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"

September 2020 to June 30, 2021

Introduction

During the current COVID-19 pandemic, many states have implemented travel recommendations or restrictions for individuals coming from another state. These travel restrictions and recommendations are fluid, may change at any time and may result in difficulty for the U.S. Nuclear Regulatory Commission (NRC) and Agreement State applicants and licensees to send individuals to the NorthStar Medical Radioisotopes, LLC, (hereafter NorthStar) facility in Beloit, Wisconsin to receive all the training needed in one-step for the applicant to be licensed for the initial possession and use of a NorthStar RadioGenix® System or for a licensee to transition to a newer unit.

NorthStar has proposed a new two-step training program. This temporary addendum to the NorthStar Medical Radioisotopes, LLC, "RadioGenix® Molybdenum-99/Technetium-99m Generator System (hereafter the RadioGenix® System) Licensing Guidance for Medical Use Licensees, Medical Use Permittees, and Commercial Nuclear Pharmacies, Revision 1" (hereafter the licensing guidance), describes the two-step training program, and licensing process that uses a license authorizations (Section 10.3.0. and addendum license condition 12) to restrict use of the particular RadioGenix® System until all training requirements are met and a new license condition (license condition "AA") to remove the use restrictions. This two-step training program, restricted authorization, and license condition provides limited regulatory relief for applicants seeking a new NRC license or a licensee seeking an amendment to an existing NRC licenses to possess and use a specific model of the RadioGenix® System during the COVID-19 pandemic. Without the two-step training and license condition, the traditional training and licensing of NorthStar RadioGenix® Systems may cause delays in the installation and distribution of domestically supplied non-fission molybdenum-99.

Use of the Addendum

This addendum is to specific sections in the guidance and is used in addition to the existing licensing guidance. The addendum does not replace any of the existing criteria, authorizations, or licensing conditions in the guidance. Unless extended, when the effective date of the addendum expires, the addendum will no longer be in effect. New applicants for the RadioGenix® System should carefully review both the licensing guidance and the addendum to assure that they adequately described their radiation safety program for a particular RadioGenix® System and requested all the licensing flexibilities needed both during and after the pandemic.

It is expected that, during the two-step training process, NorthStar will identify at least one individual and provide additional "train the trainer" training. This means a new licensee 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 individual or Radiation Safety Officer (RSO)]. The same is expected to be true at the end of the two-step training for an existing licensee that is transitioning to a new RadioGenix® System. 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.

Licensees authorized to use a specific RadioGenix® System that are transitioning to a new RadioGenix® System have additional flexibility if they first apply for and are approved for the two-step training program "notification provision" described in Section 8.3 and have the license condition "ZZZ" placed on their licenses. Once they have license condition "ZZZ," the licensee can have NorthStar install the new unit/modification and inform NRC of the installation of the new unit within 30 days of installation. The licensee is committed, by license condition, to retain documentation that the Authorized Individual(s) and RSO have successfully completed training on the new unit before the licensee's first use of the new unit.

Temporary Addendum to Section 5.1. "Authorized Individuals" [Title 10 Code of the Federal Regulations (10 CFR) 30.33(a)(3) and 10 CFR 35.12(b)(1)]

[**Note:** Paragraphs (1) and (2) are for authorized individuals already authorized to use the same model of the RadioGenix® System. Paragraph (3) describes the one-step training process and the new paragraph (4) below describes the two-step training process, which involves training on both a cold and hot unit for an authorized individual already authorized for a different RadioGenix® System.]

Addition of paragraphs A.(4)(a) and (b), preceded by an "OR"

(4) The two-step training process in this paragraph can be used during the COVID-19 pandemic.

a. Step one is for an individual already authorized for a different model[1] of the RadioGenix® System. In this step, the individual must successfully complete training using a fully functional "cold unit" (a fully functional RadioGenix® System that does not contain Mo-99) on the differences between the two RadioGenix® System models' operation, safety, and emergency procedures. The individual must also successfully perform each protocol that is different from the protocol originally trained on at least three times (or a different frequency identified for the new model, as described in the Safety Evaluation Report (SER) that can be obtained from NorthStar) in the physical presence of a NorthStar representative proctoring the protocols. This training provided by NorthStar will be for that particular model of the RadioGenix® System. A written attestation of the successful completion of the training and protocol performance for the "cold unit" of the specific model of the RadioGenix® System must be dated and signed by NorthStar.

AND

b. Step two is after the individual has already satisfactorily completed the cold unit training described above in 5.1.A(4)(a). In step two, the individual must successfully complete training on the differences in operation, safety, and emergency procedures and perform each protocol that is different from the protocol originally trained on using a fully functional "hot unit" (a fully functional RadioGenix® System containing Mo-99 that can elute Tc-99m) at least once in the physical presence of a NorthStar representative proctoring the protocols. If the protocol that changed included the two protocols remove source vessel or add/change discarded material container that has already been successfully performed on the cold unit, it does not need to be performed again on the hot unit. This training provided by NorthStar will be for that particular model of the RadioGenix® System. A written attestation of the successful completion of the training and protocol performance for the specific model of the RadioGenix® System and that the individual is able to independently perform the radiation safety related duties of an [Authorized User, Authorized Nuclear

[1] Information on the model number will be in a document referenced in the tie down condition.

Pharmacist] for the specific model of RadioGenix® System must be dated and signed by NorthStar.

[**Note**: Paragraphs B(1) through B(5) referenced below provide general training requirements that all individuals who have never been an authorized individual for a RadioGenix® System must meet. Paragraphs B(6) and B(7) describe the specific training and experience needed to be authorized to use a specific RadioGenix® System. Paragraph B(6) describes the one-step training process and new paragraph B(7) describes the two-step training process.]

Addition of paragraph B.(7), preceded by an "OR"

(7) In addition to B(1) through (5) in the guidance, has successfully completed the following two-step training and experience criteria for the same model of the RadioGenix® System the applicant will possess and use. This two-step training process can be used during the COVID-19 pandemic.

(a) Step one is successfully completing the following training provided on a "cold unit" (a fully functional RadioGenix® System that does not contain Mo-99) of the same model of a RadioGenix® System.

(i) Training on the RadioGenix® System operation, safety, and emergency procedures. This training shall be provided by NorthStar; and
(ii) Perform each of the protocols (i.e., initialize system, produce Tc-99m, add/change reagents, add source vessel, remove source vessel, sterilization, and add/change discard material container) at least three times in the physical presence of a NorthStar representative proctoring all the protocols; and
(iii) Has a written attestation, that he/she has satisfactorily completed the requirements in B.(7)(a) of this section for the "cold unit". The written attestation must be dated and signed by NorthStar.

AND

(b) Step two of the training is after the successful completion of step one of the training and consists of successfully completing the following training provided on the "hot unit" model of a RadioGenix® System, which is a fully functional RadioGenix® System connected to a Mo-99/Tc-99m source vessel and producing Tc-99m.

(i) Review of the training in the RadioGenix® System operation, safety, and emergency procedures. This training shall be provided by NorthStar; and

(ii) Perform the following protocols: initialize system, produce Tc-99m, add/change reagents, add source vessel, and sterilization at least once on the "hot unit" in the physical presence of a NorthStar representative proctoring all the protocols. The two protocols: remove source vessel and add/change discarded material container that have already been successfully performed on the cold unit do not need to be performed again; and

(iii) Has a written attestation, that he/she has satisfactorily completed the requirements in B.(7)(b) of this section and is able to independently operate and perform the radiation safety related duties of an authorized individual for the specific model of the RadioGenix® System. The written attestation must be dated and signed NorthStar.

Temporary Addendum to Section 5.2. "Radiation Safety Officer"

[**Note:** The existing guidance in Section 5.2.B. describes the one-step training process needed for an RSO identified as an RSO for a specific model of a RadioGenix® System to be the RSO for a different model. New Paragraph BB below describes the two-step training process for the same RSO moving to the different model.]

Addition of paragraph BB preceded by an "OR"

BB. Is already authorized as an RSO for a different model of the RadioGenix® System[2]. The two-step training criteria in this paragraph can be used during the COVID-19 pandemic.

(1) Step one of the training is the individual successfully completing training on the differences between the two RadioGenix® System models' radiation safety, regulatory issues, administrative controls, and emergency procedures using a "cold unit." The individual also successfully demonstrates the emergency procedures on the "cold unit" that are applicable to the RSO and are different from the original emergency procedures. This demonstration of the emergency procedures using a "cold unit" must be performed at least once in the physical presence of a NorthStar representative who can proctor the emergency procedures appropriate for an RSO. The training provided by NorthStar will be for the particular model of the RadioGenix® System that will be installed. A written attestation of the successful completion of the training and emergency procedure performance of the specific model of the RadioGenix® System using the "cold unit" must be dated and signed by NorthStar.

AND

(2) Step two of the training is after the successful completion of step one of the training and consists of a review of the differences between the two RadioGenix® System models' radiation safety, regulatory issues, administrative controls, and emergency procedures using a "hot unit." To complete step two of the training, the individual must successfully demonstrate the emergency procedures on the "hot unit" that are applicable to the RSO and are different from the original emergency procedures. This demonstration of the emergency procedures on the "hot unit" must be performed at least once in the physical presence of a NorthStar representative who can proctor the emergency procedures appropriate for an RSO. The training provided by NorthStar will be for the particular model of the RadioGenix® System. A written attestation of the successful completion of the training and emergency procedure performance for the specific model of the RadioGenix® System and the individual is able to independently perform the radiation safety related duties of an RSO for the specific model of RadioGenix® System must be dated and signed by NorthStar.

[**Note**: Paragraphs C(1) through C(3) referenced below describe the training needed for an individual who has never been an RSO for a RadioGenix® System but that every individual needs to be an RSO on a medical use or commercial nuclear pharmacy license. Paragraphs C(4) and (5) provide the additional training needed to be an RSO for a RadioGenix® System. Paragraph C(4) describes the one-step training process and the new paragraph C(5) below describes the two-step training process for the individual to be the RSO for a specific model of the RadioGenix® System.]

Addition of paragraph C(5) preceded by an "OR"

[2] Information on the model number will be in a document referenced in the tie down condition.

(5) In addition to C(1) through (3) above, successfully complete the following two-step training and experience criteria for the same model the applicant will possess and use.

(a) Step one of the training is:
(i)Training in the radiation safety, regulatory issues, administrative controls, and emergency procedures for the specific model of the RadioGenix® System using a "cold unit." This training is provided by NorthStar; and

(ii) Satisfactorily demonstrate the emergency procedures on the "cold unit" that are applicable to the RSO at least once in the physical presence of a NorthStar representative who can proctor the emergency procedures appropriate for an RSO; and

(iii) The proposed RSO has a written attestation that he/she has satisfactorily completed the requirements in C(5) using the "cold unit." The written attestation is dated and signed by NorthStar.

AND

(b) Step two of the training is after successful completion of step one and consists of:
(i) Review of the radiation safety, regulatory issues, administrative controls, and emergency procedures for the specific model of the RadioGenix® System using a "hot unit." This training is provided by NorthStar, and

(ii) Satisfactorily demonstrate the emergency procedures on the "hot unit" that are applicable to the RSO at least once in the physical presence of a NorthStar representative who can proctor the emergency procedures appropriate for an RSO, and

(iii) The proposed RSO has a written attestation that he/she has satisfactorily completed the requirements in C(5) of this section and is able to independently perform the radiation safety related duties of an RSO for the specific model of RadioGenix® System. The written attestation is dated and signed by NorthStar.

Temporary Addendum to Section 8.

Add new section

Section 8.3, "Notify NRC Within 30 Days When a New Model of the RadioGenix® System is Installed at the Facility already authorized for the use of a RadioGenix® System when using the two-step training process during the COVID-19 Pandemic."

[**Note:** While this licensing addendum is in effect, applicants and licensees that have not applied for the notification authorization described in Section 8.2, should apply for and receive authorization for both notification processes in Section 8.2 of the licensing guidance and Section 8.3 of the addendum. A licensee that already has authorization for the notification process in Section 8.2, should also apply for the notification process in Section 8.3. This will ensure that the licensee can use the notification process for the two-step training program during the pandemic and the one-step training process when the addendum expires.]

The NRC expects that, with use and increased operational experience, NorthStar will make software, hardware, or procedural changes to the RadioGenix® System that may be significant enough to result in designation of a new model number for the specific RadioGenix® System.

The particular model of RadioGenix® System that the licensee has and that the individuals using the new model are properly trained on should be clearly specified in the license application.

During the COVID-19 pandemic, the NRC has determined that the NRC licensee/applicant (both a medical use and commercial nuclear pharmacy licensee/applicant) does not need to apply for an amendment to possess and use the new model of the RadioGenix™ System installed during the pandemic, provided the applicant or licensee commits to and is authorized for the notification process and program described below.

To receive this authorization, the applicant shall commit to the following:

1. Notify the NRC within 30 days of installation, of the new model of the RadioGenix® System .

2. Ensure the following for the new model:

    a. Additional training is provided to all authorized individuals, the Radiation Safety Officer, RadioGenix® System Administrator and RadioGenix® System Administrator designee and supervised individuals.

    b. All individuals must successfully complete the training on the new model prior to their first operation of the system.
        i. For the first individuals (authorized individuals, the Radiation Safety Officer, RadioGenix® System Administrator and RadioGenix® System Administrator designee and supervised individuals) to use the new model, the training must be provided by NorthStar under the two-step training process described in the Temporary Addendums to Sections 5.1 and 5.2 of the guidance, and
        ii. For all other individuals, the training must be provided by NorthStar or an individual certified by NorthStar to provide the training on the new model of the RadioGenix® System.

    c. Records of the successful completion of this training are maintained by the licensee for the life of the license for the authorized users, the authorized nuclear pharmacists, and the Radiation Safety Officer, and for 3 years for all others. The record as a minimum includes: the model number of the RadioGenix® System, a list of the topics covered, the date of the instruction, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.
        i. For the Radiation Safety Officer and either the first authorized users or the first authorized nuclear pharmacists using the new model the record must also include, a written attestation that the individual satisfactorily completed the appropriate requirements in 5.1.A(4)(a) and (b), or A.5.1.B(7), or 5.2.BB, or 5.2.C(5) of the temporary addendum, and is able to independently perform the radiation safety related duties of a [Authorized User, Authorized Nuclear Pharmacist, or Radiation Safety Officer] for the specific model of RadioGenix® System. The written attestation is dated and signed by NorthStar, and
        ii. For all other authorized users, authorized nuclear pharmacists, and Radiation Safety Officer, the record must also include, a written attestation that the individual satisfactorily completed the requirements in 5.1.A(3) or 5.1.B(6) or 5.2.B or 5.2.C of Section 5 of the guidance, and is able to independently perform the radiation safety related duties of a [Authorized User, Authorized Nuclear Pharmacist, or Radiation Safety Officer] for the specific model of RadioGenix® System. The written attestation is

dated and signed by NorthStar or an individual certified by NorthStar to provide the training and proctor the emergency procedure.

If this authorization is approved, both the authorization and the specific training and experience commitments will be incorporated as specific license conditions on the licensee's license.

Temporary Addendum to Section 10.3 License Authorizations

Add new section

Section 10.3.0. Radionuclides, Form, Possession Limits* used for the two-step training program, and the licensing process that uses the restrictive "Authorization 9" in this section until all training requirements are met, and the license condition (license condition "AA") that removes the restricted use of the particular RadioGenix® System.

Note: Section 10.3.0 is intended for an applicant that is not authorized to possess or use a RadioGenix® System prior to the pandemic. The existing Paragraph 10.3.1 is used with the one-step training process for licensing of the RadioGenix® System.

Radionuclides: (Authorization 6)	A. Molybdenum-99/Technetium-99m B. Depleted Uranium**
Chemical/Physical Form: (Authorization 7)	A. Liquid NorthStar Molybdenum-99/Technetium-99m to be used in the RadioGenix® System B. Metal
Maximum Possession Limit: (Authorization 8)	A. 7.5 curies of Molybdenum-99/Technetium-99m per source vessel, not to exceed 40 curies total B. 162 kilograms total
Authorized Use: (Authorization 9)	A. For use of the NorthStar RadioGenix® System for possession, installation, training, and in accordance with license condition "AA," for 10 CFR 35.1000 medical use for the elution of Tc-99m in a NorthStar RadioGenix® System (or for the commercial nuclear pharmacy – in accordance with license condition "AA," for use of the NorthStar RadioGenix® System for preparation and distribution of radioactive drugs and radiochemicals for medical use in accordance with 10 CFR 32.72, and for non-medical use to authorized recipients). B. For shielding in a NorthStar RadioGenix® System transfer vessel (if this is the only depleted uranium authorized on the license).

* The intent is to license the NorthStar RadioGenix® System including the liquid NorthStar Mo-99/Tc99m solution as a separate line item. For the licensee that has both a RadioGenix® System and conventional Mo-99/Tc-99 generators, there will be three line items: one will be for the RadioGenix® System(s), one for the Mo-99 in conventional generators and the final line item for the total amount of Tc-99m eluted from both sources used to prepare radiopharmaceuticals. The Tc-99m that is eluted from the RadioGenix® System is no different than the Tc-99m eluted from fission generators. [Note to license reviewer: Ensure the total Tc-99m authorization includes

the total Tc-99m from both the RadioGenix® System and the traditional generator elutions.]

** Depending on the model used, depleted uranium may or may not be used in either the source vessel or the source transfer vessel. The manufacturer is phasing out the use of depleted uranium in the NorthStar RadioGenix® System.

Temporary Addendum to Section 10.4 License Conditions

The addendum license condition 12 is to be used with the restrictive use authorization in addendum 9 of section 10.3.0 and license condition "AA" that removes the restrictive use. This addendum license condition 12 is only for a licensee that has not been authorized for a RadioGenix® System and is applying under the two-step training program, and licensing process that uses a license condition (license condition "AA") to remove the restrictions in the authorized use of the particular RadioGenix® System when all training requirements are met.

12. [Authorized User Physician's Name] 10 CFR 35.100; 10 CFR 35.200; [other uses if appropriate]; for training and in accordance with license condition AA for the elution of Technetium-99m from the RadioGenix® System.

OR

[Authorized Nuclear Pharmacist's name] for training and in accordance with license condition AA for the elution of Technetium-99m from the RadioGenix® System.

Note: "12." is the number of the standard license condition that NRC uses for listing authorized individuals.

Add new license condition "AA"

[**NOTE:** This license condition is placed on the license when the applicant commits to using the two-step training program and provides documentation of the completion of the first step of the training process. The license condition establishes the criteria for completion of the training and full authorization to use the NorthStar RadioGenix® System for the elution of Tc-99m.]

AA. Provided the following criteria are met, the medical use licensee is authorized for 10 CFR 35.1000 medical use for the elution of Tc-99m in a NorthStar RadioGenix® System, or the commercial nuclear pharmacy is authorized for use of the NorthStar RadioGenix® System for preparation and distribution of radioactive drugs and radiochemicals for medical use in accordance with 10 CFR 32.72, and for non-medical use to authorized recipients. Also, when the criteria are met, the Authorized User Physician or the Authorized Nuclear Pharmacist is authorized for the elution of Technetium-99m from the RadioGenix® System.

1. The first Authorized Individual(s) to use the NorthStar RadioGenix® System must successfully complete both the first step and second step of the two-step training process before the first use of the NorthStar RadioGenix® System; and
2. The licensee must provide written documentation to [the specific recipient for the Regulator] signed and dated by NorthStar attesting that the first Authorized Individual(s) has satisfactorily completed the "hot unit" training requirements in 5.1.B.7 and is able to independently perform

the radiation safety related duties of an Authorized Individual for the specific model of RadioGenix® System; and
3. Before overseeing the first use the NorthStar RadioGenix® System, the RSO must successfully complete both the first step and second step of the two-step training process; and
4. The licensee must provide written documentation to [the specific recipient for the Regulator] signed and dated by NorthStar attesting that the Radiation Safety Officer has satisfactorily completed the "hot unit" training requirements in 5.2.C.(5) and is able to independently perform the radiation safety related duties of an Radiation Safety Officer for the specific model of RadioGenix® System; and
5. The licensee receives confirmation from [the regulator] that the documentation was received, and all the criteria of this license condition were met.

ZZZ. [**Note:** This license condition is only included on the license if the applicant applied for and is authorized for YY.2. and is following the two-step training process in 5.1.A.(4)(a) and (b), 5.1.B.7, 5.2.BB, and 5.2.C(5). This license condition should be used in addition to and not in lieu of license condition ZZ.]

When a new model RadioGenix® System is installed, the licensee shall ensure the following before first use of the new model RadioGenix® System:

1. Additional training is provided for all authorized individuals, Radiation Safety Officer, the RadioGenix® System Administrator, RadioGenix® System Administrator designee, and supervised individuals; and
2. Individuals must successfully complete the training on the new model prior to their first operation of the system.
    i. For the first individuals (authorized individuals, Radiation Safety Officer, RadioGenix® System Administrator and RadioGenix® System Administrator designee and supervised individuals) to use the new model, the training must be provided by NorthStar under the two-step training process described in the Temporary Addendums to Sections 5.1 and 5.2; and
    ii. For all other individuals, the training must be provided by NorthStar or an individual certified by NorthStar to provide the training on the new model of the RadioGenix® System; and
3. Records of the successful completion of this training are maintained by the licensee for the life of the license for the authorized users, the authorized nuclear pharmacists, and the Radiation Safety Officer, and for 3 years for all others; and
4. The record, at a minimum, includes: the model number of the RadioGenix® System, a list of the topics covered, the date of the instruction, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction; and
    i. For the authorized users, authorized nuclear pharmacists, and RSO that are the first individuals to use the new model; the record must also include, a written attestation that the individual satisfactorily completed the appropriate requirements in 5.1.A(4)(a) and (b), or A.5.1.B(7), or 5.2.BB, or 5.2.C(5) of the Temporary Addendum, and is able to independently perform the radiation safety related duties of the [Authorized User, Authorized Nuclear Pharmacist, or Radiation Safety Officer] for the specific model of RadioGenix® System. The written attestation is dated and signed by NorthStar; and
    ii. For all other authorized users, authorized nuclear pharmacists, and RSO, the record must also include, a written attestation that the individual satisfactorily completed the requirements in 5.1.A(3) or 5.2.B of Section 5 of the guidance, and is able to independently perform the radiation safety related duties of a

[Authorized User, Authorized Nuclear Pharmacist, or Radiation Safety Officer] for the specific model of RadioGenix® System. The written attestation is dated and signed by NorthStar or an individual certified by NorthStar to provide the training and proctor the emergency procedure.

Note: "ZZZ" is the place holder for the actual license condition number.
and
Note: The specific commitments for the above authorizations in Sections 7 and 8 and other commitments made by the licensee in Section 6 of the license guidance and addendum are, unless listed above, included in the tie down condition.

Paperwork Reduction Act Statement

This document provides voluntary guidance for implementing the mandatory information collections in 10 CFR Parts 30, 32, and 35, as well as NRC Form 313, "Application for Materials License," as well as voluntary information collections associated with the submission of a license amendment under 10 CFR 35.13. These information collections are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et. seq.) and were approved by the Office of Management and Budget (OMB), control numbers 3150-0017, 3150-0001, 3150-0010, and 3150-0120. Send comments regarding these information collections to the FOIA, Library, and Information Collections Branch (T6-A10M), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to Infocollects.Resource@nrc.gov, and to the OMB reviewer at: OMB Office of Information and Regulatory Affairs (3150-0017, 3150-0001, 3150-0010, and 3150-0120), Attn: Desk Officer for the Nuclear Regulatory Commission, 725 17th Street, NW Washington, DC 20503; e- mail: oira_submission@omb.eop.gov.