

UNITED STATES NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

December 29, 2008

Carol A. Couch, Ph.D., Director Georgia Department of Natural Resources **Environmental Protection Division** 2 Martin Luther King, Jr. Drive, SE Suite 1152, East Tower Atlanta, Georgia 30334

Dear Dr. Couch:

On December 4, 2008, the Management Review Board (MRB) met to consider the proposed final Integrated Materials Performance Evaluation Program report on the Georgia Agreement State Program. The Georgia Agreement State Program was found satisfactory, but needs improvement for four performance indicators and satisfactory for all other indicators reviewed. Overall, the MRB found the Georgia Agreement State Program adequate to protect public health and safety, but needs improvement, and compatible with the U.S. Nuclear Regulatory Commission's (NRC) program. The MRB directed NRC staff to initiate a period of monitoring of the Georgia Agreement State Program. Monitoring is an informal process that will allow NRC staff to monitor the effects of the state-wide hiring freeze, staff attrition, and weaknesses in the training and gualification programs and to take appropriate action, if necessary.

Sincerely,

/RA/

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

Enclosure: Georgia Final IMPEP Report

cc w/enclosure: See next page

cc w/encl.: Cynthia Sanders, Manager Georgia Radioactive Materials Program

> Jim Sommerville, State Liaison Officer Georgia Program Coordination Branch

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



INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM REVIEW OF THE GEORGIA AGREEMENT STATE PROGRAM

September 22-26, 2008

FINAL REPORT

Enclosure

1.0 INTRODUCTION

This report presents the results of the review of the Georgia Agreement State Program. The review was conducted during the period of September 22-26, 2008, by a review team comprised of technical staff members from the U.S. Nuclear Regulatory Commission (NRC), the Commonwealth of Massachusetts, and the State of Ohio. 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 August 27, 2004, to September 26, 2008, were discussed with Georgia managers on the last day of the review.

The review team issued a draft of this report to Georgia for factual comment on October 27, 2008. The State responded via letter from Dr. Carol A. Couch, Director, Environmental Protection Division (the Division), on November 21, 2008. A copy of the State's response is included as the attachment to this report. The Management Review Board (MRB) met on December 4, 2008, to consider the proposed final report. The MRB found the Georgia Agreement State Program adequate to protect public health and safety, but needs improvement, and compatible with NRC's program. The MRB directed NRC staff to initiate a period of monitoring of the Georgia Agreement State Program. Monitoring is an informal process that allows NRC to maintain an increased level of communication with an Agreement State Program. As part of the monitoring process, NRC will conduct quarterly calls with the appropriate representatives from the Georgia Agreement State Program.

The Georgia Agreement State Program is administered by the Georgia Department of Natural Resources (the Department) and is located within the Program Coordination Branch (the Branch) of the Division. The Branch is divided into six District Offices and five Atlanta-based programs. The Environmental Emergency Response and Radiation Control Program are Atlanta-based programs under the Branch and include the Radioactive Materials Program (the Program) and the Environmental Radiation Program that is responsible for environmental radiological surveillance and emergency response. Both are under the supervision of a single Program Manager. The Program administers the licensing and inspection duties, as well as the State's sealed source and device (SS&D) registration program. Organizational charts for the Department, the Branch, and the Program are included in the report as Appendix B.

At the time of the review, the Georgia Agreement State Program regulated 521 specific licenses authorizing the possession and use of byproduct, source, and certain special nuclear materials. The review focused on the radioactive materials program as it is carried out under Section 274b. (of the Atomic Energy Act, as amended) Agreement between NRC and the State of Georgia.

In preparation for the review, a questionnaire addressing the common and applicable noncommon performance indicators was sent to the Program on June 13, 2008. The Program provided its initial response to the questionnaire on September 4, 2008, and provided supplemental information on September 9, 2008. A copy of the questionnaire response and

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

Section 2.0 of this report covers the State's actions in response to recommendations made during the previous review. Results of the current review 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 and recommendations. The review team's recommendations are comments that relate directly to program performance by the State. A response is requested from the State to all recommendations in the final report.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous review, which covered the period of April 8, 2000, to August 26, 2004, the review team made nine recommendations in regard to program performance. The current status of each of the previous recommendations is as follows:

1. The team recommends that the Program update its inspection procedures to eliminate extensions of license inspection due dates. (Section 3.2 of the 2004 IMPEP report)

Current Status: Following the 2004 review, the Program modified its inspection procedures and eliminated the provision that allowed the extension of inspection intervals based on licensee performance. This recommendation is closed.

2. The review team recommends that the Program ensure that Notices of Violation and licensee acknowledgment letters receive appropriate supervisory review and approval. (Section 3.3 of the 2004 IMPEP report)

Current Status: Following the 2004 review, the Program modified its procedures to require management review and approval of Notices of Violations and licensee acknowledgment letters. The review, approval, and disposition of these documents are tracked through an approval log. This recommendation is closed.

3. The review team recommends that the Program develop and implement a process for conducting annual accompaniments of all radiation compliance inspectors by a supervisor. (Section 3.3 of the 2004 IMPEP report)

Current Status: The Program developed a process to help ensure that all inspectors receive annual supervisory accompaniments after the 2004 review. The Program performed supervisory accompaniments with all staff until late 2006 when the Program began to experience significant turnover. In an effort to expedite the training of new staff, management made the decision to forego accompanying the more experienced staff did not receive supervisor accompaniments from 2007 up to the time of the review. This recommendation remains open pending a period of demonstrated implementation of the process, including accompaniments of the experienced staff.

4. The review team recommends that the Program revise and implement procedures to address the handling of cases where inspections reveal a systemic breakdown in a licensee's radiation safety program and when a large number of health and safety violations are identified. (Section 3.3 of the 2004 IMPEP report)

Current Status: Following the 2004 review, the Program established enforcement guidance that addressed the importance of licensee compliance with Program requirements. The procedures describe the significance and severity of violations and provide a framework to address noncompliance with Program requirements. This recommendation is closed.

5. The review team recommends that the staff receive training on STP Procedure SA-300, identifying abnormal occurrences, and the schedule of reporting of significant events to the NRC Headquarters. (Section 3.5 of the 2004 IMPEP report)

Current Status: The review team verified that the Program had provided training to the staff on formerly Office of State and Tribal Programs (STP), now Office of Federal and State Materials and Environmental Management Programs (FSME) Procedure SA-300, "Reporting Material Events." This recommendation is closed.

6. The team recommends that the Program qualify one additional reviewer in SS&D evaluations to provide backup for the principal reviewer. (Section 4.2 of the 2004 IMPEP report)

Current Status: In January 2008, the Program hired an engineer as the backup to the primary SS&D reviewer; however, approximately 1 month later, the individual left the Program for another opportunity. Before the resulting vacancy could be filled, the Department imposed a hiring freeze. As a result, the Program Director must now perform all secondary SS&D reviews. This recommendation remains open.

7. The review team recommends that the Program develop written qualification requirements for SS&D reviewers. (Section 4.2 of the 2004 IMPEP report)

Current Status: In November 2006, the Program developed and implemented written procedures that identify the qualification and training requirements for SS&D reviewers. This recommendation is closed.

8. The team recommends that the Program establish an objective method to address defects and incidents involving SS&D evaluations that includes the identification of generic issues, trend analysis, and the communication of findings with other regulatory agencies. (Section 4.2 of the 2004 IMPEP report)

Current Status: Following the 2004 review, the Program established a written procedure for the investigation of SS&D defects and incidents. The Program also developed a license condition that requires manufacturers and distributors to report defects, deviations, or operations affecting the integrity of their products. This recommendation is closed.

9. The review team recommends that the staff with primary review and concurrence responsibilities for SS&D evaluations attend a training course on root cause analysis such as the NRC course "Root Cause/Incident Investigation Workshop" (G-205). (Section 4.2 of the 2004 IMPEP report)

Current Status: In November 2005, the primary SS&D reviewer completed NRC's Root Cause Analysis Course (G-205). 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. The indicators are: (1) Technical Staffing and Training, (2) Status of Materials Inspection Program, (3) Technical Quality of Inspections, (4) Technical Quality of Licensing Actions, and (5) Technical Quality of Incident and Allegation Activities.

3.1 Technical Staffing and Training

Issues central to the evaluation of this indicator include the Program's staffing level and staff turnover, as well as the technical qualifications and training histories of the staff. To evaluate this indicator, the review team examined the Program's response to the IMPEP questionnaire relative to this indicator, interviewed managers and staff, reviewed job descriptions and training records, and considered any possible workload backlogs.

When fully staffed, the Program is comprised of a Program Manager, eight Environmental Radiation Specialists (Specialist), one Environmental Engineer (Engineer), one Technical Assistant, and one administrative staff member. The Engineer position is currently vacant due to a hiring freeze that was imposed earlier in the year. Specialists are assigned to one of six geographical regions within the State and are responsible for licensing, inspection, and incident response activities within that region. The Specialists share responsibility for licensees in the Atlanta metropolitan area. To be considered for a Specialist position, each candidate must possess, at a minimum, a Bachelor's degree in a science field.

The review team noted that six Specialists and one Engineer left the Program during the review period. Five were fully qualified and experienced staff, and two were new hires who accepted job offers outside the Program shortly after starting with the Program. The Program successfully filled the Specialist vacancies and, for a time, was almost fully staffed. The two

senior Specialists have an average of 10 years experience with the Program; five of the staff members average 2 to 3 years experience; and the newest staff member was hired early in 2008.

The Program has a documented training program for Specialists that is similar to the training program established in NRC's Inspection Manual Chapter (IMC) 1246, "Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area." The Program Manager indicated that she is committed to ensuring that newly hired Specialists receive the training required to qualify them for their positions. In addition to NRC training courses, the Program also sends Specialists to the 5-week health physics course held in Oak Ridge, Tennessee.

While the Program has a documented training program, they do not have a documented qualification program. Specialists are qualified through a combination of education and experience, formal classroom training, in-house and on-the-job training, completion of specific tasks, and mentoring by more experienced staff. The Program has not developed a procedure designed to determine an individual's competency in each program area prior to authorizing them to work independently. Specialists are notified verbally by the Program Manager when she determines they are qualified to perform certain types of license reviews and inspections. At the time of the review, five of the eight Specialists were considered fully or mostly qualified by the Program. As discussed further in Sections 3.3 and 3.4, the review team identified key areas where Specialists that were considered qualified could have benefitted from additional experience or on-the-job training prior to being approved to work independently. The development and implementation of a formal gualification program would address the technical quality issues that the review team identified, as documented in Sections 3.3 and 3.4. The review team recommends that the State develop, document, and implement a formal gualification program for licensing and inspection activities that includes written documentation and supervisor endorsement of competency in each program area.

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

3.2 <u>Status of Materials Inspection Program</u>

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 based its evaluation on the Program's questionnaire response relative to this indicator, data gathered from the Program's database, examination of completed inspection casework, and interviews with managers and staff.

The review team verified that the Program's inspection priorities, with one exception, are consistent with the inspection priorities prescribed by NRC's IMC 2800, "Materials Inspection Program." The review team noted that inspection reports for all gamma stereotactic radiosurgery units (gamma knife) indicated the next inspection was due in three years from the previous inspection, which is inconsistent with the Priority 2 designation identified in IMC 2800. Staff stated that the Program categorized the gamma knife as a teletherapy device, which is

a specific license type identified in IMC 2800 having a 3-year inspection frequency. The Program committed to changing the priority code for gamma knife devices to match the 2-year inspection frequency found in IMC 2800.

The review team determined that, during the review period, the Program performed 229 Priority 1, 2, and 3 inspections. The Program completed 27 of these inspections overdue with four being overdue at the time of the review. The Program also completed 76 initial inspections, of which 13 were conducted overdue (greater than 12 months after license issuance). One initial inspection was overdue at the time of the review. The review team determined that the Program performed approximately 15 percent of the total Priority 1, 2, and 3, and initial inspections overdue during the review period. Discussions with Program staff revealed that most of the overdue inspections were due to staff turnover during the review period. The Program is now better staffed and the Program has a plan in place to catch up on overdue inspections. To maintain this level of performance, the Program will need to remain nearly fully staffed and address any future vacancies in a timely manner.

The review team determined that the Program adequately planned for the initial set of Increased Controls inspections. The review team evaluated the Program's prioritization methodology and found it acceptable. The Program identified 25 licensees that were subject to the Increased Controls and performed all of the initial inspections in a timely manner. At the time of the review, the Program had not performed any subsequent Increased Controls inspections of affected licensees. This issue is further discussed in Section 3.3.

The review team evaluated the Program's timeliness of issuing inspection reports. The Program has an effective and efficient process that helps ensure that inspection findings are communicated to licensees in a timely manner. Inspection findings are normally communicated to the licensee by issuing a Compliance Letter, a Notice of Violation, or a Consent Order. For minor and significant violations, the Program issues a Notice of Violation. Consent Orders are issued for escalated enforcement actions. Based on the 32 inspection files reviewed, the review team determined that the appropriate inspection correspondence was generally issued within 30 days of the inspection.

During the review period the Program granted approximately 180 reciprocity permits. Most of the licensees were candidates for inspection based upon the criteria in IMC 1220, "Processing of NRC Form 241 and Inspection of Agreement State Licensees Operating under 10 CFR 150.20." The review team determined that the Program inspected 20 percent of candidate licensees in only one of the four years covered by the review period; and, in each of the remaining years the Program inspected between 11 and 17 percent of candidate licensees. The review team noted staff turnover and the focus on completing routine inspections as factors why the Program did not inspect 20 percent of candidate reciprocity licensees each year. Being nearly fully staffed and almost caught up on the routine inspection backlog, the Program should be able to resume inspecting at least 20 percent of candidate reciprocity licensees in the future.

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

3.3 <u>Technical Quality of Inspections</u>

The review team evaluated inspection reports, enforcement documentation, inspection field notes, and interviewed the responsible inspectors for 32 radioactive materials inspections conducted during the review period. The casework examined included a cross-section of inspections conducted by three former and seven current inspectors and covered a wide variety of inspection types that included medical, academic, and research and development broadscope licensees; industrial radiography; self-shielded irradiator; medical; nuclear pharmacy; and reciprocity licensees. Appendix C lists the inspection casework files reviewed and includes case-specific comments.

The review team found that the Program's inspection procedures are generally consistent with the inspection guidance found in IMC 2800. Specialists are responsible for conducting inspections of all the various types of licensees in their assigned region. Specialists use a specific inspection form for each license type to help ensure that all relevant aspects of a particular program are reviewed. Inspection documentation parallels the inspection form, limiting the amount of narrative documentation contained in routine reports; however, reports involving violations generally have additional documentation to support the enforcement action.

The review team noted that inspection reports were generally consistent between Specialists and addressed unresolved safety issues from previous inspections. The reports also noted discussions held with licensees during exit interviews.

All routine inspection documentation is entered into the Program's electronic filing system. Upon completion of the inspection, Specialists complete a "Change Form" identifying the inspection date, next due date, and inspection results. This form is then submitted to an administrative staff member who updates the Program's database with the new information.

The Program does not require management review of inspection documentation where no findings were identified, including both routine and Increased Controls inspections. Inspections identifying violations are sent to the licensees from the office following management review and approval. Based on the evaluation of casework, the review team determined that the Specialists reviewed the applicable components of the licensees' radiation safety programs.

As noted in Section 3.2, the Program successfully completed the initial round of Increased Controls inspections. In one instance the review team identified an Increased Controls inspection where violations were identified and a Notice of Violation was issued to the licensee, but the Program did not follow up with the licensee to ensure that the violations had been corrected. The review team further found that the Program's inspection procedures and enforcement guidance did not include requirements for followup of Increased Controls inspections to ensure that previously identified violations had been corrected. The review team recommends that the State update their inspection procedures and enforcement guidance to include the requirements for followup of Increased Controls.

The review team determined that documents involving Increased Controls inspections were protected, segregated from the electronic file storage system, separated from license files, and maintained in a locked file cabinet with limited access. The documents observed were sufficiently marked as sensitive information to be withheld from public disclosure.

The Program has adequate numbers and types of radiation survey instruments to support their inspection efforts. Calibrated survey instruments, such as Geiger-Mueller detectors, scintillation detectors, micro-R meters and ion chambers, were available on site for the staff's use. Survey instruments and dosimeters are calibrated by licensed service providers and through a contract with the South Carolina Department of Health and Environmental Control. Laboratory sample analysis is provided through the mobile laboratory maintained by the Environmental Radiation Program. If needed, additional laboratory capabilities are available from licensed academic and research facilities within the State.

The review team noted that, over the review period, annual management accompaniments were not always performed on a routine basis. All Specialists were accompanied in 2005 and again in 2006. A significant number of staff left the Program in subsequent years and management made the decision to concentrate efforts on training new employees rather than accompanying the two senior staff. These two individuals were not accompanied by management from 2007 up to the time of the review. Program management intends to continue accompaniments through the end of Calendar Year 2008 and plans to include these two individuals. As noted in Section 2.0, the recommendation from the 2004 review regarding supervisory accompaniments remains open.

A member of the review team accompanied five of the Program's Specialists during the week of August 4, 2008. The Specialists conducted inspections at two hospital nuclear medicine departments, one using therapeutic radioisotopes and one using only diagnostic radioisotopes; a nuclear pharmacy; a cancer center using a high dose-rate remote afterloading device (HDR); and a custom source manufacturer. Appendix C lists the inspector accompaniments. The Specialists were generally prepared for the inspections, having reviewed the previous inspection reports, and were thorough in their administrative audits of the licensees' radiation safety programs. They conducted interviews with licensee personnel and performed confirmatory measurements. The Specialists held entrance and exit meetings with the appropriate level of licensee management.

The review team determined that, while the inspections observed during the accompaniments were generally adequate to assess basic radiological health, safety, and security at the licensed facilities, the Program's newer inspectors would have benefitted from additional training prior to being authorized to work independently. The review team noted that the newer inspectors rarely observed licensed activities in progress and, instead, focused almost exclusively on documentation. One Specialist commented during his inspection that he did not understand the meaning of some of the documentation he was reviewing. Another Specialist inspecting an HDR unit stated he believed he was authorized to inspect HDR units independently before he was comfortably ready to do so.

The review team interviewed the Specialists during accompaniments and noted that some expressed concerns that they may have been released to work independently before they were fully ready. Specialists added that there were times when they performed inspections without the added benefit of having attended a training class for the type of inspection being performed, primarily because they were unable to get into the classes. Additionally, some of the staff stated that because they did not have backgrounds in health physics, they did not always fully

comprehend all the complexities and nuances associated with some of the program areas they were responsible for licensing and inspecting. They indicated that while they have access to more experienced staff while in the office, they don't always have that luxury when in the field.

When notified of these observations, the Program Manager indicated that as the primary trainer for the Program with a large number of staff to train, there are certain restrictions on her time. She acknowledged that with her own administrative workload, little help to train the staff, and a pressing need to keep up with the work, she is often forced to shorten the training period so that work can be completed timely. The Program Manager stated that in an attempt to alleviate this problem, she had attempted to reorganize the current staff to assist with training, but was unsuccessful. She added that she is always available to help with questions and concerns, and that any Specialist can receive additional training, if requested.

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

3.4 <u>Technical Quality of Licensing Actions</u>

The review team interviewed the Specialists and examined completed licensing casework for 31 specific licenses. Licensing actions were reviewed for completeness, consistency, proper possession authorizations, 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, supervisory review, and proper signatures.

The casework was selected to provide a representative sample of licensing actions completed during the review period. Licensing actions selected for evaluation included 1 new license, 6 renewals, 18 amendments, and 6 license terminations. Files reviewed included a cross-section of license types, including: academic, medical diagnostic and therapy, brachytherapy, industrial radiography, and fixed and portable gauges. The casework sample represented work from each of the Specialists. A listing of the licensing casework reviewed, with case-specific comments, can be found in Appendix D.

The administrative staff member assigns licensing actions directly to the Specialist who is responsible for the region from which the licensing request originated. Tracking numbers are assigned and logged into a computer tracking system. Due to an unusual level of staff turnover since the 2004 review, several new Specialists are independently responsible for a geographical region. Periodically, these newer Specialists receive licensing requests in program areas where they have little or no experience in reviewing, with little formalized on-the-job training. Some Specialists expressed concerns that they felt unqualified to conduct these reviews.

Currently, on-the-job training in the licensing process is informal and lacks an established set of qualification criteria. Using State of Georgia licensing guidance that parallels NRC's NUREG-1556 series, Specialists independently review all casework assigned to them, including casework in program areas where they have little experience. The Program Manager works

with the Specialist and provides training during the review of the licensing action. The Specialist then submits the casework to the Program Manager for final review and signature. The Program Manager provides additional training to the Specialist, as needed, prior to issuance of the license. The Program Manager provides a verbal clearance when a reviewer can independently sign licensing actions.

Overall, the review team concluded that licensing actions were adequate to protect the public health and safety; however, based on the evaluation of casework, the review team noted repeated examples of issues with thoroughness, completeness, consistency, clarity, technical quality, and adherence to existing licensing guidance. Specific examples included license terminations that were completed without receiving required documentation from the licensee verifying the appropriate disposal of radioactive sources or verifying that sealed sources were not leaking prior to transfer to another licensee; license amendments that were issued releasing locations of use where both long- and short-lived radionuclides were used without receiving close-out surveys that demonstrated the absence of residual contamination; and an industrial radiography license that did not authorize temporary job sites as requested in the licensee's application. The review team noted issues involving possession authorizations, and the application of the Increased Controls and fingerprinting requirements. Followup interviews with Specialists also revealed inconsistencies among reviewers in their application of licensing guidance that is used to perform licensing reviews.

The review team evaluated the Program's financial assurance program. The review team noted that all of the instruments were originally executed documents with original signatures and were stored in a locked safe. The review team determined that the Program's financial assurance program was adequate and that the instruments were properly secured from unauthorized access.

The review team evaluated the Program's industrial radiographer certification process. The Program offers a proctored examination to applicants several times each year in a variety of locations throughout the State. Exams are contracted through the State of Texas, which grades the examinations and provides results to the Program. The review team determined the Program's overall implementation of this process is adequate.

The review team reviewed the State's program for the implementation of pre-licensing guidance. At the time of the review, the State had incorporated the essential objectives of the original prelicensing guidance that requires site visits and background checks of applicants requesting risksignificant quantities of radioactive materials. The State had not yet incorporated the essential objectives of the revised pre-licensing guidance that added site visits for any unknown applicant. As detailed in FSME Letter RCPD-08-020, dated September 22, 2008, States have 6 months from the date of the letter to incorporate the essential objectives of the revised pre-licensing guidance into their respective licensing program.

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

3.5 <u>Technical Quality of Incident and Allegation Activities</u>

In evaluating the effectiveness of the Program's actions in responding to incidents and allegations, the review team examined the response to the questionnaire relative to this indicator, evaluated selected incidents reported for Georgia in the Nuclear Material Events Database (NMED) against those contained in the Program's files, and evaluated the casework for 17 radioactive materials incidents. A listing of the casework examined can be found in Appendix E. The review team also evaluated the Program's response to three allegations involving radioactive materials reported directly to the State during the review period.

When notified of an incident or an allegation, management and staff discuss the event and determine the level of initial response based on the health and safety risk associated with the incident. The Program maintains a database for tracking the status of all incidents and allegations. The actions taken in response to an incident are documented and filed, and if the incident meets the reporting thresholds, as established in FSME Procedure SA-300, the Program notifies NRC. If an investigation is complex and extends over a period of time, NMED is appropriately updated. The Program does not use the NMED data entry software program to place events into NMED, but instead uses an internal standardized form to document the response to incidents and allegations, and e-mails this form to the NMED contractor. Since the 2004 review, the review team identified a total of 67 incidents for Georgia in NMED, of which 28 required reporting to NRC. The review team evaluated the Program's timeliness in reporting incidents to the NRC Headquarters Operations Center, and determined that, following notification from the licensee, the Program was generally timely in reporting incidents.

The incidents selected for review included medical events; lost, stolen, or abandoned radioactive material; contamination events; damaged equipment, and transportation incidents. The review team determined that the Program's responses to incidents were thorough, complete, and comprehensive. Initial responses were prompt and well coordinated, and the level of effort was commensurate with the health and safety significance. The Program immediately dispatched inspectors to a site when the possibility of an immediate threat to public health and safety existed. When no immediate threat was present and the Program determined that the licensee had qualified, competent individuals investigating the incident, the Program generally responded telephonically with an on-site followup at a later date. The review team noted that at the conclusion of investigations, Specialists documented findings and made appropriate notifications.

In evaluating the effectiveness of the Program's response to allegations, the review team evaluated the casework for three allegations. The review team concluded that the Program consistently took prompt and appropriate action in response to concerns raised. The review team noted that the Program thoroughly documented the investigations and retained all necessary documentation to appropriately close the allegations. The Program notified the allegers of the outcomes of the investigations when the allegers' identities were known. The review team determined that the Program adequately protected the identity of allegers.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Georgia's performance with respect to the indicator, Technical Quality of Incident and Allegation Activities, was 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. Georgia's Agreement does not relinquish the authority for regulation of uranium recovery activities, so only the first three non-common performance indicators were applicable to this review.

4.1 <u>Compatibility Requirements</u>

4.1.1 Legislation

Georgia became an Agreement State in December 1969. Legislative authority to create an agency and enter into an Agreement with NRC was established in the Georgia Radiation Control Act (O.C.G.A. Title 31 Chapter 13, et seq., as amended). The Department is designated as the State's radiation control agency. The review team was informed that no new legislation was passed since the last review that would affect the Program or its authority.

4.1.2 Program Elements Required for Compatibility

The Georgia Regulations for Control of Radiation, found in Chapter 391-3-17, Rules and Regulations for Radioactive Materials, apply to all ionizing radiation emitted from radionuclides. Georgia requires a license for possession and use of all radioactive material.

The review team examined the procedures used in the State's regulatory process and found that the process takes 9-12 months for rule promulgation. The public and other interested parties are offered an opportunity to comment on proposed rules during a 30-day comment period and during a public meeting. NRC is provided with drafts of the proposed rules for review and comment before the public comment period. Proposed rules are submitted to the Board of Natural Resources (the Board) for review and approval. The Board's calendar for rule adoption is tentatively set in January for that calendar year. All programs in the Department wishing to promulgate rules must get on the Board's calendar. After the proposed rules are approved by the Board, they are filed with the Secretary of State. The rules become final 20 days after filing with the Secretary of State. The Department's Rules and Regulations are not subject to "sunset" laws.

The review team evaluated the Program's response 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 State Regulations Status sheet that FSME maintains.

Since the previous review, the Program adopted nine amendments combined into one rule package that was approved by the Board on September 24, 2008. The package was then approved by the Secretary of State's Office with an effective date of November 6, 2008. Additionally, the State adopted the Increased Controls requirements on November 10, 2005, and the fingerprinting requirements on June 2, 2008, both through the issuance of license conditions.

The review team recognized the amount of progress since the last review to address the number of overdue regulations. With the adoption of the previously mentioned rulemaking package, the State is up to date with regulation development. The Program is committed to ensuring that the State maintains compatibility with the NRC by addressing upcoming regulation changes.

Current NRC policy requires that Agreement States adopt certain equivalent regulations or legally binding requirements no later than 3 years after they become effective. The review team determined that the Program was up to date on all required NRC amendments as of the adoption of the State's latest rulemaking package.

The Program will need to address the following amendments through rulemakings or by adopting alternative legally binding requirements:

- "Requirements for Expanded Definition of Byproduct Material," 10 CFR Parts 20, 30, 31, 32, 33, 35, 61, and 150 amendment (72 FR 55864), that is due for Agreement State adoption by November 30, 2010.
- "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 is due for Agreement State adoption by December 17, 2010.
- "Occupational Dose Records, Labeling Containers, and Total Effective Dose Equivalent," 10 CFR Parts 19 and 20 amendment (72 FR 68043), that is due for Agreement State adoption by February 15, 2011.

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

4.2 <u>Sealed Source and Device Evaluation Program</u>

In reviewing this indicator, the review team used three subelements to evaluate the Program's 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 Program's SS&D evaluation activities, the review team examined information contained in the Program's response to the IMPEP questionnaire for this indicator. The review team evaluated 8 of 27 SS&D actions processed during the review period. The Program completed seven new SS&D evaluations and issued 20 amendments and corrections to existing registrations since the last review. The review team noted the staff's use of guidance documents and procedures, interviewed staff members involved in SS&D evaluations, and verified the use of regulations and inspections to enforce commitments made in the applications.

4.2.1 Technical Staffing and Training

The Program currently has two individuals who are qualified to perform safety evaluations of SS&D applications, one staff Specialist and the Program Manager. The Program previously had more trained Specialists capable of performing SS&D reviews; however, due to the significant staff turnover since the last review, the Program lost those other Specialists. In response to those losses, the Program successfully hired an Engineer in January 2008; however, approximately 1 month later, the Engineer left the Program. As noted in Section 2.0, the recommendation from the 2004 regarding training a backup SS&D reviewer remains open.

The review team interviewed staff members involved in the reviews and determined that they were familiar with the procedures used to evaluate sources and devices. They also had access to applicable reference documents.

4.2.2 <u>Technical Quality of the Product Evaluation Program</u>

The review team examined eight certificates and supporting documentation (five new registrations and three amendments) for five vendors. Each of the actions was initially reviewed by a fully qualified Specialist and received secondary reviews by one of three other qualified Specialists. A listing of the SS&D certificates evaluated, with case-specific comments, can be found in Appendix F.

Analysis of the casework and interviews with staff members confirmed that the Program follows the recommended guidance from NRC's SS&D Workshop and NUREG-1556, Volume 3, Revision 1, "Consolidated Guidance About Materials Licenses – Applications for Sealed Source and Device Evaluation and Registration," with one exception as noted below. The review team determined that the depth and scope of the SS&D evaluations during the review period were adequate and addressed both the physical integrity of the product and the health and safety of the users, the public, and the environment. The registrations clearly summarized the product evaluation and provided Specialists with adequate information to license the possession and use of the product.

The review team identified one amendment adding a new sealed source to a device certificate that was incorporated as a corrected page. This practice is not consistent with the guidance in NUREG-1556, Volume 3. The addition of a new sealed source must be evaluated for engineering design and safety prior to being added to the certificate. The primary Specialist noted that the new source had the same dimensions as the other registered source and that radiation profiles had been provided and approved; however, each affected page must be amended to add a new registered source.

4.2.3 Evaluation of Defects and Incidents Regarding SS&Ds

The review team noted that following the 2004 review, the Program added a license condition to the licenses of manufacturers requiring them to report defects affecting the integrity of their products. The Program also developed written procedures for the investigation of defects and incidents involving SS&D devices. The procedure requires the primary SS&D reviewer to query NMED on a monthly basis to identify generic issues, analyze trends, and to communicate findings with other regulatory agencies. The review team noted that these queries were

conducted twice in April 2007 and once in September 2008, which is not in accordance with the new procedures. The review team discussed with the Program the possibility of amending the NMED query procedure so that reviews are performed at a less frequent interval. The review team noted that the Program is aware of issues affecting the SS&D program via routine inspections and the Part 21 equivalent license condition.

The review team noted the Program's responsiveness to customer complaints involving devices manufactured under Georgia licenses by performing quality assurance inspections on two manufacturers since the 2004 review. These inspections were directly related to problems with devices registered by Georgia and demonstrated the Program's sensitivity to complaints.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Georgia's performance with respect to the indicator, Sealed Source and Device Evaluation Program, was satisfactory.

4.3 Low-Level Radioactive Waste Disposal Program

In 1981, NRC amended its Policy Statement, "Criteria for Guidance of States and NRC in Discontinuance of NRC Authority and Assumption Thereof by States Through Agreement," to allow a State to seek an amendment for the regulation of low-level radioactive waste (LLRW) as a separate category. Those States with Agreements with NRC prior to 1981 were determined to have continued LLRW disposal authority without the need of an amendment. Although Georgia has such disposal authority, NRC has not required States to have a program for licensing a 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, it is expected to put in place a regulatory program that will meet the criteria for an adequate and compatible LLRW disposal program. There are no plans for a commercial LLRW disposal facility in Georgia. Accordingly, the review team did not evaluate this indicator.

5.0 SUMMARY

As noted in Sections 3.0 and 4.0, Georgia's performance was found satisfactory, but needs improvement, for four performance indicators: Technical Staffing and Training, Status of Materials Inspection Program, Technical Quality of Inspections, and Technical Quality of Licensing Actions. Georgia's performance was found satisfactory for the three other performance indicators reviewed. The review team made two recommendations regarding the performance of the Georgia Agreement State Program and left two recommendations from the 2004 review open. Accordingly, the review team recommended, and the MRB agreed, that the Georgia Agreement State Program. Based on the results of the current review, the review team recommended, and the MRB agreed, that NRC initiate a period of monitoring of the Georgia Agreement State Program. The review team recommended, and the MRB agreed, that a periodic meeting will take place in approximately 1 year and that next full review of the Georgia Agreement State Program will take place in approximately 4 years.

- 1. The review team recommends that the State develop, document, and implement a formal qualification program for licensing and inspection activities that includes written documentation and supervisor endorsement of competency in each program area. (Section 3.1)
- 2. The review team recommends that the State update their inspection procedures and enforcement guidance to include the requirements for timely followup of Increased Controls violations. (Section 3.3)
- 3. The review team recommends that the Program develop and implement a process for conducting annual accompaniments of all radiation compliance inspectors by a supervisor. (Section 3.3 of the 2004 IMPEP report)
- 4. The team recommends that the Program qualify one additional reviewer in SS&D evaluations to provide backup for the principal reviewer. (Section 4.2 of the 2004 IMPEP report)

LIST OF APPENDIXES AND ATTACHMENT

- Appendix A IMPEP Review Team Members
- Appendix B Georgia Organization Charts
- Appendix C Inspection Casework Reviews
- Appendix D License Casework Reviews
- Appendix E Incident Casework Reviews
- Appendix F Sealed Source & Device Casework Reviews
- Attachment November 21, 2008, Letter from Carol A. Couch Georgia's Response to Draft IMPEP Report

APPENDIX A

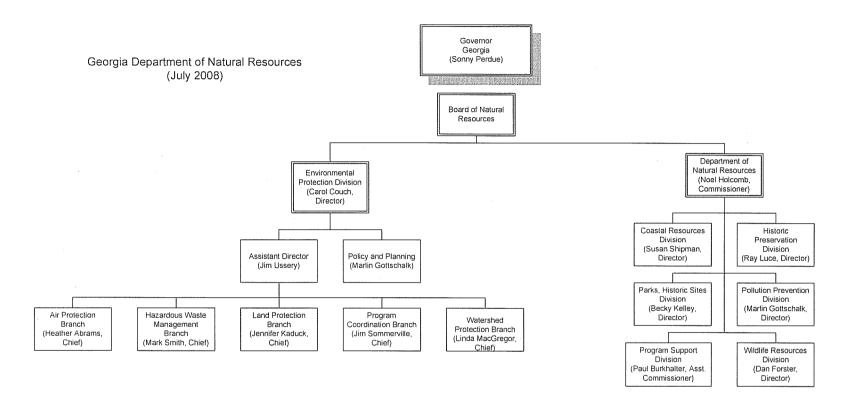
IMPEP REVIEW TEAM MEMBERS

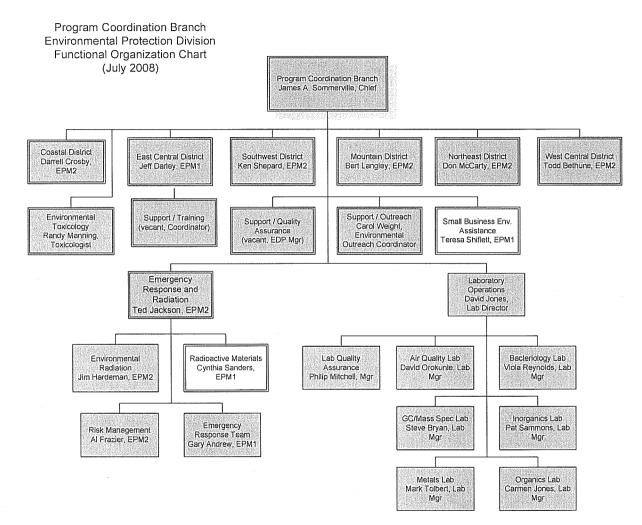
Name	Area of Responsibility
Randy Erickson, Region IV	Team Leader Compatibility Requirements Inspector Accompaniments
James Kottan, Region I	Technical Staffing and Training Technical Quality of Incident and Allegation Activities
Bryan Parker, Region I	Status of the Materials Inspection Program
Kevin Null, Region III	Technical Quality of Licensing Actions
Stephen James, Ohio	Technical Quality of Inspections
Kenath Traegde, Massachusetts	Sealed Source and Device Evaluation Program

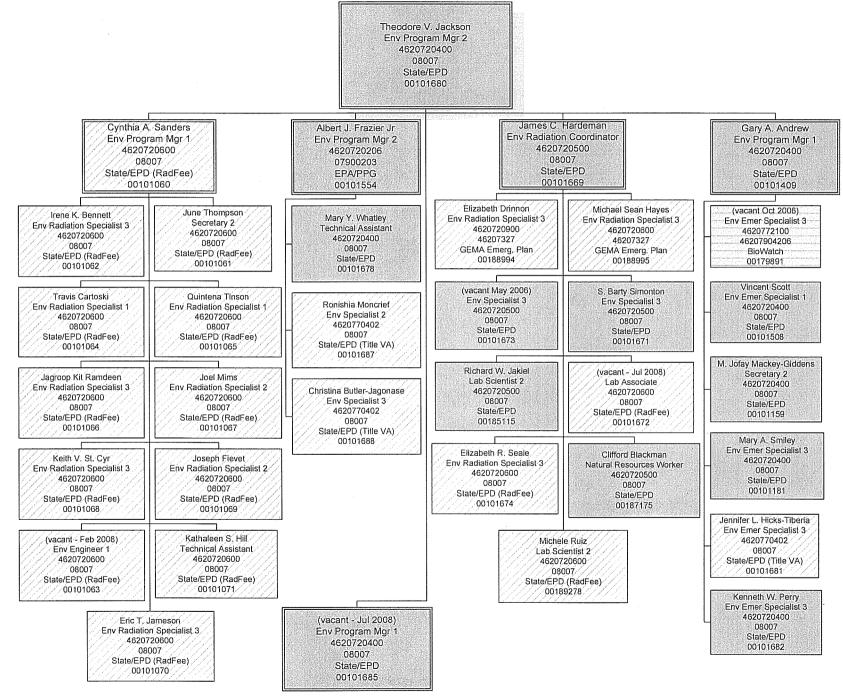
APPENDIX B

GEORGIA ORGANIZATION CHARTS

ADAMS ACCESSION NO.: ML082520656







Emergency Response & Radiation

APPENDIX C

INSPECTION CASEWORK REVIEWS

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

File No.: 1 Licensee: Hurst Boiler and Welding Inspection Type: Routine, Unannounced Inspection Date: 6/23/08 File No.: 2 Licensee: Hurst Boiler and Welding Inspection Type: Special, Announced Inspection Date: 4/4/07 File No.: 3 Licensee: JANX Integrity Group Inspection Type: Routine, Announced Inspection Date: 5/23/08 File No.: 4 Licensee: JANX Integrity Group Inspection Type: Routine, Announced Inspection Date: 1/31/08 File No.: 5 Licensee: JANX Integrity Group Inspection Type: Special, Announced Inspection Date: 9/7/06 File No.: 6 Licensee: Acuren Inspection Inspection Type: Routine, Unannounced Inspection Date: 3/19/08 File No.: 7 Licensee: Acuren Inspection Inspection Type: Routine, Announced Inspection Date: 11/15/06 File No.: 8 Licensee: Acuren Inspection Inspection Type: Special, Announced Inspection Date: 11/15/06

License No.: GA 918-1 Priority: 1 Inspector: KR

License No.: GA 918-1 Priority: 1 Inspector: ED

License No.: GA 1369-1 Priority: 1 Inspectors: EJ, JM

License No.: GA 1369-1 Priority: 1 Inspectors: EJ, JM

License No.: GA 1369-1 Priority: 1 Inspector: LP

License No.: GA 1115-1 Priority: 1 Inspector: JF

License No.: GA 1115-1 Priority: 1 Inspector: ED

License No.: GA 1115-1 Priority: 1 Inspector: ED

File No.: 9 Licensee: Sowega Testing Services Inspection Type: Routine, Announced Inspection Date: 8/15/08

File No.: 10 Licensee: Sowega Testing Services Inspection Type: Special, Announced Inspection Date: 4/12/07

File No.: 11 Licensee: Sowega Testing Services Inspection Type: Routine, Announced Inspection Date: 2/14/07

File No.: 12 Licensee: Theragenics Inspection Type: Routine, Announced Inspection Date: 8/27/08

File No.: 13 Licensee: Theragenics Inspection Type: Special, Announced Inspection Date: 4/23/08

Comment: Inspection report sent 4 months after inspection date.

File No.: 14 Licensee: Theragenics Inspection Type: Initial, Announced Inspection Date: 11/15/05

File No.: 15 Licensee: Hopewell Design Inspection Type: Routine, Announced Inspection Date: 2/15/06

Comment: Inspection report sent 4 months after inspection date.

File No.: 16 Licensee: Atlanta Oncology Associates Inspection Type: Routine, Unannounced Inspection Date: 4/14/08 License No.: GA 923-1 Priority: 1 Inspector: KR

License No.: GA 923-1 Priority: 1 Inspector: LP

License No.: GA 923-1 Priority: 1 Inspector: LP

License No.: GA 881-5 Priority: 2 Inspectors: EJ, KR, CS

License No.: GA 881-5 Priority: 2 Inspector: EJ

License No.: GA 881-5 Priority: 2 Inspector: EJ

License No.: GA 1434-1 Priority: 3 Inspector: EJ

License No.: GA 1178-1 Priority: 2 Inspector: TC

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File No.: 17 Licensee: Cardinal Health Inspection Type: Routine, Unannounced Inspection Date: 3/26/08

File No.: 18 Licensee: The Medical Center Inspection Type: Routine, Announced Inspection Date: 8/7/08

File No.: 19 Licensee: Newton Health System Inspection Type: Routine, Unannounced Inspection Date: 8/4/08

File No.: 20 Licensee: St. Joseph's Hospital Inspection Type: Routine, Unannounced Inspection Date: 7/20/06

File No.: 21 Licensee: Analytics, Inc. Inspection Type: Routine, Unannounced Inspection Date: 8/8/08

File No.: 22 Licensee: Analytics, Inc. Inspection Type: Routine, Unannounced Inspection Date: 6/20/05

File No.: 23 Licensee: GE Healthcare Inspection Type: Routine, Announced Inspection Date: 8/6/08

File No.: 24 Licensee: GE Healthcare Inspection Type: Routine, Announced Inspection Date: 11/27/06

File No.: 25 Licensee: Columbus Radiation Oncology Inspection Type: Routine, Unannounced Inspection Date: 1/22/08 License No.: GA 463-3MD Priority: 2 Inspectors: JM, IB

> License No.: GA 392-2 Priority: 2 Inspector: TC

> License No.: GA 632-1 Priority: 3 Inspector: KS

> License No.: GA 296-4 Priority: 3 Inspectors: LS, LP, KS

> License No.: GA 742-1 Priority: 3 Inspector: EJ

> License No.: GA 742-1 Priority: 3 Inspector: EJ

License No.: GA 1166-1MD Priority: 2 Inspector: IB

License No.: GA 1166-1MD Priority: 2 Inspector: IB

> License No.: GA 1256-1 Priority: 2 Inspector: TC

File No.: 26 Licensee: Medical College of Georgia Inspection Type: Special, Announced Inspection Dates: 6/12-16/06

File No.: 27 Licensee: Landis International Inspection Type: Routine, Unannounced Inspection Date: 1/14/08

File No.: 28 Licensee: Emory University Inspection Type: Special, Announced Inspection Date: 2/22/07

File No.: 29 Licensee: Emory University Inspection Type: Routine, Announced Inspection Dates: 7/10-13/06

File No.: 30 Licensee: St. Joseph Hospital Inspection Type: Routine, Unannounced Inspection Date: 8/5/08

File No.: 31 Licensee: Rome Imaging Center Inspection Type: Routine, Announced Inspection Date: 8/28/08

File No.: 32 Licensee: Nucletron Inspection Type: Reciprocity, Unannounced Inspection Date: 3/19/08 License No.: GA 1110-1 Priority: 2 Inspector: ED

License No.: GA 941-1 Priority: 3 Inspector: KR

License No.: GA 153-1 Priority: 3 Inspector: LS

License No.: GA 153-1 Priority: 3 Inspector: LS

License No.: GA 359-1 Priority: 5 Inspector: JF

License No.: GA 1413-1 Priority: 3 Inspector: JM

License No.: Reciprocity Priority: 1 Inspector: IB

INSPECTOR ACCOMPANIMENTS

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

Accompaniment No.: 1 Licensee: Newton Health System Inspection Type: Routine, Unannounced Inspection Date: 8/4/08

License No.: GA-632-1 Priority: 3 Inspector: KS

Accompaniment No.: 2 Licensee: St. Joseph Hospital Inspection Type: Routine, Unannounced Inspection Date: 8/5/08

Accompaniment No.: 3 Licensee: GE Healthcare Inspection Type: Routine, Announced Inspection Date: 8/6/08

Accompaniment No.: 4 Licensee: The Medical Center Inspection Type: Routine, Announced Inspection Date: 8/7/08

Accompaniment No.: 5 Licensee: Analytics, Inc. Inspection Type: Routine, Unannounced Inspection Date: 8/8/08 License No.: GA-359-1 Priority: 3 Inspector: JF

License No.: GA-1166359-1MD Priority: 2 Inspector: IB

> License No.: GA-239-2 Priority: 2 Inspector: TC

> License No.: GA-742-1 Priority: 3 Inspector: EJ

APPENDIX D

LICENSE CASEWORK REVIEWS

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

File No.: 1 Licensee: Allmond Lab Services Type of Action: Termination Date Issued: 6/2/06

License No.: GA 1340-1 Amendment No.: 03 License Reviewer: KR

Comment:

License was terminated without following up on licensee's statement that two licensed devices had been stolen.

File No.: 2 Licensee: Ram K. Puri, M.D Type of Action: Termination Date Issued: 10/18/06

File No.: 3 Licensee: Savannah State University Type of Action: Amendment Date Issued: 4/1/08

Comment: Location of use was removed without a close-out survey.

File No.: 4 Licensee: PET Imaging Center of Savannah Type of Action: Amendment Date Issued: 7/16/08

Comment: Location of use was removed without a close-out survey.

File No.: 5 Licensee: Evans Memorial Hospital Type of Action: Renewal Date Issued: 9/20/07

File No.: 6 Licensee: Piedmont Hospital. Type of Action: Amendment Date Issued: 9/2/08 License No.: GA 1533-1 Amendment No.: 01 License Reviewer: LP

License No.: GA 1102-1 Amendment No.: 03 License Reviewer: JF

License No.: GA 1122-1 Amendment No.: 02 License Reviewer: JF

License No.: GA 999-1 Amendment No.: 04 License Reviewer: JF

License No.: GA 292-1 Amendment No.: 54 License Reviewer: TC Georgia Final Report License Casework Reviews

File No.: 7 Licensee: The Medical Center Type of Action: Amendment Date Issued: 4/9/08

Comment:

License amendment was issued without a required license condition.

File No.: 8 Licensee: St. Joseph's Hospital Type of Action: Amendment Date Issued: 7/8/08

File No.: 9 Licensee: Hurst Boiler and Welding, Inc Type of Action: Amendment Date Issued: 6/2/08 License No.: GA 296-4 Amendment No.: 65

> License No.: GA 918-1 Amendment No.: 17 License Reviewer: KR

License Reviewer: KS

License No.: GA 239-2

License Reviewer: TC

Amendment No.: 26

Comment:

License did not authorize temporary job sites as the licensee had requested in its application for license renewal.

File No.: 10 Licensee: Northside Hospital Type of Action: Amendment Date Issued: 6/2/08

File No.: 11 Licensee: Northeast Georgia Medical Center Type of Action: Amendment Date Issued: 3/21/08

File No.: 12 Licensee: Phoebe Putney Memorial Hospital Type of Action: Amendment Date Issued: 4/30/08

File No.: 13 Licensee: Grady Memorial Hospital Corp. Type of Action: Renewal Date Issued: 8/29/08 License No.: GA 39-1 Amendment No.: 46 License Reviewer: CS

License No.: GA 199-1 Amendment No.: 36 License Reviewer: IB

License No.: GA 338-1 Amendment No.: 52 License Reviewer: KR

License No.: GA 258-2 Amendment No.: 11 License Reviewer: IB

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Licensee: Columbus Rad. Oncology Assoc. Type of Action: Amendment Date Issued: 8/17/05 License amendment was issued without a required license condition. License No.: GA 1178-1 Amendment No.: 17 License Reviewer: TC License amendment was issued without a required license condition. License amendment was issued without a required license condition. Comment: License amendment was issued without a required license condition. Comment: License amendment was issued without a required license condition.

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License No.: GA 1256-1 Amendment No.: 10 License Reviewer: LP

Comment:

Georgia Final Report

File No.: 14

License Casework Reviews

File No.: 15 Licensee: Atlanta Oncology Associates Type of Action: Renewal Date Issued: 9/5/08

Comment:

File No.: 16 Licensee: Memorial Health University Medical Center Type of Action: Renewal Date Issued: 6/10/08

Comment:

File No.: 17 Licensee: John Archibold Memorial Hospital Type of Action: Amendment Date Issued: 11/13/07

License No.: GA 78-1 Amendment No.: 39 License Reviewer: KR

File No.: 18 Licensee: Athens Regional Med. Center Type of Action: Amendment Date Issued: 12/11/07

License No.: GA 4-1 Amendment No.: 52 License Reviewer: KS

File No.: 19 Licensee: Medical Center of Central Georgia Type of Action: Amendment Date Issued: 9/18/08

License No.: GA 764-1 Amendment No.: 35 License Reviewer: KR

License No.: GA 84-1 Amendment No.: 58 License Reviewer: JF Georgia Final Report License Casework Reviews

File No.: 20 Licensee: Oconee Regional Cancer Center Type of Action: Amendment Date Issued: 6/10/08

License No.: GA 1227-1 Amendment No.: 18 License Reviewer: KR

License No.: GA 1319-1

Amendment No.: 06

License Reviewer: KR

Comment:

License amendment was issued without a required license condition.

File No.: 21 Licensee: Radiology Associates of Macon Type of Action: Amendment Date Issued: 7/17/08

Comment:

License amendment was issued without a required license condition.

File No.: 22 Licensee: IBT Type of Action: Termination Date Issued: 10/17/06

Comment:

The termination was issued without verifying that the licensee had properly disposed of their sealed sources.

File No.: 23 Licensee: Analytics, Inc. Type of Action: Amendment Date Issued: 10/25/05

File No.: 24 Licensee: Redmond Regional Medical Center Type of Action: Renewal Date Issued: 9/13/07

File No.: 25 Licensee: Northside Hospital Type of Action: Renewal Date Issued: 11/23/05

File No.: 26 Licensee: Emory Eastside Medical Center Type of Action: Amendment Date Issued: 6/11/07

License No.: GA 1366-1

Amendment No.: 09

License Reviewer: EJ

License No.: GA 742-1 Amendment No.: 24 License Reviewer: EJ

License No.: GA 165-1 Amendment No.: 42 License Reviewer: EJ

License No.: GA 748-1 Amendment No.: 19 License Reviewer: IB

License No.: GA 728-1 Amendment No.: 28 License Reviewer: IB Georgia Final Report License Casework Reviews

File No.: 27 Licensee: Digirad Imaging Type of Action: New Date Issued: 6/11/08

File No.: 28 Licensee: Chickasha of Georgia Type of Action: Termination Date Issued: 11/7/07

Comment:

No evidence that sealed sources were not properly leak-tested prior to transfer or upon receipt of sources by the transferee.

File No.: 29 Licensee: Brown & Williamson Tobacco Corp. Type of Action: Termination Date Issued: 7/2/04

Comment:

No evidence that sealed sources were not properly leak-tested prior to transfer or upon receipt of sources by the transferee.

File No.: 30 Licensee: State University of West Georgia Type of Action: Termination Date Issued: 10/18/07

File No.: 31 Licensee: Wellstar Kennestone Hospital Type of Action: Amendment Date Issued: 2/28/07 License Reviewer: SS

License No.: GA 129-2

Amendment No.: 07

License No.: GA 328-1 Amendment No.: 58 License Reviewers: LS

Comment:

License amendment was issued without a required license condition.

License No.: GA 1529-3 Amendment No.: N/A License Reviewer: IB

License No.: GA 1294-1 Amendment No.: 05 License Reviewer: EJ

License No.: GA 460-1

License Reviewer: RH

Amendment No.: 32

APPENDIX E

INCIDENT CASEWORK REVIEWS

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

File No.: 1 Licensee: Medical Center of Central Georgia Date of Incident: 9/22/04 Investigation Dates: 10/25-11/17/04

gia License No.: GA-364-1 NMED Log No.: 040838 Type of Incident: Lost Material Type of Investigation: Telephone/Report Review/Site

File No.: 2 Licensee: GA Department of Transportation Date of Incident: 12/16/2004 Investigation Date: 12/16/2004

License No.: GA-50-1 NMED Log No.: 050111 Type of Incident: Damaged Equipment Type of Investigation: Telephone/Report Review

File No.: 3 Licensee: Southern Regional Medical Center Date of Incident: 9/15/05 Investigation Date: 9/30/05

License No.: GA-1039-1 NMED Log No.: 050676 Type of Incident: Medical Event Type of Investigation: Telephone/Report Review

File No.: 4 Licensee: Emory University Dates of Incident: 10/5-6/05 Investigation Date: 10/11/05

File No.: 5 Licensee: East Coast Isotopes, Inc. Date of Incident: 12/21/05 Investigation Date: 12/21/05 License No.: GA-153-1 NMED Log No.: 050738 Type of Incident: Contamination Event Type of Investigation: Telephone/Report Review

License No.: SC-705 NMED Log No.: Not Reported Type of Incident: Lost Material (Recovered) Type of Investigation: Telephone

File No.: 6 Licensee: Gwinnitt Medical Center Date of Incident: 1/10/06 Investigation Date: 1/17/06

License No.: GA-677-1 NMED Log No.: 060047 Type of Incident: Medical Event Type of Investigation: Telephone/Report Review

File No.: 7 Licensee: Contour Engineering Date of Incident: 4/26/06 Investigation Date: 4/26/06

License No.: GA-1398-1 NMED Log No.: 060306 Type of Incident: Damaged Portable Gauge Type of Investigation: Telephone/Report Review

File No.: 8 Licensee: Miller Breweries East, Inc. Date of Incident: 3/20-25/06 Investigation Date: 4/20/06

File No.: 9 Licensee: Gallet and Associates Date of Incident: 9/27/06 Investigation Date: 10/5/06

File No.: 10 Licensee: Sumpter Regional Hospital Date of Incident: 3/1/07 Investigation Date: 3/4/07

File No.: 11 Licensee: Nova Engineering Date of Incident: 3/27/07 Investigation Date: 3/27/07

File No.: 12 Licensee: GE Healthcare Date of Incident: 11/13/07 Investigation Date: 11/13/07

File No.: 13 Licensee: Kaiser Permanente Date of Incident: 11/19/07 Investigation Date: 1/25/08

Licensee: Morehouse School of Medicine

File No.: 14

License No.: GA-564-1.13 NMED Log No.: 060281 Type of Incident: Loss of Control Type of Investigation: Telephone/Report Review

License No.: GA-1316-1 NMED Log No.: 070034 Type of Incident: Damaged Equipment Type of Investigation: Telephone/Report Review

> License No.: GA-5-1 NMED Log No.: 070173 Type of Incident: Loss of Material Type of Investigation: Site

License No.: GA-1323-1 NMED Log No.: 070182 Type of Incident: Loss of Material Type of Investigation: Telephone/Report Review

> License No.: NA NMED Log No.: 070753 Type of Incident: Transportation Type of Investigation: Site/Report Review

License No.: GA-1276-1 NMED Log No.: 080385 Type of Incident: Medical Event Type of Investigation: Telephone/Report Review

License No.: GA-703-1 NMED Log No.: NA Type of Incident: Security Type of Investigation: Telephone/LLEA Followup

File No.: 15 Licensee: Imperial Sugar Date of Incident: 2/7/08 Investigation Date: 2/7-9/08

Date of Incident: 2/4/08

Investigation Date: 2/6/08

License No.: GA-917-1 NMED Log No.: NA Type of Incident: Damage to Fixed Gauge Type of Investigation: Site

File No.: 16 Licensee: Southern Regional Medical Center Date of Incident: 5/30/08 Investigation Date: 5/30/2008

License No.: GA-1039-1 NMED Log No.: 080388 Type of Incident: Medical Event Type of Investigation: Telephone/Report Review

File No.: 17 Licensee: Analytics, Inc. Date of Incident: 8/22/08 Investigation Date: 8/28/08

License No.: GA-742-1 NMED Log No.: NA Type of Incident: Leaking Source Type of Investigation: Telephone/Report Review

APPENDIX F

SEALED SOURCE & DEVICE CASEWORK REVIEWS

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

File No.: 1 Registry No.: GA-0716-D-110-S Manufacturer: Scantech International Pty, Ltd. Date Issued: 2/4/08

Comment:

Thermal tests for the cast neutron shielding were not performed for a period of one hour as specified in ANSI N43.6-1997; thermal tests were instead performed for a period of only 30 minutes.

File No.: 2

Registry No.: GA-1077-D-101-S Manufacturer: EADS SODURN North American Inc. Date Issued: 4/4/07

File No.: 3 Registry No.: GA-0269-D102-S Manufacturer: Elekta Instrument AB Date Issued: 2/28/07 SS&D Type: Neutron Gauge Model No.: POLAB CNA Series Action Type: Amendment

SS&D Type: Medical Teletherapy Model No.: 23004 & 24001 Action Type: Amendment

Comments:

- a) The amendment for a new sealed source was incorporated on the registration as a correction page when it should have been incorporated as a full amendment, an action that does not comply with the guidance in NUREG-1556, Vol. 3, Rev. 1.
- b) The amendment letter was not referenced at the conclusion of the certificate.

File No.: 4 Registry No.: GA-0716-D-104-S Manufacturer: Scantech International Pty Ltd Date Issued: 3/23/07

SS&D Type: Sulfur, Ash, Moisture Analyzer Model No.: 9000 & 9000 Mk2 Action Type: Amendment

File No.: 5 Registry No.: GA-0269-D-104-S Manufacturer: Elekta Instrument AB Date Issued: 2/26/07

File No.: 6 Registry No.: GA-1138-D-105-S Manufacturer: Hopewell Designs, Inc. Date Issued: 7/26/05 SS&D Type: Medical Teletherapy Model No.: Leksell Gamma Knife Perflexion Action Type: New

> SS&D Type: Dosimeter Irradiator Model No.: GC88 Action Type: New

SS&D Type: Neutron Gauge Model No.: ANALYZER-5 Action Type: New Georgia Final Report Sealed Source & Device Casework Reviews

File No.: 7 Registry No.: GA-1061-S-102-S Manufacturer: International Brachytherapy SA

Date Issued: 2/16/05

File No.: 8 Registry No.: GA-0645-D-103-S Manufacturer: Theragenics Corporation

Date Issued: 7/28/04

SS&D Type: Medical Brachytherapy Model No.: OptiSeed¹⁰³ Model 1 032p OptiStrand¹⁰³ Action Type: New

SS&D Type: Medical Brachytherapy Model No.: TheraSight [™] Ocular Brachytherapy System Model 5000 Action Type: New

ATTACHMENT

November 21, 2008, Letter from Carol A. Couch Georgia's Response to Draft IMPEP Report

ADAMS Accession No.: ML083400032

Georgia Department of Natural Resources

2 Martin Luther King, Jr. Drive, SE, Suite 1152 East, Atlanta, Georgia 30334-9000 Noel Holcomb, Commissioner Environmental Protection Division Carol A. Couch, Ph.D., Director Phone: (404) 656-4713 Fax: (404) 651-5778

November 21, 2008

Mr. Randy Erickson Regional State Agreements Officer US Nuclear Regulatory Commission Region IV 612 East Lamar Blvd., Suite 400 Arlington, Texas 76011-4125

Dear Mr. Erickson:

This is in reference to your letter dated October 27, 2008, transmitting Georgia's Draft Integrated Materials Performance Evaluation Program (IMPEP) Report. We have reviewed the report and would like to provide the proposed revisions to the report listed below. We are still in the process of evaluating the two new recommendations listed in your report. However, we will provide the Nuclear Regulatory Commission (NRC) with our response to the recommendations prior to, or at the time of, the Materials Review Board (MRB) meeting in December.

Thank you for giving us an opportunity to comment on the Draft IMIPEP Report and we look forward to the opportunity to meet with the Management Review Board. We appreciate the invitational travel offer and Cynthia Sanders is our designee to attend the MRB meeting at the NRC Headquarters in Rockville, Maryland. However, our management would like to participate in the MRB meeting and would like to make arrangements with the NRC for video conferencing for the meeting on December 4, 2008. Should you require further information before the MRB meeting, please contact Jim Sommerville, Program Coordination Branch Chief, at (404) 656-3310 or Cynthia Sanders. Manager, Radioactive Materials Program at (404) 362-2675.

Sincerely,

Carol A. Couch Director_____

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The Program's comments are as follows with deletions as strikeouts and additions as bold/underlined:

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

3. The review team recommends that the Program develop and implement a process for conducting annual accompaniments of all radiation compliance inspectors by a supervisor. (Section 3.3 of the 2004 IMPEP report)

Current Status: The Program did-net did develop and implement a process to ensure that all inspectors receive annual supervisory accompaniments. The Program performed staff inspection accompaniments with all staff until late 2005 2006 when the Program began to experience significant turnover. In an effort to expedite the training of new staff, management made the decision to forego accompanying the more experienced staff in lieu of accompanying the newer staff members. During this time, the more experienced staff did not receive supervisor accompaniments for up-to 2 years 2007 through the 2008 IMPEP Review period, however management conducted 10 accompaniments with new hires and less experienced staff during this period. This recommendation remains open.

3.0 COMMON PERFORMANCE INDICATORS

3.1 <u>Technical Staffing and Training</u>

Paragraph #2:

When fully staffed, the Program is comprised of a Program Manager, <u>nine</u>-eight Environmental <u>Radiation</u> Specialists (Specialist), <u>one Environmental Engineer</u>, one Technical Assistant, and one administrative staff member. <u>One-Specialist The Environmental Engineer</u> position is currently vacant due to a hiring freeze that was imposed earlier in the year. Specialists are assigned to one of six geographical regions within the State and are responsible for licensing, inspection, and incident response activities within that region. <u>The metro Atlanta area licensees are shared among the</u> <u>Specialists</u>. To be considered for a Specialist position, each candidate must possess, at a minimum, a Bachelor's degree in a science field.

Paragraph #3:

The review team noted that seven-six Specialists and one Environmental Engineer left the Program during the review period. Five were fully qualified and experienced staff, and two were new hires who transferred to another environmental program accepted job offers elsewhere outside the Agency shortly after starting with the Program. The Program successfully filled those the Specialists vacancies and, for a time, was practically fully staffed. The two senior Specialists have an average of 10 years experience with the Program; five of the staff members average approximately 2 to 3 years experience; and the newest staff member was hired early in 2008. Comments to Georgia's Draft IMPEP Report November 21, 2008 Page 3 of 6

Paragraph #5:

While the Program has a documented training program, they do not have a documented qualification program. Specialists are qualified through a combination of education and experience, formal classroom training, in-house and on-the-job training, completion of specific tasks, and mentoring by more experienced staff. The Program has not developed a procedure designed to determine an individual's competency in each program area prior to authorizing them to work independently. Specialists are notified verbally by the Program Manager when she determines they are qualified to perform certain types of license reviews and inspections. At the time of the review, five-of the eight Specialists were considered fully or mostly qualified by the Program. As discussed further in Sections 3.3 and 3.4, the review team identified key areas where Specialists that were considered fully or mostly qualified from additional experience or on-the-job training prior to being approved to work independently. The review team recommends that the State develop, document, and implement a formal qualification program for licensing and inspection activities that includes written documentation and supervisor endorsement of competency in each program area.

3.2 Status of Materials Inspection Program

Paragraph #5:

The review team evaluated the Program's timeliness of issuing inspection reports. The Program has an effective and efficient process that helps ensure that inspection findings are normally communicated to licensees in a timely manner. Inspection findings are normally communicated to the licensee using a form similar to NRC Form 5911A, "Safety Inspection Report and Compliance-Inspection." by issuing a Compliance Letter, Notice of Violation Letter, or a Consent Order. These forms are generally used for minor violations or other deficiencies. A completed form is typically issued onsite at the completion of an inspection. For minor and significant violations, the Specialist Program may elect to issues a Notice of Violation. Consent Orders are issued for escalated enforcement actions. Based on the 32 inspection files reviewed, the review team determined that the appropriate inspection correspondence was generally issued within 30 days of the inspection, with-mest being issued on site.

3.3 <u>Technical Quality of Inspections</u>

Paragraph #1:

The review team evaluated inspection reports, enforcement documentation, inspection field notes, and interviewed the responsible inspectors for 32 radioactive materials inspections conducted during the review period. The casework examined included a cross-section of inspections conducted by four three former and seven current inspectors and covered a wide variety of inspection types that included medical, academic, and research and development broad-scope licensees; industrial radiography; self-shielded irradiator; medical; nuclear pharmacy; and reciprocity licensees. Appendix C lists the inspection casework files reviewed and includes case-specific comments.

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Paragraph #2:

The review team found that the Program's inspection procedures are generally consistent with the inspection guidance found in IMC 2800. Specialists are responsible for conducting inspections of all the various types of licensees in their assigned region. Specialists use a specific inspection checklist <u>form</u> for each license type to help ensure that all relevant aspects of a particular program are reviewed. Inspection documentation parallels the inspection checklist <u>form</u>, limiting the amount of narrative documentation contained in routine reports; however, reports involving violations generally have additional documentation to support the enforcement action. The review team noted that inspection reports were generally consistent between Specialists and addressed unresolved safety issues from previous inspections. The reports also noted discussions held with licensees during exit interviews.

Paragraph #5:

As noted in Section 3.2, the Program successfully completed the initial round of Increased Controls inspections. However, the team found that subsequent health and safety inspections of those affected licensees did not include any followup to the Increased Controls as identified in RCPD 07-006 "Continuing Inspections of Increased Controls Licensees." The Program was unaware of the issuance of RCPD 107-006 by NRC, and felt this may have been an oversight on its behalf. The team provided a copy to the Program at the time of the review. In one instance the review team identified an Increased Controls inspection where violations were identified and a Notice of Violation was issued to the licensee, but the Program did not follow up with the licensee to ensure that the violations had been corrected. The review team further found that the Program's inspection procedures and enforcement guidance did not include requirements for Increased Controls inspection followup. The review team recommends that the State update their inspection procedures and enforcement guidance to include the requirements for timely followup of Increased Controls violations.

Paragraph #8:

The review team noted that, over the review period, annual management accompaniments were not always performed on a routine basis. All Specialists were accompanied in 2005 and again in 2006. A significant number of staff left the Program in subsequent years and management made the decision to concentrate efforts on training new employees rather than accompanying the two senior staff. These two individuals went-up to 2 years without being were not accompanied by management intends to continue accompaniments through 2008 review period. However, management intends to continue accompaniments through the end of 2008, and plans to include these two individuals. As noted in Section 2.0, the recommendation from the 2004 review regarding supervisory accompaniments remains open.

Paragraph #12:

When notified of these observations, the Program Manager indicated that as the primary trainer for the Program with a large number of staff to train, there are certain restrictions on her time. She acknowledged that with her own administrative workload, little help to train the staff, and a pressing need to keep up with the work, she is often forced to shorten the

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training period so that work can be completed timely. The Program Manager stated that in an attempt to alleviate this problem, she had attempted to reorganize the current staff and hire an individual to assist with training, but was unsuccessful. She added that she is always available to help with questions and concerns, and that any Specialist can receive additional training, if requested.

3.4 Technical Quality of Licensing Actions

Paragraph #3

The administrative staff member assigns licensing actions directly to the Specialist who is responsible for the region from which the licensing request originated. Tracking numbers are assigned and logged into a computer tracking system. Due to an unusual level of staff turnover since the 2004 review, several new Specialists are independently responsible for a geographical region. Periodically these newer Specialists receive licensing requests in program areas where they have little or no experience in reviewing, with little or no formalized on-the-job training. Some Specialists expressed concerns that they felt unqualified to conduct these reviews.

Paragraph #4:

Currently, on-the-job training in the licensing process is informal and lacks an established set of qualification criteria. Utilizing State of Georgia licensing guidance that parallels NRC's NUREG-1556 series, Specialists independently review all casework assigned to them, including casework in program areas where they have little or no experience. The Manager works with the Specialist and provides training during their review of the licensing action. They then submit the casework to the Program Manager for final review and signature. The Manager does a complete second review on the licensing action, and provides further training to the Specialist as needed prior to issuance of the license. The Program Manager provides a verbal clearance when a reviewer can independently sign licensing actions.

4.0 NON-COMMON PERFOMANCE INDICATORS

4.1 <u>Compatibility Requirements</u>

4.1.2 Program Elements Required for Compatibility

Paragraph #1:

The Georgia Regulations for Control of Radiation, found in Chapter 391-3-17, Rules and Regulations for Radioactive Materials, apply to all ionizing radiation, whether emitted from radionuclides or devices. Georgia requires a license for possession and use of all radioactive material.

Paragraph #4:

Since the previous review, the Program adopted 9 amendments <u>combined into</u> one rule package that <u>was approved by the Georgia DNR Board became effective on September</u> 24, 2008, and was approved by the Secretary of State's Office with an effective date

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of November 6, 2008. Additionally, the Increased Controls requirements were adopted on November 10, 2005, and the fingerprinting requirements were adopted on June 2, 2008, both through the issuance of license conditions.

4.2 Sealed Source and Device Evaluation Program

4.2.1 <u>Technical Staffing and Training</u>

Paragraph #1:

The Program currently has two individuals who are qualified to perform safety evaluations of SS&D applications, one staff Specialist and the Program Manager. The Program previously had more trained Specialists capable of performing SS&D reviews; however, due to the significant staff turnover since the last review, the Program lost those other Specialists. In response to those losses, the Program successfully hired a Specialist an Environmental Engineer with an engineering degree in January 2008; however, approximately one month later, the Specialist-Engineer left the Program for a position-in another environmental-program new job offer outside the Agency. As noted in Section 2.0, the recommendation from the 2004 regarding training a backup SS&D reviewer remains open.

APPENDIX D LICENSING CASEWORK REVIEWS

File No.: 16

Licensee: Memorial Health University Medical Center License No.: GA 84-1 Type of Action: Renewal Amendment No.: 58 Date Issued: 6/10/08 License Reviewer: CS JF

Comment:

License amendment was issued without a required license condition.

File No.: 29 Licensee: Ft. Valley State University License No.: GA 460-1 Brown & Williamson Tobacco Corp. Type of Action: Termination Amendment No.: 32 Date Issued: 7/1-1/05 07/02/04 License Reviewer: KS RH

Comment:

No evidence that sealed sources were not properly leak-tested prior to transfer or upon receipt of sources by the transferee.