UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

September 21, 2004

Mr. Terry Pierce, Director
Division of Environmental Health
Department of Environment and Natural Resources
2728 Capital Boulevard
Raleigh, NC 27699-1630

Dear Mr. Pierce:

The Nuclear Regulatory Commission (NRC) uses the Integrated Materials Performance Evaluation Program (IMPEP) in the evaluation of Agreement State programs. Enclosed for your review is the draft IMPEP report which documents the results of the Agreement State review held in your Division on August 16 - 20, 2004. I was the team leader for the North Carolina review. The review team's preliminary findings were discussed with you and your staff on the last day of the review. The review team's proposed recommendations are that the North Carolina Agreement State program be found adequate to protect public health and safety and compatible with NRC's program.

NRC conducts periodic reviews of Agreement State programs to ensure that public health and safety are adequately protected from the hazards associated with the use of radioactive materials and that Agreement State programs are compatible with NRC's program. The process, titled IMPEP, employs a team of NRC and Agreement State staff to assess both Agreement State and NRC Regional Office radioactive materials licensing and inspection programs. All reviews use common criteria in the assessment and place primary emphasis on performance. Three additional areas have been identified as non-common performance indicators and are also addressed in the assessment. The final determination of adequacy and compatibility of each Agreement State program, based on the review team's report, will be made by a Management Review Board (MRB) composed of NRC managers and an Agreement State program manager who serves as a liaison to the MRB.

In accordance with procedures for implementation of IMPEP, we are providing you with a copy of the draft team report for review prior to submitting the report to the MRB. We welcome your comments on the draft report. We request comments within four weeks from your receipt of this letter. This schedule will permit the issuance of the final report in a timely manner that will be responsive to your needs.

The team will review the response, make any necessary changes to the report and issue it to the MRB as a proposed final report. Our preliminary scheduling places the North Carolina MRB meeting in the week of November 1, 2004. We will coordinate with you to establish the date for the MRB review of the North Carolina report and will provide invitational travel for you or your designee to attend.

NRC has video conferencing capability if it is more convenient for the Commonwealth to participate through this medium. Please contact me if you desire to establish a video conference for the meeting.

If you have any questions regarding the enclosed report, please contact me at 301-415-2328.

Thank you for your cooperation.

Sincerely,

James H Myers

James H. Myers, Team Leader
Office of State and Tribal Programs

Enclosure:
As stated

cc: Michael A. Kelly, Deputy Director
Division of Environmental Health

Beverly Hall, Chief
Radiation Protection Section
Division of Environmental Health

Walter L. Cox, III, Manager
Radioactive Materials Branch

INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF NORTH CAROLINA AGREEMENT STATE PROGRAM

August 16 - 20, 2004

DRAFT REPORT

U.S. Nuclear Regulatory Commission

1.0 INTRODUCTION

This report presents the results of the review of the North Carolina Agreement State program. The review was conducted during the period of August 16-20, 2004, by a review team comprised of technical staff members from the Nuclear Regulatory Commission (NRC) and the Agreement State of Massachusetts. Team members are identified in Appendix A. The review was conducted in accordance with the "Implementation of the Integrated Materials Performance Evaluation Program and Rescission of a Final General Statement of Policy," published in the Federal Register on October 16, 1997, and the February 26, 2004, NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." Preliminary results of the review, which covered the period of September 18, 2000 to August 20, 2004 were discussed with North Carolina management on August 20, 2004.

[A paragraph on the results of the Management Review Board (MRB) meeting will be included in the final report.]

The North Carolina Agreement State program is administered by the Radiation Protection Section (the Section) within the Division of Environmental Health (the Division), which is part of the Department of Environment and Natural Resources (the Department). Within the Section, the Radioactive Materials Branch (the Branch) administers the radioactive materials program under the Agreement. In addition, the Section's newly created Emergency Response and Environmental Branch, formerly the Environmental Radiation Branch, responds to all radiation incidents.

Organization charts for the Department, the Division, Section, and the Branch are included in the report as Appendix B. The North Carolina Agreement program regulates approximately 751 specific licenses authorizing radioactive materials. The review focused on the 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 North Carolina.

In preparation for the review, a copy of the recently revised IMPEP questionnaire was sent to the Section on June 3, 2004. The Branch provided a response to the questionnaire on July 26, 2004. A copy of the State's questionnaire response can be found on NRC's Agencywide Document Access and Management System using the Accession Number ML042160130.

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

Section 2 discusses the State's actions in response to previous IMPEP review recommendations and the review team's conclusions regarding the closure of those recommendations. Results of the current review for the IMPEP common performance

indicators are presented in Section 3. Section 4 discusses results of the applicable non-common performance indicators, and Section 5 summarizes the review team's findings and recommendations. Recommendations made by the review team are comments that relate directly to program performance by the Section. A response is requested from the Department to all recommendations in the final report.

2.0 STATUS OF ITEMS IDENTIFIED IN THE PREVIOUS REVIEW

During the previous IMPEP review, which concluded on September 22, 2000, seven recommendations were made and the results transmitted to Robin Smith, Assistant Secretary, Department of Environment and Natural Resources, on December 20, 2000. The review team's evaluation of the current status of the recommendations is as follows:

1. The review team recommends that the Branch change the inspection frequency of nuclear pharmacies from a Priority 2 to a Priority 1 in accordance with NRC's Inspection Manual Chapter (IMC) 2800 and conduct inspections at the appropriate frequency. (Section 3.1)

   Current Status: The Section revised the inspection frequency priority and it is consistent with the current NRC IMC 2800 criteria. This recommendation is closed.

2. The review team recommends that the Branch meet the reciprocity inspection frequency goals specified in NRC IMC 1220. (Section 3.1)

   Current Status: The Section exceeded the reciprocity inspection frequency goals specified in NRC IMC 1220 for the review period. This recommendation is closed.

3. The review team recommends that staff who conduct independent inspections and/or license reviews of teletherapy and brachytherapy licenses and irradiator licenses complete the teletherapy/brachytherapy course and irradiator course, or their equivalent. (Section 3.3)

   Current Status: The review team examined the Branch's training records for the staff performing teletherapy/brachytherapy and irradiator inspections. In addition the review team accompanied two Branch inspectors during medical inspections that included brachytherapy. The review team noted that staff training records document on the job training. No performance issues were identified during the accompaniments. This recommendation is closed.

4. The review team recommends that a formalized, written training program based upon the requirements specified in NRC IMC 1246 or "NRC/Organization of Agreement States Training Working Group Recommendations for Agreement State Training Programs," be developed for license reviewers and inspectors. (Section 3.3)

   Current Status: The review team noted that the current staff is trained in accordance with the requirements specified in NRC IMC 1246 or "NRC/Organization of Agreement States Training Working Group Recommendations for Agreement State Training Programs," and formal documentation of staff training is in place. The Branch's training

policy and procedures are found in Policy and Procedure Statement T-001-R, Health Physicist Training Program. The Branch uses a mentoring program for training in several areas. This recommendation is closed.

5. The review team recommends that the Nuclear Material Events Database (NMED) data be updated to reflect the status and close out of cases as appropriate, and that incident data be provided to the NRC in accordance with STP Procedure SA-300. (Section 3.5)

   Current Status: The review team noted that the Branch is providing incident data to NMED within 24 hours, when appropriate, and on a monthly basis for routine incidents. The events are closed in NMED as appropriate. This recommendation is closed.

6. The review team recommends that all registration certificates reference the specific documents which were reviewed during the safety evaluation. (Section 4.2)

   Current Status: Each registration certificate issued during the review period references the specific documents reviewed during the safety evaluations. This recommendation is closed.

7. The review team recommends that the Branch develop a tracking system to follow the status of Sealed Source and Device (SS&D) actions. (Section 4.2)

   Current Status: The team confirmed that the Branch has implemented a tracking system; however, the tracking system was only functional with test data. This recommendation is closed, but the review team's concerns regarding the Branch's databases are discussed further is Sections 3.2, Status of the Materials Inspection Program and Section 4.2.2, Technical Quality of the Product Evaluation Program. The review team made a new recommendation in Section 3.2.

3.0 COMMON PERFORMANCE INDICATORS

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

3.1 Technical Staffing and Training

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

The Branch devotes approximately 8.5 full time equivalent (FTE) to the radioactive materials program of which 7 FTE are allotted to radioactive materials licensing, inspection, compliance

and SS&D programs. The remaining 1.5 FTE includes program administration and emergency response. The Emergency Response and Environmental Branch staffing level supporting the Section's initial emergency response to all radiological incidents is six FTE, including a supervisor. Additionally, the Section uses about 25 percent of the FTE of the Special Technical Projects staff member for the development of regulations.

The Branch currently has no vacant positions. One individual transferred from the Branch to the Emergency Response and Environmental Branch and a new staff member was hired a year ago. Although the Section was re-designated and downsized from a Division since the last review, this change did not significantly affect the Branch's overall responsibilities or workload. The review team concluded that staffing under the new arrangement is adequate for the radioactive materials program. The review team noted that the Branch had stable funding during the review period due to dedicated revenue from licensee fees.

The staff is well qualified from an education, training and experience standpoint. All staff have at least a Bachelor's degree in the sciences, or equivalent training and experience. Seven experienced technical staff members have taken the NRC courses deemed appropriate for their tasks. Since August 2003, the newest staff member has completed five courses deemed appropriate for his responsibilities. The last IMPEP review recommended the Section have staff attend NRC's brachytherapy and irradiator courses when they became available. However, the Section's training funding for these courses, and others, was severely reduced over the previous four years. Management was unable to accomplish this recommendation. The team discussed the previous IMPEP team's training recommendation with management, the Section's funding difficulties over the last four years, and several other acceptable methods of qualifying staff in specific areas. The team pointed out that the results of the current IMPEP team's accompaniment of a Branch inspector during a more complex medical inspection that included a brachytherapy program. This inspection clearly demonstrated that although the inspector, had not completed the NRC brachytherapy course the inspector was, knowledgeable, experienced, and qualified well enough to perform independent brachytherapy inspections. The team suggested that the Branch consider holding a qualification "board" for this individual, based on training and on the job experience he had received since his hiring, to qualify the inspector in this area.

During the review the team was informed that some money for training had just been received by the Section and the management team was working on plans to effectively use the funding to further develop and train the staff.

The review team observed that management is committed to training and the review team found that the new staff were well trained, experienced and fully capable of inspecting these complex licenses. The review team found that the Branch's training and qualification program, based on NRC IMC 1246 and the NRC/Organization of Agreement States Working Group guidance, is adequately documented. The Section has a written training policy and management signs off on completed tasks. The Branch also maintains computer records of individual training. During the review period, the Branch, despite training funding problems, took the initiative to train new staff to acceptable standards. New employees, under the guidance of a mentor, became qualified to perform radioactive materials licensing and inspection tasks by starting with simple licenses and working towards the more complex types of licenses. When ready, the employee participates in a qualification board to test their knowledge and skills. If successful, the employee gains management sign-off on their ability to

perform the task. Using this process, the team finds that the newest staff member is fully qualified.

The North Carolina Radiation Protection Commission (the Commission) serves as an advisory group to the Division. The Commission is composed of eleven voting members, including the Chairman, and 10 "ex-officio" members. Several sub-committees report to the Commission on specific radiation issues. Members are appointed by the Governor. The Commission membership is composed of licensees, members of the public and government representatives to provide a broad overview of issues related to the regulation of radiation within the State. Prospective members must complete an ethics statement, a statement of economic interest before serving on the Commission, and recuse themselves from participation in issues where they may have a conflict of interest. In addition to its advisory role, the Commission has an administrative role in the development and promulgation of all radiation regulations within the State. The team found no evidence of any conflict of interest during this review.

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

3.2 Status of Materials Inspection Program

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

In April 2003, the Branch revised its inspection frequencies for various types of material licenses to conform with the priorities listed in the latest revision to NRC IMC 2800 "Materials Inspection Program." The team confirmed that the Branch's new inspection priorities were at least the same or more frequent than those in NRC IMC 2800. Over the review period, inspection priorities previously used by the Branch also paralleled the frequencies used by NRC.

Review of records indicated that at the time of the IMPEP review, there was one inspection currently overdue by more than 25 percent of the NRC's inspection frequency. This inspection has been scheduled to be completed by October 2004. The review team determined that of the 227 inspections of the Priority 1, 2 and 3 licenses performed by the Branch during the review period, 22 were performed overdue. The team noted that 17 of the overdue inspections, ranging from a few days to 12 months late, were for Priority 1 licenses.

With respect to initial inspections of new licenses, the Branch's inspection frequency is consistent with the guidance in NRC IMC 2800. During the review period, the Branch issued 128 new licenses and 11 of the inspections were not conducted within the one year time frame. The team found that the overdue inspections were performed seven days to one year late. Overall, the team found that 9.6 percent of the 355 core inspections, which includes new, Priority 1, 2 and 3 licenses, performed by the Branch were performed overdue. As noted

below, the review team believes the increase of overdue inspections can be attributed to the unreliability of the inspection database.

The review team determined that the Branch met and exceeded NRC's current criteria of inspecting candidate licenses (Inspection Priority 1, 2 and 3) operating under reciprocity as specified in NRC IMC 1220 for the approximately 50 core reciprocity licenses granted reciprocity during the review period. The Branch conducted 19 inspections of candidate licenses during the review period. In addition, the Branch inspected 40 non-candidate reciprocity licenses during the review period.

The review team examined the timeliness of inspection findings issued by the Branch during the review period. The Branch's goal is to complete each inspection report and the letter to the licensee summarizing the inspection findings within 30 days of the inspection's completion date. Of the 23 inspection files reviewed, only two inspection reports and findings were completed beyond the 30-day goal. The reports were 40 and 144 days late. The team attributes the 144 day delay to the unreliability of the Branch's inspection database that has been previously discussed.

The review team found that the databases and the reports produced from the databases used by the Branch to track routine, initial and reciprocity inspections contained incorrect or missing information, did not include all licenses, and produced erroneous due dates. Consequently, the team had to verify the quality of the information in the inspection databases by comparison with written information in the files. The Branch Manager confirmed that the unreliable quality of the inspection databases is the result of ongoing technical problems resulting in an ineffective tracking and management tool that contributed to some inspections being performed overdue. The team also found that other databases used by the Branch (see discussion of SS&D database tracking system in Section 4.2.2, Technical Quality of the Product Evaluation Program), also had reliability and quality problems. The review team recommends that the Branch develop and implement a reliable and comprehensive SS&D product evaluation, licensing and inspection database that serves as an effective planning, tracking and management tool.

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

3.3 Technical Quality of Inspections

The review team evaluated the inspection reports, enforcement documentation, and inspection field notes and interviewed inspectors for 15 inspections. The casework examined included inspections performed by all the Branch's materials inspectors. The review examined inspections of various license types including industrial radiography, academic, industrial and medical broad scopes, service license (source exchange), medical institution, brachytherapy, nuclear pharmacy, panoramic irradiator, manufacturing and distribution, gamma radiostereotactic surgery and research and development. Appendix C lists the inspection casework reviewed for completeness and adequacy with case-specific comments.

Based on the casework file reviews, the review team found that routine inspections covered all aspects of each licensee's radiation protection program. The inspection field notes and reports were thorough, complete, consistent, and of high quality, with sufficient documentation to

ensure that each licensee's performance with respect to health and safety was acceptable. The documentation adequately supported any cited violations. Exit interviews were held with appropriate licensee personnel. Team inspections were performed when appropriate and for training purposes.

The review team found that all inspections include a written summary of the scope of the licensed activities and any violations identified by the inspector. The review team also noted that, in cases that involved significant or ongoing violations, the Branch had exercised escalated enforcement through the issuance of orders, imposition of civil penalties, or suspension of licensed activities. The review team found that the Branch has a good process for reviewing draft inspection documentation and enforcement actions, making any needed changes and providing the inspector with feedback regarding the quality of the draft document.

The review team determined that no supervisory accompaniments were performed during 2001. This deficiency was self-identified by management and corrected. Subsequently in 2002 and 2003, each material inspector was accompanied by the Branch Manager on an annual basis. Inspector accompaniments for 2004 have been scheduled for the fourth calendar quarter. The inspector accompaniments were documented. Based on a review of the Branch's inspector accompaniment documentation for 2002-3, inspector accompaniments performed by the review team, and the experience of the inspectors, the team concluded that there were no performance issues from the lack of the supervisory accompaniments during the first part of the review period.

The review team accompanied two material inspectors on August 10-11, 2004 during the inspections of medical institutions with brachytherapy programs. These accompaniments are identified in Appendix C. During the accompaniments, each of the inspectors demonstrated appropriate performance-based inspection techniques and knowledge of the regulations. The inspectors were well prepared and thorough in their reviews of the licensees' radiation safety programs. The inspections were adequate to assess radiological health and safety at the licensed facilities.

The Section has an adequate number and selection of survey meters to support both the Branch and the Emergency Response and Environmental Branch when responding to incidents and emergency conditions. The Branch has contractors who calibrate the Branch's survey instruments on an annual basis.

Appropriate documentation of calibrated survey instruments such as Geiger-Muller meters, scintillation detectors, ion chambers, and micro-R meters was provided. Air monitoring equipment as well as prepared emergency field kits are also available for emergency use. The Branch uses the services of the State's Radiochemistry Unit in the Department of Health and Human Services. The review team visited the laboratory and its staff. Instrumentation includes intrinsic germanium and sodium iodide detectors with gamma spectroscopy capabilities, low background alpha-beta counters, liquid scintillation counters and radiochemistry capabilities. The laboratory is capable of analyzing a wide-range of environmental media.

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

3.4 Technical Quality of Licensing Actions

The review team interviewed license reviewers, evaluated the licensing process, and examined licensing casework for 13 specific licenses. Licensing actions were reviewed for completeness, consistency, proper radioisotopes and quantities, qualifications of authorized users, adequate facilities and equipment, adherence to good health physics practices, financial assurance, operating and emergency procedures, appropriateness of license conditions, and overall technical quality. The casework files were also reviewed for timeliness, use of appropriate deficiency letters and cover letters, reference to appropriate regulations, product certifications, supporting documentation, consideration of enforcement history, pre-licensing visits, supervisory review as indicated, and proper signatures. The files were checked for retention of necessary documents and supporting data.

The licensing casework was selected to provide a representative sample of licensing actions, which were completed during the review period. The sampling included the following types: panoramic irradiator, medical institution, medical private practice, portable gauge, fixed gauge, research and development, academic, research and development broad scope, and distribution of general license devices. Licensing actions reviewed included 12 renewals and one amendment. A listing of the licensing casework evaluated with case-specific comments can be found in Appendix D.

Overall, the review team found that the licensing actions were thorough, complete, consistent, and of high quality with health and safety issues properly addressed. License tie-down conditions were older versions than are currently used by NRC. The team provided the Branch with the most current license conditions post review. While the older license conditions do not present any health and safety concerns, the license conditions are not as precisely written nor are they as clear as they could be if more current versions were used. Licensing actions were backed by information contained in the file, and were inspectible. The licensee's compliance history was taken into account when reviewing renewal applications and amendments. The review team confirmed that there were no exemptions issued as indicated on the Branch's questionnaire response.

The licensing action is assigned to a reviewer on the same day it is received. There is an initial checklist that is used by the administrative staff and the reviewer to verify that the application includes the necessary administrative and technical information. Deficiencies, if any, are resolved either by letter(s) or for minor items by telephone discussions. There is a template for each type of license to ensure consistency between reviewers. The completed licensing action is checked for accuracy and completeness against a Quality Control checklist before it is signed by the Branch Manager on behalf of the Chief of the Radiation Protection Section. The Branch utilizes appropriate licensing guides, standard licensing conditions, and issues a complete license for each licensing action.

The team noted that the Branch has developed a computerized database to track general licensed devices to account for all devices possessed by various entities in North Carolina. There is an effective follow-up of bankruptcy cases with special emphasis on security of licensed material.

The review team noted that the license reviewers do not routinely check the SS&D certificate before authorizing sealed sources on the license and authorize the possession limits that the applicants request. In addition, the team determined that the qualifications and experience of

proposed authorized users are not reviewed before being listed on the license. License reviewers stated that this is reviewed during inspections and it is the licensees' responsibility to ensure that only appropriately trained individuals use licensed material.

The Branch uses templates when generating licenses. No health and safety issues were identified with the use of the templates. However, careless cutting and pasting, poor proof reading, repeated use of old versions of the license and a lack of adequate quality control may lead to gaps, conflicts, duplications, inconsistencies, and omissions that may eventually contribute to a future safety issue. For example, a licensee was authorized an isotope and had provided appropriate financial assurance for the requested possession limit. The license, however, included a condition that prohibited the licensee to possess the licensed material in amounts that required financial assurance. The review team recommends that the Branch assess their licensing quality control process and tools to improve the accuracy and consistency of licensing actions.

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

3.5 Technical Quality of Incident and Allegation Activities

In evaluating the effectiveness of the Section's actions in responding to incidents, the review team examined the Branch's response to the questionnaire relative to this indicator, reviewed the incident reports for North Carolina in the NMED against those contained in the Branch's files, and evaluated reports and supporting documentation for 10 material incidents. A list of the incident casework examined with case-specific comments is included in Appendix E. The team also reviewed the Branch's response to 12 allegations involving radioactive materials including six allegations referred to the State by the NRC during the review period.

The Emergency Response and Environmental Branch is the first responder to all events and allegations. If the event, or allegation, involves radioactive material it is immediately handed off to the Branch for investigation, evaluation and follow-up.

The incidents selected for review included the following event categories: lost and abandoned radioactive material, equipment and procedural failures, transportation, contamination and leaking source. The review team found that the Branch's response to incidents was complete and comprehensive. Initial responses were prompt and well-coordinated, and the level of effort was commensurate with the health and safety significance. The Branch dispatched inspectors for site investigations when appropriate, and took suitable enforcement and follow-up actions.

The staff member who receives the initial notification has responsibility for initial response and follow-up to the incident. Each incident receives an unique tracking number. Written procedures require that two material inspectors evaluate each incoming incident report and present it to the supervisor for direction. Complex incidents or those with potential for impacting public safety are evaluated by the Branch Manager in order to determine the appropriate response. Documentation related to an incident is placed in the Branch's incident files and includes a cover sheet that summarizes the event.

The review team identified 185 radioactive materials incidents during the review period including 42 incidents that required reporting under the NRC criteria. No additional reportable

events were identified by the team during the review of the Branch's incident files. A majority of the incidents involved naturally-occurring or accelerated-produced radioactive material (NARM), medical waste and radiation alarms at recycling facilities. The team found that reportable incidents were reported to the NRC Operations Center in a timely manner. However, the team noted considerable inconsistencies in providing follow-up NMED reports to the NMED contractor prior to 2003. The Branch Manager stated that the inconsistency was the result of software compatibility issues when entering NMED data. The follow-up information is now being provided to NMED as specified in the Office of State and Tribal Programs (STP) procedures. NMED information is provided and updated by a designated staff member.

During the review period, the Branch received 17 allegations, six of which were referred to the Branch by the NRC. The casework for 12 allegations were reviewed, including all six allegations referred by the NRC. The review of the casework indicated that the Branch took prompt and appropriate action in response to the concerns raised. Each of the allegations reviewed were appropriately closed, and the allegers were informed of the results when possible. The team found that allegations are tracked and documented internally in the same manner as incidents. Allegation files are maintained in a separate, locked file cabinet for security and protection of the alleger's identity. There were no performance issues identified from the review of the casework documentation.

North Carolina law requires that all public documents be made available for inspection and copying unless specifically exempted from disclosure under the State's Open Records Act. The review team confirmed that the Branch adequately protects an alleger's identity.

Based on the IMPEP evaluation criteria, the review team recommends that North Carolina's performance with respect to the indicator, Technical Quality of Incident and Allegation Activities, be found satisfactory.

4.0 NON-COMMON PERFORMANCE INDICATORS

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

4.1 Compatibility Requirements

4.1.1 Legislation

In addition to their response to the questionnaire, the Section provided the review team with the opportunity to review copies of legislation that affects the radiation control program. The authority under which the Section administers the Agreement is granted in the General Statutes of North Carolina, Chapter 104E, North Carolina Radiation Protection Act. The Department is designated as the State's radiation control agency.

The review team noted that legislation affecting the radiation control section was amended during the review period. This change did not result in a change to the Department's overall operational authority but did create organizational changes within the Department. On July 1, 2002 the Radiation Protection Division within the Department was re-organized and became a

Section under the existing Division of Environmental Health. The review team found the revision to the enabling legislation caused no significant impact on the Section.

4.1.2 Program Elements Required for Compatibility

The North Carolina Regulations for Control of Radiation, found in the North Carolina Administrative Code, Title 15A, Chapter 11, Radiation Protection, apply to all ionizing radiation, whether emitted from radionuclides or machines. North Carolina requires a license for possession, and use, of all radioactive material including NARM.

The review team examined the regulation promulgation procedures used by the Section. The Section identifies the need for regulation changes, requests, and obtains Commission approval to develop new rules and regulations. The Section's staff drafts proposed regulations for the Commission's Radioactive Materials Control Committee for discussion with the regulated community and concerned citizens. The Commission reviews the draft proposed regulations and authorizes an official notice of proposed rule. Once the official notice is approved, the proposed regulations are published for a minimum 60-day comment period. The comment period may be longer depending on the types or number of proposed regulations. The NRC is provided with drafts of the proposed regulations for review and comment around the time they are published for public comment. Approximately two weeks after the rule is published, a public hearing is held to allow the public and other interested parties to comment on the proposed regulations. Based on the comments received, the rule is revised as needed and is then sent to the State Rules Review Commission. The State Rules Review Commission meets monthly to review and approve regulations promulgated by all State agencies. Once the State Rules Review Commission approves the final regulations, they become effective the first day of the month following approval. However, if ten or more written objections to a specific regulation are received, the proposed regulation is submitted to the State legislature for review and approval on the first day of the next legislative session following the State Rules Review Commission's final review. If the State legislature declines to review the proposed regulation, the rule becomes effective one month after the first day the legislative session starts.

Typically, regulation promulgation requires 4-14 months. The Section has the authority to issue legally binding requirements, such as orders or license conditions. This option has not been necessary in the past. The review team discussed with the Branch manager the process described in STP Procedure SA-200 for submitting legally binding requirements to adopt to meet NRC compatibility requirements for NRC review. In addition, the Section has alternative rulemaking procedures to put regulations in place outside of the normal process. Under the Emergency Rulemaking procedure, a regulation is put in place between 6-12 days and expires on the date specified in a regulation or the temporary regulation that must be submitted for promulgation simultaneously with the Emergency Rulemaking. For Temporary Rulemaking a regulation is put in place usually within 60 days and expires either in 270 days or once a regulation is reviewed and approved under the normal Rulemaking Process, whichever happens sooner.

The Branch manager noted that, there has not been a need to use the alternative rulemaking procedures. Additionally, the Department's rules and regulations are not subject to "sunset" laws.

The team evaluated the Branch's response to the questionnaire, reviewed the status of regulations required to be adopted by the State under the NRC's Adequacy and Compatibility

Policy, and verified the adoption of regulations with data obtained from the STP State Regulation Status Tracking Sheet.

Since the previous IMPEP review, the State has adopted four amendments in one rule package that became effective in August 2002. During the 2000 IMPEP review, six amendments were identified as needing to be addressed in a future rulemaking.

During the current review, the team noted that the Branch had not submitted the following three final regulations for NRC's review:

- "Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations," (63 FR 37059) that became effective July 9, 1998.
- "Transfer for Disposal and Manifests: Minor Technical Conforming Amendment," (63 FR 50127) that became effective November 20, 1998.
- "Termination or Transfer of Licensed Activities: Recordkeeping Requirements," (61 FR 24669) that became effective June 17, 1996.
- "At the time of the 2000 review the State had in place a draft rule to meet this amendment requirement. The team noted that the NRC had determined that this rule met the adequacy and compatibility requirements established in STP Procedure SA-200 on August 18, 2000, shortly before the 2000 IMPEP review was initiated.

Section management agreed to submit these amendments for NRC review in accordance with STP Procedure SA-201.

Current NRC policy requires that Agreement States adopt certain equivalent regulation or legally binding requirements no later than three years after they become effective. The review team found that the Branch is overdue for the following NRC amendments:

- "Respiratory Protection and Controls to Restrict Internal Exposures," 10 CFR Part 20 amendment (64 FR 54543 and 64 FR 55524) that became effective February 2, 2000.
- "Energy Compensation Sources for Well Logging and Other Regulatory Clarifications," 10 CFR Part 39 amendment (65 FR20337) that became effective May 17, 2000.
- "New Dosimetry Technology," 10 CFR Parts 34, 36 and 39 amendments (65 FR63750) that became effective January 8, 2001.
- "Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material," 10 CFR Parts 30, 31 and 32 amendment (65 FR79162) that became effective February 16, 2001.

On February 10, 2004, the Branch provided the draft regulations to the NRC for review and comment. The NRC commented by letter dated March 16, 2004. The comment review period

on these regulations was scheduled to be completed on August 30, 2004 and the regulations are expected to be adopted by November 2004. The Branch will be submitting the final regulations to the NRC for review once the rulemaking process is completed.

The Branch will need to address the following four regulations in upcoming rulemaking or by adopting legally binding requirements:

- "Revision of the Skin Dose Limit," 10 CFR Part 20 amendment (67 FR 16298) that became effective April 5, 2002.
- "Medical Use of Byproduct Material," 10 CFR Part 20, 32 and 35 amendments (67 FR 20249) that became effective April 24, 2002.
- "Financial Assurance for Materials Licensees" 10 CFR Parts 30, 40 and 70 amendments (68 FR 57327) that became effective December 3, 2003.
- "Compatibility With IAEA Transportation Safety Standards and Other Transportation Safety," 10 CFR Part 71 amendment (69 FR 3697) that will become effective October 1, 2004

Based on the IMPEP evaluation criteria, the review team recommends that North Carolina's performance with respect to the indicator, Compatibility Requirements, be found satisfactory.

4.2 Sealed Source and Device (SS&D) Evaluation Program

In conducting this review, three sub-indicators were used to evaluate the Branch's performance regarding the SS&D Evaluation Program. These sub-indicators include: (1) Technical Staffing and Training; (2) Technical Quality of the Product Evaluation; and (3) Evaluation of Defects and Incidents Regarding SS&D.

In assessing the Branch's SS&D evaluation program, the review team examined the information provided in response to the IMPEP questionnaire for this indicator. The team evaluated all four SS&D registrations issued during the review period, and the supporting document files. The team evaluated the use of guidance documents and procedures, interviewed staff currently conducting SS&D evaluations, and verified the use of regulations and license conditions to enforce commitments made in the applications.

4.2.1 Technical Staffing and Training

Since the last review, two new staff members have been qualified by the Branch to perform SS&D evaluations. One of the new staff members is limited to performing concurrence reviews until he gains further casework experience and obtains management sign off. The Branch has two additional qualified SS&D reviewers.

The Branch has documented the training received by the SS&D reviewers, and the review team evaluated the qualifications of the two new staff members authorized by the Branch. One of the new members performed SS&D evaluations during the review period. Each new reviewer has worked with the Branch for over five years, has either a bachelor's degree in physical sciences or a master's degree in health physics, and has attended the NRC's SS&D workshop.

The Branch also has contractual access to a professor at North Carolina State University's Department of Material Sciences and Engineering for consultation purposes related to SS&D evaluations. The consultant has a doctoral degree in engineering and is a licensed Professional Engineer. The Branch's SS&D review procedure documents the process for use of the consultant.

4.2.2 Technical Quality of the Product Evaluation Program

The review team evaluated all four SS&D product evaluations that the Branch completed during the review period. Each case was for an SS&D registration amendment. No new, inactivated nor reactivated registrations were issued during the review period. A list of the SS&D casework examined along with specific comments are found in Appendix F.

The Branch's SS&D reviewers stated that they used the guidance in NRC's NUREG-1556, Volume 3. The team's review of the casework, written procedures and interviews with the staff, confirmed that the Branch followed the NRC SS&D guidance with a few exceptions as noted in Appendix F. Appropriate standards, Regulatory Guides, and NRC's SS&D workshop references were available and used when performing SS&D reviews. The Branch handles proprietary information by placing it in separate files.

The depth and scope of the SS&D evaluations performed during the review period were good. The evaluation documentation found in registration files was also good. The review team did not identify any missed safety issues in the casework reviewed.

The review team noted that a vendor had requested an amendment to an SS&D registration in a letter dated November 21, 2001 and that the Branch has neither requested further information from the vendor nor has it issued an amended SS&D registration as of the date of this review. The team also notes that there is no documentation in the file that would indicate that the vendor had again contacted the Branch concerning the status of their request nor is there evidence that the vendor has cancelled the requested amendment. Also, the team determined that the Branch was not aware of the pending request. The team believes that this administrative problem is due to a poorly functioning of the SS&D tracking system. Consequently, the Branch puts more reliance in a manual method of tracking that consists of reviewing the SS&D Registry, paper documents, and staff notes to follow the status of SS&D actions.

The Branch reported that a database had been developed to follow the status of SS&D actions and that the tracking system was corrupted when it was placed onto their local area network computer system. The tracking system was rebuilt just before this review and there was a demonstration on the designer's computer during the review. However, the tracking system was not useful because it contained only test data. A recommendation, as stated in Section 3.2 of this report, related to developing a quality database system is reiterated here. The system should include a process for tracking SS&D product evaluations.

4.2.3 Evaluation of Defects and Incidents Regarding SS&D

There were no new defects or incidents involving SS&D's registered with the Branch that were discovered or reported during the review period.

In November of 2000, the Branch closed a consent order agreement made between the Branch and a distributor of SS&D's. The order required that the distributor notify customers of a potential problem and also required that the distributor perform inspections and testing of certain device components. The distributor supplied the Branch with all of the information required in the order. The review team examined the SS&D registration related to the device and noted that a beneficial design change related to the device component was approved by and registered with the Branch.

Based on the IMPEP evaluation criteria, the review team recommends that North Carolina'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 North Carolina has such disposal authority, NRC has not required States to have a program for licensing a disposal facility until such time as the State has been designated as a host State for a LLRW disposal facility. When an Agreement State has been notified or becomes aware of the need to regulate a LLRW disposal facility, they are expected to put in place a regulatory program which will meet the criteria for an adequate and compatible LLRW disposal program. There are no plans for a LLRW disposal facility in North Carolina. Accordingly, the review team did not evaluate this indicator.

5.0 SUMMARY

As noted in Sections 3 and 4 above, the review team recommends that North Carolina's performance be found satisfactory for all seven applicable performance indicators. Accordingly, the review team recommends that the North Carolina Agreement State program be found adequate to protect public health and safety and compatible with NRC's program. Based on the results of the current IMPEP review, the review team recommends that the next full review should be in approximately four years.

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

RECOMMENDATIONS

1. The review team recommends that the Branch develop and implement a reliable and comprehensive SS&D product evaluation, licensing and inspection database that serves as an effective planning, tracking and management tool. (Section 3.2)

2. The review team recommends that the Branch assess their licensing quality control process and tools to improve the accuracy and consistency of licensing actions. (Section 3.4)

LIST OF APPENDICES

Appendix A	IMPEP Review Team Members
Appendix B	North Carolina Organization Charts
Appendix C	Inspection Casework Reviews
Appendix D	License Casework Reviews
Appendix E	Incident Casework Reviews
Appendix F	Sealed Source and Device Casework Reviews

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

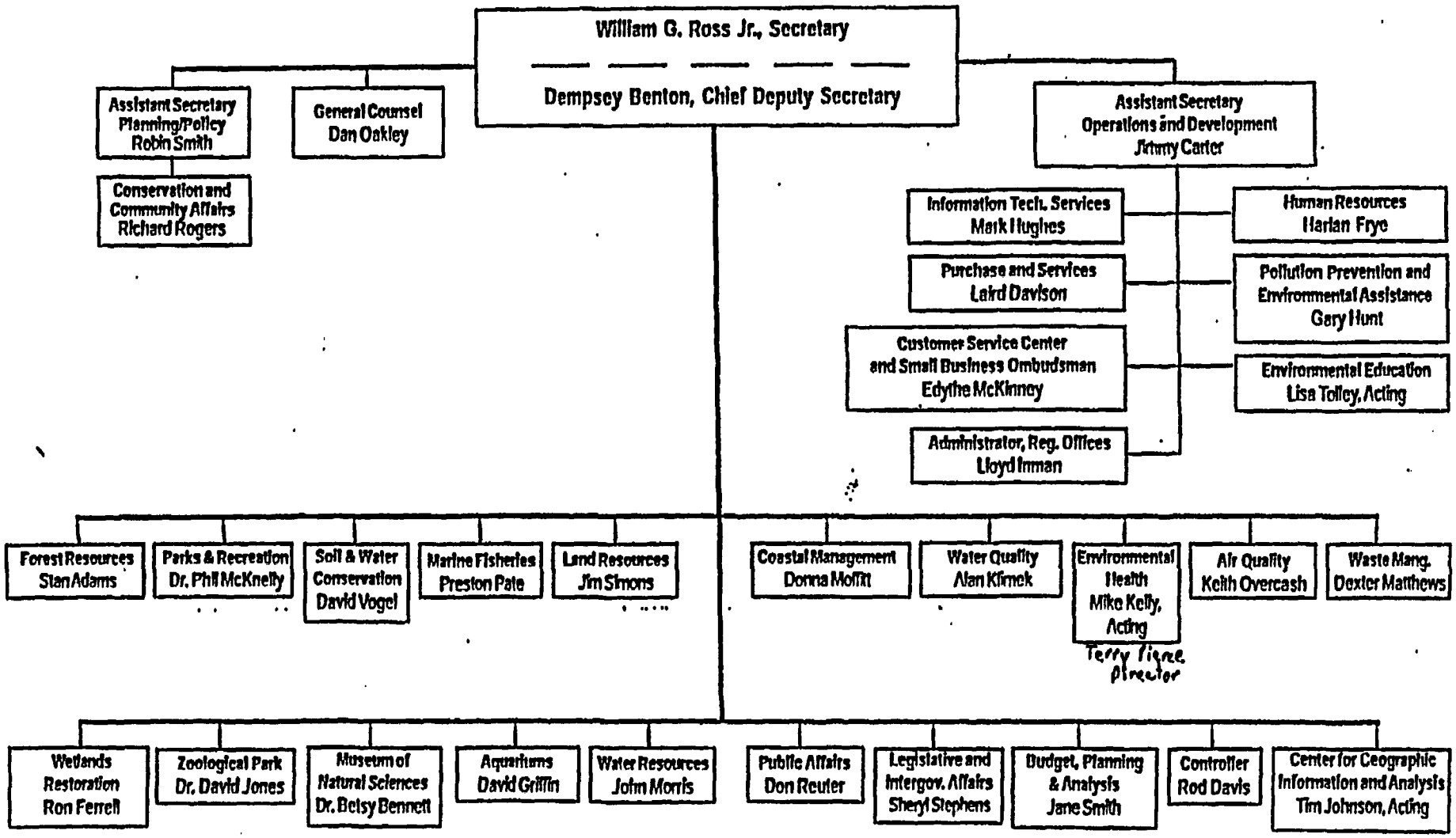
Name	Area of Responsibility
Jim Myers, STP	Team Leader Technical Staffing and Training
Duncan White, Region I	Status of Materials Inspection Program Technical Quality of Inspections Technical Quality of Incident and Allegation Activities Inspector Accompaniments
Sattar Lodhi, Region I	Technical Quality of Licensing Actions
Osiris Siurano-Perez, STP	Technical Quality of Incident and Allegation Activities Compatibility Requirements
Joshua Daehner, Massachusetts	Sealed Source and Device Evaluation Program

APPENDIX B

NORTH CAROLINA ORGANIZATION CHARTS

Attachment A

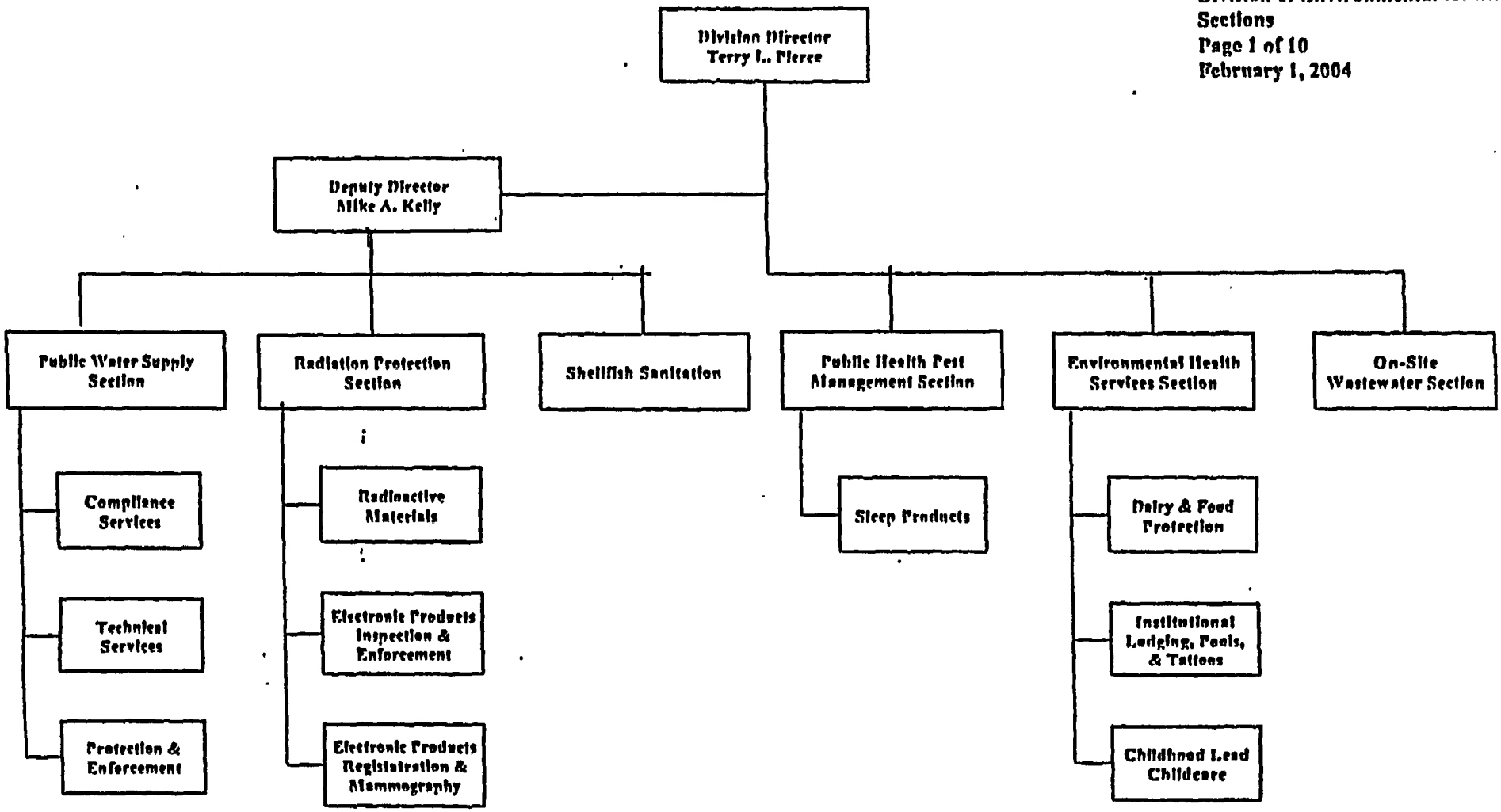
North Carolina Department of Environment and Natural Resources
Organization Chart



5.22.03

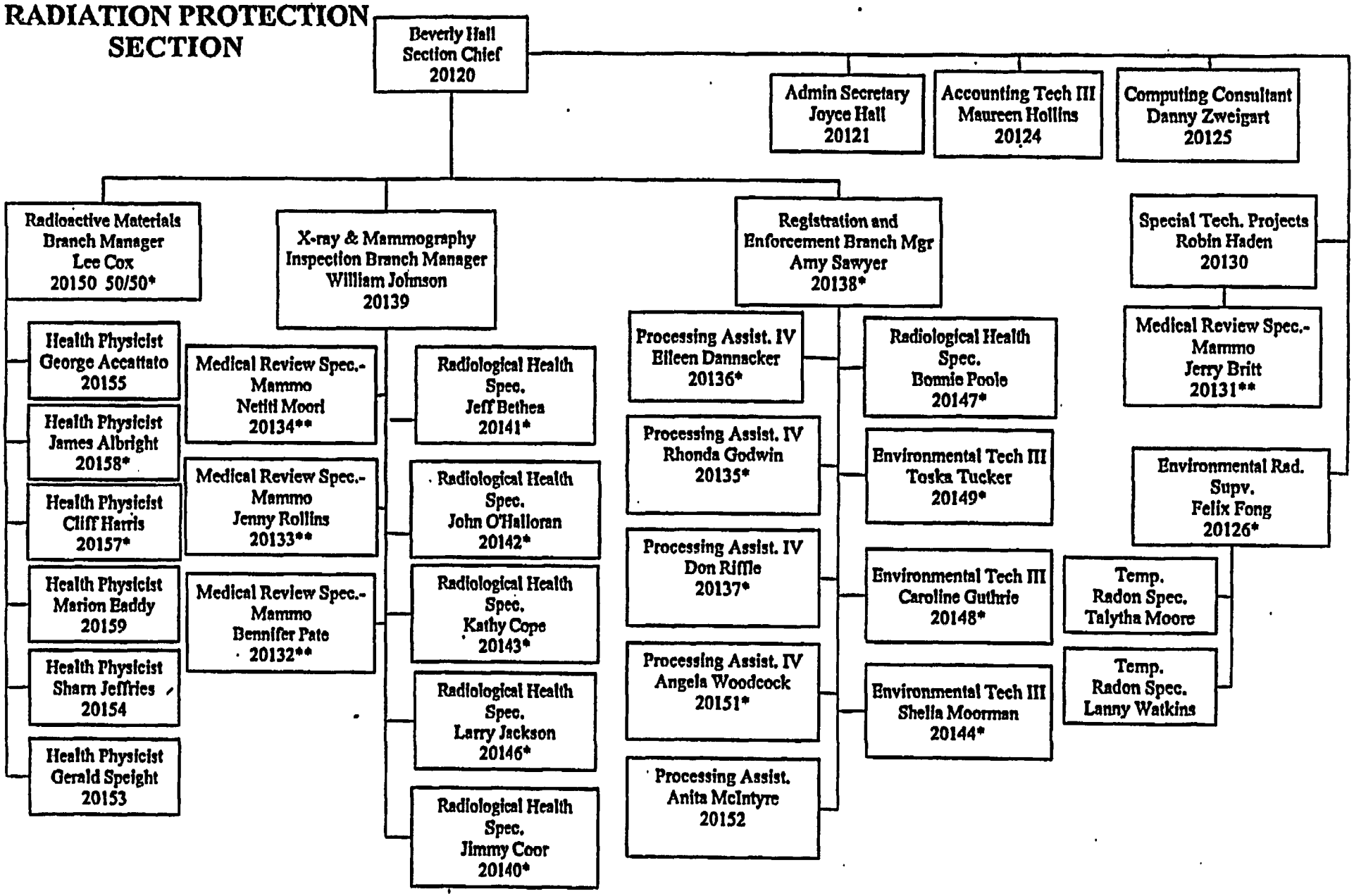
Attachment D

Division of Environmental Health
Sections
Page 1 of 10
February 1, 2004



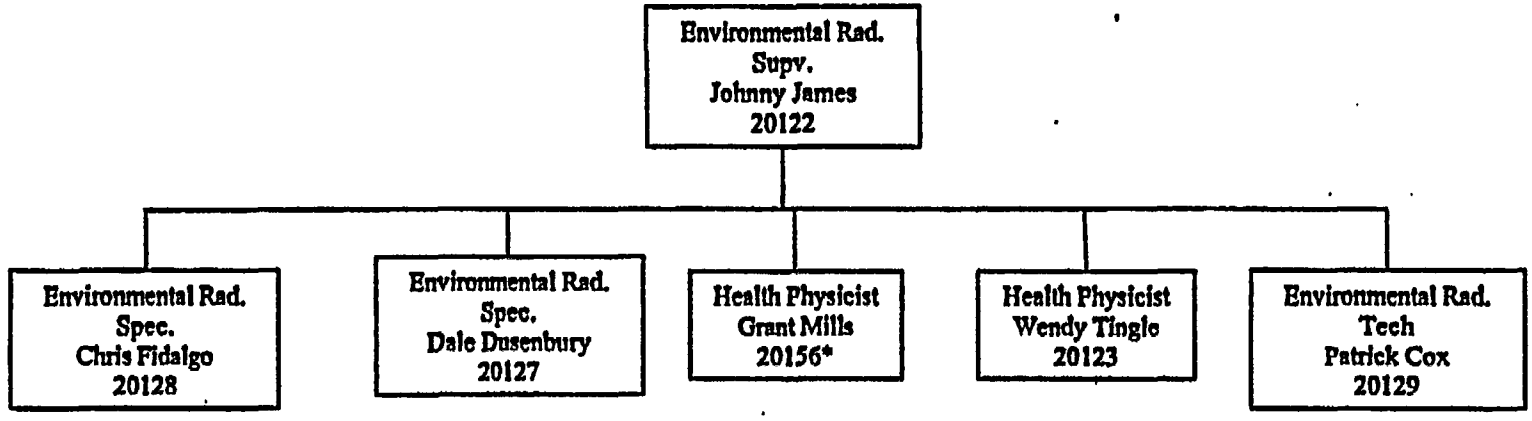
Terry L. Pierce, Director

RADIATION PROTECTION SECTION



* Fee Funded
** Contract Funded

January 2004


Environmental Rad.
Supv.
Johnny James
20122
Environmental Rad.
Spec.
Chris Fidalgo
20128
Environmental Rad.
Spec.
Dale Dusenbury
20127
Health Physicist
Grant Mills
20156*
Health Physicist
Wendy Tingle
20123
Environmental Rad.
Tech
Patrick Cox
20129

APPENDIX C

INSPECTION CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS ONLY

File No.: 1
Licensee: Cooperheat-MQS, Inc. — South Carolina License No.: 693
Location: Charlotte, NC — Inspection Type: Reciprocity, Unannounced
License Type: Industrial Radiography — Priority: 1
Inspection Date: 12/9/03 — Inspector: JA

Comment:
Inspection findings not issued to the licensee until 144 days after conclusion of inspection.

File No.: 2
Licensee: MDS Nordion — NRC License No.: 54-28275-01
Location: Rocky Mount, NC — Inspection Type: Reciprocity, Announced
License Type: Source Exchange — Priority: 3
Inspection Date: 6/26/03 — Inspector: SJ

File No.: 3
Licensee: East Carolina University — License No.: 074-0296-1
Location: Greenville, NC — Inspection Type: Routine, Unannounced
License Type: Academic Type A Broad Scope — Priority: 3
Inspection Dates: 4/26-29/04 — Inspector: JA

File No.: 4
Licensee: Presbyterian Hospital — License No.: 060-0019-1
Location: Charlotte, NC — Inspection Type: Routine, Unannounced
License Type: Brachytherapy — Priority: 3
Inspection Date: 3/19/03 — Inspector: GA

Comment:
Inspection findings not issued to the licensee until 40 days after conclusion of inspection.

File No.: 5
Licensee: Caldwell Memorial Hospital — License No.: 014-0586-1
Location: Lenoir, NC — Inspection Type: Routine, Unannounced
License Type: Medical Institution - Written Directive Required — Priority: 3
Inspection Date: 10/29/02 — Inspector: SJ

File No.: 6
Licensee: Charlotte-Mecklenberg Hospital Authority
License No.: 060-0014-3
Location: Charlotte, NC
Inspection Type: Special, Unannounced
License Type: Medical Broad Scope
Priority: 3
Inspection Dates: 2/4-7/02
Inspector: GM

Comment:
Inspection record contained personnel information (dosimetry records).

File No.: 7
Licensee: Flowserve US, Inc.
License No.: 092-0121-1
Location: Raleigh, NC
Inspection Type: Routine, Unannounced
License Type: Industrial Radiography
Priority: 2
Inspection Date: 4/30/03
Inspector: ME

File No.: 8
Licensee: Cardinal Health
License No.: 060-0794-1
Location: Charlotte, NC
Inspection Type: Special, Announced
License Type: Nuclear Pharmacy
Priority: 2
Inspection Date: 8/13/03
Inspector: GS

File No.: 9
Licensee: SteriGenics International
License No.: 001-0701-1
Location: Haw River, NC
Inspection Type: Routine, Unannounced
License Type: Panoramic Irradiator
Priority: 2
Inspection Date: 11/20/01
Inspectors: LC, GS

File No.: 10
Licensee: SRB Technologies, Inc.
License No.: 034-0534-2
Location: Winston-Salem, NC
Inspection Type: Routine, Unannounced
License Type: Manufacturing and Distribution
Priority: 5
Inspection Date: 4/7/04
Inspector: JA

Comment:
The reviewer did not appear to have verified the licensee's evaluation of the off-site doses to demonstrate that an emergency plan was not needed.

File No.: 11
Licensee: The North Carolina Baptist Hospital, Inc.
License No.: 034-0158-8
Location: Winston-Salem, NC
Inspection Type: Routine, Unannounced
License Type: Gamma Stereotactic Surgery
Priority: 3
Inspection Date: 2/27/02
Inspector: GM

File No.: 12
Licensee: Global Nuclear Fuels - Americas LLC
Location: Wilmington, NC
License Type: Industrial Type A Broad Scope
Inspection Date: 5/14/03
License No.: 065-0317-1
Inspection Type: Routine, Unannounced
Priority: 3
Inspector: GA

File No.: 13
Licensee: Research Triangle Institute
Location: Research Triangle Park, NC
License Type: Industrial Type A Broad Scope
Inspection Date: 1/20-23/04
License No.: 032-0131-1
Inspection Type: Routine, Unannounced
Priority: 3
Inspector: CH

File No.: 14
Licensee: Merix Bioscience Inc.
Location: Durham, NC
License Type: Research and Development Other
Inspection Date: 7/19/02
License No.: 032-1202-1
Inspection Type: Initial, Unannounced
Priority: 5
Inspector: ME

File No.: 15
Licensee: Cyprotex-North America
Location: Research Triangle Park, NC
License Type: Research and Development Other
Inspection Date: 12/4/02
License No.: 032-1256-1
Inspection Type: Special, Announced
Priority: 5
Inspectors: GM, LC

INSPECTOR ACCOMPANIMENTS

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

Accompaniment No.: 1
Licensee: Wake Med - Main Campus
Location: Raleigh, NC
License Type: Brachytherapy
Inspection Date: 8/10/04
License No.: 092-0297-5
Inspection Type: Routine, Unannounced
Priority: 3
Inspector: SJ

Accompaniment No.: 2
Licensee: Durham Regional Hospital
Location: Durham, NC
License Type: Brachytherapy
Inspection Date: 8/11/04
License No.: 032-0052-3
Inspection Type: Routine, Unannounced
Priority: 3
Inspector: CH

APPENDIX D

LICENSE CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS ONLY

File No. : 1
Licensee: Southeastern Radiology, PA — License No. 041-0932-2
Location: Greensboro, NC — Amendment No.: 15
License Type: Private Medical Practice — Type of Action: Renewal
Date of Action: 8/29/03 — License Reviewer: JA

Comments:
a) The licensee requested 300 microcuries but the license authorized 20 millicuries.
b) There is no procedure for assaying Sr-89 doses. The Branch reviewer assumed that therapy doses are not administered by licensee.
c) The licensee did not request and the license does not authorize generators, but a generator-related license condition is included.

File No.: 2
Licensee: Froehling & Robertson, Inc. — License No.: 060-0353-4
Location: Charlotte, NC — Amendment No.: 9
License Type: Portable Gauge — Type of Action: Renewal
Date of Action: 8/9/04 — License Reviewer: JA

Comments:
a) Authorized activities do not agree with maximum amounts in SS&D certificates.
b) The application states two different activities for the same gauge.
c) Wording of reciprocity condition is confusing.

File No.: 3
Licensee: Presbyterian Hospital - Matthews — License No.: 06-0019-4
Location: Matthews, NC — Amendment No.: 26
License Type: Medical Institution (Limited) — Type of Action: Renewal
Date of Action: 8/6/04 — License Reviewer: JA

Comments:
a) Name of authorized user missing.
b) No documentation of conversation with RSO about the authorized user.
c) The license's regular physician user conditions make the visiting authorized user license condition unnecessary.
d) DTPA requested; license authorizes xenon.
e) I-125 not requested; I-125 is authorized for medical procedures.
f) Training program for ancillary personnel is not clear.

File No.: 4
Licensee: BASF Corporation
Location: Research Triangle Park, NC
License Type: Research & Development - Limited
Date of Action: 4/30/04
License No.: 032-0760-1
Amendment No.: 37
Type of Action: Renewal
License Reviewer: JA

Comments:
a) License authorizes 5000 millicuries of Carbon 14; license condition prohibits possession of this amount.
b) Wrong action level for package surveys approved.
c) User with only experience in using only C-14 was granted authorization for other radionuclides.
d) Part of Condition 13 is missing. This error appears to have been identified by the staff but was not corrected.
e) Corrected copy of license not sent to licensee.

File No.: 5
Licensee: North Carolina State University
Location: Raleigh, NC
License Type: Pool Irradiator
Date of Action: Review completed 7/22/04
License No.: Pending
Amendment No.: N/A
Type of Action: New License
License Reviewer: JA

Comments:
a) The review of application is complete; issuance withheld pending NRC review of reactor license.
b) Proposed use of sealed sources in pool irradiator not verified using SS&D certificate.
c) Reviewer did not verify that the reactor license authorizes an irradiator in its pool.
d) Applicant refers to its reactor license and has not provided a complete radiation safety program for the proposed use.

File No.: 6
Licensee: Service Roofing & Sheet Metal Company
Location: Greenville, NC
License Type: Portable Gauge
Date of Action: 6/16/04
License No.: 074-0672-1
Amendment No.: 8
Type of Action: Renewal
License Reviewer: CH

Comment:
License possession limit does not agree with registration certificate for the model 3216 gauge.

File No.: 7
Licensee: Scotland Memorial Hospital
Location: Laurinburg, NC
License Type: Medical Institution (Limited)
Date of Action: 7/22/04
License No.: 083-0197-1
Amendment No.: 48
Type of Action: Renewal
License Reviewer: GS

File No.: 8
Licensee: Invista, S.A.R.L.
Location: Salisbury, NC
License Type: Fixed Gauge
Date of Action: 4/15/04
License No.: 080-0100-2
Amendment No.: 66
Type of Action: Renewal
License Reviewer: JA

Comment:
No condition related to installation, removal or maintenance of the gauge(s) on license.

File No.: 9
Licensee: Mercy Hospital
Location: Charlotte, NC
License Type: Medical Institution
Date of Action: 6/30/03
License No.: 060-0116-3
Amendment No.: 10
Type of Action: Renewal
License Reviewer: ME

File No.: 10
Licensee: Process Energy Company
Location: Semora, NC
License Type: Fixed Gauge
Date of Action: 2/26/04
License No.: 073-0218-10
Amendment No.: 5
Type of Action: Renewal
License Reviewer: JA

Comments:
a) The license does not state that the licensee is authorized to perform installation.
b) The service procedures do not specify who will perform the service.
c) SS&D certificates not used to verify that the proposed sources are compatible with the device.

File No.: 11
Licensee: Carolina Cardiology Associates, PA
Location: Asheboro, NC
License Type: Private Medical Practice
Date of Action: 4/6/04
License No.: 76-1135-1
Amendment No.: 6
Type of Action: Renewal
License Reviewer: CH

Comments:
a) Authorized possession limits for Cs-137 do not agree with requested limits.
b) Isotopes listed in Items 6.G., 6.J, and 6.K have no authorized use.
c) Authorized radiopharmaceuticals do not agree with those requested.
d) Standard license condition for authorized users is not used.
e) No documentation of March 22, 2004 conversation with licensee in file.

File No.: 12
Licensee: North Carolina State University
Location: Raleigh, NC
License Type: Academic R&D Broad Scope
Date of Action: 6/11/04

License No.: 092-0090-3
Amendment No.: 87
Type of Action: Renewal
License Reviewer: ME

File No.: 13
Licensee: SRB Technologies, Inc.
Location: Winston-Salem, NC
License Type: GL Distribution
Date of Action: 5/13/04

License No.: 034-0534-2
Amendment No.: 31
Type of Action: Amendment
License Reviewer: JA

Comment:

The reviewer did not appear to have verified the licensee's evaluation of the off-site doses to demonstrate that an emergency plan was not needed.

APPENDIX E

INCIDENT CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS ONLY

File No.: 1
Licensee: Forsythe Medical Center
Site of Incident: Winston-Salem, NC
Date of Incident: 10/23/02
Investigation Dates: 10/23/02 - 12/31/02

License No.: 034-0878-3
Incident Log No.: 02-40 (NMED 020975)
Type of Incident: Equipment Failure
Type of Investigation: Phone and Next Inspection

File No.: 2
Licensee: Nucor Steel
Site of Incident: Hertford, NC
Date of Incident: 2/28/02
Investigation Dates: 2/28/02 - 3/12/02

License No.: NA
Incident Log No.: 02-04 (NMED 020230)
Type of Incident: Abandoned Radioactive Material
Type of Investigation: Site

File No.: 3
Licensee: Cooperheat-MQS, Inc.
Site of Incident: Belmont, NC
Date of Incident: 2/12/02
Investigation Dates: 2/14/02 - 3/26/02

South Carolina License No.: 693
Incident Log No.: 02-03 (NMED 020435)
Type of Incident: Procedural Failure
Type of Investigation: Phone and Next Inspection

File No.: 4
Licensee: Shurtape Technologies
Site of Incident: Hickory, NC
Date of Incident: 3/02
Investigation Dates: 8/30/02 - 9/18/02

License No.: 018-0213-1
Incident Log No.: 02-34 (NMED 0304140)
Type of Incident: Leaking Source
Type of Investigation: Phone and Next Inspection

File No.: 5
Licensee: North Carolina State University
Site of Incident: Raleigh, NC
Date of Incident: 11/16/01
Investigation Date: 11/16/01

License No.: 092-0090-3
Incident Log No.: 01-37 (NMED 011045)
Type of Incident: Lost Radioactive Material
Type of Investigation: Phone and Next Inspection

File No.: 6
Licensee: Forsythe Medical Center
Site of Incident: Winston-Salem, NC
Date of Incident: 3/22/01
Investigation Date: 3/22/01

License No.: 034-878-3
Incident Log No.: 01-08 (NMED 020423)
Type of Incident: Equipment Failure
Type of Investigation: Site

File No.: 7
Licensee: Carolinas Medical Center
Site of Incident: Charlotte, NC
Date of Incident: 9/11/03
Investigation Dates: 9/11/03 - 12/12/03

License No.: 060-0116-1
Incident Log No.: 03-40 (NMED 030890)
Type of Incident: Abandoned Radioactive Material
Type of Investigation: Phone and Next Inspection

APPENDIX F

SEALED SOURCE AND DEVICE REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS ONLY

File No.: 1
Registry No.: NC-0646-D-130-S
Manufacturer: Troxler Electronic Labs
Date Issued: 9/14/00
SS&D Type: Portable Moisture Density Gauges
Models.: 3400 Series: 3430, 3430-M, 3440, 3440-M
Type of Action: Amendment

Comment:
A review checklist was not available for this amendment.

File No.: 2
Registry No.: NC-0646-D-130-S
Manufacturer: Troxler Electronic Labs
Date Issued: 12/28/01
SS&D Type: Portable Moisture Density Gauges
Models: 3400 Series: 3430, 3430-M, 3440, 3440-M
Type of Action: Amendment

Comments:
a) The header of this registration should read AMENDED IN ITS ENTIRETY.
b) The issue date of this registration should be the date that the registration received both reviewer and concurrence signatures.

File No.: 3
Registry No.: NC-0646-D-138-S
Manufacturer: Troxler Electronic Labs
Date Issued: 12/28/01
SS&D Type: Portable Moisture Density Gauges
Model: 3450
Type of Action: Amendment

File No.: 4
Registry No.: NC-0646-D-138-S
Manufacturer: Troxler Electronic Labs
Date Issued: 6/11/03
SS&D Type: Portable Moisture Density Gauges
Models: 3450 and 3451
Type of Action: Amendment

Comments:
a) A Prototype Testing section should be included in the registration. The Prototype Testing section was included in a previous version of the registration.
b) Bold type face was not used to highlight the changes that were made to the registration.
c) The header of this registration should read AMENDED IN ITS ENTIRETY.
d) The issue date of this registration should be the date that the registration received both reviewer and concurrence signatures.

Distribution:
DIR RF
SP01
KSchneider, STP
AMcCraw, STP
Osiris Siurano-Perez, STP
Duncan White, RI
Sattar Lodhi, RI
Joshua Daehler, Massachusetts

Distribution:
DIR RF DCD (SP01) PDR (YES✓)
KSchneider
AMcCraw
DWhite, Region I
SLodhi, Region I
OSiurano-Perez, STP
JDaehner, Massachusetts

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NAME	JHMyers:gd								
DATE	09/21 /04								

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