

NRC Letters dated 12/27/2016 and 10/16/2018

ORC Section	NRC Section	RATS ID	Category	Subject and Comments	ORC Actions
420-3-26-.02(10)(t)	32.72	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>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-.2(10)(t) to meet the requirements of a compatibility category B designation.</p> <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>A new 420-3-26-.02(10)(t)2(iv) was added to address 32.72(b)(3)</p> <p>420-3-26-.02(t)5(vi) was amended to add this wording.</p>
420-3-26-.02(3)	40.13	2013-2	B	<p>Unimportant quantities of source material</p> <p>AL omits the word “delivers” from 420-3-26-.02(3)(a).</p>	<p>“delivers” was added to 420-3-26-.02(3)(a)</p>

				<p>AL needs to remove 420-3-26-.02(3)(c)2.(ii) from its regulations.</p> <p>AL needs to add a regulation equivalent to 10 CFR 40.13(c)(2)(ii) “Piezoelectric ceramic containing not more than 2 percent by weight source material” to 420-3-26-.02(3)(c)2.</p> <p>AL needs to remove 420-3-26-.02(3)(c)8. from its regulations.</p> <p>AL needs to add a regulation equivalent to 10 CFR 40.13(c)(9) “The exemptions in this paragraph (c) do not authorize the manufacture of any of the products described.” to 420-3-26-.02(3)(c).</p> <p>AL lists the incorrect reference in 420-3-26-.02(3)(c)10.(ii). AL needs to reference Section “40.52” instead of Section “40.42.”</p> <p>AL needs to make the above changes in order to meet the Compatibility Category B designation assigned to 10 CFR 40.13 (except 10 CFR 40.13(c)(5)(iv) which is a compatibility category NRC).</p>	<p>420-3-26-.02(3)(c)2.(ii) was deleted in its entirety.</p> <p>An equivalent 40.13(c)(2)(ii) was added as 420-3-26-.02(3)(c)2.(ii)</p> <p>420-3-26-.02(3)(c)8. was deleted in its entirety. .02(3)(c)9. was renumbered as .02(c)8. for sequential numbering purposes.</p> <p>An equivalent 40.13(c)(9) was added as 420-3-26-.02(3)(c)9.</p> <p>The reference was corrected in 420-3-26-.02(3)(c)10(ii).</p>
420-3-26-.02(21)	71	2015-3	Various	<p>10 CFR Part 71 Transportation</p> <p>AL needs to delete 420-3-26-.02(21)(b)(i) and (ii) and replace them with the following:</p>	

				<p>(i) Where the words “NRC”, “Commission”, “Nuclear Regulatory Commission”, “United States Nuclear Regulatory Commission” or “Administrator of the appropriate Regional Office” appear in 10 CFR Part 71, substitute the words [State] Department/Agency when used in 10 CFR 71.5(b), 71.10, 71.17(c)(3), and (e), 71.85(c), 71.88(a)(4), 71.93(c), 71.95, 71.97(c), (c)(3)(iii), and (f).</p> <p>(ii) The terms “certificate of compliance, compliance holder or applicant” apply to the NRC as they are the sole authority for issuing a package Certificate of Compliance.</p> <p>(iii) 10 CFR 71.9 employee protection also applies to violations of [State] Administrative Code in XXXXX.</p> <p>(iv) Alabama form number XXXX, “Notice to Employees”, must be posted instead of NRC Form 3 that is specified in 10 CFR Part 71.</p>	<p>420-3-26-.02(21)(b)1(i) was amended.</p> <p>420-3-26-.02(21)(b)(ii) was amended.</p> <p>The Compatibility Category designation was determined to be a Category D. No changes were made.</p> <p>The Compatibility Category designation was determined to be a Category D. No changes were made.</p>
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				Alabama needs to make the above changes in order to meet the Compatibility Category designations assigned to 10 CFR Part 71.	
420-3-26-.07(45)	35.100	2007-3	H&S	<p>Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required.</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 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&S designation assigned in 10 CFR 35.100</p>	Rule 420-3-26-.07 was not part of this rule revision. The comment will be addressed at the next revision of 420-3-26-.07.