



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

June 1, 2021

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

ISSUANCE OF EXTENSION TO DECEMBER 31, 2021, OF THE 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-21-031)

Purpose: To notify the Agreement States that the U.S. Nuclear Regulatory Commission (NRC) is issuing an extension until December 31, 2021, to the enclosed temporary addendum to Revision 1 of the NorthStar Medical Radioisotopes, LLC, "RadioGenix[®] Molybdenum-99/Techneium-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).

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 process at or near the applicant/licensees site during the Coronavirus 2019 (COVID-19) public health emergency (PHE). The only changes to the Addendum are the extension date and a reference to the NorthStar request for the extension.

Discussion: Due to continued COVID-19 related disruptions to businesses in the U.S., on April 26, 2021, NorthStar requested an extension of the Temporary Addendum to at least December 31, 2021 (ML21124A188). The addendum allowed NorthStar to safely and effectively continue training their customers per the NorthStar Licensing Guidance in the use of RadioGenix[®] System. Further, NorthStar found that providing the training at or near their customer's site(s), under the addendum resulted in a more streamlined training process and found it to be equally or more effective for the customer. NorthStar concluded that providing training under the Addendum was a safe and effective way to allow continued licensing of domestic Mo-99 in spite of the COVID-19 situation in the U.S.

The attached extended 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 (301) 415-3340 or the individual named below:

POINT OF CONTACT: Maryann Ayoade
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Signed by Anderson, Brian
on 06/01/21

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

Enclosure:

Extension to December 31, 2021, of the
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"

STC-21-031 - Letter extending Expiration of the NorthStar Licensing Guidance Addendum to December 31 2021 DATE June 1, 2021

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ADAMS Accession No.: ml20268a915; ML21134A083

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