

INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM  
QUESTIONNAIRE

**Program: State of Alabama**

**Reporting Period: May 15, 2010 to May 1, 2015**

Note: If there has been no change in the response to a specific question since the last IMPEP questionnaire, the State or Region may copy the previous answer, if appropriate.

**A. GENERAL**

1. Please prepare a summary of the status of the State's or Region's actions taken in response to each of the open recommendations from previous IMPEP reviews.

**RESPONSE:**

**There are no open recommendations from the previous IMPEP.**

**B. COMMON PERFORMANCE INDICATORS**

**I. Technical Staffing and Training**

2. Please provide the following organization charts, including names and positions:

- (a) A chart showing positions from the Governor down to the Radiation Control Program Director;

**Will be provided during the review.**

- (b) A chart showing positions of the radiation control program, including management; and;

**Will be provided during the review.**

- (c) Equivalent charts for sealed source and device evaluation, low-level radioactive waste and uranium recovery programs, if applicable.

**N/A**

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<sup>1</sup> Estimated burden per response to comply with this voluntary collection request: 53 hours. Forward comments regarding burden estimate to the Records Management Branch (T-5 F52), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, and to the Paperwork Reduction Project (3150-0183), Office of Management and Budget, Washington, DC 20503. If an information collection does not display a currently valid OMB control number, NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

3. Please provide a staffing plan, or complete a listing using the suggested format below, of the professional (technical) full-time equivalents (FTE) applied to the radioactive materials program by individual. Include the name, position, and, for Agreement States, the fraction of time spent in the following areas: administration, materials licensing and compliance, emergency response, low-level radioactive waste, uranium recovery, other. If these regulatory responsibilities are divided between offices, the table should be consolidated to include all personnel contributing to the radioactive materials program. If consultants were used to carry out the program's radioactive materials responsibilities, include their efforts. The table heading should be:

<b><u>Name</u></b>	<b><u>Position</u></b>	<b><u>Area of Effort</u></b>	<b><u>FTE%</u></b>
David Walter	Director	Administration	25%
		Agreement State Program	25%
		Emergency Response	20%
		X-Ray	20%
		WIPP/SSEB	5%
		Radon	5%
David A. Turberville	Assistant Director	Administration	25%
		Agreement State Program	25%
		X-Ray	20%
		Emergency Response	20%
		Radon	5%
		WIPP/SSEB	5%
Neil Maryland	Director, Licensing and Registration	Administration	40%
		Licensing	25%
		Registration	25%
		Emergency Response	5%
		Materials Inspection	5%
Cason Coan	Radiation Physicist Senior	Licensing	75%
		Materials Inspections	10%
		RSO Duties & Other	10%
		Emergency Response	5%
Undria McCallum	Radiation Physicist Senior	Registration	80%
		X-Ray Inspection	10%
		Emergency Response	5%
		Other	5%
Myron Riley	Director, Inspection	Administration	40%
		Materials Inspection	35%
		Non-Medical X-Ray & PA Inspections	20%
		Emergency Response	5%

<b>Roger Cleckler</b>	<b>Radiation Physicist Senior</b>	<b>Materials Inspection Non-Medical X-Ray &amp; PA Inspections Emergency Response Other</b>	<b>75% 15% 5% 5%</b>
<b>Keldrick Taylor</b>	<b>Radiation Physicist</b>	<b>Materials Inspection Non-Medical X-Ray &amp; PA Inspections Emergency Response Other</b>	<b>75% 15% 5% 5%</b>
<b>Vacant</b>	<b>Director, Environmental &amp; Special Projects</b>	<b>Environmental Sampling Environmental Response Administration Radon Emergency Response Other</b>	<b>25% 25% 25% 15% 5% 5%</b>
<b>Robert Suell</b>	<b>Radiation Physicist Senior</b>	<b>Environmental Sampling Environmental Response Equipment Maintenance Other Radon Emergency Response</b>	<b>45% 25% 10% 10% 5% 5%</b>
<b>Tonya Appleyard</b>	<b>Director, Emergency Planning</b>	<b>Emergency Response Administrative</b>	<b>80% 20%</b>
<b>Kevin Hicks</b>	<b>Radiation Physicist Senior</b>	<b>Emergency Response Administrative/Miscellaneous</b>	<b>80% 20%</b>
<b>Jessica Morris</b>	<b>Radiation Physicist</b>	<b>Emergency Response Administrative/Miscellaneous</b>	<b>80% 20%</b>
<b>Bradley Grinstead</b>	<b>Director, X-Ray</b>	<b>X-Ray Administration X-Ray Compliance MQSA Other Emergency Response</b>	<b>40% 35% 10% 10% 5%</b>
<b>Nick Swindall</b>	<b>Radiation Physicist Senior</b>	<b>MQSA X-Ray Compliance X-Ray Administration Emergency Response Other</b>	<b>50% 35% 5% 5% 5%</b>
<b>Emily Hasson</b>	<b>Radiation Physicist Senior</b>	<b>X-Ray Compliance X-Ray Administration Emergency Response Other</b>	<b>85% 5% 5% 5%</b>

<b>Paul Sullivan</b>	<b>Radiation Physicist Senior</b>	<b>X-Ray Compliance X-Ray Administration Emergency Response</b>	<b>70% 25% 5%</b>
<b>Seun Koriko</b>	<b>Radiation Physicist Senior</b>	<b>X-Ray Compliance X-Ray Administration Emergency Response</b>	<b>90% 5% 5%</b>
<b>Beverly Jo Perry</b>	<b>Rad. Safety Specialist III</b>	<b>MQSA X-Ray Compliance Emergency Response</b>	<b>70% 25% 5%</b>
<b>Nitalia Pena</b>	<b>Radiation Physicist Senior</b>	<b>X-Ray Compliance X-Ray Administration Emergency Response</b>	<b>70% 25% 5%</b>
<b>Meredith Pieper</b>	<b>Radiation Physicist</b>	<b>X-Ray Compliance Emergency Response</b>	<b>95% 5%</b>
<b>Mary Frazier</b>	<b>ASA III</b>	<b>Administrative Support Emergency Response</b>	<b>95% 5%</b>
<b>Debra Akhimie</b>	<b>ASA II</b>	<b>Administrative Support</b>	<b>100%</b>
<b>Jencie Bell</b>	<b>ASA II</b>	<b>Administrative Support</b>	<b>100%</b>
<b>Janette Moss</b>	<b>Account Clerk</b>	<b>Administrative Support Emergency Response</b>	<b>95% 5%</b>

4. Please provide a listing of all new professional personnel hired into your radioactive materials program since the last review, indicate the date of hire; the degree(s) they received, if applicable; additional training; and years of experience in health physics or other disciplines, as appropriate.

**RESPONSE:**

**Emily Hasson** – Hired [REDACTED] as a Radiation Physicist in our X-Ray Compliance program; BS degrees in Chemistry and Cellular & Molecular Biology; training includes Radiological Emergency Response Operations (RERO), FEMA IS-00003, FEMA IS-00100.a (ICS-100), FEMA IS-00200.b (ICS-200), FEMA IS-00700.a (NIMS), FEMA IS-00800.b, Oak Ridge 5-Week Applied Health Physics Course, Fluoroscopy training (AAPM); 5 years experience

**Oluwaseun Koriko** – Hired [REDACTED] as a Radiation Physicist in our X-Ray Compliance program; BS in Physical Science; training includes Radiological Emergency Response Operations (RERO), Advanced Radiological Emergency Response Operations (ARERO), Oak Ridge 5-Week Applied Health Physics

Course, FEMA IS-00003, FEMA IS-00100.a (ICS-100), FEMA IS-00200.b (ICS-200), FEMA IS-00700.a (NIMS), FEMA IS-00800.b, CT training in Baltimore, Fluoroscopy training (AAPM), MQSA Courses I, II, and III (FDA); 5 years experience

**Nitalia Pena** - Hired [REDACTED] as a Radiation Physicist in our X-Ray Compliance program; B.S. Physical Science; training includes Radiological Emergency Response Operations (RERO), FEMA IS-00003, FEMA IS-00100.a (ICS-100), FEMA IS-00200.b (ICS-200), FEMA IS-00700.a (NIMS), FEMA IS-00800.b, Oak Ridge 5-Week Applied Health Physics Course, Dose Evaluation in CT, Fluoroscopy training (AAPM), MIDAS training, RASCAL training; 4.5 years experience

**Roger Cleckler** – Hired [REDACTED] as a Radiation Physicist in our Radioactive Materials Compliance program; BS in Physics; training includes Inspection Procedures (G-108), Licensing Practices and Procedures (G-109), Diagnostic and Therapeutic Nuclear Medicine (H-304), Brachytherapy, Gamma Knife, and Emerging Technologies (H-313), Transportation of Radioactive Materials (H-308), Oak Ridge 5-Week Applied Health Physics, Safety Aspects of Well Logging (H-314), Safety Aspects of Industrial Radiography (H-305), NRC Materials Control and Security Systems and Principles (S-201), Radiological Emergency Response Operations (RERO); 3.5 years experience

**Paul Sullivan** - Hired [REDACTED] as a Radiation Physicist in our X-Ray Compliance program; B.S. in Mathematics; training includes Radiological Emergency Response Operations (RERO), Oak Ridge 5-Week Applied Health Physics Course, CT training in Baltimore, Fluoroscopy training (AAPM); 3.5 years experience

**Keldrick Taylor** - Hired [REDACTED] as a Radiation Physicist in our Radioactive Materials Compliance program; BS in Electrical Engineering; training includes Inspection Procedures (G-108), Licensing Practices and Procedures (G-109), Diagnostic and Therapeutic Nuclear Medicine (H-304), Brachytherapy, Gamma Knife, and Emerging Technologies (H-313), Transportation of Radioactive Materials (H-308), Radiological Emergency Response Operations (RERO), Oak Ridge 5-Week Applied Health Physics; 1.5 years experience

**Meredith Pieper** - Hired [REDACTED] as a Radiation Physicist in our X-Ray Compliance program; BS in Chemical Engineering; training includes Radiological Emergency Response Operations (RERO), Oak Ridge 5-Week Applied Health Physics Course, Fluoroscopy training (AAPM); 1.5 years experience

**Jessica Morris** - Hired [REDACTED] as a Radiation Physicist in our Emergency Planning program; BS degree in Mathematics; training includes Radiological Emergency Response Operations (RERO), Advanced Radiological Emergency Response Operations (ARERO), Oak Ridge 5-Week Applied Health Physics Course, Health Physics in Radiation Emergencies FEMA IS-3, FEMA IS-100.b, FEMA IS-120.a, FEMA IS-200.b, FEMA IS-235.b, FEMA IS-301, FEMA

IS-302, FEMA IS-303, FEMA IS-331, FEMA IS-700.a, FEMA IS-800.b, FEMA IS-812; 1 year experience

5. Please list all professional staff who have not yet met the qualification requirements for a radioactive materials license reviewer or inspector. For each, list the courses or equivalent training/experience they need and a tentative schedule for completion of these requirements.

**RESPONSE:**

**Materials Inspector, Keldrick Taylor needs to complete S-201 Materials Control & Security Systems & Principles (has applied for the 8/10-14/2015 class), H-314, Safety Aspects of Well Logging (has applied for the 4/27-5/1/2015 class) to independently perform inspections of well logging licensees, and H-305 Industrial Radiography (has applied for the 11/2-6/2015 class) to independently perform inspections of industrial radiography licensees. Mr. Taylor has been accompanying, and will continue to accompany, other qualified inspectors performing inspections of well logging and industrial radiography licensees until he has successfully completed the above coursework.**

6. Identify any changes to your qualification and training procedure that occurred during the review period.

**RESPONSE:**

**None**

7. Please identify the technical staff that left your radioactive materials program during the review period and indicate the date they left.

**RESPONSE:**

**██████████ retired as the Director of the Program December 31, 2013.**

8. List any vacant positions in your radioactive materials program, the length of time each position has been vacant, and a brief summary of efforts to fill the vacancy.

**RESPONSE:**

**We currently have a vacancy for the Director, Environmental & Special Projects. That position was vacated by ██████████ on February 16, 2015 as he was promoted to Assistant Director of the Office. The Director, Environmental & Special Projects position contributed approximately 0.25 FTE to the Agreement State materials program. Decisions are being made regarding this position and it is expected that final actions will be taken during the last half of 2015.**

9. For Agreement States, does your program have an oversight board or committee which provides direction to the program and is composed of licensees and/or members of the public? If so, please describe the procedures used to avoid any potential conflict of interest.

**RESPONSE:**

The Radiation Advisory Board of Health was an advisory board to the State Health Officer. This board convened as needed at the request of the State Health Officer. This board had not met in over a decade, and after our latest sunset review in 2013 by the Examiners of Public Accountants, Act #2014-73 of the State Legislature repealed 22-14-5, Code of Alabama 1975. This section of the Code established the Radiation Advisory Board of Health; Therefore, the Board was abolished. The Alabama Department of Public Health acts under the State Committee of Public Health, which reviews actions of this office (such as rule changes). This committee does not direct the day-to-day activities of our office nor manage the program. Several members of the Committee work for licensees or registrants. Members of the Committee are required to file annual Ethics Commission Statements regarding their service and possible conflicts of interests.

II. Status of Materials Inspection Program

10. Please identify individual licensees or categories of licensees the State is inspecting less frequently than called for in NRC's Inspection Manual Chapter (IMC) 2800 and explain the reason for the difference. The list only needs to include the following information: license category or licensee name and license number, your inspection interval, and rationale for the difference.

**RESPONSE:**

From Office Procedure 202.

- A. **Program codes 2121 (Medical Institution - WD Not Required) and Medical Private Practice - WD Not required)** are assigned Priority 3 instead of NRC Priority 5.
- B. **Program codes 2110 (Medical Institution Broad) and 2500 (Nuclear Pharmacies)** are assigned Priority 1 instead of NRC Priority 2. For these licensees, a full inspection will be performed at least every other year. The off-year inspection will specifically focus on higher risk licensee activities and any previous areas of noncompliance.
- C. **Program codes 3218 (Nuclear Laundry) and 3219 (decontamination services)** are assigned Priority 2 instead of NRC Priority 3.

- D. **Program codes 2300 (Teletherapy) and 3511 (Irradiators Other Greater than 10,000 Ci)** are assigned Priority 3 instead of NRC Priority 5.
  - E. **All references to priority T (telephonic contact) are assigned Priority 5.** This includes program codes 3122, 3123, 3124, 3220, 11210, 22130, 22160, and 22161.
  - G. **All references to priority D (Decommissioning Activities) are assigned Priority 1.** These licensees are required to notify the Agency prior to commencing decommissioning activities. The inspections are scheduled at times when the licensee is performing decommissioning activities at a site. If no notifications are received prior to the inspection due date, the licensee is contacted by phone to verify the status of the program and to confirm that no actual decommissioning activities have been conducted. If no activities have been conducted, the inspection due date is changed to one year from the date of the contact. This is applicable to program codes 3900, 11900, 21325, and 22200.
  - H. **Program codes 3145 (NORM Possession - No Activities) and 3146 (NORM Decontamination Services)** are added and assigned Priority 3.
11. Please provide the number of routine inspections of Priority 1, 2, and 3 licensees, as defined in IMC 2800 and the number of initial inspections that were completed during each year of the review period.

	I	II	III	Initial
<b>2015</b>	<b>2</b>	<b>0</b>	<b>4</b>	<b>0</b>
<b>2014</b>	<b>38</b>	<b>7</b>	<b>44</b>	<b>10</b>
<b>2013</b>	<b>31</b>	<b>5</b>	<b>63</b>	<b>7</b>
<b>2012</b>	<b>32</b>	<b>9</b>	<b>55</b>	<b>8</b>
<b>2011</b>	<b>36</b>	<b>6</b>	<b>51</b>	<b>4</b>
<b>2010</b>	<b>36</b>	<b>3</b>	<b>53</b>	<b>8</b>

12. Please submit a table, or a computer printout, that identifies inspections of Priority 1, 2, and 3 licensees and initial inspections that were conducted overdue.
- At a minimum, the list should include the following information for each inspection that was conducted overdue during the review period:
- (1) Licensee Name
  - (2) License Number
  - (3) Priority (IMC 2800)
  - (4) Last inspection date or license issuance date, if initial inspection
  - (5) Date Due
  - (6) Date Performed
  - (7) Amount of Time Overdue



(8) Date inspection findings issued

**RESPONSE:**

**Walker Cardiology Associates      #1546 Priority 3**  
**License Issued: 11/4/2011          Due: 11/4/2012**  
**Performed: 1/24/2013                Overdue: 85 days**  
**Letter Sent: 2/13/13**

**An error was made when the licensee was entered into the database during initial license issuance. This was discovered during routine review of the database in late December 2012, and the initial inspection was performed soon thereafter.**

13. Please submit a table or computer printout that identifies any Priority 1, 2, and 3 licensees-and initial inspections that are currently overdue, per IMC 2800. At a minimum, the list should include the same information for each overdue inspection provided for Question 12 plus your action plan for completing the inspection. Also include your plan for completing the overdue inspections.

**RESPONSE:**

**None are overdue at this time**

14. Please provide the number of reciprocity licensees that were candidates for inspection per year as described in IMC 1220 and indicate the number of reciprocity inspections of candidate licensees that were completed each year during the review period.

**RESPONSE:**

**It is important to note that Alabama only allows 30 days of reciprocity each calendar year.**

	<b>Licensees Working Under Reciprocity</b>	<b>Inspected</b>
<b>2015</b>	<b>16</b>	<b>1</b>
<b>2014</b>	<b>59</b>	<b>11</b>
<b>2013</b>	<b>51</b>	<b>12</b>
<b>2012</b>	<b>54</b>	<b>2</b>
<b>2011</b>	<b>54</b>	<b>5</b>
<b>2010</b>	<b>43</b>	<b>3</b>

III. Technical Quality of Inspections

15. What, if any, changes were made to your written inspection procedures during the reporting period?

**RESPONSE:**

No changes were made to our written procedures, but we are trying a new inspection process on all new 5 year interval licensees. After the initial inspection is performed, the next routine inspection is set for 2½ years later, rather than 5 years later. We expect this will allow us to help enhance the licensee's understanding of what constitutes an effective radiation safety program, and at the same time help us build a better working relationship with them early on.

16. Prepare a table showing the number and types of supervisory accompaniments made during the review period. Include:

<b>Inspector</b>	<b>Supervisor</b>	<b>License Category</b>	<b>Date</b>
Cason Coan	Myron Riley	2120	8/19-20/2014
Cason Coan	Myron Riley	3218	10/23-24/2013
Cason Coan	Myron Riley	2230	12/5/2012
Cason Coan	Myron Riley	2500	4/18/2012
Cason Coan	Myron Riley	3225	3/17/2011
Cason Coan	Myron Riley	3121	12/16/2010
Roger Cleckler	Myron Riley	2110	6/24-27/2014
Roger Cleckler	Myron Riley	3218	10/23-24/2013
Roger Cleckler	Myron Riley	2121	7/25/2013
Roger Cleckler	Myron Riley	3320	11/27/2012
Roger Cleckler	Myron Riley	3121	2/29/2012
Roger Cleckler	Myron Riley	2201	5/23/2012
Keldrick Taylor	Myron Riley	2121	7/10/2014
Keldrick Taylor	Myron Riley	3121	2/28/2014

17. Describe or provide an update on your instrumentation, methods of calibration, and laboratory capabilities. Are all instruments properly calibrated at the present time? Were there sufficient calibrated instruments available throughout the review period?

**RESPONSE:**

Health physics staff members are provided Ludlum 14C kits that include 44-9, 44-38, and 44-2 probes, pocket dosimeters and chargers, and alarming dosimeters. These kits accompany each health physics staff member at all times. The kits are kept with staff at home during off-duty hours and when away from the office during work hours. Calibration is provided annually in-house using a Cs-137 calibrator. In addition, the Radioactive Materials Inspection Branch maintains a collection of GM meters, ion chambers, alpha scintillation counters, and microR meters for inspection and emergency response. Non-pressurized ion chambers are

calibrated in-house on a six month frequency using approved procedures. A Tech-Ops 773 Cs-137 calibration source and a Pu-238 alpha standard set are used for routine calibration of meters, as appropriate. In addition, several instruments capable of radioisotope identification are available (Thermo and Canberra analyzers) Sufficient additional meters of appropriate type are available, calibrated, and utilized to maintain Alabama's Agreement State program.

IV. Technical Quality of Licensing Actions

18. How many specific radioactive material licenses does your program regulate at this time?

**RESPONSE:**

**414 licenses as of 2/23/2015**

19. Please identify any major, unusual, or complex licenses which were issued, received a major amendment, were terminated, decommissioned, submitted a bankruptcy notification or renewed in this period.

**RESPONSE:**

**Renewed University of Alabama Birmingham, #266 in 8/12, renewed University of South Alabama, #584 in 9/13, renewed Auburn University (cobalt pool irradiator), #415 in 3/13, renewed Eastern Technologies, Inc, #947 in 12/12.**

20. Discuss any variances in licensing policies and procedures or exemptions from the regulations granted during the review period.

**RESPONSE:**

**For byproduct radioactive material, no variances in licensing policies and procedures or exemptions from the regulations were granted during the review period.**

21. What, if any, changes were made in your written licensing procedures (new procedures, updates, policy memoranda, etc.) during the reporting period?

**RESPONSE:**

**No changes were made in our written licensing procedures during the reporting period.**

22. Identify by licensee name and license number any renewal applications that have been pending for one year or more. Please indicate why these reviews have been delayed and describe your action plan to reduce the backlog.

**RESPONSE:**

**No renewal applications were pending for one year or more.**

V. Technical Quality of Incident and Allegation Activities

23. For Agreement States, please provide a list of any reportable incidents not previously submitted to NRC (See Procedure SA-300, *Reporting Material Events*, for additional guidance, OMB clearance number 3150-0178). The list should be in the following format:

<u>Licensee Name</u>	<u>License #</u>	<u>Date of Incident/Report</u>	<u>Type of Incident</u>
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**N/A**

24. Identify any changes to your procedures for responding to incidents and allegations that occurred during the period of this review.

**RESPONSE**

**No changes to the procedures for responding to incidents and allegations were made during this review period.**

C. **NON-COMMON PERFORMANCE INDICATORS**

I. Compatibility Requirements

25. Please list all currently effective legislation that affects the radiation control program. Denote any legislation that was enacted or amended during the review period.

**RESPONSE**

**There have been no changes during this review period.**

26. Are your regulations subject to a "Sunset" or equivalent law? If so, explain and include the next expiration date for your regulations.

**RESPONSE**

**The regulations themselves are not subject to sunset law. The entire program was subject to sunset review once every four years. These reviews were conducted by a state agency known as the Examiners of Public Accounts. Our most recent review was in 2013, which was followed by a recommendation to the legislature that the program be continued and that the program no longer be subjected to sunset reviews. The legislature acted favorably and passed a bill that continues the program and states that the Radiation Control Agency is no longer an enumerated agency**

subject to review by the Alabama Sunset Committee.

27. Please review and verify that the information in the enclosed State Regulation Status (SRS) sheet is correct. For those regulations that have not been adopted by the State, explain why they were not adopted, and discuss actions being taken to adopt them. If legally binding requirements were used in lieu of regulations and they have not been reviewed by NRC for compatibility, please describe their use.

**Responses are color coded with the description**

NRC Section	RATS ID	Subject & Comments	Response
32.72	2007-1 2007-3	<p><b>Manufacture, preparation, or transfer for commercial distribution of radioactive drugs, containing byproduct material for medical use under Part 35</b></p> <p>AL does not have equivalent regulations corresponding to 10 CFR 32.72(b)(3)</p>	<p>The way we interpret 32.72(b)(3) (<i>The actions authorized in paragraphs (b)(1) and (b)(2) of this section are permitted in spite of more restrictive language in license conditions.</i>) it says you can <b>never</b> have a circumstance that would override rules 32.72(b)(1) or (2). We questioned the NRC regarding this. NRC answered 10 CFR 32.72(b)(3) came into existence when a final rule was published on December 2, 1994. This rulemaking is RATS ID 1995-1. While that RATS ID does not break out specific sections of 10 CFR 32.72 and their associated compatibility it does show that at that time (and still currently) all of 10 CFR 32.72 is a compatibility category B. Under the Statements of Consideration for the rule the rationale behind its creation states “A new 32.72(b)(3) has been added to the final rule to make clear that the actions authorized in 32.72(b)(1) and (2) are permitted in spite of more restrictive language in existing license conditions and to avoid the need for many license amendments in order to implement the Commission's intentions.”</p> <p>Seeing as how this was the case for something that occurred in the 1994/1995 timeframe it might appear to not apply to current licensing as this</p>

		<p>AL needs to rewrite 420-3-26-.02(10)(t)1.(ii)(II) and (III) to read (ii) Registered or licensed with the Alabama Board of Pharmacy or another state agency as a drug manufacturer, (III) Licensed as a pharmacy by the Alabama Board of Pharmacy or another State Board of Pharmacy; [insert equivalent text to 10 CFR 32.72(a)(2)(iv)].+</p>	<p>was almost 20 years ago and could cause confusion. That said this text still does exist in NRC rule text and is a compatibility category B so therefore Agreement States are required to adopt an essentially identical regulation (regardless of whether the original intention of the regulation still applies to current licensing practice today).+ Alabama has not included this text in our revised rule because we do not have any licenses from the 1995 time frame that have not been renewed (many times over), and, therefore, would not have any license conditions that would conflict with the rules, unless it is the specific intention of the Agency for a condition to allow an exemption to the rules. License conditions are put in place to cover unique areas that are not covered in the rules, or to override the rules to make the actions required of the licensee to be either more, or less, restrictive than the rules. We must maintain that ability to assure the most effective radiation protection program. We recommend that the NRC delete 32.72(b)(3) during their next proposed changes to 10 CFR Part 32 because this rule no longer serves any purpose.</p> <p>We cannot license an applicant unless they are first licensed by the <u>Alabama Board of Pharmacy (BOP)</u>. The BOP is the only Alabama agency that can issue a license to operate as a drug manufacturer. Our Agency license covers the radiation safety aspects of their operation, but they cannot receive a radioactive materials license until the BOP gives them a pharmacy license. Licensure in another state might suffice with the Board of Pharmacy to expedite <u>Alabama licensure</u>, but if I license an</p>
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		<p>Insert an equivalent to 10 CFR 32.72(b)(4) and (b)(5) % copy of their license or registration to practice nuclear pharmacy by the Alabama Board of Pharmacy or other equivalent State Board of Pharmacy, no later than 30 days after the date that the licensee allows, under paragraphs [insert equivalent for 10 CFR 32.72(b)(2)(i) and (b)(2)(iii)] of this section, the individual to work as an authorized nuclear pharmacist+.</p>	<p>entity as a radiopharmacy without the BOP having first issued them a pharmacy license, I am in conflict with BOP rules.</p> <p>We do not allow a licensee to <u>designate</u> ANP<del>s</del>, etc. Rather, we require them to amend their license and get the approved amendment before they begin work. However, we do allow a licensee to authorize Visiting ANP status if the individual can be approved under Rule 420-3-26-.07(14). That is to maintain our responsibility to assure that an individual is licensed by the appropriate state agency in their field before we authorize them to use radioactive materials under the auspices of one of our licenses.</p>
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28. If you have not adopted all amendments within three years from the date of NRC rule promulgation, briefly describe your State's procedures for amending regulations in order to maintain compatibility with the NRC, showing the normal length of time anticipated to complete each step.

**RESPONSE:**

**It is, and always has been, a goal of this office to honor the state commitment to maintain a program that is adequate to protect the public and occupationally exposed worker, and compatible with the NRC.**

**Rule changes are drafted along with a brief explanation of the change and why the change is considered necessary. Proposed changes are reviewed by our Legal department to assure they do not conflict with other existing rules. Upon receiving legal approval, the proposed rules are packaged and sent to members of the State Committee of Public Health for consideration at the monthly meeting, usually on the third Wednesday of the month. The State Committee of Public Health must approve the dissemination of the proposed rules for public comment. Once rules are approved for release for public comment, they are also submitted to the NRC for review.**

**The Committee acts upon a recommendation of the State Health Officer to submit the proposed changes to the State Legislative Reference Service (LRS) for publication for comment. The date the changes are filed with the**

**LRS is critical based upon a pre-published calendar. If changes meet certain dates for filing, the minimum time allowed for public comment is 35 days from the actual date of publication, not the date of filing. If that early date is missed, then the changes would be filed in the next month publication, resulting in a minimum 70 days from action to end of comment period.**

**A public hearing is always conducted for proposed rule changes, and additional public hearings can be requested. These may delay further steps in the rule making process. Comments as received from the public, from hearings, from NRC and other agencies are then analyzed by the staff, and modifications to the rules are considered. Modifications to proposed rules are made, with staff explanations, along with copies of all comments received. This modified rules package is then forwarded to the State Committee of Public Health. The Committee acts upon recommendations of staff and comments received, and can either give final approval of the package or, if substantial changes are made, direct that the package go out for further public comment.**

**The process can be as short as three months, or can take much longer. Larger rule packages have taken two years to complete from beginning to end. Typically, provided no controversial issues develop, the time frame is dominated by the actual writing of the rule revisions, and the period after the initial submission to the State Committee of Public Health to the final adoption of a rule is less than six months. Without staff expressly dedicated to rule making, larger rule packages can take over a year to develop before being sent to the State Committee of Public Health.**

**If adopted, the final rule package is submitted to the LRS for publication as final rules which become officially effective 35 days after publication by the LRS.**

**While not the preferred method, the requirements of most radiation protection rules can be implemented much earlier than the time it takes for development and adoption of a new rules package by use of license conditions or policies. That is especially true of all significant health and safety rules.**

**The office has the ability to take necessary steps to protect public health and safety on very short notice (less than a work day) if needed.**

**Controversial rule changes can lead to delays. With the time consuming rule change process, every effort is made to make sure that the concerns of all parties are heard and addressed before a final rule is issued. But if rule changes have significant health and safety implications, those**



**changes can be implemented very quickly by the use of orders or license conditions. Public health and safety has not been jeopardized by the rule adoption process in Alabama.**

II. Sealed Source and Device (SS&D) Evaluation Program

29. Prepare a table listing new and amended (including transfers to inactive status) SS&D registrations of sources and devices issued during the review period. The table heading should be:

SS&D Registry of <u>Number</u>	Manufacturer, Distributor or <u>Custom User</u>	Product Type  <u>or Use</u>	Date  <u>Issued</u>	Type  <u>Action</u>
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**RESPONSE:**

**State of Alabama does not have an active SS&D program. No sources or devices have been evaluated since the previous IMPEP review.**

30. Please include information on the following questions in Section A, as they apply to the SS&D Program:

Technical Staffing and Training - Questions 2-9  
Technical Quality of Licensing Actions - Questions 18-22  
Technical Quality of Incident and Allegation Activities - Questions 23-24

**N/A**

III. Low-level Radioactive Waste Disposal Program

31. Please include information on the following questions in Section A, as they apply to the Low-Level Radioactive Waste Disposal Program:

Technical Staffing and Training - Questions 2-9  
Status of Materials Inspection Program - Questions 10-14  
Technical Quality of Inspections - Questions 15-17  
Technical Quality of Licensing Actions - Questions 18-22  
Technical Quality of Incident and Allegation Activities - Questions 23-24

**N/A**

IV. Uranium Recovery Program

32. Please include information on the following questions in Section A, as they apply to the Uranium Recovery Program:

Technical Staffing and Training - Questions 2-9  
Status of Materials Inspection Program - Questions 10-14  
Technical Quality of Inspections - Questions 15-17  
Technical Quality of Licensing Actions - Questions 18-22  
Technical Quality of Incident and Allegation Activities - Questions 23-24

**N/A**

MATERIALS REQUESTED TO BE AVAILABLE FOR  
THE ON-SITE PORTION OF AN IMPEP REVIEW

Please have the following information available for use by the IMPEP review team when they arrive at your office:

- List of open license cases, with date of original request, and dates of follow-up actions.

**Neil Maryland will provide at IMPEP**

- List of licenses terminated during review period.

**Neil Maryland will provide at IMPEP**

- Copy of current log or other document used to track licensing actions.

**Neil Maryland will provide at IMPEP**

- List of all licensing actions completed during the review period (sorted by license reviewer, if possible).

**We do not have this available in a database. Neil Maryland will provide what we have at IMPEP**

- Copy of current log or other document used to track inspections.

**Myron Riley will provide at IMPEP**

- List of all inspections completed during the review period (sorted by inspector, if possible).

**We do not have this available in a database. Alabama's data base contains the last three inspection dates for a licensee. Myron Riley will provide what we have at IMPEP**

- List of inspection frequencies by license type.

**Office Procedure #202.**

- List of all allegations occurring during the review period. Show whether the allegation is open or closed and whether it was referred by NRC.

**David Turberville will provide at IMPEP**

- List of all licenses that your agency has imposed additional security requirements upon.

**Neil Maryland will provide at IMPEP**