December 8, 2011

Robert M. Summers, Ph.D., Secretary
Maryland Department of the Environment
1800 Washington Blvd., Suite 750
Baltimore, MD 21230-1718

Dear Dr. Summers:

On November 3, 2011, the Management Review Board (MRB) met to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) report on the Maryland Agreement State Program. The MRB found the Maryland program adequate to protect public health and safety and compatible with the U.S. Nuclear Regulatory Commission's (NRC) program.

Section 5.0, page 19, of the enclosed final report contains a summary of the IMPEP team's findings and recommendations. We request your evaluation and response to the recommendations in the report within 30 days from receipt of this letter. Based on the results of the current IMPEP review, the next full review of the Maryland Agreement State Program will take place in approximately 4 years, with a periodic meeting tentatively scheduled for August 2013.

I appreciate the courtesy and cooperation extended to the IMPEP team during the review. I also wish to acknowledge your continued support for the Agreement State program. I look forward to our agencies continuing to work cooperatively in the future.

Sincerely,

/RA/

Michael F. Weber
Deputy Executive Director for Materials, Waste,
Research, State, Tribal and Compliance Programs
Office of the Executive Director for Operations

Enclosure:
Maryland Final IMPEP Report

cc w/ encl: Roland G. Fletcher, Manager
Radiological Health Program

Raymond Manley, Chief
Radioactive Material Licensing & Compliance Division

Tom Levering
Emergency Response Director
State Liaison Officer

Letter to R. Summers from Michael F. Weber dated:

SUBJECT: MARYLAND 2011 FINAL IMPEP REPORT

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF THE MARYLAND AGREEMENT STATE PROGRAM

AUGUST 8-12, 2011

FINAL REPORT

Enclosure

EXECUTIVE SUMMARY

This report presents the results of the Integrated Materials Performance Evaluation Program (IMPEP) review of the Maryland Agreement State Program. The review was conducted during the period of August 8-12, 2011, by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the Commonwealth of Massachusetts.

The Management Review Board (MRB) met on November 3, 2011, to consider the proposed final report. Based on the results of the review, the review team recommended, and the MRB agreed, that Maryland's performance be found satisfactory, but needs improvement, for the performance indicator Technical Quality of Licensing Actions, and satisfactory for the six other performance indicators reviewed.

The review team recommended, and the MRB agreed, that the Maryland Agreement State Program be found adequate to protect public health and safety, and compatible with NRC's program.

The review team made four recommendations regarding the performance of the Maryland Agreement State Program. These recommendations, which are briefly described below, included areas for improvement to correct identified performance deficiencies and weaknesses in Maryland's Agreement State Program. The review team recommends that the State: (1) take measures to ensure that sufficient information pertaining to the inspection review of items of non-compliance and effectiveness of licensee corrective actions is adequately documented in inspection records; (2) 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; (3) regarding financial assurance: take measures to ensure that financial assurance requirements are reviewed as part of significant licensing actions and during licensing renewals, evaluate the need for financial assurance related to the radionuclide production (cyclotron) licensees, and perform a review of the adequacy and validity of financial assurance mechanisms already on file; and (4) for the 25 obsolete sealed source & device registrations identified in Appendix G, 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.

Based on the results of the current IMPEP review, and in accordance with the criteria in NRC Management Directive 5.6, the review team recommended, and the MRB agreed, that the next full IMPEP review take place in approximately 4 years.

1.0 INTRODUCTION

This report presents the results of the review of the Maryland Agreement State Program. The onsite portion of the review was conducted during the period of August 8-12, 2011, by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the Commonwealth of Massachusetts. Review team members are identified in Appendix A. The review was conducted in accordance with the "Implementation of the Integrated Materials Performance Evaluation Program and Rescission of Final General Statement of Policy," published in the *Federal Register* on October 16, 1997, and NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)," dated February 26, 2004. Preliminary results of the review, which covered the period of August 25, 2007, to August 8, 2011, were discussed with Maryland managers on the last day of the review.

A draft of this report was issued to Maryland for factual comment on September 7, 2011. The State responded by electronic mail dated October 12, 2011. Copies of the State's responses are included as an Attachment to this report. The Management Review Board (MRB) met on November 3, 2011, to consider the proposed final report. The MRB found the Maryland Agreement State Program adequate to protect public health and safety and compatible with NRC's program.

The Maryland Department of the Environment (the Department) is the responsible agency for regulating the possession and use of radioactive materials in the State of Maryland. The Maryland Agreement State Program is administered by the Secretary of the Department, who reports directly to the Governor. The Radiological Health Program (the Program), under the Air and Radiation Management Administration, has been delegated the responsibility to implement the Agreement State program. The Program is divided into the Radioactive Materials Licensing and Compliance Division (the Division), the Radiation Machines Division, and a group responsible for Regulations and Radiation Exposure Strategies. Organizational charts for the Department, the Program, and the Division are presented in Appendix B.

The State has a Radiation Control Advisory Board (RCAB), which was established pursuant to the Annotated Code of Maryland, § 8-201 et seq. The statute provides that there is a RCAB in the Department. The RCAB periodically reviews the programs and policies of the Department that relate to radiation, and consults with and advises the Secretary of the Department on matters that relate to radiation including: advice on proposed legislation; emerging radiation issues; and proposed regulations. The RCAB consists of 12 members, ten of which are individuals recognized as knowledgeable about the subject of radiation and two of which are members of the public who represent the community at large. Members of the RCAB are appointed by the Secretary of the Department.

At the time of the review, the Maryland Agreement State Program reported that they regulated 598 specific licenses authorizing byproduct, source, and certain special nuclear materials. The review focused on the radioactive materials program as it is carried out under the Section 274b (of the Atomic Energy Act of 1954, as amended) Agreement between the NRC and the State of Maryland.

In preparation for the review, a questionnaire addressing the common and applicable non-common performance indicators was sent to the Program on March 29, 2011. The Program provided its response to the questionnaire via email on July 12, 2011. A publicly available version of the questionnaire response can be found in NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML112010075.

The review team's general approach for conduct of this review consisted of: (1) examination of the Program's response to the questionnaire; (2) review of applicable Maryland statutes and regulations; (3) analysis of quantitative information from the Division's databases; (4) technical review of selected regulatory actions; (5) field accompaniments of three qualified inspectors; and (6) interviews with staff and managers. The review team evaluated the information gathered against the established criteria for each common and the applicable non-common performance indicator and made a preliminary assessment of the Maryland Agreement State Program's performance.

Results of the review for the common performance indicators are presented in Section 3.0. Section 4.0 details the results of the review of the applicable non-common performance indicators, and Section 5.0 summarizes the review team's findings and recommendations. The review team's recommendations are comments that relate directly to the Program's performance. A response is requested from the State to all recommendations in the final report.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous IMPEP review, which was conducted during August 20-24, 2007, no recommendations were made in regard to program performance.

3.0 COMMON PERFORMANCE INDICATORS

Five common performance indicators are used to review NRC Regional and Agreement State radioactive materials programs. These indicators are: (1) Technical Staffing and Training, (2) Status of Materials Inspection Program, (3) Technical Quality of Inspections, (4) Technical Quality of Licensing Actions, and (5) Technical Quality of Incident and Allegation Activities.

3.1 Technical Staffing and Training

Issues central to the evaluation of this indicator include the Program's staffing level and staff turnover, as well as the technical qualifications and training histories of the staff. To evaluate these issues, the review team examined the Program's questionnaire response relative to this indicator, interviewed Program managers and staff, reviewed job descriptions and training records. The review team also considered any possible workload backlogs in evaluating this indicator.

The Division implements the radioactive materials program and consists of the Inspection Section and the Licensing Section. The Division is supervised by a Chief, who is responsible for the oversight of both the Inspection and Licensing sections. The Inspection Section is responsible for performing radiation safety inspections, responding to incidents and allegations, and monitoring decontamination and decommissioning of licensed facilities. The Licensing Section is responsible for processing license applications and amendments for the use of

radioactive material and for performing sealed source and device (SS&D) evaluations. The Inspection and Licensing Sections each have authorization for one supervisor and three technical staff positions.

At the time of the review, eight staff members, including three managers, worked full-time and two technical staff members worked part-time for the radioactive materials program. This staffing level does not include administrative support staff. During the review period, two technical staff members were hired into the Program and three technical staff members left the Program. One individual that was hired during the review period also left the Program during the review period, after having worked for the Program for less than a year and a half. The position vacated by this individual is a contractor position that is located in the Licensing Section. This position has been vacant since September 2010. At the time of the review, it was noted that the Program had initiated the process of posting this position. A staff member of the Inspection Section has been on a military duty assignment since November 2010 and is not expected to return to the Program until March 2012. Details of staffing in the SS&D program are provided in Section 4.2.1 of this report.

The Program has a documented training plan for technical staff that is consistent with the requirements in the NRC/Organization of Agreement States Training Working Group Report and NRC's Inspection Manual Chapter (IMC) 1246, "Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area." The License Reviewer Qualification Plan includes documentation of on-the-job training and formal course work for license reviewers, in addition to licensing policies, procedures, and checklists. A qualification log is maintained for each license reviewer which clearly documents the individual's progress throughout the qualification process. The Radiological Health Inspection Manual has a chapter on inspector training and qualification procedures, including detailed training logs, documentation of inspection accompaniments, and evaluation by managers to qualify individual staff. Staff members are assigned increasingly complex duties as they progress through the licensing and/or inspection qualification process. The review team noted that Program management had a strong commitment to training.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Maryland's performance with respect to the indicator, Technical Staffing and Training, be found satisfactory.

3.2 Status of Materials Inspection Program

The review team focused on five factors while reviewing this indicator: inspection frequency, overdue inspections, initial inspections of new licenses, timely dispatch of inspection findings to licensees, and performance of reciprocity inspections. The review team's evaluation was based on the Program's questionnaire response relative to this indicator, data gathered from the Program's database, examination of completed inspection casework, and interviews with Program managers and technical staff members.

The review team compared the Program's inspection frequencies for various license types to the inspection frequencies found in NRC's IMC 2800, "Materials Inspection Program." The inspection priorities used by the Program during the review period were found to be either the same or more frequent than those provided in IMC 2800. For those license types inspected

more frequently than provided in IMC 2800, the Program believes that these represent higher safety and risk significant activities and warrant more frequent inspection. The review team discussed with the Program the NRC's recent revision to IMC 2800, which was issued on November 15, 2010. Regarding inspection frequencies, the revision to IMC 2800 added a few new license program codes and associated priority codes that the Program may find useful in implementing its licensing and inspection programs.

The Program's database had limited capabilities for retrieval of inspection data from the entire review period. As a result, the review team verified the Program's inspection timeliness based on the information contained in the Program's questionnaire response, information that could be obtained from the database, interviews with Program managers, and review of the inspection casework for determination of Priority 1, 2, 3, and initial inspections. As could be determined based on the above sources of information, during the review period, the Program performed 254 Priority 1, 2, and 3 inspections. This number of inspections is based on the Program's determination of inspection priority and not those of IMC 2800, and therefore includes some inspections conducted by the Program more frequently than provided in IMC 2800. The Program's questionnaire response reported that using their priority codes for Priority 1, 2, 3 licenses, out of 254 inspections, two inspections were performed overdue (i.e. greater than 25 percent of the assigned inspection frequency) and no inspections were overdue at the time of the review. On November 2, 2011, the Inspection supervisor provided an email to the review team wherein the State reexamined the information that had previously been provided to the team and determined that no inspections were performed overdue during the review period.

The review team identified a few typographical errors in the Program's database wherein the indicated license program code did not match with the assigned inspection priority. Although in these few cases the priorities were less frequent than those of IMC 2800, the review team determined that none of the typographical errors resulted in any inspections being overdue at the time of the review. The inspection supervisor committed to review the discrepant entries and make corrections to either the license program code or inspection priority as appropriate.

During the review period, the version of IMC 2800 that was in effect was issued on September 28, 2005. This version describes, in part, that an initial inspection of a new licensee shall be completed within 12 months of license issuance. Data regarding the performance of initial inspections had to be manually verified by the Inspection Section supervisor. Based on the data obtained from the manual search, 67 initial inspections were conducted during the review period, three of which were conducted overdue. Additionally, there were six pending initial inspections, none of which were overdue at the time of the review. On November 2, 2011, the Inspection supervisor provided an email to the review team wherein the State reexamined the information that had previously been provided to the team and determined that only one initial inspection had been performed overdue during the review period. On May 4, 2011, the Program revised its "Radiological Health Program Inspection Manual." This revision addressed the changes regarding the circumstances under which an initial inspection is necessary that were described in NRC's recent revision to IMC 2800, which was issued on November 15, 2010.

Based on the revised inspection data provided by the State regarding the Program's Priority 1, 2, and 3 licensees as well as the initial inspection data, the review team calculated that the Program performed less than 1 percent of its inspections overdue during the review period.

The review team verified the Program's performance of inspections of licensees subject to the Increased Controls. At the time of the review, the Program had 25 licensees subject to the Increased Controls. Inspections of licensees subject to the Increased Controls were tracked by the Program separately from the routine inspections in order to ensure that inspections were performed in a timely manner.

The review team evaluated the Program's timeliness in issuing inspection findings. For each inspection, the inspector issues a "Form E-1, Radioactive Material Inspection Findings and Licensee Acknowledgement" to the licensee, and the licensee representative signs the form to acknowledge receipt. This form documents that an inspection was performed and communicates to the licensee that either: (1) licensed activities have not commenced under the license; (2) no non-compliances were identified; (3) non-compliances were identified but were of minor significance and documented at the conclusion of the inspection for licensee corrective action; or (4) non-compliances were identified and will be transmitted to the licensee via letter at a later date. The data regarding issuance of inspection findings to licensees was not able to be retrieved from the Program's database. The review team found that, based on a review of selected inspection casework, "E-1" forms were routinely provided to licensees at the conclusion of the onsite inspection. For inspections where non-compliances were identified and the decision was made to issue them to the licensee in a letter, the Program typically issued the letters to licensees within 30 days of the date of the inspection. A few cases were identified where letters documenting non-compliances were issued to licensees greater than 30 days from the date of the onsite inspection, but none of the cases reviewed exceeded 45 days. It was noted by the inspection supervisor that significant enforcement actions may take longer to be issued due, in part, to the level of management review necessary.

The Program grants reciprocity requests for many categories of licensees and considers all reciprocity licensees as candidates for inspection but focuses on accomplishing reciprocity inspections of Priority 1, 2, and 3 licensees. The review team found that the Program's selection of candidates for inspection differed somewhat from that described in NRC's IMC 1220 "Processing of NRC Form 241 and Inspection of Agreement State Licensees Operating under 10 CFR 150.20" but was still effective in meeting the intent of the criteria. Based on the Program's questionnaire response and a review of the Program's reciprocity files, the review team found that the Program was able to consistently perform inspections of 20 percent or more of the Priority 1, 2, and 3 reciprocity licensees annually. During each of the years of the review period, beginning with 2007, the Program performed inspections of: 33 percent, 30 percent, 41 percent, and 38 percent, respectively, of Priority 1, 2, and 3 reciprocity licensees. For 2011, at the time of the review, the Program had granted 18 reciprocity requests to Priority 1, 2, and 3 reciprocity licensees, and had already performed 5 inspections of Priority 1, 2, and 3 reciprocity licensees (28 percent).

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Maryland's performance with respect to the indicator, Status of Materials Inspection Program, be found satisfactory.

3.3 Technical Quality of Inspections

The review team evaluated 13 inspection case files that included inspection records, enforcement documentation and letters to licensees, and interviewed the inspection section

supervisor and technical staff members who were responsible for some of the radioactive materials inspections conducted during the review period. The casework reviewed covered a wide variety of inspection types, including panoramic wet-source storage irradiator, nuclear pharmacy, radionuclide production (cyclotron), industrial radiography, self-shielded irradiators, veterinary non-human use, and medical-written directives required. The casework reviewed represented inspections conducted by the inspection section supervisor, three qualified inspectors from the inspection section, and two qualified inspectors from the licensing section. A listing of the inspection casework files reviewed, with case-specific comments, is provided in Appendix C.

Based on the review of casework, the review team noted that with a few exceptions, inspection records were thorough, complete, consistent, and of high quality. When items of non-compliance were identified, inspection records and communications to licensees were of high quality and contained sufficient information to support the inspectors' findings. The review team found that inspection documentation did not always address a review by the current inspector of items of non-compliance that were identified during previous inspections. In some cases, the previous inspection was the result of an incident or event and had resulted in the issuance of non-compliances to the licensee regarding matters of health and safety significance. In these cases, the inspectors that performed the next routine inspection did not document their review of the licensee's immediate and long-term corrective actions and whether those corrective actions were sufficient and effective to correct the non-compliances and prevent recurrence of the non-compliances. The review team recommends that the State take measures to ensure that sufficient information pertaining to inspection review of items of non-compliance as well as the effectiveness of licensee corrective actions is adequately documented in inspection records.

The review team found that during the review period, the Inspection Section supervisor had accompanied all qualified inspectors performing radioactive materials inspections at least once a year. The Division Chief performed accompaniments of both the Inspection Section supervisor and the Licensing Section supervisor during the conduct of complex event investigations and pre-licensing visits, respectively. Supervisory accompaniments were documented by the accompanying manager and the supervisor's observations were discussed with the individual being accompanied.

The review team found that the Program maintained an adequate supply of appropriately calibrated survey instruments to support the inspection program and to respond to incidents and emergency conditions. The instrumentation was calibrated by an outside vendor according to the manufacturer's recommendations. Appropriate documentation of calibrated survey instruments such as Geiger-Mueller detectors, scintillation detectors, ion chambers, and micro-R meters was provided for review. Air monitoring equipment and emergency field kits were available for emergency use. Laboratory analyses of contamination wipes, as well as air, soil, and water samples, were primarily performed under contract by Maryland's Department of Health and Mental Hygiene Radiation Laboratory, which is located in Baltimore.

A review team member accompanied two qualified inspectors during inspections conducted on June 13-15, 2011 and July 28, 2011. A listing of the inspector accompaniments performed, with specific comments, is provided in Appendix C. During June 13-15, 2011, the license types inspected as part of the accompaniments included: manual brachytherapy-written directives required; nuclear medicine-written directives required; and self-shielded irradiator. Both

inspectors were well-prepared for the inspections, knowledgeable of the types of licensed activities, focused on risk-significant activities during inspections, and demonstrated appropriate performance-based inspection techniques related to radiation safety issues. During the accompaniment inspection that included the inspector's review of licensee compliance with the Increased Controls, the inspector did not adequately review some areas related to the licensee's compliance with the Increased Controls requirements. For one requirement, the inspector accepted the licensee's explanation of compliance without verifying the information. The review team member discussed this with the inspector, but the inspector did not perform any additional review, develop supporting information, review relevant records, or engage in additional inspection activities to verify the licensee's assertion.

At the conclusion of the accompaniment inspections, the review team member discussed the observations from the accompaniments with Program managers. With regards to the Increased Controls inspection, the review team member was informed that this was the inspector's first independent inspection of the Increased Controls requirements. Based on this discussion, it was mutually agreed to that the review team member would observe another Increased Controls inspection with a different qualified staff member.

The additional accompaniment inspection was performed on July 28, 2011, at an industrial radiography licensee. The inspector was well-prepared for the inspection and demonstrated appropriate performance-based inspection techniques. The inspector also utilized an inspection guide to aid in the review of the licensee's compliance with the Increased Controls. The thoroughness and quality of this inspection was higher than the earlier observed Increased Controls inspection. These observations were shared with Program managers. Program management stated that, based on the accompaniment observations, the inspectors would be provided with some additional guidance related to inspections of licensee compliance with the Increased Controls and would also be encouraged to more closely follow the inspection guide during the conduct of inspections. Program management also indicated that, as appropriate, they would perform inspection follow up related to the earlier Increased Controls licensee.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Maryland's performance with respect to the indicator, Technical Quality of Inspections, be found satisfactory.

3.4 Technical Quality of Licensing Actions

The review team examined completed licensing casework and interviewed license reviewers for 21 specific licensing actions. Licensing actions were reviewed for completeness, consistency, proper radioisotopes and quantities, qualifications of authorized users, adequacy of facilities and equipment, adherence to good health physics practices, financial assurance, operating and emergency procedures, appropriateness of license conditions, and overall technical quality. The casework was also reviewed for use of appropriate deficiency letters and cover letters, reference to appropriate regulations, supporting documentation, consideration of enforcement history, pre-licensing visits, peer/supervisory review, proper signatures, and marking/control of documents that contain sensitive information.

The licensing casework was selected to provide a representative sample of licensing actions completed during the review period. Licensing actions selected for evaluation included

two new licenses, nine renewals, three decommissioning or termination actions, and seven amendments. Casework reviewed included a cross-section of license types, including: medical broad scope, academic broad scope, medical diagnostic and therapy (including gamma stereotactic and high dose rate remote afterloader), industrial radiography, research and development, nuclear pharmacy, radionuclide production (cyclotron), portable gauge, fixed gauge, mobile nuclear medicine, panoramic and self-shielded irradiators. The casework sample represented work from three current license reviewers and two former license reviewers. A listing of the licensing casework evaluated is provided in Appendix D.

The review team confirmed that all license reviewers had signature authority for licensing actions reviewed, or were reviewed by a second reviewer while under training. The Program Manager or the Division Chief performs a technical and supervisory review on all licensing actions before issuance to the licensee. Licenses are issued for a 7-year period under a timely renewal system.

Based on the licensing casework files examined, the review team found that license tie-down conditions were stated clearly and were supported by information contained in the file. Deficiency letters clearly stated regulatory positions and often identified substantive deficiencies in the licensees' documents. The review team also identified that license reviewers are equipped with both the Program's and the NRC's licensing guides, policies, checklists, and standard license conditions specific to the type of licensing actions to ensure consistency in licenses.

Licensing actions were found to be generally complete, and with health, safety, and security issues properly addressed. For some casework files reviewed, all health and safety items as described in the NUREG-1556 "Consolidated Guidance About Materials Licenses" series of documents and the Program's licensing guidance were not adequately addressed. For example, broad scope applications often did not include acceptance criteria used by the Radiation Safety Committee for approval of new uses, users, or facilities; broad scope applications often did not identify significant activities and facilities (e.g., iodination facilities, alpha use labs) or describe approval criteria for non-research activities (e.g., portable gauge uses). In one case, a licensee's prior enforcement history was reviewed to ensure that violations were closed; however, health and safety issues identified during inspections were not specifically addressed during the licensing process. One license was terminated without submission of sealed source leak test results. 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 State regulations and appropriate licensing guidance.

One of the casework files reviewed was for a licensee that was only authorized by its license to perform service-related activities. However, this particular licensee is identified in several Maryland Sealed Source & Device registrations as a distributor of various sealed sources and devices that are used for medical applications (e.g. iridium-192 high dose-rate remote afterloaders, iodine-125 brachytherapy sources). Another consideration in this case is that some of the sources and all of the devices are manufactured outside the United States. It appears to the review team that there is no license that authorizes the distribution or oversees the manufacturing quality assurance of these sources and devices. 10 CFR 35.49 requires, in

part, that for medical use, a licensee may only use (a) sealed sources or devices manufactured, labeled, packaged, and distributed in accordance with a license issued under 10 CFR Part 30 and 10 CFR 32.74 of this chapter or equivalent requirements of an Agreement State; or (b) sealed sources or devices non-commercially transferred from a 10 CFR Part 35 licensee or an Agreement state medical use licensee. Option (b) does not apply in this case because the subject Maryland licensee is not a medical use licensee. Therefore, in accordance with (a), the review team concluded that the Maryland license should authorize distribution and oversee manufacturing quality assurance of sealed sources and devices for medical use within the United States. The State's equivalent of 10 CFR 35.49 is contained in the Code of Maryland Regulations (COMAR) 26.12.01.01 Section G.49, and its equivalent of 10 CFR 32.74, is contained in COMAR 26.12.01.01 Section C.28(l). Because licensees throughout the United States utilize these sources and devices for medical use, it is imperative that these sources and devices are provided by suppliers that are properly licensed and meet the applicable regulatory requirements to perform these activities. In its October 12, 2011, response to the draft IMPEP report, the State noted that on August 18, 2011, the subject license was appropriately amended to authorize the manufacture/distribution of sealed sources or devices for medical use. During the November 3, 2011, MRB, the State furthermore noted that it had reviewed its other licensees and found that this was the only license that did not have the appropriate language authorizing distribution.

Based on the licensing casework reviewed, the review team identified a few issues related to financial assurance. The review team found that for two radionuclide production (cyclotron) facilities, financial assurance was not submitted by the applicant/licensee or requested by the license reviewer. In addition, the review team identified that financial assurance mechanisms, including financial instruments and decommissioning funding plans, have not been reviewed and updated since their original submissions. Some of these licenses have been amended many times with the addition of facilities and activities that would increase decommissioning costs; however, the financial instruments and decommissioning funding plans have not been updated accordingly. In one case, a licensee's letter of credit had not been amended or re-issued to reflect a new bank name and a new account number. Regarding financial assurance, 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) licensees; and (3) perform a review of the adequacy and validity of financial assurance mechanisms already on file with the Program.

The review team assessed the Program's implementation of NRC's pre-licensing guidance issued on September 22, 2008, and transmitted to the Agreement States via NRC's Office of Federal and State Materials and Environmental Management Programs (FSME) Letter RCPD-08-020, "Requesting Implementation of the Checklist to Provide a Basis for Confidence That Radioactive Material Will Be Used as Specified on a License and the Checklist for Risk-Significant Radioactive Material." Following receipt of RCPD-08-020 regarding pre-licensing guidance, the Program reviewed the pre-licensing process they already had in place and determined that no changes were required. The Program performs pre-licensing checks of all new applicants. Current licensees who undergo a change of ownership are considered new applicants if their name changes and significant additional changes, such as authorized users and Radiation Safety Officer, occur; and are issued a new license concurrent with the termination of the current license. The NRC's pre-licensing guidance for conducting

pre-licensing reviews provides standard questions for business operations, facility, radiation safety operations, and personnel. The Program's pre-licensing review methods were found to be adequate to address the essential elements of NRC's pre-licensing guidance to verify that the applicant will use requested radioactive materials as intended. The review team also shared with the Program some of the methods used and questions asked by NRC related to verification of the legitimacy of applicant personnel.

The review team examined the Program's licensing practices regarding the Increased Controls and Fingerprinting requirements. The review team noted that the Program uses legally binding license conditions that meet the criteria for implementing the Increased Controls requirements, including Fingerprinting, as appropriate. The review team evaluated the Program's methodology for identifying those licenses requiring Increased Controls and Fingerprinting requirements and found the rationale to be sound; with the exception of broad scope licenses. For broad scope licenses, the license reviewers calculated the quantities of concern, and sometimes documented that the quantities of concern were exceeded, but made an assumption that the quantities would not be collocated; and therefore, did not impose the Increased Control or Fingerprinting requirements on the licensee. This assumption that sources would not be collocated was made based on information gathered during the conduct of inspections at the facilities. The review team noted that inspections are only a snapshot in time and that there were no provisions that would prohibit the licensees from co-locating the subject materials. The review team expressed that because the licenses authorized radioactive material quantities of concern that exceeded the unity rule, it would be prudent to impose the applicable license conditions on the licenses. If this were done, the responsibility would be placed on the licensee to assure that they either do not co-locate the materials and if they did they would need to implement the requirements. The Program agreed to review their practices in this area. The review team confirmed that license reviewers evaluated full implementation of the Increased Controls prior to issuance of a new license or license amendment adding radioactive materials in quantities of concern.

Regarding the Program's control of sensitive information, on May 5, 2011, the Program implemented "Increased Control-Sensitive Information Protection Procedure." This procedure addresses the identification, marking, control, handling, preparation, transportation, transmission, and destruction of documents that contain sensitive information related to the Increased Controls. Following receipt of FSME letter RCPD-11-005, "Additional Guidance and Clarification regarding the review of the Control of Sensitive Information During IMPEP Reviews," dated May 11, 2011, the Program reviewed the referenced guidance in RIS 2005-031, "Control of Security-Related Sensitive Unclassified Non-Safeguards Information Handled by Individuals, Firms, and Entities Subject to NRC Regulation of the Use of Source, Byproduct, and Special Nuclear Materials." Based on its review of the subject guidance documents, the program determined that only Increased Controls information related to Category 1 and Category 2 licensees must be controlled as sensitive information and that their procedure was appropriate and consistent with the guidance. The review team noted that the Program controls access to all their licensing and inspection files via password protection and key-card entry. Files that contained sensitive information were further secured in locked file cabinets.

Following receipt of FSME letter RCPD-10-007, "Requesting Implementation of a Policy on Maximum Possession Limits for Radioactive Material Licenses," dated June 21, 2010, the Program began a review of its portable gauge licenses and amended the licenses to include

total possession limits. The Program noted that at the time of the review, all but one portable gauge license had been amended to include a total possession limit. Other categories of licenses were under review by the Program and it was expected that the process would be completed by the end of 2011.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Maryland's performance with respect to the indicator, Technical Quality of Licensing Actions, be found satisfactory, but needs improvement.

3.5 Technical Quality of Incident and Allegation Activities

In evaluating the effectiveness of the Program's actions in responding to incidents and allegations, the review team examined the Program's response to the questionnaire relative to this indicator, evaluated selected incidents reported for Maryland in the Nuclear Material Events Database (NMED) against those contained in the Program's files, and evaluated the casework for 10 radioactive materials incidents. A listing of the incident casework examined, with case-specific comments, is provided in Appendix E. The review team also evaluated the Program's response to six allegations involving radioactive materials, including five allegations referred to the State by the NRC during the review period.

The review team examined the Program's incident and allegation processes, including written procedures for handling allegations and incident response, file documentation, notification of incidents to the NRC Headquarters Operations Center, and the use of NMED software. When a notification of an incident or allegation is received, Program managers and staff determine the level of initial response based on the potential health and safety significance associated with the incident or allegation.

The review team identified 24 events in NMED for Maryland during the review period, of which 11 required reporting to the NRC Headquarters Operations Center. A review of the Program's incident files did not reveal any additional reportable events. The review team selected 10 radioactive material incidents for evaluation. These incidents included the following types of events: lost/stolen radioactive material; potential overexposure; medical event; damaged equipment; and leaking source. The Program's responses to the incidents were found to be complete and comprehensive. Initial responses were prompt and well-coordinated, and the level of effort was commensurate with the potential health and safety significance of the event. Inspectors were dispatched for onsite investigations when appropriate. Enforcement and/or other regulatory actions were taken as appropriate. With the exception of one incident reviewed, the Program reported events to the NRC in a prompt manner. The actions taken in response to incidents were documented and filed, and the data were submitted to the NRC's contractor responsible for maintaining NMED for inclusion in the database.

In evaluating the effectiveness of the Program's response to allegations, the review team evaluated the completed casework for six allegations, including five that NRC referred to the State during the review period. The review team concluded that the Program consistently took prompt and appropriate actions in response to concerns raised. The review team noted that the Program documented the investigations of concerns and retained all necessary documentation to appropriately close the allegations. The Program notified the concerned individuals of the

conclusion of their investigations. The review team determined that the Program adequately protected the identity of concerned individuals.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Maryland's performance with respect to the indicator, Technical Quality of Incident and Allegation Activities, be found satisfactory.

4.0 NON-COMMON PERFORMANCE INDICATORS

Four non-common performance indicators are used to review Agreement State Programs: (1) Compatibility Requirements, (2) Sealed Source and Device Evaluation Program, (3) Low-level Radioactive Waste Disposal Program, and (4) Uranium Recovery Program. The NRC's Agreement with the State of Maryland does not relinquish authority to regulate a uranium recovery program, therefore only the first three non-common performance indicators were applicable to this review.

4.1 Compatibility Requirements

To assess Maryland's status with respect to this performance indicator, the review team examined the Program's questionnaire response relative to this indicator; reviewed Maryland's State Regulation Status Data Sheet (SRS), as maintained by FSME, and conducted interviews with managers and staff responsible for this program area.

4.1.1 Legislation

Maryland became an Agreement State on January 1, 1971. The current effective statutory authority for control of radiation is contained in the Annotated Code of Maryland, Environmental Article, Title 8, "Radiation," and Title 7, "Hazardous Materials and Hazardous Substances." The Department is designated as the State's radiation control agency. Maryland's statutory authority is sufficiently broad to provide authority for the regulation byproduct, source, special nuclear materials, and other radioactive materials.

The Program provided the review team with a copy of the legislation that affects the radiation control program. The review team noted that no legislation affecting the radiation control program was passed during the review period.

4.1.2 Program Elements Required for Compatibility

Maryland's regulations for the control of radiation are contained in COMAR 26.12.01.01, "Regulations for the Control of Ionizing Radiation" and apply to all persons who receive, possess, use, transfer, own, or acquire any source of radiation. COMAR 26.15, "Disposal of Controlled Hazardous Substances - Radioactive Hazardous Substances," contains statutes that govern the management of radioactive hazardous substances and addresses low-level radioactive waste issues. Maryland requires a license for the receipt, possession, use, ownership, or transfer of all radioactive material, including byproduct, source, certain quantities of special nuclear material, accelerator-produced radionuclides, and naturally-occurring materials, such as radium. Maryland also requires registration of all equipment designed to produce x-rays or other ionizing radiation.

The review team examined the State's administrative rulemaking process and found that the process takes six months to a year from the development stage to the final approval by the Secretary of the Environment, after which the rule becomes effective in 10 days. The public, NRC, other agencies, and potentially impacted licensees and registrants are offered an opportunity to comment during the process. Comments are considered and incorporated, as appropriate, before the regulations are finalized and approved by the Secretary of the Environment.

The review team noted that the State's rules and regulations are not subject to "sunset" laws. The State may adopt the regulations of another agency by reference and also has the authority to issue legally binding requirements (e.g., license conditions) in lieu of regulations until compatible regulations become effective. Changes or revisions to regulations are incorporated into COMAR by means of supplements. During the review period, four supplements to COMAR were issued that addressed regulatory changes related to the radioactive materials program

Current NRC policy requires that Agreement States adopt certain equivalent regulations or legally binding requirements no later than 3 years after the effective date of NRC's regulations. At the time of this review, the following two amendments had been previously reviewed by NRC as proposed regulations, but had not been submitted by the Program to NRC as final regulations. The review team discussed this matter with the Program, at which time it was apparent that the regulation amendments had been previously finalized but due to an oversight had not been submitted to NRC as final for review. One regulatory amendment was due for State adoption by January 31, 2009, and was made effective on June 15, 2009 with the publication of Supplement 17 to the COMAR. This regulatory amendment is not considered overdue because the State had legally binding license conditions in place prior to the adoption due date. The other regulatory amendment was due for State adoption by November 30, 2010, and was made effective on November 15, 2010, with the publication of Supplement 19 to the COMAR. During the conduct of the review, on August 10, 2011, the Program submitted the two regulatory amendments to NRC:

- "National Source Tracking System," 10 CFR Part 20 (71 FR 65685, 72 FR 59162), which was due for Agreement State adoption by January 31, 2009.

- "Exemptions From Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements," 10 CFR Parts 30, 31, 32 and 150 (72 FR 58473), which was due for Agreement State adoption by November 30, 2010.

At the time of the review, the following two amendments had been reviewed by NRC as proposed regulations, but had not been submitted to NRC as final for review. The NRC's review of the proposed regulations resulted in comments being provided to the State on March 2, 2011. At the time of the review, the State had reviewed and addressed the comments and expected that both amendments will be finalized in the next Supplement to the COMAR, which was expected to become effective in October 2011. The two regulatory amendments are:

- "Requirements for Expanded Definition of Byproduct Material," 10 CFR Part 20, 30, 31, 32, 33, 35, 61, and 150 (72 FR 55864), which was due for State adoption by November 30, 2010.

- "Occupational Dose Records, Labeling Containers, and Total Effective Dose Equivalent," 10 CFR Parts 19 and 20 (72 FR 68043), which was due for State adoption by February 15, 2011.

During the November 3, 2011, MRB, the State reported that the above two regulatory amendments were finalized with an effective date of September 19, 2011. The State expected that the regulatory amendments would be submitted to NRC as final for review in the near future.

The Program will need to address the following two regulatory amendments in upcoming rulemaking:

- "Medical Use of Byproduct Material – Authorized User Clarification," 10 CFR Part 35 (74 FR 33901), which is due for Agreement State adoption by September 28, 2012.

- "Decommissioning Planning," 10 CFR Parts 20, 30, 40, and 70 (76 FR 35512), which is due for Agreement State adoption by December 17, 2015.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Maryland's performance with respect to the indicator, Compatibility Requirements, be found satisfactory.

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

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

In assessing the Program's SS&D evaluation activities, the review team examined information provided by the Program in response to the IMPEP questionnaire for this indicator, performed a search of the national Sealed Source and Device Registry for registrations issued by Maryland, and performed NMED searches of manufacturers and distributors identified on SS&D registrations issued by Maryland. A review of new, amended, and inactivated SS&D evaluations and supporting documents covering the review period was conducted. The review team reviewed the Program's use of guidance documents and procedures, interviewed Program managers and staff, and verified the use of regulations, license conditions, and inspections to enforce commitments made in the applications.

4.2.1 Technical Staffing and Training

At the time of the review, the Program had four qualified SS&D reviewers with full signature authority to sign SS&D registration certificates. There were no newly qualified SS&D reviewers nor did any qualified SS&D reviewer leave the Program during the review period. The Program's SS&D evaluation program received support from a contractor, SAIC, Inc., during the review period. The contractor provided the Program with engineering analyses of SS&D applications received by the Program and of incidents related to products identified on SS&D registrations issued by Maryland.

The Program's four qualified reviewers with full signature authority each have a BS degree in physical and/or life sciences and have each attended the NRC SS&D workshop. The State's contractor, SAIC, Inc., provides additional support to the Program, was led by a licensed Professional Engineer who, on occasion, received additional support of another licensed Professional Engineer. The two licensed Professional Engineers were determined by the Program to have possessed, in combination, greater than 70 years experience in mechanical and nuclear engineering.

Qualification criteria for reviewers were established, implemented, and documented by the Program. The Program maintained written procedures for evaluating when engineering analysis support from its contractor was necessary. The Program had one pending new SS&D evaluation for a new registration and one pending SS&D evaluation for inactivation of a registration at the time of the on-site review.

Based on the IMPEP evaluation criteria, the review team recommends that Maryland's performance with respect to the sub-element, Technical Staffing and Training, be found satisfactory.

4.2.2 Technical Quality of the Product Evaluation Program

Information provided by the Program in response to the IMPEP questionnaire identified 14 SS&D registrations issued during the review period. The review team identified an additional three SS&D registrations that were issued during the review period. During the review period, the Program performed 17 SS&D actions: two new; 12 amended; and three inactivated SS&D registrations. The review team reviewed casework related to 12 of the 17 SS&D actions that were performed during the review period. The casework review included all supporting documentation, licenses, and inspections associated with the distributors of the sealed sources and devices. A list of the SS&D casework examined by the review team, with case-specific comments, is provided in Appendix F.

The review team's evaluation of the casework and interviews with the management and staff confirmed that the Program's policy is to follow the recommended guidance from the NRC SS&D training workshops and NUREG-1556, Volume 3, Revision 1, "Applications for Sealed Source and Device Evaluation and Registration." The review team found that appropriate review checklists were used to assure all relevant materials had been submitted and reviewed. The checklists were retained in the SS&D files along with other documents that identified the assigned reviewers. Pertinent American National Standards Institute standards, regulatory guides, and applicable references were confirmed to be available and were used when performing the SS&D reviews.

The Program's registration files contained all correspondence, engineering drawings, photographs, radiation profiles, and details of the applicant's quality assurance and quality control program. The registrations clearly summarized the product evaluation to provide license reviewers with adequate information to license the possession and use of the products. Deficiency letters clearly stated regulatory positions and all health and safety issues were properly addressed. The review team found that the evaluations were of high quality with health and safety issues properly addressed. The Program enforces the requirements of SS&D registrations through regulation, COMAR 26.12.01.01 Section C.37.

Information provided by the Program in response to the IMPEP questionnaire identified that there were 28 SS&D registrations active in Maryland. The review team discovered that 61 active Maryland registrations are identified in the national Sealed Source and Device Registry (SSDR). The review team provided the Program with a list of the 61 registrations. A discrepancy of 33 registrations was identified by the review team and confirmed by the Program. Of the 33 registrations, the Program determined that 25 registrations were obsolete and that 8 registrations were not obsolete. For two of the 25 obsolete registrations, the products identified on each registration were made part of two other Maryland SS&D registrations, prior to the review period, and the obsolete registrations had not been inactivated by the Program. For one of the 25 obsolete registrations, the products identified on the registration were last distributed in 2002. At that time, the Program staff had made note in their file to inactivate the registration, however, the Program did not inactivate the obsolete registration. For 22 of the 25 obsolete registrations, the specific licenses authorizing manufacturing and/or distribution of products identified on the SS&D registrations had each been terminated by the Program, prior to the review period, and the obsolete registrations had not been inactivated by the Program. Of these 22 obsolete registrations, nine were related to a Maryland license that was terminated in 2003 when the company relocated to another Agreement State. At that time, the Program made an effort to resolve the registration issue with the licensee and the other Agreement State but the issue was not resolved. The Program followed up with the licensee and the other Agreement State in 2006 but the issue of the obsolete sheets was still not resolved. At the time of the review, the issue related to the 9 obsolete registrations still had not been resolved.

Based on the review team's examination, and in coordination with the Program, it was found that the 25 obsolete registrations initially became obsolete prior to the review period. Specifically, the range of known dates where the registrations became obsolete spanned between January 1986 and July 2007. The range is represented by MD-0357-D-101-U when the specific license authorizing manufacturing and/or distribution of products identified on the SS&D registration had been terminated by the Program in January 1986 and by MD-0590-D-112-G when the products identified on the registration were made part of another Maryland SS&D registration, MD-0105-D-101-G in July 2007. The review team examined three registrations that had become obsolete where the three obsolete registrations were inactivated by the Program during the review period. The review team found that for the three registrations, each had been promptly transmitted for inclusion into the SSDR as inactive registrations.

Although the 25 obsolete registrations became obsolete prior to the review period, the review team discussed with the Program the need to provide the status of the 25 obsolete SS&D registrations to SSDR. It is important that the SSDR contain accurate information because NRC and Agreement State personnel have access to SSDR and use the information contained in the SSDR to make licensing decisions regarding sealed source and device products. The review team recommends that, for the 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. During the November 3, 2011, MRB, the State indicated that they are making progress toward inactivating the 25 obsolete SS&D registrations and had identified an additional 8 registrations that also warranted inactiviation.

During the on-site review, the review team provided the Program with a list of the 25 obsolete SS&D registrations. To aid in addressing the recommendation and to facilitate review of this recommendation at a later date, a list of the 25 obsolete SS&D registrations identified by the review team is provided in Appendix G.

Based on the IMPEP evaluation criteria, the review team recommends that Maryland's performance with respect to the sub-element, Technical Quality of the Product Evaluation Program, be found satisfactory.

4.2.3 Evaluation of Defects and Incidents Regarding SS&Ds

Based upon the Program's response to the questionnaire, interviews with the Program's management and staff, and the review team's searches of NMED, the review team determined that the Program received and evaluated 25 incident cases during the review period. All 25 cases were related to products from a single sealed source and device vendor that held 10 active SS&D registrations and a specific license issued by the Program.

The review team selected and reviewed all 25 incident cases. Of the 25 cases evaluated by the Program, nine cases were identified by the Program to include generic defects. Of the nine cases identified by the Program to include generic defects, four cases included products identified on one SS&D registration, four cases included products identified on another SS&D registration and one case included products identified on a third SS&D registration. Of the nine cases determined by the Program to include generic defects, eight were related to software issues and one was related to mechanical issues. The listing of the casework examined, with case specific comments, is provided in Appendix E.

The review team noted that the Program routinely monitors incidents reported to NMED and identified incidents or defects associated with SS&D products registered in Maryland for further investigation and review. Incident procedures established by the Program involving SS&Ds included use of an SS&D event flow chart developed by the Program. The flow chart includes generic fault considerations when evaluating SS&D incidents.

Based upon review of the 25 incident cases, the review team concluded that the Program is routinely evaluating the root causes of defects and incidents involving SS&D evaluations and is taking appropriate actions. The review team determined that the Program analyzed each incident, reviewed the issues, and followed up on each incident adequately and in accordance with procedures established by the Program with one exception. The one exception is that, for the single case related to a generic defect involving mechanical issues, the Program identified on the Program's SS&D event flow chart that a modification was being done to the device. However, the Program was not aware of what specific modification was being done. The incident case file did not contain any engineering drawings nor specific descriptions of what modification was being done in order to adequately evaluate generic fault considerations for this case, including a determination of whether a change or amended to the SS&D registration was warranted. The distributor of the device made a report to the Program that similar issues, related to the incident, have been discovered and resolved in other countries. The review team discussed with the Program the benefit of obtaining specific information about what modification was/is being done to the device and the need to determine whether a change or amendment of the SS&D registration is warranted. During the onsite review, the Program agreed to obtain

specific information regarding what modification was/is being done to the device and determine whether a change or amendment of the SS&D registration is warranted.

In addition to the 25 incident cases received and evaluated by the Program, the Program received three incident cases that, prior to the time of the on-site review, had not been evaluated by the Program. Each incident was related to leaking or contaminated sealed sources discovered in countries other than the United States. One of the incidents occurred in Poland on January 6, 2010. The second incident occurred in the United Kingdom on May 20, 2010. The third incident occurred in Poland on May 31, 2010. For each incident, the Program's licensee notified the Program that each problem is being reported because several facilities in the United States receive these sources from the same manufacturer and this posed an increased risk of contamination for these sites. For each incident, the licensee identified the related SS&D registration issued by Maryland which was, for the two Poland incidents, MD-0497-S-107-S and for the United Kingdom incident, MD-0497-D-115-S and also the same foreign sealed source manufacturer made part of each of the Maryland issued registrations. The review team asked Program staff whether the Program had any follow up information related to the three incidents and their potential implications for licensees in the United States. Based on these questions, during the on-site review, the Program staff requested for and received, from its licensee, additional information related to all three incidents. The licensee submitted to the Program that problems were identified at the sealed source manufacturing facility and also that device product technical manuals were changed to include additional leak testing procedures. The review team discussed with the Program the benefit of evaluating each of the three incidents, including use of the SS&D event flow chart developed by the Program, to include evaluation of generic fault considerations and determination of whether a change or amendment of any Maryland issued SS&D registration is warranted. The Program contended that these incidents occurred outside of the United States and, therefore, the Program is not required to investigate nor evaluate the incidents. The Program continued that, although the Program does not believe they are required to do so, it is prudent for the Program to evaluate each of the three incidents. The Program agreed to evaluate each of the three incidents, including use of the SS&D event flow chart developed by the Program, to include evaluation of generic fault considerations and determination of whether a change or amendment of any Maryland issued SS&D registration is warranted.

The review team did not identify any allegations received by the Program related to defects or failures of SS&D products registered in Maryland during the review period.

Based on the IMPEP evaluation criteria, the review team recommends that Maryland's performance with respect to the sub-element, Evaluation of Defects and Incidents Regarding SS&Ds, be found satisfactory.

4.2.4 SS&D Evaluation Program Summary

Based on the IMPEP evaluation criteria, for a non-common performance indicator that contains sub-elements, a single finding for the overall performance will be made by the review team. Because the review team is recommending that Maryland's performance is satisfactory for all sub-elements evaluated, based on the IMPEP evaluation criteria, the review team recommends that Maryland's overall performance with respect to the indicator, SS&D Evaluation Program, be found satisfactory.

4.3 Low-Level Radioactive Waste (LLRW) Disposal Program

In 1981, NRC amended its Policy Statement, "Criteria for Guidance of States and NRC in Discontinuance of NRC Authority and Assumption Thereof by states Through Agreement," to allow a State to seek an amendment for the regulation of LLRW as a separate category. Those States with existing Agreements prior to 1981 were determined to have continued LLRW disposal authority without the need of an amendment. Although Maryland has such authority to regulate a LLRW disposal facility, NRC has not required States to have a program for licensing a disposal facility until such time as the State has been designated as a host State for a LLRW disposal facility. When an Agreement State has been notified or becomes aware of the need to regulate a LLRW disposal facility, it is expected to put in place a regulatory program that will meet the criteria for an adequate and compatibility LLRW program. There are no plans for a commercial LLRW disposal facility in Maryland. Accordingly, the review team did not review this indicator.

5.0 SUMMARY

As noted in Sections 3.0 and 4.0 above, the review team recommended, and the MRB agreed, that Maryland's performance be found satisfactory, but needs improvement for the performance indicator Technical Quality of Licensing Actions, and satisfactory for the other six performance indicators. The review team made four recommendations regarding the performance of the State.

Overall, the review team recommended, and the MRB agreed, that the Maryland Agreement State Program be found adequate to protect public health and safety and compatible with NRC's program. Based on the results of the current IMPEP review, and in accordance with the criteria in NRC Management Directive 5.6, the review team recommended, and the MRB agreed, that the next full IMPEP review take place in approximately 4 years.

Below are the review team's recommendations, as mentioned in the report, for evaluation and implementation by the State:

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. (Section 3.3)

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. (Section 3.4)

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) licensees; and (3) perform a review of the adequacy

and validity of financial assurance mechanisms already on file with the Program. (Section 3.4)

4. The review team recommends that, for the 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. (Section 4.2.2)

LIST OF APPENDICES

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

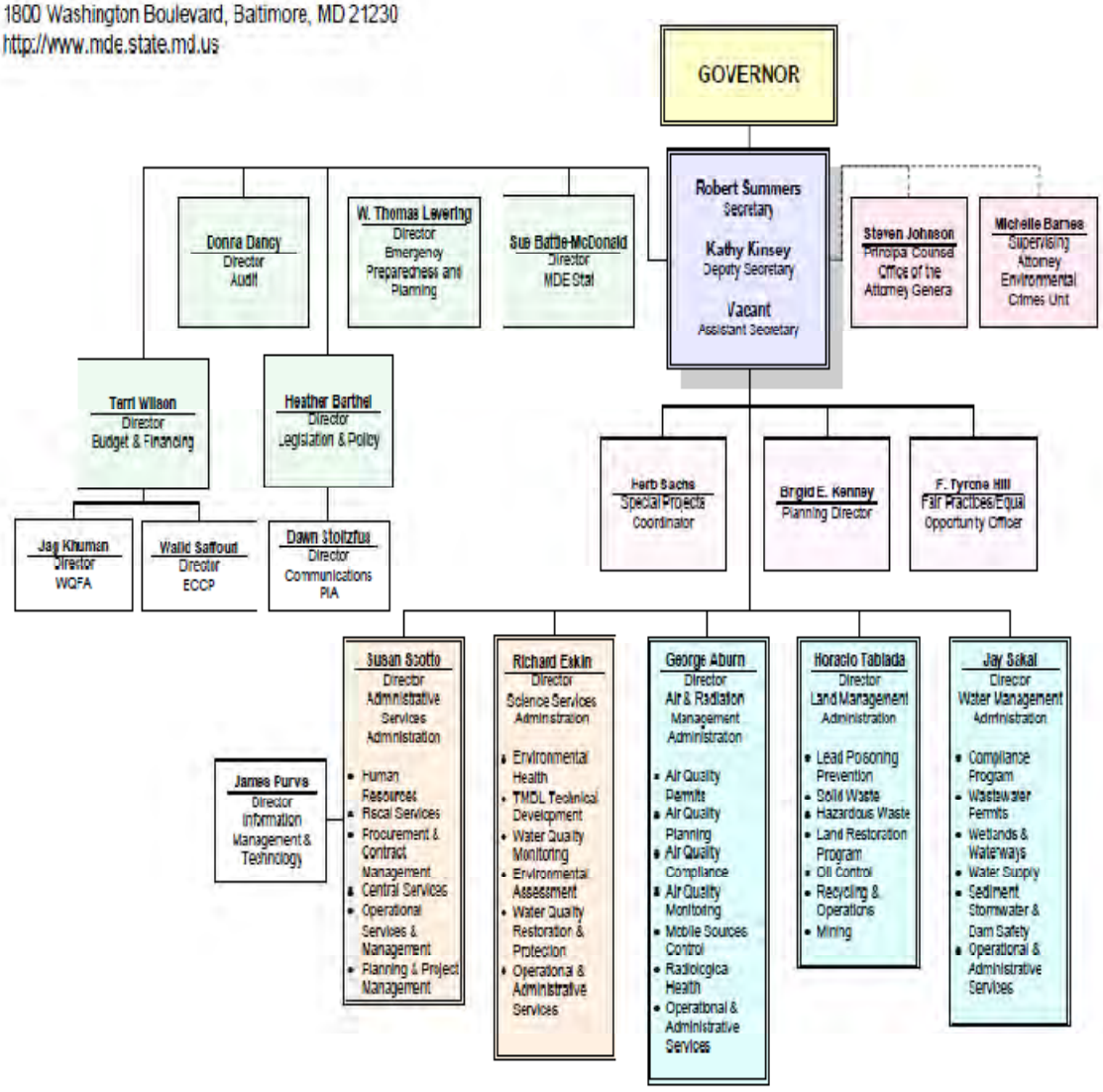
Name	**Area of Responsibility**
Janine Katanic, FSME	Team Leader Status of Materials Inspection Program Technical Quality of Inspections Inspector Accompaniments
Donna Janda, Region I	Technical Staffing and Training Technical Quality of Incident and Allegation Activities
Penny Lanzisera, Region I	Technical Quality of Licensing Actions
Solomon Sahle, FSME	Compatibility Requirements
Joshua Daehler, Massachusetts	Sealed Source and Device Evaluation Program

APPENDIX B

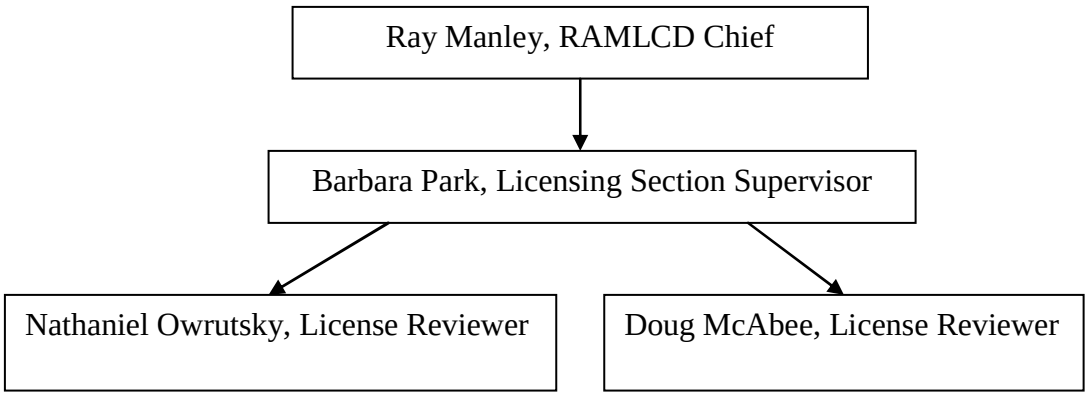
MARYLAND ORGANIZATION CHARTS

ADAMS ACCESSION NO.: ML112010077

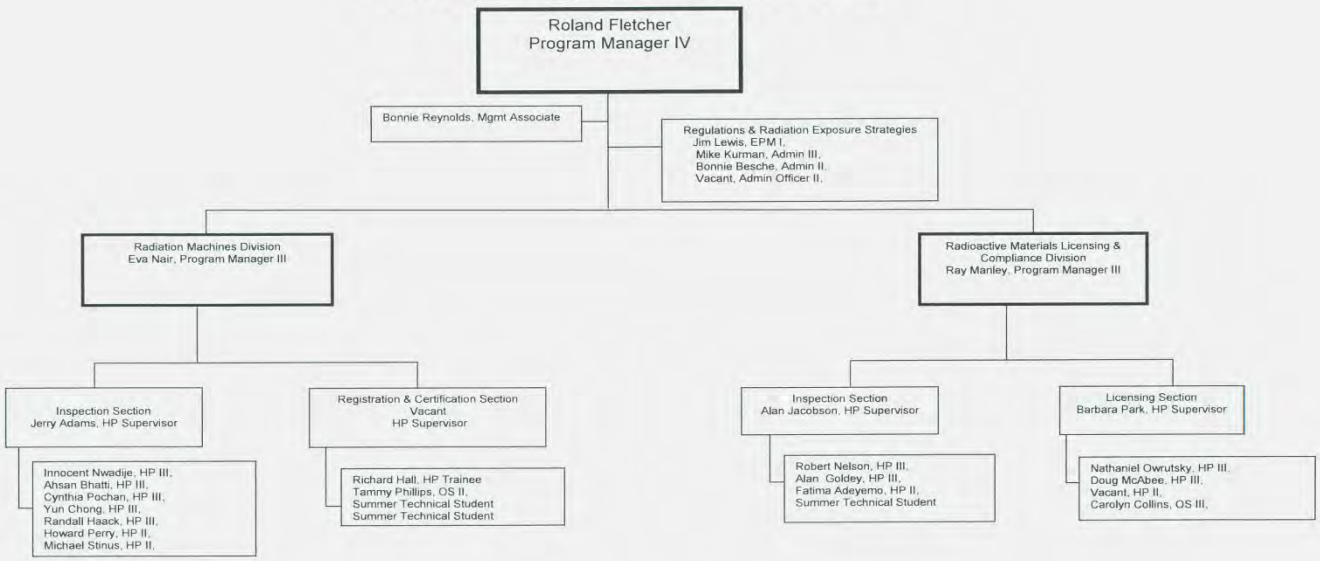
Maryland Department of the Environment
1800 Washington Boulevard, Baltimore, MD 21230
http://www.mde.state.md.us



RADIOLOGICAL HEALTH PROGRAM CHART
SEALED SOURCE AND DEVICE EVALUATION
REVIEWERS



RADIOLOGICAL HEALTH PROGRAM



APPENDIX C

INSPECTION CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS ONLY.

File No.: 1
Licensee: Radiocat — License No.: MD-05-145-01
Inspection Type: Routine, Unannounced — Priority: 5
Inspection Date: 11/6/09 — Inspector: AG

Comment:

The inspector's documented independent radiation surveys indicated that 8.41 millirem/hr was measured outside of a waste storage room door (located inside the facility). There was no documentation that an evaluation was made (or an inquiry was made to the licensee) to determine whether or not dose limits for members of the public were exceeded.

File No.: 2
Licensee: Cardinal Health — License No.: MD-33-198-01
Inspection Type: Routine, Unannounced — Priority: 2
Inspection Date: 8/25/10 — Inspectors: RN, AG, FA

Comments:

1) The inspection record did not document a review of the licensee's corrective actions related to non-compliances from the previous inspection. These non-compliances were previously issued to the licensee as a result of the Program's inspection/investigation regarding a potential occupational dose in excess of the regulatory limits.
2) The inspection record documented the inspectors' review of the radiopharmacy portion of the inspection but did not adequately document a review of the cyclotron operations portion of the inspection.

File No.: 3
Licensee: Holy Cross Hospital Radiation Treatment Center — License No.: MD-31-303-01
Inspection Type: Routine, Unannounced — Priority: 2
Inspection Date: 1/27-28/11 — Inspector: RN

File No.: 4
Licensee: Maryland Q.C. Laboratories, Inc. — License No.: MD-25-022-01
Inspection Type: Special, Announced — Priority: 1
Inspection Date: 11/17/10 — Inspector: RN

File No.: 5
Licensee: H & H X-ray Services, Inc. License No.: LA2970-L01
Inspection Type: Reciprocity, Unannounced Priority: 2
Inspection Date: 7/23/10 Inspector: RN

Comment:
The inspection record did not document a review of special security requirements.

File No.: 6
Licensee: GBMC HealthCare, Inc. License No.: MD-05-002-03
Inspection Type: Routine, Announced Priority: 3
Inspection Date: 6/14/11 Inspector: FA

Comment:
The inspection record did not document a review of the licensee's corrective actions related to non-compliances from the previous inspection. These non-compliances were previously issued to the licensee as a result of the Program's inspection/investigation regarding a lost source/medical event. The inspector did not document which corrective actions were reviewed during the current inspection and which corrective actions were not reviewed and therefore warranted review during a future inspection.

File No.: 7
Licensee: Washington Adventist Hospital License No.: MD-31-003-04
Inspection Type: Routine, Announced Priority: 2
Inspection Date: 1/25/11 Inspector: FA

File No.: 8
Licensee: Terumo Medical Corporation License No.: MD-15-007-02
Inspection Type: Routine, Announced Priority: 2
Inspection Date: 8/30/10 Inspectors: AJ, FA, AG

File No.: 9
Licensee: Berlin Radiation Therapy Treatment Center, LLC License No.: MD-47-005-01
Inspection Type: Routine, Announced Priority: 2
Inspection Date: 7/31/09 Inspector: AJ

Comment:
The inspection record did not undergo management review since the inspector was a supervisor and there were no items of non-compliances identified.

File No.: 10
Licensee: Johns Hopkins University License No.: MD-27-014-01
Inspection Type: Routine, Announced Priority: 5
Inspection Date: 4/1/09 Inspectors: NO, DM

Comment:

The supervisory review of the inspection record identified missing or incomplete data but the inspection record was not corrected.

File No.: 11
Licensee: University of Maryland College Park License No.: MD-33-004-03
Inspection Type: Routine, Announced Priority: 2
Inspection Dates: 3/25 + 4/8/10 Inspectors: RN, AG

Comment:

The inspection identified several safety-significant items of non-compliance that should have warranted timely follow up. Although the Program has visited the facility several times since the inspection, these visits were not documented in a manner that would indicate the inspector's follow up on the licensee's corrective actions related to the identified non-compliances. The Program also held a meeting with the licensee and discussed corrective actions, but this does not substitute for verification of licensee corrective actions. On 7/26/11, the Program performed other activities at the facility and also reviewed the previously identified non-compliances. Documentation of this visit was expected to be performed in the near term.

File No.: 12
Licensee: GBMC HealthCare License No.: MD-05-002-01
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 6/13/11 Inspector: FA

Comment:

The inspection record did not document a review of the licensee's corrective actions related to non-compliances from the previous inspection.

File No.: 13
Licensee: Anne Arundel Medical Center License No.: MD-03-001-05
Inspection Type: Special, Announced Priority: 5
Inspection Date: 6/15/11 Inspector: AG

INSPECTOR ACCOMPANIMENTS

The following inspector accompaniments were performed prior to the on-site IMPEP review:

Accompaniment No.: 1
Licensee: GBMC HealthCare License No.: MD-05-002-01
Inspection Type: Routine, Unannounced Priority: 2
Inspection Date: 6/13/11 Inspector: FA

Accompaniment No.: 2
Licensee: GBMC HealthCare, Inc. License No.: MD-05-002-03
Inspection Type: Routine, Announced Priority: 3
Inspection Date: 6/14/11 Inspector: FA

Accompaniment No.: 3
Licensee: Anne Arundel Medical Center License No.: MD-03-001-05
Inspection Type: Special and Routine, Announced Priority: 5
Inspection Date: 6/15/11 Inspector: AG

Comment:
The inspector did not adequately review some issues related to licensee compliance with special security requirements.

Accompaniment No.: 4
Licensee: Maryland Q.C. Laboratories, Inc. License No.: MD-25-022-01
Inspection Type: Special, Announced Priority: 1
Inspection Date: 7/28/11 Inspectors: AJ, AG

APPENDIX D

LICENSE CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS ONLY.

File No.: 1
Licensee: Nucletron Corporation — License No.: MD-27-035-01
Type of Action: Renewal — Amendment No.: 52
Date Issued: 7/11/07 — License Reviewer: BP

Comment:

The Authorized Use is listed on the license as "install, service, repair and decommission Nucletron remote afterloading brachytherapy devices at Maryland customers' facilities." The license does not authorize manufacturing or distribution, which appear to be activities conducted under this license.

File No.: 2
Licensee: Johns Hopkins Medical Institutions — License No.: MD-07-005-03
Type of Action: Renewal — Amendment No.: 53
Date Issued: 7/8/08 — License Reviewer: NO

Comments:

1) The licensing assessment performed by the license reviewer to determine the need for security requirements did not include all radionuclides subject to the security requirements.
2) A total possession limit was not provided for item 6.A.; however the Program plans to address this by the end of the year.
3) The review team noted that the broad scope licensee did not submit criteria for the licensee's Radiation Safety Committee approval of new users, new uses, and facilities.
4) The financial assurance document (letter of credit from 1996) was not amended or re-issued for a new bank name and a new account number.
5) The licensee's Decommissioning Funding Plan was not re-reviewed during the renewal and does not include costs for disposing of sources or updated costs for decommissioning since 2000.

File No.: 3
Licensee: Johns Hopkins Medical Institutions — License No.: MD-07-005-03
Type of Action: Amendment — Amendment No.: 58
Date Issued: 3/7/11 — License Reviewer: NO

Comment:

The licensing action added contaminated facilities associated with a cyclotron (PETNET), including activated foils, targets, and parts; however, financial assurance considerations were not addressed by the license reviewer.

File No.: 4
Licensee: Johns Hopkins Medical Institutions License No.: MD-07-005-03
Type of Action: Amendment Amendment No.: 56
Date Issued: 7/13/10 License Reviewer: NO

Comments:

1) The licensing action added radium-223 and americium-241; however, safety considerations for the use of alpha emitters were not addressed.
2) A total possession limit for americium-241 was not included in the license.
3) The radionuclides and quantities authorized by the license exceed the unity rule for consideration of security requirements license conditions; however, the security requirements license condition was not included on the license.

File No.: 5
Licensee: Johns Hopkins Medical Institutions License No.: MD-07-005-03
Type of Action: Amendment Amendment No.: 57
Date Issued: 8/30/10 License Reviewer: DM

Comment:

The licensing action added astatine-211; however safety considerations for use of alpha emitters were not addressed.

File No.: 6
Licensee: Maryland Transportation Authority License No.: MD-05-086-01
Type of Action: Renewal Amendment No.: 10
Date Issued: 9/10/09 License Reviewer: DM

Comment:

The license authorizes leak test analysis by the licensee; however, the licensee did not submit sufficient information to support this request and appears to have requested for an outside company to analyze leak tests.

File No.: 7
Licensee: University of Maryland at Baltimore License No.: MD-07-014-01
Type of Action: Renewal Amendment No.: 82
Date Issued: 6/22/10 License Reviewers: NO, AF

Comments:

1) The review team noted that the broad scope licensee did not submit criteria for the licensee's Radiation Safety Committee approval of new users, new uses, and facilities.
2) The license authorizes quantities that require an emergency plan (e.g., 8 curies of iodine-125 and 8 curies of iodine-131); however neither an emergency plan nor a commitment to restrict collocation of quantities was submitted.

File No.: 8
Licensee: University of Maryland Medical Center License No.: MD-07-014-07
Type of Action: New Amendment No.:00
Date Issued: 3/10/11 License Reviewer: NO

Comment:

The license application was signed by an individual (Chair of the Department of Radiation Oncology). It is unclear whether the Department Chair had sufficient authority to sign this application for a new license.

File No.: 9
Licensee: University of Maryland Medical Center License No.: MD-07-014-07
Type of Action: Amendment Amendment No.:01
Date Issued: 3/24/11 License Reviewer: NO

File No.: 10
Licensee: University of Maryland Medical Systems Group License No.: MD-07-014-06
Type of Action: Renewal Amendment No.: 36
Date Issued: 5/19/09 License Reviewer: NO

Comment:

The high dose-rate remote afterloader spot-check procedures were limited to a checklist that did not include detailed step-by-step procedures for conducting spot-checks and did not include criteria for acceptance for all checks (e.g., timer accuracy).

File No.: 11
Licensee: University of Maryland College Park License No.: MD-33-0004-01
Type of Action: Renewal Amendment No.: 143
Date Issued: 4/30/09 License Reviewer: DM

Comments:

1) The radionuclides and quantities authorized by the license exceed the unity rule for consideration of security requirements license conditions; however, the security requirements license condition was not included on the license.
2) A total possession limit not provided for item 6.B. and radionuclides, type, or total possession limit was not provided for item 6.FF. However, the Program plans to address this by the end of the year.
3) The license authorizes fixed and portable gauges, however, standard license conditions were not included for these uses and the licensing guidance for these activities does not appear to have been used.
4) The Decommissioning Funding Plan accepted from licensee dated January 9, 2007, does not include all radionuclides with half lives greater than 120 days listed on the license. Additionally, the statement of intent prepared by the licensee does not include supporting documentation.
5) The review team noted that the broad scope licensee did not submit criteria for the licensee's Radiation Safety Committee approval of new users, new uses, and facilities.

File No.: 12
Licensee: University of Maryland College Park License No.: MD-33-004-03
Type of Action: Renewal Amendment No.: 29
Date Issued: 3/25/09 License Reviewer: NO

Comments:

1) Standard license condition 87 (regarding repairs), from NUREG-1556, Volume 20, "Consolidated Guidance About Materials Licenses: Guidance About Administrative Licensing Procedures" was not included in the license.
2) Previous violations for detectors and alarm testing were not addressed specifically in the review of the renewal application. For example, the submitted procedures did not include a source re-positioning procedure. During a 2010 inspection, the previous violations were found to be repetitive from an earlier inspection and the inspector determined that re-positioning procedures were not submitted as part of the renewal application. Following the inspection, a license amendment was submitted to provide the source re-positioning procedure.

File No.: 13
Licensee: Cardinal Health License No.: MD-33-198-01
Type of Action: Amendment Amendment No.:101
Date Issued: 8/27/09 License Reviewer: DM

Comments:

1) The license amendment was to terminate the cyclotron license and add all activities and license commitments from MD-33-177-01 to this license. However, no re-review of commitments in accordance with NUREG-1556, Volume 21, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses for Production of Radioactive Material Using an Accelerator" appears to have been conducted.
2) Financial assurance was not taken into consideration or requested when the cyclotron was added to the license.

File No.: 14
Licensee: Alliance Health Care License No.: MD-33-206-01
Type of Action: New Amendment No.: 00
Date Issued: 8/25/08 License Reviewer: BP

Comment:

The license provided to document the Radiation Safety Officer's training and experience does not include all pages and it is unclear whether it is a full medical license or just a calibration license.

File No.: 15
Licensee: Functional Genetics License No.: MD-31-331-01
Type of Action: Termination Amendment No.: 05
Date Issued: 7/20/11 License Reviewer: DM

Comment:
The license was terminated, however Condition 10 was retained that lists a location of use. No licensed material is included on the license.

File No.: 16
Licensee: Functional Genetics License No.: MD-31-331-01
Type of Action: Renewal Amendment No.: 04
Date Issued: 8/4/10 License Reviewer: AF

File No.: 17
Licensee: TASR Company License No.: MD-07-032-01
Type of Action: Termination Amendment No.: 25
Date Issued: 10/27/09 License Reviewer: NO

Comments:
1) The license was terminated with a notation on the top of the license and the termination request included in the license tie-down. However, all other items remain on the license including the listing of licensed material, authorized uses, and locations of use.
2) Leak test records were not provided for sealed sources prior to license termination.

File No.: 18
Licensee: Tidewater Inc. License No.: MD-27-087-01
Type of Action: Termination Amendment No.: 04
Date Issued: 9/27/10 License Reviewer: NO

Comment:
License terminated with a notation on the top of the license and the termination request included in the license tie-down. However, all other items remain on the license including the listing of licensed material, authorized uses, and locations of use.

File No.: 19
Licensee: Tidewater Inc. License No.: MD-27-087-01
Type of Action: Amendment Amendment No.: 02
Date Issued: 7/8/08 License Reviewer: CW

File No.: 20
Licensee: Johns Hopkins Medical Institutions License No.: MD-07-005-05
Type of Action: Renewal Amendment No.: 26
Date Issued: 1/14/10 License Reviewer: NO

Comments:

1) Total possession limits were not included for all devices; however the Program plans to address this by the end of the year.
2) No response specific to “Maintenance” was included in the licensee’s application. A general license condition limiting maintenance to authorized individuals is included on the license; however, it is unclear whether “authorized individuals” are limited to the manufacturer’s representatives or other persons specifically authorized by NRC or an Agreement State to perform maintenance, as described in NUREG-1556, Volume 5.

File No.: 21
Licensee: Maryland QC Laboratories License No.: MD-25-022-01
Type of Action: Amendment Amendment No.: 55
Date Issued: 3/1/11 License Reviewer: DM

Comments:

1) Total possession limits were not included on the license; however the Program plans to address this by the end of the year.
2) Non-standard license condition included on the license allowing possession of sources in excess of possession limit by 20% for Iridium-192 or 10% for Cobalt-60. Since most SSDR’s include a maximum quantity to include shipment decay; this condition appears unnecessary.

APPENDIX E

INCIDENT CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS ONLY.

File No.: 1
Licensee: Greater Baltimore Medical Center — License No.: MD-05-002-03
Date of Incident: 8/17/08 — NMED No.: 080489
Investigation Date: 8/22/08 — Type of Incident: Lost/Stolen RAM
Type of Investigation: Site

File No.: 2
Licensee: Stone Industrial — License No.: General
Date of Incident: 2/27/09 — NMED No.: 090386
Investigation Date: 3/10/09 — Type of Incident: Lost/Stolen RAM
Type of Investigation: Site

File No.: 3
Licensee: Cardinal Health — License No.: MD-33-198-01
Date of Incident: 7/21/09 — NMED No.: 090733
Investigation Date: 9/22 & 11/24/09 — Type of Incident: Potential Overexposure
Type of Investigation: Site

File No.: 4
Licensee: University of Maryland at Baltimore — License No.: MD-07-014-01
Date of Incident: 3/9/10 — NMED No.: 100430
Investigation Date: 4/6/10 — Type of Incident: Medical Event
Type of Investigation: Site

File No.: 5
Licensee: Greater Baltimore Medical Center — License No.: MD-05-002-03
Date of Incident: 7/9/10 — NMED No.: 100397
Investigation Date: 7/27 & 8/18/10 — Type of Incident: Medical Event
Type of Investigation: Site

Comments:
1) No documentation was provided by licensee related to post-implant dose to the organ that did not receive intended dose due to dislodged source.
2) The State reported the event to NRC approximately 3 weeks late.

File No.: 6
Licensee: University of Maryland Medical Systems — License No.: MD-07-014-05
Date of Incident: 1/27/10 — NMED No.: 100174
Investigation Date: 3/21/10 & 8/6/10 — Type of Incident: Medical Event
Type of Investigation: Site

File No.: 7
Licensee: Digirad Imaging Solutions
Date of Incident: 11/1/07
Investigation Date: 1/10/08
License No.: MD-03-107-01
NMED No.: 080008
Type of Incident: Lost/Stolen RAM
Type of Investigation: Site

File No.: 8
Licensee: Hillis Carnes
Date of Incident: 3/28/08
Investigation Date: 3/28/08
License No.: MD-21-041-01
NMED No.: 090432
Type of Incident: Damaged Equipment
Type of Investigation: Site

File No.: 9
Licensee: Engineering Consulting Services
Date of Incident: 11/28/08
Investigation Date: 11/28/08
License No.: MD-03-092-01
NMED No.: 080843
Type of Incident: Damaged Equipment
Type of Investigation: Site

File No.: 10
Licensee: Prince Georges Hospital Center
Date of Incident: 8/13/09
Investigation Date: 5/10/10
License No.: MD-33-003-01
NMED No.: 100172
Type of Incident: Leaking Source
Type of Investigation: Site

SEALED SOURCE AND DEVICE INCIDENT CASEWORKS REVIEWS

File No. 1:
Licensee: Nucletron Corporation
Date of Incident: 7/14/08
Investigation Date: Not Available
License No.: MD-27-035-01
Incident Log No.: NMED 080406
Type of Incident: Equipment Malfunction
Type of Investigation: Root Cause/Generic Application

File No. 2:
Licensee: Nucletron Corporation
Date of Incident: 8/7/08
Investigation Date: Not Available
License No.: MD-27-035-01
Incident Log No.: NMED 080460
Type of Incident: Equipment Malfunction
Type of Investigation: Root Cause/Generic Application

File No. 3:
Licensee: Nucletron Corporation
Date of Incident: 6/25/09
Investigation Date: Not Available
License No.: MD-27-035-01
Incident Log No.: NMED 090571
Type of Incident: Equipment Malfunction
Type of Investigation: Root Cause/Generic Application

File No. 4:
Licensee: Nucletron Corporation License No.: MD-27-035-01
Date of Incident: 7/16/09 Incident Log No.: NMED 090614
Investigation Date: Not Available Type of Incident: Equipment Malfunction
Type of Investigation: Root Cause/Generic Application

File No. 5:
Licensee: Nucletron Corporation License No.: MD-27-035-01
Date of Incident: 2/10/10 Incident Log No.: NMED 100071
Investigation Date: Not Available Type of Incident: Equipment Malfunction
Type of Investigation: Root Cause/Generic Application

File No. 6:
Licensee: Nucletron Corporation License No.: MD-27-035-01
Date of Incident: 2/14/10 Incident Log No.: NMED 100074
Investigation Date: Not Available Type of Incident: Equipment Malfunction
Type of Investigation: Root Cause/Generic Application

File No. 7:
Licensee: Nucletron Corporation License No.: MD-27-035-01
Date of Incident: 1/18/10 Incident Log No.: NMED 100082
Investigation Date: Not Available Type of Incident: Equipment Malfunction
Type of Investigation: Root Cause/Generic Application

File No. 8:
Licensee: Nucletron Corporation License No.: MD-27-035-01
Date of Incident: 3/11/10 Incident Log No.: NMED 100118
Investigation Date: Not Available Type of Incident: Equipment Malfunction
Type of Investigation: Root Cause/Generic Application

File No. 9:
Licensee: Nucletron Corporation License No.: MD-27-035-01
Date of Incident: 6/3/10 Incident Log No.: NMED 100314
Investigation Date: Not Available Type of Incident: Equipment Malfunction
Type of Investigation: Root Cause/Generic Application

File No. 10:
Licensee: Nucletron Corporation License No.: MD-27-035-01
Date of Incident: 10/6/10 Incident Log No.: NMED 100506
Investigation Date: Not Available Type of Incident: Equipment Malfunction
Type of Investigation: Root Cause/Generic Application

File No. 11:
Licensee: Nucletron Corporation License No.: MD-27-035-01
Date of Incident: 12/22/10 Incident Log No.: NMED 110005
Investigation Date: Not Available Type of Incident: Equipment Malfunction
Type of Investigation: Root Cause/Generic Application

File No. 12:
Licensee: Nucletron Corporation
Date of Incident: 9/1/09
Investigation Date: Not Available
License No.: MD-27-035-01
Incident Log No.: NMED 110087
Type of Incident: Equipment Malfunction
Type of Investigation: Root Cause/Generic Application

File No. 13:
Licensee: Nucletron Corporation
Date of Incident: 2/10/11
Investigation Date: Not Available
License No.: MD-27-035-01
Incident Log No.: NMED 110104
Type of Incident: Equipment Malfunction
Type of Investigation: Root Cause/Generic Application

File No. 14:
Licensee: Nucletron Corporation
Date of Incident: 2/8/11
Investigation Date: Not Available
License No.: MD-27-035-01
Incident Log No.: Moses Cone Regional Cancer Center
Type of Incident: Equipment Malfunction
Type of Investigation: Root Cause/Generic Application

File No. 15:
Licensee: Nucletron Corporation
Date of Incident: 12/2/10
Investigation Date: Not Available
License No.: MD-27-035-01
Incident Log No.: Customer Site-HDR Knocked Over
Type of Incident: Equipment Malfunction
Type of Investigation: Root Cause/Generic Application

File No. 16:
Licensee: Nucletron Corporation
Date of Incident: 8/14/09
Investigation Date: Not Available
License No.: MD-27-035-01
Incident Log No.: Rush Univ. Hospital
Type of Incident: Equipment Malfunction
Type of Investigation: Root Cause/Generic Application

File No. 17:
Licensee: Nucletron Corporation
Date of Incident: 7/29/09
Investigation Date: Not Available
License No.: MD-27-035-01
Incident Log No.: 21st Century Oncology
Type of Incident: Equipment Malfunction
Type of Investigation: Root Cause/Generic Application

File No. 18:
Licensee: Nucletron Corporation
Date of Incident: 7/5/09
Investigation Date: Not Available
License No.: MD-27-035-01
Incident Log No.: MD Anderson
Type of Incident: Equipment Malfunction
Type of Investigation: Root Cause/Generic Application

File No. 19:
Licensee: Nucletron Corporation License No.: MD-27-035-01
Date of Incident: 1/20/09 Incident Log No.: Grant Riverside Methodist Hosp.
Investigation Date: Not Available Type of Incident: Equipment Malfunction
Type of Investigation: Root Cause/Generic Application

Comments:

1) This incident is a 24 hour reportable event in accordance with 10 CFR 30.50(b)(2) or equivalent Agreement State regulations. The Program received a report of this incident from the licensee on February 13, 2009, but the Program did not report the incident to NRC. Based on discussions during the onsite review, on August 12, 2011, the Program reported the event to NRC (NRC Event No. 47148).
2) A generic issue was identified by Program. The device is identified in SS&D Registration No. MD-0497-D-108-S. The program determined that a modification was being done by the licensee. The case file did not contain any engineering drawings or specific descriptions of what modification was being done.

File No. 20:
Licensee: Nucletron Corporation License No.: MD-27-035-01
Date of Incident: 3/4/09 Incident Log No.: Williams Beaumont Hosp.
Investigation Date: Not Available Type of Incident: Equipment Malfunction
Type of Investigation: Root Cause/Generic Application

File No. 21:
Licensee: Nucletron Corporation License No.: MD-27-035-01
Date of Incident: 11/12/08 Incident Log No.: Central Indiana Cancer Center
Investigation Date: Not Available Type of Incident: Equipment Malfunction
Type of Investigation: Root Cause/Generic Application

File No. 22:
Licensee: Nucletron Corporation License No.: MD-27-035-01
Date of Incident: 10/12/07 Incident Log No.: Florida Cancer Center Malfunction
Investigation Date: Not Available Type of Incident: Equipment
Type of Investigation: Root Cause/Generic Application

File No. 23:
Licensee: Nucletron Corporation License No.: MD-27-035-01
Date of Incident: 12/13/07 Incident Log No.: Gamma West Brachytherapy
Investigation Date: Not Available Type of Incident: Equipment Malfunction
Type of Investigation: Root Cause/Generic Application

File No. 24:
Licensee: Nucletron Corporation License No.: MD-27-035-01
Date of Incident: 2/7/08 Incident Log No.: Latrobe Area Hospital
Investigation Date: Not Available Type of Incident: Equipment Malfunction
Type of Investigation: Root Cause/Generic Application

File No. 25:
Licensee: Nucletron Corporation
License No.: MD-27-035-01
Date of Incident: 2/13/08
Incident Log No.: Central Indiana Cancer Center
Investigation Date: Not Available
Type of Incident: Equipment Malfunction
Type of Investigation: Root Cause/Generic Application

APPENDIX F

SEALED SOURCE AND DEVICE REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS ONLY.

File No.: 1
Registry No.: MD-0497-D-108-S SS&D Use Code: (AC) Photon-emitting Remote Afterloaders
Applicant's Name: Nucletron Corporation Type of Action: Amended Registration
Date Issued: 11/5/10 SS&D Reviewers: BP, RM

Comment:

The FDA Approval Summary was not included in the registration as recommended in Section 12.11 and Appendix D of NUREG-1556, Volume 3, Revision 1, "Applications for Sealed Source and Device Evaluation and Registration." The device did receive FDA 510k approval and the approval was maintained with the file.

File No.: 2
Registry No.: MD-0497-D-114-S SS&D Use Code: (AC) Photon-emitting Remote Afterloaders
Applicant's Name: Nucletron Corporation Type of Action: Amended Registration
Date Issued: 4/11/11 SS&D Reviewers: BP, RM

Comment:

The FDA Approval Summary was not included in the registration as recommended in Section 12.11 and Appendix D of NUREG-1556, Volume 3, Revision 1, "Applications for Sealed Source and Device Evaluation and Registration." The device did receive FDA 510k approval and the approval was maintained with the file.

File No.: 3
Registry No.: MD-0497-D-108-S SS&D Use Code: (V) General Medical Use
Applicant's Name: Nucletron Corporation Type of Action: New Registration
Date Issued: 11/20/08 SS&D Reviewers: BP, RM

Comments:

1) The first page information section of the registration incorrectly indicated the use code as "(V) General Medical Use". This use code was discontinued in 2002.
2) The FDA Approval Summary was not included in the registration as recommended in Section 12.11 and Appendix D of the NUREG-1556, Volume 3, Revision 1, "Applications for Sealed Source and Device Evaluation and Registration." The device did receive FDA 510k approval and the approval was maintained with the file.

File No. 4:
Registry No.: MD-0497-D-115-S SS&D Use Code: (AC) Photon-emitting Remote Afterloaders
Applicant's Name: Nucletron Corporation Type of Action: Amended Registration
Date Issued: 4/20/11 SS&D Reviewers: BP, RM

File No. 5:
Registry No.: MD-0497-D-115-S SS&D Use Code: (AC) Photon-emitting Remote Afterloaders
Applicant's Name: Nucletron Corporation Type of Action: New Registration
Date Issued: 3/26/10 SS&D Reviewers: BP, RM

File No. 6:
Registry No.: MD-1299-D-801-S SS&D Use Code: (AC) Photon-emitting Remote Afterloaders
Applicant's Name: Isodose Control, Inc. Type of Action: Inactivated Registration
Date Issued: 3/26/10 SS&D Reviewers: BP, RM

File No. 7:
Registry No.: MD-1299-D-101-S SS&D Use Code: (AC) Photon-emitting Remote Afterloaders
Applicant's Name: Isodose Control, Inc. Type of Action: New Registration
Date Issued: 8/28/08 SS&D Reviewers: BP, RM

File No. 8:
Registry No.: MD-1239-D-101-B SS&D Use Code: (D) Gamma Gauges
Applicant's Name: Isoscan Limited Type of Action: New Registration
Date Issued: 8/21/08 SS&D Reviewers: DM, NO

File No. 9:
Registry No.: MD-0497-D-110-S SS&D Use Code: (V) General Medical Use
Applicant's Name: Nucletron Corporation Type of Action: Amended Registration
Date Issued: 11/5/10 SS&D Reviewers: BP, RM

Comments:
1) The first page information section of the registration incorrectly indicated the use code as "(V) General Medical Use". This use code was discontinued in 2002.
2) The FDA Approval Summary was not included in the registration as recommended in Section 12.11 and Appendix D of NUREG-1556, Volume 3, Revision 1, "Applications for Sealed Source and Device Evaluation and Registration." The device did receive FDA 510k approval and the approval was maintained with the file.

File No. 10:
Registry No.: MD-1149-D-101-G SS&D Use Code: (E) Beta Gauges
Applicant's Name: Bahia 21 Corporation Type of Action: Amended Registration
Date Issued: 12/8/10 SS&D Reviewers: DM, RM

File No. 11:
Registry No.: MD-8191-D-801-G SS&D Use Code: (D) Gamma Gauges
Applicant's Name: Pettit Applied Technologies Type of Action: Inactivated Registration
Date Issued: 8/31/07 SS&D Reviewers: DM, NO

Comment:

The "Limitation and/or Other Considerations of Use" section, for this inactivated registration, incorrectly identifies that the device may be distributed. Item 13.4 of NUREG-1556, Volume 3, Revision 1, "Applications for Sealed Source and Device Evaluation and Registration" recommends indication that the product will no longer be commercially distributed but may still be approved for licensing purposes.

File No. 12:
Registry No.: MD-8191-D-802-G SS&D Use Code: (E) Beta Gauges
Applicant's Name: Pettit Applied Technologies Type of Action: Inactivated Registration
Date Issued: 8/31/07 SS&D Reviewers: DM, BP

Comment:

The "Limitation and/or Other Considerations of Use" section, for this inactivated registration, incorrectly identifies that the device may be distributed. Item 13.4 of NUREG-1556, Volume 3, Revision 1, "Applications for Sealed Source and Device Evaluation and Registration" recommends indication that the product will no longer be commercially distributed but may still be approved for licensing purposes.

APPENDIX G

LIST OF 25 OBSOLETE MARYLAND SS&D REGISTRATIONS

(1) MD-0205-D-101-G
(2) MD-0226-D-101-S
(3) MD-0226-S-102-S
(4) MD-0263-D-101-G
(5) MD-0327-D-101-G
(6) MD-0351-D-101-U
(7) MD-0351-D-102-U
(8) MD-0357-D-101-U
(9) MD-0381-D-106-S
(10) MD-0381-D-107-G
(11) MD-0381-D-108-G
(12) MD-0381-D-109-G
(13) MD-0381-D-110-G
(14) MD-0381-D-111-G
(15) MD-0381-D-112-G
(16) MD-0381-D-113-G
(17) MD-0381-D-116-G
(18) MD-0558-S-101-S
(19) MD-0558-S-102-S
(20) MD-0590-D-112-G
(21) MD-0656-D-102-G
(22) MD-0670-S-108-G
(23) MD-0691-S-101-S
(24) MD-0691-D-102-S
(25) MD-0741-S-102-S

ATTACHMENT(S)

October 12, 2011 Letter from Roland Fletcher
Maryland's Response to the Draft Report
ADAMS Accession No.: ML112910131

NRC Comment Resolution to October 20, 2011
ADAMS Accession No.: ML113000070

MARYLAND DEPARTMENT OF THE ENVIRONMENT
1800 Washington Boulevard • Baltimore MD 21230
410-537-3000 • 1-800-633-6101

Martin O'Malley
Governor

Anthony G. Brown
Lieutenant Governor

Robert M. Summers, Ph.D.
Secretary

Kathy Kinsey
Deputy Secretary

OCT 12 2011

Janine F. Katanic, PhD, CHP
Health Physicist
US Nuclear Regulatory Commission
Office of Federal and State Materials and Environmental Management Programs
Division of Materials Safety and State Agreements
Agreement State Programs Branch

RE: Maryland's Response to NRC's 2011 Draft IMPEP Report

Dear Dr. Katanic:

Please find enclosed the Maryland Department of the Environment (MDE) Radiological Health Program's (RHP) response to the draft report from the US Nuclear Regulatory Commission's Integrated Materials Performance Evaluation Program (IMPEP) audit conducted August 8-12, 2011. On behalf of the MDE Secretary and the RHP staff, we thank the IMPEP audit team for their expertise, professionalism, competence and patience during the audit.

We have attached responses and comments regarding the draft report and respectfully request that the audit team carefully reconsider both the wording and certain findings documented as reflected in our comments. Notwithstanding these concerns, Maryland firmly supports the IMPEP process and will continue to improve the adequacy and compatibility of our Program as we further our mission 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 410-537-3301 or by e-mail at rmanley@mde.state.md.us.

Sincerely,

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

RGF/REM/blr

Enclosure: Maryland's Response to NRC's 2011 Draft IMPEP Report

MARYLAND COMMENTS REGARDING THE DRAFT IMPEP REPORT

Comment 1 Item 3.2, paragraph 3

Maryland agrees with the report's opening statements that the IMPEP audit is primarily a performance based process. With that in mind, Maryland requests a rewording of the portion of the report that states "The Program's database had limited capabilities for retrieval of inspection data from the entire review period" We understand the audit team's need to acquire certain inspection data. With that in mind, RHP is currently evaluating the implementation of a new database that may assist in a more efficient retrieval of this information for future audits. As stated in the report, the team was able to successfully acquire this information for its data crunch, so we respectfully request a rewording of the report to be… *the review team verified the Program's inspection timelines based on...*

Comment 2 Item 3.2, paragraph 4

The report again makes a statement "Due to limitations in the Program's database." For the reasons given in the above comment Maryland respectfully requests a rewording of the report to be…*The performance of initial inspections was verified by*…

Comment 3 Item 3.2, paragraph 7

This paragraph states that "The data regarding the issuance of inspection findings to licensees was not able to be retrieved from the Program's database." For the reasons given in comment number 1, Maryland respectfully requests that this sentence be removed from the report.

Comment 5 Item 3.4 general

RHP respectfully requests clarification regarding the level of flexibility Agreement State Programs have specific to the NUREG 1556 Guidance (inclusive of NUREG 1556 Vol. 20). Are these licensing documents required to be explicitly followed by an Agreement State or are they guidance? Maryland concerns regarding audit findings in licensing can be found in the Comments-Appendix D.

Comment 6 Item 4.2.2

The IMPEP team provided to Maryland, as part of the audit, the 25 obsolete SS&D registrations. Maryland has conducted an in-depth review of these sheets and all current Maryland sheets in the NRC registry. It is anticipated that most of these obsolete sheets will be deactivated before the November 3, 2011 Management Review Board meeting. Maryland respectfully requests that due to our ongoing evaluation and remediation of this matter, that Appendix G be removed from the final report.

Current Status of Draft Report Recommendations

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 is adequately documented in inspection records.

   Status: Since this issue was identified, the Division Chief and the Inspection Supervisor have conducted a thorough review. Findings revealed that only a few cases lacked sufficient documentation information pertaining to inspection review of previous non-compliance items. The review also revealed that these were isolated occurrences and not indicative of a program deficiency. It is the intent of the Inspection Supervisor to focus on this type of documentation during the review of each inspection report. The Inspection Supervisor has discussed this issue with the Inspectors and provided report writing training on numerous occasions before and after this IMPEP audit. Please note that based on the casework, the IMPEP review team noted that, with a few exceptions, inspection records were thorough, complete, consistent, and of a high quality. It is our concern that this recommendation may have been based on only a few isolated cases, and not a program-wide concern. Maryland requests that the IMPEP team reconsider and remove this recommendation. Please see the comments in our response to File 2 and File 6 of Appendix-C.

2. The review team recommends that the State take measures to ensure that the Program's review of licensing actions are adequately documented and that the licensing actions are thorough and consistent with the regulations and appropriate licensing guidance.

   Status: During the August 12, 2011 IMPEP Management Exit Meeting, the audit team was informed that RHP was still unclear with the nature and scope of concerns and recommendations regarding the licensing review. We were informed, at that time that the matter would be clarified in the Draft Report Appendix D. Because it is still not totally clear to us in Appendix D, which comments are specific to the "needs for improvement" finding of the audit, and which may have been findings that would not have resulted in a "needs for improvement" we will respond to all the licensing IMPEP audit comments in this Appendix. Please note that NUREG 1556 Vol. 20 abstract indicates that the guide is intended for use by NRC staff and will be made available to Agreement State staff. Please see the comments to the IMPEP audit licensing findings in Section Comments Appendix-D.

3. The review team recommends that the State perform a review of activities conducted under the license identified in Appendix D File No. 1 and take measures as appropriate, to ensure that the license properly authorizes the manufacturer/distribution of sealed sources or devices for medical use.

Status: On August 18, 2011, the license identified in Appendix D File No.1was appropriately amended to authorize the manufacturer/distribution of sealed sources or devices for medical use.

4. The review team recommends that the State: (1) take measures to insure that financial assurance requirements are reviewed as part of significant licensing actions and during license renewal; (2) evaluate the need for financial assurance related to the radionuclide production (cyclotron) licensees; and (3) perform a review of the adequacy and validity of financial assurance mechanisms already on file with the programs.

   Status:

   (1) RHP 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 documentation will be reviewed for appropriate content, and license reviewers will conduct a thorough evaluation of financial assurance requirements during each license renewal.

   (2) Management of both cyclotron licensees in Maryland has been contacted. One licensee (same as NRC Region I) has 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. The licensee's submittal is currently under review. The other licensee (broad scope) is in the process of conducting a review of their decommissioning funding plan for submittal to RHP. 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 before the end of this year. Any deficiencies in documentation or technical sufficiency of submittals will be addressed.

5. The review team recommends that for the 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."

   Status: Maryland hopes to complete most of these deactivations by our November 3, 2011 MRB. We anticipate resolution of all deactivations by the end of this year.

Comments/Status -Appendix C

File 2

IMPEP Comment 1:

It is true that the inspection record did not document a review of the licensee's corrective actions related to non-compliance from the previous inspection. However, this finding is just one, of only a few exceptions, where inspection records were not, as stated by the IMPEP team, to be thorough, complete, consistent, and of high quality. The inspection was conducted on August 25, 2010 and the report was completed on August 30, 2010 by the Lead Inspector just prior to his military deployment. The report was brief and the inspector had numerous professional, personal, domestic and military deadlines to meet during this month and did not spend enough time on the report. Please note that no items of non-compliance or unsafe conditions were identified during this Team Inspection conducted by three Maryland Health Physicists/Inspectors. This Lead Inspector has a report writing style that includes a large volume of pertinent documents that were reviewed during the inspection. For example, if the licensee documented corrective actions in a memorandum or an audit, it would be routine for this Lead Inspector to review, discuss, evaluate and then request a copy of that document and include it in his report. Unfortunately, the attachments to this report were not available for review during this audit. In addition, this Lead Inspector was not available for interviews and questioning regarding this issue. We are confident that this Senior Inspector, with over 20 years of materials inspection experience, would have adequately addressed this comment given the opportunity. Interviews with the other two inspectors who participated in the Team Inspection revealed that the inspection adequately reviewed the licensee's corrective actions related to the previous inspection. After a careful review, we conclude that this issue is an isolated occurrence and not indicative of a programmatic deficiency that needs to be documented in a public record. We respectfully request that this comment and its recommendation be removed.

IMPEP Comment 2:

It is correct that that the inspection record did not adequately document a review of the cyclotron portion of the inspection. The inspection was conducted over a year ago and since then; the Program has taken numerous actions to improve the quality of nuclear pharmacy inspections and reports. Prior to this IMPEP audit, the NRC identified a need for NRC and Agreement State Inspectors, including inspectors with decades of experience, to receive additional structured training in nuclear pharmacy inspections. Within a month after this inspection report was written, three RHP Health Physicists completed the NRC's newly created Nuclear Pharmacy Course. Since completing this course we are better prepared to meet the NRC's expectations when conducting pharmacy inspections and preparing reports. The Inspection Supervisor also provided pharmacy inspection training to

the two materials inspectors using the knowledge and documents received at the Nuclear Pharmacy Course. We plan to train again prior to conducting the next Nuclear Pharmacy inspection. Since this issue was addressed prior to the IMPEP audit, we respectfully request that this comment be removed.

File 6

IMPEP Comment:

It is true that the report of the June 14, 2011 GBMC inspection did not document a review of the licensee's corrective actions related to non-compliance from the previous medical event investigation. The status of compliance and the licensee's corrective actions were documented in a separate report. On December 6, 2010 Ray Manley and Alan Jacobson conducted a follow-up inspection at GBMC. The inspection focused on the violations identified during the Cs-137 Low Dose Brachytherapy medical event and the licensee's corrective actions. As a result, the corrective actions were documented in a separate report. Prior to the June 14, 2011 inspection, the inspector reviewed the previous report regarding the corrective actions status of compliance with the violations identified during the Cs-137 low dose brachytherapy medical event. Interviews with GBMC personnel and a review of records conducted at the beginning of the inspection revealed that GBMC had not conducted any Cs-137 low dose rate brachytherapy since the date of the medical event. As a result, the inspection and the inspection report focused on licensed activities involving radiation therapy that were conducted since the previous inspection. Since a review of the licensee's corrective actions related to non-compliance from the previous medical event investigation was conducted prior to this inspection and the status of compliance including the licensee's corrective actions were documented in a separate report, we respectfully request that this comment be removed. Further, since this comment refers to corrected violations that apply to both safety and security of a Safeguards facility, we are concerned that it may not be appropriate to place in a public document. We respectfully request that this comment be removed.

File 10

IMPEP Comment:

We acknowledge that the Supervisor's review of the inspection record identified missing or incomplete data and the inspection record was not corrected. The Supervisor reported the issue to the Program Manager. The Program Manager conducted an extensive review that included an examination of the report, interviews with the two inspectors and numerous discussions with the Supervisor. The Program Manager also directed the Supervisor to conduct Increased Control Report Writing Training prior to the next round of IC Inspections. Since the Supervisor did identify the missing or incomplete information in the report, the issue was escalated to Program's Manager, the Program Manager conducted an

extensive review and the Supervisor implemented the Manager's directive regarding this issue, we respectfully request that this comment be removed.

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File 11

IMPEP Comment:

The March 25 & April 8, 2008 inspection identified several safety significant items of non-compliance that were corrected prior to the completion of the inspection. Please note that the licensee was not operating the panoramic irradiator without working safety systems. The irradiator was down for maintenance and repair. A formal follow-up inspection was not conducted so perhaps that is why the documentation did not meet the Team Leader's expectations. A formal follow-up inspection was not scheduled for several reasons including that the security and safety significant violations were corrected by the time of the exit interview. The main violation involved a failure of alarm transmittal component that was corrected by the end of the first day of the inspection. This component was essential for compliance with the monitor, detect, access and respond requirement of the NRC Safeguards Order. The licensee was in the process of upgrading numerous security and safety systems. On May 12, 2010 NNSA completed a Security Assessment. More improvements were completed during the month of August 2010. The Safeguards Inspection was conducted by a Maryland Inspector on September 1, 2010. On July 15, 2011 NNSA, PNNL and the licensee completed substantial security and safety upgrades. A follow-up Safeguards inspection was conducted on July 26, 2011 just prior to the IMPEP audit. Corrective actions and the status of compliance were reviewed; however, the report was yet not completed during the IMPEP Team's August 8-12, 2011 audit. The Team Leader reviewed the documentation of the safety system checks.

File 13

IMPEP Comment:

We agree that the July 22, 2011 licensee response was not adequate to correct the non-compliances. The document was under timely review during the IMPEP audit of August 8-12, 2011. The inspector discussed the deficiencies with the licensee on several occasions, explained the Department's expectations, and provided them with an opportunity to submit an additional response. On August 23, 2011 the licensee submitted a revised response letter. The Program Manager, Inspector Supervisor and the Inspector determined that the response was

acceptable. A September 14, 2011 acknowledgement letter describing this determination was sent to the licensee. Since this comment implies that the licensee's response is not adequate when, in fact the August 23, 2011 revised response was determined to be acceptable, we are concerned that it sends an incorrect statement about the licensee by placing it in a public document that will be posted on the web. We respectfully request that this comment be removed.

Accompaniment 3

The Licensee is listed as Sanford Medical Center Fargo. Please change to Anne Arundel Medical Center. Are you certain that this comment is intended for Anne Arundel Medical Center instead of Sanford Medical Center in Fargo?

During this inspection, the inspector was focused, in part on conducting a review and assembling information to document the licensee's corrective actions related to the non-compliance items identified on the previous inspection and collecting information necessary to support two violations, As noted in the report, this was the inspector's first increased controls inspection. It was conducted upon request by the IMPEP Team Leader to conduct an accompaniment of an Increased Control licensee. The previous IC inspection of this licensee was conducted on March 5, 2009. Prior to the request, we had planned to conduct the inspection at a later date. To accommodate the Team Leader's request, the inspector was trained and qualified prior to this inspection. Discussions with between the IMPEP Team Leader, the Inspector and the Inspection Supervisor after the inspection revealed that the inspector "did a good job." It was not until the next week that the Team Leader notified the RHP of the significance of this issue and the request was made to conduct an addition accompaniment. Since this comment refers to the compliance status and inspection of increased controls requirements and associated corrective actions, and it is not necessary to place in this public document, we respectfully request that it is removed.

Comments/Status -Appendix D

File 2

License number referenced should be 07-005-03

We are currently evaluating with intent to improve our understanding, implementation and use of NUREG 1556 Guidance. Following NRC's response to comment five of this document and RAMLCD staff evaluation, we will conduct additional license staff reviewer training to improve the technical level of license review in all areas where achievable.

IMPEP Comments and Status 1 & 2

RHP will review and issue amendments necessary to adequately address these comments. Any lessons learned will be addressed in licensing procedures and included as training in future license reviewer meetings.

IMPEP Comment 3:

RHP respectfully does not agree with this comment and requests that it be removed. The application as submitted contains clear documentation of broad scope responsibilities that adequately describes Radiation Control Committee (RCC) responsibilities in the areas of new users, new uses, and facilities. Page 8-18 of NUREG 1556 Vol. 11 "Program Specific Guidance about Licenses of Broad Scope" under response from applicant states that applicants for type A broad scopes should submit criteria by the RSC and RSO for approving new users and new uses. Licensee documentation submitted (as reviewed by the IMPEP team) contained commitments and scope of evaluation for training, experience, oversight supervision, qualification of investigator, evaluation for application for human use, ALARA, limit on pharmacological dose, quality of drugs, human use research subjects, and research protocol. The content and implementation of the licensee broad scope generated procedures are thoroughly reviewed during the State inspection process. Of note, because of the large scope of this licensee, it has been reviewed during every past IMPEP audit cycle with no findings identical to this IMPEP. The scope, content and review of the submitted applications have been consistent since the IMPEP process started.

IMPEP Comment 4 & 5:

Please see Maryland status to IMPEP recommendation number 5.

File 3

License number referenced should be 07-005-03

We are currently evaluating with intent to improve our understanding, implementation and use of NUREG 1556 Guidance. Following NRC's response to comment five of this document and RAMLCD staff evaluation, we will conduct additional license staff reviewer training to improve the technical level of license review in all areas where achievable.

File 4

License number referenced should be 07-005-03

We are currently evaluating with intent to improve our understanding, implementation and use of NUREG 1556 Guidance. Following NRC's response to comment five of this document and RAMLCD staff evaluation, we will

conduct additional license staff reviewer training to improve the technical level of license review in all areas where achievable.

IMPEP Comment 1:

Maryland respectfully disagrees with this comment and requests its removal. Am-241 had already previously been approved on the license and safety considerations addressed at that time. Ra-223 was being authorized and approved for safety for radiopharmaceutical use under a review and authority of an approved broad scope license RSC.

IMPEP Comment 2:

RHP will issue an amendment to address this comment. Any lessons learned will be addressed in licensing procedures and included as training in future license reviewer meetings.

IMPEP Comment 3:

As described during the audit, through inspection and discussions with the licensee, it had been determined, that the licensee did not possess and had no future intention of acquiring IC quantities of concern. However, RHP agrees that it is prudent to issue a special license condition to any licensee whose possession limit indicates a potential to exceed these IC amounts. We agree that should the licensee acquire radioactive material in excess of IC limits the condition will establish burden of regulatory action on the licensee. RHP is reviewing all licenses to determine those that the condition is appropriate and requests a copy of the NRC condition wording. Any lessons learned will be addressed in licensing procedures and included as training in future license reviewer meetings.

File 5

License number referenced should be 07-005-03

We are currently evaluating with intent to improve our understanding, implementation and use of NUREG 1556 Guidance. Following NRC's response to Comment five of this document and RAMLCD staff evaluation, we will conduct additional license staff reviewer training to improve the technical level of license review in all areas where achievable

IMPEP Comment:

Please see response and status of File 4 IMPEP Comment 1

File 6

IMPEP Comment 1:

Maryland respectfully disagrees with this comment and requests that it be removed. COMAR 26.12.01.01Section D.803 clearly addresses licensee requirements for security of all portable gauges in Maryland. In fact, from a safety and security standpoint, NRC may wish to evaluate our Section D.803(b), that in addition to NRC regulations, requires the portable gauge licensee to ensure that the source locking mechanism, for each device, is engaged in the secured and fully shielded position during storage and transport.

IMPEP Comment 2:

Maryland will amend this license to address this comment and review our other licensees to assure that this is not a programmatic problem. Any lessons learned will be addressed in licensing procedures and included as training in future license reviewer meetings.

File 7:

IMPEP Comment 1:

Please see State response to File 2 IMPEP Comment 3.

IMPEP Comment 2:

Maryland has evaluated, through the inspection process that this licensee does not need an emergency plan. However, RHP agrees that it is prudent to issue a special license condition to any licensee whose possession limit indicates a potential to exceed the emergency plan limits. We agree that should the licensee acquire radioactive material in excess of the emergency plan limits, the condition will establish burden of regulatory action on the licensee. RHP is reviewing all licenses to determine those that the condition is appropriate, and requests a copy of the NRC condition wording.

File 8:

We are currently evaluating with intent to improve our understanding, implementation and use of NUREG 1556 Guidance. Following NRC's response to comment five of this document and RAMLCD staff evaluation, we will conduct additional license staff reviewer training to improve the technical level of license review in all areas where achievable.

IMPEP Comment:

This case of question of authority will be evaluated and addressed. We will carefully evaluate guidance and our procedures to make sure that this issue is clearly defined and addressed.

File 10

IMPEP Comment:

Maryland will amend the license to address this comment and review our other licensees to assure that this is not a programmatic problem. Any lessons learned will be addressed in licensing procedures and included as training in future license reviewer meetings.

File 11

IMPEP Comment 1:

Please see response to File 4 IMPEP Comment 3.

IMPEP Comment 3:

It was not previously understood that Maryland is required to use all of NUREG 1556 Vol. 20 standard license conditions. This will hopefully be clarified upon NRC's response to our questions regarding whether Agreement State Licensing is "performance based" or NUREG 1556 Vol. 20. "prescriptive based."

IMPEP Comment 4:

Maryland will carefully review this Maryland licensee to assure that all financial assurance information required specific to a State Institution has been evaluated, documented and maintained.

IMPEP Comment 5:

Maryland respectfully disagrees with this comment for reasons previously defined in File 2 Comment 3.

File 12

IMPEP Comments 1&4:

Maryland will evaluate and issue amendments to the license to address these comments. Any lessons learned will be addressed in licensing procedures and included as training in future license reviewer meetings.

IMPEP comment 2:

RHP respectfully disagrees with this comment and requests its removal. The sealed source manufacturer and model number were provided in the applicant's June 30, 2008 submittal.

IMPEP comment 3:

RHP respectfully disagrees with this comment and requests its removal. The licensee specified two pages of Safety Office topics of user training in the applicant's June 30, 2008 submittal.

File 13

IMPEP Comment 1:

RHP will re-review the licensee commitments, even though already reviewed and approved under the previous application.

IMPEP Comment 2:

Please see response for IMPEP recommendation number four.

File 14

IMPEP Comment 1:

Maryland respectfully disagrees with this comment and requests its removal. The licensee referenced has one mobile van that is only allowed to conduct operations at those temporary locations specified in the license. The evaluation and documentation of the above, is all tied down in the licensee's application.

IMPEP Comment 2:

The individual in question was appropriately qualified as RSO during the license review. The pages authorizing the individual as the RSO on Alliance's Illinois medical PET license were inadvertently discarded. We have requested, received, and filed the entire Illinois license into the file.

File 15

IMPEP Comment:

Maryland has effectively used the same methodology and format for license termination since around the year 2000 and respectfully requests this comment to be removed. This license document terminology has been through multiple positive reviews by previous IMPEP teams. Maryland will reevaluate how we

format termination license documentation and has requested a copy of the current wording format used by NRC Region I.

File 17

IMPEP Comment 1:

Please see RHP response for File 15 IMPEP Comment

IMPEP Comment 2:

Maryland will modify our procedures to require all licensee's with sealed sources requesting termination to provide leak test records.

File 18

IMPEP Comment:

Please see RHP response for File 15 IMPEP Comment

File 20

IMPEP Comment 2:

RHP requests additional clarification on this comment. This is a broad scope licensee with authority to generate these procedures. The content and implementation of any licensee broad scope generated procedures are thoroughly reviewed during the State broad scope inspection process.

IMPEP Comment 3:

RHP will carefully review this license to assure that all authority to conduct maintenance is resolved.

Comments/Status -Appendix E

File 19-SEALED SOURCE AND DEVICE INCIDENT CASEWORK REVIEWS

IMPEP Comment 2:

RHP is currently carefully reviewing the device modification to determine if any change is needed to the licensee device's SS&D sheet.

Comments/Status -Appendix F

File 20

IMPEP Comment:

Some clarification to the comment is provided and it is respectfully requested that this comment be removed. Initially when the FDA 510K approval was not immediately available, a copy of the approval was retrieved from the licensee to prove that the approval had been made. Later that same day, the original FDA 510K approval documentation was found to be misfiled in this very large SS&D application and was in fact with the documentation. The IMPEP auditor was notified that same day regarding the finding of the document.

Comment Resolution for the October 12, 2011 letter
from the Maryland Department of the Environment (ML112910131)
Regarding the September 7, 2011, Draft IMPEP Report

Comment 1: Section 3.2, paragraph 3

Maryland agrees with the report's opening statements that the IMPEP audit is primarily a performance based process. With that in mind, Maryland requests a rewording of the portion of the report that states "The Program's database had limited capabilities for retrieval of inspection data from the entire review period" We understand the audit team's need to acquire certain inspection data. With that in mind, RHP is currently evaluating the implementation of a new database that may assist in a more efficient retrieval of this information for future audits. As stated in the report, the team was able to successfully acquire this information for its data crunch, so we respectfully request a rewording of the report to be… *the review team verified the Program's inspection timelines based on...*

Response 1:

Although the IMPEP review is a performance based approach, the common performance indicator, Status of the Materials Inspection Program, represents the quantitative aspect of materials inspections whereas the common performance indicator, Technical Quality of Inspections, represents the more performance based aspect of materials inspections. The review of the indicator, Status of the Materials Inspection Program, was challenging due to the limited capabilities of the State's database. As a result, the review team employed several other methods to determine the necessary information. Using these methods, some inspection information, such as that related to initial inspections, was able to be reviewed for the entire review period. Other information, such as that related to the issuance of inspection reports, was not able to be reviewed for the entire review period and the team made a best determination based on the available information from the resources utilized. The review team appreciates that the State is evaluating options for improvement of its database. No changes were made to the IMPEP report.

Comment 2: Section 3.2, paragraph 4

The report again makes a statement "Due to limitations in the Program's database." For the reasons given in the above comment Maryland respectfully requests a rewording of the report to be…*The performance of initial inspections was verified by*…

Response 2:

See Response 1. Paragraph 4 is related to initial inspections. Because information related to the performance of initial inspections was one of the categories of information that was able to be manually retrieved and reviewed for the entire review period, the review team has revised the report to remove "Due to limitations in the Program's database" from Section 3.2, paragraph 4.

Comment 3: Section 3.2, paragraph 7

This paragraph states that "The data regarding the issuance of inspection findings to licensees was not able to be retrieved from the Program's database." For the reasons given in comment number 1, Maryland respectfully requests that this sentence be removed from the report.

Response 3:

See Response 1. Information related to the issuance of inspection findings was not able to be reviewed for the entire review period from the Program's database. The review team made its conclusions as presented in Section 3.2, paragraph 7, based on the limited sample of inspection casework files that were reviewed. No changes were made to the IMPEP report.

Comment 4: Section 3.4, general (*Indicated as "Comment 5" in Maryland's response.)*

RHP respectfully requests clarification regarding the level of flexibility Agreement State Programs have specific to the NUREG 1556 Guidance (inclusive of NUREG 1556 Vol. 20). Are these licensing documents required to be explicitly followed by an Agreement State or are they guidance? Maryland concerns regarding audit findings in licensing can be found in the Comments-Appendix D.

Response 4:

The State, in their administrative licensing procedures reviewed by the team, appeared to have largely adopted the NUREG-1556 Series, with the exception of Volume 20, to assist in their review of licensing actions. The team noted that NUREG-1556, Volumes 1, 2, 5, 6, 9, 11, 12, and 21 were utilized by the State in performing licensing reviews. This is the reason that several comments in Appendix D addressed the NUREG-1556 series. Furthermore, on the State's web page, the licensing guidance provided to applicants/licensees is the NUREG-1556 series and not State-specific licensing guidance.

Agreement States are not required to follow the NUREG-1556 series, however; Agreement States, as a matter of compatibility, should have licensing procedures. These licensing procedures should be adequate to provide a basis of confidence that licensing actions are protective of health and safety of workers, the public, and the environment. Agreement States have the flexibility to develop their own licensing procedures or to utilize the guidance provided in the NUREG-1556 series. As noted above, in this case, it appeared to the review team that the State had adopted the NRC's NUREG 1556 series with the exception of Volume 20.

Comment 5: Section 4.2.2

The IMPEP team provided to Maryland, as part of the audit, the 25 obsolete SS&D registrations. Maryland has conducted an in-depth review of these sheets and all current Maryland sheets in the NRC registry. It is anticipated that most of these obsolete sheets will be deactivated before the November 3, 2011 Management Review Board meeting. Maryland respectfully requests that due to our ongoing evaluation and remediation of this matter, that Appendix G be removed from the final report.

Response 5:

The review team appreciates that the State is making progress toward deactivation of the obsolete registrations. As described in the draft IMPEP report, Appendix G provides the list of 25 obsolete registrations that are referred to in Recommendation 5. Appendix G serves to remove any guesswork as to which 25 obsolete registrations were identified by the review team and referenced in the recommendation. Appendix G provides information that can be used by a future review team to review and verify that the recommendation was addressed. No changes were made to the IMPEP report.

Comment 6: Status of Draft IMPEP report Recommendation 1

Since this issue was identified, the Division Chief and the Inspection Supervisor have conducted a thorough review. Findings revealed that only a few cases lacked sufficient documentation information pertaining to inspection review of previous non-compliance items. The review also revealed that these were isolated occurrences and not indicative of a program deficiency. It is the intent of the Inspection Supervisor to focus on this type of documentation during the review of each inspection report. The Inspection Supervisor has discussed this issue with the Inspectors and provided report writing training on numerous occasions before and after this IMPEP audit. Please note that based on the casework, the IMPEP review team noted that, with a few exceptions, inspection records were thorough, complete, consistent, and of a high quality. It is our concern that this recommendation may have been based on only a few isolated cases, and not a program-wide concern. Maryland requests that the IMPEP team reconsider and remove this recommendation. Please see the comments in our response to File 2 and File 6 of Appendix-C.

Response 6:

The review team reviewed 13 inspection casework files. Of those 13 inspection casework files, 3 casework files were for inspections wherein violations were identified during the previous inspection. In each of those 3 cases, the inspector's review of the previous violations was not documented. The IMPEP team recognizes that this is a small sample set; however, the review team cannot state that these were isolated occurrences because, of the 3 cases, all 3 cases did not document the review of the previous violations or indicate that the violations were not able to be reviewed and should be reviewed during a future inspection. Because the casework sample set was small, the review team also considered information that was obtained during interviews with the Inspection Supervisor as well as the available inspection staff related to practices for documenting inspections. In addition, the inspection documentation reviewed ("Radioactive Materials Inspection and Compliance Division Narrative Report Form") did not provide a "place keeper" or section/box/space for inspectors to indicate that reviews of any previous violations were performed and document and inspection observations related to those previous violations. The review team appreciates that the State is taking measures to improve its documentation of the review of previous violations. The review team has reconsidered the recommendation and believes that it should be retained in the report. The MRB can review and deliberate on this matter. No changes were made to the IMPEP report.

Comment 7: Status of Draft IMPEP report Recommendation 2

During the August 12, 2011 IMPEP Management Exit Meeting, the audit team was informed that RHP was still unclear with the nature and scope of concerns and recommendations regarding the licensing review. We were informed, at that time that the matter would be clarified in the Draft Report Appendix D. Because it is still not totally clear to us in Appendix D, which comments are specific to the "needs for improvement" finding of the audit, and which may have been findings that would not have resulted in a "needs for improvement" we will respond to all the licensing IMPEP audit comments in this Appendix. Please note that NUREG 1556 Vol. 20 abstract indicates that the guide is intended for use by NRC staff and will be made available to Agreement State staff. Please see the comments to the IMPEP audit licensing findings in Section Comments Appendix-D.

Response 7:

As was explained during the exit meetings held with the State, the review team made its recommendation that the common performance indicator, Technical Quality of Licensing Actions, be found satisfactory but needs improvement, based on the criteria in NRC Management Directive (MD) 5.6. Throughout the IMPEP review, the team kept the State informed of any licensing deficiencies identified during the review and also provided case-specific comments in the applicable appendix in the draft report. The review team believes that information related to any particular licensing deficiencies has been communicated with the State. As to the review team's recommendation that that the common performance indicator, Technical Quality of Licensing, be found "satisfactory, but needs improvement," the review team will present its reasoning to the MRB in the same fashion that this information was presented to the State at the conclusion of the IMPEP. The MRB can review and deliberate on this matter. No changes were made to the IMPEP report.

Comment 8: Status of Draft IMPEP report Recommendation 3

On August 18, 2011, the license identified in Appendix D File No.1 was appropriately amended to authorize the manufacturer/distribution of sealed sources or devices for medical use.

Response 8:

Thank you for this update. No changes were made to the IMPEP report.

Comment 9: Status of Draft IMPEP report Recommendation 4

(1) RHP 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 documentation will be reviewed for appropriate content, and license reviewers will conduct a thorough evaluation of financial assurance requirements during each license renewal.

(2) Management of both cyclotron licensees in Maryland has been contacted. One licensee (same as NRC Region I) has 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. The licensee's submittal is currently under review. The other licensee (broad scope) is in the process of conducting a review of their decommissioning funding plan for submittal to RHP. 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 before the end of this year. Any deficiencies in documentation or technical sufficiency of submittals will be addressed.

Response 9:

Thank you for this update. No changes were made to the IMPEP report.

Comment 10: Status of Draft IMPEP report Recommendation 5

Maryland hopes to complete most of these deactivations by our November 3, 2011 MRB. We anticipate resolution of all deactivations by the end of this year.

Response 10:

Thank you for this update. No changes were made to the IMPEP report.

Comment 11: Appendix C, File 2, Comment 1

It is true that the inspection record did not document a review of the licensee's corrective actions related to non-compliance from the previous inspection. However, this finding is just one, of only a few exceptions, where inspection records were not, as stated by the IMPEP team, to be thorough, complete, consistent, and of high quality. The inspection was conducted on August 25, 2010 and the report was completed on August 30, 2010 by the Lead Inspector just prior to his military deployment. The report was brief and the inspector had numerous professional, personal, domestic and military deadlines to meet during this month and did not spend enough time on the report. Please note that no items of non-compliance or unsafe conditions were identified during this Team Inspection conducted by three Maryland Health Physicists/Inspectors. This Lead Inspector has a report writing style that includes a large volume of pertinent documents that were reviewed during the inspection. For example, if the licensee documented corrective actions in a memorandum or an audit, it would be routine for this Lead Inspector to review, discuss, evaluate and then request a copy of that document and include it in his report. Unfortunately, the attachments to this report were not available for review during this audit. In addition, this Lead Inspector was not available for interviews and questioning regarding this issue. We are confident that this Senior Inspector, with over 20 years of materials inspection experience, would have adequately addressed this comment given the opportunity. Interviews with the other two inspectors who participated in the Team Inspection revealed that the inspection adequately reviewed the licensee's corrective actions related to the previous inspection. After a careful review, we conclude that this issue is an isolated occurrence and not indicative of a programmatic deficiency that needs to be documented in a public record. We respectfully request that this comment and its recommendation be removed.

Response 11:

It was unfortunate that the inspector was not available to be interviewed by the review team and that any additional inspection records related to a review of the previous violations could not be located. The review team interviewed the two other individuals who participated in the inspection and were provided with assurances that these previous violations were reviewed. The review team's concern was that the review of the previous violations was not documented as opposed to not being reviewed. As noted by the State, this was a "team inspection" and although the lead inspector was unable to document the review of previous violations prior to his military deployment, there were two other inspectors on the inspection that also did not document the review of the previous violations. No changes were made to the IMPEP report.

Comment 12: Appendix C, File 2, Comment 2

It is correct that that the inspection record did not adequately document a review of the cyclotron portion of the inspection. The inspection was conducted over a year ago and since then; the Program has taken numerous actions to improve the quality of nuclear pharmacy inspections and reports. Prior to this IMPEP audit, the NRC identified a need for NRC and Agreement State Inspectors, including inspectors with decades of experience, to receive additional structured training in nuclear pharmacy inspections. Within a month after this inspection report was written, three RHP Health Physicists completed the NRC's newly created Nuclear Pharmacy Course. Since completing this course we are better prepared to meet the NRC's expectations when conducting pharmacy inspections and preparing reports. The Inspection Supervisor also provided pharmacy inspection training to the two materials inspectors using the knowledge and documents received at the Nuclear Pharmacy Course. We plan to train again prior to conducting the next Nuclear Pharmacy inspection. Since this issue was addressed prior to the IMPEP audit, we respectfully request that this comment be removed.

Response 12:

The comment is related to a particular casework file and is not a broad overarching comment on the State's program. For this particular file, there was inadequate documentation of the cyclotron portion of the inspection. This is a separate issue from any past training that has been performed or any planned future training. No changes were made to the IMPEP report.

Comment 13: Appendix C, File 6

It is true that the report of the June 14, 2011 GBMC inspection did not document a review of the licensee's corrective actions related to non-compliance from the previous medical event investigation. The status of compliance and the licensee's corrective actions were documented in a separate report. On December 6, 2010 Ray Manley and Alan Jacobson conducted a follow-up inspection at GBMC. The inspection focused on the violations identified during the Cs-137 Low Dose Brachytherapy medical event and the licensee's corrective actions. As a result, the corrective actions were documented in a separate report. Prior to the June 14, 2011 inspection, the inspector reviewed the previous report regarding the corrective actions status of compliance with the violations identified during the Cs-137 low dose brachytherapy medical event. Interviews with GBMC personnel and a review of records conducted at the beginning of the inspection

revealed that GBMC had not conducted any Cs-137 low dose rate brachytherapy since the date of the medical event. As a result, the inspection and the inspection report focused on licensed activities involving radiation therapy that were conducted since the previous inspection. Since a review of the licensee's corrective actions related to non-compliance from the previous medical event investigation was conducted prior to this inspection and the status of compliance including the licensee's corrective actions were documented in a separate report, we respectfully request that this comment be removed. Further, since this comment refers to corrected violations that apply to both safety and security of a Safeguards facility, we are concerned that it may not be appropriate to place in a public document. We respectfully request that this comment be removed.

Response 13:

The inspection in question was one of the inspections during which a review team member accompanied the inspector. For various reasons not discussed here, the inspector did not review all of the licensee's corrective actions related to the previous violation during the inspection. During the casework review, the review team noted that there was no documentation that any review (even a partial review) of the previous violation was reviewed. Not only did the inspector not note which portions were reviewed and found to be adequate, but the inspector also did not note which corrective actions were not reviewed or not able to be reviewed. For previous violations, it is important to not only document what was reviewed but also do document what was not reviewed so that it can be reviewed during the next inspection. No changes were made to the IMPEP report.

Additionally, this licensee is not a "Safeguards facility" and has not been identified as such in the draft report. The review team did not include any Safeguards Information in the IMPEP report or identify any facilities as such. The draft IMPEP report already is a publicly available document.

Comment 14: Appendix C, File 10

We acknowledge that the Supervisor's review of the inspection record identified missing or incomplete data and the inspection record was not corrected. The Supervisor reported the issue to the Program Manager. The Program Manager conducted an extensive review that included an examination of the report, interviews with the two inspectors and numerous discussions with the Supervisor. The Program Manager also directed the Supervisor to conduct Increased Control Report Writing Training prior to the next round of IC Inspections. Since the Supervisor did identify the missing or incomplete information in the report, the issue was escalated to Program's Manager, the Program Manager conducted an extensive review and the Supervisor implemented the Manager's directive regarding this issue, we respectfully request that this comment be removed.

Response 14:

The comment is related to this particular casework file and is not a broad overarching comment on the State's program. For this particular file, when the supervisor identified and documented that there was missing or incomplete data, the inspector was not asked to correct the report and provide the missing information. In the time since, perhaps there has been additional training in this area, but the comment in the draft IMPEP report is about this particular casework file. No changes were made to the IMPEP report.

Comment 15: Appendix C, File 11

The March 25 & April 8, 2008 inspection identified several safety significant items of non-compliance that were corrected prior to the completion of the inspection. Please note that the licensee was not operating the panoramic irradiator without working safety systems. The irradiator was down for maintenance and repair. A formal follow-up inspection was not conducted so perhaps that is why the documentation did not meet the Team Leader's expectations. A formal follow-up inspection was not scheduled for several reasons including that the security and safety significant violations were corrected by the time of the exit interview. The main violation involved a failure of alarm transmittal component that was corrected by the end of the first day of the inspection. This component was essential for compliance with the monitor, detect, access and respond requirement of the NRC Safeguards Order. The licensee was in the process of upgrading numerous security and safety systems. On May 12, 2010 NNSA completed a Security Assessment. More improvements were completed during the month of August 2010. The Safeguards Inspection was conducted by a Maryland Inspector on September 1, 2010. On July 15, 2011 NNSA, PNNL and the licensee completed substantial security and safety upgrades. A follow-up Safeguards inspection was conducted on July 26, 2011 just prior to the IMPEP audit. Corrective actions and the status of compliance were reviewed; however, the report was yet not completed during the IMPEP Team's August 8-12, 2011 audit. The Team Leader reviewed the documentation of the safety system checks.

Response 15:

The comment in the IMPEP report is related to several safety-significant non-compliances and is not related to any potential security-related findings. As discussed several times with State management during the IMPEP review and exit meetings, the IMPEP report only addresses activities covered under the State's 274b Agreement with the NRC and not the State's 274i Agreement with NRC. The review team did not include any Safeguards Information in the IMPEP report or identify any facilities as such. The draft IMPEP report already is a publicly available document. As noted in the comment in the draft IMPEP report, the State performed reviews of licensee actions related to the safety-significant non-compliances while present at the facility for other reasons but the reviews were not documented. No changes were made to the IMPEP report.

Comment 16: Appendix C, File 13

We agree that the July 22, 2011 licensee response was not adequate to correct the non-compliances. The document was under timely review during the IMPEP audit of August 8-12, 2011. The inspector discussed the deficiencies with the licensee on several occasions, explained the Department's expectations, and provided them with an

opportunity to submit an additional response. On August 23, 2011 the licensee submitted a revised response letter. The Program Manager, Inspector Supervisor and the Inspector determined that the response was acceptable. A September 14, 2011 acknowledgement letter describing this determination was sent to the licensee. Since this comment implies that the licensee's response is not adequate when, in fact the August 23, 2011 revised response was determined to be acceptable, we are concerned that it sends an incorrect statement about the licensee by placing it in a public document that will be posted on the web. We respectfully request that this comment be removed.

Response 16:

When the review team examined the casework file and reviewed the licensee's response, it did not appear to be adequate to correct the non-compliances. This was discussed with the inspector. The inspector had already accepted the licensee's response and prepared a standard acknowledgement letter for the licensee. This comment was written because the inspector did not recognize that the corrective actions would not be adequate until the review team member discussed it with the inspector. It was this discussion that led to the State's request for additional information from the licensee. Understanding that the State's actions in this case were therefore ongoing at the time of the review, the comment was removed from the report.

Comment 17: Appendix C, Accompaniment 3

The Licensee is listed as Sanford Medical Center Fargo. Please change to Anne Arundel Medical Center. Are you certain that this comment is intended for Anne Arundel Medical Center instead of Sanford Medical Center in Fargo?

During this inspection, the inspector was focused, in part on conducting a review and assembling information to document the licensee's corrective actions related to the non-compliance items identified on the previous inspection and collecting information necessary to support two violations, As noted in the report, this was the inspector's first increased controls inspection. It was conducted upon request by the IMPEP Team Leader to conduct an accompaniment of an Increased Control licensee. The previous IC inspection of this licensee was conducted on March 5, 2009. Prior to the request, we had planned to conduct the inspection at a later date. To accommodate the Team Leader's request, the inspector was trained and qualified prior to this inspection. Discussions with between the IMPEP Team Leader, the Inspector and the Inspection Supervisor after the inspection revealed that the inspector "did a good job." It was not until the next week that the Team Leader notified the RHP of the significance of this issue and the request was made to conduct an addition accompaniment. Since this comment refers to the compliance status and inspection of increased controls requirements and associated corrective actions, and it is not necessary to place in this public document, we respectfully request that it is removed.

Response 17:

We regret that the name of the licensee was not correctly documented but the remaining information as well as the comment does apply to the accompaniment inspection performed at Anne Arundel Medical Center in Maryland. The name of the licensee was corrected in the IMPEP report to Anne Arundel Medical Center.

Prior to the IMPEP, the review team leader had several communications with the State regarding performing accompaniment inspections. The State was requested that at least one of the accompaniment inspections be of a facility implementing the Increased Controls. At no point prior to the accompaniment inspections was the team leader informed that inspector AG was not yet qualified for Increased Controls inspections. It was the State that assigned the inspectors to perform the selected inspections and not the review team leader. The team leader made no such request that inspector AG be trained and qualified prior to the inspection because the team leader was not informed that the individual was not yet qualified to perform that type of inspection.

It was only after the accompaniment inspection, when the team leader discussed some concerns related to the accompaniment inspection with the State that the team leader was informed that this was inspector AG's "first solo inspection" of an Increased Control licensee and that he had only recently been qualified to perform these types of inspections. When the team leader asked why the State had not previously mentioned that inspector AG had only recently been qualified and that this would be his first solo inspection of the increased controls, the team leader was told that the individual was qualified at the time of the inspection and that "it wasn't a big deal." The team leader informed the State of the specific concerns and stated that other than the discussed concerns, the inspector "did a good job" with the other aspects of the inspection, such as those related to radiation safety.

It was also at that time that the team leader was informed that the other inspector FA was not qualified to perform increased controls inspections. The team leader inquired as to whom then was qualified to perform increased controls inspections. The team leader was informed that it was inspector RN who was on military leave that had been qualified and was performing increased controls inspections prior to his military leave. The State also noted that the Inspection Supervisor AJ was a qualified increased controls inspector.

Following the discussion with the State, the team leader discussed the matter with the IMPEP Project Manager. The suggestion was made by the IMPEP Project Manager that an additional accompaniment inspection at an Increased Controls licensee be performed with the Inspection Supervisor, the only available qualified increased controls inspector. The team leader discussed this option with the State, who agreed to the additional inspector accompaniment.

The draft IMPEP report does not contain any sensitive-security related information and is a public document.

No changes were made to the IMPEP report.

Comment 18: Appendix D, File 2

License number referenced should be 07-005-03

We are currently evaluating with intent to improve our understanding, implementation and use of NUREG 1556 Guidance. Following NRC's response to comment five of this document and RAMLCD staff evaluation, we will conduct additional license staff reviewer training to improve the technical level of license review in all areas where achievable.

IMPEP Comments and Status 1 & 2

RHP will review and issue amendments necessary to adequately address these comments. Any lessons learned will be addressed in licensing procedures and included as training in future license reviewer meetings.

IMPEP Comment 3:

RHP respectfully does not agree with this comment and requests that it be removed. The application as submitted contains clear documentation of broad scope responsibilities that adequately describes Radiation Control Committee (RCC) responsibilities in the areas of new users, new uses, and facilities. Page 8-18 of NUREG 1556 Vol. 11 "Program Specific Guidance about Licenses of Broad Scope" under response from applicant states that applicants for type A broad scopes should submit criteria by the RSC and RSO for approving new users and new uses. Licensee documentation submitted (as reviewed by the IMPEP team) contained commitments and scope of evaluation for training, experience, oversight supervision, qualification of investigator, evaluation for application for human use, ALARA, limit on pharmacological dose, quality of drugs, human use research subjects, and research protocol. The content and implementation of the licensee broad scope generated procedures are thoroughly reviewed during the State inspection process. Of note, because of the large scope of this licensee, it has been reviewed during every past IMPEP audit cycle with no findings identical to this IMPEP. The scope, content and review of the submitted applications have been consistent since the IMPEP process started.

IMPEP Comment 4 & 5:

Please see Maryland status to IMPEP recommendation number 5.

Response 18: Appendix D, File 2

The license number for Appendix D, File 2, was corrected to 07-005-03.

Regarding Appendix D, File 2, Comments 1 and 2: Thank you for this update. No changes were made to the IMPEP report.

Regarding Appendix D, File 2, Comment 3: Based on the team's review of the casework file, it was found that criteria had not been submitted for approval of new users, uses, and facilities. The team found general statements regarding licensee development of criteria to ensure safe use. The Licensing Supervisor and a license reviewer indicated that such reviews of criteria are not routinely performed during renewals since this information should have been reviewed during inspections. The language of Comment 3 was modified in the report.

Regarding Appendix D, File 2, Comments 4 and 5: Thank you for this update. No changes were made to the IMPEP report.

Comment 19: Appendix D, File 3

License number referenced should be 07-005-03

We are currently evaluating with intent to improve our understanding, implementation and use of NUREG 1556 Guidance. Following NRC's response to comment five of this document and RAMLCD staff evaluation, we will conduct additional license staff reviewer training to improve the technical level of license review in all areas where achievable.

Response 19:

The license number for Appendix D, File 3, was corrected to 07-005-03.

Comment 20: Appendix D, File 4

License number referenced should be 07-005-03

We are currently evaluating with intent to improve our understanding, implementation and use of NUREG 1556 Guidance. Following NRC's response to comment five of this document and RAMLCD staff evaluation, we will conduct additional license staff reviewer training to improve the technical level of license review in all areas where achievable.

IMPEP Comment 1:

Maryland respectfully disagrees with this comment and requests its removal. Am-241 had already previously been approved on the license and safety considerations addressed at that time. Ra-223 was being authorized and approved for safety for radiopharmaceutical use under a review and authority of an approved broad scope license RSC.

IMPEP Comment 2:

RHP will issue an amendment to address this comment. Any lessons learned will be addressed in licensing procedures and included as training in future license reviewer meetings.

IMPEP Comment 3:

As described during the audit, through inspection and discussions with the licensee, it had been determined, that the licensee did not possess and had no future intention of acquiring IC quantities of concern. However, RHP agrees that it is prudent to issue a special license condition to any licensee whose possession limit indicates a potential to exceed these IC amounts. We agree that should the licensee acquire radioactive material in excess of IC limits the condition will establish burden of regulatory action on the licensee. RHP is reviewing all licenses to determine those that the condition is appropriate and requests a copy of the NRC condition wording. Any lessons learned will be addressed in licensing procedures and included as training in future license reviewer meetings.

Response 20:

The license number for Appendix D, File 4, was corrected to 07-005-03.

Regarding Appendix D, File 4, Comment 1: The team acknowledges that americium may have previously been included on the license prior to Amendment No. 56. However, the comment focuses on the failure to obtain specific facility, equipment, and safety precautions implemented for alpha emitters prior to their addition to the license. Such specific information is important due to the potential significant impact on workers, the public, and the environment. The amendment request reviewed by the team did not provide such a description. No changes were made to the IMPEP report.

Regarding Appendix D, File 4, Comment 2: Thank you for this update. No changes were made to the IMPEP report.

Regarding Appendix D, File 4, Comment 3: Thank you for this update. No changes were made to the IMPEP report.

Comment 21: Appendix D, File 5

License number referenced should be 07-005-03

We are currently evaluating with intent to improve our understanding, implementation and use of NUREG 1556 Guidance. Following NRC's response to Comment five of this document and RAMLCD staff evaluation, we will conduct additional license staff reviewer training to improve the technical level of license review in all areas where achievable

IMPEP Comment:

Please see response and status of File 4 IMPEP Comment 1

Response 21:

The license number for Appendix D, File 5, was corrected to 07-005-03.

Regarding Appendix D, File 5, Comment: The comment focuses on the failure to obtain specific facility, equipment, and safety precautions implemented for alpha emitters prior to their addition to the license. Such specific information is important due to the potential significant impact on workers, the public, and the environment. The amendment request reviewed by the team did not provide such a description. No changes were made to the IMPEP report.

Comment 22: Appendix D, File 6

IMPEP Comment 1:

Maryland respectfully disagrees with this comment and requests that it be removed. COMAR 26.12.01.01Section D.803 clearly addresses licensee requirements for security of all portable gauges in Maryland. In fact, from a safety and security standpoint, NRC may wish to evaluate our Section D.803(b), that in addition to NRC regulations, requires the portable gauge licensee to ensure that the source locking mechanism, for each device, is engaged in the secured and fully shielded position during storage and transport.

IMPEP Comment 2:

Maryland will amend this license to address this comment and review our other licensees to assure that this is not a programmatic problem. Any lessons learned will be addressed in licensing procedures and included as training in future license reviewer meetings.

Response 22:

Regarding Appendix D, File 6, Comment 1: After a review of the referenced regulation, the review team agrees that the regulation addresses all the issues contained in Standard License Condition 20 of NUREG-1556, Volume 20. The comment was removed.

Regarding Appendix D, File 6, Comment 2: Thank you for this update. No changes were made to the IMPEP report.

Comment 23: Appendix D, File 7

IMPEP Comment 1:

Please see State response to File 2 IMPEP Comment 3.

IMPEP Comment 2:

Maryland has evaluated, through the inspection process that this licensee does not need an emergency plan. However, RHP agrees that it is prudent to issue a special license condition to any licensee whose possession limit indicates a potential to exceed the emergency plan limits. We agree that should the licensee acquire radioactive material in excess of the emergency plan limits, the condition will establish burden of regulatory action on the licensee. RHP is reviewing all licenses to determine those that the condition is appropriate, and requests a copy of the NRC condition wording.

Response 23:

Regarding Appendix D, File 7, Comment 1: Based on the team's review of the casework file, it was found that criteria had not been submitted for approval of new users, uses, and facilities. The team found general statements regarding licensee development of criteria to ensure safe use. The Licensing Supervisor and a license reviewer indicated that such reviews of criteria are not routinely performed during renewals since this information should have been reviewed during inspections. The language of Comment 1 was modified in the report.

Regarding Appendix D, File 7, Comment 2: Thank you for this update. In its comment, the State asked for a copy of the license condition used by NRC in this scenario. Please see NUREG 1556, Volume 20, Standard License Condition 167. This License Condition can be used for broad scope licenses. No changes were made to the IMPEP report.

Comment 24: Appendix D, File 8

We are currently evaluating with intent to improve our understanding, implementation and use of NUREG 1556 Guidance. Following NRC's response to comment five of this document and RAMLCD staff evaluation, we will conduct additional license staff reviewer training to improve the technical level of license review in all areas where achievable.

IMPEP Comment:

This case of question of authority will be evaluated and addressed. We will carefully evaluate guidance and our procedures to make sure that this issue is clearly defined and addressed.

Response 24:

Thank you for this update. No changes were made to the IMPEP report.

Comment 25: Appendix D, File 10

IMPEP Comment:

Maryland will amend the license to address this comment and review our other licensees to assure that this is not a programmatic problem. Any lessons learned will be addressed in licensing procedures and included as training in future license reviewer meetings.

Response 25:

Thank you for this update. No changes were made to the IMPEP report.

Comment 26: Appendix D, File 11

IMPEP Comment 1:

Please see response to File 4 IMPEP Comment 3.

IMPEP Comment 3:

It was not previously understood that Maryland is required to use all of NUREG 1556 Vol. 20 standard license conditions. This will hopefully be clarified upon NRC's response to our questions regarding whether Agreement State Licensing is "performance based" or NUREG 1556 Vol. 20. "prescriptive based."

IMPEP Comment 4:

Maryland will carefully review this Maryland licensee to assure that all financial assurance information required specific to a State Institution has been evaluated, documented and maintained.

IMPEP Comment 5:

Maryland respectfully disagrees with this comment for reasons previously defined in File 2 Comment 3.

Response 26:

Regarding Appendix D, File 11, Comment 1: Thank you for this update. No changes were made to the IMPEP report.

Regarding Appendix D, File 11, Comment 3: As noted earlier, based on a review of the State's administrative licensing procedures, the State appeared to have largely adopted the NUREG-1556 Series, with the exception of Volume 20, to assist in their review of licensing actions. The team noted that NUREG-1556, Volume 1 (Portable Gauges) and Volume 4 (Fixed Gauges) was utilized by the State in performing portable and fixed gauge licensing reviews. The standard license conditions mentioned in the comment are also contained in those volumes. The language of Comment 3 was modified in the report.

Regarding Appendix D, File 11, Comment 4: Thank you for this update. No changes were made to the IMPEP report.

Regarding Appendix D, File 11, Comment 5: Based on the team's review of the casework file, it was found that criteria had not been submitted for approval of new users, uses, and facilities. The team found general statements regarding licensee development of criteria to ensure safe use. The Licensing Supervisor and a license reviewer indicated that such reviews of criteria are not routinely performed during renewals since this information should have been reviewed during inspections.. The language of Comment 5 was modified in the report.

Comment 27: Appendix D, File 12

<u>IMPEP Comments 1&4:</u>

Maryland will evaluate and issue amendments to the license to address these comments. Any lessons learned will be addressed in licensing procedures and included as training in future license reviewer meetings.

<u>IMPEP comment 2:</u>

RHP respectfully disagrees with this comment and requests its removal. The sealed source manufacturer and model number were provided in the applicant's June 30, 2008 submittal.

<u>IMPEP comment 3:</u>

RHP respectfully disagrees with this comment and requests its removal. The licensee specified two pages of Safety Office topics of user training in the applicant's June 30, 2008 submittal.

Response 27:

Regarding Appendix D, File 12, Comments 1 and 4: Thank you for this update. No changes were made to the IMPEP report.

Regarding Appendix D, File 12, Comment 2: The review team reviewed its notes for this casework file. In review of the casework file, the team reviewed an application dated September 21, 2007, and a letter dated June 23, 2008, and based Comment 2 on those documents. The team did not review a letter dated June 30, 2008 as part of its review for Amendment No. 29 and it is unclear as to whether this submittal was incorporated into the license. Assuming that the letter was part of the renewal review, properly incorporated into the license, and included the information described in Comment 2; then, the team agrees with the State. Comment 2 was removed from the report.

Regarding Appendix D, File 12, Comment 3: The review team reviewed its notes for this casework file. In review of the casework file, the team reviewed an application dated September 21, 2007, and a letter dated June 23, 2008, and based Comment 2 on those documents. The team did not review a letter dated June 30, 2008 as part of its review for Amendment No. 29 and it is unclear as to whether this submittal was incorporated into the license. Assuming that the letter was part of the renewal review, properly incorporated into the license, and included the information described in Comment 3; then, the team agrees with the State. Comment 3 was removed from the report.

Comment 28: Appendix D, File 13

IMPEP Comment 1:

RHP will re-review the licensee commitments, even though already reviewed and approved under the previous application.

IMPEP Comment 2:

Please see response for IMPEP recommendation number four.

Response 28:

Regarding Appendix D, File 13, Comment 1: Thank you for this update. No changes were made to the IMPEP report.

Regarding Appendix D, File 13, Comment 2: Thank you for this update. No changes were made to the IMPEP report.

Comment 29: Appendix D, File 14

IMPEP Comment 1:

Maryland respectfully disagrees with this comment and requests its removal. The licensee referenced has one mobile van that is only allowed to conduct operations at those temporary locations specified in the license. The evaluation and documentation of the above, is all tied down in the licensee's application.

IMPEP Comment 2:

The individual in question was appropriately qualified as RSO during the license review. The pages authorizing the individual as the RSO on Alliance's Illinois medical PET license were inadvertently discarded. We have requested, received, and filed the entire Illinois license into the file.

Response 29:

Regarding Appendix D, File 14, Comment 1: As noted in Comment 1, the review team agrees that the license limits the mobile use to specifically listed temporary locations. However, the licensee initially requested use at "temporary job sites" and there appeared to be no documented discussion with the licensee or reason as to why only specific temporary job sites were allowed. Comment 1 was removed.

Regarding Appendix D, File 14, Comment 2: Thank you for this update. No changes were made to the IMPEP report.

Comment 30: Appendix D, File 15

IMPEP Comment:

Maryland has effectively used the same methodology and format for license termination since around the year 2000 and respectfully requests this comment to be removed. This license document terminology has been through multiple positive reviews by previous IMPEP teams. Maryland will reevaluate how we format termination license documentation and has requested a copy of the current wording format used by NRC Region I.

Response 30:

The team appreciates the State's commitment to reevaluate their termination process to ensure that the licensee is notified that their facilities have been found to be appropriately decommissioned and all licensed material has been found to be appropriately disposed or transferred. The State's current method of license termination does not appear to clearly communicate this information; however, the team agrees that the notation included on these licenses confirms that the license was terminated. No changes were made to the IMPEP report.

Comment 31: Appendix D, File 17

IMPEP Comment 1:

Please see RHP response for File 15 IMPEP Comment

IMPEP Comment 2:

Maryland will modify our procedures to require all licensee's with sealed sources requesting termination to provide leak test records.

Response 31:

Regarding Appendix D, File 17, Comment 1: The team appreciates the State's commitment to reevaluate their termination process to ensure that the licensee is notified that their facilities have been found to be appropriately decommissioned and all licensed material has been found to be appropriately disposed or transferred. The State's current method of license termination does not appear to clearly communicate this information; however, the team agrees that the notation included on these licenses confirms that the license was terminated. No changes were made to the IMPEP report.

Regarding Appendix D, File 17, Comment 2: Thank you for this update. No changes were made to the IMPEP report.

Comment 32: Appendix D, File 18

IMPEP Comment:

Please see RHP response for File 15 IMPEP Comment

Response 32:

The team appreciates the State's commitment to reevaluate their termination process to ensure that the licensee is notified that their facilities have been found to be appropriately decommissioned and all licensed material has been found to be appropriately disposed or transferred. The State's current method of license termination does not appear to clearly communicate this information; however, the team agrees that the notation included on these licenses confirms that the license was terminated. No changes were made to the IMPEP report.

Comment 33: Appendix D, File 20

IMPEP Comment 2:

RHP requests additional clarification on this comment. This is a broad scope licensee with authority to generate these procedures. The content and implementation of any licensee broad scope generated procedures are thoroughly reviewed during the State broad scope inspection process.

IMPEP Comment 3:

RHP will carefully review this license to assure that all authority to conduct maintenance is resolved.

Response 33:

Regarding Appendix D, File 20, Comment 2: As stated previously, the State appeared to have adopted NUREG-1556, Volume 11 in their licensing procedures, which includes a reminder to licensees and license reviewers in the Purpose section, that guidance related to specific program areas may be found in other volumes of the NUREG-1556 series, such as NUREG-1556, Volume 5, which the State also appeared to have adopted. This guidance requests that licensees using self-shielded irradiators commit to developing procedures that meet the criteria or submit alternative procedures. In this case, the licensee committed to following the manufacturer's procedures and it was

unclear whether the manufacturer's procedures would meet the criteria. Comment 2 was removed.

Regarding Appendix D, File 20 Comment 3: Thank you for this update. No changes were made to the IMPEP report.

Comment 34: Appendix E, Sealed Source and Device Incident Casework Reviews, File 19, Comment 2

RHP is currently carefully reviewing the device modification to determine if any change is needed to the licensee device's SS&D sheet.

Response 34:

Thank you for this update. No changes were made to the IMPEP report.

Comment 35: Appendix F, File 20

Some clarification to the comment is provided and it is respectfully requested that this comment be removed. Initially when the FDA 510K approval was not immediately available, a copy of the approval was retrieved from the licensee to prove that the approval had been made. Later that same day, the original FDA 510K approval documentation was found to be misfiled in this very large SS&D application and was in fact with the documentation. The IMPEP auditor was notified that same day regarding the finding of the document.

Response 35:

There is no Appendix F, File 20. The comment will be assumed to touch upon all Appendix F casework files where FDA Approval Summary is noted to be absent from registrations (Files 1, 2, 3, and 9). The comments in Files 1, 2, 3, and 9 were not removed from the IMPEP report because maintaining the FDA approvals with the files was not at issue. Rather, the absence of the FDA Approval Summary from the registrations was at issue. The comments in Files 1, 2, 3, and 9 intended to describe that although the devices did receive FDA approval and the FDA 510k approval was maintained in the file by the State, the FDA Approval Summary was not included in the registration. As a point of clarification, for casework files 1, 2, 3, and 9, the last sentence of the comments was changed to "The device did receive FDA 510k approval and the approval was maintained with the file."