

COMPATABILITY COMMENTS ON ALABAMA FINAL REGULATIONS – NRC LETTER DATED DEC. 16, 2014

	State Section	NRC Section	RATS ID	Action	Subject and Comments
1	420-3-26-.02(21)	71.85	2004-1	Revised .02(21)(a)2.	<p>Preliminary determinations</p> <p>AL does not incorporate this section by reference.</p> <p>AL needs to incorporate this section by removing it from the list of exempted regulations specified in 420-3-26-.02(21)(a)(2) in order to meet the Compatibility Category B designation assigned to 10 CFR 71.85.</p>
2	420-3-26-.02(10)(t)	32.72	2007-1 2007-3	<p>Revised .02(10)(t)2.(i)</p> <p>No changes made See D. Walter comment, October 16, 2014 letter</p> <p>No changes made See D. Walter comment, October 16, 2014 letter</p>	<p>Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under Part 35.</p> <p>AL lists an incorrect reference in 420-3-26-.02(10)(t)(2)(i). The first sentence should be changed to read “May prepare radioactive drugs for medical use as defined in 420-3-26-.07(2) provided that...”</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>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>Comment revised from NRC letter dated May 2, 2014.</p>

3	420-3-26-.02(10)(v)	32.74	2007-1 2012-4	<p>420-3-26-.02(10)(v) is deleted in its entirety. This section is a duplicate (and older version) of 420-3-26-.02(10)(n).</p> <p>420-3-26-.02(10)(n) has the correct wording and reference to be compatible with 32.74</p>	<p>Manufacture and distribution of sources or devices containing byproduct material for medical use</p> <p>AL omits the word “transmission” between “calibration” and “or reference” in 420-3-26-.02(10)(v)1. AL lists an incorrect reference in 420-3-26-.02(10)(v)1. The text should be changed to read “... or for the uses listed in Rules 420-3-26-.07(60), (70), (72), and (90), will be approved if:.”</p> <p>AL needs to make the above changes in order to meet the Compatibility Category B designation assigned to 10 CFR 32.74.</p> <p>Comment revised from NRC letter dated May 2, 2014.</p>
4	420-3-26-.02(4)(a)	30.14	2007-2	Added as .02(4)(a)8.	<p>Exempt concentrations</p> <p>AL omits an equivalent section to 10 CFR 30.14(b) from their regulations. AL needs to add equivalent text to 10 CFR 30.14 to 420-3-26-.02(4)(a) in order to meet the Compatibility Category B designation assigned to 10 CFR 30.14.</p>
5	420-3-26-.02(4)(f)	30.18	2007-2 2007-3	Revised .02(4)(f)4.	<p>Exempt quantities</p> <p>AL lists a wrong reference in 420-3-26-.02(4)(f)4. AL needs to change the end of this paragraph to read “... by the licensee to persons exempt under this paragraph (f) or equivalent regulations...”</p> <p>AL needs to make the above change in order to meet the Compatibility Category B designation assigned to 10 CFR 30.18.</p>
6	420-3-26-.02(7)	31.5	2007-2 2007-3		<p>Certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere</p>

				<p>Revised to correct codification error in .02(7)(a)</p> <p>Revised .02(7)(a)1.(i)(I)</p> <p>Revised .02(7)(a)2.(iv)(III)</p> <p>Revised .02(7)(a)2.(xv)l.</p>	<p>AL has a codification error in 420-3-26-.02(7). AL needs to change 420-3-26-.02(7)(a)(i) to 420-3-26-.02(7)(a)1. and then subsequently change the sections following to ensure codification is correct.</p> <p>AL needs to change 420-3-26-.02(7)(a)(i)(I) to read “A specific license issued under 420-3-26-.02(10)(g); or.”</p> <p>AL lists a wrong reference in 420-3-26-.02(7)(a)2.(iv)(III). This section should read “Each record that is required by paragraph 2.(iii) of Rule...”</p> <p>AL needs to change 420-3-26-.02(7)(a)(xv)l. to read “... The registration information must be submitted to the Agency within 30 days of the date of receipt of the device(s) and annually thereafter. In addition...”</p> <p>AL needs to make the above changes to 420-3-26-.02(7)(a) in order to meet the Compatibility Category C designation assigned to 10 CFR 31.5.</p>
7	N/A	30.32(j)	2007-3	<p>Equivalent 30.32(j)(1) and (2) can be found in .02(10)(a)5.</p> <p>.02(10)(a)5.(iii) and (iv) is added to address 30.32(j)(3) and (4)</p>	<p>Application for specific licenses</p> <p>AL does not have an equivalent provision to 10 CFR 30.32(j).</p> <p>AL needs to add equivalent language to 10 CFR 30.32(j) to 420-3-26-.02(8) in order to meet the Compatibility Category B designation assigned to 10 CFR 30.32(j).</p>
8	420-3-26-.02(12)	30.34(j)	2007-3	<p>Equivalent 30.34(j)(1) can be found in .02(10)(t)4.</p> <p>Equivalent 30.34(j)(2) can be found in .02(t)1.(ii) and 3.</p>	<p>Terms and conditions of licenses</p> <p>AL omits an equivalent provision to 10CFR 30.34(j).</p> <p>AL needs to add equivalent language to 10 CFR 30.34(j) to 420-3-26-.02(12) in order to meet the Compatibility Category B</p>

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				.02(t)2. is revised to address 30.34(j)(3) .02(t)6. is added to address 30.34(j)(4)	designation assigned to 10 CFR 30.34(j).
9	N/A	32.58	2007-3	.02(10)(c)6. is added.	Same: labeling of devices AL omits an equivalent regulation to 10 CFR 32.58. AL needs to add an equivalent regulation to 10 CFR 32.58 to 420-3-26-.02 in order to meet the Compatibility Category B designation assigned to 10 CFR 32.58.
10	420-3-26-.07(45)(b)	35.100	2007-3	.07 Rule is not part of this rulemaking packet	Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required 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...) AL needs to make the above change in order to meet the Compatibility Category H&S designation assigned to 10 CFR 35.100.
11	420-3-26-.04(5)(b)3.	34.20	2012-3	.04 Rule is not part of this rulemaking packet	Performance requirements for industrial radiography equipment 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

					<p>tubes would not compromise the design safety features of the system.”</p> <p>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 34.20 (a)(2).</p> <p>Comment revised from NRC letter dated May 2, 2014.</p>
12	420-3-26-.02(4)(d)	30.19	2012-4	<p>.02(4)(d)1. Is revised</p> <p>.02(4)(d)1. Is revised</p> <p>.02(4)(d)2. Is added</p> <p>.02(4)(d)(1) is revised</p>	<p>Self-luminous products containing tritium, krypton 85, or promethium 147</p> <p>AL lists krypton-95 instead of krypton-85 in 420-3-26-.02(4)(d)1.</p> <p>AL needs to change 420-3-26-.02(4)(d)(1) to read “...products manufactured, processed, produced, or initially transferred in accordance with ...which license authorizes the initial transfer of the product to persons...”</p> <p>AL omits an equivalent regulation to 10 CFR 30.19(b). AL needs to add equivalent text to 420-3-26-.02(4)(d).</p> <p>AL needs to make the above changes in order to meet the Compatibility Category B designation assigned to 10 CFR 30.19.</p> <p>AL includes the term “imported” in 420-3-26-.02(4)(d)(1).</p> <p>AL needs to delete the term “imported” in order to meet the Compatibility Category B designation assigned to 10 CFR 30.19.</p> <p>Comment revised from NRC letter dated May 2, 2014.</p>

13	420-3-26-.02(10)(g)	32.51	2012-4	<p>References revised in .02(10)(g), (g)1., (g)4.(i), (g)4.(i)(I) and (II), (g)4.(ii)(II), (g)5.(i), (g)5.(i)(III), (IV) and (VII), (g)5.(ii)</p>	<p>Byproduct material contained in devices for use under § 31.5; requirements for license to manufacture, or initially transfer</p> <p>AL lists a wrong reference in the title to 420-3-26-.02(10)(g) and in 420-3-26-.02(10)(g)1. AL needs to change “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>Comment revised from NRC letter dated May 2, 2014.</p>
14	420-3-26-.02(10)(c)4.	32.57 (d) and (e)	2012-4	<p>.02(10)(c)4.(ii) is revised to remove Schedule A.</p> <p>.02(10)(c)5. is added to address 32.57(e)</p>	<p>Calibration or reference sources containing americium 241 or radium 226: Requirements for license to manufacture or initially transfer</p> <p>AL references that their equivalent to 10 CFR 32.57(e) is 420-3-26-.02 Schedule A, however Schedule A has been omitted from the rulemaking.</p> <p>In its equivalent to 32.57(d)(2) AL states that the source has been subject to and has satisfactorily passed appropriate tests required prescribed by 420-3-26-.02 Schedule A. However AL omits Schedule A from their regulations.</p> <p>AL needs to readopt their Schedule A or adopt equivalent text to 10 CFR 32.57 (e) and change the reference in 420-3-26-.02(10)(c)(4)(ii) in order to meet the Compatibility Category B designation assigned to 10 CFR 32.57.</p>