

September 18, 2013

James L. McNeese, CHP, Director
Office of Radiation Control
State Department of Public Health
201 Monroe Street
P.O. Box 303017
Montgomery, AL 36130-3017

Dear Mr. McNeese:

We have reviewed the June 19, 2013, letter sent by you in response to NRC comments on revised Alabama rules received by our office on June 25, 2013. These responses were reviewed by comparison to the equivalent U.S. Nuclear Regulatory Commission (NRC) rules in 10 CFR Parts 19, 20, 30, 31, 32, 33, 35, 40, 61, 70 and 150 and the 24 comments on nine amendments identified in NRC letter dated July 19, 2012. We discussed our review of the regulations with David Walter on September 16, 2013.

As a result of our review, we have retained 21 comments, amended 1 comment, and removed 2 comments from our July 19, 2012, letter. Please note that we have limited our review to regulations required for compatibility and/or health and safety. The enclosed table shows the 22 outstanding comments that need to be incorporated into Alabama's final regulations along with our rationale to your responses.

We request that when the regulations are revised and adopted as stated in the enclosed comment table, a copy of the "as published" regulations be provided to us for review. As requested in FSME Procedure SA-201, "Review of State Regulatory Requirements," please highlight the final changes, and provide a copy to Division of Materials Safety and State Agreements, FSME.

The SRS Data Sheet summarizes our knowledge of the status of other Alabama regulations, as indicated. Please let us know if you note any inaccuracies, or have any comments on the information contained in the SRS Data Sheet. This letter, including the SRS Data Sheet, is posted on the FSME website: <http://nrc-stp.ornl.gov/rulemaking.html>.

J. McNees

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If you have any questions regarding the comments, the compatibility and health and safety categories, or any of the NRC regulations used in the review, please contact Kathleen Schneider, State Regulation Review Coordinator, at (301) 415-2320 (kathleen.schneider@nrc.gov) or Monica Ford at (610) 337-5214 (monica.orendi@nrc.gov).

Sincerely,

/RA D. White for/

Pamela J. Henderson, Deputy Director
Division of Materials Safety and State Agreements
Office of Federal and State Materials
and Environmental Management Programs

Enclosures:

1. Revised Compatibility
Comment Table
2. Alabama SRS Data Sheet

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**REVISED COMPATIBILITY COMMENTS ON ALABAMA FINAL REGULATIONS
IN RESPONSE ALABAMA RESPONSE LETTER DATED JUNE 19, 2013**

| STATE SECTION | NRC SECTION | RATS ID | CATEGORY | SUBJECT and COMMENTS |
|---------------|------------------------------|----------------------------|----------|--|
| 1 | 420-3-26-.02(10)(u) 32.72 | 2006-1 2007-1 2007-3 | B | <p>Manufacture, preparation, or transfer for commercial distribution of radioactive drugs, containing byproduct material for medical use under Part 35</p> <p>Alabama (AL) does not have equivalent regulations corresponding to 10 CFR 32.72(a)(2)(iv), 32.72(a)(2)(v), 32.72(b)(3), 32.72(b)(4), 32.72(b)(5)(iii), or 32.72(b)(5)(v).</p> <p>AL needs to rewrite 420-3-26-.02(10)(u)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)]. or insert equivalent text to 10 CFR 32.72(a)(2)(v)]."</p> <p>AL needs to rewrite 420-3-26-.02(10)(u)1.(iv)(I) to say "...whether it is constructed of lead, glass, plastic, or other material, of a radioactive drug to be transferred for commercial distribution ..."</p> <p>AL needs to insert their equivalent reference to 10 CFR 32.72(a)(2)(iv) in 420-3-26-.02(10)(u)2.</p> <p>AL needs to insert their equivalent reference to 10 CFR 32.72(b)(4) in 420-3-26-.02(10)(u)2.(i).</p> <p>AL needs to rewrite 420-3-26.02(1)(u)2.(ii) to read "... to work as an authorized nuclear pharmacist if: (I) This individual qualifies as an authorized nuclear pharmacist as defined in 420-3-26-.07(2); (II) This individual meets the requirements in 420-3-26-.07(28)(b) and 420-3-26-.07(30) and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist; or (III) This individual is designated as an</p> |

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| | | | | <p>authorized nuclear pharmacist in accordance with paragraph [insert equivalent to 10 CFR 32.72(b)(4) once added] of this section.”</p> <p>AL needs to rewrite 420-3-26-.02(10)(u)2.(iii)(III) to read “The permit issued by an Agency, U.S. Nuclear Regulatory Commission, or Agreement State licensee or a Commission master materials permittee of broad scope or the authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacists, or (IV) [insert equivalent to 10 CFR 32.72(b)(5)(v)], and (V) A 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>AL needs to make the above changes in order to meet the Compatibility Category B designation assigned to 10 CFR 32.72.</p> <p>Comment from letters dated July 14, 2010, and July 19, 2012, has been amended.</p> <p>AL states in their June 19, 2013, letter, in item 1, that the AL Board of Pharmacy is the only state Agency that licenses drug manufacturers and pharmacies in AL. However, AL adopts an equivalent provision to 10 CFR 32.72(a)(2)(i) which allows a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug to be registered with the U.S. Food and Drug Administration. Since AL adopts an equivalent provision to 32.72(a)(2)(i) they should also adopt an equivalent provision to 10 CFR 32.72(a)(2)(iv). Adoption of equivalent text to 10 CFR 32.72(a)(2)(iv) does not prohibit the Pharmacy from first being licensed with the AL Board of Pharmacy before obtaining an AL radiopharmacy license.</p> <p>AL states in their June 19, 2013, letter, in item 1, that 10 CFR 32.72(a)(2)(v) is covered by their equivalent to 10 CFR 32.72(a)(2)(ii) and (iii) since they use</p> |

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| | | | | <p>the word radioactive material in the opening paragraph instead of the word byproduct material. This clarification allows for the removal of needing equivalent text to 10 CFR 32.72(a)(2)(v) from the original comment.</p> <p>AL's response in their letter dated June 19, 2013, item 1, to needing equivalent text to 10 CFR 32.72(b)(3) addresses needing equivalent text to 10 CFR 32.72(b)(4) regarding designating a pharmacist as an authorized nuclear pharmacist instead of adding language that, as stated in 10 CFR 32.72(b)(3), "The actions authorized in paragraphs (b)(1) and (b)(2) [change to AL equivalent] of this section are permitted in spite of more restrictive license conditions." AL needs to add equivalent text to 10 CFR 32.72(b)(3) to their regulations.</p> <p>AL's response in their letter dated June 19, 2013, item 1, states that they do not allow reciprocal recognition to practice pharmacy, but will allow the pharmacist to submit documentation that they are already licensed to practice pharmacy in another state as evidence that they do not have to take the written AL Pharmacy Board test. However, the individual cannot practice pharmacy in AL until after the AL Board of Pharmacy has issued them a license. By adopting essentially identical rule language to 10 CFR 32.72(b)(4) this does not prohibit AL from requiring that the individual first be licensed with the AL Board of Pharmacy. If AL chooses not to incorporate essentially identical text based on the response stating that AL does not allow licensees to "designate" individuals as authorized nuclear pharmacists then AL's regulation will be more restrictive than NRC's regulation and will not meet the definition of a Compatibility Category B. AL needs to adopt equivalent language to 10 CFR 32.72(b)(4).</p> <p>AL's response in their letter dated June 19, 2013, item 1, states that with regards to 10 CFR 32.72(b)(5)(v), AL's "definition of "radioactive material" has always included accelerator produced radioactive material and therefore we feel we should not add language that could be interpreted to mean that we did not license such material prior to the Energy Policy Act of 2005 (EPAAct)." However, AL adopting equivalent language to 10 CFR</p> |

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| 2 | 35.2 | 2006-1 | B | <p>32.72(b)(5)(v) does not convey that AL did not have authority for accelerator produced radioactive material before the EPA Act. It simply allows for an AL licensee to submit an individual, who worked in NRC/Federal jurisdiction prior to the dates mentioned in 10 CFR 32.72 (b)(5)(v), to be added to their license as an authorized nuclear pharmacist by AL, without having to provide a license with that individuals name on it or training requirements since NRC did not have authority over accelerator produced radioactive material prior to the dates listed in 10 CFR 32.72(b)(5)(v), so long as the licensee can provide documentation that only accelerator produced radioactive material was used in the practice of nuclear pharmacy at an NRC regulated facility.</p> <p>Definition: Authorized Medical Physicist</p> <p>AL omits the equivalent to paragraphs (ii) and (iv) of the 10 CFR 35.2 definition of Authorized medical physicist from their definition in 420-3-26-.07(2)(d).</p> <p>AL needs to remove the “and” after 420-3-26-.07(2)(d)(ii) and change it to an “or.”</p> <p>AL needs to make the above changes in order to meet the Compatibility Category B designation assigned to 10 CFR 35.2 Definition: Authorized Medical Physicist.</p> <p>Comment stands from letter dated July 19, 2012. In letter dated June 19, 2013, item 15, AL agrees to address the first paragraph and challenges the second paragraph of this comment.</p> <p>AL states in their June 19, 2013, letter, in item 15, an authorized medical physicist is not allowed to perform licensed activities until such time as the Agency has reviewed their training and experience and issued an amended license that indicates by name, that they are an authorized medical physicist. This makes AL’s regulation more restrictive than NRC’s regulation since 10 CFR 35.2 allows for authorized medical physicists already approved on a license to use that license to be placed on another</p> |

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| | | | | <p>license without having to resubmit their training and experience requirements.</p> <p>10 CFR 35.2 Definition: Authorized Medical Physicist is a Compatibility Category B which means that an Agreement State's regulation needs to be essentially identical to NRC's rule and cannot be more restrictive. Since AL's regulation is more restrictive, it does not meet the Compatibility Category B designation assigned to 10 CFR 35.2 Definition: Authorized Medical Physicist.</p> |
| 3 | 35.2 | 2006-1 | B | <p>Definition: Authorized Nuclear Pharmacist</p> <p>AL omits the equivalent to paragraphs (ii) and (iv) of the 10 CFR 35.2 definition of Authorized nuclear pharmacist from their definition in 420-3-26-.07(2)(e).</p> <p>AL needs to remove the "and" after 420-3-26-.07(2)(e)(ii) and (2)(e)(3) and change both to an "or."</p> <p>AL needs to make the above changes in order to meet the Compatibility Category B designation assigned to 10 CFR 35.2 Definition: Authorized Nuclear Pharmacist.</p> <p>Comment stands from letter dated July 19, 2012. In letter dated June 19, 2013, item 16, AL stated they would not address this during their next rule revision.</p> <p>AL states in their June 19, 2013, letter, in item 16, becoming an authorized and licensed nuclear pharmacist requires approval by two agencies, the AL Board of Pharmacy and the AL Office of Radiation Control. AL states that adoption of 10 CFR 35.2 Definition: Authorized Nuclear Pharmacist paragraphs (ii) and (iv) will cause conflict with another Agency's requirements. However, adding equivalent text to 420-3-26-.07(2)(e) that covers 10 CFR 35.2 Definition: Authorized Nuclear Pharmacist paragraph's (ii) and (iv) does not prohibit or bypass AL's requirement that before an</p> |

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| | | | | <p>individual can perform duties as an authorized nuclear pharmacist they must first be licensed by both the AL Board of Pharmacy and the AL Office of Radiation Control. In not accepting training and experience requirements reviewed by another Agreement State or the NRC (as evidence by being listed on a license) during the process of adding an individual to a license as an authorized nuclear pharmacist, AL's regulation is more restrictive than NRC's regulation since 10 CFR 35.2 allows for authorized nuclear pharmacists already approved on a license to use that license to be placed on another license without having to resubmit their training and experience requirements.</p> <p>10 CFR 35.2 Definition: Authorized Nuclear Pharmacist is a Compatibility Category B which means that an Agreement State's regulation needs to be essentially identical to NRC's rule and cannot be more restrictive. Since AL's regulation is more restrictive, it does not meet the Compatibility Category B designation assigned to 10 CFR 35.2 Definition: Authorized Nuclear Pharmacist.</p> |
| 4 | 35.2 | 2006-1 | B | <p>Definition: Authorized User</p> <p>AL omits the equivalent to paragraphs (ii) and (iv) of the 10 CFR 35.2 Definition of Authorized user from their definition in 420-3-26-.07(2)(f).</p> <p>AL needs to remove the "and" after 420-3-26-.07(2)(f)(ii) and change it to an "or."</p> <p>AL needs to make the above changes in order to meet the Compatibility Category B designation assigned to 10 CFR 35.2 Definition: Authorized User.</p> <p>Comment stands from letter dated July 19, 2012. In letter dated June 19, 2013, item 17, AL stated they would address this during their next rule revision.</p> <p>AL states in their June 19, 2013, letter, in item 17, an authorized user is not</p> |

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| 5 | 420-3-26-.07 (2)(gg) | 2006-1 | B | <p>allowed to perform licensed activities until such time as the Agency has reviewed their training and experience and issued an amended license that indicates by name, that they are an authorized user. This makes AL's regulation more restrictive than NRC's regulation since 10 CFR 35.2 allows for authorized users already approved on a license to use that license to be placed on another license without having to resubmit their training and experience requirements.</p> <p>10 CFR 35.2 Definition: Authorized User is a Compatibility Category B which means that an Agreement State's regulation needs to be essentially identical to NRC's rule and cannot be more restrictive. Since AL's regulation is more restrictive, it does not meet the Compatibility Category B designation assigned to 10 CFR 35.2 Definition: Authorized User.</p> |
| | 35.2 | | | <p>Definition: Radiation Safety Officer</p> <p>AL states in their definition of Radiation Safety Officer in 420-3-26-.07(2)(gg) "means an individual who meets the requirements in 420-3-26-.07(26) and 420-3-26-.07(30), and is named..." AL needs to change this to state "means an individual who meets the requirements in 420-3-26-.07(26) and 420-3-26-.07(30), or is named..."</p> <p>AL omits Commission or Agreement State license from their definition of Radiation Safety Officer in 420-3-26-.07(2)(gg).</p> <p>AL omits an equivalent to paragraph (ii) of the 10 CFR 35.2 definition of Radiation Safety Officer.</p> <p>AL needs to make the above changes in order to meet the Compatibility Category B designation assigned to 10 CFR 35.2 Definition: Radiation Safety Officer.</p> <p>Comment stands from letter dated July 19, 2012. In letter dated June 19, 2013, item 18, AL stated they would address this during their next rule revision.</p> |

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|---------------|----------------------|------------------|----------|---|
| 6 | 426-3-26-.07 (26) | 2006-1 2009-1 | B | <p>AL states in their June 19, 2013, letter, in item 18, an individual is not an Radiation Safety Officer (RSO) on an agency license until an amended license is issued and a licensee is required to name an RSO on their license and the Agency must review their training and experience and issue an amended license that indicates by name the individual as RSO. This makes AL's regulation more restrictive than NRC's regulation since 10 CFR 35.2 allows for RSO's already approved on a license to use that license to be placed on another license without having to resubmit their training and experience requirements.</p> <p>10 CFR 35.2 Definition: Radiation Safety Officer is a Compatibility Category B which means that an Agreement State's regulation needs to be essentially identical to NRC's rule and cannot be more restrictive. Since AL's regulation is more restrictive, it does not meet the Compatibility Category B designation assigned to 10 CFR 35.2 Definition: Radiation Safety Officer.</p> <p>Training for Radiation Safety Officer</p> <p>AL states in 426-3-26-.07(26)(d) "Has obtained written certification, signed by ..." AL needs to change this to state "Has obtained written attestation, signed by ..."</p> <p>AL needs to make the above change in order to meet the Compatibility Category B designation assigned to 10 CFR 35.50.</p> <p>Comment stands from letter dated July 19, 2012. In letter dated June 19, 2013, item 19, AL stated they would address this during their next rule revision.</p> |
| 7 | 35.300 | 2006-1 2007-3 | H&S | <p>Use of unsealed byproduct material for which a written directive is required</p> <p>AL needs to add "or equivalent NRC or Agreement State requirements" to 420-3-26-.07(52)(a) between "420-3-26-.02" and "or."</p> |

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| | | | | <p>AL needs to make the above change in order to meet the Compatibility Category H&S designation assigned to 10 CFR 35.300(a) and (b).</p> <p>Comment stands from letter dated July 14, 2010, and July 19, 2012. In letter dated June 19, 2013, item 14, AL stated they would address this during their next rule revision.</p> |
| 8 | 420-3-26-.02 (10)(f) | 2006-2 | B | <p>Serialization of nationally tracked sources</p> <p>AL needs to replace "(insert effective date of rule)" with "September 1, 2012," the actual effective date of the rule.</p> <p>AL needs to make the above change in order to meet the Compatibility Category B designation assigned to 10 CFR 32.201.</p> <p>Comment stands from letter dated July 19, 2012. In letter dated June 19, 2013, item 20, AL stated they would address this during their next rule revision.</p> |
| 9 | 420-3-26-.02 (4)(a) | 2007-2 | B | <p>Exempt Concentrations</p> <p>AL omits a reference in 420-3-26-.02(4)(a)1. The first sentence should read "Except as provided in paragraphs (a)2 and (3) below, ..."</p> <p>AL omits an equivalent to 10 CFR 30.14(b).</p> <p>AL needs to make the above changes in order to meet the Compatibility Category B designation assigned to 10 CFR 30.14.</p> <p>Comment stands from letter dated July 19, 2012. In letter dated June 19, 2013, item 21, AL stated they would address this during their next rule revision.</p> <p>Note: AL copied half of Comment 10 from the July 19, 2012, letter into Item</p> |

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| 10 | 420-3-26-.02 (4)(b) | 2007-2 2007-3 | B | <p>21 in their June 19, 2013. However, their response is that AL will revise its rules to be compatible with 10 CFR 30.14 so it is understood that item 21 in the June 19, 2013, letter was meant to address comment 9 from NRC's July 19, 2012, letter.</p> <p>Certain items containing byproduct material</p> <p>AL omits the phrase "or persons who initially transfer for sale or distribution the following products containing tritium, promethium 147 or radium 226" after "products" and before "any person is exempt..." in 420-3-26-.02(4)(b).</p> <p>AL omits the wording "manufactured prior to November 30, 2007" from 420-3-26-.02(4)(b)1.(viii).</p> <p>AL omits the wording "manufactured prior to December 17, 2007" from 420-3-26-.02(4)(b)2. and (b)3.</p> <p>AL omits equivalent requirements to 10 CFR 30.15(b) from their regulations.</p> <p>AL needs to make the above changes in order to meet the Compatibility Category B designation assigned to 10 CFR 30.15.</p> <p>Comment stands from letter dated July 14, 2010, and July 19, 2012. In letter dated June 19, 2013, item 22, AL stated they would address this during their next rule revision.</p> |
| 11 | 32.11 | 2007-2 | NRC | <p>Introduction of byproduct material in exempt concentrations into products or materials, and transfer of ownership or possession: Requirements for license</p> <p>AL needs to remove 420-3-26-.02(10)(j)1. and 2. from its regulations.</p> <p>AL needs to make the above change in order to meet the Compatibility Category NRC designation assigned to 10 CFR 32.11.</p> |

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| 12 | 420-3-26-.02(10)(j)3. | 2007-2 | NRC | <p>Comment stands from letter dated July 14, 2010, and July 19, 2012. In letter dated June 19, 2013, item 3, AL stated they would address this during their next rule revision.</p> <p>Same: Records and material transfer reports AL needs to remove 420-3-26-.02(10)(j)3. from its regulations.</p> <p>AL needs to make the above change in order to meet the Compatibility Category NRC designation assigned to 10 CFR 32.12.</p> <p>Comment stands from letter dated July 14, 2010, and July 19, 2012. In letter dated June 19, 2013, item 3, AL stated they would address this during their next rule revision.</p> |
| 13 | 420-3-26-.02(4)(a)2. | 2007-2 | C | <p>Same: Prohibition of introduction AL needs to remove "pursuant to 420-326-.02(10)(i) or the general license provided in 420-3-26-.02(6) or (7) of this Rule 420-3-26-.02." and replace it with "except in accordance with a license issued under 10 CFR 32.11." AL needs to make the above change in order to meet the Compatibility Category C designation assigned to 10 CFR 32.13.</p> <p>Comment stands from letter dated July 14, 2010, and July 19, 2012. In letter dated June 19, 2013, item 4, AL stated they would address this during their next rule revision.</p> |
| 14 | 420-3-26-.03(33) | 2007-3 | C | <p>General requirements AL omits the reference to their regulation corresponding to 10 CFR 20.2008 from 420-3-26-.03(33)(a)4.</p> |

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| | | | | <p>AL needs to add the above reference to 420-3-26-.03(33) in order to meet the Compatibility Category C designation assigned to 10 CFR 20.2001.</p> <p>Comment stands from letter dated July 14, 2010, and July 19, 2012. In letter dated June 19, 2013, item 6, AL stated they would address this during their next rule revision.</p> |
| 15 | 20.2006(e) | 2007-3 | B | <p>Transfer for disposal and manifests</p> <p>AL does not have a regulation corresponding to 10 CFR 20.2006(e).</p> <p>AL needs to add the above regulation in order to meet the Compatibility Category B designation assigned to 10 CFR 20.2006(e).</p> <p>Comment rescinded. See AL Regulation 420-3-26-.03(38)(b), ML12131A532 and item 5 in AL response letter dated June 19, 2013.</p> |
| 16 | 20.2008 | 2007-3 | B | <p>Disposal of 11e.(3) and 11e.(4) byproduct material</p> <p>AL does not have a regulation corresponding to 10 CFR 20.2008.</p> <p>AL needs to add the above regulation in order to meet the Compatibility Category C designation assigned to 10 CFR 20.2001.</p> <p>Comment stands from letter dated July 14, 2010, and July 19, 2012. In letter dated June 19, 2013, item 7, AL stated they would address this during their next rule revision.</p> |

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|---------------|----------------------|-------------|---------|----------|--|
| 17 | 420-3-26-.02(4)(e)2. | 30.18(b) | 2007-3 | B | <p>Exempt quantities</p> <p>AL needs to add “before September 25, 1971” between “acquired” and “under” in 420-3-26.02(4)(e)2.</p> <p>AL needs to make the above change in order to meet the Compatibility Category B designation assigned to 10 CFR 30.18(b).</p> <p>Comment stands from letter dated July 14, 2010, and July 19, 2012. In letter dated June 19, 2013, item 8, AL stated they would address this during their next rule revision.</p> |
| 18 | 420-3-26-.02(4)(c) | 30.20(a) | 2007-3 | B | <p>Gas and aerosol detectors containing byproduct material</p> <p>AL needs to replace “or” before “produce” with a “,” and add “or initially transfer for sale or distribution” between “produce” and “gas and aerosol detectors...” Also, the phrase “life of property” should read “life or property.”</p> <p>AL needs to add the word “initially” before the word transferred in 420-3-26-.02(4)(c)(1) and (2).</p> <p>AL needs to add the word “initial” before the word “transfer” in 420-3-26-.02(4)(c)(1) and (2).</p> <p>AL needs to add the following requirement to this section: “before November 30, 2007” in between “or transferred” and “in accordance” in 420-3-26-.02(4)(c)(2).</p> <p>AL needs to make the above changes in order to meet the Compatibility Category B designation assigned to 10 CFR 30.20.</p> <p>Comment stands from letter dated July 14, 2010, and July 19, 2012. In letter dated June 19, 2013, item 9, AL stated they would address this during their next rule revision.</p> |

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| 19 | 420-3-26-.02(8)(g) | 30.32(g) | 2007-3 | C | <p>Application for specific licenses</p> <p>AL does not have a regulation corresponding to 10 CFR 30.32(g)(3).</p> <p>AL needs to add the above regulation in order to meet the Compatibility Category C designation assigned to 10 CFR 30.32(g).</p> <p>Comment stands from letter dated July 14, 2010, and July 19, 2012. In letter dated June 19, 2013, item 10, AL stated they would address this during their next rule revision.</p> |
| 20 | N/A | 30.34(g) | 2007-3 | H&S | <p>Terms and conditions of licenses</p> <p>AL does not have a regulation corresponding to 10 CFR 30.34(g).</p> <p>AL needs to add the above regulation in order to meet the Compatibility Category H&S designation assigned to 10 CFR 30.34(g).</p> <p>Comment stands from letter dated July 14, 2010, and July 19, 2012. In letter dated June 19, 2013, item 11, AL stated they would address this during their next rule revision.</p> |

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|---------------|----------------------|-------------|---------|----------|--|
| 21 | 420-3-26-.02(7)(c) | 31.12 | 2007-3 | C | <p>General license for certain items and self-luminous products containing radium-226</p> <p>AL needs to replace "(entry effective date of rule)" with "September 1, 2012," the actual effective date of the rule in 420-3-26-.02(7)(c)1.</p> <p>AL needs to make the above change in order to meet the Compatibility Category C designation assigned to 10 CFR 31.12.</p> <p>Comment stands from letter dated July 19, 2012. In letter dated June 19, 2013, item 23, AL stated they would address this during their next rule revision.</p> |
| 22 | 420-3-26-.02(7)(e)4. | 32.58 | 2007-3 | B | <p>Same: labeling of devices</p> <p>AL needs to replace the word "Importer" in 420-3-26-.02(7)(e)4(ii) with the phrase "initial transferor."</p> <p>AL needs to make the above change in order to meet the Compatibility Category B designation assigned to 10 CFR 32.58.</p> <p>Comment stands from letter dated July 19, 2012. In letter dated June 19, 2013, item 24, AL stated they would address this during their next rule revision.</p> |
| 23 | N/A | 32.102 | 2007-3 | B | <p>Schedule-C Prototype tests for Calibration or reference sources containing americium-241</p> <p>AL does not have a regulation corresponding to 10 CFR 32.102.</p> <p>AL needs to add the above regulation in order to meet the Compatibility Category-B designation assigned to 10 CFR 32.102.</p> |

| STATE SECTION | NRC SECTION | RATS ID | CATEGORY | SUBJECT and COMMENTS |
|---------------|-------------|---------|----------|---|
| | | | | <p>Comment has been removed from the response letter. Although the comment was correct as written in 2012, a subsequent rulemaking (RATS ID 2012-4) removed 10 CFR 32.102 from NRC's regulations, therefore Alabama no longer needs to adopt an equivalent section to NRC's 10 CFR 32.102 as stated in our July 19, 2012, letter and their June 19, 2013, letter in item 13.</p> |
| 24 | 35.57 | 2009-1 | B | <p>Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist.</p> <p>AL omits "on a U.S. Nuclear Regulatory Commission or Agreement State" with Agency license or permit in 420-3-26-.07(29)(a) & (b).</p> <p>AL needs to make the above change in order to meet the Compatibility Category B designation assigned to 10 CFR 35.57.</p> <p>Comment stands from letter dated July 19, 2012.</p> <p>AL states in their June 19, 2013 letter, in item 25, that "the Agency does not, and has not, allowed individuals listed on an NRC or Agreement State license to be "designated" as authorized users, nuclear pharmacists, medical physicists, or RSO's, nor do we allow an authorized user, nuclear pharmacist, medical physicist, or RSO that is not already listed, by name, on an Agency license, to perform licensed duties." This makes AL's regulation more restrictive than NRC's regulation. 10 CFR 35.57 is a Compatibility Category B which means that an Agreement State's regulation needs to be essentially identical to NRC's rule and cannot be more restrictive. Since AL's regulation is more restrictive, it does not meet the Compatibility Category B designation assigned to 10 CFR 35.57.</p> |

STATE REGULATION STATUS

State: Alabama

Tracking Ticket Number: 13-26
Date: September 18, 2013

[9 amendment(s) reviewed is identified by a * at the beginning of the equivalent NRC requirement.]

| RATS ID | NRC Chronology Identification | Date Due for State Adoption | Incoming Package | Outgoing Package | Notes |
|---------|--|-----------------------------|------------------|---------------------------|---|
| 1991-1 | Safety Requirements for Radiographic Equipment Part 34 55 FR 843 (Superceded by 1997-5) | 01/10/1994 | Final | No Comments 04/02/1994 | Alabama has adopted Final Regulations equivalent to RATS ID 1997-5 |
| 1991-2 | ASNT Certification of Radiographers Part 34 56 FR 11504 (Superceded by 1997-5) | none | Not Required | Not Required | Alabama has adopted Final Regulations equivalent to RATS ID 1997-5 |
| 1991-3 | Standards for Protection Against Radiation Part 20 56 FR 23360; 56 FR 61352; 57 FR 38588; 57 FR 57877; 58 FR 67657; 59 FR 41641; 60 FR 20183; | 01/01/1994 | Final | No Comments 11/19/1997 | |
| 1991-4 | Notification of Incidents Parts 20, 30, 31, 34, 39, 40, 70 56 FR 64980 | 10/15/1994 | Final | No Comments 04/02/1994 | |
| 1992-1 | Quality Management Program and Misadministrations Part 35 56 FR 34104 (Superceded by 2002-2) | 01/27/1995 | Final | No Comments 04/02/1994 | Alabama has adopted Final Regulations equivalent to RATS ID 2002-2 |
| 1992-2 | Eliminating the Recordkeeping Requirements for Departures from Manufacturer's Instructions Parts 30, 35 57 FR 45566 | none | Not Required | Not Required | These regulation changes are not required to be adopted for purposes of Compatibility |
| 1993-1 | Decommissioning Recordkeeping and License Termination: Documentation Additions [Restricted areas and spill sites] Parts 30, 40 58 FR 39628 | 10/25/1996 | Final | No Comments 06/05/1998 | |

| RATS ID | NRC Chronology Identification | Date Due for State Adoption | Incoming Package | Outgoing Package | Notes |
|----------------|---|------------------------------------|-----------------------------|---------------------------|--|
| 1993-2 | Licensing and Radiation Safety Requirements for Irradiators Part 36 58 FR 7715 | 07/01/1996 | Final | No Comments 06/05/1998 | |
| 1993-3 | Definition of Land Disposal and Waste Site QA Program Part 61 58 FR 33886 | 07/22/1996 | Not Applicable ¹ | Not Applicable | Alabama does not have any licensees subject to these regulations. (See SECY-95-112) |
| 1994-1 | Self-Guarantee as an Additional Financial Mechanism Parts 30, 40, 70 58 FR 68726; 59 FR 1618 | none | Final | No Comments 06/05/1998 | These regulation changes are not required to be adopted for purposes of Compatibility. |
| 1994-2 | Uranium Mill Tailings Regulations: Conforming NRC Requirements to EPA Standards Part 40 59 FR 28220 | 07/01/1997 | Not Applicable | Not Applicable | Alabama does not have authority to regulate this material under its Agreement |
| 1994-3 | Timeliness in Decommissioning Material Facilities Parts 30, 40, 70 59 FR 36026 | 08/15/1997 | Final | No Comments 06/05/1998 | |
| 1995-1 | Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use Parts 30, 32, 35 59 FR 61767; 59 FR 65243; 60 FR 322 | 01/01/1998 | Final | No Comments 06/05/1998 | |
| 1995-2 | Frequency of Medical Examinations for Use of Respiratory Protection Equipment Part 20 60 FR 7900 | 03/13/1998 | Final | No Comments 06/05/1998 | |
| 1995-3 | Low-Level Waste Shipment Manifest Information and Reporting Parts 20, 61 60 FR 15649; 60 FR 25983 | 03/01/1998 | Final | No Comments 06/05/1998 | |
| 1995-4 | Performance Requirements for Radiography Equipment | 06/30/1998 | Not Required | Not required | Alabama has adopted Final Regulations equivalent to RATS ID 1997-5 |

| RATS ID | NRC Chronology Identification | Date Due for State Adoption | Incoming Package | Outgoing Package | Notes |
|---------|--|-----------------------------|------------------|---------------------------|---|
| | Part 34 60 FR 28323 (Superceded by 1997-5) | | | | |
| 1995-5 | Radiation Protection Requirements: Amended Definitions and Criteria Parts 19, 20 60 FR 36038 | 08/14/1998 | Final | No Comments 06/05/1998 | |
| 1995-6 | Clarification of Decommissioning Funding Requirements Parts 30, 40, 70 60 FR 38235 | 11/24/1998 | Final | No Comments 06/05/1998 | |
| 1995-7 | Medical Administration of Radiation and Radioactive Materials Parts 20, 35 60 FR 48623 (Superceded by 2002-2 and 2005-2) | 10/20/1998 | Final | No Comments 08/29/2000 | Alabama has adopted Final Regulations equivalent to RATS IDs 2002-2 and 2005-2 |
| 1996-1 | Compatibility with the International Atomic Energy Agency Part 71 60 FR 50248; 61 FR 28724 (Superceded by 2004-1) | 04/01/1999 | Final | No Comments 08/29/2000 | Alabama has not yet adopted RATS ID 2004-1 in final. |
| 1996-2 | One Time Extension of Certain Byproduct, Source and Special Nuclear Materials Licenses Parts 30, 40, 70 61 FR 1109 | 02/15/1999 | Not Required | Not Required | These regulation changes are not required to be adopted for purposes of Compatibility |
| 1996-3 | Termination or Transfer of Licensed Activities: Record keeping Requirements Parts 20, 30, 40, 61, 70 61 FR 24669 | 06/17/1999 | Final | No Comments 08/29/2000 | |
| 1997-1 | Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act Part 20 61 FR 65120 | 01/9/2000 | Final | No Comments 08/29/2000 | |
| 1997-2 | Recognition of Agreement State Licenses in Areas | 02/27/2000 | Final | No Comments | |

| RATS ID | NRC Chronology Identification | Date Due for State Adoption | Incoming Package | Outgoing Package | Notes |
|---------|---|-----------------------------|------------------|---------------------------|---|
| | Under Exclusive Federal Jurisdiction Within an Agreement State Part 150 62 FR 1662 | | | 08/29/2000 | |
| 1997-3 | Criteria for the Release of Individuals Administered Radioactive Material Parts 20, 35 62 FR 4120 | 05/29/2000 | Final | No Comments 08/29/2000 | |
| 1997-4 | Fissile Material Shipments and Exemptions Part 71 62 FR 5907 (Superceded by 2004-1) | 02/10/2000 | Not Required | Not Required | These regulation changes are not required to be adopted for purposes of Compatibility. (See STP-97-078) |
| 1997-5 | Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiography Operations Parts 30, 34, 71, 150 62 FR 28947 | 06/27/2000 | Final | No Comments 08/29/2000 | |
| 1997-6 | Radiological Criteria for License Termination Parts 20, 30, 40, 70 62 FR 39057 | 08/20/2000 | Final | No Comments 08/29/2000 | |
| 1997-7 | Exempt Distribution of a Radioactive Drug Containing One Micro curie of Carbon-14 Urea Part 30 62 FR 63634 | 01/02/2001 | Final | No Comments 06/05/1998 | |
| 1998-1 | Deliberate Misconduct by Unlicensed Persons Parts 30, 40, 61, 70, 71, 150 63 FR 1890; 63 FR 13773 | 02/12/2001 | Final | No Comments 10/01/2001 | |
| 1998-2 | Self-Guarantee of Decommissioning Funding by Nonprofit and Non-Bond-Issuing Licensees Parts 30, 40, 70 63 FR 29535 | 07/01/2001 | Not Required | Not Required | These regulation changes are not required to be adopted for purposes of Compatibility |
| 1998-3 | License Term for Medical Use Licenses Part 35 63 FR 31604 | 07/10/2001 | Not Required | Not Required | These regulation changes are not required to be adopted for purposes of Compatibility. (See STP-98-074) |

| RATS ID | NRC Chronology Identification | Date Due for State Adoption | Incoming Package | Outgoing Package | Notes |
|---------|--|-----------------------------|----------------------|--|---|
| | (Superseded by 2002-2) | | | | Alabama has adopted Final Regulations equivalent to RATS IDs 2002-2. |
| 1998-4 | Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations Part 34 63 FR 37059 | 07/09/2001 | Final | No Comments 08/29/2000 | |
| 1998-5 | Minor Corrections, Clarifying Changes, and a Minor Policy Change Parts 20, 32, 35, 36, 39 63 FR 39477; 63 FR 45393 | 10/26/2001 | Final | No Comments 08/29/2000 | |
| 1998-6 | Transfer for Disposal and Manifests: Minor Technical Conforming Amendment Part 20 63 FR 50127 | 11/20/2001 | Final | No Comments 08/29/2000 | |
| 1999-1 | Radiological Criteria for License Termination of Uranium Recovery Facilities Part 40 64 FR 17506 | 06/11/2002 | Not Applicable | Not Applicable | Alabama does not have authority to regulate this material under its Agreement |
| 1999-2 | Requirements for Those Who Possess Certain Industrial Devices Containing Byproduct Material to Provide Requested Information Part 31 64 FR 42269 | 10/04/2002 | Not Required | Not Required | These regulation changes are not required to be adopted for purposes of Compatibility |
| 1999-3 | Respiratory Protection and Controls to Restrict Internal Exposure Part 20 64 FR 54543; 64 FR 55524 | 02/02/2003 | Final ML021090092 | No Comments 04/25/2002 ML021160517 | |
| 2000-1 | Energy Compensation Sources for Well Logging and Other Regulatory Clarifications Part 39 65 FR 20337 | 05/17/2003 | Final ML062000076 | No Comments 08/10/2006 ML062220014 | |
| 2000-2 | New Dosimetry Technology | 01/08/2004 | Final | No Comments | |

| RATS ID | NRC Chronology Identification | Date Due for State Adoption | Incoming Package | Outgoing Package | Notes |
|---------|---|-----------------------------|--|---|-------|
| | Parts 34, 36, 39 65 FR 63750 | | ML062000076 | 08/10/2006 ML062220014 | |
| 2001-1 | Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material Parts 30, 31, 32 65 FR 79162 | 02/16/2004 | Final ML062000076 | No Comments 08/10/2006 ML062220014 | |
| 2002-1 | Revision of the Skin Dose Limit Part 20 67 FR 16298 | 04/05/2005 | Final ML052940420 | No Comments 11/08/2005 ML053120389 | |
| 2002-2 | Medical Use of Byproduct Material Parts 20, 32, 35 67 FR 20249 | 10/24/2005 | Final ML062000076 | No Comments 08/10/2006 ML062220014 | |
| 2003-1 | Financial Assurance for Materials Licensees Parts 30, 40, 70 68 FR 57327 | 12/03/2006 | Final ML062000076 | No Comments 08/10/2006 ML062220014 | |
| 2004-1 | Compatibility With IAEA Transportation Safety Standards and Other Transportation Safety Amendments Part 71 69 FR 3697 | 10/01/2007 | Final ML102080659 | Comments 08/30/2010 ML102170098 | |
| *2005-1 | Security Requirements for Portable Gauges Containing Byproduct Material Part 30 70 FR 2001 | 07/11/2008 | Final ML13176A135 License Condition ML081960176 | No Comments 09/18/2013 ML13176A123 Comments 07/28/2008 ML082100083 | |
| 2005-2 | Medical Use of Byproduct Material - Recognition of Speciality Boards Part 35 70 FR 16336; 71 FR 1926 | 04/29/2008 | Final ML062000076 | No Comments 08/10/2006 ML062220014 | |
| 2005-3 | Increased Controls for Risk-Significant Radioactive Sources (NRC Order EA-05-090) 70 FR 72128 | 12/01/2005 | License Condition ML052570218 | No Comments 09/15/2005 ML052620319 | |

| RATS ID | NRC Chronology Identification | Date Due for State Adoption | Incoming Package | Outgoing Package | Notes |
|---------|--|-----------------------------|--|--|-------|
| *2006-1 | Minor Amendments Parts 20, 30, 32, 35, 40 and 70 71 FR 15005 | 03/27/2009 | Final ML13176A135 | Comments 09/18/2013 ML13176A123 | |
| *2006-2 | National Source Tracking System - Serialization Requirements Part 32 with reference to Part 20 Appendix E 71 FR 65685 | 02/06/2007 | Final ML13176A135 | Comments 09/18/2013 ML13176A123 | |
| *2006-3 | National Source Tracking System Part 20 71 FR 65685, 72 FR 59162 | 01/31/2009 | Final ML13176A135 License Condition ML082820556 | No Comments 09/18/2013 ML13176A123 No Comments 10/21/2008 ML082820596 | |
| *2007-1 | Medical Use of Byproduct Material - Minor Corrections and Clarifications Parts 32 and 35 72 FR 45147, 54207 | 10/29/2010 | Final ML13176A135 | Comments 09/18/2013 ML13176A123 | |
| *2007-2 | Exemptions From Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements Parts 30, 31, 32, 150 72 FR 58473 | 12/17/2010 | Final ML13176A135 | Comments 09/18/2013 ML13176A123 | |
| *2007-3 | Requirements for Expanded Definition of Byproduct Material Parts 20, 30, 31, 32, 33, 35, 61, 150 72 FR 55864 | 11/30/2010 | Final ML13176A135 | Comments 09/18/2013 ML13176A123 | |
| 2007-4 | Order Imposing Fingerprinting Requirements and Criminal History Records Check Requirements for Unescorted Access to Certain Radioactive Material NRC Order EA-07-305 72 FR 70901 | 06/05/2008 | License Condition ML081090443 | No Comments 05/01/2008 ML081220314 | |

| RATS ID | NRC Chronology Identification | Date Due for State Adoption | Incoming Package | Outgoing Package | Notes |
|---------|--|-----------------------------|----------------------|--|-------|
| *2008-1 | Occupational Dose Records, Labeling Containers, and Total Effective Dose Equivalent Parts 19, 20 72 FR 68043 | 02/15/2011 | Final ML13176A135 | No Comments 09/18/2013 ML13176A123 | |
| *2009-1 | Medical Use of Byproduct Material – Authorized User Clarification Part 35 74 FR 33901 | 09/28/2012 | Final ML13176A135 | Comments 09/18/2013 ML13176A123 | |
| 2011-1 | Decommissioning Planning Parts 20, 30, 40, 70 76 FR 35512 | 12/17/2015 | | | |
| 2011-2 | Licenses, Certifications, and Approvals for Materials Licensees Parts 30, 36, 39, 40, 70, and 150 76 FR 56951 | 11/14/2014 | | | |
| 2012-1 | Change of Compatibility of 10 CFR 31.5 and 31.6 (See RATS ID: 2001-1 for Rule text) 77 FR 3640 | 01/25/2015 | | | |
| 2012-2 | Advance Notification to Native American Tribes of Transportation of Certain Types of Nuclear Waste Part 71 77 FR 34194 | 08/10/2015 | | | |
| 2012-3 | Technical Corrections Part 30, 34, 40 and 70 77 FR 39899 | 08/06/2015 | | | |
| 2012-4 | Requirements for Distribution of Byproduct Material Parts 30, 31, 32, 40 and 70 77 FR 43666 | 10/23/2015 | | | |
| 2013-1 | Physical Protection of Byproduct Material, 10 CFR Parts 20, 30, 32, 33, 34, 35, 36, 37, 39, and 71 78 FR 16922 | 03/19/2016 | | | |

| RATS ID | NRC Chronology Identification | Date Due for State Adoption | Incoming Package | Outgoing Package | Notes |
|---------|---|-----------------------------|------------------|------------------|-------|
| 2013-2 | Distribution of Source Material to Exempt Persons and to General Licensees and Revision of General License and Exemptions, 10 CFR Parts 30, 40, and 70 78 FR 32310 | 08/27/2016 | | | |

¹ IMPEP Team: verify that Alabama does not have any licensees subject to these regulations during each review.