May 10, 2002

Ms. Ann Marie DeBiase, Director
Air and Radiation Management Administration
Maryland Department of the Environment
2500 Broening Highway
Baltimore, MD 21224

Dear Ms. DeBiase:

Enclosed is the final report of the follow-up Integrated Materials Performance Evaluation Program (IMPEP) review of the Maryland radiation control program. The review was conducted by an interoffice team on August 13-16 and November 13-16, 2001. The team reviewed, in detail, the performance indicators of concern identified during the 1999 IMPEP review, Technical Quality of Licensing Actions and Sealed Source and Device (SS&D) Evaluation Program. Ms. Vivian Campbell, NRC Region IV, was the team leader for the follow-up review. The review team's preliminary findings were discussed with you and your staff on November 16, 2001.

The follow-up review team concludes that the Maryland program has improved. The review team recommended, and the Management Review Board (MRB) agreed, in changing the performance rating from satisfactory with recommendations for improvement to satisfactory for the common performance indicator, Technical Quality of Licensing. The performance rating for the non-common performance indicator, SS&D Evaluation Program (satisfactory with recommendations for improvement), will remain the same. Although the program has taken significant steps to address the recommendations in the 1999 report, all SS&D activities have not been fully completed due to the higher priority focus on improving the licensing program. The MRB continues to find the Maryland program to be adequate to protect public health and safety and compatible with NRC's program. Your letter faxed to NRC on March 20, 2002 described your staff's actions taken in response to the recommendations in the draft report. We request no additional information at this time.

In your letter, you stated that you did not anticipate the addition of new recommendations and questioned their appropriateness during a follow-up IMPEP review. The objective of any State IMPEP review is to evaluate the adequacy and compatibility of an Agreement State program, including evaluating the strengths and weaknesses of the nuclear material licensing and inspection program. Regardless of whether an entire program or specific portions of a program are reviewed, review teams have the responsibility to fully evaluate program performance, including making or closing recommendations.

Based on the results of the follow-up IMPEP review, the review team recommended, and the MRB agreed, that the Maryland Agreement State program receive a full IMPEP review in fiscal year 2003. The review team and the State agreed that the next periodic meeting could take place in October 2002.

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 Programs

Enclosure:
As stated

cc: Roland Fletcher, Manager
Radiological Health Program

Steve Collins, Assistant Manager
Office of Radiation Safety
OAS Liaison to MRB

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

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

November 13-16, 2001

FINAL REPORT

U. S. Nuclear Regulatory Commission

1.0 INTRODUCTION

This report presents the results of the follow-up review of the Maryland Department of the Environment (the Department), Radiological Health Program (the Program). This review was directed by the Management Review Board (MRB) based on the results of the March 22-26, 1999 Integrated Materials Performance Evaluation Program (IMPEP) review. The MRB directed that a follow-up review of the common performance indicator, Technical Quality of Licensing Actions and the non-common performance indicator, Sealed Source and Device (SS&D) Evaluation Program, be conducted in one year based on the finding of satisfactory with recommendations for improvement for these indicators. The State, in a letter dated May 4, 2000, requested that the follow-up review be delayed for one year due to a large resource commitment involving escalated enforcement activities with a specific licensee. At the May 31, 2000 meeting, the MRB directed the staff to report on the status of Maryland's actions to address the recommendations from the 1999 IMPEP review after the next periodic meeting. A periodic meeting was held with Maryland on June 29, 2000, and the summary of the meeting was provided to the MRB by a memorandum dated August 4, 2000. The MRB approved the State's request to delay the follow-up IMPEP review at their October 24, 2000 meeting.

The follow-up review began the week of August 13, 2001. However, the team was unable to complete the review during that week due to an illness of one team member. The follow-up review was completed the week of November 13-16, 2001. The follow-up review included evaluation of actions taken by the State to address the five recommendations made during the 1999 IMPEP review involving the two indicators discussed above.

The follow-up review was conducted by a review team consisting of technical staff members from the Nuclear Regulatory Commission (NRC) and the Commonwealth of Massachusetts. Team members are identified in Appendix A. This 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 5, 1999, NRC Management Directive (MD) 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)."

The Maryland Agreement State program is administered by the Secretary of the Department, who reports directly to the Governor. The Program is organized under the Air and Radiation Management Administration. The organizational chart for the Program is presented in Appendix B. The Radioactive Materials Licensing and Compliance Division consists of the Inspection Section and the Licensing Section. The Licensing Section is responsible for processing license applications for the use of radioactive material and for performing SS&D evaluations. The Licensing Section consists of one supervisor and three staff. At the time of the follow-up review, the Program regulated approximately 560 specific licenses, including all types of major material licensees.

A formal questionnaire addressing the specific common and non-common performance indicators was not sent to the Program. However, the Program provided additional information to supplement the information in questions 31 through 33 of the 1999 IMPEP questionnaire response from Maryland. A copy of this supplemental information can be found on the NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML020170528.

The team's approach for conducting the follow-up review consisted of: (1) examination of the Program's supplemental information identified above; (2) in-depth review of the two program indicators identified above; and (3) 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 the two performance indicators for activities conducted during the period of March 26, 1999 - November 16, 2001. Preliminary results were discussed with Maryland management on November 16, 2001.

Following the 1999 IMPEP review, the Program performed a self assessment of both program areas and developed an action plan to address the recommendations from the 1999 review, as well as any self-identified weaknesses. Based on the results of that assessment and resource issues, Program management focused on improving the licensing program initially and implemented that action plan in January 2000, which delayed actions to improve the SS&D program until Spring, 2001. Prior to the team's visit in August 2001, the Program took steps to improve the SS&D program, including: hiring and training an additional staff member to review SS&D casework in addition to materials licensing actions; designating one day a week to completing SS&D casework review; establishing a formal memorandum of understanding (MOU) with another Division within the Department that authorizes the use of a qualified engineer for SS&D reviews; and including the resolution of safety concerns on some devices, as appropriate. The Program focused resources on the SS&D program in the three months following the review team's initial visit in August 2001, and made significant improvements within that time frame.

Section 2 below discusses the results of the follow-up review of the Maryland program for the common performance indicator, Technical Quality of Licensing Actions. Section 3 discusses the results of the follow-up review for the non-common performance indicator, Sealed Source and Device Evaluation Program. Section 4 summarizes the review team's findings and recommendations resulting from the follow-up review. The Program's progress in addressing other recommendations from the 1999 review and general status of the program covered in a periodic meeting can be found in Appendix C.

2.0 COMMON PERFORMANCE INDICATOR, TECHNICAL QUALITY OF LICENSING ACTIONS

During the follow-up review, the team evaluated actions taken by the Program in response to the finding of satisfactory with recommendations for improvement made during the 1999 IMPEP review, as well as new licensing actions completed since that review.

The review team examined completed licensing casework and interviewed the staff for 20 specific licensing actions. Licensing actions were evaluated for completeness, consistency, proper isotopes and quantities used, qualifications of authorized users, adequate facilities and equipment, and operating and emergency procedures sufficient to establish the basis for licensing actions. Licenses were evaluated for overall technical quality including accuracy, appropriateness of the license, its conditions, and tie-down conditions. Casework was evaluated for timeliness; adherence to good health physics practices; reference to appropriate regulations; documentation of safety evaluation reports, product certifications or other supporting documents; consideration of enforcement history on renewals; pre-licensing visits, peer or supervisory review as indicated; and proper signature authority. The files were checked for retention of necessary documents and supporting data.

The 20 license files selected for review included work by all reviewers. The cross-section sampling included all of the Program's major licenses, including the following types of licenses: academic (broad scope and limited specific), portable gauge, industrial radiography, medical (institution and private practice), research and development, nuclear pharmacy, manufacturing and distribution, and general license distribution. Licensing actions included new licenses, renewals, amendments, financial assurance, and terminations. A list of the licenses reviewed with case-specific comments can be found in Appendix D.

The review team's evaluation of the Program's response to Recommendation 4 of the 1999 IMPEP report is presented below.

Recommendation 4

> The review team recommends that Program management implement an action plan to reduce the number of backlogged licensing actions and set goals to improve the accuracy and overall technical quality of licenses. (Section 3.4 of the 1999 IMPEP report)

Current Status

In response to this recommendation, Program management developed and implemented an action plan in January 2000. Program management took several actions which have had a positive impact on the accuracy and overall technical quality of the licensing actions. A licensing section supervisor was assigned and an additional license reviewer was hired. License reviewers meet biweekly to discuss such items as outstanding problems in reviews and implementation of new guidance. NRC's NUREG-1556 series on consolidated license guidance including the associated checklists are being utilized by staff. All licensing actions are reviewed prior to issuance. Guidance documents are placed on the Department's web site. Boilerplate language is used appropriately. Templates and current versions of licenses are placed on the Program's computer server, and all licensing actions are issued in their entirety. Licenses are converted into the new format as licensees amend or renew their licenses. Program management reports that approximately 40% of the 560 specific licenses have been converted into the new format. The Program has set timeliness goals of seven months for issuance of new licenses and renewals, and three months for amendments. Licensing actions are assigned to individual reviewers by the Licensing Section Supervisor (the Supervisor).

The Program has also upgraded the software used to track licensing actions. A variety of reports can be generated to track the status of licensing actions. The Program provides a monthly report to senior Department management on the status of "extended licenses" (renewals greater than seven months old). The team noted that there are currently 24 renewal actions greater than one year old, the oldest action being seven years old. All of these renewals are under active review by staff. This represents a reduction in the backlog of more than 50% since the 1999 review. This backlog reduction was achieved during a period when the Program focused resources on their licensing program. However, Program management indicated that the backlog reduction rate has slowed recently due to the concentrated efforts to address the concerns identified in the SS&D program during the 1999 review.

The review team evaluated seven licenses from the 1999 IMPEP review identified as having inconsistencies, being incomplete, or not properly authorizing licensed activities or materials. All these licenses had been reviewed and corrections were documented in the files. The review

team also reviewed 13 additional licensing actions completed since the 1999 review. Overall, the review team found the licensing actions thorough, complete, consistent and with health and safety issues properly addressed. Deficiency letters clearly stated regulatory positions, were used when appropriate, and identified deficiencies in the licensees' documents. Appropriate reviewer and supervisory checklists were maintained in the file. The review team did identify three files where licensee documents identified in the tie-down conditions were not contained in the correct file. Once identified to Program technical staff, the documents were located in either another file or copies were obtained from the licensee. The licenses reviewed by the team to observe the State's progress with this recommendation are listed in Appendix D.

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

The review team concludes that the technical quality of the licensing actions has shown improvement since the 1999 IMPEP review and no performance issues were identified. Although the 1999 IMPEP report found the performance with respect to this indicator to be satisfactory with recommendations for improvement, the review team is proposing a change in the finding from the 1999 report. Based on the IMPEP evaluation criteria, the review team recommends that Maryland's performance with respect to the indicator, Technical Quality of Licensing Actions, be changed to satisfactory.

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

In conducting this review, three sub-indicators were used to evaluate the Program's performance regarding their SS&D Evaluation Program. These sub-indicators include: (1) Technical Quality of the Product Evaluation; (2) Technical Staffing and Training; and (3) Evaluation of Defects and Incidents Regarding SS&Ds.

In assessing the SS&D Evaluation Program, the review team examined the information provided in the supplement to questions 31 through 33 of the 1999 IMPEP questionnaire response from Maryland. The team also evaluated actions taken by the State in response to the recommendations noted during the 1999 review, as well as new SS&D evaluations completed since that review, deficiency letters, and supporting documents. The review team noted the Program's use of guidance documents and procedures, interviewed staff and the Supervisor, who are involved in the SS&D evaluation, and verified the use of regulations and license conditions to enforce commitments made in the applications.

As discussed in Section 1, Program management focused their resources on improving the licensing program before addressing the SS&D program. The team noted several improvements to the SS&D program had occurred in March 2001. Significant progress was made in the three months following the review team's initial visit in August 2001 because the Program focused resources on the SS&D program.

3.1 Technical Quality of the Product Evaluation Program

The team reviewed a total of 15 certificates in the follow-up review which included: six certificates identified from the 1999 IMPEP report, one new certificate, six amendments, and two inactivations. The review of the six certificates from the 1999 IMPEP report was limited to the Program's actions in addressing previously identified comments. The SS&D registration certificates evaluated by the review team are listed with case-specific comments in Appendix E.

As noted in Appendix E, the review team reviewed available ongoing casework, since the Program has not completed the projected casework as anticipated in their response to the 1999 IMPEP review.

Program management determined that SS&D evaluations were not given a priority and were performed on a time available basis. In response, Program management has instituted a policy whereby one specific day each week is dedicated to SS&D casework review. In addition, the Program has implemented a management database to track timely completion of actions and provides management reports on the status of the current workload and backlogged casework. In addition, as discussed in Section 3.2, the Program has arranged for technical assistance from an engineer from another division within the Department.

The State has modified its policy requiring management signatures on registration certificates in addition to the initial and concurrence reviewers' signatures. The two management signatures have been eliminated from the registration certificate. However, the completion letter for the certificates retains a management signature, thereby maintaining management oversight.

Based on review of the work that has been completed since August 2001 under the Program's revised system, the team noted that Program staff generally followed the recommended guidance from NRC's SS&D training workshop, NUREG-1556, Vol. 3, and MD 5.6, with the exception of the State's concurrence process as discussed below. Pertinent American National Standards Institute standards, Regulatory Guides, and applicable references were used when performing SS&D reviews. Appropriate review checklists were used to assure that all relevant materials were submitted and reviewed. The checklists were contained in the registration files. However, the team noted some discrepancies in documentation which did not allow verification that the engineer and both reviewers had reviewed the casework. The review team discussed the value of such documentation with the Supervisor.

The review team noted that three files lacked documentation of deficiency questions and information obtained through meetings or phone calls. The review team discussed this issue with the Supervisor who indicated that staff would be reminded of the need to document information obtained and used to make the safety analysis for registration. Despite the limited sampling of reviews completed under the Program's revised system, the team determined through discussions with management and staff, that the product evaluations for these certificates were thorough, complete, consistent, of acceptable technical quality, and adequately addressed the integrity of the products during use and in the event of likely accidents.

The Program maintained a copy of SS&D guidance material accessible to all staff. The review team noted that policy changes were communicated to staff verbally during the course of business and during the bi-weekly meetings, due to the rapid changes currently being made in the SS&D area. The review team discussed the value of documenting policy changes in writing with an effective date and maintaining these documents with the standard guidance materials.

The review team's evaluation of the State's response to Recommendations 6, 7, and 9 of the 1999 IMPEP report is presented below.

Recommendation 6

> The review team recommends that the State promptly review registration certificates MD-1003-D-101-G and MD-1003-D-102-G, taking into consideration the deficiencies listed in Appendix F (of the 1999 IMPEP report) for each registration certificate, and amend the registration certificates accordingly. (Section 4.2.1 of the 1999 report)

Current Status

In August 2001, the Program was in the process of addressing the issues for registration certificates referenced above, but the licensee had not been responsive. The Program amended the license prohibiting distribution of the devices in question pending resolution of all issues. Since August 2001, the licensee has submitted complete re-applications for the two certificates and was granted permission, by license amendment, to continue distribution. At the time of the follow-up review, the Program had not yet issued the amendments to these certificates. The review team evaluated the licensee's submissions within the scope of the IMPEP review and agreed that safety issues had been resolved.

Based on the follow-up review, this recommendation remains open.

Recommendation 7

> The team recommends that the State, using NUREG-1556 guidance and following the description of a "concurrence review" in MD 5.6, complete a secondary review of all registration certificates issued by the State to identify any missing information and with priority of the actions based on the risk associated with the device. (Section 4.2.1 of the 1999 report)

Current Status

In March 2001, the Program sent letters to all certificate holders requesting new information for a re-review within 60 days to address this recommendation. The Program indicated that the certificates and background information will be subjected to a full review. At the time of the onsite review, approximately half of the licensees had responded to the request from the Program, however none of the re-reviews had been completed. The Supervisor indicated that the Program plans to complete the re-reviews by January 2003.

The Program developed a concurrence review checklist that detailed the scope and magnitude of the Program's concurrence review. Discussions with staff and the Supervisor during the team's August 2001 visit indicated that the Program set a policy where the concurrence review was an administrative review. The team noted that the administrative review did not fully address the requirements for a concurrence review as described in MD 5.6. Based on the August 2001 discussion, Program management modified their concurrence review to be a limited technical review. A revised checklist was generated in order to ensure that the new process was followed and documented.

The concurrence reviewer uses the reviewer checklist in NUREG-1556, Vol 3, to ensure that all areas have been addressed. The Supervisor indicated that this involves checking that the licensee has addressed each area and briefly reviewing the information to determine whether it

appears to adequately address the issue without performing a detailed review. The concurrence reviewer ensures that the certificate follows the format in NUREG-1556, Vol. 3, including cross-checking all diagrams references and ensuring all appropriate documents are included in the Reference section. It was noted that this limited technical review is not currently being performed by staff having qualifications in the engineering area, therefore the limited technical review lacks an adequate double check in this area.

The review team noted that the Program's policy of conducting the concurrence review as a limited technical review is not in accordance with the current MD 5.6 for this sub-indicator. Program management indicated that questions and concerns have been raised by Agreement States on the need for and definition of a concurrence review. Program management does not agree with the team's interpretation of the Directive's definition of concurrence review and believes that the Program's current review is sufficient to protect public health and safety. This issue is being addressed in proposed revisions to the criteria in MD 5.6 involving the SS&D evaluation programs. Given that these revisions are still under review by the Agreement States and NRC staff, the Program has chosen to maintain their current policy regarding concurrence reviews.

Based on the follow-up review, this recommendation remains open.

Recommendation 9

> The MRB recommends that the State respond to all of the review team's comments in Appendix F of the final report. (Section 4.2.4 of the 1999 IMPEP report)

Current Status

The State provided a response to the comments in the 1999 IMPEP review in a letter dated October 18, 1999, addressed to Carl Paperiello, Deputy Executive Director for Materials, Research and State Programs. The letter outlined Maryland's plan of action for both licensing and SS&D reviews. The follow-up review team examined the Program's actions involving all six certificates listed in the 1999 IMPEP report.

The status of two of the certificates was discussed in response to Recommendation 6. Of the remaining four certificates, one was completed with one remaining comment to be resolved, two were in the process of amendment approval but have yet to be completed, and one has not been addressed. Thus, five of the six certificates are close to completion and the subsequent review and approval of the amendment requests received from the respective licensees will help to close these comments. The review team noted that although progress has been made in addressing a majority of these comments, the State's response to the specific file comments from 1999 remains incomplete.

Based on the follow-up review, this recommendation remains open.

3.2 Technical Staffing and Training

The Program reported that four staff members currently have authority to sign SS&D evaluations, in addition to their responsibilities for licensing casework. The Program's combined staff effort equates to approximately 1 full-time equivalent (FTE) dedicated to

performing SS&D safety evaluations. The Program completed nine SS&D actions (excluding the six re-assessments of the 1999 casework) and 18 evaluations of incidents or failures involving Maryland products during the review period. The review team noted that the Program had spent considerable resources resolving issues with three licensees, which decreased the time staff could spend in both licensing and SS&D casework and program improvement.

The review team noted in the review of the training program that there is no clear policy on how signature authority is granted. Signature authority was granted on a case by case basis by the Supervisor. The review team recommends that the Program establish a training policy that prior to gaining signature authority, all reviewers must meet a set of standards through experience, training, and/or formal education including, at a minimum, those listed in MD 5.6.

Having only fully qualified reviewers (or qualified team reviewers) signing certificates is particularly essential given the State's decision not to perform a complete technical review for the concurrence review. A copy of NRC's draft SS&D reviewer qualification procedure was provided to the Supervisor for consideration. The team also discussed the benefit of reviewing SS&D training programs developed by other Agreement States.

The review team's evaluation of the State's response to Recommendation 8 of the 1999 IMPEP report is presented below.

Recommendation 8

> The 1996 IMPEP team recommended that an additional senior staff member be trained to perform the sealed source and device evaluations to supplement the program as it matures. The State had assigned an additional individual to the program who has completed one review to date and would also benefit from additional training and experience. The review team recommends that the State provide the staff additional training and experience in the review of sealed source and device applications and the drafting of registration certificates (including the guidance contained in NUREG 1556, Vol. 3). This should include training and experience which will meet the qualification guidance found in MD 5.6. (Section 4.2.2 of the 1999 IMPEP report)

Current Status

In general, all the reviewers are trained in Health Physics principles and have attended NRC's SS&D workshop. However, based on the interviews with the staff, it appears that some of the staff do not have a strong engineering background, either through formal training or casework experience. In order to offset this weakness in engineering training and experience, the Program has arranged for technical assistance from an engineer from another Division where reviews are passed through the engineer for technical review. The engineer has attended NRC's SS&D workshop and has advanced engineering degrees which includes experience in mechanical engineering and radiation. Starting approximately June/July 2000, the engineer was available to the staff as a resource for specific questions. A formal MOU was established in May 2001, authorizing up to 16 hours a week of the engineer's time for SS&D review.

At the time of the team's August 2001 visit, actions were sent to the engineer at the discretion of the licensing staff. The team discussed with Program management that this policy did not fully address the qualifications concern raised in the 1999 IMPEP. The team indicated that all

actions should be reviewed by an individual deemed qualified in engineering and design, which could be accomplished through trained staff or the MOU. The Supervisor agreed to review the issue with management. Effective August 20, 2001, the Program issued and implemented a policy where all SS&Ds are required to undergo an engineering review by a qualified individual. The engineering review includes evaluation of the initial request, the licensee response(s), and the final certificate, including a check of Nuclear Material Events Database (NMED) for each sealed source or device in order to assist in identifying generic or repeating problems.

In addition, the Program has developed a spreadsheet in order to track the status of actions sent to the engineer, as well as the time spent by the engineer. This allows the Program to monitor the hours spent by the engineer to ensure that the effort spent is reasonable given the work performed, and identify any potential problems in the system. This approach addresses the concerns raised in the 1999 IMPEP regarding qualifications for individuals performing registration certificate reviews.

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

3.3 Evaluation of Defects and Incidents Regarding SS&Ds

The review team queried NMED and identified 18 incidents reported nationally involving registered products from two Maryland distributors, Shimadzu and Nucletron. The team reviewed the Program's evaluation of seven of these incidents and determined that relevant issues were addressed. A list of incident casework examined with case-specific comments is included in Appendix F.

Several of the Nucletron incidents involved software or mechanical failures. Even though software is not typically included in the SS&D review process, the Program recognized the frequency of occurrence and the potential for these failures to cause misadministrations or worker doses. Nucletron is now required to report to the Program all failures of codes specified by the State. This allows the Program to monitor and determine trends of failure frequencies and types, assisting them in early identification of potential problem areas.

One mechanical failure involved a position simulator tool used with a MicroSelectron HDR remote afterloader device. The Program did not investigate this portion of the report since the position simulator tool was determined to be an associated device to the MicroSelectron HDR, and not the device itself. Since the Program had not evaluated the associated device, the review team discussed with staff whether the design of the simulator was of a similar design, where failure could indicate potential failure of the MicroSelectron. During the IMPEP review, the Program verified that the designs were different, and therefore the failure did not indicate any potential of failure in the MicroSelectron HDR. The review team discussed the overall incident evaluation process with the Program management who agreed to revise their incident evaluation process to include an assessment of any particular incident or failure for generic issues or applicability of the failure mode to other products.

In addition, the team discussed the involvement of the engineer in source and device incident evaluations. The engineering aspect of the Program's review for incidents or failures was not performed on a consistent basis. The review team recommends that the Program establish a policy that a qualified individual perform an engineering review for all incidents that may indicate a source or device problem, and source and device product failures involving Maryland vendors.

The follow-up review team found that the SS&D program has shown improvement since the August 2001 portion of the follow-up IMPEP review. However, due to the competing priority to respond to the 1999 IMPEP recommendations regarding the licensing area, the Program has not been able to fully address the recommendation made in the SS&D area, including re-review of the specific cases listed in the 1999 IMPEP review. Of the four recommendations from the 1999 IMPEP report, the follow-up review team found that one had been adequately addressed and should be closed, and three have not been completed and should remain open. In addition, two new recommendations were made. Based on the IMPEP evaluation criteria, the review team recommends that Maryland's performance with respect to the indicator, Sealed Source and Device Evaluation, continue to be found satisfactory with recommendations for improvement.

4.0 SUMMARY

As noted in Section 2 above, the follow-up review team found Maryland's performance in responding to and resolving the recommendation involving the common performance indicator, Technical Quality of Licensing Actions, to be acceptable. The review team recommends that the Technical Quality of Licensing recommendation be closed and that Maryland's performance with respect to the indicator, Technical Quality of Licensing Actions, be found satisfactory.

As noted in Section 3, the follow-up review team found that the SS&D evaluation program has shown improvement since the 1999 IMPEP review. However, due to the competing priority to implement 1999 IMPEP recommendations in the licensing area, the Program has not been able to fully address the recommendation made in the SS&D area, including re-review of the specific cases listed in the 1999 IMPEP review. The review team recommends that Maryland's performance with respect to the indicator, Sealed Source and Device Evaluation, continue to be found satisfactory with recommendations for improvement. Based on the follow-up review, the review team recommends that the Maryland program continue to be found adequate and compatible with NRC's program.

The follow-up review team recommends that the Maryland Agreement State program receive a full IMPEP review in fiscal year 2003. The review team and the Program management agreed that the next periodic meeting could take place in October 2002.

Below is a summary list of open recommendations from the 1999 report and the new recommendations from this follow-up review.

Open Recommendations from the 1999 IMPEP report:

Recommendation 6

The review team recommends that the State promptly review registration certificates MD-1003-D-101-G and MD-1003-D-102-G, taking into consideration the deficiencies listed in Appendix F (of the 1999 IMPEP report) for each registration certificate, and amend the registration certificates accordingly. (Section 4.2.1 of the 1999 report; Section 3.1 of follow-up review)

Recommendation 7

The team recommends that the State, using NUREG-1556 guidance and following the description of a "concurrence review" in MD 5.6, complete a secondary review of all registration certificates issued by the State to identify any missing information and with priority of the actions based on the risk associated with the device. (Section 4.2.1 of the 1999 report; Section 3.1 of follow-up review)

Recommendation 9

The MRB recommends that the State respond to all of the review team's comments in Appendix F of the final report. (Section 4.2.4 of the 1999 report; Section 3.1 of follow-up review)

New recommendations from the follow-up review:

Follow-up Recommendation 1

The review team recommends that the Program establish a training policy that prior to gaining signature authority, all reviewers must meet a set of standards through experience, training, and/or formal education including, at a minimum, those listed in MD 5.6. (Section 3.2)

Follow-up Recommendation 2

The review team recommends that the Program establish a policy that a qualified individual perform an engineering review for all incidents that may indicate a source or device problem, and source and device product failures involving Maryland vendors. (Section 3.3)

LIST OF APPENDICES

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	Area of Responsibility
Vivian Campbell, RIV	Team Leader
Duncan White, RI	Technical Quality of Licensing Actions Periodic Meeting
Michele Burgess, NMSS	Sealed Source and Device Evaluation Program
Kenath Traegde, Massachusetts	Sealed Source and Device Evaluation Program

APPENDIX B

MARYLAND DEPARTMENT OF THE ENVIRONMENT
AIR AND RADIATION MANAGEMENT ADMINISTRATION

RADIOLOGICAL HEALTH PROGRAM
ORGANIZATION CHART

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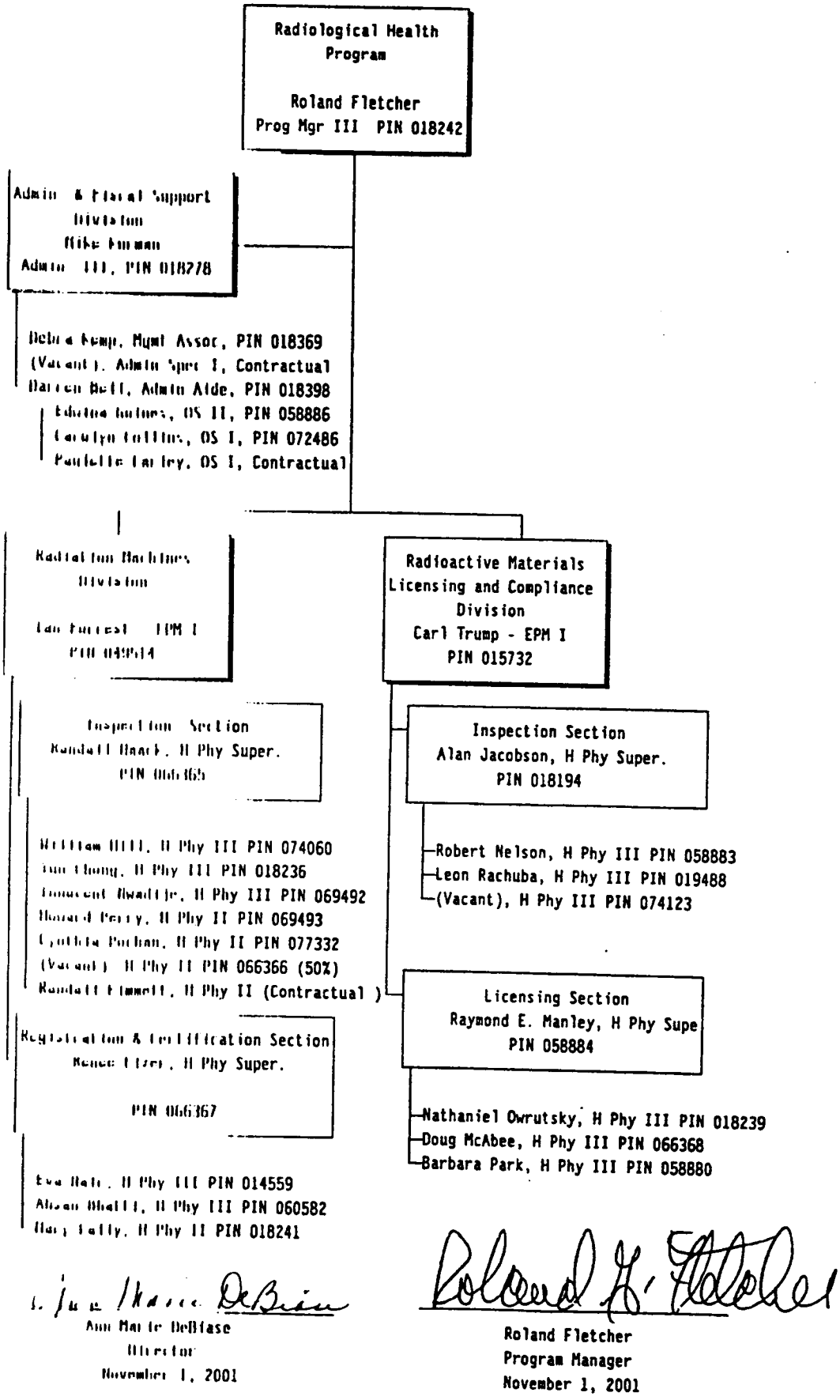
RADIOLOGICAL HEALTH PROGRAM



Ann Marie DeBiase
Director
November 1, 2001

Roland Fletcher
Program Manager
November 1, 2001

Attachment

March 20, 2002 faxed letter from Ann Marie DeBiase
Maryland's Response to Draft IMPEP Report

ML020940565

MARYLAND DEPARTMENT OF THE ENVIRONMENT
2500 Broening Highway • Baltimore, Maryland 21224
(410) 631-3000 • 1-800-633-6101 • http://www.mde.state.md.us

Parris N. Glendening
Governor

Jane T. Nishida
Secretary

Paul H. Lohaus, Director
Office of State and Tribal Programs
U.S. Nuclear Regulatory Commission
Washington DC 20555-0001

RE: Draft Report for Integrated Materials Performance Evaluation Program (IMPEP) Follow-up Review of the Maryland Agreement State Program

Dear Mr. Lohaus:

This letter responds to your January 23, 2002 correspondence conveying the draft report of the results of the Integrated Materials Performance Evaluation Program (IMPEP) follow-up review of the Maryland Agreement State Program. First of all, I appreciate the way you and the members of the IMPEP team handled the task of performing a comprehensive, professional and thorough follow-up review of the Maryland Radioactive Materials Program. We have reviewed the IMPEP team's draft report of the August 13-16 and November 13-16, 2001 MDE audit and generally find the information in the draft report to be factually accurate. Our detailed comments are noted on the attachment. The section numbers used refer to the corresponding section in the draft report.

Again, MDE is appreciative of the IMPEP team's technical and professional review of the Maryland program. Should you have any questions concerning this letter, you may contact Mr. Roland Fletcher, Manager of the Radiological Health Program at 410-631-3301.

Sincerely,

Ann Marie DeBiase

Ann Marie DeBiase, Director
Air and Radiation Management Administration

Enclosure

AMD/RGF

cc: Roland G. Fletcher

Maryland Responses to Draft Report for Integrated Materials Performance Evaluation Program (IMPEP) Follow-up Review of the Maryland Agreement State Program

1. Section 1.0, paragraph 7:

The draft report states that improvements and corrective actions to the SS&D program occurred primarily in the three months following the review team's initial visit in August 2001. This statement does not give proper credit to the significant improvements implemented in the program prior to the August 2001 audit. These include the hiring and training of an additional SS&D reviewer, the contracting and use of a qualified engineer for the review applications, commitment to a minimum one day a week work time schedule for SS&D projects, reorganization of all SS&D files, resolution of safety concerns on certain devices of concern and stronger emphasis and use of NUREG 1556 Vol. 3 guidance in the review process.

2. Section 3.0, paragraph 3

Though we agree that the Program first focused resources on the improvement of licensing actions, the report should give more recognition and credit to the significant improvements to the SS&D program (as defined above) prior to the August 2001 portion of the follow-up audit. Though licensing actions received the most intense focus initially, SS&D requirements began being addressed at the same time.

3. Section 3.1, page 6, recommendation 6, current status:

The last sentence under status states that the review team evaluated the licensee's submissions and agreed, in principle, that safety issues had been resolved. The Maryland RHP suggests that the phrase "in principle" be replaced with the phrase, "within the scope of the IMPEP review".

4. Section 3.1, page 7, recommendation 7, current status, paragraph 3:

The IMPEP team noted that a concurrence review is not being conducted in accordance with the current Management Directive 5.6. Maryland does not agree with the team's interpretation of the directive's definition of concurrence review and believes that the review, as conducted by the RHP is sufficient to protect health and safety. As acknowledged by the IMPEP team, this is an area of controversy, not only in this recommendation but also with the Agreement States. With a revision of MD 5.6 pending, this item should be closed.

5. Section 3.1, page 7, recommendation 7, current status, paragraph 4:

Same comment as above.

II. Response to Open Recommendations from the 1999 IMPEP Report:

1. **Recommendation 6:**

The review team recommends that the State promptly review registration certificates MD-1003-D-101G and MD-1003-D-102-G, taking into consideration the deficiencies listed in Appendix F (of the 1999 IMPEP report) for each registration certificate, and amend the registration certificate accordingly. (Section 4.2 of the 1999 report; Section 3.1 of follow-up review)

RESPONSE:

These two sheets are currently tasked to a SS&D reviewer. The State is still in the process of clarifying with the manufacturer certain non-safety issues, prior to the reformatting and reissuing of the registrations. Upon satisfactory response, we anticipate the resolution of all relevant Appendix F deficiencies and the reissuing of the sheets by June 2002.

2. **Recommendation 7:**

The team recommends the State, using NUREG-1556 guidance and following the description of a "concurrence review" in MD 5.6, complete a secondary review of all registration certificates issued by the State to identify any missing information and with priority of the actions based on the risk associated with the device. (Section 4.21of the 1999 report; Section 3.1 of follow-up review)

ARMA-RHP RESPONSE:

The RAM Licensing section currently has an internal target date January 1, 2003, with the goal to complete the review and reissuing of all required SS&D sheets. As described earlier in this letter, ARMA-RHP has significant concerns regarding NRC's interpretation of the requirements for concurrence review as authorized in Management Directive 5.6. It is doubtful that the January 1, 2003 date will be met if RHP must conduct any review beyond what is currently being done.

3. **Recommendation 9**:

The MRB recommends that the State respond to all the review team's comments in Appendix F of the final report. (Section 4.2.4 of the 1999 report; Section 3.1 of the follow-up review)

RESPONSE:

Maryland has already successfully addressed the majority of the comments outlined in Appendix F. ARMA-RHP anticipates that all credible remaining concerns will be addressed by January 1, 2003, unless as noted above, the NRC maintains its position on the MD 5.6 concurrence review criteria.

III. New Recommendations from the Follow-up Review:

Maryland will strive to accomplish the implementation of changes that improve our SS&D program within the framework of radiation safety and proficient device evaluation and certification. We did not, however, anticipate the addition of new recommendations during a follow-up IMPEP and question the appropriateness of this action. We recommend that the NRC carefully evaluate the use of this mechanism and assure that it does not become an ongoing program-ratcheting tool. There should also be a process through which it can be brought to a reasonable conclusion.

Follow-up Recommendation 1

The review team recommends the Program establish a training policy, so that prior to gaining signature authority, all reviewers must meet a set of standards through experience, training, and/or formal education including, at a minimum those listed in MD 5.6. (Section 3.2)

RESPONSE:

Maryland is currently evaluating and developing a procedure to govern SS&D reviewer qualifications and training. This procedure will be based on MD 5.6 requirements and tempered by our specific needs and current resources. The final procedure will be forwarded with Maryland's response to the follow-up final report.

Follow-up recommendation 2

The team recommends the Program establish a policy that a qualified individual perform an engineering review for all incidents and product failures involving Maryland vendors. (Section 3.3)

RESPONSE:

Maryland has previously investigated and resolved many generic engineering questions specific to Maryland manufacturers. The ARMA-RHP is currently evaluating and developing a procedure that will involve the evaluation by a qualified individual (currently an engineer) regarding all incidents and product failures involving Maryland vendors. However, it is still somewhat unclear as to the scope of the generic review necessary (trending, etc.) and the best means of facilitating changes in the manufacturing process regarding stakeholders concerns that may not always be safety oriented. The final procedure will be forwarded with Maryland's response to the follow-up final report.

The above Maryland responses are specific to the recommendations and observations included in the Draft Report for Integrated Materials Performance Evaluation Program (IMPEP) Follow-up Review of the Maryland Agreement State Program.