September 7, 2011

Robert M. Summers, Ph.D., Secretary
Maryland Department of the Environment
1800 Washington Boulevard
Baltimore, MD 21230

Dear Dr. Summers:

The U.S. Nuclear Regulatory Commission (NRC) uses the Integrated Materials Performance Evaluation Program (IMPEP) in the evaluation of Agreement State programs. Enclosed for your review is the draft IMPEP report that documents the results of the Agreement State review held in Maryland on August 8-12, 2011. The review team's preliminary findings were discussed with members of your staff on the last day of the review.

The NRC conducts periodic reviews of Agreement State programs to ensure that public health and safety are adequately protected from the potential hazards associated with the use of radioactive materials and that Agreement State programs are compatible with NRC's program. The process, titled IMPEP, employs a team of NRC and Agreement State staff to assess Agreement State and NRC Regional radioactive materials programs. All reviews use common criteria in the assessment and place primary emphasis on performance. Two additional areas applicable to your program were reviewed as non-common performance indicators and are also addressed in the assessment. The final determination of adequacy and compatibility of each program, based on the review team's report, is made by a Management Review Board (MRB) composed of NRC managers and an Agreement State program manager, who serves as a liaison to the MRB.

The review team is recommending that Maryland's performance be found 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 made five recommendations regarding the State's performance. The review team's proposed overall recommendation is that the Maryland Agreement State Program be found adequate to protect public health and safety, and compatible with NRC's program.

In accordance with procedures for implementation of IMPEP, I am providing you with a copy of the review team's draft report for your review and comment prior to submitting the report to the MRB. Comments are requested within four weeks from your receipt of this letter and can be emailed to me at Janine.Katanic@nrc.gov. The team will review your response, make any necessary changes to the report, and issue it to the MRB as a proposed final report.

Coordinating with your staff, I have scheduled the Maryland MRB meeting for November 3, 2011, from 10:00 AM- 12:30 PM EST. The NRC will provide invitational travel for you or your designee to attend the MRB meeting at NRC Headquarters in Rockville, Maryland. The NRC has video conferencing capability if it is more convenient for the State to participate through this medium. Please contact me if you desire to establish a video conference for the meeting or will participate in person.

If you have any questions regarding the enclosed report, please contact me at (817) 860-8151.

Thank you for your cooperation.

Sincerely,

/RA K.N. Meyer for/

Janine F. Katanic, Ph.D., CHP
Health Physicist
Division of Materials Safety and State Agreements
Office of Federal and State Materials
and Environmental Management Programs

Enclosure:
Draft Maryland IMPEP Report

cc w/encl:

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OFFICIAL RECORD

INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF THE MARYLAND AGREEMENT STATE PROGRAM

AUGUST 8-12, 2011

DRAFT 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.

Based on the results of the review, the review team recommends 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 made five 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 is adequately documented in inspection records; (2) take measures 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) perform a review of the 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 manufacture/distribution of sealed sources or devices for medical use; (4) 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 (5) 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."

The review team's proposed overall recommendation is 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 recommends 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 paragraph on the results of the Management Review Board (MRB) meeting will be included in the final report.]

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 recommends 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 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% of the assigned inspection frequency) and no inspections were overdue at the time of the review. The review team identified a few entries 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 they should have been, the review team determined that none of the errors resulted in any inspections being overdue at the time of the review. The inspection supervisor committed to review the particular 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. Due to limitations with the Program's database, 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. Of those 67 inspections, three were conducted overdue. Additionally, there were six pending initial inspections, none of which were overdue at the time of the review. 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 inspection data from 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 2 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 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 recommends 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 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 recommends 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 generally be thorough, complete, consistent, and of high quality with health, safety, and security issues properly addressed; however some of the casework reviewed identified performance issues. 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); and high dose-rate remote afterloader licensees did not submit detailed spot-check procedures as required by the regulations. 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. Some licenses were terminated without submission of sealed source leak test results. The review team recommends that the State take measures 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.

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 licensee in a different Agreement State is authorized by their respective license to manufacture some of the sources in question but is not authorized by its license to distribute the sources. Another consideration in this case is that some of the sources and all of the devices are manufactured outside the United States. Guidance provided in NUREG-1556, Volume 12, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution," states, in part, that "Some "manufacturers" are importers of materials and devices from abroad and do not require the same extent of information submission and review as a facility that produces an item. However, they are required to have a manufacturer/distributor license as the initial importer and distributor in 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. The review team recommends that the State perform a review of the 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 manufacture/distribution of sealed sources or devices for medical use.

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. Issues related to financial assurance are a matter of health and safety and are considered to be an item for adequacy for an Agreement State or NRC Regional licensing program. 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 recommends 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 recommends 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. The State has reviewed and addressed the comments and expects that both amendments will be finalized in the next Supplement to the COMAR, which is expected to become effective in October 2011. At that time, the amendments will be submitted to NRC as final for review. 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.

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 recommends 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 contractor, SAIC, Inc., as related to support provided 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 sheets 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."

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 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 recommends that Maryland's performance be found satisfactory, but needs improvement for the performance indicator Technical Quality of Licensing Actions, and satisfactory for all other performance indicators (Technical Staffing and Training; Status of the Materials Inspection Program; Technical Quality of Inspections; Technical Quality of Incident and Allegation Activities; Compatibility Requirements; and SS&D Evaluation Program). The review team made five recommendations regarding the performance of the State.

Overall, the review team recommends 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 recommends 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 is adequately documented in inspection records. (Section 3.3)

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 licensing actions are thorough and consistent with the regulations and appropriate licensing guidance. (Section 3.4)

3. The review team recommends that the State perform a review of the 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 manufacture/distribution of sealed sources or devices for medical use. (Section 3.4)

4. 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)

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.” (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

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

Comments:

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

Comments:
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

Comments:
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

Comments:
The inspection results/record did not undergo management review since the inspector was a supervisor and there were no 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

Comments:
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

Comments:

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

Comments:

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

Comments:

The licensee's response to identified non-compliances did not appear to be adequate to correct the non-compliances. The reviewer discussed this with the inspector. The Program intended to discuss this matter with the licensee.

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: Sanford Medical Center - Fargo License No.: MD-03-001-05
Inspection Type: Special and Routine, Announced Priority: 5
Inspection Date: 6/15/11 Inspector: AG

Comments:
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 – HDR Distributor — Amendment No.: 52
Date Issued: 7/11/07 — License Reviewer: BP

Comments:

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-07-0005-03
Type of Action: Renewal – Medical Broad Scope — 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 Increased Controls did not include all radionuclides subject to the Increased Controls.
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 license reviewer did not ensure that the broad scope licensee submitted adequate procedures for the licensee's Radiation Safety Committee approval of new users, new uses, and facilities to give the Program a basis of confidence that the authorizations would be protective of health and safety of the public and environment.
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-07-0005-03
Type of Action: Amendment – Medical Broad Scope — Amendment No.: 58
Date Issued: 3/7/11 — License Reviewer: NO

Comments:

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-07-0005-03
Type of Action: Amendment – Medical Broad Scope 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 Increased Controls license conditions; however, the Increased Controls license condition was not included on the license.

File No.: 5
Licensee: Johns Hopkins Medical Institutions License No.: MD-07-0005-03
Type of Action: Amendment – Medical Broad Scope Amendment No.: 57
Date Issued: 8/30/10 License Reviewer: DM

Comments:
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 – Portable Gauge Amendment No.: 10
Date Issued: 9/10/09 License Reviewer: DM

Comments:
1) The license does not include standard license condition 50, regarding locking of devices, from NUREG-1556, Volume 20, “Consolidated Guidance About Materials Licenses: Guidance About Administrative Licensing Procedures.”
2) 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 – Medical Broad Scope Amendment No.: 82
Date Issued: 6/22/10 License Reviewers: NO, AF

Comments:
1) The license reviewer did not ensure that the broad scope licensee submitted adequate procedures for the licensee’s Radiation Safety Committee approval of new users, new uses, and facilities to give the Program a basis of confidence that the authorizations would be protective of health and safety of the public and environment (e.g., iodination facilities and uses, future irradiator facility and users).
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 – Research for Emerging Stereotactic Therapy Amendment No.:00
Date Issued: 3/10/11 License Reviewer: NO

Comments:

The license application was signed by an individual (Chair of the Department of Radiation Oncology). NUREG-1556, Volume 7, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Academic, Research and Development, and Other licenses of Limited Scope", Section 8.13 Item 13 "Certification" states that representatives signing an application must be authorized to make binding commitments and to sign official documents on behalf of the applicant. 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: Amend – Research for Emerging Stereotactic Therapy 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 - HDR Amendment No.: 36
Date Issued: 5/19/09 License Reviewer: NO

Comments:

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 – Research Broad Scope 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 Increased Controls license conditions; however, the Increased Controls 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 from NUREG-1556, Volume 20, "Consolidated Guidance About Materials

Licenses: Guidance About Administrative Licensing Procedures" 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 license reviewer did not ensure that the broad scope licensee submitted adequate procedures for the licensee's Radiation Safety Committee approval of new users, new uses, and facilities to give the Program a basis of confidence that the authorizations would be protective of health and safety of the public and environment.

File No.: 12
Licensee: University of Maryland College Park License No.: MD-33-004-03
Type of Action: Renewal – Pool Irradiator 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) Source manufacturer and model number was not provided and not requested.
3) Training for users indicates that training through the University of Maryland Radiation Safety Office will be conducted but does not specify topics.
4) 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 – added Cyclotron 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 – Mobile Nuclear Medicine Amendment No.: 00
Date Issued: 8/25/08 License Reviewer: BP

Comments:
1) Temporary job sites requested by the licensee; however the license was issued for use of mobile vans at permanent locations of use and this decision was not documented in the cover letter. Inspections have confirmed that vans are stationary.
2) 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 - 3620 Amendment No.: 05
Date Issued: 7/20/11 License Reviewer: DM

Comments:
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 - 3120 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 - 3121 Amendment No.: 04
Date Issued: 9/27/10 License Reviewer: NO

Comments:

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 - 3121 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 - 3510 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) The licensee committed to adopting the manufacturer's procedures in response to operating and emergency procedures; however, it is unclear whether the manufacturer's procedures would meet the Criteria Section in NUREG-1556, Volume 5, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Self-Shielded Irradiator Licenses," and the license reviewer did not request additional information.
3) 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 – Industrial Radiography 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

Comments:
The incident was identified by the licensee on 3/6/09 and reported to the State on 3/9/09.

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

Comments:
The incident was identified by the licensee on 8/25/09 and reported to the State on 9/18/09.

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

Comments:
The event was determined to be caused by patient intervention and not reportable to NRC.

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

Comments:

The licensee reported this event to the State on 2/19/10.

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

Comments:

The licensee reported this event to the State on 12/27/07.

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

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

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

Comments:

The State followed up on the event during the next routine inspection.

SEALED SOURCE AND DEVICE INCIDENT CASEWORKS REVIEWS

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

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

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

Comments:
A generic software issue was identified by the Program. The device is identified in SS&D Registration No. MD-0497-D-114-S. The licensee issued a Customer Service Bulletin.

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
Type of Investigation: Root Cause/Generic Application

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

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

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

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

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

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

Comments:
A generic software issue was identified by the Program. The device is identified in SS&D Registration No. MD-0497-D-110-S. The licensee issued Customer Service Bulletin.

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

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

Comments:
A generic software issue was identified by the Program. The device is identified in SS&D Registration No. MD-0497-D-114-S. The licensee issued a software update.

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

Comments:
A generic software issue was identified by the Program. The device is identified in SS&D Registration No. MD-0497-D-114-S. The licensee made plans to issue software update.

File No. 18:
Licensee: Nucletron Corporation License No.: MD-27-035-01
Date of Incident: 7/5/09 Incident Log No.: MD Anderson
Investigation Date: Not Available Type of Incident: Equipment
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
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 nor 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
Type of Investigation: Root Cause/Generic Application

Comments:
A generic software issue was identified by the Program. The device is identified in SS&D Registration No. MD-0497-D-114-S. The licensee issued a software update.

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
Type of Investigation: Root Cause/Generic Application

Comments:
A generic software issue was identified by the Program. The device is identified in SS&D Registration No. MD-0497-D-108-S. The licensee issued a Customer Service Bulletin.

File No. 22:
Licensee: Nucletron Corporation License No.: MD-27-035-01
Date of Incident: 10/12/07 Incident Log No.: Florida Cancer Center
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
Type of Investigation: Root Cause/Generic Application

Comments:
A generic software issue was identified by the Program. The device is identified in SS&D Registration No. MD-0497-D-108-S. The licensee issued a software update.

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
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
Type of Investigation: Root Cause/Generic Application

Comments:
A generic software was issue identified by the Program. The device is identified in SS&D Registration No. MD-0497-D-108-S. The licensee issued a Customer Service Bulletin and a Service Information Bulletin.

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

Comments:

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.

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

Comments:

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.

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.

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.

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

Comments:

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

Comments:

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