

DATED: MAY 25, 1999; SIGNED BY: FRANK J. MIRAGLIA, JR.

Sharon Heber, M.P.H., Director
Division of Environmental Health
Florida Department of Health
2020 Capital Circle, SE, Bin #A08
Tallahassee, FL 32399-1709

Dear Ms. Heber:

On May 20, 1999, the Management Review Board (MRB) met to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) report on the Florida Agreement State Program. The MRB found the Florida program adequate to assure public health and safety and compatible with NRC's program.

Section 5.0, page 15, of the enclosed final report presents the IMPEP team's recommendations. We received your April 6, 1999 letter which described your actions taken in response to the recommendations in the draft report. We request no additional information.

Based on the results of the current IMPEP review, the next full review will be in approximately 4 years.

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

Sincerely, */RA/*

Frank J. Miraglia, Jr.
Deputy Executive Director
for Regulatory Programs

Enclosure:
As stated

cc: William A. Passetti, Chief
Bureau of Radiation Control

Sharon Heber, M.P.H., Director
 Division of Environmental Health
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 Deputy Executive Director
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Enclosure:
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cc: William A. Pasetti, Chief
 Bureau of Radiation Control

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

Distribution: See next page

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF FLORIDA AGREEMENT STATE PROGRAM

February 22 - 26, 1999

FINAL REPORT

U.S. Nuclear Regulatory Commission

1.0 INTRODUCTION

This report presents the results of the review of the Florida radiation control program. The review was conducted during the period February 22-26, 1999 by a review team comprised of technical staff members from the Nuclear Regulatory Commission (NRC) and the Agreement State of New York. Review 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, revised NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." Preliminary results of the review, which covered the period March 4, 1995 to February 21, 1999, were discussed with Florida management on February 26, 1999

A draft of this report was issued to Florida for factual comment on March 19, 1999. The State responded in a letter dated April 6, 1999. The Management Review Board (MRB) met on May 20, 1999, to consider the proposed final report. The MRB found the Florida radiation control program was adequate to protect public health and safety and compatible with NRC's program.

The Florida Agreement State program is administered by the Bureau of Radiation Control (BRC) located in the Department of Health (DOH). The BRC consists of five sections managed by a Chief. Three sections within BRC have responsibilities for radioactive materials under the Agreement, which includes inspectors in six field offices and two counties under contract. The Administrators of the Field Operations Section, Environmental Radiation Labs Section and Radioactive Materials Section report to the Chief, BRC. Organization charts for the BRC and DOH are included as Appendix B. The Florida program regulates approximately 1,169 specific licenses authorizing agreement materials. The review focused on the materials program as it is carried out under the Section 274b. (of the Atomic Energy Act of 1954, as amended) Agreement between the NRC and the State of Florida.

In preparation for the review, a questionnaire addressing the common and non-common performance indicators was sent to the State on November 13, 1998. The State provided a response to the questionnaire on January 21, 1999. A copy of the questionnaire is included in Appendix G of the draft report.

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

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 performance indicators, and Section 5 summarizes the review team's findings and recommendations. Recommendations made by the review team are comments that relate directly to program performance by the State.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

The previous review of the Florida radiation control program concluded on March 3, 1995. The review consisted of an evaluation of 30 program indicators per the 1992 Policy Statement. During the last review, two recommendations were made in the May 18, 1995 letter to Dr. Richard Hunter, Deputy State Health Officer, Department of Health and Rehabilitative Services. Both items were discussed in the NRC's February 14, 1996 letter to Florida based on the State's June 28, 1995 response letter. The team's review of the current status of the open recommendations is as follows:

1. We recommend that the pre-license inspection reports and the routine inspection reports include documentation on the method(s) used for verifying that rooms in licensee facilities are under negative pressure (when required), and the results of any measurements performed by the inspector.

Current Status: The State's pre-licensing and routine inspection reports now include the means to document methods used for verifying that rooms in licensee facilities are under negative pressure and the results of any measurements performed by the inspector. The review team noted during this review that inspectors were documenting independent measurements in the inspection reports. This recommendation is closed.

2. We recommend that a confirmatory survey be performed on the OTPO Mechanik, Inc. facility in Melbourne, Florida to determine if the former licensed facility can be released for unrestricted use.

Current Status: The OTPO Mechanik, Inc. facility requested termination of their license in November 1995 which included a closeout survey of the facility. The State performed a confirmatory survey in December 1995 at the facility. Based on the information provided by the licensee and the State's confirmatory survey, the license was terminated on January 17, 1996 and the facility released for unrestricted use. This recommendation is closed.

3.0 COMMON PERFORMANCE INDICATORS

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

3.1 Status of Materials Inspection Program

The team focused on four factors in reviewing the status of the materials inspection program: inspection frequency, overdue inspections, initial inspection of new licensees, and the timely dispatch of inspection findings to licensees. The evaluation is based on the Florida questionnaire responses relative to this indicator, data gathered from reports generated from the licensee databases, examination of inspection reports, and interviews with BRC staff.

Evaluation of Florida's inspection priorities for the materials program indicated that the maximum period for an inspection interval is four years, and 25 of the 41 licensee categories established by the State have a higher inspection frequency than similar type categories listed in NRC Inspection Manual Chapter (IMC) 2800. None of the State categories had a lower frequency of inspection. It was noted that the State uses discretion to increase inspection frequency (decrease inspection interval) based on licensee history and performance, but did not decrease inspection frequency for good performance.

The BRC currently uses a dBase IV software application for tracking inspection frequency, but will be converting to a latter generation database application in the near future. Currently, most staff have access to the database information, but updates to, and reports from the database are generated by the Radioactive Materials Section. Therefore, the Radioactive Materials Section at the Tallahassee office generates, on a quarterly basis, the schedule for the inspection groups in the field offices. A monthly status report to the Field Operations Administrator in Tallahassee reflects a statistical update of inspections performed and those due for the quarter, and emphasizes any past due by field office and licensee name.

Inspectors in the six state and two county field offices perform inspections according to the quarterly scheduling report generated by the Tallahassee office. A policy exists for establishing the date for the next scheduled inspection based on the date of the last inspection and the inspection priority. BRC considers the inspection timely if it is performed by the end of the calendar quarter in which the due date falls (regardless of the priority interval). Since the inspection frequencies for routine inspections are more frequent or as frequent as those required by the NRC, the scheduling of inspections does not fall outside of NRC requirements.

In their response to the questionnaire, the State indicated that they had no inspections overdue by more than 25% of the NRC frequency. During the review, the team verified that there were no inspections that were overdue by this criteria.

With respect to initial inspections, BRC assigns the inspection due date six months from the issuance of a new license. Since inspectors are given until the end of the calendar quarter to perform the inspection due in that quarter, this has resulted in several initial inspections being conducted outside of the six month period required by IMC 2800. Of the 30 initial inspections reviewed, nine were completed within six months, 20 were inspected between seven and nine months, and one was within 10 months. However, the existing scheduling system maintained by BRC appears to be very efficient in tracking and scheduling initial inspections. The team

considered this data and noted that the State has an established policy of performing pre-licensing visits by licensing staff and/or inspectors. This mechanism for inspecting and evaluating the initial use of radioactive material by a licensee more than adequately addresses the public health and safety concerns.

With respect to reciprocity, BRC issues a general license to all out-of-State licensees that desire to operate within Florida. Holders of out-of-State licenses are required to provide three days notification of any planned use of radioactive material at a temporary job site in Florida. The review team noted that the inspection of Priority 1 and 2 licensees granted reciprocity during the review period fell short of the goals indicated in IMC 1220. However, inspection of teletherapy, high dose afterloaders (HDR) and irradiator source services, and Priority 3 reciprocity licensees, met the IMC 1220 goal in 1998.

The BRC identified that this inspection shortfall resulted from these licensees (i.e., radiographers) entering the State to conduct licensed activities for a short time, usually 1 or 2 days. Field sites were sometimes located in remote areas of the State, making inspection of these licensees difficult. The review team noted, though, that in mid-1998, management placed emphasis on the urgency of performing reciprocity inspections, ranking them just below incident response in importance, and began tracking these inspections separately from the routine inspection to place more importance on their completion.

Timeliness of inspection correspondence issuance was evaluated during the inspection casework review. Of 53 inspection letters reviewed by the team, 31 were issued to the licensee within 30 days, 20 were issued between 31 and 35 days, one at 49 days, and one at 59 days. The 49 day report was delayed because of communications with the licensee between the inspection and the final report, and the 59 day report was considered an outlier because of a difficulty created by a mis-transfer of field notes. The review team considered the issuing of inspection correspondence timely, noting that BRC conducts approximately 500 inspections annually, and the Tallahassee office coordinates inspection correspondence from eight field offices that serves to ensure consistency for compliance of licensed activities across the State.

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

3.2 Technical Quality of Inspections

The team evaluated the inspection reports, enforcement documentation, and interviewed inspectors for 24 radioactive material inspections conducted during the review period. The casework included at least one inspector from each of the eight field offices and covered inspections of various types including: medical institutions, industrial radiography, nuclear pharmacy, irradiator, academic broad scope, medical broad scope, waste processing, transportation, mobile nuclear medicine, HDR and reciprocity. Appendix C lists the inspection casework reviewed for completeness and adequacy with case-specific comments.

Currently there are 24 radioactive material inspectors operating out of six state field offices and two county offices. All inspectors are trained to perform x-ray and radioactive materials inspections, and respond to radioactive materials incidents and incidents at nuclear power facilities.

Florida's inspection procedures are consistent with NRC procedures. The BRC tries to conduct inspections unannounced, but a majority of the time, inspections are announced a few days before the inspection. The review team noted that, of the 24 inspections evaluated, 11 were unannounced. According to the BRC annual report, 32% of the inspections were unannounced during 1998.

Based on casework, the review team noted that the routine inspections covered all aspects of the licensees' radiation programs. The review team found that inspection reports were thorough, complete, consistent, and of high quality, with sufficient documentation to ensure that licensee's performance with respect to health and safety was acceptable. The documentation supported violations, recommendations made to the licensee, unresolved safety issues, and discussions held with the licensee during exit interviews. Team inspections were performed when appropriate and for training purposes.

The inspectors fill out a report of two or more pages. The first page is the contact form and contains licensee data, persons contacted, type of inspection, time spent for the inspection, inspector's and supervisor's signature, and other administrative information. The second and subsequent pages of the inspection report are summary sheets denoting violations of regulations or license conditions, documentation to support the violations, recommendations made to the licensee, unresolved or licensing issues, and exit interview discussions and comments. This report, along with the inspection field notes, is sent to the Tallahassee Radioactive Materials Section within 15 days of the inspection.

The inspection report and field notes are reviewed and signed by the field office manager. Once received in Tallahassee, the inspection coordinator reviews the inspection findings and prepares appropriate correspondence to the licensee. The inspection coordinator contacts the inspector or office manager for clarification of the inspection findings if necessary. The Radioactive Materials Administrator reviews and concurs on all inspection correspondence. Subsequent correspondence between the licensee and the BRC is conducted with the Tallahassee office.

Inspection findings, including escalated enforcement actions, are routinely sent to the licensee around thirty days with licensee responses returned in a timely manner. Boilerplate language is used to generate compliance letters and violations to ensure consistency. Responses are reviewed and replied to in a timely manner. The inspection files were generally found to be complete and in good order. The review team noted that in two cases, the inspection documentation maintained in Tallahassee did not include field notes or the inspection report. In one case, the inspection report was prepared by the field office but was not sent to the Tallahassee office along with the contact form and in the second case, no field notes were prepared by the field office. As noted in the previous section, this mis-transfer affected the timely preparation of inspection correspondence to the licensee. The review team discussed the field offices timely transmittal of field notes to Tallahassee to facilitate the preparation of correspondence to the licensee.

Field notes have been developed to cover most types of inspections that are conducted by the BRC. These field notes provide documentation for the scope of the licensees' program and cover all areas that need to be reviewed. The information contained in the field notes is comparable with NRC's Inspection Procedure 87100.

The review team noted during the review of casework that the Jacksonville and Polk County offices developed their own field notes for the inspection of a waste processor and a panoramic irradiator, respectively. Other field offices are using existing field notes customized by each inspector for panoramic irradiators. BRC's inspection procedure manual does not include field notes for these types of licenses due to the small number of licensees in the State. The review team recommends that BRC incorporate the field notes for the inspection of waste processing and panoramic irradiator licensees in their inspection procedures manual.

Inspection accompaniments are most frequently performed by the field office manager. Senior inspectors also accompany less experienced inspectors, particularly for training purposes. In addition, the review team noted that the Field Operations Administrator will accompany field office managers. Field office managers are required to perform a minimum number of x-ray and material inspections each year to maintain proficiency. The review team noted that inspectors are accompanied at least once a year.

The Field Operations Administrator visits a field office each quarter on a rotating basis to attend a quarterly staff meeting and if necessary perform an annual office audit. Otherwise, the field office manager performs this annual field office audit.

The BRC has an adequate supply of survey instruments to support the current inspection program. Appropriate, calibrated survey instrumentation such as GM meters, scintillation detectors, ion chambers, and micro-R meters were observed to be available in the Field Offices and in the Orlando Environmental Laboratory. The Environmental Laboratory provides support to the program through radiological analyses of environmental samples and samples taken by inspectors during inspection activities, and environmental dosimetry around nuclear facilities. The laboratory also has a calibration facility that provides low and high range calibration of portable instrumentation used by local governments during emergency exercises, and portable instrumentation utilized by the BRC inspectors. Instrument repair and calibration are also available from the instrument manufacturers as needed. Instrumentation and a mobile laboratory are also available for responding to incidents as needed. The program has the capability for analyzing all types of environmental media, and evaluation of all types of radiation.

During the weeks of February 1 and 15, 1999, a review team member performed six accompaniments with inspectors from each of the State's field offices. The inspections included a private nuclear cardiology facility, two radiopharmacies, a private brachytherapy facility with an HDR unit, and two institutional nuclear medicine facilities. These accompaniments are also identified in Appendix C. During the accompaniments, the Florida inspectors conducted performance based inspections and demonstrated thorough 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 excellent, and their inspections were adequate to assess radiological health and safety at the licensed facilities.

Based on the IMPEP evaluation criteria, the review team recommends that Florida's performance with respect to the indicator, Technical Quality of Inspections, be found satisfactory.

3.3 Technical Staffing and Training

Issues associated with this indicator include the radioactive material program staffing level and staff turnover as well as the technical qualifications and training histories of the staff. To evaluate these issues, the review team examined the State's questionnaire responses related to this indicator, conducted interviews with BRC management and staff, and reviewed workload for backlog.

The BRC staffing level was stable over the review period. There are currently 54 people with various degrees of involvement with the Florida radioactive materials program, equivalent to about 20 FTEs to the Agreement program. This staffing level does not include clerical support staff. Of the 15 people in the Tallahassee central office, 10 individuals are involved with licensing full time, with the remaining five persons in management and support contributing about 30% of their time to the materials program. The remaining 39 persons are distributed among six field offices throughout the State. The inspectors spend about 18% of their time performing materials inspections, with the balance of time dedicated to x-ray equipment inspections. During the review period, three people left the Tallahassee office and two new people were hired. For the field offices, 13 positions were vacated and 10 of those positions were filled during the review period. Currently, three field office positions are vacant, and there is no intent to fill them in the immediate future, justified by the decreased frequency of required x-ray equipment inspections.

The BRC also has contracts with Polk and Broward Florida counties to perform material and x-ray inspections. Three inspectors are employed by the two counties. The counties are paid for each inspection they perform and receive a portion of the annual fee for each licensee in the county. Although the BRC does not direct administrative control over these inspectors, they receive the same training and are required to follow the same inspection and incidence response guidance as the State field offices.

Due to the relatively low turnover rate for a program this size, the staff consists of experienced personnel, with newer personnel mostly in the inspection area. Among the materials program staff, there are three with associate degrees, with the remainder having bachelor degrees or higher, with several people with multiple degrees. A recent re-designation of the health physicist positions to environmental specialist positions re-evaluated staff qualifications because the new positions require a bachelor degree or equivalent; the incumbents with associate degrees and experience were found to be bachelor degree equivalent.

Based on the lack of backlogs and the quality of the licensing actions and inspection reports, the team concluded that the number and distribution of staff appear to be adequate to maintain the program.

Training for licensing and inspection staff is similar to recommendations developed by the NRC - Organization of Agreement State Joint Working Group. Because a majority of staff has been with the BRC for a number of years beyond the review period, training records reviewed showed extensive accumulation of both NRC and BRC training courses. New personnel receive a combination of training modalities as they become available. For instance, general health physics training is provided through home study courses, in-house training material, computer-based training, university-based training (Universities of Florida and North Carolina), licensee and vendor-based training (i.e., cancer institutes, Syncor, Troxler), and professional meetings. BRC also uses NRC courses, depending on availability of courses and training funds.

Before performing an inspection independently, inspectors visit licensees' sites to observe inspections and become a lead inspector with an accompanying senior inspector or supervisor. Since each field office inspection team has a manager and a senior inspector, lead inspectors are accompanied frequently, often several times in one year, on various categories of licensees.

A good practice noted by the review team consisted of a basic health physics training module that was assembled and presented by the BRC staff. Because of the large and diversified staffing of the Florida program, BRC selected several staff members to submit topics in health physics for a five-day training program for BRC staff. Preparation consisted of video recording the instructor practice sessions, for self-critique and improvement on the course presentation.

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

3.4 Technical Quality of Licensing Actions

The review team examined completed licenses and casework for 25 licensing actions, representing the work of eight license reviewers. The license reviewers and Radioactive Materials Administrator were interviewed to supply additional information regarding licensing decisions or file contents.

Licensing actions were evaluated for completeness, consistency, proper isotopes and quantities used, qualifications of authorized users, adequate facilities and equipment, and operating and emergency procedures sufficient to establish the basis for licensing actions. Licenses were reviewed for accuracy, appropriateness of the license and of its conditions and tie-down conditions, and overall technical quality. Casework was evaluated for adherence to good health physics practices, reference to appropriate regulations, supporting documents, peer or supervisory review, and proper signature authorities. The files were checked for retention of necessary documents and supporting data.

The licensing actions reviewed included the following types of licenses: academic, medical and research and development (both broad scope and specific), industrial radiography, radiopharmacy, commercial service, large irradiator; self-shielded irradiator; portable and fixed gauges; and HDR/teletherapy. Licensing actions included three new licenses, twelve amendments, seven renewals, and three terminations. A list of these licenses with case-specific comments may be found in Appendix D.

All licensing actions are logged into a computer tracking system, assigned a control number, and reviewed by the Radioactive Materials Administrator who assigns each action. Monthly tracking reports are generated and reviewed. After an initial review, each licensing action, including the cover letter, is printed in draft, and then reviewed by a second, qualified reviewer or manager, and then by the Radioactive Materials Administrator. Reviews are documented (initialed) on the draft and sent to the Administrative Assistant. The Administrative Assistant confirms the proper review, prints the final for signature, and mails the license to the licensee. Each manager and the Radioactive Materials Administrator keeps documentation of the reviews. Boilerplate licenses as well as standard conditions for each type of amendment are used to generate all licenses and amendments thus ensuring a standard license/amendment. For all renewals, program staff verify corporate status via internet connection to the Florida Department of Corporations. All license reviewers have signature authority.

The review team found that the licensing actions were thorough, complete, consistent, and of high quality, with health and safety issues properly addressed. Tie-down conditions are backed by information contained in the file, and are inspectable. Deficiency letters clearly state regulatory positions, are used at the proper time, and identify deficiencies in the licensees' documents. Terminated licensing actions are well-documented, showing appropriate transfer and survey records. License files are complete and well organized. The program uses a combination of NRC and State regulatory guides. In addition, a number of additional guidance documents are used. Checklists for each category of license are used and kept with the license file. These documents are complete, well organized, available to reviewers, and appear to be followed.

Except for new licenses that only involve a change in ownership, pre-licensing inspections are conducted for all new applicants. These inspections are conducted normally within five days after the applicant is prepared to receive material or when the licensing action is complete. After the pre-licensing visit, the license is normally issued within a few days after the receipt of the contact form in the Tallahassee office from the inspector. If there are unresolved issues, the licensing section will address them with the applicant and reschedule the pre-licensing visit.

The program processed 5381 licensing actions during the review period. These consisted of 436 terminations, 482 new license applications, 571 renewals, and 3,892 amendments. Based on the files reviewed, actions were completed in a timely manner and complete. The review team noted that three license renewals and one termination that have been pending for extended periods without a written response by the program. This matter was discussed with BRC management to ensure that these actions are given higher priority to ensure timely completion.

Based on the IMPEP evaluation criteria, the review team recommends that Florida's performance with respect to the indicator, Technical Quality of Licensing, be found satisfactory.

3.5 Response to Incidents and Allegations

In evaluating 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 Florida in the "Nuclear Material Events Database" (NMED) against those contained in the Florida files, and evaluated the casework and supporting documentation for 12 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 10 materials allegations, five of which were referred to the State by NRC during the review period.

The review team discussed the State's incident and allegation process, file documentation, the State's equivalent to the Freedom of Information Act, NMED, and notification of incidents to the NRC Operations Center with BRC management and staff in Tallahassee and personnel in the Emergency Response Group under the Environmental Radiation Labs Section in Orlando.

When notification of an incident or an allegation is received, the Emergency Response Group Manager and staff at the Orlando office discuss the initial response and the need for an on-site investigation. The safety significance of the incident/allegation is evaluated to determine the type of response that BRC will take and to ensure that the appropriate field office is notified. After the investigation is completed, the pertinent information is forwarded to the Radioactive Materials Section at the Tallahassee office for close out approval and appropriate follow-up/enforcement actions.

The BRC has written guidance (SOP 1) for handling incidents and allegations. Although the State had no specific guidance for reporting to NMED or reference to the "Handbook on Nuclear Event Reporting in the Agreement States" in SOP 1, the staff was familiar with and followed the guidance contained in the Handbook. After a review of the incidents and discussions with staff, the review team found that all reportable materials events were appropriately reported to the NRC Operations Center. Approximately 575 other incidents that also occurred in the review period were voluntarily reported to the NMED system. SOP 1 also contains guidance on the handling of allegations. Although this guidance lacks the level of detail that is in NRC Management Directive 8.8, (e.g., the State has no definition specified for the term "allegation") the State does take prompt and appropriate action in response to the concerns raised.

The 12 incidents selected for review, out of the 136 submitted as reportable incidents, included radiation alarm events at waste facilities and steel recyclers, damaged portable gauge equipment, stolen radioactive material, loss of control of radioactive material, misadministrations, and a radiographer overexposure. 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 State took suitable enforcement action. The review team found the documentation of the response and follow-up to incidents consistent and that incidents were followed up at the next inspection or in a timely fashion. The team did note that the documentation of incident close out was not consistent. The majority of the incident close out memoranda did not contain a management signature or date.

During the review period, there were five materials allegations referred to the State by the NRC and numerous other allegations reported directly to the program. The review of the State's allegation files indicates that the State took prompt and appropriate action in response to the concerns raised. All of the allegations reviewed were appropriately closed, however the documentation of the closure was inconsistent in the same manner as that for incident close out. The review team also noted that allegations were treated and documented in the same manner as incidents. The team noted that, in accordance with State law, no measures exist to protect allegation related information except for medical records and social security numbers.

The review team recommends that BRC revise their incident and allegation procedures to document all existing State practices and to incorporate appropriate elements of OSP Procedure SA-300 "Handbook on Nuclear Event Reporting in the Agreement States" and NRC Management Directive 8.8, "Management of Allegations," particularly the required documentation and management approval for closing out incidents and allegations.

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

4.0 NON-COMMON PERFORMANCE INDICATORS

IMPEP identifies four non-common performance indicators to be used in reviewing Agreement State programs: (1) Legislation and Program Elements Required for Compatibility; (2) Sealed Source and Device Evaluation Program; (3) Low-Level Radioactive Waste Disposal Program; and (4) Uranium Recovery Program. Florida's agreement does not cover the 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

Along with their response to the questionnaire, the State provided the review team with the opportunity to review copies of legislation that effect the radiation control program. The currently effective statutory authority is contained in Chapter 404 of the Florida Statutes. The statutes were revised in 1997 to designate the Florida Department of Health as the State's radiation control agency. The BRC, Division of Environmental Health, DOH implements the radiation control program.

4.1.2 Program Elements Required for Compatibility

The Florida Control of Radiation Hazard Regulations, Chapter 64E-5, Florida Administrative Code (FAC), applies to all ionizing radiation. Florida requires a license for possession and use of all radioactive material including naturally occurring materials, such as radium, and accelerator-produced radionuclides. Florida also requires registration of all equipment designed to produce x-rays or other ionizing radiation.

The review team examined the State's administrative rulemaking process and found that the process takes three to six months from the development stage to the final filing with the Secretary of State, after which the rules become effective in twenty days. The regulation adoption process is provided in Chapter 1S-1 of the FAC. 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 the regulations are finalized, approved, and filed with the Secretary of State. 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, the NRC, and the U.S. Postal Service regulations that were in effect on May 15, 1996. The State also has the authority to issue legally binding requirements (e.g., license conditions) in lieu of regulations until compatible regulations become effective.

The team evaluated Florida's response to the questionnaire and reviewed the status of regulations required to be adopted by the State during the review period. The review team noted that following the Agency's reorganization under the Health Department, the regulations were recodified on July 17, 1997 as the Control of Radiation Hazard Regulations (CRHR), Chapter 64E-5, FAC. Following the recodification, the CRHR regulations were updated on May 18, 1998 to be compatible with NRC regulations with the adoption of NRC regulations as follows:

"Timeliness in Decommissioning of Materials Facilities," 10 CFR Parts 30, 40, and 70 amendments (59 FR 36026) that became effective August 15, 1994.

"Frequency of Medical Examinations for Use of Respiratory Protection Equipment," 10 CFR Part 20 amendment (60 FR 7900) that became effective March 13, 1995.

"Low-Level Waste Shipment Manifest Information and Reporting," 10 CFR Parts 20 and 61 amendments (60 FR 15649 and 25983) that became effective March 1, 1998. The Agreement States are to promulgate their regulations no later than March 1, 1998 so that NRC and the State would require this national system to be effective at the same time.

"Performance Requirements for Radiography Equipment," 10 CFR Part 34 amendment (60 FR 28323) that became effective June 30, 1995.

The team identified the following regulation changes and adoptions that are needed, and the State related that the regulations would be addressed in upcoming rulemakings or by adopting alternate legally binding requirements:

NRC's letter to the State dated November 24, 1997 identified two comments from the review of Florida's adoption of the 10 CFR Part 20 requirements. These comments related to: (1) the State's definition of "Occupational dose" [64E-5.101(93)]; and (2) the State's use of the term "planned exposure" instead of "planned special exposure" in the Occupational Dose Limits for Adults (64E-5.304(b)(2)).

"Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use," 10 CFR Parts 30, 32, and 35 amendments (59 FR 61767 and 65243) that became effective January 1, 1995.

"Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act," 10 CFR Part 20 amendment (61 FR 65119) that became effective January 9, 1997.

“Recognition of Agreement State Licenses in Areas Under Exclusive Federal Jurisdiction Within an Agreement State,” 10 CFR Part 150 amendment (62 FR 1662) that became effective February 27, 1997.

“Criteria for the Release of Individuals Administered Radioactive Material,” 10 CFR Parts 20 and 35 amendments (62 FR 4120) that became effective May 29, 1997.

“Licenses for Industrial Radiography and Radiation Safety - Requirements for Industrial Radiography Operations,” 10 CFR Parts 30, 34, 71, and 150 amendments (62 FR 28948) that became effective June 27, 1997.

“Radiological Criteria for License Termination,” 10 CFR Parts 20, 30, 40, and 70 amendments (62 FR 39057) that became effective August 20, 1997.

“Exempt Distribution of a Radioactive Drug Containing One Microcurie of Carbon-14 Urea,” 10 CFR Part 30 amendment (62 FR 63634) that became effective January 2, 1998.

“Deliberate Misconduct by Unlicensed Persons,” 10 CFR Parts 30, 40, 61, 70, and 150 amendments (63 FR 1890 and 13773) that became effective February 12, 1998.

“License for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations; Clarifying Amendments and Corrections,” 10 CFR Part 34 amendment (63 FR 37059) that became effective July 9, 1998.

“Minor Corrections, Clarifying Changes, and a Minor Policy Change,” 10 CFR Parts 20, 32, 35, 36, and 39 amendments (63 FR 393477 and 63 FR 45393) that became effective October 26, 1998.

“Transfer for Disposal and Manifest; Minor Technical Conforming Amendments,” 10 CFR Part 20 amendment (63 FR 50127) that became effective November 20, 1998.

The State acknowledged in a letter dated December 23, 1997 that the Part 20 equivalent regulations were oversights and that their regulations would be amended. During the review, the State related that the above regulations were being developed as a package and that the adoption process would be initiated during this calendar year. The State has deferred the medical regulation update until the final version of 10 CFR Part 35 is published which is expected by June 1999. The team noted that except for the OSP letter concerning minor discrepancies on the State's adoption of the 10 CFR Part 20 equivalent regulations and the medical regulations due in 1998, that the State has adopted all regulations and elements needed for compatibility. The review team recommends that the State complete adoption of the revisions to Part 20 to correct discrepancies identified in NRC letter dated November 24, 1997.

It is noted that Management Directive 5.9, Handbook, Part V, (1)(C)(III) provides that regulations required prior to September 3, 1997, should be adopted by the State as expeditiously as possible, but not later than three years after the September 3, 1997 effective date of the Commission Policy Statement on Adequacy and Compatibility, i.e., September 3, 2000.

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

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

4.2.1 Technical Quality of the Product Evaluation Program

During the review period, three Sealed Source and Device (SS&D) certificates were issued by the State. One certificate was for non-Atomic Energy Act (AEA) material and the other two SS&D certificates were reviewed and are identified in Appendix F.

Review of the files and interviews with the staff confirms that Florida follows the recommended guidance from the NRC SS&D training workshops. The registration files contain all correspondence, photographs, engineering drawings, radiation profiles, and results of tests conducted by the applicant. In addition, the SS&D review checklist received at the NRC SS&D workshop is used to help assure all relevant materials are submitted and reviewed. The checklist is contained in the registration file. The State indicated that the guidance in NUREG-1556, V.3, issued September 1997 will be utilized for any future reviews. All pertinent American National Standards Institute (ANSI Standards), Regulatory Guides, and workshop references were confirmed to be available and are used when performing SS&D reviews. The Radioactive Materials Administrator related that non-AEA reviews are performed in the same procedural manner and using the same references as used for AEA sources and devices.

4.2.2 Technical Staffing and Training

The Radioactive Materials Administrator conducts the SS&D reviews and is in the process of training other staff in the review of sealed sources and devices. The Radioactive Materials Administrator and the BRC Chief both have attended the SS&D workshops sponsored by NRC and both individuals have had many years of experience reviewing license applications. The Radioactive Materials Administrator also has advanced degrees in physics and both managers have many years of experience and training in health physics. Both individuals are considered fully trained for licensing and inspection under the common performance indicator, Technical Staffing and Training. The team found that the SS&D reviewers work together closely when conducting a review and discuss issues and concerns they have identified in an application. The BRC is committed to maintaining a high degree of quality in their SS&D reviews and would, if necessary, send their reviewers for additional training or seek assistance from outside sources.

4.2.3 Evaluation of Defects and Incidents Regarding SS&Ds

No incidents related to SS&Ds occurred during the review period, nor were there any defects reported.

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

4.3 Low-level Radioactive Waste (LLRW) Disposal Program

In 1981, the NRC amended its Policy Statement, "Criteria for Guidance of States and NRC in Discontinuance of NRC Authority and Assumption Thereof by States Through Agreement" to allow a State to seek an amendment for the regulation of LLRW as a separate category. Those States with existing Agreements prior to 1981 were determined to have continued LLRW disposal authority without the need of an amendment. Although Florida has LLRW disposal authority, NRC has not required States to have a program for licensing a LLRW disposal facility until such time as the State has been designated as a host State for a LLRW disposal facility. When an Agreement State has been notified or becomes aware of the need to regulate a LLRW disposal facility, they are expected to put in place a regulatory program which will meet the criteria for an adequate and compatible LLRW disposal program. There are no plans for a LLRW disposal facility in Florida. Accordingly, the review team did not review this indicator.

5.0 SUMMARY

As noted in Sections 3 and 4 above, the review team found Florida's performance to be satisfactory for all of the indicators. Accordingly, the review team recommended and the MRB concurred in finding the Florida Agreement State 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 implementation and evaluation, as appropriate, by the State. Also, the "good practice" noted in the report is identified.

RECOMMENDATIONS:

1. The review team recommends that BRC incorporate the field notes for the inspection of waste processing and panoramic irradiator licensees in their inspection procedures manual. (Section 3.2)
2. The review team recommends that BRC revise their incident and allegation procedures to document all existing State practices and to incorporate appropriate elements of OSP Procedure SA-300 "Handbook on Nuclear Event Reporting in the Agreement States" and NRC Management Directive 8.8, "Management of Allegations," particularly the required documentation and management approval for closing out incidents and allegations. (Section 3.5)

3. The review team recommends that the State complete adoption of the revisions to Part 20 to correct discrepancies identified in NRC letter dated November 24, 1997. (Section 4.1.2)

GOOD PRACTICE:

1. A good practice noted by the review team consisted of a basic health physics training module that was assembled and presented by the BRC staff that included the use of video recording the instructor practice sessions, for self-critique and improvement on the course presentation. (Section 3.3)

LIST OF APPENDICES AND ATTACHMENTS

Appendix A	IMPEP Review Team Members
Appendix B	Florida Organization Charts
Appendix C	Inspection Casework Reviews
Appendix D	License Casework Reviews
Appendix E	Incident Casework Reviews
Appendix F	Sealed Source and Device Casework Reviews
Attachment	Florida's Response to Draft IMPEP Report Dated April 6, 1999

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	Area of Responsibility
Duncan White, Region I	Team Leader Technical Quality of Inspections
Joseph DeCicco, NMSS	Status of Materials Inspection Program Technical Staffing and Training
Steven Gavitt, New York State Health	Technical Quality of Licensing Actions
Thomas O'Brien, OSP	Response to Incidents and Allegations
Richard Woodruff, Region II	Legislation and Program Elements Required for Compatibility Sealed Source and Device Evaluation Program Inspection Accompaniments

APPENDIX B

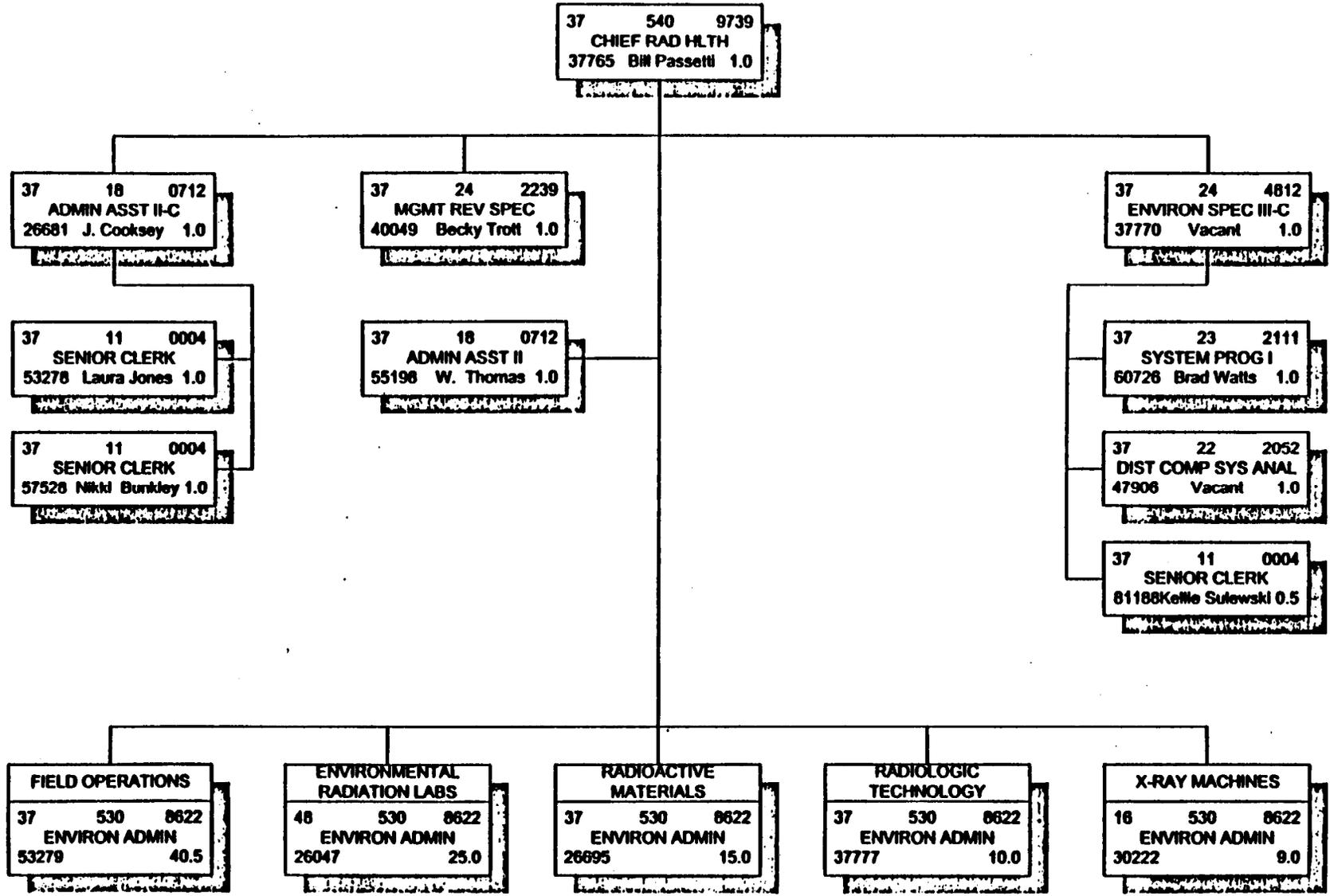
STATE OF FLORIDA

DEPARTMENT OF HEALTH
and
BUREAU OF RADIATION CONTROL

ORGANIZATION CHARTS

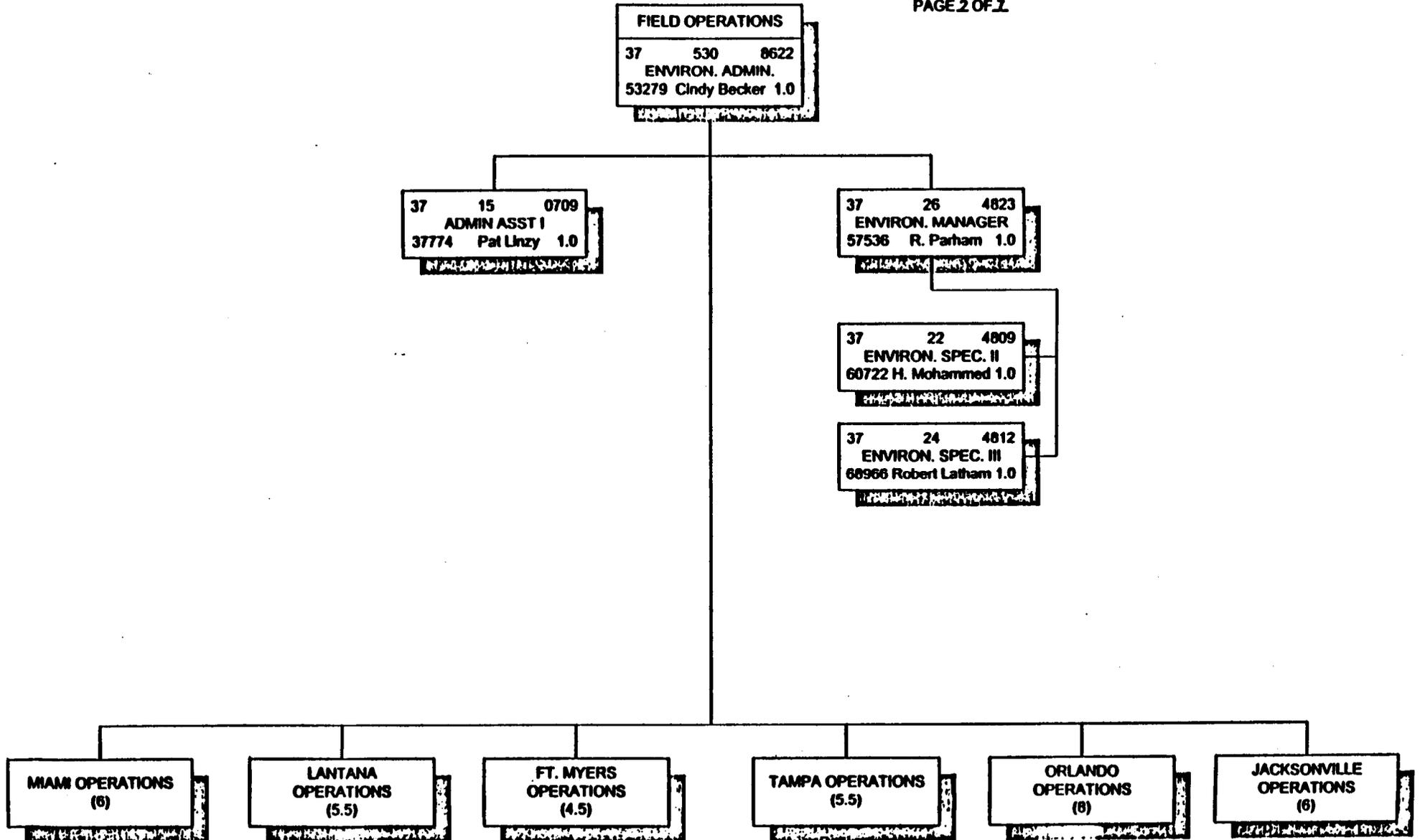
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 ENVIRONMENTAL HEALTH DIVISION
 BUREAU OF RADIATION CONTROL

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 PAGE 1 OF 2



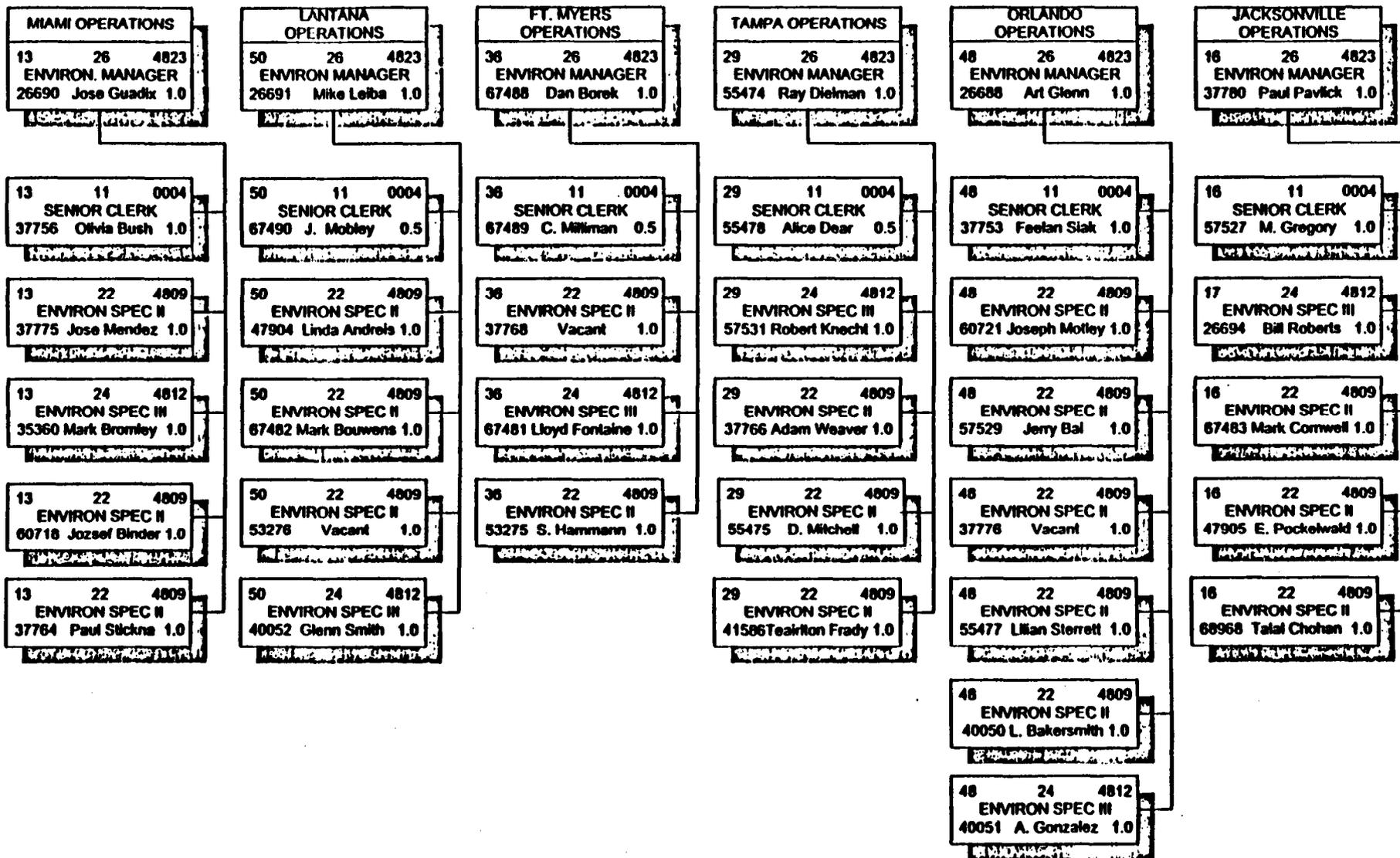
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ENVIRONMENTAL HEALTH DIVISION
BUREAU OF RADIATION CONTROL

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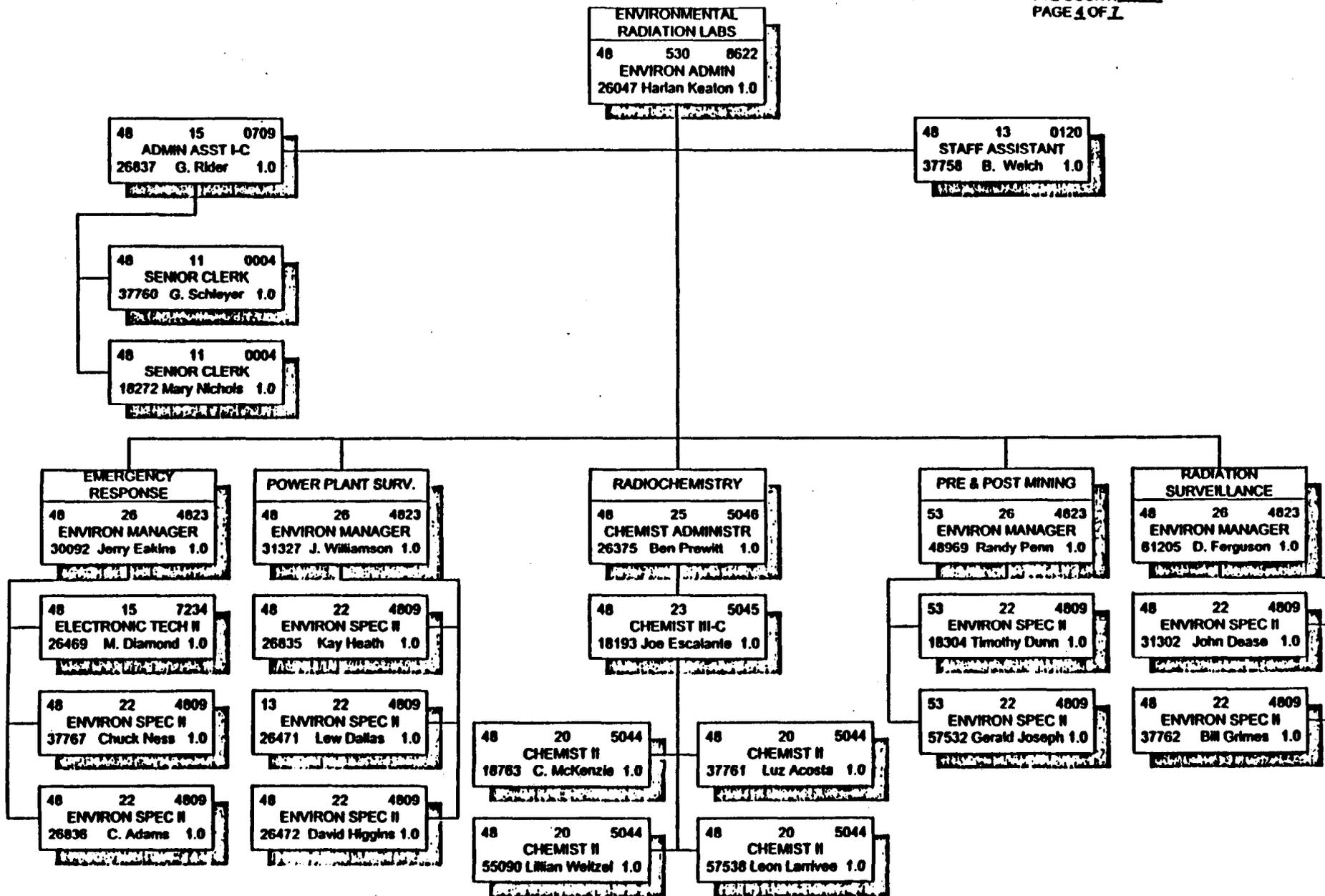
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 BUREAU OF RADIATION CONTROL

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ENVIRONMENTAL HEALTH DIVISION
BUREAU OF RADIATION CONTROL

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EFFECTIVE DATE: _____
FTE COUNT: 15.00
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**RADIOACTIVE
MATERIALS**
37 530 8622
ENVIRON ADMIN
26695 Mike Stephens 1.0

37 26 4823
ENVIRON MANAGER
31331 Paul Vause 1.0

37 24 4812
ENVIRON SPEC III
30906 Walter Cofer 1.0

37 15 0709
ADMIN ASST I-C
26680 Nancy McCoy 1.0

37 24 4812
ENVIRON SPEC III
53260 Peter Fadale 1.0

37 26 4823
ENVIRON MANAGER
26684 Debbie Gilley 1.0

37 22 4809
ENVIRON SPEC II
37769 J. Stephenson 1.0

37 22 4809
ENVIRON SPEC II
66405 Larry Shingler 1.0

37 11 0004
SENIOR CLERK
26692 Judy Jordan 1.0

37 11 0004
SENIOR CLERK
53281 Bridget Coales 1.0

37 11 0004
SENIOR CLERK
26473 Tony Jones 1.0

37 11 0004
SENIOR CLERK
57525 Monica Bryant 1.0

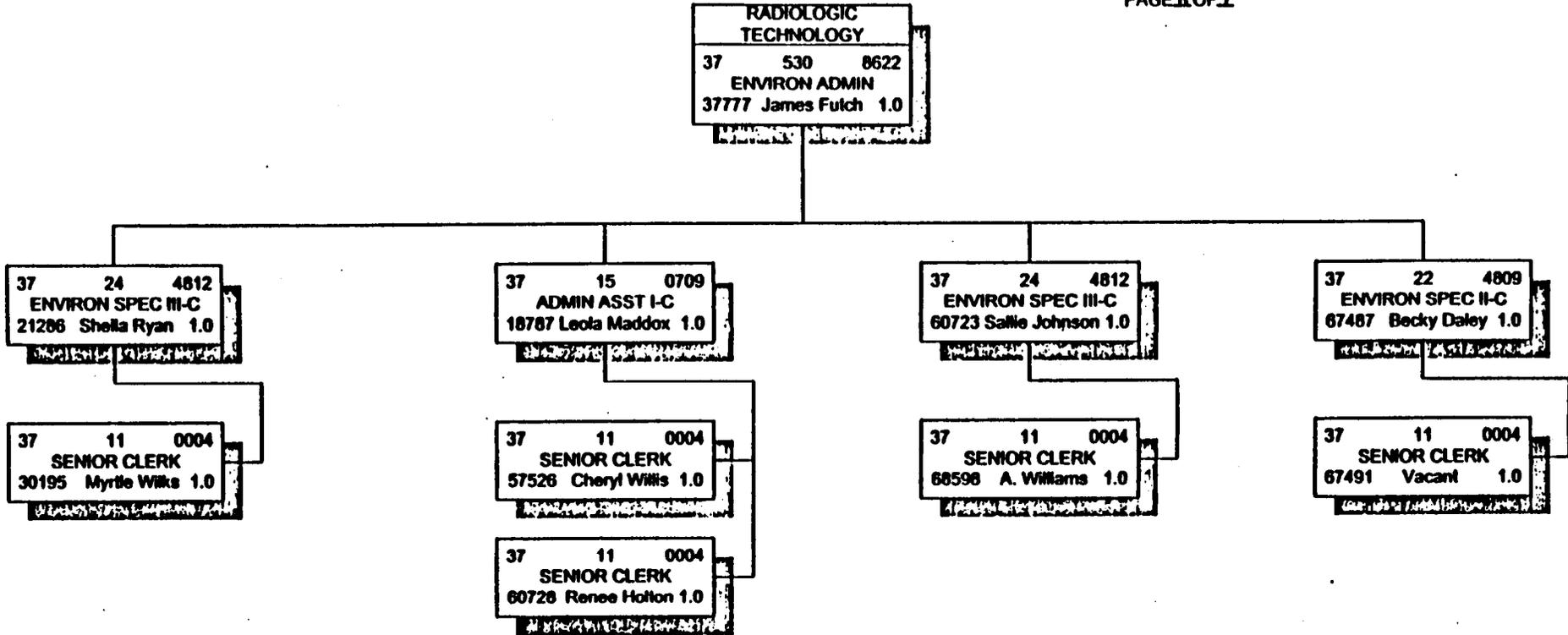
37 22 4809
ENVIRON SPEC II
57534 Richard Le 1.0

37 22 4809
ENVIRON SPEC II
57533 C. Hamilton 1.0

37 22 4809
ENVIRON SPEC II
67484 L. Mitchell 1.0

DEPARTMENT OF HEALTH
ENVIRONMENTAL HEALTH DIVISION
BUREAU OF RADIATION CONTROL

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EFFECTIVE DATE: _____
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DEPARTMENT OF HEALTH
ENVIRONMENTAL HEALTH DIVISION
BUREAU OF RADIATION CONTROL

APPROVED: _____
BUDGET ENTITY: _____
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