

## UNITED STATES NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

August 10, 2010

Donald E. Williamson, M.D. State Health Officer Department of Public Health P. O. Box 303017 Montgomery, AL 36130-3017

Dear Dr. Williamson:

On July 19, 2010, the Management Review Board (MRB) met to consider the proposed final Integrated Materials Performance Evaluation Program (IMPEP) report on the Alabama Agreement State Program. The MRB found the Alabama Agreement State Program adequate to protect public health and safety and compatible with the U.S. Nuclear Regulatory Commission's (NRC) program.

Section 5.0, page 11, of the enclosed final report contains a summary of the IMPEP review team's findings. Based on the results of the current IMPEP review, the next full review of the Alabama Agreement State Program will take place in approximately 4 years, with a periodic meeting tentatively scheduled for May 2012.

The MRB recognized that this review marked the fourth consecutive IMPEP review of the Alabama Agreement State Program in which the program was found adequate to protect public health and safety, compatible with NRC's program, and satisfactory for all performance indicators reviewed. These are the highest possible ratings for an IMPEP review. I applaud your staff for their dedication to excellence in radiation protection.

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

Sincerely,

/RA/

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

Enclosure: Alabama Final IMPEP Report

cc w/encl.: James L. McNees, CHP, Director

Alabama Office of Radiation Control



## INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM REVIEW OF THE ALABAMA AGREEMENT STATE PROGRAM

MAY 10-14, 2010

**FINAL REPORT** 

#### 1.0 INTRODUCTION

This report presents the results of the review of the Alabama Agreement State Program. The review was conducted during the period of May 10-14, 2010, by a review team composed of technical staff members from the U.S. Nuclear Regulatory Commission (NRC) and the Commonwealths of Kentucky and Pennsylvania. Team members are identified in Appendix A. The review was conducted in accordance with the "Implementation of the Integrated Materials Performance Evaluation Program and Rescission of Final General Statement of Policy," published in the *Federal Register* on October 16, 1997, and NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)," dated February 26, 2004. Preliminary results of the review, which covered the period of April 8, 2006, to May 14, 2010, were discussed with Alabama managers on the last day of the review.

A draft of this report was issued to Alabama for factual comment on June 1, 2010. The State responded by e-mail dated June 11, 2010, from James L. McNees, CHP, Director, Office of Radiation Control (the Office). A copy of the State's response is included as the Attachment to this report. The Management Review Board (MRB) met on July 19, 2010, to consider the proposed final report. The MRB found the Alabama Agreement State Program adequate to protect public health and safety and compatible with NRC's program.

The Alabama Agreement State Program is administered by the Office, which is located within the Department of Public Health (the Department). The Office Director reports to the State Health Officer, who serves as the Director of the Department. Organization charts for the Department and the Office are included as Appendix B.

At the time of the review, the Alabama Agreement State Program regulated 458 specific licenses authorizing possession and use of radioactive materials. The review focused on the radioactive materials program as it is carried out under the Section 274b. (of the Atomic Energy Act of 1954, as amended) Agreement between NRC and the State of Alabama.

In preparation for the review, a questionnaire addressing the common and applicable non-common performance indicators was sent to the Office on March 1, 2010. The Office provided its response to the questionnaire on April 15, 2010. A copy of the questionnaire response can be found in NRC's Agencywide Documents Access and Management System (ADAMS) using the Accession Number ML101470488.

The review team's general approach for conduct of this review consisted of: (1) examination of the Office's response to the questionnaire; (2) review of applicable Alabama statutes and regulations; (3) analysis of quantitative information from the Office's database; (4) technical review of selected regulatory actions; (5) field accompaniments of two inspectors; and (6) interviews with staff and managers. The review team evaluated the information gathered against the established criteria for each common and the applicable non-common performance indicator and made a preliminary assessment of the Alabama Agreement State Program's performance.

Section 2.0 of this report covers the State's actions in response to any recommendations made during previous reviews. Results of the current review of the common performance indicators

Alabama Final Report Page 2

are presented in Section 3.0. Section 4.0 details the results of the review of the applicable non-common performance indicators, and Section 5.0 summarizes the review team's findings.

#### 2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

During the previous IMPEP review, which concluded on April 7, 2006, the review team made no recommendations regarding the Alabama Agreement State Program's performance.

## 3.0 COMMON PERFORMANCE INDICATORS

Five common performance indicators are used to review NRC Regional and Agreement State radioactive materials programs. These indicators are: (1) Technical Staffing and Training, (2) Status of Materials Inspection Program, (3) Technical Quality of Inspections, (4) Technical Quality of Licensing Actions, and (5) Technical Quality of Incident and Allegation Activities.

## 3.1 <u>Technical Staffing and Training</u>

Issues central to the evaluation of this indicator include the Office's staffing level and staff turnover, as well as the technical qualifications and training histories of the staff. To evaluate these issues, the review team examined the Office's questionnaire response relative to this indicator, interviewed managers and staff, reviewed job descriptions and training records, and considered any workload backlogs.

When fully staffed, the Alabama Agreement State Program is composed of the Office Director, Assistant Director, and technical staff in two branches: the Radioactive Materials Inspection Branch and the Radioactive Materials Licensing Branch. A director heads each branch. Technical staff conducts inspections, performs licensing actions, and responds to incidents and allegations based on individual qualifications. Technical staff also has emergency response duties at Alabama's two operating nuclear power plants. Based on information provided by the Office, the review team estimated that the Office expends approximately 4.5 full-time equivalents (FTE) to administer the Agreement State program.

During the review period, one individual left the Agreement State program and no one joined the program; therefore, at the time of the review, the Office had one vacancy in the Agreement State program: the Assistant Director. The position became vacant in January 2010 after the former Assistant Director assumed the duties of the Office Director following the retirement of the former Office Director. Shortly thereafter, the former Assistant Director's promotion to the Office Director position became official. The Assistant Director position contributes approximately 0.25 FTE to the Agreement State program. The review team noted that the Assistant Director's Agreement State program duties had been temporarily absorbed by the Office Director and various technical staff members. At the time of the review, the Office had no immediate plans to fill the vacancy. The review team concluded that the vacancy does not have a major impact on the day-to-day operations of the Agreement State program as licensing and inspection backlogs have not developed since the position became vacant.

The Office has a documented training plan for technical staff that is consistent with the requirements in the NRC/Organization of Agreement States Training Working Group Report and NRC's Inspection Manual Chapter (IMC) 1246, "Formal Qualification Programs in the Nuclear

Material Safety and Safeguards Program Area." The Office uses on-the-job training, such as inspector accompaniments, to supplement formal coursework. Staff members are typically assigned increasingly complex duties as they progress through the qualification process. Staff members are authorized to perform regulatory duties independently after demonstrating competency. The Office Director signs off on all staff qualifications at the recommendation of the appropriate branch director.

The review team noted that the Office Director encourages and supports training opportunities, based on program needs. The review team concluded that the Office's staffing and training is adequate to carry out its regulatory duties.

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

## 3.2 <u>Status of Materials Inspection Program</u>

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

The review team verified that the Office's inspection frequencies for all types of radioactive materials licenses are at least the same frequency as those listed in NRC's IMC 2800, "Materials Inspection Program." The Office conducts inspections of some license types; such as medical – written directive not required, nuclear pharmacy, medical broadscope, and nuclear laundry; more frequently than prescribed by IMC 2800. The review team noted that Increased Controls inspections were being performed concurrently with routine safety inspections for applicable licensees. The review team also verified that the Office conducts inspections of multiple locations of use for multi-site licenses. In all instances reviewed by the team, the Office met or exceeded the minimum criterion of 20 percent of sites for licenses with five or more locations of use listed on the license.

The Office conducted a total of 412 Priority 1, 2, and 3 (high priority) inspections during the review period. The Office indicated in its response to the questionnaire, and the review team verified, that none of the 412 high priority inspections was conducted overdue by more than 25 percent of the inspection frequency prescribed by IMC 2800. The review team verified that no high priority inspections were overdue at the time of the review.

The review team also evaluated the Office's timeliness for conducting initial inspections. The review team noted that the Office issued 97 new licenses during the review period. The Office conducted 72 initial inspections, of which 5 were conducted greater than 12 months after license issuance as prescribed by IMC 2800. Of the 25 remaining new licenses, 12 licenses were issued to out-of-State firms with little to no work in Alabama during the review period, 4 licenses were terminated within the first 12 months, and the other 9 licenses had been issued within 12 months of the on-site portion of the IMPEP review and were not yet due for initial inspection.

Overall, the review team calculated that the Office performed 1 percent of its Priority 1, 2, and 3 and initial inspections overdue during the review period.

Page 4

The review team evaluated the Office's timeliness of issuance of inspection reports. The Office has a policy of issuing the inspection findings to licensees within 30 days from the date of the inspection. Inspectors are required to submit completed inspection reports to the Radioactive Materials Inspection Branch Director within 15 days for supervisory review. Of the 19 inspection files reviewed, the review team did not identify any inspection findings that were issued beyond the 30-day goal.

In reviewing the Office's performance of reciprocity inspections, the review team noted that Alabama regulations only allow 30 days of use of radioactive materials in the State under reciprocity compared to NRC's allowing 180 days under reciprocity in NRC jurisdiction. After 30 days, an out-of-State Alabama radioactive materials license must be obtained. During the review period, the Office received requests for reciprocity from 66 Priority 1, 2 and 3 licensees and inspected an average of 13 percent of those licensees annually. IMC 1220, "Processing of NRC Form 241 and Inspection of Agreement State Licensees Operating Under 10 CFR 150.20," requires inspection of 20 percent of candidate licensees operating under reciprocity annually. Strictly by the numbers, the Office's performance of reciprocity inspections falls below the performance criterion in IMC 1220; however, factoring in Alabama's shortened period of reciprocity, the review team concluded that the Office's performance of reciprocity inspections over the review period was acceptable. The review team noted that the shortened period of reciprocity greatly limits the Office's opportunities to catch licensees under reciprocity performing licensed work in Alabama as many of the licensees only came into Alabama for 1-2 days for a few hours at a time. Out-of-State licensees that were performing significant, longerterm work in the State were required to get an Alabama license after 30 days and these licensees were inspected in accordance with IMC 2800.

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

## 3.3 Technical Quality of Inspections

The review team evaluated inspection reports, enforcement documentation, and inspection field notes and interviewed the responsible inspector for 19 radioactive materials inspections conducted during the review period. The casework examined included a cross-section of inspections conducted by three current inspectors and covered a wide variety of inspection types. These included diagnostic nuclear medicine, high dose-rate remote afterloaders, industrial radiography, nuclear pharmacy, well logging, and research and development. The casework included initial, routine, followup, reciprocity, and Increased Controls inspections. Appendix C lists the inspection casework files reviewed.

Based on the evaluation of casework, the review team determined that inspections covered all aspects of the licensees' radiation safety and security programs. The review team noted that the inspections covered the Increased Controls, fingerprinting, and the National Source Tracking System when appropriate. The review team found that inspection reports were very thorough, complete, consistent, and of high quality with sufficient documentation to ensure that

licensees' performances with respect to health, safety, and security were acceptable. Inspection report documentation supported violations, recommendations made to licensees, and unresolved safety issues. In addition to paper copies that are maintained in Montgomery, pertinent information about each inspection is entered into the Office's electronic filing system, which is accessible to all staff members.

While on site, the review team evaluated the Office's handling and storing of sensitive documents. The review team determined that documents containing sensitive information were appropriately protected, segregated from other files (electronic and paper), and maintained in a manner to limit access. The review team found that outgoing correspondence was marked, as appropriate.

The Office has a policy to accompany all staff performing radioactive materials inspections on an annual basis. The Radioactive Materials Inspection Branch Director performs the inspector accompaniments. The review team verified that all staff members that regularly perform inspections were accompanied annually during the review period.

The review team accompanied two of the Office's inspectors during the period of April 26-28, 2010. The inspectors conducted inspections of a medical licensee, an industrial radiography licensee, and a nuclear pharmacy licensee. The inspector accompaniments are listed in Appendix C. The inspectors demonstrated performance-based inspection techniques and knowledge of the regulations. The inspectors were well trained, prepared for the inspections, and thorough in their audits of the licensees' radiation safety and security programs. The inspectors conducted interviews with appropriate personnel, observed licensed operations, conducted confirmatory measurements, and utilized good health physics practices. The inspectors held entrance and exit meetings with the appropriate level of licensee management. The review team determined that the inspections were adequate to assess radiological health, safety, and security at the licensed facilities.

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

## 3.4 Technical Quality of Licensing Actions

The review team examined completed licensing casework and interviewed license reviewers for 28 licensing actions for 22 specific licenses. Licensing actions were reviewed for completeness, consistency, proper radioisotopes and quantities, qualifications of authorized users, adequacy of facilities and equipment, adherence to good health physics practices, financial assurance, security requirements, operating and emergency procedures, appropriateness of license conditions, and overall technical quality. The casework was also reviewed for timeliness, use of appropriate correspondence, reference to appropriate regulations, supporting documentation, consideration of enforcement history, pre-licensing visits, peer or supervisory review, and proper signatures.

The licensing casework was selected to provide a representative sample of licensing actions completed during the review period. Licensing actions selected for evaluation include 12 new licenses, 2 renewals, 11 amendments, and 3 license terminations. Casework reviewed included

a cross-section of license types, including: medical and academic broadscope, medical institution – limited, private practice, mobile nuclear medicine, nuclear laundry, radiography, portable gauge, fixed gauge, and self-shielded irradiator. A listing of the licensing casework reviewed can be found in Appendix D.

The review team found that the licensing actions were thorough, complete, consistent, and of high quality with health, safety, and security issues properly addressed. License tie-down conditions were stated clearly, backed by information contained in the file and enforceable. The review team found that actions terminating licenses were well documented, included the appropriate material survey records, and contained documentation of proper disposal or transfer of radioactive material, as appropriate. The review team determined that the exemptions to Alabama's regulations that the Office granted during the review period and noted in its questionnaire response were appropriate.

During the licensing casework evaluations, the review team noted the Office's use of information technology to maintain records of authorized users, authorized nuclear pharmacists, authorized medical physicists, and radiation safety officers listed on licenses in the State of Alabama. The Office maintains the records in a searchable database that was created during the Office's normal licensing workload over the course of several years. The Office creates a record for each individual and lists each license on which that individual holds one of the aforementioned positions and, for authorized users, the modalities for which that individual has met the training and experience requirements. This database increases the efficiency of the Office's review of an individual's qualifications when a licensee requests that an individual be added to their license for a particular position or modality. With this database, the Office can quickly verify if the individual is already listed on another license in the State of Alabama and if that individual is indeed qualified to perform the duties for the position requested by the licensee. The review team recommended, and the MRB agreed, that the development and implementation of a user qualification database is a good practice.

The review team assessed the Office's implementation of the pre-licensing guidance. The Office has implemented the essential elements of NRC's pre-licensing guidance issued on September 22, 2008, and transmitted to the Agreement States via Office of Federal and State Materials and Environmental Management Programs (FSME) Letter RCPD-08-020, "Requesting Implementation of the Checklist to Provide a Basis for Confidence that Radioactive Material will be Used as Specified on a License and the Checklist for Risk-Significant Radioactive Material." The Office has a policy of hand-delivering all new licenses issued within the State of Alabama. Staff has the authority to withhold the license if suspicious activity is detected during delivery of the license. The hand-delivery of a new license constitutes a pre-licensing visit.

The review team evaluated the documentation for the pre-licensing visits of new applicants performed during the review period. The review team identified two cases where the applicant had not fully implemented the Increased Controls requirements prior to delivery and issuance of the license, as required in NRC's pre-licensing guidance. In both cases, the facilities were still under construction; therefore, the Increased Controls requirements could not be fully implemented. The staff member that delivered the licenses documented the areas of the Increased Controls requirements where the licensees were deficient. The review team clarified the requirements of the pre-licensing guidance regarding the delivery and issuance of licenses when all regulatory requirements have not been met at the time of the site visit. After the

clarification, the Office recognized the need to provide specific guidance to inspectors, who perform the majority of pre-licensing visits, on when to withhold delivery of the license if all regulatory requirements are not in place at the time of the visit. The Office prepared a draft of the guidance while the review team was still on site.

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

## 3.5 Technical Quality of Incident and Allegation Activities

In evaluating the effectiveness of the Office's actions in responding to incidents and allegations, the review team examined the response to the questionnaire relative to this indicator, evaluated selected incidents reported for Alabama in the Nuclear Material Events Database (NMED) against those contained in the Office's files, and evaluated the casework for 20 of the 98 reported radioactive materials incidents. A listing of the casework examined can be found in Appendix E. The review team evaluated the Office's response to 18 allegations involving radioactive materials reported directly to the State during the review period. The review team also reviewed the documentation for and discussed with Office managers the ongoing investigation for one allegation that NRC referred to the State during the review period.

When notified of an incident or an allegation, the inspection staff discusses the initial response and the need for an on-site investigation, based on the safety significance. The Office maintains a log book, database, and file system for tracking the status of all incidents and allegations. If the incident meets the reportability thresholds, as established in FSME Procedure SA-300, "Reporting Material Events," the Office notifies the NRC Headquarters Operations Center. If the investigation is complex and extends over a period of time, the Office updates the respective NMED record, using the NMED software. Of the 20 incidents evaluated by the review team, all had been reported to NRC within the required time frame and had been properly completed in NMED.

The incidents selected for review included lost or stolen radioactive material, medical, damaged equipment, overexposure, contamination, and equipment failures. The review team determined that the Office's responses to incidents were thorough, complete, and comprehensive. Initial responses were prompt and well coordinated, and the level of effort was commensurate with the health and safety significance. The Office immediately dispatched inspectors to a site when the possibility of an immediate threat to public health and safety existed. When no immediate threat was present and the Office determined that the licensee had qualified, competent individuals investigating the incident; the Office generally responded telephonically with subsequent review of the licensee's written report or an on-site followup at a later date. The review team noted that at the conclusion of investigations, inspectors generated narrative reports that thoroughly documented the investigations.

The review team also evaluated four radioactive materials incidents in the Office's files that were not reported to NRC to determine if the events should have been reported in accordance with the criteria in FSME Procedure SA-300. The review team determined that these events were not required to be reported under the criteria.

In evaluating the effectiveness of the Office's response to allegations, the review team evaluated the completed casework for 18 allegations. The review team concluded that the Office consistently took prompt and appropriate action in response to concerns raised. The review team noted that the Office thoroughly documented the investigations and retained all necessary documentation to appropriately close the allegations. The Office notified the allegers of the conclusion of their investigation. The review team determined that the Office adequately protected the identity of allegers.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Alabama's performance with respect to the indicator, Technical Quality of Incident and Allegation Activities, was satisfactory.

#### 4.0 NON-COMMON PERFORMANCE INDICATORS

Four non-common performance indicators are used to review Agreement State programs: (1) Compatibility Requirements, (2) Sealed Source and Device Evaluation Program, (3) Low-Level Radioactive Waste Disposal Program, and (4) Uranium Recovery Program. NRC's Agreement with Alabama does not relinquish regulatory authority for a uranium recovery program; therefore, only the first three non-common performance indicators applied to this review.

## 4.1 <u>Compatibility Requirements</u>

#### 4.1.1 Legislation

Alabama became an Agreement State on October 1, 1966. Legislative authority to create the program and enter into an Agreement with NRC was established in 1963 (Acts of 1963, No. 582). The State Board of Health is designated as the State's radiation control agency.

The review team examined one legislative bill that was passed during the review period that affected the Agreement State program. On March 4, 2010, the Governor signed a bill into effect that requires all applicants for licensure in the State of Alabama to be a citizen of the United States or a person who is legally present in the United States with appropriate documentation from the federal government. The Office Director stated that the bill had little effect on the Office's licensing practices.

## 4.1.2 Program Elements Required for Compatibility

Alabama's regulations for the control of radiation are located in Chapter 420-3-26 of the Alabama regulations for Control of Radiation and apply to ionizing radiation, whether emitted from radionuclides or devices. Alabama requires a license for possession and use of all radioactive materials, including diffuse sources of naturally occurring radioactive material.

The review team verified that the State's rulemaking process offers the public and other interested parties an opportunity to comment on proposed regulation changes. The Office sends proposed regulation changes to NRC for a compatibility review during the public comment period. After the Office addresses any comments on the proposed regulations, the rulemaking package goes to the Department's Office of General Counsel for review and the

State Committee of Public Health for approval. The review team found that the rulemaking process typically takes 5-6 months. The State has Emergency Rule capability, if public health and safety are at risk.

Although the State's rules and regulations are not subject to sunset laws, the State's radiation control agency as a whole is subject to a sunset review every 4 years by the State Legislature. The process consists of the Examiners of Public Accounts, a State agency, doing a review of the State's radiation control agency and issuing a report to the Sunset Committee of the State Legislature. If the Sunset Committee agrees with the Examiners of Public Account's report and recommendation, they then submit a bill to the full legislature to continue the program for another 4 years. In its most recent review in 2009, the Examiners of Public Accounts recommended that the program continue for another 4 years. The Sunset Committee agreed, and the Alabama Legislature voted favorably on the recommendation.

The review team evaluated Alabama's response to the questionnaire relative to this indicator, reviewed the status of regulations required to be adopted by the State under the Commission's adequacy and compatibility policy, and verified the adoption of regulations with data obtained from FSME's State Regulation Status Data Sheet.

Current NRC policy requires that Agreement States adopt certain equivalent regulations or legally binding requirements no later than 3 years after the effective date of NRC's regulations. At the time of this review, the following two amendments had not been reviewed for compatibility by NRC and were considered overdue:

 "Compatibility with IAEA Transportation Safety Standards and Other Transportation Safety Amendments," 10 CFR Part 71 amendment (69 FR 3697), that was due for Agreement State implementation on October 10, 2007.

Status: The Office did not take any specific action to address this regulation amendment, because it believes that Alabama's regulations were already compatible with this amendment. At the time of the review, the Office was preparing document to submit to NRC for a compatibility review to close out this regulation amendment.

 "National Source Tracking System – Serialization Requirements," 10 CFR Part 32 amendment (71 FR 65685), that was due for Agreement State implementation on February 6, 2007.

Status: The Office does not regulate any licensees to which these requirements apply. The Office has drafted proposed regulations that address this amendment and submitted to NRC for a compatibility review on April 19, 2010, to ensure that any future licensees will be subjected to these requirements, as appropriate. NRC notified the State of the result of its compatibility review by letter dated July 14, 2010. NRC identified no compatibility comments on the proposed regulations addressing this regulatory amendment.

The review team identified the following regulation amendments that the Office will need to address in the future:

- "Medical Use of Byproduct Material Minor Corrections and Clarifications," 10 CFR Parts 32 and 35 amendment (72 FR 45147, 54207), that is due for Agreement State adoption by October 29, 2010.
- "Requirements for Expanded Definition of Byproduct Material," 10 CFR Parts 20, 30, 31, 32, 33, 35, 61, 150 amendment (72 FR 55864), that is due for Agreement State adoption by November 30, 2010.
- "Exemptions from Licensing, General Licenses, and Distribution of Byproduct Material; Licensing and Reporting Requirements," 10 CFR Parts 30, 31, 32, 150 amendment (72 FR 58473), that is due for Agreement State adoption by December 17, 2010.
- "Occupational Dose Records, Labeling Containers, and Total Effective Dose Equivalent,"
   10 CFR Parts 19, 20 amendment (72 FR 68043), that is due for Agreement State adoption by February 15, 2011.
- "Medical Use of Byproduct Material Authorized User Clarification," 10 CFR Part 35 amendment (74 FR 33901), that is due for Agreement State adoption by September 28, 2012.

The review team noted that, at the time of the review, the Office was in the process of addressing one of the overdue amendments and all amendments that are coming due in one rulemaking package. The Office submitted its proposed regulations to NRC for a compatibility review on April 19, 2010. NRC notified the State of the result of its compatibility review by letter dated July 14, 2010. NRC identified 15 compatibility comments on the proposed regulations addressing 3 of the regulatory amendments covered by this rulemaking. The Office indicated that the rulemaking package should be adopted and effective by September 2010.

Based on the IMPEP evaluation criteria, the review team recommended, and the MRB agreed, that Alabama's performance with respect to the indicator, Compatibility Requirements, was satisfactory.

## 4.2 Sealed Source and Device Evaluation Program

Although the Alabama Agreement State Program has authority to conduct sealed source and device (SS&D) evaluations for byproduct, source, and certain special nuclear materials; the Office did not conduct any SS&D evaluations during the review period. Accordingly, the review team did not review this indicator.

## 4.3 <u>Low-Level Radioactive Waste Disposal Program</u>

In 1981, 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 low-level radioactive waste (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 the Alabama Agreement State Program has authority to regulate a LLRW disposal facility, NRC has not required States to have a program for licensing a 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, it is expected to put in place a regulatory program that will meet the criteria for an adequate and compatible LLRW program. There are no plans for a commercial LLRW disposal facility in Alabama. Accordingly, the review team did not review this indicator.

#### 5.0 SUMMARY

As noted in Sections 3.0 and 4.0 above, Alabama's performance was found satisfactory for all performance indicators reviewed. The review team made no recommendations regarding program performance by the State and identified one good practice. Overall, the review team recommended, and the MRB agreed, that the Alabama Agreement State Program is adequate to protect public health and safety and compatible with NRC's program. Based on the results of the current IMPEP review, the review team recommended, and the MRB agreed, that the next full IMPEP review take place in approximately 4 years.

Below is the good practice, as mentioned earlier in the report:

The Office has developed a searchable database to maintain records of authorized users, authorized nuclear pharmacists, authorized medical physicists, and radiation safety officers listed on licenses in the State of Alabama. The Office creates a record for each individual and lists each license on which that individual holds one of the aforementioned positions and, for authorized users, the modalities for which that individual has met the training and experience requirements. This database increases the efficiency of the Office's review of an individual's qualifications when a licensee requests that an individual be added to their license for a particular position or modality. With this database, the Office can quickly verify if the individual is already listed on another license in the State of Alabama and if that individual is indeed qualified to perform the duties for the position requested by the licensee.

## LIST OF APPENDIXES AND ATTACHMENT

Appendix A IMPEP Review Team Members

Appendix B Alabama Organization Charts

Appendix C Inspection Casework Reviews

Appendix D License Casework Reviews

Appendix E Incident Casework Reviews

Attachment June 11, 2010 E-mail from James L. McNees

Alabama's Response to the Draft Report

## APPENDIX A

## IMPEP REVIEW TEAM MEMBERS

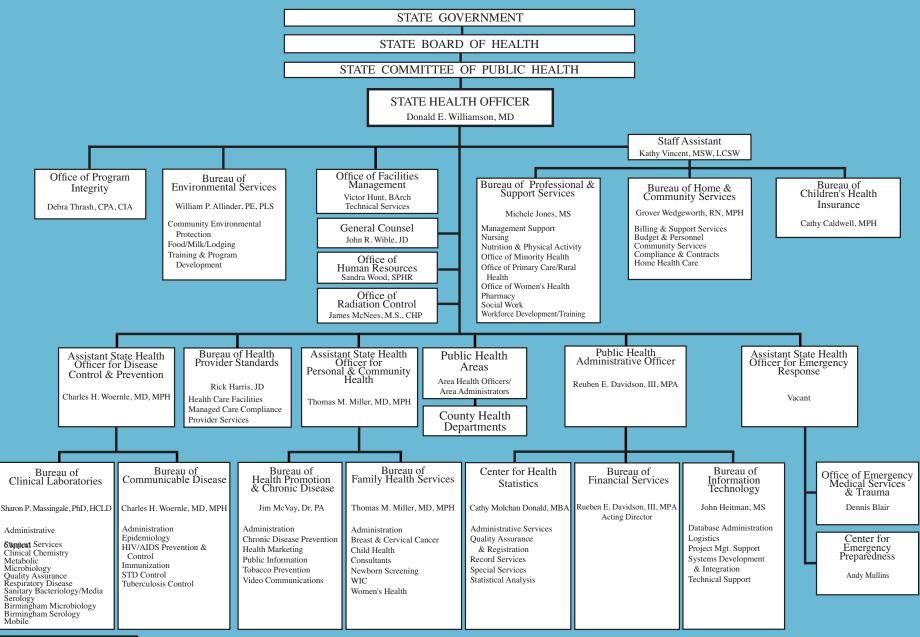
Name	Area of Responsibility
Aaron McCraw, FSME	Team Leader Technical Staffing and Training Compatibility Requirements
Dwight Shearer, Pennsylvania	Status of Materials Inspection Program Technical Quality of Inspections Inspector Accompaniments
Michele Greenwell, Kentucky	Technical Quality of Licensing Actions
James Kottan, Region I	Technical Quality of Incident and Allegation Activities

## APPENDIX B

ALABAMA ORGANIZATION CHARTS

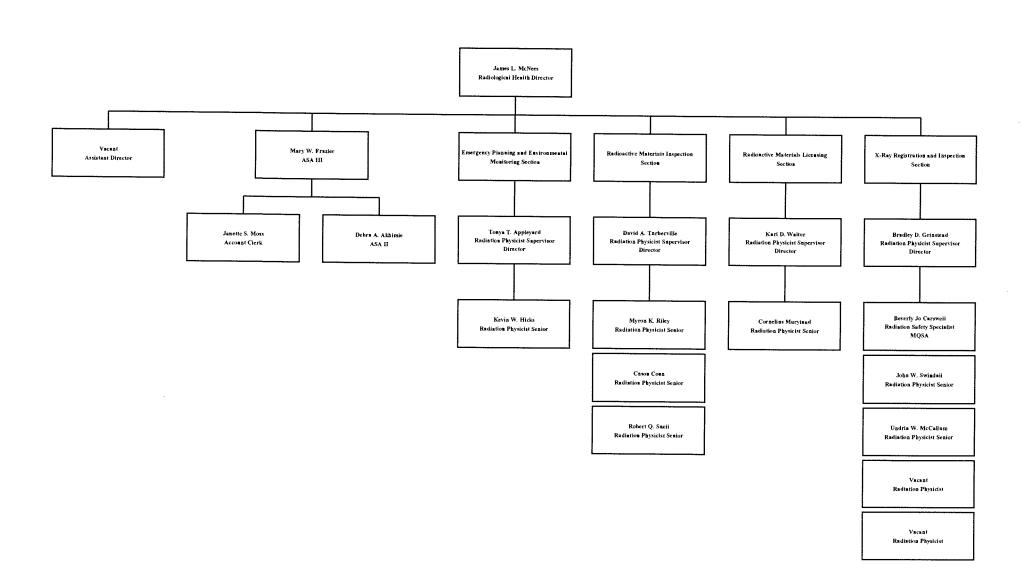
ADAMS ACCESSION NO.: ML101470512

## ALABAMA DEPARTMENT OF PUBLIC HEALTH





# Office of Radiation Control



## APPENDIX C

#### INSPECTION CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

File No.: 1

Licensee: Gadsden Nuclear Pharmacy
Inspection Type: Routine, Unannounced
Inspection Dates: 5/28/09
License No.: 1418
Priority: 1
Inspectors: MR

File No.: 2

Licensee: Gulf Coast Pharmacy
Inspection Type: Routine, Unannounced
Inspection Dates: 8/21/09
License No.: 1492
Priority: 1
Inspector: CC

File No.: 3

Licensee: Southeast Apothecary

Inspection Type: Routine, Unannounced

Inspection Dates: 8/28/09

License No.: 1461

Priority: 1

Inspectors: DT

File No.: 4

Licensee: Applied Tech Services

Inspection Type: Routine, Unannounced
Inspection Date: 2/24/10

License No.: 1454
Priority: 1
Inspectors: MR

File No.: 5

Licensee: Cardinal Health
Inspection Type: Routine, Unannounced
Inspection Date: 3/31/10
License No.: 1068
Priority: 1
Inspectors: CC

File No.: 6

Licensee: IonSouth Diagnostic

Inspection Type: Routine, Unannounced
Inspection Date: 4/21/10

License No.: 1493
Priority: 1
Inspector: MR

File No.: 7

Licensee: Quality Inspections Services
Inspection Type: Routine, Unannounced
Inspection Date: 02/23/2010
License No.: 1518
Priority: 1
Inspectors: Riley

File No.: 8

Licensee: Brookwood Medical Center
Inspection Type: Routine, Unannounced
Inspection Date: 4/27/10
License No.: 0459
Priority: 2
Inspector: CC

Page C.2 Alabama Final Report Inspection Casework Reviews File No.: 9 Licensee: Trinity Medical Center License No.: 0593 Inspection Type: Routine, Unannounced Priority: 2 Inspection Date: 9/8/09 Inspectors: CC File No.: 10 Licensee: Walker Medical Diagnostic License No.: 1428 Inspection Type: Routine, Unannounced Priority: 3 Inspection Date: 3/16/07 Inspectors: CC File No.: 11 Licensee: Venkatapuram License No.: 1389 Inspection Type: Routine, Unannounced Priority: 3 Inspection Date: 4/10/07 Inspector: CC File No.: 12 Licensee: Medworks License No.: 1343 Priority: 3 Inspection Type: Routine, Unannounced Inspection Date: 11/2/07 Inspector: CC File No.: 13 Licensee: Huntsville Cardiology License No.: 1268 Inspection Type: Routine, Unannounced Priority: 3 Inspection Date: 8/1/08 Inspector: CC File No.: 14 Licensee: Southern Company Gen License No.: 0644 Inspection Type: Routine, Unannounced Priority: 3 Inspection Date: 3/11/10 Inspector: MR File No.: 15 License No.: 0368 Licensee: Professional Services Industrials Inspection Type: Routine, Unannounced Priority: 1 Inspection Date: 9/9/09 Inspector: MR File No.: 16 Licensee: Wyle Labs License No.: 0525 Inspection Type: Routine, Unannounced Priority: 2 Inspection Date: 10/8/08 Inspector: CC

File No.: 17
Licensee: Mobile Infirmary
Inspection Type: Routine, Unannounced

Inspection Date: 5/8/09 Inspector: MR

License No.: 282

Priority: 2

Alabama Final Report Page C.3

Inspection Casework Reviews

File No.: 18

Licensee: NeXolve License No.: 1296
Inspection Type: Reciprocity. Announced Priority: 5
Inspection Date: 3/24/05 Inspector: DT

File No.: 19

Licensee: APAC - Midsouth
Inspection Type: Reciprocity, Announced
Inspection Date: 9/16/05

License No.: 0701
Priority: 5
Inspector: DT

#### INSPECTOR ACCOMPANIMENTS

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

Accompaniment No.: 1

Licensee: Brookwood Medical Center
Inspection Type: Routine, Unannounced
Inspection Date: 4/26/10
License No.: 0459
Priority: 2
Inspector: CC

Accompaniment No.: 2

Licensee: MISTRAS Group, Inc
Inspection Type: Routine, Unannounced
Inspection Date: 4/27/10
License No.: 1075
Priority: 1
Inspector: CC

Accompaniment No.: 3

Licensee: Triad Isotopes

Inspection Type: Routine, Unannounced
Inspection Date: 4/28/10

License No.: 1399
Priority: 1
Inspector: MR

## APPENDIX D

## LICENSE CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

File No.: 1

Licensee: Eastern Technologies, Inc.

Type of Action: Amendment

Date Issued: 6/9/09

License No.: 0947

Amendment No.: 19

License Reviewers: NM, DW

File No.: 2

Licensee: Auburn University

Type of Action: Amendments

Dates Issued: 2/5/09, 7/22/09

License No.: 0248

Amendment Nos.: 71 and 72

License Reviewers: NM, DW

File No.: 3

Licensee: Alabama Department of Transportation

Type of Action: Amendment

Dates Issued: 7/29/09

License No.: 0257

Amendment No.: 49

License Reviewer: NM

File No.: 4

Licensee: Digirad Imaging Solutions

Type of Action: Amendment

Date Issued: 3/9/10

License No.: 1511

Amendment No.: 11

License Reviewers: NM, DW

File No.: 5

Licensee: Baptist Medical Center

Type of Action: Amendment

Date Issued: 1/10/08

License No.: 0610

Amendment No.: 58

License Reviewers: NM, DW

File No.: 6

Licensee: The PET Center of Oxford, LLC

Type of Action: Termination

Date Issued: 2/20/09

License No.: 1386

Amendment No.: 4

License Reviewers: NM, DW

File No.: 7

Licensee: Cox Environmental and Geologic, LLC

Type of Action: Termination

Date Issued: 12/22/09

License Reviewers: NM, CC, KW

File No.: 8

Licensee: Alabama A & M License No.: 984

Type of Action: Termination Amendment No.: 7

Date Issued: 3/11/09 License Reviewers: NM, DW

File No.: 9

Licensee: University of South Alabama

Type of Action: Renewal

Date Issued: 11/14/08

License No.: 0584

Amendment No.: 67

License Reviewers: NM, DW, DT

File No.: 10

Licensee: 3-M Corporate Health Physics

Type of Action: Renewal

Date Issued: 2/5/10

License No.: 0148

Amendment No.: 53

License Reviewers: NM, DW

File No.: 11

Licensee: Nucor Steel License No.: 1472
Types of Action: New, Amendments Amendment Nos.: Various
Dates Issued: Various License Reviewers: NM, DW

File No.: 12

Licensee: Quality Inspection and Territory

Types of Action: New, Amendments

Dates Issued: Various

License No.: 1518

Amendment No.: Various

License Reviewers: NM, DW

File No.: 13

Licensee: Maintenance Dredging, LLC

Type of Action: New

Date Issued: 4/15/10

License No.: 1529

Amendment No.: N/A

License Reviewers: NM, DW

File No.: 14

Licensee: Northrop Grumann System Corporation

Type of Action: New

Date Issued: 5/15/09

License No.: 1512

Amendment No.: N/A

License Reviewer: DW

File No.: 15

Licensee: Weaver Boos Consultants

Type of Action: New

Date Issued: 7/7/09

License No.: 1517

Amendment No.: N/A

License Reviewer: DW

File No.: 16

Licensee: Progress Rail Services

Type of Action: New

Date Issued: 5/28/10

License No.: 1513

Amendment No.: N/A

License Reviewer: DW

File No.: 17

Licensee: Bunnell-Lammons Engineering

Type of Action: New

Date Issued: 9/28/09

License No.: 1521

Amendment No.: N/A

License Reviewer: DW

File No.: 18

Licensee: Eastern Shore Radiation Oncology

Type of Action: New

Amendment No.: N/A

Date Issued: 6/12/09

License Reviewers: NM, DW

File No.: 19

Licensee: Faizullah, Sayed

Type of Action: New

Date Issued: 3/2/10

License No.: 1525

Amendment No.: N/A

License Reviewers: NM, DW

File No.: 20

Licensee: Internal Medicine Center

Type of Action: New

Date Issued: 6/12/10

License No.: 1516

Amendment No.: N/A

License Reviewers: NM, DW

File No.: 21

Licensee: Thyssen Krup Steel

Type of Action: New

Date Issued: 2/25/10

License No.: 1528

Amendment No.: N/A

License Reviewer: DW

File No.: 22

Licensee: Nucor License No.: 1426
Type of Action: New Amendment No.: N/A
Date Issued: 5/10/10 License Reviewers: NM, DW

#### APPENDIX E

## INCIDENT CASEWORK REVIEWS

NOTE: CASEWORK LISTED WITHOUT COMMENT IS INCLUDED FOR COMPLETENESS.

File No.: 1

Licensee: Cardinal Health

Date of Incident: 4/11/06

Investigation Date: 5/27/06

License No.: 1168

NMED No.: 060389

Type of Incident: Medical

Type of Investigation: Licensee Report

File No.: 2

Licensee: BP Amoco Chemical Co. License No.: 0256

Date of Incident: 8/12/06 NMED No.: 060718
Investigation Date: 8/30/06 Type of Incident: Equipment Failure
Type of Investigation: Licensee Report

File No.: 3

Licensee: Building and Earth Sciences, Inc. License No.: 1266

Date of Incident: 11/12/06

Investigation Date: 11/13/06

NMED No.: 060701

Type of Incident: Lost/stolen Material

Type of Investigation: Telephone

File No.: 4

Licensee: Appalachian Cardiovascular Assoc. License No.: 1357

Date of Incident: 10/31/06

Investigation Date: 11/28/06

NMED No.: 070279

Type of Incident: Medical

Type of Investigation: Telephone

File No.: 5

Licensee: Building and Earth Sciences License No.: 1266

Date of Incident: 6/11/07 NMED No.: 070365
Investigation Date: 6/29/07 Type of Incident: Damaged Equipment
Type of Investigation: Telephone

File No.: 6

Licensee: Vital Inspection Professionals, Inc. License No.: 1118

Date of Incident: 7/26/07 NMED No.: 070484
Investigation Date: 7/26/07 Type of Incident: Equipment Failure
Type of Investigation: Telephone

File No.: 7

Licensee: Montgomery Cancer Center License No.: 1064

Date of Incident: 1/2/08 NMED No.: 080137 Investigation Date: 1/2/08 Type of Incident: Lost/stolen Material Type of Investigation: Telephone

File No.: 8

Licensee: GE Energy Inspection Services License No.: 754

Date of Incident: 5/19/08 NMED No.: 080340

Investigation Date: 5/19/08 Type of Incident: Damaged Equipment

Type of Investigation: Telephone

File No.: 9

Licensee: Birmingham Engineering License No.: 1142

and Construction Consultants

Date of Incident: 7/1/08 NMED No.: 080453

Investigation Date: 7/1/08 Type of Incident: Damaged Equipment

Type of Investigation: Site

License No.: 1142

File No.: 10

Licensee: Birmingham Engineering

and Construction Consultants

Date of Incident: 8/28/08 NMED No.: 080502

Investigation Date: 8/28/08 Type of Incident: Lost/stolen Material Type of Investigation: Telephone

File No.: 11

Licensee: Gallet and Associates License No.: 0991

Date of Incident: 1/13/09 NMED No.: 090067 Investigation Date: 1/13/09 Type of Incident: Lost/stolen Material

vestigation Date: 1/13/09

Type of Incident: Lost/stolen Material

Type of Investigation: Telephone

File No.: 12

Licensee: Bhate Engineering License No.: 0655

Date of Incident: 1/23/09 NMED No.: 090297 Investigation Date: 1/23/09 Type of Incident: Damaged Equipment

Type of Investigation: Telephone

File No.: 13

Licensee: Unified Testing Services License No.: 1128

Date of Incident: 2/11/09 NMED No.: 090450 Investigation Dates: 2/11/09 Type of Incident: Overexposure Type of Investigation: Telephone

File No.: 14

Licensee: Qore License No.: 0708

Date of Incident: 2/18/09 NMED No.: 090277 Investigation Date: 2/18/09 Type of Incident: Lost/stolen Material

Type of Incident: Los/vstoler Material Type of Investigation: Telephone

File No.: 15

Licensee: Tacoa Minerals, LLC

Date of Incident: 8/26/08

Investigation Date: 2/26/09

Type of Incident: Loss of Control

Type of Investigation: Site

File No.: 16

Licensee: B.F. Goodrich

Date of Incident: 4/23/09

Investigation Date: 4/24/09

Type of Incident: Lost/stolen Material
Type of Investigation: Telephone

File No.: 17

Licensee: Northwest Medical Center

Date of Incident: 7/23/09

Investigation Date: 7/23/09

License No.: 1368

NMED No.: 090684

Type of Incident: Contamination

Type of Investigation: Telephone

File No.: 18

Licensee: PSI, Inc. License No.: 0368

Dates of Incident: 8/20-21/09

Investigation Dates: 8/26/09, 9/9/09

Type of Incident: Equipment Failure
Types of Investigation: Telephone, Site

File No.: 19

Licensee: U.S. Steel License No.: N/A
Date of Incident: 11/17/09 NMED No.: 090845

Investigation Dates: 11/17/09, 11/20/09 Type of Incident: Abandoned Material Type of Investigation: Telephone, Site

File No.: 20

Licensee: University of Alabama at Birmingham License No.: 0266

Date of Incident: 1/6/10

Investigation Date: 1/7/10

NMED No.: 100098

Type of Incident: Medical

Type of Investigation: Telephone

## ATTACHMENT

June 11, 2010 E-mail from James L. McNees Alabama's Response to the Draft Report

ADAMS Accession No.: ML101690223

## McCraw, Aaron

From: James.McNees@adph.state.al.us
Sent: Friday, June 11, 2010 12:30 PM

To: McCraw, Aaron

**Subject:** Comments on the Alabama Draft Report

## Section 3.2. Status of Materials Inspection Program.

The last sentence of the next to last paragraph in Section 3.2 (on page 4) states:

"Out-of-State licensees that were performing significant longer-term work in the State were required to get an Alabama license after 30 days and these licensee's were inspected **annually**." Instead of "annually, we suggest the wording should be "**in accordance with IMC 2800**."

## In Section 3.3. Technical Quality of Inspections.

The second sentence of the next to last paragraph in Section 3.3 (on page 5) appears to have a "of" missing between "inspections" and "a medical licensee". We suggest revising it to read; "The inspectors conducted **of** a medical licensee, an industrial radiographer licensee, and a nuclear pharmacy licensee."

The last sentence in the second paragraph of the Section 3.3 (on page 4) which states that "all inspection documentation is entered into the Office's electronic filing system" leads one to believe that all inspection reports are entered and maintained in the Office's "electronic filing system" If this is the intent of the statement, it is incorrect. Inspectors currently type up inspection reports using Wordperfect software but the saved electronic files are saved on the inspectors computers and their is no requirement that they save these electronic files. The only inspection information maintained on an electronic filing system is the information maintained in the Approach file, which contains the dates of the three most recent inspections, the name of lead inspector for the most recent inspection, if that inspection was done when "over due," the date the next inspection is due, and if the licensee in on reduced inspection interval. Paper copies of the inspection reports and subsequent correspondence are in each licensee's file folder.

Thus we suggest that sentence be revised to read; "In addition to the paper copies that are maintained in Montgomery, all inspection pertinent information about each inspection documentation is entered into the Office's electronic filing system, is accessible to all staff members.

In Section 4.1.2 Program Elements Required for Compatibility we suggest the following revisions:

Alabama's regulations for the control of radiation are located in Chapter 420-3-26 of the Alabama regulations for Control of Radiation and apply to ionizing and non-ionizing radiation, whether emitted from radionuclides or devices. Alabama requires a license for possession and use of all radioactive materials, including diffuse sources of naturally occurring radioactive material.

The review team verified that the State's rulemaking process offers the public and other interested parties an opportunity to comment on proposed regulation changes. The Office sends proposed regulation changes to NRC for a compatibility review during the public comment period. After the Office addresses any comments on the proposed regulations, the rulemaking package goes to the Alabama Department's Office of General Counsel for review and the State Committee of Public Health for approval. The review team found that the rulemaking process typically takes 5-6 months. The State has Emergency Rule capability, if public health and safety are at risk.

Although the State's rules and regulations are not subject to sunset laws, the entire Radiation Control Agency program as a whole is subject to a sunset review every 4 years by a the State Legislature. agency called the This process consists of the Examiners of Public Accounts, a state agency, doing a review of Radiation Control and issuing a report to the Sunset Committee of the State Legislature. If the Sunset Committee finds favorably and recommends the continued existence of Radiation Control they then submit a bill to the entire Legislature authorizing continuance for another 4 years. In its most recent review in 2009, the Examiners of Public Accounts recommended that the program continue for another 4 years. The Sunset Committee agreed and the Alabama Legislature voted favorably on the recommendation.

Thank you for the opportunity to review and comment on the Alabama Draft Report.

## Jim

James L. McNees, CHP Director, Office of Radiation Control Alabama Department of Public Health Office-334-206-5368 Fax-334-206-5387 Cell- 334-850-5293