

DATED: JULY 21, 1998

SIGNED BY: HUGH L. THOMPSON, JR.

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

Dear Dr. Williamson:

On July 8, 1998 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 program adequate to protect public health and safety and compatible with NRC's program.

Section 5.0, page 12, of the enclosed final report presents the IMPEP team's recommendations and suggestions. We have received the June 16, 1998 letter from Kirksey E. Whatley, Director, Division of Radiation Control, which described the actions taken in response to the team's recommendations and suggestions. We request no additional information.

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

Mr. Whatley effectively represented the State of Alabama at the MRB meeting. During the meeting, he noted the current and past contributions from radiation control program staff and management that have been key to the success of the Alabama program. The MRB also noted the commitment from Mr. Whatley to continue the use of high performance standards in the conduct of his program's activities.

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/

Hugh L. Thompson, Jr.
Deputy Executive Director
for Regulatory Programs

Enclosure:
As stated

cc: Steven Collins
Organization of Agreement States Liaison
to the Management Review Board

Kirksey E. Whatley, Director
Division of Radiation Control
Alabama Department of Public Health

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cc: Steven Collins,
Organization of Agreement States Liaison
to the Management Review Board

bcc: Chairman Jackson
Commissioner Diaz
Commissioner McGaffigan

Kirksey E. Whatley, Director
Division of Radiation Control
Alabama Department of Public Health

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***See previous concurrence**

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INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

REVIEW OF ALABAMA AGREEMENT STATE PROGRAM

April 20 - 23, 1998

FINAL REPORT

U.S. Nuclear Regulatory Commission

1.0 INTRODUCTION

This report presents the results of the review of the Alabama radiation control program. The review was conducted during the period April 20 - 23, 1998, by a review team comprised of technical staff members from the Nuclear Regulatory Commission (NRC) and the Agreement State of Texas. Team members and their assignments 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, 1997, revised NRC Management Directive 5.6, "Integrated Materials Performance Evaluation Program (IMPEP)." 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 Alabama. Preliminary results of the review, which covered the period June 23, 1995, to April 23, 1998, were discussed with Alabama management on April 23, 1998.

A draft of this report was issued to Alabama for factual comment on May 27, 1998. The State responded in a letter dated June 16, 1998 (Attachment 1). The State's factual comments have been incorporated into the final report. The Management Review Board (MRB) met on July 8, 1998, to consider the proposed final report. The MRB found the Alabama radiation control program adequate to protect public health and safety and compatible with NRC's program.

The Alabama Agreement State program is administered by the Department of Public Health (DPH), Office of Radiation Control (ORC). The Director of the ORC reports to the State Health Officer, who serves as the Director of the Department of Public Health. The State Board of Health is the designated radiation control agency. Organization charts for the DPH and the ORC are included in Appendix B. At the time of the review, the ORC regulated 404 specific licenses.

In preparation for the review, a questionnaire addressing the common and non-common indicators was sent to the State on November 12, 1997. The State provided a response to the questionnaire on March 19, 1998. A copy of the response is included in Appendix F to the draft report.

The review team's general approach for conduct of this review consisted of: (1) examination of Alabama's response to the questionnaire; (2) review of applicable Alabama statutes and regulations; (3) analysis of quantitative information from the radiation control program licensing and inspection database; (4) technical review of selected licensing and inspection actions; (5) field accompaniments of two ORC inspectors; and (6) interviews with staff and management to answer questions or clarify issues. The team evaluated the information that it gathered against the IMPEP performance criteria for each common and applicable non-common indicator and made a preliminary assessment of the State'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 indicators, and Section 5 summarizes the review team's findings, recommendations, and suggestions. Recommendations made by the review team are comments that relate directly to program performance by the State. A response is requested from the State to all recommendations in the final report. Suggestions are comments that the review team believes could enhance the State's program. The State is requested to consider suggestions, but no response is requested.

2.0 STATUS OF ITEMS IDENTIFIED IN PREVIOUS REVIEWS

After the previous routine review, which concluded on June 23, 1995, the results were transmitted to Donald Williamson, M.D., State Health Officer, Alabama DPH on September 18, 1995. The review initially resulted in one recommendation, and the withholding of a finding for compatibility because the State had not adopted a regulation equivalent to the "Quality Management (QM) Program and Misadministrations," 10 CFR 35.32 amendment (56 FR 34104) that became effective on January 27, 1992.

Subsequent to the letter of September 18, 1995, NRC reinitiated an evaluation of the QM rule. It was decided that pending the completion of the re-evaluation, the absence of a compatible QM rule would not be used as a basis for withholding of a finding for compatibility. In a letter dated October 24, 1995, the State was notified of this action and subsequently all Agreement States were notified of the results of this re-evaluation by SP-95-184 dated December 6, 1995.

The compatibility category of the QM rule under the new Commission policy on Adequacy and Compatibility, which became effective on September 6, 1997, has been set as "D" with paragraphs (a), (b), and (c) of the rule identified as having provisions important to health and safety. Consistent with SECY 97-054 (see SP-97-057), staff will review the compatibility of both draft and final Agreement State equivalent QM rules as they are promulgated. However, the results of such reviews will not affect IMPEP review findings. A separate review of the current Alabama rule equivalent to 10 CFR 35.32(a), (b), and (c) has been completed, and the rule found to meet the compatibility and health and safety category.

Based on the above, the team determined that this recommendation should be closed.

3.0 COMMON PERFORMANCE INDICATORS

IMPEP identifies five common performance indicators to be used in reviewing both NRC Regional and Agreement State programs. These indicators 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 timely dispatch of inspection findings to the licensees. This evaluation is based on the Alabama questionnaire responses relative to this indicator, data gathered from reports generated from the licensee database, the examination of inspection casework, and interviews with the management and staff of the ORC.

A DPH memorandum dated April 16, 1998, entitled "License and Registration Inspections Priority" requires that inspections be conducted in accordance with the priority schedule in NRC Inspection Manual Chapter (IMC) 2800, with the following modifications:

- 1) All programs assigned to Priority 7 by NRC are changed to Priority 5;

- 2) Medical Institutions and Medical Private Practices not requiring a QM Plan are assigned to Priority 3 instead of Priority 5;
- 3) Academic Type B is assigned to Priority 2 instead of Priority 3; and
- 4) Stereotactic Radiosurgery is added with a Priority 1.

The April 16, 1998 memorandum further established a policy and procedure for extending inspection intervals on the basis of good licensee performance. The memorandum also established a policy and procedure for reducing inspection intervals, using a point system based on violation severity and frequency. The inspection interval extension/reduction policy differs from NRC's in two aspects: 1) in Alabama the interval extension policy "may be applied" as compared to NRC's "shall be applied;" and 2) in Alabama the decision to grant an extension is made at the time the licensee's next inspection is due, versus the IMC 2800 provision for the decision to be made at the time the current inspection is completed. The application for an increase in interval and the documentation required are essentially the same for both Alabama and NRC. No licensees had been granted interval extension prior to the review, however, there were four licensees subject to interval reduction at the time of the review.

The licensee database contains fields for 43 items of information, and is accessible to both licensing branch and inspection branch staff. Certain fields, such as the next inspection date, are changed only by management. Information retrieval can be formatted to give the type of report and information desired. For example, a monthly 'inspection due' report is generated for scheduling purposes. The report fields indicate the inspection due date, date of the last inspection performed, the licensee, and the State region(s) where the licensee is located. The inspectors use this report to formulate an inspection itinerary, which is submitted for management approval prior to departure.

The Radioactive Materials Compliance Branch (RMCB) of the ORC conducts an average of 130 inspections per year. Currently, the ORC has no overdue inspections. This performance meets and surpasses the IMPEP criteria for this indicator.

Initial inspections of new licensees are scheduled for five months after the date the license is issued. At that time, an inspector contacts the licensee. If the licensee has not acquired material during this period, the inspector asks when the licensee expects to acquire material. Depending on the licensee's response, the inspection due date may be extended up to another five months. If material is not acquired during this period, an inspection is performed before the end of the first year post license issuance. There were 40 initial inspections performed during the review period, all within the scheduled intervals for new licensees.

Alabama allows 30 days of possession of materials in State under reciprocity without payment of a fee. After 30 days, an out-of-State Alabama license (and fee payment) is required. Holders of out-of-State licenses are required to give a 3 day notification of any planned use of radioactive material at a temporary job site in Alabama. The ORC considers the out-of-State licensees to effectively be operating under reciprocity. The inspections of Priority 1 and Priority 3 licensees granted reciprocity (including the Priority 1 and Priority 3 out-of-State licensees using materials in

State) during the review period fell short of the goals indicated in IMC 1220. Seventeen percent of the Priority 1 and 14 percent of the Priority 3 licensees were inspected. Inspection of teletherapy and irradiator source services licensees and Priority 2 licensees met IMC 1220 goals.

The ORC identified this shortfall in a self-audit, but noted that many of these licensees enter into the State for jobs that require only a short time, often only a few hours, and that the job sites are frequently located in remote areas of the State. The ORC indicated that this, coupled with the costs of travel, makes inspection of these licensees very difficult. The review team suggests that the Alabama ORC continue their efforts to find ways to increase the percentage of high priority reciprocity licensees, and out-of-State licensees working in Alabama, to be inspected each year.

Fifteen inspection files were reviewed for report timeliness. The procedure for reporting inspection results is initiated by the inspector, usually immediately upon return from the field. The inspector transfers information from handwritten field notes to a computer-form, then drafts a cover letter to the licensee. The draft cover letter and computer-form notes comprise the draft report. Management reviews the draft report, and sends it to the secretarial staff to be finalized. The inspector receives the report back from the secretarial staff, assures its accuracy and completeness, and delivers it to the Director of the RMCB for signature. This procedure appears to be working very well. For the reports reviewed, seven were signed within two weeks of the inspection, and all were signed within 24 days.

In summary, Alabama meets or surpasses the IMPEP criteria in Management Directive 5.6 for the four areas reviewed for this performance indicator. Based on this, the review team recommends that Alabama's performance with respect to the indicator, Status of Materials Inspection Program, be found satisfactory.

3.2 Technical Quality of Inspections

The team reviewed the inspection reports, enforcement documentation, and inspection field notes, and interviewed inspectors for 12 material inspections conducted during the review period. The casework reviewed included inspections by three materials license inspectors, two of which are presently assigned to perform inspections. The third is no longer performing radioactive materials inspections, but is still with the program. The casework reviewed covered inspections of various license types, including: industrial radiography, portable gauge, academic broad scope, nuclear pharmacy, medical private practice, and medical institution. Appendix C lists the inspection files reviewed in depth.

To review inspectors' performance in the field, a team member accompanied two inspectors on February 11, 1998, and during the period February 25 - 27, 1998. Each inspector was accompanied on two unannounced inspections. One inspector was accompanied during the early morning inspection of a nuclear pharmacy on February 11, 1998, and at a nuclear medicine facility on February 25, 1998. The other inspector was accompanied February 26 - 27, 1998, on unannounced inspections of a medical licensee with brachytherapy (including an HDR therapy unit), and an industrial radiography licensee. These accompaniments are also identified in Appendix C. During the accompaniments, the inspectors demonstrated appropriate inspection

techniques and knowledge of the regulations. Both 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.

During the onsite review, the review team determined that the ORC is performing inspections of materials licensees on an unannounced basis, except for initial inspections. The inspectors use a packet of note forms for each major type of inspection. The inspectors used the appropriate inspection field note forms in the files reviewed. Each inspector has the forms on his computer, and prints the appropriate forms as necessary for the inspection. The review team observed that the inspectors were reviewing open items from previous inspections and any incidents or allegations that had occurred since the previous inspection. Approximately half of the inspections reviewed by the team resulted in no items of non-compliance, with appropriate letters being issued to the licensees. In the other cases, the ORC issued appropriate Notices of Violation.

During the review period, the RMCB supervisor accompanied two of the three individuals who had performed material inspections. The accompaniment reports contained sufficient details to document the areas covered. The accompanied inspector is provided a copy of the accompaniment report and receives an oral report of his performance.

The senior materials inspector had not been accompanied during the review period, until just before the review. The lack of accompaniment was identified during the ORC's self-audit, and an accompaniment of the senior materials inspector was conducted. The review team suggests that the ORC accompany all material inspectors on a yearly basis.

The review team found that the ORC maintains a sufficient number and variety of survey instruments to perform radiological surveys of material licensees. The review team examined the State's instrumentation and observed that the survey instruments were calibrated and operable. Inspectors obtain instruments from the stock for each inspection. The ORC performs its own calibration at three month intervals, with a source that is National Institute of Standards and Technology (NIST) traceable. A copy of the procedures was examined and appeared adequate. For repairs, the instrument is either returned to the manufacture or is sent to a facility that performs this service.

Based on the IMPEP evaluation criteria, the review team recommends that Alabama'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 radioactive materials program staffing levels, qualification of the staff, training, and staff turnover. To evaluate these issues, the review team examined the State's questionnaire responses related to the indicator, conducted interviews with management and staff of the ORC, and reviewed workload for backlog.

The staff of the ORC was relatively stable over the review period. There were no new hires, and only two staff members departed, both due to retirement. One was the Director of Emergency

Planning/Environmental Monitoring Section, the other was the Director of Naturally Occurring Radioactive Material Section. Due to fiscal constraints, the positions vacated by the retirements were lost. Thus, the ORC had no vacant positions during the review period. However, the losses did not cause an observable reduction in the performance of the Agreement materials program.

Due to a historic low rate of turnover, the staff consists of experienced personnel. The minimum educational requirement for a new hire is a baccalaureate degree. All current staff exceed the qualifications. The ORC has 14 technical positions, including branch directors, that are apportioned as follows: Radioactive Materials Compliance 3, Radioactive Materials Licensing 1, Emergency Planning & Environmental Monitoring 3, Mammography 1, X-Ray Compliance 5, and the Program Director. The ORC has a secretarial staff of three.

In addition to the four technical staff members in the Radioactive Materials Licensing and Compliance Branches, the Program Director spends about 23% of his time in radioactive materials licensing and inspection activities. 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.

The ORC receives support from the Alabama Department of Environmental Management's (ADEM) radiation measurements laboratory, which performs sample counting and assay services. Discussions with both ORC and laboratory staff established that the support is timely and dependable. The U.S. Environmental Protection Agency's (EPA) radiation measurements laboratory is located close to the ADEM lab, and is available for backup.

Training and qualification requirements for licensing and inspection staff are set out in a DPH memorandum dated October 20, 1997, Policy No. 417. The memorandum sets forth essentially the same training and qualification recommendations developed by the NRC - Organization of Agreement States Joint Working Group. A lead inspector is required to obtain specialized training appropriate for the type of licensees being inspected. Inspector requirements include NRC, or equivalent, training courses when available. Inspectors are also required to be accompanied by a senior staff member on an inspection prior to authorizing this inspector to perform an independent inspection. Prior experience in inspecting in the specialized area(s) is required to be a license reviewer or writer.

The training requirements set forth by the October 20, 1997, memorandum are presently met by all of the radioactive materials staff for their respective positions. All have taken the NRC courses deemed appropriate for their tasks, including the five week health physics course. The training records demonstrate that DPH management is committed to a high degree of training for the staff. However, the State Health Officer expressed concern that the cost of training, especially the five week course, may become a financial obstacle for the State in the future.

The team noted the apparent benefits to the ORC from staff participation in the nationwide materials regulatory program outside their regular work. The Director of the Licensing Branch has served on committees and working groups including the joint working group currently considering revisions to 10 CFR Part 35. The Director of the RMCB has served previously on IMPEP review teams. The ORC Director and other staff members have participated in activities of the Conference of Radiation Control Program Directors. The knowledge and experience gained from

these activities have been reflected back to the ORC. The team particularly notes and commends the self-audit function initiated by the ORC during the review period.

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

3.4 Technical Quality of Licensing Actions

The review team interviewed the Alabama license reviewer, evaluated the licensing process, and examined licensing casework for 30 specific licenses. The ORC reported having 404 specific materials licenses, issuing 51 new licenses and terminating 47 licenses since the 1995 review. The ORC utilizes one full time license reviewer, and the ORC Director performs a technical supervisory review before each licensing action is issued. All licenses are signed by the ORC Director and the State Health Officer. The State issues licenses for a five year period. The State utilizes a timely renewal system, NRC licensing guides and policies, as appropriate, and standard licensing conditions.

The licensing casework was selected to provide a representative sample of licensing actions which were completed during the review period and included all amendments to the selected licenses since the previous review. The cross-section sampling focused on the State's major licenses, new licenses, renewals, and licenses terminated during the review period. The sample included the following licensing types: broad academic; broad medical; research and development; source material; nuclear laundry; industrial radiography; portable gauges; institutional nuclear medicine; private clinics; mobile nuclear medicine; radioisotope and sealed source radiotherapy; and nuclear pharmacy. Licensing actions reviewed included 11 new, 4 renewals, 39 amendments and 6 termination files. A listing of the casework licenses with case specific comments can be found in Appendix D.

Licensing actions were reviewed for completeness, consistency, proper radioisotopes and quantities, qualifications of authorized users, adequate facilities and equipment, adherence to good health physics practices, operating and emergency procedures, appropriateness of the license conditions, and overall technical quality. The casework files were also reviewed for use of appropriate deficiency letters and cover letters, timeliness of correspondence, reference to appropriate regulations, information notices, product certifications or other supporting documents, consideration of enforcement history, pre-licensing visits, supervisory review as indicated, and proper signatures. The files were checked for retention of necessary documents and supporting data including the terminated license files.

The review team found (with the exception of one termination as discussed below) that the licensing actions were consistently very thorough, complete, of high quality, with health and safety issues properly addressed, and sufficient to establish the basis for the licensing action. The licensee's compliance history is taken into account when reviewing renewal applications and amendments as determined from documentation in the license files and/or discussions between the license reviewer and the inspectors. As discussed in the questionnaire, five exemptions were issued by the ORC during this review period. All were determined to be appropriate and well documented.

A review of the termination actions taken over the review period showed that most of the terminations were for licensees possessing only sealed sources and/or for uses of radiopharmaceuticals with short half lives. Six termination files were selected for review based upon the potential for residual contamination, and to confirm that the State's termination procedures were being implemented. In general, the review team found that terminated licensing actions were well documented, showing appropriate transfer records or appropriate disposal methods and records, confirmatory surveys, and survey records.

One case file involved the transfer of a portable gauging device to a specific licensee located in another Agreement State. The records included a handwritten "Bill of Sale" from the Alabama licensee. Other documentation in the file, and the licensee's compliance history, raised a question concerning the validity (authenticity) of the transfer records. It was also undetermined if the sealed source had been leak tested prior to the transfer.

The team considered the potential for the device to end up at an unlicensed facility, such as a metals processor. Following the team's discussion concerning this case, the ORC Director initiated a call to the State program having jurisdiction over the new owner and confirmed that the new owner had a valid license. The new owner was also contacted by telephone to confirm the transfer of the device and that the device had been leak tested. The review team recommends that NMSS evaluate the risks associated with the termination of licensees with poor compliance history, particularly where the history suggests a lack of reliability, and provide guidance on how and when a regulatory program should obtain confirmation of the validity of the license of the receiving licensee and that the materials or devices were actually received by the receiving licensee.

In discussions with the program management, the team noted that there were no major decommissioning efforts underway with regard to agreement material in Alabama. The State is working with the NRC Region II office concerning the decommissioning of the NRC licensed Ft. McClellan site located near Anniston, Alabama (NRC license number 01-02861-04). The State is assisting NRC with environmental sampling and analysis, including groundwater samples.

The sample analyses are being performed by the ADEM laboratory located in Montgomery. Discussions were held with ORC staff concerning the adequacy and timeliness of results from samples sent to the laboratory for analysis. A visit was also conducted by the IMPEP team to evaluate the capabilities of the laboratory. The team noted that the EPA's Montgomery radiation laboratory is located in adjoining property (Gunter Air Force Base). The ORC Director related that the ORC staff has a good working relationship with the EPA staff.

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

3.5 Response to Incidents and Allegations

In evaluating the effectiveness of the ORC's actions in responding to incidents, the review team examined the response to the questionnaire relative to this indicator, reviewed the incident reports for Alabama in the Nuclear Material Events Database (NMED) against those contained in the

ORC's files, and reviewed reports and supporting documentation as appropriate for six incidents. In addition, the team reviewed the files for two allegations.

The six incidents selected for review included the following incident types: stolen radioactive material, overexposures, lost radioactive material, transportation accident, improper disposal of radioactive material, and damaged equipment. A list of the incidents reviewed in depth, with comments, is included in Appendix E.

The responsibility for the initial response and follow-up actions to material incidents may be assigned to any member of the materials program. When a report is received, it is given a unique number and logged into the incident log. A brief description of the incident along with the date the incident is eventually closed are also placed in the log. Documentation related to the incident is placed in an incident file and in the appropriate license file.

ORC staff responded to two of the incidents reviewed. One of the investigations was conducted on the same day the notification was received, and the other was conducted within a week of the notification. The program reviews the licensee's report of the incident at the next inspection. The review team determined that Alabama took prompt, appropriate action in response to the incidents reviewed. The team observed that Alabama consistently addressed health and safety issues in the incident follow-up.

All incidents that required notification to the State were reported to the NRC. Reports of incidents that required notification to the State within 24 hours were provided immediately to the NRC. However, prior to this year, reporting to the NMED of follow-up and routine event reports was performed on a yearly basis. This year reporting has been performed on a quarterly basis. The review team recommends that Alabama adopt a procedure providing that follow-up and routine event reports to NMED be provided within 30 days of receipt of the report from the licensee.

In evaluating the effectiveness of Alabama's actions responding to allegations, the team examined Alabama's response to the questionnaire relative to this indicator and reviewed the casework for two allegations. Prior to 1997, allegations were not separated from incidents. For 1997, allegations were provided a separate tracking number. During the review period, it is estimated that Alabama received less than 12 allegations per year for both Agreement materials and other radiation regulatory programs. During 1997, eight allegations were received, of which four were related to Agreement materials.

One of the files reviewed was of an anonymous allegation which was not substantiated. In the other file, the allegor contacted the program directly and did not request confidentiality. The investigation substantiated the allegation and the licensee was cited. The results were provided to the allegor.

Alabama evaluates each allegation and determines the proper level of response. The team's review of Alabama's responses and files determined that the responses are appropriate and that investigations or determinations are adequately documented.

Based on the IMPEP evaluation criteria, the review team recommends that Alabama'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. Alabama's agreement does not authorize regulation of uranium recovery activities.

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 affects the radiation control program. Legislative authority to create the program and enter into an agreement with the NRC was granted in 1963 (Acts of 1963, No. 582). The State Board of Health is designated as the State's radiation control agency. The authority to enter the Southeast Interstate Low-Level Radioactive Waste Compact was granted in 1982 (Acts of 1982, No. 328). The team noted that the legislation had not changed since the previous review.

4.1.2 Program Elements Required for Compatibility

In its response to the questionnaire, Alabama indicated that all of the NRC regulatory amendments, due for adoption through March 1998, that have been identified as needed for compatibility or as having provisions significant to health and safety, have been adopted. A copy of the effective Alabama regulations, including the last amendments which became effective as of March 18, 1998, was given to the team. Separately, NRC staff has reviewed the final Alabama regulations adopted March 18, 1998, and as a result of the review, determined that the regulations meet the compatibility and health and safety categories established in OSP Internal Procedure B.7.

The March 18, 1998 rulemaking included two amendments, the Clarification of Decommissioning Funding Requirements effective for NRC licensees November 24, 1995, and exempt distribution of a radioactive drug containing one microcurie of C-14 Urea effective for NRC licensees January 2, 1998. Alabama has not adopted the amendment to 10 CFR 19.12 contained in Radiation Protection Requirements: Amended Definitions and Criteria (due 8/14/98). The other provisions of that particular NRC rulemaking have been addressed by the State. The Program Director indicated that the change to § 19.12 will be addressed, and that generally rule changes can be completed in approximately three months.

- ! “Fissile Material Shipments and Exemptions,” 10 CFR Part 71 amendment (62 FR 5907) that became effective February 10, 1997.
- ! “Licenses for Industrial Radiography and Radiation Safety - Requirements for Industrial Radiography Operations,” 10 CFR Parts 30, 34, 71, 150 amendments (62 FR 28947) that became effective June 27, 1997.
- ! “Radiological Criteria for License Termination,” 10 CFR Parts 20, 30, 40, 70 amendments (62 FR 39057) that became effective August 20, 1997.

It is noted that Management Directive 5.9, Handbook, Part V, paragraph (1)(c)(iii), provides that the above regulations should be adopted by the State as expeditiously as possible, but not later than 3 years after the effective date of the new Commission Policy Statement on Adequacy and Compatibility, i.e., September 3, 2000.

Based on IMPEP evaluation criteria, the review team recommends that Alabama’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

During the review period, no SS&D certificates were issued by the State. The team reviewed the State’s plans for reviewing a source or device if required. Although the State does not have a branch dedicated to conducting reviews, it does have the authority to collect the full cost of an evaluation, and to contract for a review by qualified persons. The team did not evaluate this indicator further.

4.3 Low-Level Radioactive Waste Disposal Program

Alabama continues to be a member of the Southeast Interstate Low-Level Radioactive Waste Compact, and is not designated as the host State. There is no activity to establish a low-level radioactive waste disposal site in the State. The team did not evaluate this indicator further.

5.0 SUMMARY

As noted in Sections 3 and 4 above, the review team found that Alabama’s performance with respect to each of the performance indicators to be satisfactory. Accordingly, the team recommended and the Management Review Board concurred, in finding the Alabama program to be adequate to protect public health and safety and compatible with NRC’s program.

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

RECOMMENDATION TO THE ALABAMA:

The review team recommends that Alabama adopt a procedure providing that follow-up and routine event reports to NMED be provided within 30 days of receipt of the report from the licensee. (Section 3.5)

RECOMMENDATION TO NRC:

The review team recommends that NMSS evaluate the risks associated with the termination of licensees with poor compliance history, particularly where the history suggests a lack of reliability, and provide guidance on how and when a regulatory program should obtain confirmation of the validity of the license of the receiving licensee, and that the materials or devices were actually received by the receiving licensee. (Section 3.4)

SUGGESTIONS:

1. The review team suggests that the Alabama ORC continue their efforts to find ways to increase the percentage of high priority reciprocity licensees, and out-of-State licensees working in Alabama, to be inspected each year. (Section 3.1)
2. The review team suggests that the ORC accompany all material inspectors on a yearly basis. (Section 3.2)

GOOD PRACTICE:

The review team identified the ORC's self-audit as a good practice. The ORC initiated the self-audit to assess the status of the comments and recommendations from the 1995 program review, and to measure the current program against the IMPEP indicators. Corrective actions and improvements in several areas were identified and implemented.

LIST OF APPENDICES AND ATTACHMENTS

Appendix A	IMPEP Review Team Members
Appendix B	Alabama Organization Chart
Appendix C	Inspection File Reviews
Appendix D	License File Reviews
Appendix E	Incident File Reviews
Attachment 1	Alabama's Response to Review Findings

APPENDIX A

IMPEP REVIEW TEAM MEMBERS

Name	Area of Responsibility
Richard Blanton, OSP	Team Leader Technical Staffing and Training Legislation and Program Elements Required for Compatibility Sealed Source and Device Evaluation Program
William Silva, Texas	Technical Quality of Inspections Response to Incidents and Allegations
Joe DeCicco, NMSS	Status of Materials Inspection Program Technical Staffing and Training
Richard Woodruff, RII RSAO	Technical Quality of Licensing Actions

APPENDIX B

ALABAMA OFFICE OF RADIATION CONTROL
ORGANIZATION CHARTS

REORGANIZATION OF THE ALABAMA DEPARTMENT OF PUBLIC HEALTH

STATE GOVERNMENT
STATE BOARD OF HEALTH
STATE COMMITTEE OF PUBLIC HEALTH
STATE HEALTH OFFICER
Donald E. Williamson, MD

Staff Assistant
Melvin Maramba, BS

Office of Facilities Management
William J. Coleman, BS
Technical Services

General Counsel
John R. White, JD

Personnel Office
Sandra Wood, MBA

Office of Radiation Control
Kirksey Whaley, MS

Staff Assistant
Kathy Vincent, MSW, LCSW

Office of Professional and Support Services
Acting Director
Kathy Vincent, MSW, LCSW
Health Care Reform & Health Care Access Unit
Management Support Unit
Pharmacy Unit
Professional Services Unit
Training Unit

Office of Program Integrity
Interim Director
Dianne Sims

Bureau of Environmental Services
Director
William P. Allinder, PE, PLS

Community Environmental Protection
Food/MSW/Lodging
Training & Program Development

Bureau of Home & Community Services
Director
Myra J. Duane, RN, MSN

Community Services
Home Health Care
Program Support
Professional Development

Office of Primary Care & Rural Health Development
Director
Lyde Bargerter, Dr PH

Primary Health
Nursery Care
Rural Health

Assistant State Health Officer for Disease Control & Prevention
Director
Charles H. Warrick, MD, MPH

Bureau of Family Health Services
Director
Thomas M. Miller, MD, MPH

Child/Adolescent Health
Oral Health
WIC
Women's Health

Public Health Areas
Area Health Officer/
Area Administrator

County Health Departments

Bureau of Health Provider Standards
Director
Rick Harris, JD

Emergency Medical Services
Health Care Facilities
Provider Services
Managed Care Compliance

Bureau of Information Services
Director
Leon Warwick, MS

Office of Financial Services
Director
Heulien E. Davidson, III, MPA

Accounting
Operations Support

Bureau of Clinical Laboratories
Director
William J. Callan, PhD

Administrative Support Services
Clinical Chemistry
Clinical Microbiology
Metabolic
Microbiology
Quality Assurance
Respiratory Disease
Sanitary Bacteriology/Media Serology
Staphylococcus Microbiology
Birmingham Serology
Director
Lillian Mellett

Bureau of Disease Control
Director
Charles H. Warrick, MD, MPH

Diabetes Epidemiology
HIV/AIDS Prevention & Control
Hypertension
Immunization
Infection Control
STD Control
Tuberculosis Control

Bureau of Health Promotion & Information
Director
Jim McVay, Dr PA

Chronic Disease Prevention
Communications Design
Injury Prevention
Public Information
Video Communications

Center for Health Statistics
Director
Dorothy S. Harshbarger, MS

Quality Assurance
Record Services
Registration
Statistical Analysis

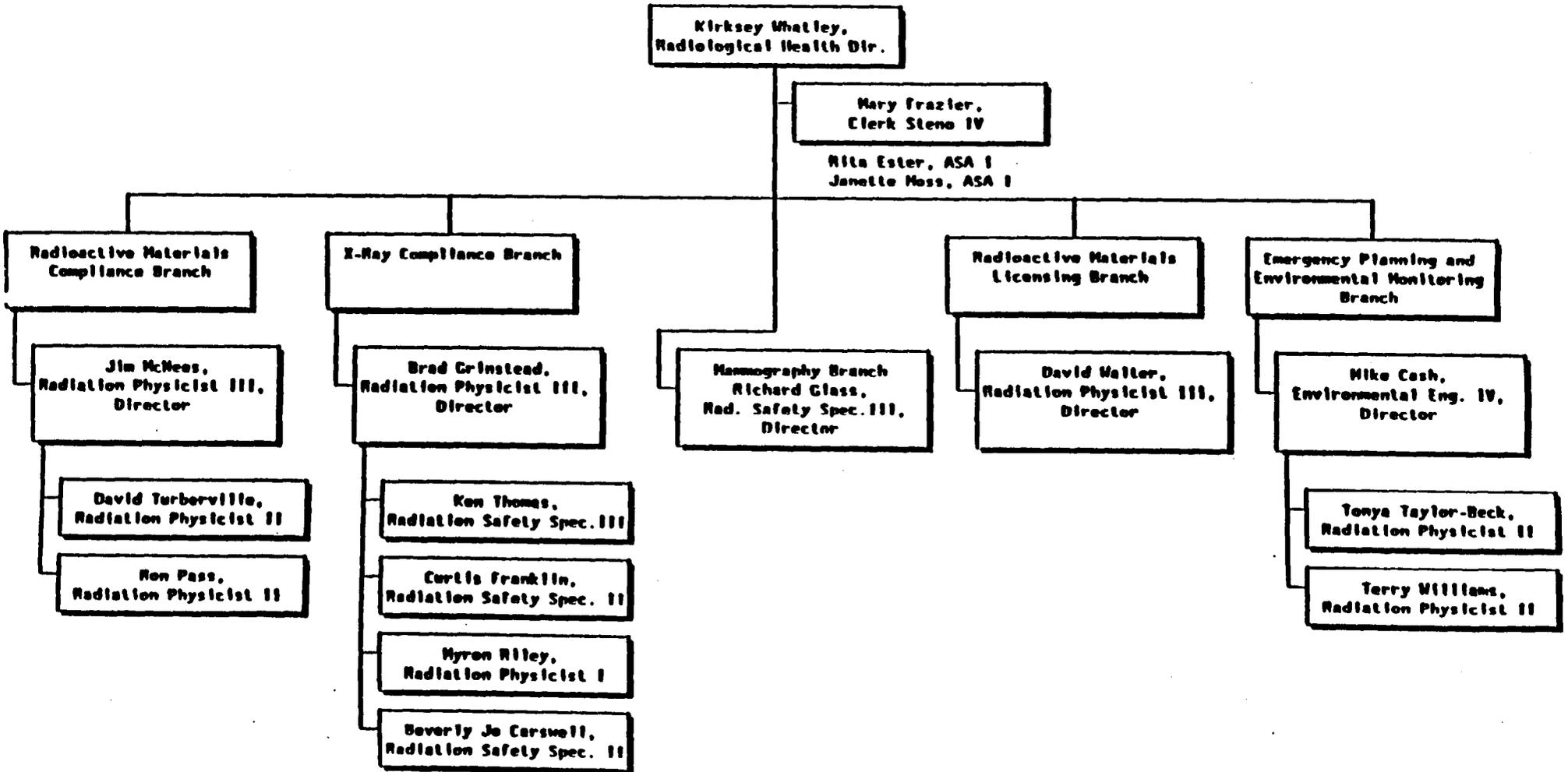
Computer Systems Center
Director
John Korman, MS

Information Technology Operations
Systems Development
Technical Support

January 30, 1978


State Health Officer

Office of Radiation Control





STATE OF ALABAMA DEPARTMENT OF
PUBLIC HEALTH

Donald E. Williamson, MD
State Health Officer

June 16, 1998

Richard L. Bangart, Director
Office of State Programs
United States Nuclear Regulatory Commission
Washington, D.C. 20555-0001

98 JUN 17 PM 1:37
NCR

Dear Mr. Bangart:

I have reviewed, with the assistance of staff, the draft IMPEP report for the State of Alabama Agreement State Program review which was held in our offices during April 20-23, 1998. In your May 27, 1998, letter you identified one recommendation, which requires a response and three suggestions. I will comment on the recommendation and suggestions as follows:

Recommendation:

"The review team recommends that Alabama adopt a procedure providing that reports of incidents that require immediate notification to the State be provided to the NRC within 24 hours of notification, and that reports of incidents that require notification to the State within 30 days be provided to the NRC monthly."

Response:

The recommendation is made not for a failure to report, but for failure to report within 30 days. Reports had previously been submitted on a quarterly basis instead of monthly. To my knowledge all required reports have been submitted to NRC.

The Office of Radiation Control (ORC) recognizes the importance of submitting reports of this nature and strongly supports the process. ORC has revised internal procedures to require that the reports be submitted to NRC as recommended by the review team.

Richard L. Bangart
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June 16, 1998

Please be advised that NRC and Agreement States will be notified as early as possible of any incident/problem that might have impact on NRC or Agreement State licensees. We will not wait 30 days. As an example, the IMPEP draft report, Page F-2, contains the report of a review for "File No. 33", and a statement that this occurrence did not meet the criteria for reporting to NRC. However, ORC did report to NRC and the event synopsis was published by NRC as an event.

The recommendation has been implemented by ORC.

Suggestion:

"The review team suggests that the Alabama ORC continue their efforts to find ways to increase the percentage of high priority reciprocity licensees, and out-of-state licensees working in Alabama, to be inspected each year."

Response:

ORC recognizes the importance of inspecting licensees working under reciprocal recognition of other agency licenses. ORC accepts the suggestion of the review team and will increase efforts to inspect more reciprocity and out-of-state licensees.

Several factors make this a difficult task. Examples include the thirty day reciprocity limit provided by the rules, the location of a high percentage of work done under reciprocity (City of Mobile shipyards, off-shore work, and oil & gas fields in Southwest Alabama - all of which involve 200 plus miles of travel), scheduling difficulties, short advance notification times, etc. Again, efforts will be made to increase inspection numbers (percentages) in this area.

Suggestion:

"The review team suggests that the ORC accompany all material inspectors on a yearly basis."

Response:

During an internal review of ORC, staff discovered that a required accompaniment for one inspector had not been made within the previous year as required by both ORC and NRC. The accompaniment had been scheduled previously; however, due to conflicts it had been canceled. Upon recognition of the problem, an accompaniment was immediately scheduled and conducted by management - prior to the review.

Richard L. Bangart

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June 16, 1998

It is the policy, and has been the policy, of ORC that supervisory accompaniments of all inspectors will be conducted at least once each year. The failure was actually corrected prior to the review.

Suggestion:

“The review team suggests that during termination of licenses with poor compliance history....confirmation of the validity of the license of the receiving licensee be obtained directly from the agency having jurisdiction, and that confirmation that the materials (devices) were received be obtained directly from the receiving licensee.”

Response:

The suggestion resulted from actions taken with the termination of one license. That licensee did have a poor performance history. The license was terminated following standard office procedure. The licensee had submitted to ORC a record of transfer containing proper information, a signed record of receipt from the receiving company including the recipient's license number and a business card of the recipient. These records were in the terminated file. That would have normally been sufficient information for termination.

Please note that this suggestion should not imply that records were not submitted to ORC with the termination request. The problem is that ORC staff did not contact the receiving out-of-state licensee to verify receipt of the americium 241 roof gauge nor was contact made with the Agreement State licensing staff to verify that the recipient actually had a license to possess the device.

The suggestion made by the review team is accepted and internal procedures have been implemented to apply this suggestion when terminating any license with poor compliance history. This suggestion had not previously been made.

The recommendation and three suggestions made by the review team are accepted, and each has been implemented, by the Office of Radiation Control.

For the record I would like to address several phrases and statements made in the body of the draft report as follows:

1. The draft report, page 3, states that ORC currently has no inspections overdue by more than 25% of the established interval. That statement is factual but does not paint a true picture. There are no overdue inspections - period. The 25% limit is a limit - the standard is “to keep up-to-date.”

Richard L. Bangart
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2. On page 3 of the draft report a statement is made that if a new licensee does not possess licensed material during the first five months of the license that the inspection frequency is extended another five months. That extension is not automatic. An inspector contacts the licensee and depending upon the judgement of the inspector and his supervisor, the inspection may be extended for five months.
3. On page 5 of the draft report a statement is made that ORC performs calibration of instruments at six month intervals. Actually calibrations are performed at three (3) month intervals.
4. Refer to Appendix D, Page D.1, of the draft report, License File No. 3. The initials of the inspector should be "RP" (Ron Pass), not "DP".
5. Refer to Page E.5 of the draft report. The comment under File No. 26, as written, could be interpreted that no documentation was in the file, when the intent should be that ORC did not verify the validity of the documentation which was actually in the file.

I would like to commend the review team of Richard Blanton, William Silva, Joe DeCicco, Richard Woodruff, and Paul Lohaus for their professionalism and courtesy. The recommendation and suggestions made by the team are accepted without contention and have, in fact, been implemented.

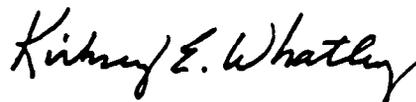
In Article V of the Alabama/NRC Agreement there appears the following statement:

"The State will use its best efforts to cooperate with the Commission and other Agreement States in the formulation of standards and regulatory programs....."

That commitment, made almost thirty two (32) years ago, remains our commitment today.

The support and assistance of NRC is recognized and appreciated. Please contact me if you have any questions regarding this letter.

Sincerely,



Kirksey E. Whatley, Director
Office of Radiation Control

KEW/jsm