May 23, 2007

Bonita Sorensen, M.D., M.B.A.
Deputy State Health Officer
Department of Health
4052 Bald Cypress Way, Bin A07
Tallahassee, FL 32399-1708

Dear Dr. Sorensen:

On April 30, 2007, the Management Review Board (MRB) met to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) report on the Florida Agreement State Program. The MRB found the Florida Agreement State Program adequate to protect public health and safety and compatible with the U.S. Nuclear Regulatory Commission's program.

Section 5.0, page 14, of the enclosed final report contains a summary of the IMPEP review team's findings and recommendation. We request your evaluation and response to the recommendation within 30 days from receipt of this letter.

Based on the results of the current IMPEP review, the next full review of the Florida Agreement State Program will take place in approximately 4 years, with a periodic meeting tentatively scheduled for February 2009.

I appreciate the courtesy and cooperation extended to the IMPEP team during the review. I also wish to acknowledge your continued support for the Agreement State Program and the excellence in program administration demonstrated by your staff, as reflected in the review team's findings. I look forward to our agencies continuing to work cooperatively in the future.

Sincerely,

/RA/

Martin J. Virgilio
Deputy Executive Director for Materials, Waste,
Research, State, Tribal, and Compliance Programs
Office of the Executive Director for Operations

Enclosure: Florida Final IMPEP Report

cc: Lisa Conti, Director
Florida Division of Environmental Health

William A. Passetti, Chief
Florida Bureau of Radiation Control

Barbara Hamrick, California
Organization of Agreement States
Liaison to the MRB

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF FLORIDA AGREEMENT STATE PROGRAM

February 12-16, 2007

FINAL REPORT

U.S. Nuclear Regulatory Commission

ENCLOSURE

1.0 INTRODUCTION

This report presents the results of the review of the Florida Agreement State Program. The review was conducted during the period of February 12-16, 2007, by a review team comprised of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the Commonwealth of Massachusetts. 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 February 8, 2003, to February 16, 2007, were discussed with Florida management on the last day of the review.

A draft of this report was issued to Florida for factual comment on March 15, 2007. The State responded by letter on March 30, 2007, from William Passetti, Chief, Bureau of Radiation Control (the Bureau). The Management Review Board (MRB) met on April 30, 2007, to consider the proposed final report. The MRB found the Florida Agreement State Program adequate to protect public health and safety and compatible with NRC's program.

The Bureau, located within the Division of Environmental Health (the Division), administers the Florida Agreement State Program. The Division is part of the Department of Health (the Department). Organization charts for the Department and the Bureau are included as Appendix B.

At the time of the review, the Florida Agreement State Program regulated approximately 1,689 specific licenses. 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 Florida.

In preparation for the review, a questionnaire addressing the common and applicable non-common performance indicators was sent to the Bureau on November 22, 2006. The Bureau provided its response to the questionnaire on January 26, 2007. A copy of the questionnaire response may be found in the NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML070600149.

The review team's general approach for conduct of this review consisted of: (1) examination of the Bureau's response to the questionnaire; (2) review of applicable Florida statutes and regulations; (3) analysis of quantitative information from the Bureau's database; (4) technical review of selected regulatory actions; (5) nine field accompaniments of Florida 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 Agreement State program's performance.

Section 2.0 of this report identifies that no recommendations were made during the previous review. Results of the current review for the common performance indicators are presented in Section 3.0. Section 4.0 discusses the results of the review of the applicable non-common performance indicators, and Section 5.0 summarizes the review team's findings and recommendations. Recommendations made by the review team are comments that relate

directly to program performance by the State. A response is requested from the State to all recommendations in the final report.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous IMPEP review, which concluded on February 7, 2003, no recommendations were made by the review team.

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 Bureau'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 Bureau's questionnaire response relative to this indicator; interviewed Bureau management 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 Bureau is managed by the Bureau Chief from the Central Office, located in Tallahassee. The Bureau consists of five Sections, three of which have responsibilities for radioactive materials under the Agreement: the Radioactive Materials Section, the Field Operations Section, and the Environmental Radiation Labs Section. All Sections are headed by an Administrator. The Radioactive Materials Administrator is responsible for materials licensing and compliance activities. The Field Operations Administrator is responsible for coordinating the inspections activities, which are conducted primarily by the six field offices and two counties under contract, Polk and Broward. The Environmental Radiation Labs Administrator, stationed in Orlando, is responsible for the Bureau's laboratory and emergency response activities.

At the time of the review, there were 62 individuals with various degrees of involvement in the radioactive materials program, totaling 21 full time equivalents (FTE). This staffing level does not include administrative support staff. Seventeen staff, including five managers, were stationed in the Central Office. Thirty-six staff were inspectors or inspection managers distributed among the six field offices and the two counties under contract. Nine staff were involved with emergency response and laboratory services in the Orlando Office.

The Bureau had a total of 24 turnovers in staff during the review period. The Bureau's turnovers can be attributed to competition with local industry for qualified staff and recent retirements of several experienced staff members. The Bureau has been able to fill vacancies in an expedient manner. At the time of the review, the Bureau had one vacancy, in the Miami Field Office. The position became vacant January 26, 2007, and the Bureau is in the process of interviewing applicants.

The Bureau Chief supports staff training opportunities, as well as staff participation in Federal and State working groups. The Bureau has a documented training plan that is consistent with the guidance in the NRC/Organization of Agreement States Training Working Group Report and NRC's Inspection Manual Chapter (IMC) 1246. They also have been developing an in-house training program that focuses on on-the-job training after completion of an orientation module developed by Bureau staff. At the time of the review, the Bureau had eight staff members that had attended the NRC Security Systems and Principles course. The Bureau was also working to develop a training module to provide in-house training equivalent to the NRC Security Systems and Principles course to qualify all inspectors for Increased Controls inspections. The review team concluded that the Bureau has an adequate and well-balanced staff to carry out its regulatory responsibilities.

The review team noted that the Bureau experienced stable funding during the review period. The Bureau is authorized to assess and collect fees for specific and general licenses, as well as for the registration of radiation machines. In addition, Florida licensees are assessed an annual licensing and inspection fee. All monies collected by the Bureau are deposited in the Radiation Protection Trust Fund, which is held and applied solely for the expenses incurred in implementing the radiation control program. The Bureau is currently amending its radioactive materials license fee schedule which will maintain full funding for the radioactive materials program.

The Advisory Council on Radiation Protection of the State of Florida (the Council), as constituted under law, acts only in an advisory role to the Bureau. Meetings of the Council are infrequent.

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

3.2 Status of Materials Inspection Program

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

The review team verified that the Bureau's inspection priorities for various license types are at least as frequent as, and typically more frequent than, similar license types listed in IMC 2800. Forty-five of the 46 license categories established by the Bureau were assigned inspection priority codes that prescribe a more frequent inspection schedule than those established in IMC 2800 for similar license types.

The review team determined that, during the review period, the Bureau conducted approximately 1,017 Priority 1, 2, and 3 inspections, based on the inspection frequencies established in IMC 2800. None of these inspections were conducted overdue, nor were any inspections overdue at the time of the review. In addition, the Bureau performed 532 initial inspections during the review period, 18 of which were conducted overdue (greater than 12

months after license issuance). The initial inspections became overdue because, when pre-licensing site visits were entered into the Bureau's inspection software system, the system was automatically assigning the next inspection date based on the routine inspection priority code, not on an initial inspection interval. This resulted in the system not capturing the appropriate initial inspection date. The Bureau self-identified this software error and has addressed the issue by manually changing the next inspection date to the appropriate time frame following a pre-licensing visit. Bureau staff with computer programming experience are currently evaluating the error to determine the most effective path forward. Overall, approximately 1.1 percent of the total Priority 1, 2, 3 and initial inspections conducted by the Bureau, during the review period, were performed overdue (18 late inspections out of 1,549 total inspections).

The review team evaluated the Bureau's timeliness in providing inspection findings to licensees. The review team determined that, during the review period, a majority of inspection findings were communicated to the licensees in less than 30 days. A sampling of 49 inspection reports indicated that 2 inspection findings were communicated to the licensees beyond the Bureau's goal of 30 days after the inspection. These reports were issued 33 and 40 days after the date of their respective inspections. In both cases, the inspectors failed to turn in their field notes to the Central Office in a timely manner, thus affecting the timely issuance of the reports.

During the review period, the Bureau granted 236 reciprocity permits, 89 of which were candidate licensees based upon the criteria in IMC 1220. The review team determined that the Bureau met and/or exceeded the NRC's criteria of inspecting 20 percent of candidate licensees operating under reciprocity in each of the four years covered by the review period.

The review team determined that with respect to Commission Staff Requirements Memorandum (SRM) for COMSECY-05-0028, on Increased Controls, the Bureau planned for the initial set of inspections of these licensees in accordance with the SRM. The review team evaluated the Bureau's prioritization methodology and found it acceptable. The Bureau elected to perform all of its Increased Controls inspections by December 2006. The Bureau currently has 60 licensees subject to the Increased Controls. Fifty-three Increased Controls inspections had been completed at the time of the review. Six Increased Controls inspections were performed and were under Bureau review, awaiting the licensees' responses. One new licensee's implementation of the Increased Controls will be inspected by June 2007 in conjunction with the initial inspection.

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

3.3 Technical Quality of Inspections

The review team evaluated the inspection reports, enforcement documentation, inspection field notes, and interviewed inspectors for 20 radioactive materials inspections conducted during the review period. The casework reviewed included inspections conducted by 15 Bureau inspectors and covered inspections of various license types, including: medical broad scope, medical institutions requiring written directives, medical private practice, fixed and portable gauges, industrial radiography, academic broad scope, irradiator, medical therapy, nuclear pharmacy, manufacturer and distribution, waste disposal and processing, Increased Controls,

and reciprocity. 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 noted that inspections covered all aspects of licensed radiation programs. The review team found that inspection reports were generally thorough, complete, consistent, and of high quality, with sufficient documentation to ensure that a licensee's performance with respect to health and safety was acceptable. The majority of the documentation supported violations, recommendations made to licensees, unresolved safety issues, and discussions held with licensees during exit interviews. Three casework files reviewed contained apparent violations that were not cited by the Bureau in correspondence sent to the licensee. The files did not contain documentation to justify not citing the apparent violations. The Bureau agreed to modify their policy on documenting non-cited violations to ensure that inspection reports and/or field notes adequately reflect all of the inspectors' observations and provide sufficient justification for not citing violations.

The inspection procedures utilized by the Bureau are generally consistent with the inspection guidance outlined in IMC 2800. An inspection report is completed by the inspector which is then reviewed and signed by the Regional Manager. Completed inspection actions are then sent to the Inspection Coordinator in the Central Office for issuance of inspection or enforcement correspondence. Supervisory accompaniments were conducted annually for all inspectors.

The review team determined that the inspection findings were appropriate and prompt regulatory actions were taken, as necessary. All inspection findings are clearly stated and documented in the report and sent to the licensee with the appropriate form or letter detailing the results of the inspection. The Bureau issues, to the licensee, either a letter indicating a clear inspection or a Notice of Violation (NOV), in letter format, detailing the results of the inspection. When the Bureau issues an NOV, the licensee is required to provide a written corrective action plan, based on the violations cited, within 30 days. All findings are reviewed by the Inspection Coordinator. The review team, through the casework review, identified that NOVs sent from the Bureau to licensees required to implement the Increased Controls requirements were not labeled as sensitive information to be withheld from public disclosure. The NOVs contained specific information regarding the requirements of the Increased Controls and how the licensee was not meeting those requirements, which is considered sensitive information. The licensees' response letters were appropriately marked as sensitive information. The review team recommends that the State evaluate the effectiveness of their existing procedures and policies for marking and handling sensitive information and modify the existing procedures or policies, if needed, to ensure that documents containing sensitive information are appropriately marked in a consistent manner.

The review team noted that the Bureau has an adequate supply of survey instruments to support their inspection program. Appropriate, calibrated survey instrumentation, such as Geiger-Mueller (GM) meters, scintillation detectors, ion chambers, micro-R meters, and a neutron detector, were observed to be available. The Bureau also has portable multi-channel analyzers. Instruments are calibrated at least annually, or as needed, at the Orlando Office, with sources that were National Institute of Standards and Technology traceable. The Bureau uses a database to track each instrument, its current location and when it is due for calibration.

Accompaniments of nine Bureau inspectors were conducted by two IMPEP team members during the weeks of January 22 and February 5, 2007. The inspectors were accompanied during health and safety inspections of medical therapy, medical private practice, and portable gauge licenses. The accompaniments are identified in Appendix C. During the accompaniments, most of the inspectors demonstrated appropriate inspection techniques, knowledge of the regulations, and conducted performance-based inspections. The inspectors were trained, well-prepared for the inspection, and thorough in their audits of the licensees' radiation safety programs. The inspectors conducted interviews with appropriate personnel, observed licensed operations, conducted confirmatory measurements, and utilized good health physics practices. The inspections were adequate to assess radiological health and safety and Increased Controls at the licensed facilities. The review team identified one instance where an inspector may have failed to observe a potential violation of Florida's regulation related to radioactive material security 10 CFR 20.1802. The review team determined this instance was an isolated event and was not indicative of a programmatic weakness. The Bureau committed to evaluate the review team's observation, as well as the inspection as a whole, and provide retraining for the inspector, as needed.

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

3.4 Technical Quality of Licensing Actions

The review team examined completed licensing casework and interviewed license reviewers for 20 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, Increased Controls, and overall technical quality. The casework was 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 casework was checked for retention of necessary documents and supporting data.

The licensing casework was selected to provide a representative sample of licensing actions completed during the review period. Licensing actions selected for evaluation included 3 new licenses, 9 renewals, 5 amendments, 2 terminations, and 1 reciprocity request. The sampling included the following license types: medical (institution - written directive required, private practice - no written directive, gamma knife, and high dose-rate remote afterloader), industrial radiography, portable gauge, academic and medical broadscope, research and development broadscope, self-shielded irradiator, waste broker, and nuclear pharmacy. A listing of the licensing 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. Licenses and correspondence are generated using standardized conditions and formats. Licensing staff appropriately used the Bureau's licensing guides, policies, and standard license

conditions. Licensees' compliance histories were taken into account when reviewing all renewal applications and major amendments.

Each licensing action is given a technical review by a license evaluator. The Radioactive Materials Administrator or a Radioactive Materials Licensing Manager performs a technical and supervisory review on all licensing actions before issuance to the licensee. All license evaluators have signature authority for licensing actions. Licenses are issued for a 5-year period under a timely renewal system.

The review team evaluated financial assurance and decommissioning activities conducted by the Bureau. The Bureau's procedure for financial assurance is specified in Subpart E to the Florida Administrative Code 64E-5.217, *Bonding of Persons Licensed Pursuant to Subpart IIC*. The Bureau also has a Reclamation Fund into which 5 percent of the licensees' annual fees are appropriated. The review team found that terminated licensing actions were well-documented, showing appropriate material transfer and survey records. The review team noted that confirmatory surveys were conducted, when appropriate. The review team identified no performance issues with the Bureau's handling of financial assurance or decommissioning.

The Bureau had, as of December 2006, six licensing actions that have been pending for one year or longer; however, the review team identified no health and safety significant impacts that are attributable to the delay in issuance of these actions.

The review team determined that outgoing documents to licensees (i.e., cover letters and licenses) containing sensitive information were not marked or identified accordingly. This issue was previously mentioned from the inspection standpoint in Section 3.3 of this report, with a resulting recommendation.

The review team identified that limited and broadscope medical licenses contained authorization limits for unsealed therapeutic materials in "as necessary" amounts. This material authorization includes iodine-131 which, if possessed in amounts greater than 10 curies, would require the licensee to develop and implement an emergency plan for responding to releases of this material. While it is unlikely that these licensed facilities possessed enough I-131 to require an emergency plan, the Bureau agreed to change their licensing guidance to require either specification of a total possession limit for these materials or insertion of a license condition on these types of licenses restricting the possession limits of these materials below the threshold requiring an emergency plan.

The review team examined the list of licensees that the Bureau determined to meet the criteria for the Increased Controls, per COMSECY-05-0028. The review team determined that the Bureau had correctly identified the licensees that require the Increased Controls based on this criteria. The Bureau also required their licensees currently under an NRC Order for additional security measures to implement the Increased Controls. 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.

Based on the IMPEP evaluation criteria, the review team recommended and the MRB agreed that Florida's performance with respect to the indicator, Technical Quality of Licensing Actions, was satisfactory.

3.5 Technical Quality of Incident and Allegation Activities

In evaluating the effectiveness of the Bureau's actions in responding to incidents and allegations, the review team examined the Bureau's response to the questionnaire relative to this indicator, evaluated selected incidents reported for Florida in the Nuclear Material Events Database (NMED) against those contained in the Bureau's files, and evaluated the casework for 11 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 Bureau's response to seven allegations involving radioactive materials, including six allegations referred to the State by the NRC during the review period.

Incident responses that are prompt, thorough, and commensurate with health and safety can instill public confidence in a radiation control program. The incidents selected for review included the following categories: medical, lost/stolen material, transportation, and equipment failure. The review team determined that the Bureau's response to incidents was complete and comprehensive. The review team noted that allegations were also considered, and treated as, incidents. Initial responses were prompt and well-coordinated, and the level of effort was commensurate with the health and safety significance. The Bureau dispatched inspectors for on-site investigations in a majority of the cases reviewed and took suitable enforcement and followup actions.

When notification of an incident or an allegation is received, the Incident Response Coordinator and staff at the Environmental Radiation Labs Section in Orlando determine the appropriate level of initial response and contact the appropriate field office. After the investigation is completed, the pertinent information is forwarded to the Radioactive Materials Section in the Central Office for closeout approval and appropriate followup and/or enforcement actions.

The review team identified 371 radioactive material incidents in NMED for Florida during the review period, of which 95 required reporting. The review team evaluated the Bureau's timeliness of reporting incidents and found that all incidents are reported in the required time frame, following the Bureau's receipt of notification from the licensees. In one case, the licensee failed to notify the State of the incident in a timely manner; however, the State promptly reported the incident to the NRC upon notification from the licensee.

Monthly reports and followup information are provided to the NRC's contractor responsible for maintaining NMED by extracting information from the State's incident database. If a reportable event is discovered due to an allegation, the Bureau reports the information to the NRC for inclusion in NMED only after the allegation has been substantiated, fully investigated, and closed. Even then, the Bureau is careful to exclude any language in the information reported that reveals that the incident was associated with an allegation.

In evaluating the effectiveness of Florida's actions responding to allegations, the review team evaluated the casework for the six allegations referred to the State by the NRC, as well as the casework for one additional allegation reported directly to the State. The Bureau evaluates each allegation and determines the proper level of response. The casework review indicated that the Bureau took prompt and appropriate action in response to all concerns raised. All of the allegations reviewed were appropriately closed, and appropriate parties were notified of the actions taken. The review team identified no performance issues from the review of the allegation casework.

The review team noted that Florida law requires that public documents be made available upon request. The Bureau makes every effort to protect an alleger's identity, but cannot guarantee full protection. During initial contact, an alleger is advised that their anonymity cannot be guaranteed. Throughout the investigation of an allegation, the Bureau does not voluntarily offer the name of an alleger in response to inquiries, but protection is limited following closure of the allegation.

Based on the IMPEP evaluation criteria, the review team recommended and the MRB agreed that Florida's performance with respect to the indicator, Technical Quality of Incident and Allegation Activities, was 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. Florida's Agreement does not relinquish authority for a Uranium Recovery Program; therefore, only the first three non-common performance indicators were applicable to this review.

4.1 Compatibility Requirements

4.1.1 Legislation

Florida became an Agreement State on July 1, 1964. The current effective statutory authority is contained in the Florida Radiation Protection Act in Title XXIX, Chapter 404, of the Florida Statutes. The Department is designated as the State's radiation control agency. The Bureau implements the radiation control program. The review team noted that no legislation affecting the radiation control program was passed during the review period.

4.1.2 Program Elements Required for Compatibility

The State's regulations for control of radiation are located in Chapter 64E-5 of the Florida Administrative Code (FAC) and apply to all ionizing radiation. Florida requires a license for possession and use of all radioactive material, including naturally-occurring and accelerator-produced radioactive material. Florida also requires registration of all equipment designed to produce x-rays or other ionizing radiation.

The Bureau's rulemaking process is governed by the Administrative Procedure Act in Title X, Chapter 120, of the Florida Statutes. The administrative process for regulation adoption is provided in Chapter 1S-1 of the Florida Administrative Code. The State's administrative rulemaking process takes approximately 6 months from drafting to finalizing a rule. After the Bureau drafts a proposed regulation, they must publish a notice of proposed rule development in the Florida Administrative Weekly, which includes an offer to hold a workshop. After the workshop, if held, the Bureau publishes another notice in the Florida Administrative Weekly of proposed rulemaking, including an offer to conduct a public hearing. Concurrently, the Bureau must prepare and send an initial rule review file to the Joint Administrative Procedures Committee, which is a legislative committee that oversees rulemaking by all State agencies. If there are no objections or changes needed, the Bureau prepares the final regulation and files it

with the Florida Secretary of State. A rule becomes effective 20 days after filing with the Secretary of State. The Bureau also has an accelerated rulemaking process for regulations required for compatibility. Under the accelerated rulemaking process, the Bureau can finalize effective rules in 45 to 60 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 Bureau'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.

The review team noted that, at the time of the review, there were a number of NRC amendments that had not been submitted to the NRC for a compatibility review, although final effective regulations were in place. The Bureau submitted a package of final regulations, itemized below, to the NRC for a compatibility review on February 14, 2007. A majority of the regulations addressed in the package became effective on September 28, 2006, which was after the Agreement State implementation date. The NRC completed its compatibility review and transmitted the results to the Bureau by letter dated April 23, 2007. The NRC's compatibility review resulted in 53 comments, which will need to be addressed by the State in upcoming rulemaking activities.

During the on-site review, the State submitted to the NRC for a compatibility review a package of final regulations to satisfy the following NRC amendments:

- "Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiography Operations," 10 CFR Part 30, 34, 71, and 150 amendments (62 FR 28947) that became effective on June 27, 1997, and was due for Agreement State adoption by June 27, 2000.

- "Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiography Operations," 10 CFR Part 34 amendment (63 FR 37059) that became effective on July 9, 1998, and was due for Agreement State adoption by July 9, 2001.

- "Transfer for Disposal and Manifests: Minor Technical Conforming Amendment," 10 CFR Part 20 amendment (63 FR 50127) that became effective on November 20, 1998, and was due for Agreement State adoption by November 20, 2001.

- "Respiratory Protection and Controls to Restrict Internal Exposure," 10 CFR Part 20 amendment (64 FR 54543 and 64 FR 55524) that became effective on February 2, 2000, and was due for Agreement State adoption by February 2, 2003.

- "Energy Compensation Sources for Well Logging and Other Regulatory Clarifications," 10 CFR Part 39 amendment (65 FR 20337) that became effective on May 17, 2000, and was due for Agreement State adoption by May 17, 2003.

- “New Dosimetry Technology,” 10 CFR Part 34, 36, and 39 amendments (65 FR 63750) that became effective on January 8, 2001, and was due for Agreement State adoption by January 8, 2004.

- “Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material,” 10 CFR Part 30, 31, and 32 amendments (65 FR 79162) that became effective on February 16, 2001, and was due for Agreement State adoption by February 16, 2004.

- “Revision of the Skin Dose Limit,” 10 CFR Part 20 amendment (67 FR 16298) that became effective on April 5, 2002, and was due for Agreement State adoption by April 5, 2005.

- “Financial Assurance for Materials Licensees,” 10 CFR Part 30, 40, and 70 amendments (68 FR 57327) that became effective on December 3, 2003, and was due for Agreement State adoption by December 3, 2006.

- "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.

- "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.

At the time of the review, the following NRC amendment was overdue for adoption and had not been addressed:

- “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.

The review team identified the following two NRC amendments that will be needed in the future:

- "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.

- “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 Bureau did self-identify that a number of regulations were overdue and redirected FTE to ensure adequate resources were dedicated to rulemaking and associated activities, but not until late in the review period. Prior to this redirection, the former Radioactive Materials Administrator split his time between licensing, compliance activities, and rulemaking. This individual now serves as an assistant to the Bureau Chief, and one of his primary responsibilities is oversight of rulemaking and associated activities, including preparing and submitting rulemaking packages to the NRC for compatibility review.

Based on the IMPEP evaluation criteria, the review team recommended and the MRB agreed that Florida's performance with respect to the indicator, Compatibility Requirements, was satisfactory, but needs improvement.

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

In conducting this review, three sub-indicators were used to evaluate the Bureau's performance regarding the SS&D Evaluation Program. These sub-indicators include: (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 Bureau's SS&D evaluation activities, the review team examined information provided by the Bureau in response to the IMPEP questionnaire on this indicator. A review of all new, amended, and inactivated SS&D evaluations and supporting documents covering the review period was conducted. The review team noted the staff's use of guidance documents and procedures, interviewed the two administrators 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 Staffing and Training

Since the last review, two of the Bureau's Administrators have conducted SS&D evaluations, both of which are qualified SS&D reviewers with full signature authority.

The Bureau's comprehensive training program is discussed in the Common Performance Indicator, Technical Staffing and Training. The Bureau has a documented qualification program for SS&D reviewers as a subsection of its overall Licensing Evaluator Qualification Procedures. This subsection includes a review of regulations, review of application guides, review of licensing actions with a manager or qualified individual, and facility site visit or inspection accompaniment. The Bureau is in the process of developing a structured in-house training program, but due to the infrequent SS&D application or amendment requests, the Bureau is focusing its resources on developing structured training programs for more frequent regulatory actions. In the interim, the Bureau will use on-the-job training for new reviewers with oversight from the two Administrators, who are the Bureau's senior SS&D reviewers.

As part of its training procedure, the Bureau grants reviewers signature authority immediately, so that they may begin their training. The Bureau believes that this method makes the reviewers more conscientious when working on SS&D actions. As part of their on-the-job training, the Bureau will use a double concurrence approach, where the two senior reviewers will both perform technical and concurrence reviews for any new application or amendment request. The Bureau plans to use the double concurrence process for the new reviewers for the foreseeable future. The Bureau has granted signature authority to two new reviewers during the review period. Both new reviewers have several years of experience in health physics and attended the NRC's SS&D workshop in 2006. At the time of the on-site review, neither of the new reviewers had worked on an SS&D review. The Bureau intends to assign the next SS&D review to one of the new reviewers.

4.2.2 Technical Quality of the Product Evaluation Program

During the review period, the Bureau processed 11 SS&D actions, including four inactivations. The casework review included all amendments, supporting documentation, licenses, and inspections associated with each of the registrations processed by the Bureau since the last review and represented cases completed by all reviewers. A listing of the SS&D certificates evaluated by the review team, with case-specific comments, may be found in Appendix F.

Analysis of the casework and interviews with the staff confirmed that the Bureau follows the recommended guidance from the NRC SS&D training workshops and NUREG-1556, Volume 3, Revision 1. Appropriate review checklists were used to assure all relevant materials had been submitted and reviewed. The checklists were retained in the SS&D or licensing files along with other documents that identified the assigned reviewers; however, several checklists in the files were not signed. This issue was discussed with the Radioactive Materials Administrator. In this discussion, the Bureau committed to verifying that the appropriate signatures were on the checklists. In cases where a checklist was not used, the Bureau included an internal office memorandum as a note for the file. 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 registration files contained all correspondence, photographs, engineering drawings, radiation profiles, and details of the applicant's quality assurance and quality control program. The registrations clearly summarized the product evaluation to provide license reviewers with adequate information to license the possession and use of the product. Deficiency letters clearly stated regulatory positions and all health and safety issues were properly addressed. The review team found that the evaluations were of high quality with health and safety issues properly addressed.

The review team noted that the Bureau lists the Florida radioactive materials license number that authorizes manufacturing and distribution of the device in the SS&D registration certificate for reference. In addition, the Bureau incorporates the SS&D registry certificate and associated documents by license condition in the manufacturing and distribution license. Bureau management stated that incorporating the registry certificate by license condition in the specific license legally authorizes them to enforce the requirements of the registration certificate.

4.2.3 Evaluation of Defects and Incidents Regarding SS&Ds

Utilizing NMED and the Bureau's response to the questionnaire, the review team examined any incidents or failures regarding SS&D registered products during the review period. The review team examined all of the events that occurred in Florida that involved equipment or source failures within the period, as well as any events that occurred nationally involving sources registered by Florida. The review team determined that the State analyzed the events, reviewed the issues, and followed up on the incidents. None of the events involving equipment or source failures within the period appeared to be generic issues.

Based on the IMPEP evaluation criteria, the review team recommended and the MRB agreed that Florida's performance with respect to the indicator, SS&D Evaluation Program, was 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 Florida 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 Florida. Accordingly, the review team did not review this indicator.

5.0 SUMMARY

As noted in Sections 3.0 and 4.0, Florida's performance was found satisfactory, but needs improvement, for the indicator, Compatibility Requirements, and satisfactory for all remaining performance indicators reviewed. The review team made one recommendation regarding the performance of the Florida Agreement State Program. Accordingly, the review team recommended and the MRB agreed that the Florida Agreement State Program was 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 recommended and the MRB agreed that the next full IMPEP review take place in approximately 4 years.

Below is the recommendation, as mentioned earlier in the report, for evaluation and implementation, as appropriate, by the State.

> The review team recommends that the State evaluate the effectiveness of their existing procedures and policies for marking and handling sensitive information and modify the existing procedures or policies, if needed, to ensure that documents containing sensitive information are appropriately marked in a consistent manner. (Section 3.3)

LIST OF APPENDIXES AND ATTACHMENT

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	**Area of Responsibility**
Dennis Sollenberger, FSME	Team Leader Technical Staffing and Training
Donna Janda, Region I	Status of Materials Inspection Program Inspector Accompaniments
Robert Gallaghar, Massachusetts	Technical Quality of Inspections Inspector Accompaniments
Michelle Beardsley, Region I	Technical Quality of Licensing Actions
Aaron McCraw, FSME	Technical Quality of Incident and Allegation Activities Compatibility Requirements
Tomas Herrera, FSME	Sealed Source and Device (SS&D) Evaluation Program

APPENDIX B

FLORIDA ORGANIZATION CHARTS

ADAMS ACCESSION NO.: ML070600149

PAGES 44-46

APPENDIX C

INSPECTION CASEWORK REVIEWS

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

File No.: 1
Licensee: Florida State University — License No.: 32-10
Inspection Type: Routine, Announced — Priority: 2
Inspection Dates: 5/16-20/05 — Inspectors: PP, RL, BR, TT

Comment:
Inspection field notes identified two apparent violations that were not cited in the letter sent to the licensee, with no justification for not citing the violations documented in the inspection file.

File No.: 2
Licensee: Tyco Healthcare Group, LP — License No.: 3007-1
Inspection Type: Routine, Announced — Priority: 1
Inspection Date: 11/29/06 — Inspector: JB

File No.: 3
Licensee: Tyco Healthcare Group, LP — License No.: 3007-1
Inspection Type: Increased Control, Announced — Priority: 1
Inspection Date: 11/29/06 — Inspector: JB

File No.: 4
Licensee: Miller School, University of Miami — License No.: 1319-3
Inspection Type: Increased Control, Announced — Priority: 1
Inspection Dates: 10/23-24/06 — Inspector: JS

Comment:
Inspection identified six violations of the Increased Controls License Condition. Notice of Violation letter was not labeled as sensitive information. Letter contained specific information regarding the requirements of the Increased Controls and how the licensee was not meeting those requirements.

File No.: 5
Licensee: Diagnostic Physics Consulting, Inc. — License No.: 1440-1
Inspection Type: Routine, Unannounced — Priority: 3
Inspection Date: 11/2/04 — Inspector: MT

File No.: 6
Licensee: Variety Children's Hospital, Inc. License No.: 0993-1
Inspection Type: Special, Announced Priority: 2
Inspection Date: 6/8/05 Inspector: FN

Comment:
Inspection conducted following report of the loss of licensed material. Inspection file documents the source was lost on 10/5/04 and reported to State on 6/6/05. Notice of Violation did not contain a citation for failure to notify, nor a reason for not issuing a violation.

File No.: 7
Licensee: Renegade Testing & Inspection, Inc. License No.: 3891-1
Inspection Type: Increased Control, Announced Priority: 1
Inspection Date: 12/29/06 Inspector: LB

File No.: 8
Licensee: Mallinckrodt Medical, Inc. License No.: 1937-4
Inspection Type: Routine, Unannounced Priority: 1
Inspection Date: 2/5/04 Inspector: JG

File No.: 9
Licensee: Florida Cardiac Consultants, Inc. License No.: 3497-1
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 2/5/07 Inspector: MB

Comment:
Apparent violation was not cited, nor did the file reflect the justification for not citing the violation.

File No.: 10
Licensee: JANX Integrity License No.: 21-16560-01(NRC)
Inspection Type: Reciprocity, Announced Priority: N/A
Inspection Dates: 3/30 - 4/1/05 Inspector: LB

File No.: 11
Licensee: Adventist Health Systems/Sunbelt, Inc. License No.: 2897-1
Inspection Type: Routine, Increased Control, Announced Priority: 1
Inspection Dates: 11/6-9, 11/15, 11/21, 11/27/06 Inspectors: LB, MY

Comment:
Notice of Violation letter dated 12/11/06 contained sensitive information. Letter was not labeled or marked as such.

File No.: 12
Licensee: Mt. Sinai Medical Center of Miami License No.: 64-14
Inspection Type: Routine, Unannounced Priority: 2
Inspection Date: 5/18/05 Inspectors: FN, LS

File No.: 13
Licensee: Cardinal Health 414, Inc. License No.: 3453-6
Inspection Type: Routine, Unannounced Priority: 1
Inspection Dates: 11/4/04, 11/8/04 Inspector: PP

File No.: 14
Licensee: Amglo Kemlite Laboratories, Inc. License No.: 3010-1
Inspection Type: Reciprocity Priority: 1
Inspection Date: 10/12/06 Inspector: TF

File No.: 15
Licensee: Perma-Fix of Florida, Inc. License No.: 2598-1
Inspection Type: Routine, Announced Priority: 0.5
Inspection Date: 2/7/07 Inspector: PP

File No.: 16
Licensee: Lockheed Martin Corporation License No.: 3137-1
Inspection Type: Routine, Announced Priority: 1
Inspection Date: 8/6/06 Inspector: PP

File No.: 17
Licensee: Digirad Imaging Solutions, Inc. License No.: 3176-8
Inspection Type: Routine, Unannounced Priority: 2
Inspection Date: 12/15/06 Inspector: RK

File No.: 18
Licensee: Halifax Hospital Medical Center License No.: 0194-3
Inspection Type: Routine, Unannounced Priority: 1
Inspection Date: 1/24/07 Inspector: MY

File No.: 19
Licensee: Iridium Holdings, Inc. License No.: 2936-1
Inspection Type: Routine, Unannounced Priority: 1
Inspection Date: 1/23/07 Inspector: RD

File No.: 20
Licensee: Southport Cardiology Associates, P.A. License No.: 3158-1
Inspection Type: Routine, Unannounced Priority: 2
Inspection Date: 1/22/07 Inspector: KT

INSPECTOR ACCOMPANIMENTS

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

Accompaniment No.: 1
Licensee: Southport Cardiology Associates, P.A. License No.: 3158-1
Inspection Type: Routine, Unannounced Priority: 2
Inspection Date: 1/22/07 Inspector: KT

Accompaniment No.: 2
Licensee: Iridium Holdings, Inc. License No.: 2936-1
Inspection Type: Routine, Announced Priority: 1
Inspection Date: 1/23/07 Inspector: RD

Accompaniment No.: 3
Licensee: Halifax Hospital Medical Center License No.: 194-3
Inspection Type: Routine, Unannounced Priority: 1
Inspection Date: 1/24/07 Inspector: MY

Accompaniment No.: 4
Licensee: Florida Medical Clinic License No.: 2534-3
Inspection Type: Initial, Announced Priority: 2
Inspection Date: 1/25/07 Inspector: SR

Accompaniment No.: 5
Licensee: Florida Cardiac Consultants, Inc. License No.: 3497-1
Inspection Type: Routine, Announced Priority: 3
Inspection Date: 2/5/07 Inspector: MB

Comments:
a) Radiation Safety Officer was not contacted during inspection.
b) Inspector failed to observe a potential security violation (refer to Section 3.3).

Accompaniment No.: 6
Licensee: Charlotte Cardiovascular Institute, Inc. License No.: 3854-1
Inspection Type: Initial, Announced Priority: 2
Inspection Date: 2/6/07 Inspector: GH

Accompaniment No.: 7
Licensee: Langan Engineering & Environmental Services, Inc. License No.: 1414-1
Inspection Type: Routine, Unannounced Priority: 2
Inspection Date: 2/7/07 Inspector: JS

Accompaniment No.: 8
Licensee: Dadeland Nuclear Imaging, d/b/a B&R Diagnostics, Inc. License No.: 3159-1
Inspection Type: Routine, Announced Priority: 2
Inspection Date: 2/8/07 Inspector: EK

Accompaniment No.: 9
Licensee: Lanzo Construction Co. License No.: 3496-1
Inspection Type: Routine, Announced Priority: 3
Inspection Date: 2/9/07 Inspector: DS

APPENDIX D

LICENSE CASEWORK REVIEWS

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

File No.: 1
Licensee: TYCO Healthcare — License No.: 3007-1
Type of Action: Renewal — Amendment No.: 13
Date Issued: 9/15/05 — License Reviewer: WK

Comment:
Outgoing license and letter not marked as sensitive information.

File No.: 2
Licensee: EI DuPont — License No.: 3868-1
Type of Action: New — Amendment No.: N/A
Date Issued: 11/14/06 — License Reviewer: TT

File No.: 3
Licensee: Southern Baptist Hospital of Florida — License No.: 155-4
Type of Action: Renewal — Amendment No.: 35
Date Issued: 2/7/07 — License Reviewer: JK

File No.: 4
Licensee: Food Technology Svcs. — License No.: 2244-1
Type of Action: Amendment — Amendment No.: 41
Date Issued: 11/1/06 — License Reviewer: LS

Comment:
Outgoing license and letter not marked as sensitive information.

File No.: 5
Licensee: Professional Engineering & Inspection Co. — License No.: 2940-1
Type of Action: Amendment — Amendment No.: N/A
Date Issued: Pending — License Reviewer: JK

Comment:
Change in control issue - referred to legal counsel.

File No.: 6
Licensee: Perma-Fix of Florida — License No.: 2598-1
Type of Action: Renewal — Amendment No.: 29
Date Issued: 7/29/05 — License Reviewer: JS

File No.: 7
Licensee: Adventist Health License No.: 2897-1
Type of Action: Amendment Amendment No.: 39
Date Issued: 11/17/06 License Reviewer: TT

Comments:
a) Therapeutic materials licensed in “as necessary” amounts.
b) Outgoing license and letter not marked as sensitive information.

File No.: 8
Licensee: Renegade Testing & Inspection License No.: 3891-1
Type of Action: New Amendment No.: 0
Date Issued: 12/29/06 License Reviewer: JS

Comment:
Outgoing license and letter not marked as sensitive information.

File No.: 9
Licensee: Youngquist Bros., Inc. License No.: 3348-1
Type of Action: Renewal Amendment No.: 5
Date Issued: 11/6/06 License Reviewer: LT

File No.: 10
Licensee: University of Florida License No.: 356-1
Type of Action: Renewal Amendment No.: 87
Date Issued: 3/24/05 License Reviewer: JS

Comment:
Outgoing license and letter not marked as sensitive information.

File No.: 11
Licensee: Technical Products Group, Inc. License No.: 3447-1
Type of Action: New Amendment No.: 0
Date Issued: 2/14/03 License Reviewer: PV

File No.: 12
Licensee: Mallinckrodt, Inc. License No.: 1937-4
Type of Action: Renewal Amendment No.: 18
Date Issued: 4/13/05 License Reviewer: JS

File No.: 13
Licensee: Mt. Sinai Medical Centers License No.: 64-14
Type of Action: Termination Amendment No.: 8
Date Issued: 2/9/06 License Reviewer: JS

File No.: 14
Licensee: Memorial Health Systems License No.: 3154-1
Type of Action: Termination Amendment No.: 3
Date Issued: 7/20/04 License Reviewer: JS

File No.: 15
Licensee: Florida State University License No.: 32-10
Type of Action: Renewal Amendment No.: 64
Date Issued: 1/11/06 License Reviewer: TT

Comments:
a) Outgoing license and letter not marked as sensitive information.
b) License Conditions 25 and 26 reference superceded NRC Regulatory Guides.

File No.: 16
Licensee: JANX Integrity Group License No.: NRC 21-16560-01
Type of Action: Reciprocity Amendment No.: N/A
Date Issued: 1/23/07 License Reviewer: JS

File No.: 17
Licensee: HDR Construction Control Group License No.: 2763-1
Type of Action: Renewal Amendment No.: 11
Date Issued: 9/22/06 License Reviewer: LT

File No.: 18
Licensee: South Broward Hospital District License No.: 2573-1
Type of Action: Renewal Amendment No.: 6
Date Issued: 10/6/05 License Reviewer: JS

Comment:
Outgoing license and letter not marked as sensitive information.

File No.: 19
Licensee: Cardinal Health 414, Inc. License No.: 3010-1
Type of Action: Amendment Amendment No.: 14
Date Issued: 8/9/06 License Reviewer: LT

File No.: 20
Licensee: Perma-Fix License No.: 2598-1
Type of Action: Amendment Amendment No.: 31
Date Issued: 3/15/06 License Reviewer: JS

APPENDIX E

INCIDENT CASEWORK REVIEWS

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

File No.: 1
Licensee: Florida Medical Center — License No.: FL-2816-1
Date of Incident: 10/14/03 — Incident Log No.: FL03-192; NMED 030847
Investigation Date: 10/21/03 — Type of Incident: Lost/Stolen RAM
Type of Investigation: Site

File No.: 2
Licensee: Certified Testing Laborartories — License No.: FL-2332-1
Date of Incident: 6/30/04 — Incident Log No.: FL04-094; NMED 040492
Investigation Date: 6/30/04 — Type of Incident: Equipment Failure
Type of Investigation: Site

File No.: 3
Licensee: Diagnostic Products Corp. — License No.: CA-2493-19
Date of Incident: 12/17/04 — Incident Log No.: FL05-009; NMED 050041
Investigation Date: N/A — Type of Incident: Transportation
Type of Investigation: N/A

File No.: 4
Licensee: University of Florida Shands Hospital — License No.: FL-0013-3
Date of Incident: 5/25/05 — Incident Log No.: FL05-086; NMED 050392
Investigation Date: 6/1/05 — Type of Incident: Medical
Type of Investigation: Licensee Report

Comment:
Event not closed in Nuclear Material Events Database (NMED) although State is no longer investigating this incident.

File No.: 5
Licensee: Variety Children's Hospital — License No.: FL-993-1
Date of Incident: 6/5/05 — Incident Log No.: FL05-088; NMED 050391
Investigation Date: 6/8/05 — Type of Incident: Lost/Stolen RAM
Type of Investigation: Site

Comments:
a) Documentation of closure not contained in State's file although no investigation ensues. Event is closed in NMED.
b) NMED record is not complete, pending a request for additional information from the NMED contractor. State responded via e-mail, but NMED record has not been updated.

File No.: 6
Licensee: Atlantic Geotechnical Services, Inc.
License No.: FL-2725-1
Date of Incident: 10/29/05
Incident Log No.: FL05-154; NMED 050725
Investigation Date: 11/1/05
Type of Incident: Lost/Stolen RAM
Type of Investigation: Site

Comment:
Device was recovered; however, closure memorandum in file indicated that device was not recovered.

File No.: 7
Licensee: Unison Industries, Inc.
License No.: FL-1594-2
Date of Incident: 1/30/06
Incident Log No.: FL06-018; NMED 060091
Investigation Date: 1/30/06
Type of Incident: Release of RAM
Type of Investigation: Site

File No.: 8
Licensee: 21st Century Oncology
License No.: FL-2667-1
Date of Incident: 4/3/06
Incident Log No.: FL06-062; NMED 060317
Investigation Date: 6/22/06
Type of Incident: Medical
Type of Investigation: Site

File No.: 9
Licensee: Florida Hospital Ormond Beach
License No.: FL-2897-1
Date of Incident: 7/21/06
Incident Log No.: FL06-098; NMED 060469
Investigation Date: 8/2/06
Type of Incident: Medical
Type of Investigation: Site

File No.: 10
Licensee: BTL Engineering
License No.: FL-1315-1
Date of Incident: 12/4/06
Incident Log No.: FL06-152; NMED 060740
Investigation Date: 12/4/06
Type of Incident: Transportation
Type of Investigation: Licensee Report

File No.: 11
Licensee: HDR Construction Control Corp.
License No.: FL-2763-1
Date of Incident: 1/1/07
Incident Log No.: FL07-001; NMED 070008
Investigation Date: 1/2/07
Type of Incident: Lost/Stolen RAM
Type of Investigation: Site

APPENDIX F

SEALED SOURCE AND DEVICE CASEWORK REVIEWS

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

File No.: 1
Registry No.: FL-1146-S-102-S — SS&D Type: (V) General Medical Use
Applicant Name: IsoAid, LLC — Type of Action: New Registration
Date Issued: 4/23/04 — SS&D Reviewers: PV, MS

Comment:
In the device description, the dimensions of the silver rod inside the titanium tube were inverted. The Bureau issued a corrected page during the IMPEP review.

File No.: 2
Registry No.: FL-1116-D-101-S — SS&D Type: (O) Ion Generators, Static Eliminators
Applicant Name: Lockheed Martin Corporation — Type of Action: Amendment
Date Issued: 1/28/04 — SS&D Reviewers: PV, MS

File No.: 3
Registry No.: FL-1116-D-101-S — SS&D Type: (O) Ion Generators, Static Eliminators
Applicant Name: Lockheed Martin Corporation — Type of Action: Amendment
Date Issued: 4/30/04 — SS&D Reviewers: PV, MS

File No.: 4
Registry No.: FL-1116-D-101-S — SS&D Type: (O) Ion Generators, Static Eliminators
Applicant Name: Lockheed Martin Corporation — Type of Action: Amendment
Date Issued: 3/2/06 — SS&D Reviewers: PV, MS

File No.: 5
Registry No.: FL-1116-D-101-S — SS&D Type: (O) Ion Generators, Static Eliminators
Applicant Name: Lockheed Martin Corporation — Type of Action: Amendment
Date Issued: 3/4/06 — SS&D Reviewers: PV, MS

File No.: 6
Registry No.: FL-1172-D-101-S — SS&D Type: (O) Ion Generators, Static Eliminators
Applicant Name: Litton Systems Inc. — Type of Action: Amendment
Date Issued: 12/5/03 — SS&D Reviewers: PV, MS

File No.: 7
Registry No.: FL-1172-D-101-S — SS&D Type: (O) Ion Generators, Static Eliminators
Applicant Name: Litton Systems Inc. — Type of Action: Amendment
Date Issued: 11/24/04 — SS&D Reviewers: PV, MS

File No.: 8
Registry No.: FL-8136-D-801-G SS&D Type: (D) Gamma Gauges
Applicant Name: Barry-Wehmiller Electronics Type of Action: Inactivation
Date Issued: 7/31/03 SS&D Reviewers: PV, MS

Comment:
The licensee did not request an inactivation; however, their manufacturing and distribution license was terminated in 1995. The State inactivated the certificate in July 2003; however, since the licensee was no longer active, the State was not able to determine how many devices were distributed nor confirm that the device had not been modified.

File No.: 9
Registry No.: FL-8137-D-803-B SS&D Type: (D) Gamma Gauges
Applicant Name: Stock Equipment Co. Type of Action: Inactivation
Date Issued: 7/31/03 SS&D Reviewers: PV, MS

Comment:
The licensee did not request an inactivation; however, their manufacturing and distribution license was inactivated in 1973. The State inactivated the certificate in July 2003; however, since the licensee was no longer active, the State was not able to determine how many devices were distributed nor confirm that the device had not been modified.

File No.: 10
Registry No.: FL-8137-S-804-S SS&D Type: (D) Gamma Gauges
Applicant Name: Stock Equipment Co. Type of Action: Inactivation
Date Issued: 7/31/03 SS&D Reviewers: PV, MS

Comment:
The licensee did not request an inactivation; however, their manufacturing and distribution license was inactivated in 1973. The State inactivated the certificate in July 2003; however, since the licensee was no longer active, the State was not able to determine how many devices were distributed nor confirm that the device had not been modified.

File No.: 11
Registry No.: FL-8137-D-805-S SS&D Type: (D) Gamma Gauges
Applicant Name: Stock Equipment Co. Type of Action: Inactivation
Date Issued: 7/31/03 SS&D Reviewers: PV, MS

Comment:
The licensee did not request an inactivation; however, their manufacturing and distribution license was inactivated in 1973. The State inactivated the certificate in July 2003; however, since the licensee was no longer active, the State was not able to determine how many devices were distributed nor confirm that the device had not been modified.

ATTACHMENT

March 30, 2007, Letter from William A. Passetti
Florida's Response to Draft IMPEP Report

ADAMS: ML071060096