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 <u>Federal Register</u> 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 <u>Status of Items Identified During the 1993 Routine Review and</u> 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 <u>Status of Materials Inspection Program</u>

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 <u>Technical Staffing and Training</u>

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

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 <u>Technical Quality of Inspections</u>

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. 0n 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 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 <u>Response to Incidents and Allegations</u>

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 crossreferencing 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 <u>Legislation and Regulations</u>

4.1.1 <u>Legislative and Legal Authority</u>

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 <u>Status and Compatibility of Regulations</u>

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

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

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 OA/OCprograms 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 <u>Technical Staffing and Training</u>

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

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

4.2.3 <u>Evaluation of Defects and Incidents Regarding SS&Ds</u>

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)
- 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)
- 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
APPENDIX B:	Georgia Organizational Chart
APPENDIX C:	Georgia Questionnaire Response
APPENDIX D:	License File Reviews
APPENDIX E:	Inspection File Reviews
APPENDIX F:	Incident File Reviews
APPENDIX G:	Sealed Source and Device Evaluation Reviews
Attachment 1:	Georgia Response to Draft Report

APPENDIX A- IMPEP REVIEW TEAM MEMBERS

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

<u>APPENDIX C</u> <u>INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM</u>

STATE RESPONSE TO QUESTIONNAIRE

Georgia Department of Natural Resources, Radioactive Materials Program

Reporting Period: October 1993 to February 1996

A. COMMON PERFORMANCE INDICATORS

I. <u>Status of Materials Inspection Program</u>

 Please prepare a table identifying the licenses with inspections that are overdue by more than 25% of the scheduled frequency set out in NRC Inspection Manual Chapter 2800 (issued 4/17/95). The list should include initial inspections that are overdue.

<u>Licensee Name</u>	Insp. Frequency <u>(Years)</u>	<u>Due Date</u>	<u>Months</u> <u>O/D</u>
Nat. Env. Testing Servc.(1258-1)	3	Init. 4/95	7
John W. Kelley, M.D.(980-1)	4	Init. 10/95	3
R. A. Bhaskaran, M.D.(979-1)	3	Init. 12/96	

- 2. Do you currently have an action plan for completing overdue inspections? If so, please describe the plan or provide a written copy with your response to this questionnaire.
 - Ans: Our inspectors are assigned inspections each 6 months and are responsible for the inspections in accordance with the Program Policy and Procedures. The licensees listed in question 1. are assigned to inspectors for inspection/follow-up. These licensees have not possessed or used radioactive material under their licenses.
- 3. Please identify individual licensees or groups of licensees the State/Region is inspecting less frequently than called

for in NRC Inspection Manual Chapter 2800 (issued 4/17/95) and state the reason for the change.

- Ans: At the end of the last Program review (10/93), our inspection frequencies were the same as those used by the NRC. In reviewing NRC Inspection Manual Chapter 2800, we note that several of our license categories are now inspected more frequently and that our nuclear laundry licensee, Interstate Nuclear Services Corp. (894-1) is now inspected less frequently; i.e., every three years instead of every two years. Our frequency for this licensee has not been changed due to a favorable compliance history.
- 4. How many licensees filed reciprocity notices in the reporting period?
 - Ans: 106
 - a. Of these, how many were industrial radiography, well-logging or other users with inspection frequencies of three years or less?
 - Ans: Eight were for industrial radiography and 96 were for portable gauges.
 - b. For those identified in 4a, how many reciprocity inspections were conducted?
 - Ans: Four reciprocity inspections were conducted.
- 5. Other than reciprocity licensees, how many field inspections of radiographers were performed?
 - Ans: Five field inspections of radiographers were performed.
- 6. For NRC Regions, did you establish numerical goals for the number of inspections to be performed during this review period? If so, please describe your goals, the number of inspections actually performed, and the reasons for any differences between the goals and the actual number of inspections performed.

II. Technical Staffing and Training

Please provide a staffing plan, or complete a listing using 7. the suggested format below, of the professional (technical) person-years of effort applied to the agreement or radioactive material program by individual. Include the name, position, and, for Agreement States, the fraction of time spent in the following areas: administration, materials licensing & compliance, emergency response, LLW, U-mills, other. If these regulatory responsibilities are divided between offices, the table should be consolidated to include all personnel contributing to the radioactive materials program. Include all vacancies and identify all senior personnel assigned to monitor work of junior personnel. If consultants were used to carry out the program's radioactive materials responsibilities, include their efforts. The table heading should be:

NAME	POSITION	AREA OF EFFORT	FTE%
T. Hill	Program Manager	Administration	100
J. Morris	Environmental Radiation Specialist Principal	Licensing/Compliance	100
H. Copeland	Environmental Radiation Specialist Principal	Administration	100
E. Drinnon	Radiation Health Specialist Principal	Licensing/Compliance	100
R. Harrell	Radiation Health Specialist Principal	Licensing/Compliance	100
C. Maryland	Radiation Health Specialist Principal	Licensing/Compliance	100
C. Taylor	Radiation Health Specialist Principal	Licensing/Compliance	100
C. Sanders	Radiation Health Specialist Principal	Licensing/Compliance	100
Vacant	Environmental Specialist	Licensing/Compliance	100

Ans:

Thomas E. Hill, Program Manager, monitors the work of junior personnel. In the future, Principal level Associates will also monitor the work of junior personnel.

8. Please provide a listing of all new professional personnel hired since the last review, indicate the degree(s) they received, if applicable, and additional training and years of experience in health physics, or other disciplines, if appropriate.

Ans: Elizabeth Drinnon and Cynthia Sanders.

Note: These individuals have prior experience and training with the Radioactive Materials program. Their training includes basic and advanced NRC training courses.

- 9. Please list all professional staff who have not yet met the qualification requirements of license reviewer/materials inspection staff (for NRC, Inspection Manual Chapters 1245 and 1246; for Agreement States, please describe your qualifications requirements for materials license reviewers and inspectors). For each, list the courses or equivalent training/experience they need to attend and a tentative schedule for completion of these requirements.
 - Ans: Radioactive Materials License Inspector Qualifications

Radioactive materials license inspectors must understand the facilities, processes, and activities of those licenses they inspect, as well as the criteria, techniques, and mechanisms of inspections. This is accomplished through formal training courses coupled with on-the-job inspection training by accompaniment with senior staff members. Usually an inspector trainee will be somewhat knowledgeable of the licensing criteria for the types of licenses they are inspecting.

Generally, each radioactive materials license inspector completes the basic inspector training courses and courses in certain subject areas prior to performing unaccompanied inspections in those subject areas. Both licensing and inspection training are covered in the courses listed in Items B through E.

Δ	Rasic	Inspector	Training	Course
А.	Dasic	THSPECTOL	rranning	COULSE

B. Diagnostic and Therapeutic Nuclear Medicine

Course

C. Safety Aspects of Industrial Radiography

D. Teletherapy and Brachytherapy Course

E. Safety Aspects of Well Logging Course

Radioactive Materials License Application Reviewer Qualifications

Radioactive materials license application reviewers must understand the facilities, equipment, processes, and activities of the programs they license, as well as the criteria, techniques, and mechanisms of licensing. This is accomplished through formal training courses coupled with on-the-job training with senior staff members.

Each reviewer must complete the following formal training courses. Some of this training may be waived on a case-bycase basis, depending on the trainee's needs, past formal training and experience and Program needs.

- A. Health Physics Technology Course
- B. Diagnostic and Therapeutic Nuclear Medicine

Course

C. Safety Aspects of Industrial Radiography

Course

- D. Teletherapy and Brachytherapy Course
- E. Licensing Practices and Procedures Course

Upon satisfactory completion of each course the reviewer is assigned licensing actions related to the topics covered in the course. The reviewer's licensing actions are closely supervised by a senior staff member.

Course

> Depending on the radioactive materials license application reviewer's previous work experience and planned reviewer activities, these additional courses may be required in order to gain knowledge necessary for special radioactive materials licensing activities.

- A. Radiological Emergency Response Course
- B. Air Sampling for Radioactive Material Course
- C. In-Place Filter Testing Course
- D. Safety Aspects of Well Logging Course
- E. Irradiator Technology Course
- F. Environmental Sampling and Analysis Course
- G. Advanced Health Physics Course

All professional staff have met the qualification requirements.

- 10. Please identify the technical staff who left the RCP/Regional DNMS program during this period.
 - Ans: Ralph McCoy and Lauren McGaughey
- III. <u>Technical Quality of Licensing Actions</u>
 - 11. Please identify any major, unusual, or complex licenses which were issued, received a major amendment, terminated or renewed in this period.

LICENSE NAME	LICENSE NUMBER	LICENSE TYPE	ACTION
Emory University	GA-153-1	Broad Scope	Renewal
Georgia State University	GA 244-1	Broad Scope	Renewal
Medical College of Georgia	GA 7-1	Broad Scope	Renewal
Honeywell Industries Automat	GA 832-1	Service and Distribution	Renewal
Automata, Inc.	GA 1288-1	Service and Distribution	New
Longyear Products Group	GA 318-1	Service and Distribution	Renewal

Scan Technologies, Inc.	GA 1299-1	Service and Distribution	New
DuPont Merck Pharmaceutical	GA 738-1	Distribution	Renewal
Diversified Pharmacy Services	GA 891-1	Nuclear Pharmacy	Renewal
Numed, Inc.	GA 1259-1	Nuclear Pharmacy	New
Rome Central Pharmacy	GA 1302-1	Nuclear Pharmacy	New
Medi-Physics, Inc.	GA 1166-1	Nuclear Pharmacy	Renewal
Elekta Radiosurgery, Inc.	GA 1153-1	Teletherapy Service	Renewal

Update the list of the State's major licensees. Include:

o Broad Licenses o LLW Disposal o LLW Brokers (All Types) o Manufacturers and Distributors o Uranium Mills o Irradiators (Other than Self-Contained) o Nuclear Pharmacies o Other Licenses With a Potential Significance for Environmental Impact

The table heading should be:

<u>Licensee Name</u>	<u>License</u> <u>Number</u>	<u>License Type</u>
University of Georgia	GA 103-1	Broad Scope
Georgia Inst. of Tech.	GA 147-1	Broad Scope
Emory University	GA 153-1	Broad Scope
Medical College of Ga.	GA 7-1	Broad Scope
Analytic, Incorporated	GA 742-1	Services & Distribution
Valmet Automation (USA)	GA 458-2	Services & Distribution of GL Gauges
Valmet Automation (USA)	GA 458- 3G	Services & Distribution of GL Gauges

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Valmet Automation (USA)	GA 458- 4G	Services & Distribution of GL Gauges
Johnson-Yokogawa Corp	GA 1192- 1	Distribution of Specific License Gauges
Nortech Systems, Ltd.	GA 858-1	Receive, distribute, survey, install and relocate specific license gauges
Ahlstrom Machinery, Inc.	GA 832-1	Service & Distribute GL devices
Interstate Nuclear Services	GA 894-1	Nuclear Laundry
Theragenics Corporation	GA 881-2	Distribution of therapy seeds
Andersen Samplers, Inc.	GA 1055- 2	Distribution of GL devices
Div Pharmacy Services Mid- Georgia	GA 891-1	Radiopharmacy
Mallinckrodt Imaging Services	GA 877-1	Radiopharmacy
Primary Source of Augusta	GA 823-2	Radiopharmacy
MPI Pharmacy Services	GA 1166- 1	Radiopharmacy
Syncor International Corp.	GA 467-1	Radiopharmacy
Syncor International Corp.	GA 467-2	Radiopharmacy
Siempelkamp Corporation	GA 1080- 1	Distribution of specific license devices
Atlanta-Tech, Inc.	GA 888-2	Distribution and services
Brainard-Kilman Drill Co.	GA 318-1	Distribution and services
Smith-Kline Beecham	GA 123-1	Distribution
Smith-Kline Beecham	GA 123-2	Distribution
Carr Scarborough Microb.	GA 793-1	Manufacturer and distribution
Dupont Merck Pharmacy Co.	GA 738-1	Distribution
Science ProdBaxter Scientific	GA 872-1	Distribution

12. Please identify any new or amended licenses added or removed from the list of licensees requiring emergency plans?

Ans: There are no licensees requiring emergency plans.

13. Discuss any variances in licensing policies and procedures or exemptions from the regulations granted during the review period.

Ans: None

- 14. What, if any, changes were made in your written licensing procedures (new procedures, updates, policy memoranda, etc.) during the reporting period?
 - Ans: The Program is currently developing standardized templates for various licensing categories and is updating all Program licensing guides. The target date for completion of templates is late March and for top-priority licensing guides, February 28, 1996. The templates and guides are expected to provide more consistency among associates in the licensing process and better inform our licensees.

Associates who have had sufficient training and experience sign their licensing actions. All licensing actions are routed to the secretary for standardized formatting and grammatical error checks before signature by the associates. Hence, the importance of standardized templates. A flowchart has been created and approved summarizing the licensing process discussed above.

15. For NRC Regions, identify by licensee name, license number and type, any renewal applications that have been pending for one year or more.

IV. <u>Technical Quality of Inspections</u>

- 16. What, if any, changes were made to your written inspection procedures during the reporting period?
 - Ans: The Program inspectors have generally followed the NRC inspection procedures in Manual Chapter 2800.
Therefore, during the review period, Manual Chapter 2800 was used as the basis for drafting the Georgia Inspection Manual. Various inspection procedures referenced in Manual Chapter 2800 are also referenced in the Georgia Inspection Manual. Some of these procedures will, in time, be rewritten as specific Georgia procedures. Others will continue to be referenced as NRC procedures to be used as the need arises.

17. Prepare a table showing the number and types of supervisory accompaniments made during the review period. Include:

<u>Supervi</u>	isor	<u> </u>	<u>Inspector</u>	<u>Licen</u>	<u>se Cat.</u>	<u>Date</u>	
Thomas	Ε.	Hill	Lauren Mc(Gaughey	Port. Gau	ge	7/1/9
Thomas	Ε.	Hill	Elizabeth	Drinnon	R & D		4 7/26/ 94
Thomas	E.	Hill	Elizabeth	Drinnon	Reciproci	ty	12/2/ 95

Thomas E. Hill visited the Southern Regional Office of the Program on 3/2-3/94 and 6/30/95.

- 18. Describe internal procedures for conducting supervisory accompaniments of inspectors in the field. If supervisory accompaniments were documented, please provide copies of the documentation for each accompaniment.
 - Ans: Supervisory accompaniments of inspectors in the field are performed in cases where the inspections are more difficult and which may present special problems or questions. Inspection reports are written by the inspectors and the report is reviewed by the supervisor.
- 19. Describe or provide an update on your instrumentation and methods of calibration. Are all instruments properly calibrated at the present time?
 - Ans: Currently all survey instruments are sent out for calibration on an annual basis. They are sent out on a rotation so that meters used to conduct a

radiography inspection are calibrated within the quarter as required of radiographers.

All instruments used for compliance surveys are in calibration. Instruments used for other purposes are not calibrated until they are needed for compliance surveys.

Number of Instrument s	Manufacturer	Model
8	EBERLINE	ESP-2
2	EBERLINE	R0-2A
6	EBERLINE	E-520
2	EBERLINE	PRM-7
1	LUDLUM	12
1	LUDLUM	19
2	EBERLINE	PRM-5-3
3	EBERLINE	PAC-1SAGA
2	EBERLINE	PAC-1SAG
1	EBERLINE	PAC-4G-3
2	EBERLINE	E-500B
1	EBERLINE	PNC-4
2	EBERLINE	E-120
2	S. R. COMP	ESD
1	N.C. CUTIE PIE	2592
1	JORDAN	AGB- 10RGSR
2	VICTOREEN	410
1	VICTOREEN	541-R

Instrumentation currently in inventory:

20. Please provide a list of the <u>most significant</u> incidents (i.e., medical misadministration, overexposures, lost and abandoned sources, incidents requiring 24 hour or less notification, etc.) that occurred in the Region/State during the review period. Information included in previous submittals to NRC need not be repeated. The list should be in the following format:

Licensee Name	License #	Date of Inciden tReport	Type of Incident
United Testing Group	General	6/2/94	Lost Device
City of Atlanta	GA486-5	6/8/94	Lost Source
Newnan Hospital	GA135-2	6/15/94	Lost Source
Georgia Power	GA40-1	1/4/95	Lost Devices
Applied Radiological Control	GA899-1	1/17/95	Lost Sources
Milliken Live Oak Plant	General	2/1/95	Fire
Gwinnett Medical Center	GA677-1	4/6/95	Overexposure (extremity)
Textron	General	7/6/95	Lost Source
Professional Services, Inc.	GA629-1	7/13/95	Fire
Emory University	GA153-1	8/2/95	Lost Sources
Emory University	GA153-1	12/8/95	Lost Sources
Georgia Baptist Medical Center	GA66-1	1/6/94	Misadministrati on (>20% error)
The Medical Center	GA239-2	4/24/94	Misadministrati on (Wrong treatment site)

21. During this review period, did any incidents occur that involved equipment or source failure or approved operating

procedures that were deficient? If so, how and when were other State/NRC licensees who might be affected notified?

Ans: a) Illinois notified our program that a leaking source was sent from Georgia Pacific to one of their licensees, Kay Ray, in Rosemount. NRC notified other states that might be affected through an abnormal occurrence report. Office of State Programs was notified.

> b) At Textron, in Americus Ga, the portion of the nozzle holding the Po-210 source became detached from the device. The source was apparently cleaned up during normal clean up operations in the room and was disposed of with the regular trash. The source was sent to the landfill. NRC was notified immediately of the device problem through the Hotline.

- 22. For incidents involving failure of equipment or sources, was information on the incident provided to the agency responsible for evaluation of the device for an assessment of possible generic design deficiency? Please provide details for each case.
 - Ans: See 21.a) The NRC contracted with an outside vendor, SRW, to perform independent evaluations on the gauging device. The results of the evaluation are complete but have not been made available to the Agreement States.

See 21.b) The NRC was notified by our staff immediately of the problem with the static eliminator through the NRC hotline. We have not heard anything further from the NRC concerning the device.

- 23. In the period covered by this review, were there any cases involving possible wrongdoing that were reviewed or are presently undergoing review? If so, please describe the circumstances for each case.
 - Ans: Three cases of possible wrong doing:
 - a. The Medical Center, Columbus, GA Numerous charges were made by a former employee including

misadministration of doses to patients, and no records of doses to patients. The investigation could not prove or disprove the allegations (Oct. 1995). The paperwork checked did not show any problems. We could not substantiate any of the

- b. Gordon Hospital RSO made false statements to an inspector. He admitted to making the statements and was asked to resign. His resignation was accepted after the license was amended for a new RSO on Dec. 14, 1995.
- c. University of Georgia Anonymous complaint filed - It was alleged that a spill occurred in a lab no date was given for the spill. A student cleaned up the spill and flushed it down the drain without reporting it to the principal investigator. Investigation showed that the spill never occurred.
- 24. Identify any changes to your procedures for handling allegations that occurred during the period of this review.

other allegations made.

Ans: None

- VI. <u>General</u>
 - 25. Please prepare a summary of the status of the State's or Region's actions taken in response to the comments and recommendations following the last review.
 - Ans: During the 1993 Program review all 30 indicators were reviewed and 27 of the indicators were satisfied. Recommendations were made relative to the three remaining indicators. These recommendations were:
 - 1. Status and Compatibility of Regulations (Category

1)

Recommendation: We recommend that the State provide within 30 days of the date of this letter (February 2, 1994) their schedule, including interim milestones, for completing all actions necessary to promulgate the

overdue regulations and other regulations needed for the purposes of compatibility.

Response dated March 7, 1994:

• Status and Compatibility of Regulations (Category I)

"Notification of Incidents" - (10 CFR Parts 20, 30 31, 34, 39, 40, and 70 amendments (56 FR 40757)). These requirements are included in Rule 391-3-17-.03(14)(b) adopted by the Board on February 23, 1994, and effective March 16, 1994.

"Safety requirements for radiographic equipment" - (10 CFR 34, amendment (55 FR 843)). These requirements, except the equivalent to § 34.21 (b), were adopted by the Board and became effective May 22, 1991. Georgia is and has been compatible with NRC on this rule and will continue to be compatible with this rule unless a similar provision for storage containers is not added by January 10, 1996.

Additional response to the Status and Compatibility of Regulations was also provided as follows:

"Emergency planning rule" - (10 CFR Parts 30, 40, and 70 amendments). This rule was included in Rule 391-3-17-.02(7)(h) adopted by the Board on February 23, 1994, and effective March 16, 1994.

• "Safety requirements for radiographic equipment" -(10 CFR 34, amendment (55 FR 843)). These requirements, except the equivalent to § 34.21 (b), were adopted by the Board and became effective May 22, 1991. Georgia is and has been compatible with NRC on this rule and will continue to be compatible with this rule unless a similar provision for storage containers is not added by January 10, 1996.

 "Notification of Incidents" - (10 CFR Parts 20, 30 31, 34, 39, 40, and 70 amendments (56 FR 40757)). These requirements are included in Rule 391-3-17-.03(14)(b) adopted by the Board on February 23, 1994, and effective March 16, 1994.

"Quality Management Program and Misadministrations"
 (10 CFR Part 35 amendment (56 FR 7715)). These requirements are included in Rule 391-3-17-.05(6)(h) and (I) in amendments adopted by the Board on February 23, 1994, and effective March 16, 1994. The specific objectives of a QMP are not included in the rule. The objectives will be amended into the rule prior to January 27, 1995 or will be incorporated into each license by condition on or before January 27, 1995.

 "License and Radiation Safety Requirements for Irradiators" - (10 CFR 36 (58 FR 7715)). This rule has been adopted as Rule 391-3-17-.09 by the Board on February 23, 1994, and effective March 16, 1994.

 "Licensing Requirements for Land Disposal of Radioactive Waste" - (10 CFR 61 (58 FR 33886)). Georgia is a member of the Southeast Compact. North Carolina is the next host state for a disposal facility to serve the Compact for 20 years. By October 25, 1996 North Carolina will have completed the site selection process and will be nearing the operational phase of the disposal facility. Therefore, Georgia requests exemption from the requirement for including amendments at 58 FR 33886 for purposes of compatibility. At such time as Georgia is designated as the next host state, we will revise our rules to be compatible with the latest applicable revision with 10 CFR Part 61.

 "Decommissioning Record keeping and License Termination" - (10 CFR Parts 30, 40, 70 and 72 (58 FR 39628)). These requirements are included in Rule 391-3-17-.02(8)(g) and were adopted by the Board on February 23, 1994, and effective March 16, 1994.

Summary: All regulations required for compatibility to date have been adopted with an effective date of March 16, 1994.

2. Status of Inspection Program (Category 1

Indicator)

Recommendation: We recommend that the State review the list of Brachytherapy after loader licensees and develop a plan for their inspection at the revised inspection frequency.

Response dated March 7, 1994:

Status of Inspection Program (Category I)

Brachytherapy after loader licensee list has been reviewed and the inspection frequency has been revised. Brachytherapy licensees will be inspected annually.

Summary: Brachytherapy after loader licensees are inspected annually except where Brachytherapy after loaders were included on a priority three medical license. The annual inspections commence following the next regularly scheduled inspection for that licensee.

3. Administrative Procedures is a Category II

Indicator

Recommendation: We recommend that the State's plans to revise the internal administrative procedures be implemented and completed as scheduled.

Response dated March 7, 1994:

Administrative Procedures (Category II)

The Program has established a Process Improvement Team. The team is reviewing guidance documents and procedures. Revised internal procedures are to be completed within the next two years.

Summary: Licensing Guide updates are scheduled for completion by February 28, 1996. Standardized inspection report forms are scheduled to be completed by May 30, 1996. Many internal policy and procedures

> documents have been revised or drafted in the past two year including: complaint procedure, comptime procedure, DOT exemption procedure, expiration procedure, incident procedure, interpretation of medical use, medical consultant policy, misadministration procedure, monitoring procedure, orientation procedure, pre-inspection procedure, promotion policy, property control policy, QMP inspection procedure, reciprocity procedure, and rule revision procedure. Other policy and procedures will be developed as the need is identified.

- 26. Provide a brief description of your program's strengths and weaknesses. These strengths and weaknesses should be supported by examples of successes, problems or difficulties which occurred during this review period.
 - Ans: The Program has implemented the self directed team approach to running the program. We think this has served to be very beneficial to the Program. All associates are held accountable for their particular roles as team player. The Program is working toward a more procedural type atmosphere with more emphasis put on the documentation of these procedures. Examples would be the development of templates, routing of licensing actions to secretary for final formatting, and rotational subject matter specialists. Hopefully, each associate will take advantage of this and concentrate on the more pressing issues such as content and quality of licensing review and inspection.

The Program has several challenges. One challenge that stands out is the lack of full staffing. Although, according to staffing ratios outlined in the past, that seemed to suggest our program is adequately staffed, associates are required to take on a lot more extra projects while licensing and inspecting workload does not decrease.

The Program needs to develop ways to measure customer satisfaction along with providing tools and techniques to help the licensee to become better informed.

- I. <u>Regulations and Legal Authority</u>
 - 27. Please list all currently effective legislation that affects the radiation control program (RCP).
 - Ans: O.C.G.A. Title 31 Chapter 13, et seq.,as amended. (Radiation Control Act). O.C.G.A. Title 50 Chapter 13, as amended. (Administrative Procedure Act).
 - 28. Are your regulations subject to a "Sunset" or equivalent law? If so, explain and include the next expiration date for your regulations.

Ans: No

29. Please complete the enclosed table based on NRC chronology of amendments. Identify those that have not been adopted by the State, explain why they were not adopted, and discuss any actions being taken to adopt them.

Ans: Please refer to Table

30. If you have not adopted all amendments within three years from the date of NRC rule promulgation, briefly describe your State's procedures for amending regulations in order to maintain compatibility with the NRC, showing the normal length of time anticipated to complete each step.

Ans: N/A

II. <u>Sealed Source and Device Program</u>

31. Prepare a table listing new and revised SS&D registrations of sealed sources and devices issued during the review period. The table heading should be:

SS&D REGISTRY #	MANUFACTURER, DISTRIBUTOR OR CUSTOMER USER	TYPE OF DEVICE OR SOURCE
GA-161-D-102-S	Atlan-Tech	Irradiator
GA-296-D-101-S	Elekta Radiosurg.	Teletherapy

GA-296-D-102-S	Elekta Radiosurg.	Teletherapy
GA-571-D-101-G	Honeywell, Inc.	Density Gauge
GA-8020-D-801- S	Nortechnics	Density Gauge
GA-8020-D-802- S	Nortechnics	Density Gauge
GA-176-D-101-S	Scan Technologies	Density Gauge
GA-176-D-102-S	Scan Technologies	Density Gauge
GA-176-D-103-S	Scan Technologies	Density Gauge
GA-176-D-101-G	Scan Technologies	Density Gauge
GA-176-D-104-G	Scan Technologies	Density Gauge
GA-176-D-105-G	Scan Technologies	Density Gauge
GA-659-D-101-S	Siempelkamp Corp.	Density Gauge
GA-596-D-101-G	Valmet Automation	Density Gauge
GA-596-D-102-G	Valmet Automation	Density Gauge
GA-596-D-103-G	Valmet Automation	Density Gauge
GA-596-D-110-G	Valmet Automation	Density Gauge
GA-596-D-111-G	Valmet Automation	Density Gauge
GA-596-D-112-G	Valmet Automation	Density Gauge
GA-596-D-113-G	Valmet Automation	Density Gauge

- 32. What guides, standards and procedures are used to evaluate registry applications?
 - Ans: NRC Reg Guide 10.10, "Guide for the Preparation of Applications for Radiation Safety Evaluation and Registration of Devices Containing Byproduct Material" NRC Reg Guide 10.11, "Guide for the Preparation of Applications for Radiation Safety Evaluation and Registration of Sealed Sources Containing Byproduct Material" NRC Reg Guide 6.9, Establishing Quality Assurance Programs for the Manufacture and Distribution of Sealed Sources and Devices Containing Byproduct Material" Policy and Guidance Directive 84-22, Revision 1, "What Source and Device Designs Require an Evaluation

State of Georgia Rules and Regulations for Radioactive Materials, Chapter 391-3-17 Workbook from the Sealed Source Device Workshop held September, 1995 Applicable ANSI Standards

33. Please include information on the following questions in Section A, as they apply to the Sealed Source and Device Program:

Technical Staffing and Training - A.II.7-10

- Ans: 7) All associates on the staff who work in licensing & inspection are also responsible for reviewing sealed source and device evaluations and writing registrations for these.
- Ans: 8) Elizabeth Drinnon and Cynthia Sanders.

Note: These individuals have prior experience and training with the Radioactive Materials program. Their training includes basic and advanced NRC training courses.

- Ans: 9) N/A All professional staff meet the qualification requirements of license reviewer/materials inspection staff.
- Ans: 10) Ralph McCoy and Lauren McGaughey.

Technical Quality of Licensing Actions - A.III.11, A.III.13-14

- Ans: 11) Valmet Automation All registration sheets amended and 2 new registration sheets issued. Scan Technologies - All registration sheets amended to show current Georgia address.
- Ans: 13) N/A No exemptions granted.
- Ans: 14) N/A No changes made to written licensing procedures for SSD review and evaluation.

Responses to Incidents and Allegations - A.V.20-23

> Ans: 20) Please provide a list of the <u>most significant</u> incidents (i.e., medical misadministration, over exposures, lost and abandoned sources, incidents requiring 24 hour or less notification, etc) that occurred in the Region/State during the review period. Information included in previous submittals to NRC need not be repeated. The list should be in the following format:

Licensee Name	License #	Date of Incident Report	Type of Incident
Johnson Yokogowa	GA1192-1	10/6/94	Servicing without a license and failure to file reciprocity
Elekta	GA1153-1	6/17/94 and 10/94	Equipment Malfunction

21. Johnson Yokogowa was not licensed to perform maintenance on their devices. They were performing maintenance prior to getting their license amended. Their customer operating manual also told the customer how to clean the device and remove and replace the source. The new manuals were sent to all customers with this procedure removed. They notified all customers in the change and told them that the customer may not work on any devices.

Elekta had a report that a couch failed to retract in Texas and was reported to us 6/17/94. Elekta was unable to reproduce the incident. The second incident in 10/94 was caused by a valve failure, no patients were involved in the process. The failure was due to foreign particles which entered the hydraulic system. The problem has been fixed and customers have been notified. A new filter system is being installed at each site.

- 22. Elekta had a valve failure which did not involve a patient. An engineering study was requested to investigate the cause. A device amendment is pending as a result of this incident.
- 23. One case of possible wrong doing: Johnson Yokogowa was jointly investigated by us and NRC. The licensee was performing service on devices before the

license was amended to allow the service, and they were performing work outside of the State of Georgia and not filing reciprocity. The licensee took sufficient, immediate corrective action to comply with the State of Georgia requirements and no further corrective action or enforcement was necessary. The licensee was fined by the NRC.

III. Low-Level Waste Program

34. Please include information on the following questions in Section A, as they apply to the Low-level Waste Program:

Status of Materials Inspection Program - A.I.1-3, A.I.6 Technical Staffing and Training - A.II.7-10 Technical Quality of Licensing Actions - A.III.11, A.III.13-

14

Technical Quality of Inspections - A.IV.16-19 Responses to Incidents and Allegations - A.V.20-23

Ans: N/A

IV. <u>Uranium Mill Program</u>

35. Please include information on the following questions in Section A, as they apply to the Uranium Mill Program:

Status of Materials Inspection Program - A.I.1-3, A.I.6 Technical Staffing and Training - A.II.7-10 Technical Quality of Licensing Actions - A.III.11, A.III.13-14 Technical Quality of Inspections - A.IV.16-19 Responses to Incidents and Allegations - A.V.20-23

Ans: N/A

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TABLE FOR QUESTION 29.

		DATE	OR		
10 CFR RULE	DATE DUE	ADOPTED	CURRENT STATUS	EXPECTED ADOPTION	
Any amendment due prior to 1991. Identify each regulation (refer to the Chronology of Amendments)	N/A		All done prior to last Program review	N/A	
Decommissioning; Parts 30, 40, 70	7/27/91		Not cited during last Program review so we have already adopted the requirements	N/A	
Emergency Planning; Parts 30, 40, 70	4/7/93	3/16/94	391-3-1702(7)(h)		
Standards for Protection Against Radiation; Part 20	1/1/94	Emr. 1/1/94 perm. 3/16/94	391-3-1703		
Safety Requirements for Radiographic Equipment; Part 34	1/10/94	10/24/94	391-3-1704(5)(a)&(b)		
Notification of Incidents; Parts 20, 30, 31, 34, 39, 40, 70	10/15/94	3/16/94	391-3-1703(14)(b)		
Quality Management Program and Misadministrations; Part 35	1/27/95	3/16/94	391-3-1705(6)(h)		

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		DATE	OR		
10 CFR RULE	DATE DUE	ADOPTED	CURRENT STATUS	EXPECTED ADOPTION	
Licensing and Radiation Safety Requirements for Irradiators; Part 36	7/1/96	3/16/94	391-3-1709		
Definition of Land Disposal and Waste Site Q Program; Part 61	7/22/96	Not req'd	Reviewed 391-3-17- .03(12)(f) prior to 3/94 revision. No amendments required		
Decommissioning Recordkeeping: Documentation Additions; Parts 30, 40, 70	10/25/96	3/16/94	391-3-1702(8)(g)		
Self-Guarantee as an Additional Financial Mechanism; Parts 30, 40, 70	1/28/97		No action taken	2/97	
Uranium Mill Tailings: Conforming to EPA Standards; Part 40	7/1/97		No action required	N/A	
Timeliness in Decommissioning Parts 30, 40, 70	8/15/97		No action taken	2/97	
Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use; Parts 30, 32, 35	1/1/98		No action taken	2/97	

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	DATE DUE	DATE ADOPTED	OR		
10 CFR RULE			CURRENT STATUS	EXPECTED ADOPTION	
Frequency of Medical Examinations for Use of Respiratory Protection Equipment	3/13/98		No action taken	2/97	
Low-Level Waste Shipment Manifest Information and Reporting	3/1/98		No action taken	2/97	
Performance Requirements for Radiography Equipment	6/30/98		No action taken	2/97	
Radiation Protection Requirements: Amended Definitions and Criteria	8/14/98		No action taken	2/97	
Clarification of Decommissioning Funding Requirements	11/24/98		No action taken	2/97	
10 CFR Part 71: Compatibility with the International Atomic Energy Agency	4/1/99		No action taken	2/97	

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APPENDIX D LICENSE FILE REVIEWS

File No. 1 Licensee: Rome Central Pharmacy license No: GA-1302-1 Amendment Nos: N/A Location: Rome, GA License Type: Nuclear Pharmacy Type of Action: New License Dates License Issued: 11/17/95 License Reviewers: RH Comments: a) There is no indication that a prelicensing visit was performed. There were numerous references to NRC regulations. The licensee should be required to refer b) to Georgia regulations. File No. 2 Licensee: Scan Technologies, Inc. License No: GA-1299-2G Location: Norcross, GA Amendment No: 1 License Type: Device Manuf./Distributor Type of Action: New & Amendment Date Lic. & Amend. Issued: 10/23/95 & 1/26/96 license Reviewer: FD Comment: a) The licensee's submittal lacks documentation of a manufacturing QA/QC program. File No. 3 Licensee: Scan Technologies, Inc. License No: GA-1299-1 Location: Norcross, GA Amendment No: 1 & 2 License Type: Possession & Service Type of Action: New & Amendments Date Lic. & Amends. Issued: 10/12/95, 12/8/95 & 1/26/96 License Reviewer: ED

File No. 4

Georgia Final Report Page C.2 license File Reviews Licensee: Georgia State University license No: GA-244-1 Location: Atlanta, GA Amendment Nos: 19, 20 & 21 Type of Action: Renewal & Amendments License Type: Broad Academic Date Amends. Issued: 6/24/95, 3/2/95 & 11/3/95 license Reviewer: IM Comments: a) Handwritten note from RSO dated 6/13/94 provided telephone list of users & operators manual for an irradiator, but file lacks deficiency letter. This file lacks documentation of review of prior compliance history. b) Files No. 5 Licensee: Honeywell, Inc. License No: GA-832-1G Location: Atlanta, GA Amendment Nos: 26 License Type: Device Distributor Type of Action: Renewal Date Renewal Issued: 1/31/94 license Reviewer: RH Comment: a) This file lacks documentation of review of prior compliance history (2/2/93 inspection with

File No. 6 Licensee: Longyear Products Group Location: Stone Mountain, GA License Type: Device Distribution & Servicing Date Renewal issued: 3/29/95

13 violations).

License No: GA-318-1 Amendment No: 32 Type of Action: Renewal License Reviewer: CT

Comment:

a) Radiation safety manual needs updating re: ALARA commitment, RSO duties, training, Ops & emergency procedures and personnel monitoring.

File Nos. 7 Licensee: Elekta Radiosurgery, Inc. Location: Atlanta, GA License Type: Device Servicing Date Renewal issued: 7/5/95

License No: GA-1153-1 Amendment No: 5 Type of Action: Renewal Reviewer: LM

Comment:

a) The application is minimal in content, needs comprehensive safety manual.

File No. 8 Licensee: Dupont Merck Pharmaceutical, Co. Location: S.E. Atlanta, GA License Type: Radiopharmaceutical Distribution Date Renewal Issued: 9/20/95

License No: GA-738-1 Amendment No: 12 Type of Action: Renewal Reviewers: CS

Comment: a) This file lacks documentation of review of the licensee's prior compliance history.

File No. 9 Licensee: Hunt and Associates Location: Rome, GA License Type: Portable Gauge Date Amendment Issued: 8/25/95

File No. 10 Licensee: The Medical Center Hospital License No: GA-1095-1 Amendment No: 4 Type of Action: Termination License Reviewer: TH

License No: GA-239-1

Location: Columbus, GA License Type: Teletherapy Date Amendment Issued: 11/14/95

File No. 11 Licensee: Unified Testing Services, Inc. Location: S.E. Marietta, GA License Type: Industrial Radiography Date Terminated: 1/4/96

File No. 12 Licensee: Medi-Physics, Inc. Location: Atlanta, GA License Type: Radiopharmacy Date of Amendment: 3/31/95

File No. 13 Licensee: Automata, Inc. Location: Marietta, GA License Type: Device Service & Distribution Date issued: 5/10/95

Comment:
a) License reviewer not clearly identified.

Amendment No: 15 Type of Action: Termination

License Reviewer: CS

License No: GA-1380-1 Amendment No: N/A Type of Action: New License Reviewer: ED

License No: GA-1166-1MD Amendment No: 9 Type of Action: Renewal License Reviewers: TH

License No: GA-1288-1 Amendment No: N/A Type of Action: New License Reviewer: ?

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File No. 14 Licensee: Cancer Center of Gwinnett Location: Lawrenceville, GA License Type: Radiotherapy Date Amendment issued: 9/6/94

File No. 15 Licensee: Patient Services Center Location: Carrollton, GA License Type: Nuclear Medicine Date Amendment Issued: 7/13/95

File No. 16 Licensee: Bartow Paving Company, Inc. Location: Cartersville, GA License Type: Portable Gauge Date Amendment Issued: 4/24/95 License No: GA-1082-1 Amendment No: 2 Type of Action: Termination License Reviewer: RH

License No: GA-1217-1 Amendment No: 5 Type of Action: Termination License Reviewer: RH

License No: GA-875-1 Amendment No: 4 Type of Action: Termination Reviewer: NM

APPENDIX E INSPECTION FILE REVIEWS

File No.: 1 Licensee: Tanner Medical Center Location: Carrollton, GA License Type: Institutional Medical & Therapy Inspection Date: 09/08/95

License No.: GA-120-2 Inspection Type: Routine, announced Priority: 3 Inspectors: CM

Comment:

a) The inspection report was not filed in the license folder. The inspector was able to reproduce the report from computer files and a copy was provided to the report. A QA problem.

File No.: 2 Licensee: Applied Technical Services Location: Marietta, GA License Type: Industrial Radiography, fixed Inspection Date: 09/26/95

License No.: GA-896-1 Inspection Type: Routine, announced Priority: 1 Inspectors: CM

Comments:

- a) Additional information is needed in the report to document who was performing radiographic work, and how it was determined that the person was only a trainee.
- b) The report was not reviewed by supervisor.
- c) Additional QA is needed to properly document the correct dates of the previous inspection, the current inspection, and the acknowledgement letter date in the file report, and letter to the licensee following the inspection.

File No.: 3 Licensee: Columbus Cancer Center Location: Columbus, GA License Type: Private, Brachytherpy, afterloading Inspection Date: 08/23/95

License No.: GA-1256-1 Inspection Type: Routine, announced Priority: 1 Inspectors: CS

Comments:

- a) Additional details are needed in the report to describe the instrument (with calibration date) used by the inspector for independent measurements.
- b) Additional information is needed to determine if the facility was as described in the license application (any changes).

File No.: 4 Licensee: Dekalb Medical Center Location: Decatur, GA License Type: Teletherapy Inspection Date: 08/18/95

License No.: GA-62-1 Inspection Type: Routine, announced Priority: 1 Inspectors: CS

File No.: 5 Licensee: Radiotherapy Clinic of Georgia Location: Decatur, GA License Type: Private, eye applicator Inspection Date: 08/25/95

License No.: GA-848-4 Inspection Type: Routine, announced Priority: 3 Inspectors: CT

Comment:

a) The Scope of the Inspection stated that independent measurements were performed; however, no sources were on site and available for surveys and there was no documentation of any surveys performed by the inspector. This is a QA problem resulting from the use of standard paragraphs from the computer and with no peer or supervisory review.

File No.: 6

Licensee: Northside Imaging Location: Atlanta, GA License Type: Private Medical and iodine therapy Inspection Date: 01/25/96

License No.: GA-836-1 Inspection Type: Routine, announced Priority: 5 Inspectors: CT

Comments:

- a) This inspection was an accompaniment by R. L. Woodruff.
- b) Additional details are needed in the report to identify where the surveys were taken by the inspector and the specific results.
- c) Additional efforts were needed to interview the technologist who performs work at the facility on a part time basis and to evaluate the personal monitoring utilized by the technologist.
- d) The previous inspection was performed on 2/9/93 with a NOV issued on 3/22/93. No response was received from the licensee and the status of the noncompliance was not confirmed until the current inspection. The items of noncompliance were related to record keeping and not health and safety. This is a QA problem.

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File No.: 7 Licensee: Diversified Pharmacy Location: Macon, GA License Type: Nuclear Pharmacy Inspection Date: 01/24/95

Inspection Type: Routine, announced Priority: 2 Inspectors: ELD

License No.: GA-891-1MD

Comments:

- a) No QA performed on the report by management and incorrect dates were recorded on the report for the previous inspection and the current inspection.
- b) Additional details are needed to describe the radiation levels detected at the specific areas surveyed during the independent measurements conducted by the inspector.

File No.: 8 Licensee: TN Technologies (Roundrock, TX licensee) Location: Clinchfield, GA License Type: Gauge Service License Inspection Date: 01/23/96

License No.: L03524

Inspection Type: Announced, reciprocity Priority: NA Inspectors: ELD

Comments:

- a) The inspection report listed the results of the independent measurements as "readings were all at the expected levels." Additional information is needed to document the specific radiation levels detected at specific locations.
- b) Additional information is needed to document what was discussed at the exit meeting held with the licensee's Field Representative during the inspection, and the reply.

File No.: 9 Licensee: Unified Testing Services, Inc. (Brent, AL licensee) Location: Lockheed, GA License No.: AL-1128 Inspection Type: Reciprocity, announced

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License Type: Industrial Radiography Inspection Date: 12/7/95 Priority: 1 Inspectors: CM

Comments:

- a) The inspector related that the inspection was announced because of the difficulty in obtaining access to the area.
- b) The report indicated that incidents had been reported to the Department of Transportation. The inspector related that this answer on the report was an error and no incidents had occurred. This resulted from a lack of QA on the report, and because the report forms in the computer have not been standardized for use by the staff.

File No.: 10 Licensee: Oconee Regional Cancer Center Location: Dublin, GA License Type: Private, brachytherapy & afterloading Inspection Date: 10-27-95

License No.: GA-1227-1 Inspection Type: Routine, announced Priority: 1 Inspectors: REH

Comments:

- a) Additional confirmatory measurements are needed on the HDR device and/or storage area.
- b) Additional information is needed to document that the facility was as licensed.
- c) More information is needed to document if any incidents have occurred and or recorded.

File No.: 11 Licensee: Macon Northside Hospital Location: Macon, GA License Type: Institutional with therapy Inspection Date: 01/24/96

License No.: GA-861-1 Inspection Type: Routine, announced Priority: 3 Inspectors: REH

Comments:

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- a) Additional details are needed to document what was discussed during the exit meeting and the licensee's verbal response.
- b) Additional details are needed in the Notice of Violation to document what isotopes were prescribed by Dr. Oliver.
- c) The previous NOV dated 03/30/93 was not tracked or status followed until the current inspection. The noncompliance was related to record keeping and not health and safety. A QA problem.
- d) Additional details are needed to document if any incidents had occurred and/or recorded.
- e) This inspection was an accompaniment by R. L. Woodruff.

File No.: 12 Licensee: Georgia Institute of Technology Location: Atlanta, GA License Type: Broad Academic Inspection Date: 12/11-13/95

License No.: GA-147-1 Inspection Type: Routine, announced Priority: 2 Inspectors: CT & RH

Comment:

a) Additional information is needed to describe the instrument(s) used for independent measurements.

File No.: 13 Licensee: Industrial NDT Company, Inc. Location: Garden City, GA License Type: Industrial Radiography Inspection Date: 07/11/95

File No.: 14 Licensee: Satilla Regional Cancer Treatment Center License No.: GA-540-1 Inspection Type: Announced, routine Priority: 1 Inspectors: JM

License No.: GA-991-1

Page E.7 Georgia Final Report Inspection File Reviews Location: Waycross, GA Inspection Type: Initial, announced License Type: Private, strontium-89 therapy Priority: 3 Inspection Date: 12/14/95 Inspectors: JM Comment: a) Additional information is needed to document if the licensee had any misadministration or recordable events. File No.: 15 Licensee: East Coast Diagnostics, Inc. License No.: GA-984-1MD Location: Savannah, GA Inspection Type: Routine, announced License Type: Nuclear Pharmacy Priority: 1 Inspection Date: 12-15-95 Inspectors: JM File No.: 16 Licensee: APAC-Georgia, Inc. License No.: GA-314-1 Location: Smyrna, GA Inspection Type: Routine, announced License Type: Portable Gauge Priority: 3 Inspection Date: 11/27/95 Inspectors: CM File No.: 17 Licensee: Southeastern Diagnostic, Inc. License No.: GA-1254-1 Inspection Type: Initial, announced Location: Waycross, GA License Type: Mobile Nuclear Medicine Priority: 2 Inspection Date: 10-26-94 Inspectors: RH & TH Comments:

a) Licensee ownership changed without notification to the State, the licensee was cited and a copy of the State's ownership procedure was provided to the Licensee with the

acknowledgement letter. The ownership item of noncompliance was not followed up (closed out) and without any action being taken to change the license ownership. Additional QA is needed to resolve the noncompliance and close out the item before the next inspection.

- b) The licensee committed to a Radiation Safety Committee; however, the inspection report documented this item as "N/A." Additional information is needed to document the status of this item in the report, and what action (if any) was recommended to the licensee, and this information coordinated with the license reviewer.
- c) Additional information was needed to document dose calibrator constancy checks, and annual and quarterly RSO reviews.
- d) The inspection was a record review only and efforts should be made to also inspect the van's operation at an on-site facility.
- e) A copy of the enforcement letter should also be provided for information purposes to the South Carolina Bureau of Radiological Health. The licensee's home office is located in South Carolina and also licensed by the State of SC.

File No.: 18 Licensee: J.L. Shepherd and Assoc. (A California licensee) Location: Atlanta, GA License Type: Source Removal, Service Company Inspection Date: 12/1-2/95

License No.: CA-1777-70

Insp. Type: Unannounced, reciprocity Priority: 1 Inspectors: ELD & TH

APPENDIX F INCIDENT FILE REVIEWS

File Number: 1 Incident Log Number: GA-93-15I Licensee: Gallet Associates license: Alabama 991 Type of Event: Stolen Gauge Site of Event: Gainesville, GA Investigation Type:Phone Date of Event: 11/22/93Investigation Date: 11/23/93 Summary of Incident: A Campbell Pacific Nuclear density gauge, containing radioactive material (RAM), was stolen from a locked trailer. Gallet Associates notified the police department and local media (who aired the story on 11/24/93). A few days later the gauge was found. File Number: 2 Incident Log Number: GA-94-01I Licensee: National Records and Archives license: N/A Type of Event: Contamination Site of Event: National Records and Archives Date of Event: 1/5-7/94 Investigation Type:Correspondence Investigation Date: N/A Summary of Incident: During a DOE survey two boxes of punch cards stored at the facility were identified as having measurable Uranium contamination on the punch cards not on the boxes. The two boxes were sent to Y-12 for storage. Incident Number: Log GA-94-04I File Number: 3 Licensee Georgia Tech License Number: GA 147-1 Site of Event: Palmer Station, Antarctica Type of Event: Leaking Source Date of Event: 1/18/94 Investigation Type: Correspondence Investigation Date: N/A Summary of Incident: A Ni-63 source was crushed en route to Palmer Station. The source was reformed and put to use. A leak test performed on 1/19/94 showed no contamination. On 1/21/94 notification was made that the source ID sticker was contaminated and a second leak test showed slightly greater than 0.005

Page F.2 Georgia Final Report Incident File Reviews microCi of contamination. The source was removed and the equipment was decontaminated. The source is awaiting disposal. Comment: a) Incident is still open. File Number: 4 Incident Log Number: GA-94-07I Licensee: Georgia Pacific License Number: GA 269-1 Site of Event: Arlington Heights. IL Type of Event: Leaking Source Investigation Type: Site Date of Event: 4/22/94 Investigation Date: 4/27/94 Summary of Incident: A leaking two curie Cs-137 source was received at the Rosemount facility in Arlington Heights. An investigation was conducted on 4/27/94 at Georgia Pacific and on 5/26/94 confirmatory surveys were done. Comment: a) Case still open. File Number: 5 Incident Log Number: GA-94-101 Licensee: Cobb Place 8 Theater License Number: GL Type of Event: Leaking Source Site of Event: Kennesaw, GA Date of Event: 5/18/94 Type of Investigation: Phone Investigation Date: 5/18/94 Summary of Incident: A man called the NRC Operation Center to report a leaking and defective exit sign (8.93 Ci of Tritium/sign). The vertical part of the T was not lit. Call was forwarded to the State of

Georgia. Tom Hill talked to the manager of the facility and the service company. Service Company to remove the sign, package it and send it back to the manufacture.

File Number: 6 Incident Log Number: GA 94-111 Licensee: Numed, Inc. license Number: GA 1259-1 Site of Incident: Doerun, GA Type of Event: Transportation Date of Event: 5/26/94 Type of Investigation: Phone Investigation Date 5/26/94 Summary of Incident: Traffic accident involving vehicle returning to pharmacy and carrying empty containers; RSO went to scene and performed radiation surveys and found no spills. Closed on 7/21/94 when written report received. Comment: a) Incident not mentioned in inspection report (inspection done on 8/2/94) and a copy of incident report not in RAM file. File Number: 7 Incident Log Number: GA 94-12I Licensee: Becton Dickinson license Number: N/A Site of Incident: Roswell, GA Type of Event: Abandoned RAM Date of Event: 5/31/94 Type of Investigation: Site Investigation Date: 5/31/94 Summary of Incident: Nine cases of BACTEC test kits and bacteria culture media were found in a trash area at the storage warehouse (288 microCi/case of C-14). They were turned over to a representative of Becton Dickinson for proper disposal. Incident Log Number: GA-94-13I File Number: 8 Licensee: United Testing Group License Number: GL

Site of Incident: 3121 Presidential Drive Date of Event: 6/1/94 Type of Event: Lost RAM Type of Investigation: Phone

Investigation Date 6/2/94

Summary of Incident: In July 1993 Technology Applications Division of Professional Services Industries merged with Specto Metrics to form United Testing Group. They moved to Specto Metrics address, but since they did not use the gauge they cannot confirm it was moved to the new site. Around May 22, 1994, they decided to use the gauge but could not locate the device. During the week of May 29 they called Princeton Gamma-Tech to report the loss. One last attempt to locate the instrument was done on 6/1/94, but could not locate it at either location. Called the State on 6/2/94. (Lost device was a Princeton Gamma-Tech Model 100 SN 636 with a 50 mCi Fe-55 source)

File Number: 9 Licensee: City of Atlanta Site of Incident: Pollution Control Laboratory Date of Event: 6/6/9 Investigation Date: 6/8/94 Summary of Incident: Licensee could not locate a Victoreen (Fisher 4800) gas chromatograph while filling out an inventory to correct an inspection citation. Had been in storage for approximately 20 years, previous inspection showed it was there in 1988.

File Number: 10 Licensee: Electa Radiosurgery Site of Incident: Dallas, TX Date of Event. 6/16/94 Investigation Date: 6/17/94 Summary of Incident: Couch of Gamma Knife failed to retract. Could not duplicate event. Incident Log Number: GA 94-15I Licensee Number: GA 1153-1 Type of Event: Equipment Failure Type of Investigation: Correspondence

File Number: 11Incident Log Number: GA 94-16ILicensee: Newnan HospitalLicense Number: GA 135-2

Site of Incident: Hospital Type of Event: Lost RAM Date of Event: 5/19/94 Type of Investigation: Phone Investigation Date: 6/8/94 Summary of Incident: On 5/19/94 the nuclear medicine tech was preparing to do the dose calibrator check, but discovered the Cs-137 check source was missing. Checked with the agency tech who was there the day before, surveyed room and incinerator, and checked with the pharmacy but could not locate the source.

File Number: 12 Licensee: Law Engineering Co Site of Incident: Folkston, GA Date of Event 10/13/94 Investigation Date: 10/14/94 Summary of Incident: Incident Log Number: GA 94-18I License Number: N/A Type of Event: Other Type of Investigation: Site

Call from Carlton County Sheriffs Department about a plastic case bearing radiation labels that was found in a dumpster. Turned out to be a Troxler moisture density gauge transport case with serial number 19109 on the case. It was traced through Troxler to Law Engineering in Miami, FL. The case had been stolen in 3/93 but not the gauge. The case was turned over to Law Engineering in Brunswick, GA to return to Miami.

Page F.6 Georgia Final Report Incident File Reviews Incident Log Number: GA 94-21I File Number: 13 Licensee: Georgia Power Company License Number: GA 40-1 Site of Incident: Plant Hammond Type of Event: Loss of Control Date of Event: 10/31/94 Type of Investigation: Correspondence Investigation Date N/A Summary of Incident: Three Texas Nuclear (16 mCi) sources were removed by Babcock and Wilcox Construction Company on 10/31/94 at plant Hammond during an outage at unit 2. GPC was not aware of the source removal until 11/23/94. Licensee located gauges and found shutters open and gauges in good condition. They estimate four workers received 24 mrem each. Comment: a) Copy of incident not in RAM file. File Number: 14 Incident Log Number: GA 94-23I Licensee: Applied Radiological Control License Number: GA 899-1 Site of Incident: Kennesaw, GA Type of Event: Loss RAM Date of Event: 12/19/94 Type of Investigation: Phone Investigation Date: 1/17/95 Summary of Incident: At the conclusion of a project in Detroit, MI two sources (Am-241 67.98 nCi and Sr-90 10 nCi) were placed in one of several boxes to be shipped back along with some miscellaneous material. Several days later the boxes were unpacked. On 12/13/94 an inventory was performed and the sources could not be located. File Number: 15 Incident Log Number: GA 94-25I Licensee: Emory University License Number: GA 153-1 Type of Event: Possible Overexposure Site of Incident: School of Medicine Date of Event: 1/28/94 Type of Investigation: Correspondence

Investigation Date: 1/4/95
Summary of Incident:

Film badge showed a reading of 7460 mrem. Individual entered a Cyclotron mini-cell after the production of F-18 FDG (~208 mCi activity in cell). Licensee felt that the high reading was due to contamination of the badge and calculated a more probable exposure of 2670 mrem.

Comment:

a) Copy not in RAM file.

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Page F.8 Georgia Final Report Incident File Reviews Incident Log Number: GA 95-01I File Number: 16 Licensee: Geo Science License Number: GA 1211-1 Site of Incident: McDonough, GA Type of Event: Damage to Equipment Date of Event: 2/6/95 Type of Investigation: Phone Investigation Date: 2/6/95 Summary of Incident: Troxler moisture density gauge model 3411 was crushed by a Caterpillar D6 dozer. Area was limited to access while tech phoned supervisor who called the radiation safety officer who went to the site. RSO checked the gauge and found that the shutter was closed. He surveyed the area and found no sign of contamination. Returned the gauge to the office where he leak tested, packaged and shipped the gauge to Troxler for disposal. File Number: 17 Incident Log Number: GA 95-04I Licensee Milliken Live Oak Plant License Number: GL Site of Incident: LaGrange. GA Type of Event: Damage to Equipment Date of Event 1/31/95 Type of Investigation: Site Investigation Date: 2/1/95 Summary of Incident: A fire destroyed the plant where five fixed gauges and one portable gauge was located. Four gauges were found intact, but the portable gauge was destroyed although the source maintained its integrity. All sources were sent for disposal. File Number: 18 Incident Log Number: GA 95-061 Licensee: Gwinnett Medical Center License Number: GA 677-1 Site of Incident: Lawrenceville, GA Type of Event: Overexposure Date of Event: 4/6/95 Type of Investigation: Site Investigation Date: 4/7 & 7/30/95 Summary of Incident: Two radiation physicist at the hospital handled what they assumed was a "dummy" Ir-192 brachytherapy ribbon, but was actually a loaded ribbon. They placed the "dummy" in the patient to

determine location and on the way back past the nuclear medicine department a gamma camera turned "white." At that point the ribbon contained seeds. Estimated doses were Physicist B - 1256 rem to tho hand, Physicist A 43.3 rem to the hand and 110 mrem fetal dose.

File Number: 19Incident Log Number: GA 95-071Licensee: Numed, Inc.License Number: GA 1259-1Site of Incident: Cordele, GAType of Event: TransportationDate of Event: 6/21/95Type of Investigation: PhoneInvestigation Date: 6/21/95Summary of Incident: A vehicle carrying Tc-99m unit doses was involved in a minor accident. Nodamage to the packages.Automation

Comment:

a) Not mentioned in inspection report (inspection done on 9/26/95) and not in RAM file.

Page F.10 Georgia Final Report Incident File Reviews File Number: 20 Incident Log Number: GA 95-08I Licensee. Textron License Number: GL Site of Incident: Americus, GA Type of Event: Loss of RAM Date of Event: 5/31/95 Type of Investigation Correspondence Investigation Date: 6/19/95 Summary of Incident: An air nozzle Containing a Po-210 source became detached from the air hose during use. Licensee was unable to find and believes it went to a landfill. File Number: 21 Incident Log Number: GA 95-091 Licensee: Professional Services Inc. license Number: GA 629-1 Site of Incident: Martinez, GA Type of Event: Damage to Equipment Type of Investigation: Site Date of Event: 7/12/95 Investigation Date: 7/13/95 Summary of Incident: A fire at the gauge operators house damaged a moisture density gauge that was stored in a truck in the garage. State personnel conducted an area survey and found no contamination. Gauge was sent to Campbell Pacific Nuclear for disposal. File Number: 22 Incident Log Number: GA 95-11I Licensee: Emory University License Number: GA 153-1 Type of Event: Loss of Control Site of Incident: Atlanta, GA Date of Event: 9/14/95 Type of Investigation: Correspondence Date of Investigation: 10/16/95 Summary of Incident: Material from Emory set off the monitor at the landfill. Licensee went out to the landfill to recover the material, which turned out to be ~75 microCi of I-131 in urine. Incident Log Number: GA 95-1211 File Number: 23 Licensee: Emory University License Number: 153-1 Site of Incident: Atlanta Type of Event: Lost RAM Date of Event: 8/1-2/95 Type of Investigation: ?

Investigation Date: ? Summary of Incident: Lost sealed source (7 mCi of Sr-90/Y-90) use for brachytherapy in pigs. At the end of the procedure sources were counted and all were thought to be present. Then catheter was rinsed. The next day the catheter was reloaded and it was apparent that one source was missing because the line was short. A survey showed 50 mr/hr exposure under the sink around the drain pipe. Before the drain could be removed the water was turned on and no radiation levels could then be found.

Comment:

a) Documentation of investigation not in file.

Georgia Final Report Incident File Reviews Incident Log Number: GA 95-15I File Number: 24 Licensee: Emory University License Number: 153-1 Site of Incident: Atlanta Type of Event: Lost RAM Date of Event: 11/6/95 Type of Investigation: Phone Investigation Date: 11/6/95 Summary of Incident: A patient received 16 seeds (I-131) and was moved to another room without the required survey. The two catheters fell out, were examined and reinserted. The catheters were removed at the required time and placed in safe storage. A seed count on the follow day revealed that one seed was missing. All areas were surveyed but the seed was not found. File Number: 25 Incident Log Number: GA 96-03I License Number: N/A Licensee: N/A Site of Incident: Loganville, GA Type of Event: Abandoned RAM Date of Event: 2/7/96 Type of Investigation: Site Investigation Date: 2/7/96 Summary of Incident: Walton County Fire Department found some equipment from a doctors office in an old abandoned house including several containers marked as radioactive. ERP investigated and found two "pigs" containing vials of unknown liquid, an old shield which had been used and labeled to store I-131 tablets, and a "pig" with Mo-99 dose calibration source (which was determined to have decayed). All material had decayed to background levels. Incident Log Number: GA 93-12M File Number: 26 License: Emory University License Number: GA 153-1 Site of Incident: Atlanta Type of Event: Misadministration Type of Investigation: Next Inspection Date of Event: 10/7/93 Summary of Incident: In-111 (0.5999 mCi) leukocyte injection given to wrong patient. Proper information written on medical requisition form, but imprinted with wrong patient name.

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File Number: 27Incident Log Number: GA 93-13MLicensee: Newton General HospitalLicense Number: GA 632-1Site of Incident: Covington, GAType of Event: MisadministrationDate of Event: 11/2/93Type of Investigation Next InspectionSummary of Incident:Physicians order transcribed for wrong patient (3.36 mCi Thallous Chloride).

File Number: 28Incident Log Number: GA 93-14MLicensee: John D. Archbold Memorial HospitalLicense Number: GA 78-1Site of Incident: Thomasville, GAType of Event: MisadministrationDate of Event: 12/1/93Type of Investigation: Next InspectionSummary of Incident:11 Mci Tc-99 pertectnetate given to pregnant patient.

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Page F.14 Georgia Final Report Incident File Reviews Incident Log Number: GA 93-15M File Number: 29 Licensee: Regional Imaging Center License Number: GA 1093-1 Site of Incident: Macon. GA Type of Event: Misadministration Date of Event: 12/28/95 Type of Investigation: Next Inspection Summary of Incident: Patient administered wrong pharmaceutical Tc 99m pertectnetate instead of Tc 99m HDP. Mislabeled syringe. File Number: 30 Incident Log Number: GA 93-16M Licensee: Georgia Baptist Medical Center license Number: GA 66-1 Type of Events: Misadministration Site of Incident: Radiation Oncology Type of Investigation: Next Inspection Date of Event: 12/28/93 Summary of Incident: Tandem and ring applications reversed on Houdek applicator on HDR, resulting in a delivered dose of 273 cGy instead of 500 cGy. Comment: Report not in radioactive materials file and not mentioned in report from inspection done on a) 11/21/94. File Number: 31 Incident Log Number: GA 94-01M Licensee: Crisp Regional Hospital License Number: GA 074-1 Type of Event: Misadministration Site of Incident: Cordele. GA Date of Event: 1/7/94 Type of Investigation: Next inspection Summary of Incident: Wrong Patient given dose of 4.025 mCi of Tc 99m MAA. ID bracelet and chart not checked. Incident Log Number: GA 95-01M File Number: 32 Licensee: Emory University License Number: GA 153-1 Site of Incident: Nuclear Medicine Department Type of Event: Misadministration

Georgia Final Report Page F.15 Incident File Reviews Type of Investigation: Next Inspection Date of Event: 3/22/95 Summary of Incident: Patient prescribed a dose of 5 mCi P-32 Phosphate. Technologist prepared dose in 10cc plastic syringe and administered the dose. Shortly after the technologist reviewed the assay procedure with the radiopharmacy technologist, where it was discovered that the tech used the dose calibrator setting for a glass vial and only 3.82 mCi was actually given. Patient was called back and administered the rest of the dose. Incident Log Number: GA 95-02M File Number: 33 Licensee: The Medical Center, Inc License Number: GA 239-2 Site of Incident: Columbus, GA Type of Event: Misadministration Type of Investigation: Next Inspection Date of Event: 4/17/95 Summary of Incident:

Sr-90 eye applicator used to treat patient's right eye instead of the left eye ~10 Gy to eye.

APPENDIX G SEALED SOURCE AND DEVICE EVALUATION REVIEWS

File No.: 1 Registry No.: GA-269-D-101-S Manufacturer: Elekta Radiosurgery, Inc.

Comment:

a) Need actual prototype test results.

File No.: 2 Registry No.: GA-176-D-(101 thru 105)-S Manufacturer: Scan Technologies, Inc.

Comments:

- a) These SS&D Registry Certificates were re-issued to reflect a recent move to Georgia from NRC territory.
- b) These SS&D Registry Certificates should be re-evaluated in their entirety and the licensee should be required to submit a manufacturing QA/QC program tied to devices as they are distributed under the Georgia license.

File No.: 3 Registry No.: GA-571-D-101-G Manufacturer: Honeywell, Inc.

SS&D Type: Beta & Gamma Gauges Date Issued: 9/21/94

SS&D Type: Density Gauges

Date Issued: 10/23/95

Comments:

- a) This is a reevaluation of SS&D Registry Certificate, NC-221-D-101-U, dated 1/26/73.
- b) Need prototype test results or certification from third party.
- c) Manufacturer QA/QC program documentation needs updating.
- d) Reference is made to new temperature resistant plastic components, but

no specific list of these parts was on file.

SS&D Type: Teletherapy Date Issued: 11/20/95 & 12/4/95

Page G.2 Georgia Draft Report SS&D Evaluation Reviews File No.: 4 Registry No.: GA-596-D-111-G SS&D Type: Beta Gauge Manufacturer: Valmet Automation, Inc. Date Issued: 11/16/93 & 7/12/94 Comments: a) Diagram too small, insufficient detail. Manufacturer QA/QC program documentation needs updating. b) File No.: 5 Registry No.: GA-596-D-112-G SS&D Type: Gamma Gauge Manufacturer: Valmet Automation, Inc. Date Issued: 6/29/94 Comments: This is a reevaluation of a source head design previously approved as a) GA-596-D-107-G except that the airgap may now extend to "8 inches". There was no mention of a physical barrier to prevent limbs from entering the radiation field (1.0 Curie source). There is no mention of tamper-proof screws. b) File No.: 6 Registry No.: GA-596-D-113-G SS&D Type: XRF/Beta Gauge Manufacturer: Valmet Automation, Inc. Date Issued: 11/9/95 File No.: 7 Registry No.: GA-659-D-101-S SS&D Type: Gamma Gauge Manufacturer: Siempelkamp (North America) Corp. Date Issued: 10/5/94 Comment: Detailed engineering drawings are on file, however, they lack an English language a) translation.

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