

July 7, 2021

Michelle R. Beardsley, Health Physicist
 State Regulation Review Coordinator
 U.S. Nuclear Regulatory Commission (NRC)
 ASPB/MSTRINMSS
 Washington, DC 20555

Dear Ms. Beardsley:

Attached is a copy of the “as published” revisions to the North Dakota Radiological Health Rules as identified below. Because North Dakota adopts the NRC rules by reference, the State sections in the attachments correspond to the following NRC regulations with markups included. These revisions have included changes made in response to the two comments identified in your September 25, 2020 letter.

RATS ID: 2018-1

<u>NRC Section</u>	<u>Title</u>	<u>State Section</u>
§ 30.34 (g)	Terms and conditions of licenses	33.1-10-03.1-01 [§ 30.34]
§ 32.72 (a)(4) revised, (b)(5)(i) revised, (d) new	Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under part 35.	33.1-10-20-01 [§ 32.72]
§ 35.2	Definitions	33.1-10-07.2-01 [§ 35.2]
§ 35.12	Application for license, amendment, or renewal	33.1-10-07.2-01 [§ 35.12]
§ 35.13	License amendments	33.1-10-07.2-01 [§ 35.13]
§ 35.14	Notifications	33.1-10-07.2-01 [§ 35.14]

<u>NRC Section</u>	<u>Title</u>	<u>State Section</u>
§ 35.15	Exemptions regarding Type A specific licenses of broad scope	33.1-10-07.2-01 [§ 35.15]
§ 35.24 (b) and (c)	Authority and responsibilities for the radiation protection program	33.1-10-07.2-01 [§ 35.24]
§ 35.40	Written directives	33.1-10-07.2-01 [§ 35.40]
§ 35.41	Procedures for administrations requiring a written directive	33.1-10-07.2-01 [§ 35.41]
§ 35.50	Training for Radiation Safety Officer and Associate Radiation Safety Officer	33.1-10-07.2-01 [§ 35.50]
§ 35.51	Training for an authorized medical physicist	33.1-10-07.2-01 [§ 35.51]
§ 35.55	Training for an authorized nuclear pharmacist	33.1-10-07.2-01 [§ 35.55]
§ 35.57	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist	33.1-10-07.2-01 [§ 35.57]
§ 35.65	Authorization for calibration, transmission and reference sources	33.1-10-07.2-01 [§ 35.65]
§ 35.190	Training for uptake, dilution, and excretion studies	33.1-10-07.2-01 [§ 35.190]

<u>NRC Section</u>	<u>Title</u>	<u>State Section</u>
§ 35.204	Permissible molybdenum-99, strontium-82, and strontium-85 concentrations	33.1-10-07.2-01 [§ 35.204]
§ 35.290	Training for imaging and localization studies	33.1-10-07.2-01 [§ 35.290]
§ 35.300	Use of unsealed byproduct material for which a written directive is required	33.1-10-07.2-01 [§ 35.300]
§ 35.390	Training for use of unsealed byproduct material for which a written directive is required	33.1-10-07.2-01 § [35.390]
§ 35.392	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)	33.1-10-07.2-01 [§ 35.392]
§ 35.394	Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)	33.1-10-07.2-01 [§ 35.394]
§35.396	Training for the parenteral administration of unsealed byproduct material requiring a written directive	33.1-10-07.2-01 § [35.396]
§ 35.400	Use of sources for manual Brachytherapy	33.1-10-07.2-01 [§ 35.400]

<u>NRC Section</u>	<u>Title</u>	<u>State Section</u>
§ 35.433	Strontium-90 sources for ophthalmic treatments	33.1-10-07.2-01 [§ 35.433]
§ 35.490	Training for use of manual brachytherapy sources	33.1-10-07.2-01 [§ 35.490]
§ 35.491	Training for ophthalmic use of strontium-90	33.1-10-07.2-01 [§ 35.491]
§ 35.500	Use of sealed sources and medical devices for diagnosis	33.1-10-07.2-01 [§ 35.500]
§ 35.590	Training for use of sealed sources and medical devices for diagnosis	33.1-10-07.2-01 [§ 35.590]
§ 35.600	Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit	33.1-10-07.2-01 [§ 35.600]
§ 35.610	Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units	33.1-10-07.2-01 [§ 35.610]
§ 35.655	Full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units	33.1-10-07.2-01 [§ 35.655]
§ 35.690	Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units	33.1-10-07.2-01 [§ 35.690]

<u>NRC Section</u>	<u>Title</u>	<u>State Section</u>
§ 35.2024	Records of authority and responsibilities for radiation protection programs	33.1-10-07.2-01 [§ 35.2024]
§ 35.2310	Records of safety instruction	33.1-10-07.2-01 [§ 35.2310]
§ 35.2655	Records of full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units	33.1-10-07.2-01 [§ 35.2655]
§ 35.3045	Report and notification of a medical event	33.1-10-07.2-01 [§ 35.3045]
§ 35.3204 new	Report and notification for an eluate exceeding permissible molybdenum-99, strontium-82, and strontium-85 concentrations	33.1-10-07.2-01 [§ 35.3204]

RATS ID: 2018-2

<u>NRC Section</u>	<u>Title</u>	<u>State Section</u>
§ 37.7(a)	Communications	33.1-10-22-01 [§ 37.7(a)]
§ 37.77	Advance notification of shipment of category I quantities of radioactive material	33.1-10-22-01 [§ 37.77]
§ 37.81(g)	Reporting of events	33.1-10-22-01 [§ 37.81(g)]
§ 70.5	Communications	33.1-10-17-01 [§ 70.5]
§ 70.32	Conditions of licenses	33.1-10-17-01 [§ 70.32]
§ 71.97	Advance notification of shipment of irradiated reactor fuel and nuclear waste	33.1-10-13.1-01 [§ 71.97]

RATS ID: 2018-3

<u>NRC Section</u>	<u>Title</u>	<u>State Section</u>
§ 34.101(c)	Notifications	33.1-10-05.1-01 [§ 34.101(c)]
§ 37.23(b)(2)	Access authorization program requirements	33.1-10-22-01 [§ 37.23(b)(2)]
§ 37.43(d)(2), (d)(3) introductory text, (d)(3)(i), (d)(5) through (7), and (d)(8)(ii)	General security program requirements	33.1-10-22-01 [§ 37.43(d)(2), (d)(3) introductory text, (d)(3)(i), (d)(5) through (7), and (d)(8)(ii)]
§ 37.45(b)	LLEA coordination	33.1-10-22-01 [§ 37.45(b)]
§ 37.77(a)(1)	Advance notification of shipment of category I quantities of radioactive material	33.1-10-22-01 [§ 37.77(a)(1)]
§ 71.97(c)(3)	Advance notification of shipment of irradiated reactor fuel and nuclear waste	33.1-10-13.1-01 [§ 71.97(c)(3)]

RATS ID: 2019-1

<u>NRC Section</u>	<u>Title</u>	<u>State Section</u>
§ 37.23(b)(2)	Access authorization program requirements	33.1-10-22-01 [§ 37.23(b)(2)]
§ 37.27(c)(1) and (2)	Requirements for criminal history records checks of individuals granted unescorted access to category 1 or category 2 quantities of radioactive material	33.1-10-22-01 [§ 37.27(c)(1) and (2)]

RATS ID: 2019-2

<u>NRC Section</u>	<u>Title</u>	<u>State Section</u>
§ 37.7(a)	Communications	33.1-10-22-01 [§ 37.7(a)]
§ 71.1	Communications and records	33.1-10-13.1-01 [§ 71.1]
§ 71.17(c)(3)	General License: NRC approved package	33.1-10-13.1-01 [§ 71.17(c)(3)]
§ 71.95	Reports	33.1-10-13.1-01 [§ 71.95]
§ 71.101	Quality Assurance requirements	33.1-10-13.1-01 [§ 71.101]

We believe adoption of these sections will satisfy the compatibility and health and safety categories established in the office of Nuclear Material Safety and Safeguards (NMSS) Procedure SA-200.

If you have any questions, please feel free to contact me at 701-328-6410 or dstradinger@nd.gov.

Sincerely,



David Stradinger
Manager
Radiation Control Program

DWS: