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

July 14, 2014

Mr. W. Lee Cox, III, Chief
Radiation Protection Section
Division of Health Service Regulation
Department of Health and Human Services
3825 Barrett Drive
Raleigh, NC 27609

Dear Mr. Cox:

On June 5, 2014, the Management Review Board (MRB) met to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) report on the North Carolina Agreement State Program. The MRB found the North Carolina program adequate to protect public health and safety, but needs improvement, and compatible with the U.S. Nuclear Regulatory Commission's program.

Section 5.0, page 14 of the enclosed final report contains a summary of the IMPEP team's findings. The review team made three recommendations in regard to program performance by the North Carolina Agreement State Program during this review. Based on the results of the current IMPEP review, the next full review of the North Carolina Agreement State Program will take place in approximately 4 years, with a periodic meeting tentatively scheduled in 1 year.

I appreciate the courtesy and cooperation extended to the IMPEP team during the review. I also wish to acknowledge your continued support for the Agreement State program. I look forward to our agencies continuing to work cooperatively in the future.

Sincerely,

/RA/

Michael F. Weber
Deputy Executive Director for Materials, Waste,
Research, State, Tribal, and Compliance Programs
Office of the Executive Director for Operations

Enclosure:
North Carolina Final IMPEP Report

cc: Jennifer Opila, CO
Organization of Agreement States
Liaison to the MRB

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Letter to W. Cox from Michael F. Weber dated July 14, 2014

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF THE NORTH CAROLINA AGREEMENT STATE PROGRAM

MARCH 3 - 7, 2014

FINAL REPORT

Enclosure

EXECUTIVE SUMMARY

This report presents the results of the Integrated Materials Performance Evaluation Program (IMPEP) review of the North Carolina Agreement State Program. The review was conducted during the period of March 3 - 7, 2014, by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of Florida.

Based on the results of this review, the review team recommended that North Carolina's performance be found satisfactory but needs improvement for the indicators Technical Staffing and Training, Status of the Materials Inspection Program, and Sealed Source and Device Evaluation Program, and satisfactory for the remaining indicators reviewed. The MRB disagreed with the team's finding of satisfactory, but needs improvement for the indicator Status of the Materials Inspection Program and directed that the Program be found "satisfactory" for this indicator, as it appeared that the State had a process in place which ensured that public health and safety was not compromised. The review team recommended that North Carolina enter into a period of Monitoring. The MRB disagreed with this recommendation as the team did not identify any performance issues which impacted public health, safety and security.

The review team found that the two recommendations from the 2009 IMPEP review regarding strengthening the incident and response process to ensure timely reporting of events, and making regulatory changes to resolve NRC generated comments to regulation review letters were addressed by the State and can be closed.

The review team made three recommendations regarding the performance of the North Carolina Agreement State Program.

Accordingly the review team recommended, and the MRB agreed, that the North Carolina Agreement Sate Program is adequate to protect public health and safety, but needs improvement, and is compatible with the NRC's program. The review team recommended, and the MRB agreed, that the next IMPEP review take place in approximately four years and that a periodic meeting be held in one year.

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 March 3 - 7, 2014, by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the State of Florida. 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 February 28, 2009 to March 7, 2014, were discussed with North Carolina managers on the last day of the review.

A draft of this report was provided to North Carolina for factual comment on April 16, 2014. The State responded by letters dated May 7, 2014, and June 3, 2014. Copies of the State's responses are included as an Attachment to this report. A Management Review Board (MRB) met on June 5, 2014, to consider the proposed final report. The MRB found the North Carolina Agreement State Program adequate to protect public health and safety, but needs improvement, and compatible with the NRC's program.

The North Carolina Agreement State Program is administered by the Radiation Protection Section (the Section) within the Division of Health Service Regulation (the Division). The Division is part of the Department of Health and Human Services (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 618 specific licenses authorizing possession and use of radioactive 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 the NRC and the State of North Carolina.

In preparation for the review, a questionnaire addressing the common and applicable non-common performance indicators was initially sent to the Branch by electronic mail on November 20, 2013, and by regular mail on January 9, 2014. The Branch provided its response to the questionnaire on February 12, 2014. A copy of the questionnaire response can be found in NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML14044A057.

The review team's general approach for conduct of this review consisted of (1) examination of the Branch'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 four inspectors; and (6) interviews with staff and managers. The review team evaluated the information gathered against the established criteria for each common and the 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 describes the State's actions in response to recommendations made during previous reviews. Results of the review for 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 the Program's performance.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous IMPEP review, which concluded on February 27, 2009, the review team made two recommendations regarding the North Carolina Agreement State Program's performance. The status of the recommendations is as follows:

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)"

   Status: Following the 2009 IMPEP review, North Carolina acknowledged that reporting to the NRC was not as strong as it could be due to misunderstanding the reporting requirements for incidents with 24 hour reporting requirements; and due to procedural ambiguity about which staff was responsible for making incident notification to the NRC. North Carolina has addressed these issues by revising its procedure, assigning notification responsibilities to specific staff members, and providing SA-300 training to the staff. The incident response procedures were modified to require all incidents be evaluated against the NRC reporting requirements and various sections of the North Carolina Regulations for Protection against Radiation. The revised procedures established an incident assessment team leader who is responsible for determining if, and when, notification needs to be made to the NRC in accordance with Office of Federal and State Materials and Environmental Management Programs (FSME) Procedure SA-300. The Radiation Protection Branch assigned the responsibility for making the notification to the Nuclear Materials Events Database (NMED) Manager. The review team examined several NMED incident files and determined that North Carolina had significantly improved reporting incidents to the NRC and had sufficiently strengthened its incident response process to ensure incidents are reported in accordance with SA-300. This recommendation is closed.

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)"

   Status: North Carolina has addressed the NRC comments from letters dated August 15, 2006, and June 30, 2008, along with the six amendments that were overdue for adoption. North Carolina finalized these regulations on October 1, 2013. The final regulations have been submitted to the NRC for review and the review is expected to be completed before the May 27, 2014, MRB meeting. This recommendation is closed.

3.0 COMMON PERFORMANCE INDICATORS

Five common performance indicators are used to review the 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

Considerations 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 Branch's questionnaire response relative to this indicator, interviewed managers and staff, reviewed job descriptions and training records, and considered workload backlogs.

The Branch is managed by the Branch Manager. Additionally the Branch has a lead for radioactive materials licensing and a lead for radioactive materials inspection. The Branch is responsible for inspection, licensing and compliance activities, emergency response activities, and sealed source and device evaluations.

At the time of the review, there were nine technical staff members with various degrees of involvement in the radioactive materials program, the Branch Manager, the Section Chief and one administrative assistant, totaling approximately 10.75 full-time equivalents (FTE). In September 2013, the Branch Manager was given a reduced managerial role in order to allow him the time to perform duties of the vacated Environmental Program Consultant position. This was necessary to make leadership changes and to continue the regulation writing efforts which became void due to the vacancy. The Section Chief has been the acting Radioactive Material Branch Manager since that time.

The Branch also utilizes two contract employees when needed. One contract employee helps with engineering reviews for sealed source and device applications and the other contract employee helps the Branch with regulation promulgation and with issues regarding the Branch's License Tracking System (LTS) database. During the review period six technical staff left the program. Each time a vacancy was created during the review period the Branch has been able to fill the position. Two technical staff positions were vacant at the time of this review which when filled would add an additional two FTE to the program. These vacancies are the result of two technical staff that left in September 2013 and October 2013. One of the vacant positions has already been posted and the Branch plans to start the interview process for qualified candidates the week after the onsite review. The Branch plans to submit paperwork to post for the other vacant position after the first vacancy is filled. The review team determined that, when fully staffed, staffing levels are adequate for the Agreement State program.

Through interviews with staff and review of the IMPEP questionnaire, the review team determined that all currently qualified Branch inspectors were trained appropriately and fully qualified. The review team concluded that the three technical staff currently going through the licensing qualification process is unaware of what licensing actions they are qualified to perform. These reviewers also do not have a good understanding of the training qualification program and what is required to become a qualified license reviewer. The review team found that

licensing actions are presented to the staff in an unconventional manner rather than by increasing complexity. This practice has led to ineffective training of newer staff and has led to a lack of understanding of what is needed for each licensing action (Section 3.4 Technical Quality of Licensing Actions). The Branch has a documented training plan for technical staff. However, the training plan has not been updated since 2004 and is not consistent with the requirements in the NRC/Organization of Agreement States Training Working Group Report and NRC's Inspection Manual Chapter (IMC) 1248, "Formal Qualification Program for Federal and State Material and Environmental Management Programs." The review team recommended, and the MRB agreed, that that the State update its training qualification program to be consistent with IMC 1248, "Formal Qualification Program for Federal and State Material and Environmental Management Programs" and the State apply this program to all technical staff currently going through the qualification process and all new staff that are hired. At the MRB meeting, the State reported that it had taken actions to address this recommendation immediately after the review.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that North Carolina's performance with respect to the indicator, Technical Staffing and Training, be found satisfactory, but needs improvement.

3.2 Status of Materials Inspection Program

The review team focused on five factors while reviewing this indicator: inspection frequency, overdue inspections, initial inspections of new licenses, timely dispatch of inspection findings to licensees, and performance of reciprocity inspections. The review team's evaluation was based on the Branch's questionnaire response relative to this indicator, data gathered from the Branch's database, examination of completed inspection casework, and interviews with management and staff.

The review team verified that the Branch's inspection frequencies for all types of radioactive material licenses are the same as similar license types listed in IMC 2800, "Materials Inspection Program." The Branch conducted 490 Priority 1, 2, and 3 inspections during the review period, based on the inspection frequencies established in IMC 2800. Twenty-nine of these inspections were conducted overdue by more than 25 percent of the inspection frequency prescribed in IMC 2800. In addition, the Branch performed 71 initial inspections during the review period, 21 of which were conducted overdue. The initial inspections that were completed overdue were completed between one month and three years past the due date. As required by IMC 2800, initial inspections should be conducted within 12 months of license issuance. The review team recommended, and the MRB agreed, that the State implement procedures and a new tracking system to ensure that less than 10 percent of Priority 1, 2, and 3 and initial inspections are completed overdue.

Overall, the review team calculated that the Branch performed nine percent of its inspections overdue during the review period. The initial inspections were conducted late due to database entry errors and improper tracking. The Branch's database issues extend beyond the missed initial inspections. Prior to the onsite review the Branch found approximately 200 data entry errors in the inspection database. While onsite the review team found additional database entry errors. The Branch is aware of the issues with the database. To address the issues the Branch plans to perform a quality assurance check on the current database and is looking at

implementing a new temporary database. The temporary database would be in place until the Branch is able to fully integrate inspection data into its LTS. The Branch expects to fully implement the LTS for inspections in the next year.

The review team evaluated the Branch's timeliness in providing inspection findings to licensees. A sampling of 28 inspection reports indicated that none of the inspection findings were communicated to the licensees beyond the Branch's goal of 30 days after the inspection. During the review period, the Branch granted 224 reciprocity permits, 150 of which were candidate licensees 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 exceeded the NRC's criteria of inspecting 20 percent of candidate licensees operating under reciprocity in each of the five years covered by the review period.

The team discussed at length findings of satisfactory and satisfactory but needs improvement for this indicator. Based on the IMPEP evaluation criteria, a finding of satisfactory could be made when less than 10 percent of all Priority 1, 2, and 3 and initial inspections are conducted overdue. However the team determined that (1) a significant number of initial inspections were completed overdue, and (2) the Branch was unaware of the number of initial inspections that were completed overdue.

Therefore, the review team recommended, that North Carolina's performance with respect to the indicator, Status of Materials Inspection Program, be found satisfactory, but needs improvement. The MRB disagreed with the team's Finding and directed that this indicator be found satisfactory. The MRB determined that the Program met the criteria for a finding of "satisfactory", and determined the Program had a process in place which ensured that public health and safety was not compromised.

3.3 Technical Quality of Inspections

The review team evaluated inspection reports, enforcement documentation, inspection field notes, and interviewed the responsible inspectors for 28 radioactive materials inspections conducted during the review period. The casework examined included a cross-section of inspections conducted by both current and former inspectors and covered a wide variety of inspection types. These included academic, research and development, industrial radiography, self-shielded irradiator, service provider, high dose-rate remote after loader, 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 NRC's IMC 2800. After the conclusion of each inspection, inspectors who are all home-based, complete the inspection reports and send them electronically to the Branch. Letters conveying inspection findings are mailed to the respective licensees from the office after Branch management review and approval. This process typically is completed within two weeks after the completion of the inspection. Documentation is maintained electronically in the Branch's electronic filing system.

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 items of non-compliance. Escalated enforcement actions are taken when appropriate.

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 or other designated senior staff completed accompaniments of all qualified radioactive materials inspectors in Calendar Years 2009 through 2014.

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.

One review team member accompanied four of the Branch's inspectors during the week of January 27 - 31, 2014. The inspectors were accompanied during health and safety and security inspections of medical institutions including diagnostic and therapeutic uses including unsealed radioiodine therapy and PET imaging, and radiography facilities. 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 recommended, and the MRB agreed, 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 25 specific licensing actions. 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, 7 renewals, 2 terminations, and 14 amendments. Files reviewed included a cross-section of license types: broad scope, medical diagnostic and therapy including high dose rate remote afterloader, unsealed radioiodine therapy, temporary/permanent implant brachytherapy, gamma knife, industrial radiography, research and development, nuclear pharmacy, and panoramic irradiators. The casework sample represented work from nine current and former license reviewers. A list of the licensing casework evaluated with case-specific comments is provided in Appendix D.

All licensing actions are initially entered into the LTS and assigned to the license reviewers by an administrative assistant. The LTS system is used to generate the licensing documents in a standardized format. License reviewers use standardized sets of conditions specific to the type of licensed program to ensure consistency in the licenses. The review team attributed the consistent use of templates to the overall quality noted in the casework reviews. One limitation of the LTS system was noted by the team. Specifically, the field in LTS associated with "Chemical and Physical Form" did not allow for the insertion of text in Item 7 of a license, and therefore did not allow for the addition of manufacturer and model numbers for sealed sources in this location. This was noted in all licenses generated by the LTS system. In these instances, the Branch has placed the information in other locations on the license. Following discussions with the review team, the Branch will revisit how licenses are developed and ensure that manufacturer and model numbers are appropriately on the license.

Currently four technical staff members review license applications and write licenses. Three of the four license reviewers are new to the program since the last IMPEP review and are in various stages of the training and qualification process. Technical staff use the Branch's licensing guides and NUREG-1556 series guidance documents, policies, checklists, and standard license conditions specific to the type of licensing actions to ensure consistency in licenses. Deficiencies are addressed and the license is prepared for a quality assurance (QA) review.

The team noted that none of three license reviewers hired since the previous IMPEP review had obtained signature authority. The senior license reviewer does have signature authority and

performs a quality assurance review of all licensing actions prior to signing the license. Deficiencies in the license review and errors on the prepared license identified by the quality assurance review are documented on a quality assurance checklist. Deficiencies identified in the review of the application and errors found in the prepared license are brought to the attention of the license reviewer and used as a method of training. Deficiencies and errors in the license are addressed and the final license is issued. Licenses are issued for a five year period under a timely renewal system.

Licensing actions were generally found to be thorough, complete, consistent, and of acceptable technical quality with health and safety issues properly addressed. However, the review team noted examples of issues with licensing actions that were due to insufficient training of the license reviewers and quality assurance reviews (see recommendation in Section 3.1, Technical Staffing and Training). For example, three medical licenses were identified that included the addition of two authorized users and one authorized nuclear pharmacist without obtaining complete documentation of their training, experience, and preceptor attestation. In two cases, an incomplete review of the application resulted in licensee requests not being addressed which included a name change, the removal of an authorized user and the addition of a location of use. Other examples include a failure to identify incorrect references in license conditions, incomplete license conditions, and multiple typographical errors.

License tie-down conditions were stated clearly and inspectable. Deficiencies in the application were usually addressed via e-mail or telephone calls to the licensee. Deficiency e-mails clearly stated regulatory position, were used at the proper time, and identified substantive deficiencies in the licensees' documents. Documentation of licensing actions was often split between the paper file and LTS, and in some cases it appeared that records of deficiency calls or e-mails were not retained. The team found that in four of the files reviewed, supporting documentation was not found in the license file. Terminated licensing actions were well documented, showing appropriate transfer and survey records.

The Branch performs pre-licensing checks on all new applicants. The pre-licensing review methods incorporate the essential elements of NRC's revised pre-licensing guidance to verify that the applicant will use requested radioactive materials as intended. Each applicant is subject to an onsite evaluation of their radiation safety and security programs prior to license receipt. This practice ensures that applicants have adequate radiation safety and security programs in place prior to the licensees' taking possession of radioactive material. This also serves as the pre-licensing visit. The Branch has a policy of hand-delivering all new and renewed licenses.

The review team examined the Branch's licensing practices regarding the Increased Controls and Fingerprinting Orders. The review team noted that the State uses legally binding license conditions that meet the criteria for implementing the Increased Controls Orders, including fingerprinting, as appropriate. The review team analyzed the Branch'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 Branch requires full implementation of the Increased Controls prior to issuance of a new license or license amendment that meets the established criteria.

The review team examined the Branch's development and implementation of its procedure for the control of sensitive information. The Branch presented the review team with what was described as a marked up draft version of a procedure entitled, "Radioactive Materials Branch (RMB) Practices for Control and Protection of Sensitive Information," dated July 10, 2007. This draft procedure addresses the identification, marking, control, handling, preparation, transportation, transmission, and destruction of documents that contain sensitive information. While this procedure was identified as a draft document, the review team determined from the casework reviewed, that the Branch was implementing the procedure.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, 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 and allegations, the review team examined the Branch's response to the questionnaire relative to this indicator, evaluated selected incidents reported for North Carolina in NMED against those contained in the Branch's files, and evaluated the casework for ten radioactive materials incidents. A list of the incident casework examined, may be found in Appendix E. The review team also evaluated the Branch's response to two allegations involving radioactive materials, including one allegation referred to the State by the NRC during the review period.

The incidents selected for review included the following categories: lost/stolen radioactive material, potential overexposure, medical event, damaged equipment, and leaking sources. The review team determined 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 on-site investigations in five of the cases reviewed and took suitable enforcement and follow-up actions. If the incident met the reportability thresholds, as established in FSME Procedure SA-300 "Reporting Material Events," the State notified the NRC Headquarters Operations Center and entered the information into NMED, in a prompt manner.

The review team examined the Branch's implementation of its incident and allegation processes, including written procedures for handling allegations and incident response, file documentation, notification of incidents to the NRC Headquarters Operations Center, and the use of NMED software. When notification of an incident or an allegation is received, the Incident Assessment Team Leader along with the Branch Manager determines the appropriate level of initial response.

The review team identified 70 radioactive material incidents in NMED for North Carolina during the review period, of which 53 required reporting. Three non-reportable incidents in NMED for North Carolina were reviewed for reportability and found to be correctly categorized as non-reportable by the Branch. The review team selected 10 radioactive material incidents for evaluation. Initial responses were prompt and well-coordinated, and the level of effort was commensurate with the potential health and safety significance of the event. Inspectors were dispatched for onsite investigations when appropriate. Enforcement and/or other regulatory actions were taken as appropriate. The Branch reported events to the NRC in a prompt

manner. The actions taken in response to incidents were documented and filed, and the data was submitted to the NRC's contractor responsible for maintaining NMED for inclusion in the database.

In evaluating the effectiveness of the Branch's response to allegations, the review team evaluated the completed casework for two allegations, including one that the NRC referred to the State during the review period. The review team concluded that the Branch took prompt and appropriate actions in response to concerns raised. The review team noted that the Branch documented the investigations of concerns and retained all necessary documentation to appropriately close the allegations. The Branch notified the concerned individuals of the conclusion of their investigations. The review team determined that the Branch adequately protected the identity of concerned individuals.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, 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. The NRC's Agreement with North Carolina does not relinquish regulatory authority for uranium recovery. North Carolina does have authority over low-level radioactive waste disposal; however, North Carolina has not been designated as a host State for a disposal facility. Therefore, only the first two non-common performance indicators applied to this review.

4.1 Compatibility Requirements

4.1.1 Legislation

North Carolina became an Agreement State on August 1, 1964. The current effective statutory authority is contained in Chapter 104E of the North Carolina General Statutes. In Section 104E-6, the Department is designated as the State's radiation control agency. The Branch implements the radiation control program.

The review team noted that one piece of legislation affecting the radiation control program, House Bill 74, was passed during the review period. This bill requires a review of all regulations promulgated by the State every 10 years. Regulations that are not reviewed and approved prior to the end of the review period automatically expire. The Branch will be required to review all radiation protection rules in July 2018 and then report to the Rules Review Committee as to whether the rules are necessary or not necessary and what if any public impact the rule has.

4.1.2 Program Elements Required for Compatibility

The North Carolina regulations governing radiation protection requirements are located in The North Carolina Administrative Code, Title 15A, Chapter 11, "Regulations for Protection against Radiation" apply to all ionizing radiation. North Carolina requires a license for possession and use of all radioactive material.

The review team examined the State's administrative rulemaking process and found that the process takes 12 to 18 months from the development stage to the final approval by the Rules Review Commission, after which the rule becomes effective. The public, NRC, other agencies, and potentially impacted licensees and registrants are offered an opportunity to comment during the process. Comments are considered and incorporated, as appropriate, before the regulations are finalized and approved.

As noted above in Section 4.1.1, the State's rules and regulations are now subject to sunset laws. The State has the authority to issue legally binding requirements (e.g., license conditions) in lieu of regulations until compatible regulations become effective.

During the review period, the Branch submitted nine final regulation amendments, nine proposed regulation amendments, and no legally binding license conditions to the NRC for a compatibility review. Current NRC policy requires that Agreement States adopt certain equivalent regulations or legally-binding requirements no later than three years after they become effective. The Branch's nine proposed rules became final in the State in October 2013. However, the Branch overlooked needing to submit those regulations to the NRC for final review. The review team brought this to the Branch's attention and the Branch submitted these regulations to the NRC for review while the team was onsite. Six of the nine amendments were overdue for State adoption at the time of submission. At the time of this review, there were no amendments overdue for adoption.

The Branch is currently drafting proposed regulations to address regulation amendments coming due for adoption. The Branch also plans to implement a license condition by March 2015 to address Title 10 Code of Federal Regulations Part 37. A complete list of upcoming regulation amendments that will need to be addressed can be found on the NRC website at the following address: http://nrc-stp.ornl.gov/rss_regamendents.html.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, 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 the Branch's response to the IMPEP questionnaire, performed a search of the SS&D Registry for

registrations issued by North Carolina, and performed NMED searches of manufacturers and distributors identified on SS&D registrations issued by North Carolina. A review of new and amended SS&D evaluations and supporting documents covering the review period was conducted. The review team noted the staff's use of guidance documents and procedures; interviewed managers and staff; and verified the use of regulations, license conditions, and inspections to enforce commitments made in the applications.

4.2.1. Technical Staffing and Training

SS&D evaluation responsibilities are distributed between two qualified reviewers, with one additional reviewer scheduled to attend the NRC's SS&D Workshop in the near future. Both qualified reviewers have degrees in a physical science and have attended the NRC's SS&D Workshop. Two other individuals who were qualified to perform SS&D registries in the current reporting period are no longer with the Branch.

The Branch also has a contract with a professional engineer to provide assistance in SS&D reviews. He is a professor at North Carolina State University, Department of Nuclear Engineering, College of Engineering. He has an engineering doctoral degree and is a licensed Professional Engineer. The team reviewed his contract with the Branch to verify that the standards listed in NUREG 1556 Volume 3, Revision 1 are satisfied.

The Branch has an adequate training process that consists of attending the NRC SS&D Workshop and shadowing qualified reviewers. At the beginning of the onsite review this training was not included as part of any written documented training plan as described in Section 3.1 above. The Branch developed and provided to the review team a draft written SS&D training plan during the onsite review.

4.2.2 Technical Quality of the Product Evaluation Program

During the review period, the Branch completed four SS&D actions from three manufacturers/distributors. Three of the actions were amendments, and one was a new application. One of the amendments was an administrative change that did not require a technical SS&D evaluation. There was no inactivation of SS&D registrations or emerging technology evaluations processed during the review period. The review team evaluated all four SS&D actions from three files processed during the review period. The casework reviewed included the two current qualified reviewers and one reviewer who is no longer with the Branch. A listing of the SS&D registries evaluated by the review team, with case-specific comments, may be found in Appendix F.

In assessing the Branch's SS&D evaluation activities, the review team examined information contained in the questionnaire response and interviewed program staff and managers. The review team confirmed that the Branch follows the recommended guidance from the NRC SS&D Workshop, NUREG-1556, Volume 3, applicable and pertinent American National Standards Institute (ANSI) standards and Military Standards, ISO-9001, and North Carolina's regulations, statutes, policies and procedures. The review team verified that these documents were available and were used appropriately in performing SS&D reviews.

As a means to legally enforce the commitments made for the SS&D actions the Branch's policy is to incorporate these commitments into the radioactive materials license authorizing distribution by listing the SS&D registry number in the issued license document. It is the policy of the Branch to issue the license amendment prior to or concurrently with the issuance of the registration sheet. During the onsite visit, the team found one instance where the Branch omitted listing the active SS&D registry sheets in the radioactive materials distribution license and therefore did not provide a means to legally enforce these commitments. Subsequent to the onsite visit, an amendment was issued to correct this license.

In addition, the team found that multiple correspondences listed in the issued SS&D registry sheets during the review period, and the Branch's requests for additional information were missing. The missing documents included the registry amendment submittal, Branch's request for additional information and registrants' replies. Even through the SS&D registry numbers were listed in the issued license document, the registry commitments made would not be legally enforceable without the Branch possessing these commitment documents. During the onsite visit, the Branch obtained three of the missing documents from the licensee for one of the issued SS&D registrations and was in the process of obtaining missing documents for the other registries. In addition, for this one, SS&D registration, the Branch performed the evaluation based on sound conservative assumptions and deficiency correspondence clearly stated regulatory positions to ensure public health and safety is adequately protected. Good health physics practices were implemented throughout this review. Interviewing the principal and concurrent reviewer in what they considered during the review of the other two registries, the team determined that the registry commitments were received, reviewed and deficiency requests timely made based on their knowledge of the registry details. The review team believes the evaluations were based on sound conservative assumption to ensure public health and safety is adequately protected. During the onsite review, the Branch was in the process of obtaining the missing documents.

The Branch accepts licensee commitments via paper and electronic media such as e-mail. They also are in the process of going "paperless" and are scanning paper documents into a document imaging system. This process may contain elements that contributed to the lack of availability of documents listed above.

The review team noted that some of the SS&D registries did not clearly identify information for a regulatory agency to license the product. The review team found that one registration did not properly identify the source activity, number of sources or which sources are to be used in a new model added to the registry sheet. Another registry indicated that the licensing authority is required to obtain certain information prior to authorizing the use, but the SS&D documents did not provide an answer. Two registries did not follow the format and content recommended in NUREG-1556, Volume 3 regarding use code descriptions, and another contained typographical errors. These formatting issues did not adversely impact the technical quality or content of the reviews; however, because the registrations are used nationally, the documents should be consistent with national standards. The review team recommended, and the MRB agreed, that the State identify, develop, and implement processes to ensure official sealed source and device registry documents are complete, legible, accounted for, and are readily accessible to those who are determined to have a need for the information.

4.2.3 Evaluation of Defects and Incidents Regarding SS&Ds

Based upon the Branch's response to the questionnaire, interview of Branch personnel, and the review team's searches of NMED, the team did not find any events reported that involved equipment or source failures listed under the Branch's SS&D registries. The Branch also did not receive any NRC notification about potential generic SS&D issues discovered during NRC's trend analysis of NMED events. The Branch's ability to respond to incidents as described in Section 3.5 is adequate to respond to SS&D product defect issues.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that North Carolina's performance with respect to the indicator, Sealed Source and Device Evaluation Program, be found satisfactory, but needs improvement.

4.3 Low-Level Radioactive Waste (LLRW) Disposal Program

In 1981, the NRC amended its Policy Statement, "Criteria for Guidance of States and NRC in Discontinuance of NRC Regulatory 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. 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, 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 review this indicator.

5.0 SUMMARY

As noted in Sections 3.0 and 4.0 above, the review team recommended that North Carolina's performance be found satisfactory but needs improvement for the indicators Technical Staffing and Training, Status of the Materials Inspection Program, and Sealed Source and Device Evaluation Program, and satisfactory for the remaining indicators reviewed. The MRB disagreed with the team's finding of satisfactory, but needs improvement for the indicator Status of the Materials Inspection Program and directed that the Program be found "satisfactory" for this indicator, as it appeared that the State had a process in place which ensured that public health and safety was not compromised. The review team recommended that North Carolina enter into a period of Monitoring. The MRB disagreed with this recommendation as the team did not identify any performance issues which impacted public health, safety and security.

The review team found that the two recommendations from the 2009 IMPEP review regarding strengthening the incident and response process to ensure timely reporting of events, and making regulatory changes to resolve NRC generated comments to regulation review letters were addressed by the State and can be closed. The review team made three recommendations regarding the performance of the North Carolina Agreement State Program.

Accordingly the review team recommended, and the MRB agreed, that the North Carolina Agreement State Program is adequate to protect public health and safety, but needs improvement, and is compatible with the NRC's program. The review team recommended, and

the MRB agreed, that the next IMPEP review take place in approximately four years and that a periodic meeting be held in one year.

Below are the review team's recommendations, as mentioned in the report, for evaluation and implementation by the State:

RECOMMENDATIONS

1. The review team recommends that the State update its training qualification program to be consistent with IMC 1248, "Formal Qualification Program for Federal and State Material and Environmental Management Programs" and the State apply this program to all technical staff currently going through the qualification process and all new staff that are hired. (Section 3.1)

2. The review team recommends that the State implement procedures and a new tracking system to ensure that less than 10 percent of Priority 1, 2, and 3 and initial inspections are completed overdue. (Section 3.2)

3. The review team recommends that the State identify, develop and implement processes to ensure official sealed source and device registry documents are complete, legible, accounted for, and are readily accessible to those who are determined to have a need to know the information. (Section 4.2.2)

LIST OF APPENDICES

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APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	**Area of Responsibility**
Randy Erickson, Region IV	Team Leader Technical Quality of Inspections Inspector Accompaniments
Monica Ford, Region I	Technical Staffing and Training Status of the Materials Inspection Program Compatibility Requirements
Binesh Tharakan, Region IV	Technical Quality of Incident and Allegation Activities Inspector Accompaniments
Tara Weidner, Region I	Technical Quality of Licensing Actions
Michael Stephens, Florida	Sealed Source and Device Evaluation Program Technical Quality of Incident and Allegation Activities

APPENDIX B

NORTH CAROLINA ORGANIZATION CHARTS

ADAMS ACCESSION NO.: ML14072A091

APPENDIX C

INSPECTION CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

File No.: 1
Licensee: Charlotte-Mecklenburg Hospital Authority — License No.: 060-0014-3
Inspection Type: Special/Announced — Priority: 2
Inspection Date: 9/22/11 — Inspector: GM

File No.: 2
Licensee: WakeMed Health & Hospitals — License No.: 092-0297-6
Inspection Type: Routine/Unannounced — Priority: 2
Inspection Date: 7/25/12 — Inspector: RC

File No.: 3
Licensee: Duke Health Raleigh Hospital — License No.: 092-0582-1
Inspection Type: Routine/Unannounced — Priority: 3
Inspection Date: 1/30/14 — Inspector: CH

File No.: 4
Licensee: Acuren Inspections, Inc. — License No.: 092-1466-1
Inspection Type: Routine/Unannounced — Priority: 1
Inspection Date: 2/14/13 — Inspector: JA

File No.: 5
Licensee: Acuren Inspections, Inc. — License No.: 092-1466-1
Inspection Type: Routine/Unannounced — Priority: 1
Inspection Date: 1/17/12 — Inspector: SJ

File No.: 6
Licensee: Capital Heart Associates, PA — License No.: 092-1127-1
Inspection Type: Routine/Unannounced — Priority: 3
Inspection Date: 12/22/11 — Inspector: RC

File No.: 7
Licensee: Nordion — License No.: 161-0133-R
Inspection Type: Reciprocity/Unannounced — Priority: 0
Inspection Date: 6/30/09 — Inspectors: CH, RC

File No.: 8
Licensee: Pharmalucence — License No.: 121-0098-R
Inspection Type: Reciprocity/Unannounced — Priority: 0
Inspection Date: 12/8/11 — Inspectors: SJ, GM

File No.: 9
Licensee: Applied Technical Services License No.: 140-0292-R
Inspection Type: Reciprocity/Unannounced Priority: 0
Inspection Date: 10/23/13 Inspector: CH

File No.: 10
Licensee: Rex Heart and Vascular Specialists License No.: 092-0160-5
Inspection Type: Initial/Unannounced Priority: 3
Inspection Date: 10/13/10 Inspector: HB

File No.: 11
Licensee: Kernersville Medical Center License No.: 034-0878-8
Inspection Type: Delivery/Unannounced Priority: 3
Inspection Date: 2/21/11 Inspector: CH

File No.: 12
Licensee: Triad Isotopes, Inc. License No.: 092-1512-1
Inspection Type: Routine/Unannounced Priority: 2
Inspection Date: 9/23/11 Inspector: HB

File No.: 13
Licensee: Terracon Consultants, Inc. License No.: 074-1064-1
Inspection Type: Routine/Unannounced Priority: 1
Inspection Date: 2/21/13 Inspector: SN

File No.: 14
Licensee: The Roberts Company License No.: 074-0979-1
Inspection Type: Routine/Unannounced Priority: 1
Inspection Date: 1/4/11 Inspector: RC

File No.: 15
Licensee: NC Radiation Therapy Management Services, Inc. License No.: 044-1276-2
Inspection Type: Routine/Unannounced Priority: 2
Inspection Date: 3/13/09 Inspector: CH

File No.: 16
Licensee: PETNET Solutions, Inc. License No.: 032-1229-1
Inspection Type: Field/Unannounced Priority: 2
Inspection Date: 12/2/09 Inspector: CH

File No.: 17
Licensee: PETNET Solutions License No.: 032-1229-1
Inspection Type: Routine/Unannounced Priority: 2
Inspection Date: 9/27/10 Inspector: SJ

File No.: 16
Licensee: Carolina Radiation Medicine License No.: 074-1276-4
Inspection Type: Routine/Unannounced Priority: 2
Inspection Date: 3/15/12 Inspector: SN

File No.: 17
Licensee: Cancer Centers of North Carolina License No.: 092-1352-1
Inspection Type: Routine/Unannounced Priority: 2
Inspection Date: 6/20/12 Inspector: RC

File No.: 18
Licensee: Cone Health Cancer Center Radiation Oncology License No.: 041-0021-3
Inspection Type: Routine/Unannounced Priority: 2
Inspection Date: 2/17/14 Inspector: CH

File No.: 19
Licensee: S&ME, Inc. License No.: 092-0922-1
Inspection Type: Routine/Unannounced Priority: 1
Inspection Date: 7/25/12 Inspector: SN

File No.: 20
Licensee: Cardinal Health 414 LLC License No.: 025-0794-10
Inspection Type: Routine/Unannounced Priority: 2
Inspection Date: 11/10/09 Inspector: RC

File No.: 21
Licensee: MISTRAS Group, Inc. License No.: 090-1058-1
Inspection Type: Routine/Announced Priority: 1
Inspection Date: 6/12/13 Inspector: SJ

File No.: 23
Licensee: Vidant Medical Center License No.: 074-1457-2
Inspection Type: Special/Announced Priority: 1
Inspection Date: 2/13/13 Inspector: GM

File No.: 24
Licensee: ECS Carolinas, LLP License No.: 041-0253-8
Inspection Type: Special/Announced Priority: 1
Inspection Date: 1/27/14 Inspector: GM

File No.: 25
Licensee: Nucor Corporation License No.: 046-1152-1
Inspection Type: Special/Announced Priority: 1
Inspection Date: 1/30/14 Inspector: GM

File No.: 26
Licensee: University of North Carolina – Chapel Hill License No.: 068-0214-3
Inspection Type: Special/Announced Priority: 2
Inspection Date: 3/14/13 Inspector: GM

File No.: 27
Licensee: University of North Carolina Hospitals License No.: 068-0565-1
Inspection Type: Special/Announced Priority: 2
Inspection Date: 3/15/13 Inspector: GM

File No.: 28
Licensee: Team Industrial Services, Inc. License No.: 060-1536-1
Inspection Type: Pre-Licensing Special/Announced Priority: 1
Inspection Date: 11/21/13 Inspector: GM

INSPECTOR ACCOMPANIMENTS

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

Accompaniment No.: 1
Licensee: ECS Carolinas, LLP License No.: 041-0253-8
Inspection Type: Special/Announced Priority: 1
Inspection Date: 1/27/14 Inspector: GM

Accompaniment No.: 2
Licensee: Wake Radiology Diagnostic Imaging License No.: 092-0668-1
Inspection Type: Routine/Announced Priority: 3
Inspection Date: 1/28/14 Inspector(s): SN

Accompaniment No.: 3
Licensee: Duke Health Raleigh Hospital License No.: 092-0582-1
Inspection Type: Routine/Announced Priority: 3
Inspection Date: 1/30/14 Inspector: CH

Accompaniment No.: 4
Licensee: Acuren Inspections, Inc. License No.: 092-1466-1
Inspection Type: Routine/Announced Priority: 1
Inspection Date: 1/31/14 Inspector: SJ

APPENDIX D

LICENSE CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

File No.: 1
Licensee: Sampson Regional Medical Center — License No.: 082-0407-4
Type of Action: New — Amendment No.: N/A
Date Issued: 3/22/10 — License Reviewer: GS

Comments:
a) Reviewer described communications with licensee regarding technical issues; however, there was no record in the license file.
b) License condition referred to an incorrect reference.

File No.: 2
Licensee: Coastal Carolina Healthcare — License No: 025-1131-2
Type of Action: New — Amendment No.: N/A
Date Issued: 12/18/13 — License Reviewer: CF

File No.: 3
Licensee: Sterigenics — License No.: 001-0701-1
Type of Action: Renewal (Financial assurance) — Amendment No.: 50
Date Issued: 8/9/10 — License Reviewer: GS

File No.: 4
Licensee: AMEC Environmental & Infrastructure, Inc. — License No.: 041-0082-8
Type of Action: Renewal — Amendment No.: 19
Date Issued: 8/6/09 — License Reviewer: RC

Comments:
a) Location of use listed in the application was not added to the license.
b) License condition 12 did not reference the user training program.
c) Reviewer described communications with licensee regarding technical issues; however, there was no record in the license file.

File No.: 5
Licensee: Wake Medical Raleigh Campus — License No.: 092-0297-6
Type of Action: Renewal — Amendment No.: 14
Date Issued: 1/19/13 — License Reviewer: DS

File No.: 6
Licensee: Moses H. Cone Memorial Hospital License No.: 41-0021-1
Type of Action: Renewal Amendment No.: 94
Date Issued: 4/5/10 License Reviewer: RC

Comment: Reviewer described communications with licensee regarding technical issues; however, there was no record in the license file.

File No.: 7
Licensee: Piedmont Endocrinology, PA License No.: 018-1269-1
Type of Action: Renewal Amendment No.: 5
Date Issued: 5/18/09 License Reviewer: WT

File No.: 8
Licensee: Piedmont Endocrinology, PA License No.: 018-1269-1
Type of Action: Renewal Amendment No.: 6
Date Issued: 2/26/14 License Reviewer: CF

File No.: 9
Licensee: Wake Forest Baptist License No.: 034-0158-8
Type of Action: Renewal Amendment No.: 13
Date Issued: 9/18/09 License Reviewer: HB

Comment: Reviewer described communications with licensee regarding technical issues; however, there was no record in the license file.

File No.: 10
Licensee: Regional Physicians Cardiology License No.: 041-0119-3
Type of Action: Termination Amendment No.: 3
Date Issued: 12/2/13 License Reviewer: LB

File No.: 11
Licensee: AMEC Environmental & Infrastructure, Inc. License No.: 041-0082-8
Type of Action: Termination Amendment No.: 25
Date Issued: 7/19/13 License Reviewer: RC

File No.: 12
Licensee: AMEC Environmental & Infrastructure, Inc. License No.: 041-0082-8
Type of Action: Amendment Amendment No.: 24
Date Issued: 1/24/12 License Reviewer: DS

File No.: 13
Licensee: AMEC Environmental & Infrastructure, Inc. License No.: 041-0082-8
Type of Action: Amendment Amendment No.: 23
Date Issued: 8/9/11 License Reviewer: PH

Comment: License condition No. 12 did not reference the user training program.

File No.: 14
Licensee: AMEC Environmental & Infrastructure, Inc. License No.: 041-0082-8
Type of Action: Amendment Amendment No.: 22
Date Issued: 6/9/11 License Reviewer: RC

Comment: License condition No. 12 did not reference the user training program.

File No.: 15
Licensee: AMEC Environmental & Infrastructure, Inc. License No.: 041-0082-8
Type of Action: Amendment Amendment No.: 21
Date Issued: 4/13/10 License Reviewer: RC

Comment: License condition No. 12 did not reference the user training program.

File No.: 16
Licensee: Cape Fear Heart Associates License No.: 010-1114-4
Type of Action: Amendment Amendment No.: 1
Date Issued: 3/5/13 License Reviewer: LB

Comment: Authorized user added to the license without proper documentation of supervised work experience.

File No.: 17
Licensee: Wake Forest Baptist License No.: 034-0158-8
Type of Action: Amendment Amendment No.:16
Date Issued: 2/17/14 License Reviewer: CF

Comments:
a) Reviewer did not address the name change requested by the licensee.
b) Reviewer described communications with licensee regarding technical issues; however, there was no record in the license file.

File No.: 18
Licensee: Rex Healthcare License No.: 092-0160-1
Type of Action: Amendment Amendment No.: 104
Date Issued: 7/31/13 License Reviewer: DS

File No.: 19
Licensee: Duke Health Raleigh Hospital License No.: 092-0582-1
Type of Action: Amendment Amendment No.: 51
Date Issued: 9/11/13 License Reviewer: RK

Comment: Authorized user added to the license without preceptor attestation.

File No.: 20
Licensee: Duke Health Raleigh Hospital License No.: 092-0582-1
Type of Action: Amendment Amendment No.: 50
Date Issued: 6/8/11 License Reviewer: HB

File No.: 21
Licensee: Wake Heart & Vascular Associates License No.: 092-1167-3
Type of Action: Amendment Amendment No.: 16
Date Issued: 8/30/13 License Reviewer: RK

Comment: Reviewer did not address licensee's request to remove an authorized user.

File No.: 22
Licensee: Shertech Pharmaceuticals, LLC License No.: 060-1203-2
Type of Action: Amendment Amendment No.: 15
Date Issued: 8/30/13 License Reviewer: CF

File No.: 23
Licensee: Shertech Pharmaceuticals, LLC License No.: 060-1203-2
Type of Action: Amendment Amendment No.: 14
Date Issued: 10/10/12 License Reviewer: RC

Comment: Reviewer did not verify prospective authorized nuclear pharmacists' recentness of training and experience.

File No.: 24
Licensee: Wilson Medical Center License No.: 098-0035-1
Type of Action: Amendment Amendment No.: 69
Date Issued: 10/8/13 License Reviewer: RC

File No.: 25
Licensee: JANX Integrity Group, Inc. License No.: 085-1117-2
Type of Action: Amendment Amendment No.: 2
Date Issued: 9/25/13 License Reviewer: CF

APPENDIX E

INCIDENT CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

File No.: 1
Licensee: Albemarle Hospital
Date of Incident: 8/23/12
Investigation Date: 8/24/12
License No.: 070-0126-1
NMED No.: N/A
Type of Incident: Lost RAM
Type of Investigation: Site

File No.: 2
Licensee: Wake Forest University Baptist Medical Center
Date of Incident: 6/27/12
Investigation Date: 6/27/12
License No.: 034-0158-1
NMED No.: N/A
Type of Incident: Potential Medical Event
Type of Investigation: Telephone

File No.: 3
Licensee: Carolina Imaging Center of Fayeteville
Date of Incident: 7/19/12
Investigation Date: 8/1/12
License No.: 026-1113-1
NMED No.: N/A
Type of Incident: Potential Medical Event
Type of Investigation: Site

File No.: 4
Licensee: Lake Norman Regional Medical Center
Date of Incident: 11/19/09
Investigation Date: 12/29/09
License No.: 049-0527-3
NMED No.: 100003
Type of Incident: Medical Event
Type of Investigation: Inspection Follow-up

File No.: 5
Licensee: Carolina East Medical Center
Date of Incident: 5/21/12
Investigation Date: 6/11/12
License No.: 025-0421-3
NMED No.: 120341
Type of Incident: Medical Event
Type of Investigation: Site

File No.: 6
Licensee: ECS Carolinas
Date of Incident: 7/31/12
Investigation Date: 7/31/12
License No.: 092-0253-1
NMED No.: 120452
Type of Incident: Damaged Equipment
Type of Investigation: Site

File No.: 7
Licensee: Frye Regional Medical Center
Date of Incident: 7/7/12
Investigation Date: 8/8/12
License No.: 018-0377-2
NMED No.: 120492
Type of Incident: Medical Event
Type of Investigation: Site

File No.: 8
Licensee: Gerdau Charlotte
Date of Incident: 10/25/12
Investigation Date: 10/25/12
License No.: N/A
NMED No.: 120644
Type of Incident: Lost RAM
Type of Investigation: Telephone

File No.: 9
Licensee: Wesley Long Medical Center
Date of Incident: 7/10/13
Investigation Date: 9/5/13
License No.: 041-0021-3
NMED No.: 130402
Type of Incident: Lost RAM
Type of Investigation: Inspection Follow-up

File No.: 10
Licensee: Systems Services Corporation
Date of Incident: 5/15/13
Investigation Date: 8/16/13
License No.: 090-1071-1
NMED No.: 130246
Type of Incident: Transportation/Contamination
Type of Investigation: Site

APPENDIX F

SEALED SOURCE AND DEVICE CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

File No.: 1
Registry No.: NC-0646-D-128-S SS&D Type: (G) Portable Moisture Density Gauges
Applicant Name: Troxler Electronics Laboratories, Inc. Type of Action: Amend in Entirety
Date Issued: 2/23/12 SS&D Reviewers: HB/RC

Comments:

a) The license does not indicate that new models possess the correct number of sources, the maximum activity or prohibit the introduction of unauthorized sources into devices.
b) SS&D commitments not legally binding to the radioactive materials license.
c) Reference documents not in the registry file for review.
d) The principle use code is listed as "(G) Field Measurement of Asphalt Content" instead of "(G) Portable Moisture Density Gauges" as listed in NUREG 1556 Volume 3, Revision 1.

File No.: 2
Registry No.: NC-1311-S-101-S SS&D Type: (AA) Manual Brachytherapy
Applicant Name: CivaTech Oncology, Inc. Type of Action: New
Date Issued: 6/28/13 SS&D Reviewers: SJ/RC

Comments:

a) Limitations section indicates the licensing authority is to obtain information that is not provided by the manufacturer
b) The principal use code is listed "(AA) Manual Brachytherapy (Therapeutic Line Sources)" instead of "(AA) Manual Brachytherapy" as listed in NUREG 1556 Volume 3, Revision 1.
c) Reference documents not in the registry file for review

File No.: 3
Registry No.: NC-0585-D-107-G SS&D Type: (W) Self Luminous Sources
Applicant Name: SRB Technologies, Inc. Type of Action: Amend in Entirety
Dates Issued: 11/12/13 & 1/31/14 SS&D Reviewers: RC/SJ

Comments:

a) Reference documents not in the registry file for review
b) The principle use code listed "(W) Self Luminous Applications" instead of "(W) Self Luminous Sources as listed in NUREG 1556 Volume 3, Revision 1 and formatting error on page 1 for the "CUSTOM DEVICE" listing.

ATTACHMENTS

May 7, 2014 Letter from W. Lee Cox
North Carolina Response to the Draft Report
ADAMS Accession No.: ML14133A275

June 3, 2014 Letter from W. Lee Cox
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