September 28, 2000

Howard K. Koh, M.D., M.P.H.
Commissioner
Massachusetts Department of Public Health
250 Washington Street, 2nd Floor
Boston, MA 02114

Dear Dr. Koh:

Enclosed is the final report of the follow-up Integrated Materials Performance Evaluation Program (IMPEP) review of the Massachusetts Sealed Source and Device (SS&D) Evaluation Program. The review was conducted by an NRC/Agreement State team during the period June 19-21, 2000. The team reviewed in detail the non-common performance indicator of concern identified during the 1998 IMPEP review, SS&D Evaluation Program.

The review team found that the SS&D Evaluation Program has improved and has responded to and resolved the two recommendations from the 1998 IMPEP review for the performance indicator, SS&D Evaluation Program. Three new recommendations were made, two of which involved specific comments on SS&D certificates. The team also noted that the SS&D Evaluation Program should more closely follow the national format in documenting product evaluations in SS&D registry certificates.

We appreciate receiving Mr. Hallisey's August 15, 2000 letter commenting on the draft IMPEP report. We recognize that much of the information contained in current Massachusetts SS&D registration certificates was transferred from NRC certificates when the Commonwealth became an Agreement State. We have revised the report to reflect your comments on Recommendation #1, but we continue to support the recommendation. NRC staff will discuss with your staff possible ways to clarify the wording on the certificate mentioned in Recommendation #1.

Based on the follow-up IMPEP review, the Management Review Board finds that there is no change to the finding resulting from the January 1998 IMPEP review, that the Massachusetts radiation protection program is adequate to protect public health and safety and compatible with NRC's program.

Section 3 on pages 6 and 7 of the enclosed final report presents the follow-up team's recommendations. Based on previous correspondence, discussions during the follow-up review, and your response to the draft IMPEP report, no response is necessary for Recommendations #2 and #3. We request that you inform us of your plans to address the first recommendation within 30 days of the receipt of this letter.

Based on the results of the follow-up IMPEP review, the next IMPEP review will be scheduled in approximately two years.

I appreciate the courtesy and cooperation extended to the IMPEP team during the follow-up review and your support of the radiation control program. I look forward to our agencies continuing to work cooperatively in the future.

Sincerely,

***/RA/***

Carl J. Paperiello
Deputy Executive Director
for Materials, Research and
State and Tribal Programs

Enclosure:
As stated

cc: Nancy Ridley, Assistant Commissioner
Massachusetts Department of Public Health

Robert M. Hallisey, Director
Radiation Control Program

Stephen McGrail
Massachusetts State Liaison Officer

Alice Rogers
Texas Natural Resource Conservation Commission
Organization of Agreement States Liaison to MRB

I appreciate the courtesy and cooperation extended to the IMPEP team during the follow-up review and your support of the radiation control program. I look forward to our agencies continuing to work cooperatively in the future.

Sincerely,

***/RA/***
Carl J. Paperiello
Deputy Executive Director
for Materials, Research and
State and Tribal Programs

Enclosure:
As stated

cc: Nancy Ridley, Assistant Commissioner
Massachusetts Department of Public Health
Robert M. Hallisey, Director
Radiation Control Program
Stephen McGrail
Massachusetts State Liaison Officer
Alice Rogers
Texas Natural Resource Conservation Commission
Organization of Agreement States Liaison to MRB

bcc: Chairman Meserve
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
Commissioner Merrifield

Distribution:
DIR RF
SDroggitis
KSchneider
LRakovan
RBlanton, ASPO
DCool, NMSS
GDeegan, NMSS
STreby, OGC
BPoole, OGC
FCameron, OGC
TCombs, OCA (2)
UBhachu, NMSS
MStephens, FL
DWhite, RI
RBores, RI
DCD (SP01) PDR (YES*/*)
Massachusetts File

**DOCUMENT NAME: G:\IMPEP\2000 MA Final Follow-Up IMPEP 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 | | NMSS:D | | OGC | | STP:D | | MRSDED | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| NAME | LBolling:kk | | FCombs (By LBolling) | | WFKane (By MVirgilio) | | KDCyr (By SHLewis) | | PHLohaus | | CJPaperiello | |
| DATE | 09/12/00 | | 09/12/00 | | 09/26/00 | | 09/25/00 | | 09/27/00 | | 09/28/00 | |

INTEGRATED MATERIALS PERFORMANCE EVALUATION
PROGRAM (IMPEP) FOLLOW-UP REVIEW OF
THE MASSACHUSETTS RADIATION CONTROL PROGRAM

JUNE 19 - 21, 2000

# FINAL REPORT

U. S. Nuclear Regulatory Commission

## 1.0 INTRODUCTION

This report presents the results of the follow-up review of the Massachusetts Department of Public Health, Radiation Control Program (RCP) conducted June 19-21, 2000. This follow-up review was directed by the Management Review Board (MRB) based on the results of the January 12-16, 1998 Integrated Materials Performance Evaluation Program (IMPEP) review. The MRB stated that a limited scope IMPEP follow-up review focusing on the non-common performance indicator, Sealed Source and Device (SS&D) Evaluation Program, should be conducted two years from the date of the January 12-16, 1998 review based on the satisfactory with recommendations for improvement finding for this indicator. The follow-up review also included evaluation of actions taken by the Commonwealth to address the two recommendations and one suggestion made during the January 12-16, 1998 IMPEP review involving this indicator.

The follow-up review was conducted by a review team consisting of technical staff members from the Nuclear Regulatory Commission (NRC) and the State of Florida. Team members are identified in Appendix A. The follow-up review was conducted in accordance with the "Policy Statement on Adequacy and Compatibility of Agreement State Programs," published in the Federal Register on September 3, 1997 (62 FR 46517), and the November 5, 1999, Revised NRC Management Directive (MD) 5.6, "Integrated Materials Performance Evaluation Program."

The Massachusetts Agreement State program is administered by the RCP, located in the Department of Public Health. Organization charts are included as Appendix B. At the time of the follow-up review, the Massachusetts program regulated approximately 600 specific licenses, including all types of major licensees except for uranium mill tailings.

In preparation for the follow-up review, a questionnaire addressing the indicator, SS&D Evaluation Program and current program status was sent to the RCP on May 10, 2000. The RCP provided a response to the questionnaire on June 8, 2000.

The team's approach for conducting the follow-up review consisted of: (1) an examination of the RCP's response to the questionnaire; (2) an in-depth review of the program indicator, SS&D Evaluation Program, for the period of January 16, 1998 - June 19, 2000, including a technical review of selected SS&D program documentation and evaluation of the RCP's actions in response to the two recommendations involving this indicator; (3) a discussion of the status of the RCP's actions to address the remaining six recommendations in the 1998 report; and (4) interviews with staff and management to answer questions or clarify issues. The review team evaluated the information that it gathered against the IMPEP performance criteria for the non-common performance indicator, SS&D Evaluation Program, for activities conducted during the period of January 16, 1998 - June 19, 2000. Preliminary results were discussed with the RCP management on June 21, 2000.

Section 2 below discusses the results of the follow-up review of the RCP program for the non-common performance indicator, SS&D Evaluation Program. Section 3 summarizes the review team's findings and recommendations resulting from the follow-up review. The Commonwealth's progress in addressing other recommendations from the 1998 review can be found in Appendix C.

## 2.0 NON-COMMON PERFORMANCE INDICATOR, SEALED SOURCE AND DEVICE EVALUATION PROGRAM

During the follow-up review, the team evaluated actions taken by the RCP in response to the two recommendations noted during the 1998 review, as well as newly completed SS&D registry certificates.

Recommendation 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 MD 5.6. (Section 4.2.1 of the 1998 report).

Current Status

The December 1998 Periodic Meeting summary noted that the RCP had reviewed the current policy and procedures for its SS&D program with their SS&D staff. The SS&D program had sufficient staff to perform two independent reviews for sheets consistent with MD 5.6. Each sheet also receives supervisory review. The Commonwealth indicated that their policy and procedures for their SS&D program are consistent with MD 5.6. The RCP has recently revised its policy and procedures for the SS&D program to clarify the policy on first and second reviewer qualifications and responsibilities, management review, and to reflect recent changes in management structure. The revision is consistent with MD 5.6.

Based on the follow-up review, the team considers this recommendation closed.

Recommendation 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 of the 1998 report).

Current Status

The Commonwealth has established a Training Qualification Record for each member of the staff. The record documents the basic, specialized and advanced training which is required of each staff member. Management sign-offs are required for each course or alternative training area, including on-the-job training. Management then assigns work based on an assessment of the staff's documented training and experience.

Based on the follow-up review, the team considers this recommendation closed.

## 2.1 Technical Quality of Product Evaluations Program

The team reviewed SS&D actions, deficiency correspondence, and checklists for nine SS&D cases, staffing and training, and responses to incidents and allegations. SS&D certificates were

reviewed for accuracy, appropriateness of authorizations, tie-down statements, and overall technical quality. Casework was evaluated for timeliness, adherence to good radiation safety practices, acceptable engineering practices, references to appropriate regulations, documentation of safety evaluation reports, manufacturing Quality Assurance/Quality Control (QA/QC), supporting documents, peer or supervisory review as indicated, and proper signature authority. The files were checked for retention of necessary documents and other supporting data.

The review team noted that the SS&D evaluation program receives good management support and oversight. The inspection tracking system has been expanded to include all open dockets (licensing, SS&D and inspections). The Program Supervisor obtains and reviews a system print-out each week and otherwise as needed. A meeting is then held with the licensing and inspection section supervisors to track the progress of all pending cases. Written feedback on completed cases is provided by the section supervisors to the Program Supervisor each week. Cases and personnel can then be re-assigned as needed.

Nine SS&D case files were selected for review including work performed by all reviewers. The cross-section sampling included all of the Commonwealth's major SS&D manufacturer/distributors as defined by the Commonwealth, including the following types: gas chromatography, industrial radiography, medical high dose-rate (HDR) afterloader, and well logging. SS&D actions included new certificates, renewals, amendments, and terminations. SS&D actions during the review period included issuance of three new certificates and four amendments, two conversions and one inactivation totaling ten SS&D actions. A list of the SS&D files reviewed with case specific comments can be found in Appendix D.

The review team concludes that the SS&D evaluation program has shown improvement since the 1998 IMPEP review, however, additional areas for improvement in the technical quality of product evaluations were identified. The RCP staff has gained experience in this area due to the case work transferred from the NRC upon the effective date of their Agreement. The RCP has also been presented with an unusual challenge in absorbing 214 SS&D registry certificates from the State of Illinois. Each of these certificates will require an assessment for inactivation or amendment for continued use in the SS&D registry.

Based on review of the nine selected SS&D casework files, the review team found that the SS&D files were maintained in an orderly manner and correspondence was filed chronologically. Management involvement in the program is at the appropriate level.

The review team noted that one certificate MA-0628-D-137-S, contains conditions of use which could be misinterpreted as either granting a generic exemption, or implying that no exemption is required. The circumstances in this case were unique, so there was no available guidance or precedent for Massachusetts to follow. NRC staff will discuss with Massachusetts possible ways to clarify the wording on the certificate. The review team recommends that the RCP coordinate with NRC staff possible ways to revise SS&D registry certificate MA-0628-D-137-S, to make clear that a generic exemption has not been granted, and that a specific exemption is needed to use the device under special conditions.

Based on discussion with the RCP staff and review of the case files, the review team noted that radiographic source changer model 650, identified in SS&D registry certificate MA-0628-D-127-S dated February 9, 2000, does not currently meet the performance requirements for radiographic operations detailed in 10 CFR 34.20. This device is not equipped with a positive lock mechanism which will secure the source. Also the registry certificate lists both devices that meet 10 CFR 34.20 and devices that do not meet 10 CFR 34.20, which creates uncertainty for the SS&D registry certificate user as to which limiting conditions pertain to a given model. A statement in the Safety Analysis Summary, that the model 650 source changer is acceptable for licensing, is inconsistent with current policy concerning the 650 model changer. The review team recommends that the RCP reevaluate the radiographic source changers in SS&D registry certificate MA-0628-D-127-S dated February 9, 2000, especially model 650, which does not meet the performance requirements for radiographic operations detailed in 10 CFR 34.20. The SS&D registry certificate should be revised by RCP to reflect this reevaluation and those limitations necessary for the use of these devices. The SS&D registry certificate should reflect these modifications in the section on Limitations and/or Other Considerations of Use. A separate registration certificate should be issued for the devices which meet the 10 CFR 34.20 requirements.

The review team discussed with RCP staff NRC Information Notice 95-58 issued on December 18, 1995 whereby NRC informed its licensees that all radiographic exposure devices and associated equipment in use after January 1, 1996, needed to comply with the requirements specified in 10 CFR 34.20. All requests for exemptions to the 10 CFR 34.20 requirements have been submitted for NRC's evaluation by the specific user of the devices and not the manufacturers. The review team also discussed with RCP staff that the RCP should consider conducting periodic QA/QC inspections of its licensed SS&D manufacturers to enhance the technical quality of product evaluations.

Additional case specific comments are attached to this report as Appendix D. These comments center around numerous non-safety related variances from the format for documenting SS&D evaluations as described in NUREG-1556, Volume 3, "Application for Sealed Source and Device Evaluation and Registration." The Commonwealth indicated that where possible and practical the guidance in NUREG-1556, Volume 3, was utilized to compile the SS&D registration certificates. The RCP updated and re-issued their procedure for processing registration applications on June 6, 2000. This procedure was reviewed and no comments were developed as a result of the review.

The review team recommends that in the interest of national consistency, and where practical, the RCP closely follow the format for documenting product evaluations in SS&D registry certificates as detailed in NUREG-1556, Volume 3.

The review team recommends that Massachusetts' performance with respect to the sub-indicator, Technical Quality of Product Evaluation Program, be found satisfactory with recommendations for improvement.

## 2.2 Technical Staffing and Training

During the review period, the RCP was reorganized. The Acting Program Supervisor was promoted to Program Supervisor and one of the three reviewers was promoted to Supervisor of the SS&D/Licensing Section. The SS&D/Licensing Section currently has two reviewers who divide their time between licensing and SS&D reviews. During the review period the RCP hired an SS&D reviewer with an extensive industrial licensing and product evaluation background. The RCP also lost an experienced SS&D/License reviewer who resigned in May 2000. The RCP hired a replacement who began work on July 3, 2000. The RCP management indicated that staffing levels for the SS&D evaluation program are adequate at present, but can easily be adjusted to cope with any increases in the number of SS&D applications.

The review team examined the training and experience folders for the staff and management involved in the SS&D evaluation program. The educational qualifications for the current staff were evaluated in 1998 and found to be acceptable. Based on recommendations from the 1998 IMPEP review, the RCP established a Training Qualification Record to document basic, specialized and advanced training obtained by the staff. Each staff member must document his or her training, whether formal, alternative or on-the-job. This record is reviewed and initialed by management so that staff may receive credit for the training. The RCP is to be commended for its exceptional documentation of on-the-job training. The review team noted that the record for a new employee clearly indicated a listing of assignments, license numbers, program code, licensee type, dates and the names of the RCP mentors. In addition to the listing, a brief narrative was attached to the record which explained the specific activity performed for each case, i.e., licensing, inspection, SS&D review, etc. The RCP, as a matter of policy, cross trains its staff. Individuals with unique education and experience are consulted and contribute to SS&D reviews.

The review team discussed with RCP changing the sequence of courses taken to enhance the skills of the SS&D reviewers. The review team believes that moving the following courses from the advanced training category to the required basic training category will accomplish this enhancement: Safety Aspects of Industrial Radiography Course, Teletherapy/Brachytherapy Course and the Root Causes/Incident Investigation Workshop. This should also help newly hired SS&D reviewers to obtain fully qualified status in a shorter period of time.

The review team recommends that Massachusetts' performance with respect to the sub-indicator, Technical Staffing and Training, be found satisfactory.

## 2.3 Evaluation of Defects and Incidents Regarding Sealed Sources and Devices

During the review period, the Commonwealth reported six incidents involving equipment failure or malfunction. The review team examined each file and noted that the RCP staff promptly and appropriately responded to these incidents and no overexposures or medical misadministrations were reported. The incident reports submitted to the Nuclear Materials Event Database corresponded to those contained in the RCP's incident log. As needed, the RCP staff conducts on-site investigations of licensed SS&D manufacturers with special attention to QA/QC programs. The SS&D incident files were orderly and incidents were filed chronologically. The review team noted that, in one case, a licensed SS&D manufacturer is approximately 60-days overdue in providing a final report to the RCP on a leaking radiography source from overseas. The review

team noted that during the review period, there were no allegations related to the SS&D evaluation program.

Attached to this report, as Appendix E, are summaries of the six incidents involving equipment failure or malfunction.

The review team recommends that Massachusetts' performance with respect to the sub-indicator, Evaluation of Defects and Incidents Regarding Sealed Sources and Devices, be found satisfactory.

## 3.0 SUMMARY

The follow-up review team found Massachusetts' performance in responding to and resolving the two recommendations involving the non-common performance indicator, Sealed Source and Device Evaluation Program, to be acceptable.

As noted in Section 2 above, the follow-up review team found Massachusetts' performance to be satisfactory with recommendations for improvement for the sub-indicator, Technical Quality of the Product Evaluation Program. The review team found Massachusetts' performance to be satisfactory for the sub-indicators, Technical Staffing and Training and Evaluation of Defects and Incidents Regarding Sealed Sources and Devices. Overall, the review team recommends that Massachusetts' performance with respect to the indicator, SS&D Evaluation Program, continue to be found satisfactory with recommendations for improvement.

Accordingly, since there is no change to the findings resulting from the January 1998 IMPEP review, the review team recommended and the Management Review Board agreed to continue to find the Massachusetts' program to be adequate to protect public health and safety and compatible with NRC's program.

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

1. The review team recommends that the RCP coordinate with NRC staff possible ways to revise SS&D registry certificate MA-0628-D-137-S, to make clear that a generic exemption has not been granted, and that a specific exemption is needed to use the device under special conditions. (Section 2.1)

2. The review team recommends that the RCP reevaluate the radiographic source changers in SS&D registry certificate MA-0628-D-127-S dated February 9, 2000, especially model 650, which does not meet the performance requirements for radiographic operations detailed in 10 CFR 34.20. The SS&D registry certificate should be revised by RCP to reflect this reevaluation and those limitations necessary for the use of these devices. The SS&D registry certificate should reflect these modifications in the section on Limitations and/or Other Considerations of Use. A separate registration certificate should be issued for devices which meet the 10 CFR 34.20 requirements. (Section 2.1)

3. The review team recommends that in the interest of national consistency, and where practical, the RCP closely follow the format for documenting product evaluations in SS&D registry certificates as detailed in NUREG-1556, Volume 3. (Section 2.1)

## LIST OF APPENDICES AND ATTACHMENTS

## APPENDIX A

## SS&D IMPEP REVIEW TEAM MEMBERS

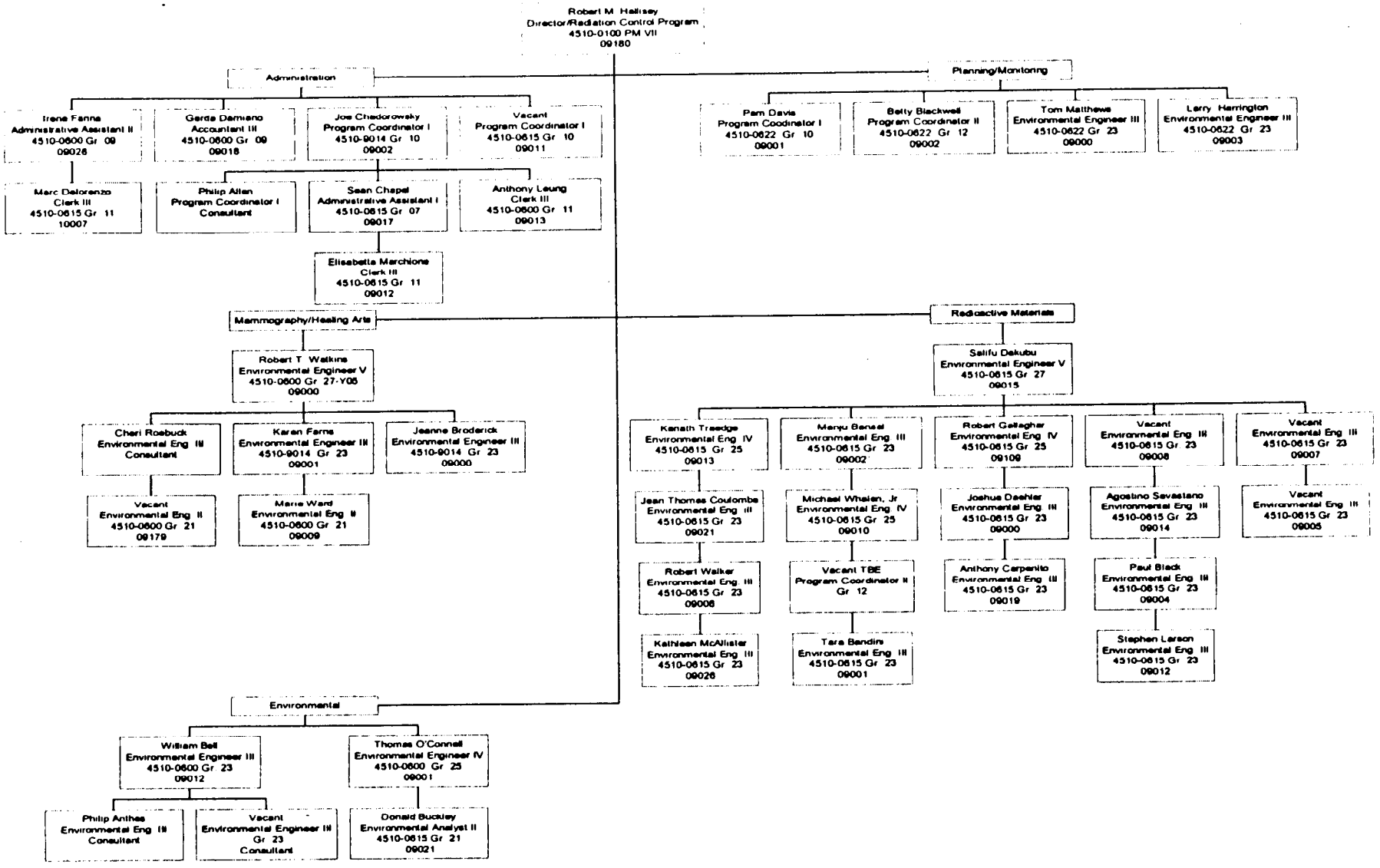
| Name | Area of Responsibility |
|---|---|
| Lloyd Bolling, STP | Team Leader<br>Technical Staffing and Training |
| Ujagar Bhachu, NMSS | Technical Quality of Product Evaluation Program |
| Michael Stephens, Florida | Evaluation of Defects and Incidents Regarding Sealed Sources and Devices |
| Duncan White, Region I | Periodic Meeting |

**APPENDIX B**

**COMMONWEALTH OF MASSACHUSETTS**

**ORGANIZATION CHARTS**
**(ML003736028)**

# Department of Public Health
# Bureau of Health Quality Management
# Radiation Control Program
# As of June 19, 2000



NAMES AND POSITIONS OF CURRENT
SEALED SOURCE AND DEVICE EVALUATION PROGRAM
(Effective 6/21/00)

Dr. Salifu Dakubu, Supervisor
Radioactive Materials Program
Environmental Engineer V

Kenath Traegde, Supervisor
Licensing and SS&D Section
Environmental Engineer IV

| | | |
|---|---|---|
| Agostino Savastano | Robert Walker | Vacant (7/3/2000) |
| Env. Engineer III | Env. Engineer III | Env. Engineer III |

Recommendation 3

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

Response from December 1998 Periodic Meeting Summary

> The Program Director and the Program Supervisor have performed 10 accompaniments in 1998. The remaining inspector will be accompanied within the next two weeks.

Current Status

The Program Supervisor indicated that inspection accompaniments are now performed by the Materials Inspection Section Supervisor. According to RCP management, the program is meeting their goal of at least an annual accompaniment for each inspector.

This recommendation should be verified at the next IMPEP review.

Recommendation 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)

Response from December 1998 Periodic Meeting Summary

> Since the IMPEP review, the total staffing for the materials program has increased from seven to 10 individuals. The Program Director stated that RCP has approval to hire four more individuals in 1999 and is currently pursuing quality candidates for these positions.

Current Status

The review team noted that the RCP has filled vacant positions in the program with quality candidates with a combination of individuals from other government agencies, private industry, and local universities to meet their program demands, particularly in the area of SS&D. The program had one vacancy, but a candidate for this position was selected and began work on July 3, 2000.

This recommendation should be closed at the next IMPEP review.

Recommendation 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)

Response from December 1998 Periodic Meeting Summary

> RCP maintains a training qualification record for its staff that includes basic, specialized and advanced training areas or courses for inspectors, license reviews and sealed source and device (SS&D) reviewers. The Commonwealth also contracted a radiography course held in November 1998 through one of its licensees (Amersham).

Current Status

The review team examined the training records for new employees and noted that the RCP maintains excellent records of each individual's training received, inspection performed or accompanied, or licensing actions reviewed.

This recommendation should be closed at the next IMPEP review.

Recommendation 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 from December 1998 Periodic Meeting Summary

> RCP has received four allegations this year, two of which were anonymous. Known allegers were provided periodic written feedback regarding the actions taken by RCP to resolve their concerns.

Current Status

The review team discussed the RCP's allegation program with their allegation coordinator and reviewed a select number of files. Written periodic feedback on the disposition of the allegations back to the allegers was noted in all files reviewed by the team. Since the December 1998 Periodic Meeting, the NRC referred five allegations to the RCP for their action. All referred allegations were investigated and all but one has been closed. The remaining open allegation involved an extensive investigation and enforcement action by the RCP and is currently undergoing final management review for closure.

This recommendation should be closed at the next IMPEP review.

## APPENDIX C

## STATUS OF RECOMMENDATIONS FROM THE PREVIOUS REVIEW

Recommendation 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 from December 1998 Periodic Meeting Summary

> Since the last review, RCP has issued approximately 30 new licenses with nearly all licensees inspected within six months. Within six months of license issue, RCP staff calls the licensee to determine if licensed activities have commenced and an inspection is conducted.

Current Status

RCP indicated that they continue to perform initial inspections of licensees within six months of the receipt of licensed material, within six months after commencement of licensed activities, or within one year of license issuance, whichever comes first. Initial inspections are announced.

This recommendation should be verified at the next IMPEP review.

Recommendation 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 from December 1998 Periodic Meeting Summary

> The RCP has performed approximately 15 to 20 reciprocity inspections this year. To facilitate the performance of reciprocity inspections, an individual on the materials staff is assigned on a weekly basis to review incoming reciprocity requests for possible inspections.

Current Status

The RCP uses NRC's reciprocity inspection goals outlined in Inspection Manual Chapter 1220. The Program Supervisor indicated that the number of reciprocity inspections RCP performs exceeds these goals.

This recommendation should be verified at the next IMPEP review.

**ATTACHMENT 1**

**MASSACHUSETTS COMMENTS ON DRAFT FOLLOW-UP IMPEP REPORT DATED AUGUST 15, 2000 (ML003745309)**

The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Radiation Control Program
174 Portland Street, 5th Floor, Boston, MA 02114
(617) 727-6214 (617) 727-2098 - Fax

ARGEO PAUL CELLUCCI
GOVERNOR

JANE SWIFT
LIEUTENANT GOVERNOR

WILLIAM D. O'LEARY
SECRETARY

HOWARD K. KOH, MD, MPH
COMMISSIONER



August 15, 2000

Paul H. Lohaus, Director
Office of State Programs
Nuclear Regulatory Commission
Washington, D.C. 20555-0001

Dear Mr. Lohaus:

The purpose of this letter is to respond to the draft Integrated Materials Performance Evaluation Program (IMPEP) report, which you forwarded to Dr. Howard K. Koh the Commissioner of the Massachusetts Department of Public Health (MDPH), dated July 25, 2000, which documents the results of the Agreement State review held here at the Radiation Control Program (RCP) from June 19-21, 2000. Dr. Koh has asked me to respond directly to you on the draft IMPEP report and also to represent the MDPH at any Management Review Board (MRB) meeting, should such a meeting be scheduled.

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. Lloyd Bolling, Nuclear Regulatory Commission (NRC), who was the team leader for this Massachusetts follow-up review of the Sealed Source and Device Evaluation Program. We would also like to compliment the team for the very professional manner in which they performed their activities. The Massachusetts Review Team has both experience and expertise which 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's Program.

We are also very pleased that the Team found our program performance to be satisfactory for the two sub-indicators, Technical Staffing and Training and Evaluation of Defects and Incidents Regarding Sealed Sources and Devices. We have made specific responses to each of the three

recommendations (Attachment A) and while we agree with the majority of the report, we disagree with the first recommendation for the reasons given in our response in this attachment.

We appreciate the opportunity to comment on the draft report and look forward to seeing the final report

Sincerely,

Robert M. Hallisey, Director
Radiation Control Program

CC: Commissioner Howard K. Koh, MD, Mph
Nancy Ridley, Assistant Commissioner

**Attachment A**

**Response to Recommendations**

As a general comment, we would like to draw attention to the three related documents involved in the use of sealed sources and devices and properly distinguish between them, the information each needs to contain and the role it plays. The three documents are the SS&D certificate which is in the registry referred to in 10 CFR 32.210, the specific license authorizing the manufacture and distribution of a source or device, and the specific license authorizing the use of a source or device. Persons are authorized to use sources or devices if they have been manufactured and distributed by persons specifically licensed to do so. The authorization is given in the form of a license with any appropriate limitations. Any manufacturer, importer or initial distributor of a sealed source or device containing a sealed source whose product is intended for use under a specific license may submit a request to the Agency for evaluation of radiation safety information about its product and for filing an evaluation sheet in the U.S. Nuclear Regulatory Commission "Registry of Radioactive Sealed Sources and Devices". In addition to other requirements, a request for evaluation of a device containing a sealed source is required to include the following radiation safety information:

1. proposed uses for the device;
2. manufacturer, model number, chemical and physical form and maximum quantity of radioactivity in the sealed source or sources to be used in the device;
3. details of design of the sealed source, including blueprints, engineering drawings or annotated drawings;
4. details of construction of the sealed source including a description of materials used in construction;
5. radiation profile of a prototype device;
6. procedures for and results of prototype testing;
7. details of quality control procedures to be followed in manufacture;
8. a description or facsimile of labeling to be affixed to the device;
9. leak testing procedures;
10. *a description of potential hazards in installation, service, maintenance, handling, use and operation of the device;*
11. *information about installation, service and maintenance procedures;*
12. *handling, operating and safety instructions; and*
13. *any additional information, including experimental studies and tests, required by the Agency to facilitate a determination of the safety of the device as required by 105 CMR 120.125 (10 CFR 30.33).* **[*Italics for emphasis*]**

The certificate of registration acknowledges the availability of the submitted information for inclusion in an application for a specific license proposing use of the product. Particularly pertinent aspects of this information may also be incorporated into the package insert with the

product. Aspects of the submitted information may be incorporated, by a regulatory authority, into the possession and use license in the form of restrictions or requirements. But first, the information needs to be elicited and incorporated into the certificate. These general remarks guide our specific comments on the draft report.

A correction is needed on page 4 of the draft report, the penultimate sentence of the penultimate paragraph, should read " The RCP updated and re-issued their procedure on June 6, 2000 for processing registration applications."

*RECOMMENDATIONS:*

1. The review team recommends that industrial radiography exposure devices, identified on SS&D registry certificate MA-0628-D-137-S, which do not meet the performance requirements for radiographic operations detailed in 10 CFR 34.20, should be modified or authorized for storage only. It is further recommended that any exemption granted these devices be modified to apply only to Massachusetts industrial radiography licensees on a case-by-case basis, upon application, review and approval by the RCP. Exemptions of this type should be reflected in the Limitations and/or Other Considerations of Use section of this SS&D registry certificate. (Section 2.1).

   *RESPONSE:*

   The Code of Massachusetts Regulation 105 CMR 120.315(A)(1) prescribes that each radiographic exposure device, source assembly, sealed source, and associated equipment shall meet the criteria set forth by ANSI N432-1980. This standard was reviewed for guidance on conditions for the use of radiography devices under plausible accidental conditions. Section 8.4 of ANSI N432-1980 describes the requirements for the accident drop tests at 1 meter and 9 meters. These tests are almost identical to those conducted during Type B testing.

   Testing of the Models 676, 684, 680, and 741, series of cameras to DOT Type B shipping specifications conducted by AEA Technology QSA, Inc. demonstrated that these models did not pass the 9 meter test. As a result, the overpack, or OP, was designed and tested for shipping purposes under DOT regulations. However, all models passed the 1 meter drop test. These tests were conducted prior to September, 1999 and were available at the time of the inspection. These data were used to qualify the cameras for use outside of the overpack. Additional testing performed in April of 2000 confirmed that the cameras passed a 4 foot accidental drop test outside of the overpack. The results of the April 2000 tests were available at the Agency at the time of this review in June of 2000. The attention of the review team has been drawn to these data and copies have been transmitted to a member of the review team.

There were several other conditions specified on the use of the cameras as described in MA-0628-D-137-S. These included the requirements that the devices are not to be used more than 4 feet above the working platform; the lock assembly end of the device is to be facing upward when lifting; redundant safety strapping is to be used when lifting; and the shipping plate is to be installed over the lock when lifting. These limitations were specified on use of the cameras outside of the overpack and written instructions were required to be included with each shipment. The product is shipped with a package insert which contains the required information. A copy of the insert is held on file as part of the submission and was available at the time of the IMPEP.

The summary statement in Item 1 above implies that a special exemption applies to use of the model series 680, 741, 676, and 684 cameras. It is our interpretation that the certificate does not provide any special exemptions and that all the stated limitations on the use and lifting of the cameras defined the parameters for the safe use outside of the overpack at heights less than 4 feet above the working platform. These limitations provide information on the known bounds of safety to the regulatory Agencies. They do not, in themselves, constitute a license.

The term "working platform" was used to define the base of the area of use. This same terminology was used in the SS&D draft certificate submitted to us on October 22, 1999. A working platform was considered to be a reasonable condition for the use of the cameras outside of the overpack.

The NRC has also stated that the model 676 and 684 cameras do not meet the requirements of 10 CFR 34.20, implying that this section of the SS&D certificate was improper. However, the certificate actually contains the evaluation for the 676 and 684 series of cameras. The Models A, B, AE, and BE versions meet the requirements of 10 CFR 34.20. The versions not modified to add the automatic locking mechanism do not meet the requirements of 10 CFR 34.20 and are not in use.

Taking into account our general comments, and given the conditions stated above, we have concluded that for the Models 676, 680, 684, and 741 series of cameras, it is appropriate to state in the certificate that:

**"Under certain conditions, restrictions of size and weight limits in the work environment may not permit the use of the models 680 and 741 in their protective box. In order to permit their use under these circumstances, these devices may be used outside their protective box at work sites, provided:**

1. **They are not used more than four feet off the working platform;**
2. **The lock assembly end of the device is facing upward when lifting;**
3. **Redundant safety strapping is used when lifting;**
4. **The shipping plate is installed over the lock when lifting.**

**These limits on use also apply to the model series 676 and 684 when they are being used above the working platform."**

Certificate Number MA-0628-D-137-S should remain unmodified.

2. The review team recommends that radiographic source changer model 650, identified in SS&D registry certificate MA-0628-D-127-S dated February 9, 2000, be modified to meet the performance requirements for radiographic equipment operations detailed in 10 CFR 34.20. This device should either be retrofitted, used with an approved over-pack or authorized for storage only. The SS&D registry certificate should reflect these modifications in the section on Limitations and/or Other Considerations of Use. (Section 2.1)

*RESPONSE:*

The Agency has noted that the use of the device Model Number 650 source changer has expired by condition on January 10, 1996. Certificate Number NR-0628-D-127-S, dated September 29, 1995, states that "... The Model 650 has not been found to meet the requirements of 10 CFR Part 34 for source changers and storage containers in use after January 10, 1996." This was a statement of expiration that existed at the time this certificate was under the jurisdiction of the NRC. All original review material for this condition was completed by the NRC on September 29, 1995 and is contained in the registration file provided to the Agency on March 21, 1997.

This statement was "carried over" from the original certificate to the amended certificate Number MA-0628-D-127-S. Contact with AEA Technology QSA, Inc. revealed that the Model 650 is no longer manufactured and no longer in service. Therefore, the Agency has amended certificate number MA-0628-D-127-S to remove all references to Model 650. This amendment was completed on June 27, 2000.

3. The review team recommends that in the interest of national consistency, and where practical, that the Commonwealth closely follow the format for documenting product evaluations in SS&D registry certificates as detailed in NUREG-1556, Volume 3.

*RESPONSE:*

The Agency agrees to maintain consistency to the registry format outlined in NUREG-1556, Volume 3. Each new certificate will contain the contents outlined in Chapter 12 of NUREG-1556, including the header, first page information, description, labeling, diagrams, conditions of normal use, prototype testing, external radiation levels, quality assurance and control, limitations and other conditions or use, safety analysis summary, references, issuing agency, and attachments. Each new certificate will also comply with

the dimension requirements of Chapter 12.15 of NUREG-1556. Existing certificates will comply with Chapter 13 of NUREG-1556, "Modification to Existing Registration Certificates," which includes amendments , corrections, combining registration certificates, transfers to inactive status, and re-activiation inactive registration certificates.

It should be noted that many of the specific comments reported by the IMPEP team were related to existing certificates that were in effect "carried over" to the Agency prior to amendment. The Agency recognizes the need for this national standard and will amend existing certificates to the guidelines established in NUREG-1556, Volume 3.