(Georgia, final letter, 1996)
DATED: JULY 8, 1996 SIGNED BY: HUGH L. THOMPSON, JR.

Mr. Harold F. Reheis, Director
Environmental Protection Division
Georgia Department of Natural Resources
East Floyd Towers, 1152-East
205 Butler Street, S.E.
Atlanta, GA 30334

Dear Mr. Reheis:

On June 21, 1996, 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 considered and concurred with the review team's recommendation that the Georgia program be found adequate to protect public health and safety and compatible with NRC's regulatory program. Based on State performance, the next IMPEP review will be scheduled in four years, unless program concerns develop that require an earlier evaluation.

Section 5 (page 18) of the enclosed final report presents the IMPEP team's recommendations. We request your evaluation and response to those recommendations within 30 days from receipt of this letter.

I appreciate the courtesy and cooperation extended to the IMPEP team during the review.

Sincerely,

Hugh L. Thompson, Jr.
Deputy Executive Director for
Nuclear Materials Safety,
Safeguards,and Operations Support

Enclosure:
As stated

cc: James L. Setser, Chief
Program Coordination Branch
Thomas E. Hill, Manager
Radioactive Materials Program

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Environmental Protection Division
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Thomas E. Hill, Manager
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bcc: Chairman Jackson
Commissioner Rogers
Commissioner Dicus

Distribution: See next page.

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF GEORGIA AGREEMENT STATE PROGRAM

February 12-16, 1996

FINAL REPORT

Office of State Programs

U.S. Nuclear Regulatory Commission

1.0 INTRODUCTION

This report presents the results of the review of the Georgia radiation control program. The review was conducted during the period February 12-16, 1996, by a review team comprised of technical staff members from the Nuclear Regulatory Commission (NRC) and the Agreement State of Tennessee. Team members are identified in Appendix A. The review was conducted in accordance with the "Interim Implementation of the Integrated Materials Performance Evaluation Program Pending Final Commission Approval of the Statement of Principles and Policy for the Agreement State Program and the Policy Statement on Adequacy and Compatibility of Agreement State Programs," published in the Federal Register on October 25, 1995 and the September 12, 1995, NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." Preliminary results of the review, which covered the period November 1993 to February 1996, were discussed with Georgia management on February 16, 1996.

A draft of this report was issued to Georgia for factual comment on March 28, 1996. The State of Georgia responded in a letter dated April 22, 1996 (Attachment 1) and the comments were incorporated into the proposed final report. The Management Review Board (MRB) met on June 21, 1996, to consider the proposed final report. The MRB concurred in the team's overall recommendation and found that the Georgia radiation control program was adequate to protect public health and safety and was compatible with the NRC's regulatory program.

The radiation control program is located in the State's Department of Natural Resources (DNR). Within DNR, the Georgia radiation control program is administered by a Program Manager in the Environmental Protection Division. An organization chart is included as Appendix B. The Georgia program regulates approximately 500 individual specific licenses. The review focused on the materials program as it is carried out under the Section 274b. (of the Atomic Energy Act of 1954, as amended) Agreement between the NRC and the State of Georgia.

In preparation for the review, a questionnaire addressing the common and non-common indicators was sent to the State on January 3, 1996. Georgia provided its response to the questionnaire on January 24, 1996. A copy of that response is included as Appendix C to this report.

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

Section 2 below discusses the State's actions in response to recommendations made following 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 indicators, and Section 5 summarizes the review team's findings and recommendations.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

The previous routine review concluded on November 5, 1993, and the results were transmitted to Mr. Harold F. Reheis, Director, Environmental Protection Division, Department of Natural Resources, on February 2, 1994. NRC visited the program again in November 1994 to evaluate the status of open issues identified in the 1993 review. The results of this visit were transmitted to Mr. Thomas E. Hill, the Radioactive Materials Program Manager, on December 8, 1994.

2.1 Status of Items Identified During the 1993 Routine Review and 1994 Review Visit

The November 1994 review visit evaluated the status of two recommendations identified as part of the 1993 review. The IMPEP team looked at each item again to determine whether or not the current Georgia program had taken additional actions to close open recommendations. These recommendations are summarized below:

(1) The 1993 reviewer recommended that the State provide its schedule for completing all actions needed to promulgate any overdue regulations and other regulations needed for the purposes of compatibility.

Current Status: Georgia revised a number of its regulations in March and October 1994. The March 1994 revision was extensive. It included: Emergency Planning (equivalent to 10 CFR Parts 30, 40 and 70), Standards for Protection Against Radiation (Part 20), Incident Notification (Parts 20, 30, 31, 34, 39, 40, and 70), Medical Quality Management (Part 35), Irradiators (Part 36), and Decommissioning Recordkeeping (Parts 30, 40, and 70). The October 1994 revision promulgated the Safety Requirements for Radiographic Equipment (Part 34) Rule. The 1994 review visit had withheld a finding of compatibility pending a review of the Part 20 regulation by an Office of State Programs' contractor. However, because Georgia has adopted the Part 20 regulations, compatibility findings will not be withheld pending completion of the contractor's analysis. If it is later found that additional changes are required, these concerns will be transmitted to the State. Therefore, with these revisions, the State's regulations are found to be compatible with NRC's through the remainder of calendar year 1996. This recommendation is closed.

(2) The 1993 reviewer recommended that the State continue with plans to revise its administrative procedures.

Current Status: Since the IMPEP review is performance-based and no significant concerns were noted, no further followup of this issue is needed. 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 include: (1) Status of Materials Inspection Program, (2) Technical Staffing and Training, (3) Technical Quality of Licensing Actions, (4) Technical Quality of Inspections, and (5) Response to Incidents and Allegations.

3.1 Status of Materials Inspection Program

The team focused on four factors in reviewing this indicator: (1) inspection frequency, (2) overdue inspections, (3) initial inspection of new licenses, and (4) timely dispatch of inspection findings to licensees.

Review of the State's inspection priorities showed that the State's inspection frequencies for various types or groups of licenses are, with few exceptions, at least as frequent as similar license types or groups listed in the frequency schedule in the NRC Inspection Manual Chapter (IMC) 2800. Although the State had not incorporated some of the April 1995 revisions to IMC 2800, with the exception of the two instances noted below, the State is conducting inspections at the same frequency or more frequently than NRC currently requires. Examples include: (1) teletherapy license inspections are conducted as a Priority 1 in Georgia vs. NRC's change to Priority 3; (2) portable gauges, which Georgia considers as a Priority 3, are treated by NRC as a Priority 5; and (3) a number of the measuring systems and analytical instruments which Georgia codes as a Priority 6, NRC considers as a Priority 7. When these preliminary findings were raised with the Georgia staff, the State indicated it would be scheduling a staff meeting to discuss the NRC's changes to IMC 2800 in more detail.

Two categories were noted for which the NRC revisions to IMC 2800 were more conservative than the Georgia frequencies. In one of the two, Georgia was already aware of the NRC change affecting nuclear laundries (Priority 3 changed to Priority 2), but the State had extended the inspection cycle for its only nuclear laundry based on the licensee's strong program and favorable compliance history. The IMPEP reviewer nonetheless recommended that Georgia make the priority change in its inspection tracking system, and the State did so during the course of the review. (This change applies to the nuclear laundry category in general, but does not preclude Georgia from extending the inspection schedule for individual licensees).

The second area in which Georgia's inspection priorities were found to be less conservative was for Sr-90 eye applicators. The revised IMC 2800 specifies an inspection Priority of 3, whereas Georgia's tracking system indicated these licensees were Priority 4. Once again, the IMPEP team recommended that Georgia make the necessary revision in its tracking system, and the State staff made the change during this review. Of seven eye applicator licensees, the review team noted that six had been inspected since the time of the last review.

In its response to the questionnaire, Georgia indicated that it had no overdue inspections at any time during the review period. The review team confirmed this by reviewing several printouts and statistics supplied by the State for all inspections completed in 1994, 1995, and early 1996. The number of completed inspections was compared with the number projected for the category based on its inspection frequency. In addition, a 100% audit was performed of industrial radiographers and remote afterloaders (both of which are Priority 1 categories). This audit confirmed that 9 of the 11 radiographers had been inspected at least once in the past 13 months, and the other 2 were new licenses which were not yet due for initial inspections. A similar review of the 11 afterloader licenses confirmed that inspections had been conducted in all instances within the past 15 months.

With respect to initial inspections of new licensees, the team reviewed a list of 34 new licenses issued in the period from January 1994 to July 1995. IMC 2800 provides guidance that new licenses are to be inspected within 6 months of receipt of material, within 6 months of beginning licensed activities, or within 12 months of license issuance, whichever comes first.

The review determined that 29 of the 34 new licenses had been inspected at least once, and that 24 of the 29 had been inspected within 7 months of license issuance. The other five were inspected within 11 months of license issuance. However, five initial inspections were scheduled but not yet conducted. Georgia identified three other licenses issued before 1994 that were beyond the above intervals. Two of the three were private practice physicians; and the other was a portable gauge license. These licenses were issued in a period between November 1991 and October 1993. The Georgia inspectors remained in frequent telephone contact with these new licensees, although they had accepted the licensees' statements that no licensed material and no operations involving the material were underway, without inspecting them. The IMPEP team recommended that the State implement IMC 2800 guidance in this area, which would require an inspection of all new licenses within a year of license issuance.

The team also evaluated the State's timeliness in issuing inspection findings. Using a State printout that showed inspection completion dates and report issuance dates, the IMPEP team tabulated the turnaround time for all 340 inspections completed since January 1994. The inspection findings were issued to licensees in an average of 11 days, well within NRC's 30 day goal. In fact, in 93 percent of the inspections, the findings were issued within 30 days. Some of the Georgia staff members credited their strong performance in this area to the State's commitment to issue findings within 15 working days.

The State reported in its response to the questionnaire that 106 requests for reciprocity were received during the review period, of which 8 were from industrial radiographers and 96 from portable gauge users. The State reported performing five reciprocity inspections. Two reciprocity inspections were of industrial radiographers and three were for users of portable gauging devices. It also reported conducting five field inspections on industrial radiography licensees. The State is beginning a protocol that would allow reciprocity filings to be submitted by electronic mail.

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

3.2 Technical Staffing and Training

Issues central to the evaluation of this indicator include: (1) the radioactive materials program staffing level, (2) the technical qualifications of the staff, (3) technical staff training, and (4) staff attrition. To evaluate these issues, the review team examined the State's questionnaire responses relative to this indicator, interviewed DNR management and staff, and considered any possible backlogs in licensing or compliance actions.

The Radioactive Materials Program includes one Program Manager, two clerical support staff members, an Environmental Radiation Specialist who performs administrative and computer support functions for the program, five Radiological Health Specialists based in Atlanta and another based in Brunswick. At the time of the review, another Radiological Health Specialist position was vacant, but the Program Manager indicated that a selection had been made and an offer was expected shortly. When this position is filled, the program will be fully staffed with a total of 11 individuals (10 in Atlanta). This will provide adequate staffing for a program of this size.

The program recently adopted a team-oriented approach to licensing, inspection, and event response, which resulted in a more complete integration of these functions by the Radiation Health Specialists (also called

Associates). The sealed source and device evaluations, which currently comprise only a small element of the State's activities are assigned to other individuals, although there are plans to train the new recruit (who has a Nuclear and Mechanical Engineering background) to work in this area.

With respect to incoming licensing work, the cases are assigned in turn to the various Associates. Upcoming inspections are reviewed on a semi-annual basis, and the Associates draft their own schedules within a three-month window of the assigned next inspection date. Each of the Associates has full signature authority for licensing and inspection activities, based on his or her educational and practical experience. This reflects a policy change implemented in 1995 by the Program Manager as part of the team approach, which is being used more widely in Georgia State government.

The IMPEP team readily appreciated some of the benefits of this approach (i.e., improved report timeliness, more individual accountability for quality performance, employee empowerment), but was initially concerned that the practice might open the possibility that assignments could be made to individuals not well-qualified to handle them. However, this possibility is minimized since the Associates are Subject Matter Specialists for various categories of licenses. This allows other Associates to rely on the specialists to provide them supplemental technical support for licensing actions and inspections outside their own areas of expertise. In addition, the Program Manager indicated that he is continuing to spot-check a percentage of the inspection reports, and would monitor the assignments of any new hirees until they had demonstrated the same levels of technical understanding as the current staff.

This team approach was feasible since all current technical staff members had met (or been waived on a case-by-case basis from) the qualification requirements for licensing and inspection staff including: the Inspection Procedures course, the Diagnostic and Therapeutic Nuclear Medicine course, Safety Aspects of Industrial Radiography, Teletherapy and Brachytherapy, Safety Aspects of Well Logging, Health Physics Technology, and the Licensing Practices and Procedures course. The State's response also indicated that any new reviewers' licensing actions would be closely supervised by senior staff, and that new inspectors would be accompanying more senior inspectors until they had met the qualification requirements.

The technical staff has Bachelor's and Master's level degrees in biology, health physics, or related disciplines, and many have extensive experience in other regulatory programs or radiological chemistry. Both of the two individuals added to the program during this review period, had been part of this program in past years. One accepted an internal transfer to the State's Water Monitoring Program, but returned to the radiation control program in May 1994. The second individual came to the Georgia program from the South Carolina radiation control program, left State government to pursue private consulting and returned to the Georgia program in May 1995.

The two returnees to the program offset two losses that took place in late 1994 and mid-1995. According to the Program Manager, these individuals left to attend more closely to family matters. Although the program was understaffed by one, at most times during this review cycle, minimal adverse program impacts were observed (no licensing or inspection backlogs) due to the extra efforts of staff.

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

3.3 Technical Quality of Licensing Actions

The review team examined casework and interviewed the reviewers for 16 specific licenses. Licensing actions were reviewed for completeness, consistency, proper radionuclides and quantities used, qualifications of authorized users, adequate facilities and equipment, and operating and emergency procedures sufficient to establish the basis for licensing actions. Casework was reviewed 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 authorities. Licenses were reviewed for accuracy, appropriateness of the license and of its conditions and tie-down conditions, and overall technical quality. The files were checked for retention of necessary documents and supporting data.

The cases were selected to provide a representative sample of licensing actions which had been completed in the review period and to include work by all reviewers. The cross-section sampling included 16 of the State's major licenses and included the following types: device servicing, nuclear medicine, teletherapy, academic broad scope, nuclear pharmacy, research and development, device manufacturing and distribution, and industrial radiography (temporary jobsites). Licensing actions reviewed included five new licenses, six renewals, five amendments, and five terminations. A list of these licenses with case-specific comments can be found in Appendix D.

The review team found that the licensing actions were generally thorough, complete, consistent, and of acceptable quality with health and safety issues properly addressed. A basic license template resides on the program's local access network (LAN) and each staff member has access via personal computer. The Southern Regional Office in Brunswick is also connected to the LAN which facilitates the transfer of documents and general communications. Standard and special license tie-down conditions were almost always stated clearly, backed by information contained in the file, and inspectable. The licensee's compliance history appears to be taken into account when reviewing renewal applications, however, this was not always documented. Reviewers are authorized to independently evaluate licensing actions and sign their own licenses. Although there is no routine supervisory or peer review, a select sample of the completed licensing actions are reviewed by the Program Manager. The review team verified that supervisory involvement was evident in a select number of licensing actions during the review of licensing casework. It should be noted, however, that these cases were completed before the current team approach was established. The staff currently utilizes NRC licensing guides, however, checklists are not routinely used. No potentially significant health and safety issues were identified.

The review team found that the current staff is well trained and experienced in a broad range of licensing activities. Licensing cases are assigned to the staff on a rotating basis. The licensing program is structured to identify one prime contact person and one backup person for each category of license. This approach effectively utilizes the staff's education, experience and interest in specific license categories. These individuals work together to track policy and guidance documents, develop internal procedures, review NRC regulations, draft Georgia regulations and evaluate licensing actions in their assigned license categories. Other staff members consult with the prime and backup contacts when complex or unique issues arise. These assignments are rotated periodically to give each individual an opportunity to work on all categories of licenses.

The State is to be commended for its efforts in establishing the first certification testing program for industrial radiographers in the South East United States. To date over 100 radiographers from Georgia and surrounding States have taken the examination and approximately 90 of them have received a passing grade.

The casework was reviewed for adequacy and consistency with the NRC procedures, and to determine if the State's procedures were being followed and implemented. Discussions were held with the license reviewers concerning the casework evaluated during the review, and to determine their understanding and implementation of the procedures. It was determined that the license reviewers were implementing the State's licensing procedures with the exception of the comment on documenting reviews of licensees' compliance histories noted above.

The IMPEP team also reviewed a copy of the State's Strategic Plan which identifies the various program goals for the upcoming year, and lays out assignments related to licensing, inspections, regulations development, and guidance documents among the Associates and the Program Manager. Soon-to-be-completed licensing guides are expected to provide even greater standardization and consistency to the licensing process.

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

3.4 Technical Quality of Inspections

The team reviewed the inspection reports, enforcement documentation, and the database information for 18 materials inspections conducted during the review period. The casework included all of the State's materials inspectors and covered a sampling of the higher priority categories of license types as follows: two institutional medical with therapy, three private medical with therapy, one private medical with brachytherapy and afterloading, one teletherapy, one eye applicator, one mobile nuclear medicine, two nuclear pharmacies, one broad academic, one fixed location industrial radiography, two temporary location industrial radiography including a field site inspection under reciprocity, two service companies under reciprocity, and one portable gauge. Appendix E provides a list of the inspection cases reviewed in depth with case-specific comments.

The State has developed inspection procedures and inspection report forms based upon the NRC Inspection Manual Chapter (IMC) 2800 and Inspection Procedure (IP) 87100 series documents. These documents are maintained on the State's computer system for use and reference. The inspection procedures and techniques utilized by the State were reviewed and in general determined to be consistent with the inspection guidance provided in IMC 2800 and IP 87100.

One inconsistency with IMC 2800 was noted in the procedures for routine inspections. The State's procedures permit all routine inspections to be announced. Of the eighteen casework files, only one reciprocity inspection was found to be unannounced. Also during the inspector accompaniment at one licensee facility, the licensee admitted to having prepared for the inspection by organizing the records, and only one patient was scheduled for later in the day. The State inspector agreed with the review team member that the licensee may have rescheduled and reduced the patient workload for the day. On the other accompaniment at a local facility, the State inspector related that when the licensee was contacted to set up the inspection, the licensee wanted to postpone the inspection. When the inspection was conducted, it was noted that only two patients were scheduled for that day. Based upon this information,

it appears that the "announcement" of routine inspections does not always permit the inspector to observe the licensee's staff during routine use of licensed materials. The review team recommends that the State's "announced" inspection policy be revised to provide for more unannounced routine inspections and reciprocity inspections. More consistency with the policy in IMC 2800 would result.

The State's inspection policy also requires a pre-inspection form to be sent to medical licensee's management approximately 60 days prior to the anticipated inspection. This form is a tool designed to focus the licensee's managers on the requirements of their licensed radiation safety program and provides feedback to the State for inspection planning purposes. The State representatives related during the review that this procedure has received favorable comments from the licensees and has been a useful tool for the licensees to manage their radiation safety programs.

Two inspector accompaniments were performed by a review team member during the period of January 24-25, 1996. One inspector was accompanied on an inspection of a private medical facility authorized for diagnostic procedures and iodine therapy, and another inspector was accompanied to an institution type medical facility authorized for diagnostic and therapeutic procedures. These accompaniments are identified in file numbers 6 and 11 in Appendix E. All of the other inspectors have been accompanied during previous reviews. On the accompaniments, the Georgia inspectors demonstrated appropriate inspection techniques and knowledge of the regulations. The inspectors were well prepared and thorough in their reviews of the licensees' radiation safety programs. Overall, the technical performance of the inspectors was satisfactory, and their inspections were adequate to assess radiological health and safety at the licensed facilities.

In response to the questionnaire, the State reported that two inspectors were accompanied by the Program Manager of the Radioactive Materials Program during 1994 and one accompaniment was conducted during the 1995 review period. In addition, the Program Manager performed an audit of the Southern Regional Office in both 1994 and 1995. The Program Manager further reported that junior inspectors train with senior inspectors before they are allowed to perform independent inspections. The team verified these accompaniments in the computer system and verified two accompaniments during the casework review. Three of the six inspectors have not been accompanied by supervisors since the last review. We believe that supervisory accompaniments provide management with important insight into the quality of the inspection program. The review team recommends that the State consider adopting a policy of annual accompaniments of all inspectors, and that accompaniments be performed by a supervisor or another senior inspector and the results documented.

The casework was mostly selected from a listing of inspections performed during the previous 6 months by each inspector. The data management coordinator provided a listing of these inspections for each inspector. The casework sample was taken from the most current inspections to reflect the updated regulations, inspection procedures, and to reflect the inspector's training and experience.

The casework was reviewed for adequacy and consistency with the NRC procedures, and to determine if the State's procedures were being followed and implemented. Discussions were held with each of the inspectors (except Mr. Morris in the Southern Regional Office) concerning the casework evaluated during the review, and to determine their understanding and implementation of the procedures. Inspectors were implementing the State's inspection and enforcement procedures, and with the exception to the announced inspection policy, these procedures are consistent with NRC's procedures.

The inspection report forms were found to be generally consistent with the types of information and data collected under IMC 2800. The State uses separate supplements to the inspection report form for various license categories, such as nuclear medicine, teletherapy, medical sealed source, radiopharmacy, bone analyzer, in-vitro medical, eye applicator, industrial radiography, calibration services, miscellaneous, and naturally occurring radioactive material type licenses. In general, the inspection form supplements provide documentation of the scope of the inspection, licensee and radiation safety organization, scope of licensee's program, material uses, procedures, posting and labeling, leak tests, surveys, instrumentation, dosimetry, shipping and receiving, incidents, interviews with staff, confirmatory surveys, items of non-compliance, and exit interviews.

Based upon the review of casework files and the discussions with the staff, it was determined that on occasion inspectors will modify the computerized inspection forms by deleting some of the information on the form. Discussions with the inspectors concerning the specific casework determined that the deleted information was not applicable to the specific cases under review. However, the deleted topics in the reports convey the appearance that the inspection was incomplete and certain topics were not addressed by the inspector during the inspection. We suggest that the State complete their adoption of standardized inspection forms and that all topics on the form be addressed in the written inspection report. For the most part, the review team found that the inspection reports contained only minor discrepancies from standard practice which were related to insufficient details on certain topics in the reports.

The review team also noted that the inspectors sign their own enforcement letters, and these letters and reports are only spot checked by supervisors for quality assurance (QA). Three of the reports had errors in the enforcement letter or the inspection report related to dates of the inspection, dates of previous inspections, or content of the scope of the inspection, items that we believe relate to quality assurance. This observation, when combined with the comments from the previous paragraph, indicates the need for additional supervisory or peer review of reports and letters for quality assurance prior to the dispatch of letters to the licensee. The review team suggests that the State reassess its quality assurance policy of having only spot checks on letters and inspection reports, and the team suggests that all reports and enforcement letters receive a second party review.

Discussions were held with four of the inspectors concerning their procedures for evaluating the licensee's medical quality management (QM) program during inspections. Each inspector had a different response on what information is needed to determine compliance with the medical QM rule, and how to obtain the information and document compliance. The review team suggests that the State develop additional inspector guidance on the review of licensee medical QM programs and how the review should be documented in inspection reports.

In addition, casework files were reviewed to confirm that enforcement correspondence was being maintained in a consistent manner. After the inspections are completed, the enforcement letter dates are entered into the computer system and the action for tracking the enforcement correspondence remains with the inspector until a response is received from the licensee. In general, the enforcement documentation was determined to be adequate and consistent with procedures. However, two of the files contained a Notice of Violation (NOV) documented for the previous inspection, but no record of response from either licensee was documented and the status of the noncompliance was left open without closing the correspondence loop until the current inspection was performed. The reviewer considered these outstanding

items of non-compliance and they were determined to be matters related to recordkeeping requirements and not health and safety issues. We believe that the failure to "close the loop" on these cases is indicative of a quality assurance weakness in the enforcement tracking system. The review team recommends that the State's current system for tracking enforcement actions and correspondence be reevaluated and revised as appropriate to assure that enforcement actions are closed out in a consistent and timely manner.

It was noted that the State has a variety of portable instruments for routine confirmatory surveys and use during incidents and emergency conditions. The instruments were a good mix of low range GM tubes and pancake probes, micro R meters, high range instruments, instrumentation with calibration standards for alpha detection, a neutron rem ball, and a portable multichannel analyzer. The Environmental Radiation Program maintains a mobile laboratory van for use in emergencies and emergency exercises and also has numerous portable radiation instruments and air monitoring equipment available if needed. The portable instruments used during the inspector accompaniments were observed to be operational and calibrated and the portable instruments maintained in the office were also observed to be calibrated. Program staff explained that instruments are calibrated at least on an annual basis, and staggered so as to always have instruments calibrated within the calendar quarter for use during industrial radiography inspections.

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

3.5 Response to Incidents and Allegations

In evaluating the effectiveness of the State's actions in responding to incidents and allegations, the review team examined the State's response to the IMPEP questionnaire relative to this indicator and reviewed the casework files of incidents, allegations and misadministrations. Events listed in the Nuclear Material Events Database were also reviewed and compared to cases obtained from the questionnaire and the State's own files. Additionally, the review team interviewed the Program Manager and Associates assigned to incident response.

The responsibility for initial response and followup to incidents and allegations involving radioactive materials is shared between the Radioactive Materials Program and the Environmental Radiation Program. The Environmental Radiation Program is a sister program within the Department of Natural Resources and provides assistance in environmental monitoring, obtaining samples and sample analyses. Written internal procedures exist for handling incidents, complaints (allegations), and misadministrations. These procedures and accompanying summary forms are available to the staff on the Department's LAN system. Event calls or reports received by the Associates are handled by them or are assigned to the Associates by the Program Manager. By procedure, the Associates independently assess the significance of each event and are required to respond within 24 hours by conducting an onsite inspection or investigation, by making telephone contact followed by written correspondence, or by writing a note to file for followup at a later date. The Program Manager is informed of the initial call and any subsequent followup or resolution of the case.

The review team examined the State's response to 33 events that included all misadministrations and incidents reported since the last review, except for those involving non-Agreement material. The events reviewed involved lost radioactive material, damaged equipment, equipment failures, leaking sources, misadministrations, tripped monitors at a landfill, abandoned material, and

overexposures. In addition to the above, 13 allegation files were reviewed. These files involved several technical and administrative issues and included all of the allegations received since the last review. The review team noted that the event files were maintained independently from the licensees' radioactive materials (licensing and inspection) files. A list of the casework files, with comments, is attached as Appendix F.

Based on the cases reviewed, the review team found that the State's response satisfied the performance criteria for this indicator. The level of the response was appropriate to the type of incident and was handled in a reasonable time frame from the initial notification to the closeout of the incident. The State notified the NRC in accordance with NRC guidance. Allegations were responded to with the appropriate investigation and followup action, and the results were related to the person or the organization that notified the State of the allegation.

In addition to the regular complaint (allegation) file, the review team examined a number of allegations made to the State regarding the safety and security of nuclear materials used at the campus of the Georgia Institute of Technology in Atlanta. Similar complaints were made directly to the NRC which were forwarded to the State for their review and appropriate followup. The State provided a prompt and thorough response to a September 1995 letter from NRC which forwarded a list of allegations. The State is currently drafting responses to three letters that were received from NRC in early February 1996. The review team examined the four NRC letters, discussed the draft responses to the most recent correspondence and the response to the September 1995 letter, with the Program Manager. The review team concurred in the approach taken by the Program Manager which involves consultation with other State agencies in order to provide a more accurate response to the list of concerns forwarded from NRC.

The review team recommends that the program's internal procedures for handling incidents, allegations, and misadministrations be revised to include the NRC's 24-hour Emergency Operations Center telephone number as the first point of contact with the NRC for events which require immediate or 24-hour reporting by licensees. Each procedure should also reference guidance provided in All Agreement States letter SP-95-036 dated March 22, 1995, regarding the reporting criteria and format for reporting events to the NRC. The review team suggests that the Associates document their reviews of events, in the licensee's radioactive materials file, for each reportable event. Although this is not a direct health and safety related concern, such cross-referencing will serve to alert the other Associates to potential program problems before they complete licensing actions or conduct inspections. The review team also suggests that the State document the resolution and closeout of two incidents noted in the casework file review.

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

4.0 NON-COMMON PERFORMANCE INDICATORS

IMPEP identifies four non-common performance indicators to be used in reviewing Agreement State programs: (1) Legislation and Regulations, (2) Sealed Source and Device Evaluation Program, (3) Low-Level Radioactive Waste Disposal Program, and (4) Uranium Recovery. Georgia has no agreement to regulate uranium recovery operations, so only the first three non-common performance indicators were applicable to this review.

4.1 Legislation and Regulations

4.1.1 Legislative and Legal Authority

With response to the questionnaire that there had been no change to the State legislation, the review team did not review the legislation but relied on previous reviews where State legislation was determined to be adequate. Although the State indicated there were no changes to legislation in the questionnaire that affects the radiation control program, the review team discussed both the radiation control act and the administrative procedures act with the staff. The codes listed below grant the Department of Natural Resources the authority to promulgate rules and regulations to be utilized in the administration of the radiation control program.

The legal authority establishing the Radiation Control Program and its regulations is derived from the State Radiation Control Act (O.C.G.A. Title 31 Chapter 13, et seq., as amended). Further authority for program activities is addressed in the State Administrative Procedures Act (O.C.G.A. Title 50 Chapter 13, as amended). The State does not have a sunset provision in its rules.

4.1.2 Status and Compatibility of Regulations

Georgia's final equivalent rules and amendments to the following NRC rules became effective on March 16, 1994: "Licensing and Radiation Safety Requirement for Irradiators," 10 CFR Part 36; "Decommissioning Recordkeeping and License Termination: Documentation Additions," 10 CFR Parts 30, 40, and 70; "Standards for Protection Against Radiation," 10 CFR Part 20; "Notification of Incidents," 10 CFR Parts 20, 30, 31, 34, 39, 40, and 70; "Quality Management Program and Misadministrations," 10 CFR Part 35; and "Emergency Planning," 10 CFR Parts 30, 40, and 70. These regulations were promulgated within the three year period. The regulation entitled, "Safety Requirements for Radiographic Equipment," 10 CFR Part 34 due for adoption on January 10, 1994, was adopted on October 24, 1994. NRC staff has reviewed the amended regulations and has found these regulations are compatible with equivalent NRC regulations.

According to information provided in the questionnaire, since the State does not regulate uranium recovery operations or a low-level radioactive waste disposal facility, it does not have a rule equivalent to NRC's 10 CFR Part 61 and NRC's regulations applicable to uranium recovery contained in 10 CFR Part 40. Therefore, it will not adopt the regulations equivalent to the following NRC rules:

- "Definition of Land Disposal and Waste Site QA Program," 10 CFR Part 61 amendments (58 FR 33886) that became effective on July 22, 1993.

- "Uranium Mill Tailings Regulations: Conforming NRC Requirements to EPA Standards," 10 CFR Part 40 amendments (59 FR 28220) that became effective on July 1, 1994.

Current NRC policy on adequacy and compatibility requires that Agreement States adopt certain equivalent regulations no later than 3 years after they become effective. At the time of the review, the State had not begun the process of promulgation of the following rules necessary for a compatible program:

- "Timeliness of Decommissioning of Materials Facilities," 10 CFR Parts 30, 40, and 70 amendments (59 FR 36026) that became effective August 15, 1994.

- "Preparation, Transfer for Commercial Distribution and Use of Byproduct Material for Medical Use," 10 CFR Parts 30, 32, and 35 amendments (59 FR 61767, 59 FR 65243, 60 FR 322) that became effective on January 1, 1995.

- "Frequency of Medical Examinations for Use of Respiratory Protection Equipment," 10 CFR Part 20 amendments (60 FR 7900) that became effective on March 13, 1995. Note, this rule is designated as a Division 2 matter of compatibility. Division 2 compatibility allows the Agreement States flexibility to be more stringent (i.e., the State could choose to continue to require annual medical examinations).

- "Low-Level Waste Shipment Manifest Information and Reporting," 10 CFR Parts 20 and 61 amendments (60 FR 15649, 60 FR 25983) that will become effective March 1, 1998. Georgia and other Agreement States are expected to have an equivalent rule effective on the same date.

- "Performance Requirements for Radiography Equipment," 10 CFR Part 34 amendments (60 FR 28323) that became effective June 30, 1995.

- "Radiation Protection Requirements: Amended Definitions and Criteria," 10 CFR Parts 19 and 20 amendments (60 FR 36038) that became effective August 14, 1995.

- "Medical Administration of Radiation and Radioactive Materials," 10 CFR Part 20 and 35 amendments (60 FR 50248) that became effective October 20, 1995.

- "Clarification of Decommissioning Funding Requirements," 10 CFR Parts 30, 40, and 70 amendments (60 FR 38235) that became effective November 24, 1995.

- "Compatibility with the International Atomic Energy Agency," 10 CFR Part 71 amendment (60 FR 50248) that became effective April 1, 1996.

- "Self-Guarantee as an Additional Financial Mechanism," 10 CFR Parts 30, 40, and 70 amendments (58 FR 68726 and 59 FR 1618) that became effective on January 28, 1994. Note, this rule is designated as a Division 2 matter of compatibility. Division 2 compatibility allows the Agreement States flexibility to be more stringent (i.e., the State could choose not to adopt self-guarantee as a method of financial assurance). If a State chooses not to adopt this regulation, the State's regulation, however, must contain provisions for financial assurance that include at least a subset of those provided in NRC's regulations, e.g., prepayment, surety method (letter of credit or line of credit), insurance or other guarantee method (e.g., a parent company guarantee).

The review team examined the procedures used in the State's regulation promulgation process and found that the public and other interested parties are offered an opportunity to comment on proposed regulations during a 30-day comment period and during the required public hearing. According to program management, the NRC is provided with drafts for comment on the proposed regulations early in the promulgation process. The regulations are forwarded to the Board of Natural Resources for 30 days for review and approval. The rules become effective 20 days after approval by the Board. A copy of the final regulation is then provided to NRC.

The State's regulations were compatible with those of the NRC at the time of the review, including all regulations necessary for a compatible program that are due by January 1997. During discussions with the review team, program

management explained that they would begin the process of preparing draft revisions to the regulations in 1996 for new regulations due in 1997. The expected date for completion of this effort is February 1997. The State's formal regulation promulgation process takes approximately 9-12 months.

Based on the IMPEP evaluation criteria, the review team recommends that Georgia's performance with respect to the indicator, Legislation, and Regulations, be found satisfactory.

4.2 Sealed Source and Device Evaluation Program

In assessing the State's Sealed Source & Device (SS&D) evaluation program, the review team examined information provided by the State 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 observed the Staff's use of guidance documents and procedures, and interviewed the staff and Program Manager involved in SS&D evaluations.

4.2.1 Technical Quality of the Product Evaluation Program

The review team examined seven new or revised SS&D registry certificates and their supporting documentation. The certificates reviewed covered the period since the last program review in October 1993 and represented cases completed by five reviewers. The SS&D certificates issued by the State and evaluated by the review team are listed with case-specific comments in Appendix G. The overall quality of the evaluations was good, with only minor technical comments. There was a noticeable improvement in documentation required of the applicants and in the detail of the evaluations when comparing 1994 to 1995 certificates. The State does have procedures in place to protect proprietary information submitted in support of an evaluation. Policy and guidance documents were on file and being utilized by the staff. The basic format for a SS&D certificate resides on the program's LAN system along with completed certificates. All Associates have access to this information through their personal computers. The review team observed that either the Program Manager or a senior level reviewer co-signs each completed SS&D registry certificate to verify their audit of the application and the original reviewer's conclusions.

The review of SS&D casework files revealed that there are at least two Georgia licensed distributors of SS&Ds that are designed, manufactured and/or partly assembled in foreign countries. These distributors should be required to obtain detailed Quality Assurance/Quality Control (QA/QC) programs regarding the SS&D product manufacturing process from their foreign suppliers. Detailed QA/QC program commitments should be submitted to Georgia by the distributors and incorporated into the SS&D certificates and the distribution licenses. The Georgia distributors would then be responsible for assuring that the manufacturing commitments are upheld and the State can review them during routine compliance inspections. QA/QC inspections of the foreign manufacturer's processes are the responsibility of the Georgia distributor or documentation from third party inspections is acceptable.

Improvements in the nationwide effort to evaluate SS&Ds containing radioactive material led to NRC adoption of 10 CFR 30.32 (g) on "Application for Specific Licenses" and 10 CFR 32.210 entitled, "Registration of Product Information." These regulations were not initially identified as items of compatibility for Agreement States with SS&D evaluation programs. All Agreement States letter SP-95-116 dated July 25, 1995, announced Commission approval of minimum standards for Agreement States desiring to maintain authority to evaluate SS&Ds. In keeping with this guidance, the review team recommends that the

State adopt regulations compatible with 10 CFR 30.32 (g) and 10 CFR 32.210. These regulations require manufacturers/distributors to submit certain key product information in support of an SS&D evaluation and permits the State to enforce against those commitments. More specific guidance in this area is contained in Regulatory Guide 6.9 dated February 1995 entitled, "Establishing Quality Assurance Programs for the Manufacture and Distribution of Sealed Sources Containing Byproduct Material." It should be noted that SS&D casework comments on manufacturer QA/QC programs were based on evaluations performed by program staff before issuance of the current (1995) guidance in this area.

In October 1995, the State issued several amended SS&D certificates for Scan Technologies, Inc., a distributor of gauging devices containing radioactive material. The amendments were issued to reflect a change in location of the distributor and to allow the continued distribution of devices distributed under an NRC license and regulations. The Program Manager reported that the State intends to conduct a re-evaluation of all Scan Technologies registered products with special emphasis on manufacturing QA/QC and confirm all commitments previously made by Scan Technologies to the NRC.

4.2.2 Technical Staffing and Training

The State reported that the current staff (Associates) all have at least a Bachelor's degree in physical or biological sciences and several Associates have Master's degrees in radiological science. All Associates have completed the NRC recommended core training courses for materials licensing personnel. Several Associates have completed more advanced training such as the SS&D evaluation workshop. Formal course work and on-the-job training allows the Associates to operate independently in this area.

All current Associates are authorized to evaluate and issue SS&D certificates.

4.2.3 Evaluation of Defects and Incidents Regarding SS&Ds

During the review period the State requested and received technical assistance from the NRC in the form of an engineering consulting firm's analysis of a device failure. The failure was related mainly to an improper service procedure during initial installation of the device. It was also discovered that the design and placement of an electrical circuit could potentially cause a second but unrelated device failure. The State staff worked with the manufacturer to notify other regulatory agencies and all known users of the device, established a schedule for inspection/repair and amended the SS&D certificate to reflect the change. A second technical assistance request was made and completed on a new design for the failed component. A draft SS&D certificate for this new design was reviewed and discussed with the State staff. The final version of this certificate will be issued shortly.

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

4.3 Low-Level Radioactive Waste (LLRW) Disposal Program

In 1981, the NRC amended its Policy Statement, "Criteria for Guidance of States and NRC in Discontinuance of NRC 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 LLRW disposal authority, NRC has not required States to have a program for licensing a LLRW disposal facility until such time as the State has been

designated as a host state for a LLRW disposal facility. When an Agreement State has been notified or becomes aware of the need to regulate a LLRW disposal facility, they are expected to put in place a regulatory program which will meet the criteria for an adequate and compatible LLRW disposal program. There are no plans for a LLRW disposal facility in Georgia. Accordingly, the review team did not review this indicator.

5.0 SUMMARY

As noted in Sections 3 and 4 above, the review team found the State's performance with respect to each of the performance indicators to be satisfactory. The MRB concurred in the team's individual and overall recommendations and found that the Georgia program was adequate to protect public health and safety and was compatible with NRC's regulatory program.

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

1. The review team recommends that Georgia reevaluate its procedures for scheduling initial inspections to ensure that all licensees are inspected within 12 months of license issuance, regardless of whether or not they possess material or perform licensed operations. (Section 3.1)

2. The review team recommends that the State's "announced" inspection policy be revised to provide for more unannounced routine inspections and reciprocity inspections. More consistency with the policy in IMC 2800 would result. (Section 3.4)

3. The review team recommends that the State consider for adoption a policy of annual accompaniments of all inspectors, and that these accompaniments be performed by a supervisor or another senior inspector and the results documented. (Section 3.4)

4. The review team suggests that the State complete their adoption of standardized inspection forms and that all topics on the form be addressed in the written inspection report. (Section 3.4)

5. The review team suggests that the State reassess its quality assurance policy of having only spot checks on letters and inspection reports, and the team suggests that all reports and enforcement letters receive a second party review. (Section 3.4)

6. The review team suggests that the State develop additional inspector guidance for the review of licensee medical QM programs and how the reviews are to be documented in inspection reports. (Section 3.4)

7. The review team recommends that the State's current system for tracking enforcement actions and correspondence be reevaluated and revised as appropriate to assure that enforcement actions are closed out in a consistent and timely manner. (Section 3.4)

8. The review team recommends that the program's internal administrative procedures for reporting Misadministrations, Complaints and Incidents be revised to reflect the most recent NRC guidance regarding the primary contact, event reporting criteria and the event report format. (Section 3.5)

9. The review team recommends that Associates document their reviews of events, in the licensee's radioactive materials file, for each reportable event. (Section 3.5)

10. The review team suggests that the State document the resolution and closeout of two incidents noted in the casework file review. (Section 3.5)

11. The review team recommends that manufacturers and distributors of sealed sources or devices be required to establish and implement a manufacturing Quality Assurance/Quality Control (QA/QC) Program. (Section 4.2)

12. The review team recommends that Georgia adopt regulations compatible with 10 CFR 30.32 (g) and 10 CFR 32.210 in order to maintain an effective SS&D evaluation program. (Section 4.2)

LIST OF APPENDICES AND ATTACHMENTS

APPENDIX A- IMPEP REVIEW TEAM MEMBERS

Lloyd Bolling, OSP	Team Leader Technical Quality of Licensing Legislation and Regulations Sealed Source and Device Reviews
Richard Woodruff, RII	Technical Quality of Inspections
George Deegan, NMSS	Status of Materials Inspection Program Technical Staffing and Training
Allen Grewe, Tennessee	Incidents and Allegations