



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

July 25, 2023

Ruth E. McBurney
Executive Director
Conference of Radiation Control
Program Directors, Inc.
201 Brighton Park Blvd, Suite 1
Frankfort, KY 40601

Dear Ruth McBurney:

We reviewed the proposed revisions to the Suggested State Regulations (SSRs) in Part G, "Use of Radionuclides in the Healing Arts", received by our office on March 6, 2023. These regulations were reviewed by comparison to the equivalent U.S. Nuclear Regulatory Commission (NRC) rules in Title 10 of the *Code of Federal Regulations* Part 35, as applicable. We discussed our review of the regulations with you on July 18, 2023.

As a result of our review, we have 17 comments and 8 editorial comments that have been identified in Enclosure 1. We have determined that if the SSR Part G were revised to incorporate our comments and without other significant change, they would meet the compatibility and health and safety categories established in the Office of Nuclear Material Safety and Safeguards (NMSS) Procedure SA-200, "Compatibility Categories and Health and Safety Identification for NRC Regulations and Other Program Elements."

We request that a copy of the revised SSR Part G be provided to us for review and federal concurrence. As requested in Office of Nuclear Material Safety and Safeguards (NMSS) Procedure SA-201, "Review of State Regulatory Requirements," please highlight the final changes.

The State Regulation Status (SRS) Data Sheet in Enclosure 2 summarizes our knowledge of the status of other Conference of Radiation Control Program Directors (CRCPD) SSRs, 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 NRC website <https://www.nrc.gov/materials/toolboxes/regulation/crcpd-suggestions>.

If you have any questions regarding the review, the compatibility and health and safety categories, or any of the NRC regulations used in the review, please contact my staff at AgreementStateRegs.Resource@nrc.gov.

Sincerely,



Signed by Giantelli, Adelaide
on 07/25/23

Adelaide S. Giantelli, Chief
State Agreement and Liaison Programs Branch
Division of Materials Safety, Security, State,
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosures:

1. Compatibility and Editorial Comments
2. CRCPD SRS Data Sheet

SUBJECT: CRCPD REVISED SUGGESTED STATE REGULATIONS, PART G
Date July 25, 2023

DISTRIBUTION:

DIR RF 23-20

TClark, NMSS

ADAMS Accession No. ML23067A385 and ML23205A181 letter

OFFICE	NMSS/MSST	NMSS/MSST	OGC	NMSS/MSST
NAME	HAkhavannik	SSahle	BHarris	AGiantelli
DATE	07/24/2023	07/24/2023	07/18/2023	07/25/2023

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COMPATIBILITY COMMENTS ON CRCPD PROPOSED REGULATIONS

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
1	G.2	§35.2	N/A	B	<p>Definitions</p> <p>For the definition of, “authorized medical physicist,” the reference to G.51 should be updated to G.51(a). The word “or” should be removed at the end of G.51b(i). Under G51b(iv), the word “license” should be added after “master material”.</p> <p>For the definition of, “authorized nuclear pharmacist,” update the phrase “G.55a or G.59” to say “G.55a and G.59”.</p> <p>These changes need to be done to meet the Compatibility Category B designation assigned to 10 CFR 35.2.</p>
2	G.11a	§35.11(a)	N/A	[C]	<p>License required</p> <p>CRCPD G.11a includes a reference to G.11c. CRCPD needs to update G.11a to remove the reference to G.11c that is currently reserved and because G.11c is designated a NRC compatibility category and cannot be adopted by the Agreement States.</p>
3	G.27	§35.27	N/A	H&S	<p>Supervision</p> <p>CRCPD G.27c references paragraphs G.21a and G.21b but needs to be corrected to reference G.27a and G.27b.</p> <p>These references need to be corrected to meet the Compatibility Category H&S designation for 10 CFR 35.27.</p>
4	G.30	N/A	N/A	N/A	<p>Duties of Authorized User and Authorized Medical Physicist</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
					<p>CRCPD G.30.c(i) states that only the authorized medical physicists (AMP) or designee perform the periodic spot checks as described in G.642, G.643, G.645. However, this conflicts with G.642.b, G.643.b, and G.645.b(i), which state that the AMP need not perform the periodic spot checks.</p> <p>This conflict needs to be resolved to ensure consistent regulatory compliance.</p>
5	G.50	§35.50	N/A	B	<p>Training for Radiation Safety Officer</p> <p>CRCPD G.50b.i.2 states, “master materials license” but needs to be corrected to state, “master materials licensee”.</p> <p>This needs to be corrected to meet the Compatibility Category B designation for 10 CFR 35.50.</p>
6	G.51	§35.51	N/A	B	<p>Training for an authorized medical physicist</p> <p>G.51a includes “the Nuclear Regulatory Commission or an Agreement State” but needs to be corrected to state, “Agency, the Nuclear Regulatory Commission or an Agreement State”.</p> <p>This needs to be corrected to meet the Compatibility Category B designation for 10 CFR 35.51.</p>
7	G.67a, b, c, e, & g	§35.67(a), (b), (c), (e), & (g)	N/A	H&S	<p>Requirements for possession of sealed sources and brachytherapy sources</p> <p>CRCPD G.67.c states that the</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
					<p>sample's leak test must be measured to, "detect the presence of 185 becquerels (0.005 µCi) or more of radioactive material in the sample," whereas 10 CFR 35.67(b)(2)(c) does not specify "or more".</p> <p>G.67.c needs to be updated to remove, "or more", to meet the Compatibility Category H&S designation assigned to 10 CFR 35.67(b).</p>
8	G.75b	§35.57(b)	N/A	C	<p>Release of individuals containing unsealed byproduct material or implants containing byproduct material</p> <p>CRCPD G.75b states, "A licensee shall provide the released individual, or the individual's parent or guardian, with instructions, including oral and written instructions..." while 10 CFR 35.57(b) does not specify "oral".</p> <p>Including the option to provide oral instructions is less restrictive. CRCPD G.75b needs to be updated to say "including both oral and written" or to remove "oral" to meet the Compatibility Category C designation for 10 CFR 35.57.</p>
9	G.200	§35.200	N/A	H&S	<p>Use of unsealed byproduct material for imaging and localization for which a written directive is not required</p> <p>CRCPD G.200.a.ii references C.28h but it should reference C.24h. Additionally, G.200.b.iii references G.290.b.i and G.290.b.ii but should reference G.200.b.i and G.200.b.ii.</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
					These references need to be corrected to meet the Compatibility Category H&S designation assigned to 10 CFR 35.200.
10	G.290	§35.290	N/A	B	<p>Training for imaging and localization studies</p> <p>G.290.b is missing the equivalent to the phrase found in 10 CFR 35.290(b), "...and meets the requirements in §35.290(c)(1)(ii)(G)".</p> <p>G.290.b needs to be updated to add, "...and meets the requirements in G.290.c.ii.2.g" to meet the Compatibility Category B designation assigned to 10 CFR 35.290.</p> <p>G.290.c.ii does not include the word "independently" and needs to be updated to say, "...individual has satisfactorily completed the requirements in G.290c.i and is able to independently fulfill..". This is required to meet the Compatibility Category B designation assigned to 10 CFR 35.290.</p>
11	G.310a	§35.310(a)	N/A	H&S	<p>Safety instruction</p> <p>G.310.a says, "To satisfy this agreement, the instruction shall be appropriate with ..." while 10 CFR 35.310a says, "To satisfy this requirement, the instruction must be commensurate with...". G.310a needs to be updated to say, "commensurate with" to meet the H&S Compatibility Category assigned to 10 CFR 35.310(a).</p>
12	G.415	§35.415	N/A	H&S	<p>Safety precautions</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
					G.415(b)(1) needs to be changed to include an “and” at the end of the phrase instead of an “or” to meet the H&S Compatibility Category assigned to 10 CFR 35.415.
13	G.610	§35.610	N/A	H&S	<p>Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units</p> <p>G.610.g needs to be updated to reference “G.610d.ii.2” in G.610.g instead of “G.610d.ii” to meet the H&S Compatibility Category assigned to 10 CFR 35.610(g).</p>
14	G.633	§35.633	N/A	H&S	<p>Full calibration measurements on remote afterloader units</p> <p>G.633d need to be updated to reference G.633.a instead of G.630a to meet the H&S Compatibility Category assigned to 10 CFR 35.633.</p>
15	G.645	§35.645	N/A	H&S	<p>Periodic spot-checks for gamma stereotactic radiosurgery units</p> <p>G.645.b.ii needs to remove the phrase, “required by G.645a.i.” as it limits the spot checks to only those performed monthly.</p> <p>This change needs to be done to meet the H&S Compatibility Category assigned to 10 CFR 35.645.</p>
16	G.3045	§35.3045	N/A	C	<p>Report and notification of a medical event</p> <p>G.3045a.ii.1 needs to remove the, “outside of the treatment site,” phrase to meet the essential objective of 10 CFR 35.3045(a)(2)(i) and meet the</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
					Compatibility Category C assigned to 10 CFR 35.3045.
17	G.3047	§35.3047	N/A	C	<p>Report and notification of a dose to an embryo/fetus or a nursing child</p> <p>G.3047b needs to remove the phrase, “that was not specifically approved, in advance, by the authorized user,” as it makes the requirement less restrictive and does meet the essential objective of 10 CFR 3047(b).</p> <p>These changes must be done in order to meet the Compatibility Category C assigned to 10 CFR 35.3047.</p>

EDITORIAL COMMENTS ON CRCPD PROPOSED REGULATIONS

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
1	G.14	§35.14	N/A	D	CRCPD needs to correct G.14.a.i.(2) which describes any additional case experience required for an authorized user under G.390 when it should be G.300.
2	G.65	§35.65	N/A	D	<p>Authorization for calibration, transmission and reference sources</p> <p>G.65.a.ii contains the phrase, “[a]ny radioactive material with a half-life of not longer then 120 days in individual amounts not to exceed 0.56 gigabecquerels (15 mCi)”. This should be a separate G.65.a.iii regulation. The current G.65.iii should be updated to G.65.a.iv.</p>
3	G.190	§35.190	N/A	B	<p>Training for uptake, dilution and excretion studies</p> <p>Consider updating G.190.a to replace “Toolbox” webpage to “Toolkit” webpage.</p>
4	G.392	§35.392	N/A	B	<p>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)</p> <p>Consider updating the title of G.392 to, “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)” to match §35.392.</p>
5	G.394	§35.394	N/A	B	<p>Training for the oral administration of sodium iodide I-131 requiring a</p>

STATE SECTION		NRC SECTION	RATS ID	CATEGORY	SUBJECT and COMMENTS
					<p>written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries)</p> <p>Consider updating the title of G.394 to, "Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries)" to match §35.394.</p>
6	G.433	§35.433	N/A	N/A	<p>Strontium-90 sources for ophthalmic treatments</p> <p>Consider updating the title of the section to remove "decay of" before "Strontium-90". The section title was changed in 2014 to reflect expanded information and requirements.</p>
7	G.610	§35.610	N/A	H&S	<p>Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units</p> <p>Consider updating G.610.a.iv to say, "[t]hese procedures must include..." instead of "[t]his procedure" to reflect the possibility of multiple procedures.</p>
8	G.3045 G.3047 G.3067	§35.3045 §35.3047 §35.3067	N/A	C	<p>Consider updating G.3045d, G.3047d, and G.3067 to include CRCPD's Suggested State Regulation A.12 "Communications" which is the equivalent to 10 CFR 30.6(a).</p>

CRCPD STATE SUGGESTED REGULATION STATUS SHEET

[amendment(s) reviewed identified by a * at the beginning of the equivalent NRC requirement.]

Tracking Ticket Number: 23-20
DATE: July 25, 2023

CRCPD PART/ TITLE	NRC REGULATION- 10 CFR Parts	PROPOSED/ REVISED/FINAL	FEDERAL CONCURRENCE GIVEN? Yes/No DATE OF DOCUMENT/ADAMS ML# of Package	COMMENTS
A-General Provisions	19, 20, 30, 31, 32, 34, 35, 36, 39, 40, 61, 70, 71, and 150.	Proposed- comments Revised- Comments Revised- No comments	No 3/30/11 ML110610112 No 02/28/22 ML22026A343 Yes 04/18/22 ML22101A174	The submitted Part A SSRs were updated to reflect the changes related to 10 CFR Parts 19 and 20 through RATS ID 2021-1.
B- Regulation of Radiation Machine Facilities and Assoc. Healthcare Professionals	N/A			
C- Licensing of Radioactive Material	30, 31, 32, 40, 70	Final; no comments Proposed; Comments Final; No Comments	Yes 5/12/10 ML101040766 No 05/01/19 ML19044A444 Yes 8/26/21 ML21235A111	
D- Standards for Radiation Protection	20	Proposed; Comments Revised; Comments	No 3/30/11 ML110610112 No 02/28/22	The submitted Part D SSRs were updated to reflect the

		Revised- No comments	ML22026A343 Yes 04/18/22 ML22101A174	changes through RATS ID 2021-1.
E- Radiation Safety Requirements for Industrial Radiography Operations	34	Final; no comments Revised; no comments	Yes 2/22/16 ML16036A047 Yes 12/13/21 ML21330A073	The submitted Part E SSRs were updated to reflect the changes through RATS ID 2020-1.
F- Medical Diagnostic and Interventional X-Rays and Imaging Systems	N/A			
*G- Use of Radionuclides in the Healing Arts	35	Proposed; comments Revised; comments	No 4/1/10 ML100600666 No 07/25/2023 ML23067A385	
H- Radiation Safety Requirements for non-medical radiation generating devices	N/A			
J- Notices, Instructions and Reports to Workers, Inspections	19	Proposed; comments Revised; comments Revised; No comments	No 3/30/11 ML110610112 No 02/28/22 ML22026A343 Yes 04/18/22 ML22101A174	The submitted Part J SSRs were updated to reflect the changes through RATS ID 2020-3.
N- Regulation and Licensing of TENORM	N/A			

O- Decommissioning	30, 40, 70	Final; no comments	Yes 11/13/00 ML003770059	The submitted Part O SSRs were updated to reflect the changes related to 10 CFR Part 20* through RATS ID 2011-1.
		Revised; no comments	Yes 02/28/22 ML22026A343	
Q- Licensing and Radiation Safety Requirements for Irradiators	36	Proposed; no comments	No 7/11/15 ML051930005	The submitted Part Q SSRs were updated to reflect the changes through RATS ID 2020-1.
		Revised; no comments	Yes 12/13/21 ML21330A073	
		Final; no comments	Yes 2/3/22 ML22026A430	
R- Control of Radiation "Radon"	N/A			
S- Requirements for Financial Assurance	30, 40, 70		3/24/05	
T- Transportation of Radioactive Material	71	Final; no comments	Yes 9/9/14 ML14093A159	The submitted Part T SSRs were updated to reflect the changes through RATS ID 2021-2.
		Revised; comments	No 03/31/22 ML22066A027	
		Revised; No comments	Yes 04/26/22 ML22101A127	
U- Licensing Requirements for Uranium and Thorium Processing and related radioactive materials	40	Final; no comments	Yes 4/16/15 ML15077A212	

V- Physical Protection of Category I & II Quantities of Radioactive Materials	37	Final; no comments Revised; comment Final; No comments	Yes 11/19/14 ML14294A568 No 12/13/21 ML21330A073 Yes 2/3/22 ML22026A430	The submitted Part V SSRs were updated to reflect the changes through RATS ID 2021-2.
W- Radiation Safety Requirements for Well Logging Operations and Subsurface Tracer Studies	39	Proposed; comments Revised; Comments Final; No comments	No 1/30/15 ML14279A456 No 12/13/21 ML21330A073 Yes 2/3/22 ML22026A430	The submitted Part W SSRs were updated to reflect the changes through RATS ID 2020-1.
X- Therapeutic Radiation machines	N/A			
Z- Medical Credentialing	N/A			