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

January 16, 2020

ALL AGREEMENT STATES

AVAILABILITY OF REVISION 1 OF THE NORTHSTAR MEDICAL RADIOISOTOPES, LLC, RADIOGENIX™ MOLYBDENUM-99/TECHNETIUM-99M GENERATOR SYSTEM, LICENSING GUIDANCE FOR MEDICAL USE LICENSEES, MEDICAL USE PERMITTEES, AND COMMERCIAL NUCLEAR PHARMACIES (STC-20-006)

Purpose: To notify the Agreement States of the publication of revision 1 of the NorthStar Medical Radioisotopes, LLC, RadioGenix™ Molybdenum-99/Technetium-99m Generator System Licensing Guidance for Medical Use Licensees, Medical Use Permittees, and Commercial Nuclear Pharmacies.

Background: On February 2018, the U.S. Food and Drug Commission approved the NorthStar Medical Radioisotopes, LLC, RadioGenix™ Molybdenum-99/Technetium-99m Generator System (hereafter the RadioGenix™ System), and the U.S. Nuclear Regulatory Commission (NRC) published the licensing guidance for the RadioGenix™ System models 1.0a and 1.1. The RadioGenix™ System was determined to be regulated for medical use under Title 10 Code of Federal Regulation Part 35 Subpart K "Other Medical Uses of Byproduct Material or Radiation from Byproduct Material." At that time, it was also determined that a commercial nuclear pharmacy that is not specifically authorized for the RadioGenix™ System would not meet the requirements in 10 CFR 30.33, “General requirements for issuance of specific licenses,” without providing additional training and experience for individuals, and making certain commitments to address specific training and safety provisions. The guidance document provided applicants with an acceptable means of satisfying the requirements for a license for the use of the RadioGenix™ System models 1.0a and 1.1 and was not intended to be the only means of satisfying requirements for a license.

Subsequently NorthStar Medical Radioisotopes, LLC, developed the RadioGenix™ System Model 1.2 which contains hardware, software, and firmware changes that require additional training, operational changes and safety procedures. As a result, a working group consisting of NRC and Agreement State staff developed revision 1 of the licensing guidance.

Discussion: Enclosed is revision 1 of the RadioGenix™ System licensing guidance. The major changes to the guidance are: 1) the inclusion of the model designations in applying for a license, but not listing the model number on the license; 2) use of the Safety Evaluation Report (SER) to include information on new models, including a table in the SER describing the specific model number with its required training and experience and the appropriate version of the licensing guidance for that model; 3) revision of the training and experience section of the licensing guidance to clarify the type of training needed to use and operate both the current and future models; 4) adding new optional programs that the applicant can apply for and receive authorization for without future amendments; 5) restructuring of the guidance to move the optional programs (e.g., Sections 7.4 and 7.5 in the original guidance) into Sections 7 and 8 of the commitment sections of the guidance; 6) adding new license conditions; and 7) clarifying when the authorizations are listed on the license and when the commitments are included in the tie down conditions of the license.

The guidance document will be posted on NRC's public Web site at: https://www.nrc.gov/materials/miau/med-use-toolkit/emerg-licensed-med-tech.html. The SER can be accessed through the NRC's Sealed Source and Device Registry home page at: (https://scp.nrc.gov/ssdr.html). If you have any questions, please contact me at 301-415-0324, or Donna-Beth Howe at (301) 415-5441 or donna-beth.howe@nrc.gov.

Sincerely,

/RA/

Leira Cuadrado, Acting Branch Chief
State Agreement and Liaison Programs Branch
Division of Materials Safety, Security, State,
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Revision 1 of NorthStar Medical Radioisotopes, LLC RadioGenix™ Molybdenum-99/Technetium-99m Generator System Licensing Guidance for Medical Use Licensees, Medical Use Permittees, and Commercial Nuclear Pharmacies

SUBJECT: AVALIBILITY OF REVISION 1 OF THE NORTHSTAR MEDICAL RADIOISOTOPES, LLC, RADIOGENIX™ MOLYBDENUM-99/TECHNETIUM-99M GENERATOR SYSTEM, LICENSING GUIDANCE FOR MEDICAL USE LICENSEES, MEDICAL USE PERMITTEES, AND COMMERCIAL NUCLEAR PHARMACIES (STC-20-006)

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