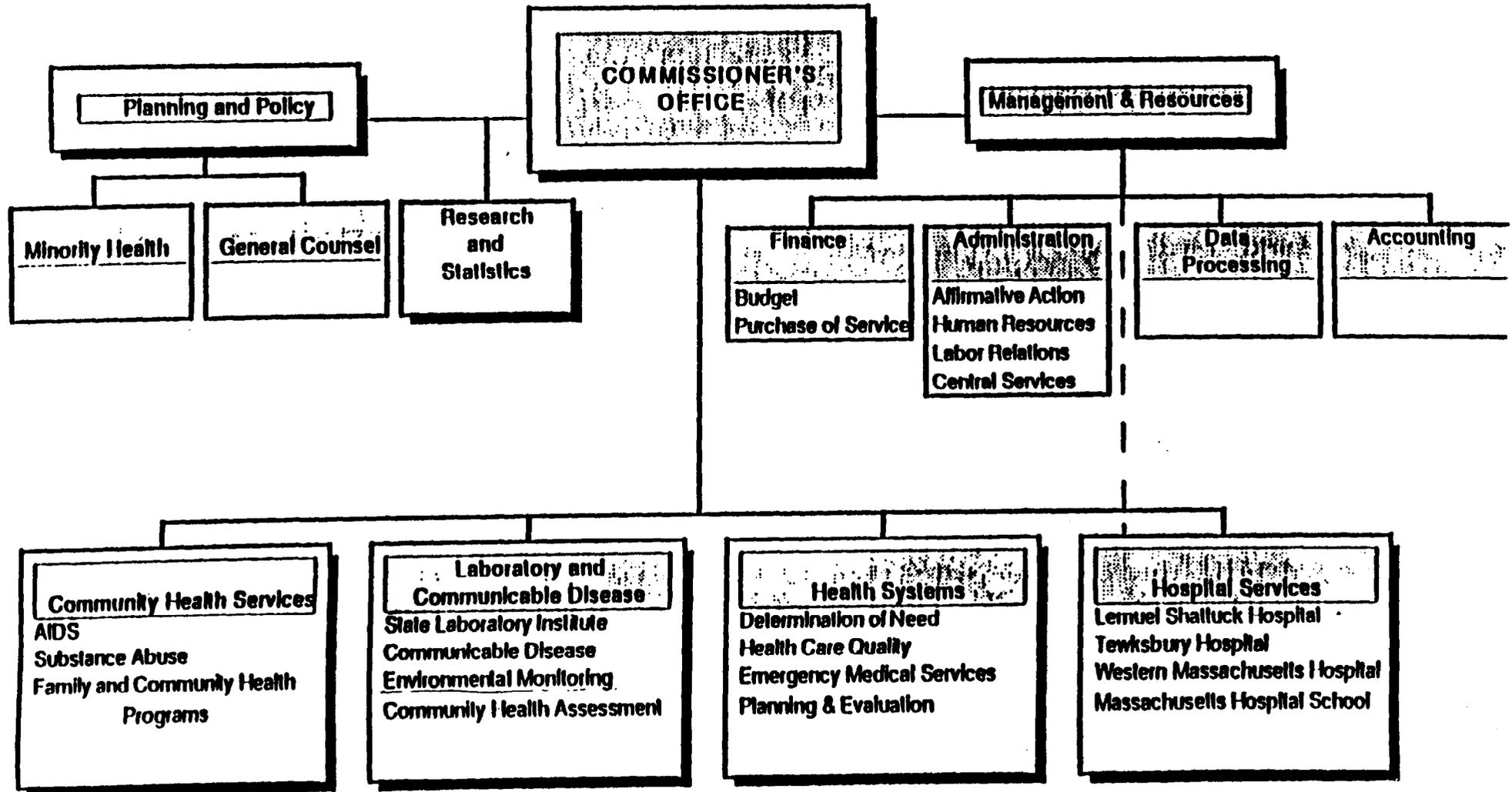
IMPEP REVIEW TEAM MEMBERS

Name	Area of Responsibility
James Lynch, RIII	Team Leader Status of Materials Inspection Program Technical Staffing and Training
Richard Blanton, OSP	Technical Quality of Licensing Actions Legislation and Program Elements Required for Compatibility
Cynthia Sanders, Georgia	Technical Quality of Inspections Response to Incidents and Allegations
Duncan White, RI	Technical Quality of Inspections Response to Incidents and Allegations
Michele Burgess, NMSS	Sealed Source and Device Evaluation Program

APPENDIX B
COMMONWEALTH OF MASSACHUSETTS
EXECUTIVE OFFICES AND DEPARTMENTS
AND
RADIATION CONTROL PROGRAM

ORGANIZATION CHARTS

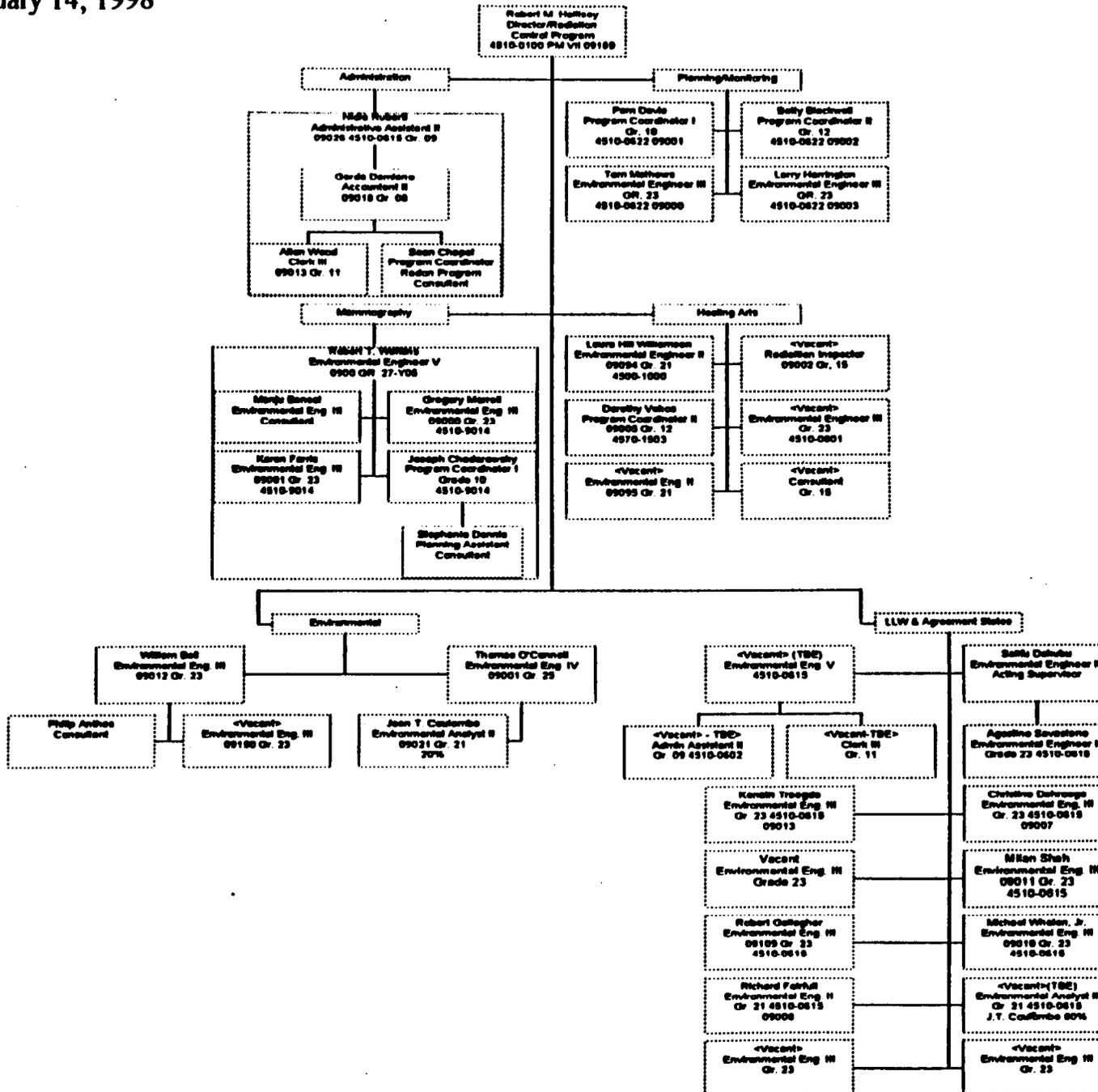
COMMONWEALTH OF MASSACHUSETTS
 DEPARTMENT OF PUBLIC HEALTH



Interim Organizational Chart

January 14, 1998

Department of Public Health Bureau of Health Quality Management Radiation Control Program



APPENDIX C

COMMONWEALTH OF MASSACHUSETTS

IMPEP QUESTIONNAIRE RESPONSE



The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Radiation Control Program

305 South Street, Jamaica Plain, MA 02130
(617) 727-6214 (617) 727-2098 - Fax

ARGEO PAUL CELLUCCI
GOVERNOR

WILLIAM D. O'LEARY
SECRETARY

HOWARD K. KOH, MD, MPH
COMMISSIONER

March 16, 1998

Richard L. Bangart, Director
Office of State Programs
Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Dear Mr. Bangart: *Pick*

The purpose of this letter is to respond to the draft IMPEP report, which you forwarded to Dr. Howard K. Koh the Commissioner of the Massachusetts Department of Public Health (MDPH), dated February 10, 1998, which documents the results of the Agreement State review held here at the Radiation Control Program (RCP) from January 12-16, 1998. Dr. Koh has asked me to respond directly to you on the draft IMPEP report and also to represent the MDPH at the Management Review Board Meeting.

On behalf of the members of the Radioactive Materials Unit of the RCP, I would like to take this opportunity to thank you and the members of the IMPEP Review Team for the positive nature of this draft IMPEP report. We would like to especially compliment Mr. James Lynch, the NRC Region III Agreement States Officer, who was the team leader for this Massachusetts Agreement State Review. We would also like to compliment the team for the very professional manner in which they performed their activities and to comment that this newer collaborative performance based process definitely appears to us to be far superior to the previous review process, which as a new Agreement State, we never had the opportunity to experience but have heard so much about. The composition of the Massachusetts Review Team represented a complimentary mix of experience and expertise that, in our opinion, made for a very effective review process and a very positive learning experience for members of our staff. Of course, we are very pleased that the review team's proposed recommendations are that the Massachusetts Agreement State

Program be found adequate to protect public health and safety and compatible with the NRC Program.

As a general comment, we find that the draft IMPEP report for Massachusetts is mostly accurate in the factual findings with the exception of specific minor corrections and comments as stated below. However, we have three major concerns as follows:

- A) As a new Agreement State under the revised Agreement State approval process, which evolved as a result of the 1992 GAO report, we feel very strongly that the IMPEP review was scheduled too soon after the Agreement had been signed. Most of the materials reviewed by the Team were in the final Agreement State package, and I think all agreed that there was not sufficient licensing and inspection action since the Agreement was signed to effect a comprehensive IMPEP Review. In the interest of helping our fellow "wanabee" states who are next in line to become Agreement States, we would strongly recommend that the initial IMPEP Review of a new Agreement State not occur before 18 months have elapsed since the signing of the Agreement. More ideally, we think that two years post Agreement signing is appropriate.
- B) Consistent with the previous comment concerning insufficient activities to evaluate, we would also like to strongly suggest that the IMPEP Review Team take into consideration the licensing, inspection activities, technical staff training, response to incidents/allegations, enforcement activities, and sealed source and device evaluations that a program has done in the NARM area. Even though we clearly recognize that the NRC does not regulate NARM, we certainly should be looking at a State's experience in the NARM area as an indication of the State's ability as an Agreement State for the IMPEP Review. You should be aware that the Conference of Radiation Control Program Directors, Inc. (CRCPD), uses a state's experience in the Agreement State area in evaluating that state for consideration as a Licensing State.
- C) While we know that four of the five members of the IMPEP Team performed their activities under the IMPEP Review process by looking at all issues from performance based criteria, we would be remiss not to comment from our perspective that the individual on the IMPEP Review Team evaluating our sealed source and device activities did not have the same perspective. We felt that this individual's questioning during the evaluation was primarily a specific comparison between how Massachusetts performs sealed source and device evaluations and how the NRC does this same activity. Any attempt on our part to re-focus on performance based

objectives was not accepted. We respectfully submit a suggestion that the Sealed Source and Device Review be performance based.

Specific comments on the draft IMPEP report are as follows:

- a. The reference to Massachusetts Regulations for Control of Radiation Section 1.0 § 4 should read 120.000.
- b. In Section 3.2 § 2 the statement that apparent violations noted in the field notes were subsequently not cited as violations in correspondence to the licensee and that there was no explanation or documentation provided in the file as to why the apparent violations were not cited after supervisory review is not entirely correct. Our inspection files are made up of field notes, summary report with a section for identified violations and their characterization, sometimes continuing communication with the licensee to settle a minor apparent violation as a non-cited violation, and a final letter documenting the inspection findings to the licensee. Within the scope of these four areas of inspection information the reasons can be found for any particular disposition of inspection findings.

Specifically, in only one case (Cashing, Goins, et.al.) was the apparent violation noted but not properly documented; in one case (Thielsch Engineering), the proper documentation was recorded in the file and the licensee was cited; and, in three cases (Diacrin, Inc., Childrens' Hospital, and Biovest, Inc.), the files do not reflect apparent violations which were not cited.

In the sixth case (APPENDIX D File.: 13.), the effluent release data noted by the inspector was at the stack. The inspector failed to note that the licensee had documented a minimum dilution factor of 40 at the position of the most impacted member of the population. The licensee was relying on two different methods of calculation, using stack data, to show compliance with the applicable regulations. The files show a telephone log in which the inspector discusses with the licensee that there is no violation.

- c. In Section 4.2.2 the Supervisor's Ph.D. is in Bio-Physics.
- d. The third paragraph of this section starting with "In general...." is technically unsound and unfounded and should be withdrawn.
- e. Section entitled "Recommendations"

1. The review team recommends that initial inspections of licensees be performed within six months of the licensee's receipt of licensed material, within six months after commencement of licensed activities, or within one year of license issuance, whichever comes first, consistent with IMC 2800. (Section 3.1)

Response:

The directive in our inspection procedures manual states a similar goal as in the recommendation above. Our inspection procedures manual states in part:

"Initial inspections of all licensees in any priority. The time interval from license issuance to an on-site inspection is based on whether the licensee has possessed material or performed operations under the license (i.e., initiated licensed activities). Initial inspections of new licenses should be announced. Initial inspections of licensees shall be performed within 1 year of license issuance, within 6 months of receipt of licensed material, or within 6 months of beginning licensed activities, whichever comes first."

Because the inspection is announced we are able to verify whether the licensee is in receipt of licensed material any time within the set year.

2. The review team recommends that the Commonwealth increase the number of reciprocity inspections to better evaluate the health and safety implications of out-of state companies working in Massachusetts (Section 3.1)

Response:

The review team have noted the stepped up effort to increase the number of reciprocity inspections. This is a continuing undertaking.

3. The review team recommends that program managers conduct annual field accompaniments of each inspector to assess performance. (Section 3.2)

Response:

It is policy to have supervisory accompaniment of each inspector once a year. There are plans afoot to implement this policy.

4. The review team recommends that, due to current program demands and the projected increase in workload, program management closely monitor the filing of the RCP vacancies. (Section 3.3)

Response:

The two Environmental Engineer III vacancies have been posted and will be filled upon closing.

5. The review team recommends that the Commonwealth manage the training program to ensure that staff receive required training courses to fulfill RCP qualifications requirements for inspectors and license reviewers. (Section 3.3)

Response:

The current training program in place is a combination of the use of courses provided by NRC (whenever available to us) and courses and workshops we arrange using local resources. This is stated in our qualification criteria in the radioactive materials regulatory program area as follows:

Personnel assigned to conduct inspections or license reviews in the radioactive materials program area must demonstrate competence in the requirements for their individual inspection or licensing areas, as listed in Appendix A of NRC Manual Chapter 1246. The Agency, will from time to time, establish the criteria for competence, which in any case, will include successful completion of some of the courses provided by NRC or their equivalent.

6. The review team recommends that the RCP provide written periodic feedback on the disposition of allegations to allegers in accordance with Commonwealth procedures. (Section 3.5)

Response:

We shall review our processes to ensure that we provide written periodic feedback on the disposition of allegations to allegers in accordance with our written procedures.

7. The review team recommends that the Commonwealth review current policy and procedures, and update or establish

policy and procedures as necessary, including definition of concurrence reviews consistent with the current Management Directive 5.6. (Section 4.2.1)

Response:

The current policy and procedure for the review and concurrence in the sealed source and device area is defined in our manual as follows:

Peer Review and Signature

A draft copy of the new Registry Certificate is made and attached to the "Sealed Source and Device Review" form and routed to a second reviewer who concurs and/or makes comments on the review form. Any comments generated by the second reviewer are discussed as necessary with the peer reviewer and appropriate revisions and/or corrections are then made to the draft sealed source and device Registry Certificate. The final Registry Certificate is prepared and signed by the primary and secondary reviewer. The Certificate is not transmitted outside until the program supervisor has reviewed the file and signed off on tracking sheet. This approach seems to be satisfactory in a performance based review.

8. The review team recommends that the Commonwealth establish a signature authority qualification program for all, including current, SEALED SOURCE AND DEVICE reviewers. (Section 4.2.2)

Response:

Signature authority is given through the process of the supervisor signing off on the tracking sheet to signify approval.

We appreciate the opportunity to comment on the draft report and look forward to the Management Review Board meeting at which time I will be prepared to more extensively discuss any of the above.

Sincerely,

A handwritten signature in black ink, appearing to read "Bob", with a stylized flourish at the end.

Robert M. Hallisey, Director
Radiation Control Program

:pjd

cc: Commissioner Howard K. Koh, MD, MPH
Nancy Ridley, Assistant Commissioner