



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

September 29, 2020

ALL AGREEMENT STATES, NMSS, REGIONS I, III, AND IV

ISSUANCE OF TEMPORARY ADDENDUM TO 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-20-068)

Purpose: To notify the Agreement States that the U.S. Nuclear Regulatory Commission (NRC) is issuing the enclosed temporary addendum to 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" (Agencywide Documents Access and Management System Accession No. ML20009C049). The addendum is effective September 2020 through June 2021.

Background: The addendum was developed by a joint NRC-Agreement State working group in response to a request by NorthStar Medical Radioisotopes, LLC (hereafter NorthStar) to accept a two-step training program during the Coronavirus 2019 (COVID-19) public health emergency (PHE). During the current COVID-19 PHE, many states have implemented travel restrictions. These travel restrictions make it difficult for NRC and Agreement State applicants and licensees to attend training at NorthStar's facility in Beloit, Wisconsin. Training on the NorthStar RadioGenix® Molybdenum-99/Technetium-99m Generator System (hereafter the RadioGenix® System) is required before the new applicant can possess and use the RadioGenix® System or a licensee transitions to a new model. Without the two-step training, limited authorizations, and license conditions, the traditional training and licensing of NorthStar RadioGenix® Systems may cause delays in the installation and distribution of domestically supplied non-fission molybdenum-99.

Discussion: This temporary addendum describes the two-step training program, and a licensing process that uses license authorizations (license authorization 9 and license condition 12) to restrict the use of the particular RadioGenix® System model until all training requirements are met, and a license condition (license condition "AA") that removes the use restrictions once the two-step training is complete for the authorized individuals and Radiation Safety Officer. An existing licensee transitioning to a new model will use the two-step training process by requesting the notification process in Section 8.3 (which is based on the two-step training program) and authorized by license condition "ZZZ." This training and corresponding licensing process provides limited regulatory relief for applicants seeking to possess and use the RadioGenix® System for the first time or licensees seeking to transition to a new model of the RadioGenix® System during the COVID-19 PHE.

The addendum does not replace any of the existing criteria, authorizations, or licensing conditions in the guidance. It is expected that new applicants and licensees will use both the licensing guidance and the addendum when requesting a licensing action for the RadioGenix® System. Unless extended, when the effective date of the addendum expires on June 30, 2021, the addendum will no longer be in effect.

In addition, NorthStar expects to provide additional training to a least one individual to become a NorthStar certified trainer during the two-step training program. This means that licensees will have at least one fully trained Authorized Individual who is also certified by NorthStar to provide training on the specific RadioGenix® System, proctor the training and attest to the completion of the training and ability of another trainee to function independently as an [Authorized User or Authorized Nuclear Pharmacist]. Once this happens, the authorized individual who is qualified and certified by NorthStar will be able to train others at the facility in accordance with the existing one step training process.

The attached addendum will be posted on NRC's public Web site with the NorthStar guidance (<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 (817) 200-1596 or the individual named below:

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Enclosure:
Temporary Addendum
to 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 Medical Use Permittees, and
Commercial Nuclear Pharmacies

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DATED: September 29, 2020

DISTRIBUTION:

Kevin Williams, NMSS/MSST

ADAMS Accession No.: ML20268A915

***via email**

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