



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, Director
Air and Radiation Management Administration

Enclosure

AMD/RGF

cc: Roland G. Fletcher

*Rec'd
4/4/02
DCD
SP05*

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 "concurrency 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 4.21 of 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.