



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

December 17, 2021

ALL AGREEMENT STATES, CONNECTICUT, INDIANA

ISSUANCE OF REVISION 2 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-21-085)

Purpose: To notify the Agreement States that the U.S. Nuclear Regulatory Commission (NRC) is issuing the attached revision 2 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" (Agencywide Documents Access and Management System (ADAMS) Accession No. ML21350A064)." Revision 2 integrates the guidance from revision 1 (ADAMS Accession No. ML20009C049) and the "Temporary Addendum to 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, Revision 1," effective from September 2020 to June 30, 2021, and extended to December 31, 2021 (ADAMS Accession No. ML21134A082).

Background: Revision 2 was developed by a joint NRC-Agreement State working group in response to a request by NorthStar Medical Radioisotopes, LLC (hereafter NorthStar) to continue recognition of the two-step training process after the expiration date of the temporary Addendum. This is not a substantive revision of the guidance. It integrates the Addendum into the existing text of Revision 1 of the RadioGenix® System guidance. By incorporating the guidance from the Addendum into the formal guidance, the two-step licensing and two-step training and experience processes will become permanent options for NRC licensees.

In the process of integrating the two documents, the working group retained the single-step licensing and training and experience processes while making the two-step training and experience and two-step licensing processes permanently available to the NRC licensees. Also, during the integration of the two documents, the working group rearranged some of the text and rephrased some of the concepts to provide additional clarification, provided additional notes to applicants, licensees, and license reviewers, and made minor editorial changes to provide a coherent document. Examples of these changes are included in Enclosure 2. The NRC continues to point out that that applicants/licensees in Agreement States should check with the Agreement State regulator to see if it will accept the NRC notification processes and the two-step licensing process described in the guidance.

The attached licensing guidance will be posted on NRC's public Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/emerg-licensed-med-tech.html>).

If you have any questions regarding this correspondence, please contact me at 301-415-3436 or one of the individuals listed below:

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Signed by Anderson, Brian
on 12/17/21

Brian C. Anderson, Chief
State Agreement and Liaison Programs Branch
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and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

Enclosures:

1. Revision 2 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 Medical Use Permittees, and Commercial Nuclear Pharmacies," (ML21350A064)
2. Examples of changes made in Revision 2

Enclosure 2 – Examples of Changes Made in Revision 2

The following are examples of where text was rearranged, and the subject of the notes added:

1. Paragraph 3.2 was added to the “Licensing Guidance” Section to provide an early overview of the single-step and two-step licensing processes.
2. Section 5, “Training and Experience,” includes introductory information on the single-step and two-step training and experience processes and a brief discussion of the benefit of using these processes with the notification processes found in Section 8.
3. Paragraphs 5.1.B and C and 5.2.B and C integrate the single-step and two-step training and experience criteria and describe the documentation necessary for the authorized individuals and Radiation Safety Officer.
4. Paragraph 8.2 provides a notification pathway for training AUs, ANPs and experienced authorized individuals on the licensee’s model of the RadioGenix® System.
5. Paragraph 8.3 integrates both the single-and two-step training and experience processes into the notification process for installing a new model of the RadioGenix® System.
6. Subject matter of new “Notes”:
 - a. When a notification process can and cannot be used.
 - b. When an amendment is needed to be able to use the two-step licensing process and/or the two-step training and experience process.
 - c. What happens if the notification processes are used correctly and what happens if the licensee does not follow the commitments agreed to in a notification authorization.
 - d. The licensing mechanics of issuing a license by the two-step licensing process and the built-in “notification properties” of license condition “AA.”

STC-21-085 Agreement State Letter NorthStar Revision 2 of Licensing Guidance Package DATE
December 17, 2021

DISTRIBUTION:

ADAMS Accession No.: ML21306A115

*** via email**

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