

October 29, 2010

Thomas A. Conley, Chief
Radiation & Asbestos Control Section
Department of Health and Environment
Bureau of Air and Radiation
1000 SW Jackson, Suite 310
Topeka, KS 66612-1366

Dear Mr. Conley:

We have reviewed the proposed changes to Kansas Radiological Health Rules, "Kansas Department of Health and Environment Standards for Protection Against Radiation," received by our office on August 19, 2010. These regulations were reviewed by comparison to the equivalent Nuclear Regulatory Commission (NRC) rules in 10 CFR Parts 19, 20, 30, 31, 32, 33, 35, 40, 61, 70 and 150 and the requirements of the six amendments identified in the enclosed State Regulation Status (SRS) Data Sheet. We discussed our review of the regulations with Isabelle Busenitz on October 21, 2010.

As a result of our review, we have 19 comments that have been identified in the enclosure. Please note that we have limited our review to regulations required for compatibility and/or health and safety. Under our current procedure, a finding that the Kansas regulations meet the compatibility and health and safety categories of the equivalent NRC regulation may only be made based on a review of the final Kansas regulations. However, we have determined that if your proposed regulations were adopted, incorporating our comments and without other significant change, they would meet the compatibility and health and safety categories established in the Office of Federal and State Materials and Environmental Management Programs (FSME) Procedure [SA-200](#).

We request that when the proposed regulations are adopted and published as final regulations, a copy of the "as published" regulations be provided to us for review. As requested in FSME Procedure [SA-201](#), "Review of State Regulatory Requirements," please highlight the final changes, and provide a copy to Division of Materials Safety and State Agreements, FSME.

The SRS Data Sheet summarizes our knowledge of the status of other Kansas regulations and legally binding requirements, as indicated. Please let us know if you note any inaccuracies, or have any comments on the information contained in the SRS Data Sheet. This letter, including the SRS Data Sheet, is posted on the FSME website: <http://nrc-stp.ornl.gov/rulemaking.html>.

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If you have any questions regarding the comments, the compatibility and health and safety categories, or any of the NRC regulations used in the review, please contact Kathleen Schneider, State Regulation Review Coordinator at (301) 415-2320 (kathleen.schneider@nrc.gov) or Nicole Coleman at (301) 415-1048 (nicole.coleman@nrc.gov).

Sincerely,

/RA/

Terrence Reis, Deputy Director
Division of Materials Safety and State Agreements
Office of Federal and State Materials and
Environmental Management Programs

Enclosures:
As state

[Concurrence Page]

Enclosures: As stated

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Incoming Document: ML102360612

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COMPATIBILITY COMMENTS ON *KANSAS* PROPOSED REGULATIONS

STATE SECTION	NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
1 28-35-181m	32.72(b)(5)	2007-1	B	<p>Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under Part 35.</p> <p>Kansas needs to replace, in 28-35-181m (f)(5), the term “<i>Board of pharmaceutical specialties</i>” with “<i>specialty board whose certification process has been recognized...</i>”</p> <p>Kansas needs to make the above change in order to meet Compatibility Category B designation assigned to 10 CFR 32.72(b)(5).</p>
2 28-35-192g 30.18		2007-2 2007-3	B	<p>Exempt quantities</p> <p>Kansas regulation 25-35-192g(a) needs to add the terms “owns, receives” before “or transfers.”</p> <p>Kansas regulation 25-35-192g(b) needs to add the term “owns” after “or transfers.”</p> <p>Kansas needs to make the above changes in order to meet the Compatibility Category B designation assigned to 10 CFR 30.18.</p>
3 28-35-178b 31.5		2007-2	B	<p>Certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized atmosphere</p> <p>Kansas regulation 28-35-178b(b)(8)(C)(ii) omits, “Removes, alters, covers, or clearly and unambiguously augments the existing label (otherwise required by (c)(1) of this section).”</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
					Kansas needs to make the above change in order to meet the Compatibility Category B designation assigned to 10 CFR 31.5.
4	N/A	20.1003 30.4 150.3	2007-3 H&S		<p>Definition</p> <p>Kansas omits the definition of <i>discrete source</i>.</p> <p>Kansas needs to adopt the essential objectives of the definition of discrete source in order to meet the Compatibility Category H&S designation assigned to 10 CFR 20.1003, 30.4 and 150.3.</p>
5	28-35-135w	20.1003	2007-3	B	<p>Definition</p> <p>Kansas needs to insert the word “transuranic” before “waste” in 28-35-135w(a)(1)(E).</p> <p>Kansas should revise 28-35-135w(a)(1)(C) to read “byproduct material as defined in paragraph (2), (3) and (4) of the definition of byproduct material in 10 CFR 20.1003, dated December 1, 2009.”</p> <p>Kansas needs to make the above changes in order to meet the Compatibility Category B designation assigned to 10 CFR 20.1003.</p>
6	Appendix B, Table 3	Part 20, Appendix B	2007-3 A		<p>ALIs and DACs of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage</p> <p>Kansas needs to add Nitrogen and Oxygen to the applicable tables.</p> <p>Kansas needs to make the above change in order to meet the Compatibility Category A designation assigned to 10 CFR 20, App. B</p>

STATE SECTION	NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
7	28-35-175a 30.3(a)	2007-3	C	<p>Activities requiring license</p> <p>Kansas regulation needs to include “manufacture and produce” as being conducted only with a specific or general license.</p> <p>Kansas needs to make the above change in order to meet the Compatibility Category C designation assigned to 10 CFR 30.3(a).</p>
8	N/A 30.4	2007-3	C	<p>Definition</p> <p>Kansas omits the definition of <i>consortium</i>.</p> <p>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.</p>
9	N/A 30.32(g)	2007-3	C	<p>Application for specific licenses</p> <p>Kansas regulations omit an equivalent section to 10 CFR 30.32(g) from their regulations.</p> <p>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).</p>
10	28-35-181m/181b/180a	30.32(j)	2007-3	<p>Application for specific licenses</p> <p>Kansas regulations omit an equivalent section to 10 CFR 30.32(j) from their regulations.</p> <p>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).</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
11	N/A 30.34(g)		2007-3	H&S	<p>Terms and conditions of licenses</p> <p>Kansas regulations omit an equivalent section to 10 CFR 30.34(g) from their regulations.</p> <p>Kansas needs to adopt the essential objectives of this requirement in order to meet the Compatibility Category H&S designation assigned to 10 CFR 30.34(g).</p>
12	28-35-181m 30.34(j)		2007-3	B	<p>Terms and conditions of licenses</p> <p>Kansas regulations omit an equivalent section to 10 CFR 30.34(j) from their regulations.</p> <p>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).</p>
13	28-35-197a 30.71		2007-3	B	<p>Schedule B</p> <p>Kansas needs to add the following elements to 28-35-197a: Germanium 68 (Ge 68), Gold 195 (Au195), Yttrium 88 (Y88).</p> <p>Kansas needs to make the above change in order to meet the Compatibility Category B designation assigned to 10 CFR 30.71.</p>
14	28-35-178b 31.5(b)(1) & (c)(13)		2007-3 B		<p>Certain detecting, measuring, gauging, or controlling devices and/or an ionizing atmosphere</p> <p>Current Kansas regulations exclude those devices listed in 31.5(c)(13)(i) from the general license granted under this part. These devices, with these radionuclides, would need to be specifically licensed in Kansas, which is more restrictive than NRC's regulations.</p> <p>Kansas regulations have the essential elements of the NRC, but are more</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
					restrictive than the NRC's GL rule. As noted in the September 20, 2007 All Agreement States Letter FSME-07-087, the determination on this provision will be held in abeyance until such time that the NRC completes the GL device rulemaking initiated in August 2007.
15	N/A 31.12		2007-3	C	<p>General license for certain items and self-luminous products containing radium-226</p> <p>Kansas regulations omit an equivalent section to 10 CFR 31.12 from their regulations.</p> <p>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.</p>
16	28-35-181j 32.57		2007-3	B	<p>Calibration or reference sources containing americium-241 or radium- 226: Requirements for license to manufacture or initially transfer</p> <p>Kansas regulation, 28-35-181j(5), should incorporate the phrase "and the five prototype sources have satisfactorily passed the prototype test" between "or radium-226," and "as follows."</p> <p>Kansas needs to make the above change in order to meet the Compatibility Category B designation assigned to 10 CFR 32.57.</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
17	28-35-181m 32.72(b)(4) and (b)(5)(iv)		2007-3 B		<p>Manufacture, preparation, or transfer for commercial distribution of radioactive drugs, containing byproduct material for certain in vitro clinical or laboratory testing under general license</p> <p>Kansas regulations omit the requirements of 32.72(b)(4) and (b)(5)(iv).</p> <p>Kansas needs to incorporate 10 CFR 32.72(b)(4) and (b)(5)(iv) in order to meet the Compatibility Category B designation assigned to 10 CFR 32.72.</p>
18	28-35-264 35.2		2007-3	H&S	<p>Definition</p> <p>Kansas omits the definition of <i>positron emission tomography (PET) radionuclide production facility</i>.</p> <p>Kansas needs to adopt the essential objectives of the definition of <i>positron emission tomography (PET) radionuclide production facility</i> in order to meet the Compatibility Category H&S designation assigned to 10 CFR 35.2.</p>
19	28-35-334 19.13		2008-1	C	<p>Notification and reports to individuals</p> <p>In 28-35-334(b), the reference to K.A.R. 28-35-217b (General Surveys) should be to K.A.R. 28-35-217a (Conditions requiring individual monitoring...)</p> <p>Kansas needs to make the above change in order to meet the Compatibility Category C designation assigned to 10 CFR 19.13.</p>

STATE REGULATION STATUS

State: Kansas

Tracking Ticket Number: 10-42

[6 amendment(s) reviewed is identified by a ★

Date: October 29, 2010

at the beginning of the equivalent NRC requirement.]

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
1991-1	Safety Requirements for Radiographic Equipment Part 34 55 FR 843 (Superceded by 1997-5)	01/10/1994	Final ML060940369		Kansas has adopted Final Regulations equivalent to RATS ID: 1997-5.
1991-2	ASNT Certification of Radiographers Part 34 56 FR 11504 (Superceded by 1997-5)	none	Final ML060940369		Kansas has adopted Final Regulations equivalent to RATS ID: 1997-5.
1991-3	Standards for Protection Against Radiation Part 20 56 FR 23360; 56 FR 61352; 57 FR 38588; 57 FR 57877; 58 FR 67657; 59 FR 41641; 60 FR 20183;	01/01/1994	Final	No Comments 12/30/1997	
1991-4	Notification of Incidents Parts 20, 30, 31, 34, 39, 40, 70 56 FR 64980;	10/15/1994	Final ML060940369		
1992-1	Quality Management Program and Misadministrations Part 35 56 FR 34104 (Superceded by 2002-2)	01/27/1995	Not Required	Not Required	Kansas has adopted Final Regulations equivalent to RATS ID: 2002-2.
1992-2	Eliminating the Recordkeeping Requirements for Departures from Manufacturer's Instructions Parts 30, 35 57 FR 45566	none	Not Required	Not Required	These regulation changes are not required to be adopted for purposes of Compatibility.
1993-1	Decommissioning Recordkeeping and License Termination: Documentation Additions [Restricted areas and spill sites] Parts 30, 40 58 FR 39628	10/25/1996	Final	No Comments 01/03/1997	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
1993-2	Licensing and Radiation Safety Requirements for Irradiators Part 36 58 FR 7715	07/01/1996	Final ML060940369	No Comments 05/18/2006 ML061370535	
1993-3	Definition of Land Disposal and Waste Site QA Program Part 61 58 FR 33886	07/22/1996	Not Applicable ¹	Not Applicable	Kansas does not have any licensees subject to these regulations. (See SECY-95-112)
1994-1	Self-Guarantee as an Additional Financial Mechanism Parts 30, 40, 70 58 FR 68726; 59 FR 1618	none	Not Required	Not Required	These regulation changes are not required to be adopted for purposes of Compatibility.
1994-2	Uranium Mill Tailings Regulations: Conforming NRC Requirements to EPA Standards Part 40 59 FR 28220	07/01/1997	Not Applicable	Not Applicable	Kansas does not have authority to regulate this material under its Agreement.
1994-3	Timeliness in Decommissioning Material Facilities Parts 30, 40, 70 59 FR 36026	08/15/1997	Final ML060940369	No Comments 05/18/2006 ML061370535	
1995-1	Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use Parts 30, 32, 35 59 FR 61767; 59 FR 65243; 60 FR 322	01/01/1998	Final ML060940369	No Comments 05/18/2006 ML061370535	
1995-2	Frequency of Medical Examinations for Use of Respiratory Protection Equipment	03/13/1998	Final ML060940369	No Comments 05/18/2006 ML061370535	
1995-3	Low-Level Waste Shipment Manifest Information and Reporting Parts 20, 61 60 FR 15649; 60 FR 25983	03/01/1998	Final ML060940369	No Comments 05/18/2006 ML061370535	
1995-4	Performance Requirements for Radiography Equipment Part 34 60 FR 28323 (Superceded by 1997-5)	06/30/1998	Final ML060940369		Kansas has adopted Final Regulations equivalent to RATS ID: 1997-5.

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
1995-5	Radiation Protection Requirements: Amended Definitions and Criteria Parts 19, 20 60 FR 36038	08/14/1998	Final ML060940369	No Comments 05/18/2006 ML061370535	
1995-6	Clarification of Decommissioning Funding Requirements Parts 30, 40, 70 60 FR 38235	11/24/1998	Final ML060940369	No Comments 05/18/2006 ML061370535	
1995-7	Medical Administration of Radiation and Radioactive Materials Parts 20, 35 60 FR 48623 (Superseded by 2002-2 and 2005-2)	10/20/1998	Final ML060940369		Kansas has adopted Final Regulations equivalent to RATS IDs: 2002-2 and 2005-2.
1996-1	Compatibility with the International Atomic Energy Agency Part 71 60 FR 50248; 61 FR 28724 (Superseded by 2004-1)	04/01/1999	Not Required	Not Required	Kansas has adopted Final Regulations equivalent to RATS ID: 2004-1.
1996-2	One Time Extension of Certain Byproduct, Source and Special Nuclear Materials Licenses Parts 30, 40, 70 61 FR 1109	02/15/1999	Not Required	Not Required	These regulation changes are not required to be adopted for purposes of Compatibility.
1996-3	Termination or Transfer of Licensed Activities: Record keeping Requirements Parts 20, 30, 40, 61, 70 61 FR 24669	06/17/1999	Final ML060940369	No Comments 05/18/2006 ML061370535	
1997-1	Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act Part 20 61 FR 65120	01/9/2000	Final ML060940369	No Comments 05/18/2006 ML061370535	
1997-2	Recognition of Agreement State Licenses in Areas Under Exclusive Federal Jurisdiction Within an Agreement State Part 150 62 FR 1662	02/27/2000	Final ML060940369	No Comments 05/18/2006 ML061370535	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
1997-3	Criteria for the Release of Individuals Administered Radioactive Material Parts 20, 35 62 FR 4120	05/29/2000	Final ML060940369	No Comments 05/18/2006 ML061370535	
1997-4	Fissile Material Shipments and Exemptions Part 71 62 FR 5907 (Superceded by 2004-1)	02/10/2000	Not Required	Not Required	These regulation changes are not required to be adopted for purposes of Compatibility. (See STP-97-078) Kansas has adopted Final Regulations equivalent to RATS ID: 2004-1.
1997-5	Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiography Operations Parts 30, 34, 71, 150 62 FR 28947	06/27/2000	Final ML060940369	No Comments 05/18/2006 ML061370535	
1997-6	Radiological Criteria for License Termination Parts 20, 30, 40, 70 62 FR 39057	08/20/2000	Final ML072010244	No Comments 08/30/2007 ML072390354	
1997-7	Exempt Distribution of a Radioactive Drug Containing One Micro curie of Carbon-14 Urea Part 30 62 FR 63634	01/02/2001	Final ML060940369	No Comments 05/18/2006 ML061370535	
1998-1	Deliberate Misconduct by Unlicensed Persons Parts 30, 40, 61, 70, 71,	02/12/2001	Final ML060940369	No Comments 05/18/2006 ML061370535	
1998-2	Self-Guarantee of Decommissioning Funding by Nonprofit and Non-Bond-Issuing Licensees Parts 30, 40, 70 63 FR 29535	07/01/2001	Not Required	Not Required	These regulation changes are not required to be adopted for purposes of Compatibility.
1998-3		07/10/2001	Not Required	Not Required	These regulation changes are not required to be adopted for purposes of Compatibility. (See STP-98-074) Kansas has adopted Final Regulations equivalent to RATS ID: 1997-5.

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
1998-4	Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations Part 34 63 FR 37059	07/09/2001	Final ML060940369	No Comments 05/18/2006 ML061370535	
1998-5	Minor Corrections, Clarifying Changes, and a Minor Policy Change Parts 20, 35, 36 63 FR 39477; 63 FR 45393	10/26/2001	Final ML060940369	No Comments 05/18/2006 ML061370535	
1998-6	Transfer for Disposal and Manifests: Minor Technical Conforming Amendment Part 20 63 FR 50127	11/20/2001	Final ML060940369	No Comments 05/18/2006 ML061370535	
1999-1	Radiological Criteria for License Termination of Uranium Recovery Facilities Part 40 64 FR 17506	06/11/2002	Not Applicable	Not Applicable	Kansas does not have the authority to regulate this material under its Agreement.
1999-2	Requirements for Those Who Possess Certain Industrial Devices Containing Byproduct Material to Provide Requested Information Part 31 64 FR 42269	10/04/2002	Not Required	Not Required	These regulation changes are not required to be adopted for purposes of Compatibility.
1999-3	Respiratory Protection and Controls to Restrict Internal Exposure Part 20 64 FR 54543; 64 FR 55524	02/02/2003	License Condition ML052510063	No Comments 09/22/2005 ML052660291	
2000-1	Energy Compensation Sources for Well Logging and Other Regulatory Clarifications Part 39 65 FR 20337	05/17/2003	Final ML072010244	No Comments 08/30/2007 ML072390354	
2000-2	New Dosimetry Technology Parts 34, 36, 39 65 FR 63750	01/08/2004	Final ML060940369	No Comments 05/18/2006 ML061370535	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
2001-1	Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct	02/16/2004	Final ML072010244	Comments 08/30/2007 ML072390354	
2002-1	Revision of the Skin Dose Limit Part 20 67 FR 16298	04/05/2005	Final ML060940369	No Comments 05/18/2006 ML061370535	
2002-2	Medical Use of Byproduct Material Parts 20, 32, 35 67 FR 20249	10/24/2005	Final ML070851184	No Comments 04/23/2007 ML071140120	
2003-1	Financial Assurance for Materials Licensees Parts 30, 40, 70 68 FR 57327	12/03/2006	Final ML060940369	No Comments 05/18/2006 ML061370535	
2004-1	Compatibility With IAEA Transportation Safety Standards and Other Transportation Safety Amendments Part 71 69 FR 3697	10/01/2007	Final ML060940369	No Comments 05/18/2006 ML061370535	
2005-1	Security Requirements for Portable Gauges Containing Byproduct Material Part 30 70 FR 2001	07/11/2008	Final ML072010244	No Comments 08/30/2007 ML072390358	
2005-2	Medical Use of Byproduct Material - Recognition of Specialty Boards Part 35	04/29/2008	Final ML060940369	No Comments 05/18/2006 ML061370535	
2005-3	Increased Controls for Risk-Significant Radioactive Sources	12/01/2005	License Condition ML052650212	No Comments 09/27/2005 ML052650327	
*2006-1	Minor Amendments Parts 20, 30, 32, 35, 40 and 70	03/27/2009	Proposed ML102360612	No Comments 10/29/2010 ML102810058	
2006-2	National Source Tracking System - Serialization Requirements Part 32 with reference to Part 20 Appendix E 71 FR 65685	02/06/2007	Final ML072010244	No Comments 08/30/2007 ML072390354	
2006-3	National Source Tracking System Part 20 71 FR 65685, 72 FR 59162	01/31/2009	Final ML072820581	No Comments 10/30/2007 ML073040008	

RATS ID	NRC Chronology Identification	Date Due for State Adoption	Incoming Package	Outgoing Package	Notes
*2007-1	Medical Use of Byproduct Material - Minor Corrections and Clarifications Parts 32 and 35 72 FR 45147, 54207	10/29/2010	Proposed ML102360612	Comments 10/29/2010 ML102810058	
*2007-2	Exemptions From Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements Parts 30, 31, 32, 150 72 FR 58473	12/17/2010	Proposed ML102360612	Comments 10/29/2010 ML102810058	
*2007-3	Requirements for Expanded Definition of Byproduct Material Parts 20, 30, 31, 32, 33, 35, 61, 150 72 FR 55864	11/30/2010	Proposed ML102360612	Comments 10/29/2010 ML102810058	
2007-4	Order Imposing Fingerprinting Requirements and Criminal History Records Check Requirements for Unescorted Access to Certain Radioactive Material NRC Order EA-07-305 72 FR 70901	06/05/2008	License Condition ML081270294	No Comments 05/14/2008 ML081350450	
*2008-1	Occupational Dose Records, Labeling Containers, and Total Effective Dose Equivalent Parts 19, 20 72 FR 68043	02/15/2011	Proposed ML102360612	Comments 10/29/2010 ML102810058	
*2009-1	Medical Use of Byproduct Material – Authorized User Clarification Part 35 74 FR 33901	09/28/2012	Proposed ML102360612	No Comments 10/29/2010 ML102810058	

¹ IMPEP Team: verify that Kansas does not have any licensees subject to these regulations during each review.