March 25, 2003

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

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

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

Karen D. Cyr, General Counsel
/RA By Rosetta O. Virgilio Acting for

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

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

This memorandum transmits to the Management Review Board (MRB) a proposed final report (Attachment 1) documenting the IMPEP review of the Florida Radiation Control Program. The review of the Florida program was conducted by an interoffice team during the period of February 3 - 7, 2003. The team issued a draft report to Florida on March 6, 2003 for factual comment. Florida responded to the findings and conclusions of the review by e-mail dated March 18, 2003 from William A. Passetti, Chief, Bureau of Radiation Control, Florida Department of Health (Attachment to the proposed final report).

The review team found Florida's performance to be satisfactory for all performance indicators. Accordingly, the review team recommends finding the Florida Agreement State program to be adequate to protect public health and safety and compatible with NRC's program. Based on the results of the current IMPEP review, the review team recommends that the next full review should be in approximately 4 years.

The MRB meeting to consider the Florida report is scheduled for **Tuesday, April 15, 2003, from 2:00 p.m. to 4:00 p.m., in One White Flint North, Room O-3-B-4**. In accordance with Management Directive 5.6, the meeting is open to the public. The agenda for that meeting is attached (Attachment 2).

If you have any questions prior to the meeting, please contact me at 415-2325 or Vivian Campbell at 817-860-8143.

Attachments:
As stated

cc: Bonita Sorensen, M.D., M.B.A.
Deputy State Health Officer
Department of Health

Daniel Parker, Senior Management Analyst II
Acting Director, Division of Environmental Health

William A. Passetti, Chief
Bureau of Radiation Control

Pearce O'Kelley, SC
OAS Liaison to the MRB

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF FLORIDA AGREEMENT STATE PROGRAM

February 3-7, 2003

PROPOSED FINAL REPORT

U.S. Nuclear Regulatory Commission

ATTACHMENT 1

1.0 INTRODUCTION

This report presents the results of the review of the Florida Agreement State program. The review was conducted during the period February 3-7, 2003, by a review team consisting of technical staff members from the Nuclear Regulatory Commission (NRC) and the Agreement State of Ohio. Team members are identified in Appendix A. The team was accompanied by two representatives from the U.S. General Accounting Office. The review was conducted in accordance with the "Implementation of the Integrated Materials Performance Evaluation Program and Rescission of a Final General Statement of Policy," published in the Federal Register on October 16, 1997, and the November 5, 1999, NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." Preliminary results of the review, which covered the period of February 26, 1999, to February 7, 2003, were discussed with Florida management on February 7, 2003.

[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). The Bureau Chief reports to the Director of the Division of Environmental Health (the Division) located in the Department of Health (the Department). The Bureau consists of five sections managed by the Bureau Chief. Three sections within the Bureau, Field Operations, Environmental Radiation Labs and Radioactive Materials, have responsibilities for radioactive materials under the Agreement. The Department is the designated radiation control agency (See Section 4.1). Organization charts are included in Appendix B. At the time of the review, the Florida Agreement State program regulated 1383 specific licenses authorizing Agreement and non-Atomic Energy Act materials. The review focused on the materials program as it is carried out under the Section 274b. (of the Atomic Energy Act of 1954, as amended) Agreement between the NRC and the State of Florida.

In preparation for the review, a questionnaire addressing the common and non-common performance indicators was sent to the Bureau on October 31, 2002. The Bureau provided a response to the questionnaire on January 17, 2003. During the review, the review team identified areas in the questionnaire response that needed to be modified. The State provided an amended questionnaire response on February 12, 2003. Copies of the questionnaire responses may be found on NRC's Agencywide Document Access and Management Systems using the Accession Numbers ML030300287 and ML030510559.

The review team's general approach for conduct of this review consisted of: (1) examination of Florida's responses to the questionnaire; (2) review of applicable Florida statutes and regulations; (3) analysis of quantitative information from the radiation control program licensing and inspection data base; (4) technical review of selected licensing and inspection actions; (5) field accompaniments of nine Bureau inspectors; and (6) interviews with staff and management to answer questions or clarify issues. The review team evaluated the information that it gathered against the IMPEP performance criteria for each common and applicable non-common performance indicators and made a preliminary assessment of the Florida Agreement State program's performance.

Section 2 below discusses the State's actions in response to recommendations made following the previous IMPEP review. Results of the current review for the IMPEP common performance

indicators are presented in Section 3. Section 4 discusses results of the applicable non-common performance indicators, and Section 5 summarizes the review team's findings.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous IMPEP review, which concluded on February 26, 1999, three recommendations were made and transmitted to Ms. Sharon Heber, M.P.H., Director, Division of Environmental Health, on May 25, 1999. The team's review of the current status of the recommendations are as follows:

1. The review team recommends that the Bureau incorporate the field notes for the inspection of waste processing and panoramic irradiator licensees in their inspection procedures manual. (Section 3.2)

   Current Status: Copies of the field notes for the inspection of waste processing and panoramic irradiator licensees were provided to the review team. The Bureau has incorporated the field notes into their electronic inspection procedures manual. The review team noted that the hard copy inspection procedures manual referred inspectors to the electronic manual to obtain copies of these infrequently used field notes. This recommendation is closed.

2. The review team recommends that the Bureau revise their incident and allegation procedures to document all existing State practices and to incorporate appropriate elements of OSP Procedure SA-300, "Handbook on Nuclear Event Reporting in the Agreement States" and NRC Management Directive 8.8, "Management of Allegations," particularly the required documentation and management approval for closing out incidents and allegations. (Section 3.5)

   Current Status: Copies of the Bureau Standard Operating Procedure (SOP) 1 dated October 2002 were provided to the review team. Additions to the SOP since the previous IMPEP review include thorough documentation of incident and allegation response procedures, as well as additional information on reporting of events to the NRC. Incident response files are closed out with proper management approval. This recommendation is closed.

3. The review team recommends that the State complete adoption of the revisions to Part 20 to correct discrepancies identified in NRC letter dated November 24, 1997. (Section 4.1.2)

   Current Status: The review team found that the State corrected the minor discrepancies in the State's adoption of the 10 CFR Part 20 equivalent regulations effective October 8, 2000. This recommendation is closed.

3.0 COMMON PERFORMANCE INDICATORS

IMPEP identifies five common performance indicators to be used in reviewing both NRC Regional and Agreement State programs. These indicators are: (1) Technical Staffing and Training; (2) Status of Materials Inspection Program; (3) Technical Quality of Inspections; (4) Technical Quality of Licensing Actions; and (5) Response to Incidents and Allegations.

3.1 Technical Staffing and Training

Issues central to the evaluation of this indicator include the 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 responses relative to this indicator, interviewed Bureau management and staff, reviewed job descriptions and training records, and considered any possible workload backlogs.

The Bureau is managed from the Central office located in Tallahassee. The Radioactive Materials Administrator is responsible for materials licensing and compliance activities. The Field Operations Administrator is responsible for coordinating the inspection activities, which are conducted primarily by the six field offices and two counties under contract, Polk and Broward. The Environmental Radiation Lab Administrator, located in Orlando, is responsible for the Bureau's laboratory and emergency response activities.

At the time of the review, there were 58 individuals with various degrees of involvement with the Florida radioactive materials program with a total of 20 full time equivalents (FTE) assigned to implement the materials licensing and inspection program. This staffing level does not include administrative support staff. Fifteen staff were located in the Central office, including five managers. Thirty-four staff were inspectors 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 21 turnovers in staff during the review period, equivalent to 6 FTE assigned to the Agreement program. The Bureau's turnover was due primarily to competition with local industry for qualified staff. Nevertheless, the Bureau has generally been able to fill vacancies in an expedient manner. At the time of the review, the Bureau had four vacancies, one in the Central office and three in the Miami office. Bureau management does not intend to fill one of the vacancies in the Miami office due to their current workload. The review team concluded that the Bureau has a well balanced staff, and a sufficient number of trained personnel to carry out regulatory duties.

The Bureau has a documented training and qualification program for licensing and inspection staff that is based on the NRC/Organization of Agreement States Joint Working Group report. Adequate qualification is determined through a combination of education and experience, formal classroom training, and on-the-job training. The technical staff are classified as Environmental Scientists and Specialists. Staff members are required to have a bachelors degree or equivalent experience in the physical sciences. The license evaluators and inspectors are required to maintain individual Qualification Journals. The staff must document completion of each module and receive management sign off prior to being authorized to perform assigned tasks independently. The team observed that the Bureau has exhibited a strong commitment to training. The Bureau recently posted and filled a new position, Training

Coordinator, dedicated to developing an in-house training program. The Bureau's goal is to develop a task oriented training program using available resources within the State.

The review team noted that the Bureau has experienced stable funding during the review period. The Bureau is authorized to charge and collect fees for specific and general licenses and 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 and enforcing the radiation control program.

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

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

The Bureau uses a database (VARCO) to track all inspection data. A list of inspections due is provided to each field office on a quarterly basis. The Bureau considers inspections timely if performed by the end of the calendar quarter in which the due date falls regardless of the priority. A monthly status report is provided to all field office managers that tracks the status of all assigned inspections, inspection data, enforcement actions, reciprocity inspections, and any new, terminated, or revoked licenses.

The team's review of the Bureau's inspection priorities verified that inspection frequencies for various types of licenses are at least as frequent as, or more frequent than, similar license types listed in NRC Inspection Manual Chapter (IMC) 2800. Twenty-nine of the 41 license categories established by the State are inspected more frequently than similar license types listed in IMC 2800. The Bureau's maximum inspection interval is four years.

In their response to the questionnaire, the Bureau indicated that there were no inspections currently overdue by more than 25% of the NRC frequency. This information was verified by review of the inspection data provided to the team. The Bureau performs approximately 600 routine inspections annually. The team determined that there were no core routine inspections currently overdue and that only four core routine inspections were conducted overdue during the review period.

With respect to initial inspections of new licensees, the Bureau requires that Priority 1 licensees be inspected within one month of issuance date, and new licensees of all other priorities be inspected within six months of the license issuance date. In addition, Chapter 404 of the Florida Statutes requires that a new license be issued if a licensee undergoes a change in ownership or controlling interest. These licensees were also inspected as new licensees and included in the initial inspection data. The Bureau has a policy of assigning inspections on a quarterly basis and considers inspections timely if performed by the end of the assigned calendar quarter. Furthermore, the Bureau conducts pre-licensing visits of all new licenses. The review team examined the Bureau's initial inspection data and determined that of the 345 new licenses issued during the review period, only six were overdue for inspection at the time the inspection was conducted. The 1999 IMPEP team determined, and the Management Review Board (MRB) concurred, that the Bureau's policy for inspecting and evaluating the initial use of radioactive material by a licensee more than adequately addressed public health and safety concerns. Based on the results of this review, the review team continues to agree with the MRB's determination.

During the review period, the Bureau granted 223 reciprocity permits, of which, 220 permits were core licensees based on IMC 1220. The review team noted that the Bureau's reciprocity inspection policy requires that 50 percent of Priority 1, 2, and 3 licensees, 30 percent of Priority 4 licensees, and 25 percent of Priority 5 licensees be inspected each year. The review team discussed NRC's current reciprocity inspection goal of inspecting 20 percent of candidate core licensees operating under reciprocity each year. The team determined that the Bureau met and exceeded the IMC 1220 criteria for the entire review period.

The timeliness of the issuance of inspection findings was evaluated during the inspection casework review. The Bureau requires all inspection correspondence to licensees to be issued within 30 days following the date of the inspection. For 57 routine inspection files examined, all inspection findings were sent to the licensees within 30 days.

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

3.3 Technical Quality of Inspections

The team evaluated the inspection reports, enforcement documentation, and inspection field notes, and interviewed staff for 57 radioactive materials inspections conducted during the review period. The casework reviewed included inspections by 32 materials license inspectors from eight field offices, and covered inspections of various types including: medical institution, medical private practice, high dose-rate afterloader, gamma stereotactic unit, mobile nuclear medicine, fixed and portable gauges, industrial radiography, academic broad scope, nuclear pharmacy, service provider, waste processor, veterinary use, and uranium products. Appendix C lists the inspection casework files reviewed for completeness and adequacy with case-specific comments.

All inspections were performed by inspectors operating out of six field offices and two county offices. All inspectors performed radioactive materials inspections and x-ray inspections, and were available to respond to radioactive materials incidents. The Bureau's inspection procedures were consistent with NRC inspection procedures.

Based on the casework file reviews, the review team found that routine inspections covered all aspects of the licensee's radiation protection program. Inspection reports were thorough, complete, consistent, and of high quality, with sufficient documentation to ensure acceptable performance with respect to health and safety by the licensee. Exit interviews were held with appropriate licensee personnel. Team inspections were performed when appropriate and for training purposes.

Inspectors prepared an inspection report of two or more pages, which included basic information about the licensee, a summary of the inspection, and the apparent violations with supporting documentation. The inspector also prepared field notes, which provided more details about the inspection. These documents were reviewed and signed by the field office manager, then sent to the Radioactive Materials section in the Central office. The inspection report and field notes were reviewed by an Inspection Coordinator in the Central office, who prepared a letter to the licensee documenting compliance with Bureau regulations, or a letter of non-compliance listing violations. Bureau representatives stated that about 50 percent of the routine inspections result in letters of non-compliance, which was confirmed by the casework reviewed by the team. Prior to issuing a letter of non-compliance, telephone discussions were held between Bureau inspectors and staff if additional information or clarification was required. All letters were reviewed and concurred on by the Radioactive Materials Administrator before being sent to the licensee.

The inspection documentation usually supported the cited violations, recommendations made to licensees, unresolved safety issues, and discussions held with the licensee during exit meetings. The review team noted a few instances of violations that lacked support as written (e.g., citing a regulation instead of license condition, lack of regulatory basis, vague or general language), some of which were contested by the licensee. The review team also noted a few instances of inadequate review of the licensee's response (e.g., responses did not address the violation, no corrective actions were provided in several contested cases). However, these appeared to be isolated cases with no common cause, and were not representative of the overall quality of inspection documentation.

All licensee correspondence describing corrective actions to violations, or contesting violations, was reviewed by the Inspection Coordinator. Of the casework selected, the review team identified a number of cases in which licensees contested violations. Bureau staff stated that contested violations were discussed with the appropriate inspector prior to determining if a violation would be upheld or rescinded. The Inspection Coordinator prepared letters responding to the licensees, stating if corrective actions were sufficient, and in the case of contested violations, if the violations were upheld or rescinded. The Radioactive Materials Administrator concurred on all response letters prior to being sent to the licensees. Currently, the Bureau tracks only one type of contested violations. The review team discussed expanding the tracking system to include all inspections that result in contested violations, in order to determine if the number of contested violations is appropriate for their program and Bureau management agreed. In addition, Bureau management plans to review the contested violations to determine if any consistent cause can be identified and corrected, if necessary.

The review team accompanied nine materials inspectors from seven field offices during the periods of January 6-10, 2003, and January 27-31, 2003. The inspections included: medical institution, medical private practice, brachytherapy, high dose-rate afterloader, nuclear pharmacy, and industrial radiography. The facilities inspected are identified in Appendix C.

During the accompaniments, the inspectors demonstrated appropriate performance-based, risk informed inspection techniques and knowledge of the regulations. Inspectors were well prepared and thorough in their reviews of the licensees' radiation safety programs. The review team noted that each inspector performed appropriate surveys during the inspections, using survey instruments which were calibrated and operable. Overall, the technical performance of the inspectors was excellent, and their inspections were adequate to assess radiological health and safety at the licensed facilities.

During the review period, Bureau staff performed audits and accompaniments of all individuals who performed materials inspections. The Bureau differentiated audits, which are performed to evaluate staff performance, from accompaniments which included evaluation but primarily served as cross-training. Audits were performed of each inspector by each field office manager, prior to approval of the inspector to perform independent inspections of various types of licensee programs. Each field office manager was audited by the Field Operations Administrator during the review period. Accompaniments of new inspectors were performed by senior inspectors, and by field office managers with inspectors. Cross training of staff was accomplished by licensing staff accompanying inspection staff. The audit and accompaniment reports contained sufficient details to document the areas covered.

The Bureau maintained an adequate number and variety of survey instruments to perform radiological surveys of materials licensees. Most survey meters used by Bureau inspectors were calibrated by the Radiation Surveillance section of the Bureau's Environmental Radiation Lab in Orlando, with sources that were National Institute of Standards and Technology traceable. Because instrument calibrations were performed in self-contained shielded calibration devices, survey instruments which did not fit the devices were sent directly from the field offices for outside calibration. The Environmental Radiation Lab also maintained a large number and variety of calibrated instruments for incident response, such as GM detectors, ion chambers, microR meters, and scintillation detectors. A database was used to track each instrument calibrated at the facility, its current location, and when the instrument must be returned to the facility for calibration. During the review period, instruments were adequately and appropriately calibrated for the field offices, and an effective tracking system ensured that calibrated instruments were always available for inspectors.

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 evaluators for 20 specific licenses. Licensing actions were reviewed for completeness, consistency, proper radioisotopes and quantities used, qualifications of authorized users, adequate facilities and equipment, and operating and emergency procedures sufficient to establish the basis for licensing actions. Licenses were evaluated for overall technical quality including accuracy, appropriateness of the license, its conditions, and tie-down conditions. Casework was

evaluated for timeliness; adherence to good health physics practices, reference to appropriate regulations, documentation of safety evaluation reports, product certifications or other supporting documentation, consideration of enforcement history on renewals, pre-licensing visits, peer or supervisory review as indicated, and proper signature authority. The files were checked for retention of necessary documents and supporting data.

Licensing casework was selected to provide a representative sample of licensing actions that were completed during the review period. The sampling included the following types of licenses: academic, irradiator, industrial radiography, portable gauge, medical institution, medical private practice, radioisotope and sealed source radiotherapy and nuclear pharmacies. Licensing actions selected for evaluation included six new licenses, four renewals, five amendments and five termination files. A listing of the licenses evaluated with case-specific comments can be found in Appendix D.

Overall, the review team found that the licensing actions were thorough, complete, consistent, and of acceptable quality with health and safety issues properly addressed. License tie-down conditions were stated clearly, backed by information contained in the file, and inspectable. The licensee's compliance history was taken into account when reviewing renewal applications and amendments. The exemptions noted in the questionnaire responses were determined to be appropriate and well documented by license conditions. The license evaluators appropriately used the Bureau's licensing guides and policies and standard licensing conditions.

Each licensing action is technically reviewed 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 each licensing action is issued. License evaluators have signature authority for licensing actions. The Bureau issues licenses for a five-year period under a timely renewal system.

The review team evaluated financial assurance and decommissioning activities conducted by the Bureau. The team concluded that the Bureau handles financial assurance appropriately. The team found that terminated licensing actions were well documented. The files included the appropriate material transfer records and survey records. Confirmatory surveys for license terminations were conducted when appropriate. There were no performance issues identified with the handling of financial assurance or decommissioning by the Bureau.

As discussed in Section 3.2, Florida Statutes require a new license be issued if a licensee undergoes a change in ownership or controlling interest. The review team noted that termination actions resulting from this change specifically provided a reference to the new license. However, the new license did not provide a reference to the terminated license. The team discussed with Bureau management the potential loss of, or difficulty in retrieving, site-specific history that may be important to decommissioning the site in the future. Bureau management agreed to explore options with the State's legal counsel to ensure that the history of a site can be tracked when a new license is issued for a specific site.

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 Response to Incidents and Allegations

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

The incidents selected for review included the following categories: misadministration, lost/stolen material, overexposure, leaking sources, transportation, contamination, loss of control, and damaged equipment. The review team found that the Bureau's response to incidents was complete and comprehensive. Initial responses were prompt and well-coordinated, and the level of effort was commensurate with the health and safety significance. The Bureau dispatched inspectors for on-site investigations when appropriate, and took suitable enforcement and follow-up actions.

When notification of an incident or an allegation is received, the Incident Response Coordinator and staff at the Environmental Radiation Lab in Orlando discuss what level of initial response is appropriate 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 close out approval and appropriate follow-up/enforcement actions.

The review team identified 397 incidents in NMED for Florida during the review period, including 110 incidents that required reporting. The Bureau reports incidents that require immediate notification to the NRC within 24 hours of notification, and incidents that require notification to the NRC within 30 days at the end of each month. Monthly reports and follow-up information are provided by extracting information from the State's Access incident database. The review team discussed with program staff what information should be reported to the NRC for inclusion in NMED, specifically when the information pertains to an allegation. It was decided that any event that met a reporting requirement should be reported, regardless of how the Bureau was informed of the event. In other words, if a reportable event was discovered due to an allegation, the Bureau should report the information to NRC for inclusion in NMED only after the allegation has been substantiated, fully investigated, and closed. Even then, the Bureau should be 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 examined the Bureau's questionnaire responses relative to this indicator. The casework for the five allegations referred by the NRC was reviewed as well as the case work for four additional allegations reported directly to the State. The Bureau evaluates each allegation and determines the proper level of response. The review of the casework and the Bureau files indicated that the Bureau took prompt and appropriate action in response to the concerns raised. All of the allegations reviewed were appropriately closed and appropriate parties were notified of the actions taken. The review team noted that allegations were treated and documented internally in the same manner as incidents. There were no performance issues identified from the review of the casework documentation.

The review team noted that Florida law requires that public documents be made available upon request. The State makes every effort to protect an alleger's identity, but it cannot be guaranteed. During the initial telephone contact, the alleger is advised that their anonymity cannot be guaranteed.

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

4.0 NON-COMMON PERFORMANCE INDICATORS

IMPEP identifies four non-common performance indicators to be used in reviewing Agreement State programs: (1) Legislation and Program Elements Required for Compatibility; (2) Sealed Source and Device Evaluation Program; (3) Low-Level Radioactive Waste Disposal Program; and (4) Uranium Recovery Program. Florida's Agreement does not authorize uranium recovery, so only the first three non-common performance indicators were applicable to this review.

4.1 Legislation and Program Elements Required for Compatibility

4.1.1 Legislation

In addition to their response to the questionnaire, the Bureau provided the review team with the opportunity to review copies of legislation that affect the radiation control program. 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 of Radiation Control within the Division of Environmental Health in the Department 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 materials, such as radium, and accelerator-produced radionuclides. Florida also requires registration of all equipment designed to produce x-rays or other ionizing radiation.
The Department's rulemaking 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 review team examined the State's administrative rulemaking process and found that the process takes three to six months from the development stage to the final filing with the Secretary of State, after which the rule becomes effective in twenty days. After the Bureau drafts the proposed regulations, they must publish a notice of proposed rule development in the Florida Administrative Weekly offering 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. This is a legislative committee which 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 review team noted that the State's rules and regulations are not subjected to "sunset" laws. The State can also 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 responses to the questionnaire, reviewed the status of regulations required to be adopted by the State under the Commission's adequacy and compatibility policy, and verified the adoption of regulations with data obtained from the Office of State and Tribal Program's (STP) State Regulation Status Data Sheet.

During the on-site review, the team found that the following regulation, due February 2, 2003, had not been adopted.

- "Respiratory Protection and Controls to Restrict Internal Exposures," 10 CFR Part 20 amendment (64 FR 54543; 64 FR 55524) that became effective February 2, 2000.

The Bureau has a draft of the proposed regulations and anticipates sending them to NRC for comment in May 2003. Currently, the Bureau does not have a licensee requiring a respiratory program. However, Bureau management stated that they would adopt alternate legally binding requirements if needed.

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

- "Energy Compensation Sources for Well Logging and Other Regulatory Clarifications," 10 CFR Part 39 amendments (65 FR 20337) that became effective on May 17, 2000. The Bureau is currently working on a draft of the proposed regulations.

- "New Dosimetry Technology," 10 CFR Parts 34, 36, and 39 amendments (65 FR 63749) that became effective January 8, 2001. The Bureau has chosen to specifically identify new dosimetry technology in their regulations and has added optically stimulated luminescence (OSL) dosimeters to applicable sections.

- "Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material," 10 CFR Parts 30, 31, and 32 amendments (65 FR 79162) that became effective February 16, 2001. 10 CFR 32.52(a) and 32.52(b) amendments were to be implemented by States within 6 months, August 16, 2001. The Bureau addressed this amendment by adding a license condition to affected licenses prior to August 16, 2001. The Bureau also provided copies of the license condition to NRC for information in response to All Agreement State Letter STP-01-028, dated March 2001. NRC has reviewed these conditions and determined that they meet the compatibility requirements. The remaining portion of this amendment is due February 16, 2004.

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

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

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

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 their SS&D Evaluation Program. These sub-indicators include: (1) Technical Quality of the Product Evaluation; (2) Technical Staffing and Training; and (3) Evaluation of Defects and Incidents Regarding SS&Ds.

In assessing the Bureau's SS&D Evaluation Program, the review team examined information provided by the Bureau in response to the IMPEP questionnaire on this indicator. A review of all new and amended SS&D evaluations and supporting documents covering the review period was conducted. The team observed the staff's use of guidance documents and procedures, interviewed the two managers involved in SS&D evaluations, and verified the use of regulations, license conditions, and inspections to enforce commitments made in the applications.

4.2.1 Technical Quality of the Product Evaluation Program

The Bureau processed 13 SS&D actions since the last IMPEP review, including four inactivations. The 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. The SS&D certificates evaluated by the review team are listed with case-specific comments 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, issued July 1998. Appropriate review checklists were used to assure all relevant materials had been submitted and reviewed. The checklists were retained in the registration files. All pertinent American National Standards Institute standards, Regulatory Guides, and applicable references were confirmed to be available and were used when performing SS&D reviews.

The registration files contained all correspondence, photographs, engineering drawings, radiation profiles, and details of the applicant's quality assurance and quality control (QA/QC) 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 determined that the product evaluations were thorough, complete, consistent, of acceptable technical quality, and adequately addressed the integrity of the products during use and in the event of an accident.

The team also reviewed the specific licenses associated with the SS&D casework and determined that they were thorough, complete, and of good technical quality. The 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.

During inspections of the SS&D facilities, the Bureau supplements their inspection record with a detailed "Sealed & Unsealed Radioactive Material" inspection form that also serves as the inspection procedure. The team evaluated this form by comparing it with the NRC Inspection Procedure (IP) 87125, "Materials Processor/Manufacturer Programs." The team noted that the Bureau's inspection record did not address the source or device review, or the QA/QC inspection elements found in the NRC procedure. Inspection of these elements assure that the licensee's products are being manufactured and distributed in accordance with the SS&D certificates, and that the licensee's QA/QC programs have been fully implemented. Through discussions with Bureau staff, the review team determined that the Bureau was inspecting these elements during inspections of SS&D facilities, but not documenting their findings. Bureau management agreed to modify their inspection field notes in order to document the inspection of the source or device review, and the QA/QC program of the device manufacturer.

4.2.2 Technical Staffing and Training

The Materials Licensing Manager is the principal SS&D reviewer and has authority to sign the registration certificates. The Manager has a Bachelor of Science degree, many years of experience in health physics, licensing, inspection, and several years experience conducting SS&D evaluations. The Manager has completed all of the training modules for the materials program, and received SS&D training under the direct supervision of the Radioactive Materials Administrator. However, he has not attended NRC's SS&D workshop.

The Radioactive Materials Administrator performs a concurrence review which is also an independent evaluation. The Administrator has advanced degrees in physics, completed all of the modular training for the materials program, and many years experience in health physics and materials licensing. The Administrator has attended several SS&D workshops.

The Bureau is committed to maintaining a high standard of quality in their SS&D reviews. Bureau management indicated that they would like to sponsor a SS&D workshop in the State of Florida similar to the one scheduled this year in California. If a workshop can be arranged, the Bureau intends to provide training to their entire licensing staff and invite other Agreement

States to participate.

4.2.3 Evaluation of Defects and Incidents Regarding SS&Ds

No incidents related to malfunctioning devices or products authorized by Florida SS&D certificates were reported during the review period. The review team verified that no incidents had occurred by searching the NMED system and making inquires of both Florida and NRC staff.

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 (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 existing 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 and 4 above, the review team found Florida's performance to be satisfactory for all seven performance indicators. Accordingly, the review team recommends finding the Florida Agreement State program to be adequate to protect public health and safety and compatible with NRC's program. Based on the results of the current IMPEP review, the review team recommends that the next full review should be in approximately 4 years. The review team made no recommendations.

LIST OF APPENDICES AND ATTACHMENTS

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	**Area of Responsibility**
Vivian Campbell, Region IV	Team Leader Technical Staffing and Training
Richard Woodruff, Region II	Status of Materials Inspection Program Sealed Source and Device Evaluation Inspector Accompaniments
Elizabeth Ullrich, Region I	Technical Quality of Inspections Inspector Accompaniments
Lance Rakovan, STP	Response to Incidents and Allegations
Shawn Smith, STP	Legislation and Program Elements Required for Compatibility
Michael Snee, Ohio	Technical Quality of Licensing Actions

APPENDIX B

FLORIDA ORGANIZATION CHARTS
ML030440681

APPENDIX C

INSPECTION CASEWORK REVIEWS

NOTE 1: CASEWORK LISTED WITHOUT COMMENT ARE INCLUDED FOR COMPLETENESS ONLY; NO SIGNIFICANT COMMENTS WERE IDENTIFIED BY THE IMPEP TEAM.

NOTE 2: Priorities listed are Florida Priorities -
Priority 1 inspection frequency = 0.5 year
Priority 2 inspection frequency = 1 year
Priority 3 inspection frequency = 2 years
Priority 4 inspection frequency = 3 years
Priority 5 inspection frequency = 4 years

File No.: 1
Licensee: Amisur (North Ridge Hospital Center) Inc. License No.: 1080-3
Location: Fort Lauderdale, FL Inspection Type: Routine, Announced
License Type: Medical Institution Priority: 3
Inspection Date: 2/20/02 Inspector: VR

File No.: 2
Licensee: Jacksonville Electric Authority License No.: 1586-1
Location: Jacksonville, FL Inspection Type: Routine, Announced
License Type: Fixed Gauge Priority: 4
Inspection Date: 11/19/02 Inspector: RD

File No.: 3
Licensee: PermaFix of Florida, Inc. License No.: 2598-1
Location: Gainesville, FL Inspection Type: Routine, Announced
License Type: Waste Processor Priority: 1
Inspection Date: 9/9/02 Inspector: PP

File No.: 4
Licensee: Robert P. Boswell, DVM, PA License No.: 2645-1
Location: West Palm Beach, FL Inspection Type: Routine, Unannounced
License Type: Veterinary Imaging Priority: 4
Inspection Date: 9/30/02 Inspector: JM

File No.: 5
Licensee: Cardiology Physicians, P. A. License No.: 3236-1
Location: Ormond Beach, FL Inspection Type: Initial, Unannounced
License Type: Medical Private Practice Priority: 4
Inspection Date: 11/16/01, 11/21/01 Inspector: JM

File No.: 6
Licensee: Concept Medical Diagnostic Center, Inc. License No.: 3420-1
Location: Delray Beach, FL Inspection Type: Pre-Licensing, Announced
License Type: Medical Private Practice Priority: 4
Inspection Date: 11/14/02 Inspector: GS

File No.: 7
Licensee: Diagnostic Radiology Centers, Inc. License No.: 3169-1
Location: Daytona Beach, FL Inspection Type: Initial, Unannounced
License Type: Medical Private Practice Priority: 4
Inspection Date: 3/22/01 Inspector: JM

File No.: 8
Licensee: Edward R. Bermudez, MD, P. A. License No.: 2911-1
Location: Sarasota, FL Inspection Type: Routine, Announced
License Type: Medical Private Practice Priority: 4
Inspection Date: 11/29/01 Inspector: SH

File No.: 9
Licensee: Florida Coastal Cardiology, P. A. License No.: 2994-1
Location: Apalachicola, FL Inspection Type: Routine, Unannounced
License Type: Mobile Nuclear Medicine Priority: 4
Inspection Date: 9/27/02 Inspector: RL

Comments:
a) The 10/11/02 letter of non-compliance, violation #2 contains a statement not supported by the inspector's report and field notes.
b) The 10/11/02 letter of non-compliance, violation #3 is not clear.
c) Field Notes Sections VII.D, Events, and VIII, Inspector Surveys, were not completed.
d) As a result of this inspection, the license type was changed from mobile nuclear medicine to its current classification of medical private practice. The change was appropriate and is noted only to clarify the difference in license type from that shown on the current license list.

File No.: 10
Licensee: HNTB Corporation License No.: 3387-1
Location: Orlando, FL Inspection Type: Pre-License, Announced
License Type: Portable Gauge Priority: 4
Inspection Date: 7/30/01 Inspector: PP

File No.: 11
Licensee: Galencare, Inc. License No.: 2369-1
dba Columbia Northside Medical Center Inspection Type: Routine, Unannounced
Location: St. Petersburg, FL Priority: 3
License Type: Medical Institution Inspector: GC
Inspection Date: 12/11 -12/01

File No.: 12
Licensee: Largo Medical Center, Inc. License No.: 1284-1
Location: Largo, FL Inspection Type: Routine, Unannounced
License Type: Medical Institution Priority: 3
Inspection Date: 1/3-4/01 Inspector: TF, CG

Comment:
a) Insufficient review of licensee response letter dated 2/16/01: (1) response to violation #3 did not address corrective actions. Bureau response dated 3/5/01 did not identify this lack of response and stated that no further correspondence required. (2) Bureau later determined that the licensee response to violation #6 was not sufficient, and issued a third letter dated 3/23/01 discussing the problem with the licensee's response, provided example of acceptable corrective action, and stated no further correspondence required.

File No.: 13
Licensee: Miami Beach Healthcare Group, Ltd. License No.: 2516-3
Location: Aventura, FL Inspection Type: Initial, Announced
License Type: Medical Private Practice Priority: 4
Inspection Date: 6/18/02 Inspector: LA

File No.: 14
Licensee: Nuclear Studies of South Florida, P. A.
dba Metabolic Imaging of Boca License No.: 2741-1
Location: Fort Lauderdale, FL Inspection Type: Routine, Unannounced
License Type: Medical Private Practice Priority: 4
Inspection Date: 12/5/00 Inspector: MB

Comment:
a) The pre-license inspection of License No. 2741-2 was mis-filed in the folder for 2741-1.

File No.: 15
Licensee: Naples Community Hospital dba North Collier Hospital License No.: 1275-4
Location: Naples, FL Inspection Type: Routine, Unannounced
License Type: Medical Institution Priority: 3
Inspection Date: 10/22/02 Inspector: SH

File No.: 16
Licensee: Nuclear Studies of South Florida, P. A.
dba Metabolic Imaging of South Florida License No.: 2741-2
Location: Fort Lauderdale, FL Inspection Type: Pre-license, Announced
License Type: Mobile Nuclear Medicine Priority: 4
Inspection Date: 8/1/02 Inspector: MK

File No.: 17
Licensee: Pankat Ghandi, MD License No.: 3070-1
Location: Jacksonville, FL Inspection Type: Initial, Announced
License Type: Medical Private Practice Priority: 4
Inspection Date: 6/23/00 Inspector: PP

File No.: 18
Licensee: Polk County Testing Laboratory License No.: 1351-1
Location: Winter Haven, FL Inspection Type: Routine, Announced
License Type: Portable Gauge Priority: 4
Inspection Date: 4/25/00 Inspector: TM

File No.: 19
Licensee: Radiology Associates of Tampa, P. A.
dba Tower Diagnostic Center License No.: 2546-1
Location: Tampa, FL Inspection Type: Routine, Unannounced
License Type: Medical Private Practice Priority: 4
Inspection Date: 7/12-13/02 Inspector: TF

Comments:
a) Licensee letter dated 8/27/01 contested violations #2 and #3 and did not provide corrective actions. The Bureau letter dated 10/12/01 upheld the violations but did not ask for corrective actions.
b) Violation #2, which cites a regulatory requirement, specifically identifies a violation of expectations for demonstrating compliance with that regulation. The licensee's 8/27/01 letter requested written guidance or reference discussing these expectations, but the Bureau's 10/12/01 letter stated that no such reference is available. This is the same expectation that caused third letter described in File No. 12.

File No.: 20
Licensee: South Florida Baptist Hospital License No.: 1313-1
Location: Plant City, FL Inspection Type: Routine, Unannounced
License Type: Medical Institution Priority: 4
Inspection Date: 9/13/02 Inspector: GC

File No.: 21
Licensee: Styperek Glass Enterprises, Inc. License No.: 2284-1
Location: Boynton Beach, FL Inspection Type: Routine, Unannounced
License Type: Medical Private Practice Priority: 4
Inspection Date: 1/10/02 Inspector: MB

File No.: 22
Licensee: Tenet Good Samaritan, Inc. dba Good Samaritan Hospital License No.: 3278-1
Location: West Palm Beach, FL Inspection Type: Routine, Unannounced
License Type: Gamma Stereotactic Unit Priority: 2
Inspection Date: 1/15-16, 2/19, and 2/21/02 Inspector: ML

File No.: 23

Licensee: USCC Florida Acquisition Corporation License No.: 3253-1
Location: Jacksonville, FL Inspection Type: Initial, Announced
License Type: Medical Private Practice Priority: 4
Inspection Date: 2/15/02 Inspector: TC

File No.: 24
Licensee: Syncor International Corporation License No.: 1264-9
Location: Jupiter, FL Inspection Type: Routine, Unannounced
License Type: Nuclear Pharmacy Priority: 2
Inspection Date: 8/9/02 Inspector: RD

Comment:
a) Violations in letter of non-compliance dated 8/30/02 may be cited against incorrect requirements.

File No.: 25
Licensee: Coastal Pharmacy Services, Inc. License No.: 2497-1
Location: Daytona Beach, FL Inspection Type: Routine, Unannounced
License Type: Nuclear Pharmacy Priority: 2
Inspection Date: 2/19-20/02 Inspector: LB

File No.: 26
Licensee: Desoto Memorial Hospital License No.: 1371-2
Location: Arcadia, FL Inspection Type: Routine, Unannounced
License Type: Medical Institution Priority: 3
Inspection Date: 4/26/01 Inspector: LF

File No.: 27
Licensee: Professional Service Industries, Inc. License No.: 22-13
Location: Oakbrook Terrace, FL Inspection Type: Routine, Announced
License Type: Industrial Radiography Priority: 2
Inspection Date: 10/11, 10/14/02 Inspector: AG

Comment:
a) Letter of non-compliance dated 11/29/02 cited regulation with 4 criteria; licensee contested violation because only 1 of the 4 criteria was not met.

File No.: 28
Licensee: Boca Raton Community Hospital License No.: 550-2
Location: Boca Raton, FL Inspection Type: Routine, Announced
License Type: High Dose-Rate Afterloader Priority: 2
Inspection Date: 6/26/02 Inspector: JM

File No.: 29
Licensee: Coral Springs Diagnostic Center, Ltd. License No.: 3108-2
Location: Coral Springs, FL Inspection Type: Pre-license, Announced
License Type: Medical Private Practice Priority: 4
Inspection Date: 3/10/00 Inspector: MK

File No.: 30
Licensee: MRI Scan Center, Inc. License No.: 3403-1
Location: Plantation, FL Inspection Type: Pre-license, Announced
License Type: Medical Private Practice Priority: 4
Inspection Date: 10/8/02 Inspector: MK

File No.: 31
Licensee: Nuclear Specialists, Inc. License No.: 3230-1
Location: Sanford, FL Inspection Type: Routine, Announced
License Type: Mobile Nuclear Medicine Priority: 3
Inspection Date: 12/11/01 Inspector: JB

File No.: 32
Licensee: Manatee Memorial Hospital, L.P.
dba Manatee Memorial Hospital License No.: 2651-1
Location: Bradenton, FL Inspection Type: Routine, Unannounced
License Type: Medical Institution Priority: 3
Inspection Date: 7/19/02 Inspector: LF

Comment:
a) Incorrect violation issued.

File No.: 33
Licensee: TBE Group, Inc. License No.: 2279-4
Location: Clearwater, FL Inspection Type: Pre-license, Announced
License Type: Portable Gauge Priority: 4
Inspection Date: 12/12/02 Inspector: TF

File No.: 34
Licensee: Radiology Regional Center, P. A. License No.: 1478-1
Location: Ft. Myers, FL Inspection Type: Routine, Announced
License Type: Medical Private Practice Priority: 4
Inspection Date: 10/25/01 Inspector: SH

File No.: 35
Licensee: North Broward Hospital District
dba Coral Springs Medical Center License No.: 1838-1
Location: Coral Springs, FL Inspection Type: Routine, Unannounced
License Type: Medical Institution Priority: 3
Inspection Date: 9/26/01 Inspector: VR

File No.: 36

Licensee: CF Industries
License No.: 903-1
Location: Plant City, FL
Inspection Type: Routine, Announced
License Type: Portable Gauge
Priority: 4
Inspection Date: 9/13/00
Inspector: AM

File No.: 37
Licensee: US Agri-Chemicals Corporation
License No.: 114-4
Location: Fort Meade, FL
Inspection Type: Initial, Announced
License Type: Uranium/Thorium possession
Priority: 4
Inspection Date: 7/5/01
Inspector: TN, RA

File No.: 38
Licensee: Central Testing Laboratory, Inc.
License No.: 3187-2
Location: Leesburg, FL
Inspection Type: Initial, Announced
License Type: Portable Gauge
Priority: 4
Inspection Date: 4/18/01
Inspector: JB

File No.: 39
Licensee: Fernando Diaz, M.D.
License No.: 1444-1
Location: Hollywood, FL
Inspection Type: Routine, Announced
License Type: Medical Private Practice
Priority: 4
Inspection Date: 6/24/02
Inspector: MK

File No.: 40
Licensee: Sam Pontillo
License No.: 2613-1
Location: Longwood, FL
Inspection Type: Routine, Announced
License Type: Services
Priority: 4
Inspection Date: 2/28/02
Inspector: AG

File No.: 41
Licensee: Goodman Cardiopulmonary Associates, M.D., P.A.
dba Cardiopulmonary Associates
License No.: 2130-1
Location: Fort Lauderdale, FL
Inspection Type: Routine, Unannounced
License Type: Medical Private Practice
Priority: 4
Inspection Date: 1/13/03
Inspector: MK

File No.: 42
Licensee: Airfoil Technologies of Florida, Inc. dba ATI (Southeast)
License No.: 3017-1
Location: Boynton Beach, FL
Inspection Type: Routine, Unannounced
License Type: Source Material
Priority: 5
Inspection Date: 1/27/00 and 2/9/00
Inspector: WM

File No.: 43
Licensee: A (Square) Concrete Testing and Engineering, Inc. License No.: 3320-1
Location: Key West, FL Inspection Type: Pre-license, Announced
License Type: Portable Gauge Priority: 4
Inspection Date: 12/4/01 Inspector: SI

File No.: 44
Licensee: US Pet Imaging, LLC License No.: 3331-1
Location: Sarasota, FL Inspection Type: Pre-license, Announced
License Type: Medical Private Practice Priority: 4
Inspection Date: 1/17/02 Inspector: MT

File No.: 45
Licensee: Charles Freeble, III, M.D., P.A. License No.: 1881-1
Location: St. Petersburg, FL Inspection Type: Routine, Unannounced
License Type: Medical Private Practice Priority: 4
Inspection Date: 12/27/00, 1/5/02 Inspector: RD

File No.: 46
Licensee: Bay Hospital, Inc. dba Gulf Coast Medical Center License No.: 1182-1
Location: Panama City, FL Inspection Type: Routine, Announced
License Type: Medical Institution Priority: 2
Inspection Date: 7/26/02 Inspector: BR

File No.: 47
Licensee: Westchester General Hospital, Inc. License No.: 1274-1
Location: Miami, FL Inspection Type: Routine, Unannounced
License Type: Medical Institution Priority: 3
Inspection Date: 1/17/02 Inspector: SI

File No.: 48
Licensee: University of Miami License No.: 1319-3
Location: Miami, FL Inspection Type: Routine, Announced
License Type: High Dose-Rate Afterloader Priority: 2
Inspection Date: 9/11-12/02 Inspector: FN

Comment:
a) Incorrect violation issued and rescinded.

File No.: 49
Licensee: John P. Hocke, M.D., P.A. License No.: 1484-1
Location: St. Petersburg, FL Inspection Type: Routine, Unannounced
License Type: Medical Private Practice Priority: 4
Inspection Date: 11/21/02 Inspector: RD

File No.: 50
Licensee: Mercy Hospital License No.: 63-2
Location: Miami, FL Inspection Type: Routine, Announced
License Type: High Dose-Rate Afterloader Priority: 2
Inspection Date: 3/20/02 Inspector: LA

File No.: 51
Licensee: Florida Medical Center License No.: 2816-1
Location: Lauderdale Lakes, FL Inspection Type: Routine, Unannounced
License Type: Medical Institution Priority: 3
Inspection Date: 5/21/02 Inspector: VR

File No.: 52
Licensee: University of Miami License No.: 1319-3
Location: Miami, FL Inspection Type: Routine, Unannounced
License Type: High Dose-Rate Afterloader Priority: 2
Inspection Date: 7/4, 7/12-13, 7/16-18, and 8/6/01 Inspector: FN, JG

Comment:
a) Licensee disagreed with violation #3 and did not provide corrective actions. Because the Bureau neither upheld nor rescinded the violation, (responded that no additional information was needed) it is unclear if the next inspector, finding the same conditions, should or should not identify an apparent violation.

File No.: 53
Licensee: MV Geophysical Surveys, Inc. License No.: 3009-1
Location: Ft. Myers, FL Inspection Type: Routine, Announced
License Type: Portable Gauge Priority: 3
Inspection Date: 12/10/01 Inspector: MT

File No.: 54
Licensee: PET Scans of America Corporation License No.: 3165-1
Location: St. Petersburg, FL Inspection Type: Routine, Unannounced
License Type: Mobile Nuclear Medicine Priority: 4
Inspection Date: 4/19/01 Inspector: DM

File No.: 55
Licensee: PETNET/Pharmalogic, LLC License No.: 2728-3
Location: Fort Lauderdale, FL Inspection Type: Routine, Announced
License Type: Nuclear Pharmacy Priority: 2
Inspection Date: 2/7/02 Inspector: VR

Comment:
a) Incorrect violation issued and rescinded.

File No.: 56
Licensee: Genesis Pharmacy Services, Inc. License No.: 2975-1
Location: Tampa, FL Inspection Type: Routine, Unannounced
License Type: Nuclear Pharmacy Priority: 2
Inspection Date: 6/27/02 Inspector: TF, GC

File No.: 57
Licensee: Florida State University License No.: 32-10
Location: Tallahassee, FL Inspection Type: Routine, Announced
License Type: Broad Scope - Academic Priority: 3
Inspection Date: 5/21-24/01 Inspector: PP, MC, BR, DP, CH

Comment:
a) Incorrect violation issued, rescinded.

INSPECTOR ACCOMPANIMENTS

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

Accompaniment No.: 1
Licensee: Mercy Hospital, Inc. License No.: 63-1
Location: Miami, FL Inspection Type: Routine, Announced
License Type: Medical Institution Priority: 3
Inspection Date: 1/7/03 Inspector: FN

Accompaniment No.: 2
Licensee: South Florida Cardiology Associates License No.: 2686-1
Location: Pembroke Pines, FL Inspection Type: Routine, Unannounced
License Type: Medical Private Practice Priority: 4
Inspection Date: 1/8/03 Inspector: MK

Accompaniment No.: 3
Licensee: Martin Memorial Medical Center, Inc. License No.: 1215-2
Location: Stuart, FL Type Inspection: Routine, Unannounced
License Type: Brachytherapy, High Dose-Rate Afterloader Priority: 2
Inspection Date: 1/9/03 Inspector: ML

Accompaniment No.: 4
Licensee: GE Energy & Industrial Services License No.: 2861-1
Location: Jacksonville, FL Type Inspection: Routine, Unannounced
License Type: Industrial Radiography Priority: 2
Inspection Date: 01/28/03 Inspector: MC

Accompaniment No.: 5
Licensee: Captech Group, Inc
Location: Tallahassee, FL
License Type: Nuclear Pharmacy
Inspection Date: 1/30/03
License No.: 2608-1
Type Inspection: Routine, Unannounced
Priority: 2
Inspector: RL

Accompaniment No.: 6
Licensee: Morton Plant Mease Health Care Inc.
Location: Clearwater, FL
License Type: Medical Institution
Inspection Date: 1/28/03
License No.: 21-1
Type Inspection: Routine, Unannounced
Priority: 3
Inspector: TF, RK

Accompaniment No.: 7
Licensee: Central Florida Regional Hospital, Inc.
Location: Sanford, FL
License Type: Medical Institution
Inspection Date: 1/29/03
License No.: 2490-1
Type Inspection: Routine, Unannounced
Priority: 3
Inspector: JB

Accompaniment No.: 8
Licensee: Lakeland Regional Medical Center, Inc.
Location: Lakeland, FL
License Type: Medical Institution
Inspection Date: 1/31/03
License No.: 189-1
Type Inspection: Routine, Announced
Priority: 3
Inspector: TM

APPENDIX D

LICENSE CASEWORK REVIEWS

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

File No.: 1
Licensee: Central Pharmacy Services — License No.: 3273-4
Location: Gainesville, FL — Amendment: 0
License Type: Nuclear Pharmacy — Type of Action: New
Date Issued: 10/8/02 — License Reviewer: PV

File No.: 2
Licensee: Trumbull Corporation — License No.: 3384-1
Location: Fort Lauderdale, FL — Amendment No.: 0
License Type: Portable Gauge — Type of Action: New
Date Issued: 7/17/02 — License Reviewer: JS

File No.: 3
Licensee: Tallahassee Medical Center — License No.: 1367-2
Location: Tallahassee, FL — Amendment No.: 0
License Type: Intravascular Brachytherapy — Type of Action: New
Date Issued: 5/16/02 — License Reviewer: SS

File No.: 4
Licensee: HMA Santa Rosa Medical Center — License No.: 3356-1
Location: Milton, FL — Amendment No.: 0
License Type: Medical Institution — Type of Action: New
Date Issued: 4/2/02 — License Reviewer: JK

File No.: 5
Licensee: Florida Power Corporation — License No.: 3317-2
Location: Crystal River, FL — Amendment No.: 0
License Type: Industrial Radiography — Type of Action: New
Date Issued: 12/20/01 — License Reviewer: WC

File No.: 6
Licensee: Baptist Hospital, Inc. — License No.: 158-4
Location: Pensacola, FL — Amendment No.: 0
License Type: Intravascular Brachytherapy — Type of Action: New
Date Issued: 8/14/02 — License Reviewer: DG

File No.: 7
Licensee: Tampa Electric Company — License No.: 1235-01
Location: Apollo Beach, FL — Amendment No.: 25
License Type: Fixed & Portable Gauges — Type of Action: Renewal
Date Issued: 12/5/02 — License Reviewer: DW

File No.: 8
Licensee: Sarasota Radiation and Medical Oncology Center
Porter, PA
License No.: 1146-2
Location: Sarasota, FL
Amendment No.: 24
License Type: Medical Private Practice, Sr-90 Eye Applicators
Type of Action: Renewal
Date Issued: 9/6/02
License Reviewer: JS

File No.: 9
Licensee: Radiation Therapy Centers of Brevard, Inc.
License No.: 1857-2
Location: Rockledge, FL
Amendment No.: 13
License Type: High Dose-Rate Afterloader
Type of Action: Renewal
Date Issued: 12/23/02
License Reviewer: DG

File No.: 10
Licensee: BCI Engineers & Scientist, Inc.
License No.: 1054-1
Location: Lakeland, FL
Amendment No.: 18
License Type: Portable Gauge
Type of Action: Renewal
Date Issued: 11/20/02
License Reviewer: JK

File No.: 11
Licensee: 21st Century Oncology, Inc.
License No.: 2902-1
Location: Fort Myers, FL
Amendment No.: 9
License Type: High Dose-Rate Afterloader
Type of Action: Termination
Date Issued: 10/17/02
License Reviewer: JS

File No.: 12
Licensee: Professional Service Industries, Inc.
License No.: 22-22
Location: Fort Myers, FL
Amendment No.: 2
License Type: Portable Gauge
Type of Action: Termination
Date Issued: 10/22/02
License Reviewer: DW

File No.: 13
Licensee: Westinghouse Electric Company, LLC
License No.: 2999-1
Location: Pensacola, FL
Amendment No.: 1
License Type: Industrial Radiography
Type of Action: Termination
Date Issued: 6/14/00
License Reviewer: LS

File No.: 14
Licensee: St. Petersburg-Suncoast Medical Group
License No.: 2765-1
Location: St. Petersburg, FL
Amendment No.: 5
License Type: Medical Private Practice
Type of Action: Termination
Date Issued: 10/30/00
License Reviewer: MS

File No.: 15
Licensee: Key West Oncology Associates, P.A. License No.: 2756-1
Location: Key West, FL Amendment No.: 6
License Type: High Dose-Rate Afterloader Type of Action: Termination
Date Issued: 12/21/00 License Reviewer: WC

File No.: 16
Licensee: South Miami Hospital License No.: 34-3
Location: Miami, FL Amendment No.: 5
License Type: High Dose-Rate Afterloader Type of Action: Amendment
Date Issued: 5/22/02 License Reviewer: DG

File No.: 17
Licensee: University of Miami License No.: 1319-2
Location: Miami, FL Amendment No.: 18
License Type: Irradiator Type of Action: Amendment
Date Issued: 9/12/01 License Reviewer: DG

File No.: 18
Licensee: Food Technology Service, Inc License No.: 2244-1
Location: Mulberry, FL Amendment No.: 25
License Type: Irradiator Type of Action: Amendment
Date Issued: 12/18/02 License Reviewer: PV

File No.: 19
Licensee: Saint Vincent's Medical Center License No.: 14-1
Location: Jacksonville, FL Amendment No.: 113
License Type: Medical Institution Type of Action: Amendment
Date Issued: 1/28/03 License Reviewer: JS

File No.: 20
Licensee: Municipal Testing Laboratory, Inc. License No.: 2682-1
Location: Miami, FL Amendment No.: 2
License Type: Portable Gauge Type of Action: Amendment
Date Issued: 1/29/03 License Reviewer: JM

APPENDIX E

INCIDENT CASEWORK REVIEWS

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

File No.: 1
Licensee: KCCS, Inc. License No.: 3087-1
Site of Incident: Kissimmee, FL Incident Log No.: FL02-017 (NMED #020160)
Date of Incident: 2/3/02 Type of Incident: Lost/Stolen Material
Investigation Date: 2/4/02, 2/21/02 Type of Investigation: On-Site

File No.: 2
Licensee: Halifax Medical Center License No.: 194-3
Site of Incident: Daytona Beach, FL Incident Log No.: FL00-018 (NMED #000150)
Date of Incident: 1/31/00 Type of Incident: Misadministration
Investigation Date: 2/5/00 Type of Investigation: On-Site

Comment:
NMED report complete, but not closed.

File No.: 3
Licensee: Waste Management, Inc. License No.: N/A
Site of Incident: Ft. Myers, FL Incident Log No.: FL99-109 (NMED #990672)
Date of Incident: 8/19/99 Type of Incident: Loss of Control
Investigation Date: 8/19/99 Type of Investigation: On-Site

Comment:
NMED report complete, but not closed.

File No.: 4
Licensee: South Broward Hospital District
dba Memorial Regional Hospital License No.: 0008-1
Site of Incident: Hollywood, FL Incident Log No.: FL00-80 (NMED #000396)
Date of Incident: 5/3/00 Type of Incident: Leaking Source
Investigation Date: 5/5/00 Type of Investigation: Phone

Comments:
a) NMED report complete, but not closed.
b) Discovery date not in NMED.

File No.: 5
Licensee: H. Lee Moffit Cancer Center & Research Center, Inc. License No.: 1739-1
Site of Incident: Tampa, FL Incident Log No.: FL01-179 (NMED #020200)
Date of Incident: 12/20/01 Type of Incident: Misadministration
Investigation Date: 12/21/01, 1/4/02 Type of Investigation: On-Site

Comment:
Casework from FL01-079 found in incident file.

File No.: 6
Licensee: NDT & Inspections License No.: 2941-1
Site of Incident: Pembroke Pines, FL Incident Log No.: FL99-39 (NMED #990182)
Date of Incident: 3/17/99 Type of Incident: Lost/Stolen Material
Investigation Date: 3/18/99 Type of Investigation: On-Site

Comment:
NMED report complete, but not closed.

File No.: 7
Licensee: AEA Technology License No.: 12-8361(Massachusetts)
Site of Incident: Miami, FL Incident Log No.: FL02-196
Date of Incident: 12/23/02 Type of Incident: Transportation
Investigation Date: 12/23/02 Type of Investigation: On-Site

Comment:
Even though incident involved State of Massachusetts licensee, the State was not contacted.

File No.: 8
Licensee: Ruskin Animal Hospital License No.: 2863-1
Site of Incident: Lakeland, FL Incident Log No.: FL01-050 (NMED #010664)
Date of Incident: 5/8/01 Type of Incident: Loss of Control
Investigation Date: 5/8/01 Type of Investigation: On-Site

Comment:
NMED report complete, but not closed.

File No.: 9
Licensee: H. W. Lochner License No.: 2333-1
Site of Incident: Ocoee, FL Incident Log No.: FL99-45 (NMED #990205)
Date of Incident: 3/29/99 Type of Incident: Damage to Equipment
Investigation Date: 3/29/99 Type of Investigation: On-Site

Comment:
NMED report complete, but not closed.

File No.: 10
Licensee: Civil Services, Inc. License No.: 2161-1

Site of Incident: Jacksonville, FL
Incident Log No.: FL03-003 (NMED #030043)
Date of Incident: 1/3/03
Type of Incident: Damage to Equipment
Investigation Date: 1/8/03
Type of Investigation: On-Site

Comment:
NMED report complete, but not closed.

File No.: 11
Licensee: Ameristeel
License No.: N/A
Site of Incident: Baldwin, FL
Incident Log No.: FL01-076 (NMED #010689)
Date of Incident: 7/13/01
Type of Incident: Contamination Event
Investigation Date: 7/14/01, 8/2-6/01
Type of Investigation: On-Site

File No.: 12
Licensee: AMISUB (North Ridge Hospital), Inc.
dba North Ridge Medical Center
License No.: 1080-3
Site of Incident: Pompano Beach, FL
Incident Log No.: FL02-167 (NMED #021152)
Date of Incident: 11/5/02
Type of Incident: Loss of Control
Investigation Date: 11/5/02
Type of Investigation: Phone

APPENDIX F

SEALED SOURCE AND DEVICE CASEWORK REVIEWS

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

File No.: 1
Registry No.: FL-1172-D-101-S
Manufacturer: Litton Systems, Inc.
Date Issued: 7/26/02
SS&D Type: Static Eliminator for Laser Systems
Model No.: Laser Systems Series - LANTERN, T.S., MM, ITS, MM/U, F/A-18, MM Taiwan, LLYR, ITS, LAMPS, TADS, ATP, JS, Dark Star

Comment:
The inspection report did not contain documentation regarding status of licensee's QA and QC program.

File No.: 2
Registry No.: FL-1116-D-101-S
Manufacturer: Lockheed Martin Corporation
Date Issued: 2/12/02
SS&D Type: Static Eliminator
Model No.: Laser Target Series - NITEHAWK LANTERN, COMANCHE, SNIPER

Comment:
The inspection report did not contain documentation regarding status of licensee's QA and QC program.

File No.: 3
Registry No.: FL-1146-S-101-S
Manufacturer: Isoaid, L.L.C.
Date Issued: 6/25/02
SS&D Type: Brachytherapy Seed
Model No.: IAI-125A (Advantage TM I-125)

Comment:
The inspection report did not contain documentation regarding status of licensee's QA and QC program.

File No.: 4
Registry No.: FL-8121-D-801-S
Manufacturer: Amdel Limited
Date Issued: 3/9/01
SS&D Type: Coal Slurry Analyzer
Model No.: OLA-100

File No.: 5
Registry No.: FL-8121-D-802-S
Manufacturer: Amdel Limited
Date Issued: 3/9/01
SS&D Type: Coal Slurry Analyzer
Model No.: CSA Series: (AM213,AM222, AM263/10EeX5)

File No.: 6
Registry No.: FL-8121-D-803-S
Manufacturer: Amdel Limited
Date Issued: 3/9/01
SS&D Type: Coal Slurry Analyzer
Model No.: AM282

File No.: 7
Registry No.: FL-8128-D-804-B
Manufacturer: Trace Analytical, Inc.
Date Issued: 4/26/02
SS&D Type: Ion Mobility Spectrometer
Model No.: Phemto-Chem Series 100 Series and MM Series

Agenda for Management Review Board Meeting
April 15, 2003, 2:00 p.m. - 4:00 p.m., O-3-B-4

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

2. Consideration of the Florida IMPEP Report.

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

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

   C. Comments

3. Presentation by Pearce O'Kelley, Chair, Organization of Agreement States, and Cindy Cardwell, Chairperson, Conference of Radiation Control Program Directors, Inc.

4. Results of Periodic Meetings

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

6. Establishment of Precedents

7. Adjournment

Invitees:

Carl Paperiello, EDO	Vivian Campbell, RIV
Paul Lohaus, STP	Lance Rakovan, STP
Martin Virgilio, NMSS	Richard Woodruff, RII
Karen Cyr, OGC	Elisabeth Ullrich, RI
Pearce O'Kelley, SC	Shawn Smith, STP
William Passetti, FL	Michael Snee, OH
Michael Stephens, FL	Josephine Piccone, STP
Cindy Cardwell, TX	Kathleen Schneider, STP
Michael Weber, NSIR	Andrew Mauer, STP
Osiris Siurano, STP	Michael Henry, LA

ATTACHMENT 2

ATTACHMENT

March 18, 2003 E-mail from Mr. William Passetti
Florida's Response to Draft IMPEP Report
ML030840217