

December 20, 2000

Ms. Robin Smith, Assistant Secretary
North Carolina Department of Environment
and Natural Resources
1601 Mail Service Center
Raleigh, NC 27699-1601

Dear Ms. Smith:

On December 8, 2000, 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 assure public health and safety and compatible with the Nuclear Regulatory Commission's program.

Section 5.0, page 15, of the enclosed final report presents the IMPEP team's recommendations. We received the December 6, 2000 letter from Ms. J. Robin Hadin which described your staff's actions taken in response to the recommendations in the draft report. We request no additional information.

Based on the results of the current IMPEP review, the next full review will be in approximately four years.

I appreciate the courtesy and cooperation extended to the IMPEP team during the review and your support of the Radiation Control Program. I look forward to our agencies continuing to work cooperatively in the future.

Sincerely,

/RA/

Carl J. Paperiello
Deputy Executive Director
for Materials, Research and
State and Tribal Programs

Enclosure:
As stated

cc: Richard M. Fry, Director
Division of Radiation Protection
Department of Environment and Natural Resources

Alice Rogers, TX
Agreement State Liaison to
the Management Review Board

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cc: Richard M. Fry, Director
Division of Radiation Protection
Department of Environment and Natural Resources

bcc: Chairman Meserve
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
Commissioner Merrifield

Alice Rogers, TX
Agreement State Liaison to
the Management Review Board

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STP-AG-21

INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF NORTH CAROLINA AGREEMENT STATE PROGRAM

September 18-22, 2000

FINAL REPORT

U.S. Nuclear Regulatory Commission

1.0 INTRODUCTION

This report presents the results of the review of the North Carolina radiation control program. The review was conducted during the period September 18-22, 2000, by a review team comprised of technical staff members from the Nuclear Regulatory Commission (NRC) and the Agreement State of Mississippi. Team members are identified in Appendix A. The review was conducted in accordance with the "Implementation of the Integrated Materials Performance Evaluation Program and Rescission of a Final General Statement of Policy," published in the Federal Register on October 16, 1997, and the November 5, 1999, NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." Preliminary results of the review, which covered the period December 15, 1995 to September 18, 2000 were discussed with North Carolina management on September 22, 2000.

A draft of this report was issued to North Carolina for factual comment on October 20, 2000. The State responded in letters dated November 21, 2000 and December 6, 2000. The Management Review Board (MRB) met on December 8, 2000, to consider the proposed final report. The MRB found the North Carolina radiation control program was adequate to protect public health and safety and compatible with NRC's program.

The North Carolina Agreement State Program is administered by North Carolina's Department of Environment and Natural Resources (the Department) and is located within the Division of Radiation Protection (the Division). The Division Director manages four sections: the Radioactive Materials Section (the Section), two electronic products sections, and a nuclear facilities and environmental radiation surveillance section. The Section is under the supervision of a Section Chief. An organization chart for the Department of Environment and Natural Resources is included as Appendix B. At the time of the review, the North Carolina program regulated 656 specific licenses authorizing agreement materials. The review focused on the materials program as it is carried out under the Section 274b. (of the Atomic Energy Act of 1954, as amended) Agreement between the NRC and the State of North Carolina.

In preparation for the review, a questionnaire addressing the common and non-common performance indicators was sent to the Division on July 3, 2000. The Division provided a response to the questionnaire on August 31, 2000. During the review, discussions with Division staff resulted in the responses being further developed. A copy of the questionnaire responses is included as Appendix G to proposed final report.

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

Section 2 below discusses the Division's actions in response to recommendations made following the previous IMPEP review. Results of the current review for the IMPEP common performance indicators are presented in Section 3. Section 4 discusses results of the applicable non-common performance indicators, and Section 5 summarizes the review team's findings and recommendations. Recommendations made by the review team are comments that relate directly to program performance by the Division. A response is requested from the Division to all recommendations in the final report.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous IMPEP review, which concluded on December 15, 1995, ten recommendations were made and transmitted to Mr. Jonathan B. Howes, Secretary, North Carolina Department of Environment, Health, and Natural Resources, on January 30, 1996. The team's review of the current status of these recommendations is as follows:

1. The review team recommends that the State fill existing vacancy as soon as possible.

Current Status: The vacant position was filled on March 3, 1996. This recommendation is closed.
2. The review team recommends that the State consider peer and supervisory review of licensing products to include review of all background information and correspondence.

Current Status: The review team verified that peer and supervisory reviews of licensing actions are being performed. In addition, a checklist was developed for the supervisory and peer review for all licensing documents. This recommendation is closed.
3. The review team recommends: (a) that all inspection reports include a summary of the exit meeting discussion, as addressed by internal guidance, including the licensee's comments regarding items of noncompliance; and (b) that inspectors make every effort to hold exit meetings at the highest possible management level.

Current Status: The review team verified that all inspection reports reviewed included exit summaries, and that exits are noted to be conducted with the highest management level possible. This recommendation is closed.
4. The review team recommends that the State consider adopting a policy of annual supervisory accompaniments of all materials inspectors.

Current Status: The Division reported in the response to the questionnaire that annual inspection accompaniments were performed during calendar years 1997 and 1998. However, because of an illness of the past section chief, no inspector accompaniments were conducted in 1999. To date, two inspector accompaniments have been conducted in 2000. This recommendation is closed.
5. The review team recommends that the State evaluate the process for promulgating compatibility regulations to better ensure that the State meets the 3-year time frame.

Current Status: The Division has re-evaluated their internal process for promulgating regulations. The review team found that the regulations needed for compatibility are being adopted within the 3-year time frame. This recommendation is closed.

6. The review team recommends that the State consider developing written guidance for preserving the integrity of proprietary information furnished by the manufacturer when issuing SS&D registry sheets.

Current Status: The State issued a Policy and Procedure Statement, No. N005, entitled "Control of Proprietary Information," dated May 26, 1998. The procedure addressed adequately the administrative and record keeping issues in handling and storing proprietary information. The review team noted that the procedure is implemented and followed. The procedure is in compliance with the applicable laws of the State of North Carolina. A review team member discussed with staff possible improvements in handling proprietary information. This recommendation is closed.

7. With respect to the sealed source and device evaluation program, the review team recommends that (a) the State clarify the Troxler source ratings and evaluate Troxler's QA plan to ensure that it includes health physics evaluation; and (b) that the necessary attachments to the American Duesenberg certificate be distributed.

Current Status:

- (a) The State clarified Troxler's source classification by requesting an itemized listing from Troxler and evaluating the licensee's response. Similarly, the State reviewed the QA program utilizing a checklist and found it acceptable.
 - (b) The State reviewed the case and issued an inactive certificate (NR-801-D-101-S). The content of the case file is limited to the two certificates. The staff indicated that they have conducted an extensive search to locate the certificate holder as well as any units which still could be in use. The staff informed the review team that they were not able to locate either the certificate holder or any of the devices. The results of the staff's search were conveyed to the team orally, because the results were not documented in the file. This recommendation is closed.
8. The review team recommends that the State consider keeping records of LLRW staff members' technical training and participation in workshops, conferences, etc., in the individual's training files and also maintain a collective staff training record to help formalize such training as an ongoing requirement for the position and to better allow management to assess the training level of the staff.

Current Status: On April 7, 2000, the North Carolina Radiation Protection Commission's report to the North Carolina General Assembly concluded that the State does not need a central facility for storage or disposal of low-level radioactive waste (LLRW) as long as North Carolina waste generators have continued access to existing out-of-state disposal and treatment facilities. Since this recommendation was made, no further LLRW activities have been conducted by the State. This recommendation is closed.

9. The review team recommends that consideration be given to changing the LLRW section filing procedures to ensure that surveillance reports become part of the licensing database subject to internal QA inspections.

Current Status: Refer to Current Status of Recommendation 8. This recommendation is closed.

10. The review team recommends consideration of an internal audit on the SAR review database during input to the new database to assure that all LLRW section review leaders are entering data properly.

Current Status: Refer to Current Status of Recommendation 8. This recommendation is closed.

3.0 COMMON PERFORMANCE INDICATORS

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

3.1 Status of Materials Inspection Program

The team focused on four factors in reviewing this indicator: inspection frequency, overdue inspections, initial inspections of new licenses, and timely dispatch of inspection findings to licensees. The review team's evaluation is based on the North Carolina questionnaire responses relative to this indicator, data gathered independently from the Division's licensing and inspection data tracking system, the examination of complete licensing and inspection casework, and interviews with managers and staff.

A review of the Division's inspection priorities revealed that the inspection frequencies for the various types of licenses are the same or more frequent than similar license types listed in NRC Inspection Manual Chapter (IMC) 2800, with one exception. The exception is that nuclear pharmacies were identified as a Priority 2 instead of a Priority 1. The assignment of Priority 2 for Nuclear Medicine inspections was due to IMC 2800's unclear description of the category. The review team recommends that NRC review the descriptions in IMC 2800 for the category of nuclear pharmacies to ensure that the assignment of priorities is clear.

In their response to the questionnaire, the Section Chief reported that the Section completed 15 inspections overdue by more than 25% of the NRC frequency. However, during the review it was determined that this number did not account for 8 nuclear pharmacy inspections that were overdue because of the Priority 2 category assignment. The review team found that in general, the core licenses are inspected at regular intervals in accordance with frequencies prescribed in NRC IMC 2800, even with the identification of the additional 8 overdue inspections. The review team recommends that the Division change the inspection frequency of nuclear pharmacies from a Priority 2 to a Priority 1 in accordance with NRC's IMC 2800 and conduct inspections at the appropriate frequency.

Although the Division did not have a formal procedure in place at the time of the review, the Division may extend the inspection frequency based on the compliance history of the licensee.

With respect to initial inspections of new licensees, the team evaluated a list of licensing actions and determined that there were 210 new licenses issued during the review period. All of the initial inspections from a random sampling of 10 new licenses were performed within 6 months. After issuance, new licenses are hand delivered to licensees. The inspector uses the opportunity to discuss the requirements of the license and the regulations with the licensee. If adequate training, facilities or equipment is not available, the inspector may choose not to present the license. The Division feels that this initial face-to-face meeting with the licensees is a very valuable tool in future compliance with license conditions. The visit allows the Division to make sure that the safety program is in place and permits open discussion of the licensee's compliance requirements.

The timeliness of the issuance of inspection findings was evaluated during the inspection casework review. All of the inspection findings were transmitted to the licensees within the Division's goal of 30 work days following the inspection.

To evaluate the Division's reciprocity inspection program, the review team obtained a computer printout of data for the years of 1998 through 2000. With regard to core licensees (Priorities 1, 2, and 3), the Section received 19 requests for reciprocity in 1998; 19 requests for reciprocity in 1999; and 18 requests for reciprocity at the time of the review in 2000. The Section performed six reciprocity inspections in 1998, five in 1999, and three in 2000. The Division has developed a new computer tracking system to allow them to maintain a reciprocity database for conducting inspections. The review team recommends that the Division meet the reciprocity inspection frequency goals specified in NRC's IMC 1220.

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

3.2 Technical Quality of Inspections

The team evaluated the inspection reports, enforcement documentation, and inspection field notes and interviewed inspectors for 18 radioactive materials inspections conducted during the review period. The casework included all 7 of the Section's materials license inspectors, and covered inspections of various types including radiography, medical broad, academic broad, HDR, gamma stereotactic, irradiator, well logging, nuclear pharmacy, and medical. Appendix C lists the inspection casework files reviewed for completeness and adequacy with case-specific comments.

Based on casework, the review team noted that the routine inspections covered all aspects of the licensee's radiation program. The inspection reports were thorough, complete, consistent, and of high quality, with sufficient documentation to ensure that licensee's performance with respect to health and safety were acceptable. The documentation supported violations, recommendations made to the licensee, and unresolved safety issues. Exit interviews were held with appropriate licensee personnel and discussions were well documented in the reports. Several of the casework files indicated that team inspections were performed. Team inspections are used in their mentoring training program.

The inspection procedures utilized by the Section are consistent with the inspection guidance outlined in NRC's IMC 2800. Inspection reports are in a format that adequately covers all inspection areas for each inspection type. The Section Chief was in the process of updating some of the inspection field forms during the review.

North Carolina has an adequate number and types of survey meters to support the current inspection program. Survey meters are calibrated at least annually by a consultant. Appropriate, calibrated survey instruments such as GM meters, scintillation detectors, ion chambers, micro-R meters, and neutron meters were observed. They also have portable multi-channel analyzers that can be used in the field at inspection sites. Contamination wipes are sent to the North Carolina State Laboratory for analysis.

During the review period, inspector accompaniments were performed by the Section Chief on each of the staff at least annually, except in 1999. No inspector accompaniments were performed in 1999 due to an illness of the Section Chief. At the time of the review, the new Section Chief had performed two inspector accompaniments in 2000, and planned to perform the other accompaniments in the near future.

Four inspectors were accompanied during inspections by a review team member in August 2000 and during the week of the IMPEP review. The accompaniments included a permanent radiographic facility, a temporary job site radiography license, and two nuclear cardiologist private practice licenses. These accompaniments are also identified in Appendix C.

During the accompaniments, each inspector demonstrated appropriate inspection techniques and knowledge of the regulations. They prepared themselves for the inspection by reviewing the license folder prior to the inspection. The inspectors appeared well trained and thorough in the inspection of the licensee's radiation safety programs. Inspections were unannounced and performance based. Each inspector conducted effective interviews with appropriate licensee personnel. Inspectors either observed or required the licensee to demonstrate performance of licensed activities. Overall, each inspector utilized good health physics practices and their inspections were adequate to assess radiological health and safety 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.

3.3 Technical Staffing and Training

Issues central to the evaluation of this indicator include the Division'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 State's questionnaire responses relative to this indicator, interviewed Division management and staff, and considered any possible workload backlogs.

The Section Chief for the Section supervises two administrative and seven technical staff members. The technical staff members are classified as health physicists. The Section is fully staffed and there have been five turnovers since the last IMPEP review. Vacancies were filled in an expedient manner.

All of the technical staff members are trained to perform license reviews and inspections. The team determined that the Division has a well balanced staff, and a sufficient number of trained personnel to carry out the regulatory duties of the Section. Two health physicists are assigned to the review and inspection of Sealed Source & Device (SS&D) licenses which is discussed further in Section 4.2.

During the review of the training records, the team noted that only one member of the technical staff had completed the teletherapy and brachytherapy core course or the irradiator specialized course. Although the review team found no performance issues in the licensing or inspection of these licensees, the team believes that all technical staff performing brachytherapy licensing or inspections would benefit from the teletherapy and brachytherapy course or equivalent training. In addition, because North Carolina has three irradiators, the review team believes that the technical staff would also benefit from the irradiator training course or its equivalent. The Division Director expressed a strong commitment to training. The review team recommends that staff who conduct independent inspections and/or license reviews of teletherapy and brachytherapy licenses and irradiator licenses complete the teletherapy/brachytherapy course and irradiator course, or their equivalent.

In addition, the review team found that the Division has not developed a written training program. The need for a written training program for the SS&D reviewers was also identified (Section 4.2.2). The review team recommends that a formalized, written training program based upon the requirements specified in IMC 1246 or "NRC/OAS Training Working Group Recommendations for Agreement State Training Programs," be developed for license reviewers and inspectors.

All radiation health physicists are required to have bachelor's degrees or equivalent training in the physical and/or life sciences. New hires are allowed to work with the more senior staff and under the guidance of the Section Chief until appropriate training and experience is received, and until the individual obtains the confidence to perform the assigned tasks independently. A mentoring program has been established and mentoring journals for the technical staff have been developed. The Section Chief and senior health physicists review the licensing work performed by the junior personnel and accompany them during inspections to assure regulatory consistency and quality of work performed. The team confirmed the qualifications of the staff hired since the 1995 IMPEP review and verified their performance through licensing and compliance casework and inspection accompaniments.

The North Carolina Radiation Protection Commission, part of the Department of Environment and Natural Resources, is empowered by State statute to promulgate rules and regulations to be followed in the administration of a radiation protection program. Currently the Radiation Protection Commission has 11 governor-appointed public voting members and 10 non-voting ex officio members. The Division Director is one of the ex officio members. The review team examined the State's conflict of interest policy that is applicable to the Radiation Protection Commission. It was noted that the Governor has appointed an ethics committee to review potential or the appearance of conflicts of interest. At the start of every Radioactive Protection Commission meeting, the Chairman or his designee reads an Ethics Awareness and Conflict of Interest Reminder. Members are required to recuse themselves from matters posing a potential conflict of interest.

Based on the team's finding and 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.

3.4 Technical Quality of Licensing Actions

The review team examined completed licensing casework and interviewed the staff for 21 specific licenses. Licensing actions were evaluated for completeness, consistency, proper isotopes and quantities used, qualifications of authorized users, adequate facilities and equipment, and operating and emergency procedures sufficient to establish the basis for licensing actions. Licenses were evaluated for overall technical quality including accuracy, appropriateness of the license, its conditions, and tie-down conditions. Casework was evaluated for timeliness; adherence to good health physics practices; reference to appropriate regulations; documentation of safety evaluation reports, product certifications or other supporting documents; consideration of enforcement history on renewals; pre-licensing visits, peer or supervisory review as indicated; and proper signature authority. The files were checked for retention of necessary documents and supporting data.

The licensing casework was selected to provide a representative sample of licensing actions that were completed during the review period. The sampling included the following types: industrial radiography, medical (institution and private practice), nuclear pharmacy, academic and industrial broad scope, service, pool irradiator, manufacturing and distribution, and well logging. Types of licensing actions selected for evaluation included two new licenses, ten amendments to existing licenses, seven license renewals, and two license terminations. In discussions with the Division Manager, it was noted that there were no major decommissioning efforts underway with regard to agreement material in North Carolina. Also, there were no identified sites with potential decommissioning difficulties equivalent to those sites in NRC's Site Decommissioning Management Plan. A list of the licenses evaluated with case-specific comments can be found in Appendix D.

The casework evaluation indicated that the staff follows appropriate licensing guides during the review process to ensure that licensees submit information necessary to support their request. The review team found the checklists used for each type of program to be comprehensive and incorporated excellent notes to assist the staff with their review of the applications. Deficiencies were addressed by letters and documented telephone conversations containing appropriate regulatory language. The use of license templates by the staff also resulted in notable consistency between reviewers. Overall, the review team found that the licensing actions were thorough, complete, consistent, of high quality and properly addressed health and safety issues.

Several licensing actions examined by the team required the licensee to submit financial assurance. The originals of the financial assurance documents are maintained in a secure cabinet. Generic paragraphs were included in letters issued to specific classes of licensees requesting them to review their needs for financial assurance.

The team found that terminated licensing actions were well documented, including the appropriate material transfer records and survey records. An evaluation of the licensing actions over the review period revealed that most terminations were for licensees possessing sealed sources. These files showed that documentation of proper disposal or transfer was provided.

Licenses are renewed on a five-year frequency. Licenses that are under timely renewal are amended as necessary to assure that public health and safety issues are addressed during the period that the license is undergoing the renewal process. Deficiencies are addressed by letters and documented telephone conferences which used appropriate regulatory language. Each licensing action is reviewed by a second individual and then reviewed by management prior to issuance. All licenses are signed by the Section Chief.

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 Response to Incidents and Allegations

In evaluating the effectiveness of the Division's actions in responding to incidents, the review team examined the Division'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 North Carolina files, and evaluated the casework and supporting documentation for 13 material incidents. A list of the incident casework examined with case-specific comments is included in Appendix E. The team also reviewed the State's response to 12 allegations involving radioactive materials including six allegations referred to the State by the NRC during the review period.

The review team discussed the Division's incident and allegation procedure, file documentation, the State's equivalent to the Freedom of Information Act, NMED, and notification of incidents to the NRC Operations Center with the Materials Section Chief, the Radiological Emergency Response Coordinator, and selected staff.

The Section and the Division's Emergency Response Coordinator have responsibility for initial response and follow-up to incidents and allegations involving radioactive materials. Written procedures require that two qualified health physicists evaluate each incoming incident report and present it to the supervisor for direction. All complex incidents or those with potential for impacting public safety are evaluated by the Section Chief, the Director, and the Radiation Protection Manager in order to determine the appropriate response. Review of casework indicates that this approach provides effective response actions and does not delay the response time.

Written procedures exist for handling incidents, some of which are considered allegations under NRC terminology. These procedures and accompanying summary forms are available to all staff on the Program's Local Area Network system and as hard copy in the file room. Incident calls or reports are handled by the individual receiving the notification, or are assigned to another staff member by the Section Chief. The Section Chief is informed of the initial call and any subsequent follow up or resolution of the case.

The Section had 164 materials incidents during the review period of which 79 incidents were reportable under the NRC criteria. The staff commented that the other incidents involved waste materials such as medical waste going into land fills. Thirteen incidents were selected for review. The incidents included: contaminated material, damaged devices, misadministrations, and stolen gauges. The review team found that the Division's response to incidents was generally complete and comprehensive. Initial responses were prompt and well-coordinated,

and the level of effort was commensurate with the health and safety significance. Inspectors were dispatched for on-site investigations when appropriate and the Division took suitable enforcement action including coordination with the license reviewers, other agencies and follow up, as appropriate.

Generally, the team found that significant incidents were appropriately reported to the NRC Operations Center in a timely manner, however, the team noted considerable inconsistency in providing NMED reports to the NMED contractor prior to this year. The Section Chief related that the inconsistency was the result of software compatibility problems when entering NMED data. The incident data is now being provided to NMED as requested by the Office of State and Tribal Programs (STP) procedures. The Division's incident procedure does not reference the Office of State and Tribal Programs Procedure SA-300, *Handbook on Nuclear Event Reporting in the Agreement States*, however, a copy of the SA-300 Handbook was available in the Section's procedure manual. The team noted during the incident casework review that four of the NMED reports needed to be updated and closed out, one NMED incident report could not be located in the Section files, and three incident reports needed additional information to be submitted to the NMED database. The review team also noted that the procedure for handling misadministrations does not require misadministrations be evaluated against the abnormal occurrence criteria as specified in the SA-300 Handbook. The team discussed these issues with the Section Chief and the staff member responsible for NMED data entry. The review team recommends that the NMED data be updated to reflect the status and close out of cases as appropriate, and that incident data be provided to the NRC in accordance with STP Procedure SA-300.

During the review period, six allegations were referred to the Division by the NRC. The casework for these allegations was reviewed as well as the casework for six additional allegations reported directly to the Division. The review of the casework and the Division's files indicated that the Section took prompt and appropriate action in response to the concerns raised. All but two of the allegations reviewed were appropriately closed with written letters to the allegor. The team noted that allegations were treated and documented internally in the same manner as incidents. With the exception of the two cases where the allegor was not notified of the actions taken and results of the Division's investigations, there were no performance issues identified. The team also noted that North Carolina law requires that all public documents be made available for inspection and copying unless specifically exempted from disclosure under the State's Open Records Act. The Division makes every effort to protect an allegor's identity.

The Division's procedures for handling allegations are incorporated into the incident response procedures. A separate allegation procedure has not been developed. The team found that all allegations are filed with the incidents with the exception of one that was filed in a separate locked file cabinet. The team and the Section Chief discussed the merits of filing all allegations in a separate locked cabinet for security and protection of the allegor's identity, as well as updating the procedures to include appropriate references to allegations, their tracking, documentation, and handling of files to help assure performance under this indicator.

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

4.0 NON-COMMON PERFORMANCE INDICATORS

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

4.1 Legislation and Program Elements Required for Compatibility

4.1.1 Legislation

Along with their response to the questionnaire, the Division provided the review team with the opportunity to review copies of legislation that affects the radiation control program. Legislative authority to create an agency and enter into an agreement with the NRC 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 no legislation affecting the radiation control program was passed since being found adequate during the previous review, and found that the State legislation is adequate.

4.1.2 Program Elements Required for Compatibility

The North Carolina Regulations for Control of Radiation, found in the North Carolina Administrative Code, Title 15A, Chapter 11, Radiation Protection, apply to all ionizing radiation, whether emitted from radionuclides or devices. North Carolina requires a license for possession, and use, of all radioactive material including naturally occurring materials, such as radium, and accelerator-produced radionuclides.

The review team examined the procedures used in the Division's regulatory process and found that the public and other interested parties are offered an opportunity to comment on proposed rules during a 30-day comment period and during a public meeting. The NRC is provided with drafts for comment on the proposed rules early in the promulgation process. The Division requests and obtains departmental approval to develop new rules and publishes an intent to pursue rulemaking. The Radiation Protection Commission has the Radioactive Materials Control Committee (the Committee) draft the rules for discussion with the regulated community and concerned citizens, reviews the work of the Committee, and authorizes an official notice of proposed rule. A public hearing is held on the proposed rule, the rule is revised as needed and is then sent to the Radiation Protection Commission for adoption. The State has a Rules Review Commission that reviews and approves new rules and the General Assembly is provided a time period in which to veto the rule. Typically, rule promulgation requires 4 to 14 months and the Department's Rules and Regulations are not the subject of "sunset" laws.

The team evaluated the Division's responses to the questionnaire, reviewed the status of regulations required to be adopted by the State under the NRC's Adequacy and Compatibility Policy, and verified the adoption of regulations with data obtained from the Office of State and Tribal Programs Regulation Assessment Tracking System.

The team identified the following regulation changes and adoptions that will be needed in the future. The Division Director related that these regulations would be addressed in an upcoming rulemaking scheduled for fiscal year 2001. The State's fiscal year 2001 is from July 2000 through June 2001.

- "Minor Corrections, Clarifying Changes, and a Minor Policy Change," 10 CFR Parts 20, 35, and 36 amendments (63 FR 39347 and 63 FR 45393) that became effective October 26, 1998.
- "Deliberate Misconduct by Unlicensed Persons," 10 CFR Parts 30, 40, 61, 70, and 150 amendments (63 FR 1890 and 13773) that became effective February 12, 1998.
- "License for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations; Clarifying Amendments and Corrections," 10 CFR Part 34 amendment (63 FR 37059) that became effective July 9, 1998.
- "Termination of Transfer of Licensed Activities: Recordkeeping Requirements," 10 CFR Parts 20, 30, 40, 61, and 70 amendments (61 FR 24669) that became effective June 17, 1999.
- "Respiratory Protection and Controls to Restrict Internal Exposures," 10 CFR Part 20 amendment (64 FR 54543 and 64 FR 55524) that became effective February 2, 2000.
- "Energy Compensation Sources for Well Logging and Other Regulatory Clarifications," 10 CFR Part 39 amendment (65 FR20337) that became effective May 17, 2000.

During the review, the Division Director related that four of the above regulations have been drafted and will be combined as a package of regulations to be adopted in fiscal year 2001.

Based on the IMPEP evaluation criteria, the review team recommends that North Carolina's performance with respect to the indicator, Legislation and Program Elements Required for Compatibility, be found satisfactory.

4.2 Sealed Source and Device (SS&D) Evaluation

In assessing the Division's SS&D evaluation, the review team examined information provided by the State in response to the IMPEP questionnaire on this indicator. A review of selected amended and inactivated SS&D evaluations and supporting documents covering the review period was conducted. The team observed the staff's use of guidance documents and procedures, interviewed the staff and Division Director involved in SS&D evaluations, and verified the use of regulations and license conditions to enforce commitments made in the applications.

4.2.1 Technical Quality of the Product Evaluation Program

The Division did not process any new registrations, but completed approximately four amendments and issued 20 or more inactivation certificates since the last review. The review team selected nine cases from the registry that had been amended or inactivated in their entirety. The review included all amendments, supporting documentation, licenses, and inspections associated with each of the registrations selected. The certificates reviewed covered the period since the last Division review in December 1995 and represented cases completed by the principal reviewers. The SS&D certificates issued by the Division and evaluated by the review team are listed with case-specific comments in Appendix F.

Analysis of the casework and interviews with staff confirmed that the Division follows the recommended guidance from the NRC SS&D training workshops and NUREG-1556, Volume 3, issued in September 1997. All pertinent American National Standards Institute standards, Regulatory Guides, and applicable references were confirmed to be available and were used when performing SS&D reviews. Appropriate review checklists were used to assure that all relevant materials are submitted and reviewed. The checklists are contained in the registration files. The review team noted that the quality of the checklists showed a continual improvement during the period; specifically, staff notes indicated a steadily increasing comprehensiveness of safety evaluations. However, the checklists were not dated and signed; therefore, records were not traceable.

The registration files contained all correspondence, photographs, engineering drawings, radiation profiles, and results of tests conducted by the applicant. The files were well organized in a consistent manner. The files were divided into subdivisions with the following subjects: current certificate, application, transmittals, manuals, superceded (certificates), and confidential/proprietary information. Deficiency letters clearly stated regulatory positions and health and safety issues were properly addressed. The team determined that product evaluations were thorough, complete, consistent, of acceptable technical quality, and adequately addressed the integrity of the products during use and in the event of likely accidents.

Registrations clearly summarized the product evaluation and provide license reviewers with adequate information to license the possession and use of the product. However, the team noted that, in the registration certificates, the references in most cases did not list the specific documents which had been reviewed during the safety evaluation. Specifically, the references did not list the documents with title, author, or date. Instead of defining each document, general terms were used to combine the content of the file into generic groups such as "all information" and "all engineering drawings" submitted by the applicant and currently in the SS&D review file.

The review team recommends that all registration certificates reference the specific documents which were reviewed during the safety evaluation.

The Division reported in the questionnaire that 18 SS&D actions were completed since the previous review. However, the review team identified six more cases (NC-8043-D801-S, NC-646-D-803-S, NC-646-D-804-S, NC-646-D-805-S, NC-646-D-809-S, NC-646-D-811-S) which had not been listed in the response to the questionnaire. Based on the sequential numbering of the deactivation cases, there may be others which had not been listed. Staff members estimated that the backlog may be about five cases. The review team found that cases, licensee requests for action, assignment dates to staff, and cases completed, were not being logged or tracked. For example, the team found that a certificate holder had requested deactivation for some models in a February 2000 letter, but that no SS&D reviewer had been assigned to the action. The SS&D reviewers completed the cases on the basis of their memory for a need for an action. Based on these observations, the team noted that the incomplete listing of SS&D cases may be attributable to the fact that the Division does not use a tracking system to follow the status of SS&D cases. The review team recommends that the Division develop a tracking system to follow the status of SS&D actions.

In 1994, the NRC conducted a review of the North Carolina radiation control program relating to the State's program for performing SS&D product evaluations. Following the review, the State initiated an effort to re-evaluate and update the previously issued SS&D registry sheets. The progress of the re-evaluation process was found satisfactory (Item 2.2, IMPEP Final Report, December 11-15, 1995). At the time of the review in 1995, not all casework had been completed. During this review, the team noted that the registry sheet of Humboldt Scientific, Inc. (NC-365-D-101-S) has not yet been updated. The Division initiated an update in 1996, by requesting additional information from the vendor. The information was reviewed and the reviewer identified deficiencies which were to be resolved, but no further action has been taken. As discussed in the MRB meeting and in the December 6, 2000 letter to Mr. Lohaus from North Carolina, the Division is presently addressing the update of the registry sheet with the renewal of the Humboldt Scientific, Inc license in its entirety, which includes a submission of a new quality assurance manual.

4.2.2 Technical Staffing and Training

Following the Division's previous IMPEP review, two reviewers were assigned to review all SS&D registrations as part of their duties. The two reviewers alternate for primary and concurrence reviews. The reviewers are health physicists by college education and have attended additional training courses such as NRC's SS&D Workshop to supplement their education. Additional engineering expertise is also readily available to the staff on an as needed basis. The State has retained under contract the assistance of a professor of nuclear engineering from North Carolina State University. The outside consultant has provided engineering analysis for the resolution of an equipment failure issue. The team reviewed the results of the analysis and found it adequate. The consultant has not yet been needed for SS&D safety evaluations. The team determined that the reviewers meet the technical training required for SS&D reviews as described under the guidance. However, the team noted that the Division has not developed formalized written training requirements for SS&D reviewers.

4.2.3 Evaluation of Defects and Incidents Regarding SS&Ds

No incidents or defects related to SS&D issues were reported concerning the devices (products) registered by the State of North Carolina, during the review period. The team also verified that there were no reported incidents through discussions with the SS&D reviewers and a review of the incidents as discussed under Section 3.5.

An on-line search by manufacturer utilizing the NMED system was conducted by the team, and no incidents were identified that were related to any malfunctioning devices or products considered during this review. Division staff demonstrated their abilities to conduct computer searches for NMED data concerning specified SS&D devices and manufacturers.

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

4.3 Low-Level Radioactive Waste (LLRW) Disposal Program

In 1981, the NRC amended its Policy Statement, "Criteria for Guidance of States and NRC in Discontinuance of NRC Authority and Assumption Thereof by States Through Agreement" to allow a State to seek an amendment for the regulation of LLRW as a separate category. Those States with existing Agreements prior to 1981 were determined to have continued LLRW disposal authority without the need of an amendment. On April 7, 2000, the North Carolina Radiation Protection Commission's report to the North Carolina General Assembly concluded that the State does not need a central facility for storage or disposal of LLRW as long as North Carolina waste generators have continued access to existing out-of-state disposal and treatment facilities. Since this recommendation, no further LLRW activities have been conducted by the State. Accordingly, the review team did not review this indicator.

5.0 SUMMARY

As noted in Sections 3 and 4 above, the review team found North Carolina's performance to be satisfactory for all seven performance indicators. Accordingly, the review team recommended and the MRB concurred in finding the North Carolina Agreement State Program to be adequate and compatible with NRC's program. Based on the results of the current IMPEP review, the next full review will be in approximately 4 years.

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

RECOMMENDATIONS FOR THE STATE:

1. The review team recommends that the Division change the inspection frequency of nuclear pharmacies from a Priority 2 to a Priority 1 in accordance with NRC's IMC 2800 and conduct inspections at the appropriate frequency. (Section 3.1)
2. The review team recommends that the Division meet the reciprocity inspection frequency goals specified in NRC's IMC 1220. (Section 3.1)
3. The review team recommends that staff who conduct independent inspections and/or license reviews of teletherapy and brachytherapy licenses and irradiator licenses

complete the teletherapy/brachytherapy course and irradiator course, or their equivalent. (Section 3.3)

4. The review team recommends that a formalized, written training program based upon the requirements specified in IMC 1246 or "NRC/OAS Training Working Group Recommendations for Agreement State Training Programs," be developed for license reviewers and inspectors. (Section 3.3)
5. The review team recommends that the NMED data be updated to reflect the status and close out of cases as appropriate, and that incident data be provided to the NRC in accordance with STP Procedure SA-300. (Section 3.5)
6. The review team recommends that all registration certificates reference the specific documents which were reviewed during the safety evaluation. (Section 4.2)
7. The review team recommends that the Division develop a tracking system to follow the status of SS&D actions. (Section 4.2)

RECOMMENDATION FOR NRC:

1. The review team recommends that NRC review the descriptions in IMC 2800 for the category of nuclear pharmacies to ensure that the assignment of priorities is clear. (Section 3.1)

LIST OF APPENDICES AND ATTACHMENTS

Appendix A	IMPEP Review Team Members
Appendix B	North Carolina Organization Charts
Appendix C	Inspection Casework Reviews
Appendix D	License Casework Reviews
Appendix E	Incident Casework Reviews
Appendix F	Sealed Source & Device Casework Reviews
Attachment	November 21, 2000 and December 6, 2000 Letters from J. Robin Haden, North Carolina Responses to the Draft IMPEP Report

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	Area of Responsibility
M. Linda McLean, Region IV	Team Leader Technical Staffing and Training
Richard Woodruff, Region II	Response to Incidents and Allegations Legislation and Program Elements Required for Compatibility
Deborah Piskura, Region III	Technical Quality of Licensing Actions
John Jankovich, NMSS	Sealed Source and Device Evaluation Program
B. J. Smith, Mississippi	Technical Quality of Inspections Status of Materials Inspection Program

APPENDIX B

NORTH CAROLINA

DEPARTMENT OF ENVIRONMENT AND NATURAL RESOURCES

ORGANIZATION CHART
(ML003766080)

APPENDIX C

INSPECTION CASEWORK REVIEWS

NOTE: ALL CASEWORK LISTED WITHOUT COMMENT ARE INCLUDED FOR COMPLETENESS ONLY; NO SIGNIFICANT COMMENTS WERE IDENTIFIED BY THE IMPEP TEAM.

File No.: 1
Licensee: Cape Fear Valley Medical Center License No.: 0173-2
Location: Fayetteville, NC License Type: Medical Institution QMP Required
Inspection Type: Routine, Announced Priority: 2
Inspection date: 7/26/99 Inspector: GA

File No.: 2
Licensee : Janx License No.: 1117-1
Location: King, NC License Type: Industrial Radiography
Inspection Type: Field, Unannounced Priority: 1
Inspection date: 7/18/00 Inspector: WC

File No.: 3
Licensee: Cleveland Reg. Medical Center License No.: 0219-3
Location: Shelby, NC License Type: Medical Institution QMP Required
Inspection Type: Initial, Unannounced Priority: 2
Inspection date: 4/4/00 Inspector: GA

File No.: 4
Licensee: East Carolina University License No.: 0296-1
Location: Greenville, NC License Type: Academic Broad A
Inspection Type: Routine, Unannounced Priority: 1
Inspection date: 5/25-28/99 Inspector: GS

File No.: 5
Licensee: Mid Carolina Cardiology License No.: 0872-1
Location: Mathews, NC License Type: Medical Private/No QMP
Inspection Type: Routine, Unannounced Priority: 3
Inspection date: 4/6/99 Inspector: GS

Comment:

a) No exit meeting documented with RSO and/or management.

File No.: 6
Licensee: Law Engineering License No.: 0082-8
Location: Greensboro, NC License Type: Industrial Radiography
Inspection Type: Field, Unannounced Priority: 1
Inspection date: 8/25/00 Inspector: GM

File No.: 7

Licensee: N. Carolina Nuclear Pharmacy
Location: Greensboro, NC
Inspection Type: Routine, Announced
Inspection date: 1/27/97

License No.: 0780-1
License Type: Nuclear Pharmacy
Priority: 2
Inspector: JE

Comments:

- a) IMC 2800 frequency is Priority 1, but North Carolina is Priority 2.
- b) No inspection done since 1/27/97 at the time of review.

File No.: 8

Licensee: Syncor
Location: Charlotte, NC
Inspection Type: Routine, Unannounced
Inspection date: 9/1/99

License No.: 0794-1
License Type: Nuclear Pharmacy
Priority: 2
Inspector: GM

Comments:

- a) IMC 2800 frequency is Priority 1, but North Carolina is Priority 2.
- b) Previous inspection performed 8/6/97.

File No.: 9

Licensee: Regional Cancer Center
Location: Asheville, NC
Inspection Type: Routine, Unannounced
Inspection date: 2/24/00

License No.: 0984-1
License Type: HDR
Priority: 1
Inspector: JA

File No.: 10

Licensee: N. Carolina Baptist Hospital
Location: Winston-Salem, NC
Inspection Type: Routine, Unannounced
Inspection date: 9/27/99

License No.: 0158-8
License Type: Stereotactic Radiosurgery
Priority: 1
Inspector: SJ/JA

File No.: 11

Licensee: Abbott Labs
Location: Rocky Mount, NC
Inspection Type: Routine, Unannounced
Inspection date: 3/23/99

License No.: 0969-1
License Type: Irradiator
Priority: 1
Inspector: JE/GA

File No.: 12

Licensee: Troxler Electronic Labs
Location: Research Park, NC
Inspection Type: Routine, Unannounced
Inspection date: 4/25/00

License No.: 0182-1
License Type: Manuf. & Distrib., Other
Priority: 3
Inspector: WC/SJ/GM

File No.: 13

Licensee: Geophex, Ltd.
Location: Raleigh, NC
Inspection Type: Initial, Unannounced
Inspection date: 1/29/99

License No.: 1118-1
License Type: Well-Logging
Priority: 2
Inspector: WC

File No.: 14

Licensee: Duke University
Location: Durham, NC
Inspection Type: Routine, Announced
Inspection date: 8/9-13/99

License No.: 0247-1
License Type: Academic Broad A
Priority: 1
Inspectors: SJ/GS/JA/WC/JE

Comment:

a) No supervisory review documented.

File No.: 15

Licensee: Jacksonville Hospital
Location: Jacksonville, NC
Inspection Type: Routine, Unannounced
Inspection date: 8/28/00

License No.: 0025-1
License Type: Med Institution/QMP
Priority: 2
Inspector: SJ

File No.: 16

Licensee: Coastal Nuc. Pharmacy
Location: New Bern, NC
Inspection Type: Routine, Unannounced
Inspection date: 2/19/99

License No.: 1001-1
License Type: Nuclear Pharmacy
Priority: 2
Inspectors: JA/GA

Comments:

a) IMC 2800 frequency is Priority 1, but North Carolina is Priority 2.
b) Previous inspection performed 1/16/97.

File No.: 17

Licensee: Gamma RX
Location: Arden, NC
Inspection Type: Routine, Unannounced
Inspection date: 9/23/99

License No.: 0780-3
License Type: Nuclear Pharmacy
Priority: 2
Inspector: GA

Comments:

a) IMC 2800 frequency is Priority 1, but North Carolina is Priority 2.
b) Previous inspection performed 12/4/97.

File No.: 18

Licensee: JANX
Location: King, NC
Inspection Type: Initial, Unannounced
Inspection date: 5/20/99

License No.: 1117-1
License Type: Industrial Radiography
Priority: 1
Inspector: GA

INSPECTOR ACCOMPANIMENTS

In addition, the following inspection accompaniments were performed as part of the on-site IMPEP review.

Accompaniment No.: 1

Licensee: Wake Radiology Imaging

Location: Cary, NC

Inspection Type: Routine, Unannounced

Inspection date: 8/23/00

License No.: 0668-3

License Type: Med Private/No QMP

Priority: 3

Inspector: GS

Accompaniment No.: 2

Licensee: S & ME

Location: Raleigh, NC

Inspection Type: Routine, Unannounced

Inspection date: 8/23/00

License No.: 0922-1

License Type: Industrial Radiography

Priority: 1

Inspector: JA

Accompaniment No.: 3

Licensee: E. Vogt Valve Co.

Location: Raleigh, NC

Inspection Type: Routine, Unannounced

Inspection date: 8/24/00

License No.: 0121-1

License Type: Industrial Radiography

Priority: 1

Inspector: GA

Accompaniment No.: 4

Licensee: Wake Heart Associates

Location: Raleigh, NC

Inspection Type: Initial, Unannounced

Inspection date: 9/20/00

License No.: 1167-1

License Type: Med. Private/No QMP

Priority: 3

Inspector: JE

APPENDIX D
LICENSE CASEWORK REVIEWS

NOTE: ALL CASEWORK LISTED WITHOUT COMMENT ARE INCLUDED FOR COMPLETENESS ONLY; NO SIGNIFICANT COMMENTS WERE IDENTIFIED BY THE IMPEP TEAM.

File No.: 1

Licensee: Abbott Labs
Location: Rocky Mount, NC
Amendment No.: 5
Date Issued: 3/2/99

License No.: 064-0969-1
License Type: Pool Irradiator
Type of Action: Renewal
License Reviewer: JE

Comment:

a) No deficiency letter or telephone conversation record in the file.

File No.: 2

Licensee: Albemarle Hospital
Location: Elizabeth City, NC
Amendment No.: 49
Date Issued: 1/12/98

License No.: 070-0126-1
License Type: Medical Institution
Type of Action: Amendment
License Reviewer: BH

File No.: 3

Licensee: Alexander Community Hospital
Location: Taylorsville, NC
Amendment No.: 16
Date Issued: 8/15/00

License No.: 002-0618-1
License Type: Medical Institution
Type of Action: Amendment
License Reviewer: GS

File No.: 4

Licensee: Calib-Ray, Ltd.
Location: Durham, NC
Amendment No.: 13
Date Issued: 6/17/99

License No.: 032-0620-1
License Type: Instrument Calibration Service
Type of Action: Amendment
License Reviewer: GA

File No.: 5

Licensee: Cardiac Imaging Limited Partnership-NCI
Location: Fayetteville, NC
Amendment No.: 16
Date Issued: 8/21/00

License No.: 026-1122-1
License Type: Mobile Nuclear Medicine
Type of Action: Amendment
License Reviewer: JE

File No.: 6

Licensee: James C. Barbot d/b/a Carolina Nuclear Instruments, Inc.
Location: Raleigh, NC
Amendment No.: 5
Date Issued: 11/19/99

License No.: 092-0631-1
License Type: Manufacturer/Service
Type of Action: Termination
License Reviewer: JA

File No.: 7

Licensee: Digirad Imaging Systems
Location: Burlington, NC
Amendment No.: 17
Date Issued: 10/9/96

License No.: 001-1014-1
License Type: Mobile Nuclear Medicine
Type of Action: Amendment
License Reviewer: GM

File No.: 8

Licensee: Duke University
Location: Durham, NC
Academic Amendment No.: 64
Date Issued: 6/16/98

License No.: 032-0247-1
License Type: Type A Broad Scope
Type of Action: Renewal
License Reviewer: WC

File No.: 9

Licensee: Gamma RX
Location: Arden, NC
Amendment No.: 16
Date Issued: 4/9/96

License No.: 011-0780-3
License Type: Nuclear Pharmacy
Type of Action: Renewal
License Reviewer: GM

Comment:

- a) Program type mis-classified as manufacturing and distribution (specific licensees) rather than nuclear pharmacy. This also changed the inspection priority code.

File No.: 10

Licensee: Geophex, Ltd.
Location: Raleigh, NC
Amendment No.: 2
Date Issued: 3/23/99

License No.: 092-1118-1
License Type: Well Logging
Type of Action: Amendment
License Reviewer: WC

File No.: 11

Licensee: Glaxo Wellcome, Inc.
Location: Research Triangle Park, NC
Amendment No.: 7
Date Issued: 5/13/99

License No.: 032-1029-1
License Type: Type A Broad Scope R&D
Type of Action: Amendment
License Reviewer: JE

File No.: 12

Licensee: High Point Regional
Location: High Point, NC
Amendment No.: 12
Date Issued: 1/20/00

License No.: 041-0119-2
License Type: Medical Institution (brachytherapy)
Type of Action: Amendment
License Reviewer: GA

File No.: 13

Licensee: Law Engineering and Environmental Services, Inc.
Location: Charlotte, NC
Amendment No.: 29
Date Issued: 5/6/99

License No.: 060-0082-1
License Type: Industrial Radiography
Type of Action: Renewal
License Reviewer: GS

File No.: 14

Licensee: Lenoir Memorial Hospital
Location: Kinston, NC
Amendment No.: 27
Date Issued: 6/12/2000

License No.: 054-0488-2
License Type: Medical Institution
Type of Action: Renewal
License Reviewer: GA

File No.: 15

Licensee: New Hanover Radiation Oncology
Location: Wilmington, NC
Amendment No.: 5
Date Issued: 11/12/99

License No.: 065-0860-1
License Type: Medical Institution (HDR)
Type of Action: Renewal
License Reviewer: GM

File No.: 16

Licensee: The North Carolina Baptist Hospital, Inc.
Location: Winston-Salem, NC
Amendment No.: n/a
Date Issued: 7/6/99

License No.: 034-0158-8
License Type: Medical Institution (gamma knife)
Type of Action: New
License Reviewers: GM

File No.: 17

Licensee: North East Medical Center
Location: Huntersville, NC
Amendment No.: 4
Date Issued: 4/13/99

License No.: 060-0028-5
License Type: Medical Private Practice
Type of Action: Termination
License Reviewer: WC

File No.: 18

Licensee: S.K. McBryde, Inc.
Location: Greensboro, NC
Amendment No.: 16
Date Issued: 3/9/99

License No.: 041-0766-1
License Type: Industrial Radiography
Type of Action: Amendment
License Reviewer: GM

File No.: 19

Licensee: Titan Atlantic Group, Inc.
Location: Raleigh, NC
Amendment No.: 2
Date Issued: 7/28/99

License No.: 092-1064-1
License Type: Industrial Radiography
Type of Action: Amendment
License Reviewer: WC

File No.: 20

Licensee: Troxler Electronic Laboratories, Inc.
Location: Research Triangle Park, NC
Amendment No.: 76
Date Issued: 12/23/99

License No.: 032-0182-1
License Type: Manufacturing and Distribution
Type of Action: Renewal
License Reviewer: JE

File No.: 21

Licensee: Wake Forest University School of Medicine
and North Carolina Baptist Hospital

License No.: 034-0158-1

Location: Winston-Salem, NC

License Type: Type A Broad Scope Medical

Amendment No.: 92

Type of Action: Amendment

Date Issued: 4/13/00

License Reviewer: SJ

APPENDIX E

INCIDENT CASEWORK REVIEWS

NOTE: ALL CASEWORK LISTED WITHOUT COMMENT ARE INCLUDED FOR COMPLETENESS ONLY; NO SIGNIFICANT COMMENTS WERE IDENTIFIED BY THE IMPEP TEAM.

File No.: 1

Licensee: Barnhill Construction

Site of Incident: Hwy 64, Martin County

Date of Incident: 06/14/99

Investigation Date: 06/14/99

License No.: NC-092-0958-1

Incident Log No.: 99-13

Type of Incident: Damaged Portable Gauge

Type of Investigation Type: Telephone

Summary of Incident and Final Disposition: Licensee notified the State that a Troxler gauge had been damaged when a truck ran over the device at a work site (NMED event number 990384). Licensee secured the device and returned device to the manufacturer for evaluation. Source assembly was not damaged, source did not leak, no excessive exposures occurred, and the device ownership was transferred back to manufacturer for a replacement device.

File No.: 2

Licensee: Bladen County Hospital

Site of Incident: Highway 24 near Clinton, NC

Date of Incident: 06/27/97

Investigation Date: 06/30/97

License No.: NC-009-0614-1

Incident Log No.: 97-20

Type of Incident: Transportation

Type of Investigation Type: On-site

Summary of Incident and Final Disposition: A courier was transporting a shipment of two spent Tc-99 generators for return to the manufacturer (NMED event number 980322). Two boxes fell from the transport vehicle and a motorist stopped the courier. The courier recovered one box but the other box was picked up by another motorist who turned the package in to the local police. The Division responded to the event, surveyed the generator, conducted contamination smears, and traced the generator to the licensee. The licensee returned the used generator to the manufacturer. No loss of material or excessive exposure to personnel occurred.

File No.: 3

Licensee: Central Carolina Hospital

Site of Incident: Sanford, NC

Date of Incident: 09/11/96

Investigation Date: 11/12/96

License No. : NC-0386-2

Incident Log No.: 96-6

Type of Incident: Diagnostic Misadministration

Type of Investigation Type: On-site

Summary of Incident and Final Disposition: The licensee reported that a patient injected with technetium-99m was imaged for a bone scan, but the material was isolated in the kidney (NMED event number 960578). The Division conducted an investigation and reviewed documentation from the radiopharmacy. The licensee believes that the patient received the wrong material but the pharmacy maintained that the proper material was delivered. Information in the file suggests that other drugs in the patient's body could have caused an altered biodistribution of the material to the patient's kidney.

Comment:

- a) The NMED event report has not been updated with the results of the Division's investigation.

File No.: 4

Licensee: Craven Regional Medical Center

Site of Incident: New Bern, NC

Date of Incident: 06/11/97

Investigation Date: 07/22/97

License No.: NC-205-0421-3

Incident Log No.: 97-19

Type of Incident: Contaminated Rock

Type of Investigation Type: On-site

Summary of Incident and Final Disposition: The licensee notified the Division that a technologist had contaminated a rock with technetium-99m, then told students that the rock was a meteorite and asked them to survey it (NMED event number 970618). An investigation by the licensee established the event was a joke. The Division reviewed the licensee's report, conducted an on-site investigation including interviews and corrective actions taken by the licensee, and took enforcement actions. Exposures were determined to be minimal.

File No.: 5

Licensee: Mobile Nuclear Medicine Service

Site of Incident: North Wildesboro, NC

Date of Incident: 1/3/97

Investigation Date: 1/7/97

License No.: NC-035-0985-1

Incident Log No.: 97-02

Type of Incident: Lost Sources

Type of Investigation Type: On-site

Summary of Incident and Final Disposition: The licensee notified the Division that five calibration sources had been removed from their mobile van (NMED event number 970028). One source was a 250 microcuries cesium-137 source and the other sources were non-AEA material. The Division conducted an investigation over a period of several months as the licensee was going out of business and no longer had operations in the State. The check sources were never located and believed to have been disposed through normal trash when the vehicle was cleaned.

Comment:

a) The NMED report was not updated with the results of the Division's investigations.

File No.: 6

Licensee: Quality NDE, Inc.

Site of Incident: Roaring River, NC

Date of Incident: 1/18/99

Investigation Date: None

License No.: NC-085-1117-1

Incident Log No.: 00-33

Type of Incident: Broken Drive Cable

Type of Investigation Type: By Correspondence

Summary of Incident and Final Disposition: The licensee reported the event (NMED event number 000588) to the Division on 2/9/99 by letter, which described the event, actions taken, and licensee corrective actions. The event file was misplaced and not discovered until August of 2000. Three radiographers were involved with the source recovery and no person received more than 8 millirem. The licensee determined that the failure was caused by cyclic fatigue and a revised equipment inspection program was implemented.

File No.: 7

Licensee: Carolinas Medical Center

Site of Incident: Charlotte, NC

Date of Incident: 9/9/99

Investigation Date: 9/20/99

License No.: NC-060-0014-3

Incident Log No.: 99-08

Type of Incident: Therapy Misadministration

Type of Investigation Type: Correspondence

Summary of Incident and Final Disposition: The licensee reported a therapy misadministration to the lung of a patient in which 600 rads were given to the wrong treatment area of the lung (NMED event number 000700). The treatment was intended to start at 10 centimeters and move incrementally at three centimeter steps. The dose was delivered starting at 100 millimeters instead of the prescribed 10 centimeters distance. The device was a GammaMed 12-I High-Dose-Rate after loader. The patient was notified of the error and the physician reported that there would be no significant effects. The Division will follow up on the licensee's corrective actions (procedural changes) at the next scheduled inspection.

Comments:

- a) The NMED report was not updated with additional data, such as: prescribed dose, dose delivered to the intended site and the unintended site, organ site receiving the unintended dose, manufacturer and model number of the HDR unit, and the activity of the source.
- b) The initial evaluation of the event did not include all information needed for the report and there was no documentation that the abnormal occurrence criteria had been considered.
- c) An onsite evaluation soon after receiving the licensee's report would have clarified the circumstances and details of the event, as well as the licensee's corrective actions.

File No.: 8

Licensee: Duke University Medical Center

Site of Incident: Durham, NC

Date of Incident: 10/7/98

Investigation Date: 3/15/96

License No.: NC-032-0347-4

Incident Log No.: 99-003

Type of Incident: Therapy Misadministration

Type of Investigation Type: On-site

Summary of Incident and Final Disposition: A patient received 90 to 130 rads to the right cheek due to the use of the incorrect size of catheter with a brachytherapy high dose rate applicator (NMED event number 960171). The HDR was an Omnitron unit with 4.6 curies of iridium-192. Cause of the event was determined to be human error in entering the catheter length into the computer. The Division conducted an on-site evaluation and evaluated the corrective actions taken by the licensee.

File No.: 9

Licensee: Roadway Express
Site of Incident: Durham, NC
Date of Incident: 7/8/96
Investigation Date: 7/10/96

License No.:N/A
Incident Log No.: 497
Type of Incident: Potential Spill
Type of Investigation Type: Correspondence

Summary of Incident and Final Disposition: Roadway Express reported an event involving a drum of Low Specific Activity (LSA) material that was damaged (punctured) by a fork lift at their facility (NMED event number 960330). There was no release of radioactive materials as determined by a consultant's survey and evaluation.

File No.: 10

Licensee: Sterigenics International Corporation
Site of Incident: Charlotte, NC
Date of Incident: 5/13/99
Investigation Date: 5/14/99

License No.:NC-960-0974-1
Incident Log No.:99-02
Type of Incident: Stuck Source Rack
Type of Investigation Type: Correspondence

Summary of Incident and Final Disposition: The licensee reported that the irradiator (containing two megacuries of cobalt-60) experienced an electrical failure and a source rack failed to return to the safe position (NMED event number 990316). The source rack was manually lowered to the safe shielded position and the licensee conducted extensive tests but could not duplicate the event. Licensee and manufacturer concluded that the cause of the event was due to general power loss combined with a discharge of the back up power (UPS) system on the control console. License was amended to provide for monthly checks of the UPS functionality and safety interlocks, and the inspection reports verify that these checks are being performed.

Comment:

- a) The NMED report noted that INEEL had requested additional information on the event, and the Division staff was unable to confirm what information was needed.

File No.: 11

Licensee: Rex Healthcare
Site of Incident: Raleigh, NC
Date of Incident: 10/7/98
Investigation Date: 2/18/99

License No.: NC-092-0160-001
Incident Log No.: 99-003
Type of Incident: Misadministration
Type of Investigation Type: Correspondence

Summary of Incident and Final Disposition: A patient's prostate was underdosed with iodine-125 seeds due to the physical conditions of the patient and the quality of the diagnostic patient evaluation using an ultrasound procedure prior to the radiation treatment (NMED event number 990033). Only 20% of the intended organ received the prescribed dose. The patient was reevaluated and supplemental dose with beam radiation was prescribed. No short or long term effects to the patient are anticipated. The misadministration and corrective actions were followed up during the next inspection on 3/26/99.

Comment:

- a) The licensee report did not include information such as number of seeds, seed supplier, and activity.

File No.: 12

Licensee: Rex Healthcare

Site of Incident: Raleigh, NC

Date of Incident: 10/9/98

Investigation Date: 3/26/99

License No.: NC-092-0160-1

Incident Log No.: 99-007

Type of Incident: Misadministration

Type of Investigation Type: On-site

Summary of Incident and Final Disposition: A brachytherapy misadministration occurred when a patient was overdosed by about 33% (NMED event number 990334). The event resulted from human error during the interpretation of a prior written directive instead of an amended directive. The patient's pre-treatment dose was calculated at 16,000 rad rather than the correct 12,000 rad. The Division followed up on the event and the licensee's corrective actions during the next inspection on 3/26/99.

Comments:

- a) The report did not include additional information on the number, supplier and activity of the seeds, and the dose to the organ.
- b) The misadministration report evaluation did not contain any documentation concerning the evaluation of the circumstances against abnormal occurrence criteria.

File No.: 13

Licensee: S. K. McBride

Site of Incident: Summerfield, NC

Date of Incident: 5/19/97

Investigation Date: Unknown

License No.: NC-041-0766-1

Incident Log No.: Unknown

Type of Incident: Drive Cable Broken

Type of Investigation Type: Unknown

Summary of Incident and Final Disposition: The NMED event report (NMED 970849) summary discusses an event involving a broken drive cable to a SPEC radiographic camera. The Division conducted a routine inspection of the license on 7/7/97 in which the incident was noted in the inspection report. However, the Division could not locate the incident report or evaluation during the review.

Comment:

- a) A copy of the report was not obtained for the Division's records.

APPENDIX F

SEALED SOURCE AND DEVICE REVIEWS

NOTE: ALL CASEWORK LISTED WITHOUT COMMENT ARE INCLUDED FOR COMPLETENESS ONLY; NO SIGNIFICANT COMMENTS WERE IDENTIFIED BY THE IMPEP TEAM.

File No.: 1

Registry No.: NC-646-D-131-S

Manufacturer: Troxler Electronic Laboratories, Inc.

Date Issued: 11/19/96

SS&D Type: Thin Layer Density Gauge

Model No.: 4640, 4640-B

File No.: 2

Registry No.: NC-646-D-810-S

Manufacturer: Troxler Electronic Laboratories, Inc.

Date Issued: 7/23/98

SS&D Type: Portable Surface Moisture/Density Gauge

Model No.: 2401

File No.: 3

Registry No.: NC-646-D-811-S

Manufacturer: Troxler Electronic Laboratories, Inc.

Date Issued: 7/23/98

SS&D Type: Portable Surface Moisture/Density Gauge

Model No.: 2402

File No.: 4

Registry No.: NC-646-D-137-S

Manufacturer: Troxler Electronic Laboratories, Inc.

Date Issued: 4/3/95, amended 4/3/96

SS&D Type: Laboratory Moisture Content Gauge

Model No.: 4232

Comment:

- a) In a letter dated January 31, 1996, Troxler requested a correction of page 5 of the registry sheet dated October 19, 1995. The records did not indicate how the request was resolved.

File No.: 5

Registry No.: NC-646-D-138-S

SS&D Type: Road Reader Plus Moisture/Density Gauge

Manufacturer: Troxler Electronic Laboratories, Inc.

Model No.: 3450

Date Issued: 3/14/00

Comments:

- a) Troxler's letter dated February 25, 2000 provided response to the State's deficiency questions and, in addition, requested inactivation of the Model 3401/3401B and 3411/3411B devices. The records did not indicate how the request was resolved.
- b) The amendment issued on March 14, 2000 did not indicate the changes in bold with respect to the previous registration sheet, dated November 7, 1996.
- c) The references in the registration certificate did not list the manufacturer's letters dated February 13, 1996, and April 11, 1996, which contained significant design changes and modifications. Similarly, the references did not list the information which the manufacturer provided in letters dated June 20, 1996, July 10, 1996, October 16, 1996, and October 30, 1996.
- d) The registration sheet dated January 15, 1999 and mailed out with cover letter dated January 15, 1999 was not signed by the reviewers.
- e) Regarding the quality assurance program, the registration sheet stated that "a copy of the program is on file with the Division..." but the records did not make a traceable reference indicating that the program was located in the materials license file (No. 032-0182).

File No.: 6

Registry No.: Radioactive Materials License No. 032-0182

SS&D Type: QA Program

Manufacturer: Troxler Electronic Laboratories, Inc.

Model No.: Applicable to all models

Date Issued: 5/23/00

Comments:

- a) The checklist was not signed and dated.
- b) The review and acceptance of the quality assurance program was not recorded for the SS&D system.

File No.: 7

Registry No.: NC-8043-D-801-S

SS&D Type: Manufacturing Density Gauge

Manufacturer: American Duesenberg Bosson, Inc.

Model No.: AME3B

Date Issued: 7/13/95

Comments:

- a) The file did not contain records regarding the inactivation review of Registration Certificate No. NC-127-101-G.
- b) The classification of the device had been changed from generally distributed (G) to specific (S). Records regarding the reclassification were not in the file. The staff recalled that the change in classification was made as a safety precaution in order to assure that if any transfer of the device takes place in the future, the device should only be used by a specifically licensed entity due to the unavailability of the vendor. However, Reviewer's Note No. 2 (p. 5), stating that "this device must be specifically licensed in all future licensing actions," did not convey the intention clearly.
- c) There is a typographical error in the certificate listing the prototype impact test force as 300 grams instead of 200 grams in the original document.

File No.: 8

Registry No.: NC-646-D802-S

SS&D Type: Portable Surface Moisture Gauge

Manufacturer: Troxler Electronic Laboratories, Inc.

Model No.: 1401

Date Issued: 7/23/98

File No.: 9

Registry No.: NC-646-D-803-S

SS&D Type: Portable Surface Moisture Gauge

Manufacturer: Troxler Electronic Laboratories, Inc.

Model No.: 1402

Date Issued: 7/23/98.

File No.: 10

Registry No.: NC-646-D-820-S

SS&D Type: Surface Moisture Content Gauge

Manufacturer: Troxler Electronic Laboratories, Inc.

Model No.: 3205 and 3215

Date Issued: 7/15/99

File No.: 11

Registry No.: NC-356-D-101-S

SS&D Type: Nuclear Moisture/Density Gauge

Manufacturer: Humboldt Scientific, Inc.

Model No.: 5001

Date Issued: February 1986, Revised: November 1988

Comment:

- a) The State has not updated the registration sheet in accordance with previous reviews conducted in 1994 and 1995. The State requested additional information from the manufacturer in 1996, reviewed the information and identified deficiencies by completing an SS&D checklist. The checklist was not dated and signed. No further action has been conducted.

ATTACHMENT

NOVEMBER 21, 2000 LETTER FROM J. ROBIN HADEN
NORTH CAROLINA RESPONSE TO THE DRAFT IMPEP REPORT
(ML003772534)

DECEMBER 6, 2000 LETTER FROM J. ROBIN HADEN
NORTH CAROLINA RESPONSE TO THE DRAFT IMPEP REPORT
(ML003777156)