September 19, 2007

Mr. George Aburn, Director
Air and Radiation Management Administration
Maryland Department of the Environment
1800 Washington Boulevard, Suite 705
Baltimore, MD 21230

Dear Mr. Aburn:

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, which documents the results of the Agreement State review held in Maryland on August 20-24, 2007. I was the team leader for the review. The review team's preliminary findings were discussed with Angelo Bianca, Roland Fletcher, and other members of your staff on the last day of the review. The review team's proposed recommendations are that the Maryland Agreement State Program be found adequate to protect public health and safety and compatible with NRC's program.

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 both Agreement State and NRC Regional radioactive materials programs. All reviews use common criteria in the assessment and place primary emphasis on performance. Three additional areas applicable to your program have been identified as non-common performance indicators and are also addressed in the assessment. The final determination of adequacy and compatibility of each Agreement State 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.

In accordance with procedures for implementation of IMPEP, we are 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. This schedule will permit the issuance of the final report in a timely manner that will be responsive to your needs.

The team will review the response, make any necessary changes to the report, and issue it to the MRB as a proposed final report. Our preliminary scheduling places the Maryland MRB meeting in the week of November 5, 2007. I will coordinate with you to establish the date for the MRB review of the Maryland report. NRC will provide invitational travel for you or your designee to attend the MRB. 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.

If you have any questions regarding the enclosed report, please contact me at (301) 415-2598.

Thank you for your cooperation.

Sincerely,

/RA/
Duncan White, Chief
State Agreements and Industrial Safety Branch
Division of Material Safety and State Agreements
Office of Federal and State Materials
and Environmental Management Programs

Enclosure:
As stated

cc w/ encl: Roland G. Fletcher, Program Manager
Radiological Health Program
Air and Radiation Management Administration
Department of the Environment

Raymond E. Manley, Chief
Radioactive Materials Licensing and Compliance Division
Radiological Health Program
Air and Radiation Management Administration
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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF THE MARYLAND AGREEMENT STATE PROGRAM

AUGUST 20-24, 2007

DRAFT REPORT

U.S. Nuclear Regulatory Commission

ENCLOSURE

1.0 INTRODUCTION

This report presents the results of the review of the Maryland Agreement State Program. The review was conducted during the period of August 20-24, 2007, by a review team comprised of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of Maine. 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 the February 26, 2004, NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." Preliminary results of the review, which covered the period of July 26, 2003, to August 20, 2007, 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 environmental and radiological hazards 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) and the Radiation Machines Division. Organizational charts for the Department, the Program, and the Division are presented in Appendix B.

At the time of the review, the Maryland Agreement State Program regulated 633 specific licenses authorizing Agreement and non-AEA 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 28, 2007. The Program provided its response to the questionnaire on July 20, 2007, and an updated response on September 4, 2007. A copy of the updated questionnaire response may be found in the NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML072560263.

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

Section 2.0 of this report covers the State's actions in response to recommendations made during the previous review. Results of the current 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.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous IMPEP review, which concluded on July 25, 2003, the review team made three recommendations in regard to program performance by the State. The results of the review were transmitted to Mr. Thomas C. Snyder, Director, Air and Radiation Management Administration, on December 2, 2003.

The review team's evaluation of the current status of the recommendation is as follows:

1. The review team recommends that the State fill the current vacancies in the Program as soon as possible. (Section 3.1 of the 2003 report)

   Current Status: The Division was fully staffed at the time of the review. Details of the Division's staffing level are discussed in Section 3.1 of this report. This recommendation is closed.

2. The review team recommends that the Program implement an action plan to ensure that core inspections, including initial inspections, are performed in accordance with the NRC's inspection priorities. (Section 3.2 of the 2003 report)

   Current Status: The team determined that all core inspections were performed in accordance with the NRC's inspection priorities listed in Inspection Manual Chapter (IMC) 2800. At the time of the review, the Division had no overdue radioactive materials inspections. Details of the status of inspections are discussed in Section 3.2 of this report. This recommendation is closed.

3. The review team recommends that the Program conduct an appropriate evaluation of all licensing actions involving name changes and possible change in ownership/control. (Section 3.4 of the 2003 report)

   Current Status: The review team verified that the Division took appropriate action in evaluating all licensing actions and developing and implementing new licensing guidance. Details of the Division's actions are discussed in Section 3.4 of this report. This recommendation is closed.

3.0 COMMON PERFORMANCE INDICATORS

IMPEP identifies five common performance indicators to be used in reviewing 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; and reviewed job descriptions, training plans, 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 Licensing Section is responsible for processing license applications for the use of radioactive material and for performing sealed source and device (SS&D) evaluations. 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 and the Inspection Section each have authorization for one supervisor and three staff positions. At the time of the review, nine staff members, including managers and one contractor, worked full-time for the radioactive materials program. This staffing level does not include administrative support staff.

Until May 2006, the Division used the services of an engineer from elsewhere in the Department to perform SS&D evaluations. Since April 2007, the Division has used a contractor to perform these evaluations. Details of staffing in the SS&D program are provided in Section 4.2.1 of this report.

At the time of the review, the Division had no vacancies; however, during the review period, the Division experienced several periods of time in which the Inspection Section was not fully staffed. During most of the review period, the Inspection Section was down by one staff member. From July 2003 to September 2003 and from January 2007 to May 2007, the Inspection Section had only one inspector on staff. The Program addressed the staffing shortages by having Program supervisors and two license reviewers, who are also qualified radioactive materials inspectors, conduct inspections of Priority 1, 2, and 3 licensees. The staffing shortage resulted in a temporary backlog of inspections of Priority 5 licensees. This backlog is currently being addressed.

The review team noted that, although the Division was fully staffed at the time of the review, the loss of one staff member could adversely impact performance. Program funding decreased during the review period (see Section 4.1.2 for more details), challenging the Program's ability to fund training for new staff.

The staff are well-trained and qualified from an education and experience standpoint. All have Bachelor's degrees in the sciences. The Program has a documented training plan, the Radiological Health Inspection Manual, that is consistent with the guidance in the NRC/Organization of Agreement States Training Working Group Report and IMC 1246. The Radiological Health Inspection Manual has a chapter on training and qualification procedures, detailing training, inspection accompaniments, and evaluation by managers to qualify individual staff. Inspector requirements include NRC training courses, when available, or equivalents. The review team noted that Program management has exhibited a strong commitment to training. At the time of the review, the Program had five staff members that had attended the NRC's Security Systems and Principles Course. The Program also takes advantage of on-the-

job training opportunities. New staff members have also received training from other providers, including the Federal Emergency Management Agency, commercial vendors, and local educational institutions.

The Radiation Control Advisory Board of the State of Maryland, as constituted under the law, acts in a purely advisory role to the Department. The Ethics Law addresses ownership interests, employment, receipt of gifts, misuse of confidential information, activities of formal officials, representational activities, and misuse of position.

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 in 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 responses relative to this indicator, data obtained from the Program's database, examination of completed inspection casework, and interviews with managers and staff.

The review team verified that the Division's inspection priorities for various license types are at least as frequent as similar license types listed in IMC 2800. The Program utilizes inspection frequencies for various types of radioactive material licenses to conform with the priorities listed in NRC's Temporary Instruction 2800/033, Revision 02, "Revised Materials Inspection Program." The inspection priorities used during the review period were found to be generally the same as those listed in NRC Inspection Manual Chapter (IMC) 2800, although some categories of licenses were assigned inspection priority codes that prescribed a more frequent inspection schedule than those currently prescribed in IMC 2800. The review team identified 16 license categories that the Division inspects on a more aggressive schedule based on the Division's evaluation of radiological hazard and complexity of licensees.

During the review period, the Division conducted 302 routine inspections of Priority 1, 2, and 3 licenses and 147 initial inspections of new licenses. No inspections were completed or are currently overdue by more than 25 percent of the respective inspection priority listed in IMC 2800.

The review team examined the timeliness of inspection findings issued by the Division during the review period. Inspection findings are generally communicated to licensees in a timely manner. The Division's goal is to complete each inspection report and deliver the Notice of Violation, as appropriate, to the licensee within 30 days of the inspection's completion date. Of the 17 inspection files reviewed, all licensees were given a record of inspection at the conclusion of the inspection; however, six Notices of Violation were issued to licensees beyond the Division's goal. In all six cases, the violations were complicated or required extensive review before being sent to the licensee. In addition, two inspections that involved the assistance of the Maryland Attorney General's Office before issuance of the inspection report to the licensee did not meet the 30-day goal.

The review team determined that the Division granted reciprocity to 64 candidate licensees during the review period. The review team determined that the Division met and/or exceeded the NRC's goal of inspecting 20 percent of candidate licensees operating under reciprocity in each of the four years covered by the review period. The Division conducted 28 total inspections of candidate reciprocity licensees during the review period. In addition, the Division inspected 14 percent of non-candidate reciprocity licensees during the review period.

The review team determined that with respect to Commission Staff Requirements Memorandum (SRM) for COMSECY-05-0028, on Increased Controls, the Division planned for the initial set of inspections of these licensees in accordance with the SRM. The review team evaluated the Division's prioritization methodology and found it acceptable. The Program currently has 27 licensees that are subject to the Increased Controls. The Division elected to perform all of its Increased Controls inspections by July 1, 2007. The review team determined that the Division had met its goal and completed all of its Increased Controls inspections.

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 the inspection reports, enforcement documentation, and inspection field notes and interviewed inspectors for 17 radioactive materials inspections conducted during the review period. The casework examined included inspections performed by five of the Division's radioactive materials inspectors, including an inspector who is a new hire and only partially qualified. The review team examined inspections of various license types, including: industrial radiography, medical broad scope, medical institutions requiring written directives, nuclear pharmacy, irradiators, sealed source production and distribution, and Increased Controls. Appendix C lists the inspection casework files reviewed, with case-specific comments, as well as the results of the inspector accompaniments.

Based on the evaluation of casework, the review team found that routine inspections covered all aspects of the licensees' radiation safety programs. The inspection reports were thorough, complete, consistent, and of high quality, with sufficient documentation to ensure that licensees' performances with respect to health, safety, and security were acceptable. The documentation adequately supported the cited violations. Exit interviews were held with appropriate licensee personnel. Team inspections were performed when appropriate and for training purposes.

The review team found that routine inspections included a written summary of the scope of the licensed activities and violations identified by the inspector. The review team also noted that, in cases that involved significant and/or ongoing violations, the Division had exercised escalated enforcement action through the issuance of orders, imposition of civil penalties, or suspension of licensed activities. The review team found that the Division had a good process for reviewing draft inspection documentation and enforcement actions, making any needed changes and providing the inspector with feedback regarding the quality of the draft document.

The inspectors, including the supervisors, were accompanied at least once a year. All accompaniments were documented and kept on file.

The Program maintains an adequate supply of survey meters to support the inspection program, as well as to respond to incidents and emergency conditions. The Program has contractors who calibrate their survey instruments on an annual basis. Appropriate documentation of calibrated survey instruments such as GM meters, scintillation detectors, ion chambers, and micro-R meters was provided. Air monitoring equipment, as well as prepared emergency field kits, are available for emergency use. Contamination wipes are primarily evaluated at the Maryland Laboratory Administration facility located in Baltimore. This facility is also capable of other analyses, including gamma spectroscopy of air, soil, and water samples.

The review team accompanied three materials inspectors during the week of July 22, 2007, during health and safety inspections of a pool irradiator and two medical institutions licensed for diagnostic and therapeutic nuclear medicine. The accompaniments are identified in Appendix C. During the accompaniments, each of the inspectors demonstrated appropriate performance-based inspection techniques and knowledge of the regulations. The inspectors were well-prepared and thorough in their reviews of the licensees' radiation safety programs. The inspections were adequate to assess radiological health and safety at the licensed facilities.

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 interviewed license reviewers, evaluated the licensing process, and examined licensing casework for 17 licensing actions for 16 specific licenses. Licensing actions were reviewed for completeness, consistency, proper radioisotopes and quantities, qualifications of authorized users, adequate facilities and equipment, adherence to good health physics practices, financial assurance, operating and emergency procedures, appropriateness of the license conditions, and overall technical quality. The casework was also reviewed for timeliness, use of appropriate deficiency letters and cover letters, reference to appropriate regulations, supporting documentation, consideration of enforcement history, pre-licensing visits, peer/supervisory review, and proper signature authority. The files were checked for retention of necessary documents and supporting data.

The licensing casework was selected to provide a representative sample of licensing actions that were completed during the review period. The sampling included the following license types: specific medical, research and development, broad scope medical, medical therapy, radiopharmacy, portable gauge, industrial radiography, broad scope research and development, medical gamma knife, and high dose-rate remote afterloader. Licensing actions reviewed included three new licenses, three renewals, nine amendments, two terminations, and one financial assurance instrument. A listing of the license casework evaluated, with case-specific comments, may be found in Appendix D.

The review team found that the licensing actions were thorough, complete, consistent, and of high quality with health, safety, and security issues properly addressed. License tie-down conditions were stated clearly, backed by information contained in the file, and auditable. Deficiency letters clearly stated regulatory positions, are used at the appropriate time, and identified deficiencies in the licensees' documents.

Licensing actions are assigned to one of three license reviewers by the Licensing Section Supervisor, who also performs licensing reviews in order to reduce the backlog of pending actions. The status of all licensing actions are tracked on a database. The Licensing Section generates licenses and correspondence with standardized conditions and formats. The Licensing Section Supervisor reviews and initials all licenses before being sent to the Program Manager for signature. As of June 2003, the Licensing Section changed its license renewal frequency from a 5-year period to a 7-year period under a timely renewal system. The license reviewers utilize NRC licensing guides (NUREG-1556 series), as appropriate. The Program issues a complete license for each licensing action.

No major decommissioning actions were completed over the review period; however, the review team evaluated two termination actions. The review team found that terminations were well-documented, showing appropriate transfer records or appropriate disposal methods and records, confirmatory surveys, and survey records.

At the time of the review, no licensing actions were overdue. The review team determined that the Division's policy, whereby timeliness does not count against a particular licensing action when the licensee is responding to requests for additional information from the licensing staff, contributed to the timely dispatch of licensing actions.

The review team found that the Division has a policy of listing the radiation oncologists (authorized users), the neurosurgeons, and the medical physicists (all part of the medical team that must be present during treatment) under the authorized user license condition for gamma knife licenses. The review team discussed with the Division the benefits of listing the neurosurgeons and the medical physicists under a separate license condition to avoid confusing them as authorized users of the gamma knife.

During the 2003 IMPEP review, the team determined that three of four amendment actions containing requests for a name change and possible change in ownership/control of the license were not reviewed although the licensing staff was aware of the change in ownership/control guidance in NUREG-1556, Volume 15. In response to the recommendation in the 2003 report, the Division implemented new licensing guidance to ensure these type of requests were adequately reviewed. During this review, the review team verified that the Division implemented the guidance and has been reviewing all actions involving a name change and possible change in ownership/control.

The Division has a long-standing policy for conducting pre-licensing visits for all new applications for radioactive materials licenses. The visit covers all areas of an applicant's proposed radiation safety program and confirms the legitimacy of the applicant's need for radioactive materials. All pre-licensing visits are documented and signed by the inspector and the applicant's management representative.

The review team examined the list of licensees that the Division identified as meeting the criteria for the Increased Controls, per COMSECY-05-0028. The review team determined that the Division had correctly identified the licensees that required the Increased Controls based on this criteria. Each licensee was issued a license amendment requiring the Increased Controls in accordance with the time lines established by the Commission in the SRM for COMSECY-05-0028. The Division has the means to issue the Increased Controls to any new or amended licenses meeting the criteria, as well.

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.

3.5 Technical Quality of Incident and Allegation Activities

To evaluate the effectiveness of the Division'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 Division's files, and evaluated the casework for 10 radioactive materials incidents. A listing of the incident casework examined, with case-specific comments, may be found in Appendix E. The review team also evaluated the Program's response to 13 allegations, 7 of which were referred to the State by the NRC during the review period.

The review team discussed the Program's incident and allegation processes, including 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 discuss the event and determine the level of initial response based on the health and safety risk associated with the event. The actions taken in response to an event are documented and filed, and the data are submitted to the NRC's contractor responsible for maintaining NMED for inclusion in the database.

The review team identified 35 events in NMED for Maryland during the review period, of which 25 required reporting to the NRC Headquarters Operations Center. A review of the Division'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: damaged equipment, transportation, lost/stolen radioactive material, contamination, potential overexposure, and medical. The Division's responses to the incidents were complete and comprehensive. Initial responses were prompt and well-coordinated, and the level of effort was commensurate with the health and safety significance. Inspectors were dispatched for on-site investigations when appropriate. Enforcement and/or other regulatory actions were taken as appropriate.

The review team noted a majority of the incidents involved either damaged or lost/stolen portable gauges. In addition, the review team noted that the Division responded to two incidents involving Radium-226 that required a significant level of effort by the Division. These incidents involved contaminated railcars and instrumentation removed from older aircraft.

In evaluating the effectiveness of the Division's actions responding to allegations, the review team evaluated the casework for seven allegations referred to the State by the NRC and six received directly by the State. The casework review indicated that the Division took prompt and appropriate action in response to the concerns raised. The allegations were appropriately closed, and the appropriate parties were notified of the actions taken.

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

IMPEP identifies four non-common performance indicators to be used in reviewing 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. Maryland's Agreement does not include the authority to regulate uranium recovery activities; therefore, only the first three non-common performance indicators were applicable to this review.

4.1 Compatibility Requirements

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. 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 statutes for the control of radiation are contained in COMAR 26.12.01.01, "Regulations for the Control of Ionizing Radiation." COMAR 26.15, "Disposal of Controlled Hazardous Substances - Radioactive Hazardous Substances," contains statutes specific to low-level radioactive waste issues. Maryland requires a license for the possession and use of all radioactive material, including naturally-occurring materials, such as radium, and accelerator-produced radionuclides. 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 6 to 12 months from the development stage to the final approval by the Secretary of the Environment, after which the rule becomes effective in 10 days.

The review team noted that the State's rules and regulations are not subject to "sunset" laws. The State may adopt other agency's regulations by reference and has the authority to issue legally binding requirements (e.g., license conditions) in lieu of regulations until compatible regulations become effective.

The review team evaluated the Program's response to the questionnaire relative to this indicator, reviewed the status of regulations required to be adopted by the State under the Commission's adequacy and compatibility policy, and verified the adoption of regulations with data obtained from the Office of Federal and State Materials and Environmental Management Programs's (FSME) State Regulation Status Sheet.

On June 28, 2007, the NRC provided comments to the State on a package of proposed regulations which included the following:

- "Medical Use of Byproduct Material," 10 CFR Part 20, 32, and 35 amendments (67 FR 20249) that became effective on October 24, 2002, and was due for Agreement State adoption by October 24, 2005.

- "Medical Use of Byproduct Materials - Recognition of Specialty Boards," 10 CFR Part 35 amendment (70 FR 16336, 71 FR 1926) that became effective on April 29, 2005, and is due for Agreement State adoption by April 29, 2008.

- "Security Requirements for Portable Gauges Containing Byproduct Material," 10 CFR Part 30 amendment (70 FR 2001) that became effective on July 11, 2005, and is due for Agreement State adoption by July 11, 2008.

The State amended the above listed regulations based on the NRC's comments and expects the amendments to be adopted in final by November 2007.

The review team identified the following two NRC amendments that need to be addressed:

- "Compatibility with IAEA Transportation Safety Standards and Other Transportation Safety Amendments," 10 CFR Part 71 amendment (69 FR 3697) that became effective on October 1, 2004, and is due for Agreement State adoption by October 1, 2007.

- "Minor Amendments," 10 CFR Part 20, 30, 32, 35, 40 and 70 amendments (71 FR 15005) that became effective March 27, 2006, and is due for Agreement State adoption by March 27, 2009

The review team discussed the Program's funding status with Program managers. Since the last review in 2003, the Program has seen an overall decrease in funding for the program. In 2003, the Program received approximately 65 percent of its funding from fees and 35 percent from the general fund. Currently, all funding for the Program is through fees. Since there has been no increase in fees since 2002, the Program's budget has effectively decreased by 35 percent. Program managers indicated that they have sufficient funds for the current fiscal year that ends on June 30, 2008. The Program has drafted their fee regulations to include a substantial increase in fees to go into effect in July 2008. During the on-site exit meeting, the review team discussed this matter with Department managers. Department managers were aware of the funding situation and were supportive of increasing fees.

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 conducting this review, the review team used three sub-elements to evaluate the Division's performance regarding the SS&D Evaluation Program. The three 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 SS&D Evaluation Program, the review team examined information provided in the Program's response to the IMPEP questionnaire on this indicator; reviewed a sample of new, amended, and inactivated SS&D evaluations and supporting documents completed during

the review period; verified the Division's use of guidance documents and procedures; and interviewed managers and staff.

4.2.1 Technical Staffing and Training

The Division has four staff members who are fully qualified to conduct SS&D safety evaluations and have signature authority to sign SS&D registration certificates. The review team identified no changes in the Division's staffing or the staff's qualifications since the previous review regarding those staff members who conduct SS&D evaluations. Consequently, the review team did not examine the Division's training procedures or the training records of the four qualified individuals.

The review team noted that the Division's staff did not have the opportunity during the review period to address the traditionally broad spectrum of SS&D cases. Specifically, due to the limited product lines of the SS&D vendors who submitted applications to the Division during the review period, the Division's staff could only review two types of devices (high-dose remote afterloader and gamma gauge). As a consequence of a limited scope of SS&D activities, the staff's skills were not fully utilized or adequately challenged. The review team noted that in its evaluation of the two inactivation cases, some administrative issues had not been addressed in accordance with nationwide practices. The review team concluded that the Division's SS&D reviews adequately addressed all safety issues. The review team discussed the potential benefit of Division staff working with NRC or other Agreement State SS&D groups to perform a variety of SS&D tasks in order to enhance their skill levels.

The Division currently utilizes outside resources to conduct engineering analyses. Engineering staff was available from elsewhere within the Department until October 2005 and then again between December 2005 and May 2006. In April 2007, the Division contracted for engineering support with SAIC, Inc. To determine the qualifications of the engineering support, the review team reviewed the contract files and conducted a telephone interview with contract personnel assigned by the contractor to perform SS&D safety evaluations on behalf of the State. The review team also reviewed the technical quality of engineering analyses provided by SAIC, Inc. The review team found that the contracting process, the qualification and relevant professional experience of the SAIC, Inc., personnel, and the quality of the engineering analyses that were performed were adequate to supplement the skill level of the Division's staff.

At the time of the review, the Division did not have a backlog of SS&D cases. One case was open and under timely review. The review team concluded that the SS&D staffing level was adequate.

4.2.2 Technical Quality of the Product Evaluation Program

During the review period, the Program processed 18 SS&D actions, including new device reviews, amendments, and inactivations. The review team selected eight SS&D case files for review including work performed by all qualified staff members. The SS&D actions were selected to represent a variety of actions which included two new certificates, four amendments, one inactivation, and one correction. The selected actions included a variety of the Program's SS&D manufacturers and distributors. A listing of the SS&D certificates evaluated, with case-specific comments, may be found in Appendix F.

The review team evaluated the conduct of safety evaluations and the use of deficiency correspondence and checklists for SS&D actions. Casework was evaluated for timeliness, adherence to good radiation safety practices and acceptable engineering practices, references to appropriate regulations, documentation of safety evaluation reports, review of manufacturing Quality Assurance/Quality Control (QA/QC), and use of peer or supervisory review and signature authority. The files were checked for retention of necessary documents and other supporting data. The SS&D certificates were reviewed for accuracy, appropriateness of authorizations, tie-down statements, and overall technical quality.

The review team found that the evaluations were of high quality with health and safety issues properly addressed. Analysis of the casework and interviews with the staff confirmed that the Division followed the recommended guidance from the NRC SS&D training workshops and the relevant guidance document, NUREG-1556, Volume 3, Revision 1. All applicable and pertinent regulations, industry standards, and applicable references were available and used appropriately in performing SS&D reviews. The registration files contained all correspondence, photographs, engineering drawings, radiation profiles, and details of the applicant's quality assurance and quality control program. Appropriate review checklists, which were retained in the case files, were used to assure that all relevant materials were submitted and reviewed. Deficiency letters were used when appropriate and clearly stated regulatory positions. The registration certificates summarized the product evaluation and provided license reviewers with adequate information on areas requiring additional attention in licensing the possession, use, and distribution of the products.

The review team found that the SS&D files were maintained in an orderly manner and correspondence was filed chronologically, facilitating the accessibility of the records. Each SS&D case file contained a Table of Contents, which further facilitated access to relevant documents. The review team noted the Division established additional quality assurance measures. Specifically, the Division completed each SS&D case using two checklists unique to the Division's SS&D program, in addition to the universally-used technical checklist in NUREG-1556, Volume 3, Revision 1. The review team noted the Division's use of a 'completeness review checklist,' which delineates in great detail the specific issues that must be addressed in the registration certificate, and a 'concurrence review checklist,' which assures that the concurring SS&D reviewer would not miss the significant issues in completing the casework. The review team recommends that the Division's use of the two checklists be identified as a good practice.

4.2.3 Evaluation of Defects and Incidents Regarding SS&Ds

Utilizing NMED and the Program's response to the questionnaire, the review team selected and evaluated a sample of 10 incidents and/or equipment failures reported during the review period that occurred in Maryland or that occurred nationally involving SS&D products registered in Maryland. The review team also evaluated the Division's response to one allegation received by the Division that was related to the SS&D evaluation program.

The Division maintains multiple tracking systems to identify and resolve issues that involve SS&D failures: (1) a list of emergency responses/incidents, (2) a list of allegations, and (3) a list of Nucletron device events. In addition, Division staff conducts periodic searches of NMED several times a year to identify issues that may be related to SS&D products registered in Maryland.

The review team determined that the Division analyzed the events, reviewed the issues, and followed up on the incidents adequately and in accordance with applicable guidance. None of the events involving equipment or source failures within the period appeared to be generic issues. A listing of the incident casework examined, with case-specific comments, is included in Appendix E. The Program's handling of SS&D related incidents is consistent with the review team's conclusions for the Division's handling of other radioactive material incidents discussed in Section 3.5.

The Program developed an "Event Flow Chart," which leads to decision points to identify major issues involved in the event evaluation through a series of yes/no questions. The major issues that are addressed by the flow chart include such issues as human errors, the manufacturer's root cause analysis, the need for engineering analysis The review team noted that the Division applied the Event Flow Chart retroactively to incident reviews that had already been closed out in order to determine the validity of the earlier resolutions. In four instances the Event Flow Chart identified the need for engineering analyses. The Division utilized its engineering contractor to perform the analyses. The results of the analyses confirmed Division staff's earlier conclusions. The review team recommends that the Division's development and use of the Event Flow Chart be identified as a good practice.

Based on the IMPEP evaluation criteria, the review team recommends that Maryland's performance with respect to the indicator, SS&D Evaluation Program, be found satisfactory.

4.3 Low-Level Radioactive Waste (LLRW) Disposal Program

In 1981, the NRC amended its Policy Statement "Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory 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 Agreements prior to 1981 were determined to have continued LLRW disposal authority without the need of an amendment. Although the Maryland Agreement State Program has LLRW disposal authority, NRC has not required States to have a program for licensing a LLRW 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, they are expected to put in place a regulatory program which will meet the criteria for an adequate and compatible LLRW disposal program. There are no plans for a 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, the review team found Maryland's performance to be satisfactory for all performance indicators reviewed. The review team made no recommendations regarding program performance and identified two potential good practices. Accordingly, 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, the review team recommends that the next full IMPEP review take place in approximately 4 years.

LIST OF APPENDIXES

Appendix A	IMPEP Review Team Members
Appendix B	Maryland Organization Charts
Appendix C	Inspection Casework Reviews
Appendix D	License Casework Reviews
Appendix E	Incident Casework Reviews
Appendix F	Sealed Source and Device Casework Reviews

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	**Area of Responsibility**
Duncan White, FSME	Team Leader Technical Quality of Incident and Allegation Activities
Donna Janda, Region I	Technical Staffing and Training Compatibility Requirements
Shawn Seeley, Maine	Status of Materials Inspection Program Technical Quality of Inspections Inspector Accompaniments
James Mullauer, Region III	Technical Quality of Licensing Actions
John Jankovich, FSME	Sealed Source and Device (SS&D) Evaluation Program

APPENDIX B

MARYLAND ORGANIZATION CHARTS

ADAMS ACCESSION NO.: ML072560263
PAGES 2-4

APPENDIX C

INSPECTION CASEWORK REVIEWS

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

File No.: 1
Licensee: Howard County General Hospital — License No.: 27-016-01
Inspection Type: Routine, Unannounced — Priority: 3
Inspection Date: 7/25/07 — Inspector: CW

Comment:
Inspector's confirmatory surveys were not documented.

File No.: 2
Licensee: University of Maryland — License No.: 33-004-03
Inspection Type: Routine, Unannounced — Priority: 2
Inspection Date: 7/26/07 — Inspector: DA

File No.: 3
Licensee: Advanced Radiology — License No.: 27-047-01
Inspection Type: Routine, Unannounced — Priority: 3
Inspection Date: 7/24/07 — Inspector: FA

File No.: 4
Licensee: Memorial Hospital at Easton — License No.: 41-001-03
Inspection Type: Routine, Unannounced — Priority: 2
Inspection Date: 7/6/07 — Inspector: DA

Comment:
Notice of Violation (NOV) was not sent within 30 days from date of inspection.

File No.: 5
Licensee: Team Industrial Services — License No.: 03-079-01
Inspection Type: Routine, Announced — Priority: 1
Inspection Date: 6/29/06 — Inspector: RN

Comment:
The serial number for the inspector's survey instrument used during inspection was not recorded in the field notes.

File No.: 6
Licensee: Team Industrial Services — License No.: 03-079-01
Inspection Type: Routine, Announced — Priority: 1
Inspection Date: 6/29/06 — Inspector: RN

Comment:
The serial number for the inspector's survey instrument used during inspection was not recorded in the field notes.

File No.: 7
Licensee: MQC License No.: 25-022-01
Inspection Type: Special, Announced Priority: 1
Inspection Dates: 11/27/06, 2/28/07 Inspectors: AJ, DA

Comment:
Inspections results were sent to licensee 71 days after the inspection.

File No.: 8
Licensee: Cardinal Health License No.: 05-148-01
Inspection Type: Routine, Unannounced Priority: 2
Inspection Date: 5/17/07 Inspector: DA

Comment:
Notice of violation was sent to licensee 69 days after the inspection.

File No.: 9
Licensee: University of Maryland-Baltimore License No.: 07-014-01
Inspection Type: Routine, Unannounced Priority: 2
Inspection Dates: 2/2-3/06 Inspectors: DA, RN, FA

Comment:
Notice of violation was sent to licensee 122 days after the inspection.

File No.: 10
Licensee: Neutron Products, Inc. License No.: 31-025-04/05
Inspection Type: Routine, Unannounced Priority: 1
Inspection Dates: 7/26-28/06 Inspectors: AJ, RN, DA

Comment:
Notice of violation was sent to licensee 59 days after the inspection.

File No.: 11
Licensee: Neutron Products, Inc. License No.: 31-025-01
Inspection Type: Routine, Unannounced Priority: 1
Inspection Dates: 6/30/05, 7/1/05 Inspector: RN

Comment:
Notice of violation was sent to licensee 52 days after the inspection.

File No.: 12
Licensee: University of Maryland-College Park License No.: 33-004-01
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 2/15-16/07 Inspector: DA

Comment:
Notice of violation was sent to licensee 52 days after the inspection.

File No.: 13
Licensee: Radiation Service Organization, Inc. License No.: 33-021-02
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 3/10/06 Inspector: RN

File No.: 14
Licensee: Holy Cross Hospital License No.: 31-001-01
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 7/24/06 Inspector: DA

File No.: 15
Licensee: Advanced Radiology License No.: 25-024-01
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 6/3/05 Inspector: DA

File No.: 16
Licensee: American Cardiovascular Imaging, LLC License No.: 33-195-01
Inspection Type: Initial, Unannounced Priority: 3
Inspection Date: 7/12/07 Inspectors: FA, DA

File No.: 17
Licensee: Testing Technologies, Inc. License No.: NRC 45-25007-01
Inspection Type: Reciprocity, Unannounced Priority: 1
Inspection Date: 8/29/06 Inspector: RN

INSPECTOR ACCOMPANIMENTS

The following inspection accompaniments were made as part of the on-site IMPEP review:

Accompaniment No.: 1
Licensee: Advanced Radiology License No.: 27-047-01
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 7/24/07 Inspector: FA

Accompaniment No.: 2
Licensee: Howard County General Hospital License No.: 27-016-01
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 7/25/07 Inspector: CW

Accompaniment No.: 3
Licensee: University of Maryland License No.: 33-004-03
Inspection Type: Routine, Unannounced Priority: 2
Inspection Date: 7/26/07

APPENDIX D

LICENSE CASEWORK REVIEWS

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

File No.: 1
Licensee: Union Hospital of Cecil County — License No.: 15-001-01
Type of Action: Renewal — Amendment No.: 45
Date Issued: 2/27/07 — Reviewers: DM, CW

Comments:
a) Wrong date for letter used in tie down license condition.
b) Radiation Safety Officer (RSO) signed renewal request, not licensee management.
c) Checklist used by the license reviewers was not completed.

File No.: 2
Licensee: Union Hospital of Cecil County — License No.: 15-001-01
Type of Action: Amendment — Amendment No.: 46
Date Issued: 2/28/07 — License Reviewer: RM

File No.: 3
Licensee: Nutramax Labs, Inc. — License No.: 25-037-01
Type of Action: Renewal — Amendment No.: 06
Date Issued: 4/13/07 — License Reviewer: DM

Comments:
a) Licensee did not commit to a specific calibration frequency.
b) Response letter dated 1/29/07 containing commitments for package receipt, monitoring logs, disposal logs and radiation safety survey logs not referenced in tie down condition.

File No.: 4
Licensee: Sinai Hospital of Baltimore — License No.: 07-011-01
Type of Action: Amendment — Amendment No.: 126
Date Issued: 4/27/07 — License Reviewer: NO

File No.: 5
Licensee: John R. McLean, M.D. & Associates, P.A. — License No.: 45-016-01
Type of Action: Termination — Amendment No.: 12
Date Issued: 5/23/07 — License Reviewer: BP

File No.: 6
Licensee: Frederick Memorial Health Care System — License No.: 21-001-03
Type of Action: New — Amendment No.: N/A
Date Issued: 3/29/07 — License Reviewer: DM

Comment:
File contained no record of deficiency phone call that requested additional information.

File No.: 7
Licensee: John R. Marsh — License No.: 43-001-02
Type of Action: Amendment — Amendment No.: 30
Date Issued: 6/5/07 — License Reviewer: CW

File No.: 8
Licensee: Washington County Hospital Association — License No.: 43-001-03
Type of Action: Amendment — Amendment No.: 19
Date Issued: 6/5/07 — License Reviewer: CW

File No.: 9
Licensee: Stanley Medical Research Institution — License No.: 31-365-01
Type of Action: New — Amendment No.: N/A
Date Issued: 7/3/07 — License Reviewer: CW

File No.: 10
Licensee: Petnet Pharmaceuticals, Inc. — License No.: 07-213-01
Type of Action: Amendment — Amendment No.: 02
Date Issued: 7/20/05 — License Reviewer: DM

File No.: 11
Licensee: Doctors Community Hospital — License No.: 33-029-01
Type of Action: Renewal — Amendment No.: 65
Date Issued: 8/21/06 — License Reviewer: DM

File No.: 12
Licensee: Schnabel Engineering North, LLC — License No.: 05-174-01
Type of Action: Amendment — Amendment No.: 27
Date Issued: 12/28/06 — License Reviewer: NO

File No.: 13
Licensee: Bowie PET Scan, LLC — License No.: 33-165-01
Type of Action: Termination — Amendment No.: 02
Date Issued: 12/28/05 — License Reviewer: NO

File No.: 14
Licensee: Maryland QC Laboratories, Inc. — License No.: 25-022-01
Type of Action: Amendment — Amendment No.: 46
Date Issued: 6/21/07 — License Reviewer: CW

File No.: 15
Licensee: University of Maryland — License No.: 33-004-01
Type of Action: Amendment — Amendment No.: 136
Date Issued: 7/23/07 — License Reviewer: NO

File No.: 16
Licensee: John Hopkins Medical Institution License No.: 07-005-13
Type of Action: Amendment Amendment No.: 12
Date Issued: Not Recorded License Reviewer: NO

File No.: 17
Licensee: St. Joseph Radiation Oncology Center License No.: 05-211-01
Type of Action: New Amendment No.: N/A
Date Issued: 2/8/07 License Reviewer: BP

Comments:
a) Duties of the Radiation Safety Officer and frequency of calibration of survey instruments were not found in the file.
b) Licensee did not address Deficiency No. 1, which requested a commitment to include dry runs during the training of authorized users.
c) Fax and e-mail dated 2/8/07 were not signed by the licensee.
d) Tie down condition indicates a letter dated January 17, 2007; it should be January 15, 2007.

APPENDIX E

INCIDENT CASEWORK REVIEWS

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

File No.: 1
Licensee: MAFI Associates Consultants Engineering
Date of Incident: 12/22/04
Investigation Date: 12/22/04
License No.: 31-270-01
Incident Log No.: NMED 050007
Type of Incident: Damage to Equipment
Type of Investigation: Site

File No.: 2
Licensee: Northwest Hospital
Date of Incident: 10/26/04
Investigation Date: 10/29/04
License No.: 05-034-03
Incident Log No.: NMED 040777
Type of Incident: Transportation
Type of Investigation: Site

File No.: 3
Licensee: Carroll County General Hospital
Date of Incident: 3/16/04
Investigation Date: 3/19/04
License No.: 13-001-02
Incident Log No.: NMED 040540
Type of Incident: Lost Radioactive Material
Type of Investigation: Site

File No.: 4
Licensee: Cardinal Health
Date of Incident: 1/1/05
Investigation Date: 1/1-4/05
License No.: 31-270-01
Incident Log No.: NMED 050021
Type of Incident: Transportation
Type of Investigation: Site

File No.: 5
Licensee: Joseph Smith
Date of Incident: 9/2/04
Investigation Date: 9/24/04
License No.: N/A
Incident Log No.: NMED 040726/040728
Type of Incident: Contamination
Type of Investigation: Site

File No.: 6
Licensee: CTI Core Drilling Services
Date of Incident: 6/30/05
Investigation Date: 7/11/05
License No.: NRC 45-25383-01
Incident Log No.: N/A
Type of Incident: Potential Overexposure
Type of Investigation: Site

File No.: 7
Licensee: Mallinckrodt
Date of Incident: 11/8/05
Investigation Date: 11/9/05
License No.: 33-088-01
Incident Log No.: NMED 050748
Type of Incident: Lost Radioactive Material
Type of Investigation: Phone/Next Inspection

File No.: 8
Licensee: John Hopkins Medical Institute License No.: 07-005-03
Date of Incident: 3/2/06 Incident Log No.: NMED 060187
Investigation Date: 3/14/06 Type of Incident: Stolen Radioactive Material
Type of Investigation: Site

File No.: 9
Licensee: Diageo License No.: General License
Date of Incident: 7/1/06 Incident Log No.: NMED 070134
Investigation Date: 2/16/07 Type of Incident: Lost Radioactive Material
Type of Investigation: Site

Comment:
Licensee did not report loss of material to the State until January 2007.

File No.: 10
Licensee: Mount Sinai Hospital License No.: 07-011-01
Date of Incident: 9/29/03 Incident Log No.: NMED 030798
Investigation Date: 10/7/03 Type of Incident: Medical Event
Type of Investigation: Site

SEALED SOURCE AND DEVICE INCIDENT CASEWORK REVIEWS

File No.: 11
Licensee: Nucletron Corp. License No.: 27-035-01
Date of Incident: 1/23/07 Incident Log No.: NMED 070012
Investigation Date: 3/23/07 Type of Incident: Maintenance Test Failure
Type of Investigation: Root Cause/Generic Application

File No.: 12
Licensee: Nucletron Corp. License No.: 27-035-01
Date of Incident: 12/22/06 Incident Log No.: N/A
Investigation Date: 6/19/07 Type of Incident: Equipment Malfunction
Type of Investigation: Root Cause/Generic Application

File No.: 13
Licensee: Nucletron Corp. License No.: 27-035-01
Date of Incident: 3/22/06 Incident Log No.: N/A
Investigation Date: 6/16/06 Type of Incident: Equipment Malfunction
Type of Investigation: Root Cause/Generic Application

File No.: 14
Licensee: Nucletron Corp. License No.: 27-035-01
Date of Incident: 1/06/05 Incident Log No.: NMED 050471
Investigation Date: 1/06/06 Type of Incident: Equipment Malfunction
Type of Investigation: Manufacturer's Site

File No.: 15
Licensee: Nucletron Corp. License No.: 27-035-01
Date of Incident: 4/6/05 Incident Log No.: NMED 050222
Investigation Date: 6/28/05 Type of Incident: Maintenance Test Failure
Type of Investigation: Root Cause/Generic Application

File No.: 16
Licensee: Nucletron Corp. License No.: 27-035-01
Date of Incident: 9/8/03 Incident Log No.: NMED 030724
Investigation Date: 1/21/04 Type of Incident: Equipment Malfunction
Type of Investigation: Root Cause/Generic Application

File No.: 17
Licensee: Nucletron Corp. License No.: 27-035-01
Date of Incident: 7/12/04 Incident Log No.: NMED 050179
Investigation Date: NMED Review/2004 Type of Incident: Maintenance Test Failure
Type of Investigation: Root Cause/Generic Application

File No.: 18
Licensee: Nucletron Corp. License No.: 27-035-01
Date of Incident: 3/8/06 Incident Log No.: NMED 060643
Investigation Date: 5/17/07 Type of Incident: Software Failure
Type of Investigation: Root Cause/Generic Application

File No.: 19
Licensee: Data Measurement Corp. License No.: 088-01/02
Date of Incident: 7/13/04 Incident Log No.: NMED 050179
Investigation Date: N/A Type of Incident: Equipment Damage
Type of Investigation: None

Comment:
The Program did not identify the event in NMED since codes did not reference Maryland.

File No.: 20
Licensee: Adaptive Technologies, Inc. License No.: 31-076-02
Date of Incident: 2/4/04 Incident Log No.: NMED 040199
Investigation Date: NMED Review/2004 Type of Incident: Failed Leak Test
Type of Investigation: Root Cause/Generic Application

APPENDIX F

SEALED SOURCE AND DEVICE CASEWORK REVIEWS

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

File No.: 1
Registry No.: MD-1239-D-101-B — SS&D Type: (D) Gamma Gauge
Applicant Name: Carter Holt Harvey Ltd. — Type of Action: New
Date Issued: 4/26/05 — Reviewers: DM, NO

File No.: 2
Registry No.: MD-1239-D-101-B — SS&D Type: (D) Gamma Gauge
Applicant Name: IsoScan Ltd. — Type of Action: Amendment
Date Issued: 10/19/06 — Reviewers: DM, NO

File No.: 3
Registry No.: MD-1239-D-101-B — SS&D Type: (D) Gamma Gauge
Applicant Name: IsoScan Ltd. — Type of Action: Correction
Date Issued: 11/30/06 — Reviewers: DM, NO

File No.: 4
Registry No.: MD-0497-D-111-S — SS&D Type: (V) General Medical Use
Applicant Name: Nucletron Corp. — Type of Action: New
Date Issued: 3/22/05 — Reviewers: BP, RM

File No.: 5
Registry No.: MD-0497-D-111-S — SS&D Type: (V) General Medical Use
Applicant Name: Nucletron Corp. — Type of Action: Amendment
Date Issued: 8/12/05 — Reviewers: BP, RM

File No.: 6
Registry No.: MD-0497-D-114-S — SS&D Type: (V) General Medical Use
Applicant Name: Nucletron Corp. — Type of Action: New
Date Issued: 6/12/07 — Reviewers: BP, RM

File No.: 7
Registry No.: MD-0113-D-801-G — SS&D Type: (E) Beta Gauge
Applicant Name: Adaptive Technologies, Inc . — Type of Action: Inactivation
Date Issued: 5/18/06 — Reviewers: BP, RM

File No.: 8
Registry No.: MD-1003-D-801-G — SS&D Type: (D) Gamma Gauge
Applicant Name: Pettit Applied Technologies, Inc. — Type of Action: Inactivation
Date Issued: 8/2/06 — Reviewers: DM, RM

Comment:

The registration certificate was amended to show that the vendor's license was terminated, but the vendor number (i.e. 1003) was not changed to an inactive vendor number (i.e. 8000 series).