



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

January 15, 2020

MEMORANDUM TO: James M. Trapp, Director
Division of Nuclear Materials Safety
Region I

David L. Pelton, Director
Division of Nuclear Materials Safety
Region III

Mary C. Muessle, Director
Division of Nuclear Materials Safety
Region IV

FROM: Christian E. Einberg, Chief **/RA/**
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

SUBJECT: PUBLICATION OF REVISION 1, NORTHSTAR MEDICAL
RADIOISOTOPES LLC, RADIOGENIX™ MOLYBDENUM-99/
TECHNETIUM-99M GENERATOR SYSTEM LICENSING
GUIDANCE FOR MEDICAL USE LICENSEES, MEDICAL USE
PERMITTEES AND COMMERCIAL NUCLEAR PHARMACIES

On February 2018, the U.S. Food and Drug Administration approved the NorthStar Medical Radioisotopes, LLC, RadioGenix™ Molybdenum-99/Techneium-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 guidance document provided applicants with one acceptable means of satisfying the requirements for a license for the use of the RadioGenix™ System models 1.0a and 1.1.

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.

CONTACT: Donna-Beth Howe, NMSS/MSST
301-415-5441

Enclosed is revision 1 of the RadioGenix™ System licensing guidance. The major changes to the guidance are: 1) the inclusion of the model designations when 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 continues to include standard language and formatting developed by the NRC's Medical Radiation Safety Team for all emerging technology licensing guidance documents (e.g, cover page; table of contents; document revision date; page numbers; example license language for radionuclide, form, possession limits, and purpose of use).

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 301-415-5422, or Donna-Beth Howe of my staff at (301) 415-5441 or donna-beth.howe@nrc.gov.

Enclosure:

Revision 1, NorthStar Medical Radioisotopes
LLC, Radiogenix™ Molybdenum-99/
Technetium-99m Generator System

SUBJECT: PUBLICATION OF REVISION 1, NORTHSTAR MEDICAL RADIOISOTOPES LLC,
RADIOGENIX™ MOLYBDENUM-99/ TECHNETIUM-99M GENERATOR SYSTEM
LICENSING GUIDANCE FOR MEDICAL USE LICENSEES, MEDICAL USE
PERMITTEES AND COMMERCIAL NUCLEAR PHARMACIES

ADAMS Accession No.: ML20009C048 (Pkg)

***via email**

OFFICE	MSST	MSST	OGC NLO*
NAME	DBHowe	CEinberg	A Gindelman
DATE	11/21/2019	1/15/2020	11/21/2019

OFFICIAL RECORD COPY