

DATED: MARCH 26, 1996

SIGNED BY: RICHARD L. BANGART FOR
HUGH L. THOMPSON, JR.T

Mr. Jonathan B. Howes, Secretary
Department of Environment, Health,
and Natural Resources
3825 Barrett Drive
Post Office Box 27687
Raleigh, NC 27611-7687

Dear Mr. Howes:

On March 20, 1996, 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 considered and concurred with the review team's recommendation that the North Carolina program be found adequate to protect public health and safety and compatible with NRC's regulatory program. Based on State performance, the next IMPEP review will be scheduled in four years, unless program concerns develop that require an earlier evaluation.

NRC recognizes the efforts of North Carolina and the other Agreement States to maintain an adequate and compatible program. During the MRB meeting, the impact of high staff turnover on the North Carolina's Agreement Program was discussed. North Carolina's efforts to improve the program while at the same time devoting significant effort in hiring and training new staff by experienced staff is commendable. Your consideration of methods to minimize staff turnover could result in further strengthening of the program. For example, other Agreement States have examined salary structures in their assessment of staff turnover.

Section 5 (page 22) of the enclosed final report presents the IMPEP team's recommendations. We request your evaluation and response to those recommendations within 30 days from receipt of this letter.

I appreciate the courtesy and cooperation extended to the IMPEP team during the review.

Sincerely, */RA BY RICHARD L. BANGART FOR/*

Hugh L. Thompson, Jr.
Deputy Executive Director for
Nuclear Materials Safety, Safeguards,
and Operations Support

Enclosure:
As stated

cc: Linda Bray Rimer, Department of
Environment, Health, and
Natural Resources (DEHNR)
Dayne Brown, DEHNR
Billy Cameron, State Liaison Officer

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF NORTH CAROLINA AGREEMENT STATE PROGRAM

December 11-15, 1995

FINAL REPORT

Office of State Programs

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 December 11-15, 1995, by a review team comprised of technical staff members from the Nuclear Regulatory Commission (NRC) and the Agreement State of Utah. Team members are identified in Appendix A. The review was conducted in accordance with the "Interim Implementation of the Integrated Materials Performance Evaluation Program Pending Final Commission Approval of the Statement of Principles and Policy for the Agreement State Program and the Policy Statement on Adequacy and Compatibility of Agreement State Programs," published in the Federal Register on October 25, 1995 and the September 12, 1995, NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." Preliminary results of the review, which covered the period December 13, 1993 to December 15, 1995, were discussed with North Carolina management on December 15, 1995.

A draft of this report was issued to North Carolina for factual comment on January 30, 1996. The State of North Carolina responded in a letter dated February 21, 1996 (Attachment 1) and the comments were incorporated into the proposed final report. The Management Review Board (MRB) met on March 20, 1996, to consider the proposed final report. The MRB concurred in the team's overall recommendation and found that the North Carolina's program was adequate to protect public health and safety and was compatible with NRC's regulatory program.

The Department of Environment, Health, and Natural Resources (DEHNR) is a cabinet-level agency within North Carolina State government. The Secretary, DEHNR, is appointed by and reports directly to the Governor. Within DEHNR, the North Carolina radiation control program is administered by the Division of Radiation Protection (DRP). The DRP organization chart is included as Appendix B. The North Carolina program regulated 538 specific licensees and was in the process of licensing a low-level radioactive waste disposal site at the time of the review. In addition to its radioactive materials and low-level radioactive waste disposal programs, DRP is responsible for regulating electronic products and conducts other functions related to nuclear facility safety, environmental monitoring, and emergency planning. 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 indicators was sent to the State on October 17, 1995. North Carolina provided its response to the questionnaire on November 20, 1995. A copy of that response is included as Appendix C to this report.

The review team's general approach for conduct of this review consisted of: (1) examination of North Carolina's response to the questionnaire; (2) review of applicable North Carolina statutes and regulations; (3) analysis of quantitative information from the DRP licensing and inspection data base; (4) technical review of selected files; (5) field accompaniments of three 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 non-common indicator and made a preliminary assessment of DRP's performance. As noted above, that preliminary assessment was discussed with program management before the team's departure.

Section 2 below discusses the State's actions in response to recommendations made following the previous review. Results of the current review for the IMPEP common performance indicators are presented in Section 3. Section 4 discusses results of the applicable non-common indicators, and Section 5 summarizes the review team's findings and recommendations.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

The previous routine review concluded on December 10, 1993, and the results were transmitted to Jonathan Howes, Secretary, Department of Environment, Health, and Natural Resources, on April 6, 1994. A special review of the State's sealed source and device product evaluations was held during the period April 18-22, 1994, with the results transmitted to Mr. Howes on December 28, 1994.

2.1 Status of Items Identified During December 1993 Routine Review

The December 1993 review resulted in two recommendations for action by the State. (1) It was recommended that the State expedite the adoption of regulations equivalent to the NRC 10 CFR Part 34 amendment, "Safety Requirements for Industrial Radiographic Equipment," as well as other regulations needed to maintain compatibility. (2) Because of the complexity of the major licenses issued by the State, it was recommended the staffing level be increased to 1.5 person-years per 100 specific licenses.

(1) On July 7, 1995, North Carolina provided the Office of State Programs (OSP) with copies of their compatible final equivalent regulations. The State regulations were determined to be compatible in correspondence dated October 27, 1995, from Richard L. Bangart, Director, Office of State Programs, to Dayne Brown, Director, Division of Radiation Protection. (2) The State's satisfactory rating in all performance indicators during this review confirms that the staffing level was adequate during the review period. The review team considers both items closed.

2.2 Status of Items Identified in April 1994 Special Review of Sealed Source and Device Product Evaluations

Deficiencies found during the April 1994 special review of the State's sealed source and device (SS&D) product evaluations resulted in the NRC's decision to withhold a finding of adequacy to protect the public health and safety. In their July 1995 response to the NRC recommendations, the State submitted an action plan for improving their SS&D evaluation procedures and for reevaluating and updating previously issued SS&D registry sheets. After reviewing all new and revised SS&D evaluations completed since the special review, the review team found that the deficiencies found in the special review have now been corrected and the State's performance in this indicator is satisfactory. The review team considers this item to be closed.

3.0 COMMON PERFORMANCE INDICATORS

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

3.1 Status of Materials Inspection Program

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

Review of the State's inspection priorities showed that the State's inspection frequencies for various types or groups of licenses are at least as frequent as similar license types or groups listed in the frequency schedule in the NRC Inspection Manual Chapter 2800 (IMC 2800). Inspection frequencies under the State's system range from 1-year to 4-year intervals. The State requires more frequent inspections in some license categories as follows: institutional and private medical facilities are inspected on a 2-year frequency compared with an NRC 3-year or 5-year frequency; broad academic licenses have a 1-year frequency compared with an NRC 3-year frequency; and portable gauges have a 3-year frequency compared with the NRC 5-year frequency. The inspection frequencies of licenses selected for license and inspection file reviews were compared with the frequencies listed in the State's data system and verified to be consistent with the State's system and as frequent as similar license types under the IMC 2800 system.

In their response to the questionnaire, North Carolina indicated that as of November 1, 1995, only three licenses identified as core inspections in IMC 2800 were overdue by more than 25 percent of the NRC frequency. This number is well within the 10 percent criterion for overdue inspections of Management Directive 5.6. Two of the licenses are scheduled for inspection by the end of January 1996, and the other, an academic broad license, will be inspected by the end of April, 1996. The inspection interval for this broad license was extended to permit the licensee's new Radiation Safety Officer to become familiar with the licensee's safety program. The State explained that the compliance history of this licensee supports the extension of the inspection period.

With respect to initial inspections of new licensees, the team reviewed the inspection tracking data system and verified that the initial inspections had been entered into the tracking system. Discussions with staff members were conducted to determine how initial inspections are assigned and how data are entered into the system. The administrative staff enters data on a monthly basis, and then a quality check is performed by supervision based upon a computer printout used for inspection planning. It was also noted that two of the inspection files selected for casework reviews were initial inspections.

The timeliness of the issuance of inspection findings was also evaluated during the inspection file review. Out of 16 files examined, all of the inspection correspondence had been sent to the licensee within 30 days after completion of the inspection except for one escalated enforcement case which is awaiting action by the North Carolina Office of Attorney General.

The State reported in their response to the questionnaire that 131 requests for reciprocity were received during the review period, of which 30 were from industrial radiographers and 77 from portable gauge users. The State reported performing three field inspections of reciprocity licensees. They also reported conducting 17 field inspections on other industrial radiography licensees. The State utilizes a license condition that requires all licensees using temporary locations to notify DRP of work being performed in the State

and provide information on when and where the work will take place. This information is posted on a bulletin board along with requests for reciprocity. This allows the staff to select field inspections as needed and perform the inspections in an efficient manner.

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

3.2 Technical Staffing and Training

Issues central to the evaluation of this indicator include the radioactive materials program staffing level, technical qualifications of the staff, training, and staff turnover. To evaluate these issues, the review team examined the State's questionnaire responses relative to this indicator, interviewed DRP management and staff, and considered any possible backlogs in licensing or compliance actions. Technical staffing and training for the low-level radioactive waste disposal program are addressed in Section 4.3.3 below.

The DRP organization chart shows that the radioactive materials program was funded for one program supervisor and eight health physicists at the time of the review. However, one of the health physicist positions was vacant and one was staffed on a part-time basis. The licensing and inspection functions of the program are integrated, and therefore, all health physicists perform duties in licensing, inspection, and event response. Because of the need for continuity and specialized training, however, sealed source and device evaluations are assigned to two specific individuals. Balance between the licensing and inspection functions is achieved by basing staff assignments on program needs.

Program managers explained that successful candidates for technical positions are required to have bachelor's degrees or at least three years experience and equivalent training in radiation protection. The review team reviewed the qualifications of the technical staff and concluded that the State has been able to recruit well-qualified individuals. All health physicists have at least a bachelor's degree in science and several have advanced degrees. The DRP deputy director is a certified health physicist.

According to information provided in the questionnaire, the State's training program requires all newly hired health physicists to attend the NRC core training courses in licensing, inspection procedures, industrial radiography, and medical, as well as the 2-week or 5-week health physics course, depending on the level of the individual's education. The State also explained the in-house training process in their response. Briefly, new staff are assigned increasingly complex licensing duties under the direction of senior staff and accompany experienced inspectors during increasingly complicated inspections. New staff are assigned independent inspections after demonstrating competence during accompaniments by the radioactive materials section supervisor. DRP program managers demonstrated a strong commitment to staff training during the review.

Staff turnover was high during this review period as four experienced health physicists left the program. According to program management, the State has been able to recruit well-educated staff from local universities. However, State representatives indicated low salaries offered by the State in comparison to other employers in the area have made it difficult to retain experienced staff. In their response to the questionnaire, the State reported that the four health physicists hired since August 1994 had little work experience other than the experience gained during their educational pursuits.

At the time of the review, three of the new health physicists had not taken the licensing course, and one had not taken the inspection procedures course; however, the State advised the review team that the training classes are scheduled. The review team interviewed each health physicist and was satisfied that duties assigned to new staff are commensurate with their training and experience.

In the questionnaire and during discussions with the review team, DRP managers emphasized that it has taken a considerable effort on the part of all existing staff members to complete all the health and safety related work of the program throughout the review period. As a means to increase program efficiency, the State explained that they are in the process of establishing a local area network (LAN) and are planning to add the position of LAN manager. The review team agrees that the installation of a LAN would improve staff efficiency by providing the means to collectively store, retrieve, and transmit information.

During the review, program management announced that the supervisor of the radioactive materials section had accepted a promotion to an engineering position in the low-level radioactive waste disposal section, leaving her key position vacant. This vacancy, along with an already vacant health physicist position, could potentially affect the ability of the program to adequately protect public health and safety. During the MRB meeting, the State indicated that the supervisor position had been filled. The review team recommends that the State fill the existing vacancy as soon as possible.

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

3.3 Technical Quality of Licensing Actions

The review team examined casework and interviewed the reviewers for nineteen specific licenses. Licensing actions were reviewed 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. Casework was reviewed for timeliness, adherence to good health physics practices, reference to appropriate regulations, documentation of safety evaluation reports, product certifications or other supporting documents, consideration of enforcement history on renewals, pre-licensing visits, peer or supervisory review as indicated, and proper signature authorities. Licenses were reviewed for accuracy, appropriateness of the license and of its conditions and tie-down conditions, and overall technical quality. The files were checked for retention of necessary documents and supporting data.

The cases were selected to provide a representative sample of licensing actions which had been completed in the review period and to include work by all reviewers. The cross-section sampling included thirteen of the State's major licenses and included the following types: large irradiator, medical broad scope (with a HDR afterloader), academic broad scope, nuclear pharmacy, research and development, mobile nuclear medicine, manufacturing and distribution, and industrial fixed radiography. Licensing actions included two new licenses, four renewals, ten amendments, and three terminations. A list of these licenses with case-specific comments can be found in Appendix D.

The review team found that the licensing actions were generally thorough, complete, consistent, and of acceptable quality with health and safety issues properly addressed. Special license tie-down conditions were almost always

stated clearly, backed by information contained in the file, and inspectable. The licensee's compliance history was taken into account when reviewing renewal applications. The State's licensing guides and license policy procedures were revised and updated during the review period, and reviewers were observed to have good research skills in using these and other licensing documents. With few exceptions, reviewers appropriately used the new licensing guides and accompanying check sheets. The licensing supervisor reviews and signs all new or renewed licenses and amendments. No potentially significant health and safety issues were identified.

The review team found that, because of the high staff turnover, some new reviewers had not attended the NRC licensing course. As discussed in Section 3.2, the State reported that those reviewers are scheduled for upcoming courses. Licensing weaknesses identified by the review team appeared to relate to the inexperienced license reviewers, the minimal staffing of the program during the review period, and the need for improved peer and supervisory review. Reviewers did not always use correct guidance, and as a result, issued some inappropriate deficiency letters. For example, new reviewers inappropriately asked a gas chromatograph applicant to perform a survey to determine compliance with public dose limits and, in other cases, missed asking how volatile gas releases would be measured. One license amendment and several background and tie-down documents were missing from the files. The review team recommends that consideration be given to peer and supervisory review of licensing products to include review of all background information and correspondence.

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.

3.4 Technical Quality of Inspections

The team reviewed the inspection reports, enforcement documentation, and the data base information for 16 materials inspections conducted during the review period. The casework included all of the State's materials inspectors and covered a sampling of the higher priority categories of license types as follows: four institutional and one private medical, one mobile nuclear medicine, two nuclear pharmacies, one broad medical, one broad academic, two large irradiators, one fixed location industrial radiography, two temporary location industrial radiography including a field site inspection, and one portable gauge. Appendix E provides a list of the inspection cases reviewed in depth with case-specific comments.

In addition, several spot checks were performed on the files to verify that enforcement correspondence was being maintained in a consistent manner and to verify the implementation of the proper inspection frequency. In all cases, license files selected from the data base for the spot checks were determined to have the proper inspection frequency and current inspection findings and correspondence. Some of the inspection files were also reviewed during the license file review, thus providing further insight on how the State considers inspection findings when completing a licensing action.

The inspection procedures and techniques utilized by the State were reviewed and determined to be consistent with the inspection guidance provided in IMC 2800. The inspection report forms were found to be consistent with the types of information and data collected under IMC 2800. The report forms provided documentation of inspection findings in a consistent manner and in accordance with State policies and internal procedures. The State uses separate supplements to the inspection report form for various classes of

license types, such as medical, portable gauges, fixed gauges, industrial radiography, accelerators, irradiators, gas chromatographs, broad licenses, and service type licenses. In general, the inspection form supplements provide documentation of licensee and radiation safety organization, scope of licensee's program, material uses, procedures, leak tests, surveys, instrumentation, dosimetry, incidents, interviews with staff, confirmatory surveys, items of non-compliance, and exit interviews.

For the most part, the review team found that the inspection reports contained only minor discrepancies, when compared to State internal guidance or standard practice. Four of the reports contained references to who was present during the exit meetings but did not summarize the discussion. In one case, the inspection was at a temporary job site and the exit meeting was held with the radiographer in the field, rather than the manager at the licensee's office. The review team recommends that (a) all inspection reports include a summary of the exit meeting discussion, as addressed by internal guidance, including the licensee's comments regarding items of non-compliance; and (b) inspectors make every effort to hold exit meetings at the highest possible management level.

Three inspector accompaniments were performed by a review team member during the period of November 14-15, 1995. Two inspectors were accompanied during the early morning inspection of a nuclear pharmacy facility, and another inspector was accompanied to a fixed radiographic facility. These accompaniments are also identified in Appendix E. All of the other inspectors have been accompanied during previous reviews. On the accompaniments, the North Carolina inspectors demonstrated appropriate inspection techniques and knowledge of the regulations. The inspectors were well prepared and thorough in their reviews of the licensees' radiation safety programs. Overall, the technical performance of the inspectors was satisfactory, and their inspections were adequate to assess radiological health and safety at the licensed facilities.

In response to the questionnaire, the State reported that three inspectors were accompanied by the radioactive materials section chief during the review period and provided copies of the fieldwork evaluation forms for each accompaniment. The State further reported that supervisory accompaniments are required for junior staff before they are allowed to perform independent inspections but that accompaniments of senior inspectors are not required. The review team considered the unusually high demands placed on supervisory staff during this review period because of the high staff turnover rate, the effort necessary to update regulations, and the need to reevaluate previously issued SS&D registrations. However, supervisory accompaniments provide management with important insight into the quality of the inspection program. The review team recommends that the State consider for adoption a policy of annual supervisory accompaniments of all inspectors.

It was noted that the State has a variety of portable instruments for routine confirmatory surveys and use during incidents and emergency conditions. The instruments were a good mix of low range GM tubes and pancake probes, micro R meters, high range instruments, instrumentation with calibration standards for alpha detection, a neutron rem ball, a portable multichannel analyzer, and the Environmental Laboratory maintains a mobile laboratory van for use in emergencies and emergency exercises. Air monitoring equipment is also available. The portable instruments used during the inspector accompaniments were observed to be operational and calibrated. The portable instruments maintained in the office were also observed to be calibrated. Program staff explained that instruments are calibrated at least on an annual basis, and

staggered so as to always have instruments calibrated within the calendar quarter for use during industrial radiography inspections.

It was found that the State is generally performing unannounced inspections of materials licensees, except for initial inspections and geographically-distant locations. Inspections of broad licenses are also announced.

Inspectors sign all routine enforcement correspondence. All of the inspection results and routine enforcement letters were verified as having been reviewed and signed off by the supervisor before issuing the results to licensees. The review team concluded that this supervisory review enhanced the quality of the inspection and enforcement documents. The inspectors are also cross trained as license reviewers which also strengthens the continuity of the regulatory program. The review team agreed with program management that the State's proposed LAN system would allow additional standardization and implementation of inspection modules, enforcement language, and tracking systems.

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.

3.5 Response to Incidents and Allegations

In evaluating the effectiveness of the State's actions in responding to incidents and allegations, the review team examined the State's response to the questionnaire relative to this indicator and reviewed the casework of eight incidents and six allegations. In addition, the review team interviewed the DRP director, deputy director, the radioactive materials supervisor, and the health physicists assigned to incident response.

It was found that within the DRP, responsibility for initial response and follow up actions to materials incidents and allegations rests solely with the radioactive materials section. Written procedures require two qualified health physicists to evaluate each incoming incident report or allegation and present it to the supervisor for direction. All complex events or those with potential for impacting public safety are evaluated by the radioactive materials supervisor, the director, and the deputy director in order to determine the appropriate response. Review of the files indicated that this approach provided effective response actions and did not delay the response time.

The review team examined the State's response to eight events that were identified as significant in the incident log provided by the State and the NMED file provided by the NRC Office for Analysis and Evaluation of Operational Data. Events reviewed involved a repeated switch failure at a large pool irradiator, a broken rack cable at a second large pool irradiator, radioactive contamination at a hospital, missing radioactive material, a leaking source, and three cases in which radiation monitors were tripped because of improper disposal of sources. Six allegation files involving a variety of technical and administrative issues were selected from a list provided by the State. A list of the incident casework with comments is included in Appendix F.

In the cases reviewed in depth, the review team found that the State's response was well within the performance criteria. Incident response was prompt and well-coordinated, and the level of effort was commensurate with health and safety significance. As a general rule, health physicists were dispatched to the site when appropriate. The State took suitable corrective and enforcement actions, notified the NRC as appropriate, and followed the

progress of the investigation through until close out. Allegations were responded to promptly with appropriate investigations and follow up actions. Proper procedures were used for the control of information, and the results of the investigation were promptly related to the alleged.

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 Regulations, (2) Sealed Source and Device Evaluation Program, (3) Low-Level Radioactive Waste Disposal Program, and (4) Uranium Recovery Operations. Because North Carolina has no agreement to regulate uranium recovery operations, only the first three performance indicators were applicable to this review.

4.1 Legislation and Regulations

4.1.1 Legislative and Legal Authority

Along with their response to the questionnaire, the State provided the review team with copies of legislation that affects the radiation control program. DEHNR is designated as the State radiation protection agency in the General Statutes of North Carolina, Chapter 104E, North Carolina Radiation Protection Act. The Act creates the North Carolina Radiation Protection Commission, and grants the Commission the authority to promulgate rules and regulations to be followed in the administration of a radiation protection program, including a low-level radioactive waste disposal facility.

4.1.2 Status and Compatibility of Regulations

North Carolina's final equivalent amendments to the following rules became effective in May 1995, after being approved on a temporary basis in August 1994: "Safety Requirements for Industrial Radiographic Equipment," 10 CFR Part 34; "Notification of Incidents," 10 CFR Parts 20, 30, 31, 34, 39, 40, and 70; and "Quality Management Program and Misadministrations" 10 CFR Part 35. In correspondence dated October 27, 1995, OSP indicated the State regulations were compatible, based on NRC staff review of the amended regulations.

According to information provided in the questionnaire, the State has drafted regulations equivalent to the following NRC rules:

- "Licensing and Radiation Safety Requirements for Irradiators," 10 CFR Part 36 amendments (58 FR 7715) that became effective July 1, 1993. The State reported that all irradiator licenses issued since July 1993 implement the rule through license conditions.
- "Decommissioning Recordkeeping and License Termination: Documentation Additions," 10 CFR Parts 30, 40, 70, and 72 amendments (58 FR 39628) that became effective on October 25, 1993.
- "Self-Guarantee as an Additional Financial Mechanism," 10 CFR Parts 30, 40, and 70 amendments (58 FR 68726 and 59 FR 1618) that became effective on January 28, 1994.

- "Timeliness in Decommissioning of Materials Facilities," 10 CFR Parts 30, 40, and 70 amendments (59 FR 36026) that became effective on August 15, 1994.
- "Performance Requirements for Radiography Equipment," 10 CFR Part 34 amendments (60 FR 28323) that became effective on June 30, 1995.

The following rules are under review, but have not been drafted:

- "Definition of Land Disposal and Waste Site QA Program," 10 CFR Part 61 amendments (58 FR 33886) that became effective on July 22, 1993.
- "Preparation, Transfer for Commercial Distribution and Use of Byproduct Material for Medical Use," 10 CFR Parts 30, 32 and 35 amendments (59 FR 61767, 59 FR 65243, 60 FR 322) that became effective on January 1, 1995.
- "Frequency of Medical Examinations for Use of Respiratory Protection Equipment," 10 CFR Part 20 amendments (60 FR 7900) that became effective on March 13, 1995. Note, this rule is designated as a Division 2 matter of compatibility. Division 2 compatibility allows the Agreement States flexibility to be more stringent (i.e., the State could choose to continue to require annual medical examinations).
- "Low-Level Waste Shipment Manifest Information and Reporting," 10 CFR Parts 20 and 61 amendments (60 FR 15649, 60 FR 25983) that will become effective March 1, 1998. North Carolina and other Agreement States are expected to have that equivalent rule effective on the same date.

The State has not started review of the following compatibility rules:

- "Radiation Protection Requirements: Amended Definitions and Criteria," 10 CFR Parts 19 and 20 amendments (60 FR 36038) that became effective August 14, 1995.
- "Clarification of Decommissioning Funding Requirements," 10 CFR Parts 30, 40, and 70 amendments (60 FR 38235) that became effective November 24, 1995.
- "Compatibility with the International Atomic Energy Agency," 10 CFR Part 71 amendment (60 FR 50248) that will become effective April 1, 1996.

The review team examined the procedures used in the State's regulation promulgation process and found that the public is offered the opportunity to comment on proposed regulations in public hearings. According to program management, the NRC is provided with drafts for comment on the proposed regulations early in the promulgation process and again prior to final adoption.

Although the State's regulations were compatible with those of the NRC at the time of the review, not all compatibility regulations had been adopted within the three-year time frame prescribed in the performance criteria. During discussions with the review team, program management explained that they are aware of the importance of maintaining compatible regulations and the State plans to make every effort to maintain compatibility. However, they pointed out that recent legislative changes have placed additional constraints on adopting new regulations. It is less likely that the State can continue to adopt effective regulations within 3 years for new regulations. The review team recommends that the State evaluate the process for promulgating

compatibility regulations to better ensure that the State meets the three-year time frame.

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

4.2 Sealed Source and Device Evaluation Program

In evaluating the State's SS&D evaluation program, the review team studied the information provided by the State relative to this indicator in their response to the questionnaire, reviewed the casework and background information of all certificates of registration issued since the April 1994 review, reviewed new procedures and guidance, and interviewed the DRP staff and managers responsible for SS&D evaluations.

In response to the NRC's recommendations following the April 1994 special SS&D review, on July 17, 1995, the State submitted an action plan for improving their SS&D evaluation procedures and for reevaluating and updating previously issued SS&D registry sheets. The review team found that DRP had made excellent progress in meeting the goals set forth in the plan. The reevaluation effort is being conducted with a lot of planning in the priorities of reviews, with the single thought that those with health and safety concern are to be given higher priority. Under the action plan, each SS&D manufacturer was required to submit complete sets of updated product information to enable DRP to perform the reevaluations and updates. The State explained that progress on the reevaluation plan is not moving as fast as they would like because they have encountered difficulty getting the level of detail from the vendors needed to initiate a product safety evaluation. The review team noted that some of the devices were approved many years ago before a formalized registration process was in place. These products have historically been in use in the United States with few reported design problems. The staff has been diligent in their efforts to collect old information and update the original safety approvals, and have strong management support in this area. Details of the status of the reevaluation program are provided by the State in Appendix C.

4.2.1 Technical Quality of the Product Evaluation Program

The review team reviewed the files of the seven new or revised SS&D registry sheets issued since the April 1994 review, including the State's approval of a newly designed source rod used in several different Troxler extendable source machines. The SS&D registry sheets issued by the State and evaluated by the review team are listed with case-specific comments in Appendix G. Overall, the quality of the evaluations was good, with only minor technical comments, and showed a vast improvement since the April 1994 review. The review team, however, found that the State has no procedures for handling proprietary information used in evaluating SS&D products. Documents containing proprietary information were sometimes attached to registry sheets distributed publicly. 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. The review team identified two other items that need action by the State. (1) The Troxler drawings show an ANSI classification requirement of C54444 for sources they use. However, they are using an IPL source with a rating of C66535. It could not be determined if this was an oversight or if the performance specification is not being met by Troxler. (2) The American Duesenberg Bosson registry sheet for a gamma gauge did not have the necessary attachments. The review team recommends that (1) the State clarify the Troxler source ratings

and evaluate Troxler's QA plan to ensure that it includes health physics evaluation; and (2) that the necessary attachments to the American Duesenberg certificate be distributed.

It was noted that the State has a very well defined regulatory basis for its SS&D registry program. This basis is found in §.0117 of the North Carolina Regulations for Protection Against Radiation, which incorporates by reference 10 CFR part 32 including 32.210. This, in conjunction with §.0327 (f) gives the State a firm basis to conduct and inspect against source or device evaluation. The incorporation also clearly defines the approval criteria and the type of information to be submitted by the applicant.

4.2.2 Technical Staffing and Training

The State reported that a two-person team with combined staff efforts equalling approximately one FTE is dedicated to performing safety evaluations. Both staff members have master's degrees, one in physics, the other in environmental health. The senior of the two reviewers attended the SS&D workshop training and is spending about 75 percent of his time in this area. He demonstrated to the review team an ability to understand and interpret the information submitted by applicants as described in the performance criteria. The junior reviewer also attended the workshop but has not performed independent SS&D evaluations. He expressed a need to become familiar with the process first. An offer was extended to the State for this reviewer to work with the Sealed Source Safety Section at NRC Headquarters, and his management is considering that option. The review team is aware that promotion of the radioactive materials supervisor and the recent high turnover rate of the State program presents potential for weaknesses to develop. However, these potential weaknesses appear to be offset by the staff's dedication to a quality product, the use of a team approach to performing the evaluations, management support, and the ability to seek outside engineering consultants for assistance as needed.

4.2.3 Evaluation of Defects and Incidents Regarding SS&Ds

The State is following up on two SS&D-related incidents, one involving a source rod break on Troxler equipment and the other involving a broken cable attached to a source rack hoist for a category IV irradiator. The State's responses to these incidents were evaluated by the review team and are included in the incidents reviewed in section 3.5 of this report.

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 the process of evaluating this performance indicator, the review team studied the State's responses to the questionnaire, compared North Carolina LLRW statutes and regulations with those of the NRC, evaluated the qualifications of the technical staff and contractors, reviewed the State's written procedures and plans, examined parts of the site characterization report and associated documents, reviewed parts of the safety analysis report (SAR), surveillance reports, audits, and contractor reports, and interviewed all staff and managers assigned to the LLRW program.

4.3.1 Introduction

In 1987 the North Carolina Legislature formed the Low Level Radioactive Waste Management Authority (LLRWMA) for the purpose of developing a low-level radioactive waste disposal facility within the State of North Carolina. DEHNR is granted authority to regulate LLRW activities under the General Statutes of North Carolina, Chapter 104E, North Carolina Radiation Protection Act. Within DEHNR, the North Carolina LLRW program is administered by the DRP.

In 1989 Chem Nuclear Systems, Inc. (CNSI) was selected to site, construct, operate and close such a facility. A site characterization plan for two sites was submitted to DRP in June 1990. DRP commented on the plan through a series of memoranda and open meetings between July 1990 and August 1991, and the plan was approved August 16, 1991.

According to DRP officials, during the characterization effort, DRP met with CNSI at 3-month intervals to review the CNSI approach. The State raised a number of major objections to the conduct of site characterization. CNSI made a number of adjustments but key issues remained unresolved and, in April 1993, LLRWMA requested a statement of detailed concerns from DRP. Detailed concerns were provided by DRP on May 13, 1993. The site characterization report was submitted in October 1993 and the SAR was submitted on December 13, 1993. The SAR was found to be incomplete and CNSI was directed to furnish additional information. At the end of January 1994, CNSI had provided sufficient information for DRP to begin detailed review.

In March 1994, DRP sent 38 interrogatories to CNSI detailing major problems in the hydrologic characterization, requiring more field work and also requesting a field work plan. By August 1994, 556 additional interrogatories had been transmitted to CNSI, including requests for construction details for some of the engineered barriers. In November 1994, LLRWMA hired the firm of Harding-Lawson to evaluate the DRP review. The Harding-Lawson evaluation, released in April 1995, expressed agreement with the DRP concerns.

In November 1995, CNSI stated that resolving the DRP concerns would add approximately \$20,000,000 to the cost of the facility and the site would likely not be licensed until mid-1998. CNSI is expected to submit an issue resolution plan to the LLRWMA in January 1996. The LLRWMA will decide whether or not to continue pursuing a license for the proposed site.

On December 13, 1995, the LLRWMA Executive Director spoke before the North Carolina Joint Legislative Commission on Governmental Operations in regard to the status of activities, revenues, and expenditures of the project. A review team member attended that session where the Legislative Commission was advised that LLRWMA has spent approximately \$87 million thus far on the project and that DRP has spent approximately \$6 million on licensing activities.

4.3.2 Status of Low-Level Radioactive Waste Disposal Inspection

The applicant is presently in the pre-license stage and the DRP inspection program consists of surveillances of site characterization work at the site and Quality Assurance (QA) audits. The review team found that the State has been diligent in conducting surveillances and audits. Fifteen surveillance reports are on file for 1994, and 23 are on file for 1995. In addition a QA informational audit was performed on the applicant in September-October 1995. DRP's QA manual requires audits to be performed at least on an annual basis.

A database is being established which will have the capability of maintaining and retrieving statistical data on the status of the LLRW inspection program.

The DRP License Application Review Management Plan provides for periodic inspections including tests on waste, facilities, and environment and an operational inspection program to be defined in advance of issuing a license for operations. By regulation, the licensee is required to provide an office and storage space for a resident State inspector at the facility.

4.3.3 Technical Staffing and Training

DRP's LLRW section has six full-time employees and three employees devoting approximately 50 percent of their time to LLW. Two of the 50 percent employees may devote up to 100 percent of their time as needed. Current demand is about 50 percent. In addition, the North Carolina Geological Survey has three full-time employees assigned to the LLRW project; the North Carolina Groundwater Section has three full-time employees assigned; and the North Carolina Air Quality Section has one full-time employee assigned. Other State agencies provide part-time help on an as-needed basis for areas including waste quality, forest resources, epidemiology, and cultural resources. Contractual assistance has been obtained for performance assessment (PA) and engineering from Rogers and Associates Engineering Corporation in Salt Lake City, Utah; in hydrology, PA, and QA from ERM Program Management Company in McLean, Virginia; and in program management from Environmental Issues Management, Inc., in Seattle, Washington.

The review team reviewed the training records and interviewed the eight technical staff members assigned to the LLRW section, and found that all technical staff hold bachelor's or advanced degrees in appropriate scientific fields. In Appendix C, the State identifies the staff members assigned to the LLRW program and lists their training and experience. Review of the training procedures show that all individuals are required to be familiar with DRP LLRW review procedures and applicable NRC NUREGS such as 1199, 1200, and 1300. In addition, senior level personnel are required to be familiar with NRC QA-related NUREGS 1293 and 1383. From the interviews, it was determined that all personnel appeared to be qualified for their positions of responsibility either through education and/or experience. Also from the interviews, it was determined that all have participated in additional technical training either through college courses, government sponsored courses, or workshops. The review team encourages DRP management to take an active role in supporting professional licensing of the technical staff. This should be especially encouraged for staff without graduate degrees or degrees specific to their title and position of responsibility.

The qualifications of the three contractors were also reviewed. Each of the contractors appeared qualified for the responsibilities assigned.

The overlap in skills provided for in the program through contractors and participating State agencies is expected to help to lessen possible adverse effects from staff turnovers.

The review team found that the qualifications of the technical staff are commensurate with expertise identified as necessary to regulate a low-level radioactive waste disposal facility. Management has developed and implemented a training program for staff. Staff trends that could have an adverse impact on the quality of the program are tracked, analyzed and addressed. 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.

4.3.4 Technical Quality of Licensing Actions

The technical quality of LLRW licensing actions was evaluated with regard to aspects considered essential to performance assessment. These aspects included comparison of pertinent sections of the North Carolina regulations with 10 CFR 61, programmatic aspects of the review process, and issues under resolution of sufficient complexity to evaluate the technical adequacy of the review process.

The North Carolina low-level waste regulations, Title 15A, Chapter 11 §.1200 Land Disposal of Radioactive Waste, were compared with the parts of 10 CFR 61 which govern performance assessment. Specifically the North Carolina regulations were compared to Subpart C of 10 CFR 61, "Performance Objectives," and parts 61.50 through 61.53 of Subpart D, "Technical Requirements for Land Disposal Facilities." The North Carolina regulations were found to be completely compatible with Subpart C of 10 CFR 61. The North Carolina regulations were found to be equivalent to Subpart D 61.50 to 61.53 with the following exceptions:

- In 10 CFR 61.50(a)(7), the Commission will consider an exception to the requirement that the disposal site will provide sufficient depth to the water table that groundwater intrusion will not occur. North Carolina regulations do not provide for this exception and require that the disposal facility be at least seven feet above the seasonal high water table.
- North Carolina regulations also require that areas shall be avoided that are recharge areas for sole source aquifers or drinking water supply watersheds unless it can be demonstrated with reasonable assurance that the disposal site can be designed, constructed, operated, and closed without an unreasonable risk to an aquifer or drinking water supplies. 10 CFR 61 does not have this requirement.
- North Carolina regulations state that waste disposal shall not take place within 1000 ft. of drinking water wells, except for on-site wells controlled by the licensee and used to supply water solely to the facility. 10 CFR 61 does not have this requirement.
- North Carolina regulations require the incorporation of engineered barriers that will complement and where appropriate, improve the land facilities ability to isolate the radioactive waste through the institutional control period. 10 CFR 61 does not have this requirement.
- Mixed waste is prohibited. The Radiation Protection Commission may waive this prohibition if specified conditions are met. 10 CFR 61 does not have this prohibition.
- North Carolina regulations require a description of an action plan which would be implemented in the event of unforeseen differences between expected and actual behavior of the disposal system. North Carolina's requirements in this area are significantly more detailed than the 10 CFR 61 requirements.

These differences, however, do not make the North Carolina regulations incompatible with 10 CFR 61 for the purposes of performance assessment. The team notes that the prohibition on the disposal of mixed waste can be a

compatibility issue. However, since some other Agreement States that regulate the disposal of low-level radioactive waste have similar prohibitions, the review team recommends that the issue of Agreement State prohibition of mixed waste disposal be resolved generically by NRC.

In regard to programmatic aspects of the review program, the License Application Review Management Plan (LARMP) and its implementation was evaluated. The LARMP requires the formation of a review team with an identified LLRW Section staff lead reviewer for each section of the SAR. The LARMP also requires the establishment of an integration team to assure that the review is integrated across all applicable disciplines. DRP has a contractual arrangement with ERM to provide senior-level technical expertise to the integration team. ERM is the primary PA contractor. DRP is extremely interested in developing and maintaining a process which will assure efficiency and quality in its evaluation and has used one of its contractors to assess its program in this regard. The November 2, 1995, Environmental Issues contractors report was reviewed. Recommendations from this report are being considered for implementation. Discussions with the LLRW section chief, indicate a management understanding of PA basic steps and how PA can help make a finding with reasonable assurance.

In evaluating the State's review and resolution of technical issues, the review team selected four issues in the areas of source term, engineered barrier performance, hydrologic transport and dose assessment.

- Interrogatory Number 06-A-17 (6/17/94) requested the applicant to justify the IMPACTS methodology. The interrogatory asked specific questions about coefficients used in the methodology and provided technical discussions as to why such coefficients may or may not be applicable to the site. The interrogatory referenced the NRC Draft Branch Technical Position (BTP) on LLRW PA as not endorsing generic codes and cautioning against the use of certain parameters. DRP provided minutes of conference calls and meetings with the applicant. On October 2, 1995, CNSI transmitted an interim report to DRP providing for alternative means of calculating the groundwater source term. The issue appears to be moving toward adequate resolution.
- Interrogatories 03-A-006 (3/16/94) and 03-A-052 (8/18/94) requested detailed drawings and technical discussions regarding the design of the infiltration cap. The DRP review of the conceptual design of the infiltration cap as presented in the SAR determined that the cap as conceptualized may not be constructable using conventional engineering and construction techniques and, therefore, may not perform as intended. DRP requested construction details before proceeding further with an evaluation of the cap. In December 1994, CNSI transmitted a draft of their revised cover design and construction details to DRP. DRP expressed further concerns in a letter dated March 14, 1995. In October 1995, CNSI made a presentation of their overall systems model to DRP which included a revised cover design. DRP engineers expect resolution in the near future.
- Interrogatories 02-A-119 (8/18/94), 02-A-120 (8/18/94), and 02-A-126 (8/18/94) were directed at saturated zone modeling, characterization, and scale effects. Interrogatory 02-A-119 resulted from the recognition by DRP that fractured rock could probably not be successfully modeled as an equivalent porous media (EPM). Interrogatory 02-A-120 requested three dimensional geologic data at aquifer test sites so that pumping tests could be effectively planned and interpreted. Interrogatory 02-A-126 requested geostatistical analysis around various well cluster

packered intervals as a means to understand scale effects on the value of hydraulic conductivity at the site. Letters to CNSI on October 12, 1992, and later on February 15, 1993, before completion of the SAR, expressed concern about the EPM assumption and the need for more complete geologic understanding. The Harding-Lawson Associates report issued in April 1995, also expressed concern about the validity of the EPM model and expressed the need for detailed 3-D hydrogeology. On November 2, 1995, a presentation to DRP by CNSI and other LLRWMA contractors presented a revised modeling approach which will incorporate hydrologically significant geologic features, test alternate conceptual models including continuum and discrete fracture approaches, simulate multiple scales of features and allow for model confirmation at large and detailed scales. The issue appears to be moving toward adequate resolution.

- Interrogatory 06-A-018 (6/17/94) was directed at dose calculations incorporating decay products of Th-232 and U-238. It requested CNSI to provide a performance assessment including maximum dose even if it occurred after 1,500 years. This issue was discussed further at a source term/PA topical meeting at DRP on July 20, 1994. CNSI replied to the interrogatory claiming that DRP requirements on period of performance were stricter than those of NRC. CNSI reiterated this concern in a letter dated September 13, 1994, to DRP and cited NRC PG-8-08 as limiting the period of consideration of decay products of thorium and uranium to 1000 years for decommissioning of nuclear facilities. The 10,000 year period of the Draft BTP on PA was acknowledged, however. On September 22, 1994, a public meeting was held to discuss performance assessment. At the meeting a DRP consultant noted that the cited period of performance (1000 years) was for decommissioning of nuclear power plants. In this meeting CNSI requested a written statement from DRP addressing the required time period for performance. On November 2, 1995, DRP issued a letter stating that for the first few thousand years, CNSI should assess performance in detail and assess whole body dose rate equivalents by nuclide, pathway, and scenario. After the first few thousand years, CNSI may use simplifying and conservative assumptions to bound peak dose. CNSI must also demonstrate an understanding of nuclides important to dose, factors affecting mobility and transport of radionuclides, decay and ingrowth, and the general time frame within which associated doses will result. DRP expects resolution based on the November 2, 1995, letter.

The review team found that pre-licensing interactions with the applicant are occurring on a regular basis. Applicable guidance documents are available to reviewers in most cases, and are generally followed. Public meetings in accordance to the State administrative laws have occurred. Review of certain technical aspects of the low-level waste license files indicates that aspect of the license review is generally thorough, complete, consistent, and of acceptable technical quality. Health and safety issues are properly addressed. An evaluation of the license review process indicates that the process is thorough and consistent. No potentially significant health and safety issues can be linked to licensing practices.

4.3.5 Technical Quality of Inspections

Review of this area focused on the scope, completeness, and technical accuracy of inspections and related documentation and consisted of a review of the surveillances and QA audits performed by DRP.

DRP uses surveillance reports to document all visits by DRP personnel or contractors to the site and includes documentation of meetings with the applicant, site tours, and surveillance of data collection. A review of the surveillances found them to be generally in accordance with the requirements of QAP-10, "Surveillances." However, a master list of surveillances conducted was not readily available. In addition, the numbering of early surveillances (1994) appeared to be in error. The numbering system also indicated that some surveillance reports may be missing from the file. At present, surveillance reports are prepared by technical staff and are not logged by the QA manager prior to filing. 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.

The team reviewed DRP's plans for the new licensing database, which does include surveillance reports, and concluded that the computerized data base should help to eliminate these problems. The review team feels that errors of the type found during the review team's review of the document tracking system may cause significantly greater problems for the operation of a computer database. 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.

The review team reviewed the LLRW Disposal Facility Project Quality Assurance Plan (QAP) to determine its compatibility with NRC NUREG-1293 "Quality Assurance Guidance for Low-level Radioactive Waste Disposal Facility." The QAP was issued on October 15, 1993, and contains descriptions of the plan's organization, the QA program and other areas as addressed in NUREG 1293. The QAP also contains an implementation matrix showing the implementation procedures for pertinent sections of the QAP and the applicable sections of NUREG 1293. From this matrix QP-10, "Surveillance Inspection," and QP-18, "Quality Assurance Audits," were selected for comparison to NUREG-1293. Both were found to conform with the general guidance as presented in NUREG-1293.

The results of two audits performed by LLRW staff were reviewed. The first audit was an internal audit of DRP LLRW performed in August 1995. This audit was performed at the request of the section chief and was performed for the purpose of checking the quality of internal documentation in the areas of document review records, internal review records, interrogatories, letters of transmittal to CNSI, and training records for contractor personnel. Computer databases containing information are to be audited later. The overall objective was to ensure that review documentation is traceable and retrievable. Problems were identified, corrective actions outlined, and preventive measures were suggested in the internal audit report. As of December 1995, over 95 percent of the required corrective actions have been completed.

The second audit reviewed was Information Audit 95-001, performed on CNSI and Law Engineering at CNSI on intermittent days between September 11, 1995, and October 27, 1995, by LLRW personnel and technical auditors from North Carolina Geological Survey. The purpose of the audit was to review the evaluation and documentation of rock core data by the applicant and its contractor. Records showed the audit to be conducted in accordance with QAP-18 and consisted of a pre-audit meeting, the preparation of QA and technical check lists, the audit, and a post audit meeting. However, a number of discrepancies were noted during the audit and an audit report is in preparation. The quality of the information audit (95-001) appeared to be excellent but very narrowly focused and resource intensive. During discussions with the LLRW managers, the review team pointed out that shorter audits on a wider variety of performance

assessment significant areas may be a more efficient use of resources and that involvement of the PA contractor in the selection of audit subjects and in the conduct of appropriate audits should be considered.

4.3.6 Response to Incidents and Allegations

There were no reported allegations in the area of LLRW. The State explained to the review team that allegations directed to the low-level radioactive waste program will be handled in the same manner as those of the radioactive materials program, which was discussed earlier in Section 3.5 of this report.

The recommendations made in the LLRW performance indicator are administrative in nature, and do not directly affect public health and safety.

Based on the IMPEP evaluation criteria for the above five performance areas, the review team recommends that North Carolina's performance with respect to the indicator, Low-level Radioactive Waste Disposal Program, be found satisfactory.

5.0 SUMMARY

As noted in Sections 3 and 4 above, the review team found the State's performance with respect to each of the performance indicators to be satisfactory. Accordingly, the team recommends the MRB find the North Carolina program to be adequate to protect public health and safety and compatible with NRC's program. The MRB found the North Carolina program to be adequate to protect public health and safety and compatible with NRC's program.

Below is a summary list of recommendations, as mentioned in earlier sections of the report, for action by the State.

1. The review team recommends that the State fill existing vacancy as soon as possible. (Section 3.2)
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. (Section 3.3)
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 non-compliance; and (b) that inspectors make every effort to hold exit meetings at the highest possible management level. (Section 3.4)
4. The review team recommends that the State consider adopting a policy of annual supervisory accompaniments of all materials inspectors. (Section 3.4)
5. The review team recommends that the State evaluate the process for promulgating compatibility regulations to better ensure that the State meets the three-year time frame. (Section 4.1)
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. (Section 4.2)

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. (Section 4.2)
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. (Section 4.3.3)
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. (Section 4.3.5)
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. (Section 4.3.5)

For NRC, the review team recommends that the issue of the compatibility of Agreement State programs that prohibit the disposal of mixed waste be resolved as a generic issue.

LIST OF APPENDICES AND ATTACHMENTS

- Appendix A IMPEP Review Team Members
- Appendix B North Carolina DRP Organization Chart
- Appendix C North Carolina's Questionnaire Response
- Appendix D License File Reviews
- Appendix E Inspection File Reviews
- Appendix F Incident File Reviews
- Appendix G Sealed Source and Device Evaluation Reviews
- Attachment 1 North Carolina's Response to Review Findings

APPENDIX A
IMPEP REVIEW TEAM MEMBERS

Name	Area of Responsibility
Jack Hornor, RIV, WCFO	Team Leader Technical Staffing and Training Incidents and Allegations Legislation and Regulations
Richard Woodruff, RII	Status of Materials Inspection Program Technical Quality of Inspections
Susan Giddings, Utah	Technical Quality of Licensing
Steve Baggett, NMSS/IMNS	Sealed Source and Device Evaluation Program
Rex Wescott, NMSS/DWM	Low Level Radioactive Waste Program

APPENDIX B
NORTH CAROLINA DIVISION OF RADIATION PROTECTION
ORGANIZATION CHARTS