October 30, 2003

MEMORANDUM TO: Carl J. Paperiello, Deputy Executive Director
for Materials, Research and State Programs

Paul H. Lohaus, Director
Office of State and Tribal Programs

Martin J. Virgilio, Director
Office of Nuclear Material Safety and Safeguards

Karen D. Cyr, General Counsel

/RA By Kathleen N. Schneider

FROM: Josephine M. Piccone, Deputy Director **Acting for/**
Office of State and Tribal Programs

SUBJECT: INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM (IMPEP) REVIEW OF THE MARYLAND RADIATION CONTROL PROGRAM

This memorandum transmits to the Management Review Board (MRB) a proposed final report (Attachment 1) documenting the IMPEP review of the Maryland Radiation Control Program. The review of the Maryland program was conducted by an interoffice team during the period of July 21-25, 2003. The team issued a draft report to Maryland on August 25, 2003 for factual comment. Maryland responded to the findings and conclusions of the review by letter dated October 7, 2003 from Thomas C. Snyder, Director, Maryland Air and Radiation Management Administration (Attachment to the proposed final report).

The review team found Maryland's performance to be satisfactory for four performance indicators, and satisfactory with recommendation for improvement for three performance indicators. Accordingly, the review team recommends finding the Maryland Agreement State program to be 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 review should be in approximately four years. The review team made three recommendations.

The MRB meeting to consider the Maryland report is scheduled for **Monday, November 10, 2003, from 2:00 p.m. to 4:00 p.m., in One White Flint North, Room O-3-B4**. In accordance with Management Directive 5.6, the meeting is open to the public. The agenda for that meeting is attached (Attachment 2).

If you have any questions prior to the meeting, please contact me at 415-2325 or Duncan White at 610-337-5042.

Attachments:
As stated

cc: Thomas C. Snyder, Director
Air and Radiation Management Administration
Maryland Department of the Environment

Roland G. Fletcher, Manager
Radiological Health Program

OAS Liaison to the MRB

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF MARYLAND AGREEMENT STATE PROGRAM

July 21-25, 2003

PROPOSED FINAL REPORT

U.S. Nuclear Regulatory Commission

ATTACHMENT 1

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 July 21-25, 2003, by a review team consisting of technical staff members from the Nuclear Regulatory Commission (NRC) and the Agreement State of Georgia. 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 a Final General Statement of Policy," published in the Federal Register on October 16, 1997, and the November 5, 1999, NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." Preliminary results of the review, which covered the period of March 26, 1999, to July 21, 2003, were discussed with Maryland management on July 25, 2003. Review of the two performance indicators, Technical Quality of Licensing and the Sealed Source and Device (SS&D) Evaluation Program, covers the period from the 2001 follow-up review. The review of the remaining five performance indicators covers the four year period from the 1999 IMPEP 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 agency within the State of Maryland that regulates environmental and radiation hazards. 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) is organized under the Air and Radiation Management Administration. The Program includes the Radioactive Materials Licensing and Compliance Division (the Division) and the Radiation Machines Division. The Division consists of the Inspection Section and the Licensing Section. Organizational charts for the Department are presented in Appendix B. At the time of the review, the Maryland Agreement State program regulated 580 specific licenses authorizing Agreement and non-AEA materials. The review focused on the 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 non-common performance indicators was sent to the Program on April 28, 2003. The Program provided a response to the questionnaire on June 30, 2003. The questionnaire provided information covering the period from the November 2001 follow-up review to July 21, 2003. Copies of the questionnaire response may be found on NRC's Agencywide Document Access and Management Systems (ADAMS) using the Accession Number ML032130145.

The review team's general approach for conduct of this review consisted of: (1) examination of Maryland's responses to the questionnaire; (2) review of applicable Maryland statutes and regulations; (3) analysis of quantitative information from the radiation control program licensing and inspection database; (4) technical review of selected licensing and inspection actions; (5) field accompaniments of three Program inspectors; and (6) interviews with staff and management to answer questions or clarify issues. The review team evaluated the information that it gathered against the IMPEP performance 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 below discusses the State's actions in response to recommendations made following previous reviews and the team's conclusions regarding close-out of the recommendations.

Results of the current review for the IMPEP common performance indicators are presented in Section 3. Section 4 discusses results of the applicable non-common performance indicators, and Section 5 summarizes the review team's findings. Recommendations made by the review team are comments that relate directly to program performance by the Program. A response is requested from the Program to all recommendations in the final report.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous IMPEP review, which concluded on March 26, 1999, nine recommendations were made and transmitted to Mr. Arthur W. Ray, Deputy Secretary, Maryland Department of the Environment, on July 6, 1999. Additionally, a follow-up IMPEP review, which concluded on November 16, 2001, had two new recommendations and closed two recommendations (No. 4 and 8) from the 1999 report. These were transmitted to Ms. Ann Marie DeBiase, Director, Maryland Department of the Environment, on May 10, 2002. The team's review of the current status of the recommendations are as follows:

Recommendations from the 1999 IMPEP Review report:

1. The review team recommends that the State take action to have the Waste Management Administration revise the definition of "Person" in the low-level radioactive waste regulations, Code of Maryland Regulations (COMAR) 26.14.01.02B(28)(e) that was identified in both the 1993-94 review and the 1995 follow-up review. (Section 2.0 of the 1999 report)

   Current Status: The team confirmed that the definition of "person" in the low-level radioactive waste regulations was revised and incorporated in the Code of Maryland Regulations (COMAR) 26.14.01.02B(28)(e) effective June 29, 1999. This recommendation is closed.

2. The review team recommends that all inspection documentation be reviewed and signed by the Program management before the inspection correspondence is issued to the licensee. (Section 3.2 of the 1999 report)

   Current Status: Discussions with the Inspection Section Supervisor and review of casework during the assessment of Technical Quality of Inspections indicated that all inspection-related documentation is reviewed and signed by the appropriate level of Program management before inspection correspondence, including enforcement actions, is issued. This recommendation is closed.

3. The review team recommends that the State evaluate present and future staffing needs of the Program and develop a strategy that will assure the Program's continued adequacy and compatibility. (Section 3.3 of the 1999 report)

   Current Status: During the review, the team reviewed and discussed the Program's staffing levels. This recommendation is closed; however, a new recommendation is made in Section 3.1.

5. The review team recommends that the State revise their allegation procedure to incorporate appropriate elements following NRC guidance documents. (Section 3.5 of the 1999 report)

   Current Status: The Program revised their allegation procedure effective July 31, 2001, to include appropriate elements of NRC guidance documents. The Department's legal counsel has reviewed and signed off on the procedure. This recommendation is closed.

6. The review team recommends that the State promptly review registration certificates MD- 1003-D-101-G and MD-1003-D-102-G, taking into consideration the deficiencies listed in Appendix F for each registration certificate, and amend the registration certificates accordingly. (Section 4.2.1 of the 1999 report)

   Current Status: In August 2001, the Program was in the process of addressing the issues for the registration certificates referenced above, but the licensee had not been responsive. The Program amended the license prohibiting distribution of the devices in question pending resolution of all issues. Since August 2001, the licensee submitted complete re-applications for the two certificates and was granted permission, by license amendment, to continue distribution. At the time of the follow-up review, the Program had not yet issued the amendments to these certificates. The review team evaluated the licensee's submissions and agreed that safety issues had been resolved.

   On July 10, 2003, the Program issued an amendment to registry certificate MD-1003-D-101-G. During the review of the application, the Program addressed the items listed in Appendix F of the 1999 IMPEP report. On October 16, 2002, the Program issued registry certificate MD-1003-D-801-G, which inactivated MD-1003-D-102-G. Even though the files only contain the current documentation (the Licensing Section Supervisor indicated that the older documentation for the devices has not been found after the Department's October 2002, move), the review team determined that the current certificates are adequate for licensing purposes. The health and safety issues that had been identified in MD-1003-D-102-G have been addressed through the inactivation of the certificate and the fact that, as of July 21, 2003, only 4 units remained in service. This recommendation is closed.

7. The team recommends that the State, using NUREG-1556 guidance and following the description of a "concurrence review" in Management Directive 5.6, complete a secondary review of all registration certificates issued by the State to identify any missing information and with priority of the actions based on the risk associated with the device. (Section 4.2.1 of the 1999 report)

   Current Status: As of June 21, 2003, the Program has completed a secondary review of approximately 30 of the Program's 45 registry sheets. The Licensing Section Supervisor noted that one of the manufacturers in the State will be moving its operations to California. Consequently, the Program will conduct a secondary review of the manufacturer's 18 registration sheets. The Program expects to complete these reviews by July 2004.

   The review team noted the Program's disagreement with the definition of "concurrence review" and also informed the Program of the pending revision to that definition as listed

in NRC Management Directive 5.6. The team noted that the use of an engineering review, in addition to the initial and concurrence reviews, results in a registry sheet that addresses both the physical integrity of the product and the health and safety of the users, the public, and the environment. This recommendation is closed.

9. The MRB recommends that the State respond to all of the review teams comments in Appendix F of the final report. (Section 4.2.4 of the 1999 IMPEP report)

   Current Status: The State provided a response to the comments in the 1999 IMPEP review in a letter dated October 18, 1999, addressed to Carl Paperiello, Deputy Executive Director for Materials, Research and State Programs. The letter outlined Maryland's plan of action for both licensing and SS&D reviews. The follow-up review team examined the Program's actions involving all six certificates listed in the 1999 IMPEP report. The status of two of the certificates was discussed in response to Recommendation 6. Regarding the other four certificates, all four have been amended. The review team confirmed that the Program addressed all comments during the review and issuance of the certificates. This recommendation is closed.

Recommendations from the 2001 follow-up IMPEP Review report:

1. The review team recommends that the Program establish a training policy that prior to gaining signature authority, all reviewers must meet a set of standards through experience, training, and/or formal education including, at a minimum, those listed in Management Directive 5.6. (Section 3.2 of the 2001 report)

   Current Status: The Program issued a memorandum titled "Qualification and Training for Signature Authority for Sealed Source and Device Reviews" on November 14, 2002. This document established the experience, training, and formal education requirements that must be attained before signature authority is granted. The team reviewed the memorandum and determined that it is acceptable and meets the criteria listed in Management Directive 5.6. This recommendation is closed.

2. The review team recommends that the Program establish a policy that a qualified individual perform an engineering review for all incidents that may indicate a source or device problem, and source and device product failures involving Maryland vendors. (Section 3.3 of the 2001 report)

   Current Status: The Program issued a memorandum on November 14, 2002, that details the process the Program will follow when an incident or malfunction is reported regarding a source or device registered on a Maryland SS&D certificate. The team reviewed the memorandum and determined that it is acceptable for the review of incidents involving sources and devices. This recommendation is closed.

3.0 COMMON PERFORMANCE INDICATORS

IMPEP identifies five common performance indicators to be used in reviewing both NRC Regional and Agreement State 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) Response to Incidents and Allegations.

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 responses relative to this indicator, interviewed program management and staff, reviewed job descriptions and training records, and considered any possible workload backlogs.

The Program consists of two Divisions, the Radioactive Materials Licensing and Compliance Division (the Division) and the Radiation Machines Division. 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 SS&D evaluations. The Licensing Section and the Inspection Section each have authorization for one supervisor and three staff. At the time of the review, eight staff members worked full-time with the Agreement State radioactive materials program, including management. The retirement of two individuals from the Division in 2002 has had an impact on the Program. Neither position was filled at the time of the review due to a State-wide hiring freeze.

There are currently two vacancies in the Division, the Division Chief and one inspector. In addition, one inspector has been on active military duty since November 2002. The duties of the Division Chief are being performed by the two Section Supervisors. The Program has addressed the inspection staffing shortage by moving one reviewer from the Licensing Section (this individual is a qualified materials inspector) and by hiring one individual (a former x-ray inspector from the Program) into the Inspection Section. In addition, the Program has entered into a memorandum of understanding (MOU) with another Department's program to use an engineer for SS&D evaluations. The MOU authorizes up to 16 hours a week of the engineer's time. The Program Manager is attempting to acquire more hours for future SS&D work. The Division Chief position will not be immediately filled. However, during the week of the review, management converted the position to an inspector position and received authorization to submit an exception request to post the position. Due to the hiring freeze, an exception request is the first step in the hiring process and requires management approval.

The State of Maryland is facing a severe budget crisis and is taking steps to reduce the size of its government. The State has cut nearly 1800 vacant positions statewide and has instituted a hiring freeze. An open position in the Radiation Machines Division has received approval to be filled. The Program Manager indicated that an exception request has been filed, the position has been posted, and interviews have been conducted to fill the position. The Program Manager indicated that the Program has money allocated for the positions in both Divisions; however, exception requests need to be filed to be able to post the positions. The Radiation Machines Division has three vacancies.

Based on the impact of the long term vacancies in the Program and Program's current workload (see discussions in Sections 3.2, 3.3 and 4.1.2), the review team does not believe that the current staffing level is adequate to properly implement the Agreement State program. In order to assess their resource needs, the team discussed the need for the Program to conduct a staffing assessment. The assessment should take into account the additional FTE needed for complex licensees such as those discussed in Section 3.3. The State requested assistance

in assessing their staffing levels. The review team discussed the merits of using the Staff Needs Analysis forms referenced in STP Procedure SA-700, "Processing an Agreement," Appendix B, to assess the Program's staffing needs. In addition, the team believes that the difficulty in filling the positions are part of the root causes of the workload backlogs in conducting inspections and adopting regulations for compatibility, as noted in Sections 3.2 and 4.1 The review team recommends that the State fill the current vacancies in the program as soon as possible, and evaluate staffing needs to assure program adequacy and compatibility.

The staff are well trained and qualified from an education and experience standpoint. All have Bachelor's degrees in the sciences. Inspector requirements include NRC training courses, when available, or equivalents. The team noted that Program management has exhibited a strong commitment to training. It has been noted that on October 8-9, 2003, Program staff assisted the NRC by providing training to two NRC interns and one International Atomic Energy fellowship candidate. Management's commitment to staff training is evident in the quickness in which the staff members have received approval to attend core courses offered by the NRC. The transferred staff have taken NRC's 5-Week Health Physics Course and additional core courses to become qualified inspectors. In addition, the Section Supervisors provide on-the-job training for Program staff. The new staff member has also received training from other providers, including the Department of Energy, the Federal Emergency Management Agency, commercial vendors, and local educational institutions. The Radiological Health Inspection Manual has a chapter on training and qualification procedures; utilizing previous training; core and specialized training; inspection accompaniments; and evaluation by management to qualify individual staff. The review team examined the manual and found it to be comprehensive. Staff training is well documented.

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 with recommendations for improvement.

3.2 Status of Materials Inspection Program

The review team focused on five factors in reviewing the status of the materials inspection program: inspection frequency, overdue inspections, initial inspections of new licensees, timely dispatch of inspection findings to licensees, and the performance of reciprocity inspections. The review team's evaluation is based on the Program's questionnaire responses relative to this indicator, data gathered independently from the Program's licensing and inspection data tracking system, the examination of completed licensing and inspection casework, and interviews with managers and staff.

In June 2003, the Program revised its inspection frequencies for various types of material licenses to conform with the priorities listed in NRC's Temporary Instruction 2800/033, Revision 02, "Revised Materials Inspection Program." The previous inspection priorities, which were used for the majority of the review period, were found to be generally the same as those listed in NRC Inspection Manual Charter (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 team believes that the revised priorities are appropriate, yet additional changes may be necessary once NRC officially revises their inspection priorities in October 2003.

Review of records indicated that at the time of the IMPEP review, there were four overdue inspections. The review team found it difficult to determine which, if any, of the overdue inspections were core inspections without a manual review of files. The review team determined that of the 361 core inspections performed during the review period, 46 were performed late. The team noted that 20 percent of the Priority 1 and 2 inspections performed during the review period were performed overdue, ranging from three days to 21 months late.

With respect to initial inspections of new licenses, the review team evaluated 25 of the 112 licenses issued during the review period and determined the appropriate initial inspection due date based on NRC IMC 2800 guidance. Of the 25 new licenses reviewed, two of the initial inspections were not conducted within the six month or one year time frame, as appropriate; however, pre-licensing visits were conducted with these licensees. Overall, the team found that 13 percent of all core and initial inspections reviewed, including the current overdue inspections, were performed overdue. The team also discussed with Program management the issue of the continuing backlog of core inspections, which are generally the more safety-significant inspections, in evaluating staffing level needs, since these inspections are normally required to be performed by inspectors who have greater training and experience than entry-level inspectors. 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 inspections priorities.

The review team determined that the Program granted 50 core reciprocity licenses during the review period. The Program satisfied the 20 percent criteria prescribed in NRC IMC 1220 by conducting 20 inspections of core reciprocity licensees during the review period. In addition, the Program inspected 11 percent of non-core reciprocity licensees during the review period.

The review team examined the timeliness of inspection findings issued by the Program during the review period. The Program has an effective and efficient process which ensures that inspection findings are communicated to licensees in a timely manner. The Program'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 ten core licensee files reviewed, all inspection reports were issued within the 30-day goal with the exception of two inspections that involved the assistance of the Department investigative personnel examining potential licensee wrongdoing.

Based on the IMPEP evaluation criteria, the review team recommends that Maryland's performance with respect to the indicator, Status of the Materials Inspection Program, be found satisfactory with recommendations for improvement.

3.3 Technical Quality of Inspections

The team evaluated the inspection reports, enforcement documentation, and inspection field notes and interviewed inspectors for a total of twelve inspections. The casework examined included inspections performed by five of the Program's materials inspectors, including a relatively new inspector who is partially qualified. The review team examined core inspections of various license types including industrial radiography, medical broad scope, medical institution with quality management program, nuclear pharmacy, irradiators, and sealed source production and distribution. In addition, two inspection reports of non-core licensees performed by the newest inspector were reviewed by the team. Appendix C lists the inspection casework files reviewed for completeness and adequacy with case-specific comments.

Based on the casework file reviews, the review team found that routine inspections covered all aspects of the licensee's radiation protection program. The inspection reports were thorough, complete, consistent, and of high quality, with sufficient documentation to ensure that licensee's performance with respect to health and safety was 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 include 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 Program had exercised escalated enforcement through the issuance of orders, imposition of civil penalties, or suspension of licensed activities. The team found that the Program has 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 team reviewed the progress the Program has made with regard to Neutron Products, Inc. (NPI) and noted that the Program continues to pursue appropriate enforcement and remediation options. The team noted the apparently disproportionate amount of the Program's inspection and enforcement resources consumed by the NPI case. Program staff indicated that about one FTE of effort is expended on this one licensee, which holds four licenses. During discussions, Program staff shared with the review team the options the Program has available to them regarding further steps in pursuit of a timely legal resolution of the case, in light of the ever-increasing costs of remediation and waste disposal.

The Inspection Section Supervisor conducts supervisory accompaniments of each material inspector once a year. These inspector accompaniments were documented by the accompanying supervisor.

The review team accompanied three materials inspectors during the week of July 7, 2003, during inspections of an irradiator, a portable nuclear moisture/density gauge operator, and a medical institution licensed for diagnostic and therapeutic nuclear medicine. These accompaniments are identified in Appendix C. The inspections were unannounced consistent with Program policy. 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.

The Program has an adequate number and types of survey meters to support the current inspection program as well as for responding 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 also 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 analysis including gamma spectroscopy of air, soil and water.

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 21 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 files were also reviewed for timeliness, use of appropriate deficiency letters and cover letters, reference to appropriate regulations, product certifications, supporting documentation, consideration of enforcement history, pre-licensing visits, supervisory review as indicated, and proper signatures. 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 which were completed during the review period. The sampling included the following types: broad scope - research and development, general license distribution, manufacturing and distribution, medical institution - limited, medical broad scope, private practice, research and development, nuclear pharmacy, fixed gauge, calibration service, and in-vitro laboratory. Licensing actions reviewed included two new, four renewals, seven amendments, four decommissioning, and one financial assurance. A listing of the casework licenses evaluated with case specific comments can be found in Appendix D.

Overall, the review team found that the licensing actions were thorough, complete, consistent, and of high quality with health and safety issues properly addressed. License tie-down conditions were stated clearly, backed by information contained in the file, and inspectable.

Deficiency letters clearly state regulatory positions, are used at the proper time, and identify deficiencies in the licensees' documents. Terminated licensing actions are well documented, showing appropriate transfer and survey records.

Licensing actions are assigned to one of two license reviewers by the Licensing Section Supervisor who, in addition, 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 five-year period to a seven-year period under a timely renewal system. The Licensing Section utilizes NRC licensing guides (NUREG 1556 series) as appropriate, uses standard licensing conditions, and issues a complete license for each licensing action.

Decommissioning actions completed over the review period involving licensees removing a building or location of use were reviewed. One termination action was reviewed. The review team found that decommissioning licensing actions were well documented, showing appropriate transfer records or appropriate disposal methods and records, confirmatory surveys, and survey records. The team reviewed two pending renewal actions greater than one year old, and one amendment greater than 6 months old and determined that they did not contain any health and safety issues due to the extended review period.

The team reviewed four amendment actions containing requests for a name change and possible change in ownership/control of the license. The team found that, while the reviewers were aware of the change in ownership/control guidance in NUREG 1556, Vol. 15, it was not applied in three of the four cases reviewed. While the team did not identify any potential health and safety issues in two of the actions, there were concerns identified with the other two amendments. One amendment approved a name change that was requested by an individual who did not identify his title/position within the company and was not a previous contact person at the licensee. The second amendment approved this same individual's request to name himself as Radiation Safety Officer. In both instances, the information contained in NUREG-1556, Vol. 15, for this type of amendment request, was not requested by the Program from the licensee. In subsequent correspondence, the individual identified himself as the Corporate Radiation Protection Officer, so the team believes that this individual was an authorized administrative official; however, it was never confirmed by the Program. The review team recommends that the Program follow the guidance for all licensing actions involving name changes and possible change in ownership/control.

The review team and the Program discussed the benefits of altering the scheduling of inspections as a result of licensing actions that result in significant changes to the licensee's program (e.g., increasing the types, amounts, or uses of radioactive materials or adding a new location of use, etc.). This topic is especially important since the Program recently extended the frequencies of routine inspections for most program codes.

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 Response to Incidents and Allegations

In evaluating the effectiveness of the Program's actions in responding to incidents, the review team examined the Program's responses to the questionnaire relative to this indicator, reviewed the incident reports for Maryland in the Nuclear Materials Event Database (NMED) against those contained in the Program's files, and evaluated reports and supporting documentation for 12 incidents. A list of the incident casework examined with case-specific comments is included in Appendix E. The review team also reviewed the Program's response to seven allegations involving radioactive material. Four allegations were referred to the State by the NRC during the review period.

The incidents selected for review included the following event categories: stolen and abandoned radioactive material, misadministration, release of radioactive material, equipment failure, overexposure, contamination, leaking source, and damage to equipment. The review team found that the Program's response to incidents was complete and comprehensive. Initial responses were prompt and well-coordinated, and the level of effort was commensurate with the health and safety significance. The Program dispatched inspectors for on-site investigations when appropriate, and took suitable enforcement and follow-up actions.

The responsibility for initial response and follow-up actions to materials incidents is assigned to the Inspection Section Supervisor. Upon receipt, staff reviews the report and decides on the appropriate response. Documentation related to an incident is placed in the Program's incident files and the appropriate license files.

The Program follows the NRC's "Handbook on Nuclear Material Event Reporting in the Agreement States" for the reporting requirements of incidents. Prior to the on-site review, the review team identified 23 incidents in NMED for Maryland during the review period. The review team noted that only reportable events (requiring 24 hour notification) and routine events and/or event updates (requiring 30-day notification) were reported to the NMED. Monthly reports and follow-up information are submitted electronically using the NMED software by the Licensing Section Supervisor. When the Program's local NMED events were compared to those events in the national database, the team noted that five events, four related to the Agreement State program, were in the local database but not in the national database. The team also noted that some events in the local database were complete and closed out, but this status was not reflected in the national database. Since other events and updates were successfully submitted to NMED from the same time periods, Program management stated that they would contact the NMED contractor to determine if there is a software issue or will resubmit the event information to NMED, as necessary. A review of the Program's event files by the team did not identify any additional events that required reporting to NMED.

In evaluating the effectiveness of Maryland's actions responding to allegations, the review team examined the Program's questionnaire responses relative to this indicator and the Program's allegation procedure. The casework for seven allegations were reviewed. Four allegations were referred to the State by the NRC and three were reported directly to the State. The Program evaluates each allegation and determines the proper level of response. The review of the casework and the files indicated that the Program took prompt and appropriate action in response to the concerns raised. Each of the allegations reviewed were appropriately closed, and the allegers were informed of the results when possible. There were no performance issues identified from the review of the casework documentation.

The review team noted that Maryland law requires that all public documents be made available for inspection and copying. The State is able to withhold the identity of an alleger. Prior to allowing documents to be reviewed by the public, the files are reviewed by the Division, the Program, and the Department's legal staff.

Based on the IMPEP evaluation criteria, the review team recommends that Maryland's performance with respect to the indicator, Response to Incidents and Allegations, 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) Legislation and Program Elements Required for Compatibility; (2) Sealed Source and Device Evaluation Program; (3) Low-Level Radioactive Waste Disposal Program; and (4) Uranium Recovery Program. Maryland's Agreement does not authorize uranium recovery, so only the first three non-common performance indicators were applicable to this review.

4.1 Legislation and Program Elements Required for Compatibility

4.1.1 Legislation

The current effective statutory authority for the Program 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 Agreement State Program was passed during the review period.

4.1.2 Program Elements Required for Compatibility

The statutes are contained in COMAR 26.12.01.01 "Regulations for the Control of Ionizing Radiation" (1994) that applies to all 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 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 regulation adoption process is provided in Title 10, "Government Procedures," Subtitle 1, "Administrative Procedures Acts - Regulations." 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 State can adopt other agency regulations by reference. The State also 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 responses to the questionnaire, 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 State and Tribal Program's (STP) State Regulation Status Data Sheet. Since the previous IMPEP review, the Program adopted 12 amendments in three rule packages that became effective in June 1999, February 2000, and April 2002.

Current NRC policy requires that Agreement States adopt certain equivalent regulations or legally binding requirements no later than three years after they become effective. The review team found that the Program currently has 10 overdue NRC amendments. For the following seven amendments, the NRC reviewed the State's proposed regulations for these amendments and determined that if the proposed regulations are adopted without significant changes, they would meet the NRC's compatibility and health and safety requirements.

- "Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act," 10 CFR Part 20 amendment (61 FR 65120) that became effective January 9, 1997. The State expects that this regulation will become effective in September 2003.

- "Recognition of Agreement State Licensees in Areas Under Exclusive Federal Jurisdiction Within an Agreement State," 10 CFR 150 amendment (62 FR 1662) that became effective February 27, 1997. State expects that this regulation will become effective in September 2003.

- "Exempt Distribution of a Radioactive Drug Containing One Microcurie of Carbon-14 Urea," 10 CFR Part 30 amendment (62 FR 63634) that became effective January 2, 1998. The State expects that this regulation will become effective in September 2003.

- "Deliberate Misconduct by Unlicensed Persons," 10 CFR Parts 30, 40, 61, 70, and 150 amendments (63 FR 1890 and 63 FR 13773) that became effective February 12, 1998. The State expects that this regulation will become effective in September 2003.

- "Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations," 10 CFR Part 34 amendment (63 FR 37059) that became effective July 9, 1998.

- "Minor Corrections, Clarifying Changes and a Minor Policy Change," 10 CFR Parts 20, 35 and 36 amendments (63 FR 39477 and 45393) that became effective October 26, 1998.

- "Transfer for Disposal and Manifests: Minor Technical Conforming Amendment," 10 CFR Part 20 amendment (63 FR50127) that became effective November 20, 1998. The State has drafted proposed regulations for this amendment and submitted them to the NRC for review on July 3, 2003.

- "Respiratory Protection and Controls to Restrict Internal Exposures," 10 CFR Part 20 amendment (64 FR 54543; 64 FR 55524) that became effective February 2, 2000. The State has drafted proposed regulations for this amendment and submitted them to the NRC for review on July 3, 2003. The NRC reviewed the State's proposed regulations for this amendment in August 2003, and determined that they meet the NRC's

compatibility requirements when the one comment identified is addressed. There are currently no Maryland licensees authorized to use, or actively using, respiratory protection or controls to restrict internal exposures.

- "Energy Compensation Sources for Well Logging and Other Regulatory Clarifications," 10 CFR Part 39 amendment (65 FR 20337) that became effective May 17, 2000. The State drafted proposed regulations for this amendment and submitted them to the NRC for review on July 3, 2003. The NRC reviewed the State's proposed regulations for this amendment in August 2003, and determined that they meet the NRC's compatibility requirements when the one comment identified is addressed. There are currently no Maryland licensees authorized for this activity.

- "Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material," 10 CFR Parts 30, 31, and 32 amendments (65 FR 79162) that became effective February 16, 2001. 10 CFR 32.52 (a) and (b) amendments were to be implemented by States within six months, August 16, 2001. The Program was not aware that a portion of this amendment is required to be implemented within six months. The Program stated that they will address the overdue portion of this amendment by adding a license condition to the four or five affected licensees by September 2003.

The Program stated that the delay in adopting the first four NRC amendments listed above (Supplement 8 to the State's "Regulations for the Control of Ionizing Radiation") was due to the resolution of legal issues by the Department's attorneys with regard to the adoption of the Deliberate Misconduct Rule. The team determined that further delays with the adoption of the overdue NRC amendments was primarily due to the vacant manager position for the Radioactive Materials Division (see discussion in Section 3.1) who had the primary responsibility for keeping the States' regulations compatible. As indicated in Section 3.1, the responsibilities for this position are currently shared by the Supervisors of the Materials Licensing and Inspection Sections.

The Program will need to address the following four regulations in upcoming rulemakings or by adopting alternate legally binding requirements:

- "New Dosimetry Technology," 10 CFR Parts 34, 36, and 39 amendments (65 FR 63749) that became effective January 8, 2001.

- "Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material," 10 CFR Parts 30, 31, and 32 amendments (65 FR 79162) that became effective February 16, 2001. The remaining portion of this amendment is due February 16, 2004.

- "Revision of the Skin Dose Limit," 10 CFR Part 20 amendment (67 FR 16298) that became effective April 5, 2002.

- "Medical Use of Byproduct Material," 10 CFR 20, 32, and 35 amendments (67 FR 20249) that became effective October 24, 2002.

Based on IMPEP evaluation criteria, the review team recommends that Maryland's performance with respect to the indicator, Legislation and Program Elements Required for Compatibility, be found satisfactory with recommendations for improvement.

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

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

In assessing the Program's SS&D evaluation program, the review team examined information provided by the Program in response to the IMPEP questionnaire on this indicator. The team also evaluated actions taken by the Program in response to the recommendations noted during the 1999 review and the 2001 follow-up review. A review of selected new and amended SS&D evaluations and supporting documents covering the review period was conducted. The team noted the staff's use of guidance documents and procedures, interviewed the staff and the Licensing Section Supervisor involved in SS&D evaluations, and verified the use of regulations, license conditions, and inspections to enforce commitments made in the applications.

4.2.1 Technical Quality of the Product Evaluation Program

The Program issued a total of 19 SS&D registry certificates since the follow-up review in November 2001, including seven inactivations. Two additional applications were in the evaluation process during this IMPEP review. The review team examined a total of 10 certificates, and their supporting documentation, including two new, six amendments, two inactivations, and five certificates relating to the closure of open recommendations. The certificates reviewed covered the period since the follow-up review, starting with a review of certificates identified in open recommendations, and represented cases completed by all reviewers. The SS&D certificates evaluated by the review team are listed with case-specific comments in Appendix F.

The Program has continued its practice of having dedicated five days each month to perform SS&D casework reviews. Additionally, as discussed in Section 4.2.2, the Program has continued to utilize technical assistance from an engineer within the Department. This has enabled the Program to reduce its backlog of SS&D casework and respond to the recommendations made during the 1999 and 2001 IMPEP reviews.

Analysis of the casework and interviews with the staff confirmed that the Program follows the recommended guidance from the NRC SS&D training workshops and NUREG-1556, Volume 3, issued July 1998. Appropriate review checklists, including the Program's Engineering Review Checklist, were used to assure all relevant materials had been submitted and reviewed. The checklists were retained in the registration files. All pertinent American National Standards Institute standards, Regulatory Guides, and applicable references were confirmed to be available and were used when performing SS&D reviews.

The Program has implemented an additional step in its concurrence review process. After the certification has been prepared and signed by the initial reviewer, it goes through an engineering review to ensure that design and structural integrity have been addressed, and a

concurrence review to ensure that health, safety, and licensing issues have been addressed. The Program's concurrence review process produces a registry certificate that adequately addresses both the physical integrity of the product and the health and safety of the users, the public, and the environment.

The registration files contained all correspondence, photographs, engineering drawings, radiation profiles, and details of the applicant's quality assurance and quality control (QA/QC) program. In instances where references are common among multiple certificates, the Program has established a separate file for those references and has made notations in the appropriate SS&D folders. The registrations clearly summarize the product evaluation to provide license reviewers with adequate information to license the possession and use of the product. Deficiency letters clearly stated regulatory positions and all health and safety issues were properly addressed. The review team determined that the product evaluations were thorough, complete, consistent, of acceptable technical quality, and adequately addressed the integrity of the products during use and in the event of an accident.

The review team queried the SS&D registry and identified a total of 58 active and 12 inactive certificates among 19 companies in the State. A closer review indicated that some of the certificates belong to companies that are no longer in business. As of June 21, 2003, the Program identified 12 active distributors with a combined total of 50 active certificates. Additionally, six distributors accounted for the 19 certificates issued during this review period.

4.2.2 Technical Staffing and Training

The Program reported that four staff members currently have authority to sign SS&D evaluations, in addition to their responsibilities for licensing casework. However, one of those individuals has been on loan to the Inspection Section since January 2003, to address staffing shortages. The Program currently dedicates approximately 1-2 days per week to the performance of SS&D reviews. The current SS&D staffing level as described in this section is adequate for the needs of the Program.

The review team noted that the Program issued a memorandum formalizing its signature authority requirements on November 14, 2002. Prior to that date, signature authority was granted on a case-by-case basis by the Licensing Section Supervisor.

The Program is continuing to utilize the services of an engineer from within the Department to complement the skills and experience of the full-time staff. As noted in the 2001 follow-up review, the engineer has attended NRC's SS&D workshop, has advanced engineering degrees, and experience in mechanical engineering and radiation safety. A formal MOU was established in May 2001, authorizing up to 16 hours a week of the engineer's time for SS&D review. The Program plans to send the engineer to a health physics course to qualify him for signature authority.

4.2.3 Evaluation of Defects and Incidents Regarding SS&Ds

Utilizing NMED and the Program's response to the questionnaire, the review team identified two separate incidents or failures involving one Maryland product during the review period. The product was the Nucletron Model 105.999 HDR. The first failure mode involved deficiencies in the treatment software that resulted in the inadvertent changing of the step size. The Program

coordinated with the NRC and FDA to resolve the matter. As reflected in modifications to its SS&D certificates, Nucletron has since modified the software and has upgraded all units in use in the United States, Canada, Mexico, and Puerto Rico. This issue was initially addressed during the 2001 follow-up review.

The second failure mode was that the source failed to automatically return to the shielded position. All attempts to utilize automatic backups, including the emergency stop button and treatment room door interlocks, did not engage the backup motor. The source was eventually returned to the shielded position via the device's hand crank. The Program's investigation and manufacturer's testing and evaluation of the affected components did not indicate a reproducible failure. The Program, with the assistance of the engineer described in Section 4.2.2, performed a detailed review of the manufacturer's testing protocols and scenarios and arrived at the same conclusion as the manufacturer, that this failure was not generic in nature.

Based on the IMPEP evaluation criteria, the review team recommends that Maryland's performance with respect to the indicator, Sealed Source and Device 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 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 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 and 4 above, the review team found Maryland's performance to be satisfactory for four performance indicators, and satisfactory with recommendation for improvement for three performance indicators. Accordingly, the review team recommends finding the Maryland Agreement State program to be 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 review should be in approximately four years. The review team made three recommendation.

Below is a summary list of the recommendations from this IMPEP review:

1. The review team recommends that the State fill the current vacancies in the program as soon as possible, and evaluate staffing needs to assure program adequacy and compatibility. (Section 3.1)

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 inspections priorities. (Section 3.2)

3. The review team recommends that the Program follow the guidance for all licensing actions involving name changes and possible change in ownership/control. (Section 3.4)

LIST OF APPENDICES AND ATTACHMENTS

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	**Area of Responsibility**
Linda McLean, Region IV	Team Leader Technical Staffing and Training
Duncan White, Region I	Response to Incidents and Allegations Legislation and Program Elements Required for Compatibility
John Pelchat, Region II	Status of Materials Inspection Program Technical Quality of Inspections Inspector Accompaniments
Michelle Beardsley, Region I	Technical Quality of Licensing Actions
Eric Jameson, Georgia	Sealed Source and Device Evaluation Program

APPENDIX B

MARYLAND ORGANIZATION CHARTS
ML032130335

APPENDIX C

INSPECTION CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS ONLY; NO SIGNIFICANT COMMENTS WERE IDENTIFIED BY THE IMPEP TEAM.

File No.: 1
Licensee: Holy Cross Hospital License No.: 31-001-01
Location: Silver Spring, MD Inspection Type: Routine, Unannounced
License Type: Therapeutic Nuclear Medicine Priority: 3
Inspection Date: 2/14/02 Inspector: AJ

File No.: 2
Licensee: Alpha Omega License No.: California CA-3925-19
Location: Baltimore, MD (temporary job site) Inspection Type: Reciprocity, Unannounced
License Type: Therapy Source Service Priority: N/A
Inspection Date: 1/23/03 Inspector: AJ, RM

File No.: 3
Licensee: Saint Joseph's Hospital License No.: 05-005-01
Location: Towson, MD Inspection Type: Routine, Unannounced
License Type: Nuclear Medicine, Therapy & Research Priority: 1
Inspection Date: 1/29/02 Inspector: RN

File No.: 4
Licensee: MDS Nordion, Inc. License No.: NRC 54-28275-01
Location: Elkton, MD (temporary job site) Inspection Type: Reciprocity, Unannounced
License Type: Irradiator Source Service Priority: N/A
Inspection Date: 6/3/03 Inspector: ML, AJ

File No.: 5
Licensee: Rad America License No.: 05-051-03
Location: Baltimore, MD Inspection Type: Routine, Unannounced
License Type: High-Dose Rate Remote Afterloader Priority: 1
Inspection Date: 4/29/03 Inspector: NO

File No.: 6
Licensee: Neutron Products, Inc. License No.: 31-025-01
Location: Dickerson, MD Inspection Type: Routine, Unannounced
License Type: Source Manufacturer, Irradiator Priority: 1
Inspection Date: 6/24, 6/27, 7/2/02 Inspector: AJ, RN

File No.: 7
Licensee: Accurate Technologies, Inc (United Evaluation Inc.) License No.: NRC 29-28358-01
Location: Temporary Job Site Inspection Type: Reciprocity, Reactive
License Type: Industrial Radiographer Priority: N/A
Inspection Date: 10/05, 10/16/01 Inspector: AJ, RM, RN

File No.: 8
Licensee: Mallinckrodt, Inc. License No.: 05-105-01
Location: Baltimore, MD Inspection Type: Routine, Unannounced
License Type: Nuclear Pharmacy Priority: 1
Inspection Date: 6/27/03 Inspector: NO

File No.: 9
Licensee: Campbell & Nolan Associates License No.: 25-030-01
Location: Forest Hill, MD (temporary job site) Inspection Type: Routine, Unannounced
License Type: Portable Gauge Priority: 5
Inspection Date: 7/9/03 Inspector: ML

File No.: 10
Licensee: Syncor/Cardinal Health License No.: 31-263-01
Location: Silver Spring, MD Inspection Type: Routine, Unannounced
License Type: Nuclear Pharmacy Priority: 1
Inspection Date: 4/2/03 Inspector: NO

INSPECTOR ACCOMPANIMENTS

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

Accompaniment No.: 1
Licensee: University of Maryland License No.: 33-004-03
Location: College Park, MD Inspection Type: Routine, Unannounced
License Type: Pool Irradiator Priority: 1
Inspection Date: 7/8/03 Inspector: RM

Accompaniment No.: 2
Licensee: Campbell & Nolan Associates License No.: 25-030-01
Location: Forest Hill, MD (temporary job site) Inspection Type: Routine, Unannounced
License Type: Portable Gauge Priority: 5
Inspection Date: 7/9/03 Inspector: ML

Accompaniment No.: 3
Licensee: Harbor Hospital Center License No.: 07-012-01
Location: Baltimore, MD Inspection Type: Routine, Unannounced
License Type: Diagnostic & Therapeutic Nuclear Medicine Priority: 3
Inspection Date: 7/10/03 Inspector: NO

APPENDIX D

LICENSE CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS ONLY; NO SIGNIFICANT COMMENTS WERE IDENTIFIED BY THE IMPEP TEAM.

File No.: 1
Licensee: Smith's Detection/ETG, Inc. License No.: 25-044-01
Location: Baltimore, MD Amendment No.: 28
License Type: Measuring Systems, Analytic gauges Type of Action: Decommissioning
Date Issued: 9/20/02 License Reviewer: NO

File No.: 2
Licensee: Howard Co. Gen. Hospital License No.: 27-016-01
Location: Columbia, MD Amendment No.: NA
License Type: Medical Institution-limited. Type of Action: Amendment
Date Issued: Pending License Reviewer: DM

Comment:
Action reviewed for pending health and safety issues.

File No.: 3
Licensee: Human Genome Sciences, Inc. License No.: 31-220-01
Location: Rockville, MD Amendment No.: 35
License Type: Research and Development Type of Action: Amendment
Date Issued: 4/18/03 License Reviewer: DM

File No.: 4
Licensee: Nucletron Corp. License No.: 27-035-01
Location: Columbia, MD Amendment No.: 45
License Type: Manufacturing and Distribution Type of Action: Amendment
Date Issued: 5/27/03 License Reviewer: BP

File No.: 5
Licensee: Stanley B. Wadsworth License No.: 05-095-01
Location: Baltimore, MD Amendment No.: NA
License Type: Calibration/leak Test Service Type of Action: Renewal
Date Issued: Pending License Reviewer: NO, BP

Comment:
Action reviewed for pending health and safety issues.

File No.: 6
Licensee: Charles River Labs. License No.: 31-208-01
Location: Rockville, MD Amendment No.: 11
License Type: Research and Development Type of Action: Amendment
Date Issued: 11/14/02 License Reviewer: DM

Comment:
Letter requesting name change was not signed by proper official. No deficiency letter or phone call was made requesting additional information as specified in guidance.

File No.: 7
Licensee: Charles River Labs License No.: 31-208-01
Location: Rockville, MD Amendment No.: 12
License Type: Research and Development Type of Action: Amendment
Date Issued: 11/27/02 License Reviewer: NO

Comment:
Letter requested change in RSO; not signed by proper official.

File No.: 8
Licensee: Syncor Int'l Corp. License No.: 31-263-01
Location: Silver Spring, MD Amendment No.: 71
License Type: Nuclear Pharmacy Type of Action: Amendment
Date Issued: 1/31/03 License Reviewer: BP

Comment:
Change in ownership request; not signed by officials from both parties.

File No.: 9
Licensee: Johns Hopkins Med. Institution License No.: 07-005-12
Location: Baltimore, MD Amendment No.: 2
License Type: Private Practice-PET facility Type of Action: Amendment
Date Issued: 10/25/02 License Reviewer: DM

Comment:
Change in ownership request; not signed by officials from both parties.

File No.: 10
Licensee: Howard County General Hospital License No.: 27-016-01
Location: Columbia, MD Amendment No.: NA
License Type: Medical Institution-limited Type of Action: Amendment
Date Issued: Pending License Reviewer: DM

File No.: 11
Licensee: Nova Screen Bio Sciences Corp. License No.: 03-062-01
Location: Hanover, MD Amendment No.: 12
License Type: Research and Development Type of Action: Amendment
Date Issued: 9/10/02 License Reviewer: DM

File No.: 12
Licensee: Orchid Cellmark License No.: 31-168-01
Location: Germantown, MD Amendment No.: 15
License Type: In-vitro Laboratory Type of Action: Termination
Date Issued: 3-/4/03 License Reviewer: NO

File No.: 13
Licensee: Johns Hopkins Med. Inst. License No.: 07-019-12
Location: Baltimore, MD Amendment No.: NA
License Type: R&D Broadscope Type of Action: Renewal
Date Issued: Pending License Reviewer: BP

Comment:
Action reviewed for pending health and safety issues.

File No.: 14
Licensee: Calvert Memorial Hospital License No.: 09-003-01
Location: Prince Frederick, MD Amendment No.: 37
License Type: Medical Institution-limited Type of Action: Amendment
Date Issued: 11/20/02 License Reviewer: NO

File No.: 15
Licensee: Johns Hopkins Medical Inst. License No.: 07-005-10
Location: Baltimore, MD Amendment No.: 10
License Type: Medical Broadscope Type of Action: Renewal
Date Issued: 2/6/02 License Reviewer: CT

File No.: 16
Licensee: Constellation Power Source Generation, Inc. License No.: 03-027-04
Location: Baltimore, MD Amendment No.: 11
License Type: Fixed Gauge Type of Action: Renewal
Date Issued: 1/15/03 License Reviewer: BP

File No.: 17
Licensee: Johns Hopkins Medical Institute License No.: 07-005-13
Location: Baltimore, MD Amendment No.: NA
License Type: Gamma Knife Type of Action: New
Date Issued: 1/8/03 License Reviewer: BP

File No. : 18
Licensee: University of Maryland at Baltimore License No.: 07-014-01
Location: Baltimore, MD Amendment No.: 58
License Type: R&D Broadscope Type of Action: Renewal
Date issued: 5/14/02 License Reviewer: BP

File No.: 19
Licensee: Bahia 21 Corp. License No.: 31-306-01
Location: Rockville, MD Amendment No.: NA
License Type: Device Distribution Type of Action: New
Date issued: 10/31/01 License Reviewer: DM

File No.: 20
Licensee: Life Technologies-Invitrogen Corp. License No.: 31-080-01
Location: Rockville, MD Amendment No.: NA
License Type: Research and Development Type of Action: Termination
Date issued: 1/14/03 License Reviewer: NO

File No.: 21
Licensee: Human Genome Sciences License No.: 31-220-01
Location: Rockville, MD Amendment No.: NA
License Type: Research and Development Type of Action: Financial Assurance
Date issued: Executed 4/99 License Reviewer: LR

APPENDIX E

INCIDENT CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS ONLY; NO SIGNIFICANT COMMENTS WERE IDENTIFIED BY THE IMPEP TEAM.

File No.: 1
Licensee: KCI Technologies Inc. License No.: 05-150-01
Site of Incident: Laytonsville, MD Incident Log No.: NMED 990439
Date of Incident: 7/15/99 Type of Incident: Damage to Equipment
Investigation Date: 7/15/99 Type of Investigation: Site

File No.: 2
Licensee: EBA Engineering Inc. License No.: 07-144-01
Site of Incident: Beltsville, MD Incident Log No.: NMED 990787
Date of Incident: 10/25/99 Type of Incident: Stolen Radioactive Material
Investigation Date: 10/26/99 Type of Investigation: Site and Phone

Comment:
Event closed in local database, but national database not updated.

File No.: 3
Licensee: W.L. Gore and Associates License No.: General Licensee
Site of Incident: Elkton, MD Incident Log No.: NMED 020274
Date of Incident: 2/21/02 Type of Incident: Leaking Source
Investigation Date: 2/21/02 Type of Investigation: Site

Comment:
Event closed in local database, but national database not updated.

File No.: 4
Licensee: Fairfield Property (Nucor Steel) License No.: General License
Site of Incident: Baltimore, MD Incident Log No.: NMED 020230
Date of Incident: 2/28/02 Type of Incident: Abandoned Radioactive Material
Investigation Date: 2/28/02 Type of Investigation: Site and Phone

Comment:
NMED record does not indicate final disposal option used.

File No.: 5
Licensee: University of Maryland at Baltimore License No.: 07-014-01
Site of Incident: Baltimore, MD Incident Log No.: MD010003001
Date of Incident: 5/8/01 Type of Incident: Equipment Failure
Investigation Date: 5/9/01 Type of Investigation: Site and Phone

Comment:
Event in local database, but not found in national database.

File No.: 6
Licensee: Environmental Technologies Group License No.: 05-012-01
Site of Incident: Baltimore, MD Incident Log No.: MD000007001
Date of Incident: 9/15/00 Type of Incident: Contamination
Investigation Date: 10/30/00 Type of Investigation: Site and Phone

Comment:
Event in local database, but not found in national database.

File No.: 7
Licensee: Doctor's Community Hospital License No.: 33-029-01
Site of Incident: Lanham, MD Incident Log No.: NMED 020646
Date of Incident: 4/1-30/02 Type of Incident: Overexposure
Investigation Date: 8/1/02 Type of Investigation: Site

File No.: 8
Licensee: Maryland Regional Cancer Care License No.: 31-303-01
Site of Incident: Silver Springs, MD Incident Log No.: NMED 020845
Date of Incident: 9/6/02 Type of Incident: Equipment Failure
Investigation Date: 9/9/02 Type of Investigation: Site

Comment:
Event closed in local database, but national database not updated.

File No.: 9
Licensee: Franklin Square Hospital Center License No.: 05-32-02
Site of Incident: Baltimore, MD Incident Log No.: NMED 010474
Date of Incident: 5/10/01 Type of Incident: Misadministration
Investigation Date: 5/22/01 Type of Investigation: Site

File No.: 10
Licensee: Neutron Products License No.: 31-025-01
Site of Incident: Shady Grove, MD Incident Log No.: NMED 020646
Date of Incident: 6/27/02 Type of Incident: Release of Radioactive Material
Investigation Date: 6/27/02 Type of Investigation: Site

File No.: 11
Licensee: University of Maryland License No.: 07-014-05
Site of Incident: Baltimore, MD Incident Log No.: NMED 000812
Date of Incident: 4/20/00 Type of Incident: Misadministration
Investigation Date: 4/26-28/00 Type of Investigation: Site

File No.: 12
Licensee: Professional Service Industries NRC License No.: 12-16941-01 (reciprocity)
Site of Incident: Columbia, MD Incident Log No.: NMED 020292
Date of Incident: 3/15/02 Type of Incident: Stolen Radioactive Material
Investigation Date: 3/28/02 Type of Investigation: Site and Phone

APPENDIX F

SEALED SOURCE AND DEVICE CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS ONLY; NO SIGNIFICANT COMMENTS WERE IDENTIFIED BY THE IMPEP TEAM.

File No.: 1
Distributor: Pettit Applied Technologies
Model: PAT Model 1000
Date Issued: 7/10/03
Registry No.: MD-1003-D-101-G
SS&D Type: Thickness Gauge
Type of Action: Amendment
Reviewers: DM, RM

Comment:
Previous correspondence referring to previous issue of certificate was not included in file. The supervisor stated that manufacturer resubmitted application in its entirety

File No.: 2
Distributor: Pettit Applied Technologies
Model: CPC-48
Date Issued: 10/16/02
Registry No.: MD-1003-D-801-G
SS&D Type: Beta Gauge
Type of Action: Inactivation
Reviewers: DM, RM

Comment:
File only contained inactivation certificate (no previous supporting documentation). The Licensing Section Supervisor stated that documents have been missing since office move in September 2002.

File No.: 3
Distributor: Smith's Detection (formerly ETG)
Model: Various
Date Issued: 04/16/03
Registry No.: MD-0263-D-102-G
SS&D Type: Chemical Agent Detector
Type of Action: Amendment
Reviewers: BP, RM

Comment:
Reference #3 (SS&D registry # NR-476-S-151-S) needs to reflect new registry # CA-406-S-215-S as listed in letter dated 9/26/2001.

File No.: 4
Distributor: Nucletron
Model: DRN 07736 (was 105.002)
Date Issued: 1/18/01
Registry No.: MD-497-S-107-S
SS&D Type: HDR Brachytherapy Source
Type of Action: Amendment
Reviewers: RM, DM

Comment:
Certificate still does not describe material of construction of plug (refer to 2001 IMPEP Follow-up Final Report).

File No.: 5
Distributor: Nucletron
Model: 105.999
Date Issued: 6/27/2003
Registry No.: ME-497-D-108-S
SS&D Type: HDR Brachytherapy Device
Type of Action: Amendment
Reviewers: BP, RM

File No.: 6
Distributor: Bahia 21 Corporation
Model: MO-2M
Date Issued: 11/7/01
Registry No.: MD-1149-D-101-G
SS&D Type: Hand-held Explosives Vapor Detector
Type of Action: New
Reviewers: DM, RM

File No.: 7
Distributor: Bahia 21 Corporation
Model: MO-2M
Date Issued: 10/10/02
Registry No.: MD-1149-D-101-G
SS&D Type: Hand-held Explosives Vapor Detector
Type of Action: Amendment
Reviewers: DM, RM

Comments:
a) E-mail reference dated 2/1/01 was not in file.
b) There was no documentation to support change in activity. The Licensing Section Supervisor indicated it was for loading tolerance.

File No.: 8
Distributor: Shimadzu Scientific Instruments
Model: ECD-8/9/14; ECD-17; ECD-14C; ECD-2010
Date Issued: 4/9/03
Registry No.: MD-600-D-101-B
SS&D Type: E-capture Detector
Type of Action: Amendment
Reviewers: RM, BP

Comments:
a) Previous (original) issue of certificate and references was not in file.
b) Review was started by a different reviewer than the signatures on the certificate.
c) Device manufacturer is located in Japan, certificate should reflect this (i.e., separate listings for manufacturer and distributor).

File No.: 9
Distributor: Nucletron
Model: Selectron HDR
Date Issued: 4/22/02
Registry No.: MD-497-D-802-S
SS&D Type: HDR Remote Afterloader Brachytherapy Unit
Type of Action: Inactivation
Reviewers: BP, RM

Comment:
Manufacturer’s customer information bulletin, which brought about returns from service and inactivation, was not in file.

File No.: 10
Distributor: Nucletron Registry No.: MD-497-D-110-S
Model: Seed Selectron 130.001 SS&D Type: Seed Brachytherapy Afterloader
Date Issued: 5/21/02 Type of Action: New
Reviewers: RM, BP

Comment:
Registry lists a reference as 4/15/02; document in file shows date as 4/8/02.

ATTACHMENT

October 7, 2003 Letter from Thomas C. Snyder, Director,
Maryland Air and Radiation Management Administration

ML032880190

Agenda for Management Review Board Meeting
November 10, 2003, 2:00 p.m. - 4:00 p.m., O-3-B4

1. MRB Chair convenes meeting. Introduction of MRB members, review team members, Maryland representatives, and other representatives participating through telephone bridge or video conferencing.

2. Consideration of the Maryland IMPEP Report.

   A. Presentation of Findings Regarding Maryland Program and Discussion.
      - Technical Staffing and Training
      - Status of Materials Inspection Program
      - Technical Quality of Inspections
      - Technical Quality of Licensing Actions
      - Response to Incidents and Allegations
      - Legislation and Program Elements Required for Compatibility
      - Sealed Source and Device Evaluation Program

   B. MRB Consultation/Comments on Issuance of Report.
      - Adequacy and Compatibility Rating
      - Recommendation for Next IMPEP Review

   C. Comments

3. Status of IMPEP Reviews and Heightened Oversight/Monitoring Activities

4. Establishment of Precedents/Lessons Learned

5. Adjournment

Invitees:

Carl Paperiello, EDO
Paul Lohaus, STP
Martin Virgilio, NMSS
Karen Cyr, OGC
Eric Jameson, GA
Lance Rakovan, STP
Aaron McCraw, STP
OAS Liaison to the MRB
Linda McLean, Region IV
Duncan White, Region I
John Pelchat, Region II
Michelle Beardsley, Region I
Roland Fletcher, MD
Josephine Piccone, STP
Osiris Siurano, STP

ATTACHMENT 2