

NRC Letter dated 12/27/2016

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><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-.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><b>COMMENT STANDS FROM NRC LETTER DATED AUGUST 19, 2016</b></p> <p><b>Note:</b> AL provided a rationale for not addressing this comment in their submitted comment resolution document (ML16314D996).</p> <p>As written, AL’s proposed regulations are not essentially identical to NRC’s and as such, cause inconsistency and have transboundary implications. They do not</p>	No actions.

				<p>meet the Compatibility Category B designation assigned to 32.72. For example, AL’s proposal to omit the equivalent regulation to 10 CFR 32.72(b)(3) would allow AL to issue license conditions that are less restrictive, which is inconsistent and not essentially identical for compatibility category B designation. Similarly, AL’s proposal for the equivalent regulation to 10 CFR 32.72(b)(5) is more restrictive, which is also not essentially identical for compatibility category B designation</p>	
420-3-26-.02(3)	40.13	2013-2	B	<p><b>Unimportant quantities of source material</b> AL omits the word “delivers” from 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>“delivers” was added to 420-3-26-.02(3)(a)</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>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>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>
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