April 1, 2010

Ms. Ruth E. McBurney
Executive Director
Conference of Radiation Control
Program Directors, Inc.
1030 Burlington Lane, Suite 4B
Frankfort, KY 40601

Dear Ms. McBurney:

We have reviewed the proposed Suggested State Regulations (SSR) Part G, "Use of Radionuclides in the Healing Arts." These regulations were received by our office on February 3, 2010 and were reviewed by comparison to the equivalent Nuclear Regulatory Commission (NRC) rules in 10 CFR Part 35. We discussed our review of the regulations with Sue Smith on March 26, 2009.

As a result of our review, we have eight 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 CRCPD Suggested State Regulations meet the compatibility and health and safety categories of the equivalent NRC regulation so that NRC can provide federal concurrence on the SSRs may only be made based on a review of the final SSR Part G regulations as approved by the CRCPD Executive Board. However, we have determined that if the proposed Part G 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 approved by the CRCPD Executive Board as final SSRs, a copy of the "approved" regulations be provided to us for review for federal concurrence. As requested in FSME Procedure SA-201, "Review of State Regulatory Requirements," please highlight the final changes, and provide a copy to the Division of Materials Safety and State Agreements, FSME.

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 Kathy Schneider, State Regulation Review Coordinator at 301-415-2320 (kathleen.schneider@nrc.gov) or Michelle Beardsley at 610-337-6942 (michelle.beardsley@nrc.gov).

Sincerely,

/RA T. Reis for/

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

Enclosure:
As stated

cc: Gwyn Galloway, UT, SR-C Chair
Earl Fordam, WA, SSR Council Chair

[Concurrence Page]

Enclosures: As stated

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COMPATIBILITY COMMENTS ON CRCPD PROPOSED SUGGESTED STATE REGULATIONS (SSR) PART G

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
1	G.21	35.27	N/A	H&S	**Supervision** In Section G.21(b)(i), SSR Part G omits the phrase: ”in addition to the requirements in j.12 of these regulations.” SSR Part G needs to add the above phase for consistence with G.21(a)(i) which embodies the essential objectives to meet the Compatibility Category H&S designation assigned to 10 CFR 35.27(b)(1).
2	G.22	35.40 (a) and (b)	N/A	H&S	**Written Directives** In Section G.22(b)(ii), SSR Part G states that the written directive should contain the “number” of target coordinate settings. 10 CFR 35.40 (b)(3) states the “values” of target coordinate settings. SSR Part G needs to delete the word “number” and insert the word “values” in Section G.22 (b)(ii) in order to embody the essential objectives to meet the Compatibility Category H&S designation assigned to 10 CFR 35.40.

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
3	G.32	35.60 (a) and (b)	N/A	H&S	**Possession, use, and calibration of instruments to measure the activity of unsealed byproduct Material** In Section G.32 (b), SSR Part G states that the licensee shall "test" the instrumentation. 10 CFR 35.60 (b) states that the licensee shall "calibrate" the instrumentation. "Calibration" goes beyond testing in that the dictionary definition also includes "the rectification of the graduation of (any instrument giving quantitative measurements)". SSR Part G needs to delete the word "test" and insert the word "calibrate" in Section G.32 (b) in order to embody the essential objectives to meet the Compatibility Category H&S designation assigned to 10 CFR 35.60.
4	G.36	35.67	N/A	H&S	**Requirements for possession of sealed sources and brachytherapy sources** In Section G.36, SSR Part G does not include equivalent requirements to 10 CFR 35.67 (c) which requires the licensee to measure the sample so that the leak test can detect the presence of 185 Bq (0.005 µCi) of radioactive material in the sample. SSR Part G needs to add a requirement to Section G.36 which embodies the essential objectives to meet the Compatibility Category H&S designation assigned to 10 CFR 35.67(c).

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
5	G.56	35.392	N/A	B	**Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries)** 1) Section G.56(b) does not include the equivalent to 10 CFR 35.394, i.e. Section G.57; further, they reference Section G.56(b)(ii)(1) or (2) for which there is no corresponding regulation.; 2) Section G.56(c)(iii) states "Has obtained written attestation that the individual has completed the requirements in G.57c.i. and G57c.ii"; the correct reference should be "G.56c.i. and G.56c.ii" which are the equivalent regulations to 10 CFR 35.392 (c)(1) and (c)(2); 3) Section G.56(c)(iii) includes Section G.58 which is equivalent to 10 CFR 35.396; this is not one of the authorizations allowed in 10 CFR 35.392 (c)(3). SSR Part G needs to make the above changes to Section G.56 in order to meet the Compatibility Category B designation assigned to 10 CFR 35.392.
6	G.58	35.396	N/A	B	**Training for the parenteral administration of unsealed byproduct material requiring a written directive** Section G.58 (a) states "Is an authorized user …for uses listed in G.55b.ii(6)(c) **AND** (d)". 10 CFR 35.396 allows for uses listed in 10 CFR 35.390(b)(1)(ii)(G)(3) **OR** 10 CFR 35.390(b)(1)(ii)(G)(4), SSR Part G needs to change Section G.58(a) to allow the authorized user to be a physician who is authorized for uses listed in Section

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
					G.55b.ii(6)(c) or (d) in order to meet the Compatibility Category B designation assigned to 10 CFR 35.396.
7	G.71	35.600	N/A	C	**Use of a sealed source in a remote afterloader unit, teletherapy unit or gamma stereotactic radiosurgery unit** Section G.71(b) states, in part, "in accordance with an **effective** IDE application…". This should state "an **active** IDE application…" SSR Part G needs to make the above change to the wording in Section G.71(b) in order to meet the Compatibility Category C designation assigned to 10 CFR 35.600.
8	G.75, 76 & 77	35.615	N/A	H&S	**Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units** SSR Part G omits the requirement of 35.615(a) requiring a door at each entrance to a treatment room. The SSR Part G allows for a door or an electronic means of surveillance. Further, in paragraphs (a)(i)(ii) and (iii) SSR Part G states "treatment interlock system" ; 35.615 (b)(1) (2) and (3) states "treatment room entrance doors" SSR Part G needs to add a requirement which embodies the essential objectives of 10 CFR 35.615(a), i.e. requiring a door or physical barrier to each treatment room, in order to meet the Compatibility Category H&S designation assigned to 10 CFR 35.615.