



# MARYLAND DEPARTMENT OF THE ENVIRONMENT

1800 Washington Boulevard • Baltimore MD 21230  
410-537-3000 • 1-800-633-6101 • [www.mde.state.md.us](http://www.mde.state.md.us)

Martin O'Malley  
Governor

Robert M. Summers, Ph.D.  
Secretary

Anthony G. Brown  
Lieutenant Governor

JAN 11 2012

Michael F. Weber  
Deputy Executive Director for Materials Waste,  
Research, State, Tribal and Compliance Programs  
Office of the Executive Director for Operations  
U.S. Nuclear Regulatory Commission  
Washington, D.C. 20555-0001

Dear Mr. Weber:

Thank you for your December 8, 2011 letter to the Maryland Department of the Environment (MDE) transmitting the Final Report of the Integrated Materials Performance Evaluation Program (IMPEP) August 8-12, 2011 review of the Agreement State Program. Maryland's response to the Final Report recommendations is attached.

MDE thanks the IMPEP audit team for their expertise, professionalism, competence and patience during the audit. Maryland is a staunch supporter of the IMPEP process and we intend to continuously improve the adequacy and compatibility of our Program and our ability to protect both occupational staff and the public against the hazards of ionizing radiation. Should you have any questions regarding this response please contact Ray Manley at 410-537-3191 or by e-mail at [rmanley@mde.state.md.us](mailto:rmanley@mde.state.md.us).

Sincerely,

Roland G. Fletcher, Manager IV  
Radiological Health Program  
Air and Radiation Management Administration

*RFM*  
RGF/REM/cc



## MARYLAND RESPONSE TO THE 2011 IMPEP FINAL REPORT

### **Recommendation 1:**

**The review team recommends that the State take measures to ensure that sufficient information pertaining to the inspection review of items of non-compliance as well as the effectiveness of licensee corrective actions is adequately documented in inspection records.**

#### *Response:*

*Maryland's follow-up review of this IMPEP audit finding revealed that the failure to document sufficient information pertaining to the inspection review of items of non-compliance as well as the effectiveness of licensee corrective actions was limited to only a few reports. Subsequent to the audit finding, all radioactive material inspectors have received additional training emphasizing the importance of documenting sufficient information pertaining to the inspection review of items of non-compliance as well as the effectiveness of all licensee corrective actions. Finally, the Inspection Supervisor will carefully review each inspector report to evaluate conformance to this inspection documentation.*

### **Recommendation 2:**

**The review team recommends that the State perform a self-assessment of selected licensing actions issued during the review period, and on a routine basis in the future, to ensure that the Program's review of licensing actions are adequately documented and that licensing actions are thorough and consistent with the regulations and appropriate licensing guidance.**

#### *Response:*

*Maryland will perform a self-assessment of selected licensing actions issued during the review period, and on a routine basis in the future, to ensure that the Program's review of licensing actions are adequately documented and that licensing actions are thorough and consistent with the regulations and appropriate licensing guidance. An outline of the assessment process is as follows:*

#### *Licensing Assessment Plan:*

##### *A. Review of Past Licensing Actions*

- 1. Twenty-five licensing actions conducted during the four years previous to the 2011 IMPEP will be selected for follow-up review. The selections will*

*be based on licenses of: concern identified during the IMPEP; a high level of complexity; a high level of health and safety impact (i.e medical therapy); and diversity of different radioactive material use.*

- 2. The above actions will be reviewed to assure they have adequate documentation and that they are thorough and consistent with the regulations and appropriate licensing guidance. Any concerns will be documented and addressed. If any programmatic concerns are identified the number of assessed licenses will be expanded to address those concerns,*
- 3. The licensing section will use this license assessment opportunity to review the best application of both NRC and Maryland licensing guidance in our licensing process. Any lessons-learned and improvements will be incorporated into the licensing process. It is our intent not to just meet adequate licensing standards, but to exceed.*

#### *B. Ongoing Review of Licensing Actions*

- 1. The Licensing Supervisor will continue to review all new licensing actions prior to issuance.*
- 2. A portion of all licensing staff meetings will be devoted to quality assurance of licensing actions inclusive of review of quality and content of both Maryland and NUREG 1556 series guidance.*
- 3. The quality of selected recent licensing actions will be reviewed each quarter (end of March, June, September, December) by the licensing reviewers, Inspection Supervisor, and Division Chief starting March of 2012. Reviews will be documented and any concerns or training of staff addressed. Policies and procedures will be updated as needed.*

#### **Recommendation 3:**

**The review team recommends that the State (1) take measures to ensure that financial assurance requirements are reviewed as part of significant licensing actions and during licensing renewals; (2) evaluate the need for financial assurance related to the radionuclide production (cyclotron) licenses; and (3) perform a review of the adequacy and validity of financial assurance mechanism already on file with the Program.**

#### Response:

*Maryland will (1) take measures to ensure that financial assurance requirements are reviewed as part of significant licensing actions and during licensing renewals. Maryland will conduct a thorough review of NRC and other appropriate technical guidance specific to financial assurance and develop training for all RAMLCD technical*

staff in order to improve both the licensing and the inspection process of financial assurance. All current licensee financial assurance documentation will be reviewed for appropriate content, and license reviewers will conduct a thorough evaluation of financial assurance requirements during each significant licensing action or renewal. Licensing procedures will be amended to assure that these reviews occur and reviewer training will be conducted regarding all new procedures and decommissioning/financial assurance review lessons-learned. (2) Management of both cyclotron licensees in Maryland have been contacted. One licensee (same as NRC Region I) submitted justification as to why financial assurance is not required and an amendment request certifying that the activity of activation products will never exceed those levels requiring a financial instrument. After a careful review of the request, an amendment will be issued to the licensee the week of January 9, 2012, that resolves that the licensee will not be required to have financial assurance. The other licensee (broad scope) has conducted an updated review of their decommissioning funding plan (DFP) and has submitted it to Maryland. Maryland is currently conducting a review of this submitted DFP against the guidance listed in Section 4.1 of NUREG 1557 Volume 3 "Consolidated NMSS Decommissioning Guidance-Financial Assurance, Recordkeeping, and Timeliness." The review will assure that all radioactive material requiring financial assurance has been adequately addressed. (3) RHP will carefully perform a review of the adequacy and validity of financial assurance mechanisms already on file with the Program and any deficiencies in documentation or technical sufficiency of submittals will be addressed by the end of March 2012.

#### **Recommendation 4:**

**The review team recommends that, for all 25 obsolete SS&D registrations identified in Appendix G, the Program take actions to submit the status of those registrations for inclusion in the national Sealed Source and Device Registry, to include transfer of each registration to inactive status as recommended in Section 13.4 of NUREG 1556 , Volume 3, Revision 1, "Applications for Sealed Source and Device Evaluation and Registration," and to take measures to ensure that future registrations that become obsolete are inactivated in a timely manner.**

#### **Response:**

*Maryland will take actions to submit the status of the 25 obsolete SS&D registrations identified in Appendix G, for inclusion in the national Sealed Source and Device Registry; to include transfer of each registration to inactive status as recommended in Section 13.4 of NUREG 1556 , Volume 3, Revision 1, "Applications for Sealed Source and Device Evaluation and Registration;" and to take measures to ensure that future registrations that become obsolete are deactivated in a timely manner. Currently Maryland has submitted to the NRC 17 requests for deactivation of the 25 listed sheets. Of the nine additional sheets identified by the Program requiring deactivation, nine requests for deactivation have been submitted to the NRC. In summary, a total of 26 requests for deactivation of SSD have thus far been submitted. The 8 remaining sheets requiring deactivation are in progress and will be submitted to NRC by the end of*

*January 2012. Licensing procedures will be modified to assure that reviewers conduct an evaluation for deactivation for all appropriate Maryland device/source manufacturers and/or distributors upon licensee request or termination of the license. Twice a year the Program will cross compare our list of Maryland SS&Ds against all Maryland sheets identified in the NRC Registry.*