

December 7, 2004

Carol A. Couch, Ph.D.
Director, Environmental Protection Division
Georgia Department of Natural Resources
2 Martin Luther King, Jr., Drive, S.E.
Suite 1152, East Floyd Tower
Atlanta, Georgia 30334-9000

Dear Dr. Couch:

On November 18, 2004, the Management Review Board (MRB) met to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) report on the Georgia Agreement State Program. The MRB found the Georgia program adequate, but needs improvement, and compatible with the U.S. Nuclear Regulatory Commission's program.

Section 5.0, page 13, of the enclosed final report presents the IMPEP team's recommendation for the State of Georgia. We request your evaluation and response to the recommendations within 30 days from receipt of this letter.

Based on the results of the current IMPEP review, the next full review will be in approximately four years.

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

Sincerely,

/RA/

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

Enclosure:
As stated

cc: James A. Somerville, Acting Branch Chief
Program Coordination Branch
Environmental Protection Division

Cynthia Sanders, Acting Program Manager
Radioactive Materials Program

Thomas Conley, KS
OAS Liaison to the MRB

INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM
REVIEW OF GEORGIA AGREEMENT STATE PROGRAM

August 23 - 26, 2004

FINAL REPORT

U.S. Nuclear Regulatory Commission

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 August 23 - 26, 2004, by a review team comprised of technical staff members from the Nuclear Regulatory Commission (NRC) and the Agreement State of Oklahoma. Team members are identified in Appendix A. The review was conducted in accordance with the "Implementation of the Integrated Materials Performance Evaluation Program and Rescission of a Final General Statement of Policy," published in the Federal Register on October 16, 1997, and the February 26, 2004, NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." Preliminary results of the review, which covered the period April 8, 2000 to August 26, 2004 were discussed with Georgia management on August 26, 2004.

A draft of this report was issued to Georgia for factual comment on September 27, 2004. The State responded by letter October 27, 2004. The Management Review Board (MRB) met on November 18, 2004 to consider the proposed final report. The MRB found the Georgia radiation control program adequate, but needs improvement, and compatible with NRC's 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 Environmental Protection Division (the Division). The Branch is divided into six programs and five regional offices; however, two programs have responsibility for the materials program, the Radioactive Materials Program (the Program) and the Environmental Radiation Program. The Program which administers the licensing and inspection portion of the Agreement State Program is under the supervision of a Program Manager. An organization chart for the Department is included in the report as Appendix B. At the time of the review, the Georgia program regulated 503 specific licenses authorizing Agreement materials. The review focused on the materials program as it is carried out under the Section 274b. (of the Atomic Energy Act, as amended) Agreement between the NRC and the State of Georgia.

In preparation for the review, a copy of the recently revised IMPEP questionnaire addressing the common and non-common performance indicators was sent to the Program on July 1, 2004. The Program provided a response to the questionnaire on August 5, 2004. A copy of the questionnaire response can be found on NRC's Agencywide Documents Access and Management System using the Accession Number ML042190303.

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 licensing and inspection database; (4) technical review of selected licensing and inspection actions; (5) field accompaniments of two Georgia inspectors; and (6) interviews with staff and management to answer questions and clarify issues. The team evaluated the information that it gathered against the IMPEP performance criteria for each common and non-common performance indicator and made a preliminary assessment of the radiation control program's performance.

Section 2 below discusses the Program's actions in response to recommendations made during the previous 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. Section 5 summarizes the review team's findings and recommendations. Recommendations made by the review team are comments that relate directly to performance by

the Program. A response is requested from the Division to all recommendations in the draft report.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous IMPEP review, which concluded on April 7, 2000, one recommendation was made and transmitted to Mr. Harold F. Reheis, Director, Environmental Protection Division, Georgia Department of Natural Resources on July 13, 2000. The team's review of the current status of this recommendation is as follows:

1. The review team recommends that the Program review all Georgia licenses to ascertain if they require financial assurance, and take appropriate action on each affected license to ensure that all licenses meet the State's financial assurance requirements. (Section 3.4)

Current Status: Discussions with staff, a review of selected license files and the list of standard license conditions, indicates that the financial assurance requirements are being applied to the appropriate licenses. The review team looked closely at financial assurance documentation, license templates and completed licensing actions. Financial assurance documents were kept locked in a safe. The documentation was reviewed and appeared to be in order. License templates contained the necessary limiting language and the staff has been trained on the use of the templates and financial assurance requirements. Licenses reviewed as part of the casework contained appropriate radioisotope limits and/or limiting language as a condition of the license. 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; (5) Technical Quality of Incident and Allegation Activities.

3.1 Technical Staffing and Training

Evaluation of this performance indicator included a review of the Program's staffing level and staff turnover, as well as the technical qualifications and training histories of the staff. To evaluate these issues, the review team examined the Program's response to the IMPEP questionnaire relative to this indicator, interviewed management and staff, and considered such factors as workload backlogs.

The Program devotes approximately nine full time equivalent (FTE) to the radioactive materials program, of which seven FTE are allotted for radioactive materials licensing, inspection, compliance and sealed source and device (SS&D) evaluation. The remaining two FTE include program management, database management and emergency response. Currently the Program has one technical vacancy. No significant licensing or inspection casework backlogs were noted.

The Acting Program Manager supervises two administrative staff and seven technical staff members. The technical staff members are classified as Environmental Radiation Specialist (Specialist) 1, 2 or 3. The seven current technical positions are filled at the Specialist 3 level. During the review period, the Program Manager retired on September 30, 2003 and a Specialist 3 has been serving as acting manager since October 1, 2003. A Specialist 3 left the Program in

April 2001 and a former Specialist rejoined the Program in August 2001. At the time of this review, the Program Manager's position and one Specialist's position remained unfilled for ten months.

The Program divided the State into six regional areas and has assigned one Specialist, responsible for licensing, inspections and incident response to each area. One Specialist is assigned to work out of the area office in Savannah and the remaining staff work in the Atlanta office. One Specialist is assigned to license, inspect and evaluate SS&D manufacturers which will be discussed further in Section 4.2. All Specialists are trained and qualified to independently review licenses, perform inspections and respond to incidents. One Specialist is assigned to operate and maintain the Program's technical database system. The review team determined that the technical staff is currently sharing an increased workload to cover the vacant technical staff position.

The Program utilizes a written training program for license reviewers and inspectors based on the requirements specified in NRC Manual Chapter (MC) 1246. Qualification journals have been developed for each of the Specialists. The minimum educational requirements for a Specialist is a bachelor's degree or equivalent training in physical or life sciences. As part of their initial training, Specialists are sent to the 5-week Health Physics course and to other basic regulatory training offered by NRC. The Program's training plan calls for new staff to work with more senior staff and under the direct supervision of the Program Manager until they acquire a level of training and experience to operate independently. The training plan requires the Program Manager to review licensing casework and accompany junior level staff in order to assure regulatory consistency and an adequate level of performance. The team confirmed the qualifications of the Specialists currently on staff. One new Specialist was hired during the review period, however, she is experienced, previously employed by the Program, and no new training was required.

The Environmental Radiation Program within the Branch provides support in environmental monitoring, obtaining samples and sample analyses. The Environmental Radiation Program's staffing level is eight FTE, including a manager, that supports the Radioactive Materials Program's response to radiological incidents. The staff are trained to respond immediately to materials related incidents at the request of the Radioactive Materials Program Manager.

The Board of Natural Resources (the Board) is a constitutionally established board and is empowered by State statute with all the general policy-making functions of the Department. The Board consists of 16 Governor appointed members; one member each from the 12 voting districts and four at-large members. Through the Division, a Medical Advisory Committee (Committee) five physicians and a medical physicist is available to the Program. The Committee is consulted regarding the training of physicians and physicists who apply for authorization for the medical use of radionuclides. The Committee also advises the Program in the review of rulemaking and on NRC initiatives in the medical area.

The review team examined the State's new conflict of interest policy which is applicable to the Board and the Committee. The new policy, issued in January 2003, takes the form of an Executive Order "Establishing a Code of Ethics for Executive Branch Officers and Employees." The Executive Order requires all employees to recuse themselves on matters of self interest in order to avoid "even the appearance of a conflict of interest."

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, 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 inspections of new licenses, timely dispatch of inspection findings to licensees and the performance of reciprocity inspections. The review team's evaluation is based on the Georgia questionnaire response relative to this indicator, data from the Program's inspection data tracking system, the examination of completed licensing and inspection casework files, and interviews with managers and staff.

The review team determined that, the Program had only four inspections overdue by more than 25 percent of the NRC frequency out of over 250 Priority 1, 2 and 3 inspections completed. The four overdue inspections, were considerably overdue, for example three Priority 1 inspections were overdue by 50, 14 and 13 months. The review team discussed with the Acting Program Manager the need to update their inspection procedures to eliminate extensions which are not allowed under the 2003 revision of MC 2800. Until February 2004, inspectors were able to extend the inspection frequency by filling out an "Inspection Change Form." Although the Program had adopted a policy of not extending inspection due dates and eliminated the use of the "Inspection Change Form," inspection procedures were not revised to reflect this policy change. The root cause of the four overdue inspections appears to be an oversight on the part of the inspectors.

A review of the Program's inspection priorities revealed that, as of February 2004, the inspection frequencies for the various types of Georgia licenses are the same as MC 2800. The Program's previous inspection frequencies were compatible with NRC's and allowed for extensions in inspection intervals based on good licensee performance. With respect to initial inspections of new licenses, the team evaluated a list of licensing actions and determined that there were 139 new licenses issued during the review period. The team determined that there were no overdue initial inspections. A random sampling of 13 of these new licenses were reviewed to verify initial inspection timeliness. All had been inspected within 6 to 12 months in accordance with MC 2800.

Although the Program adopted a policy consistent with MC 2800 which no longer extends inspection due dates, the Program has not yet revised its inspection procedures to reflect this change. This is the root cause of inappropriate inspection due date extensions noted in the casework review. The review team recommends that the Program update its inspection procedures to eliminate extensions of license inspection due dates.

The timeliness of the issuance of inspection findings was evaluated by the Team's review of the database and review of inspection casework. Based on a review of inspection casework, inspection findings were transmitted to the licensees within the Program's goal of 15 days following the inspection. Inspectors have the option of issuing a Violation Acknowledgment Form, which is similar to NRC Form 591, if no items or only minor items of noncompliance are identified during an inspection.

To evaluate the Program's reciprocity inspection program, the review team obtained a computer printout of data for the years of 2000 through 2004. The Program met the NRC's current criteria of inspecting licensees operating under reciprocity as specified in MC 1220.

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 the Materials Inspection Program, be found satisfactory.

3.3 Technical Quality of Inspections

The team evaluated the inspection reports and enforcement documentation and interviewed inspectors for 15 inspections conducted during the review period. The review included casework from all of the Program's materials inspectors, and covered inspections of various types including industrial radiography (fixed and non-fixed facilities), generally licensed device distribution, teletherapy service, portable gauge, manufacturing and distribution and various medical uses. Appendix C lists the inspection casework reviewed for completeness and adequacy with case-specific comments.

Based on casework, the review team noted that routine inspections covered all aspects of the licensee's radiation programs. The review team found that inspection reports were thorough, complete, consistent, and of high quality, with sufficient documentation to ensure that the licensee's performance with respect to health and safety was acceptable. The documentation supported violations, recommendations made to the licensee and discussions held with the licensee during exit interviews. A potential performance issue was identified in that the Program Manager does not sign off on inspection reports, Notices of Violations (NOV), as required by the IMPEP Handbook 5.6 criteria. This includes cases where the licensee has had repeated violations, multiple violations and NOV cover letters specifying programmatic breakdown or lack of management control over the radiation safety program.

In almost every case, follow-up inspections address previous violations. In two cases, inspectors extended the inspection due date although the previous inspection found significant violations. This is contrary to Procedure 05.01 of Georgia's Inspection Manual. Four cases were identified where there was no reply to the NOV from the licensee and where acknowledgment letters, assessing licensee corrective actions, were not sent. For two of these cases, the licensee was able to fax in a copy of their response, which was added to the case file during this review. Details on these cases are documented in Appendix C.

The Program's performance in handling inspection correspondence and follow up is occasionally inconsistent. The root cause of this inconsistency is that the inspection casework did not have supervisory review. The review team recommends that the Program ensure that NOV and licensee acknowledgment letters receive appropriate supervisory review and approval.

During the review period, inspector accompaniments were not routinely performed by the Program Manager on each of the staff on an annual basis as required by the IMPEP Handbook 5.6 criteria. A total of six accompaniments were conducted during the years of 2000 to 2004. These accompaniments covered only four inspectors. The review team was informed that all six Specialists were working at the Specialist 3 or Senior level and that all Specialists have been with the Program for five years or longer. The review team was further informed that it is the Program's philosophy to train and closely supervise new staff until they have achieved a level of confidence and competence to function independently. At that point each Specialist is held accountable for their work through their performance appraisal. The review team recommends that the Program develop and implement a process for conducting annual accompaniments of all radiation compliance inspectors by a supervisor.

The Program has adequate numbers and types of radiation survey instruments to support their inspection efforts. Calibrated survey instruments such as Geiger-Mueller meters, scintillation meters, micro-R meters and ion chambers were available onsite for use by the staff. Specific instruments are not assigned to staff, rather the Specialists sign-out the appropriate instrument as needed from the storage area. Survey Instruments and dosimeters are calibrated by the vendors, by contract with the South Carolina Department of Health and Environmental Control, and by Georgia Tech. Routine and expedited laboratory sample analysis is provided by Georgia Tech through a standard contract. The Environmental Radiation Program maintains a mobile laboratory.

The review team accompanied two materials inspectors on August 12 and 13, 2004 and observed their activities during inspections of two medical institutions requiring written directives. These accompaniments are identified in Appendix C. During the accompaniments, both inspectors demonstrated appropriate performance-based inspection techniques and knowledge of the regulations. The inspectors were well prepared and thorough in their reviews of the licensees' radiation safety programs. The inspections were adequate to assess radiological health and safety at the licensed facilities.

The Program's "Compliance and Enforcement Guide" does not address programmatic breakdown in licensee radiation safety programs and the handling of inspections with a large number of health and safety violations. A review of inspection casework noted two cases where multiple violations, including loss of management control of the radiation safety program, which should have focused Program staff's attention to the licensee's response to the NOV letter and placed the case in escalated enforcement space. The root cause of this is a lack of specific guidance on the handling of more complex compliance enforcement cases. The review team recommends that the Program revise and implement procedures to address the handling of cases where inspection findings reveal a systemic breakdown in a licensee's radiation safety program and when a large number of health and safety violations are identified.

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, be found satisfactory, but needs improvement.

3.4 Technical Quality of Licensing Actions

The review team interviewed license reviewers, evaluated the licensing process and examined licensing casework for 24 specific licenses. Licensing actions were evaluated for completeness, consistency, proper isotopes 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 documents; 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.

The 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: industrial radiography, medical (institution and private practice), nuclear pharmacy, academic broad scope, manufacturing and distribution, portable and fixed gauge, and veterinary. Types of licensing

actions selected for evaluation included two new licenses, 16 amendments (including one bankruptcy), four renewals and two terminations. Work from all reviewers was evaluated. A list of the licenses evaluated with case-specific comments can be found in Appendix D.

The review team found that the licensing actions were thorough, complete, consistent, of high quality and properly addressed health and safety issues. The use of templates by the staff also resulted in consistency between reviewers. Each license reviewer has proper signature authority to sign their own licensing actions. The casework evaluation indicated that the staff follows appropriate licensing guides during the review process to ensure that licensees submit information necessary to support their request. The review team found the checklists used for each license type to be comprehensive and incorporated notes to assist the staff with their review of the applications. Most of the time, deficiencies were addressed by letters and documented telephone conversations containing appropriate regulatory language.

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 Licensing Actions, be found satisfactory.

3.5 Technical Quality of Incident and Allegation Activities

In evaluating the effectiveness of the Program's actions in responding to incidents, the review team examined the Program's 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 Georgia files, and evaluated the casework and supporting documentation for 11 materials incidents. A list of the incident casework examined with the case-specific comments is included in Appendix E. The team also reviewed the Program's response to 10 allegations involving radioactive materials including four allegations referred to the State by NRC during the review period.

The Program had 37 reportable radioactive materials incidents during the review period. The incidents selected for review included the following: loss of radioactive material, damaged devices, leaking sources, medical events, and stolen gauges. The review team found that the Program's response to incidents was complete and comprehensive. Initial responses were prompt and well coordinated. The level of effort was commensurate with the health and safety significance. Staff communicated well with each other and provided back-up when needed. Inspectors were dispatched for onsite investigations when appropriate, and the Program took suitable enforcement action including coordination with the license reviewers and follow up, as appropriate.

The review team discussed the Program's incident procedure, file documentation, the State's equivalent to the Freedom of Information Act, NMED, and notification of incidents to the NRC with the Acting Program Manager and selected staff. The responsibility for initial response and follow up to incidents and allegations involving radioactive materials is shared between the Program and the Environmental Radiation Program. Written procedures exist for handling incidents, including a specific procedure for medical misadministrations. The Program does not use the NMED data entry software program to store events, instead, staff use a MS Word standardized form on the local area network to document the response to incidents and allegations. An information technology coordinator is responsible for e-mailing information to the NMED contractor on a monthly basis.

Program performance in timely reporting of incidents to NRC has degraded since the 2000 IMPEP review. Eight of the eleven incidents reviewed were significant events per Office of State and Tribal Programs (STP) Procedure SA-300 entitled "Reporting Material Events" and should have been reported to the NRC within 24 hours of notification to the Program by their licensee. Six of those eight significant events were not reported by the Program to the NRC in the 24-hour period. Five of these events were eventually sent to NRC via the NMED monthly upload of event data from the Program.

The sixth incident, a recent significant medical event unreported to NRC, was discovered during the IMPEP review. The review team determined the event to be a potential abnormal occurrence which may require reporting to Congress. This event illustrates that the Program is responding to the incidents, but not routinely reporting significant events to the NRC. The NRC is eventually receiving the event data, but not in a timely manner for significant events and potential abnormal occurrences. It is unclear from staff interviews if staff are familiar or use STP Procedure SA-300 guidance which is available. The team discussed this issue with the Program Manager and the staff member responsible for NMED data entry. Program staff did not participate in the Event Reporting training offered at the NRC Region II office in Atlanta in 2003. The root cause of this untimely reporting, by the Program, of significant events and abnormal occurrences stems from a need for additional staff training in this area. 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.

During the review period, eight allegations were referred to the Program by the NRC and six allegations were reported directly to the Program. The casework for ten allegations were reviewed. The review of the casework indicated that the Program took prompt and appropriate action in response to the concerns raised. The review team noted that in seven of the ten allegations reviewed there was no formal closure with the concerned individual. In addition, an allegation procedure was not available for staff to reference. The Program Manager noted each individual is responsible for responding to incidents and allegations and are reviewed explicitly on these items during the employee performance appraisal. The review team believes that the additional use of an allegation procedure rather than solely depending on appraisal elements would ensure consistent quality in overall performance of allegation efforts. The review team originally recommended that the Program develop an allegations procedure based on NRC's Management Directive 8.8, "Management of Allegations," including an explicit section on informing the concerned individual of the final disposition of the allegation. During the MRB discussions, the Program management reported that they had already developed a new allegation procedure in response to the draft IMPEP finding. The MRB recommended, and the team agreed, to eliminate this recommendation.

The team also noted that Georgia law requires that all public documents be made available for inspection and copying unless specifically exempted from disclosure under Georgia's Open Records Act. The Program makes every effort to protect an alleege's identity, but it cannot be guaranteed.

Based on the IMPEP evaluation criteria, the review team recommended that Georgia's performance with respect to the indicator, Technical Quality of Incident and Allegation Activities, be found satisfactory, but needs improvement. In light of the actions taken by the Program in regards to allegations, the MRB recommended, and the team agreed, that the team's finding with respect to this indicator be changed to satisfactory.

4.0 NON-COMMON PERFORMANCE INDICATORS

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

4.1 Compatibility Requirements

4.1.1 Legislation

Legislative authority to create an agency and enter into an Agreement with the NRC is granted 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, which 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, whether emitted from radionuclides or devices. Georgia requires a license for possession, and use, of all radioactive material including naturally occurring materials, such as radium, and accelerator-produced radionuclides.

The review team examined the procedures used in the State's regulatory process and found that 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. The NRC is provided with drafts of the proposed rules for review and comment before the public comment period. The proposed rules are forwarded to the Board for review and approval. The Board's calendar for rule adoption is tentatively set in January for that calendar year and all programs in the Department wishing to promulgate rules must get on the Board's calendar. After the proposed rules are adopted by the Board, they must be filed with the Secretary of State. Twenty days after filing the rules become final. Typically, rule promulgation requires 9 to 12 months, including drafting of revisions. The Department's Rules and Regulations are not subject to "sunset" laws.

The 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 STP's State Regulations Status Data Sheet. Since the previous IMPEP review, the Program adopted 17 amendments in two rule packages that became effective in June 2002 and July 2003.

Current NRC policy requires that Agreement States adopt certain equivalent regulations or legally binding requirements no later than three years after they become effective. The review team found that the Program currently has no overdue NRC amendments.

The Program will need to address the following regulation in upcoming rulemakings or by adopting alternative legally binding requirements:

- “Revision of the Skin Dose Limit,” 10 CFR Part 20 amendment (67 FR 16298) that became effective April 5, 2002. This amendment would be addressed by license condition until the State’s equivalent to the 10 CFR Part 35, “Training and Experience” amendment is promulgated. The two amendments will be promulgated as a single package.

The review team discussed the need for the Program to send the proposed license condition to NRC for review and comment. The license condition will serve as a legally binding requirement until the amendment is adopted. The team noted that Georgia has already adopted the major revision to 10 CFR Part 35, “Medical Use of Byproduct Material,” which is required for adoption by Agreement States no later than October 24, 2005.

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

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

4.2.1 Technical Staffing and Training

The Program reported that one staff member currently has authority to perform initial reviews and three others have authority to concur on SS&D casework. The three concurrence reviewers have extensive licensing experience, have completed the NRC’s SS&D workshop and have performed SS&D evaluations in the past. The current SS&D staffing level as described in this section is adequate for the needs of the Program. However, should the staff member with authority for initial reviews not be available, the Program would not be able to conduct SS&D evaluations in a timely fashion. The review team believes that the Program could alleviate this situation if other staff members could also be developed to perform initial reviews either by cross-training in Georgia, or by training visits to other Agreement States or to NRC for conducting primary reviews. The team recommends that the Program qualify one additional Specialist in SS&D evaluations to provide backup for the principal reviewer.

The review team found that the Program does not have formal qualification requirements for SS&D reviewers. However, the staff is sufficiently qualified at the present time to perform safety evaluations on the basis of the training courses taken, work experience, and attendance at the NRC SS&D workshop. The review team recommends that the Program develop written qualification requirements for SS&D reviewers.

Based on the IMPEP evaluation criteria, the review team recommended and the MRB agreed that the Program's performance with respect to the sub-indicator, Technical Staffing and Training, be found satisfactory.

4.2.2 Technical Quality of the Product Evaluation Program

The Program issued a total of 42 SS&D registry actions involving 15 licensees since the previous review in April 2000. The review team examined a total of 12 certificates, and their supporting documentation. The review included seven vendors, seven new registrations and five amendments. All of these cases were conducted by the one staff member who is fully qualified for SS&D reviews; and the certificates represented cases that were concurred on by three other staff members with training for SS&D approval. 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 Program follows the recommended guidance from the NRC SS&D training workshops and NUREG-1556, Volume 3. The depth and scope of the SS&D evaluations during the review period were adequate. The registrations clearly summarize the product evaluation to provide license reviewers with adequate information to license the possession and use of the product. The Program's SS&D review process produces a registry certificate that adequately addresses both the physical integrity of the product and the health and safety of the users, the public, and the environment.

The team noted that the SS&D licensees generally submitted applications that were adequate. The SS&D evaluator needed to request relatively little additional information. The review team did not identify any missed safety issues in the reviewed evaluations. The files were adequate and complete. The Program handles proprietary information by placing it in separate files which were readily available. However, the review checklists, particularly for the earlier cases during the review period, were not made part of the file, and thus, it was difficult to verify that the reviewer evaluated all the pertinent issues in the safety evaluation. This was discussed with the Program Manager and the State agreed to include review checklists with each evaluation.

The review team identified a potential good practice in noting that the Program registered a sealed source as part of a device evaluation. In common practice, if a source is not currently registered, the sealed source must be registered as part of the device and the registration certificate usually notes in the text that the source is approved for use in such an application only. However, the Program makes such source registrations prominent by placing a note on the first page in the sealed source designation place.

The Program completed the majority of the cases in a timely fashion, i.e. within six months after receiving the applications. Only two cases took an unusually long time, one and two years respectively. There were eight open cases at the time of the review, four cases were within the six month period, four were open for 22, 24, 40 and 41 months. The Program does not have a method for prioritization of the casework and the SS&D Action Log, presented to the review team, recorded only when the various actions had been completed, but did not list due dates. This was discussed with the Program Manager and the State agreed to more closely monitor the SS&D Action Log.

Based on the IMPEP evaluation criteria, the review team recommended and the MRB agreed that the Program's performance with respect to the sub-indicator, Technical Quality of the Product Evaluation Program, be found satisfactory.

4.2.3 Evaluation of Defects and Incidents Regarding SS&Ds

Utilizing NMED and the Program's response to the questionnaire, the review team reviewed incidents or failures regarding SS&D registered products during the review period. The team conducted two reviews: events within the boundaries of Georgia, and events nationwide involving the products of Georgia licensees.

The team reviewed ten of 37 events that occurred in Georgia within the period. None of the ten were related to SS&D failures.

There are 15 SS&D vendors in Georgia. Six of the 15 vendors were selected and events involving products from these six vendors were reviewed. Five of the vendors had a total of 12 reportable events, none were related to hardware failures. The sixth vendor, a distributor of medical equipment, had 45 events, 36 of these events (80 percent) which could be attributable to equipment malfunction. In addition, the vendor's SS&D file contained 14 letters from the licensee, dated between November 1, 2000, and April 29, 2004, reporting source leakage exceeding the statutory limit of 0.005 FCi.

The review team did not find evidence in the State's files that the Program analyzed the events, reviewed the issues, or followed up on the incidents. The review team noted that during interviews, the staff expressed the opinion orally, without references or data, that the device performance had improved during the review period from one failure per 1,000 applications to one failure per 2,000 applications and, therefore, no action from the Program was necessary.

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. 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).

The team noted that the Program conducted an inspection of a vendor on August 13 and 16, 2004. The previous inspection was conducted on May 26, 1998. At the time of this review, the Program had not yet issued a final inspection report.

The review team recommends that the Program's performance with respect to the sub-indicator, Evaluation of Defects and Incidents Regarding SS&Ds, be found unsatisfactory.

Overall, based on the IMPEP evaluation criteria and consideration of the three sub-indicators in total, the review team recommended and the MRB agreed that Georgia's performance with respect to the indicator, Sealed Source and Device Evaluation Program, be found satisfactory, but needs improvement.

4.3 Low-Level Radioactive Waste (LLRW) Disposal Program

In 1981, the NRC amended its Policy Statement, "Criteria for Guidance of States and NRC in Discontinuance of NRC Authority and Assumption Thereof by States Through Agreement" to allow a State to seek an amendment for the regulation of LLRW as a separate category. Those States with existing Agreements prior to 1981 were determined to have continued LLRW disposal authority without the need of an amendment. Although 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, 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 Georgia. Accordingly, the review team did not evaluate this indicator.

5.0 SUMMARY

As noted in Sections 3 and 4 above, the review team found Georgia's performance to be satisfactory for five performance indicators, and satisfactory but needs improvement for the performance indicators, Technical Quality of Inspections, and Sealed Source and Device Evaluation Program. Accordingly, the review team recommended and the MRB concurred in finding that the Georgia Agreement State program be found adequate, but needs improvement, and compatible with NRC's program. Based on the results of the current IMPEP review, the review team recommended and the MRB concurred that the next full review should be in approximately four years.

Below is a summary list of recommendations, as mentioned in earlier sections of the report, for evaluation and implementation, as appropriate, by the State.

RECOMMENDATIONS:

1. The team recommends that the Program update its inspection procedures to eliminate extensions of license inspection due dates. (Section 3.2)
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)
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)
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)
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)
6. The team recommends that the Program qualify one additional Specialist in SS&D evaluations to provide backup for the principal reviewer. (Section 4.2)
7. The review team recommends that the Program develop written qualification requirements for SS&D reviewers. (Section 4.2)
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)

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)

GOOD PRACTICE:

The review team identified a good practice, and the MRB agreed, in noting that the Program registered a sealed source as part of a device evaluation. In common practice, if a source is not currently registered, the sealed source must be registered as part of the device and the registration certificate usually notes in the text that the source is approved for use in such an application only. However, the Program makes such source registrations prominent by placing a note on the first page in the sealed source designation place.

LIST OF APPENDICES 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 and Device Casework Reviews
Attachment	October 27, 2005 Letter from James A. Sommerville Georgia's Response to Draft IMPEP Report

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

<u>Name</u>	<u>Area of Responsibility</u>
Lloyd Bolling, STP	Team Leader Technical Staffing and Training Compatibility Requirements
Sheri Minnick, Region I	Status of Materials Inspection Program Technical Quality of Inspections
Pamela Bishop, Oklahoma	Technical Quality of Licensing Actions
Duncan White, Region I	Inspector Accompaniments
Terry Brock, STP	Technical Quality of Incident and Allegation Activities
John Jankovich, NMSS	Sealed Source and Device Evaluation Program

APPENDIX B
GEORGIA ORGANIZATION CHARTS

ADAMS ML043370008

APPENDIX C

INSPECTION CASEWORK REVIEWS

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

File No.: 1

Licensee: Thermo Anderson

Location: Smyrna, GA

Inspection Dates: 6/9/03, 6/14/03

License No.: 1055-2G

Inspection Type: Routine, Announced

Priority: 3

Inspector: EJ

Comments:

- a) Previous inspection was conducted in June 1999. June 2003 inspection was overdue, as listed in Program's overdue inspection query.
- b) Report was issued 37 days late. Ten violations were issued in the NOV along with a paragraph in the cover letter on loss of management control of radiation safety program.
- c) Results of the inspection were not communicated to program management.
- d) Licensee response dated October 15, 2003 was misfiled, but found during the IMPEP review.
- e) No acknowledgment letter was sent.

File No.: 2

Licensee: Elekta Instruments

Location: Norcross, GA

Inspection Date: 1/30/01

License No.: 1153-1

Inspection Type: Routine, Announced

Priority: 3

Inspector: EJ

File No.: 3

Licensee: Roof Testing

Location: Lilburn, GA

Inspection Date: 7/2/02

License No.: 1448-1

Inspection Type: Initial, Unannounced

Priority: 5

Inspector: IB

Comment:

The review team discussed with Program staff potential options on source disposal.

File No.: 4

Licensee: Hopewell Designs

Location: Alpharetta, GA

Inspection Date: 5/2/02

License No.: 1434-1

Inspection Type: Initial, Announced

Priority: 3

Inspector: EJ

File No.: 5

Licensee: Applied Technical Services

Location: Garden City, GA

Inspection Date: 3/10/04

License No.: 896-1

Inspection Type: Routine, Unannounced

Priority: 1

Inspector: ED, LS

File No.:6

Licensee: Sowega Testing Service

Location: Leesburg, GA

Inspection Date: 6/25/01

License No.: 923-1

Inspection Type: Routine, Announced

Priority: 1

Inspector: RH

Comments:

- a) NOV issued on June 29, 2001 with two violations (lack of equipment inspection and radiographer refresher training). No response to the NOV received.
- b) Next inspection was done on January 27, 2003, longer than the one year frequency. When interviewed, the inspector stated that he extended the inspection date by six months due to good inspection history.
- c) The January 2003 follow-up inspection report, states that "no non-compliance items cited during the previous inspection." This is incorrect in that the previous inspection had two violations as stated above.
- d) On August 25, 2004, the licensee faxed in their reply to the NOV at the request of the Program, during the IMPEP review.

File No.: 7

Licensee: PET Imaging, LLC

Location: Ellaville, GA

Inspection Date: 10/24/01

License No.: 1429-1

Inspection Type: Initial, Announced

Priority: 2

Inspector: LP

File No.: 8

Licensee: Atlanta Oncology

Location: Atlanta, GA

Inspection Date: 3/22/01

License No.: 1178-1

Inspection Type: Routine, Announced

Priority: 1

Inspector: LP, CS

File No.: 9

Licensee: Cartersville Medical Center

Location: Cartersville, GA

Inspection Date: 8/12/04

License No.: 796-1

Inspection Type: Routine, Unannounced

Priority: 3

Inspector: LS

File No.: 10

Licensee: Hurst Boiler & Welding Company

Location: Coolidge, GA

Inspection Date: 3/24/03

License No.: 918-1

Inspection Type: Routine, Unannounced

Priority: 2

Inspector: RH

Comments:

- a) A NOV was issued on April 10, 2003 (lack of equipment inspections and semi-annual inspections). Inspection due date extended to June 2004, which is contrary to the Program's inspection procedures.
- b) No reply to the NOV could be found in the files.

File No.: 11

Licensee: Palmyra Medical Center

License No.: 424-1

Location: Albany, GA
Inspection Date: 10/20/03

Inspection Type: Routine, Unannounced
Priority: 3
Inspector: RH

Comment:

A NOV was issued in November 2003, however no reply to the NOV could be located in the files. On August 25, 2004, during the review, the Program had the licensee fax in the reply to the NOV.

File No.: 12

Licensee: Houston Medical Center
Location: Warner Robins, GA
Inspection Date: 6/14/04

License No.: 260-1
Inspection Type: Routine, Unannounced
Priority: 3
Inspector: RH

Comments:

- a) A NOV was issued on June 21, 2004 with 14 violations and a paragraph in the cover letter on concern over management control of the radiation safety program. Results of the inspection were not communicated to Program management.
- b) Licensee replied to the NOV in a June 30, 2004 letter, refuting four of the violations. On August 4, 2004 a standard acknowledgment letter was sent without discussion of refuted violations.

File No.:13

Licensee: Northside Hospital
Location: Atlanta, GA
Inspection Date: 1/27/04

License No.: 39-1
Inspection Type: Routine, Announced
Priority: 1
Inspector: IB

File No.: 14

Licensee: St. Francis Hospital
Location: Columbus, GA
Inspection Date: 3/17/03

License No.: 631-2
Inspection Type: Routine, Unannounced
Priority: 3
Inspector: LP

File No.: 15

Licensee: SE Medical Center
Location: Brunswick
Inspection Date: 8/6/02

License No.: 131-1
Inspection Type: Routine, Announced
Priority: 3
Inspector: ED

INSPECTOR ACCOMPANIMENTS

The following inspection accompaniments were made as part of the onsite IMPEP review:

Accompaniment No.: 1

Licensee: Cartersville Medical Center
Location: Cartersville, GA
Inspection Date: 8/12/03

License No.: 796-1
Inspection Type: Routine, Unannounced
Priority: 3

Inspector: LS

Accompaniment No.: 2
Licensee: Stephens County Hospital
Location: Toccoa, GA
Inspection Date: 8/13/04

License No.: 496-1
Inspection Type: Routine, Unannounced
Priority: 3
Inspector: IB

APPENDIX D

LICENSE CASEWORK REVIEWS

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

File No.: 1

Licensee: American Cardiovascular Research Institute
Location: Norcross, GA
Date issued: 9/13/02

License No.: GA 1391-1
Amendment No.: 6
Type of Action: Amendment
License Reviewer: IB

Comments:

- a) The attachment to the August 23, 2002 letter was not specifically tied down.
- b) The licensee requested that an isotope be approved for use in rats in both the August 23, 2002 and September 13, 2002 letters, however, the use in Condition Q only mentioned rabbits and pigs.
- c) The licensee provided additional information in a letter dated September 13, 2002. The license file did not contain a deficiency record fully documenting the reviewer's request for additional information.

File No.: 2

Licensee: Grady Memorial Hospital
Location: Atlanta, GA
Date issued: 11/14/02

License No.: GA 258-2
Amendment No.: 8
Type of Action: Renewal
License Reviewer: IB

Comment:

- a) No documentation of a review of compliance history prior to issuance of the renewal.

File No.: 3

Licensee: Oconee Regional Cancer Center
Location: Dublin, GA
Date issued: 10/3/03

License No.: GA 1227-1
Amendment No.: 10
Type of Action: Amendment
License Reviewer: REH

File No.: 4

Licensee: Athens Isotope, Inc.
Location: Athens, GA
Date issued: 5/10/04

License No.: GA 1386-1
Amendment No.: 4
Type of Action: Amendment
License Reviewer: LP

File No.: 5

Licensee: Georgia Childhood Lead Poisoning Prevention Center

Location: Decatur, GA

Date issued: 6/29/04

License No.: GA 1261-1

Amendment No.: 7

Type of Action: Renewal

License Reviewer: IB

Comments:

- a) The application for renewal was signed by the licensee's Assistant Director, however, the license tie down for the application says it was signed by a different person, the licensee's radiation safety officer.
- b) No documentation of a review of compliance history prior to issuance of the renewal.

File No.: 6

Licensee: Applied Technical Services, Inc.

Location: Marietta, GA

Date issued: 6/23/04

License No.: GA 896-1

Amendment No.: 43

Type of Action: Amendment

License Reviewer: LS

Comment:

Three obsolete devices were still listed on the license without restriction, despite the fact that they did not meet current regulatory standards.

File No.: 7

Licensee: Cardinal Health

Location: Doraville, GA

Date issued: 6/9/04

License No.: GA 467-1MD

Amendment No.: 77

Type of Action: Amendment

License Reviewer: LP

File No.: 8

Licensee: Palmyra Medical Center.

Location: Albany, GA

Date issued: 12/19/03

License No.: GA 424-1

Amendment No.: 25

Type of Action: Amendment

License Reviewer: REH

File No.: 9

Licensee: Douglas Medical Group.

Location: Douglasville, GA

Date issued: 5/24/04

License No.: GA 1503-1

Amendment No.: 1

Type of Action: Amendment

License Reviewer: LS

File No.: 10

Licensee: P.E.T. Imaging, LLC

Location: Ellaville, GA

Date issued: 4/28/04

License No.: GA 1429-1

Amendment No.: 3

Type of Action: Amendment

License Reviewer: LP

Comment:

A letter dated March 24, 2004 containing information pertinent to the amendment was not tied down.

File No.: 11

Licensee: J. B. Glover (Glover Machine Works)

Location: Marietta, GA

Date issued: 4/9/04

License No.: GA 362-1

Amendment No.: 7

Type of Action: Termination

License Reviewer: REH

Comments:

- a) Copies of leak tests were not requested before termination of the license, despite leak tests not having been conducted on sources in storage since 1989.
- b) A review of receipts and disposals was not conducted prior to termination.

File No.: 12

Licensee: John D. Archbold Memorial Hospital

Location: Thomasville, GA

Date issued: 10/10/03

License No.: GA 78-1

Amendment No.: 35

Type of Action: Amendment

License Reviewer: REH

File No.: 13

Licensee: Georgia Power

Location: Atlanta, GA

Date issued: 4/19/04

License No.: GA 40-1

Amendment No.: 26

Type of Action: Amendment

License Reviewer: LP

Comment:

Receipt by transferee(s) of transferred sources was not confirmed by reviewer when a facility was closed and the location removed from the license. A courtesy e-mail from the licensee stating that shipment of the sources had taken place was in the file.

File No.: 14

Licensee: Honeywell International, Inc.

Location: Deluth, GA

Date issued: 6/17/04

License No.: GA 832-1G

Amendment No.: 40

Type of Action: Renewal

License Reviewer: EJ

Comment:

No documentation of a review of prior compliance history before issuance of a renewal.

File No.: 15

Licensee: JanX

Location: Parma, MI

Date issued: 1/29/04

License No.: GA 1369-1

Amendment No.: 3

Type of Action: Renewal

License Reviewer: LP

Comment:

No documentation of a review of prior compliance history before issuance of a renewal.

File No.: 16

Licensee: Kennestone Cardiovascular
Location: Marietta, GA
Date issued: 6/16/04

License No.: GA 1416-1
Amendment No.: 4
Type of Action: Amendment
License Reviewer: LS

File No.: 17

Licensee: Radiocat, LLC
Location: Marietta, GA
Date issued: 12/11/02

License No.: GA 1312-1
Amendment No.: 6
Type of Action: Amendment
License Reviewer: LS

File No.: 18

Licensee: Southern Regional Medical Center
Location: Riverdale, GA
Date issued: 6/25/03

License No.: GA 1039-1
Amendment No.: 22
Type of Action: Amendment
License Reviewer: LP

File No.: 19

Licensee: Emory Adventist Hospital
Location: Smyrna, GA
Date issued: 8/6/03

License No.: GA 395-1
Amendment No.: 25, 26
Type of Action: Amendment
License Reviewer: LS

Comment:

Item 3, on the first page of the license, should be updated each time the license is renewed or amended.

File No.: 20

Licensee: S & M E, Inc.
Location: Savannah, GA
Date issued: 4/11/03

License No.: GA 981-1
Amendment No.: 6
Type of Action: Termination
License Reviewer: ED

Comment:

Copies of leak tests of sealed sources were not requested before termination of the license.

File No.: 21

Licensee: Durango Paper Company
Location: St. Mary's, GA
Date issued: 12/19/02

License No.: GA 582-1
Amendment No.: 9
Type of Action: Amendment
License Reviewer: ED

File No.: 22

Licensee: Longview Inspection
Location: Savannah, GA
Date issued: 6/28/04

License No.: GA 1115-1
Amendment No.: 2
Type of Action: Amendment
License Reviewer: ED

File No.: 23

Licensee: Medical College of Georgia Health, Inc.

Location: Augusta, GA

Date issued: 6/29/00

License No.: GA 1110-1

Amendment Nos.: 0

Type of Action: New

License Reviewer: ED

File No.: 24

Licensee: Williamette Industries

Location: Savannah, GA

Date issued: 5/18/00

License No.: GA 1109-1

Amendment No.: 0

Type of Action: New

License Reviewer: ED

APPENDIX E

INCIDENT CASEWORK REVIEWS

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

File No.: 1

Licensee: McGill Schnabel
Site of Incident: Barrett Parkway, GA
Date of Incident: 6/15/00
Investigation Date: 6/15/00

License No.: 1360-1
Incident Log No.: GA-2000-13i
Type of Incident: Damaged Gauge
Type of Investigation: Written Report

File No.: 2

Licensee: St. Joseph's Hospital
Site of Incident: Savannah, GA
Date of Incident: 1/17/01
Investigation Date: 1/19/01

License No.: GA 48-1
Incident Log No.: GA-01-01i
Type of Incident: Medical Event
Type of Investigation Type: Site

File No.: 3

Licensee: Non-licensee
Site of Incident: Hartsfield International Airport
Date of Incident: 2/3/01
Investigation Date: 2/3/01

License No.: NA
Incident Log No.: GA-2001-04i
Type of Incident: Damaged package
Type of Investigation: Site

File No.: 4

Licensee: Nycomed Amersham
Site of Incident: Atlanta, GA
Date of Incident: 6/25/01
Investigation Dates: 7/2/01, 7/11/01

License No.: GA-677-1
Incident Log No.: GA-2001-010i
Type of Incident: Contaminated Package
Type of Investigation: Written Report

File No.: 5

Licensee: R&D Testing and Drilling
Site of Incident: Atlanta, GA
Date of Incident: 8/26/01
Investigation Dates: 9/11/01, 9/12/01

License No.: GA-1075-1
Incident Log No.: GA-2001-17i
Type of Incident: Stolen Gauge
Type of Investigation: Telephone

Comment:

Significant event not reported by Program to NRC within the 24-hour schedule.

File No.: 6

Licensee: Northside Hospital Cancer Center
Site of Incident: Atlanta, GA
Date of Incident: 6/10/02
Investigation Date: 6/24/02

License No.: GA-39-2
Incident Log No.: GA-2002-17i
Type of Incident: Medical Event
Type of Investigation: Telephone

Comment:

Significant event not reported by Program to NRC within the 24-hour schedule.

File No.: 7

Licensee: Promina Gwinnett Health System
Site of Incident: Atlanta, GA
Date of Incident: 8/28/02
Investigation Date: 9/18/02

License No.: 677-1
Incident Log No.: GA-2002-23i
Type of Incident: Lost Material
Type of Investigation: Site

Comment:

Significant event not reported by Program to NRC within the 24-hour schedule.

File No.: 8

Licensee: Volunteer NDT Corporation
Site of Incident: Cartersville, GA
Date of Incident: 12/4/02
Investigation Date: 12/30/02

License No.: TN-R033139-C04
Incident Log No.: GA-2003-04i
Type of Incident: Stuck Source
Type of Investigation: Telephone

File No.: 9

Licensee: Gallet & Associates
Site of Incident: Atlanta, GA
Date of Incident: 12/12/03
Investigation Date: 12/12/03

License No.: GA-1316-1
Incident Log No.: GA-2003-032i
Type of Incident: Stolen Gauge
Type of Investigation: Telephone

File No.: 10

Licensee: Geotechnical & Environmental Services
Site of Incident: Albany, GA
Date of Incident: 3/3/04
Investigation Date: 4/1/04

License No.: GA-1388-1
Incident Log No.: GA-2004-07i
Type of Incident: Stolen Gauge
Type of Investigation: Written Report

Comment:

Significant event not reported by Program to NRC within the 24-hour schedule.

File No.: 11

Licensee: Southern Regional Medical Center
Site of Incident: Riverdale, GA
Date of Incident: 7/1/04
Investigation Date: 7/1/04

License No.: GA-1039-1
Incident Log No.: GA-2004-22i
Type of Incident: Medical Event
Type of Investigation: Written Report

Comments:

- a) Significant event not reported by Program to NRC within the 24-hour schedule.
- b) A potential abnormal occurrence reportable to Congress by NRC.

APPENDIX F

SEALED SOURCE AND DEVICE REVIEWS

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

File No.: 1

Registry No.: GA-269-S-103-S

Manufacturer: Electra Instruments, Inc.

Date Issued: 3/19/01

SS&D Type: Medical
Model No.: 43047 and 43685

File No.: 2

Registry No.: GA-269-D-102-S

Manufacturer: Electra Instruments, Inc.

Date Issued: 3/26/01

SS&D Type: Medical
Model No.: Leksell Gamma System

Comment:

The application or the incoming letter, requesting addition of source Models 43047 and 43685, is not listed in the references. However, the cover letter, transmitting the amendment from the Program to the licensee, refers to a request dated February 23, 2001.

File No.: 3

Registry No.: GA-1138-D101-S

Manufacturer: Hopewell Designs, Inc.

Date Issued: 7/19/01

SS&D Type: Industrial
Model No.: G10 Series

Comment:

No checklist in the file.

File No.: 4

Registry No.: GA-1138-D-101-S

Manufacturer: Hopewell Designs, Inc.

Date Issued: 3/25/03

SS&D Type: Industrial
Model No.: G10 Series

Comments:

- a) A checklist is present in the file; but only one page is completed. The checklist is not dated or signed.
- b) The material and construction of the label are not in the application and no deficiency question was asked.

File No.: 5

Registry No.: GA-1138-D-102-S

Manufacturer: Hopewell Designs, Inc.

Date Issued: 9/29/03

SS&D Type: Industrial
Model No.: GC60

File No.: 6

Registry No.: GA-1073-D-102-S

Manufacturer: IMS Measuring Systems, Inc.

Date Issued: 1/11/01

SS&D Type: Industrial
Model No.: 5246-XX Series

File No.: 7

Registry No.: GA-596-D-104-G

Manufacturer: Metso Automation USA, Inc.

Date Issued: 6/18/01

SS&D Type: Industrial

Model No.: 8210

Comment:

The first page states that the registration was “[a]mended in its entirety for a name change of the company, but only the first page was updated, and consequently, the Reference Section does not list current correspondence since 1981 and 1982.

File No.: 8

Registry No.: GA-1115-D-101-S

Manufacturer: Novoste Corp.

Date Issued: 8/4/00

SS&D Type: Medical

Model No.: Beta-Cath System, A1000 Series

Comment:

Important training issues were emphasized in the text by using bold fonts. In SS&D practice, bold fonts are customarily used to show changes from one amendment to another. Thus, in this case using bold fonts to highlight important issues may lead the reader to assume that the bold text was added as an amendment. Alternative highlighting methods, such as capitalization, may alleviate the situation.

File No.: 9

Registry No.: GA-1208-D-101-G

Manufacturer: Paper Making Control Service, Inc.

Date Issued: 3/1/04

SS&D Type: Industrial

Model No.: MV Series

File No.: 10

Registry No.: GA-1148-D-101-S

Manufacturer: Proxima Therapeutics, Inc.

Date Issued: 9/11/01

SS&D Type: Medical

Model No.: GliaSite RTS System

File No.: 11

Registry No.: GA-1148-D-101-S

Manufacturer: Proxima Therapeutics, Inc.

Date Issued: 10/7/03

SS&D Type: Medical

Model No.: GliaSite RTS System

File No.: 12

Registry No.: GA-716-D-103-S

Manufacturer: Scan Technologies

Date Issued: 5/8/01

SS&D Type: Industrial

Model No.: 9200 Series, 9500 Series

ATTACHMENT

October 27, 2004 Letter from James A. Sommerville
Georgia's Response to the Draft IMPEP Report

ADAMS: ML043100517