

Comments on RATS 2007-2, and 2007-3: Exemptions From Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements, and Requirements for Expanded Definition of Byproduct Material
10 CFR Parts 30, 31, and 32
(72 FR 58473, 55864)
RATS ID: 2007-2, 2007-3
Effective Date: January 14, 2019

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
§ 30.18 (RATS 2007-2, 2007-3)	Exempt quantities	28-35-192g	B	Kansas regulation 28-35-192g(b) needs to add the term “owns” after “or transfers.” Kansas needs to make the above change in order to meet the Compatibility Category B designation assigned to 10 CFR 30.18. COMMENT STANDS from NRC letter dated October 26, 2010.	Yes	No	“Owns” was placed before “or transfers.” It is functionally identical.
§ 30.4 (RATS ID 2007-3)	Definition	28-35-135c(v)	C	Kansas omits the definition of <i>consortium</i> . Kansas needs to adopt the essential objectives of the definition of <i>consortium</i> in order to meet the Compatibility Category C designation assigned to 10 CFR 30.4. COMMENT STANDS from NRC letter dated October 26, 2010.	No	No	(v) "Consortium" means an association of medical use licensees and a positron emission tomography (PET) radionuclide production facility in the same geographical area that jointly own or share the operation and maintenance cost of the PET radionuclide production facility that produces PET radionuclides for use in producing radioactive drugs within the consortium for noncommercial distributions among its associated members for medical use.

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§ 30.32(g) (RATS ID 2007-3)	Application for specific licenses	28-35-179a	C	Kansas regulations omit an equivalent section to 10 CFR 30.32(g) from their regulations. Kansas needs to adopt the essential objectives of this requirement in order to meet the Compatibility Category C designation assigned to 10 CFR 30.32(g). COMMENT STANDS from NRC letter dated October 26, 2010.	Yes	Yes	30.32(g)(1) is covered by 179a(e). 30.32(g)(2) is covered by 179a(f). 179a(f) references information required in 28-35-181e. 181e was revoked in 2011. Kansas has a package currently under proposal that it can add language to, at your discretion, in order to close this issue. We submit this in order to narrow the scope of the issue to only 30.32(g)(2). 30.32(g)(3) is covered by 179a(g). 30.32(g)(4) is covered by 179a(h).
§ 30.32(j) (RATS ID 2007-3)	Application for specific licenses	28-35-181m(h)	B	Kansas regulations omit an equivalent section to 10 CFR 30.32(j) from their regulations. Kansas needs to incorporate 10 CFR 30.32(j) in their regulations to meet the Compatibility Category B designation assigned to 10 CFR 30.32(j). COMMENT STANDS from NRC letter dated October 26, 2010.	Yes	No	Regulations were adapted into Kansas required language. No significant change in effect.

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§ 30.34(j) (RATS ID 2007-3)	Terms and conditions of licenses	28-35-181m	B	Kansas regulations omit an equivalent section to 10 CFR 30.34(j) from their regulations. Kansas needs to incorporate 10 CFR 30.34(j) in their regulations to meet the Compatibility Category B designation assigned to 10 CFR 30.34(j). COMMENT STANDS from NRC letter dated October 26, 2010.	Yes	Yes	(j)(1) is covered by (i) (j)(2)(ii) is covered by (g) (j)(3) is covered by (h)(2) and (3) (j)(2)(i) is not currently covered, but will be under proposed regulation. See proposed regulation below, which is addressed in the proposed regulations letter to the Michelle Beardsley at the NRC dated 12/12/2019. <u>In proposed regulation package: “(g) Each licensee shall satisfy the labeling requirements specified in subsection (e).”</u>
§ 30.71 (RATS ID 2007-3)	Schedule B	28-35-197b	B	Kansas needs to add the following elements to 28-35-197a: Germanium 68 (Ge68), Gold 195 (Au195), Yttrium 88 (Y88). Kansas also needs to add the element Xenon 135 (Xe135) to 28-35-197a and correct the entry “ Yttrium 175 (Yb175)” to “ Ytterbium 175 (Yb175).” Kansas needs to make the above change in order to meet the	No	No	Adopted by reference, as of the 2007 update.

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				Compatibility Category B designation assigned to 10 CFR 30.71. COMMENT Revised from NRC letter dated October 26, 2010.			
§ 31.12 (RATS ID 2007-3)	General license for certain items and self-luminous products containing radium-226	28-35-178i	C	Kansas regulations omit an equivalent section to 10 CFR 31.12 from their regulations. Kansas needs to adopt the essential objectives of this requirement in order to meet the Compatibility Category C designation assigned to 10 CFR 31.12. COMMENT STANDS from NRC letter dated October 26, 2010.	No	No	
32.72(b)(4) and (b)(5)(iv) (RATS ID 2007-3)	Manufacture, preparation, or transfer for commercial distribution of radioactive drugs, containing byproduct material for certain in vitro clinical or laboratory testing under general license	28-35-181m	B	In 28-35-181m(f)(4), Kansas omitted the requirement in 32.72(b)(4)(i) and (ii) which addresses individuals preparing only radioactive drugs containing accelerator-produced radioactive material and those practicing at government agency or Federally recognized Indian Tribe before November 30, 2007. These provisions need to be included in the Kansas regulations. Although 28-35-181m(f)(5)(A) was revised to address the previous comment on the draft regulation (See ML102810063), Kansas omitted “Nuclear Regulatory Commission” from the list of licenses. The sentence should be revised as	Yes	No	Comment revised due to Kansas required language.

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				<p>follows: “A copy of each individual’s certification by a specialty board whose certification process has been recognized as specified in 10 CFR 35.55(a), as adopted by reference in K.A.R. 28-35-264, or the department, nuclear regulatory commission, or agreement state license, or ...”. Kansas needs to make the above change in order to meet the Compatibility Category B designation assigned to 10 CFR 32.72. COMMENT Revised from NRC letter dated October 26, 2010.</p>			