

September 24, 2003

Mr. C. Earl Hunter
Commissioner
South Carolina Department of
Health and Environmental Control
2600 Bull Street
Columbia, SC 29201

Dear Commissioner Hunter:

On September 9, 2003, the Management Review Board (MRB) met to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) report on the South Carolina Agreement State Program. The MRB found the South Carolina program adequate to protect public health and safety and compatible with the Nuclear Regulatory Commission's (NRC) program. No recommendations were made by the review team for the State.

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. I also wish to acknowledge your continued support for the Radiation Control Program and the excellence in program administration demonstrated by your staff as reflected in the team's findings. I look forward to our agencies continuing to work cooperatively in the future.

Sincerely,

/RA by Carl J. Paperiello Acting For/

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

Enclosure:
As stated

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C. Earl Hunter

September 24, 2003

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF SOUTH CAROLINA AGREEMENT STATE PROGRAM

June 9 - 13, 2003

FINAL REPORT

U.S. Nuclear Regulatory Commission

1.0 INTRODUCTION

This report presents the results of the review of the South Carolina radiation control program. The review was conducted during the period June 9 - 13, 2003, by a review team comprised of technical staff members from the Nuclear Regulatory Commission (NRC) and the Agreement State of Massachusetts. Team members are identified in Appendix A. The review was conducted in accordance with the "Implementation of the Integrated Materials Performance Evaluation Program and Rescission of a Final General Statement of Policy," published in the [Federal Register](#) on October 16, 1997, and the November 25, 1998, NRC [Management Directive 5.6](#), "Integrated Materials Performance Evaluation Program (IMPEP)." Preliminary results of the review, which covered the period of July 17, 1999 to June 13, 2003 were discussed with South Carolina management on June 13, 2003.

A draft of this report was issued to South Carolina for factual comment on July 11, 2003. The State responded by letter dated August 27, 2003. The Management Review Board (MRB) met on September 9, 2003 to consider the proposed final report. The MRB found the South Carolina radiation control program adequate to protect public health and safety and compatible with NRC's program.

The South Carolina Agreement State program is located in the Department of Health and Environmental Control (the Department). Within the Department, the Division of Radioactive Waste Management (the Division) is responsible for the oversight of the Barnwell radioactive waste disposal site and approximately 14 other licenses for waste-related operations. The Bureau of Radiological Health (the Bureau) administers the radioactive materials program. The Division of Radioactive Materials is located in the Bureau. Organization charts for the Department, Division, and Bureau are included as Appendix B. The South Carolina program regulates approximately 357 specific licenses authorizing Agreement materials in addition to the Barnwell site. The review focused on the program as it is carried out under the Section 274.b (of the Atomic Energy Act of 1954, as amended) Agreement between the NRC and the State of South Carolina.

In preparation for the review, a questionnaire addressing the common and non-common performance indicators was sent to the State on April 29, 2003. The Bureau and the Division provided responses to the questionnaire electronically on May 27, 2003. Copies of the questionnaire responses can be found on NRC's Agencywide Document Access and Management System using the Accession Number ML031910223.

The review team's general approach for conduct of the review consisted of: (1) examination of South Carolina's responses to the questionnaire; (2) review of applicable South Carolina statutes and regulations; (3) analysis of quantitative information from the State's licensing and inspection data base; (4) technical evaluation of selected licensing and inspection actions; (5) accompaniments of three South 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 State's actions in response to recommendations made following the previous IMPEP review and the team's conclusions regarding close-out of the recommendations. Results of the current review for the IMPEP common performance indicators are presented in Section 3. Section 4 discusses results of the applicable non-common performance indicators, and Section 5 summarizes the review team's findings, recommendations, and a good practice identified during the review.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous program review, which concluded on July 16, 1999, three recommendations were made and the results transmitted to Douglas E. Bryant, Commissioner, Department of Health and Environmental Control, on October 26, 1999. The review team's evaluation of the current status of the recommendations are as follows:

1. The review team recommends that the State provide training to technical personnel, either by formal course work or equivalent, in the areas of medical brachytherapy and irradiator technology.

Current Status: The State has followed up on this recommendation and staff received training in brachytherapy and irradiator technology. This recommendation is closed.

2. The review team recommends that the State provide draft regulations to STP for compatibility review, in accordance with STP procedure [SA-200](#).

Current Status: Since the 1999 IMPEP review, the State has been submitting draft regulations to STP for compatibility review in accordance with SA-200. The State has submitted rules for compatibility review in a timely fashion and all rules required at the time of this review are in place. This recommendation is closed.

3. The review team recommends that the State obtain copies of the engineering drawings for the SC-0679-D-101-S registered device, and review the drawings for accuracy with the original application, and maintain them in their files.

Current Status: The State obtained copies of the engineering drawings shortly after the 1999 review. The drawings were reviewed and are in the file. 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) Technical Staffing and Training; (2) Status of Materials Inspection Program; (3) Technical Quality of Inspections; (4) Technical Quality of Licensing Actions; and (5) Response to Incidents and Allegations.

3.1 Technical Staffing and Training

Issues central to the evaluation of this indicator include the radioactive materials program staffing level and staff turnover, as well as the technical qualifications and training of the staff. To evaluate these issues, the review team examined the State's questionnaire responses relative to this indicator and interviewed the program management and staff.

The radioactive materials program in the Bureau is staffed with the Bureau Chief, a Radioactive Materials Division Director, an Industrial Program Manager, a Medical Program Manager and three health physicists. Both Program Managers and the technical staff members perform duties in licensing, inspection, and event response. In response to the questionnaire, the State reported that the Bureau Chief spends about 50 percent of his effort supervising the radioactive materials program, while the other managers devote all of their time to the program. Since the last review, there has been no staff turnover. The Bureau's radioactive materials program is currently fully staffed.

The radioactive waste program in the Division is staffed with the Assistant Director, a Radioactive Waste Management Section Manager, two engineers, three health physicists, an on-site health physics inspector at the Barnwell site, two administrative staff, and a consultant. The State reported that the Assistant Director spends about 75 percent of his effort supervising the radioactive waste program. The Section Manager and the other staff spend 100 percent of their effort in the waste program, except for one environmental engineer at 75 percent, and the consultant who is a part time employee. The Division is responsible for the Barnwell site, radioactive waste related licensees, and decommissioning activities. The Division is currently fully staffed.

The review team concluded that the staffing levels in both the Bureau and the Division programs are adequate.

The qualifications of the staff were determined from the questionnaire, training records, and interviews of personnel. South Carolina has a training program in place for staff which is comparable with the "NRC/OAS Working Group Recommendations for Agreement State Training Programs." Staff are well qualified from an education and experience standpoint. All have Bachelor degrees in the sciences, or equivalent training and experience. The license reviewers/inspectors attend the training courses as prescribed by NRC Inspection Manual Chapter (IMC)1246 and have received training in the areas needed for their assignments. They are very familiar with South Carolina regulations, policies, and procedures. Management is supportive of staff training and demonstrated a commitment to staff training during the review.

The review team discussed the role of the Technical Advisory Radiation Control Council (the Council) with the Bureau Chief. The Council serves as an advisory committee to the radiation control program and meets twice a year or as needed. The team evaluated all meeting minutes since the last IMPEP review. No evidence of any conflict of interest issues were identified. Council members are subject to the State Ethics Act.

Based on the IMPEP evaluation criteria, the review team recommended and the MRB agreed that South Carolina's performance with respect to the indicator, Technical Staffing and Training, was satisfactory.

3.2 Status of Materials Inspection Program

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

Approximately two years ago, the Bureau converted its mainframe computer system to a PC-based system, the Environmental Facility Information System (EFIS), which enables staff to write its own queries and reports. All inspection overdue calculations are performed by the computer program. The Bureau's Industrial and Medical Program Managers print out reports for materials inspections which are coming due in the next six months. The printout identifies the last inspection date, the inspection due date, and the 25 percent overdue date, consistent with NRC IMC 2800. The Managers then assign inspections to staff members.

The team's review of the Bureau's inspection priorities revealed that inspection frequencies for each type of license were the same or more frequent than similar license types listed in NRC IMC 2800. Medical private practices with no quality management program and some gauges are inspected more frequently than indicated by NRC IMC 2800. The Bureau's maximum inspection interval is five years.

In their response to the questionnaire, South Carolina indicated that there were no inspections currently overdue by more than 25 percent of the NRC frequency. The State performs approximately 120 routine inspections annually of which 75 are core inspections. The team confirmed that there were no core routine inspections overdue at the time of the review and determined that only three core routine inspections were conducted overdue during the review period.

The Bureau requires that new licensees be inspected within six months of license issuance or within six months of first receiving radioactive materials, but always within one year of license issuance. All 89 initial inspections completed during the review period were performed within the above criteria, which is consistent with NRC IMC 2800, and none were overdue at the time of the review.

The timeliness of the issuance of inspection findings was evaluated during the inspection casework review. Most of the State's routine inspections, approximately 70 percent, result in immediate issuance of a Form 591 Field Compliance Form. Other inspection findings are dispatched to licensees within 30 days of completing an inspection. For 28 routine inspection files examined, only one set of inspection findings was not sent to the licensee within 30 days. Documentation in the licensee's file attributed the tardiness to the inspector's illness.

The Bureau issues reciprocity permits based on their July 1 - June 30 fiscal year. During the review period, the Bureau granted 264 reciprocity permits, of which, 44 permits were core licensees based on NRC IMC 1220. The review team noted that the Bureau's previous reciprocity inspection policy required that 50 percent of Priority 1, 2, and 3 reciprocity licensees and 10 percent of all non-core reciprocity licensees be inspected each year. Since NRC Temporary Instruction (TI) 1220/001 was issued as All Agreement States Letter STP-01-034, the Bureau has changed its goal to 20 percent of core inspections and non-core to be inspected "as resources and events dictate." The team determined that the State met and exceeded the NRC IMC 1220 criteria for the entire review period.

Based on the IMPEP evaluation criteria, the review team recommended and the MRB agreed that South Carolina's performance with respect to the indicator, Status of Materials Inspections Program, was satisfactory.

3.3 Technical Quality of Inspections

The team evaluated the inspection reports, enforcement documentation, and inspection field notes, and interviewed staff for 31 radioactive materials inspections conducted during the review period. The casework reviewed included inspections by both the Division and the Bureau, and covered inspections of various types including: medical broad scope, medical institution, medical private practice, mobile nuclear medicine, research & development, fixed and portable gauges, industrial radiography, pool irradiator, manufacturing & distribution, nuclear pharmacy, service provider, decontamination, depleted uranium processor, and waste processor. Appendix C lists the inspection casework files reviewed with case-specific comments.

Based on the casework file reviews, the review team found that routine inspections covered all aspects of the licensee's radiation protection program. Inspection reports were thorough, complete, consistent, and of high quality, with sufficient documentation to ensure acceptable performance with respect to health and safety by the licensee. Exit interviews were held with appropriate licensee personnel. Team inspections were performed when appropriate and for training purposes.

At the time of the review, there were eight radioactive material inspectors at the Division and six at the Bureau. All inspectors are trained to perform radioactive materials inspections and respond to radioactive materials incidents. South Carolina's inspection procedures are consistent with NRC's procedures. Both the Bureau and the Division try to conduct unannounced inspections, however, sometimes inspections may be announced a few days before the inspection. The review team noted that only six of the 28 routine inspection files evaluated were unannounced during this review period as compared to 12 of 22 being unannounced during the last IMPEP review.

The review team noted that many industrial radiography inspections are office inspections and do not take place while the radiographer is working in the field. For example, one licensee, Soil Consultants, did not receive a field inspection during this, or the last IMPEP review period, for a total of eight years without a field inspection. While the Soil Consultants example may be unusual, it is the review team's opinion that the Bureau should place more emphasis on conducting field inspections based on the national program experience in industrial radiography.

The team also notes that a TI is currently in use at NRC that provides for an increased frequency for field inspections. The review team recommends that NRC adopt and disseminate final guidance on field inspections for industrial radiography operations in the interest of establishing an identifiable national materials program standard.

Inspection files were generally found to be complete and in good order. Bureau inspectors may write either a narrative or use a checklist-type inspection report. Boilerplate language is used for compliance letters and violations to ensure consistency. The review team noted that many of the inspection reports contained highly detailed information such as the listing of each radiation detector, its serial number, and last calibration date; and the listing of each licensee employee along with their external and internal doses per year. This level of detail could be an indicator that the inspections are less performance-based. The inspection report is examined and signed by the Radioactive Materials Division Director. Licensee responses to inspection reports are evaluated and replied to in a timely manner.

All Division inspection reports are written in a narrative fashion. Inspection reports contain licensee data, persons contacted, type of inspection, inspector's and supervisor's signature, documentation to support violations, recommendations made to the licensee, unresolved or licensing issues, independent measurements, and exit interview discussions and comments. Division reports are initialed by the Assistant Director and/or the Radioactive Waste Management Section Manager.

During the accompaniments, each of the inspectors demonstrated appropriate performance-based inspection techniques and knowledge of the regulations. The inspectors were well prepared and thorough in their reviews of the licensees' radiation safety programs. The inspections were adequate to assess radiological health and safety at the licensed facilities.

During the review period, Bureau management performed accompaniments of all individuals who performed materials inspections annually. The accompaniments were usually completed by the Bureau Industrial and Medical Program Managers. The accompaniment reports contained sufficient details to document the areas covered.

The review team noted that senior management accompaniments of the Bureau's Industrial and Medical Program Managers appears to be an informal process that is not documented. The review team notes that the NRC's guidance in this area is not clear as to where the cutoff point for inspector accompaniments occurs. Depending on interpretation of the existing guidance, mid-level supervisors who may perform inspections on an occasional basis, or who may participate only in team inspections may, or may not, require an accompaniment. The review team recommends that NRC clarify which supervisory levels require an inspection accompaniment, the frequency of those accompaniments and what level of documentation is appropriate.

The Bureau and the Division have an adequate supply of survey instruments to support the current inspection program. Appropriate, calibrated survey instrumentation such as Geiger-Mueller meters, scintillation detectors, ion chambers, and micro-R meters were observed to be available. Most instruments are calibrated by the Department of Health and Environmental Control's calibration facility, which is a Certified Regional Calibration facility. The Department's

Environmental Laboratory and a contract laboratory provide support to the program through radiological analyses of environmental samples and samples taken by inspectors during inspections, as well as environmental dosimetry around nuclear facilities. Instrument repair and calibration is also available from the instrument manufacturers as needed. A mobile laboratory is available for responding to incidents. The laboratory has the capability for analyzing all types of environmental media, and evaluation of all types of radiation.

Based on the IMPEP evaluation criteria, the review team recommended and the MRB agreed that South Carolina's performance with respect to the indicator, Technical Quality of Inspections, was satisfactory.

3.4 Technical Quality of Licensing Actions

The review team examined completed licensing casework and interviewed license evaluators for 15 specific licenses. Licensing actions were reviewed for completeness, consistency, proper radioisotopes 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 documentation, 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.

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 of licenses: academic, irradiator, industrial radiography, portable gauge, medical institution, medical private practice, radioisotope and sealed source radiotherapy, and nuclear pharmacies. Licensing actions selected for evaluation included four new licenses, four renewals, four amendments, and three termination files. A listing of the licenses evaluated with case-specific comments can be found in Appendix D.

The team found that the licensing actions were very thorough, complete, consistent, of high quality, and properly addressed health and safety issues. The licensee's compliance history is taken into account when reviewing renewal applications as determined from discussions with the license reviewers. The casework evaluation indicated that Bureau staff follow their licensing guides during the review process to ensure that licensees submit the information necessary to support their request. The licensing guides are similar to NRC guides. The team found the checklists/worksheets for each type of program to be comprehensive and incorporated excellent notes to reviewers to assist in the review of applications.

The previous review team noted that some licenses authorizing use of high dose rate (HDR) brachytherapy devices did not include the specific HDR license conditions that are utilized as standard practice by the NRC and other Agreement States. The Bureau informed the previous team that it had developed license conditions in 1999 for HDR units and these conditions would be incorporated on future HDR licenses and renewals. A review of selected medical licensees

that had authorization on their licenses for HDR brachytherapy devices indicated that the appropriate license conditions had been incorporated.

Specific classes of licensees are requested to review their financial assurance requirements by letter. One licensing action examined by the team required the licensee to submit 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 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 one individual and then discussed with management prior to issuance. All licenses are signed by the Bureau Chief or a designee.

Based on the IMPEP evaluation criteria, the review team recommended and the MRB agreed that South Carolina's performance with respect to the indicator, Technical Quality of Licensing Actions, was satisfactory.

3.5 Response to Incidents and Allegations

To evaluate the effectiveness of the State's actions in responding to incidents, the review team examined the State's response to the questionnaire regarding this indicator, evaluated selected incidents reported for South Carolina in the "Nuclear Material Events Database" (NMED) against those contained in the South Carolina files, and evaluated the casework and supporting documentation for 15 radioactive material incidents. A list of incident casework examined along with case-specific comments is contained in Appendix E. The team also evaluated the State's response to two radioactive materials allegations which were referred to the State by NRC during the review period.

The review team discussed the State's incident and allegation processes, file documentation, the State's equivalent to the Freedom of Information Act, NMED, and notification of incidents to the NRC Operations Center with the management and selected staff. In addition, the State's understanding and use of the NMED system was verified by a team member during a demonstration of a search for data, and through the generation of specific reports requested during the review.

When notification of an incident is received, management and staff discuss the health and safety risk associated with the incident, the information needed, the need for an on-site investigation, and coordination with other agencies. The actions taken in response to the event are documented in a report, filed, and the data entered into the NMED system. Enforcement actions or other regulatory actions are taken as appropriate. The team confirmed that the State has the most recent NRC guidance for reporting incidents, and that persons from the Bureau will attend the upcoming NMED workshop in the NRC, Region II office.

The Bureau had 18 reportable radioactive materials incidents during the review period and 15 were selected for casework review. The incidents included three lost or stolen sources, one industrial radiography disconnect, two excessive occupational exposures, one irradiator source rack jam, one irradiator frayed cable, one non-radiation related fatality, three damaged gauges, two equipment malfunctions, and one leaking source. The review team found that the State's responses to incidents were complete and comprehensive. Initial responses were prompt and well-coordinated. The level of effort was commensurate with the health and safety significance. Inspectors were dispatched for on-site investigations when appropriate and the Bureau took suitable enforcement action, including coordination with the Division and follow up, as appropriate.

The Division responded that their office did not have any "reportable" incidents under NRC criteria, but had numerous responses to alarms at hazardous waste sites and landfills because of medical and NORM material. The Division's incident log was reviewed to verify this information. There were no performance issues identified during the incident casework reviews and the review of incident logs in the Bureau or the Division.

During the review period, one allegation was referred to the Bureau, and one allegation was referred to the Division by NRC. These allegations were also received directly by the agencies from the concerned individuals. Both allegations were examined in detail by the review team and the respective agency files show that the agencies took prompt and appropriate action in response to the concerns raised. The allegations were appropriately closed and no performance issues identified from the review of the casework documentation.

The Bureau and the Division updated their respective allegation procedures during the review period, and the procedures were determined to meet the IMPEP criteria, the Office of State and Tribal Programs (STP) Procedure [SA-105](#), "Response to Incidents and Allegations," and the NRC Management Directive 8.8, "Management of Allegations," revised February 4, 1999.

Based on the IMPEP evaluation criteria, the review team recommended and the MRB agreed that South Carolina's performance with respect to the indicator, Response to Incidents and Allegations, was satisfactory.

4.0 NON-COMMON PERFORMANCE INDICATORS

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

4.1 Legislation and Program Elements Required for Compatibility

4.1.1 Legislation

South Carolina became an Agreement State in 1969. The State provided the review team with a copy of the legislation that affects the radiation control program. There have been no changes since the last review. There is no "sunset" requirements for this legislation. The current statutory authority is contained in the 1976 Code of Laws of South Carolina, Section 13-7-10 through 100, the Atomic Energy and Radiation Control Act; Section 13-7-110 through 200, Radioactive Waste and Transportation Act; and Section 48-2-10, Environmental Fees. The most applicable rule section for the Department is Section 13-7-40. The Department is designated the State's radiation control agency and implements the radiation control program.

4.1.2 Program Elements Required for Compatibility

The South Carolina Department of Health and Environmental Control Radioactive Materials Regulations 61-63, Title A, apply to all materials that emit ionizing radiation. These regulations were promulgated pursuant to Section 13-7-40 et. seq. of the South Carolina Code (as amended) of the Atomic Energy and Radiation Control Act. South Carolina requires a license for possession and use of all radioactive material including naturally occurring materials, such as radium, and accelerator-produced radionuclides. South Carolina also requires registration of all equipment designed to produce x-rays or other ionizing radiation and tanning beds.

The regulation adoption process is provided in Department Administrative Policy No. 111, revised September 14, 1995 and issued as Edition One on October 13, 1997 in cooperation with the Legislative Council of the South Carolina General Assembly. The review team examined this process and found that rulemaking takes about six to nine months from the development stage to publication of the final rule in the State Register. Rules become effective 14 days after the final filing process is completed. The public, the NRC, other agencies, and all potentially impacted licensees and registrants are offered an opportunity to comment during the process. Comments are considered and incorporated, as appropriate, before regulations are finalized, approved, and published in the State Register. The State can adopt other agency regulations by reference, which has been done with respect to transportation regulations adopted by the U. S. Department of Transportation. This process was affirmed by the South Carolina Attorney General's opinion dated February 12, 1999. The State also has the authority to issue legally binding requirements, e.g., license conditions, until compatible regulations become effective. South Carolina can adopt regulations needed for compatibility with approval from the Board, whereas, other regulations, such for fees, must receive approval from the State legislature.

The State follows the procedures established in [SA-201](#) for submitting proposed and final regulations to STP for compatibility determinations. Regulations were routinely submitted by the State over the last four years. The last set of rule changes were submitted to STP for review under the procedures in SA-201 on February 19, 2003. The rules were determined to be compatible with NRC's regulations as described in STP letter dated March 12, 2003 and the accompanying State Regulation Status sheet that summarizes the NRC's knowledge of the South Carolina regulations. The State was made aware of an upcoming change that will also

require the submission of license conditions for compatibility review. At the time of the review, there were no license conditions in use that would require submission for compatibility review.

The team reviewed the status of regulations required to be adopted by the State during the review period using the State's response to the questionnaire as verified with the data obtained from the STP Regulation Assessment Tracking System. The team also discussed the status of required regulations with Bureau and Division staff. The review team notes that since the last IMPEP review in July 1999, the State has adopted 14 regulations required for compatibility. Twelve of the regulations were completed before the required implementation date. One regulation involving clarifying amendments and corrections to radiation safety requirements for industrial radiographic operations was implemented on time by license condition. The corresponding rule was implemented three months later. One regulation was found to be overdue by approximately two months. The review team attributes this success to the diligence, discipline and expert knowledge of the Department staff member responsible for rulemaking.

The review team identified the following regulation changes and adoptions that will be needed in the future, and the State related that the regulations would be addressed in upcoming rulemakings:

“Revision of the Skin Dose Limit,” 10 CFR Part 20 amendment (67 FR 16298) that became effective April 5, 2002.

“Medical Use of Byproduct Material,” 10 CFR 20, 32, and 35 amendments (67 FR 20249) that became effective April 24, 2002.

Based on IMPEP evaluation criteria, the review team recommended and the MRB agreed that South Carolina's performance with respect to the indicator, Legislation and Program Elements Required for Compatibility, was satisfactory.

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

The Bureau has not processed an SS&D evaluation since the last IMPEP review. The team determined based on interviews with the staff and management that should the Bureau receive a request to process a new, or modify an existing, SS&D that the Bureau would follow the recommended guidance as provided in NRC's SS&D training workshops and NUREG-1556, Volume 3, issued July 1998. Appropriate checklists will be used to assure all relevant information has been submitted and reviewed and will be maintained in the files. All pertinent American National Standards Institute standards, Regulatory Guides, and applicable references are currently available and will be checked for currency when performing SS&D reviews. In addition, Bureau management indicated that should they receive an SS&D evaluation request they would contact other Agreement States, or NRC, who routinely perform SS&D evaluations for assistance to assure that the latest technical information is considered when conducting the evaluation.

4.3 Low-Level Radioactive Waste (LLRW) Disposal Program

Chem-Nuclear Systems, LLC (Chem-Nuclear) is licensed by the State of South Carolina to handle, process, store, and dispose of LLRW. The Department administers the Chem-Nuclear disposal license for the Barnwell, South Carolina site. The Department's regulatory authority is derived from the South Carolina Atomic Energy and Radiation Control Act, Section 13-7-40, 1976, S.C. Code of Laws (as amended). The license establishes regulatory conditions and procedures that Chem-Nuclear must comply with regarding waste acceptance criteria, site construction, maintenance, environmental monitoring, stabilization and closure. Chem-Nuclear began its operation of shallow land disposal of LLRW at Barnwell in 1971. The license has been amended frequently and renewed seven times, last in 1995. The current license expired in July 2000, and is currently in timely renewal. Under timely renewal, Chem-Nuclear may continue to operate the facility under the existing license and regulations until the Department takes final action on the application for renewal. The application for renewal was submitted on April 27, 2000. The Department has provided a request for additional information and Chem-Nuclear is expected to respond in the summer of 2003. Two concurrent events have delayed the renewal of the license: the creation of the Atlantic Compact in 2000 and the evaluation of the Environmental Radiological Performance Verification (ERPV). The ERPV is being reviewed as part of the renewal package. The State formed a Blue Ribbon Panel of experts to provide a third-party independent review of the ERPV, and Chem-Nuclear will provide a revised ERPV, responding to the comments of the Blue Ribbon Panel, in July, 2003.

Under the restrictions of the Atlantic Compact, the amount of waste allowed to be received by the Barnwell facility reduces over the years. This fiscal year's limit is 70,000 cubic feet. Barnwell is expected to receive approximately 55,000 cubic feet by July 2003, the end of the 2003 fiscal year. The allowed waste volume decreases yearly until it is 35,000 cubic feet in fiscal year 2008. In May 1999, the Department determined that the estimated disposal capacity of the site was approximately 3.2 million cubic feet. Since then, the site has received 410,368 cubic feet of waste, leaving a remaining approximate capacity of 2.8 million cubic feet.

In conducting this IMPEP review, five sub-indicators were employed to evaluate South Carolina's performance regarding its LLRW disposal program. These sub-indicators include: (1) Technical Staffing and Training; (2) Status of Low-Level Radioactive Waste Disposal Inspection; (3) Technical Quality of Inspections; (4) Technical Quality of Licensing Actions; and (5) Response to Incidents and Allegations.

The LLRW program review was performed by conducting an evaluation of relevant background materials and an examination of the State's response to the questionnaire. In addition to the review of information and interviews with the Division's staff and management during the period of June 8 - 13, 2003, a two-day site visit to the Barnwell LLRW disposal facility was conducted on June 2-3, 2003 by two team members. At the site, the team met with the Department's site inspector, examined facility operations and overall site conditions, and accompanied an inspector on the Department's weekly site inspection.

The results of the LLRW disposal program review will be discussed under each of the above five non-common performance sub-indicators. Team conclusions are based on assessment of each of these sub-indicators, as well as on field observations and discussions with Department staff.

4.3.1 Technical Staffing and Training

The review team evaluated the Division's staffing plan. The Division currently has seven full-time technical staff, including one Section Manager, two environmental engineers, three health physicists, and the site inspector, as well as an Assistant Division Director and one contractor. All staff members have Bachelor degrees or higher, or equivalent training and experience. During the review period, two staff members retired. One of these staff members is working for the Division as a part time consultant. The Division hired a new site inspector due to the retirement of the previous site inspector. The review team concluded that the current staffing level is adequate for the program. Division turnover is very low with vacant positions readily filled.

Staff training is adequate and comparable to NRC IMC 1246. Two inspectors are scheduled to attend the Inspection Procedures course in October, 2003. The review team and the site inspector discussed the Division's inspection procedure to identify and characterize waste packages to ensure compliance with license conditions and State regulations. Further, the team conducted informal meetings with each of the staff members to discuss inspection procedures, inspection reports, and their technical backgrounds. The review team finds that the Division has an adequate level of well trained, experienced, and professional staff.

The Division contracted a licensed radiological laboratory to examine and perform necessary radiological analyses for environmental samples and samples collected during inspections. The contract laboratory is also used to ensure adequate quality assurance in radiological inspection measurements and environmental monitoring data.

4.3.2 Status of Low-Level Radioactive Waste Disposal Inspection

The review team examined the status of the LLRW inspection program regarding the frequency of State inspections of the disposal facility licensee. The review team found that inspections are conducted daily, by the on-site Division site inspector; weekly, by Division environmental engineers or health physicists; and annually by specialized professionals and managers. The review team confirmed the frequency of inspections through review of the site inspector logbook, and weekly and annual inspection reports. The frequency of inspections exceeded the annual inspection requirement specified in NRC IMC 2800.

The review team analyzed the State's capability for maintaining and retrieving data on the status of the inspection program. The Division maintained records of weekly and annual inspection reports. The site inspector maintains a log of each waste shipment received by the waste facility. The review team examined weekly and annual inspection reports, as well as waste shipment, reports, and found them to be complete. Licensee's responses and closure of inspection issues were well documented.

4.3.3 Technical Quality of Inspections

The annual and weekly inspection reports, as well as the site inspector logbook, were examined by the review team. Division inspections were technically accurate, thorough, complete, consistent, and of high quality with sufficient documentation to ensure that the licensee's

performance with respect to health and safety were acceptable. Staff technical analysis and rationale appeared sound without any technical flaws or errors. Inspectors appropriately performed independent measurements and analyses.

Division inspectors communicated inspection findings to the licensee in a timely fashion, documented licensee responses to inspection findings, and closed outstanding inspection issues. Division inspectors, the Section Manager and the Assistant Director participated in preparation, review, and approval of the annual inspection reports.

The review of the questionnaire response and discussions with Division staff confirmed that adequate calibrated instrumentation was available. The Department supplied instrumentation to the Transportation police in 1999 and the police maintain the calibration for that equipment. These instruments are not being used regularly for confirmation surveys. Because the Transportation police maintain, store, and use the survey instruments without assistance or oversight from the Department, the review team discussed with the Department several options to improve this situation. One possibility is that these instruments might be transferred permanently to the Transportation police.

The Division makes efficient use of digital images to document site and shipment conditions. Variations are photographed for future use or to send to the shipper in the case of a violation. The MRB found this to be a good practice as it efficiently documents violation information and the exact details of the violation to the shipper. The practice could be extended to other inspection processes such as radiography field inspections or gauge inspections.

The review team also examined documentation regarding the LLRW facility's daily, planned closure, and post-closure operations. The site inspector kept records of waste shipments, type, originator, volume, and activity. The detail and completeness of the site inspector's records have increased since the previous IMPEP review. Records of the staff's exposure as well as quarterly data on environmental data were maintained. Copies of verification data submitted to Chem-Nuclear for class types (specifically for Class C waste) were kept along with copies of the waste disposal requests submitted by the waste originators (or waste brokers). The Division also kept good records of informal plans for site closure. These plans covered future waste volume to be received, maximum capacity of the site for disposal, and financial assurance funds for site closure.

The review team examined the State's program to monitor the Barnwell site's condition during operations. The Division reviews characterization of disposal trenches and depth of the water table. Staff documented trench construction to ensure structural stability and took action regarding any deviations from the approved designs. Characterization of site performance is also carried out through enforcement of environmental surveillance license conditions. The Division reviews air sampling and monitoring well data. Selected groundwater wells are sampled quarterly by Chem-Nuclear, with Division oversight, and samples are split with the Division for analysis. The Division's split samples are analyzed by General Engineering Laboratories, an EPA-licensed laboratory, to conduct radiological analyses and to examine Chem-Nuclear environmental data. The team found the Division's oversight of the characterization program very thorough, consistent and of high quality. The Division has added

a requirement for Chem-Nuclear to provide temporal trends in groundwater concentrations at selected wells on an annual basis. The first report is due to the Department in the fall of 2003.

4.3.4 Technical Quality of Licensing Actions

The review team evaluated licensing actions for the LLRW disposal facility. The Division maintains complete licensing records regarding licenses, amendments and renewals. The team examined the Division's approaches and procedures to control the type of waste products disposed at the facility. Typically, the Division reviews the "Radioactive Waste Prior Notification and Manifest Forms," before waste shipments are made. This review is done to ensure that waste characteristics and classifications are adequately analyzed and documented. Further, the Division requires an advance verification of Class C waste. Waste originators go through a comprehensive analysis to demonstrate that radioactive waste is not greater than Class C. The Division has procedures and license conditions to ensure that the licensee does not accept radioactive waste for storage or disposal unless the shipper has completed the required information for the waste shipment on the NRC's LLRW Manifest Forms 540 "Shipping Papers," 541 "Container and Waste Description," and 542 "Manifest Index and Regional Compact Tabulation," as applicable, or approved equivalent forms.

Overall, the team found that Division licensing actions were very thorough, complete, consistent, of high quality and properly addressed health and safety issues. The State also monitors the limits of maximum radioactivity, mass, and volume of each waste shipment, and the total annual waste inventory at the facility. The Division also examines waste types to ensure that unusual hazardous materials, or potential hazardous material, such as gaseous, chemical, free standing liquids, or pyrophoric, are excluded from waste shipments.

The review team determined that the Division strictly enforces license conditions regarding waste type, waste class, activity, and volume, including granting variances under certain circumstances. The review team evaluated several of the variances granted and found the Division's actions are very thorough, complete, consistent, of high quality, and properly address health and safety issues.

The review team noted that site data continues to show offsite tritium releases; however, the Division's estimate of doses from such releases are less than allowable limits under the State regulations. Initial trending analyses indicate that the final covers appear to be effective as the onsite tritium concentrations are decreasing. However, the offsite concentrations have increased over the performance period and it is not clear that the peak concentrations have reached the site boundary. The new requirement for trending data will greatly enhance the State's ability to evaluate this issue.

The review team assessed the Division decommissioning procedures regarding disposal capacity, site closure, and environmental surveillance. The team evaluated the Division licensing guides, policies, memoranda, and adopted regulations. The program was found to have adequate internal licensing guides and general licensing procedures. The Division also adopted NRC's regulations and common LLRW guidance documents.

The team examined the safety reports applicable to site operations, license amendments, and licensing decisions. In most cases, licensing actions did not warrant preparation of safety reports other than those submitted by waste generators or Chem-Nuclear. In some complex cases, engineering reports and safety analyses were provided for specific waste shipments such as reactor pressure vessels. The Division conducted adequate critical reviews of engineering and safety reports regarding non-routine waste disposal.

The Division provides opportunities for public involvement regarding licensing actions. Public hearings are not typically held for radioactive material license renewals and have not been held for renewals of this license in the past. However, to provide a more open process, the Division will hold a public hearing to receive comments regarding the license renewal. The Division is planning to conduct the hearing in Columbia, South Carolina. Opportunity for the public to provide written comments on the draft technical evaluation of the renewal package will also be provided.

The review team examined documentation of interactions with the licensee to ensure proper and clear communication of license conditions and regulatory requirements. Staff found complete and timely documentation of interactions with the licensee and clear regulatory requirements. No significant disagreements were noted with the licensee regarding implementation of the regulations and license conditions.

The team reviewed licensing actions pertaining to aspects of health physics, hydrology, and structural engineering. Reviews of public and radiation worker exposure were thorough and documented. Actions taken by the Division to require mitigative measures to address releases were very thorough, prompt, complete, consistent, of high quality and properly address health and safety issues. Actions regarding engineering assessment for transport and disposal of steam generators were of high technical quality and well implemented. The current staff review, including weekly inspections, of the cover design and other surface water management issues is adequate for current operations. The review team and Division staff discussed the importance of controlling surface water runoff and the need for active and passive maintenance of the site post closure. The Division agreed with the review team that the services of a surface water hydrologist during the development of the closure plan would be beneficial.

4.3.5 Response to Incidents and Allegations

The review team did not identify any incidents or allegations of safety concerns regarding the Barnwell LLRW disposal facility. The Division has procedures available to handle incidents and allegations that have been revised since the previous IMPEP review.

Based on the IMPEP evaluation criteria, the review team recommended and the MRB agreed that South Carolina's performance with respect to the indicator, Low-Level Radioactive Waste Disposal Program, was satisfactory.

5.0 SUMMARY

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

Below is a summary list of recommendations, as mentioned in earlier sections of the report, for evaluation and implementation, as appropriate, by the NRC. Also, the good practice noted in the report is identified.

RECOMMENDATIONS:

1. The review team recommends that NRC adopt and disseminate final guidance on field inspections for industrial radiography operations in the interest of establishing an identifiable national materials program standard. (Section 3.3)
2. The review team recommends that NRC clarify which supervisory levels require an inspection accompaniment, the frequency of those accompaniments and what level of documentation is appropriate. (Section 3.3)

GOOD PRACTICE:

The Division makes efficient use of digital images to document site and shipment conditions. Variations are photographed for future use or to send to the shipper in the case of a violation. The MRB found this to be a good practice as it efficiently documents violation information and the exact details of the violation to the shipper. The practice could be extended to other inspection processes such as radiography field inspections or gauge inspections.

LIST OF APPENDICES

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Attachment	August 27, 2003 letter from C. Earl Hunter, Commissioner, South Carolina Department of Health and Environmental Control

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	Area of Responsibility
James Myers, STP	Team Leader Legislation and Program Elements Required for Compatibility Sealed Source and Device Evaluation Program
Richard Woodruff, Region II	Response to Incidents and Allegations Technical Staffing and Training Inspector Accompaniments
Anthony Gaines, Region IV	Technical Quality of Licensing Actions
Michael Whalen, Jr., Massachusetts	Status of Materials Inspection Program Technical Quality of Inspections
Christopher McKenney, NMSS Melanie Wong, NMSS	Low-Level Radioactive Waste Disposal Program

APPENDIX B
SOUTH CAROLINA ORGANIZATION CHARTS
ML031910216

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Assistant Bureau Chief

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Director

Helen Grant

HW Compliance & Enforcement
Cheryl Coleman,
Manager

Lorria Caswell
LaTonya Derrick
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Carroll Burley
John Cooper
Eric DeBeaugrine
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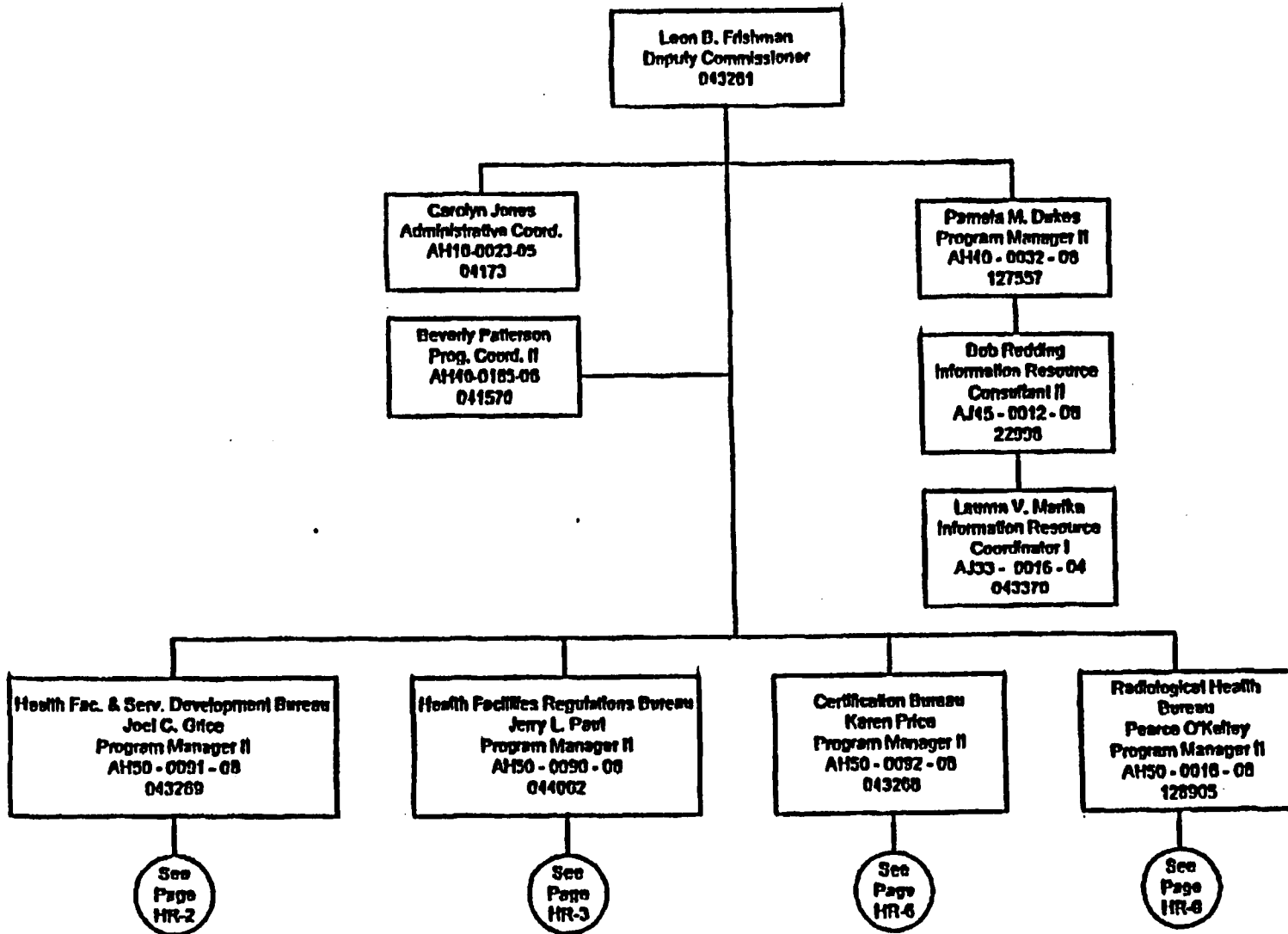
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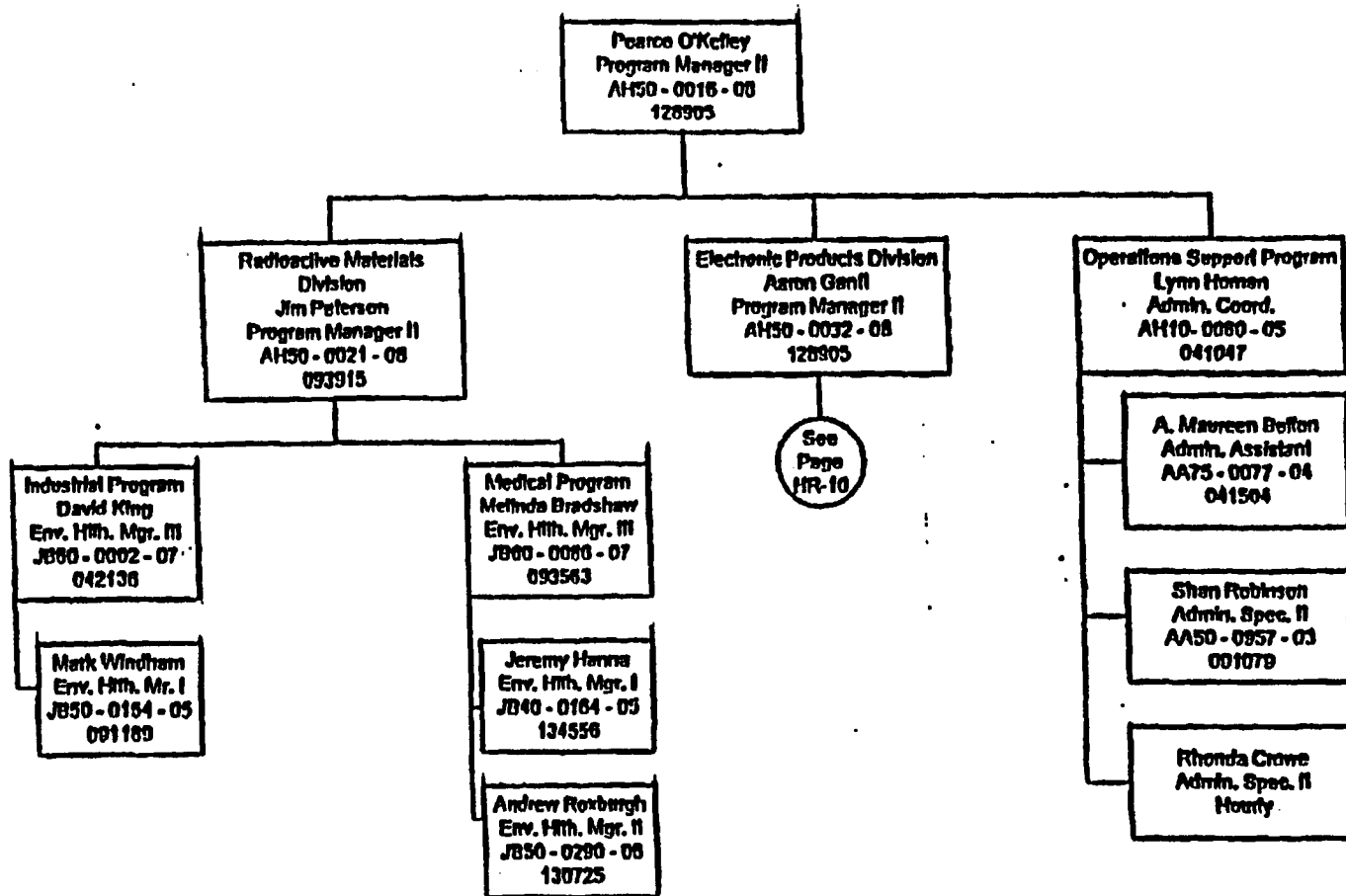
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Vacant

HEALTH REGULATION



Radiological Health Bureau



ATTACHMENT

August 27, 2003 letter from C. Earl Hunter, Commissioner,
South Carolina Department of Health and Environmental Control

ML032410335

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C. Earl Hunter, Commissioner

Promoting and protecting the health of the public and the environment.

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L. Michael Blackmon
Coleman F. Buckhouse, MD

August 27, 2003

James H. Myers, Health Physicist
Office of State and Tribal Programs
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Dear Mr. Myers:

I would like to thank you on behalf of staff for the opportunity to review the U.S. Nuclear Regulatory Commission's (NRC) July 11, 2003 draft Integrated Materials Performance Evaluation Program (IMPEP) report. We also appreciate the professional manner in which the performance evaluation was conducted. The Department has reviewed the report and has the following comments addressing the technical and clerical accuracy of the report:

1. Page 6, Section 3.3, discusses collection of certain inspection data and that some information collected may be contrary to the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPPA). The Bureau's record keeping has been reviewed by our HIPPA compliance group and is in compliance with agency standards. We feel that comments on HIPPA are outside of the scope of IMPEP and should not be included in the NRC report.
2. Page 6, Section 3.3, second paragraph, regarding the sentence, "*Division reports are initialed by the Division Director.*" This sentence should read, "*Division reports are initialed by the Assistant Director and/or the Section Manager.*"
3. Page 10, Section 4.1.2, the first sentence of the first paragraph should state, "*Radioactive Materials Regulation 61-63, Title A, apply to all material that emit ionizing radiation.*"
4. Page 10, Section 4.1.2, the second sentence of the second paragraph should read, "*The review team examined this process and found that the rulemaking takes about six to nine months from the development stage to publication of the final rule in the State Register.*"
5. Page 10, Section 4.1.2, the fifth sentence of the second paragraph should read, "*Comments are considered and incorporated, as appropriate, before regulations are finalized, approved, and published in the State Register.*"

6. Page 10, Section 4.1.2, in the final sentence of the second paragraph the word *Council* should be replaced by the word *Board*.
7. Page 12, Section 4.3, the second sentence of the second paragraph should read, "*This fiscal year's limit is 70,000 cubic feet.*"
8. Page 12, Section 4.3, the last sentence of the second paragraph should read, "*in May 1999 DHEC determined that the estimated disposal capacity of the site was approximately 3.2 million cubic feet. Since then, the site has received 410,368 cubic feet of waste leaving a remaining approximate capacity of 2.8 million cubic feet.*"
9. Page 12, Section 4.3.1, the fourth sentence of the first paragraph should read, "*During the review period two staff members retired. One of these staff members is working for the Division as a part time consultant.*" In addition, one administrative employee moved to take another position within state government. The Division replaced this administrative employee during the review period.
10. Page C.6, for File No.: 31, the inspector should be *MB* not *JH*.
11. Page C.7, for Accompaniment No.: 1, the license number should be *675* not *047-02*.

We thank the team for their comprehensive review of South Carolina's Agreement State Program and for the courtesy and professionalism they demonstrated throughout the process. If you have any questions concerning these comments, please contact Pearce O'Kelley at (803) 545-4400 or Henry Porter at (803) 896-4240.

Sincerely,



C. Earl Hunter, Commissioner
SC Department of Health and Environmental Control