March 26, 2009

Mr. Dee Freeman
Secretary
Department of Environment & Natural Resources
1601 Mail Service Center
Raleigh, NC 27699-1601

Dear Mr. Freeman:

The U.S. 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 that documents the results of the Agreement State review held in North Carolina on February 23-27, 2009. I was the team leader for the review. The review team's preliminary findings were discussed with Mr. Bill Laxton, Chief Deputy Secretary (outgoing); Mr. Manly Wilder, Chief Deputy Secretary (incoming); and other members of 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 potential 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 Agreement State and NRC Regional radioactive materials programs. All reviews use common criteria in the assessment and place primary emphasis on performance. Three additional areas applicable to your program have been identified as non-common performance indicators and are also addressed in the assessment. The final determination of adequacy and compatibility of each program, based on the review team's report, is 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 review team's draft report for your review and comment prior to submitting the report to the MRB. Comments are requested within 4 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 your response, make any necessary changes to the report, and issue it to the MRB as a proposed final report. Coordinating with your staff, I scheduled the North Carolina MRB meeting for May 5, 2009, from 9:00-11:00 a.m. EDT. NRC will provide invitational travel for you or your designee to attend the MRB meeting at NRC Headquarters in Rockville, Maryland. NRC has video conferencing capability if it is more convenient for the State 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 (630) 829-9661.

Thank you for your cooperation.

Sincerely,

/RA/

James L. Lynch
State Agreements Officer

Enclosure:
Draft North Carolina IMPEP Report

cc w/encl:
Manly Wilder, Chief Deputy Secretary
W. Lee Cox, III, Acting Chief
Cindy Becker, State of FL

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United States Nuclear Regulatory Commission

Protecting People and the Environment

INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF THE NORTH CAROLINA AGREEMENT STATE PROGRAM

February 23-27, 2009

DRAFT REPORT

Enclosure

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 February 23-27, 2009, by a review team comprised of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the States of Florida and Texas. Team members are identified in Appendix A. The review was conducted in accordance with the "Implementation of the Integrated Materials Performance Evaluation Program and Rescission of Final General Statement of Policy," published in the *Federal Register* on October 16, 1997, and NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)," dated February 26, 2004. Preliminary results of the review, which covered the period of August 21, 2004, to February 27, 2009, were discussed with North Carolina managers on the last day of the review.

[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). The Division 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, which performs the majority of responsibilities of the Agreement State program. Organization charts for the Department, the Division, and the Section are included in Appendix B.

At the time of the review, the North Carolina Agreement State Program regulated 760 specific licenses authorizing byproduct, source, and certain special nuclear materials. The review focused on the radioactive materials program as it is carried out under the Section 274b. (of the Atomic Energy Act of 1954, as amended) Agreement between NRC and the State of North Carolina.

In preparation for the review, a questionnaire addressing the common and applicable non-common performance indicators was sent to the Section on September 8, 2008. The Section provided its response to the questionnaire on November 20, 2008. A copy of the questionnaire response can be found in NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML083470347.

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

Section 2.0 of this report covers the State's actions in response to recommendations made during the previous review. Results of the current review of the common performance indicators are presented in Section 3.0. Section 4.0 details the results of the review of the applicable non-

common performance indicators, and Section 5.0 summarizes the review team's findings and recommendations. The review team's recommendations are comments that relate directly to program performance by the State. A response is requested from the State to all recommendations in the final report.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous IMPEP review, which concluded on August 20, 2004, the review team made two recommendations regarding program performance. The current status of each recommendation is as follows:

1. The review team recommends that the Branch develop and implement a reliable and comprehensive licensing and inspection, and sealed source and device (SS&D) product evaluation database that serves as an effective planning, tracking and management tool. (Sections 3.2 and 4.2 of the 2004 IMPEP report)

   Current Status: In 2005, the Branch began using one operating system (XP-Pro) on a single new server for their licensing, inspection, and SS&D database. The review team found the current system to be an effective planning, tracking and management tool. The Branch expects to upgrade to an Oracle database in the near future to further enhance their database capabilities. This recommendation is closed.

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 of the 2004 IMPEP report)

   Current Status: Following the 2004 review, the Branch modified its license reviewer checklists. The Branch also revised its process to ensure that quality assessments, both administrative and supervisory, are performed on each licensing action. Additionally, license review timeliness expectations were increased to allow more time for licensing actions and allow additional focus on quality. The review team's evaluation of licensing actions identified an overall excellent level of quality. This recommendation is closed.

3.0 COMMON PERFORMANCE INDICATORS

Five common performance indicators are used to review NRC Regional and Agreement State radioactive materials programs. 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 Branch'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 questionnaire response relative to this indicator, interviewed managers and staff, reviewed job descriptions and training records, and considered any possible workload backlogs.

The Radiation Protection Section is headed by the Section Chief. This position is currently vacant due to the retirement of the former Section Chief on December 31, 2008. The Deputy Section Chief is currently the Acting Section Chief.

The Section includes the [Radioactive Materials] Branch, the Emergency Response/Environmental Monitoring Branch, and the Radon Program Branch. The Branch is responsible for radioactive materials licensing, inspection, security, low-level radioactive waste, general licenses, and SS&D reviews. The Branch consists of nine technical staff positions (Health Physicists), an administrative assistant, and the Branch Manager. The Branch Health Physicists all perform licensing, inspection, and incident response activities.

Three staff members left the Branch during the review period. One individual transferred to another part of State government, and the other two resigned. Two of the vacated positions were filled with the hiring of a Health Physicist Trainee in 2006 and a Health Physicist in 2008. One technical staff position was vacant at the time of the review, but the Branch was in the process of filling the vacancy.

The Branch has a documented training and qualification program for technical staff members. The training and qualification program is equivalent to NRC Inspection Manual Chapter (IMC) 1246, "Formal Qualification Programs in the Nuclear Material Safety and Safeguards Program Area," and is consistent with the NRC and Organization of Agreement States Training Working Group Recommendations for Agreement State Training Programs. Qualification is achieved through a combination of education and experience, formal classroom training, and on-the-job training. Staff members are required to have a Bachelor's degree or equivalent experience in a physical or biological science or engineering.

The review team found that the Branch maintains training and qualification records for each staff member. The review team noted that no Branch staff had attended NRC's irradiator training course, although there are four large pool irradiators located in North Carolina. The review team observed that licensing and inspection of the irradiators has been adequate and without incident; however, the review team believes that attendance at the irradiator training course would strengthen the Branch's regulation of these four licensees. The Acting Section Chief agreed that the training course would be beneficial and indicated that he would pursue enrolling at least one staff member in the course. Overall, the review team concluded that Section management encourages and supports training opportunities, based on program needs and funding.

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 this indicator: inspection frequency, overdue inspections, initial inspections of new licensees, timely dispatch of inspection findings to licensees, and performance of reciprocity inspections. The review team's evaluation is based

on the Section's questionnaire response relative to this indicator, data gathered independently from the Branch's licensing and inspection database, the examination of completed licensing and inspection casework, and interviews with managers and staff.

The review team verified that the Branch's inspection frequencies for various types of licenses are at least as frequent as the inspection frequencies prescribed by IMC 2800, "Materials Inspection Program," for equivalent license types. The Branch's inspection frequencies mirror NRC's inspection frequencies.

The Branch conducted 651 inspections of high priority (Priority 1, 2, and 3) licensees and 126 initial inspections during the review period. The review team determined that, at the time of the review, no inspections were overdue and that 9 Priority 1, 2, and 3 inspections and 14 initial inspections were completed overdue during the review period. The review team calculated that less than 3 percent of the 777 Priority 1, 2, and 3 and initial inspections performed by the Branch were performed overdue during the review period.

The review team evaluated the Branch's timeliness of issuance of inspection reports to licensees. The Branch has an effective and efficient process to ensure that inspection reports are completed and that findings are communicated to licensees in a timely manner. Of the 25 inspection files reviewed, 3 of the inspection reports and findings were completed beyond the 30-day goal. Two of the late reports were attributed to the training of a new inspector and the other was simply an oversight.

During the review period, the Branch granted 26 reciprocity licenses that were candidates for inspection based upon the criteria in IMC 1220, "Processing of NRC Form 241 and Inspection of Agreement State Licensees Operating under 10 CFR 150.20." The review team determined that the Branch inspected 12 (46 percent) of the candidate reciprocity licensees during the review period and exceeded the criterion of inspecting at least 20 percent of candidate reciprocity licensees during the review period, as prescribed by IMC 1220.

The review team determined that the Branch adequately implemented an inspection program for Increased Controls licensees, including fingerprinting. All Increased Controls inspections were performed in a timely manner, as required by NRC guidance. The review team determined that the Branch adequately planned for the initial set of Increased Controls inspections of affected licensees. The review team evaluated the Branch's prioritization methodology and found it acceptable. The Branch adopted a 1-year re-inspection frequency for these licensees, which represents a conservative approach to meeting the intent of the Increased Controls program.

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

3.3 Technical Quality of Inspections

The review team evaluated inspection reports, enforcement documentation, and inspection field notes and interviewed the responsible inspectors for 20 radioactive materials inspections conducted during the review period. The casework examined included a cross-section of inspections conducted by three former and five current inspectors and covered a wide variety of

inspection types. These included: academic, research and development, industrial radiography, pool irradiator, self-shielded irradiator, service provider, high dose-rate remote afterloader, medical, nuclear pharmacy, manufacturing and distribution, reciprocity, and Increased Controls licensees. Appendix C lists the inspection casework files reviewed and includes case-specific comments.

The Branch's inspection procedures are consistent with the inspection guidance found in IMC 2800. After the conclusion of each inspection, inspectors dispatched inspection findings to the respective licensees from the office after Branch management review and approval. The Branch Manager's review of each inspection report was appropriately documented and all inspection documentation was entered into the Section's electronic filing system, accessible to all staff members.

Based on the evaluation of casework, the review team determined that inspections covered all aspects of the licensees' radiation safety programs. The review team noted that inspection reports were thorough, complete, consistent, and of high quality with sufficient documentation to ensure that licensees' performances with respect to health, safety, and security were acceptable. Inspection report documentation supported violations, recommendations made to licensees, unresolved safety issues, and discussions held with licensees during exit interviews. The Branch appropriately required written responses from licensees describing corrective actions to address any infractions, deficiencies, or unresolved issues. Escalated enforcement was used, as needed.

The review team determined that documents involving Increased Controls inspections were protected and maintained in a locked file cabinet with limited access. Files were held in individual color coded folders, identifying each licensee subject to the Increased Controls. Documents observed were sufficiently marked as sensitive information to be withheld from public disclosure.

The Branch has a policy to perform supervisory accompaniments of all inspectors annually. The review team determined that the Branch Manager conducted formal, announced accompaniments of all qualified radioactive materials inspectors in Calendar Years 2004 through 2008.

The review team verified that the Branch maintains an adequate supply of appropriately calibrated survey instruments to support the inspection program, as well as to respond to radioactive materials incidents and emergency conditions. Instruments used to support the materials inspection program are sent to either a commercial service provider or the manufacturer for calibration.

The Branch receives laboratory and sample analysis support from the State laboratory, located in Raleigh. The State laboratory is a licensee of the Branch and performs sample analysis for multiple programs within the Department. The laboratory had a wide array of analytical equipment capable of detailed radiochemistry analysis. The Branch also has a mobile laboratory for use during reactor exercises and events. The mobile laboratory has a germanium detector and a proportional counter for counting environmental samples, as well as a plastic scintillator/portal monitor, and extensive communications capabilities.

The review team accompanied three of the Branch's inspectors in January 2009. The inspectors conducted inspections at a gauge manufacturer, a research and development facility, and a hospital brachytherapy program. One of the inspections included a review of the licensee's implementation of the Increased Controls. Appendix C lists the inspector accompaniments. The inspectors demonstrated performance-based inspection techniques and knowledge of the regulations. The inspectors were well trained, prepared for the inspections, and thorough in their audits of the licensees' radiation safety programs. The inspectors conducted interviews with appropriate personnel, observed licensed operations, conducted confirmatory measurements, and utilized good health physics practices. The inspectors held entrance and exit meetings with the appropriate level of licensee management. The review team determined that the inspections were adequate to assess radiological health, safety, and security at the licensed facilities.

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 examined completed licensing casework and interviewed license reviewers for 26 specific licenses. Licensing actions were reviewed for completeness, consistency, proper radioisotopes and quantities, qualifications of authorized users, adequacy of facilities and equipment, adherence to good health physics practices, financial assurance, operating and emergency procedures, appropriateness of license conditions, and overall technical quality. The casework was also reviewed for timeliness, use of appropriate deficiency letters and cover letters, reference to appropriate regulations, supporting documentation, consideration of enforcement history, pre-licensing visits, peer/supervisory review, and proper signatures.

The licensing casework was selected to provide a representative sample of licensing actions completed during the review period. Licensing actions selected for evaluation included 2 new licenses, 3 renewals, and 21 amendments. Files reviewed included a cross-section of license types, including: medical diagnostic and therapy, brachytherapy, gamma knife, pool irradiators, industrial radiography, research and development, nuclear pharmacy, and manufacturers. The casework sample represented work from each of the license reviewers. A listing of the licensing casework reviewed, with case-specific comments, can be found in Appendix D.

All licensing actions in the Branch are assigned a tracking number and logged into a computer tracking system. License reviewers use boilerplate licenses specific to the type of licensing actions to ensure consistency in standard licenses. If needed, the reviewer generates a deficiency letter and produces a draft licensing action upon final resolution of all deficiency items. The draft licensing action receives a quality assurance review by the administrative assistant and the Branch Manager.

Based on the casework evaluated, the review team concluded that the licensing actions were of high quality and consistent with the Branch's procedures, the State's regulations, and good health physics practices. The review team attributed the consistent use of templates and quality assurance reviews to the overall quality noted in the casework reviews.

The review team evaluated several license files where financial assurance for decommissioning was required. Those licensees had submitted decommissioning funding plans, as required under North Carolina's regulations. The review team's evaluation revealed that the Branch appropriately identified licensees required to maintain financial assurance and had taken appropriate steps to ensure that the licensees remained compliant with the financial assurance requirements. The review team verified that financial instruments were appropriately protected from loss or theft.

The Branch performs pre-licensing checks of all new applicants and new authorized users. The Branch's methods incorporate the essential elements of NRC's revised pre-licensing guidance to verify that the applicant will use requested radioactive materials as intended that was distributed to the Agreement States via Office of Federal and State Materials and Environmental Management Programs (FSME) Letter RCPD-08-020, dated September 22, 2008. The Branch checks all applicants against records with the North Carolina Secretary of State's Office for proper business registration. Additionally, the Branch uses various on-line search mechanisms and interagency communications to verify the identity of individuals. The Branch has a policy of hand-delivering all new and renewed licenses. Each applicant is subject to an on-site evaluation of their radiation safety and security programs prior to receipt of the initial license. This practice ensures that applicants have adequate radiation safety and security programs in place prior to taking possession of radioactive material. This practice meets the essential objective of a "pre-licensing visit."

The review team examined the Branch's licensing practices in regard to the Increased Controls and Fingerprinting Orders. The review team noted that the Branch added legally binding license conditions to the licenses that met the criteria for implementing the Increased Controls, including fingerprinting, as appropriate. The review team analyzed the Section's methodology for identifying those licenses and found the rationale was thorough and accurate. The review team confirmed that license reviewers evaluated new license applications and license amendments using the same criteria.

The review team evaluated the Branch's efforts to implement the National Source Tracking System (NSTS) requirements for certain licensees. The Branch amended all subject licenses with legally binding license conditions, which were approved by NRC in June 2008. Most sealed source inventories were loaded into the system by the January 31, 2009 deadline. The review team identified that one licensee, a newly licensed pool irradiator, did not have the appropriate NSTS license condition and, therefore, was not added to the system. During the on-site review, the license was appropriately amended to include the NSTS license condition. The Acting Section Chief stated that the licensee's sealed source inventory would be promptly entered into NSTS.

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 Branch's actions in responding to incidents, the review team examined the Section's response to the questionnaire relative to this indicator, evaluated

selected incidents reported for North Carolina in the Nuclear Material Events Database (NMED) against those contained in the Branch's files, and evaluated the casework for 14 of 57 reportable radioactive materials incidents. A listing of the casework examined, with case-specific comments, can be found in Appendix E. The review team also evaluated the Branch's response to 10 allegations involving radioactive materials reported to the State during the review period, including 5 that the NRC referred to the State.

When notified of an incident or an allegation, the Branch Manager and staff discuss the initial response and the need for an on-site investigation, based on the safety significance. The Branch maintains a database for tracking the status of all incidents and allegations.

The incidents selected for review included medical events, lost radioactive material, an overexposure, damaged equipment, leaking sources, and equipment failures. The review team determined that the Branch's responses to incidents were thorough, complete, and comprehensive. Initial responses were prompt and well coordinated, and the level of effort was commensurate with the health and safety significance. The Branch immediately dispatched inspectors to a site when the possibility of an immediate threat to public health and safety existed. When no immediate threat was present and the Branch determined that the licensee had qualified, competent individuals investigating the incident, the Branch generally responded telephonically with an on-site followup at a later date. The review team noted that, at the conclusion of investigations, inspectors generated narrative reports that thoroughly documented the investigations. Records were stored in the Section's electronic filing system and in hard copy. The review team confirmed that all records containing sensitive information were appropriately marked and protected.

Of the 14 incidents evaluated by the review team, nine had not been reported to the NRC Headquarters Operations Center within the required time frame due to a misunderstanding of the timeliness requirement in FSME Procedure SA-300 "Reporting Material Events." This lack of timely reporting had no safety significance. When notification of an incident was received, the incident response procedure required an assessment to determine if immediate notification to the NRC was required. The procedure did not, however, contain additional guidance for other frequencies of reporting, such as 24-hour reports. There was a misunderstanding by staff that timely NMED reporting met these notification requirements. During the review, the Branch Manager provided training to the staff to reflect the requirements of FSME Procedure SA-300. The Branch Manager stated that the incident response procedure would be modified appropriately to avoid future misunderstandings. All of the reportable incidents had been properly characterized in NMED. The NMED contractor commented to the review team that North Carolina's participation in the database was exemplary. The review team recommends that the State strengthen its incident response process to ensure that incidents will be reported to the NRC as required by FSME Procedure SA-300.

In assessing the effectiveness of the Branch's response to allegations, the review team evaluated the casework for ten allegations. The review team concluded that the Branch consistently took prompt and appropriate action in response to concerns raised. The review team noted that the Branch thoroughly documented the investigations and retained all necessary documentation to appropriately close the allegations. The Branch notified the allegers of the conclusion of their investigation. The review team determined that the Branch adequately protected the identity of allegers.

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

Four non-common performance indicators are used to review Agreement State programs: (1) Compatibility Requirements, (2) Sealed Source and Device Evaluation Program, (3) Low-Level Radioactive Waste Disposal Program, and (4) Uranium Recovery Program. NRC's Agreement with the State of North Carolina does not relinquish the authority to regulate uranium recovery activities; therefore, only the first three non-common performance indicators were applicable to this review.

4.1 Compatibility Requirements

4.1.1 Legislation

North Carolina became an Agreement State in 1964. 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, at the time of the review, a bill was before the 2009 Legislative Session to amend the General Statutes to broaden the language for establishing annual fees and to collect fees from operators and users of low-level radioactive waste facilities. The bill would increase the Section's fee-supported funding from 70 percent to 100 percent. It also would allow recovery of actual costs incurred during event response.

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, "Regulations for Protection Against Radiation," apply to all ionizing radiation, whether emitted from radionuclides or machines. North Carolina requires a license for possession and use of all radioactive material.

The review team examined the State's rulemaking process and found that the process takes approximately 4 to 14 months from the developmental stage to final rule adoption. The Section identifies the need for new regulations or changes to existing regulations to the North Carolina Radiation Protection Commission. After receiving approval from the North Carolina Radiation Protection Commission, the Section drafts proposed regulations for discussion with the regulated community and concerned citizens, including a minimum 60-day comment period. NRC is provided drafts of the proposed regulations for review and comment around the time they are published for public comment. Approximately 2 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. The State Rules Review Commission reviews and approves regulations promulgated by all State agencies. Unless significant numbers of comments are received, the regulations become effective the next month after approval by the State Rules Review

Commission. The Department's rules and regulations are not subject to "sunset" laws. The Department has the authority to issue legally binding requirements, such as orders or license conditions, in lieu of regulations.

The review team evaluated the Section's response to the questionnaire relative to this indicator, reviewed the status of regulations required to be adopted by the State under NRC's adequacy and compatibility policy, and verified the adoption of regulations with data obtained from the State Regulation Status Sheet that FSME maintains.

Since the previous IMPEP review, the State adopted nine rule packages. With these adoptions, North Carolina is up to date on regulation development; however, two of those rule packages resulted in comments from NRC that have not yet been resolved. The first package, submitted to NRC in 2006, involved general license regulation. NRC's comment letter, dated August 15, 2006, identified five comments regarding regulations that were less restrictive than NRC's regulations. The second package, submitted to NRC in 2008, involved medical use and transportation of radioactive materials. NRC's comment letter, dated June 30, 2008, identified seven comments that need to be addressed for compatibility. The Acting Section Chief explained that the Section lost its regulatory coordinator in 2008 and, due to competing priorities, regulation development was temporarily put on hold. The regulation development process is now assigned to the Branch Manager, who recently began the regulatory process by communicating the needed compatibility changes to the North Carolina Radiation Protection Commission. The review team recommends that the State, to maintain compatibility with the NRC, make appropriate regulatory changes to resolve NRC-generated comments as noted in regulation review letters.

The review team identified the following NRC amendments that the State will need to address in the future. The Acting Section Chief related that the amendments would be addressed in upcoming rulemakings or through the adoption of alternate legally binding requirements:

- "Minor Amendments," 10 CFR Parts 20, 30, 32, 35, 40 and 70 amendment (71 FR 15005), that is due for Agreement State adoption by March 27, 2009.

- "Medical Use of Byproduct Material – Minor Corrections and Clarifications," 10 CFR Parts 32 and 35 amendment (72 FR 45147 and 72 FR 54207), that is due for Agreement State adoption by October 29, 2010.

- "Requirements for Expanded Definition of Byproduct Material," 10 CFR Parts 20, 30, 31, 32, 33, 35, 61, and 150 amendment (72 FR 55864), that is due for Agreement State adoption by November 30, 2010.

- "Exemptions From Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements," 10 CFR Parts 30, 31, 32 and 150 amendment (72 FR 58473), that is due for Agreement State adoption by December 17, 2010.

- "Occupational Dose Records, Labeling Containers, and Total Effective Dose Equivalent," 10 CFR Parts 19 and 20 amendment (72 FR 68043), that is due for Agreement State adoption by February 15, 2011.

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

4.2 Sealed Source and Device Evaluation Program

In reviewing this indicator, the review team used three subelements to evaluate the Branch's performance regarding the Sealed Source and Device (SS&D) Evaluation Program. These subelements were: (1) Technical Staffing and Training; (2) Technical Quality of the Product Evaluation Program; and (3) Evaluation of Defects and Incidents Regarding SS&Ds.

In assessing the Branch's SS&D evaluation activities, the review team examined information contained in the Section's response to the IMPEP questionnaire for this indicator. The review team evaluated seven SS&D evaluations and supporting documents processed during the review period. The review team noted the staff's use of guidance documents and procedures, interviewed staff members involved in SS&D evaluations, and verified the use of regulations and inspections to enforce commitments made in the applications.

4.2.1 Technical Staffing and Training

The Branch has two reviewers who are qualified to perform safety evaluations of SS&D applications. Both have degrees in a physical science or engineering and have attended NRC's SS&D Workshop.

The review team interviewed staff members involved in the reviews and determined that they were familiar with the procedures used in the evaluation of sources and devices. The review team confirmed that all applicable and pertinent American National Standards Institute standards, NUREG-1556 Series guides, NRC Regulatory Guides, and applicable references were available and used appropriately in performing the SS&D reviews. The Branch also retains the services of a Professional Engineer to supplement staff efforts in specialized areas such as material science/analysis and system safety evaluations. The review team determined that the Branch's staffing level for SS&D reviews is adequate for the current workload.

4.2.2 Technical Quality of the Product Evaluation Program

The review team evaluated a cross section of the SS&D actions issued during the review period. The casework reviewed represented the efforts of the two current SS&D reviewers and two former SS&D reviewers. The actions included one new device and six amendments to existing device registries. A list of SS&D casework examined can be found in Appendix F.

Analysis of the casework and interviews with staff members confirmed that the Branch follows the recommended guidance from the NRC's SS&D Workshop and NUREG-1556, Volume 3, Revision 1, "Consolidated Guidance About Materials Licenses – Applications for Sealed Source and Device Evaluation and Registration." Registrations clearly summarized the product evaluations to provide license reviewers with adequate information to license the possession

and use of the products. Deficiency letters clearly stated regulatory positions and all health and safety issues were addressed. The review team determined that the product evaluations were thorough, complete, consistent, of acceptable technical quality, and adequately addressed the integrity of the products during use and under accident conditions.

4.2.3 Evaluation of Defects and Incidents Regarding SS&Ds

No incidents related to SS&D defects involving sources or devices registered by the State of North Carolina were reported during the review period. Incident procedures are in place should an SS&D-related incident occur. The Branch Manager was aware of the need to look at such incidents as potentially generic in nature with possible wide-ranging effects.

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 Disposal Program

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

5.0 SUMMARY

As noted in Sections 3.0 and 4.0, the review team found North Carolina's performance to be satisfactory for all seven performance indicators reviewed. The review team made two recommendations regarding program performance by the State. 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 IMPEP review of the North Carolina Agreement State Program take place in approximately 4 years.

Below are the review team's 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 State strengthen its incident response process to ensure that incidents will be reported to the NRC as required by FSME Procedure SA-300. (Section 3.5)

2. The review team recommends that the State, to maintain compatibility with the NRC, make appropriate regulatory changes to resolve NRC-generated comments as noted in regulation review letters. (Section 4.1.2)

LIST OF APPENDICES

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APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	**Area of Responsibility**
James Lynch, Region III	Team Leader Technical Quality of Licensing Actions Compatibility Requirements Inspector Accompaniments
James Kottan, Region I	Technical Staffing and Training Technical Quality of Incident and Allegation Activities
Geoffrey Warren, Region III	Technical Quality of Inspections
Cynthia Becker, Florida	Status of Materials Inspection Program
D. Ray Jisha, Texas	Technical Quality of Licensing Actions Sealed Source and Device Evaluation Program

APPENDIX B

NORTH CAROLINA ORGANIZATION CHARTS

ADAMS ACCESSION NO.: ML082520670

APPENDIX C

INSPECTION CASEWORK REVIEWS

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

File No.: 1
Licensee: JANX Integrity Group Inc. License No.: 085-1117-1
Inspection Type: Routine, Announced Priority: 1
Inspection Date: 3/13/07 Inspector: SJ

File No.: 2
Licensee: Cardinal Health License No.: 025-0794-10
Inspection Type: Routine, Unannounced Priority: 2
Inspection Date: 3/1/05 Inspector: GA

File No.: 3
Licensee: Duke University License No.: 032-0247-1
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 7/17/06 Inspectors: SJ, et al.

Comment:
Inspection report included information copied from the previous inspection report, including the description of a violation that had since been corrected.

File No.: 4
Licensee: Research Triangle Institute License No.: 032-0131-1
Inspection Type: Routine, Announced Priority: 3
Inspection Date: 2/13/07 Inspector: SJ

File No.: 5
Licensee: North Carolina State University License No.: 092-0090-3
Inspection Type: Special, Announced Priority: 2
Inspection Date: 2/14/07 Inspector: GM

File No.: 6
Licensee: Gaston Memorial Hospital License No.: 036-0203-2
Inspection Type: Routine, Unannounced Priority: 2
Inspection Date: 8/21/07 Inspector: JA

File No.: 7
Licensee: New Hanover Regional Medical Center License No.: 065-0037-4
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 2/26/08 Inspector: RC

File No.: 8
Licensee: Albemarle Hospital, Inc. License No.: 070-0126-1
Inspection Type: Routine, Unannounced Priority: 3
Inspection Dates: 4/4/07 and 5/7/07 Inspector: JA

File No.: 9
Licensee: Raleigh Medical Group License No.: 092-1457-1
Inspection Type: Pre-Licensing Site Visit Priority: 5
Inspection Date: 6/20/08 Inspector: JA

File No.: 10
Licensee: Sterigenics U.S., Inc. License No.: 060-0974-1
Inspection Type: Special, Announced Priority: 2
Inspection Date: 6/24/08 Inspector: SJ

File No.: 11
Licensee: Wake Radiology Oncology Services License No.: 092-1086-1
Inspection Type: Routine, Unannounced Priority: 2
Inspection Date: 2/11/08 Inspector: CH

File No.: 12
Licensee: Baker Testing Services Inc. License No.: 049-1441-1
Inspection Type: Special, Announced Priority: 1
Inspection Date: 12/3/07 Inspector: GM

File No.: 13
Licensee: Digirad Imaging Solutions License No.: 065-1014-5
Inspection Type: Initial, Unannounced Priority: 3
Inspection Date: 6/7/07 Inspectors: CH, RC

File No.: 14
Licensee: North Carolina Baptist Hospital License No.: 034-0158-1
Inspection Type: Special, Announced Priority: 2
Inspection Date: 9/13/06 Inspector: JA

File No.: 15
Licensee: Diabetes and Endocrinology Consultants, PC License No.: 016-1316-1
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 2/6/08 Inspector: RC

File No.: 16
Licensee: Humboldt Scientific License No.: 092-0750-1
Inspection Type: Routine, Unannounced Priority: 5
Inspection Date: 7/17/07 Inspectors: CH, RC

File No.: 17
Licensee: Cleveland County Healthcare System License No.: 023-0219-1
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 5/3/05 Inspector: GS

File No.: 18
Licensee: H&H X-Ray Services License No.: 111-0322-R
Inspection Type: Reciprocity, Unannounced Priority: 1
Inspection Date: 7/31/08 Inspector: CH

Comment:
Licensee's response to a Notice of Violation was not in the file.

File No.: 19
Licensee: Hospira, Inc. License No.: 064-0969-1
Inspection Type: Routine, Unannounced Priority: 2
Inspection Date: 3/20/07 Inspector: JA

File No.: 20
Licensee: Siemens Medical Solutions USA, Inc. License No.: 092-0895-1
Inspection Type: Special, Announced Priority: 5
Inspection Date: 12/12/05 Inspector: ME

INSPECTOR ACCOMPANIMENTS

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

Accompaniment No.: 1
Licensee: Duke Raleigh Hospital License No.: 092-0582-4
Inspection Type: Initial, Announced Priority: 3
Inspection Date: 1/6/09 Inspector: JA

Accompaniment No.: 2
Licensee: InstroTek, Inc. License No.: 092-1073-1
Inspection Type: Routine, Unannounced Priority: 3
Inspection Date: 1/7/09 Inspector: RC

Accompaniment No.: 3
Licensee: GlaxoSmithKline License No.: 032-1029-2
Inspection Type: Special, Announced Priority: 2
Inspection Date: 1/8/09 Inspector: GM

APPENDIX D

LICENSE CASEWORK REVIEWS

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

File No.: 1
Licensee: Becton Dickinson and Company License No.: 032-0369-3
Type of Action: Amendment Amendment No.: 2
Date Issued: 7/3/08 License Reviewer: GM

Comment:
License was missing required license condition.

File No.: 2
Licensee: Research Triangle Institute License No.: 032-0131-1
Type of Action: Renewal Amendment No.: 91
Date Issued: 8/3/05 License Reviewer: CH

Comment:
Licensee renewal application was not in the file.

File No.: 3
Licensee: Hospira, Inc. License No.: 064-0969-1
Type of Action: Renewal Amendment No.: 12
Date Issued: 11/10/08 License Reviewer: RC

File No.: 4
Licensee: Sterigenics U.S., Inc. License No.: 060-0974-1
Type of Action: Amendment Amendment No.: 30
Date Issued: 10/29/08 License Reviewer: GS

File No.: 5
Licensee: JANX integrity Group License No.: 068-1117-1
Type of Action: Amendment Amendment No.: 13
Date Issued: 10/29/08 License Reviewer: WT

File No.: 6
Licensee: Cumberland Cardiology License No.: 026-1460-1
Type of Action: New Amendment No.: 0
Date Issued: 7/30/08 License Reviewer: JA

File No.: 7
Licensee: Troxler Electronic Laboratories License No.: 032-0182-1
Type of Action: Amendment Amendment No.: 4
Date Issued: 4/11/08 License Reviewer: ME

File No.: 8
Licensee: Cardinal Health License No.: 025-0794-11
Type of Action: Amendment Amendment No.: 9
Date Issued: 12/8/06 License Reviewer: JA

File No.: 9
Licensee: Catawba Valley Medical Center License No.: 018-0292-1
Type of Action: Amendment Amendment No.: 112
Date Issued: 8/22/07 License Reviewer: GM

File No.: 10
Licensee: Pitt County Memorial Hospital License No.: 074-0296-9
Type of Action: Amendment Amendment No.: 15
Date Issued: 1/28/09 License Reviewer: HB

File No.: 11
Licensee: MACTEC Engineering & Consulting, Inc. License No.: 060-0082-1
Type of Action: Amendment Amendment No.: 37
Date Issued: 12/5/08 License Reviewer: GM

File No.: 12
Licensee: Wake Radiation Oncology License No.: 092-1086-1
Type of Action: Amendment Amendment No.: 8
Date Issued: 10/29/08 License Reviewer: GS

Comment:
Generic license condition authorizing a fictitious device was left on license instead of being updated to be specific to this facility.

File No.: 13
Licensee: Presbyterian Hospital License No.: 060-0019-1
Type of Action: Amendment Amendment No.: 28
Date Issued: 3/13/05 License Reviewer: JA

File No.: 14
Licensee: University of North Carolina License No.: 068-0565-1
Type of Action: Renewal Amendment No.: 43
Date Issued: 11/24/08 License Reviewer: GS

File No.: 15
Licensee: Moses Cone Regional Cancer Center License No.: 041-0021-3
Type of Action: New Amendment No.: 10
Date Issued: 1/6/09 License Reviewer: HB

File No.: 16
Licensee: Alamance Cancer Center License No.: 001-0117-2
Type of Action: Amendment Amendment No.: 9
Date Issued: 1/15/09 License Reviewer: LC

File No.: 17
Licensee: High Point Regional Hospital License No.: 041-0119-2
Type of Action: Amendment Amendment No.: 25
Date Issued: 1/15/09 License Reviewer: LC

File No.: 18
Licensee: North Carolina Baptist Hospital License No.: 034-0158-9
Type of Action: Amendment Amendment No.: 8
Date Issued: 2/9/09 License Reviewer: HB

File No.: 19
Licensee: Cape Fear Valley Health System License No.: 026-0173-2
Type of Action: Amendment Amendment No.: 30
Date Issued: 1/28/09 License Reviewer: HB

File No.: 20
Licensee: Wayne Radiation Oncology License No.: 096-0186-2
Type of Action: Amendment Amendment No.: 21
Date Issued: 1/28/09 License Reviewer: GS

File No.: 21
Licensee: Gaston Memorial Hospital License No.: 036-0203-2
Type of Action: Amendment Amendment No.: 14
Date Issued: 1/28/09 License Reviewer: HB

File No.: 22
Licensee: Moore Regional Hospital License No.: 063-0585-1
Type of Action: Amendment Amendment No.: 52
Date Issued: 2/11/09 License Reviewer: HB

Comment:
A license condition did not specify make and model of device.

File No.: 23
Licensee: New Hanover Radiation Oncology License No.: 065-0860-1
Type of Action: Amendment Amendment No.: 13
Date Issued: 11/7/08 License Reviewer: ME

File No.: 24
Licensee: 21st Century Oncology License No.: 011-1276-1
Type of Action: Amendment Amendment No.: 36
Date Issued: 1/8/09 License Reviewer: GS

File No.: 25
Licensee: NC Radiation Therapy Management Services
License No.: 044-1276-2
Type of Action: Amendment
Amendment No.: 12
Date Issued: 10/29/08
License Reviewer: GS

File No.: 26
Licensee: Carolina Radiation Medicine
License No.: 074-1276-4
Type of Action: Amendment
Amendment No.: 5
Date Issued: 2/5/09
License Reviewer: GS

APPENDIX E

INCIDENT CASEWORK REVIEWS

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

File No.: 1
Licensee: Charlotte-Mecklenburg Hospital
License No.: 060-0014-3
Date of Incident: 1/27/09
NMED Log No.: 090151
Investigation Date: Ongoing
Type of Incident: Medical Event
Type of Investigation: Site

Comment:
The Branch did not report this event to the NRC Operations Center in a timely manner.

File No.: 2
Licensee: Charlotte-Mecklenburg Hospital
License No.: 060-0014-3
Date of Incident: 1/20/09
NMED Log No.: 090102
Investigation Date: 1/21/09
Type of Incident: Leaking Source
Type of Investigation: Telephone

Comment:
The Branch did not report this event to the NRC Operations Center in a timely manner.

File No.: 3
Licensee: ECS Carolinas
License No.: 041-0253-4
Date of Incident: 1/19/09
NMED Log No.: 090100
Investigation Date: 1/19/09
Type of Incident: Lost Material
Type of Investigation: Telephone/Site Visit

Comment:
The Branch did not report this event to the NRC Operations Center in a timely manner.

File No.: 4
Licensee: QSL
License No.: 090-1058-1
Date of Incident: 1/13/09
NMED Log No.: 090077
Investigation Date: Ongoing
Type of Incident: Overexposure
Type of Investigation: Telephone/Site Visit

File No.: 5
Licensee: Flowserve
License No.: 092-0121-1
Date of Incident: 8/6/08
NMED Log No.: 080559
Investigation Date: 8/7/08
Type of Incident: Equipment Failure
Type of Investigation: Telephone

File No.: 6
Licensee: Froehling & Robertson
License No.: 092-0353-6
Date of Incident: 6/27/08
NMED Log No.: 080378
Investigation Date: 6/27/08
Type of Incident: Damage to Equipment
Type of Investigation: Telephone

File No.: 7
Licensee: S & ME, Inc.
License No.: 092-0922-1
Date of Incident: 4/10/08
NMED Log No.: 080310
Investigation Date: 5/5/08
Type of Incident: Equipment Failure
Type of Investigation: Telephone

File No.: 8
Licensee: Virginia Mason Medical Center
License No.: 060-0014-3
Date of Incident: 3/11/08
NMED Log No.: 080170
Investigation Date: 3/14/08
Type of Incident: Leaking Source
Type of Investigation: Telephone

Comment:
The Branch did not report this event to the NRC Operations Center in a timely manner.

File No.: 9
Licensee: Memorial Mission Hospital
License No.: 011-0091-4
Date of Incident: 1/29/08
NMED Log No.: 080071
Investigation Date: 1/30/08
Type of Incident: Lost Material
Type of Investigation: Telephone

File No.: 10
Licensee: Carolinas Medical Center
License No.: 060-0014-1
Date of Incident: 10/12/07
NMED Log No.: 070640
Investigation Date: 10/16/07
Type of Incident: Leaking Source
Type of Investigation: Telephone

Comment:
The Branch did not report this event to the NRC Operations Center in a timely manner.

File No.: 11
Licensee: Memorial Mission Hospital
License No.: 011-1203-1
Date of Incident: 4/24/07
NMED Log No.: 070263
Investigation Date: 4/26/07
Type of Incident: Medical Event
Type of Investigation: Telephone/Site

Comment:
The Branch did not report this event to the NRC Operations Center in a timely manner.

File No.: 12
Licensee: Carolinas Medical Center
License No.: 060-0014-3
Date of Incident: 1/17/06
NMED Log No.: 060049
Investigation Date: 1/18/06
Type of Incident: Medical Event
Type of Investigation: Telephone

Comment:
The Branch did not report this event to the NRC Operations Center in a timely manner.

File No.: 13
Licensee: DuPont
License No.: 026-1851-0G
Date of Incident: 6/1/05
NMED Log No.: 050615
Investigation Date: 8/31/05
Type of Incident: Loss of Control
Type of Investigation: Telephone

Comment:
The Branch did not report this event to the NRC Operations Center in a timely manner.

File No.: 14
Licensee: Duke University
License No.: 032-0247-4
Date of Incident: 11/15/04
NMED Log No.: 040859
Investigation Date: 11/16/04
Type of Incident: Medical Event
Type of Investigation: Telephone

Comment:
The Branch did not report this event to the NRC Operations Center in a timely manner.

APPENDIX F

SEALED SOURCE & DEVICE CASEWORK REVIEWS

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

File No.: 1
Registry No.: NC-646-D-130-S
Applicant Name: Troxler Electronics Laboratories
Date Issued: 6/12/06
SS&D Type: Portable Gauge
Type of Action: Amendment
Reviewers: SJ, GS

File No.: 2
Registry No.: NC-646-D-128-S
Applicant Name: Troxler Electronics Laboratories
Date Issued: 3/20/08
SS&D Type: Portable Gauge
Type of Action: Amendment
Reviewers: ME, GS

File No.: 3
Registry No.: NC-1252-D-101-G
Applicant Name: General Dynamics
Date Issued: 6/14/06
SS&D Type: Chemical Agent Vapor Detector
Type of Action: New
Reviewers: SJ, ME

File No.: 4
Registry No.: NC-585-D-103-G
Applicant Name: SRB Technologies, Inc.
Date Issued: 2/19/07
SS&D Type: Self-Lighting Sign
Type of Action: Amendment
Reviewers: GS, ME

File No.: 5
Registry No.: NC-585-D-105-G
Applicant Name: SRB Technologies, Inc.
Date Issued: 7/26/07
SS&D Type: Self-Luminous Fixed Marker
Type of Action: Amendment
Reviewers: GS, ME

File No.: 6
Registry No.: NC-585-S-102-S
Applicant Name: SRB Technologies, Inc.
Date Issued: 2/19/07
SS&D Type: Self-Luminous Tritium Lamp
Type of Action: Amendment
Reviewers: GS, ME

File No.: 7
Registry No.: NC-585-D-801-E
Applicant Name: SRB Technologies, Inc.
Date Issued: 1/11/05
SS&D Type: Self-Lighting Sign
Type of Action: Amendment
Reviewers: SJ, GA