

COMPATABILITY COMMENTS ON ALABAMA PROPOSED REVISIONS – NRC LETTER DATED AUGUST 19, 2016

	State Section	NRC Section	RATS ID	Subject and Comments	State Response
1	420-3-26-.02(10)(t)	32.72	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 omits an equivalent regulation to 10 CFR 32.72(b)(3). AL needs to add an equivalent regulation to 10 CFR 32.72(b)(3) to 420-3-26-02(10)(t) to meet the Compatibility Category B designation assigned to 10 CFR 32.72.</p>	<p>No changes were made to the rule. The way the Agency interprets 32.72(b)(3) (“The actions authorized in paragraphs (b)(1) and (b)(2) of this section are permitted in spite of more restrictive language in license conditions.”), it appears to state you can <b>never</b> have a circumstance that would override rules 32.72(b)(1) or (2). This is not true, and incorporating the NRC text into our rules would prohibit the Agency from being able to provide exceptions to the rules by means of license conditions, even if alternative methods proposed by the licensee would provide a higher degree of radiation safety than the rule.</p> <p>The Agency questioned NRC regarding this matter. NRC responded “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</p>

					<p>32.72 is a compatibility category B.”</p> <p>“Per the Statements of Consideration for the NRC 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 I can see how it might appear to not apply to current licensing as this 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).”</p> <p>The Agency has not included this rule text in the revised rule because we do not have any licenses from the 1995 time frame that have not been renewed, and therefore would not have any license conditions that would conflict with the rules. Placing such text in our rules completely defeats any license conditions that do not agree with our equivalent to 32.71(b)(1)</p>
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				<p>AL omits “no later than 30 days after the date that the licensee allows, under paragraphs 420-3-26-.02(10)(t)(2)(ii)(I) and (III), the individual to work as an authorized nuclear pharmacist” from the end of 420-3-26-.02(10)(t)(5)(v).</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><b>COMMENTS STAND FROM NRC LETTER DATED December 6, 2014/ML14323A466</b></p>	<p>and (2). 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.</p> <p>No changes were made to 420-3-26-.02(10)(t)(5)(v). The Agency does not license a pharmacist to use radioactive material until that pharmacist is first licensed by the Alabama Board of Pharmacy. The Agency requires a licensee to amend their license and get the approved amendment before allowing an authorized nuclear pharmacist to begin work. This is done 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 licensed radioactive material.</p>
2	420-3-26-.07(45)(b)	35.100	2007-3	<p><b>Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required</b></p> <p>AL lists the wrong references in 420-3-26-.07(45)(b). AL needs to correct this provision to say “...an authorized user and who meets the requirements specified in</p>	<p>This proposed rulemaking packet did not include Rule 420-3-26-.07. The comment will be addressed at a later date.</p>

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				<p>420-3-26-.07(51) or 420-3-26-.07(56) and 420-3-26-.07(51)(c)(1)(ii)(VII), or an individual ...)</p> <p>AL needs to make the above change in order to meet the Compatibility Category H&amp;S designation assigned to 10 CFR 35.100.</p> <p><b>AL DID NOT ADDRESS STATE 07 RULE IN THIS SUBMISSION. COMMENT STANDS FROM NRC LETTER DATED December 6, 2014/ML14323A466</b></p>	
3	420-3-26-.04(5)(b)3.	34.20	2012-3	<p><b>Performance requirements for industrial radiography equipment</b></p> <p>AL needs to change 420-3-26-.04(5)(b)3. to read “Modification of radiographic exposure devices, source changers, and source assemblies and associated equipment is prohibited unless the design of any replacement component, including source holder, source assembly, controls or guide tubes would not compromise the design safety features of the system.” AL needs to make the above change in order to meet the Compatibility Category B designation assigned to 10 CFR 34.20(a)(1), (b), (d), and (e) and the Compatibility Category D designation assigned to 10 CFR</p>	<p>This proposed rulemaking packet did not include Rule 420-3-26-.04. The comment will be addressed at a later date.</p>

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				<p>34.20 (a)(2).</p> <p><b>AL DID NOT ADDRESS STATE SECTION 04 RULE IN THIS SUBMISSION.</b></p> <p><b>COMMENT STANDS FROM NRC LETTER DATED December 6, 2014/ML14323A466</b></p>	
4	420-3-26-.02(10)(g)5.ii.	32.51	2012-4	<p><b>Byproduct material contained in devices for use under § 31.5; requirements for license to manufacture, or initially transfer</b></p> <p>In response to our previous comment below: AL indicated that they were going to change 420-3-26-.02(10)(g)5.ii. from “420-3-26-.02(7)(b)” to “420-3-26-.02(7)(a).”</p> <p>AL needs to make the above change in order to meet the Compatibility Category B designation assigned to 10 CFR 32.51.</p> <p><b>COMMENT STANDS FROM NRC LETTER DATED December 6, 2014/ML14323A466</b></p>	<p>The reference was changed from 420-3-26-.02(7)(b) to 420-3-26-.02(7)(a) in 420-3-26-.02(10)(g)5.(ii).</p>