April 19, 2011

Shairi R. Turner, M.D.
Deputy Secretary for Health
Department of Health
4052 Bald Cypress Way, Bin A00
Tallahassee, FL 32399-1702

Dear Dr. Turner:

The U.S. Nuclear Regulatory Commission (NRC) uses the Integrated Materials Performance Evaluation Program (IMPEP) in the evaluation of Agreement State programs. Enclosed for your review is the draft IMPEP report that documents the results of the Agreement State review held in Florida on March 28 to April 1, 2011. I was the team leader for the review. The review team's preliminary findings were discussed with you on the last day of the review. The review team's proposed recommendations are that the Florida Agreement State Program be found adequate to protect public health and safety and compatible with NRC's program.

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

In accordance with procedures for implementation of IMPEP, we are providing you with a copy of the review team's draft report for your review and comment prior to submitting the report to the MRB. Comments are requested within 4 weeks from your receipt of this letter. This schedule will permit the issuance of the final report in a timely manner that will be responsive to your needs.

The team will review your response, make any necessary changes to the report, and issue it to the MRB as a proposed final report. Coordinating with your staff, I scheduled the Florida MRB meeting for Tuesday, June 7, 2011, from 1:00 p.m. to 3:00 p.m. EDT. NRC will provide invitational travel for you or your designee to attend the MRB meeting at NRC Headquarters in Rockville, Maryland. NRC has video conferencing capability if it is more convenient for the State to participate through this medium. Please contact me if you desire to establish a video conference for the meeting.

If you have any questions regarding the enclosed report, please contact me at (630) 829-9661.

Thank you for your cooperation.

Sincerely,

/RA/

James L. Lynch
State Agreements Officer

Enclosure:
Draft Florida IMPEP Report

cc w/encl: Lisa Conti, Director
Division of Environmental Health
William Passetti, Chief
Bureau of Radiation Control

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United States Nuclear Regulatory Commission

Protecting People and the Environment

INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF THE FLORIDA AGREEMENT STATE PROGRAM

MARCH 28 - APRIL 1, 2011

DRAFT REPORT

Enclosure

EXECUTIVE SUMMARY

This report presents the results of the IMPEP review of the Florida Agreement State Program. The review was conducted during the period of March 28-April 1, 2011, by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of Illinois.

Based on the results of this review, Florida's performance was found satisfactory, but needs improvement, for the indicator, Compatibility Requirements, and satisfactory for the six remaining performance indicators reviewed. The finding for the Compatibility Requirements indicator remains unchanged from the previous IMPEP review. Progress has been made on the indicator, but the State has not yet addressed a number of outstanding NRC comments regarding earlier regulation packages. In addition, two regulation amendments were overdue for adoption by the State.

The review team did not make any recommendations regarding program performance by the State and determined that the recommendation from the 2007 IMPEP review, regarding document security markings, should be closed. Accordingly, the review team recommends that the Florida Agreement State Program is adequate to protect public health and safety and is compatible with NRC's program. The review team recommends that the next IMPEP review take place in approximately four years.

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 March 28 to April 1, 2011, by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of Illinois. Team members are identified in Appendix A. The review was conducted in accordance with the "Implementation of the Integrated Materials Performance Evaluation Program and Rescission of Final General Statement of Policy," published in the *Federal Register* on October 16, 1997, and NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)," dated February 26, 2004. Preliminary results of the review, which covered the period of February 17, 2007, to April 1, 2011, were discussed with Florida managers on the last day of the review.

[A paragraph on the results of the Management Review Board (MRB) meeting will be included in the final report.]

The Florida Agreement State Program is administered by the Bureau of Radiation Control (the Bureau), which is located within the Division of Environmental Health (the Division). 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 1,719 specific licenses authorizing possession and use of radioactive materials. The review focused on the radioactive materials program as it is carried out under the Section 274b. (of the Atomic Energy Act of 1954, as amended) Agreement between 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 December 14, 2010. The Bureau provided its response to the questionnaire on March 11, 2011. A copy of the questionnaire response can be found in NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML110750665.

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) field accompaniments of 15 inspectors, and (6) interviews with staff and managers. The review team evaluated the information gathered against the established criteria for each common and the applicable non-common performance indicator and made a preliminary assessment of the Florida Agreement State Program's performance.

Section 2.0 of this report covers the State's actions in response to recommendations made during previous reviews. Results of the current review of the common performance indicators are presented in Section 3.0. Section 4.0 details the results of the review of the applicable non-common performance indicators, and Section 5.0 summarizes the review team's findings.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous IMPEP review, which concluded on February 16, 2007, the review team made one recommendation regarding the Florida Agreement State Program's performance. The current status of the recommendation is as follows:

> 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 of the 2007 IMPEP Report)
>
> Current Status: The State implemented a procedure to ensure that all outgoing documents containing sensitive information are appropriately marked. Internal documents were already being appropriately marked prior to the IMPEP review in 2007. The limitation on this procedure is that, in accordance with the State's Sunshine Law, only security-related information pertaining to physical security systems (e.g., alarm systems, room diagrams) can be withheld from the public. The review team confirmed that license and inspection documents were marked appropriately, in accordance with the limitations noted above. This recommendation is closed.

3.0 COMMON PERFORMANCE INDICATORS

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

3.1 Technical Staffing and Training

Issues central to the evaluation of this indicator include the 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 managers and staff, reviewed job descriptions and training records, and considered workload backlogs.

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

At the time of the review, there were 61 technical staff members with various degrees of involvement in the radioactive materials program, totaling approximately 21 full-time

equivalents (FTE). Sixteen staff members, including managers, were stationed in the Central Office. Thirty-six staff members were inspectors or inspection managers distributed among the six field offices and the two counties under contract. Nine staff members were involved with emergency response and laboratory services in the Orlando office. No positions were vacant at the time of this review. The review team determined that staffing levels were adequate for the Agreement State program.

The Bureau has a documented training plan for technical staff that is consistent with the requirements in the NRC/Organization of Agreement States Training Working Group Report and NRC's Inspection Manual Chapter (IMC) 1246, "Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area." Since Florida spreads the radioactive materials inspection load over many inspectors (typically only 20 percent of an inspector's workload), it is very difficult to schedule all of the inspectors for formal training courses. Limited availability for Florida staff in NRC training courses, coupled with periodic out-of-state travel restrictions, requires the Bureau to use internal training to meet its needs. The Bureau developed a 3-day fundamental Applied Radiation Protection course for technical staff. This core training, plus on-the-job training and audits by inspection managers provides the basic training needs for license reviewers and inspectors. Staff members are assigned increasingly complex duties as they progress through the qualification process. The review team concluded that the Bureau's training program is adequate to carry out its regulatory duties and noted that Florida management supports the Bureau training program.

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

3.2 Status of Materials Inspection Program

The review team focused on five factors while reviewing this indicator: inspection frequency, overdue inspections, initial inspections of new licenses, timely dispatch of inspection findings to licensees, and performance of reciprocity inspections. The review team's evaluation was based on the 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 Florida's inspection frequencies for all types of radioactive material licenses are at least as frequent as, and typically more frequent than, similar license types listed in IMC 2800, "Materials Inspection Program." 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 Bureau conducted approximately 2,100 high priority (Priority 1, 2, and 3) inspections during the review period, based on the inspection frequencies established in IMC 2800. Only one of these inspections was conducted overdue by more than 25 percent of the inspection frequency prescribed in IMC 2800. In addition, the Bureau performed approximately 400 initial inspections during the review period, three of which were conducted overdue. As required by IMC 2800, initial inspections should be conducted within 12 months of license issuance. The initial inspections were conducted late due to database entry errors. The Bureau self-identified the errors and provided additional training to database personnel. Overall, the review team

calculated that the Bureau performed less than one percent of its inspections overdue during the review period.

The review team evaluated the Bureau's timeliness in providing inspection findings to licensees. A sampling of 40 inspection reports indicated that none of the inspection findings were communicated to the licensees beyond the Bureau's goal of 30 days after the inspection.

During the review period, the Bureau granted 158 reciprocity permits, 46 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.

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

3.3 Technical Quality of Inspections

The review team evaluated the inspection reports, enforcement documentation, inspection field notes, and interviewed inspectors for 22 radioactive materials inspections conducted during the review period. The casework reviewed included inspections conducted by 18 Bureau inspectors and covered inspections of various license types, including: medical broad scope, medical institutions, medical private practice, portable gauges, industrial radiography, veterinary use, panoramic and self-shielded irradiators, gamma knife, nuclear pharmacy, mobile nuclear medicine, and Increased Controls. Appendix C lists the inspection casework files reviewed, with case-specific comments, as well as the results of the inspector accompaniments.

Based on the evaluation of casework, the review team 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.

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 electronically 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 were clearly stated and documented in the reports and sent to the licensees with the appropriate 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, which details 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 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 neutron detectors, was observed to be available. The Bureau also has portable multi-channel analyzers located in offices across the State. Instruments are calibrated at least annually, or as needed, at the Orlando Office, with National Institute of Standards and Technology traceable sources. The Bureau uses a database to track each instrument, its current location, and next calibration date.

Accompaniments of 15 Bureau inspectors were conducted by three IMPEP team members during the week of March 7, 2011. The inspectors were accompanied during health and safety inspections of source manufacturing, radiography, nuclear pharmacy, irradiator, medical therapy, and medical private practice licenses. The accompaniments are identified in Appendix C. During the accompaniments, 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 would benefit from additional medical brachytherapy training. 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 and provide appropriate training for the inspector, as needed.

Based on the IMPEP evaluation criteria, the review team recommends that Florida's performance with respect to the indicator, Technical Quality of Inspections, be found satisfactory.

3.4 Technical Quality of Licensing Actions

The review team examined completed licensing casework and interviewed license reviewers for 22 specific licensing actions. Licensing actions were reviewed for completeness, consistency, proper radioisotopes and quantities, qualifications of authorized users, adequacy of facilities and equipment, adherence to good health physics practices, financial assurance, operating and emergency procedures, appropriateness of license conditions, and overall technical quality. The casework was also reviewed for timeliness, use of appropriate deficiency letters and cover letters, reference to appropriate regulations, supporting documentation, consideration of enforcement history, pre-licensing visits, peer/supervisory review, and proper signatures.

The licensing casework was selected to provide a representative sample of licensing actions completed during the review period. Licensing actions selected for evaluation included 5 new licenses, 4 renewals, 3 decommissioning or termination actions, and 10 amendments.

Files reviewed included a cross-section of license types, including: broadscope, medical diagnostic and therapy (including gamma knife and high dose rate remote afterloader), brachytherapy, industrial radiography, research and development, nuclear pharmacy, gauges, manufacturers, panoramic and self-shielded irradiators. The casework sample represented work from 10 license reviewers. A listing of the licensing casework evaluated is provided in Appendix D.

Overall, 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 and were supported by information contained in the file. Deficiency letters clearly stated regulatory positions, were used at the proper time, and identified substantive deficiencies in the licensees' documents. Terminated licensing actions were well documented, showing appropriate transfer and survey records. All licensing actions are entirely paperless and are maintained in the Bureau's electronic laserfiche system. License reviewers use the Bureau's licensing guides, policies, checklists, and standard license conditions specific to the type of licensing actions to ensure consistency in licenses.

All license evaluators have signature authority for licensing actions. 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. Licenses are issued for a 5-year period under a timely renewal system.

Based on the casework evaluated, the review team concluded that the licensing actions were of high quality and consistent with the NUREG-1556 guidance documents, the State's regulations, and good health physics practices. The review team attributed the consistent use of templates and quality assurance reviews to the overall quality noted in the casework reviews.

The Bureau performs pre-licensing checks of all new applicants. Current licensees who undergo a change of ownership are considered new applicants and are issued a new license concurrent with the termination of the current license. The Bureau's pre-licensing review methods incorporate the essential elements of NRC's revised pre-licensing guidance to verify that the applicant will use requested radioactive materials as intended. All new licensees receive a pre-licensing site visit which includes an evaluation of the applicant's radiation safety and security programs prior to receipt of the initial license.

The review team examined the Bureau's licensing practices regarding the Increased Controls and Fingerprinting Orders. The review team noted that the State uses legally binding license conditions that meet the criteria for implementing the Increased Controls Orders, including fingerprinting, as appropriate. The review team analyzed the Bureau's methodology for identifying those licenses and found the rationale was thorough and accurate. The review team confirmed that license reviewers evaluated new license applications and license amendments using the same criteria. The Bureau requires full implementation of the Increased Controls prior to issuance of a new license or license amendment that meets the established criteria.

Based on the IMPEP evaluation criteria, the review team recommends that Florida's performance with respect to the indicator, Technical Quality of Licensing Actions, be found 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 10 allegations involving radioactive materials, including 8 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, 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 all of the cases reviewed and took suitable enforcement and follow-up actions. If the incident met the reportability thresholds, as established in the Office of Federal and State Materials and Environmental Management Programs (FSME) Procedure SA-300 "Reporting Material Events," the State notified the NRC Headquarters Operations Center and entered the information into NMED, in a prompt manner.

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 follow-up and/or enforcement actions.

The review team identified 227 radioactive material incidents in NMED for Florida during the review period, of which 118 required reporting. Seven non-reportable incidents in NMED for Florida were reviewed for reportability and found to be correctly categorized as non-reportable by the Bureau. 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.

Monthly reports and follow-up 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 eight allegations referred to the State by the NRC, as well as the casework for two additional allegations 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 recommends that Florida's performance with respect to the indicator, Technical Quality of Incident and Allegation Activities, be found satisfactory.

4.0 NON-COMMON PERFORMANCE INDICATORS

Four non-common performance indicators are used to review Agreement State programs: (1) Compatibility Requirements, (2) Sealed Source and Device Evaluation Program, (3) Low-Level Radioactive Waste Disposal Program, and (4) Uranium Recovery Program. NRC's Agreement with Florida does not relinquish regulatory authority for a uranium recovery program; therefore, only the first three non-common performance indicators applied 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.

Florida's rulemaking process was changed in 2010. Criteria were established that determines whether a proposed rule has to be submitted for legislative approval. In January 2011, Executive Order 11-001 halted all rules in process and requires rules to receive review and approval from the Governor's Office. The newly established Office of Fiscal Accountability and Regulatory Reform will now review all proposed rules before publication. The deadline for submission of rules to the Governor's office is July 1, 2011, for consideration by the Florida Legislature 2012 session. After legislative approval is received, it is anticipated that it may take up to 12 months to complete a rule.

4.1.2 Program Elements Required for Compatibility

The Florida regulations governing radiation protection requirements 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. 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 FAC. With the changes described above now in effect, the State's administrative rulemaking process takes approximately 12 months from drafting to finalizing a rule. After the Bureau drafts a proposed regulation, they must publish a notice in the Florida Administrative Weekly (FAW) offering to hold public workshops about the proposed regulations. After the workshops (if held), the Bureau publishes a notice in the FAW of proposed rulemaking and offers the opportunity for a public hearing on the proposed rules. 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. The final rule must be filed within 90 days of the notice of the proposed rule.

The review team evaluated Florida'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 State Regulation Status Sheet that FSME maintains.

During the review period, Florida submitted seven final regulation amendments, one proposed regulation amendment and one legally binding license condition to the NRC for a compatibility review. Five of the amendments were overdue for State adoption at the time of submission. The NRC's compatibility review resulted in 38 comments, which will need to be addressed by the State in upcoming rulemaking activities. The following five amendments were submitted overdue during this review period:

- "Medical Use of Byproduct Material," 10 CFR Parts 20, 32, and 35 amendment (67 FR 20249), that was due for Agreement State adoption on October 24, 2005.

- "Medical Use of Byproduct Material – Recognition of Specialty Boards," 10 CFR Part 35 amendment (70 FR 16336, 71 FR 1926) that was due for Agreement State adoption on April 29, 2008.

- "Minor Amendments," 10 CFR Parts 20, 30, 32, 35, 40, and 70 amendment (71 FR 15005) that was due for Agreement State adoption on March 27, 2009.

- "National Source Tracking System – Serialization Requirements," 10 CFR Part 32 with reference to Part 20 Appendix E amendment (71 FR 65685) that was due for Agreement State adoption on February 6, 2007.

- "Occupational Dose Records, Labeling Containers, and Total Effective Dose Equivalent," 10 CFR Parts 19 and 20 amendment (72 FR 68043) that was due for Agreement State adoption on January 3, 2011.

According to the Bureau's Environmental Health Program Consultant, who is responsible for oversight of rulemaking and associated activities, the Bureau is reviewing the NRC comments

on the final regulation amendments submitted during this review period and plans to address the comments in upcoming rulemaking.

Current NRC policy requires that Agreement States adopt certain equivalent regulations or legally binding requirements no later than 3 years after the effective date of NRC's regulations. At the time of this review, the following two amendments were overdue:

- "Exemptions from Licensing, General Licenses, and Distribution of Byproduct Material; Licensing and Reporting Requirements," 10 CFR Parts 30, 31, 32, and 150 amendment (72 FR 58473), that was due for Agreement State adoption by December 17, 2010.

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

The Bureau is currently drafting proposed regulations for these two amendments and plans to submit them to NRC for review by June 2011. The review team noted that the State had made significant process in the promulgation of regulations since the last IMPEP review, but still faced challenges in negotiating the arduous State regulatory process.

Based on the IMPEP evaluation criteria, the review team recommends that Florida's performance with respect to the indicator, Compatibility Requirements, be found satisfactory, but needs improvement.

4.2 Sealed Source and Device Evaluation Program

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

In assessing the Florida SS&D evaluation activities, the review team examined the information provided in response to the IMPEP questionnaire and evaluated the SS&D registry sheets and supporting documents processed during the review period. The team also evaluated SS&D staff training records; certain reported incidents involving products authorized in Florida SS&D registrations, the use of guidance documents and procedures, and interviewed the staff currently conducting SS&D evaluations.

4.2.1. Technical Staffing and Training

SS&D evaluation responsibilities are distributed between two reviewers, with one additional reviewer in training. Another individual who evaluated most of the SS&D registries in the current reporting period is no longer with the Bureau.

The Bureau has a documented qualification program for SS&D reviewers as a subsection of its overall Licensing Evaluator Qualification Procedures. 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 qualified senior SS&D reviewers.

The Bureau currently has three qualified reviewers, although one individual has not performed any SS&D evaluations. All three individuals have completed the NRC SS&D Workshop. The new reviewer in training will be trained in-house with oversight from the senior SS&D reviewers. As part of its training, 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 active 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.

4.2.2 Technical Quality of the Product Evaluation Program

During the review period, the Bureau processed six SS&D actions. Five of the actions were amendments, with one new application. There were no inactivations of SS&D registrations or emerging technology evaluations processed during the review period. The review team evaluated all six actions processed during the review period. The casework selected for review was representative of two qualified reviewers (one of whom is no longer with the Bureau) and one reviewer in-training. A listing of the SS&D certificates evaluated by the review team, with case-specific comments, may be found in Appendix F.

The review team identified that one of the SS&D registries issued was not signed by two qualified individuals. The concurrence reviewer for the new SS&D had not completed the in-house SS&D training program and is not considered a qualified reviewer. The Bureau has an internal policy that two qualified individuals review the SS&D application and a third individual in-training may also review the SS&D application. Several unusual circumstances played a role in the review of this SS&D application. The initial review and initial letter requesting additional information from the applicant was completed by a qualified reviewer. He left State employment after the initial review and prior to issuance of the SS&D certificate. The second qualified reviewer, who peer reviewed the work of the initial reviewer, took over the project. He completed his review of the device and issued the registry. The concurrence signature for the SS&D registry was signed by the individual in-training. Therefore, the SS&D registration was not signed by two qualified reviewers.

Florida Statute Title X, Chapter 120, Section 120.60, requires an agency to approve or deny an application for a license within 90 days after receipt of a completed application. If the application is not approved or denied within the 90-day timeframe, within 15 days after conclusion of a public hearing held on the application, or within 45 days after a recommended order is submitted to the agency, the application is considered approved unless the recommended order directs that the agency deny the license. Due to the untimely departure of the original qualified reviewer and the 90-day statutory requirement, the Bureau's time to complete the review and issue the SS&D registration was limited. The second qualified individual completed the review; however, the other qualified individual on staff was unable to review the submittal in a timely fashion. The reviewer in-training was available and performed the concurrence review. The Bureau submitted a Technical Assistance Request (TAR) to the NRC for this SS&D. The TAR requested NRC's assistance in interpretation of the regulations

regarding the definition of a generally licensed device and distribution of these devices to general licensees. Due to Florida statutory time limitations on issuance of registrations and licenses, the Bureau was required to issue the registry prior to receiving NRC's response, and was thus not able to consider the TAR response prior to issuance of the SS&D.

The Bureau performed evaluations based on sound conservative assumptions to ensure public health and safety was adequately protected. Good health physics practices were implemented throughout this review. Since the original review was performed by a qualified individual and the second qualified individual peer reviewed the first reviewer's work and completed the SS&D registry, although the actual concurrence reviewer had not completed the training, the team determined that two qualified individuals actually reviewed the SS&D submittal and therefore determined that the Bureau met the intent of the requirement of having two qualified individuals perform the review. All other SS&D registrations completed during the review period were signed by two qualified reviewers.

In assessing the Bureau's SS&D evaluation activities, the review team examined information contained in the questionnaire response and interviewed program staff and managers. The review team confirmed that the Bureau follows the recommended guidance from the NRC SS&D Workshop, NUREG-1556 Series Guidance, applicable and pertinent American National Standards Institute (ANSI) standards and Military Standards, ISO-9001 and Florida regulations, statutes, policies and procedures. The review team verified these documents were available and used appropriately in performing SS&D reviews.

Deficiency letters clearly stated regulatory positions and all health and safety issues were addressed. The review team determined that product evaluations were complete and adequately addressed the integrity of the products during use and in the event of accidents.

4.2.3 Evaluation of Defects and Incidents Regarding SS&Ds

Utilizing NMED, the review team examined four incidents involving SS&D registered products during the review period. The review team examined all events that occurred in Florida that involved equipment or source failures within the period, as well as any events that occurred nationally involving sources/devices registered by the Bureau. The review team determined that the State analyzed the events, reviewed the issues, and followed up on the incidents. None of the events involving sources/devices manufactured or distributed by a licensee with a SS&D registered in Florida were related to manufacturing or design of the product.

Based on the IMPEP evaluation criteria, the review team recommends that Florida's performance with respect to the indicator, Sealed Source and Device Evaluation Program, be found satisfactory.

4.3 Low-level Radioactive Waste 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. 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 above, Florida's performance was found satisfactory, but needs improvement, for the indicator, Compatibility Requirements, and satisfactory for the remaining performance indicators reviewed. The review team did not make any recommendations regarding program performance by the State and determined that the recommendation from the 2007 IMPEP review should be closed. Accordingly, the review team recommends that the Florida Agreement State Program is adequate to protect public health and safety and is compatible with NRC's program. Based on the results of the current IMPEP review, the review team recommends that the next full IMPEP review take place in approximately four years.

LIST OF APPENDICES

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

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	**Area of Responsibility**
Jim Lynch, Region III	Team Leader Technical Staffing and Training Inspector Accompaniments
Donna Janda, Region I	Technical Quality of Licensing Actions Compatibility Requirements Inspector Accompaniments
Solomon Sahle, FSME	Status of Materials Inspection Program
Anthony Gaines, Region IV	Technical Quality of Inspections Technical Quality of Incident & Allegation Activities Inspector Accompaniments
Sandi Kessinger, Illinois	Sealed Source and Device Evaluation Program Technical Quality of Licensing Actions

APPENDIX B

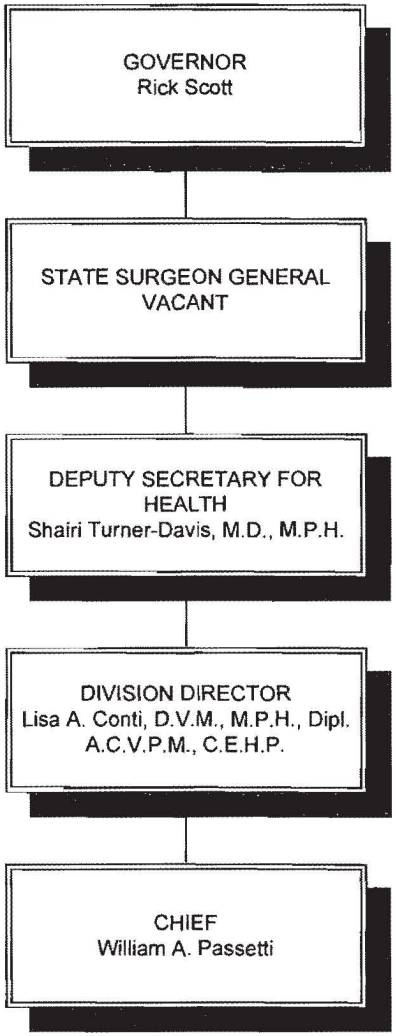
FLORIDA ORGANIZATION CHARTS

ADAMS ACCESSION NO.: ML110750665

DEPARTMENT OF HEALTH

Appendix 1

ENVIRONMENTAL HEALTH DIVISION
BUREAU OF RADIATION CONTROL

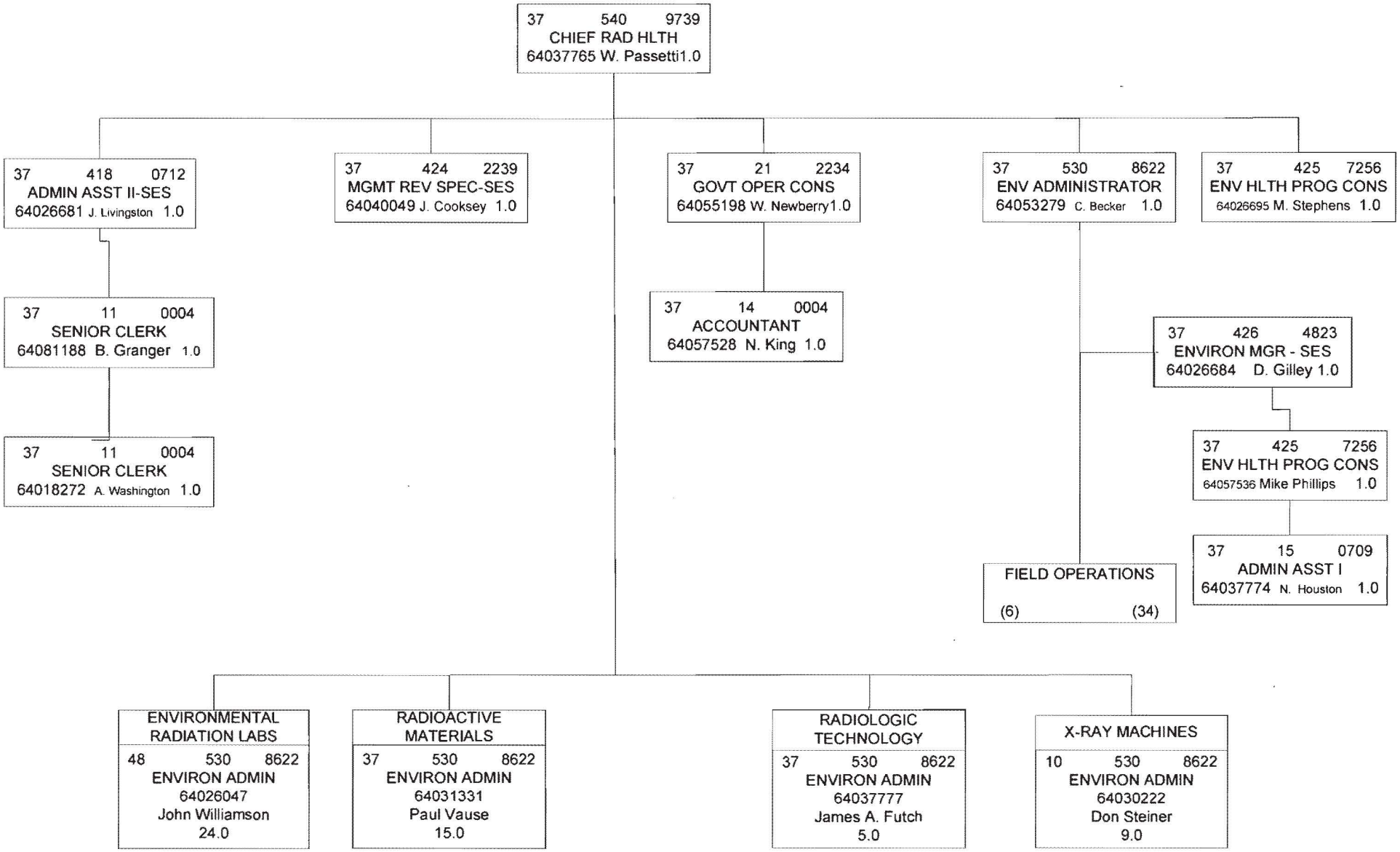


March 7, 2011

Appendix 2

DEPARTMENT OF HEALTH
ENVIRONMENTAL HEALTH DIVISION
BUREAU OF RADIATION CONTROL

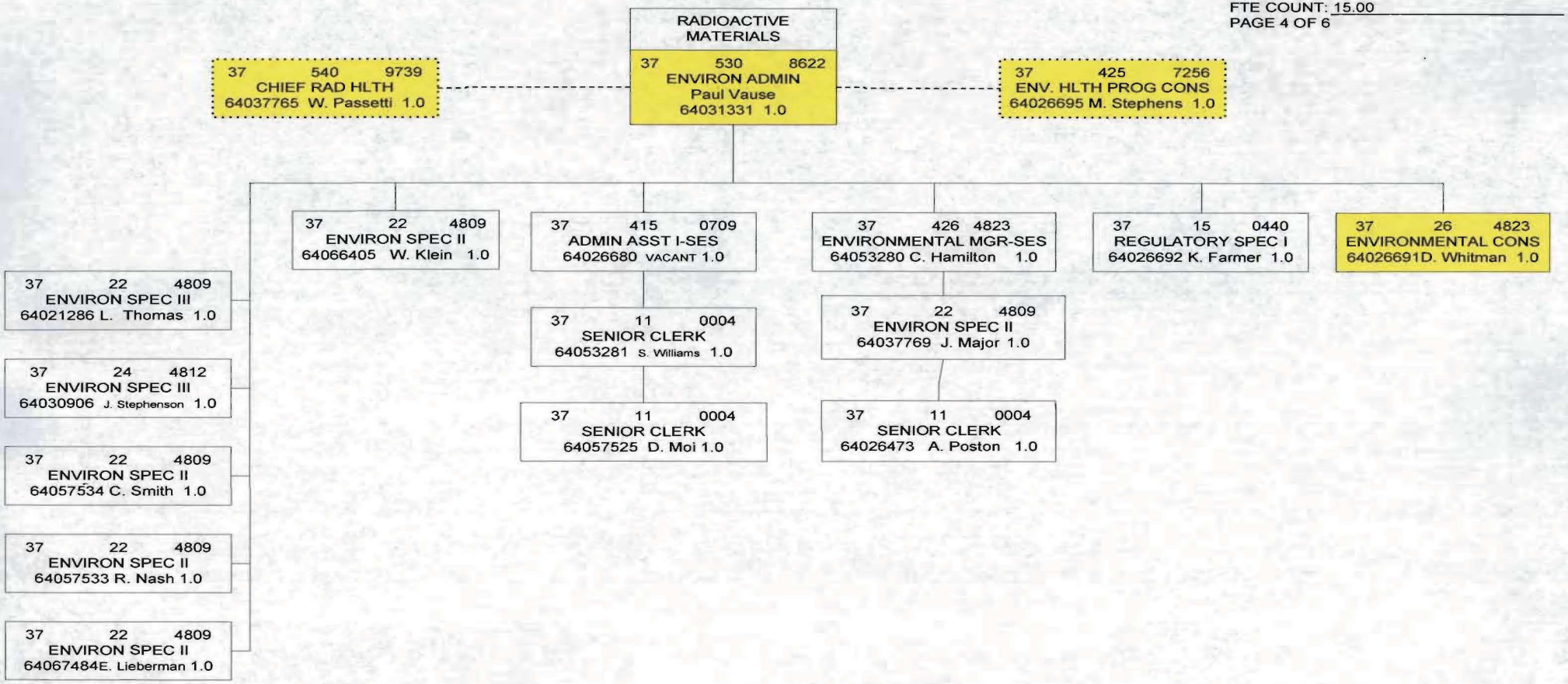
APPROVED: _____
BUDGET ENTITY: 64200600
EFFECTIVE DATE: _____
FTE COUNT: 99



Appendix 3

DEPARTMENT OF HEALTH
ENVIRONMENTAL HEALTH DIVISION
BUREAU OF RADIATION CONTROL

APPROVED:
BUDGET ENTITY: 64200600
EFFECTIVE DATE:
FTE COUNT: 15.00
PAGE 4 OF 6



March, 2011

APPENDIX C

INSPECTION CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

File No.: 1
Licensee: University of Florida License No.: 0031-3
Inspection Type: Special, Announced Priority: 2
Inspection Date: 11/28/07 Inspectors: BT, TT

File No.: 2
Licensee: Cardiology Diagnostics Imaging, Inc. License No.: 3119-2
Inspection Type: Routine, Announced Priority: 5
Inspection Date: 4/29/08 Inspector: FN

File No.: 3
Licensee: Southwest Volusia Healthcare Corporation License No.: 2467-1
Inspection Type: Routine, Unannounced Priority: 3
Inspection Dates: 10/7-8/08 Inspector: DD

File No.: 4
Licensee: Cardiology Consultants, P.A. License No.: 3516-2
Inspection Type: Routine, Unannounced Priority: 5
Inspection Dates: 2/2-5/09 Inspectors: DD, JB

File No.: 5
Licensee: V.P. Jeyabarath, M.D., P.A. License No.: 4062-1
Inspection Type: Routine, Unannounced Priority: 5
Inspection Date: 1/23/09 Inspector: AO

File No.: 6
Licensee: Orlando Heart and Vascular Center, LLC License No.: 3939-1
Inspection Type: Routine, Announced Priority: 5
Inspection Date: 6/4/09 Inspector: HS

File No.: 7
Licensee: Palmetto Open MRI, Inc. License No.: 3650-1
Inspection Type: Routine, Announced Priority: 5
Inspection Date: 5/6/09 Inspector: JS

File No.: 8
Licensee: Yovaish Engineering Sciences, Inc. License No.: 2649-1
Inspection Type: Routine, Unannounced Priority: 5
Inspection Date: 2/25/10 Inspector: LB

File No.: 9
Licensee: Nodarse and Associates, Inc. License No.: 2429-5
Inspection Type: Routine, Unannounced Priority: 5
Inspection Dates: 8/11-12/10 Inspectors: TM, CB

File No.: 10
Licensee: Veterinary Internis License No.: 3190-1
Inspection Type: Routine, Unannounced Priority: 5
Inspection Date: 2/15/11 Inspector: HS

File No.: 11
Licensee: Food Technology Services, Inc. License No.: 2244-1
Inspection Type: Routine, Announced Priority: 2
Inspection Date: 3/9/11 Inspector: TM

File No.: 12
Licensee: Bayfront Medical Center, Inc. License No.: 0023-2
Inspection Type: Routine, Announced Priority: 2
Inspection Date: 5/28/10 Inspector: SR

File No.: 13
Licensee: Halifax License No.: 0194-5
Inspection Type: Routine, Announced Priority: 5
Inspection Date: 11/15/10 Inspector: DD

File No.: 14
Licensee: Cardinal Health 414, LLC License No.: 3453-1
Inspection Type: Routine, Unannounced Priority: 2
Inspection Date: 11/19/09 Inspector: GH

File No.: 15
Licensee: Formweld Fitting, Inc. License No.: 3472-1
Inspection Type: Routine, Announced Priority: 2
Inspection Date: 3/11/11 Inspector: BR

File No.: 16
Licensee: Tampa Radiation Oncology, P.C. License No.: 4152-1
Inspection Type: Routine, Unannounced Priority: 2
Inspection Date: 2/9/11 Inspector: SR

File No.: 17
Licensee: Triad Isotopes, Inc. License No.: 3920-12
Inspection Type: Routine, Announced Priority: 2
Inspection Date: 10/19/10 Inspector: LG

File No.: 18
Licensee: Cardiovascular Diagnostic Image, Inc. License No.: 3119-2
Inspection Type: Routine, Announced Priority: 5
Inspection Date: 6/3/09 Inspectors: JG, EK, WL

File No.: 19
Licensee: Space Science Services, Inc. License No.: 0140-2
Inspection Type: Routine, Announced Priority: 1
Inspection Dates: 11/19-27/07 Inspector: LB

Comment: Corrective actions for a repeat violation did not appear to be adequate. The licensee just stated that they had corrected the problem, which was similar to their response for the original violation.

File No.: 20
Licensee: Law and Associates, Inc. License No.: 2466-1
Inspection Type: Routine, Unannounced Priority: 5
Inspection Dates: 4/23-25/08 Inspectors: DD, HS

File No.: 21
Licensee: RCOA Imaging Services, Inc. License No.: 3110-4
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 2/22/11 Inspector: DB

File No.: 22
Licensee: Marlin Engineering, Inc. License No.: 2886-1
Inspection Type: Routine, Unannounced Priority: 5
Inspection Dates: 7/11-16/07 Inspector: JS

INSPECTOR ACCOMPANIMENTS

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

Accompaniment No.: 1
Licensee: Port Saint Lucie Surgery Center, LTD License No.: 3957-1
Inspection Type: Routine, Announced Priority: 3
Inspection Date: 3/7/11 Inspector: NP

Accompaniment No.: 2
Licensee: Innovative American Technology, Inc. License No.: 4209-1
Inspection Type: Initial, Announced Priority: 1
Inspection Date: 3/8/11 Inspector: LG

Accompaniment No.: 3
Licensee: Denis R. Weinberg, M.D. and Associates Corporation License No.: 3213-1
Inspection Type: Routine, Announced Priority: 3
Inspection Date: 3/9/11 Inspector: WL

Accompaniment No.: 4
Licensee: Cardinal Health 414, LLC License No.: 3469-2
Inspection Type: Routine, Announced Priority: 2
Inspection Date: 3/10/11 Inspector: MK

Accompaniment No.: 5
Licensee: Bethesda Memorial Hospital License No.: 0658-2
Inspection Type: Routine, Announced Priority: 2
Inspection Date: 3/11/11 Inspector: RB

Accompaniment No.: 6
Licensee: Certified Testing Laboratories, Inc. License No.: 2332-1
Inspection Type: Routine, Announced Priority: 1
Inspection Date: 3/7/11 Inspector: HS

Accompaniment No.: 7
Licensee: IBA Molecular North America, Inc. License No.: 3287-1
Inspection Type: Routine, Announced Priority: 2
Inspection Date: 3/8/11 Inspector: RC

Accompaniment No.: 8
Licensee: Southwest Volusia Healthcare Corporation License No.: 2467-2
Inspection Type: Initial, Announced Priority: 2
Inspection Date: 3/9/11 Inspector: DD

Accompaniment No.: 9
Licensee: GE Inspection Services, Inc. License No.: 2861-1
Inspection Type: Routine, Unannounced Priority: 1
Inspection Date: 3/10/11 Inspector: MC

Accompaniment No.: 10
Licensee: Formweld Fitting, Inc. License No.: 3472-1
Inspection Type: Routine, Announced Priority: 1
Inspection Date: 3/11/11 Inspector: BR

Accompaniment No.: 11
Licensee: Specialists in Urology, P.A. License No.: 4149-1
Inspection Type: Routine, Announced Priority: 2
Inspection Date: 3/7/11 Inspector: MB

Comment: The inspector would benefit from additional brachytherapy training.

Accompaniment No.: 12
Licensee: National Inspection and Consultants, Inc. License No.: 2850-1
Inspection Type: Routine, Announced Priority: 1
Inspection Date: 3/8/11 Inspector: LF

Accompaniment No.: 13
Licensee: Food Technology Services, Inc. License No.: 2244-1
Inspection Type: Routine, Announced Priority: 2
Inspection Date: 3/9/11 Inspector: TM

Accompaniment No.: 14
Licensee: Petnet Solutions, Inc. License No.: 3887-4
Inspection Type: Routine, Announced Priority: 2
Inspection Date: 3/10/11 Inspector: DM

Accompaniment No.: 15
Licensee: IsoAid, LLC License No.: 3196-1
Inspection Type: Routine, Announced Priority: 2
Inspection Date: 3/11/11 Inspector: AO

APPENDIX D

LICENSE CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

File No.: 1
Licensee: Cardinal Health 414, LLC — License No.: 3453-8
Type of Action: Renewal — Amendment No.: 19
Date Issued: 5/1/08 — License Reviewer: LT

File No.: 2
Licensee: Tyco Healthcare Group, LP — License No: 3007-1
Type of Action: Renewal — Amendment No.: 24
Date Issued: 8/4/10 — License Reviewer: TT

File No.: 3
Licensee: University of Central Florida — License No.: 4187-1
Type of Action: New — Amendment No.: 0
Date Issued: 1/21/10 — License Reviewer: TT

File No.: 4
Licensee: Adventist Health Systems/Sunbelt, Inc. — License No.: 2897-1
Type of Action: Amendment — Amendment No.: 54
Date Issued: 9/20/10 — License Reviewer: MG

File No.: 5
Licensee: Morton Plant Gamma Knife, LLC — License No.: 3667-1
Type of Action: Termination — Amendment No.: 14
Date Issued: 4/29/10 — License Reviewer: JS

File No.: 6
Licensee: St. Anthony's Hospital, Inc. — License No.: 0294-3
Type of Action: New — Amendment No.: 0
Date Issued: 2/11/10 — License Reviewer: LT

File No.: 7
Licensee: Triad Isotopes, Inc. — License No.: 3920-3
Type of Action: Amendment — Amendment No.: 3
Date Issued: 6/16/08 — License Reviewer: BT

File No.: 8
Licensee: Team Industrial Services, Inc. — License No.: 3721-1
Type of Action: Renewal — Amendment No.: 7
Date Issued: 11/19/10 — License Reviewer: DW

File No.: 9
Licensee: Baptist Medical Center of Nassau, Inc. License No.: 2523-1
Type of Action: Amendment Amendment No.: 24
Date Issued: 12/2/10 License Reviewer: EL

File No.: 10
Licensee: Anazao Health Corporation License No.: 2975-1
Type of Action: Amendment Amendment No.: 34
Date Issued: 12/27/10 License Reviewer: EL

Comment: The file contained no documentation regarding safety procedures related to licensee's request to add P-32 use to the license for research and development activities.

File No.: 11
Licensee: Tenet St. Mary's Inc. License No.: 3279-1
Type of Action: Amendment Amendment No.: 18
Date Issued: 6/22/10 License Reviewer: MG

File No.: 12
Licensee: Clinical P.E.T. of Ocala, LLC License No.: 3355-1
Type of Action: Amendment Amendment No.: 9
Date Issued: 5/8/09 License Reviewer: KF

File No.: 13
Licensee: Rad Onc Group, LLC License No.: 3989-1
Type of Action: New Amendment No.: 0
Date Issued: 10/24/07 License Reviewer: JS

File No.: 14
Licensee: Lee Memorial Health System License No.: 2695-2
Type of Action: Termination Amendment No.: 11
Date Issued: 4/1/09 License Reviewer: JS

File No.: 15
Licensee: Alliance Surgical Center, LLC License No.: 4213-1
Type of Action: New Amendment No.: 0
Date Issued: 8/26/10 License Reviewer: JS

File No.: 16
Licensee: Martin Memorial Medical Center, Inc. License No.: 1215-3
Type of Action: Amendment Amendment No.: 33
Date Issued: 6/5/09 License Reviewer: KF

File No.: 17
Licensee: Food Technology Services, Inc. License No.: 2244-1
Type of Action: Amendment Amendment No.: 48
Date Issued: 7/21/10 License Reviewer: LT

File No.: 18
Licensee: University of Miami License No.: 1319-1
Type of Action: Amendment Amendment No.: 54
Date Issued: 10/22/10 License Reviewer: EL

File No.: 19
Licensee: Space Science Services, Inc. License No.: 0140-2
Type of Action: Amendment Amendment No.: 21
Date Issued: 1/21/09 License Reviewer: LT

File No.: 20
Licensee: Lifescan Institutes of America, LLC License No.: 3418-1
Type of Action: Termination (Revocation) Amendment No.: 2
Date Issued: 6/13/07 License Reviewer: CH

Comment: File contained no documentation of final disposition of radioactive material and no documentation of close out surveys.

File No.: 21
Licensee: Florida Blood Services, Inc. License No.: 4055-1
Type of Action: New Amendment No.: 0
Date Issued: 7/14/08 License Reviewer: JS

File No.: 22
Licensee: Intersil Communications, Inc. License No.: 3044-1
Type of Action: Renewal Amendment No.: 6
Date Issued: 11/30/07 License Reviewer: JK

APPENDIX E

INCIDENT CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

File No.: 1
Licensee: University of Florida Shandis Hospital
Date of Incident: 7/11/07
Investigation Date: 7/13/07
License No.: 0031-1
NMED No.: 070439
Type of Incident: Medical Event
Type of Investigation: Site

File No.: 2
Licensee: Tierra, Inc.
Date of Incident: 12/7/07
Investigation Date: 12/7/07
License No.: 2307-2
NMED No.: 070756
Type of Incident: Lost/Stolen RAM
Type of Investigation: Site

File No.: 3
Licensee: Cardinal Health 414, LLC
Date of Incident: 3/19/08
Investigation Date: 4/15/08
License No.: 3453-2
NMED No.: 080417
Type of Incident: Lost/Stolen RAM
Type of Investigation: Site

File No.: 4
Licensee: Saint Vincent Medical Center, Inc.
Date of Incident: 9/10/08
Investigation Date: 10/17/08
License No.: 0014-6
NMED No.: 080694
Type of Incident: Medical Event
Type of Investigation: Site

File No.: 5
Licensee: IsoAid, LLC
Date of Incident: 12/31/08
Investigation Date: 7/27/10
License No.: 3196-1
NMED No.: 100399
Type of Incident: Overexposure
Type of Investigation: Site

Comment: This incident was discovered during an inspection in 2010.

File No.: 6
Licensee: Renegade Testing and Inspection, Inc.
Date of Incident: 5/12/09
Investigation Date: 5/12/09
License No.: 3891-1
NMED No.: 090624
Type of Incident: Damaged Equipment
Type of Investigation: Site

File No.: 7
Licensee: Condotte America, Inc.
Date of Incident: 12/15/09
Investigation Date: 12/15/09
License No.: 3622-1
NMED No.: 090881
Type of Incident: Lost/Stolen RAM
Type of Investigation: Site

File No.: 8
Licensee: Florida Bureau of Radiation Control
Date of Incident: 3/6/10
Investigation Date: 4/6/10
License No.: 0001-3
NMED No.: 100176
Type of Incident: Lost/Stolen RAM
Type of Investigation: Site

File No.: 9
Licensee: 21st Century Oncology
Date of Incident: 3/31/10
Investigation Date: 4/1/10
License No.: 1797-2
NMED No.: 100249
Type of Incident: Lost/Stolen RAM
Type of Investigation: Site

File No.: 10
Licensee: Target Engineering Group, Inc.
Date of Incident: 6/7/10
Investigation Date: 06/7/10
License No.: 3366-1
NMED No.: 100296
Type of Incident: Lost/Stolen RAM
Type of Investigation: Site

File No.: 11
Licensee: Anderson Columbia Co., Inc.
Date of Incident: 12/14/10
Investigation Date: 12/14/10
License No.: 2708-1
NMED No.: 100603
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.

File No.: 1
Registry No.: FL-1146-S-101-S SS&D Type: (AA) Manual Brachytherapy
Applicant Name: IsoAid, LLC Type of Action: Amendment
Date Issued: 9/7/07 SS&D Reviewers: TT, PV

Comments:
a) Exposure rate measurements were not calculated for the maximum source quantity.
b) Surface exposure rates were not listed.
c) Tolerances were not listed for physical dimensions of the source.

File No.: 2
Registry No.: FL-1146-S-102-S SS&D Type: (AA) Manual Brachytherapy
Applicant Name: IsoAid, LLC Type of Action: Amendment
Date Issued: 9/7/07 SS&D Reviewers: TT, PV

Comments:
a) Exposure rate measurements were not calculated for the maximum source quantity.
b) Surface exposure rates were not listed.
c) Tolerances were not listed for physical dimensions of the source.

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: 10/2/07 SS&D Reviewers: TT, PV

File No.: 4
Registry No.: FL-1172-D-101-S SS&D Type: (O) Ion Generators, Static Eliminators
Applicant Name: Northrop Grumman Type of Action: Amendment
Date Issued: 12/30/07 SS&D Reviewers: TT, PV

File No.: 5
Registry No.: FL-1172-D-101-S SS&D Type: (O) Ion Generators, Static Eliminators
Applicant Name: Northrop Grumman Type of Action: Amendment
Date Issued: 12/10/08 SS&D Reviewers: TT, PV

Comment: The approved quality assurance manual did not reference the current manufacturer for this device.

File No.: 6
Registry No.: FL-1334-D-101-G SS&D Type: (T) Other (Power Generation)
Applicant Name: City Labs, Inc. Type of Action: New Application
Date Issued: 10/28/10 SS&D Reviewers: PV, CH

Comments:

a) The SS&D registry does not contain signatures of two qualified individuals. The concurrence review was performed by a reviewer in-training.
b) The SS&D registry does not clarify that the source is not approved for use in any other device.
c) Device labeling listed in the SS&D registry does not comply with generally licensed device labeling requirements.
d) The diagram on page 9 and parts of the diagram on page 10 are illegible in the Bureau's files; as well as on the NRC SS&D database.