April 9, 2008

Ruth E. McBurney, Executive Director
Office of Executive Director
Conference of Radiation Control Program Directors
205 Capital Avenue
Frankfort, KY 40601

Dear Ms. McBurney:

We have reviewed the final revision to Part C of the Suggested State Regulations (SSR), received by our office on February 12, 2008. These regulations were reviewed by comparison to the equivalent Nuclear Regulatory Commission (NRC) rules in 10 CFR Parts 30, 31, 32, 40, 70 and 150. We discussed our review of the regulations with you on April 1, 2008.

As a result of our review, we have 12 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. We have determined that if these regulations are revised, 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.

Our review included the incorporation of equivalent NRC amendments issued prior to August 2005. The following amendments still need to be addressed in the next revision to Part C:

- "Minor Amendments – 10 CFR Parts 20, 30, 32, 35, 40 and 70," (71 FR 15005) that became effective March 27, 2006 and are due for State adoption by March 27, 2009.

- "National Source Tracking System – Serialization Requirements," 10 CFR Part 32 with reference to Part 20 Appendix E (71 FR 65685) that became effective on February 6, 2007 and are due for State adoption by February 6, 2010.

- "Medical Use of Byproduct Material – Minor Corrections and Clarifications," 10 CFR Parts 32 and 35 (72 FR 45147, 72 FR 54207) that became effective October 29, 2007 and are due for State adoption by October 29, 2010.

- "Exemptions from Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements," 10 CFR Parts 30, 31, 32 and 150 (72 FR 58473) that became effective December 17, 2007 and are due for State adoption by December 17, 2010.

- "Requirements for Expanded Definition of Byproduct Material," 10 CFR Parts 20, 30, 31, 32, 33, 35, 61, and 150 (72 FR 55864) that became effective November 30, 2007 and are due for State adoption by November 30, 2010.

The Conference of Radiation Control Program Directors (CRCPD) will need to resubmit Part C to address changes necessary with the implementation of these amendments. The rationale for the 2008 version of Part C should be revised to reflect that this version of Part C does not address the above amendments and that States considering an Agreement with NRC will need to address the comments attached and the above amendments to meet the compatibility and health and safety categories.

We request that when you revise your regulations to address our comments, 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 location of any changes made by the CRCPD, in response to our comments and provide a copy to FSME.

This letter is posted on the FSME website: http://www.hsrd.ornl.gov/nrc/rulemaking.htm. 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 (email: kxs@nrc.gov) or Monica Orendi at 301-415-3938 (email: mlo1@nrc.gov).

Sincerely,

\ ***RA by ADWhite for*** \

Robert J. Lewis, Director
Division of Materials Safety and State Agreements
Office of Federal and State Materials and
Environmental Management Programs

Enclosures:
As stated

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Robert J. Lewis, Director
Division of Materials Safety and State Agreements
Office of Federal and State Materials and
Environmental Management Programs

Enclosures: As stated

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COMPATIBILITY COMMENTS ON FINAL CRCPD PART C REGULATIONS

STATE SECTION		NRC SECTION	10 CFR Part	CATEGORY	SUBJECT and COMMENTS
1	Sec. C.4.a	30.14	Part 30	B	**Exempt Concentrations** SSR Part C misses a reference in Section C.4.a.i. The first line of the paragraph should read "Except as provided in C.4.a.ii and C.4.a.iv …". SSR Part C needs to make the above change in order to meet the Compatibility Category B designation assigned to 10 CFR 30.14.
2	Sec. C.4.c.i	30.15	Part 30	B	**Certain Items Containing Byproduct Material** SSR Part C Section C.4.c.i does not have an equivalent provision to 10 CFR Part 30.15(b). According to the Rationale for Part C an attempt to resolve this comment was made by adding additional language to C.4.c.i which states "or persons who desire to initially transfer for sale or distribute such products containing radioactive material". Although this addition is correct and is needed to meet the Compatibility designation for 10 CFR 30.15(a) it does not cover the incorporation of 10 CFR 30.15(b). SSR Part C Section C.4.c.i needs to add C.4.c.i.10 incorporating an essentially identical provision to 10 CFR 30.15(b) in order to meet the Compatibility Category B designation assigned to 10 CFR 30.15.
3	Sec. C.4.c.iv	30.16	Part 30	B	**Resins Containing Scandium-46 and Designed for Sand-Consolidation in Oil Wells** SSR Part C Section C.4.c.iv is missing

STATE SECTION		NRC SECTION	10 CFR Part	CATEGORY	SUBJECT and COMMENTS
					the phrase “for sale or distribution” after the words “initially transferred” in the fourth line of this section. Also Section C.4.c.iv should remove the reference to 10 CFR 32.16 and only leave the reference to 10 CFR 32.17. SSR Part C Section C.4.c.iv needs to make the above changes in order to meet the Compatibility Category B designation assigned to 10 CFR 30.16.
4	Sec. C.4.c.ii	30.19	Part 30	B	**Self-luminous Products Containing Tritium, Krypton-85, or Promethium-147** SSR Part C Section C.4.c.ii omits an equivalent section to 10 CFR 30.19(b). Also the rationale for Part C states that the words “or equivalent regulations of an Agreement State” were added to be consistent with 10 CFR 30.19(b). However this phrase does not cover the incorporation of 10 CFR 30.19(b) and needs to be removed because 10 CFR 32.22 is a Compatibility Category NRC and would not have equivalent Agreement State regulations as stated in Section C.4.c.ii (1). SSR Part C Section C.4.c.ii needs to address the above changes in order to meet the Compatibility Category B designation assigned to 10 CFR 30.19.
5	Sec. C.4.c.iii	30.20	Part 30	B	**Gas and Aerosol Detectors Containing Byproduct Material** SSR Part C Section C.4.c.iii omits a regulation equivalent to 10 CFR

STATE SECTION		NRC SECTION	10 CFR Part	CATEGORY	SUBJECT and COMMENTS
					30.20(b). SSR Part C Section C.4.c.iii needs to make the above change in order to meet the Compatibility Category B designation assigned to 10 CFR 30.20.
6	Sec. C.4.c.v	30.21	Part 30	B	**Radioactive Drug: Capsules Containing Carbon-14 Urea for "In Vivo" Diagnostic Use for Humans** SSR Part C Section C.4.c.v.1 has a wrong reference in line 1. It should read "Except as provided in C.4.c.v.2 and C.4.c.v.3…" instead of "Except as provided in C.4.c.vi.2 and C.4.c.vi.3…". SSR Part C Section C.4.c.v.1 needs to make the above change in order to meet the Compatibility Category B designation assigned to 10 CFR 30.21.
7	Sec. C.20	30.31	Part 30	C	**Types of Licenses** SSR Part C Section C.20.b does not include a reference to NRC's Part 39, which is equivalent to SSR Part W. Section C.20.b needs to add Part W to its list of provisions in order to meet the Compatibility Category C designation assigned to 10 CFR 30.31.
8	Sec. C.22.g	31.9	Part 31	C	**General License to Own Byproduct Material** SSR Part C Section C.22.g deletes the words "manufacture, produce, transfer, receive" from the list of things the general license does not authorize. SSR Part C Section C.22.g needs to add the above wording to meet the

STATE SECTION		NRC SECTION	10 CFR Part	CATEGORY	SUBJECT and COMMENTS
					Compatibility Category C designation assigned to 10 CFR 31.9.
9	Sec. C.28.d	32.51	Part 32	B	**Byproduct Material Contained in Devices For Use Under §31.5: Requirements For License to Manufacture or Initially Transfer** SSR Part C Section C. 28.d.3.c.ii does not include the reference to having the name of the "initial transferor" on the required label (See 10 CFR 32.51(a)(3)(iii)) instead it lists the word "distributor" on the label. SSR Part C Section C.28.d.3.c.ii needs to address the above change in order to meet the Compatibility Category B designation assigned to 10 CFR 32.51.
10	Sec. C.21.e	40.25	Part 40	C	**General License For Use of Certain Industrial Products or Devices** SSR Part C Sec. C.21.e.ii does not encompass industrial products or devices that have been "initially transferred", it only includes regulation over industrial products or devices that have been manufactured. SSR Part C Section C.21.e.ii needs to add the words "or initially transferred" after the word "manufactured" in the second sentence in order to meet the Compatibility Category C designation assigned to 10 CFR 40.25.
11	Sec. C.22	70.20	Part 70	C	**General License to Own Special Nuclear Material** SSR Part C Section C.22 omits a provision meeting the essential objectives of 10 CFR 70.20. SSR Part C needs to add a provision to Section C.22 which incorporates the essential objectives of 10 CFR

STATE SECTION		NRC SECTION	10 CFR Part	CATEGORY	SUBJECT and COMMENTS
					70.20 in order to meet the Compatibility Category C designation assigned to 10 CFR 70.20.
12	Part C All Sections	RATS IDs: 2006-1, 2006-3, 2007-1, 2007-2, 2007-3	Parts 20, 30, 31, 32, 35, 40, 61, 70, 150	Multiple	SSR Part C needs to incorporate all of the applicable regulation changes from March 27, 2006 forward (see letter). SSR Part C needs to make the above changes in order to meet the Compatibility Category designations assigned to 10 CFR Parts 20, 30, 31, 32, 35, 40, 61, 70, 150.